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 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 statements and technical 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 technical 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. S109 of this supplement.

Technical review. A balanced review and analysis of the literature on a scientific or medical topic related to diabetes. The technical review provides a scientific rationale for a position statement and undergoes peer review before submission to the Professional Practice Committee for approval. A list of recent technical reviews is included on page S105 of this supplement.

Consensus statement. A comprehensive examination by a panel of experts (i.e., consensus panel) of a scientific or medical issue related to diabetes. A consensus statement 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 statement 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 statement is not subject to subsequent review or approval and does not represent official Association opinion. A list of recent consensus statements is included on p. S107 of this supplement.

The Association's Professional Practice Committee is responsible for reviewing ADA technical reviews 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, and registered dietitians who have expertise in a range of areas, including adult and pediatric endocrinology, epidemiology and public health, lipid research, hyperten-

Table 1—*ADA evidence-grading system for clinical practice recommendations*

Level of evidence	Description
A	Clear evidence from well-conducted, generalizable, randomized controlled trials 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., the "all or none" rule developed by the Centre for Evidence-Based Medicine at Oxford Supportive evidence from well-conducted randomized controlled trials 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
B	Supportive evidence from well-conducted cohort studies, including: • 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
C	Supportive evidence from poorly controlled or uncontrolled studies, including: • 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 to historical controls) • Evidence from case series or case reports Conflicting evidence with the weight of evidence supporting the recommendation
E	Expert consensus or clinical experience

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sion, and preconception and pregnancy care. All members of the Professional Practice Committee are required to disclose potential conflicts of interest to the American Diabetes Association.

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 after a given recommendation in parentheses.

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 glycemic 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 2008 Clinical Practice Recommendations

Beginning with the 2005 supplement, the Clinical Practice Recommendations contained only the "Standards of Medical Care in Diabetes" and selected other position statements. This change was made to emphasize the importance of the "Standards" as the best source to determine the recommendations of the American Diabetes Association (ADA). The position statements in the supplement are updated yearly. Position statements not included in the supplement will be updated as necessary and republished when updated. A list of recent position statements not included in this supplement appears on p. S109.

Revisions to the 2008 Clinical Practice Recommendations

- ADA Statements and ADA Position Statements have been combined under the category of ADA Position Statements. Such statements may be authored or unauthored, are reviewed and approved by the Professional Practice Committee and Executive Committee of the Association, and represent an official point of view of ADA.
- "The Standards of Medical Care in Diabetes—2008" has undergone substantial revisions compared with the 2007 version; the revisions are based on updated literature reviews and the desire to make the document more user-friendly. The following summarizes significant additions and revisions to the 2008 standards:

Additions to the "Standards of Medical Care in Diabetes"

- An executive summary on page S5 outlines all recommendations in the "Standards of Medical Care in Diabetes—2008"
- Table 5 lists screening recommendations and diagnostic cut points for gestational diabetes
- Table 6 summarizes interventions and results of diabetes prevention trials
- The "Approach to treatment" section includes a section on the general treatment of type 1 diabetes, in addition to the section on the general treatment of type 2 diabetes
- A table summarizing the evidence for statin therapy in people with diabetes has been added (Table 10).

Revisions to the "Standards of Medical Care in Diabetes"

- Testing for pre-diabetes in asymptomatic patients (previously screening for diabetes):
  - A more explicit recommendation to consider testing adults of any age who are overweight or obese and have additional risk factors for diabetes

- Prevention/delay of type 2 diabetes:
  - In addition to lifestyle counseling, metformin may be considered in those who are at very high risk (combined impaired fasting glucose and impaired glucose tolerance plus other risk factors) and who are obese and under 60 years of age. (E)

Diabetes care:

- Components of the comprehensive diabetes evaluation revised
- Continuous glucose monitoring may be a supplemental tool to SMBG for selected patients with type 1 diabetes, especially those with hypoglycemia unawareness. (E)
- Glycemic goals have been listed in a separate table (Table 8)
- Revisions to the language about glycemic goals:
  - Lowering A1C to an average of ~7% has clearly been shown to reduce microvascular and neuropathic complications of diabetes and possibly macrovascular disease. Therefore, the A1C goal for nonpregnant adults in general is <7%. (A)
  - Epidemiologic studies have suggested an incremental (albeit, in absolute terms, a small) benefit to lowering A1C from 7% into the normal range. Therefore, the A1C goal for selected individual patients is as close to normal (<6%) as possible without significant hypoglycemia. (B)
  - Less stringent A1C goals may be appropriate for patients with a history of severe hypoglycemia, patients with limited life expectancies, children, individuals with comorbid conditions, and those with longstanding diabetes and minimal or stable microvascular complications. (E)

- The "Approach to treatment" section on type 2 diabetes has been revised
- The "Medical Nutrition Therapy" section has been revised; updates to this section include the following revised recommendations for weight loss:
  - For weight loss, either low-carbohydrate or low-fat calorie-restricted diets may be effective in the short-term (up to 1 year). (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)

- The section previously titled "Referral for diabetes management" has been titled "When treatment goals are not met"
- The "Hypoglycemia" section has been revised to include more about prevention and hypoglycemia unawareness, with an additional recommendation:
  - Individuals with hypoglycemia unawareness or one or more episodes of severe hypoglycemia should be advised to raise their glycemic targets to strictly avoid further hypoglycemia for at least several weeks in order to partially reverse hypoglycemia unawareness and reduce risk of future episodes. (B)

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Prevention and management of diabetes complications:

- Hypertension/blood pressure control section: the number of treatment recommendations has been reduced to emphasize use of angiontensin converting-enzyme (ACE) inhibitors or angiotensin receptor blockers (ARBs).
- Dyslipidemia/lipid management section: the number of treatment recommendations has been reduced to emphasize use of statins for most patients. Several recommendations have been revised:
  - If drug-treated patients do not reach the above targets on maximal tolerated statin therapy, a reduction in LDL cholesterol of ~40% from baseline is an alternative therapeutic goal. (A)
  - Triglyceride levels <150 mg/dl (1.7 mmol/l) and HDL cholesterol levels >40 mg/dl (1.0 mmol/l) in men and >50 mg/dl (1.3 mmol/l) in women are desirable. However, LDL cholesterol–targeted statin therapy remains the preferred strategy. (C)

- Nephropathy screening and treatment: the number of recommendations has been reduced to emphasize use of ACE inhibitors or ARBs

Diabetes care in specific populations:

- Children and adolescents with type 1 diabetes:
  - Consider age when setting glycemic goals in children and adolescents with type 1 diabetes, with less stringent goals for younger children. (E)
  - Initial dyslipidemia therapy should consist of optimization of glucose control and medical nutrition therapy using a Step 2 American Heart Association 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 is recommended in patients who, after MNT and lifestyle changes, have LDL cholesterol >160 mg/dl (4.1 mmol/l) or have LDL cholesterol >130 mg/dl (3.4 mmol/l) and one or more cardiovascular disease risk factors. (E)

- New section on hypothyroidism, with new recommendations:
  - Patients with type 1 diabetes should be screened for thyroid peroxidase and thyroglobulin antibodies at diagnosis. (E)
  - Thyroid-stimulating hormone (TSH) concentrations should be measured after metabolic control has been established. If normal, they should be rechecked every 1–2 years or if the patient develops symptoms of thyroid dysfunction, thyromegaly, or an abnormal growth rate. Free T4 should be measured if TSH is abnormal. (E)

- The section on older adults now includes the following recommendations:
  - Older adults who are functional, cognitively intact, and have significant life expectancy should receive diabetes treatment using goals developed for younger adults. (E)
  - Glycemic goals for older adults not meeting the above criteria may 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 timeframe 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 timeframe of primary or secondary prevention trials. (E)
  - Screening for diabetic complications should be individualized in older adults, but particular attention should be paid to complications that would lead to functional impairment. (E)

Diabetes care in specific settings

- Diabetes care in the hospital: Glycemic goals have been modified slightly:
  - Critically ill patients: blood glucose levels should be kept as close to 110 mg/dl (6.1 mmol/l) as possible and generally <140 mg/dl (7.8 mmol/l). (A) These 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. Because cohort data suggest that outcomes are better in hospitalized patients with fasting glucose <126 mg/dl and all random glucoses <180–200 mg/dl, these goals are reasonable if they can be safely achieved. Insulin is the preferred drug to treat hyperglycemia in most cases. (E)

- Diabetes care in the school and day care setting: recommendations have been slightly revised to incorporate only the diabetes medical management plan, as health care providers would not be involved with 504 plans.
- The "Emergency and disaster preparedness" section: based on the ADA Task Force report, the following new recommendations have been added:
  - People with diabetes should maintain a disaster kit that includes items important to their diabetes self-management and continuing medical care. (E)
  - The kit should be reviewed and replenished at least twice yearly. (E)

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Executive Summary: Standards of Medical Care in Diabetes—2008

These standards of care are intended to provide clinicians, patients, researchers, payors, and other interested individuals with the components of diabetes care, treatment goals, and tools to evaluate the quality of care. While individual preferences, comorbidities, and other patient factors may require modification of goals, targets that are desirable for most patients with diabetes are provided. These standards are not intended to preclude more extensive evaluation and management of the patient by other specialists as needed.

The recommendations included are screening, diagnostic, and therapeutic actions that are known or believed to favorably affect health outcomes of patients with diabetes. A grading system developed by the American Diabetes Association 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.

For more detailed information, refer to the full document: "Standards of Medical Care in Diabetes—2008."

TOPIC AREAS AND RECOMMENDATIONS

Diagnosis of Diabetes

- The fasting plasma glucose (FPG) text is the preferred test to diagnose diabetes in children and nonpregnant adults. (E)
- Use of the A1C for the diagnosis of diabetes is not recommended at this time. (E)

Testing for Pre-diabetes and Diabetes

- Testing to detect pre-diabetes and type 2 diabetes in asymptomatic people should be considered in adults who are overweight or obese (BMI ≥25 kg/m^2) and who have one more more additional risk factors for diabetes. In those without these risk factors, testing should begin at age 45. (B)
- If tests are normal, repeat testing should be carried out at least at 3-year intervals. (E)
- To test for pre-diabetes or diabetes, either an FPG test or 2-h oral glucose tolerance test (OGTT; 75-g glucose load), or both, is appropriate. (B)
- An OGTT may be considered in patients with impaired fasting glucose (IFG) to better define the risk of diabetes. (E)
- In those identified with pre-diabetes, identify and, if appropriate, treat other CVD risk factors. (B)

Testing for Type 2 Diabetes in Children

- Test children who are overweight (BMI >85th percentile for age and sex, weight for height >85th percentile, or weight >120% of ideal for height) and have two of the following risk factors:
  - Family history of type 2 diabetes in first- or second-degree relative
  - Race/ethnicity (Native American, African American, Latino, Asian American, Pacific Islander)
  - Signs of insulin resistance or conditions associated with insulin resistance (acanthosis nigricans, hypertension, dyslipidemia, or polycystic ovary syndrome [PCOS])
  - Maternal history of diabetes or gestational diabetes mellitus (GDM) (E)
- Testing should begin at age 10 years or at onset of puberty, if puberty occurs at a younger age, and be repeated every 2 years. (E)
- The FPG is the preferred test. (E)

Detection and Diagnosis of GDM

- Screen for GDM using risk factor analysis and, if appropriate, use of an OGTT. (C)
- Women with GDM should be screened for diabetes 6–12 weeks postpartum and should be followed up with subsequent screening for the development of diabetes or pre-diabetes. (E)

Prevention/Delay of Type 2 Diabetes

- Patients with impaired glucose tolerance (IGT) (A) or IFG (E) should be given counseling on weight loss of 5–10% of body weight, as well as on increasing physical activity to at least 150 min per week of moderate activity such as walking.
- Follow-up counseling appears to be important for success. (B)
- Based on potential cost savings of diabetes prevention, such counseling should be covered by third-party payors. (E)
- In addition to lifestyle counseling, metformin may be considered in those who are at very high risk (combined IFG and IGT plus other risk factors) and who are obese and under 60 years of age. (E)
- Monitoring for the development of diabetes in those with pre-diabetes should be performed every year. (E)

Self-monitoring of Blood Glucose (SMBG)

- SMBG should be carried out three or more times daily for patients using multiple insulin injections or insulin pump therapy. (A)
- For patients using less frequent insulin injections, noninsulin therapies, or medical nutrition therapy (MNT) alone, SMBG may be useful in achieving glycemic goals. (E)
- To achieve postprandial glucose tar-

Abbreviations: ABI, ankle-brachial index; ADA, American Diabetes Association; ARB, angiotensis receptor blocker; CBG, capillary blood glucose; CHD, Coronary heart disease; CKD, chronic kidney disease; CVD, cardiovascular disease; DMMP, diabetes medical management plan; DPN, distal symmetric polyneuropathy; DSME, diabetes self-management education; FPG, fasting plasma glucose; GDM, gestational diabetes mellitus; GFR, glomerular filtration rate; IFG, impaired fasting glucose; IGT, impaired glucose tolerance; MNT, medical nutrition therapy; NPDR, proliferative diabetic retinopathy; OGTT, oral glucose tolerance test; PAD, peripheral arterial disease; PDR, proliferative diabetic retinopathy; SMBG, self-monitoring of blood glucose; TSH, thryoid-stimulating hormone.

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gets, postprandial SMBG may be appropriate. (E)
- When prescribing SMBG, ensure that patients receive initial instruction in, and routine follow-up evaluation of, SMBG technique and their ability to use data to adjust therapy. (E)
- Continuous glucose monitoring may be a supplemental tool to SMBG for selected patients with type 1 diabetes, especially those with hypoglycemia unawareness. (E)

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 allows for timely decisions on therapy changes, when needed. (E)

Glycemic Goals
- Lowering A1C to an average of ~7% has clearly been shown to reduce microvascular and neuropathic complications of diabetes and, possibly, macrovascular disease. Therefore, the A1C goal for nonpregnant adults in general is <7%. (A)
- Epidemiologic studies have suggested an incremental (albeit, in absolute terms, a small) benefit to lowering A1C from 7% into the normal range. Therefore, the A1C goal for selected individual patients is as close to normal (<6%) as possible without significant hypoglycemia. (B)
- Less stringent A1C goals may be appropriate for patients with a history of severe hypoglycemia, patients with limited life expectancies, children, individuals with comorbid conditions, and those with longstanding diabetes and minimal or stable microvascular complications. (E)

Medical Nutrition Therapy (MNT)
General recommendations
- Individuals who have pre-diabetes 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. (B)
- MNT should be covered by insurance and other payors. (E)

Energy balance, overweight, and obesity
- In overweight and obese insulin-resistant individuals, modest weight loss has been shown to reduce insulin resistance. Thus, 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 or low-fat calorie-restricted diets may be effective in the short term (up to 1 year). (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)

Primary prevention of 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 high 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)

Dietary fat intake in diabetes management
- Saturated fat intake should be <7% of total calories. (A)
- Intake of *trans* fat should be minimized. (E)

Carbohydrate intake in diabetes management
- Monitoring carbohydrate, whether by carbohydrate counting, exchanges, or experience-based estimation, remains a key strategy in achieving glycemic control. (A)
- For individuals with diabetes, the use of the glycemic index and glycemic load may provide a modest additional benefit for glycemic control over that observed when total carbohydrate is considered alone. (B)

Other nutrition recommendations
- Sugar alcohols and nonnutritive sweeteners are safe when consumed within the acceptable daily intake levels established by the Food and Drug Administration (FDA). (A)
- If adults with diabetes choose to use alcohol, daily intake should be limited to a moderate amount (one drink per day or less for adult women and two drinks per day or less for adult men). (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)
- Benefit from chromium supplementation in people with diabetes or obesity has not been conclusively demonstrated and, therefore, cannot be recommended. (E)

Diabetes Self-Management Education (DSME)
- People with diabetes should receive DSME according to national standards when their diabetes is diagnosed and as needed thereafter. (B)
- Self-management behavior change is the key outcome of DSME and should be measured and monitored as part of care. (E)
- DSME should address psychosocial issues, since emotional well-being is strongly associated with positive diabetes outcomes. (C)
- DSME should be reimbursed by third-party payors. (E)

Physical Activity
- People with diabetes should be advised to perform at least 150 min/week of moderate-intensity aerobic physical activity (50–70% of maximum heart rate). (A)
- In the absence of contraindications, people with type 2 diabetes should be encouraged to perform resistance training three times per week. (A)

Psychosocial Assessment and Care
- Assessment of psychological and social situation should be included as an ongoing part of the medical management of diabetes. (E)
- Psychosocial screening and follow-up should 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)
- Screen for psychosocial problems such as depression, anxiety, eating disorders, and cognitive impairment when adherence to the medical regimen is poor. (E)

Hypoglycemia
- 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 in its administration. Glucagon administration is not limited to health care professionals. (E)
- Individuals with hypoglycemia unawareness or one or more episodes of severe hypoglycemia should be advised to raise their glycemic targets to strictly avoid further hypoglycemia for at least several weeks in order to partially reverse hypoglycemia unawareness and reduce risk of future episodes. (B)

Immunization
- Annually provide an influenza vaccine to all diabetic patients ≥6 months of age. (C)
- Provide at least one lifetime pneumococcal vaccine for adults with diabetes. A one-time revaccination is recommended for individuals ≥65 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)

Hypertension/Blood Pressure Control

Screening and diagnosis
- Blood pressure should be measured at every routine diabetes visit. Patients found to have systolic blood pressure ≥130 mmHg or diastolic blood pressure ≥80 mmHg should have blood pressure confirmed on a separate day. Repeat systolic blood pressure ≥130 mmHg or diastolic blood pressure ≥80 mmHg confirms a diagnosis of hypertension. (C)

Goals
- Patients with diabetes should be treated to a systolic blood pressure <130 mmHg. (C)
- Patients with diabetes should be treated to a diastolic blood pressure <80 mmHg. (B)

Treatment
- Patients with a systolic blood pressure of 130–139 mmHg or a diastolic blood pressure of 80–89 mmHg may be given lifestyle therapy alone for a maximum of 3 months, and then, if targets are not achieved, be treated with addition of pharmacological agents. (E)
- Patients with more severe hypertension (systolic blood pressure ≥140 or diastolic blood pressure ≥90 mmHg) at diagnosis or follow-up should receive pharmacologic therapy in addition to lifestyle therapy. (A)
- Pharmacologic 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. If needed to achieve blood pressure targets, a thiazide diuretic should be added to those with an estimated glomerular filtration rate (GFR) ≥50 ml/min per 1.73 m^2 and a loop diuretic for those with an estimated GFR <50 ml/min per 1.73 m^2. (E)
- Multiple drug therapy (two or more agents at maximal doses) is generally required to achieve blood pressure targets. (B)
- If ACE inhibitors, ARBs, or diuretics are used, kidney function and serum potassium levels should be closely 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, measure fasting lipid profile at least annually. 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; 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 cardiovascular disease (CVD) (A)
  - without CVD who are over the age of 40 and have one or more other CVD risk factors. (A)
- For patients at lower risk than those mentioned above (e.g., without overt CVD and under the age of 40), statin therapy should be considered in addition to lifestyle therapy if LDL cholesterol remains >100 mg/dl or in those with multiple CVD risk factors. (E)
- In individuals without overt CVD, the primary goal is an LDL cholesterol <100 mg/dl (2.6 mmol/l). (A)
- 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. (E)
- If drug-treated patients do not reach the above targets on maximal tolerated statin therapy, a reduction in LDL cholesterol of ~40% from baseline is an alternative therapeutic goal. (A)
- Triglycerides levels <150 mg/dl (1.7 mmol/l) and HDL cholesterol levels >40 mg/dl (1.0 mmol/l) in men and >50 mg/dl (1.3 mmol/l) in women are desirable. However, LDL cholesterol–targeted statin therapy remains the preferred strategy. (C)
- Combination therapy using statins and other lipid-lowering agents may be considered to achieve lipid targets but has not been evaluated in outcome studies for either CVD outcomes or safety. (E)
- Statin therapy is contraindicated in pregnancy. (E)

Antiplatelet Agents
- Use aspirin therapy (75–162 mg/day) as a secondary prevention strategy in diabetic individuals with a history of CVD. (A)
- Use aspirin therapy (75–162 mg/day) as a primary prevention strategy in

those with type 1 or type 2 diabetes at increased cardiovascular risk, including those who are >40 years of age or who have additional risk factors (family history of CVD, hypertension, smoking, dyslipidemia, or albuminuria). (A)
- Aspirin therapy is not recommended in people under 30 years of age, due to lack of evidence of benefit, and is contraindicated in patients under the age of 21 years because of the associated risk of Reye's syndrome. (E)
- Combination therapy using other antiplatelet agents such as clopidrogel in addition to aspirin should be used in patients with severe and progressive CVD. (C)
- Other antiplatelet agents may be a reasonable alternative for high-risk patients with aspirin allergy, with bleeding tendency, who are receiving anticoagulant therapy, with recent gastrointestinal bleeding, and with clinically active hepatic disease who are not candidates for aspirin therapy. (E)

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

Coronary Heart Disease (CHD) Screening and Treatment
Screening
- In asymptomatic patients, evaluate risk factors to stratify patients by 10-year risk, and treat risk factors accordingly. (B)

Treatment
- In patients with known CVD, ACE inhibitor, aspirin, and statin therapy (if not contraindicated) should be used to reduce the risk of cardiovascular events. (A)
- In patients with a prior myocardial infarction, add β-blockers (if not contraindicated) to reduce mortality. (A)
- In patients >40 years of age with another cardiovascular risk factor (hypertension, family history, dyslipidemia, microalbuminuria, cardiac autonomic neuropathy, or smoking), ACE inhibitor, aspirin, and statin therapy (if not contraindicated) should be used to reduce the risk of cardiovascular events. (B)
- In patients with treated congestive heart failure (CHF), metformin and thiazolidinedione (TZD) use are contraindicated. (C)

Nephropathy Screening and Treatment
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. (E)
- 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 micro- or macroalbuminuria, either ACE inhibitors or ARBs should be used. (A)
- While there are no adequate head-to-head comparisons of ACE inhibitors and ARBs, there is clinical trial support for each of the following statements:
  - In patients with type 1 diabetes, with hypertension and any degree of albuminuria, ACE inhibitors have been shown to delay the progression of nephropathy. (A)
  - In patients with type 2 diabetes, hypertension, and microalbuminuria, both ACE inhibitors and ARBs have been shown to delay the progression to macroalbuminuria. (A)
  - In patients with type 2 diabetes, hypertension, macroalbuminuria, and renal insufficiency (serum creatinine >1.5 mg/dl), ARBs have been shown to delay the progression of nephropathy. (A)
  - If one class is not tolerated, the other should be substituted. (E)
- Reduction of protein intake to 0.8–1.0 g · kg body wt^{-1} · day^{-1} in individuals with diabetes and the earlier stages of CKD and to 0.8 g · kg body wt^{-1} · day^{-1} in the later stages of CKD may improve measures of renal function (e.g., urine albumin excretion rate and GFR) and is recommended. (B)
- When ACE inhibitors, ARBs, or diuretics are used, monitor serum creatinine and potassium levels for the development of acute kidney disease and hyperkalemia. (E)
- Continued monitoring of urine albumin excretion to assess both the response to therapy and the progression of disease is recommended. (E)
- Consider referral to a physician experienced in the care of kidney disease when there is uncertainty about the etiology of kidney disease (active urine sediment, absence of retinopathy, rapid decline in GFR), 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 adolescents 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)
- Women with preexisting 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 nonproliferative diabetic retinopathy (NPDR), or any proliferative diabetic retinopathy (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)
- 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)

Neuropathy Screening and Treatment
- All patients should be screened for distal symmetric polyneuropathy (DPN) at diagnosis 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)
- Educate all patients about self-care of the feet. For those with DPN, facilitate enhanced foot care education and refer for special footware. (B)
- Screening for signs and symptoms of autonomic neuropathy 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 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 can be accomplished in a primary care setting and should include the use of a monofilament, tuning fork, palpation, and a visual examination. (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 loss of protective sensation and structural abnormalities, or have history of prior lower-extremity complications to foot care specialists for ongoing preventive care and life-long 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)

Children and adolescents
Glycemic control
- Consider age when setting glycemic goals in children and adolescents with type 1 diabetes, with less stringent goals for younger children. (E)

Nephropathy
- Annual screening for microalbuminuria, with a random spot urine sample for microalbumin-to-creatinine ratio, should be initiated once the child is 10 years of age and has had diabetes for 5 years. (E)
- Confirmed, persistently elevated microalbumin levels on two additional urine specimens should be treated with an ACE inhibitor, titrated to normalization of microalbumin excretion if possible. (E)

Hypertension
- Treatment of high-normal blood pressure (systolic or diastolic blood pressure consistently above the 90th percentile for age, sex, and height) should include 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, pharmacologic treatment should be initiated. (E)
- Pharmacologic 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 initiated as soon as the diagnosis is confirmed. (E)
- ACE inhibitors should be considered for the initial treatment of hypertension. (E)

Dyslipidemia
Screening
- If there is a family history of hypercholesterolemia (total cholesterol >240 mg/dl) or a cardiovascular event before age 55 years, or if family history is unknown, then a fasting lipid profile should be performed on children >2 years of age soon after diagnosis (after glucose control has been established). If family history is not of concern, then the first lipid screening should be performed at puberty (≥10 years). All children diagnosed with diabetes at or after puberty should have a fasting lipid profile performed soon after diagnosis (after glucose control has been established). (E)
- For both age groups, if lipids are abnormal, annual monitoring is recommended. If LDL cholesterol values are within the accepted risk levels (<100 mg/dl [2.6 mmol/l]), a lipid profile should be repeated every 5 years. (E)

Treatment
- Initial therapy should consist of optimization of glucose control and MNT using a Step 2 American Heart Association 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 is recommended 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. (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. (E)
- 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
- Patients with type 1 diabetes who become symptomatic for celiac disease should be screened, using tissue transglutaminase (tTg) antibodies or antiendomysial antibodies (anti-EMA), with documentation of normal serum immunoglobulin A (IgA) levels. (E)
- Children with positive antibodies should be referred to a gastroenterologist for evaluation. (E)
- Children with confirmed celiac disease should have consultation with a dietitian and be placed on a gluten-free diet. (E)

Hypothyroidism

- Patients with type 1 diabetes should be screened for thyroid peroxidase and thyroglobulin antibodies at diagnosis. (E)
- Thryoid-stimulating hormone (TSH) concentrations should be measured after metabolic control has been established. If normal, they should be rechecked every 1–2 years, or if the patient develops symptoms of thyroid dysfunction, thyromegaly, or an abnormal growth rate. Free T4 should be measured if TSH is abnormal. (E)

Preconception Care

- A1C levels should be as close to normal as possible (<7%) in an individual patient before conception is attempted. (B)
- All women with diabetes and childbearing potential should be educated about the need for good glucose control before pregnancy and should participate in family planning. (E)
- Women with diabetes who are contemplating pregnancy should be evaluated and, if indicated, treated for diabetic retinopathy, nephropathy, neuropathy, and CVD. (E)
- Medications used by such women should be evaluated before 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)

Older Adults

- Older adults who are functional, cognitively intact, and have significant life expectancy should receive diabetes treatment using goals developed for younger adults. (E)
- Glycemic goals for older adults not meeting the above criteria may 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 diabetic complications should be individualized in older adults, but particular attention should be paid to complications that would lead to functional impairment. (E)

Diabetes Care in the Hospital
Recommendations

- 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: blood glucose levels should be kept as close to 110 mg/dl (6.1 mmol/l) as possible and generally <140 mg/dl (7.8 mmol/l). (A) These 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. Because cohort data suggest that outcomes are better in hospitalized patients with fasting glucose <126 mg/dl and all random glucoses <180–200 mg/dl, these goals are reasonable if they can be safely achieved. Insulin is the preferred drug to treat hyperglycemia in most cases. (E)
- Due to concerns regarding the risk of hypoglycemia, some institutions may consider these blood glucose levels to be overly aggressive for initial targets. Through quality improvement, glycemic goals should systematically be reduced to the recommended levels. (E)
- Scheduled prandial insulin doses should be appropriately timed in relation to meals and should be adjusted according to point-of-care glucose levels. The traditional sliding-scale insulin regimens are ineffective as monotherapy and are generally not recommended. (C)
- Using correction dose or "supplemental" insulin to correct premeal hyperglycemia in addition to scheduled prandial and basal insulin is recommended. (E)
- Glucose monitoring with orders for correction insulin should be initiated in any patient not known to be diabetic who receives therapy associated with high risk for hyperglycemia, including high-dose glucocorticoids therapy, initiation of enteral or parenteral nutrition, or other medications such as octreotide or immunosuppressive medications. (B) If hyperglycemia is documented and persistent, initiation of basal/bolus insulin therapy may be necessary. Such patients should be treated to the same glycemic goals as patients with known diabetes. (E)
- A plan for treating hypoglycemia should be established for each patient. Episodes of hypoglycemia in the hospital should be tracked. (E)
- All patients with diabetes admitted to the hospital should have an A1C obtained if the result of testing in the previous 2–3 months is not available. (E)
- A diabetes education plan including "survival skills education" and follow-up should be developed for each patient. (E)
- Patients with hyperglycemia in the hospital who do not have a diagnosis of diabetes should have appropriate plans for follow-up testing and care documented at discharge. (E)

Diabetes Care in the School and Day Care Setting

- An individualized diabetes medical management plan (DMMP) should be developed by the parent/guardian and the student's diabetes health care team. (E)
- An adequate number of school personnel should be trained in the necessary diabetes procedures (including monitoring of blood glucose levels and the administration of insulin and glucagon) and in the appropriate response to high and low blood glucose levels. These school personnel need not be health care professionals. (E)
- As specified in the DMMP and as developmentally appropriate, the student with diabetes should have immediate access to diabetes supplies at all times, should be permitted to monitor his or her blood glucose level, and should be able to take appropriate action to treat hypoglycemia in the classroom or anywhere the student may be in conjunction with a school activity. (E)

Diabetes Care at Diabetes Camps

- Each camper should have a standardized medical form completed by his/her family and the physician managing the diabetes. (E)
- Camp medical staff should be led by a physician with expertise in managing type 1 and type 2 diabetes, and should include nurses (including diabetes educators and diabetes clinical nurse specialists) and registered dietitians with expertise in diabetes. (E)
- All camp staff, including physicians,

nurses, dietitians and volunteers, should undergo background testing to ensure appropriateness in working with children. (E)

Diabetes Management in Correctional Institutions

- Correctional staff should be trained in the recognition, treatment, and appropriate referral for hypo- and hyperglycemia, including serious metabolic decompensation. (E)
- 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 upon entry. Insulin-treated patients should have a capillary blood glucose (CBG) determination within 1–2 h of arrival. Staff should identify patients with type 1 diabetes who are at high risk for diabetic ketoacidosis (DKA) with omission of insulin. (E)
- Medications and MNT should be continued without interruption upon entry into the correctional environment. (E)
- In the correctional setting, policies and procedures should enable CBG monitoring to occur at the frequency necessitated by the patient's glycemic control and diabetes regimen, and should require staff to notify a physician of all CBG results outside of a specified range, as determined by the treating physician. (E)
- For all inter-institutional transfers, a medical transfer summary should be transferred with the patient, and diabetes supplies and medication should accompany the patient. (E)
- Correctional staff should begin discharge planning with adequate lead time to ensure continuity of care and facilitate entry into community diabetes care. (E)

Emergency and Disaster Preparedness

- People with diabetes should maintain a disaster kit that includes items important to their diabetes self-management and continuing medical care. (E)
- The kit should be reviewed and replenished at least twice yearly. (E)

Hypoglycemia and Employment/Licensure

- 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)

Third-Party Reimbursement for Diabetes Care, Self-Management Education, and Supplies

- Patients and practitioners should have access to all classes of antidiabetic medications, equipment, and supplies without undue controls. (E)
- MNT and DSME should be covered by insurance and other payors. (E)

Standards of Medical Care in Diabetes—2008

AMERICAN DIABETES ASSOCIATION

Diabetes is a chronic illness that requires continuing medical care and patient self-management education to prevent acute complications and to reduce the risk of long-term complications. Diabetes care is complex and requires that many issues, beyond glycemic control, be addressed. 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, payors, and other interested individuals with the components of diabetes care, treatment goals, and tools to evaluate the quality of care. While individual preferences, comorbidities, and other patient factors may require modification of goals, targets that are desirable for most patients with diabetes are provided. These standards are not intended to preclude more extensive evaluation and management of the patient by other specialists as needed. For more detailed information, refer to refs. 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 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.

I. CLASSIFICATION AND DIAGNOSIS

A. Classification

In 1997, ADA issued new diagnostic and classification criteria (4); in 2003, modifications were made regarding the diagnosis of impaired fasting glucose (5). 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 AIDS or after organ transplantation)
- Gestational diabetes mellitus (GDM) (diabetes diagnosed during pregnancy)

Some patients cannot be clearly classified as type 1 or type 2 diabetes. 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 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

Recommendations

- The fasting plasma glucose (FPG) test is the preferred test to diagnose diabetes in children and nonpregnant adults. (E)
- Use of the A1C for the diagnosis of diabetes is not recommended at this time. (E)

Criteria for the diagnosis of diabetes in nonpregnant adults are shown in Table 2. Three ways to diagnose diabetes are available, and each must be confirmed on a subsequent day unless unequivocal symptoms of hyperglycemia are present. Although the 75-g oral glucose tolerance test (OGTT) is more sensitive and modestly more specific than the FPG to diagnose diabetes, it is poorly reproducible and difficult to perform in practice. Because of ease of use, acceptability to patients, and lower cost, the FPG is the preferred diagnostic test. Although the FPG is less sensitive than the OGTT, the vast majority of people who do not meet diagnostic criteria for diabetes by the FPG but would by the OGTT will have an A1C value well below 7.0% (6).

Although the OGTT is not recommended for routine clinical use, it may be

The recommendations in this article are based on the evidence reviewed in the following publication: Standards of care for diabetes (Technical Review). *Diabetes Care* 17:1514–1522, 1994.

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Abbreviations: ABI, ankle-brachial index; ACE, angiotensin-converting enzyme; ADAG, A1C-Derived Average Glucose; ARB, angiotensin receptor blocker; CAD, coronary artery disease; CBG, capillary blood glucose; CHD, coronary heart disease; CHF, congestive heart failure; CKD, chronic kidney disease; CMS, Centers for Medicare and Medicaid Services; CSII, continuous subcutaneous insulin infusion; CVD, cardiovascular disease; DCCT, Diabetes Control and Complications Trial; DKA, diabetic ketoacidosis; DMMP, diabetes medical management plan; DPN, distal symmetric polyneuropathy; DPP, Diabetes Prevention Program; DRS, Diabetic Retinopathy Study; DSME, diabetes self-management education; DSMT, diabetes self-management training; eAG, estimated average glucose; ECG, electrocardiogram; EDIC, Epidemiology of Diabetes Interventions and Complications; ERP, education recognition program; ESRD, end-stage renal disease; ETDRS, Early Treatment Diabetic Retinopathy Study; FDA, Food and Drug Administration; FPG, fasting plasma glucose; GDM, gestational diabetes mellitus; GFR, glomerular filtration rate; ICU, intensive care unit; IFG, impaired fasting glucose; IGT, impaired glucose tolerance; MICU, medical ICU; MNT, medical nutrition therapy; NDEP, National Diabetes Education Program; NPDR, nonproliferative diabetic retinopathy; OGTT, oral glucose tolerance test; PAD, peripheral arterial disease; PDR, proliferative diabetic retinopathy; PPG, postprandial plasma glucose; RAS, renin-angiotensin system; RDA, recommended dietary allowance; SICU, surgical ICU; SMBG, self-monitoring of blood glucose; TSH, thyroid-stimulating hormone; TZD, thiazolidinedione; UKPDS, U.K. Prospective Diabetes Study.

