Standards of Medical Care in Diabetes

AMERICAN DIABETES ASSOCIATION

CONTENTS

Originally approved 1988. Most recent review/revision, October 2004.

Abbreviations: ABI, ankle-brachial index; AMI, acute myocardial infarction; ARB, angiotensin receptor blocker; CAD, coronary artery disease; CBG, capillary blood glucose; CHD, coronary heart disease; CHF, congestive heart failure; CSII, continuous subcutaneous insulin injection; CVD, cardiovascular disease; DCCB, dihydropyridine calcium channel blocker; DCCT, Diabetes Control and Complications Trial; DKA, diabetic ketoacidosis; DPP, Diabetes Prevention Program; DSME, diabetes self-management education; DRS, Diabetic Retinopathy Study; ECG, electrocardiogram; eGFR, estimated glomerular filtration rate; ESRD, end-stage renal disease; ETDRS, Early Treatment Diabetic Retinopathy Study; FPG, fasting plasma glucose; GCT, glucose challenge test; GDM, gestational diabetes mellitus; GFR, glomerular filtration rate; HRC, high-risk characteristic; ICU, intensive care unit; IFG, impaired fasting glucose; IGT, impaired glucose tolerance; MNT, medical nutrition therapy; NPDR, nonproliferative diabetic retinopathy; OGTT, oral glucose tolerance test; PAD, peripheral arterial disease; PDR, proliferative diabetic retinopathy; PPG, postprandial plasma glucose; SMBG, self-monitoring of blood glucose; UKPDS, U.K. Prospective Diabetes Study.

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 Bode (Ed.): *Medical Management of Type 1 Diabetes* (1), Burant (Ed): *Medical Management of Type 2 Diabetes* (2), and Klingensmith (Ed): *Intensive Diabetes Management* (3).

The recommendations included are 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, the ADA issued new diagnostic and classification criteria (4); in 2003, modifications were made regarding the diagnosis of impaired fasting glucose (IFG) (5). The classification of diabetes includes four clinical classes:

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 Center 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 ● 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 ● 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

- 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, and drug or chemical induced).
- Gestational diabetes mellitus (GDM) (diagnosed during pregnancy).

B. Diagnosis

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 fasting plasma glucose (FPG) to diagnose diabetes, it is poorly reproducible and rarely performed in practice. Because of ease of use, acceptability to patients, and lower cost, the FPG is the preferred diagnostic test. It should be noted that the vast majority of people who meet diagnostic criteria for diabetes by OGTT, but not by FPG, will have an A1C value <7.0%. The use of the A1C for the diagnosis of diabetes is not recommended at this time.

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 a FPG or an 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)

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

Recommendations

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

II. SCREENING FOR DIABETES

There is a major distinction between diagnostic testing and screening. When an individual exhibits symptoms or signs of the disease, diagnostic tests are performed, and such tests do not represent screening. The purpose of screening is to identify asymptomatic individuals who are likely to have diabetes. Separate diagnostic tests using standard criteria are required after positive screening tests to establish a definitive diagnosis as described above.

Type 1 diabetes

Generally, people with type 1 diabetes present with acute symptoms of diabetes and markedly elevated blood glucose lev-

Table 2—*Criteria for the diagnosis of diabetes*

1.	Symptoms of diabetes 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 diabetes include polyuria, polydipsia, and unexplained weight loss.
	OR
2.	FPG ≥126 mg/dl (7.0 mmol/l). Fasting is defined as no caloric intake for at least 8 h.
	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. The OGTT is not recommended for routine clinical use, but may be required in the evaluation of patients with IFG (see text) or when diabetes is still suspected despite a normal FPG as with the postpartum evaluation of women with GDM.

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

1.	Testing for diabetes should be considered in all individuals at age 45 years and above, particularly in those with a BMI ≥25 kg/m^2* and, if normal, should be repeated at 3-year intervals.
2.	Testing should be considered at a younger age or be carried out more frequently in individuals who are overweight (BMI ≥25 kg/m^2*) and have additional risk factors, as follows: ● are habitually physically inactive ● have a first-degree relative with diabetes ● are members of a high-risk ethnic population (e.g., African American, Latino, Native American, Asian American, Pacific Islander) ● have delivered a baby weighing >9 lb or have been diagnosed with GDM ● are hypertensive (≥140/90 mmHg) ● have an HDL cholesterol level <35 mg/dl (0.90 mmol/l) and/or a triglyceride level >250 mg/dl (2.82 mmol/l) ● have PCOS ● on previous testing, had IGT or IFG ● have other clinical conditions associated with insulin resistance (acanthosis nigricans) ● have a history of vascular disease

*May not be correct for all ethnic groups. PCOS, polycystic ovary syndrome.

Table 4—*Testing for type 2 diabetes in 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 (Native American, African American, Latino, Asian American, Pacific Islander)
- Signs of insulin resistance or conditions associated with insulin resistance (acanthosis nigricans, hypertension, dyslipidemia, or PCOS)

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

Clinical judgment should be used to test for for diabetes in high-risk patients who do not meet these criteria. PCOS, polycystic ovary syndrome.

els. Because of the acute onset of symptoms, most cases of type 1 diabetes are detected soon after symptoms develop. Widespread clinical testing of asymptomatic individuals for the presence of autoantibodies related to type 1 diabetes cannot be recommended at this time as a means to identify individuals at risk. Reasons for this include the following: *1*) cutoff values for some of the immune marker assays have not been completely established in clinical settings; *2*) there is no consensus as to what action should be taken when a positive autoantibody test result is obtained; and *3*) because the incidence of type 1 diabetes is low, testing of healthy children will identify only a very small number (<0.5%) who at that moment may be "pre-diabetic." Clinical studies are being conducted to test various methods of preventing type 1 diabetes in high-risk individuals (e.g., siblings of type 1 diabetic patients). These studies may uncover an effective means of preventing type 1 diabetes, in which case targeted screening may be appropriate in the future.

Type 2 diabetes

Type 2 diabetes is frequently not diagnosed until complications appear, and approximately one-third of all people with diabetes may be undiagnosed. Individuals at high risk should be screened for diabetes and pre-diabetes. Criteria for testing for diabetes in asymptomatic, undiagnosed adults are listed in Table 3. The effectiveness of early diagnosis through screening of asymptomatic individuals has not been determined (6).

Screening should be carried out within the health care setting. Either an FPG test or 2-h OGTT (75-g glucose load) is appropriate. The 2-h OGTT identifies people with IGT, and thus more people who at increased risk for the development of diabetes and CVD. It should be noted that the two tests do not necessarily detect the same individuals (7). The FPG test is more convenient to patients, more reproducible, less costly, and easier to administer than the 2-h OGTT (4,5). Therefore, the recommended initial screening test for nonpregnant adults is the FPG.

The incidence of type 2 diabetes in children and adolescents has increased dramatically in the last decade. Consistent with screening recommendations for adults, only children and youth at increased risk for the presence or the development of type 2 diabetes should be tested (8) (Table 4).

The effectiveness of screening may also depend on the setting in which it is performed. In general, community screening, outside a health care setting, may be less effective because of the failure of people with a positive screening test to seek and obtain appropriate follow-up testing and care or, conversely, to ensure appropriate repeat testing for individuals who screen negative. That is, screening outside of clinical settings may yield abnormal tests that are never discussed with a primary care provider, low compliance with treatment recommendations, and a very uncertain impact on long-term health. 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 (9,10).

On the basis of expert opinion, screening should be considered by health care providers at 3-year intervals beginning at age 45 years, particularly in those with BMI ≥25 kg/m^2. The rationale for this interval is that false negatives will be repeated before substantial time elapses, and there is little likelihood of an individual developing any of the complications of diabetes to a significant degree within 3 years of a negative screening test result. Testing should be considered at a younger age or be carried out more frequently in individuals who are overweight and have one or more of the other risk factors for type 2 diabetes.