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Table 1—*ADA evidence-grading system for clinical practice recommendations*

Level of evidence	Description
A	Clear evidence from well-conducted, generalizable, randomized controlled trials 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 Oxford Supportive evidence from well-conducted randomized controlled trials 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
B	Supportive evidence from well-conducted cohort studies, including: • 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
C	Supportive evidence from poorly controlled or uncontrolled studies, including: • 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 Conflicting evidence with the weight of evidence supporting the recommendation
E	Expert consensus or clinical experience

useful for further evaluation of patients in whom diabetes is still strongly suspected but who have normal FPG or impaired fasting glucose (IFG) (see Section 1.C).

Due to lack of evidence on prognostic significance and diagnostic thresholds, the use of the A1C for the diagnosis of diabetes is not recommended at this time.

C. Diagnosis of pre-diabetes

Hyperglycemia not sufficient to meet the diagnostic criteria for diabetes is categorized as either IFG or impaired glucose tolerance (IGT), depending on whether it is identified through the FPG or the OGTT:

- IFG = FPG 100 mg/dl (5.6 mmol/l) to 125 mg/dl (6.9 mmol/l)
- IGT = 2-h plasma glucose 140 mg/dl (7.8 mmol/l) to 199 mg/dl (11.0 mmol/l)

IFG and IGT have been officially termed "pre-diabetes." Both categories of pre-diabetes are risk factors for future diabetes and for cardiovascular disease (CVD) (7).

II. TESTING FOR PRE-DIABETES AND DIABETES IN ASYMPTOMATIC PATIENTS

Recommendations

- Testing to detect pre-diabetes and type 2 diabetes in asymptomatic people should be considered in adults who are overweight or obese (BMI ≥25 kg/m^2) and who have one or more additional risk factors for diabetes (Table 3). In those without these risk factors, testing should begin at age 45. (B)
- If tests are normal, repeat testing should be carried out at least at 3-year intervals. (E)
- To test for pre-diabetes or diabetes, either an FPG test or a 2-h OGTT (75-g glucose load) or both are appropriate. (B)
- An OGTT may be considered in patients with IFG to better define the risk of diabetes. (E)
- In those identified with pre-diabetes, identify and, if appropriate, treat other CVD risk factors. (B)

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. Type 2 diabetes has a long asymptomatic phase and significant clinical risk markers. Diabetes may be identified anywhere along a spectrum of clinical scenarios ranging from a seemingly low-risk individual who happens to have glucose testing, to a higher-risk individual who the provider tests because of high suspicion of diabetes, to the symptomatic patient. The discussion herein is primarily framed as testing for diabetes in those without symptoms. Testing for diabetes will also detect individuals with pre-diabetes.

A. Testing for pre-diabetes and type 2 diabetes in adults

Type 2 diabetes is frequently not diagnosed until complications appear, and approximately one-third of all people with diabetes may be undiagnosed. Although the effectiveness of early identification of pre-diabetes and diabetes

Table 2—*Criteria for the diagnosis of diabetes*

1.	FPG ≥126 mg/dl (7.0 mmol/l). Fasting is defined as no caloric intake for at least 8 h.*
	OR
2.	Symptoms of hyperglycemia and a casual plasma glucose ≥200 mg/dl (11.1 mmol/l). Casual is defined as any time of day without regard to time since last meal. The classic symptoms of hyperglycemia include polyuria, polydipsia, and unexplained weight loss.
	OR
3.	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.*

*In the absence of unequivocal hyperglycemia, these criteria should be confirmed by repeat testing on a different day (5).

Table 3—*Criteria for testing for pre-diabetes and diabetes in asymptomatic adult individuals*

1. Testing should be considered in all adults who are overweight (BMI ≥25 kg/m^2*) and have additional risk factors:
   - physical inactivity
   - first-degree relative with diabetes
   - members of a high-risk ethnic population (e.g., African American, Latino, Native American, Asian American, and Pacific Islander)
   - women who delivered a baby weighing >9 lb or were diagnosed with GDM
   - hypertension (≥140/90 mmHg or on therapy for hypertension)
   - HDL cholesterol level <35 mg/dl (0.90 mmol/l) and/or a triglyceride level >250 mg/dl (2.82 mmol/l)
   - women with polycystic ovarian syndrome (PCOS)
   - IGT or IFG on previous testing
   - other clinical conditions associated with insulin resistance (e.g., severe obesity and acanthosis nigricans)
   - history of CVD
2. In the absence of the above criteria, testing for pre-diabetes and 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 and risk status.

*At-risk BMI may be lower in some ethnic groups.

through mass testing of asymptomatic individuals has not been definitively proven (and rigorous trials to provide such proof are unlikely to occur), pre-diabetes 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 (8). Additionally, the duration of glycemic burden is a strong predictor of adverse outcomes, and effective interventions exist to prevent progression of pre-diabetes to diabetes (see Section IV) and to reduce risk of complications of diabetes (see Section VI).

Recommendations for testing for pre-diabetes and diabetes in asymptomatic, undiagnosed adults are listed in Table 3. Testing should be considered in all adults with BMI ≥25 kg/m^2 and one or more risk factors for diabetes. Because age is a major risk factor for diabetes, testing of those without other risk factors should begin no later than age 45.

Either FPG testing or the 2-h OGTT is appropriate for testing. The 2-h OGTT identifies people with either IFG or IGT and, thus, more prediabetic people at increased risk for the development of diabetes and CVD. It should be noted that the two tests do not necessarily detect the same prediabetic individuals (9). The efficacy of interventions for primary prevention of type 2 diabetes (10–16) has primarily been demonstrated among individuals with IGT, not among individuals with IFG (who do not also have IGT). As noted in the diagnosis section (I.B), the FPG test is more convenient, more reproducible, less costly, and easier to administer than the 2-h OGTT (4,5). An OGTT may be useful in patients with IFG to better define the risk of diabetes.

The appropriate interval between tests is not known (17). The rationale for the 3-year interval is that false negatives 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.

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 appropriate follow-up testing and care, and, conversely, there may be failure to ensure appropriate repeat testing for individuals who test negative. Community screening may also be poorly targeted, i.e., it may fail to reach the groups most at risk and inappropriately test those at low risk (the worried well) or even those already diagnosed (18,19).

B. Testing for type 2 diabetes in children

The incidence of type 2 diabetes in adolescents has increased dramatically in the last decade, especially in minority populations (20), although the disease remains rare in the general population (21). Consistent with recommendations for adults, children and youth at increased risk for the presence or the development of type 2 diabetes should be tested (22). The recommendations of the ADA consensus statement on type 2 diabetes in children and youth are summarized in Table 4.

C. Screening for type 1 diabetes

Generally, people with type 1 diabetes present with acute symptoms of diabetes and markedly elevated blood glucose levels, and most cases are diagnosed soon after the onset of hyperglycemia. Widespread clinical testing of asymptomatic individuals for the presence of autoantibodies related to type 1 diabetes cannot currently be recommended as a means to identify individuals at risk, for several reasons: *1*) cutoff values for the immune marker assays have not been completely established or standardized for clinical settings; *2*) there is no consensus as to what follow-up testing should be undertaken when a positive autoantibody test result is obtained; and *3*) because the incidence of type 1 diabetes is low, testing of healthy individuals will identify only a very small number (<0.5%) who at that moment may be "prediabetic." Finally, though clinical studies are being conducted to test various methods of preventing type 1 diabetes in high-risk individuals, no effective intervention has yet been identified. If studies uncover an effective means of preventing type 1 diabetes, targeted screening (e.g., siblings of type 1 children) may be appropriate in the future.

Table 4—*Testing for type 2 diabetes in asymptomatic children*

Criteria
- Overweight (BMI >85th percentile for age and sex, weight for height >85th percentile, or weight >120% of ideal for height)

Plus any two of the following risk factors:
- Family history of type 2 diabetes in first- or second-degree relative
- Race/ethnicity (e.g., Native American, African American, Latino, Asian American, and Pacific Islander)
- Signs of insulin resistance or conditions associated with insulin resistance (e.g., acanthosis nigricans, hypertension, dyslipidemia, or PCOS)
- Maternal history of diabetes or GDM

Age of initiation: age 10 years or at onset of puberty, if puberty occurs at a younger age

Frequency: every 2 years

Test: FPG preferred

III. DETECTION AND DIAGNOSIS OF GESTATIONAL DIABETES MELLITUS (GDM)

Recommendations

- Screen for GDM using risk factor analysis and, if appropriate, use of an OGTT. (C)
- Women with GDM should be screened for diabetes 6–12 weeks postpartum and should be followed up with subsequent screening for the development of diabetes or pre-diabetes. (E)

Gestational diabetes mellitus is defined as any degree of glucose intolerance with onset or first recognition during pregnancy (4). Although most cases resolve with delivery, the definition applies whether or not the condition persists after pregnancy and does not exclude the possibility that unrecognized glucose intolerance may have antedated or begun concomitantly with the pregnancy. Approximately 7% of all pregnancies (ranging from 1 to 14% depending on the population studied and the diagnostic tests used) are complicated by GDM, resulting in more than 200,000 cases annually.

Because of the risks of GDM to the mother and neonate, screening and diagnosis are warranted. The screening and diagnostic strategies, based on the 2004 ADA position statement on gestational diabetes mellitus (23), are outlined in Table 5.

Results of the Hyperglycemia and Adverse Pregnancy Outcomes study were reported at ADA's 67th Annual Scientific Sessions in June 2007. This 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 may call for careful reconsideration of the diagnostic criteria for GDM.

Because women with a history of GDM have a greatly increased subsequent risk for diabetes (24), they should be screened for diabetes 6–12 weeks postpartum, using standard criteria, and should be followed up with subsequent screening for the development of diabetes or pre-diabetes, as outlined in Section II. For information on the National Diabetes Education Program (NDEP) campaign to prevent type 2 diabetes in women with GDM, go to www.ndep.nih.gov/diabetes/pubs/NeverTooEarly Tipsheet.pdf.

Table 5—*Screening for and diagnosis of GDM*

Carry out GDM risk assessment at the first prenatal visit.

Women at very high risk for GDM should be screened for diabetes as soon as possible after the confirmation of pregnancy. Criteria for very high risk are:
- Severe obesity
- Prior history of GDM or delivery of large-for-gestational-age infant
- Presence of glycosuria
- Diagnosis of PCOS
- Strong family history of type 2 diabetes

Screening/diagnosis at this stage of pregnancy should use standard diagnostic testing (Table 2)

All women of higher than low risk of GDM, including those above not found to have diabetes early in pregnancy, should undergo GDM testing at 24–28 weeks of gestation. Low risk status, which does not require GDM screening, is defined as women with *all* of the following characteristics:
- Age <25 years
- Weight normal before pregnancy
- Member of an ethnic group with a low prevalence of diabetes
- No known diabetes in first-degree relatives
- No history of abnormal glucose tolerance
- No history of poor obstetrical outcome

Two approaches may be followed for GDM screening at 24–28 weeks:

1. Two-step approach:
   A. Perform initial screening by measuring plasma or serum glucose 1 h after a 50-g oral glucose load. A glucose threshold after 50-g load of ≥140 mg/dl identifies ~ 80% of women with GDM, while the sensitivity is further increased to ~ 90% by a threshold of ≥130 mg/dl.
   B. Perform a diagnostic 100-g OGTT on a separate day in women who exceed the chosen threshold on 50-g screening.
2. One-step approach (may be preferred in clinics with high prevalence of GDM): Perform a diagnostic 100-g OGTT in all women to be tested at 24–28 weeks.

The 100-g OGTT should be performed in the morning after an overnight fast of at least 8 h.

A diagnosis of GDM requires at least two of the following plasma glucose values:

Fasting: ≥95 mg/dl (≥5.3 mmol/l)
1 h: ≥180 mg/dl (≥10.0 mmol/l)
2 h: ≥155 mg/dl (≥8.6 mmol/l)
3 h: ≥140 mg/dl (≥7.8 mmol/l)

IV. PREVENTION/DELAY OF TYPE 2 DIABETES

Recommendations

- Patients with IGT (A) or IFG (E) should be given counseling on weight loss of 5–10% of body weight, as well as on 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 potential cost savings of diabetes prevention, such counseling should be covered by third-party payors. (E)
- In addition to lifestyle counseling, metformin may be considered in those who are at very high risk (combined IFG and IGT plus other risk factors) and who are obese and under 60 years of age. (E)
- Monitoring for the development of diabetes in those with pre-diabetes should be performed every year. (E)

Randomized controlled trials have shown that individuals at high risk for developing diabetes (those with IFG, IGT, or both) can be given interventions that significantly decrease the rate of onset of diabetes (10–16). These interventions include an intensive lifestyle modification program that has been shown to be very effective (~58% reduction after 3 years), and use of the pharmacologic agents metformin, acarbose, orlistat, and rosiglitazone, each of which has been shown to decrease incident diabetes to various degrees. A summary of major diabetes prevention trials is shown in Table 6.

Based on the results of clinical trials and the known risks of progression of

Table 6—*Therapies proven effective in diabetes prevention trials*

Study (reference)‡	*n*	Population	Age (years)	Duration (years)	Follow up	Intervention (daily dose)	Control subjects (%/year)	Relative risk
Finnish DPS (15)	522	IGT, BMI ≥25 kg/m^2	55	3.2	92	Individual diet/exercise	6	0.42 (0.30–070)
DPP (14)	2,161*	IGT, BMI ≥24 kg/m^2, FPG >5.3 (95)	51	3	93	Individual diet/exercise	10	0.42 (0.34–0.52)
Pan et al. (22)	259*	IGT (randomized groups)	45	6	92	Group diet/ exercise	16	0.62 (0.44–0.86)
Kosaka et al. (23)	458	IGT (men), BMI = 24 kg/m^2	~55	4	92	Individual diet/exercise	2	0.33 (0.10–1.0)†
Indian DPP (24)	269*	IGT	46	2.5	95	Individual diet/exercise	22	0.71 (0.63–0.79)
DPP (14)	2,155*	IGT, BMI >24 kg/m^2, FPG >5.3	51	2.8	93	Metformin (1,700 mg)	10	0.69 (0.57–0.83)
Indian DPP (24)	269*	IGT	46	2.5	95	Metformin (500 mg)	22	0.74 (0.65–0.81)
STOP NIDDM (16)	1,419	IGT, FPG >5.6	54	3.2	96	Acarbose (300 mg)	13	0.75 (0.63–0.90)
XENDOS (18)	3,277	BMI >30 kg/m^2	43	4	43	Orlistat (360 mg)	2	0.63 (0.46–0.86)
DPP (25)	1,067*	IGT, BMI >24 kg/m^2, FPG >5.3	51	0.9	93	Troglitazone (400 mg)	12	0.25 (0.14–0.43)†
TRIPOD (26)	266	Previous GDM	35	2.5	67	Troglitazone (400 mg)	12	0.45 (0.25–0.83)
DREAM (17)	5,269	IGT or IFG	55	3.0	94	Rosiglitazone (8 mg)	9	0.40 (0.35–0.46)

Reprinted with permission (25). *Number of participants in the indicated comparisons and not the total randomized; †calculated from information in the article; ‡references are numbered as in original publication (25). DPP, Diabetes Prevention Program; DPS, Diabetes Prevention Study; GDM, gestational diabetes mellitus; STOP, Study to Prevent Non-Insulin Dependent Diabetes; TRIPOD, Troglitazone in Prevention of Diabetes; XENDOS, Xenical in the prevention of Diabetes in Obese Subjects.

pre-diabetes to diabetes, an ADA consensus development panel in 2007 (7) concluded that persons with pre-diabetes (IGT and/or IFG) should be counseled on lifestyle changes with goals similar to those of the Diabetes Prevention Program (DPP) (5–10% weight loss and moderate physical activity of ~30 min/day). Regarding the more difficult issue of drug therapy for diabetes prevention, the consensus panel felt that metformin should be the only drug considered for use in diabetes prevention. For other drugs, the issues of cost, side effects, and lack of persistence of effect in some studies led the panel to not recommend their use for diabetes prevention. Metformin use was recommended only for very high-risk individuals (combined IGT and IFG, and with at least one other risk factor). In addition, the panel highlighted the evidence that in the DPP, treatment with metformin had the most relative effectiveness in those with BMI of at least 35 kg/m^2 and those under age 60.

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 glycemic 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 physician-coordinated team. Such teams may include, but are not limited to, physicians, nurse practitioners, physician's assistants, nurses, dietitians, pharmacists, 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 an active role in their care.

The management plan should be formulated as an individualized 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 each aspect is understood and agreed on by the patient and the care providers and that the goals and treatment plan are reasonable. Any plan should recognize diabetes self-management education (DSME) 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 personality, cultural factors, and presence of compli-

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, 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, meal plan, physical activity patterns, and 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, 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
  - Thyroid-stimulating hormone in type 1 diabetes, dyslipidemia or women over age 50
- Referrals
  - Annual dilated eye exam
  - Family planning for women of reproductive age
  - Registered dietitian for MNT
  - Diabetes self-management education
  - Dental examination
  - Mental health professional, if needed

*See appropriate referrals for these categories.

cations 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) and A1C measurement. In addition, in recent years technologies for continuous monitoring of interstitial glucose have entered the market.

a. Self-monitoring of blood glucose

Recommendations

- SMBG should be carried out three or more times daily for patients using multiple insulin injections or insulin pump therapy. (A)
- For patients using less frequent insulin injections, noninsulin therapies, or medical nutrition therapy (MNT) alone, SMBG may be useful in achieving glycemic goals. (E)
- To achieve postprandial glucose targets, postprandial SMBG may be appropriate. (E)
- When prescribing SMBG, ensure that patients receive initial instruction in, and routine follow-up evaluation of, SMBG technique and their ability to use data to adjust therapy. (E)
- Continuous glucose monitoring may be a supplemental tool to SMBG for selected patients with type 1 diabetes, especially those with hypoglycemia unawareness. (E)

ADA's consensus and position statements on SMBG provide a comprehensive review of the subject (26,27). 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 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), MNT, and physical activity.

The frequency and timing of SMBG should be dictated by the particular needs and goals of the patients. SMBG is especially important for patients treated with insulin to monitor for and prevent asymptomatic hypoglycemia and hyperglycemia. For most patients with type 1 diabetes and pregnant women taking insulin, SMBG is recommended three or more times daily. For this population, it is often difficult to reach A1C targets safely without hypoglycemia with the minimum of three daily tests. The optimal frequency and timing of SMBG for patients with type 2 diabetes on noninsulin therapy is not known but should be sufficient to facilitate reaching glucose goals. A meta-analysis of SMBG in non–insulin-treated patients with type 2 diabetes concluded that some regimen of SMBG was associated with a reduction in A1C of ~0.4%. However, many of the studies in this analysis also included patient education with diet and exercise counseling and, in some cases, pharmacologic intervention, making it difficult to assess the contribution of SMBG alone to improved control (28).

Because the accuracy of SMBG is instrument and user dependent (29), it is important to evaluate each patient's monitoring technique, both initially and at regular intervals thereafter. In addition, optimal use of SMBG requires proper in-

Table 8—*Summary of glycemic recommendations for adults with diabetes*

A1C	<7.0%*
Preprandial capillary plasma glucose	70–130 mg/dl (3.9–7.2 mmol/l)
Peak postprandial capillary plasma glucose†	<180 mg/dl (<10.0 mmol/l)
Key concepts in setting glycemic goals:	
• A1C is the primary target for glycemic control	
• Goals should be individualized based on:	
• duration of diabetes	
• pregnancy status	
• age	
• comorbid conditions	
• hypoglycemia unawareness	
• individual patient considerations	
• More stringent glycemic goals (i.e., a normal A1C, <6%) may further reduce complications at the cost of increased risk of hypoglycemia	
• Postprandial glucose may be targeted if A1C goals are not met despite reaching preprandial glucose goals	

*Referenced to a nondiabetic range of 4.0–6.0% using a DCCT-based assay. †Postprandial glucose measurements should be made 1–2 h after the beginning of the meal, generally peak levels in patients with diabetes.

terpretation of the data. Patients should be taught how to use the data to adjust food intake, exercise, or pharmacological therapy to achieve specific glycemic goals, and these skills should be re-evaluated periodically.

In recent years, methods to sample interstitial fluid glucose (which correlates highly with blood glucose) in a continuous and minimally invasive way have been developed. Most microdialysis systems are inserted subcutaneously, while an early system employed "reverse iontophoresis" to move glucose across the skin. The concentration of glucose is then measured by a glucose oxidase electrode detector. These systems require calibration with SMBG readings, and the latter are still recommended for making treatment decisions. Continuous glucose sensors have alarms for hypo- and hyperglycemia. Small studies in selected patient populations have shown good correlation of readings with SMBG and decreases in the mean time spent in hypo- and hyperglycemic ranges compared with blinded sensor use (30). Although continuous glucose sensors would seem to show great promise in diabetes management, as yet no rigorous controlled trials have demonstrated improvements in long-term glycemia.

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 point-of-care testing for A1C allows for timely decisions on therapy changes, when needed. (E)

Because A1C is thought to reflect average glycemia over several months (29), and has strong predictive value for diabetes complications (10,31), 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 a patient's glycemic targets (Table 8) 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 women) may be tested more frequently than every 3 months. The availability of the A1C result at the time that the patient is seen (point-of-care testing) has been reported to result in increased intensification of therapy and improvement in glycemic control (32,33).

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 (29). 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 SMBG testing 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 9 contains the correlation between A1C levels and mean plasma glucose levels based on data from the Diabetes Control and Complications Trial (DCCT) (34). The correlation is based on relatively sparse data from a primarily Caucasian type 1 diabetic population. Preliminary results of the multicenter A1C-Derived Average Glucose (ADAG) Trial, presented at the European Association for the Study of Diabetes meeting in September 2007, confirmed a close correlation of A1C with mean glucose in patients with type 1, type 2, or no diabetes. Final results of this study, not available at the time this statement was completed, should allow more accurate reporting of the estimated average glucose (eAG) and improve patients' understanding of this measure of glycemia. An updated version of Table 9, based on final results of the ADAG Trial, will be available at www.diabetes.org after publication of the study's findings in 2008.

Table 9—*Correlation between A1C level and mean plasma glucose levels on multiple testing over 2–3 months*

A1C (%)	Mean plasma glucose	
	mg/dl	mmol/l
6	135	7.5
7	170	9.5
8	205	11.5
9	240	13.5
10	275	15.5
11	310	17.5
12	345	19.5

These estimates are based on DCCT data (34). An updated version of this table, based on final results of the ADAG Trial, will be available at www.diabetes.org after publication of the study's findings in 2008.

2. Glycemic goals

Recommendations

- Lowering A1C to an average of ~7% has clearly been shown to reduce microvascular and neuropathic complications of diabetes and, possibly, macrovascular disease. Therefore, the A1C goal for nonpregnant adults in general is <7%. (A)
- Epidemiologic studies have suggested an incremental (albeit, in absolute terms, a small) benefit to lowering A1C from 7% into the normal range. Therefore, the A1C goal for selected individual patients is as close to normal (<6%) as possible without significant hypoglycemia. (B)
- Less stringent A1C goals may be appropriate for patients with a history of severe hypoglycemia, patients with limited life expectancies, children, individuals with comorbid conditions, and those with longstanding diabetes and minimal or stable microvascular complications. (E)

Glycemic control is fundamental to the management of diabetes. The DCCT, a prospective, randomized, controlled trial of intensive versus standard glycemic control in type 1 diabetes, showed definitively that improved glycemic control is associated with sustained decreased rates of microvascular (retinopathy and nephropathy) as well as neuropathic complications (35). Follow up of the DCCT cohorts in the Epidemiology of Diabetes Interventions and Complications (EDIC) study has shown persistence of this effect in previously intensively treated subjects, even though their glycemic control has been equivalent to that of previous standard arm subjects during follow-up (36,37). In addition, EDIC has shown a significant reduction of the rate of cardiovascular outcomes in the previous intensive arm (38).

In type 2 diabetes, the Kumamoto study (39) and the UK Prospective Diabetes Study (UKPDS) (40,41) demonstrated significant reductions in microvascular and neuropathic complications with intensive therapy. The potential of intensive glycemic control to reduce CVD in type 2 diabetes is supported by epidemiological studies (31,40–42) and a meta-analysis (43), but has not yet been demonstrated in a randomized clinical trial. Several large trials are currently under way to address this issue.

In each of these large randomized prospective clinical trials, treatment regimens that reduced average A1C to ~7% (~1% above the upper limits of normal) were associated with fewer long-term microvascular complications; however, intensive control was found to increase the risk of severe hypoglycemia, most notably in the DCCT, and to lead to weight gain (31,44).

Epidemiological analyses of the DCCT and UKPDS (31,35) 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 complications, albeit the absolute risk reductions become much smaller. Given the substantially increased risk of hypoglycemia (particularly in those with type 1 diabetes) and the relatively much greater effort required to achieve near-normoglycemia, the risks of lower targets may outweigh the potential benefits 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, at patient and provider judgment, have glycemic targets as close to normal as possible without significant hypoglycemia becoming a barrier.

Recommended glycemic goals for nonpregnant individuals are shown in Table 8. The recommendations are based on data for A1C. The listed blood glucose goals are levels that appear to correlate with achievement of an A1C of <7%. Less stringent treatment goals may be appropriate for patients with limited life expectancies, in children, and in individuals with comorbid conditions. Severe or frequent hypoglycemia is an indication for the modification of treatment regimens, including setting higher glycemic goals.

Neither the DCCT nor the UKPDS addressed patient populations with long durations of diabetes. Clinical experience suggests that it is uncommon for significant microvascular disease to begin after 20–30 years of diabetes. Furthermore, hypoglycemia unawareness becomes more prevalent with long duration of diabetes. Therefore, in patients with longstanding diabetes (three or more decades) and minimal or stable microvascular complications, the risk-to-benefit ratio for stringent A1C goals appears high.

The issue of pre- versus postprandial SMBG targets is complex (45). 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 (46). 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 the glycemic control trials such as the DCCT relied overwhelmingly on preprandial SMBG. Thus, a reasonable recommendation is: In 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 will likely lower A1C and may improve outcomes.

In regard to glycemic control for women with GDM, recommendations from the Fourth International Workshop-Conference on Gestational Diabetes Mellitus (47) suggested lowering maternal capillary whole-blood glucose concentrations to:

- 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)

Comparable plasma-referenced capillary blood glucose values suggested in the ADA Position Statement on GDM (14) are:

- Preprandial: ≤105 mg/dl (5.8 mmol/l), and either:
  - 1-h postmeal: ≤155 mg/dl (8.6 mmol/l) or
  - 2-h postmeal: ≤130 mg/dl (7.2 mmol/l)

3. Approach to treatment

a. Therapy for type 1 diabetes. The DCCT clearly showed that intensive insulin therapy (three or more injections per day of insulin or continuous subcutaneous insulin infusion [CSII, or insulin

pump therapy]) was a key part of improved glycemia and better outcomes (35). 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 marked increase 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 were designed to be more "physiological" in their pharmacokinetics and pharmacodynamics, and are associated with less hypoglycemia with equal A1C lowering in type 1 diabetes (48,49).

Therefore, recommended therapy for type 1 diabetes consists of the following components: *1*) use of multiple dose insulin injections (3–4 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 many 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 (3,48,50).

b. Therapy for type 2 diabetes. ADA and the European Association for the Study of Diabetes published a consensus statement on the approach to management of hyperglycemia in individuals with type 2 diabetes (51). Highlights of this approach are *1*) intervention at the time of diagnosis with metformin in combination with lifestyle changes (MNT and exercise) and *2*) continuing timely augmentation of therapy with additional agents (including early initiation of insulin therapy) as a means of achieving and maintaining recommended levels of glycemic control (i.e., A1C <7% for most patients). The overall objective is to achieve and maintain glycemic levels as close to the nondiabetic range as possible and to change interventions at as rapid a pace as titration of medications allows.

The algorithm took into account the evidence for A1C-lowering of the individual interventions, their synergies, and their expense. Of note, the consensus algorithm was developed before publications that raised concerns about increased risk of myocardial infarction with use of rosiglitazone (52,53) and before addition of black box warnings about congestive heart failure (CHF) for both rosiglitazone and pioglitazone. This new information may prompt greater caution in using the thiazolidinediones. Other medications such as pramlintide, exenatide, α-glucosidase inhibitors, the glinides, and dipeptidyl peptidase IV inhibitors were not included in the consensus algorithm, owing to less glucose-lowering effectiveness, limited clinical data, and/or relative expense. However, they may be appropriate choices in individual patients to achieve glycemic goals. Initiation of insulin at time of diagnosis is recommended for individuals presenting with weight loss or other severe hyperglycemic symptoms or signs. For a list of currently approved diabetes medications, see http://ndep.nih.gov/diabetes/pubs/Drug tables supplement.pdf.

D. MEDICAL NUTRITION THERAPY (MNT)

General recommendations

- Individuals who have pre-diabetes 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. (B)
- MNT should be covered by insurance and other payors. (E)

Energy balance, overweight, and obesity

- In overweight and obese insulin-resistant individuals, modest weight loss has been shown to reduce insulin resistance. Thus, 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 or low-fat calorie-restricted diets may be effective in the short term (up to 1 year). (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)

Primary prevention of 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 high 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)

Dietary fat intake in diabetes management

- Saturated fat intake should be <7% of total calories. (A)
- Intake of *trans* fat should be minimized. (E)

Carbohydrate intake in diabetes management

- Monitoring carbohydrate intake, whether by carbohydrate counting, exchanges, or experience-based estimation, remains a key strategy in achieving glycemic control. (A)
- For individuals with diabetes, the use of the glycemic index and glycemic load may provide a modest additional benefit for glycemic control over that observed when total carbohydrate is considered alone. (B)

Other nutrition recommendations

- Sugar alcohols and nonnutritive sweeteners are safe when consumed within the acceptable daily intake levels established by the Food and Drug Administration (FDA). (A)
- If adults with diabetes choose to use alcohol, daily intake should be limited to a moderate amount (one drink per day or less for adult women and two drinks per day or less for adult men). (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)
- Benefit from chromium supplementation in people with diabetes or obesity has not been conclusively demonstrated and, therefore, cannot be recommended. (E)

MNT is an integral component of diabetes prevention, management, and self-management education. ADA recognizes

that, in addition to its important role in preventing and controlling diabetes, nutrition is 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," published in 2007 and updated for 2008 (54). Achieving nutrition-related goals requires a coordinated team effort that includes the active involvement of the person with pre-diabetes or diabetes. Because of the complexity of nutrition issues, it is recommended that a registered dietitian 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 of ~1% in type 1 diabetes and 1–2% in type 2 diabetes, depending on the duration of diabetes (55,56). Meta-analyses of studies in nondiabetic, free-living subjects report that MNT reduces LDL cholesterol by 15–25 mg/dl (57), while clinical trials support a role for lifestyle modification in treating hypertension (58).

Because of the effects of obesity on insulin resistance, weight loss is an important therapeutic objective for overweight or obese individuals with pre-diabetes or diabetes (59). Short-term studies have demonstrated that moderate weight loss (5% of body weight) in subjects with type 2 diabetes is associated with decreased insulin resistance, improved measures of glycemia and lipemia, and reduced blood pressure (60); longer-term studies (≥52 weeks) showed mixed effects on A1C in adults with type 2 diabetes (61–63), and results were confounded by pharmacologic weight loss therapy. Sustained weight loss is difficult for most people to accomplish. However, the multifactorial intensive lifestyle intervention employed in the DPP, which included reduced intake of fat and calories, led to weight loss averaging 7% at 6 months and maintenance of 5% weight loss at 3 years, and these outcomes were associated with a 58% reduction in the incidence of type 2 diabetes (10). The Look AHEAD (Action for Health in Diabetes) study 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 (64). When completed, the Look AHEAD study should provide insight into the effects of long-term weight loss on important clinical outcomes.

The optimal macronutrient distribution of weight loss diets has not been established. Although low-fat diets have traditionally been promoted for weight loss, several randomized controlled trials found that subjects on low-carbohydrate diets (<130 g/day of carbohydrate) lost more weight at 6 months than subjects on low-fat diets (65,66); however, at 1 year, the difference in weight loss between the low-carbohydrate and low-fat diets was not significant and weight loss was modest with both diets. Another study of overweight women randomized to one of four diets showed significantly more weight loss at 12 months with the Atkins low-carbohydrate diet than with higher-carbohydrate diets (67). Changes in serum triglyceride and HDL cholesterol were more favorable with the low-carbohydrate diets. In one study, those subjects with type 2 diabetes demonstrated a greater decrease in A1C with a low-carbohydrate diet than with a low-fat diet (66). A recent 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 (68).

The recommended dietary allowance (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 (69).

Although numerous studies have attempted to identify the optimal mix of macronutrients for meal plans of people with diabetes, it is unlikely that one such combination of macronutrients exists. The best mix of carbohydrate, protein, and fat appears to vary depending on individual circumstances. For those individuals seeking guidance on macronutrient distribution in healthy adults, the Dietary Reference Intakes (DRIs) may be helpful (69). 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).

The primary goal with respect to dietary fat in individuals with diabetes is to limit saturated fatty acids, *trans* fatty acids, and cholesterol intake so as to reduce risk for CVD. 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 (70).

The FDA has approved five nonnutritive sweeteners for use in the U.S.: acesulfame potassium, aspartame, neotame, saccharin, and sucralose. Before being allowed on the market, all underwent rigorous scrutiny and were shown to be safe when consumed by the public, including people with diabetes and women during pregnancy. Reduced-calorie sweeteners approved by the FDA include sugar alcohols (polyols) such as erythritol, isomalt, lactitol, maltitol, mannitol, sorbitol, xylitol, tagatose, and hydrogenated starch hydrolysates. The use of sugar alcohols appears to be safe; however, they may cause diarrhea, especially in children.

Reimbursement for MNT

MNT, when delivered by a registered dietitian according to nutrition practice guidelines, is reimbursed as part of the Medicare program as overseen by the Centers for Medicare and Medicaid Services (CMS) (www.cms.hhs.gov/medicalnutritiontherapy).