Recommendations

- Screening to detect pre-diabetes (IFG or IGT) and diabetes should be considered in individuals ≥45 years of age, particularly in those with a BMI ≥25 kg/m^2. Screening should also be con-

sidered for people who are <45 years of age and are overweight if they have another risk factor for diabetes (Table 3). Repeat testing should be carried out at 3-year intervals. (E)
- Screen for pre-diabetes and diabetes in high-risk, asymptomatic, undiagnosed adults and children within the health care setting. (E)
- Either an FPG test or 2-h OGTT (75-g glucose load) is appropriate (B)
- The FPG is the preferred test to screen for pre-diabetes and diabetes. The OGTT may also be used to screen for pre-diabetes or diabetes in high-risk adults. (E)

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

Risk assessment for GDM should be undertaken at the first prenatal visit. Women with clinical characteristics consistent with a high risk for GDM (those with marked obesity, personal history of GDM, glycosuria, or a strong family history of diabetes) should undergo glucose testing as soon as possible (11). An FPG ≥126 mg/dl or a casual plasma glucose ≥200 mg/dl meets the threshold for the diagnosis of diabetes and needs to be confirmed on a subsequent day unless unequivocal symptoms of hyperglycemia are present. 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. Testing should follow one of two approaches:

- One-step approach: perform a diagnostic 100-g OGTT
- 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 100-g 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 identifies ~80% of women with GDM, and the yield is further increased to 90% by using a cutoff of ≥130 mg/dl.

Diagnostic criteria for the 100-g OGTT are as follows: ≥95 mg/dl fasting, ≥180 mg/dl at 1 h, ≥155 mg/dl at 2 h, and ≥140 mg/dl at 3 h. Two or more of the plasma glucose values must be met or exceeded for a positive diagnosis. The test should be done in the morning after an overnight fast of 8–14 h. The diagnosis can be made using a 75-g glucose load, but that test is not as well validated for detection of at-risk infants or mothers as the 100-g OGTT.

Low-risk status requires no glucose testing, but this category is limited to those women meeting all of the following characteristics:

- Age <25 years.
- Weight normal before pregnancy.
- Member of an ethnic group with a low prevalence of GDM.
- No known diabetes in first-degree relatives.
- No history of abnormal glucose tolerance.
- No history of poor obstetric outcome.

Recommendations

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

IV. PREVENTION/DELAY OF TYPE 2 DIABETES

Studies have been initiated in the last decade to determine the feasibility and benefit of various strategies to prevent or delay the onset of type 2 diabetes. Five well-designed randomized controlled trials have been reported (12–16). The strategies shown to be effective in preventing diabetes relied on lifestyle modification or glucose-lowering drugs that have been approved for treating diabetes.

In the Finnish study (12), middle-aged obese subjects with IGT were randomized to receive either brief diet and exercise counseling (control group) or intensive individualized instruction on weight reduction, food intake, and guidance on increasing physical activity (intervention group). After an average follow-up of 3.2 years, there was a 58% relative reduction in the incidence of diabetes in the intervention group compared with the control subjects.

In the Diabetes Prevention Program (DPP) (13), enrolled subjects were slightly younger and more obese but had nearly identical glucose intolerance compared with subjects in the Finnish study. About 45% of the participants were from minority groups (e.g., African American, Hispanic), and 20% were ≥60 years of age. Subjects were randomized to one of three intervention groups, which included the intensive nutrition and exercise counseling ("lifestyle") group or either of two masked medication treatment groups: the biguanide metformin group or the placebo group. The latter interventions were combined with standard diet and exercise recommendations. After an average follow-up of 2.8 years, a 58% relative reduction in the progression to diabetes was observed in the lifestyle group, and a 31% relative reduction in the progression of diabetes was observed in the metformin group compared with control subjects. On average, 50% of the lifestyle group achieved the goal of ≥7% weight reduction, and 74% maintained at least 150 min/week of moderately intense activity.

In the Da Qing Study (16), men and women from health care clinics in the city of Da Qing, China, were screened with OGTT, and those with IGT were randomized by clinic to a control group or to one of three active treatment groups: diet only, exercise only, or diet plus exercise. Subjects were reexamined biannually, and after an average of 6 years follow-up the diet, exercise, and diet-plus-exercise interventions were associated with 31, 46, and 42% reductions in risk of developing type 2 diabetes, respectively.

Two other studies, each using a different class of glucose-lowering agent, have shown a reduction in progression to diabetes with pharmacological intervention. In the Troglitazone in Prevention of Diabetes (TRIPOD) study (14), Hispanic women with previous GDM were randomized to receive either placebo or troglitazone (a drug now withdrawn from commercial sale in the U.S. but belonging to the thiazolidinedione class). After a median follow-up of 30 months, troglitazone treatment was associated with a 56% relative reduction in progression to diabetes. In the STOP-NIDDM trial (15), participants with IGT were randomized in a double-blind fashion to receive either the α-glucosidase inhibitor acarbose or a placebo. After a mean follow-up of 3.3 years, a 25% relative risk reduction in progression to diabetes, based on one OGTT, was

observed in the acarbose-treated group compared with the placebo group. If this diagnosis was confirmed by a second OGTT, a 36% relative risk reduction was observed in the acarbose group compared with the placebo group.

Our knowledge of the early stages of hyperglycemia that portend the diagnosis of diabetes, and the recent success of major intervention trials, clearly show that individuals at high risk can be identified and diabetes delayed, if not prevented. The cost-effectiveness of intervention strategies is unclear, but the huge burden resulting from the complications of diabetes and the potential ancillary benefits of some of the interventions suggest that an effort to prevent diabetes is worthwhile.

Lifestyle modification

In well-controlled studies that included a lifestyle intervention arm, substantial efforts were necessary to achieve only modest changes in weight and exercise, but those changes were sufficient to achieve an important reduction in the incidence of diabetes. In the Finnish Diabetes Prevention Study, weight loss averaged 9.2 lb at 1 year, 7.7 lb after 2 years, and 4.6 lb after 5 years (12); "moderate exercise," such as brisk walking, for 30 min/day was suggested. In the Finnish study, there was a direct relationship between adherence with the lifestyle intervention and the reduced incidence of diabetes.

In the DPP (13), the lifestyle group lost ~12 lb at 2 years and 9 lb at 3 years (mean weight loss for the study duration was ~12 lb or 6% of initial body weight). In both of these studies, most of the participants were obese (BMI >30 kg/m^2).

A low-fat (<25% fat) intake was recommended; if reducing fat did not produce weight loss to goal, calorie restriction was also recommended. Participants weighing 120–174 lb (54–78 kg) at baseline were instructed to follow a 1,200-kcal/day diet (33 g fat); participants weighing 175–219 lb (79–99 kg) were instructed to follow a 1,500-kcal/day diet (42 g fat); those 220–249 lb (100–113 kg) were instructed to follow an 1,800-kcal/day diet (50 g fat); and those >250 lb (114 kg) were instructed to follow a 2000-kcal/day diet (55 g fat).

Pharmacological interventions

Three diabetes prevention trials used pharmacological therapy, and all have reported a significant lowering of the incidence of diabetes. The biguanide metformin reduced the risk of diabetes by 31% in the DPP (13), the α-glucosidase inhibitor acarbose reduced the risk by 32% in the STOP-NIDDM trial (15), and the thiazolidinedione troglitazone reduced the risk by 56% in the TRIPOD study (14).

In the DPP, metformin was about half as effective as diet and exercise in delaying the onset of diabetes overall, but it was nearly ineffective in older individuals (≥60 years of age) or in those who were less overweight (BMI <30 kg/m^2). Conversely, metformin was as effective as lifestyle modification in individuals aged 24–44 years or in those with a BMI ≥35 kg/m^2. Thus, the population of people in whom treatment with metformin has equal benefit to that of a lifestyle intervention is only a small subset of those who are likely to have pre-diabetes (IFG or IGT).

There are also data to suggest that blockade of the rennin-angiotensin system (17) may lower the risk of developing diabetes, but more studies are necessary before these drugs can be recommended for preventing diabetes.

Lifestyle or medication?

The DPP is the only study in which a comparison of the two was made, and lifestyle modification was nearly twice as effective in preventing diabetes (58 vs. 31% relative reductions, respectively). The greater benefit of weight loss and physical activity strongly suggests that lifestyle modification should be the first choice to prevent or delay diabetes. Modest weight loss (5–10% of body weight) and modest physical activity (30 min daily) are the recommended goals. Because this intervention not only has been shown to prevent or delay diabetes, but also has a variety of other benefits, health care providers should urge all overweight or sedentary individuals to adopt these changes, and such recommendations should be made at every opportunity.

When all factors are considered, there is insufficient evidence to support the use of drug therapy as a substitute for, or routinely used in addition to, lifestyle modification to prevent diabetes. Public health messages, health care professionals, and health care systems should all encourage behavior changes to achieve a healthy lifestyle. Further research is necessary to understand better how to facilitate effective and efficient programs for the primary prevention of type 2 diabetes.

Recommendations

- Individuals at high risk for developing diabetes need to become aware of the benefits of modest weight loss and participating in regular physical activity. (A)
- Patients with IGT should be given counseling on weight loss as well as instruction for increasing physical activity. (A)
- Patients with IFG should be given counseling on weight loss as well as instruction for increasing physical activity. (E)
- Follow-up counseling appears important for success. (B)
- Monitoring for the development of diabetes should be performed every 1–2 years. (E)
- Close attention should be given to, and appropriate treatment given for, other CVD risk factors (e.g., tobacco use, hypertension, dyslipidemia). (A)
- Drug therapy should not be routinely used to prevent diabetes until more information is known about its cost-effectiveness. (E)

V. DIABETES CARE

A. Initial evaluation

A complete medical evaluation should be performed to classify the patient, detect the presence or absence of diabetes complications, assist in formulating a management plan, and provide a basis for continuing care. If the diagnosis of diabetes has already been made, the evaluation should review the previous treatment and the past and present degrees of glycemic control. Laboratory tests appropriate to the evaluation of each patient's general medical condition should be performed. A focus on the components of comprehensive care (Table 5) 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

Table 5—*Components of the comprehensive diabetes evaluation*

Medical history
- Symptoms, results of laboratory tests, and special examination results related to the diagnosis of diabetes
- Prior A1C records
- Eating patterns, nutritional status, and weight history; growth and development in children and adolescents
- Details of previous treatment programs, including nutrition and diabetes self-management education, attitudes, and health beliefs
- Current treatment of diabetes, including medications, meal plan, and results of glucose monitoring and patients' use of data
- Exercise history
- Frequency, severity, and cause of acute complications such as ketoacidosis and hypoglycemia
- Prior or current infections, particularly skin, foot, dental, and genitourinary infections
- Symptoms and treatment of chronic eye; kidney; nerve; genitourinary (including sexual), bladder, and gastrointestinal function (including symptoms of celiac disease in type 1 diabetic patients); heart; peripheral vascular; foot; and cerebrovascular complications associated with diabetes
- Other medications that may affect blood glucose levels
- Risk factors for atherosclerosis: smoking, hypertension, obesity, dyslipidemia, and family history
- History and treatment of other conditions, including endocrine and eating disorders
- Assessment for mood disorder
- Family history of diabetes and other endocrine disorders
- Lifestyle, cultural, psychosocial, educational, and economic factors that might influence the management of diabetes
- Tobacco, alcohol, and/or controlled substance use
- Contraception and reproductive and sexual history

Physical examination
- Height and weight measurement (and comparison to norms in children and adolescents)
- Sexual maturation staging (during pubertal period)
- Blood pressure determination, including orthostatic measurements when indicated, and comparison to age-related norms
- Fundoscopic examination
- Oral examination
- Thyroid palpation
- Cardiac examination
- Abdominal examination (e.g., for hepatomegaly)
- Evaluation of pulses by palpation and with auscultation
- Hand/finger examination
- Foot examination
- Skin examination (for acanthosis nigricans and insulin-injection sites)
- Neurological examination
- Signs of diseases that can cause secondary diabetes (e.g., hemochromatosis, pancreatic disease)

Laboratory evaluation
- A1C
- Fasting lipid profile, including total cholesterol, HDL cholesterol, triglycerides, and LDL cholesterol
- Test for microalbuminuria in type 1 diabetic patients who have had diabetes for at least 5 years and in all patients with type 2 diabetes; some advocate beginning screening of pubertal children before 5 years of diabetes
- Serum creatinine in adults (in children if proteinuria is present)
- Thyroid-stimulating hormone in all type 1 diabetic patients; in type 2 if clinically indicated
- Electrocardiogram in adults, if clinically indicated
- Urinalysis for ketones, protein, sediment

Referrals
- Eye exam, if indicated
- Family planning for women of reproductive age
- MNT, as indicated
- Diabetes educator, if not provided by physician or practice staff
- Behavioral specialist, as indicated
- Foot specialist, as indicated
- Other specialties and services as appropriate

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. 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,

Table 6—*Summary of recommendations for adults with diabetes*

Glycemic control	
A1C	<7.0%*
Preprandial capillary plasma glucose	90–130 mg/dl (5.0–7.2 mmol/l)
Peak postprandial capillary plasma glucose†	<180 mg/dl (<10.0 mmol/l)
Blood pressure	<130/80 mmHg
Lipids‡	
LDL	<100 mg/dl (<2.6 mmol/l)
Triglycerides	<150 mg/dl (<1.7 mmol/l)
HDL	>40 mg/dl (>1.1 mmol/l)§

Key concepts in setting glycemic goals:
- A1C is the primary target for glycemic control
- Goals should be individualized
- Certain populations (children, pregnant women, and elderly) require special considerations
- Less intensive glycemic goals may be indicated in patients with severe or frequent hypoglycemia
- More stringent glycemic goals (i.e. a normal A1C, <6%) may further reduce complications at the cost of increased risk of hypoglycemia (particularly in those with type 1 diabetes)
- 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. ‡Current NCEP/ATP III guidelines suggest that in patients with triglycerides ≥200 mg/dl, the "non-HDL cholesterol" (total cholesterol minus HDL) be used. The goal is ≤130 mg/dl (31). §For women, it has been suggested that the HDL goal be increased by 10 mg/dl.

and presence of complications of diabetes or other medical conditions. 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.

C. Glycemic control

1. Assessment of glycemic control. Techniques are available for health providers and patients to assess the effectiveness of the management plan on glycemic control.

a. *Self-monitoring of blood glucose*. The ADA's consensus statements on self-monitoring of blood glucose (SMBG) provide a comprehensive review of the subject (18,19). Major clinical trials assessing the impact of 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, medical nutrition therapy (MNT), and physical activity.

The frequency and timing of SMBG should be dictated by the particular needs and goals of the patients. Daily 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. The optimal frequency and timing of SMBG for patients with type 2 diabetes on oral agent therapy is not known but should be sufficient to facilitate reaching glucose goals. Patients with type 2 diabetes on insulin typically need to perform SMBG more frequently than those not using insulin. When adding to or modifying therapy, type 1 and type 2 diabetic patients should test more often than usual. The role of SMBG in stable diet-treated patients with type 2 diabetes is not known.

Because the accuracy of SMBG is instrument- and user-dependent (20), it is important for health care providers to evaluate each patient's monitoring technique, both initially and at regular intervals thereafter. In addition, optimal use of SMBG requires proper interpretation 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. Health professionals should evaluate at regular intervals the patient's ability to use SMBG data to guide treatment.

Recommendations

- Clinical trials using insulin that have demonstrated the value of tight glycemic control have used SMBG as an integral part of the management strategy. (A)
- SMBG should be carried out three or more times daily for patients using multiple insulin injections. (A)
- For patients using less frequent insulin injections or oral agents or MNT alone, SMBG is useful in achieving glycemic goals. (E)
- To achieve postprandial glucose targets, postprandial SMBG may be appropriate. (E)
- Instruct the patient in SMBG and routinely evaluate the patient's technique and ability to use data to adjust therapy. (E)

b. *A1C*. By performing an A1C test, health providers can measure a patient's average glycemia over the preceding 2–3 months (20) and, thus, assess treatment efficacy. A1C testing should be performed routinely in all patients with diabetes, first to document the degree of glycemic control at initial assessment and then as part of continuing care. Since the A1C test reflects mean glycemia over the preceding 2–3 months, measurement approximately every 3 months is required to determine whether a patient's metabolic control has been reached and maintained within the target range. Thus, regular performance of the A1C test permits detection of departures from the target (Table 6) in a timely fashion. For any individual patient, the frequency of A1C testing

Table 7—*Correlation between A1C level and mean plasma glucose levels on multiple testing over 2–3 months (21)*

	Mean plasma glucose	
A1C (%)	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

should be dependent on the clinical situation, the treatment regimen used, and the judgment of the clinician.

Glycemic control is best judged by the combination of the results of the patient's SMBG testing (as performed) and the current A1C result. The A1C should be used not only to assess the patient's control over the preceding 2–3 months but also as a check on the accuracy of the meter (or the patient's self-reported results) and the adequacy of the SMBG testing schedule. Table 7 contains the correlation between A1C levels and mean plasma glucose levels based on data from the Diabetes Control and Complications Trial (DCCT) (21).

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)

2. Glycemic goals. Glycemic control is fundamental to the management of diabetes. Prospective randomized clinical trials such as the DCCT (22) and the U.K. Prospective Diabetes Study (UKPDS) (23,24) have shown that improved glycemic control is associated with sustained decreased rates of retinopathy, nephropathy, and neuropathy (25). In these 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 and weight gain (26,27). The potential of intensive glycemic control to reduce CVD is supported by epidemiological studies (22–27) and a recent meta-analysis (28), but this potential benefit on CVD events has not yet been demonstrated in a randomized clinical trial.