E. DSME

Recommendations

- People with diabetes should receive DSME according to national standards when their diabetes is diagnosed and as needed thereafter. (B)
- Self-management behavior change is the key outcome of DSME and should be measured and monitored as part of care. (E)
- DSME should address psychosocial issues, since emotional well-being is

strongly associated with positive diabetes outcomes. (C)
- DSME should be reimbursed by third-party payors. (E)

DSME is an essential element of diabetes care (71–77), and the National Standards for DSME (78) are based on evidence for its benefits. Education helps people with diabetes initiate effective self-care when they are first diagnosed. Ongoing DSME also helps people with diabetes maintain effective self-management as their diabetes presents new challenges and as treatment advances become available. DSME helps patients optimize metabolic control, prevent and manage complications, and maximize quality of life, in a cost-effective manner (79).

Evidence for the benefits of DSME

Since the 1990s, there has been a shift from a didactic approach, with DSME focusing on providing information, to a skill-based approach that focuses on helping those with diabetes make informed self-management choices. Several studies have found that DSME is associated with improved diabetes knowledge and improved self-care behavior (72), improved clinical outcomes such as lower A1C (73,74,76,77,80), lower self-reported weight (72), and improved quality of life (75). Better outcomes were reported for DSME interventions that were longer and included follow-up support (72), that were tailored to individual needs and preferences (71), and that addressed psychosocial issues (71,72,76). Both individual and group approaches have been found effective (81,82). There is increasing evidence for the role of a community health worker in delivering diabetes education in addition to the core team (83).

The National Standards for DSME

ADA-recognized DSME programs have staff who must be certified diabetes educators or have recent experience in diabetes education and management. The curriculum of ADA-recognized DSME programs must cover all nine areas of diabetes management, with the assessed needs of the individual determining which areas are addressed. The ADA Education Recognition Program (ERP) is a mechanism to ensure that diabetes education programs meet the National Standards and provide quality diabetes care.

Reimbursement for DSME

DSME, when provided by a program that meets ADA ERP standards, is reimbursed as part of the Medicare program as overseen by the Centers for Medicare and Medicaid Services (CMS) (www.cms.hhs.gov/DiabetesSelfManagement).

F. Physical activity

Recommendations

- People with diabetes should be advised to perform at least 150 min/week of moderate-intensity aerobic physical activity (50–70% of maximum heart rate). (A)
- In the absence of contraindications, people with type 2 diabetes should be encouraged to perform resistance training three times per week. (A)

ADA technical reviews on exercise in patients with diabetes have summarized the value of exercise in the diabetes management plan (84,85). 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 (10–12). 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 (86). Higher levels of exercise intensity are associated with greater improvements in A1C and in fitness (87).

Frequency and type of exercise

A U.S. Surgeon General's report (88) recommended that most adults accumulate at least 30 min of moderate-intensity activity on most, ideally all, days of the week. The studies included in the meta-analysis of effects of exercise interventions on glycemic control (86) 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 per week of moderate-intensity exercise, had a beneficial effect on glycemia in those with pre-diabetes. Therefore, it seems reasonable to recommend ~150 min of exercise per week for people with diabetes.

Resistance exercise improves insulin sensitivity to about the same extent as aerobic exercise (89). Clinical trials have provided strong evidence for the A1C-lowering value of resistance training in older adults with type 2 diabetes (90,91), and for an additive benefit of combined aerobic and resistance exercise in adults with type 2 diabetes (92).

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 (93). 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 advanced 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 ketotic, exercise can worsen hyperglycemia and ketosis (94); 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) (95,96). 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 (97).

Peripheral neuropathy. Decreased pain sensation in the extremities results in increased risk of skin breakdown and infection and of Charcot joint destruction. Therefore, in the presence of severe peripheral neuropathy, it may be best to encourage non–weight-bearing activities such as swimming, bicycling, or arm exercises (98,99).

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 (98). Autonomic neuropathy is also strongly associated with CVD in people with diabetes (100,101). 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; thus, there is likely no need for any specific exercise restrictions for people with diabetic kidney disease (102).

G. Psychosocial assessment and care

Recommendations

- Assessment of psychological and social situation should be included as an ongoing part of the medical management of diabetes. (E)
- Psychosocial screening and follow-up should 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)
- Screen for psychosocial problems such as depression, anxiety, eating disorders, and cognitive impairment when adherence to the medical regimen is poor. (E)

Psychological and social problems can impair the individual's (103–108) or family's (109) ability to carry out diabetes care tasks and can 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.

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 (110). Patients are likely to exhibit psychological vulnerability at diagnosis and when their medical status changes, i.e., the end of the honeymoon period, when the need for intensified treatment is evident, and when complications are discovered (105,107).

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, resources (financial, social, and emotional) (106), and psychiatric history (107,110,111). Screening tools are available for a number of these areas (112). Indications for referral to a mental health specialist familiar with diabetes management may include gross noncompliance with medical regimen (by self or others) (111), depression with the possibility of self-harm (104,113), debilitating anxiety (alone or with depression), indications of an eating disorder (114), and cognitive functioning that significantly impairs judgment (113). It is preferable to incorporate psychological assessment and treatment into routine care rather than wait for identification of a specific problem or deterioration in psychological status (115). Although the clinician may not feel qualified to treat psychological problems, utilizing the patient-provider relationship as a foundation for further treatment can increase the likelihood that the patient will accept referral for other services. It is important to establish that emotional well-being is part of diabetes management (110).

H. 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 8). Intensification of the treatment regimen is suggested and may include assessment of barriers to adherence including income; educational attainment; and competing demands, including those related to family responsibilities and family dynamics; culturally appropriate and enhanced DSME; comanagement with a diabetes team; referral to a medical social worker for assistance with insurance coverage; change in pharmacological therapy; initiation of or increase in SMBG; more frequent contact with the patient; and referral to an endocrinologist.

I. Intercurrent illness

The stress of illness, trauma, and/or surgery frequently aggravates glycemic control and may precipitate diabetic ketoacidosis (DKA) or nonketotic hyperosmolar state, both of which are life-threatening conditions that require immediate medical care to prevent complications and death (116). 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 the 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 ensured. 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 VIII.A. For further information on management of DKA or nonketotic hyperosmolar state, refer to the ADA position statement on hyperglycemic crises (116).

J. Hypoglycemia

Recommendations

- 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 in its administration. Glucagon administration is not limited to health care professionals. (E)
- Individuals with hypoglycemia unawareness or one or more episodes of severe hypoglycemia should be advised to raise their glycemic targets to strictly avoid further hypoglycemia for at least several weeks in order to partially reverse hypoglycemia unawareness and reduce risk of future episodes. (B)

Hypoglycemia is the leading limiting factor in the glycemic management of type 1 and insulin-treated type 2 diabetes (117). 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. Protein added to carbohydrate does not impair the glycemic response, but also has no benefit in preventing subsequent hypoglycemia. Added fat may retard and then prolong the acute glycemic response (118). 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. Teaching people with diabetes to balance insulin use, carbohydrate intake, and exercise is a necessary but not always sufficient strategy. 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 counterregulation and awareness to some extent in many patients (117,119,120). Hence, patients with one or more episodes of severe hypoglycemia may benefit from at least short-term relaxation of glycemic targets.

K. Immunization

Recommendations
- Annually provide an influenza vaccine to all diabetic patients ≥6 months of age. (C)
- Provide at least one lifetime pneumococcal vaccine for adults with diabetes. A one-time revaccination is recommended for individuals ≥65 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)

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% (121).

Safe and effective vaccines are available that can greatly reduce the risk of serious complications from these diseases (122,123). In a case-control series, influenza vaccine was shown to reduce diabetes-related hospital admission by as much as 79% during flu epidemics (122). There is sufficient evidence to support that people with diabetes have appropriate serologic and clinical responses to these vaccinations. The Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices recommends influenza and pneumococcal vaccines for all individuals of any age with diabetes (http://www.cdc.gov/vaccines/recs). For a complete discussion on the prevention of influenza and pneumococcal disease in people with diabetes, consult the technical review and position statement on this subject (121,124).

VI. PREVENTION AND MANAGEMENT OF DIABETES COMPLICATIONS

A. CVD

CVD is the major cause of morbidity and mortality for individuals with diabetes and is 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 cardiovascular risk factors in preventing or slowing CVD in people with diabetes. Evidence is summarized in the following sections and reviewed in detail in the ADA technical reviews on hypertension (125), dyslipidemia (126), aspirin therapy (127), and smoking cessation (128), and in the AHA/ADA scientific statement on prevention of CVD in people with diabetes (129). Emphasis should be placed on reducing cardiovascular risk factors, and clinicians should be alert for signs and symptoms of atherosclerosis.

1. Hypertension/blood pressure control

Recommendations

Screening and diagnosis
- Blood pressure should be measured at every routine diabetes visit. Patients found to have systolic blood pressure

≥130 mmHg or diastolic blood pressure ≥80 mmHg should have blood pressure confirmed on a separate day. Repeat systolic blood pressure ≥130 mmHg or diastolic blood pressure ≥80 mmHg confirms a diagnosis of hypertension. (C)

Goals

- Patients with diabetes should be treated to a systolic blood pressure <130 mmHg. (C)
- Patients with diabetes should be treated to a diastolic blood pressure <80 mmHg. (B)

Treatment

- Patients with a systolic blood pressure of 130–139 mmHg or a diastolic blood pressure of 80–89 mmHg may be given lifestyle therapy alone for a maximum of 3 months and then, if targets are not achieved, be treated with addition of pharmacological agents. (E)
- Patients with more severe hypertension (systolic blood pressure ≥140 or diastolic blood pressure ≥90 mmHg) at diagnosis or follow-up should receive pharmacologic therapy in addition to lifestyle therapy. (A)
- Pharmacologic 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. If needed to achieve blood pressure targets, a thiazide diuretic should be added to those with an estimated glomerular filtration rate (GFR) (see below) ≥50 ml/min per 1.73 m^2 and a loop diuretic for those with an estimated GFR <50 ml/min per 1.73 m^2. (E)
- Multiple drug therapy (two or more agents at maximal doses) is generally required to achieve blood pressure targets. (B)
- If ACE inhibitors, ARBs, or diuretics are used, kidney function and serum potassium levels should be closely 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 follow the guidelines established for nondiabetic individuals: measurement in the seated position, with feet on the floor and arm supported at heart level, and after 5 min of rest. Elevated values should be confirmed on a separate day. Because of the clear synergistic risks of hypertension and diabetes, the diagnostic cut-off for a diagnosis of hypertension is lower in people with diabetes (blood pressure ≥130/80) than those without diabetes (blood pressure ≥140/90 mmHg) (130).

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, and in studies in nondiabetic populations, home measurements may better correlate with CVD risk than office measurements (131,132). However, the preponderance of the clear evidence of benefits of treatment of hypertension in people with diabetes is based on office measurements.

Treatment goals

Randomized clinical trials have demonstrated the benefit (reduction of coronary heart disease [CHD] events, stroke, and nephropathy) of lowering blood pressure to <140 mmHg systolic and <80 mmHg diastolic in individuals with diabetes (130,133–135). Epidemiologic analyses show that blood pressures >115/75 mmHg are associated with increased cardiovascular event rates and mortality in individuals with diabetes (130,136,137). Therefore, a target blood pressure goal of <130/80 mmHg is reasonable if it can be safely achieved. The ongoing Action to Control Cardiovascular Risk in Diabetes (ACCORD) trial is designed to determine whether lowering systolic blood pressure to <120 mmHg provides greater cardiovascular protection than a systolic blood pressure level of <140 mmHg in patients with type 2 diabetes (www.accord.org).

Treatment strategies

Although there are no well-controlled studies of diet and exercise in the treatment of hypertension in individuals with diabetes, studies in nondiabetic individuals have shown antihypertensive effects similar to pharmacologic monotherapy of reducing sodium intake and excess body weight; increasing consumption of fruits, vegetables, and low-fat dairy products; avoiding excessive alcohol consumption; and increasing activity levels (130,138). These nonpharmacological strategies may also positively affect glycemia and lipid control. Their effects on cardiovascular events have not been established. An initial trial of nonpharmacologic therapy may be reasonable in diabetic individuals with mild hypertension (systolic blood pressure 130–139 mmHg or diastolic blood pressure 80–89 mmHg). If the blood pressure is ≥140 mmHg systolic and/or ≥90 mmHg diastolic at the time of diagnosis, pharmacologic therapy should be initiated along with nonpharmacologic therapy (130).

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 (139–141). 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 (130, 142,143).

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 (144). In patients with CHF, including diabetic subgroups, ARBs have been shown to reduce major CVD outcomes (145–148), and in type 2 diabetic patients with significant nephropathy, ARBs were superior to calcium channel blockers for

reducing heart failure (149–151). Although evidence for distinct advantages of RAS inhibitors on CVD outcomes in diabetes remains conflicting (133,152), 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 (130). 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 below).

An important caveat is that most patients with hypertension require multidrug therapy to reach treatment goals, especially diabetic patients whose targets are lower. Many patients will require three or more drugs to reach target goals (130).

During pregnancy in diabetic women with chronic hypertension, target blood pressure goals of systolic blood pressure 110–129 mmHg and diastolic blood pressure 65–79 mmHg are reasonable, as they contribute to long-term maternal health. Lower blood pressure levels may be associated with impaired fetal growth. During pregnancy, treatment with ACE inhibitors and ARBs is contraindicated, since they are likely to cause fetal damage. Antihypertensive drugs known to be effective and safe in pregnancy include methyldopa, labetalol, diltiazem, clonidine, and prazosin. Chronic diuretic use during pregnancy has been associated with restricted maternal plasma volume, which might reduce uteroplacental perfusion (153).

2. Dyslipidemia/lipid management

Recommendations

Screening

- In most adult patients, measure fasting lipid profile at least annually. 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; 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 and have one or more other CVD risk factors. (A)
- For lower-risk patients than those specified above (e.g., without overt CVD and under the age of 40), statin therapy should be considered in addition to lifestyle therapy if LDL cholesterol remains >100 mg/dl or in those with multiple CVD risk factors (E)
- In individuals without overt CVD, the primary goal is an LDL cholesterol <100 mg/dl (2.6 mmol/l). (A)
- 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. (E)
- If drug-treated patients do not reach the above targets on maximal tolerated statin therapy, a reduction in LDL cholesterol of ~40% from baseline is an alternative therapeutic goal. (A)
- 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. However, LDL cholesterol–targeted statin therapy remains the preferred strategy. (C)
- Combination therapy using statins and other lipid-lowering agents may be considered to achieve lipid targets but has not been evaluated in outcome studies for either CVD outcomes or safety. (E)
- Statin therapy is contraindicated in pregnancy. (E)

Evidence for benefits of lipid-lowering therapy

Patients with type 2 diabetes have an increased prevalence of lipid abnormalities, which contributes to their high risk of CVD. For the past decade or more, multiple clinical trials demonstrated significant effects of pharmacologic (primarily statin) therapy on CVD outcomes in subjects with CHD and for primary CVD prevention (154). Sub-analyses of diabetic subgroups of larger trials (155–159) and trials specifically in subjects with diabetes (160,161) showed significant primary and secondary prevention of CVD events ± CHD deaths in diabetic populations. As shown in Table 10, and similar to findings in nondiabetic subjects, re-

Table 10—*Reduction in 10-year risk of major CVD end points (CHD death/nonfatal MI) in major statin trials, or substudies of major trials, in diabetic subjects* (n = *16,032*)

Study (ref.)	CVD prevention	Statin dose and comparator	RRR	ARR	LDL cholesterol reduction
4S-DM (155)	2^o	Simvastatin 20–40 mg vs. placebo	85.7 to 43.2% (50%)	42.5%	186 to 119 mg/dl (36%)
ASPEN 2^o (160)	2^o	Atorvastatin 10 mg vs. placebo	39.5 to 24.5% (34%)	12.7%	112 to 79 mg/dl (29%)
HPS-DM (156)	2^o	Simvastatin 40 mg vs. placebo	43.8 to 36.3% (17%)	7.5%	123 to 84 mg/dl (31%)
CARE-DM (157)	2^o	Pravastatin 40 mg vs. placebo	40.8 to 35.4% (13%)	5.4%	136 to 99 mg/dl (27%)
TNT-DM (158)	2^o	Atorvastatin 80 mg vs. 10 mg	26.3 to 21.6% (18%)	4.7%	99 to 77 mg/dl (22%)
HPS-DM (156)	1^o	Simvastatin 40 mg vs. placebo	17.5 to 11.5% (34%)	6.0%	124 to 86 mg/dl (31%)
CARDS (161)	1^o	Atorvastatin 10 mg vs. placebo	11.5 to 7.5% (35%)	4%	118 to 71 mg/dl (40%)
ASPEN 1^o (160)	1^o	Atorvastatin 10 mg vs. placebo	11.0 to 7.9% (19%)	1.9%	114 to 80 mg/dl (30%)
ASCOT-DM (159)	1^o	Atorvastatin 10 mg vs. placebo	11.1 to 10.2% (8%)	0.9%	125 to 82 mg/dl (34%)

Studies were of differing lengths (3.3–5.4 years) and used somewhat different outcomes, but all reported rates of CVD death and nonfatal MI. In this tabulation, results of the statin on 10-year risk of major CVD end points (CHD death/nonfatal MI) are listed for comparison between studies. Correlation between 10-year CVD risk of the control group and the ARR with statin therapy is highly significant ($P = 0.0007$). Analyses provided by Craig Williams, Pharm.D., Oregon Health & Science University, 2007. ARR, absolute risk reduction; RRR, relative risk reduction.

Table 11—*Summary of recommendations for glycemic, blood pressure, and lipid control for adults with diabetes*

A1C	<7.0%*
Blood pressure	<130/80 mmHg
Lipids	
LDL cholesterol	<100 mg/dl (<2.6 mmol/l)†

*Referenced to a nondiabetic range of 4.0–6.0% using a DCCT-based assay. †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.

duction in "hard" CVD outcomes (CHD death and nonfatal myocardial infarction) can be more clearly seen in diabetic subjects 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.

Low HDL cholesterol levels, which are 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 (162). In a study conducted in a nondiabetic cohort, nicotinic acid reduced CVD outcomes (163). Gemfibrozil has been shown to decrease rates of CVD events in subjects without diabetes (164,165) and in the diabetic subgroup in one of the larger trials (164). However, in a large trial specific to diabetic patients, fenofibrate failed to reduce overall cardiovascular outcomes (166).

Dyslipidemia treatment and target lipid levels

For most patients with diabetes, the first priority of dyslipidemia therapy (unless severe hypertriglyceridemia is the immediate issue) is to lower LDL cholesterol to a target goal of <100 mg/dl (2.60 mmol/l) (167). 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. 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 aged 40 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 lowering LDL cholesterol.

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 of 40 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 proportionately similar (though not statistically significant) reduction in risk to patients with type 2 diabetes (156). 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 LDL cholesterol 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 (168). As can be seen in Table 10, 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.

Recent clinical trials in high-risk patients, such as those with acute coronary syndromes or previous cardiovascular events (169–171), 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 (172).

The addition of other drugs such as ezetimibe to statins may achieve lower LDL cholesterol goals, but no data are available as to whether such combination therapy is more effective than a statin alone in preventing cardiovascular events.

Treatment of other lipoprotein fractions

Severe hypertriglyceridemia may warrant immediate therapy of this abnormality with lifestyle and usually pharmacologic therapy (fibric acid derivative or niacin) to reduce the risk of acute pancreatitis. In the absence of severe hypertriglyceridemia, therapy targeting HDL cholesterol or triglycerides has intuitive appeal but lacks the evidence base of statin therapy (162). If the HDL cholesterol is <40 mg/dl and the LDL cholesterol between 100 and 129 mg/dl, gemfibrozil 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 recent studies demonstrate that 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 (173,174).

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 than gemfibrozil (175). Several ongoing trials may provide much-needed evidence for the effects of combination therapy on cardiovascular outcomes.

3. Antiplatelet agents

Recommendations

- Use aspirin therapy (75–162 mg/day) as a secondary prevention strategy in those with diabetes with a history of CVD. (A)
- Use aspirin therapy (75–162 mg/day) as a primary prevention strategy in those with type 1 or 2 diabetes at increased cardiovascular risk, including

those who are >40 years of age or who have additional risk factors (family history of CVD, hypertension, smoking, dyslipidemia, or albuminuria). (A)
- Aspirin therapy is not recommended in people under 30 years of age, due to lack of evidence of benefit, and is contraindicated in patients under the age of 21 years because of the associated risk of Reye's syndrome. (E)
- Combination therapy using other antiplatelet agents such as clopidrogel in addition to aspirin should be used in patients with severe and progressive CVD. (C)
- Other antiplatelet agents may be a reasonable alternative for high-risk patients with aspirin allergy, with bleeding tendency, who are receiving anticoagulant therapy, with recent gastrointestinal bleeding, and with clinically active hepatic disease who are not candidates for aspirin therapy. (E)

The use of aspirin in diabetes is reviewed in detail in the ADA technical review (127) and position statement (176) on this topic. Aspirin has been recommended for primary (177,178) and secondary (179,180) prevention of cardiovascular events in high-risk diabetic and nondiabetic individuals. One large meta-analysis and several clinical trials demonstrate the efficacy of using aspirin as a preventive measure for cardiovascular events, including stroke and myocardial infarction. Many trials have shown an ~30% decrease in myocardial infarction and a 20% decrease in stroke in a wide range of patients, including young and middle-aged patients, patients with and without a history of CVD, males and females, and patients with hypertension.

Dosages used in most clinical trials ranged from 75 to 325 mg/day. There is little evidence to support any specific dose, but using the lowest possible dosage may help reduce side effects (181). Conversely, a randomized trial of 100 mg of aspirin daily showed less of a primary prevention effect, without statistical significance, in the large diabetic subgroup in contrast to significant benefit in those without diabetes (182), raising the issue of aspirin resistance in those with diabetes. There is no evidence for a specific age at which to start aspirin, but at ages <30 years, aspirin has not been studied.

Clopidogrel has been demonstrated to reduce CVD events in diabetic individuals (183). Adjunctive therapy in very-high-risk patients or as alternative therapy in aspirin-intolerant patients should be considered.

4. Smoking cessation

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

Issues of smoking in diabetes are reviewed in detail in the ADA technical review (128) and position statement (184) on this topic. 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. Cigarette smoking contributes to one of every five deaths in the U.S. and is the most important modifiable cause of premature death. Much of the prior work documenting the impact of smoking on health did not separately discuss results on subsets of individuals with diabetes, suggesting that the identified risks are at least equivalent to those found in the general population. Other studies of individuals with diabetes consistently found a heightened risk of CVD and premature death among smokers. Smoking is also related to the premature development of microvascular complications of diabetes and may have a role in the development of type 2 diabetes.

A number of large randomized clinical trials have demonstrated the efficacy and cost-effectiveness of smoking cessation counseling in changing smoking behavior and reducing tobacco use. The routine and thorough assessment of tobacco use is important as a means of preventing smoking or encouraging cessation. Special considerations should include assessment of level of nicotine dependence, which is associated with difficulty in quitting and relapse (185,186).

5. CHD screening and treatment

Recommendations

Screening
- In asymptomatic patients, evaluate risk factors to stratify patients by 10-year risk, and treat risk factors accordingly. (B)

Treatment
- In patients with known CVD, ACE inhibitor, aspirin, and statin therapy (if not contraindicated) should be used to reduce the risk of cardiovascular events. (A)
- In patients with a prior myocardial infarction, add β-blockers (if not contraindicated) to reduce mortality. (A)
- In patients >40 years of age with another cardiovascular risk factor (hypertension, family history, dyslipidemia, microalbuminuria, cardiac autonomic neuropathy, or smoking), ACE inhibitor, aspirin, and statin therapy (if not contraindicated) should be used to reduce the risk of cardiovascular events. (B)
- In patients with treated CHF, metformin and thiazolidinedione (TZD) use are contraindicated. (C)

CHD screening and treatment are reviewed in detail in the ADA consensus statement on CHD in people with diabetes (187), and screening for CAD is reviewed in a recently updated consensus statement (93). 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 will have silent ischemia on screening tests (100,188).

Cardiovascular risk factors should be assessed at least once a year. 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, statin, and ACE inhibitor therapy, unless there are contraindications to a particular drug class.

Candidates for a further cardiac testing include those with *1*) typical or atypical cardiac symptoms and *2*) an abnormal resting electrocardiogram (ECG). The screening of asymptomatic patients remains controversial, especially as intensive medical therapy, indicated in diabetic patients at high risk for CVD, has an increasing evidence base for providing equal outcomes to invasive revascularization, including in diabetic patients (189). There is also recent preliminary evidence that silent myocardial ischemia may reverse over time, adding to the controversy concerning aggressive screening strategies (190).

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. (E)
- 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 micro- or macroalbuminuria, either ACE inhibitors or ARBs should be used. (A)
- While there are no adequate head-to-head comparisons of ACE inhibitors and ARBs, there is clinical trial support for each of the following statements:
  - In patients with type 1 diabetes, with hypertension and any degree of albuminuria, ACE inhibitors have been shown to delay the progression of nephropathy. (A)
  - In patients with type 2 diabetes, hypertension, and microalbuminuria, both ACE inhibitors and ARBs have been shown to delay the progression to macroalbuminuria. (A)
  - In patients with type 2 diabetes, hypertension, macroalbuminuria, and renal insufficiency (serum creatinine >1.5 mg/dl), ARBs have been shown to delay the progression of nephropathy. (A)
  - If one class is not tolerated, the other should be substituted. (E)

- Reduction of protein intake to 0.8–1.0 g · kg body wt^{-1} · day^{-1} in individuals with diabetes and the earlier stages of CKD and to 0.8 g · kg body wt^{-1} · day^{-1} in the later stages of CKD may improve measures of renal function (e.g., urine albumin excretion rate and GFR) and is recommended (B)
- When ACE inhibitors, ARBs, or diuretics are used, monitor serum creatinine and potassium levels for the development of acute kidney disease and hyperkalemia. (E)
- Continued monitoring of urine albumin excretion to assess both response to therapy and progression of disease is recommended. (E)
- Consider referral to a physician experienced in the care of kidney disease when there is uncertainty about the etiology of kidney disease (active urine sediment, absence of retinopathy, rapid decline in GFR), 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 end-stage renal disease (ESRD). Persistent albuminuria in the range of 30–299 mg/24 h (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. Microalbuminuria is also a well-established marker of increased CVD risk (191,192). Patients with microalbuminuria who progress to macroalbuminuria (≥300 mg/24 h) are likely to progress to ESRD (193,194). 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 of microalbuminuria and the progression of micro- to macroalbuminuria in patients with type 1 (195,196) and type 2 (40,41) diabetes. The UKPDS provided strong evidence that control of blood pressure can reduce the development of nephropathy (133). 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 from micro- to macroalbuminuria and can slow the decline in GFR in patients with macroalbuminuria (150, 151,197). In type 2 diabetes with hypertension and normoalbuminuria, ACE inhibition has been demonstrated to delay progression to microalbuminuria (198).

In addition, ACE inhibitors have been shown to reduce major CVD outcomes (i.e., myocardial infarction, stroke, death) in patients with diabetes (144), thus further supporting the use of these agents in patients with microalbuminuria, a CVD risk factor. ARBs have also been shown to reduce the rate of progression from micro- to macroalbuminuria as well as ESRD in patients with type 2 diabetes (199–201). Some evidence suggests that ARBs have a smaller magnitude of rise in potassium compared with ACE inhibitors in people with nephropathy (202,203). 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 (149), 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 helps slow the progression of albuminuria, GFR decline, and occurrence of ESRD (204–207). Protein restriction should 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 (207).

Assessment of albuminuria status and renal function

Screening for microalbuminuria can be performed by measurement of the albumin-to-creatinine ratio in a random spot collection (preferred method); 24-h or timed collections are more burdensome and add little to prediction or accuracy (208,209). 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 -positive determinations as a result of variation in urine concentration due to hydration and other factors.

Abnormalities of albumin excretion are defined in Table 12. 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 crossed one of these diagnostic thresholds. Exercise within 24 h, infection, fever, CHF, marked hyperglycemia, and marked hy-

Table 12—*Definitions of abnormalities in albumin excretion*

Category	Spot collection (μg/mg creatinine)
Normal	<30
Microalbuminuria	30–299
Macro (clinical)-albuminuria	300

pertension 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 13) is primarily based on GFR levels and therefore differs from other systems in which staging is based primarily on urinary albumin excretion (210). Studies have found decreased GFR in the absence of increased urine albumin excretion in a substantial percentage of adults with diabetes (211,212). Epidemiologic evidence suggests that a substantial fraction of those with chronic kidney disease in the setting of diabetes have little or no detectable albuminuria (211). Serum creatinine should therefore be measured at least annually in all adults with 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. GFR can be estimated using formulae such as the Cockroft-Gault equation or a prediction formula using data from the Modification of Diet and Renal Disease study (213). GFR calculators are available at http://www.nkdep.nih.gov. Many clinical laboratories now report estimated GFR in addition to serum creatinine.

The role of continued annual quantitative assessment of albumin excretion after diagnosis of microalbuminuria 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 abnormal albuminuria (>30 mg/g) to the normal 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 estimated GFR is <60 ml/min per 1.73 m^2, screening for anemia, malnutrition, and metabolic bone disease is indicated. 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 (active urine sediment, absence of retinopathy, rapid decline in GFR), difficult management issues, 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 (214,215). 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 adolescents 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)
- 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)
- The presence of retinopathy is not a contraindication to aspirin therapy for cardioprotection, as this therapy does

Table 13—*Stages of CKD*

Stage	Description	GFR (ml/min per 1.73 m^2 body surface area)
1	Kidney damage* with normal or increased GFR	90
2	Kidney damage* with mildly decreased GFR	60–89
3	Moderately decreased GFR	30–59
4	Severely decreased GFR	15–29
5	Kidney failure	<15 or dialysis

*Kidney damage defined as abnormalities on pathologic, urine, blood, or imaging tests. Adapted from ref. 209.

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 (216), the presence of nephropathy (217), and hypertension (218). 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 (35,40,41). Lowering blood pressure has been shown to decrease the progression of retinopathy (133). Several case series and a controlled prospective study suggest that pregnancy in type 1 diabetic patients may aggravate retinopathy (219,220); laser photocoagulation surgery can minimize this risk (220).

One of the main motivations for screening for diabetic retinopathy is the established efficacy of laser photocoagulation surgery in preventing visual loss. Two large trials, the Diabetic Retinopathy Study (DRS) and the Early Treatment Diabetic Retinopathy Study (ETDRS), provide the strongest support for the therapeutic benefits of photocoagulation surgery.

The DRS (221) 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. The benefit was greatest among patients whose baseline evaluation revealed high-risk characteristics (chiefly disc neovascularization or vitreous hemorrhage). Given the risks of modest loss of visual acuity and contraction of the visual field from panretinal laser surgery, such therapy is primarily recommended for eyes with PDR approaching or having high-risk characteristics.

The ETDRS (222) 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, but not for mild or moderate NPDR. In older-onset patients with severe NPDR or less-than-high-risk PDR, the risk of severe visual loss or vitrectomy was reduced ~50% by early laser photocoagulation surgery at these stages.

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. This preventive effect 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 (223), 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 (224) and who have a significant risk of prevalent diabetic retinopathy at the 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 (225–227), while examinations will be required more frequently if retinopathy is progressing.

Examinations can also be done with retinal photographs (with or without dilation of the pupil) read by experienced experts. In-person exams are still necessary when the photos are unacceptable and for follow-up of abnormalities detected. This technology 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 (228).

Results of eye examinations should be documented and transmitted to the referring health care professional. For a detailed review of the evidence and further discussion of diabetic retinopathy, see ADA's technical review and position statement on this subject (229,230).

D. Neuropathy screening and treatment

Recommendations

- All patients should be screened for distal symmetric polyneuropathy (DPN) at diagnosis 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)
- Educate all patients about self-care of the feet. For those with DPN, facilitate enhanced foot care education and refer for special footware. (B)
- Screening for signs and symptoms of autonomic neuropathy 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 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 (231).

The early recognition and appropriate management of neuropathy in the patient with diabetes is important for a number of reasons: *1*) nondiabetic neuropathies may be present in patients with diabetes and may be treatable; *2*) a number of treatment options exist for symptomatic diabetic neuropathy; *3*) up to 50% of DPN may be asymptomatic and patients are at risk of insensate injury to their feet; *4*) autonomic neuropathy may involve every system in the body; and *5*) cardiovascular autonomic neuropathy causes substantial morbidity and mortality. Specific treatment for the underlying nerve damage is currently not available, other than improved glycemic control, which may slow progression but not reverse neuronal loss. Effective symptomatic treatments are available for some

Table 14—*Table of drugs to treat symptomatic DPN*

Class	Examples	Typical doses*
Tricyclic drugs	Amitriptyline	10–75 mg at bedtime
	Nortriptyline	25–75 mg at bedtime
	Imipramine	25–75 mg at bedtime
Anticonvulsants	Gabapentin	300–1,200 mg t.i.d.
	Carbamazepine	200–400 mg t.i.d.
	Pregabalin†	100 mg t.i.d.
5-hydroxytryptamine and norepinephrine uptake inhibitor	Duloxetine†	60–120 mg daily
Substance P inhibitor	Capsaicin cream	0.025–0.075% applied t.i.d. or q.i.d.

*Dose response may vary; initial doses need to be low and titrated up; †has FDA indication for treatment of painful diabetic neuropathy.

manifestations of DPN and autonomic neuropathy (231).

Diagnosis of neuropathy

Distal symmetric polyneuropathy

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 (231).

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, "brittle diabetes," and hypoglycemic autonomic failure (232).

Cardiovascular autonomic neuropathy, a CVD risk factor (93), is the most studied and clinically important form of diabetic autonomic neuropathy. Cardiovascular autonomic neuropathy may be indicated by resting tachycardia (>100 bpm), orthostasis (a fall in systolic blood pressure >20 mmHg upon standing), or other disturbances in autonomic nervous system function involving the skin, pupils, or gastrointestinal and genitourinary systems (232).

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 (232).

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 (232).

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 efficacy confirmed in published randomized controlled trials, with several FDA-approved for the management of painful DPN. See Table 14 for examples of agents to treat DPN pain.

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 (231). 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 can be accomplished in a primary care setting and should include the use of a monofilament, tuning fork, palpation, and a visual examination. (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 for those with a history of prior ulcer or amputation. (B)
- Refer patients who smoke, have loss of protective sensation and structural abnormalities, or have history of prior lower-extremity complications to foot care specialists for ongoing preventive care and life-long 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 manage-

ment of risk factors can prevent or delay adverse outcomes.

The risk of ulcers or amputations is increased in people who have had diabetes >10 years, are male, have poor glucose control, or have cardiovascular, retinal, or renal complications. The following foot-related risk conditions are associated with an increased risk of amputation:

- Peripheral neuropathy with loss of protective sensation
- Altered biomechanics (in the presence of neuropathy)
- Evidence of increased pressure (erythema, hemorrhage under a callus)
- Bony deformity
- PAD (decreased or absent pedal pulses)
- A history of ulcers or amputation
- Severe nail pathology

All individuals with diabetes should receive an annual foot examination to identify high-risk foot conditions. This examination should include assessment of protective sensation, foot structure and biomechanics, vascular status, and skin integrity. Evaluation of neurological status in the low-risk foot should include a quantitative somatosensory threshold test, using the Semmes-Weinstein 5.07 (10-g) monofilament. The skin should be assessed for integrity, especially between the toes and under the metatarsal heads. Patients at low risk may benefit from education on foot care and footwear.

The presence of erythema, warmth, or callus formation may indicate areas of tissue damage with impending breakdown. Bony deformities, limitation in joint mobility, and problems with gait and balance should be assessed. People with one or more high-risk foot conditions should be evaluated more frequently for the development of additional risk factors. People with neuropathy should have a visual inspection of their feet at every visit with a health care professional.

People with neuropathy (e.g., erythema, warmth, callus, or measured pressure) or evidence of increased plantar 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., hammertoes, 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.

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 (233) suggested that a screening ABI be performed in patients older than 50 years of age and be considered in patients younger than 50 years 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, medication, and surgical options (233).

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 loss of protective sensation should be educated on ways to substitute other sensory modalities (hand palpation, visual inspection) for surveillance of early foot problems. The patient's 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.

For a detailed review of the evidence and further discussion, see ADA's technical review and position statement on preventive foot care (234,235).

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. For a complete discussion, see ADA's consensus statement on diabetic foot wound care (236).

VII. DIABETES CARE IN SPECIFIC POPULATIONS

A. Children and adolescents

1. Type 1 diabetes

Three-quarters of all cases of type 1 diabetes are diagnosed in individuals <18 years of age. Because children are not simply "small adults," 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 insulin sensitivity related to sexual maturity, physical growth, ability to provide self-care, and unique neurologic vulnerability to hypoglycemia. Attention to such issues as family dynamics, developmental stages, and physiologic 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, because of current and historical restraints placed on conducting research in children, expert opinion and a review of available and relevant experimental data are summarized in a recent ADA statement (237).

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. At the time of initial diagnosis, it is essential that diabetes education is provided in a timely fashion, with the expectation that the balance between adult supervision and self-care should be defined by, and will evolve according to, physical, psychological, and emotional maturity. MNT should be provided at diagnosis, and at least annually thereafter, by an individual experienced with the nutritional needs of the growing child and the behavioral issues that have an impact on adolescent diets.

a. Glycemic control

Recommendations

- Consider age when setting glycemic goals in children and adolescents with type 1 diabetes, with less stringent goals for younger children. (E)

Table 15—*Plasma blood glucose and A1C goals for type 1 diabetes by age-group*

Values by age (years)	Plasma blood glucose goal range (mg/dl)		A1C	Rationale
	Before meals	Bedtime/ overnight		
Toddlers and preschoolers (0–6)	100–180	110–200	<8.5% (but >7.5%)	High risk and vulnerability to hypoglycemia
School age (6–12)	90–180	100–180	<8%	Risks of hypoglycemia and relatively low risk of complications prior to puberty
Adolescents and young adults (13–19)	90–130	90–150	<7.5%	• Risk of severe hypoglycemia • Developmental and psychological issues • A lower goal (<7.0%) is reasonable if it can be achieved without excessive hypoglycemia

Key concepts in setting glycemic goals:
- Goals should be individualized and lower goals may be reasonable based on benefit-risk assessment.
- Blood glucose goals should be higher than those listed above in children with frequent hypoglycemia or hypoglycemia unawareness.
- Postprandial blood glucose values should be measured when there is a discrepancy between pre-prandial blood glucose values and A1C levels.

While current standards for diabetes management reflect the need to maintain glucose control as near to normal as safely possible, special consideration must be given to the unique risks of hypoglycemia in young children. Glycemic goals 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." Their counterregulatory mechanisms are immature, and they may lack the cognitive capacity 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 adults, children younger than 5 years of age are at risk for permanent cognitive impairment after episodes of severe hypoglycemia (238–240). Extensive evidence indicates that near normalization of blood glucose levels is seldom attainable in children and adolescents after the honeymoon (remission) period. The A1C level achieved in the "intensive" adolescent cohort of the DCCT group was >1% higher than that achieved by adult DCCT subjects and above current ADA recommendations for patients in general. However, the increased frequency of use of basal bolus regimens (including insulin pumps) in youth from infancy through adolescence has been associated with more children reaching ADA blood glucose targets (241,242) in those families in which both parents and the child with diabetes are motivated to perform the required diabetes-related tasks.

In selecting glycemic goals, the benefits on long-term health outcomes of achieving a lower A1C must be weighed against the unique risks of hypoglycemia and the difficulties achieving near-normoglycemia 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 microalbumin-to-creatinine ratio, should be initiated once the child is 10 years of age and has had diabetes for 5 years. (E)
- Confirmed, persistently elevated microalbumin levels on two additional urine specimens should be treated with an ACE inhibitor titrated to normalization of microalbumin excretion if possible. (E)

ii. Hypertension

Recommendations
- Treatment of high-normal blood pressure (systolic or diastolic blood pressure consistently above the 90th percentile for age, sex, and height) should include 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, pharmacologic treatment should be initiated. (E)
- Pharmacologic 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 initiated as soon as the diagnosis is confirmed. (E)
- ACE inhibitors should be considered for the initial treatment of hypertension. (E)

Hypertension in childhood is defined as an average systolic or diastolic blood pressure ≥95th percentile for age, sex, and height percentile measured on at least three separate days. "High-normal" blood pressure is defined as an average systolic or diastolic blood pressure ≥90th but <95th percentile for age, sex, and height percentile measured 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 (total cholesterol >240 mg/dl) or a cardiovascular event before

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

Treatment
- Initial therapy should consist of optimization of glucose control and MNT using a Step 2 American Heart Association diet aimed at a decrease in the amount of saturated fat in the diet. (E)
- After the age of 10, the addition of a statin is recommended in patients who, after MNT and lifestyle changes, have LDL cholesterol >160 mg/dl (4.1 mmol/l) or have LDL cholesterol >130 mg/dl (3.4 mmol/l) and one or more CVD risk factors. (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 (243–245) and clinical (246) CVD. Although intervention data are lacking, the American Heart Association (AHA) categorizes type 1 children in the highest tier for cardiovascular risk, and recommends both lifestyle and pharmacologic treatment for those with elevated LDL cholesterol levels (247). 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 does not interfere with normal growth and development (248,249).

For children over the age of 10 with persistent elevation of LDL cholesterol despite lifestyle therapy, statins should be considered. Neither long-term safety nor cardiovascular outcome efficacy has been established for children. However, recent studies have shown short-term safety equivalent to that seen in adults, as well as efficacy in lowering LDL cholesterol levels, improving endothelial function, and causing regression of carotid intimal thickening (250–252). No statin is approved for use under the age of 10, and statin treatment should generally not be used in type 1 children before this age.

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. (E)
- 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 most commonly occurs after the onset of puberty and after 5–10 years of diabetes duration, 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
- Patients with type 1 diabetes who become symptomatic for celiac disease should be tested by measuring tissue transglutaminase or anti-endomysial antibodies, with documentation of normal serum IgA levels. (E)
- Children with positive antibodies should be referred to a gastroenterologist for evaluation. (E)
- Children with confirmed celiac disease should have consultation with a dietitian and be placed on a gluten-free diet. (E)

Celiac disease is an immune-mediated disorder that occurs with increased frequency in patients with type 1 diabetes (1–16% of individuals compared with 0.3–1% in the general population) (253,254). Symptoms of celiac disease include diarrhea, weight loss or poor weight gain, growth failure, abdominal pain, chronic fatigue, malnutrition due to malabsorption and other gastrointestinal problems, and unexplained hypoglycemia or erratic blood glucose concentrations.

vi. Hypothyroidism

Recommendations
- Patients with type 1 diabetes should be screened for thyroid peroxidase and thyroglobulin antibodies at diagnosis. (E)
- Thyroid-stimulating hormone (TSH) concentrations should be measured after metabolic control has been established. If normal, they should be rechecked every 1–2 years, or if the patient develops symptoms of thyroid dysfunction, thyromegaly, or an abnormal growth rate. Free T4 should be measured if TSH is abnormal. (E)

Auto-immune thyroid disease is the most common autoimmune disorder associated with diabetes, occurring in 17–30% of patients with type 1 diabetes (255). The presence of thyroid auto-antibodies is predictive of thyroid dysfunction (generally hypothyroidism, but less commonly hyperthyroidism) (256). Subclinical hypothyroidism may be associated with increased risk of symptomatic hypoglycemia (257) and with reduced linear growth (258). Hyperthyroidism alters glucose metabolism, potentially resulting in deterioration of metabolic control.

c. "Adherence"

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 into adolescence. Health care providers who care for children and adolescents, therefore, must be capable of evaluating the behavioral, emotional, and psychosocial factors that interfere with implementation and then must work with the individual and family to resolve problems that occur and/or to modify goals as appropriate.

d. School and day care.

Since a sizable portion of a child's day is spent in school, close communication with school or day care personnel is essential for optimal diabetes management, safety, and maximal academic opportunities. See Section VIII.B, "Diabetes Care in the School and Day Care Setting," for further discussion.

2. Type 2 diabetes

The incidence of type 2 diabetes in adolescents is increasing, especially in ethnic minority populations (20). Distinction between type 1 and type 2 diabetes in children can be difficult, 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 since treatment regimens, educational approaches, and dietary counsel will differ markedly between the two diagnoses. Because type 2 diabetes has a significant incidence of hypertension, dyslipidemia, and microalbuminuria at diagnosis (259), it is recommended that screening for the comorbidities and complications of diabetes, including fasting lipid profile, microalbuminuria assessment, and dilated eye examinations, begin at the time of diagnosis. The ADA consensus statement (22) provides guidance on the prevention, screening, and treatment of type 2 diabetes and its comorbidities in young people.

B. Preconception care

Recommendations

- A1C levels should be as close to normal as possible (<7%) in an individual patient before conception is attempted. (B)
- All women with diabetes and childbearing potential should be educated about the need for good glucose control before pregnancy and should participate in family planning. (E)
- Women with diabetes who are contemplating pregnancy should be evaluated and, if indicated, treated for diabetic retinopathy, nephropathy, neuropathy, and CVD. (E)
- Medications used by such women should be evaluated before 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)

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 >1% above the normal range for a nondiabetic pregnant woman.

Preconception care of diabetes appears to reduce the risk of congenital malformations. Five nonrandomized 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 (260–264). 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). 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 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*) ensure effective contraception until stable and acceptable glycemia is achieved, and *4*) identify, evaluate, and treat long-term diabetic complications such as retinopathy, nephropathy, neuropathy, hypertension, and CHD.

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 (265). 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. 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 ADA's technical review (266) and position statement (267) on this subject.

C. Older adults

Recommendations

- Older adults who are functional, cognitively intact, and have significant life expectancy should receive diabetes treatment using goals developed for younger adults. (E)
- Glycemic goals for older adults who do not meet the above criteria may 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 timeframe 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

timeframe of primary or secondary prevention trials. (E)
- Screening for diabetic 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.

The American Geriatric Society's guidelines for improving the care of the older person with diabetes mellitus (268) have 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 who are newly diagnosed may have had years of undiagnosed diabetes with resultant complications or may have few complications from the disease. 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 and who are active, have good cognitive function, and are willing to undertake the responsibility of self-management should be encouraged to do so and be treated using the goals for younger adults with diabetes.

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 than from tight glycemic control alone. There is strong evidence from clinical trials of the value of treating hypertension in the elderly (269). 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 older adults whose life expectancies equal or exceed the timeframes seen in clinical trials.

Special care is required in prescribing and monitoring pharmacologic therapy in older adults. Metformin is often contraindicated because of renal insufficiency or significant heart failure. TZDs can cause fluid retention, which may exacerbate or lead to heart failure. They are contraindicated in patients with CHF (New York Heart Association class III and IV), and if used at all should be used very cautiously in those with, or at risk for, milder degrees of CHF. 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. Drugs should be started at the lowest dose and titrated up gradually until targets are reached or side effects develop.

Screening for diabetic 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.

VIII. DIABETES CARE IN SPECIFIC SETTINGS

A. Diabetes care in the hospital

Recommendations
- 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: blood glucose levels should be kept as close to 110 mg/dl (6.1 mmol/l) as possible and generally <140 mg/dl (7.8 mmol/l). (A) These 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. Since cohort data suggest that outcomes are better in hospitalized patients with fasting glucose <126 mg/dl and all random glucoses <180–200, these goals are reasonable if they can be safely achieved. Insulin is the preferred drug to treat hyperglycemia in most cases. (E)
  - Due to concerns regarding the risk of hypoglycemia, some institutions may consider these blood glucose levels to be overly aggressive for initial targets. Through quality improvement, glycemic goals should systematically be reduced to the recommended levels. (E)
- Scheduled prandial insulin doses should be appropriately timed in relation to meals and should be adjusted according to point-of-care glucose levels. The traditional sliding-scale insulin regimens are ineffective as monotherapy and are generally not recommended. (C)
- Using correction dose or "supplemental" insulin to correct premeal hyperglycemia in addition to scheduled prandial and basal insulin is recommended. (E)
- Glucose monitoring with orders for correction insulin should be initiated in any patient not known to be diabetic who receives therapy associated with high risk for hyperglycemia, including high-dose glucocorticoids therapy, ini-

tiation of enteral or parenteral nutrition, or other medications such as octreotide or immunosuppressive medications. (B) If hyperglycemia is documented and persistent, initiation of basal/bolus insulin therapy may be necessary. Such patients should be treated to the same glycemic goals as patients with known diabetes. (E)
- A plan for treating hypoglycemia should be established for each patient. Episodes of hypoglycemia in the hospital should be tracked. (E)
- All patients with diabetes admitted to the hospital should have an A1C obtained if the result of testing in the previous 2–3 months is not available. (E)
- A diabetes education plan including "survival skills education" and follow-up should be developed for each patient. (E)
- Patients with hyperglycemia in the hospital who do not have a diagnosis of diabetes should have appropriate plans for follow-up testing and care documented at discharge. (E)

The management of diabetes in the hospital is extensively reviewed in an ADA technical review (270). This review, as well as a consensus statement by the American Association of Clinical Endocrinologists (AACE) with cosponsorship by ADA (271,272) and a report of a joint ADA-AACE task force on the topic (273), forms the basis for the discussion and guidelines in this section.

The literature on hospitalized patients with hyperglycemia typically describes three categories:

- Medical history of diabetes: diabetes has been previously diagnosed and acknowledged by the patient's treating physician.
- Unrecognized diabetes: hyperglycemia (fasting blood glucose 126 mg/dl or random blood glucose 200 mg/dl) occurring during hospitalization and confirmed as diabetes after hospitalization by standard diagnostic criteria but unrecognized as diabetes by the treating physician during hospitalization.
- Hospital-related hyperglycemia: hyperglycemia (fasting blood glucose 126 mg/dl or random blood glucose ≥200 mg/dl) occurring during the hospitalization that reverts to normal after hospital discharge.

The prevalence of diabetes in hospitalized adult patients is not precisely known. In the year 2000, 12.4% of hospital discharges in the U.S. listed diabetes as a diagnosis, but this is likely an underestimate. The prevalence of diabetes in hospitalized adults is conservatively estimated at 12–25%, depending on the thoroughness used in identifying patients. In the year 2003, there were 5.1 million hospitalizations with diabetes as a listed diagnosis, a 2.3-fold increase over 1980 rates (274).

The management of hyperglycemia in the hospital was traditionally considered secondary in importance to the condition that prompted admission (273).

A rapidly growing body of literature supports targeted glucose control in the hospital setting for potential improved mortality, morbidity, and health economic outcomes. Hyperglycemia in the hospital may result from stress; decompensation of type 1, 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 vasopressors.

1. In-hospital hyperglycemia and outcomes

a. General medicine and surgery. Observational studies suggest an association between hyperglycemia and increased mortality. Surgical patients with at least one blood glucose value >220 mg/dl (12.2 mmol/l) on the first postoperative day have significantly higher infection rates (275).

When admissions on general medicine and surgery units were studied, patients with new hyperglycemia had significantly increased in-hospital mortality, as did patients with known diabetes. In addition, length of stay was higher for the new hyperglycemic group, and patients in either hyperglycemic group were more likely to require intensive care unit (ICU) care and transitional or nursing home care. Better outcomes were demonstrated in patients with fasting and admission blood glucose <126 mg/dl (7 mmol/l) and all random blood glucose levels <200 mg/dl (11.1 mmol/l) (276).

b. CVD and critical care. A significant relationship exists between blood glucose levels and mortality in the setting of acute myocardial infarction. A meta-analysis of 15 studies compared in-hospital mortality in both hyper- and normoglycemic patients with and without diabetes. In subjects without known diabetes whose admission blood glucose averaged 109.8 mg/dl (6.1 mmol/l), the relative risk for in-hospital mortality was increased significantly. When diabetes was present and admission glucose averaged 180 mg/dl (10 mmol/l), risk of death was moderately increased compared with patients who had diabetes but less hyperglycemia on admission (277). Another study (278) demonstrated a strong independent relationship between admission blood glucose values and both in-hospital and 1-year mortality; rates were significantly lower in subjects with admission plasma glucose <100.8 mg/dl (5.6 mmol/l) than in those with plasma glucose 199.8 mg/dl (11 mmol/l).

These studies focused on admission blood glucose as a predictor of outcomes, rather than inpatient glycemic management per se. Higher admission plasma glucose levels in patients with a prior history of diabetes could reflect the degree of glycemic control in the outpatient setting, thus linking outpatient glycemic control to outcomes in the inpatient population. In patients without a prior history of diabetes, admission hyperglycemia could represent case finding of patients with previously undiagnosed diabetes, an unmasking of risk in a population at high risk for diabetes, or more severe illness at admission.

In the initial Diabetes and Insulin-Glucose Infusion in Acute Myocardial Infarction study (279,280), insulin-glucose infusion followed by at least 3 months of subcutaneous insulin treatment in diabetic patients with acute myocardial infarction improved long-term survival. Mean blood glucose in the intensive insulin intervention arm was 172.8 mg/dl (9.6 mmol/l), compared with 210.6 mg/dl (11.7 mmol/l) in the "conventional" group. The broad range of blood glucose levels within each arm limits the ability to define specific blood glucose target thresholds.

Three more recent studies (281–283) using an insulin-glucose infusion did not show a reduction in mortality in the intervention groups. However, in each of these studies, blood glucose levels were positively correlated with mortality. In the Hyperglycemia: Intensive Insulin Infusion In Infarction (HI-5) Study, a decrease in both CHF and reinfarction was observed in the group receiving intensive insulin therapy for at least 24 h.

c. Cardiac surgery. Attainment of targeted glucose control in patients with diabetes undergoing cardiac surgery is

associated with reduced mortality and risk of deep sternal wound infections (284,285) and supports the concept that perioperative hyperglycemia is an independent predictor of infection in patients with diabetes (286), with the lowest mortality in patients with blood glucose <150 mg/dl (8.3 mmol/l) (287).

d. Critical care. A mixed group of patients with and without diabetes admitted to a surgical ICU (SICU) were randomized to receive intensive insulin therapy (target blood glucose 80–110 mg/dl [4.4–6.1 mmol/l]) or conventional therapy. Intensive insulin therapy achieved a mean blood glucose of 103 mg/dl (5.7 mmol/l) and was associated with reduced mortality during the ICU stay and decreased overall in-hospital mortality (288). Hospital and ICU survival were linearly associated with ICU glucose levels, with the highest survival rates occurring in patients achieving an average blood glucose <110 mg/dl (6.1 mmol/l) (289).

A subsequent study of a similar intervention in patients in a medical ICU (MICU) (290) showed that the group receiving intensive insulin therapy had reduced morbidity but no difference in mortality overall. Death rates were significantly lower in those patients who were treated for >3 days; these patients could not be identified before therapy. A recent meta-analysis concluded that insulin therapy in critically ill patients had a beneficial effect on short-term mortality in different clinical settings (291).

2. Glycemic targets in hospitalized patients

There is relatively strong evidence from randomized controlled trials for a glycemic target of blood glucose <110 mg/dl (6.1 mmol/l) in patients in critical care units (288–290). However, the incidence of severe hyperglycemia (blood glucose <40 mg/dl) in the MICU study was 18.7%, much greater than the 5.1% observed in the SICU population. The identification of hypoglycemia as an independent risk factor for death in the MICU population may merit caution in widely promoting the 80–110 mg/dl target range for all critically ill populations (292). Two recent trials were discontinued because of difficulty achieving desired target ranges of blood glucose and unacceptably high rates of hypoglycemia (293,293a).

For patients on general medical-surgical units, the evidence for specific glycemic goals is less definitive. Epidemiologic and physiologic data suggest that lower blood glucose levels are associated with improved outcomes. Glycemic targets similar to those of outpatients may be difficult to achieve in the hospital due to the effects of stress hyperglycemia, altered nutritional intake, and multiple interruptions to medical care. Blood glucose levels shown to be associated with improved outcomes in these patients (fasting glucose <126 mg/dl and all blood glucose readings <180–200 mg/dl) would appear reasonable, if they can be safely achieved.

In both the critical care and non–critical care venue, glycemic goals must take into account the individual patient's situation as well as hospital system support for achieving these goals. A continuous quality improvement strategy may facilitate gradual improvement in mean glycemia hospital-wide.

3. Treatment options in hospitalized patients

a. Noninsulin glucose-lowering agents. No large studies have investigated the potential roles of various noninsulin glucose-lowering agents on outcomes of hospitalized patients with diabetes. Use of the various noninsulin classes in the inpatient setting presents some specific issues.

The long action of sulfonylureas and their predisposition to hypoglycemia in patients not consuming their normal nutrition serve as relative contraindications to routine use of these agents in the hospital (294). While the meglitinides, repaglinide and neteglinide, theoretically would produce less hypoglycemia than sulfonylureas, lack of clinical trial data for these agents, and the fact that they are primarily prandial in effect, would preclude their use. The major limitation to metformin use in the hospital is a number of specific contraindications to its use, related to risk of lactic acidosis, many of which occur in the hospital. The most common risk factors for lactic acidosis in metformin-treated patients are cardiac disease, including CHF, hypoperfusion, renal insufficiency, old age, and chronic pulmonary disease (295). Lactic acidosis is a rare complication in the outpatient setting (296), despite the relative frequency of risk factors (297). However, in the hospital the risks of hypoxia, hypoperfusion, and renal insufficiency are much higher, and it is prudent to avoid the use of metformin in most patients.

TZDs are not suitable for initiation in the hospital because of their delayed onset of effect. In addition, they increase intravascular volume, a particular problem in those predisposed to CHF and potentially a problem for patients with hemodynamic changes related to admission diagnoses (e.g., acute coronary ischemia) or interventions common in hospitalized patients. Pramlintide and exenatide work mainly by reducing postprandial hyperglycemia, so they would not be appropriate for patients not eating (NPO) or with reduced caloric consumption. Furthermore, initiation of these drugs in the inpatient setting would be problematic, due to alterations in normal food intake and their propensity to induce nausea initially. There is limited experience and no published data on the DPP-IV inhibitors in the hospital setting, but there are no specific safety concerns. They are mainly effective on postprandial glucose and therefore would have limited effect in patients who are not eating.

In summary, each of the major classes of noninsulin glucose-lowering drugs has significant limitations for inpatient use. Additionally, they provide little flexibility or opportunity for titration in a setting where acute changes often demand these characteristics. Therefore insulin, when used properly, is preferred for the majority of hyperglycemic patients in the hospital setting.

b. Insulin

i. Subcutaneous insulin therapy. Subcutaneous insulin therapy may be used to attain glucose control in most hospitalized patients with diabetes outside of the critical care arena. The components of the daily insulin dose requirement can be met by a variety of insulins, depending on the particular hospital situation. Subcutaneous insulin therapy should cover both basal and nutritional needs, and is subdivided into scheduled insulin and supplemental, or correction-dose, insulin. Correction-dose insulin therapy is an important adjunct to scheduled insulin, both as a dose-finding strategy and as a supplement when rapid changes in insulin requirements lead to hyperglycemia. If correction doses are frequently required, the appropriate scheduled insulin doses should be increased to accommodate the increased insulin needs. There are no studies comparing human regular insulin with rapid-acting analogs for use as correction-dose insulin.

The traditional "sliding-scale" insulin regimens, usually consisting of regular in-

sulin without any intermediate or long-acting insulins, have been shown to be ineffective when used as monotherapy in patients with an established insulin requirement (298–300). One problems with sliding-scale insulin regimens is that the sliding-scale regimen prescribed on admission is likely to be used throughout the hospital stay without modification, even when control remains poor. Additionally, sliding-scale insulin therapy treats hyperglycemia after it has already occurred, instead of preventing the occurrence of hyperglycemia. This "reactive" approach can lead to rapid changes in blood glucose levels, exacerbating both hyper- and hypoglycemia.

A recent study demonstrated the safety and efficacy of using basal-bolus insulin therapy utilizing weight-based dosing in insulin-naïve hospitalized patients with type 2 diabetes (301). Glycemic control, defined as a mean blood glucose <140 mg/dl, was achieved in 68% of patients receiving basal-bolus insulin versus only 38% of those receiving sliding-scale insulin alone. There were no differences in hypoglycemia between the two groups. It is important to note that the patients in this study were obese, and the doses used in this study (0.4–0.5 units · kg^{-1} · day^{-1}) are higher that what may be required in patients who are more sensitive to insulin, such as those who are lean or who have type 1 diabetes.

ii. Intravenous insulin infusion. The only method of insulin delivery specifically developed for use in the hospital is continuous intravenous infusion, using regular crystalline insulin. There is no advantage to using rapid-acting analogs, the structural modifications of which increase the rate of absorption from subcutaneous depots, in an intravenous insulin infusion. The medical literature supports the use of intravenous insulin infusion in preference to the subcutaneous route of insulin administration for several clinical indications among nonpregnant adults. These include DKA and nonketotic hyperosmolar state; general preoperative, intraoperative, and postoperative care; the postoperative period following heart surgery; following organ transplantation; with cardiogenic shock; exacerbated hyperglycemia during high-dose glucocorticoid therapy; type 1 diabetic patients who are NPO; or in critical care illness in general. It may be used as a dose-finding strategy in anticipation of initiation or reinitiation of subcutaneous insulin therapy in type 1 or type 2 diabetes.

Many institutions use insulin infusion algorithms that can be implemented by nursing staff. Although numerous algorithms have been published, there have been no head-to-head comparisons between insulin infusion strategies. Algorithms should incorporate the concepts that maintenance requirements differ between patients and change over the course of treatment. Ideally, intravenous insulin algorithms should consider both the current and previous glucose level, the rate of change of plasma glucose, and the current intravenous insulin infusion rate. For all algorithms, frequent bedside glucose testing is required, but the ideal frequency is not known.

iii. Transition from intravenous to subcutaneous insulin therapy. For those who will require subcutaneous insulin, the very short half-life of intravenous insulin necessitates administering the first dose of subcutaneous insulin before discontinuation of the intravenous insulin infusion. If short- or rapid-acting insulin is used, it should be injected 1–2 h before stopping the infusion. If intermediate- or long-acting insulin is used alone, it should be injected 2–3 h before. A combination of short-/rapid- and intermediate-/long-acting insulin is usually preferred. Basal insulin therapy can be initiated at any time of the day, and should not be withheld to await a specific dosing time, such as bedtime. A recent clinical trial demonstrated that a regimen using 80% of the intravenous insulin requirement over the preceding 24 h, divided into basal and bolus insulin components, was effective at achieving blood glucose levels between 80 and 150 mg/dl following discontinuation of the intravenous insulin (302).

4. Self-management in the hospital

Self-management of diabetes in the hospital 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 intake, 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. For patients conducting self-management in the hospital, it is imperative that basal, prandial, and correction doses of insulin and results of bedside glucose monitoring are recorded as part of the patient's hospital medical record. While many institutions allow patients on insulin pumps to continue these devices in the hospital, others express concern regarding use of a device unfamiliar to staff, particularly in patients who are not able to manage their own pump therapy. If a patient is too ill to self-manage either multiple daily injections or CSII, then appropriate subcutaneous doses can be calculated on the basis of their basal and bolus insulin needs during hospitalization, with adjustments for changes in nutritional or metabolic status.

5. Preventing hypoglycemia

Hypoglycemia, especially in insulin-treated patients, is the leading limiting factor in the glycemic management of type 1 and type 2 diabetes (117). In the hospital, multiple additional risk factors for hypoglycemia are present, even among patients who are neither "brittle" nor tightly controlled. Patients with or without diabetes may experience hypoglycemia in the hospital in association with altered nutritional state, heart failure, renal or liver disease, malignancy, infection, or sepsis (303,304). Additional triggering events leading to iatrogenic hypoglycemia include sudden reduction of corticosteroid dose, altered ability of the patient to self-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.

6. Diabetes care providers in the hospital

Inpatient diabetes management may be effectively provided by primary care physicians, endocrinologists, or hospitalists, but involvement of appropriately trained specialists or specialty teams may reduce

length of stay, improve glycemic control, and improve outcomes (305–308). In the care of diabetes, implementation of standardized order sets for scheduled and correction-dose insulin may reduce reliance on sliding-scale management. A team approach is needed to establish hospital pathways. To achieve glycemic targets associated with improved hospital outcomes, hospitals will need multidisciplinary support for using insulin infusion therapy outside of critical care units or will need to develop protocols for subcutaneous insulin therapy that effectively and safely achieve glycemic targets (309).

7. DSME in the hospital

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. Patients receive sufficient information and training to enable them to go home safely. Those newly diagnosed with diabetes or who are new to insulin and/or blood glucose monitoring need to be instructed before discharge to help ensure safe care upon returning home. Those patients hospitalized because of a crisis related to diabetes management or poor care at home need education to prevent subsequent episodes of hospitalization.

8. MNT in the hospital

Hospital diets continue to be ordered by calorie levels based on the "ADA diet." However, since 1994 the ADA has not endorsed any single meal plan or specified percentages of macronutrients, and the term "ADA diet" should no longer be used. Current nutrition recommendations advise individualization based on treatment goals, physiologic parameters, and medication usage. Because of the complexity of nutrition issues in the hospital, a registered dietitian, knowledgeable and skilled in MNT, should serve as an inpatient team member. The dietitian is responsible for integrating 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 (310,311).

9. Bedside blood glucose monitoring

Implementing intensive diabetes therapy in the hospital setting requires frequent and accurate blood glucose data. This measure is analogous to an additional "vital sign" for hospitalized patients with diabetes. Bedside glucose monitoring using capillary blood has advantages over laboratory venous glucose testing because the results can be obtained rapidly at the "point of care," where therapeutic decisions are made.

Bedside blood glucose testing is usually performed with portable meters that are similar or identical to devices for home SMBG. Staff training and ongoing quality control activities are important components of ensuring accuracy of the results. Ability to track the occurrence of hypo- and hyperglycemia is necessary. Results of bedside glucose tests should be readily available to all members of the care team.

For patients who are eating, commonly recommended testing frequencies are premeal and at bedtime. For patients not eating, testing every 4–6 h is usually sufficient for determining correction insulin doses. Patients on continuous intravenous insulin typically require hourly blood glucose testing until the blood glucose levels are stable, then every 2 h.

10. Continuous blood glucose monitoring in the hospital

The introduction of real-time blood glucose monitoring as a tool for outpatient diabetes management has potential benefit for the inpatient population (312). However, at this time, data are lacking examining this new technology in the acutely ill patient population. Until more studies are published, it is premature to use continuous blood glucose monitoring in the hospital except in a research setting.

B. Diabetes care in the school and day care setting

Recommendations

- An individualized diabetes medical management plan (DMMP) should be developed by the parent/guardian and the student's diabetes health care team. (E)
- An adequate number of school personnel should be trained in the necessary diabetes procedures (including monitoring of blood glucose levels and administration of insulin and glucagon) and in the appropriate response to high and low blood glucose levels. These school personnel need not be health care professionals. (E)
- As specified in the DMMP and as developmentally appropriate, the student with diabetes should have immediate access to diabetes supplies at all times, should be permitted to monitor his or her blood glucose level, and should be able to take appropriate action to treat hypoglycemia in the classroom or anywhere the student may be in conjunction with a school activity. (E)

There are ~206,000 individuals <20 years of age with diabetes in the U.S., most of whom attend school and/or some type of day care and need knowledgeable staff to provide a safe environment. Despite legal protections, including coverage of children with diabetes under Section 504 of the Individuals with Disabilities Education Act of 1991, children in the school and day care setting still face discrimination. The ADA position statement on diabetes care in the school and day care setting (313) provides the legal and medical justifications for the recommendations provided herein.

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. Parents and the health care team should provide school systems and day care providers with the information necessary for children with diabetes to participate fully and safely in the school/day care experience by developing an individualized DMMP.

An adequate number of school personnel should be trained in the necessary diabetes procedures (e.g., blood glucose monitoring and insulin and glucagon administration) and in the appropriate responses to high and low blood glucose levels to ensure that at least one adult is present to perform these procedures in a timely manner while the student is at school, on field trips, and participating in school-sponsored extracurricular activities. These school personnel need not be health care professionals, although the school nurse may be instrumental in training nonmedical individuals.

The student with diabetes should have immediate access to diabetes supplies at all times, with supervision as needed. The student should be able to ob-

tain a blood glucose level and respond to the results as quickly and conveniently as possible, minimizing the need for missing instruction in the classroom and avoiding the risk of worsening hypoglycemia if the child must go somewhere else for treatment. The student's desire for privacy during testing and insulin administration should also be accommodated.

ADA and partner organizations have developed tools for school personnel to provide a safe and nondiscriminatory educational environment for all students with diabetes (314,315).

C. Diabetes care at diabetes camps

Recommendations

- Each camper should have a standardized medical form completed by his/her family and the physician managing the diabetes. (E)
- Camp medical staff should be led by with a physician with expertise in managing type 1 and type 2 diabetes, and includes nurses (including diabetes educators and diabetes clinical nurse specialists) and registered dietitians with expertise in diabetes. (E)
- All camp staff, including physicians, nurses, dietitians and volunteers, should undergo background testing to ensure appropriateness in working with children. (E)

The concept of specialized residential and day camps for children with diabetes has become widespread throughout the U.S. and many other parts of the world. The mission of diabetes camps is to provide a camping experience in a safe environment. An equally important goal is to enable children with diabetes to meet and share their experiences with one another while they learn to be more personally responsible for their disease. For this to occur, a skilled medical and camping staff must be available to ensure optimal safety and an integrated camping/educational experience (316).

Each camper should have a standardized medical form completed by his/her family and the physician managing the diabetes that details the camper's past medical history, immunization record, and diabetes regimen. The home insulin dosage should be recorded for each camper, including type(s) of insulin used, number and timing of injections and the correction factor and carbohydrate ratios used for determining bolus dosages for basal-bolus regimens. Campers using CSII should also have their basal rates specified. Because camp is often associated with more physical activity than experienced at home, the insulin dose may have to be decreased during camp (316).