Recommended glycemic goals for nonpregnant individuals are shown in Table 6. A major limitation to the available data are that they do not identify the optimum level of control for particular patients, as there are individual differences in the risks of hypoglycemia, weight gain, and other adverse effects. Furthermore, with multifactorial interventions, it is unclear how different components (e.g., educational interventions, glycemic targets, lifestyle changes, and pharmacological agents) contribute to the reduction of complications. There are no clinical trial data available for the effects of glycemic control in patients with advanced complications, the elderly (≥65 years of age), or young children (<13 years of age). Less stringent treatment goals may be appropriate for patients with limited life expectancies, in the very young or older adults, and in individuals with comorbid conditions. Severe or frequent hypoglycemia is an indication for the modification of treatment regimens, including setting higher glycemic goals.

More stringent goals (i.e., a normal A1C, <6%) can be considered in individual patients based on epidemiological analyses that suggest that there is no lower limit of A1C at which further lowering does not reduce the risk of complications, at the risk of increased hypoglycemia (particularly in those with type 1 diabetes). However, the absolute risks and benefits of lower targets are unknown. The risks and benefits of an A1C goal of <6% are currently being tested in an ongoing study (ACCORD [Action to Control Cardiovascular Risk in Diabetes]) in type 2 diabetes.

Elevated postchallenge (2-h OGTT) glucose values have been associated with increased cardiovascular risk independent of FPG in some epidemiological studies. Postprandial plasma glucose (PPG) levels >140 mg/dl are unusual in nondiabetic individuals, although large evening meals can be followed by plasma glucose values up to 180 mg/dl. There are now pharmacological agents that primarily modify PPG and thereby reduce A1C in parallel. Thus, in individuals who have premeal glucose values within target but who are not meeting A1C targets, consideration of monitoring PPG 1–2 h after the start of the meal and treatment aimed at reducing PPG values <180 mg/dl may lower A1C. However, it should be noted that the effect of these approaches on micro- or macrovascular complications has not been studied (29).

For information on glycemic control for women with GDM, refer to the ADA position statement "Gestational Diabetes Mellitus" (11). For information on glycemic control during pregnancy in women with preexisting diabetes, refer to *Medical Management of Pregnancy Complicated by Diabetes* (3rd ed.) (30).

Recommendations

- Lowering A1C has been associated with a reduction of microvascular and neuropathic complications of diabetes. (A)
- Develop or adjust the management plan to achieve normal or near-normal glycemia with an A1C goal of <7%. (B)
- More stringent goals (i.e., a normal A1C, <6%) can be considered in individual patients and in pregnancy. (B)
- A lower A1C is associated with a lower risk of myocardial infarction and cardiovascular death. (B)
- Aggressive glycemic management with insulin may reduce morbidity in patients with severe acute illness, perioperatively, following myocardial infarction and in pregnancy. (B)
- Less stringent treatment goals may be appropriate for patients with a history of severe hypoglycemia, patients with limited life expectancies, very young children or older adults, and individuals with comorbid conditions. (E)

D. MNT

MNT is an integral component of diabetes management and DSME. A review of the evidence and detailed information can be found in the ADA technical review and position statement in this area (32,33). People with diabetes should receive individualized MNT as needed to achieve treatment goals, preferably provided by a registered dietitian familiar with the components of diabetes MNT. Goals of MNT that apply to all individuals with diabetes are as follows:

- Attain and maintain recommended metabolic outcomes, including glucose and A1C levels, LDL cholesterol, HDL cholesterol, triglyceride levels, blood pressure, and body weight (Table 6).

- Prevent and treat the chronic complications and comorbidities of diabetes. Modify nutrient intake and lifestyle as appropriate for the prevention and treatment of obesity, dyslipidemia CVD, hypertension, and nephropathy.
- Improve health through healthy food choices and physical activity.
- Address individual nutritional needs, taking into consideration personal and cultural preferences and lifestyle, while respecting the individual's wishes and willingness to change.

Goals of MNT that apply to specific situations include the following:

- For youth with type 1 diabetes (34), provide adequate energy to ensure normal growth and development; integrate insulin regimens into usual eating and physical activity habits.
- For youth with type 2 diabetes, who are often overweight/obese, facilitate appropriate changes in eating and physical activity habits.
- For pregnant and lactating women, provide adequate energy and nutrients needed for optimal outcomes. In pregnancy, counting and recording carbohydrate intake contributes to optimal glycemic control.
- For older adults, provide for the nutritional and psychosocial needs of an aging individual.
- For individuals treated with insulin or insulin secretagogues, provide self-management education for treatment (and prevention) of hypoglycemia, acute illnesses, and exercise-related blood glucose problems.
- For individuals at risk for diabetes, decrease risk by encouraging physical activity and promoting foods choices that facilitate moderate weight loss or at least prevent weight gain.

Achieving nutrition-related goals requires a coordinated team effort that includes the person with diabetes. Because of the complexity of nutrition issues, it is recommended that a registered dietitian, knowledgeable and skilled in implementing nutrition therapy into diabetes management and education, is the team member who provides MNT. However, it is essential that all team members are knowledgeable about nutrition therapy and are supportive of the person with diabetes who needs to make lifestyle changes.

MNT involves a nutrition assessment to evaluate the patient's food intake, metabolic status, lifestyle and readiness to make changes, goal setting, dietary instruction, and evaluation. To facilitate adherence, the plan should be individualized and take into account cultural, lifestyle, and financial considerations. Monitoring of glucose and A1C, lipids, blood pressure, and renal status is essential to evaluate nutrition-related outcomes. If goals are not met (Table 6), changes must be made in the overall diabetes care and management plan.

Dietary carbohydrate (35). Regulation of blood glucose to achieve near normal levels is a primary goal in the management of diabetes, and thus, dietary techniques that limit hyperglycemia following a meal are important in limiting the complications of diabetes. Both the amount (grams) of carbohydrate as well as the type of carbohydrate in a food influence blood glucose level. The total amount of carbohydrate consumed is a strong predictor of glycemic response, and thus, monitoring total grams of carbohydrate, whether by use of exchanges or carbohydrate counting, remains a key strategy in achieving glycemic control. A recent analysis of the randomized, controlled trials that have examined the efficacy of the glycemic index (a measure of the effect of type of carbohydrate) on overall blood glucose control indicates that the use of this technique can provide an additional benefit over that observed when total carbohydrate is considered alone.

Low carbohydrate diets are not recommended in the management of diabetes. Although dietary carbohydrate is the major contributor to postprandial glucose concentration, it is an important source of energy, water soluble vitamins and minerals, and fiber. Thus, in agreement with the National Academy of Sciences-Food and Nutrition Board, a recommended range of carbohydrate intake is 45–65% of total calories. In addition, because the brain and central nervous system have an absolute requirement for glucose as an energy source, restricting total carbohydrate to <130 g/day is not recommended.

Weight management (36). Overweight and obesity are strongly linked to the development of type 2 diabetes and can complicate its management. Obesity is also an independent risk factor for hypertension and dyslipidemia as well as CVD, which is the major cause of death in those with diabetes. Moderate weight loss improves glycemic control, reduces CVD risk, and can prevent the development of type 2 diabetes in those with pre-diabetes. Therefore, weight loss is an important therapeutic strategy in all overweight or obese individuals who have type 2 diabetes or are at risk for developing diabetes. The primary approach for achieving weight loss, in the vast majority of cases, is therapeutic lifestyle change, which includes a reduction in energy intake and an increase in physical activity. A moderate decrease in caloric balance (500–1,000 kcal/day) will result in a slow but progressive weight loss (1–2 lb/week). For most patients, weight loss diets should supply at least 1,000–1,200 kcal/day for women and 1,200–1,600 kcal/day for men.

Physical activity is an important component of a comprehensive weight management program. Regular, moderate intensity, physical activity enhances long-term weight maintenance. Regular activity also improves insulin sensitivity, glycemic control, and selected risk factors for CVD (i.e., hypertension and dyslipidemia), and increased aerobic fitness decreases the risk of coronary heart disease (CHD). Initial physical activity recommendations should be modest, based on the patient's willingness and ability, gradually increasing the duration and frequency to 30–45 min of moderate aerobic activity 3–5 days per week, when possible. Greater activity levels of at least 1 h/day of moderate (walking) or 30 min/day of vigorous (jogging) activity may be needed to achieve successful long-term weight loss.