The diabetes camping experience is short-term, with food and activity different than the home environment. Thus, goals of glycemic control at camp are to avoid extremes in blood glucose levels rather than attempting optimization of intensive glycemic control (316).

During camp, a daily record of the camper's progress should be made, including all blood glucose levels and insulin dosages. To ensure safety and optimal diabetes management, multiple blood glucose determinations should be made throughout each 24-h period: before meals, at bedtime, after or during prolonged and strenuous activity, and in the middle of the night when indicated for prior hypoglycemia. If major alterations of a camper's regimen appear to be indicated, it is important to discuss this with the camper and the family in addition to the child's local physician. The record of what transpired during camp should be discussed with the family at the end of the camp session and a copy sent to the child's physician (316).

Each camp should secure a formal relationship with a nearby medical facility so that camp medical staff can refer to this facility for prompt treatment of medical emergencies. ADA requires that the camp medical director be a physician with expertise in managing type 1 and type 2 diabetes. Nursing staff should include diabetes educators and diabetes clinical nurse specialists. Registered dietitians with expertise in diabetes should have input into the design of the menu and the education program. All camp staff, including medical, nursing, nutrition, and volunteer staff, should undergo background testing to ensure appropriateness in working with children (316).

D. Diabetes management in correctional institutions

Recommendations

- Correctional staff should be trained in the recognition, treatment, and appropriate referral for hypo- and hyperglycemia, including serious metabolic decompensation. (E)
- 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 upon entry. Insulin-treated patients should have a capillary blood glucose (CBG) determination within 1–2 h of arrival. Staff should identify patients with type 1 diabetes who are at high risk for DKA with omission of insulin. (E)
- Medications and MNT should be continued without interruption upon entry into the correctional environment. (E)
- In the correctional setting, policies and procedures should enable CBG monitoring to occur at the frequency necessitated by the patient's glycemic control and diabetes regimen, and should require staff to notify a physician of all CBG results outside of a specified range, as determined by the treating physician. (E)
- For all inter-institutional transfers, a medical transfer summary should be transferred with the patient, and diabetes supplies and medication should accompany the patient. (E)
- Correctional staff should begin discharge planning with adequate lead time to ensure continuity of care and facilitate entry into community diabetes care. (E)

At any given time, >2 million people are incarcerated in prisons and jails in the U.S., and it is estimated that nearly 80,000 of these inmates have diabetes. In addition, many more people with diabetes pass through the corrections system in a given year (317).

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. 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 (317).

Reception screening should emphasize patient safety. In particular, rapid identification of all insulin-treated individuals with diabetes is essential in order to identify those at highest risk for hypo- and hyperglycemia and DKA. All insulin-treated patients should have a CBG determination within 1–2 h of arrival. 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. It is essential that medica-

tion and 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 hyper- or hypoglycemia (317).

Patients must have access to prompt treatment of hypo- and hyperglycemia. Correctional staff should be trained in the recognition and treatment of these conditions, and appropriate staff should be trained to administer glucagon. 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 (317).

Correctional institutions should have systems in place to ensure that insulin administration and meals are coordinated to prevent hypo- and hyperglycemia, taking into consideration the transport of residents off site and the possibility of emergency schedule changes. The frequency of CBG monitoring will vary by patients' glycemic control and diabetes regimens. Policies and procedures should ensure that the health care staff has adequate knowledge and skills to direct the management and education of individuals with diabetes (317).

Patients in jails may be housed for a short period of time before being transferred or released, and patients in prison may be transferred within the system several times during their incarceration. Transferring a patient with diabetes from one correctional facility to another requires a coordinated effort, as does planning for discharge. The ADA Position Statement on Diabetes Management in Correctional Institutions (317) should be consulted for more information on this topic.

E. Emergency and disaster preparedness

Recommendations

- People with diabetes should maintain a disaster kit that includes items important to their diabetes self-management and continuing medical care. (E)
- The kit should be reviewed and replenished at least twice yearly. (E)

The difficulties encountered by people with diabetes and their health care providers in the wake of Hurricane Katrina (318) highlight the need for people with diabetes to be prepared for emergencies, whether natural or otherwise, affecting a region or just their household. Such preparedness will lessen the impact an emergency may have on their condition. It is recommended that people with diabetes keep a waterproof and insulated disaster kit ready with items critically important to their self-management. These may include glucose testing strips, lancets, and a glucose-testing meter; medications including insulin in a cool bag; syringes; glucose tabs or gels; antibiotic ointments/creams for external use; glucagon emergency kits; and photocopies of relevant medical information, particularly medication lists and recent lab tests/procedures if available. If possible, prescription numbers should be noted, since many chain pharmacies throughout the country will refill medications based on the prescription number alone. In addition, it may be important to carry a list of contacts for national organizations, such as the American Red Cross and ADA. This disaster kit should be reviewed and replenished at least twice yearly (319).

IX. HYPOGLYCEMIA AND EMPLOYMENT/LICENSURE

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)

Any person with diabetes, whether insulin treated or non–insulin treated, should be eligible for any employment for which he/she is otherwise qualified. Despite the significant medical and technological advances made in managing diabetes, discrimination in employment and licensure against people with diabetes still occurs. This discrimination is often based on apprehension that the person with diabetes may present a safety risk to the employer or the public, a fear sometimes based on misinformation or lack of up-to-date knowledge about diabetes. Perhaps the greatest concern is that hypoglycemia will cause sudden unexpected incapacitation. However, most people with diabetes can manage their condition in such a manner that there is minimal risk of incapacitation from hypoglycemia (320).

Because the effects of diabetes are unique to each individual, it is inappropriate to consider all people with diabetes the same. People with diabetes should be individually considered for employment based on the requirements of the specific job. Factors to be weighed in this decision include the individual's medical condition, treatment regimen (MNT, noninsulin drugs, and/or insulin), and medical history, particularly in regard to the occurrence of incapacitating hypoglycemic episodes (320).

X. THIRD-PARTY REIMBURSEMENT FOR DIABETES CARE, SELF-MANAGEMENT EDUCATION, AND SUPPLIES

Recommendations

- Patients and practitioners should have access to all classes of antidiabetic medications, equipment, and supplies without undue controls. (E)
- MNT and DSME should be covered by insurance and other payors. (E)

To achieve optimal glucose control, the person with diabetes must have access to health care providers who have expertise in the field of diabetes. Treatments and therapies that improve glycemic control and reduce the complications of diabetes will also significantly reduce health care costs. Access to the integral components of diabetes care, such as health care visits, diabetes supplies and medications, and self-management education, is essential. All medications and supplies related to the daily care of diabetes, such as syringes, strips, and meters, must also be reimbursed by third-party payors (321).

It is recognized that the use of formularies, prior authorization, and provisions such as competitive bidding can manage provider practices as well as costs to the potential benefit of payors and patients. However, any controls should ensure that all classes of antidiabetic agents with unique mechanisms of action and all classes of equipment and supplies designed for use with such equipment are available to facilitate achieving glycemic goals and to reduce the risk of complications. Without appropriate safeguards, undue controls could constitute an obstruction of effective care (321).

Medicare and many other third-party payors cover DSME (the CMS term is diabetes self-management training [DSMT]) and MNT. The qualified beneficiary who meets the diagnostic criteria

and medical necessity can receive an initial benefit of 10 h of DSMT and 3 h of MNT, with a potential total of 13 h of initial benefits. However, not all Medicare beneficiaries with diabetes will qualify for both MNT and DSMT benefits. More information on Medicare policy, including follow-up benefits, is available at www.diabetes.org/for-health-professionals-and-scientists/recognition.jsp or on the CMS Web sites: www.cms.hhs.gov/DiabetesSelfManagement (DSME) and www.cms.hhs.gov/MedicalNutritionTherapy (diabetes MNT) reimbursement.

XI. STRATEGIES FOR IMPROVING DIABETES CARE

The implementation of the standards of care for diabetes has been suboptimal in most clinical settings. A recent report (322) indicated that only 37% of adults with diagnosed diabetes achieved an A1C of <7%, only 36% had a blood pressure <130/80 mmHg, and just 48% had a total cholesterol <200 mg/dl. Most distressing was that only 7.3% of people with diabetes achieved all three treatment goals.

While numerous interventions to improve adherence to the recommended standards have been implemented, the challenge of providing uniformly effective diabetes care has thus far defied a simple solution. A major contributor to suboptimal care is a delivery system that too often is fragmented, lacks clinical information capabilities, often duplicates services, and is poorly designed for the delivery of chronic care. The Institute of Medicine has called for changes so that delivery systems provide care that is evidence-based, patient-centered, and systems-oriented, and takes advantage of information technologies that foster continuous quality improvement. Collaborative, multidisciplinary teams should be best suited to provide such care for people with chronic conditions like diabetes and to empower patients' performance of appropriate self-management. Alterations in reimbursement that reward the provision of quality care, as defined by the attainment of quality measures developed by such programs as the ADA/National Committee for Quality Assurance Diabetes Provider Recognition Program, will also be required to achieve desired outcome goals.

The NDEP recently launched a new online resource to help health care professionals better organize their diabetes care. The www.betterdiabetescare.nih.gov Web site should help users design and implement more effective health care delivery systems for those with diabetes.

In recent years, numerous health care organizations, ranging from large health care systems such as the U.S. Veteran's Administration to small private practices, have implemented strategies to improve diabetes care. Successful programs have published results showing improvement in process measures such as measurement of A1C, lipids, and blood pressure. Effects on in important intermediate outcomes, such as mean A1C for populations, have been more difficult to demonstrate (323–325) although examples do exist (326–330). Successful interventions have been focused at the level of health care professionals, delivery systems, and patients. Features of successful programs reported in the literature include:

- Improving health care professional education regarding the standards of care through formal and informal education programs.
- Delivery of DSME, which has been shown to increase adherence to standard of care.
- Adoption of practice guidelines, with participation of health care professionals in the process. Guidelines should be readily accessible at the point of service, such as on patient charts, in examining rooms, in "wallet or pocket cards," on PDAs, or on office computer systems. Guidelines should begin with a summary of their major recommendations instructing health care professionals what to do and how to do it.
- Use of checklists that mirror guidelines have been successful at improving adherence to standards of care.
- Systems changes, such as provision of automated reminders to health care professionals and patients, reporting of process and outcome data to providers, and especially identification of patients at risk because of failure to achieve target values or a lack of reported values.
- Quality improvement programs combining continuous quality improvement or other cycles of analysis and intervention with provider performance data.
- Practice changes, such as clustering of dedicated diabetes visits into specific times within a primary care practice schedule and/or visits with multiple health care professionals on a single day and group visits.
- Tracking systems with either an electronic medical record or patient registry have been helpful at increasing adherence to standards of care by prospectively identifying those requiring assessments and/or treatment modifications. They likely could have greater efficacy if they suggested specific therapeutic interventions to be considered for a particular patient at a particular point in time (331).
- A variety of nonautomated systems, such as mailing reminders to patients, chart stickers, and flow sheets, have been useful to prompt both providers and patients.
- Availability of case or (preferably) care management services, usually by a nurse (332). Nurses, pharmacists, and other nonphysician health care professionals using detailed algorithms working under the supervision of physicians and/or nurse education calls have also been helpful. Similarly, dietitians using MNT guidelines have been demonstrated to improve glycemic control.
- Availability and involvement of expert consultants, such as endocrinologists and diabetes educators.

Evidence suggests that these individual initiatives work best when provided as components of a multifactorial intervention. Therefore, it is difficult to assess the contribution of each component; however, it is clear that optimal diabetes management requires an organized, systematic approach and involvement of a coordinated team of health care professionals.

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Diagnosis and Classification of Diabetes Mellitus

AMERICAN DIABETES ASSOCIATION

DEFINITION AND DESCRIPTION OF DIABETES MELLITUS

— Diabetes mellitus 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 various 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.

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 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, type I diabetes, or juvenile-onset diabetes, results from a

The information that follows is based largely on the reports of the Expert Committee on the Diagnosis and Classification of Diabetes (*Diabetes Care* 20:1183–1197, 1997, and *Diabetes Care* 26:3160–3167, 2003).

Abbreviations: FPG, fasting plasma glucose; GAD, glutamic acid decarboxylase; GCT, glucose challenge test; GDM, gestational diabetes mellitus; HNF, hepatocyte nuclear factor; IFG, impaired fasting glucose; IGT, impaired glucose tolerance; MODY, maturity-onset diabetes of the young; WHO, World Health Organization.

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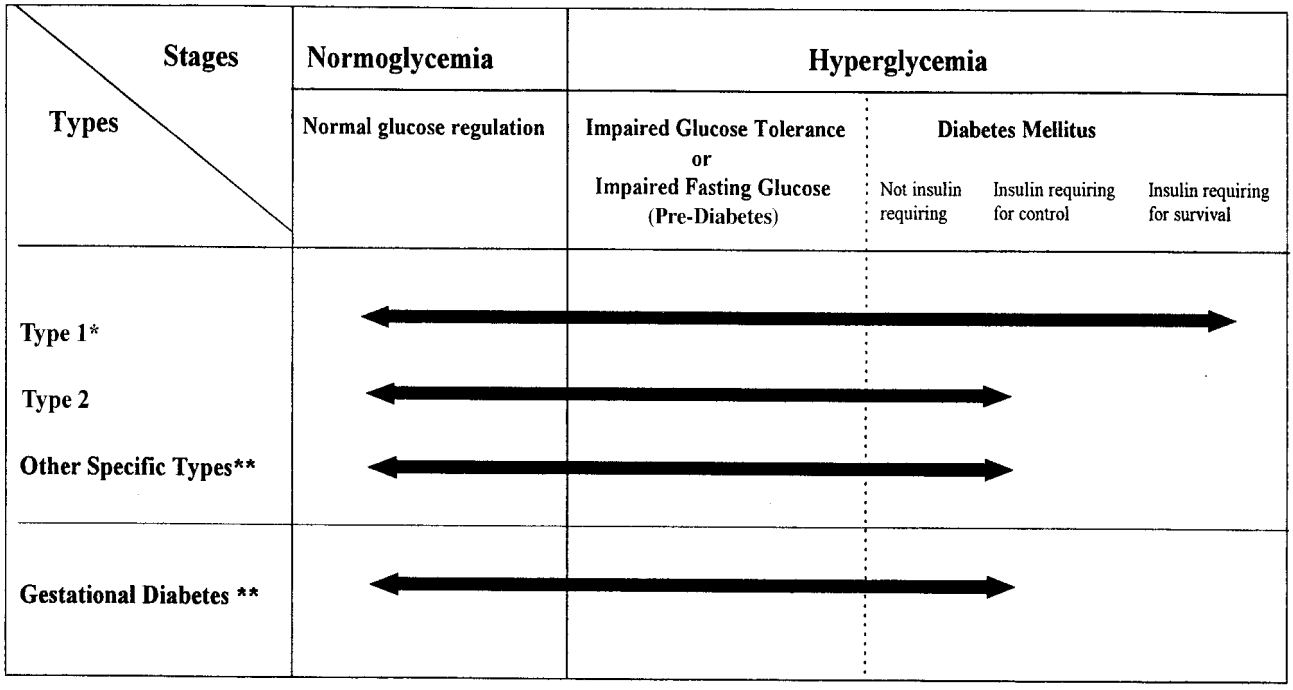

Figure 1—*Disorders of glycemia: etiologic types and stages. *Even after presenting in ketoacidosis, these patients can briefly return to normoglycemia without requiring continuous therapy (i.e., "honeymoon" remission); **in rare instances, patients in these categories (e.g., Vacor toxicity, type 1 diabetes presenting in pregnancy) may require insulin for survival.*

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 glutamic acid decarboxylase (GAD_{65}), 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 fasting 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 ketoacidosis, 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 ketoacidosis 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 II 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. Ketoacidosis seldom occurs spontaneously in this type of diabetes; when seen, it usually arises in association with the stress of another ill-

ness such as infection. This form of diabetes frequently goes undiagnosed for many years because the hyperglycemia develops gradually and at earlier stages is often not severe enough for the patient to notice any of the classic symptoms of diabetes. Nevertheless, such patients are at increased risk of developing macrovascular and microvascular complications. Whereas patients with this form of diabetes may have insulin levels that appear normal or elevated, the higher blood glucose levels in these diabetic patients would be expected to result in even higher insulin values had their β-cell function been normal. Thus, insulin secretion is defective in these patients and insufficient to compensate for insulin resistance. Insulin resistance may improve with weight reduction and/or pharmacological treatment of hyperglycemia but is seldom restored to normal. The risk of developing this form of diabetes increases with age, obesity, and lack of physical activity. It occurs more frequently in women with prior GDM and in individuals with hypertension or dyslipidemia, and its frequency varies in different racial/ethnic subgroups. It is often associated with a strong genetic predisposition, more so than is the autoimmune form of type 1 diabetes. However, the genetics of this form of diabetes are complex and not clearly defined.

Other specific types of diabetes

Genetic defects of the β-cell. Several forms of diabetes are associated with monogenetic defects in β-cell function. These forms of diabetes are frequently characterized by onset of hyperglycemia at an early age (generally before age 25 years). They are referred to as maturity-onset diabetes of the young (MODY) and are characterized by impaired insulin secretion with minimal or no defects in insulin action. They are inherited in an autosomal dominant pattern. Abnormalities at six genetic loci on different chromosomes have been identified to date. The most common form is associated with mutations on chromosome 12 in a hepatic transcription factor referred to as hepatocyte nuclear factor (HNF)-1α. A second form is associated with mutations in the glucokinase gene on chromosome 7p and results in a defective glucokinase molecule. Glucokinase converts glucose to glucose-6-phosphate, the metabolism of which, in turn, stimulates insulin secretion by the β-cell. Thus, glucokinase serves as the "glucose sensor" for the β-cell. Because of defects in the glucokinase gene, increased plasma levels of glucose are necessary to elicit normal levels of insulin secretion. The less common forms result from mutations in other transcription factors, including HNF-4α, HNF-1β, insulin promoter factor (IPF)-1, and NeuroD1.

Point mutations in mitochondrial DNA have been found to be associated with diabetes mellitus and deafness The most common mutation occurs at position 3243 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, pancreatectomy, and pancreatic carcinoma. With the exception of that caused by cancer, damage to the pancreas must be extensive for diabetes to occur; adrenocarcinomas 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 hemochromatosis 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, Cushing's 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.

Somatostatinoma- 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 unclear 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 recog-

Table 1—*Etiologic classification of diabetes mellitus*

I. Type 1 diabetes (β-cell destruction, usually leading to absolute insulin deficiency)
  A. Immune mediated
  B. Idiopathic
II. Type 2 diabetes (may range from predominantly insulin resistance with relative insulin deficiency to a predominantly secretory defect with insulin resistance)
III. Other specific types
  A. Genetic defects of β-cell function
    1. Chromosome 12, HNF-1α (MODY3)
    2. Chromosome 7, glucokinase (MODY2)
    3. Chromosome 20, HNF-4α (MODY1)
    4. Chromosome 13, insulin promoter factor-1 (IPF-1; MODY4)
    5. Chromosome 17, HNF-1β (MODY5)
    6. Chromosome 2, *NeuroD1* (MODY6)
    7. Mitochondrial DNA
    8. Others
  B. Genetic defects in insulin action
    1. Type A insulin resistance
    2. Leprechaunism
    3. Rabson-Mendenhall syndrome
    4. Lipoatrophic diabetes
    5. Others
  C. Diseases of the exocrine pancreas
    1. Pancreatitis
    2. Trauma/pancreatectomy
    3. Neoplasia
    4. Cystic fibrosis
    5. Hemochromatosis
    6. Fibrocalculous pancreatopathy
    7. Others
  D. Endocrinopathies
    1. Acromegaly
    2. Cushing's syndrome
    3. Glucagonoma
    4. Pheochromocytoma
    5. Hyperthyroidism
    6. Somatostatinoma
    7. Aldosteronoma
    8. Others
  E. Drug- or chemical-induced
    1. Vacor
    2. Pentamidine
    3. Nicotinic acid
    4. Glucocorticoids
    5. Thyroid hormone
    6. Diazoxide
    7. β-adrenergic agonists
    8. Thiazides
    9. Dilantin
    10. α-Interferon
    11. Others
  F. Infections
    1. Congenital rubella
    2. Cytomegalovirus
    3. Others
  G. Uncommon forms of immune-mediated diabetes
    1. "Stiff-man" syndrome
    2. Anti–insulin receptor antibodies
    3. Others
  H. Other genetic syndromes sometimes associated with diabetes
    1. Down's syndrome
    2. Klinefelter's syndrome
    3. Turner's syndrome
    4. Wolfram's syndrome
    5. Friedreich's ataxia
    6. Huntington's chorea
    7. Laurence-Moon-Biedl syndrome
    8. Myotonic dystrophy
    9. Porphyria
    10. Prader-Willi syndrome
    11. Others
IV. Gestational diabetes mellitus (GDM)

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.

nized 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 mellitus. These include the chromosomal abnormalities of Down's syndrome, Klinefelter's syndrome, and Turner's syndrome. Wolfram's 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.

Gestational diabetes mellitus (GDM)

GDM is defined as any degree of glucose intolerance with onset or first recognition during pregnancy. The definition applies regardless of whether insulin or only diet modification is used for treatment or whether the condition persists after pregnancy. It does not exclude the possibility that unrecognized glucose intolerance may

Table 2—*Criteria for the diagnosis of diabetes*

1.	FPG ≥126 mg/dl (7.0 mmol/l). Fasting is defined as no caloric intake for at least 8 h.*
	OR
2.	Symptoms of hyperglycemia and a casual plasma glucose ≥200 mg/dl (11.1 mmol/l). Casual is defined as any time of day without regard to time since last meal. The classic symptoms of hyperglycemia include polyuria, polydipsia, and unexplained weight loss.
	OR
3.	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.*

*In the absence of unequivocal hyperglycemia, these criteria should be confirmed by repeat testing on a different day.

have antedated or begun concomitantly with the pregnancy. GDM complicates ~4% of all pregnancies in the U.S., resulting in ~135,000 cases annually. The prevalence may range from 1 to 14% of pregnancies, depending on the population studied. GDM represents nearly 90% of all pregnancies complicated by diabetes.

Deterioration of glucose tolerance occurs normally during pregnancy, particularly in the 3rd trimester.

Impaired glucose tolerance (IGT) and impaired fasting glucose (IFG)

The Expert Committee (1,2) recognized an intermediate group of subjects whose glucose levels, although not meeting criteria for diabetes, are nevertheless too high to be considered normal. This group is defined as having fasting plasma glucose (FPG) levels ≥100 mg/dl (5.6 mmol/l) but <126 mg/dl (7.0 mmol/l) *or* 2-h values in the oral glucose tolerance test (OGTT) of ≥140 mg/dl (7.8 mmol/l) but <200 mg/dl (11.1 mmol/l). Thus, the categories of FPG values are as follows:

- FPG <100 mg/dl (5.6 mmol/l) = normal fasting glucose;
- FPG 100–125 mg/dl (5.6–6.9 mmol/l) = IFG (impaired fasting glucose);
- FPG ≥126 mg/dl (7.0 mmol/l) = provisional diagnosis of diabetes (the diagnosis must be confirmed, as described below).

The corresponding categories when the OGTT is used are the following:

- 2-h postload glucose <140 mg/dl (7.8 mmol/l) = normal glucose tolerance;
- 2-h postload glucose 140–199 mg/dl (7.8–11.1 mmol/l) = IGT (impaired glucose tolerance);
- 2-h postload glucose ≥200 mg/dl (11.1 mmol/l) = provisional diagnosis of diabetes (the diagnosis must be confirmed, as described below).

Patients with IFG and/or IGT are now referred to as having "pre-diabetes" indicating the relatively high risk for development of diabetes in these patients. In the absence of pregnancy, IFG and IGT are not clinical entities in their own right but rather risk factors for future 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 the metabolic syndrome, which includes obesity (especially abdominal or visceral obesity), dyslipidemia of the high-triglyceride and/or low-HDL type, and hypertension. It is worth mentioning that medical nutrition therapy aimed at producing 5–10% loss of body weight, exercise, and certain pharmacological agents have been variably demonstrated to prevent or delay the development of diabetes in people with IGT; the potential impact of such interventions to reduce cardiovascular risk has not been examined to date.

Note that many individuals with IGT are euglycemic in their daily lives. Individuals with IFG or IGT may have normal or near normal glycated hemoglobin levels. Individuals with IGT often manifest hyperglycemia only when challenged with the oral glucose load used in the standardized OGTT.

DIAGNOSTIC CRITERIA FOR DIABETES MELLITUS

— The criteria for the diagnosis of diabetes are shown in Table 2. Three ways to diagnose diabetes are possible, and each, in the absence of unequivocal hyperglycemia, must be confirmed, on a subsequent day, by any one of the three methods given in Table 2. The use of the hemoglobin A1c (A1C) for the diagnosis of diabetes is not recommended at this time.

Diagnosis of GDM

The criteria for abnormal glucose tolerance in pregnancy are those of Carpenter and Coustan (3). Recommendations from the American Diabetes Association's Fourth International Workshop-Conference on Gestational Diabetes Mellitus held in March 1997 support the use of the Carpenter/Coustan diagnostic criteria as well as the alternative use of a diagnostic 75-g 2-h OGTT. These criteria are summarized below.

Testing for gestational diabetes. Previous recommendations included screening for GDM performed in all pregnancies. However, there are certain factors that place women at lower risk for the development of glucose intolerance during pregnancy, and it is likely not cost-effective to screen such patients. Pregnant women who fulfill *all* of these criteria need not be screened for GDM.

This low-risk group comprises women who

- are <25 years of age
- are a normal body weight
- have no family history (i.e., first-degree relative) of diabetes
- have no history of abnormal glucose metabolism
- have no history of poor obstetric outcome
- are not members of an ethnic/racial group with a high prevalence of diabetes (e.g., Hispanic American, Native American, Asian American, African American, Pacific Islander)

Risk assessment for GDM should be undertaken at the first prenatal visit. Women with clinical characteristics consistent with a high risk of GDM (marked obesity, personal history of GDM, glycosuria, or a strong family history of diabetes) should undergo glucose testing (see below) as soon as feasible. If they are found not to have GDM at that initial screening, they should be retested between 24 and 28 weeks of gestation. Women of average risk should have testing undertaken at 24–28 weeks of gestation.

A fasting plasma glucose level >126 mg/dl (7.0 mmol/l) or a casual plasma glucose >200 mg/dl (11.1 mmol/l) meets the threshold for the diagnosis of diabetes. In the absence of unequivocal hyper-

Table 3—*Diagnosis of GDM with a 100-g or 75-g glucose load*

	mg/dl	mmol/l
100-g glucose load		
Fasting	95	5.3
1-h	180	10.0
2-h	155	8.6
3-h	140	7.8
75-g glucose load		
Fasting	95	5.3
1-h	180	10.0
2-h	155	8.6

Two or more of the venous plasma concentrations must be met or exceeded for a positive diagnosis. The test should be done in the morning after an overnight fast of between 8 and 14 h and after at least 3 days of unrestricted diet (≥150 g carbohydrate per day) and unlimited physical activity. The subject should remain seated and should not smoke throughout the test.

glycemia, the diagnosis must be confirmed on a subsequent day. Confirmation of the diagnosis precludes the need for any glucose challenge. In the absence of this degree of hyperglycemia, evaluation for GDM in women with average or high-risk characteristics should follow one of two approaches.

One-step approach. Perform a diagnostic OGTT without prior plasma or serum glucose screening. The one-step approach may be cost-effective in high-risk patients or populations (e.g., some Native-American groups).

Two-step approach. Perform an initial screening by measuring the plasma or serum glucose concentration 1 h after a 50-g oral glucose load (glucose challenge test [GCT]) and perform a diagnostic OGTT on that subset of women exceeding the glucose threshold value on the GCT. When the two-step approach is used, a glucose threshold value >140 mg/dl (7.8 mmol/l) identifies ~80% of women with GDM, and the yield is further increased to 90% by using a cutoff of >130 mg/dl (7.2 mmol/l).

With either approach, the diagnosis of GDM is based on an OGTT. Diagnostic criteria for the 100-g OGTT are derived from the original work of O'Sullivan and Mahan (4) modified by Carpenter and Coustan (3) and are shown in the top of Table 3. Alternatively, the diagnosis can be made using a 75-g glucose load and the glucose threshold values listed for fasting, 1 h, and 2 h (Table 2, bottom); however, this test is not as well validated as the 100-g OGTT.

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Nutrition Recommendations and Interventions for Diabetes

A position statement of the American Diabetes Association

AMERICAN DIABETES ASSOCIATION

Medical nutrition therapy (MNT) is important in preventing diabetes, managing existing diabetes, and preventing, or at least slowing, the rate of development of diabetes complications. It is, therefore, important at all levels of diabetes prevention (see Table 1). MNT is also an integral component of diabetes self-management education (or training). This position statement provides evidence-based recommendations and interventions for diabetes MNT. The previous position statement with accompanying technical review was published in 2002 (1) and modified slightly in 2004 (2). This statement updates previous position statements, focuses on key references published since the year 2000, and uses grading according to the level of evidence available based on the American Diabetes Association evidence-grading system. Since overweight and obesity are closely linked to diabetes, particular attention is paid to this area of MNT.

The goal of these recommendations is to make people with diabetes and health care providers aware of beneficial nutrition interventions. This requires the use of the best available scientific evidence while taking into account treatment goals, strategies to attain such goals, and changes individuals with diabetes are willing and able to make. Achieving nutrition-related goals requires a coordinated team effort that includes the person with diabetes and involves him or her in the decision-making process. It is recommended that a registered dietitian, knowledgeable and skilled in MNT, be the team member who plays the leading role in providing nutrition care. However, it is important that all team members, including physicians and nurses, be knowledgeable about MNT and support its implementation.

MNT, as illustrated in Table 1, plays a role in all three levels of diabetes-related prevention targeted by the U.S. Department of Health and Human Services. Primary prevention interventions seek to delay or halt the development of diabetes. This involves public health measures to reduce the prevalence of obesity and includes MNT for individuals with pre-diabetes. Secondary and tertiary prevention interventions include MNT for individuals with diabetes and seek to prevent (secondary) or control (tertiary) complications of diabetes.

GOALS OF MNT FOR PREVENTION AND TREATMENT OF DIABETES

Goals of MNT that apply to individuals at risk for diabetes or with pre-diabetes

To decrease the risk of diabetes and cardiovascular disease (CVD) by promoting healthy food choices and physical activity leading to moderate weight loss that is maintained.

Goals of MNT that apply to individuals with diabetes

1) Achieve and maintain

- Blood glucose levels in the normal range or as close to normal as is safely possible
- A lipid and lipoprotein profile that reduces the risk for vascular disease
- Blood pressure levels in the normal range or as close to normal as is safely possible

2) To prevent, or at least slow, the rate of development of the chronic complications of diabetes by modifying nutrient intake and lifestyle

3) To address individual nutrition needs, taking into account personal and cultural preferences and willingness to change

4) To maintain the pleasure of eating by only limiting food choices when indicated by scientific evidence

Goals of MNT that apply to specific situations

1) For youth with type 1 diabetes, youth with type 2 diabetes, pregnant and lactating women, and older adults with diabetes, to meet the nutritional needs of these unique times in the life cycle.

2) For individuals treated with insulin or insulin secretagogues, to provide self-management training for safe conduct of exercise, including the prevention and treatment of hypoglycemia, and diabetes treatment during acute illness.

EFFECTIVENESS OF MNT

Recommendations

- Individuals who have pre-diabetes or diabetes should receive individualized MNT; such therapy is best provided by a registered dietitian familiar with the components of diabetes MNT. (B)
- Nutrition counseling should be sensitive to the personal needs, willingness to change, and ability to make changes of the individual with pre-diabetes or diabetes. (E)

Clinical trials/outcome studies of MNT have reported decreases in HbA_{1c} (A1C) of ~1% in type 1 diabetes and 1–2% in type 2 diabetes, depending on the duration of diabetes (3,4). Meta-analysis of studies in nondiabetic, free-living subjects and expert committees report that MNT reduces LDL cholesterol by 15–25 mg/dl (5,6). After initiation of MNT, improvements were apparent in 3–6 months. Meta-analysis and expert committees also support a role for lifestyle modification in treating hypertension (7,8).

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Abbreviations: CHD, coronary heart disease; CKD, chronic kidney disease; CVD, cardiovascular disease; DPP, Diabetes Prevention Program; FDA, Food and Drug Administration; GDM, gestational diabetes mellitus; MNT, medical nutrition therapy; RDA, recommended dietary allowance; USDA, U.S. Department of Agriculture.

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Table 1—*Nutrition and MNT*

Primary prevention to prevent diabetes:	Secondary prevention to prevent complications:	Tertiary prevention to prevent morbidity and mortality:
• Use MNT and public health interventions in those with obesity and pre-diabetes	• Use MNT for metabolic control of diabetes	• Use MNT to delay and manage complications of diabetes

ENERGY BALANCE, OVERWEIGHT, AND OBESITY

Recommendations

- In overweight and obese insulin-resistant individuals, modest weight loss has been shown to improve insulin resistance. Thus, weight loss is recommended for all such individuals who have or are at risk for diabetes. (A)
- For weight loss, either low-carbohydrate or low-fat calorie-restricted diets may be effective in the short term (up to 1 year). (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)
- Weight loss medications may be considered in the treatment of overweight and obese individuals with type 2 diabetes and can help achieve a 5–10% weight loss when combined with lifestyle modification. (B)
- Bariatric surgery may be considered for some individuals with type 2 diabetes and BMI ≥35 kg/m^2 and can result in marked improvements in glycemia. The long-term benefits and risks of bariatric surgery in individuals with pre-diabetes or diabetes continue to be studied. (B)

The importance of controlling body weight in reducing risks related to diabetes is of great importance. Therefore, these nutrition recommendations start by considering energy balance and weight loss strategies. The National Heart, Lung, and Blood Institute guidelines define overweight as BMI ≥25 kg/m^2 and obesity as BMI ≥30 kg/m^2 (9). The risk of comorbidity associated with excess adipose tissue increases with BMIs in this range and above. However, clinicians should be aware that in some Asian populations, the proportion of people at high risk of type 2 diabetes and CVD is significant at BMIs of >23 kg/m^2 (10). Visceral body fat, as measured by waist circumference ≥35 inches in women and ≥40 inches in men, is used in conjunction with BMI to assess risk of type 2 diabetes and CVD (Table 2) (9). Lower waist circumference cut points (≥31 inches in women, ≥35 inches in men) may be appropriate for Asian populations (11).

Because of the effects of obesity on insulin resistance, weight loss is an important therapeutic objective for individuals with pre-diabetes or diabetes (12). However, long-term weight loss is difficult for most people to accomplish. This is probably because the central nervous system plays an important role in regulating energy intake and expenditure. Short-term studies have demonstrated that moderate weight loss (5% of body weight) in subjects with type 2 diabetes is associated with decreased insulin resistance, improved measures of glycemia and lipemia, and reduced blood pressure (13). Longer-term studies (≥52 weeks) using pharmacotherapy for weight loss in adults with type 2 diabetes produced modest reductions in weight and A1C (14), although improvement in A1C was not seen in all studies (15,16). Look AHEAD (Action for Health in Diabetes) is a large National Institutes of Health–sponsored clinical trial designed to determine if long-term weight loss will improve glycemia and prevent cardiovascular events (17). When completed, this study should provide insight into the effects of long-term weight loss on important clinical outcomes.

Evidence demonstrates that structured, intensive lifestyle programs involving participant education, individualized counseling, reduced dietary energy and fat (~30% of total energy) intake, regular physical activity, and frequent participant contact are necessary to produce long-term weight loss of 5–7% of starting weight (1). The role of lifestyle modification in the management of weight and type 2 diabetes was recently reviewed (13). Although structured lifestyle programs have been effective when delivered in well-funded clinical trials, it is not clear how the results should be translated into clinical practice. Organization, delivery, and funding of lifestyle interventions are all issues that must be addressed. Third-party payers may not provide adequate benefits for sufficient MNT frequency and time to achieve weight loss goals (18).

Exercise and physical activity, by themselves, have only a modest weight loss effect. However, exercise and physical activity are to be encouraged because they improve insulin sensitivity independent of weight loss, acutely lower blood glucose, and are important in long-term maintenance of weight loss (1). Weight loss with behavioral therapy alone also has been modest, and behavioral approaches may be most useful as an adjunct to other weight loss strategies.

Standard weight loss diets provide

Table 2—*Classification of overweight and obesity by BMI, waist circumference, and associated disease risk*

			Disease risk*	
	BMI (kg/m^2)	Obesity class	WC: men ≤40 inches; women ≤35 inches	WC: men ≥40 inches; women ≥35 inches
Underweight	<18.5			
Normal	18.5–24.9			
Overweight	25.0–29.9		Increased	High
Obesity	30.0–34.9	I	High	Very high
	35.0–39.9	II	Very high	Very high
Extreme obesity	≥40	III	Extremely high	Extremely high

*Disease risk for type 2 diabetes, hypertension, and CVD. Adapted from ref. 9. WC, waist circumference.

500–1,000 fewer calories than estimated to be necessary for weight maintenance and initially result in a loss of ~1–2 lb/week. Although many people can lose some weight (as much as 10% of initial weight in ~6 months) with such diets, without continued support and follow-up, people usually regain the weight they have lost.

The optimal macronutrient distribution of weight loss diets has not been established. Although low-fat diets have traditionally been promoted for weight loss, two randomized controlled trials found that subjects on low-carbohydrate diets lost more weight at 6 months than subjects on low-fat diets (19,20). Another study of overweight women randomized to one of four diets showed significantly more weight loss at 12 months with the Atkins low-carbohydrate diet than with higher-carbohydrate diets (20a). However, at 1 year, the difference in weight loss between the low-carbohydrate and low-fat diets was not significant and weight loss was modest with both diets. Changes in serum triglyceride and HDL cholesterol were more favorable with the low-carbohydrate diets. In one study, those subjects with type 2 diabetes demonstrated a greater decrease in A1C with a low-carbohydrate diet than with a low-fat diet (20). A recent 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 (21). Further research is needed to determine the long-term efficacy and safety of low-carbohydrate diets (13). The recommended dietary allowance (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 (22). 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 (22).

Meal replacements (liquid or solid prepackaged) provide a defined amount of energy, often as a formula product. Use of meal replacements once or twice daily to replace a usual meal can result in significant weight loss. Meal replacements are an important part of the Look AHEAD weight loss intervention (17). However, meal replacement therapy must be continued indefinitely if weight loss is to be maintained.

Very-low-calorie diets provide ≤800 calories daily and produce substantial weight loss and rapid improvements in glycemia and lipemia in individuals with type 2 diabetes. When very-low-calorie diets are stopped and self-selected meals are reintroduced, weight regain is common. Thus, very-low-calorie diets appear to have limited utility in the treatment of type 2 diabetes and should only be considered in conjunction with a structured weight loss program.

The available data suggest that weight loss medications may be useful in the treatment of overweight individuals with and at risk for type 2 diabetes and can help achieve a 5–10% weight loss when combined with lifestyle change (14). According to their labels, these medications should only be used in people with diabetes who have BMI >27.0 kg/m^2.

Gastric reduction surgery can be an effective weight loss treatment for obesity and may be considered in people with diabetes who have BMI ≥35 kg/m^2. A meta-analysis of studies of bariatric surgery reported that 77% of individuals with type 2 diabetes had complete resolution of diabetes (normalization of blood glucose levels in the absence of medications), and diabetes was resolved or improved in 86% (23). In the Swedish Obese Subjects study, a 10-year follow-up of individuals undergoing bariatric surgery, 36% of subjects with diabetes had resolution of diabetes compared with 13% of matched control subjects (24). All cardiovascular risk factors except hypercholesterolemia improved in the surgical patients.

NUTRITION RECOMMENDATIONS AND INTERVENTIONS FOR THE PREVENTION OF DIABETES (PRIMARY PREVENTION)

Recommendations

- 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 high 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)
- There is not sufficient, consistent information to conclude that low–glycemic load diets reduce the risk for diabetes. Nevertheless, low–glycemic index foods that are rich in fiber and other important nutrients are to be encouraged. (E)
- Observational studies report that moderate alcohol intake may reduce the risk for diabetes, but the data do not support recommending alcohol consumption to individuals at risk of diabetes. (B)
- No nutrition recommendation can be made for preventing type 1 diabetes. (E)
- Although there are insufficient data at present to warrant any specific recommendations for prevention of type 2 diabetes in youth, it is reasonable to apply approaches demonstrated to be effective in adults, as long as nutritional needs for normal growth and development are maintained. (E)

The importance of preventing type 2 diabetes is highlighted by the substantial worldwide increase in the prevalence of diabetes in recent years. Genetic susceptibility appears to play a powerful role in the occurrence of type 2 diabetes. However, given that population gene pools shift very slowly over time, the current epidemic of diabetes likely reflects changes in lifestyle leading to diabetes. Lifestyle changes characterized by increased energy intake and decreased physical activity appear to have together promoted overweight and obesity, which are strong risk factors for diabetes.

Several studies have demonstrated the potential for moderate, sustained weight loss to substantially reduce the risk for type 2 diabetes, regardless of whether weight loss was achieved by lifestyle changes alone or with adjunctive therapies such as medication or bariatric-surgery (see ENERGY BALANCE section) (1). Moreover, both moderate-intensity and vigorous exercise can improve insulin

sensitivity, independent of weight loss, and reduce risk for type 2 diabetes (1).

Clinical trial data from both the Finnish Diabetes Prevention study (25) and the Diabetes Prevention Program (DPP) in the U.S (26) strongly support the potential for moderate weight loss to reduce the risk for type 2 diabetes. The lifestyle intervention in both trials emphasized lifestyle changes that included moderate weight loss (7% of body weight) and regular physical activity (150 min/week), with dietary strategies to reduce intake of fat and calories. In the DPP, subjects in the lifestyle intervention group reported dietary fat intakes of ~34% of energy at baseline and 28% of energy after 1 year of intervention (27). A majority of subjects in the lifestyle intervention group met the physical activity goal of 150 min/week of moderate physical activity (26,28). In addition to preventing diabetes, the DPP lifestyle intervention improved several CVD risk factors, including dsylipidemia, hypertension, and inflammatory markers (29,30). The DPP analysis indicated that lifestyle intervention was cost-effective (31), but other analyses suggest that the expected costs needed to be reduced (32).

Both the Finnish Diabetes Prevention study and the DPP focused on reduced intake of calories (using reduced dietary fat as a dietary intervention). Of note, reduced intake of fat, particularly saturated fat, may reduce risk for diabetes by producing an energy-independent improvement in insulin resistance (1,33,34), as well as by promoting weight loss. It is possible that reduction in other macronutrients (e.g., carbohydrates) would also be effective in prevention of diabetes through promotion of weight loss; however, clinical trial data on the efficacy of low-carbohydrate diets for primary prevention of type 2 diabetes are not available.

Several studies have provided evidence for reduced risk of diabetes with increased intake of whole grains and dietary fiber (1,35–37). Whole grain–containing foods have been associated with improved insulin sensitivity, independent of body weight, and dietary fiber has been associated with improved insulin sensitivity and improved ability to secrete insulin adequately to overcome insulin resistance (38). There is debate as to the potential role of low–glycemic index and –glycemic load diets in prevention of type 2 diabetes. Although some studies have demonstrated an association between glycemic load and risk for diabetes, other studies have been unable to confirm this relationship, and a recent report showed no association of glycemic index/glycemic load with insulin sensitivity (39).

Thus, there is not sufficient, consistent information to conclude that low–glycemic load diets reduce risk for diabetes. Prospective randomized clinical trials will be necessary to resolve this issue. Nevertheless, low–glycemic index foods that are rich in fiber and other important nutrients are to be encouraged. A 2004 American Diabetes Association statement reviewed this issue in depth (40), and issues related to the role of glycemic index and glycemic load in diabetes management are addressed in more detail in the CARBOHYDRATE section of this document.

Observational studies suggest a U- or J-shaped association between moderate consumption of alcohol (one to three drinks [15–45 g alcohol] per day) and decreased risk of type 2 diabetes (41,42), coronary heart disease (CHD) (42,43), and stroke (44). However, heavy consumption of alcohol (greater than three drinks per day), may be associated with increased incidence of diabetes (42). If alcohol is consumed, recommendations from the 2005 USDA Dietary Guidelines for Americans suggest no more than one drink per day for women and two drinks per day for men (45).

Although selected micronutrients may affect glucose and insulin metabolism, to date, there are no convincing data that document their role in the development of diabetes.

Diabetes in youth

No nutrition recommendations can be made for the prevention of type 1 diabetes at this time (1). Increasing overweight and obesity in youth appears to be related to the increased prevalence of type 2 diabetes, particularly in minority adolescents. Although there are insufficient data at present to warrant any specific recommendations for the prevention of type 2 diabetes in youth, interventions similar to those shown to be effective for prevention of type 2 diabetes in adults (lifestyle changes including reduced energy intake and regular physical activity) are likely to be beneficial. Clinical trials of such interventions are ongoing in children.

NUTRITION RECOMMENDATIONS FOR THE MANAGEMENT OF DIABETES (SECONDARY PREVENTION)

Carbohydrate in diabetes management

Recommendations

- A dietary pattern that includes carbohydrate from fruits, vegetables, whole grains, legumes, and low-fat milk is encouraged for good health. (B)
- Monitoring carbohydrate, whether by carbohydrate counting, exchanges, or experienced-based estimation remains a key strategy in achieving glycemic control. (A)
- The use of glycemic index and load may provide a modest additional benefit over that observed when total carbohydrate is considered alone. (B)
- Sucrose-containing foods can be substituted for other carbohydrates in the meal plan or, if added to the meal plan, covered with insulin or other glucose-lowering medications. Care should be taken to avoid excess energy intake. (A)
- As for the general population, people with diabetes are encouraged to consume a variety of fiber-containing foods. However, evidence is lacking to recommend a higher fiber intake for people with diabetes than for the population as a whole. (B)
- Sugar alcohols and nonnutritive sweeteners are safe when consumed within the daily intake levels established by the Food and Drug Administration (FDA). (A)

Control of blood glucose in an effort to achieve normal or near-normal levels is a primary goal of diabetes management. Food and nutrition interventions that reduce postprandial blood glucose excursions are important in this regard, since dietary carbohydrate is the major determinant of postprandial glucose levels. Low-carbohydrate diets might seem to be a logical approach to lowering postprandial glucose. However, foods that contain carbohydrate are important sources of energy, fiber, vitamins, and minerals and are important in dietary palatability. Therefore, these foods are important components of the diet for individuals with diabetes. Issues related to carbohydrate and glycemia have previously been extensively reviewed in American Diabetes Association reports and nutrition recom-

mendations for the general public (1,2, 22,40,45).

Blood glucose concentration following a meal is primarily determined by the rate of appearance of glucose in the blood stream (digestion and absorption) and its clearance from the circulation (40). Insulin secretory response normally maintains blood glucose in a narrow range, but in individuals with diabetes, defects in insulin action, insulin secretion, or both impair regulation of postprandial glucose in response to dietary carbohydrate. Both the quantity and the type or source of carbohydrates found in foods influence postprandial glucose levels.

Amount and type of carbohydrate. A 2004 ADA statement addressed the effects of the amount and type of carbohydrate in diabetes management (40). As noted previously, the RDA for carbohydrate (130 g/day) is an average minimum requirement (22). There are no trials specifically in patients with diabetes restricting total carbohydrate to <130 g/day. However, 1-year follow-up data from a small weight-loss trial (20) indicate, among the subset with diabetes, that the reduction in fasting glucose was 21 mg/dl (1.17 mmol/l) and 28 mg/dl (1.55 mmol/l) for the low-carbohydrate and low-fat diets, respectively, with no significant difference for change in A1C levels. The 1-year follow-up data also indicate that the macronutrient composition of the treatment groups only differed with respect to carbohydrate intake (mean intake of 230 vs. 120 g). Thus, questions about the long-term effects on intake and metabolism, as well as safety, need further research.

The amount of carbohydrate ingested is usually the primary determinant of postprandial response, but the type of carbohydrate also affects this response. Intrinsic variables that influence the effect of carbohydrate-containing foods on blood glucose response include the specific type of food ingested, type of starch (amylose versus amylopectin), style of preparation (cooking method and time, amount of heat or moisture used), ripeness, and degree of processing. Extrinsic variables that may influence glucose response include fasting or preprandial blood glucose level, macronutrient distribution of the meal in which the food is consumed, available insulin, and degree of insulin resistance.

The glycemic index of foods was developed to compare the postprandial responses to constant amounts of different carbohydrate-containing foods (46). The glycemic index of a food is the increase above fasting in the blood glucose area over 2 h after ingestion of a constant amount of that food (usually a 50-g carbohydrate portion) divided by the response to a reference food (usually glucose or white bread). The glycemic loads of foods, meals, and diets are calculated by multiplying the glycemic index of the constituent foods by the amounts of carbohydrate in each food and then totaling the values for all foods. Foods with low glycemic indexes include oats, barley, bulgur, beans, lentils, legumes, pasta, pumpernickel (coarse rye) bread, apples, oranges, milk, yogurt, and ice cream. Fiber, fructose, lactose, and fat are dietary constituents that tend to lower glycemic response. Potential methodological problems with the glycemic index have been noted (47).

Several randomized clinical trials have reported that low–glycemic index diets reduce glycemia in diabetic subjects, but other clinical trials have not confirmed this effect (40). Moreover, the variability in responses to specific carbohydrate-containing food is a concern (48). Nevertheless, a recent meta-analysis of low–glycemic index diet trials in diabetic subjects showed that such diets produced a 0.4% decrement in A1C when compared with high–glycemic index diets (49). However, it appears that most individuals already consume a moderate–glycemic index diet (39,50). Thus, it appears that in individuals consuming a high–glycemic index diet, low–glycemic index diets can produce a modest benefit in controlling postprandial hyperglycemia.

In diabetes management, it is important to match doses of insulin and insulin secretagogues to the carbohydrate content of meals. A variety of methods can be used to estimate the nutrient content of meals, including carbohydrate counting, the exchange system, and experience-based estimation. By testing pre- and postprandial glucose, many individuals use experience to evaluate and achieve postprandial glucose goals with a variety of foods. To date, research has not demonstrated that one method of assessing the relationship between carbohydrate intake and blood glucose response is better than other methods.

Fiber. As for the general population, people with diabetes are encouraged to choose a variety of fiber-containing foods such as legumes, fiber-rich cereals (≥5 g fiber/serving), fruits, vegetables, and whole grain products because they provide vitamins, minerals, and other substances important for good health. Moreover, there are data suggesting that consuming a high-fiber diet (~50 g fiber/day) reduces glycemia in subjects with type 1 diabetes and glycemia, hyperinsulinemia, and lipemia in subjects with type 2 diabetes (1). Palatability, limited food choices, and gastrointestinal side effects are potential barriers to achieving such high-fiber intakes. However, increased fiber intake appears to be desirable for people with diabetes, and a first priority might be to encourage them to achieve the fiber intake goals set for the general population of 14 g/1,000 kcal (22).

Sweeteners. Substantial evidence from clinical studies demonstrates that dietary sucrose does not increase glycemia more than isocaloric amounts of starch (1). Thus, intake of sucrose and sucrose-containing foods by people with diabetes does not need to be restricted because of concern about aggravating hyperglycemia. Sucrose can be substituted for other carbohydrate sources in the meal plan or, if added to the meal plan, adequately covered with insulin or another glucose-lowering medication. Additionally, intake of other nutrients ingested with sucrose, such as fat, need to be taken into account, and care should be taken to avoid excess energy intake.

In individuals with diabetes, fructose produces a lower postprandial glucose response when it replaces sucrose or starch in the diet; however, this benefit is tempered by concern that fructose may adversely affect plasma lipids (1). Therefore, the use of added fructose as a sweetening agent in the diabetic diet is not recommended. There is, however, no reason to recommend that people with diabetes avoid naturally occurring fructose in fruits, vegetables, and other foods. Fructose from these sources usually accounts for only 3–4% of energy intake.

Reduced calorie sweeteners approved by the FDA include sugar alcohols (polyols) such as erythritol, isomalt, lactitol, maltitol, mannitol, sorbitol, xylitol, tagatose, and hydrogenated starch hydrolysates. Studies of subjects with and without diabetes have shown that sugar alcohols produce a lower postprandial glucose response than sucrose or glucose and have lower available energy (1). Sugar alcohols contain, on average, about 2 calories/g (one-half the calories of other sweeteners such as sucrose). When calculating carbohydrate content of foods containing sugar alcohols, subtraction of half

the sugar alcohol grams from total carbohydrate grams is appropriate. Use of sugar alcohols as sweeteners reduces the risk of dental caries. However, there is no evidence that the amounts of sugar alcohols likely to be consumed will reduce glycemia, energy intake, or weight. The use of sugar alcohols appears to be safe; however, they may cause diarrhea, especially in children.

The FDA has approved five nonnutritive sweeteners for use in the U.S. These are acesulfame potassium, aspartame, neotame, saccharin, and sucralose. Before being allowed on the market, all underwent rigorous scrutiny and were shown to be safe when consumed by the public, including people with diabetes and women during pregnancy. Clinical studies involving subjects without diabetes provide no indication that nonnutritive sweeteners in foods will cause weight loss or weight gain (51).

Resistant-starch/high-amylose foods. It has been proposed that foods containing resistant starch (starch physically enclosed within intact cell structures as in some legumes, starch granules as in raw potato, and retrograde amylose from plants modified by plant breeding to increase amylose content) or high-amylose foods, such as specially formulated cornstarch, may modify postprandial glycemic response, prevent hypoglycemia, and reduce hyperglycemia. However, there are no published long-term studies in subjects with diabetes to prove benefit from the use of resistant starch.

Dietary fat and cholesterol in diabetes management

Recommendations

- Limit saturated fat to <7% of total calories. (A)
- Intake of *trans* fat should be minimized. (E)
- In individuals with diabetes, limit dietary cholesterol to <200 mg/day. (E)
- Two or more servings of fish per week (with the exception of commercially fried fish filets) provide n-3 polyunsaturated fatty acids and are recommended. (B)

The primary goal with respect to dietary fat in individuals with diabetes is to limit saturated fatty acids, *trans* fatty acids, and cholesterol intakes so as to reduce risk for CVD. Saturated and *trans* fatty acids are the principal dietary determinants of plasma LDL cholesterol. In nondiabetic individuals, reducing saturated and *trans* fatty acids and cholesterol intakes decreases plasma total and LDL cholesterol. Reducing saturated fatty acids may also reduce HDL cholesterol. Importantly, the ratio of LDL cholesterol to HDL cholesterol is not adversely affected. Studies in individuals with diabetes demonstrating the effects of specific percentages of dietary saturated and *trans* fatty acids and specific amounts of dietary cholesterol on plasma lipids are not available. Therefore, because of a lack of specific information, it is recommended that the dietary goals for individuals with diabetes be the same as for individuals with preexisting CVD, since the two groups appear to have equivalent cardiovascular risk. Thus, saturated fatty acids <7% of total energy, minimal intake of *trans* fatty acids, and cholesterol intake <200 mg daily are recommended.

In metabolic studies in which energy intake and weight are held constant, diets low in saturated fatty acids and high in either carbohydrate or *cis*-monounsaturated fatty acids lowered plasma LDL cholesterol equivalently (1,52). The high-carbohydrate diets (~55% of total energy from carbohydrate) increased postprandial plasma glucose, insulin, and triglycerides when compared with high–monounsaturated fat diets. However, high–monounsaturated fat diets have not been shown to improve fasting plasma glucose or A1C values. In other studies, when energy intake was reduced, the adverse effects of high-carbohydrate diets were not observed (53,54). Individual variability in response to high-carbohydrate diets suggests that the plasma triglyceride response to dietary modification should be monitored carefully, particularly in the absence of weight loss.

Diets high in polyunsaturated fatty acids appear to have effects similar to monounsaturated fatty acids on plasma lipid concentrations (55–58). A modified Mediterranean diet, in which polyunsaturated fatty acids were substituted for monounsaturated fatty acids, reduced overall mortality in elderly Europeans by 7% (59). Very-long-chain n-3 polyunsaturated fatty acid supplements have been shown to lower plasma triglyceride levels in individuals with type 2 diabetes who are hypertriglyceridemic. Although the accompanying small rise in plasma LDL cholesterol is of concern, an increase in HDL cholesterol may offset this concern (60). Glucose metabolism is not likely to be adversely affected. Very-long-chain n-3 polyunsaturated fatty acid studies in individuals with diabetes have primarily used fish oil supplements. Consumption of ω-3 fatty acids from fish or from supplements has been shown to reduce adverse CVD outcomes, but the evidence for α-linolenic acid is sparse and inconclusive (61). In addition to providing n-3 fatty acids, fish frequently displace high–saturated fat–containing foods from the diet (62). Two or more servings of fish per week (with the exception of commercially fried fish filets) (63,64) can be recommended.

Plant sterol and stanol esters block the intestinal absorption of dietary and biliary cholesterol. In the general public and in individuals with type 2 diabetes (65), intake of ~2 g/day plant sterols and stanols has been shown to lower plasma total and LDL cholesterol. A wide range of foods and beverages are now available that contain plant sterols. If these products are used, they should displace, rather than be added to, the diet to avoid weight gain. Soft gel capsules containing plant sterols are also available.

Protein in diabetes management

Recommendations

- For individuals with diabetes and normal renal function, there is insufficient evidence to suggest that usual protein intake (15–20% of energy) should be modified. (E)
- In individuals with type 2 diabetes, ingested protein can increase insulin response without increasing plasma glucose concentrations. Therefore, protein should not be used to treat acute or prevent nighttime hypoglycemia. (A)
- High-protein diets are not recommended as a method for weight loss at this time. The long-term effects of protein intake >20% of calories on diabetes management and its complications are unknown. Although such diets may produce short-term weight loss and improved glycemia, it has not been established that these benefits are maintained long term, and long-term effects on kidney function for persons with diabetes are unknown. (E)

The Dietary Reference Intakes' acceptable macronutrient distribution range for protein is 10–35% of energy intake, with 15% being the average adult intake in the U.S. and Canada (22). The RDA is 0.8 g good-quality protein · kg

body wt^{-1} · day^{-1} (on average, ~10% of calories) (22). Good-quality protein sources are defined as having high PDCAAS (protein digestibility–corrected amino acid scoring pattern) scores and provide all nine indispensable amino acids. Examples are meat, poultry, fish, eggs, milk, cheese, and soy. Sources not in the "good" category include cereals, grains, nuts, and vegetables. In meal planning, protein intake should be greater than 0.8 g · kg^{-1} · day^{-1} to account for mixed protein quality in foods.

The dietary intake of protein for individuals with diabetes is similar to that of the general public and usually does not exceed 20% of energy intake. A number of studies in healthy individuals and in individuals with type 2 diabetes have demonstrated that glucose produced from ingested protein does not increase plasma glucose concentration but does produce increases in serum insulin responses (1,66). Abnormalities in protein metabolism may be caused by insulin deficiency and insulin resistance; however, these are usually corrected with good blood glucose control (67).

Small, short-term studies in diabetes suggest that diets with protein content >20% of total energy reduce glucose and insulin concentrations, reduce appetite, and increase satiety (68,69). However, the effects of high-protein diets on long-term regulation of energy intake, satiety, weight, and the ability of individuals to follow such diets long term have not been adequately studied.

Dietary protein and its relationships to hypoglycemia and nephropathy are addressed in later sections.

Optimal mix of macronutrients

Although numerous studies have attempted to identify the optimal mix of macronutrients for the diabetic diet, it is unlikely that one such combination of macronutrients exists. The best mix of carbohydrate, protein, and fat appears to vary depending on individual circumstances. For those individuals seeking guidance as to macronutrient distribution in healthy adults, the Dietary Reference Intakes (DRIs) may be helpful (22). It must be clearly recognized that regardless of the macronutrient mix, total caloric intake must be appropriate to weight management goals. Further, individualization of the macronutrient composition will depend on the metabolic status of the patient (e.g., lipid profile).

Alcohol in diabetes management

Recommendations

- If adults with diabetes choose to use alcohol, daily intake should be limited to a moderate amount (one drink per day or less for women and two drinks per day or less for men). (E)
- To reduce risk of nocturnal hypoglycemia in individuals using insulin or insulin secretagogues, alcohol should be consumed with food. (E)
- In individuals with diabetes, moderate alcohol consumption (when ingested alone) has no acute effect on glucose and insulin concentrations but carbohydrate coingested with alcohol (as in a mixed drink) may raise blood glucose. (B)

Abstention from alcohol should be advised for people with a history of alcohol abuse or dependence, women during pregnancy, and people with medical problems such as liver disease, pancreatitis, advanced neuropathy, or severe hypertriglyceridemia. If individuals choose to use alcohol, intake should be limited to a moderate amount (less than one drink per day for adult women and less than two drinks per day for adult men). One alcohol containing beverage is defined as 12 oz beer, 5 oz wine, or 1.5 oz distilled spirits. Each contains ~15 g alcohol.

Moderate amounts of alcohol, when ingested with food, have minimal acute effects on plasma glucose and serum insulin concentrations (42). However, carbohydrate coingested with alcohol may raise blood glucose. For individuals using insulin or insulin secretagogues, alcohol should be consumed with food to avoid hypoglycemia. Evening consumption of alcohol may increase the risk of nocturnal and fasting hypoglycemia, particularly in individuals with type 1 diabetes (70). Occasional use of alcoholic beverages should be considered an addition to the regular meal plan, and no food should be omitted. Excessive amounts of alcohol (three or more drinks per day), on a consistent basis, contributes to hyperglycemia (42).

In individuals with diabetes, light to moderate alcohol intake (one to two drinks per day; 15–30 g alcohol) is associated with a decreased risk of CVD (42). The reduction in CVD does not appear to be due to an increase in plasma HDL cholesterol. The type of alcohol-containing beverage consumed does not appear to make a difference.

Micronutrients in diabetes management

Recommendations

- There is no clear evidence of benefit from vitamin or mineral supplementation in people with diabetes (compared with the general population) who do not have underlying deficiencies. (A)
- 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)
- Benefit from chromium supplementation in individuals with diabetes or obesity has not been clearly demonstrated and therefore can not be recommended. (E)

Uncontrolled diabetes is often associated with micronutrient deficiencies (71). Individuals with diabetes should be aware of the importance of acquiring daily vitamin and mineral requirements from natural food sources and a balanced diet. Health care providers should focus on nutrition counseling rather than micronutrient supplementation in order to reach metabolic control of their patients. Research including long-term trials is needed to assess the safety and potentially beneficial role of chromium, magnesium, and antioxidant supplements and other complementary therapies in the management of type 2 diabetes (71a,71b). In select groups such as the elderly, pregnant or lactating women, strict vegetarians, or those on calorie-restricted diets, a multivitamin supplement may be needed (1).

Antioxidants in diabetes management. Since diabetes may be a state of increased oxidative stress, there has been interest in antioxidant therapy. Unfortunately, there are no studies examining the effects of dietary intervention on circulating levels of antioxidants and inflammatory biomarkers in diabetic volunteers. The few small clinical studies involving diabetes and functional foods thought to have high antioxidant potential (e.g., tea, cocoa, coffee) are inconclusive. Clinical trial data not only indicate the lack of benefit with respect to glycemic control and progression of complications but also provide evidence of the potential harm of vitamin E, carotene, and other antioxidant supplements (1,72,73). In addition, available data do not support the use of antioxidant supplements for CVD risk reduction (74).

Chromium, other minerals, and herbs in diabetes management. Chromium, potassium, magnesium, and possibly zinc deficiency may aggravate carbohydrate intolerance. Serum levels can readily detect the need for potassium or magnesium replacement, but detecting deficiency of zinc or chromium is more difficult (75). In the late 1990s, two randomized placebo-controlled studies in China found that chromium supplementation had beneficial effects on glycemia (76–78), but the chromium status of the study populations was not evaluated either at baseline or following supplementation. Data from recent small studies indicate that chromium supplementation may have a role in the management of glucose intolerance, gestational diabetes mellitus (GDM), and corticosteroid-induced diabetes (76–78). However, other well-designed studies have failed to demonstrate any significant benefit of chromium supplementation in individuals with impaired glucose intolerance or type 2 diabetes (79,80). Similarly, a meta-analysis of randomized controlled trials failed to demonstrate any benefit of chromium picolinate supplementation in reducing body weight (81). The FDA concluded that although a small study suggested that chromium picolinate may reduce insulin resistance, the existence of such a relationship between chromium picolinate and either insulin resistance or type 2 diabetes was uncertain (http:/www.cfsan.fda.gov/~dms/qhccr.html).

There is insufficient evidence to demonstrate efficacy of individual herbs and supplements in diabetes management (82). In addition, commercially available products are not standardized and vary in the content of active ingredients. Herbal preparations also have the potential to interact with other medications (83). Therefore, it is important that health care providers be aware when patients with diabetes are using these products and look for unusual side effects and herb-drug or herb-herb interactions

NUTRITION INTERVENTIONS FOR SPECIFIC POPULATIONS

Nutrition interventions for type 1 diabetes

Recommendations

- For individuals with type 1 diabetes, insulin therapy should be integrated into an individual's dietary and physical activity pattern. (E)
- Individuals using rapid-acting insulin by injection or an insulin pump should adjust the meal and snack insulin doses based on the carbohydrate content of the meals and snacks. (A)
- For individuals using fixed daily insulin doses, carbohydrate intake on a day-to-day basis should be kept consistent with respect to time and amount. (C)
- For planned exercise, insulin doses can be adjusted. For unplanned exercise, extra carbohydrate may be needed. (E)

The first nutrition priority for individuals requiring insulin therapy is to integrate an insulin regimen into their lifestyle. With the many insulin options now available, an appropriate insulin regimen can usually be developed to conform to an individual's preferred meal routine, food choices, and physical activity pattern. For individuals receiving basal-bolus insulin therapy, the total carbohydrate content of meals and snacks is the major determinant of bolus insulin doses (84). Insulin-to-carbohydrate ratios can be used to adjust mealtime insulin doses. Several methods can be used to estimate the nutrient content of meals, including carbohydrate counting, the exchange system, and experience-based estimation. The DAFNE (Dose Adjustment for Normal Eating) study (85) demonstrated that patients can learn how to use glucose testing to better match insulin to carbohydrate intake. Improvement in A1C without a significant increase in severe hypoglycemia was demonstrated, as were positive effects on quality of life, satisfaction with treatment, and psychological well-being, even though increases in the number of insulin injections and blood glucose tests were necessary.

For planned exercise, reduction in insulin dosage is the preferred method to prevent hypoglycemia (86). For unplanned exercise, intake of additional carbohydrate is usually needed. Moderate-intensity exercise increases glucose utilization by 2–3 mg · kg^{-1} · min^{-1} above usual requirements (87). Thus, a 70-kg person would need ~10–15 g additional carbohydrate per hour of moderate intensity physical activity. More carbohydrate is needed for intense activity.

A 2005 American Diabetes Association statement addresses diabetes MNT for children and adolescents with type 1 diabetes (88).

Nutrition interventions for type 2 diabetes

Recommendations

- Individuals with type 2 diabetes are encouraged to implement lifestyle modifications that reduce intakes of energy, saturated and *trans* fatty acids, cholesterol, and sodium and to increase physical activity in an effort to improve glycemia, dyslipidemia, and blood pressure. (E)
- Plasma glucose monitoring can be used to determine whether adjustments in foods and meals will be sufficient to achieve blood glucose goals or if medication(s) needs to be combined with MNT. (E)

Healthy lifestyle nutrition recommendations for the general public are also appropriate for individuals with type 2 diabetes. Because many individuals with type 2 diabetes are overweight and insulin resistant, MNT should emphasize lifestyle changes that result in reduced energy intake and increased energy expenditure through physical activity. Because many individuals also have dyslipidemia and hypertension, reducing saturated and *trans* fatty acids, cholesterol, and sodium is often desirable. Therefore, the first nutrition priority is to encourage individuals with type 2 diabetes to implement lifestyle strategies that will improve glycemia, dyslipidemia, and blood pressure.

Although there are similarities to those above for type 1 diabetes, MNT recommendations for established type 2 diabetes differ in several aspects from both recommendations for type 1 diabetes and the prevention of diabetes. MNT progresses from prevention of overweight and obesity, to improving insulin resistance and preventing or delaying the onset of diabetes, and to contributing to improved metabolic control in those with diabetes. With established type 2 diabetes treated with fixed doses of insulin or insulin secretagogues, consistency in timing and carbohydrate content of meals is important. However, rapid-acting insulins and rapid-acting insulin secretagogues allow for more flexible food intake and lifestyle as in individuals with type 1 diabetes.

Increased physical activity by individuals with type 2 diabetes can lead to improved glycemia, decreased insulin resistance, and a reduction in cardiovascular risk factors, independent of change in body weight. At least 150 min/week of moderate-intensity aerobic physical ac-

tivity, distributed over at least 3 days and with no more than 2 consecutive days without physical activity is recommended (89). Resistance training is also effective in improving glycemia and, in the absence of proliferative retinopathy, people with type 2 diabetes can be encouraged to perform resistance exercise three times a week (89).

Nutrition interventions for pregnancy and lactation with diabetes

Recommendations

- Adequate energy intake that provides appropriate weight gain is recommended during pregnancy. Weight loss is not recommended; however, for overweight and obese women with GDM, modest energy and carbohydrate restriction may be appropriate. (E)
- Ketonemia from ketoacidosis or starvation ketosis should be avoided. (C)
- MNT for GDM focuses on food choices for appropriate weight gain, normoglycemia, and absence of ketones. (E)
- Because GDM is a risk factor for subsequent type 2 diabetes, after delivery, lifestyle modifications aimed at reducing weight and increasing physical activity are recommended. (A)

Prepregnancy MNT includes an individualized prenatal meal plan to optimize blood glucose control. During pregnancy, the distribution of energy and carbohydrate intake should be based on the woman's food and eating habits and plasma glucose responses. Due to the continuous fetal draw of glucose from the mother, maintaining consistency of times and amounts of food eaten are important to avoidance of hypoglycemia. Plasma glucose monitoring and daily food records provide valuable information for insulin and meal plan adjustments.