Recommendations

- People with 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)
- Both the amount (grams) of carbohydrate as well as the type of carbohydrate in a food influence blood glucose level. Monitoring total grams of carbohydrate, whether by use of exchanges or carbohydrate counting, remains a key strategy in achieving glycemic control. The use of the glycemic index/glycemic load can provide an additional benefit over that observed when total carbohydrate is considered alone. (B)
- Low carbohydrate diets (restricting total carbohydrate to <130 g/day) are not

recommended in the management of diabetes. (E)
- Weight loss is recommended for all overweight (BMI 25.0–29.9 kg/m^2) or obese (BMI ≥30.0 kg/m^2) adults, who have, or who are at risk for developing, type 2 diabetes. (E)
- The primary approach for achieving weight loss is therapeutic lifestyle change, which includes a reduction in energy intake and/or an increase in physical activity. A moderate decrease in caloric balance (500–1,000 kcal/day) will result in a slow but progressive weight loss (1–2 lb/week). For most patients, weight loss diets should supply at least 1,000–1,200 kcal/day for women and 1,200–1,600 kcal/day for men. (E)
- Initial physical activity recommendations should be modest, based on the patient's willingness and ability, gradually increasing the duration and frequency to 30–45 min of moderate aerobic activity 3–5 days per week, when possible. Greater activity levels of at least 1 h/day of moderate (walking) or 30 min/day of vigorous (jogging) activity may be needed to achieve successful long-term weight loss. (E)

E. Physical activity

ADA technical reviews on exercise in patients with diabetes have summarized the value of exercise in the diabetes management plan (37,38). 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 (12,13,16) .

Before beginning a physical activity program, the patient with diabetes should have a detailed medical evaluation with appropriate diagnostic studies. This examination should screen for the presence of macro- and microvascular complications that may be worsened by the physical activity program (see next section regarding CHD screening). Identification of areas of concern will allow the design of an individualized physical activity plan that can minimize risk to the patient.

All levels of physical activity, including leisure activities, recreational sports, and competitive professional performance, can be performed by people with diabetes who do not have complications and have good glycemic control. The ability to adjust the therapeutic regimen (insulin therapy and MNT) to allow safe participation is an important management strategy.

Recommendations
- A regular physical activity program, adapted to the presence of complications, is recommended for all patients with diabetes who are capable of participating. (B)

F. Psychosocial assessment and care

Psychological and social state can impact the patient's ability to carry out diabetes care tasks (39–44). As a result, health status may be compromised. Family conflict around diabetes care tasks is also common and may interfere with treatment outcomes (45). 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 (46).

Key opportunities for screening of psychosocial status occur at diagnosis, during regularly scheduled management visits, during hospitalizations, at discovery of complications, or at the discretion of the clinician when problems in glucose control, quality of life, or adherence are identified (47). Patients are likely to exhibit psychological vulnerability at diagnosis and when their medical status changes: the end of the honeymoon period, when the need for intensified treatment is evident and when complications are discovered (42,44).

Psychosocial screening 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), (43) and psychiatric history (44,47,48). Particular attention needs to be paid to gross noncompliance with medical regimen (due to self or others) (39,48), depression with the possibility of self-harm (40,41), indications of an eating disorder (49) or a problem that appears to be organic in origin, and cognitive functioning that significantly impairs judgment (41). In these cases, immediate referral for further evaluation by a mental health specialist familiar with diabetes management should occur. Behavioral assessment of management skills is also recommended.

It is preferable to incorporate psychological treatment into routine care rather than waiting for identification of a specific problem or deterioration in psychological status (46). Screening tools can facilitate this goal, and 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 wellbeing is part of diabetes management (47).

Recommendations
- Preliminary assessment of psychological and social status should be included as part of the medical management of diabetes. (E)
- Psychosocial screening 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)
- Screening for psychosocial problems such as depression, eating disorders, and cognitive impairment is needed when adherence to the medical regimen is poor. (E)
- It is preferable to incorporate psychological treatment into routine care rather than to wait for identification of a specific problem or deterioration in psychological status. (E)

G. Referral for diabetes management

For a variety of reasons, some people with diabetes and their health care providers do not achieve the desired goals of treatment (Table 6). Intensification of the treatment regimen is suggested and includes identification (or assessment) of barriers to adherence, culturally appropriate and enhanced DSME, comanagement with a diabetes team, change in pharmacological therapy, initiation of or increase in SMBG, more frequent contact with the patient, and referral to an endocrinologist.

H. Intercurrent illness

The stress of illness, trauma, and/or surgery frequently aggravates glycemic control and may precipitate diabetic ketoacidosis (DKA) or nonketotic hyperosmolar state. Any condition leading to deterioration in glycemic control necessitates more frequent monitoring of blood

glucose and urine or blood ketones. A vomiting illness accompanied by ketosis may indicate DKA, a life-threatening condition that requires immediate medical care to prevent complications and death; the possibility of DKA should always be considered (50). Marked hyperglycemia requires temporary adjustment of the treatment program and, if accompanied by ketosis, frequent interaction with the diabetes care team. The patient treated with oral glucose-lowering agents or MNT alone may temporarily require insulin. Adequate fluid and caloric intake must be assured. Infection or dehydration is more likely to necessitate hospitalization of the person with diabetes than the person without diabetes. The hospitalized patient should be treated by a physician with expertise in the management of diabetes, and recent studies suggest that achieving very stringent glycemic control may reduce mortality in the immediate postmyocardial infarction period (51). Aggressive glycemic management with insulin may reduce morbidity in patients with severe acute illness (52).

For information on management of patients in the hospital with DKA or nonketotic hyperosmolar state, refer to the ADA position statement titled "Hyperglycemic Crises in Diabetes" (50).

I. Immunization

Influenza and pneumonia are common, preventable infectious diseases associated with high mortality and morbidity in the elderly and in people with chronic diseases. 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. Based on a case-control series, influenza vaccine has been shown to reduce diabetes-related hospital admission by as much as 79% during flu epidemics (53). 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%.

Safe and effective vaccines are available that can greatly reduce the risk of serious complications from these diseases (54,55). There is sufficient evidence to support that people with diabetes have appropriate serologic and clinical responses to these vaccinations. The Centers for Disease Control's Advisory Committee on Immunization Practices recommends influenza and pneumococcal vaccines for all individuals >65 years of age as well as for all individuals of any age with diabetes.

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 (56,57).

Recommendations

- Annually provide an influenza vaccine to all diabetic patients 6 months of age or older. (C)
- Provide at least one lifetime pneumococcal vaccine for adults with diabetes. A one-time revaccination is recommended for individuals >64 years of age previously immunized when they were <65 years of age if the vaccine was administered >5 years ago. Other indications for repeat vaccination include nephrotic syndrome, chronic renal disease, and other immunocompromised states, such as after transplantation. (C)

VI. PREVENTION AND MANAGEMENT OF DIABETES COMPLICATIONS

A. CVD

CVD is the major cause of mortality for individuals with diabetes. It is also a major contributor to morbidity and direct and indirect costs of diabetes. Type 2 diabetes is an independent risk factor for macrovascular disease, and its common coexisting conditions (e.g., hypertension and dyslipidemia) are also risk factors.

Studies have shown the efficacy of reducing cardiovascular risk factors in preventing or slowing CVD. Evidence is summarized in the following sections and reviewed in detail in the ADA technical reviews on hypertension (58), dyslipidemia (59), aspirin therapy (60), and smoking cessation (61) and the consensus statement on CHD in people with diabetes (62). Emphasis should be placed on reducing cardiovascular risk factors, when possible, and clinicians should be alert for signs and symptoms of atherosclerosis.

1. Hypertension/blood pressure control. Hypertension (HTN) (blood pressure ≥140/90 mmHg) is a common comorbidity of diabetes, affecting the majority of people with diabetes, depending on type of diabetes, age, obesity, and ethnicity. HTN is also a major risk factor for CVD and microvascular complications such as retinopathy and nephropathy. In type 1 diabetes, HTN is often the result of underlying nephropathy. In type 2 diabetes, HTN may be present as part of the metabolic syndrome (i.e., obesity, hyperglycemia, and dyslipidemia) that is accompanied by high rates of CVD.

Randomized clinical trials have demonstrated the benefit (reduction of CHD events, stroke, and nephropathy) of lowering blood pressure to <130 mmHg systolic and <80 mmHg diastolic in individuals with diabetes (63–66). Epidemiologic analyses show that blood pressure >115/75 mmHg is associated with increased cardiovascular event rates and mortality in individuals with diabetes (63,67,68). Therefore, a target blood pressure goal of <130/80 mmHg is reasonable if it can be safely achieved.

Although there are no well-controlled studies of diet and exercise in the treatment of HTN in individuals with diabetes, reducing sodium intake and body weight (when indicated); increasing consumption of fruits, vegetables, and low-fat dairy products; avoiding excessive alcohol consumption; and increasing activity levels have been shown to be effective in reducing blood pressure in nondiabetic individuals (69). These nonpharmacological strategies may also positively affect glycemia and lipid control. Their effects on cardiovascular events have not been well measured.

Lowering of blood pressure with regimens based on antihypertensive drugs, including ACE inhibitors, angiotensin receptor blockers (ARBs), β-blockers, diuretics, and calcium channel blockers, has been shown to be effective in lowering cardiovascular events. Several studies suggest that ACE inhibitors may be superior to dihydropyridine calcium channel blockers (DCCBs) in reducing cardiovascular events (70,71). Additionally, in people with diabetic nephropathy indicate that ARBs may be superior to DCCBs for reducing cardiovascular events (72). Conversely, in the recently completed International Verapamil Study (INVEST) of >22,000 people with coronary artery dis-

ease (CAD) and hypertension, the non-DCCB, verapamil, demonstrated a similar reduction in cardiovascular mortality to a β-blocker. Moreover, this relationship held true in the diabetic subgroup (73).

ACE inhibitors have been shown to improve cardiovascular outcomes in high-cardiovascular-risk patients with or without HTN (74,75). In patients with congestive heart failure (CHF), ACE inhibitors are associated with better outcomes when compared with ARBs. In one study an ARB was superior to a β-blocker as a therapy to improve cardiovascular outcomes in a subset of diabetic patients with HTN and left ventricular hypertrophy (76). The compelling effect of ACE inhibitors or ARBs in patients with albuminuria or renal insufficiency provide additional rationale for use of these agents (see section VI B. below).

The ALLHAT (Antihypertensive and Lipid-Lowering Treatment to Prevent Heart Attack Trial), a large randomized trial of different initial blood pressure pharmacological therapies, found no large differences between initial therapy with a chlorthalidone, amlodipine, and lisinopril. Diuretics appeared slightly more effective than other agents, particularly for reducing heart failure (77). The α-blocker arm of the ALLHAT was terminated after interim analysis showed that doxazosin was substantially less effective in reducing CHF than diuretic therapy (78).

Before beginning treatment, patients with elevated blood pressures should have their blood pressure reexamined within 1 month to confirm the presence of HTN. Systolic blood pressure ≥160 mmHg or diastolic blood pressure ≥100 mmHg, however, mandates that immediate pharmacological therapy be initiated. Patients with HTN should be seen as often as needed until the recommended blood pressure goal is obtained and then seen as necessary (63). In these patients, other cardiovascular risk factors, including obesity, hyperlipidemia, smoking, presence of microalbuminuria (assessed before initiation of treatment), and glycemic control, should be carefully assessed and treated. Many patients will require three or more drugs to reach target goals.

During pregnancy in diabetic women with chronic HTN, target blood pressure goals of systolic blood pressure 110–129 mmHg and diastolic blood pressure 65–79 mmHg are reasonable as they may 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.

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. (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 hypertension (systolic blood pressure ≥140 mmHg or diastolic blood pressure ≥90 mmHg) should receive drug therapy in addition to lifestyle and behavioral therapy. (A)
- Multiple drug therapy (two or more agents at proper doses) is generally required to achieve blood pressure targets. (B)
- Patients with a systolic blood pressure of 130–139 mmHg or a diastolic blood pressure of 80–89 mmHg should be given lifestyle and behavioral therapy alone for a maximum of 3 months and then, if targets are not achieved, in addition, be treated with pharmacological agents that block the renin-angiotensin system. (E)
- Initial drug therapy should be with a drug class demonstrated to reduce CVD events in patients with diabetes (ACE inhibitors, ARBs, β-blockers, diuretics, and calcium channel blockers). (A)
- All patients with diabetes and hypertension should be treated with a regimen that includes either an ACE inhibitor or an 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. (E)
- If ACE inhibitors, ARBs, or diuretics are used, monitor renal function and serum potassium levels. (E)
- 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, ACE inhibitors and ARBs have been shown to delay the progression to macroalbuminuria. (A)
  - In those with type 2 diabetes, hypertension, macroalbuminuria, and renal insufficiency, ARBs have been shown to delay the progression of nephropathy. (A)
- 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)
- In elderly hypertensive patients, blood pressure should be lowered gradually to avoid complications. (E)
- Patients not achieving target blood pressure despite multiple drug therapy should be referred to a physician experienced in the care of patients with hypertension. (E)
- Orthostatic measurement of blood pressure should be performed in people with diabetes and hypertension when clinically indicated. (E)

2. Dyslipidemia/lipid management. Patients with type 2 diabetes have an increased prevalence of lipid abnormalities that contributes to higher rates of CVD. Lipid management aimed at lowering LDL cholesterol, raising HDL cholesterol, and lowering triglycerides has been shown to reduce macrovascular disease and mortality in patients with type 2 diabetes, particularly those who have had prior cardiovascular events. In studies using HMG (hydroxymethylglutaryl) CoA reductase inhibitors (statins), patients

with diabetes achieved significant reductions in coronary and cerebrovascular events (79–82). In two studies using the fibric acid derivative gemfibrozil, reductions in cardiovascular end points were also achieved (83,84).

Target lipid levels are shown in Table 6. Lifestyle intervention including MNT, increased physical activity, weight loss, and smoking cessation should allow some patients to reach these lipid levels. 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 transunsaturated fat intake. Glycemic control can also beneficially modify plasma lipid levels. Particularly in patients with very high triglycerides and poor glycemic control, glucose lowering maybe necessary to control hypertriglyceridemia. Pharmacological treatment is indicated if there is an inadequate response to lifestyle modifications and improved glucose control. However, in patients with clinical CVD and LDL >100 mg/dl, pharmacological therapy should be initiated at the same time that lifestyle intervention is started. In patients with diabetes aged <40 years similar consideration for LDL lowering therapy should be given if they have increased cardiovascular risk (e.g., additional cardiovascular risk factors or long duration of diabetes). Very little clinical trial data exists in patients in this age-group.

The first priority of pharmacological therapy is to lower LDL cholesterol to a target goal of <100 mg/dl (2.60 mmol/l) or therapy to achieve a reduction in LDL of 30–40%. For LDL lowering, statins are the drugs of choice. Other drugs that lower LDL include nicotinic acid, ezetimbe, bile acid sequestrants, and fenofibrate (31,85).

The Heart Protection Study (82) demonstrated that in people with diabetes over the age of 40 years with a total cholesterol >135 mg/dl, LDL reduction of ~30% from baseline with the statin simvastatin was associated with an ~25% reduction in the first event rate for major coronary artery events independent of baseline LDL, preexisting vascular disease, type or duration of diabetes, or adequacy of glycemic control. Similarly in the Collaborative Atorvastatin Diabetes Study (CARDS) study (86), patients with type 2 diabetes randomized to atorvastatin 10 mg daily had a significant reduction in cardiovascular events including stroke.

Recent clinical trials in high-risk patients, such as those with acute coronary syndromes or previous cardiovascular events (87–89), have demonstrated that more aggressive therapy with high doses of statins to achieve an LDL of <70 mg/dl led to a significant reduction in further events. The risk of side effects with high doses of statins is significantly outweighed by the benefits of such therapy in these high-risk patients. Therefore a reduction in LDL to a goal of <70 mg/dl is an option in very-high-risk patients with overt CVD (85).

Relatively little data are available on lipid lowering therapy in subjects with type 1 diabetes. In the Heart Protection Study ~600 patients with type 1 diabetes had a proportionately similar, but not statistically significant, reduction in risk as in the patients with type 2 diabetes. Although the data are not definitive, consideration should be given to similar lipid-lowering therapy in patients with type 1 diabetes as in type 2 diabetes, particularly if they have other cardiovascular risk factors or features of the metabolic syndrome.

If the HDL is <40 mg/dl and the LDL is between 100 and 129 mg/dl, a fibric acid derivative or niacin might be used. Niacin is the most effective drug for raising HDL but can significantly increase blood glucose at high doses. More recent studies demonstrate that at modest doses (750–2,000 mg/day), significant benefit with regards to LDL, HDL, and triglyceride levels are accompanied by only modest changes in glucose that are generally amenable to adjustment of diabetes therapy (90,91).