MNT for GDM primarily involves a carbohydrate-controlled meal plan that promotes optimal nutrition for maternal and fetal health with adequate energy for appropriate gestational weight gain, achievement and maintenance of normoglycemia, and absence of ketosis. Specific nutrition and food recommendations are determined and subsequently modified based on individual assessment and self-monitoring of blood glucose. All women with GDM should receive MNT at the time of diagnosis. A recent large clinical trial reported that treatment of GDM with nutrition therapy, blood glucose monitoring, and insulin therapy as required for glycemic control reduced serious perinatal complications without increasing the rate of cesarean delivery as compared with routine care (90). Maternal health–related quality of life was also improved.

Hypocaloric diets in obese women with GDM can result in ketonemia and ketonuria. However, moderate caloric restriction (reduction by 30% of estimated energy needs) in obese women with GDM may improve glycemic control without ketonemia and reduce maternal weight gain. Insufficient data are available to determine how such diets affect perinatal outcomes. Daily food records, weekly weight checks, and ketone testing can be used to determine individual energy requirements and whether a woman is undereating to avoid insulin therapy.

The amount and distribution of carbohydrate should be based on clinical outcome measures (hunger, plasma glucose levels, weight gain, ketone levels), but a minimum of 175 g carbohydrate/day should be provided (22). Carbohydrate should be distributed throughout the day in three small- to moderate-sized meals and two to four snacks. An evening snack may be needed to prevent accelerated ketosis overnight. Carbohydrate is generally less well tolerated at breakfast than at other meals.

Regular physical activity can help lower fasting and postprandial plasma glucose concentrations and may be used as an adjunct to improve maternal glycemia. If insulin therapy is added to MNT, maintaining carbohydrate consistency at meals and snacks becomes a primary goal.

Although most women with GDM revert to normal glucose tolerance postpartum, they are at increased risk of GDM in subsequent pregnancies and type 2 diabetes later in life. Lifestyle modifications after pregnancy aimed at reducing weight and increasing physical activity are recommended, as they reduce the risk of subsequent diabetes (26,91). Breast-feeding is recommended for infants of women with preexisting diabetes or GDM; however, successful lactation requires planning and coordination of care (92). In most situations, breast-feeding mothers require less insulin because of the calories expended with nursing. Lactating women have reported fluctuations in blood glucose related to nursing sessions, often requiring a snack containing carbohydrate before or during breast-feeding (92).

Nutrition interventions for older adults with diabetes

Recommendations

- Obese older adults with diabetes may benefit from modest energy restriction and an increase in physical activity; energy requirement may be less than for a younger individual of a similar weight. (E)
- A daily multivitamin supplement may be appropriate, especially for those older adults with reduced energy intake. (C)

The American Geriatrics Society emphasizes the importance of MNT for older adults with diabetes. For obese individuals, a modest weight loss of 5–10% of body weight may be indicated (93,94). However, an involuntary gain or loss of >10 lb or 10% of body weight in <6 months should be addressed in the MNT evaluation (1,95,96). Physical activity is needed to attenuate loss of lean body mass that can occur with energy restriction. Exercise training can significantly reduce the decline in maximal aerobic capacity that occurs with age, improve risk factors for atherosclerosis, slow the age-related decline in lean body mass, decrease central adiposity, and improve insulin sensitivity—all potentially beneficial for the older adult with diabetes (89,97). However, exercise can also pose potential risks such as cardiac ischemia, musculoskeletal injuries, and hypoglycemia in patients treated with insulin or insulin secretagogues.

NUTRITION RECOMMENDATIONS FOR CONTROLLING DIABETES COMPLICATIONS (TERTIARY PREVENTION)

Microvascular complications

Recommendations

- Reduction of protein intake to 0.8–1.0 $g \cdot kg\ body\ wt^{-1} \cdot day^{-1}$ in individuals with diabetes and the earlier stages of chronic kidney disease (CKD) and to 0.8 $g \cdot kg\ body\ wt^{-1} \cdot day^{-1}$ in the later stages of CKD may improve measures of renal function (urine albumin excretion rate, glomerular filtration rate) and is recommended. (B)
- MNT that favorably affects cardiovascular risk factors may also have a favorable effect on microvascular complications such as retinopathy and nephropathy. (C)

Progression of diabetes complications may be modified by improving glycemic control, lowering blood pressure, and, potentially, reducing protein intake. Normal protein intake (15–20% of energy) does not appear to be associated with risk of developing diabetic nephropathy (1), but the long-term effect on development of nephropathy of dietary protein intake >20% of energy has not been determined. In several studies of subjects with diabetes and microalbuminuria, urinary albumin excretion rate and decline in glomerular filtration were favorably influenced by reduction of protein intake to 0.8–1.0 g · kg body wt^{-1} · day^{-1} (see PROTEIN IN DIABETES MANAGEMENT section) (98–101). Although reduction of protein intake to 0.8 g · kg body wt^{-1} · day^{-1} was prescribed, subjects who were not able to achieve this level of reduction also showed improvements in renal function (99,100).

In individuals with diabetes and macroalbuminuria, reducing protein from all sources to 0.8 g · kg body wt^{-1} · day^{-1} has been associated with slowing the decline in renal function (1,102); however, such reductions in protein need to maintain good nutritional status in patients with chronic renal failure (103). Although several studies have explored the potential benefit of plant proteins in place of animal proteins and specific animal proteins in diabetic individuals with microalbuninuria, the data are inconclusive (1,104).

Observational data suggest that dyslipidemia may increase albumin excretion and the rate of progression of diabetic nephropathy (105). Elevation of plasma cholesterol in both type 1 and 2 diabetic subjects and plasma triglycerides in type 2 diabetic subjects were predictors of the need for renal replacement therapy (106). Whereas these observations do not confirm that MNT will affect diabetic nephropathy, MNT designed to reduce the risk for CVD may have favorable effects on microvascular complications of diabetes.

Treatment and management of CVD risk

Recommendations

- Target A1C is as close to normal as possible without significant hypoglycemia. (B)
- For patients with diabetes at risk for CVD, diets high in fruits, vegetables, whole grains, and nuts may reduce the risk. (C)
- For patients with diabetes and symptomatic heart failure, dietary sodium intake of <2,000 mg/day may reduce symptoms. (C)
- In normotensive and hypertensive individuals, a reduced sodium intake (e.g., 2,300 mg/day) with a diet high in fruits, vegetables, and low-fat dairy products lowers blood pressure. (A)
- In most individuals, a modest amount of weight loss beneficially affects blood pressure. (C)

In the EDIC (Epidemiology of Diabetes Interventions and Complications) study, the follow-up of the DCCT (Diabetes Control and Complications Trial), intensive treatment of type 1 diabetic subjects during the DCCT study period improved glycemic control and significantly reduced the risk of the combined end point of cardiovascular death, myocardial infarction, and stroke (107). Adjustment for A1C explained most of the treatment effect. The risk reductions obtained with improved glycemia exceeded those that have been demonstrated for other interventions such as cholesterol and blood pressure reductions. Observational data from the UKPDS suggest that CVD risk in type 2 diabetes is also proportionate to the level of A1C elevation (107a).

There are no large-scale randomized trials to guide MNT recommendations for CVD risk reduction in individuals with type 2 diabetes. However, because CVD risk factors are similar in individuals with and without diabetes, benefits observed in nutrition studies in the general population are probably applicable to individuals with diabetes. The previous section on dietary fat addresses the need to reduce intake of saturated and *trans* fatty acids and cholesterol.

Hypertension, which is predictive of progression of micro- as well as macrovascular complications of diabetes, can be prevented and managed with interventions including weight loss, physical activity, moderation of alcohol intake, and diets such as DASH (Dietary Approaches to Stop Hypertension). The DASH diet emphasized fruits, vegetables, and low-fat dairy products; included whole grains, poultry, fish, and nuts; and was reduced in fats, red meat, sweets, and sugar-containing beverages (7,108,109). The effects of lifestyle interventions on hypertension appear to be additive.

Reduction in blood pressure in people with diabetes can occur with a modest amount of weight loss, although there is great variability in response (1,7). Regular aerobic physical activity, such as brisk walking, has an antihypertensive effect (7). Although chronic excessive alcohol intake is associated with an increased risk of hypertension, light to moderate alcohol consumption is associated with reductions in blood pressure (7).

Heart failure and peripheral vascular disease are common in individuals with diabetes, but little is known about the role of MNT in treating these complications. Nutrition recommendations from the American College of Physicians/American Heart Association suggest moderate sodium restriction (<2,000 mg/day) for patients with structural heart disease or symptomatic heart failure (110). Alcohol intake is discouraged in patients at high risk for heart failure.

NUTRITION INTERVENTIONS FOR ACUTE COMPLICATIONS AND SPECIAL CONSIDERATIONS FOR PATIENTS WITH COMORBIDITIES IN ACUTE AND CHONIC CARE FACILITIES

Hypoglycemia

Recommendations

- Ingestion of 15–20 g glucose is the preferred treatment for hypoglycemia, although any form of carbohydrate that contains glucose may be used. (A)
- The response to treatment of hypoglycemia should be apparent in 10–20 min; however, plasma glucose should be tested again in ~60 min, as additional treatment may be necessary. (B)

In individuals taking insulin or insulin secretagogues, changes in food intake, physical activity, and medication can contribute to the development of hypoglycemia. Treatment of hypoglycemia (plasma glucose <70 mg/dl) requires ingestion of glucose or glucose-containing foods. The acute glycemic response correlates better with the glucose content than with the carbohydrate content of the food (1). With insulin-induced hypoglycemia, 10 g oral glucose raises plasma glucose levels by ~40 mg/dl over 30 min, while 20 g oral glucose raises plasma glucose levels by ~60 mg/dl over 45 min. In each case, glucose levels often begin to fall ~60 min after glucose ingestion (111).

Table 3—*Major nutrition recommendations and interventions*

Effectiveness of MNT
- Individuals who have pre-diabetes or diabetes should receive individualized MNT; such therapy is best provided by a registered dietitian familiar with the components of diabetes MNT. (B)
- Nutrition counseling should be sensitive to the personal needs, willingness to change, and ability to make changes of the individual with pre-diabetes or diabetes. (E)

Energy balance, overweight, and obesity
- In overweight and obese insulin-resistant individuals, modest weight loss has been shown to improve insulin resistance. Thus, weight loss is recommended for all such individuals who have or are at risk for diabetes. (A)
- For weight loss, either low-carbohydrate or low-fat calorie-restricted diets may be effective in the short term (up to 1 year). (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)
- Weight loss medications may be considered in the treatment of overweight and obese individuals with type 2 diabetes and can help achieve a 5–10% weight loss when combined with lifestyle modification. (B)
- Bariatric surgery may be considered for some individuals with type 2 diabetes and BMI $\geq$35 kg/m^2 and can result in marked improvements in glycemia. The long-term benefits and risks of bariatric surgery in individuals with pre-diabetes or diabetes continue to be studied. (B)

Preventing diabetes (primary prevention)
- 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 high risk for type 2 diabetes should be encouraged to achieve the USDA recommendation for dietary fiber (14 g fiber/1,000 kcal) and foods containing whole grains (one-half of grain intake). (B)
- There is not sufficient, consistent information to conclude that low–glycemic load diets reduce the risk for diabetes. Nevertheless, low–glycemic index foods that are rich in fiber and other important nutrients are to be encouraged. (E)
- Observational studies report that moderate alcohol intake may reduce the risk for diabetes, but the data do not support recommending alcohol consumption to individuals at risk of diabetes. (B)
- No nutrition recommendation can be made for preventing type 1 diabetes. (E)
- Although there are insufficient data at present to warrant any specific recommendations for prevention of type 2 diabetes in youth, it is reasonable to apply approaches demonstrated to be effective in adults, as long as nutritional needs for normal growth and development are maintained. (E)

Controlling diabetes (secondary prevention)

Carbohydrate in diabetes management
- A dietary pattern that includes carbohydrate from fruits, vegetables, whole grains, legumes, and low-fat milk is encouraged for good health. (B)
- Monitoring carbohydrate, whether by carbohydrate counting, exchanges, or experienced-based estimation, remains a key strategy in achieving glycemic control. (A)
- The use of glycemic index and load may provide a modest additional benefit over that observed when total carbohydrate is considered alone. (B)
- Sucrose-containing foods can be substituted for other carbohydrates in the meal plan or, if added to the meal plan, covered with insulin or other glucose-lowering medications. Care should be taken to avoid excess energy intake. (A)
- As for the general population, people with diabetes are encouraged to consume a variety of fiber-containing foods. However, evidence is lacking to recommend a higher fiber intake for people with diabetes than for the population as a whole. (B)
- Sugar alcohols and nonnutritive sweeteners are safe when consumed within the daily intake levels established by the FDA. (A)

Fat and cholesterol in diabetes management
- Limit saturated fat to <7% of total calories. (A)
- Intake of *trans* fat should be minimized. (E)
- In individuals with diabetes, lower dietary cholesterol to <200 mg/day. (E)
- Two or more servings of fish per week (with the exception of commercially fried fish filets) provide n-3 polyunsaturated fatty acids and are recommended. (B)

Protein in diabetes management
- For individuals with diabetes and normal renal function, there is insufficient evidence to suggest that usual protein intake (15–20% of energy) should be modified. (E)
- In individuals with type 2 diabetes, ingested protein can increase insulin response without increasing plasma glucose concentrations. Therefore, protein should not be used to treat acute or prevent nighttime hypoglycemia. (A)

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Table 3—*Continued*

- High-protein diets are not recommended as a method for weight loss at this time. The long-term effects of protein intake >20% of calories on diabetes management and its complications are unknown. Although such diets may produce short-term weight loss and improved glycemia, it has not been established that these benefits are maintained long term, and long-term effects on kidney function for persons with diabetes are unknown. (E)

Alcohol in diabetes management

- If adults with diabetes choose to use alcohol, daily intake should be limited to a moderate amount (one drink per day or less for women and two drinks per day or less for men). (E)
- To reduce risk of nocturnal hypoglycemia in individuals using insulin or insulin secretagogues, alcohol should be consumed with food. (E)
- In individuals with diabetes, moderate alcohol consumption (when ingested alone) has no acute effect on glucose and insulin concentrations but carbohydrate coingested with alcohol (as in a mixed drink) may raise blood glucose. (B)

Micronutrients in diabetes management

- There is no clear evidence of benefit from vitamin or mineral supplementation in people with diabetes (compared with the general population) who do not have underlying deficiencies. (A)
- 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)
- Benefit from chromium supplementation in individuals with diabetes or obesity has not been clearly demonstrated and therefore can not be recommended. (E)

Nutrition interventions for type 1 diabetes

- For individuals with type 1 diabetes, insulin therapy should be integrated into an individual's dietary and physical activity pattern. (E)
- Individuals using rapid-acting insulin by injection or an insulin pump should adjust the meal and snack insulin doses based on the carbohydrate content of the meals and snacks. (A)
- For individuals using fixed daily insulin doses, carbohydrate intake on a day-to-day basis should be kept consistent with respect to time and amount. (C)
- For planned exercise, insulin doses can be adjusted. For unplanned exercise, extra carbohydrate may be needed. (E)

Nutrition interventions for type 2 diabetes

- Individuals with type 2 diabetes are encouraged to implement lifestyle modifications that reduce intakes of energy, saturated and *trans* fatty acids, cholesterol, and sodium and to increase physical activity in an effort to improve glycemia, dyslipidemia, and blood pressure. (E)
- Plasma glucose monitoring can be used to determine whether adjustments in foods and meals will be sufficient to achieve blood glucose goals or if medication(s) needs to be combined with MNT. (E)

Nutrition interventions for pregnancy and lactation with diabetes

- Adequate energy intake that provides appropriate weight gain is recommended during pregnancy. Weight loss is not recommended; however, for overweight and obese women with GDM, modest energy and carbohydrate restriction may be appropriate. (E)
- Ketonemia from ketoacidosis or starvation ketosis should be avoided. (C)
- MNT for GDM focuses on food choices for appropriate weight gain, normoglycemia, and absence of ketones. (E)
- Because GDM is a risk factor for subsequent type 2 diabetes, after delivery, lifestyle modifications aimed at reducing weight and increasing physical activity are recommended. (A)

Nutrition interventions for older adults with diabetes

- Obese older adults with diabetes may benefit from modest energy restriction and an increase in physical activity; energy requirement may be less than for a younger individual of a similar weight. (E)
- A daily multivitamin supplement may be appropriate, especially for those older adults with reduced energy intake. (C)

Treating and controlling diabetes complications (tertiary prevention)

Microvascular complications

- Reduction of protein intake to 0.8–1.0 g · kg body wt^{-1} · day^{-1} in individuals with diabetes and the earlier stages of CKD and to 0.8 g · kg body wt^{-1} · day^{-1} in the later stages of CKD may improve measures of renal function (urine albumin excretion rate, glomerular filtration rate) and is recommended. (B)
- MNT that favorably affects cardiovascular risk factors may also have a favorable effect on microvascular complications such as retinopathy and nephropathy. (C)

Treatment and management of CVD risk

- Target A1C is as close to normal as possible without significant hypoglycemia. (B)
- For patients with diabetes at risk for CVD, diets high in fruits, vegetables, whole grains, and nuts may reduce the risk. (C)
- For patients with diabetes and symptomatic heart failure, dietary sodium intake of <2,000 mg/day may reduce symptoms. (C)
- In normotensive and hypertensive individuals, a reduced sodium intake (e.g., 2,300 mg/day) with a diet high in fruits, vegetables, and low-fat dairy products lowers blood pressure. (A)
- In most individuals, a modest amount of weight loss beneficially affects blood pressure. (C)

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Table 3—*Continued*

Hypoglycemia
- Ingestion of 15–20 g glucose is the preferred treatment for hypoglycemia, although any form of carbohydrate that contains glucose may be used. (A)
- The response to treatment of hypoglycemia should be apparent in 10–20 min; however, plasma glucose should be tested again in ~60 min, as additional treatment may be necessary. (B)

Acute illness
- During acute illnesses, insulin and oral glucose-lowering medications should be continued. (A)
- During acute illnesses, testing of plasma glucose and ketones, drinking adequate amounts of fluids, and ingesting carbohydrate are all important. (B)

Acute health care facilities
- Establishing an interdisciplinary team, implementation of MNT, and timely diabetes-specific discharge planning improves the care of patients with diabetes during and after hospitalizations. (E)
- Hospitals should consider implementing a diabetes meal-planning system that provides consistency in the carbohydrate content of specific meals. (E)

Long-term care facilities
- The imposition of dietary restrictions on elderly patients with diabetes in long-term care facilities is not warranted. Residents with diabetes should be served a regular menu, with consistency in the amount and timing of carbohydrate. (C)
- An interdisciplinary team approach is necessary to integrate MNT for patients with diabetes into overall management. (E)
- There is no evidence to support prescribing diets such as "no concentrated sweets" or "no sugar added." (E)
- In the institutionalized elderly, undernutrition is likely and caution should be exercised when prescribing weight loss diets. (B)

Although pure glucose may be the preferred treatment, any form of carbohydrate that contains glucose will raise blood glucose (111). Adding protein to carbohydrate does not affect the glycemic response and does not prevent subsequent hypoglycemia. Adding fat, however, may retard and then prolong the acute glycemic response. During hypoglycemia, gastric-emptying rates are twice as fast as during euglycemia and are similar for liquid and solid foods.

Acute illness

Recommendations
- During acute illnesses, insulin and oral glucose-lowering medications should be continued. (A)
- During acute illnesses, testing of plasma glucose and ketones, drinking adequate amounts of fluids, and ingesting carbohydrate are all important. (B)

Acute illnesses can lead to the development of hyperglycemia and, in individuals with type 1 diabetes, ketoacidosis. During acute illnesses, with the usual accompanying increases in counterregulatory hormones, the need for insulin and oral glucose-lowering medications continues and often is increased. Testing plasma glucose and ketones, drinking adequate amounts of fluid, and ingesting carbohydrate, especially if plasma glucose is <100 mg/dl, are all important during acute illness. In adults, ingestion of 150–200 g carbohydrate daily (45–50 g every 3–4 h) should be sufficient to prevent starvation ketosis (1).

Patients with diabetes in acute health care facilities

Recommendations
- Establishing an interdisciplinary team, implementation of MNT, and timely diabetes-specific discharge planning improves the care of patients with diabetes during and after hospitalizations. (E)
- Hospitals should consider implementing a diabetes meal-planning system that provides consistency in the carbohydrate content of specific meals. (E)

Hyperglycemia in hospitalized patients is common and represents an important marker of poor clinical outcome and mortality in both patients with and without diabetes (112). Optimizing glucose control in these patients is associated with better outcomes (113). An interdisciplinary team is needed to integrate MNT into the overall management plan (114,115). Diabetes nutrition self-management education, although potentially initiated in the hospital, is usually best provided in an outpatient or home setting where the individual with diabetes is better able to focus on learning needs (114,115).

There is no single meal planning system that is ideal for hospitalized patients. However, it is suggested that hospitals consider implementing a consistent-carbohydrate diabetes meal-planning system (114,115). This systems uses meal plans without a specific calorie level but consistency in the carbohydrate content of meals. The carbohydrate contents of breakfast, lunch, dinner, and snacks may vary, but the day-to-day carbohydrate content of specific meals and snacks is kept constant (114,115). It is recommended that the term "ADA diet" no longer be used, since the ADA no longer endorses a single nutrition prescription or percentages of macronutrients.

Special nutrition issues include liquid diets, surgical diets, catabolic illnesses, and enteral or parenteral nutrition (114,115). Patients requiring clear or full liquid diets should receive ~200 g carbohydrate/day in equally divided amounts at meal and snack times. Liquids should not be sugar free. Patients require carbohydrate and calories, and sugar-free liquids do not meet these nutritional needs. For tube feedings, either a standard enteral formula (50% carbohydrate) or a lower–carbohydrate content formula (33–40% carbohydrate) may be used. Calorie needs for most patients are in the range of 25–35 kcal/kg every 24 h. Care must be taken not to overfeed patients because this can exacerbate hyperglycemia. After surgery, food intake should be initiated as quickly as possible. Progression from clear liquids to full liquids to solid foods should be completed as rapidly as tolerated.

Patients with diabetes in long-term care facilities

Recommendations

- The imposition of dietary restrictions on elderly patients with diabetes in long-term care facilities is not warranted. Residents with diabetes should be served a regular menu, with consistency in the amount and timing of carbohydrate. (C)
- An interdisciplinary team approach is necessary to integrate MNT for patients with diabetes into overall management. (E)
- There is no evidence to support prescribing diets such as "no concentrated sweets" or "no sugar added." (E)
- In the institutionalized elderly, undernutrition is likely and caution should be exercised when prescribing weight loss diets. (B)

Although the prevalence of undiagnosed diabetes in elderly nursing home residents is high, not all of such individuals require pharmacologic therapy (115,116). Older residents with diabetes in nursing homes tend to be underweight rather than overweight (114). Low body weight has been associated with greater morbidity and mortality in this population (114,115). Experience has shown that residents eat better when they are given less restrictive diets (115,116). Specialized diabetic diets do not appear to be superior to standard diets in such settings (117,118). Meal plans such as no concentrated sweets, no sugar added, low sugar, and liberal diabetic diet also are no longer appropriate. These diets do not reflect current diabetes nutrition recommendations and unnecessarily restrict sucrose. (These types of diets are more likely in long-term care facilities than acute care.) Making medication changes to control glucose, lipids, and blood pressure rather than implementing food restrictions can reduce the risk of iatrogenic malnutrition. The specific nutrition interventions recommended will depend on a variety of factors, including age, life expectancy, comorbidities, and patient preferences (119).

SUMMARY: NUTRITION RECOMMENDATIONS AND INTERVENTIONS FOR DIABETES

— Major nutrition recommendations and interventions for diabetes are listed in Table 3. Monitoring of metabolic parameters, including glucose, A1C, lipids, blood pressure, body weight, and renal function is essential to assess the need for changes in therapy and to ensure successful outcomes. Many aspects of MNT require additional research.

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Diabetes Care in the School and Day Care Setting

AMERICAN DIABETES ASSOCIATION

Diabetes is one of the most common chronic diseases of childhood. There are about 176,000 individuals <20 years of age with diabetes in the U.S. (1). About one in every 400–600 children and adolescents has type 1 diabetes (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 of 1991 (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 provided 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 the later development of diabetes complications, with improved glycemic control decreasing the risk of these complications (16,17). To achieve glycemic control, a child must monitor blood glucose frequently, follow a meal plan, and take medications. 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, 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 (3,18,19,20,34). 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 coaches, school nurses, 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 should be developed by the parent/ guardian and the student's diabetes health care team. 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. The Diabetes Medical Management Plan should address the specific needs of the child and provide specific instructions for each of the following:

1. Blood glucose monitoring, including the frequency and circumstances requiring blood glucose checks.
2. Insulin administration (if necessary), including doses/injection times prescribed for specific blood glucose values, 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.

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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.

Figure 1 includes a sample Diabetes Medical Management Plan. For detailed information on the symptoms and treatment of hypoglycemia and hyperglycemia, refer to the *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 Diabetes Medical Management Plan.

II. Responsibilities of the various care providers (3)

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

1. All materials and equipment 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.
2. Supplies to treat hypoglycemia, including a source of glucose and a glucagon emergency kit, if indicated in the Diabetes Medical Management Plan.
3. Information about diabetes and the performance of diabetes-related tasks.
4. 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.
5. Information about the student's meal/snack schedule. The parent should work with the school 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.
6. In most locations and increasingly, a signed release of confidentiality from the legal guardian will be required so that the health care team can communicate with the school. Copies should be retained both at school and in the health care professionals' offices.

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

1. Training to all adults who provide education/care for the student on the symptoms and treatment of hypoglycemia and hyperglycemia and other emergency procedures. An adult and back-up adult(s) trained to *1*) perform fingerstick blood glucose monitoring and record the results; 2) take appropriate actions for blood glucose levels outside of the target ranges as indicated in the student's Diabetes Medical Management Plan; and *3*) test the urine or blood for ketones, when necessary, and respond to the results.
2. 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.
3. If indicated by the child's developmental capabilities and the Diabetes Medical Management Plan, an adult and back-up adult(s) trained in insulin administration.
4. An adult and back-up adult(s) trained to administer glucagon, in accordance with the student's Diabetes Medical Management Plan.
5. A location in the school to provide 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 to 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 Diabetes Medical Management Plan.
6. An adult and back-up adult(s) 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 also will notify the parent/guardian in advance of any expected changes in the school schedule that affect the student's meal times or exercise routine. Young children should be reminded of snack times.
7. Permission for the student to see the school nurse and other trained school personnel upon request.
8. Permission for the student to eat a snack anywhere, including the classroom or the school bus, if necessary to prevent or treat hypoglycemia.
9. Permission to miss school without consequences for 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.
10. Permission for the student to use the restroom and have access to fluids (i.e., water) as necessary.
11. An appropriate location for insulin and/or glucagon storage, if necessary.
12. Information on serving size and caloric, carbohydrate, and fat content of foods served in the school (27).

An adequate number of school personnel should be trained in the necessary diabetes procedures (e.g., blood glucose monitoring, insulin and glucagon administration) and in the appropriate response to high and low blood glucose levels to ensure that at least one adult is present to perform these procedures in a timely manner while the student is at school, on field trips, and during extracurricular activities or other school-sponsored events (3,18,20). These school personnel need not be health care professionals (3,9,20, 28,33,35).

The student with diabetes should have immediate access to diabetes supplies at all times, with supervision as needed. Provisions similar to those described above must be available for field trips, extracurricular activities, other school-sponsored events, and on transportation provided by the school or day

Date of Plan _____ **Diabetes Medical Management Plan** Effective Dates_____

This plan should be completed by the student's personal health care team and parents/guardian. It should be reviewed with relevant school staff and copies should be kept in a place that is easily accessed by the school nurse, trained diabetes personnel, and other authorized personnel.

Student's Name _____ DOB_____ Date of Diabetes Diagnosis _____

Grade_____ Homeroom Teacher_____ Physical Condition: Diabetes Type 1 Diabetes Type 2

Contact Information

Parent/Guardian #1 _____ Address_____

Phone: Work_____ Home_____ Cell_____

Parent/Guardian #2_____ Address_____

Work_____ Home_____ Cell_____

Student's Doctor/Health Care Provider:

Name_____ Address_____

Phone:_____ Emergency Number:_____

Other Emergency Contacts:

Name_____ Relationship_____

Phone: Work_____ Home_____ Cell_____

Notify parents/guardian or emergency contact in the following situations:_____

_____

_____

Blood Glucose Monitoring

Target range for blood glucose is 70-150 70-180 Other

Usual times to check blood glucose:_____

Times to do extra blood glucose checks (circle all that apply)

Before exercise After exercise

Student exhibits symptoms of hyperglycemia Student exhibits symptoms of hypoglycemia

Other (explain)_____

Can student perform own blood glucose? Yes No

Exceptions:_____

_____

Type of blood glucose meter student uses: _____

Insulin

Usual lunchtime dose:_____

Base does of Humalog/Novolog/Regular Insulin at lunch (circle type of rapid-/short-acting insulin used) is _____ units or does flexible dosing using

_____ units/_____ grams carbohydrate.

Use of other insulin at lunch (circle type of insulin used): intermediate/NPH/lente _____ units or basal/Lantus/Ultralente _____units.

Insulin Correction Doses

Parental authorization should be obtained before administering a correction dose for high blood glucose levels: Yes No

_____ units if blood glucose is _____ to _____ mg/dl _____ units if blood glucose is _____ to _____ mg/dl

_____ units if blood glucose is _____ to _____ mg/dl _____ units if blood glucose is _____ to _____ mg/dl

_____ units if blood glucose is _____ to _____ mg/dl

Figure 1—*Diabetes Medical Management Plan.*

Can student give own injections? Yes No

Can student determine correct amount of insulin? Yes No

Can student draw correct dose of insulin? Yes No

_____Parents are authorized to adjust the insulin dosage under the following circumstances_____

_____

For Students With Insulin Pumps:

Type of pump:_____ Basal rates: _____ 12 a.m. to _____

_____ _____ to _____ _____ _____ to _____

Type of insulin in pump: _____

Type of infusion set: _____

Insulin/carbohydrate ratio: _____ Correction factor: _____

Student pump abilities/skills _____ Needs assistance: _____

Count carbohydrates:	Yes	No
Bolus correct amount for carbohydrates consumed	Yes	No
Calculate and administer corrective bolus	Yes	No
Calculate and set basal profiles	Yes	No
Calculate and set temporary basal rate	Yes	No
Disconnect pump	Yes	No
Reconnect pump at infusion set	Yes	No
Prepare reservoir and tubing	Yes	No
Insert infusion set	Yes	No
Troubleshoot alarms and malfunctions	Yes	No

For Students Taking Oral Diabetes Medication:

Type of medication: _____ Timing: _____

Other medications: _____ Timing: _____

Meals and Snacks Eaten at School

Is student independent in carbohydrate calculations and management? Yes No

Meal/snack _____ Time: _____ Food content/amount _____

Breakfast _____

Mid-A.M. snack _____

Lunch _____

Mid-P.M. snack _____

Dinner _____

Snack before exercise? Yes No

Snack after exercise? Yes No

Other times to give snacks and content/amount: _____

Preferred snack foods: _____

Foods to avoid, if any: _____

FIG. 1—*Continued*

Instructions for when food is provided to the class (e.g., as part of a class party or food sampling event): _____

_____

Exercise and Sports

A fast-acting carbohydrate such as _____ should be available at the site of exercise or sports.

Restrictions on activity if any _____

Student should not exercise if blood glucose level is below _____ mg/dl or above _____ mg/dl or if a moderate to large urine ketones are present.

Hypoglycemia (Low Blood Sugar)

Usual symptoms of hypoglycemia: _____

Treatment of hypoglycemia: _____

Glucagon should be given if the student is unconscious, having a seizure (convulsion), or unable to swallow.

Route _____, Dosage _____, site for glucagon injection: _____arm, _____thigh, _____other.

If Glucagon is required, administer it promptly, then call 911 or other emergency assistance and the parents/guardian.

Hyperglycemia (High Blood Sugar)

Usual symptoms of hyperglycemia: _____

Treatment of hyperglycemia: _____

Urine should be checked for ketones when blood glucose level are above _____ mg/dl.

Treatment for Ketones: _____

Supplies to Be Kept at School:

_____ Blood glucose meter, blood glucose test strips, batteries for meter

_____ Lancet device, lancets, gloves, etc.

_____ Urine ketone strips

_____ Insulin vials and syringes

_____Insulin pump and supplies

_____ Insulin pen, pen needles, insulin cartridges

_____ Fast-acting source of glucose

_____ Carbohydrate containing snack

_____ Glucagon emergency kit

Signatures

This Diabetes Medical Management Plan has been approved by:

_____ _____

Student's Physician / Health Care Provider Date

Acknowledged and received by:

_____ _____

Student's Parent / Guardian Date

_____ _____

Student's Parent / Guardian Date

_____ _____

Student's Parent / Guardian Date

FIG. 1—*Continued*

Table 1—*Resources for teachers, child care providers, parents, and health professionals*

Helping the Student with Diabetes Succeed: A Guide for School Personnel, National Diabetes Education Program, 2003; available online at http://www.ndep.nih.gov/diabetes/pubs/Youth_SchoolGuide.

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care facility to enable full participation in school activities.

It is the school's legal responsibility to provide appropriate training to school staff on diabetes-related tasks and in the treatment of diabetes emergencies. This training should be provided by health care professionals with expertise in diabetes unless the student's health care provider determines that the parent/guardian is able to provide the school personnel with sufficient oral and written information to allow the school to have a safe and appropriate environment for the child. If appropriate, members of the health care team should provide instruction and materials to the parent/guardian to facilitate the education of school staff. Educational materials from the American Diabetes Association and other sources targeted to school personnel and/or parents are available. Table 1 includes a listing of appropriate resources.

III. Expectations of the student in diabetes care

Children and youths should be able to implement their diabetes care at school with parental consent to the extent that is appropriate for 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 very individual and variable, and a child's capabilities and willingness to provide self-care should be respected (18).

1. *Preschool and day care.* The preschool child is usually unable to perform diabetes tasks independently. By 4 years of age, children may be expected to generally cooperate in diabetes tasks.
2. *Elementary school.* The child should be expected to cooperate in all diabetes tasks at school. By age 8 years, most children are able to perform their own fingerstick blood glucose tests with supervision. By age 10, some children can administer insulin with supervision.
3. *Middle school or junior high school.* The student should be able to administer insulin with supervision and perform self-monitoring of blood glucose under usual circumstances when not experiencing a low blood glucose level.
4. *High school.* The student should be able to perform self-monitoring of blood glucose under usual circumstances when not experiencing low blood glucose levels. In high school, adolescents should be able to administer insulin without supervision.

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.

MONITORING BLOOD GLUCOSE IN THE CLASSROOM — It is best for a student with diabetes to monitor a blood glucose level and to 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 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 Diabetes Medical Management Plan (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 (3)

— 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 afflicting 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, lightheadedness, irritability, confusion, and drowsiness. 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 (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 can cause 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).

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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 hypo- and hyperglycemia 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 hypo- or hyperglycemia 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 hypo- 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 5 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

Originally approved 1989. Most recent review, 2007.

Abbreviations: CBG, capillary blood glucose; DKA, diabetic ketoacidosis; GDM, gestational diabetes mellitus; MNT, medical nutrition therapy.

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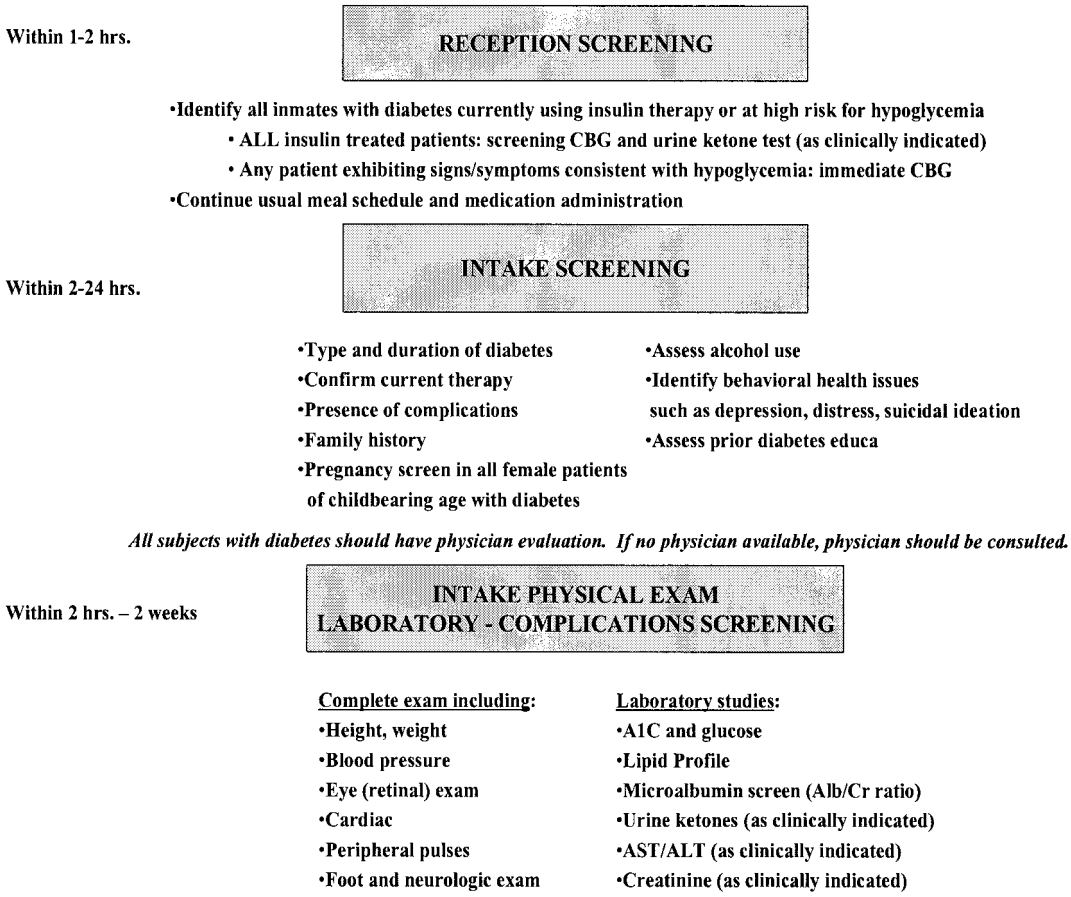

Figure 1—*Essential components of the initial history and physical examination. Alb/Cr ratio, albumin-to-creatinine ratio; ALT, alanine aminotransferase; AST, aspartate aminotransferase.*

who are at high risk should be considered for blood glucose screening. If pregnant, a risk assessment for gestational diabetes 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 comorbid 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 di-

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

A1C	<7.0%*
Blood pressure	<130/80 mmHg
Lipids	
LDL cholesterol	<100 mg/dl (<2.6 mmol/l)†

*Referenced to a nondiabetic range of 4.0–6.0% using a DCCT-based assay. †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.

abetes control is the first step in facilitating self-management. This education enables the patient to identify better food 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 Principles and Recommendations in 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 appropriate 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).

Hyperglycemia

Severe hyperglycemia 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 <60 mg/dl. Severe hypoglycemia 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 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. If 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)

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.

- 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 <130/80 mmHg.
- Cardiac: People with type 2 diabetes are at a particularly high risk of coronary artery disease. Cardiovascular disease 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 <130/80 mmHg.

MONITORING/TESTS OF GLYCEMIA — Monitoring of CBG is a strategy that allows caregivers and peo-

ple 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" (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 polices, 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 is diabetes
- 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 initial 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

Table 2—*Major components of diabetes self-management education*

Survival skills	Daily management issues
• Hypo-/hyperglycemia • Sick day management • Medication • Monitoring • Foot care	• Disease process • Nutritional management • Physical activity • Medications • Monitoring • Acute complications • Risk reduction • Goal setting/problem solving • Psychosocial adjustment • Preconception care/pregnancy/gestational diabetes management

summary that includes the patient's 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 heath 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, addi-

tional CBG monitoring is necessary and additional carbohydrate snacks may be required.

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.

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Hypoglycemia and Employment/Licensure

AMERICAN DIABETES ASSOCIATION

In 1984, in recognition of the tremendous progress made in the treatment and daily management of diabetes, the American Diabetes Association adopted the following policy on employment.

> Any person with diabetes, whether insulin dependent or non–insulin dependent, should be eligible for any employment for which he/she is otherwise qualified.

Despite the significant medical and technological advances made in managing diabetes, discrimination in employment and licensure against people with diabetes still occurs. This discrimination is often based on apprehension that the person with diabetes may present a safety risk to the employer or the public—a fear sometimes based on misinformation or lack of up-to-date knowledge about diabetes. Perhaps the greatest concern is that hypoglycemia will cause sudden unexpected incapacitation.

Hypoglycemia occurs from a relative excess of insulin in the blood and results in excessively low blood glucose levels. The level of glucose that produces symptoms of hypoglycemia varies from person to person and for the same person under different circumstances. Hypoglycemia usually occurs gradually and is generally associated with typical warning signs, which may include rapid heartbeat, perspiration, shakiness, anxiety, and hunger. When symptoms occur, preventive action can be taken by eating carbohydrates. A hypoglycemic reaction is not ordinarily associated with a loss of consciousness or a seizure. However, if warning signs are absent or ignored and the blood glucose level continues to fall, more severe hypoglycemia may lead to an alteration of mental function that proceeds to confusion, stupor, and finally to unconsciousness. Most individuals with diabetes never suffer such severe hypoglycemia. Those who experience recurrent episodes should be individually evaluated and, when appropriate, the employment position should be modified.

Hypoglycemia does not occur in people with diabetes who are treated with only medical nutrition therapy (MNT) and exercise and is rare in people treated with α-glucosidase inhibitors, biguanides, or thiazolidinediones. Except in elderly or chronically ill individuals or in association with prolonged fasting, severe hypoglycemia is unlikely to occur when appropriate doses of any oral glucose-lowering agents are used to manage blood glucose. Most people recognize the early warning signs of hypoglycemia and can quickly counteract them by eating. Furthermore, the proper use of systems that allow rapid and accurate self-monitoring of blood glucose levels can assist people in avoiding significant hypoglycemia. Thus, most people with diabetes can manage their condition in such a manner that there is a minimal risk of incapacitation from hypoglycemia.

In summary, because the effects of diabetes are unique to each individual, it is inappropriate to consider all people with diabetes the same. People with diabetes should be individually considered for employment based on the requirements of the specific job. Factors to be weighed in this decision include the individuals medical condition, treatment regimen (MNT, oral glucose-lowering agent, and/or insulin), and medical history, particularly in regard to the occurrence of incapacitating hypoglycemic episodes.

The recommendations in this paper are based on the evidence reviewed in the following publication: Hypoglycemia in diabetes (Technical Review). *Diabetes Care* 26:1902–1912, 2003.

Approved 1990. Most recent review/revision, 2007.

Abbreviations: MNT, medical nutrition therapy.

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Third-Party Reimbursement for Diabetes Care, Self-Management Education, and Supplies

AMERICAN DIABETES ASSOCIATION

Diabetes is a chronic disease that affects >20 million Americans (1) and is characterized by serious, costly, and often fatal complications. The total cost of diagnosed diabetes in the U.S. in 2002 was estimated to be $132 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 paper 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 U.K. 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" 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. 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

The recommendations in this paper are based on the evidence reviewed in the following publications: Diabetes self-management education (Technical Review). *Diabetes Care* 18:1204–1214, 1995; and National standards for diabetes self-management education programs (Technical Review). *Diabetes Care* 18:100–116, 1995.

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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 existent 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.

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POSITION STATEMENTS

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/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 technical review or other review of published literature. They are reviewed on an annual basis and updated as needed. Listed below are recent position statements.

Screening for Type 2 Diabetes
Diabetes Care 27 (Suppl. 1):S11–S14, 2004

Prevention or Delay of Type 2 Diabetes
Diabetes Care 27 (Suppl. 1):S47–S54, 2004

Diabetes Nutrition Recommendations for Health Care Institutions
Diabetes Care 27 (Suppl. 1):S55–S57, 2004

Physical Activity/Exercise and Diabetes
Diabetes Care 27 (Suppl. 1):S58–S62, 2004

Preventive Foot Care in Diabetes
Diabetes Care 27 (Suppl. 1):S63–S64, 2004

Hypertension Management in Adults With Diabetes
Diabetes Care 27 (Suppl. 1):S65–S67, 2004

Dyslipidemia Management in Adults With Diabetes
Diabetes Care 27 (Suppl. 1):S68–S71, 2004

Aspirin Therapy in Diabetes
Diabetes Care 27 (Suppl. 1):S72–S73, 2004

Smoking and Diabetes
Diabetes Care 27 (Suppl. 1):S74–S75, 2004

Preconception Care of Women With Diabetes
Diabetes Care 27 (Suppl. 1):S76–S78, 2004

Nephropathy in Diabetes
Diabetes Care 27 (Suppl. 1):S79–S83, 2004

Retinopathy in Diabetes
Diabetes Care 27:S84–S87, 2004

Gestational Diabetes Mellitus
Diabetes Care 27 (Suppl. 1):S88–S90, 2004

Tests of Glycemia in Diabetes
Diabetes Care 27 (Suppl. 1):S91–S93, 2004

Hyperglycemic Crises in Diabetes
Diabetes Care 27 (Suppl. 1):S94–S102, 2004

Hospital Admission Guidelines for Diabetes
Diabetes Care 27 (Suppl. 1):S103, 2004

Bedside Blood Glucose Monitoring in Hospitals
Diabetes Care 27 (Suppl. 1):S104, 2004

Pancreas Transplantation in Type 1 Diabetes
Diabetes Care 27 (Suppl. 1):S105, 2004

Insulin Administration
Diabetes Care 27 (Suppl. 1):S106–S109, 2004

Continuous Subcutaneous Insulin Infusion
Diabetes Care 27 (Suppl. 1):S110, 2004

Influenza and Pneumococcal Immunization in Diabetes
Diabetes Care 27 (Suppl. 1):S111–S113, 2004

Concurrent Care
Diabetes Care 27 (Suppl. 1):S132, 2004

Prevention of Type 1 Diabetes
Diabetes Care 27 (Suppl. 1):S133, 2004

Unproven Therapies
Diabetes Care 27 (Suppl. 1):S135, 2004

Weight Management
Diabetes Care 27:2067, 2004

Dietary Carbohydrate
Diabetes Care 27:2266, 2004

Children and Adolescents With Type 1 Diabetes
Diabetes Care 28:186, 2005

Neuropathy
Diabetes Care 28:956, 2005

Metabolic Syndrome
Diabetes Care 28:2289, 2005

Pancreas and Islet Transplantation in Type 1 Diabetes
Diabetes Care 29:935, 2006

Generic Drugs
Diabetes Care 30:173, 2007

National Standards for Diabetes Self-Management Education

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Diabetes self-management education (DSME) is a critical element of care for all people with diabetes and is necessary in order to improve patient outcomes. The National Standards for DSME are designed to define quality diabetes self-management education and to assist diabetes educators in a variety of settings to provide evidence-based education. Because of the dynamic nature of health care and diabetes-related research, these Standards are reviewed and revised approximately every 5 years by key organizations and federal agencies within the diabetes education community.

A Task Force was jointly convened by the American Association of Diabetes Educators and the American Diabetes Association in the summer of 2006. Additional organizations that were represented included the American Dietetic Association, the Veteran's Health Administration, the Centers for Disease Control and Prevention, the Indian Health Service, and the American Pharmaceutical Association. Members of the Task Force included a person with diabetes; several health services researchers/behaviorists, registered nurses, and registered dietitians; and a pharmacist.

The Task Force was charged with reviewing the current DSME standards for their appropriateness, relevance, and scientific basis. The Standards were then reviewed and revised based on the available evidence and expert consensus. The committee convened on 31 March 2006 and 9 September 2006, and the Standards were approved 25 March 2007.

DEFINITION AND OBJECTIVES — Diabetes self-management education (DSME) is the ongoing process of facilitating the knowledge, skill, and ability necessary for diabetes self-care. This process incorporates the needs, goals, and life experiences of the person with diabetes 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.

GUIDING PRINCIPLES — Before the review of the individual Standards, the Task Force identified overriding principles based on existing evidence that would be used to guide the review and revision of the DSME Standards. These are:

1. Diabetes education is effective for improving clinical outcomes and quality of life, at least in the short-term (1–7).
2. DSME has evolved from primarily didactic presentations to more theoretically based empowerment models (3,8).
3. There is no one "best" education program or approach; however, programs incorporating behavioral and psychosocial strategies demonstrate improved outcomes (9–11). Additional studies show that culturally and age-appropriate programs improve outcomes (12–16) and that group education is effective (4,6,7,17,18).
4. Ongoing support is critical to sustain progress made by participants during the DSME program (3,13,19,20).
5. Behavioral goal-setting is an effective strategy to support self-management behaviors (21).

STANDARDS

Structure

Standard 1. *The DSME entity will have documentation of its organizational structure, mission statement, and goals and will recognize and support quality DSME as an integral component of diabetes care.*

Documentation of the DSME organizational structure, mission statement, and goals can lead to efficient and effective provision of services. In the business literature, case studies and case report investigations on successful management strategies emphasize the importance of clear goals and objectives, defined relationships and roles, and managerial support (22–25). While this concept is relatively new in health care, business and health policy experts and organizations have begun to emphasize written commitments, policies, support, and the importance of outcome variables in quality improvement efforts (22,26–37). The continuous quality improvement literature also stresses the importance of developing policies, procedures, and guidelines (22,26).

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Abbreviations: CQI, continuous quality improvement; DSME, diabetes self-management education; DSMS, diabetes self-management support; FHL, functional health literacy; JCAHO, Joint Commission on Accreditation of Health Care Organizations.

A table elsewhere in this issue shows conventional and Système International (SI) units and conversion factors for many substances.

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Documentation of the organizational structure, mission statement, and goals can lead to efficient and effective provision of DSME. Documentation of an organizational structure that delineates channels of communication and represents institutional commitment to the educational entity is critical for success (38–42). According to the Joint Commission on Accreditation of Health Care Organizations (JCAHO) (26), this type of documentation is equally important for small and large health care organizations. 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 (22,26, 33,35–37). In 2005, JACHO published the *Joint Commission International Standards for Disease or Condition-Specific Care*, which outlines national standards and performance measurements for diabetes and addresses diabetes self-management education as one of seven critical elements (26).

Standard 2. *The DSME entity shall appoint an advisory group to promote quality. This group shall include representatives from the health professions, people with diabetes, the community, and other stakeholders.*

Established and new systems (e.g., committees, governing bodies, advisory groups) provide a forum and a mechanism for activities that serve to guide and sustain the DSME entity (30,39–41). Broad participation of organization(s) and community stakeholders, including health professionals, people with diabetes, consumers, and other community interest groups, at the earliest possible moment in the development, ongoing planning, and outcomes evaluation process (22,26,33,35,36,41) can increase knowledge and skills about the local community and enhance collaborations and joint decision-making. The result is a DSME program that is patient-centered, more responsive to consumer-identified needs and the needs to the community, more culturally relevant, and of greater personal interest to consumers (43–50).

Standard 3. *The DSME entity will determine the diabetes educational needs of the target population(s) and identify resources necessary to meet these needs.*

Clarifying the target population and determining its self-management educational needs serve to focus resources and maximize health benefits (51–53). The assessment process should identify the educational needs of all individuals with diabetes, not just those who frequently attend clinical appointments (51). DSME is a critical component of diabetes treatment (2,54,55), yet the majority of individuals with diabetes do not receive any formal diabetes education (56,57). Thus, identification of access issues is an essential part of the assessment process (58). Demographic variables, such as ethnic background, age, formal educational level, reading ability, and barriers to participation in education, must also be considered to maximize the effectiveness of DSME for the target population (13–19,43–47,59–61).

Standard 4. *A coordinator will be designated to oversee the planning, implementation, and evaluation of diabetes self-management education. The coordinator will have academic or experiential preparation in chronic disease care and education and in program management.*

The role of the coordinator is essential to ensure that quality diabetes education is delivered through a coordinated and systematic process. As new and creative methods to deliver education are explored, the coordinator plays a pivotal role in ensuring accountability and continuity of the educational process (23,60–62). The individual serving as the coordinator will be most effective if there is familiarity with the lifelong process of managing a chronic disease (e.g., diabetes) and with program management.

Process

Standard 5. *DSME will be provided by one or more instructors. The instructors will have recent educational and experiential preparation in education and diabetes management or will be a certified diabetes educator. The instructor(s) will obtain regular continuing education in the field of diabetes management and education. At least one of the instructors will be a registered nurse, dietitian, or pharmacist. A mechanism must be in place to ensure that the participant's needs are met if those needs are outside the instructors' scope of practice and expertise.*

Diabetes education has traditionally been provided by nurses and dietitians. Nurses have been utilized most often as instructors in the delivery of formal DSME (2,3,5,63–67). With the emergence of medical nutrition therapy (66–70), registered dietitians became an integral part of the diabetes education team. In more recent years, the role of the diabetes educator has expanded to other disciplines, particularly pharmacists (73–79). Reviews comparing the effectiveness of different disciplines for education report mixed results (3,5,6). Generally, the literature favors current practice that utilizes the registered nurse, registered dietitian, and the registered pharmacist as the key primary instructors for diabetes education and members of the multidisciplinary team responsible for designing the curriculum and assisting in the delivery of DSME (1–7,77). In addition to registered nurses, registered dietitians, and pharmacists, a number of studies reflect the ever-changing and evolving health care environment and include other health professionals (e.g., a physician, behaviorist, exercise physiologist, ophthalmologist, optometrist, podiatrist) (48,80–84) and, more recently, lay health and community workers (85–91) and peers (92) to provide information, behavioral support, and links with the health care system as part of DSME.

Expert consensus supports the need for specialized diabetes and educational training beyond academic preparation for the primary instructors on the diabetes team (64,93–97). Certification as a diabetes educator 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 (98). An additional credential that indicates specialized training beyond basic preparation is board certification in advanced Diabetes Management (BC-ADM) offered by the American Nurses Credentialing Center (ANCC), which is available for master's prepared nurses, dietitians, and pharmacists (48,84,99).

DSME has been shown to be most effective when delivered by a multidisciplinary team with a comprehensive plan of care (7,31,52,100–102). Within the multidisciplinary team, team members work interdependently, consult with one another, and have shared objectives (7,103,104). The team should have a collective combination of expertise in the clinical care of diabetes, medical nutrition therapy, educational methodologies, teaching strategies, and the psychosocial and behavioral aspects of diabetes self-management. A referral mechanism should be in place to ensure that the individual with diabetes receives education from those with appropriate training and credentials. It is essential in this collaborative and integrated team approach that individuals with diabetes are viewed as

leaders of their team and assume an active role in designing their educational experience (7,20,31,100–102,104).

Standard 6. *A written curriculum reflecting current evidence and practice guidelines, with criteria for evaluating outcomes, will serve as the framework for the DSME entity. Assessed needs of the individual with pre-diabetes and diabetes will determine which of the content areas listed below are to be provided:*

- 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

People with diabetes and their families and caregivers have a great deal to learn in order to become effective self-managers of their diabetes. A core group of topics are commonly part of the curriculum taught in comprehensive programs that have demonstrated successful outcomes (1,2,3,6,105–109). The curriculum, a coordinated set of courses and educational experiences, includes learning outcomes and effective teaching strategies (110–112). The curriculum is dynamic and needs to reflect current evidence and practice guidelines (112–117). Current educational research reflects the importance of emphasizing practical, problem-solving skills, collaborative care, psychosocial issues, behavior change, and strategies to sustain self-management efforts (31,39,42,48,98,118–122).

The content areas delineated above provide instructors with an outline for developing this curriculum. It is important that the content be tailored to match each individual's needs and adapted as necessary for age, type of diabetes (including pre-diabetes and pregnancy), cultural influences, health literacy, and other comorbidities (123,124). The content areas are designed to be applicable in all settings and represent topics that can be developed in basic, intermediate, and advanced levels. Approaches to education that are interactive and patient-centered have been shown to be effective (83,119,121,122,125–127).

These content areas are presented in behavioral terms and thereby exemplify the importance of action-oriented, behavioral goals and objectives (13,21,55,121–123,128,129). Creative, patient-centered experience-based delivery methods are effective for supporting informed decision-making and behavior change and go beyond the acquisition of knowledge.

Standard 7. *An individual assessment and education plan will be developed collaboratively by the participant and instructor(s) to direct the selection of appropriate educational interventions and self-management support strategies. This assessment and education plan and the intervention and outcomes will be documented in the education record.*

Multiple studies indicate the importance of individualizing education based on the assessment (1,56,68,131–135). The assessment includes information about the individual's relevant medical history, age, cultural influences, health beliefs and attitudes, diabetes knowledge, self-management skills and behaviors, readiness to learn, health literacy level, physical limitations, family support, and financial status (10–17,19,131,136–138). The majority of these studies support the importance of attitudes and health beliefs in diabetes care outcomes (1,68,134,135,138,139).

In addition, functional health literacy (FHL) level can affect patients' self-management, communication with clinicians, and diabetes outcomes (140,141). Simple tools exist for measuring FHL as part of an overall assessment process (142–144).

Many people with diabetes experience problems due to medication costs, and asking patients about their ability to afford treatment is important (144). Comorbid chronic illness (e.g., depression and chronic pain) as well as more general psychosocial problems can pose significant barriers to diabetes self-management (104,146–151); considering these issues in the assessment may lead to more effective planning (149–151).

Periodic reassessment determines attainment of the educational objectives or the need for additional and creative interventions and future reassessment (7,97,100,152). A variety of assessment modalities, including telephone follow-up and other information technologies (e.g., Web-based, automated phone calls), may augment face-to-face assessments (97,99).

While there is little direct evidence on the impact of documentation on patient outcomes, it is required to receive payment for services. In addition, documentation of patient encounters guides the educational process, provides evidence of communication among instructional staff, may prevent duplication of services, and provides information on adherence to guidelines (37,64,100,131,153). Providing information to other members of the patient's health care team through documentation of educational objectives and personal behavioral goals increases the likelihood that all of the members will address these issues with the patient (37,98,153).

The use of evidence-based performance and outcome measures has been adopted by organizations and initiatives such as the Centers for Medicare and Medicaid Services (CMS), the National Committee for Quality Assurance (NCQA), the Diabetes Quality Improvement Project (DQIP), the Health Plan Employer Data and Information Set (HEDIS), the Veterans Administration Health System, and JCAHO (26,154).

Research 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 (100,153–155).

Standard 8. *A personalized follow-up plan for ongoing self management support will be developed collaboratively by the participant and instructor(s). The patient's outcomes and goals and the plan for ongoing self management support will be communicated to the referring provider.*

While DSME is necessary, it is not sufficient for patients to sustain a lifetime of diabetes self-care (55). Initial improvements in metabolic and other outcomes diminish after ~6 months (3). To sustain behavior at the level of self-management needed to effectively manage diabetes, most patients need ongoing diabetes self-management support (DSMS).

DSMS is defined as activities to assist the individual with diabetes to implement and sustain the ongoing behaviors needed to manage their illness. The type of support provided can include behavioral, ed-

ucational, psychosocial, or clinical (13,121–123).

A variety of strategies are available for providing DSMS both within and outside the DSME entity. Some patients benefit from working with a nurse case manager (7,20,98,157). Case management for DSMS can include reminders about needed follow-up care and tests, medication management, education, behavioral goal-setting, and psychosocial support/connection to community resources.

The effectiveness of providing DSMS through disease-management programs, trained peers and health community workers, community-based programs, use of technology, ongoing education and support groups, and medical nutrition therapy has also been established (7,13,89–92,101,121–123,158–159).

While the primary responsibility for diabetes education belongs to the DSME entity, patients benefit by receiving reinforcement of content and behavioral goals from their entire health care team (100). Additionally, many patients receive DSMS through their provider. Thus, communication is essential to ensure that patients receive the support they need.

Outcomes

Standard 9. *The DSME entity will measure attainment of patient-defined goals and patient outcomes at regular intervals using appropriate measurement techniques to evaluate the effectiveness of the educational intervention.*

In addition to program-defined goals and objectives (e.g., learning goals, metabolic, and other health outcomes), the DSME entity needs to assess each patient's personal self-management goals and his/her progress toward those personal goals. The AADE7 self-care behaviors provide a useful framework for assessment and documentation. Diabetes self-management behaviors include physical activity, healthy eating, medication taking, monitoring blood glucose, diabetes self-care related problem solving, reducing risks of acute and chronic complications, and psychosocial aspects of living with diabetes (112,160). Assessments of patient outcomes should occur at appropriate intervals. The interval depends on the outcome itself and the timeframe provided within the selected goals. For some areas, the indicators, measures, and timeframes may be based on guidelines from professional organizations or government agencies. In addition to assessing progress toward personal behavioral goals, a plan needs to be in place to communicate personal goals and progress to other team members.

The AADE Outcome Standards for Diabetes Education specify self-management behavior as the key outcome (112,160). Knowledge is an outcome to the degree that it is actionable (i.e., knowledge that can be translated into self-management behavior). In turn, effective self-management is one (but not the only) contributor to longer-term, higher-order outcomes such as clinical status (e.g., control of glycemia, blood pressure, and cholesterol), health status (e.g., avoidance of complications), and subjective quality of life. Thus, patient self-management behaviors are at the core of the outcomes evaluation.

Standard 10. *The DSME entity will measure the effectiveness of the education process and determine opportunities for improvement using a written continuous quality improvement plan that describes and documents a systematic review of the entities' process and outcome data.*

Diabetes education must be responsive to advances in knowledge, treatment strategies, educational strategies, psychosocial interventions, and the changing health care environment. Continuous quality improvement (CQI) is an iterative, planned process (161) that leads to improvement in the delivery of patient education (162). The CQI plan should define quality based on and consistent with the organization's mission, vision, and strategic plan and include identifying and prioritizing improvement opportunities (163). Once improvement projects are identified and selected, the plan should incorporate timelines and important milestones including data collection, analysis, and presentation of results (163). 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 (163–164). Process measures are often targeted to those processes that typically impact the most important outcomes. Measuring both process and outcomes helps to ensure that change is successful without causing additional problems in the system (164).

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TECHNICAL REVIEWS

A technical review is a balanced review and analysis of the literature on a scientific or medical topic related to diabetes. The technical review provides a scientific rationale for a position statement and undergoes critical peer review before submission to the Professional Practice Committee for approval. In some cases, original research publications, conference proceedings, or other comprehensive review articles are used as the basis for a position statement instead of a technical review. Listed below are recent technical reviews.

Economic Analysis of Diabetes Interventions	Klonoff DC, Schwartz DM: An economic analysis of interventions for diabetes. *Diabetes Care* 23:390–404, 2000
Exercise	Sigal RJ, Kenny GP, Wasserman DH, Castaneda-Sceppa C: Physical activity/exercise and type 2 diabetes. *Diabetes Care* 27:2518–2539, 2004
Hospitals	Clement S, Braithwaite SS, Magee MF, Ahmann A, Smith EP, Schafer RG, Hirsh IB: Management of diabetes and hyperglycemia in hospitals. *Diabetes Care* 27:553–591, 2004
Hyperglycemic Crises	Kitabchi AE, Umpierrez GE, Murphy MB, Barrett EJ, Kreisberg RA, Malone JI, Wall BM: Management of hyperglycemic crises in patients with diabetes. *Diabetes Care* 24:131–153, 2001
Hypertension	Arauz-Pacheco C, Parrott MA, Raskin P: The treatment of hypertension in adult patients with diabetes. *Diabetes Care* 25:134–147, 2002
Hypoglycemia	Cryer PE, Davis SN, Shamoon H: Hypoglycemia in diabetes. *Diabetes Care* 26:1902–1912, 2003
Immunizations	Smith SA, Poland GA: Use of influenza and pneumococcal vaccines in people with diabetes. *Diabetes Care* 23:95–108, 2000
Laboratory Analysis	Sacks DB, Bruns DE, Goldstein DE, Maclaren NK, McDonald JM, Parrott M: Guidelines and recommendations for laboratory analysis in the diagnosis and management of diabetes mellitus. *Diabetes Care* 25:750–786, 2002 (Reprinted from *Clin Chem* 48:436–472, 2002)

Neuropathy	Vinik AI, Maser RE, Mitchell BD, Freeman R: Diabetic autonomic neuropathy. *Diabetes Care* 26:1553–1579, 2003
	Boulton AJ, Malik RA, Arezzo JC, Sosenko JM: Diabetic somatic neuropathies. *Diabetes Care* 27:1458–1486, 2004
Nutrition Recommendations and Principles	Franz MJ, Bantle JP, Beebe CA, Brunzell JD, Chiasson JL, Garg A, Holzmeister LA, Hoogwerf B, Mayer-Davis E, Mooradian AD, Purnell JS, Wheeler M: Evidence-based nutrition principles and recommendations for the treatment and prevention of diabetes and related complications. *Diabetes Care* 25:148–198, 2002
Pancreas Transplantation	Robertson RP, Davis C, Larsen J, Stratta R, Sutherland DER: Pancreas and islet transplantation for patients with diabetes. *Diabetes Care* 23:112–116, 2000
Retinopathy	Fong DS, Aiello LP, Ferris FL III, Klein R: Diabetic retinopathy. *Diabetes Care* 27:2540–2553, 2004
Screening for Type 2 Diabetes	Engelgau MM, Narayan KM, Herman WH: Screening for type 2 diabetes. *Diabetes Care* 23:1563–1580, 2000
Tests of Glycemia	Goldstein DE, Little RR, Lorenz RA, Malone JI, Nathan D, Peterson CM, Sacks DB: Tests of glycemia in diabetes. *Diabetes Care* 27:1761–1773, 2004

COMMITTEE REPORTS & CONSENSUS STATEMENTS

Expert Committee Reports

The Expert Committee on the Diagnosis and Classification of Diabetes Mellitus: Follow-up Report on the Diagnosis of Diabetes Mellitus
Diabetes Care 26:3160–3167, 2003

Workgroup Reports

American Diabetes Association Statement on Emergency and Disaster Preparedness: A Report of the Disaster Response Task Force
Diabetes Care 30:2395–2398, 2007

American Diabetes Association Workgroup on Hypoglycemia: Defining and Reporting Hypoglycemia in Diabetes: a Report of the American Diabetes Association Workgroup on Hypoglycemia
Diabetes Care 28:1245–1249, 2005

Consensus Statements

A consensus statement is a comprehensive examination by a panel of experts (i.e., consensus panel) of a scientific or medical issue related to diabetes. A consensus statement 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 statement 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 statement is not subject to subsequent review or approval and **does not represent official association opinion.** Listed below are recent consensus statements.

Screening for Coronary Artery Disease in Patients With Diabetes
*Diabetes Care*30:2729–2736, 2007

Consensus Statement on the Worldwide Standardization of the Hemoglobin A1C Measurement: The American Diabetes Association, European Association for the Study of Diabetes, International Federation of Clinical Chemistry and Laboratory Medicine, and the International Diabetes Federation
Diabetes Care 30:2399–2400, 2007

Use of Insulin Pump Therapy in the Pediatric Age-Group: Consensus Statement from the European Society for Paediatric Endocrinology, the Lawson Wilkins Pediatric Endocrine Society, and the International Society for Pediatric and Adolescent Diabetes, endorsed by the American Diabetes Association and the European Association for the Study of Diabetes
Diabetes Care 30:1653–1662, 2007

Waist Circumference and Cardiometabolic Risk: A Consensus Statement from Shaping America's Health: Association for Weight Management and Obesity Prevention; NAASO, The Obesity Society; the American Society for Nutrition; and the American Diabetes Association
Diabetes Care 30:1647–1652, 2007

Computer Modeling of Diabetes and Its Complications: A Report on the Fourth Mount Hood Challenge Meeting
Diabetes Care 30:1638–1646, 2007

Impaired Fasting Glucose and Impaired Glucose Tolerance: Implications for Care
Diabetes Care 30:753–759, 2007

Hyperglycemic Crises in Adult Patients With Diabetes
Diabetes Care 29:2739–2748, 2006

Management of Hyperglycemia in Type 2 Diabetes: A Consensus Algorithm for the Initiation and Adjustment of Therapy: A Consensus Statement From the American Diabetes Association and the European Association for the Study of Diabetes
Diabetes Care 29:1963–1972, 2006

American College of Endocrinology and American Diabetes Association Consensus Statement on Inpatient Diabetes and Glycemic Control: A Call to Action
Diabetes Care 29:1955–1962, 2006

Physical Activity/Exercise and Type 2 Diabetes
Diabetes Care 29:1433–1438, 2006

Diabetic Ketoacidosis in Infants, Children, and Adolescents
Diabetes Care 29:1150–1159, 2006

Guidelines for Computer Modeling of Diabetes and Its Complications
Diabetes Care 27:2262–2265, 2004

Consensus Development Conference on Antipsychotic Drugs and Obesity and Diabetes
Diabetes Care 27:596–601, 2004

Thiazolidinedione Use, Fluid Retention, and Congestive Heart Failure
Diabetes Care 27:256–263, 2004

Peripheral Arterial Disease in People with Diabetes
Diabetes Care 26:3333–3341, 2003

Management of Dyslipidemia in Children and Adolescents with Diabetes
Diabetes Care 26:2194–2197, 2003

Postprandial Blood Glucose
Diabetes Care 24:775–778, 2001

Type 2 Diabetes in Children and Adolescents
Diabetes Care 23:381–389, 2000