Combination therapy, with a statin and a fibrate or statin and niacin, may be efficacious for patients needing 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 seems to be lower when statins are combined with fenofibrate than gemfibrozil. There is also a risk of a rise in plasma creatinine, particularly with fenofibrate. It is important to note that clinical trials with fibrates and niacin have demonstrated benefits in patients who were not on treatment with statins and that there is no data available on reduction of events with such combinations. The risks may be greater in patients who are treated with combinations of these drugs with high doses of statins.

Recommendations

Screening

- In adult patients, test for lipid disorders at least annually and more often if needed to achieve goals. In adults with low-risk lipid values (LDL <100 mg/dl, HDL >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 and cholesterol intake, weight loss (if indicated), and increased physical activity has been shown to improve the lipid profile in patients with diabetes. (A)
- In individuals with diabetes over the age of 40 years with a total cholesterol ≥135 mg/dl, without overt CVD, statin therapy to achieve an LDL reduction of 30 −40% regardless of baseline LDL levels is recommended. The primary goal is an LDL <100 mg/dl (2.6 mmol/l). (A)
- For individuals with diabetes aged <40 years without overt CVD, but at increased risk (due to other cardiovascular risk factors or long duration of diabetes), who do not achieve lipid goals with lifestyle modifications alone, the addition of pharmacological therapy is appropriate and the primary goal is an LDL cholesterol <100 mg/dl (2.6 mmol/l). (C)
- People with diabetes and overt CVD are at very high risk for further events and should be treated with a statin. (A)
- A lower LDL cholesterol goal of <70 mg/dl (1.8 mmol/l), using a high dose of a statin, is an option in these high risk patients with diabetes and overt CVD. (B)
- Lower triglycerides to <150 mg/dl (1.7 mmol/l) and raise HDL cholesterol to >40 mg/dl (1.15 mmol/l). In women, an HDL goal 10 mg/dl higher (>50 mg/dl) should be considered. (C)
- Lowering triglycerides and increasing HDL cholesterol with a fibrate is associated with a reduction in cardiovascular events in patients with clinical CVD, low HDL, and near-normal levels of LDL. (A)
- Combination therapy employing statins and fibrates or niacin may be nec-

essary to achieve lipid targets but has not been evaluated in outcomes studies for either CVD event reduction or safety. (E)
- Statin therapy is contraindicated in pregnancy. (E)

3. Anti-platelet agents. The use of aspirin in diabetes is reviewed in detail in the ADA technical review (60) and position statement (92) on aspirin therapy. Aspirin has been recommended as a primary (93,94) and secondary therapy to prevent cardiovascular events in 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 no evidence to support any specific dose, but using the lowest possible dosage may help reduce side effects. 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 rates in diabetic individuals (95). Adjunctive therapy in very high-risk patients or as alternative therapy in aspirin-intolerant patients should be considered.

Recommendations
- Use aspirin therapy (75–162 mg/day) as a secondary prevention strategy in those with diabetes with a history of myocardial infarction, vascular bypass procedure, stroke or transient ischemic attack, peripheral vascular disease, claudication, and/or angina. (A)
- Use aspirin therapy (75–162 mg/day) as a primary prevention strategy in those with 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)
- Use aspirin therapy (75–162 mg/day) as a primary prevention strategy in those with type 1 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). (C)
- People with aspirin allergy, bleeding tendency, receiving anticoagulant therapy, recent gastrointestinal bleeding, and clinically active hepatic disease are not candidates for aspirin therapy. Other anti-platelet agents may be a reasonable alternative for patients with high risk. (E)
- Aspirin therapy should not be recommended for patients under the age of 21 years because of the increased risk of Reye's syndrome associated with aspirin use in this population. People under the age of 30 years have not been studied. (E)

4. Smoking cessation. Issues of smoking in diabetes are reviewed in detail in the ADA technical review (61) and position statement (96) on smoking cessation. 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 morbidity and premature death associated with the development of macrovascular complications 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 counseling in changing smoking behavior. Such studies, combined with others specific to individuals with diabetes, suggest that smoking cessation counseling is effective in reducing tobacco use (97,98).

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.

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)

5. CHD screening and treatment. CHD screening and treatment are reviewed in detail in the ADA consensus statement on CHD in people with diabetes (62). To identify the presence of CHD in diabetic patients without clear or suggestive symptoms of CAD, a risk factor-based approach to the initial diagnostic evaluation and subsequent follow-up is recommended. A recent study concluded that using current guidelines fails to detect a significant percentage of patients with silent ischemia (99).

At least annually, cardiovascular risk factors should be assessed. These risk factors include dyslipidemia, hypertension, smoking, a positive family history of premature coronary disease, and the presence of micro- or macroalbuminuria. Abnormal risk factors should be treated as described elsewhere in these guidelines. Patients at increased CHD risk should receive aspirin and may warrant an ACE inhibitor.

Candidates for a diagnostic cardiac stress test include those with *1*) typical or atypical cardiac symptoms and *2*) an abnormal resting electrocardiogram (ECG). Candidates for a screening cardiac stress test include those with *1*) a history of peripheral or carotid occlusive disease; *2*) sedentary lifestyle, age >35 years, and plans to begin a vigorous exercise program; and *3*) two or more of the risk factors noted above.

Current evidence suggests that noninvasive tests can improve assessment of future CHD risk. There is, however, no current evidence that such testing in asymptomatic patients with risk factors improves outcomes or leads to better utilization of treatments (100).

Patients with abnormal exercise ECG and patients unable to perform an exercise ECG require additional or alternative testing. Currently, stress nuclear perfusion and stress echocardiography are valuable next-level diagnostic procedures. A consultation with a cardiolo-

gist is recommended regarding further work-up.

Recommendations

- In patients >55 years of age, with or without hypertension but with another cardiovascular risk factor (history of CVD, dyslipidemia, microalbuminuria, or smoking), an ACE inhibitor (if not contraindicated) should be considered to reduce the risk of cardiovascular events. (A)
- In patients with a prior myocardial infarction or in patients undergoing major surgery, β-blockers, in addition, should be considered to reduce mortality. (A)
- Refer patients with signs and symptoms of CVD or with positive noninvasive test for CAD to a cardiologist for further evaluation. (E)
- In asymptomatic patients consider a risk factor evaluation to stratify patients by 10-year risk and treat risk factors accordingly. (B)
- In asymptomatic patients consider screening for CAD based on the criteria outlined above. Such screening might include stress ECG and/or stress echocardiography and/or perfusion imaging. (E)
- In patients with treated CHF, metformin use is contraindicated. The thiazolidinediones are associated with fluid retention, and their use can be complicated by the development of CHF. Caution in prescribing thiazolidinediones in the setting of known CHF or other heart diseases as well as in patients with preexisting edema or concurrent insulin therapy is required. (C)

B. Nephropathy screening and treatment

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 (101,102).

Patients with microalbuminuria who progress to macroalbuminuria (≥300 mg/24 h) are likely to progress to ESRD over a period of years (103,104). Over the past several years, 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 (105,106) and type 2 diabetes (23,24). The UKPDS provided strong evidence that control of blood pressure can reduce the development of nephropathy (64). 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) achieved with 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 glomerular filtration rate (GFR) in patients with macroalbuminuria (64,107–109) .

In addition, ACE inhibitors have been shown to reduce severe CVD (i.e., myocardial infarction, stroke, and death), thus further supporting the use of these agents in patients with microalbuminuria (74). 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 (110–112). Some evidence suggests that ARBs have a smaller magnitude of rise in potassium compared with ACE inhibitors in people with nephropathy (73). With regard to slowing the progression of nephropathy, the use of DCCBs as initial therapy is not more effective than placebo. Their use in nephropathy should be restricted to additional therapy to further lower blood pressure in patients already treated with ACE inhibitors or ARBs (72). In the setting of albuminuria or nephropathy, in patients unable to tolerate ACE inhibitors and/or ARBs, consider the use of non-DCCBs, β-blockers, or diuretics for the management of blood pressure (73,113).

A meta-analysis of several small studies has shown that protein restriction may be of benefit in some patients whose nephropathy seems to be progressing despite optimal glucose and blood pressure control (114).

Screening for microalbuminuria can be performed by three methods: *1*) measurement of the albumin-to-creatinine ratio in a random, spot collection (preferred method); *2*) 24-h collection with creatinine, allowing the simultaneous measurement of creatinine clearance; and *3*) timed (e.g., 4-h or overnight) collection.

Table 8—*Definitions of abnormalities in albumin excretion*

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

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 hypertension may elevate urinary albumin excretion over baseline values.

The analysis of a spot sample for the albumin-to-creatinine ratio is strongly recommended by most authorities (115,116). The other two alternatives (24-h collection and a timed specimen) are rarely necessary. 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 less expensive than the recommended methods but is susceptible to false-negative and false-positive determinations as a result of variation in urine concentration due to hydration and other factors.

At least two of three tests measured within a 6-month period should show elevated levels before a patient is designated as having microalbuminuria. Abnormalities of albumin excretion are defined in Table 8.

Screening for microalbuminuria is indicated in pregnancies complicated by diabetes, since microalbuminuria in the absence of urinary tract infection is a strong predictor of superimposed preeclampsia. In the presence of macroalbuminuria or urine dipstick proteinuria, estimation of GFR by serum creatinine or 24-h urine creatinine clearance is indicated to stage the patient's renal disease, and other tests may be necessary to diagnose preeclampsia.

Physicians may use the Levey modification of the Cockcroft and Gault equation to calculate estimated GFR (eGFR) from serum creatinine and to stage the patient's re-

nal disease (117). The eGFR can easily be calculated by accessing http://www.kidney.org/kls/professionals/gfr_calculator.cfm.

The role of annual microalbumuria assessment is less clear after diagnosis of microalbuminuria and institution of ACE inhibitor or ARB therapy and blood pressure control. Most experts, however, recommend continued surveillance to assess both response to therapy and progression of disease. Some experts suggest that reducing urine microalbuminuria to the normal or near-normal range, if possible, may improve renal and cardiovascular prognosis. This approach has not been formally evaluated in prospective trials.

Consider referral to a physician experienced in the care of diabetic renal disease either when the GFR has fallen to <60 ml · min^{-1} · 1.73 m^{-2} or if difficulties occur in the management of hypertension or hyperkalemia. It is suggested that consultation with a nephrologist be obtained when the GFR is <30 ml · min^{-1} · 1.73 m^{-2}. Early referral of such patients has been found to reduce cost and improve quality of care and keep people off dialysis longer (118). For a complete discussion on the treatment of nephropathy, see the ADA position statement "Diabetic Nephropathy" (119)

Recommendations

General recommendations

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

Screening

- Perform an annual test for the presence of microalbuminuria in type 1 diabetic patients with diabetes duration of ≥5 years and in all type 2 diabetic patients, starting at diagnosis and during pregnancy. (E)

Treatment

- In the treatment of both micro- and macroalbuminuria, either ACE inhibitors or ARBs should be used except during pregnancy. (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, 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)
- With presence of nephropathy, initiate protein restriction to ≤0.8 g · kg^{-1} body wt^{-1} · day^{-1} (~10% of daily calories), the current adult-recommended dietary allowance for protein. Further restriction may be useful in slowing the decline of GFR in selected patients. (B)
- With regards to slowing the progression of nephropathy, the use of DCCBs as initial therapy is not more effective than placebo. Their use in nephropathy should be restricted to additional therapy to further lower blood pressure in patients already treated with ACE inhibitors or ARBs. (B)
- In the setting of albuminuria or nephropathy, in patients unable to tolerate ACE inhibitors and/or ARBs, consider the use of non-DCCBs, β-blockers, or diuretics for the management of blood pressure. Use of non-DCCBs may reduce albuminuria in diabetic patients, including during pregnancy. (E)
- If ACE inhibitors, ARBs, or diuretics are used, monitor serum potassium levels for the development of hyperkalemia. (B)
- Consider referral to a physician experienced in the care of diabetic renal disease when the eGFR has fallen to <60 ml · min^{-1} · 1.73 m^{-2} or if difficulties occur in the management of hypertension or hyperkalemia. (B)

C. Retinopathy screening and treatment

Diabetic retinopathy is a highly specific vascular complication of both type 1 and type 2 diabetes. The prevalence of retinopathy is strongly related to the duration of diabetes. Diabetic retinopathy is estimated to be the most frequent cause of new cases of blindness among adults aged 20–74 years.

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 of diabetic retinopathy (22–24). In addition to glycemic control, several other factors seem to increase the risk of retinopathy. The presence of nephropathy is associated with retinopathy. High blood pressure is an established risk factor for the development of macular edema and is associated with the presence of proliferative diabetic retinopathy (PDR). Lowering blood pressure, as demonstrated by the UKPDS, has been shown to decrease the progression of retinopathy. Several case series and a controlled prospective study suggest that pregnancy in type 1 diabetic patients may aggravate retinopathy (119a). During pregnancy and 1-year postpartum, retinopathy may be transiently aggravated; laser photocoagulation surgery can minimize this risk (120).

Patients 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. 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. Subsequent examinations for type 1 and type 2 diabetic patients should be repeated annually by an ophthalmologist or optometrist who is knowledgeable and experienced in diagnosing the presence of diabetic retinopathy and is aware of its management. Less frequent exams (every 2–3 years) may be considered with the advice of an eye care professional in the setting of a normal eye exam (121–123). Examinations will be required more frequently if retinopathy is progressing.

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

The DRS tested whether scatter (panretinal) photocoagulation surgery could reduce the risk of vision loss from PDR. Severe visual loss (i.e., best acuity of 5/200 or worse) was seen in 15.9% of un-

treated versus 6.4% of treated eyes. The benefit was greatest among patients whose baseline evaluation revealed high-risk characteristics (HRCs) (chiefly disc neovascularization or vitreous hemorrhage with any retinal neovascularization). Of control eyes with HRCs, 26% progressed to severe visual loss versus 11% of treated eyes. Given the risk of a modest loss of visual acuity and of contraction of visual field from panretinal laser surgery, such therapy has been primarily recommended for eyes approaching or reaching HRCs.

The ETDRS established the benefit of focal laser photocoagulation surgery in eyes with macular edema, particularly those with clinically significant macular edema. In patients with clinically significant macular edema after 2 years, 20% of untreated eyes had a doubling of the visual angle (e.g., 20/50 to 20/100) compared with 8% of treated eyes. Other results from the ETDRS indicate that, provided careful follow-up can be maintained, scatter photocoagulation surgery is not recommended for eyes with mild or moderate non-PDR (NPDR). When retinopathy is more severe, scatter photocoagulation surgery should be considered, and usually should not be delayed, if the eye has reached the high-risk proliferative stage. In older-onset patients with severe NPDR or less than high-risk PDR, the risk of severe visual loss and vitrectomy is reduced ~50% by laser photocoagulation surgery at these earlier stages.

Laser photocoagulation surgery in both the DRS and the ETDRS 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.

For a detailed review of the evidence and further discussion, see the ADA technical review and position statement on this subject (119a,124,125).

Recommendations

General recommendations

- Optimal glycemic control can substantially reduce the risk and progression of diabetic retinopathy. (A)
- Optimal blood pressure control can reduce the risk and progression of diabetic retinopathy. (A)
- Aspirin therapy does not prevent retinopathy or increase the risks of hemorrhage. (A)

Screening

- Adults 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 who is knowledgeable and experienced in diagnosing the presence of diabetic retinopathy and is aware of its management. Less frequent exams (every 2–3 years) may be considered with the advice of an eye care professional in the setting of a normal eye exam. Examinations will be required more frequently if retinopathy is progressing. (B)
- When planning pregnancy, women with preexisting diabetes should have a comprehensive eye examination and should be counseled on the risk of development and/or progression of diabetic retinopathy. Women with diabetes who become pregnant should have a comprehensive eye examination in the first trimester and close follow-up throughout pregnancy and for 1-year postpartum. This guideline does not apply to women who develop GDM because such individuals are not at increased risk for diabetic retinopathy. (B)

Treatment

- Laser therapy can reduce the risk of vision loss in patients with HRCs. (A)
- 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)

D. Foot care

Amputation and foot ulceration are the most common consequences of diabetic neuropathy and major causes of morbidity and disability in people with diabetes. Early recognition and management of independent 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.
- Peripheral vascular disease (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. 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. 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. 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 neuropathy or evidence of increased plantar pressure may be adequately managed with well-fitted walking shoes or athletic shoes. Patients should be educated on the implications of sensory loss and the ways to substitute other sensory modalities (hand palpation, visual inspection) for surveillance of early problems. People with evidence of increased plantar pressure (e.g., erythema, warmth, callus, or measured pressure) should use footwear that cushions and re-

distributes the 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, and bunions) may need extra-wide shoes or depth shoes. People with extreme bony deformities (e.g., Charcot foot) that cannot be accommodated with commercial therapeutic footwear may need custom-molded shoes.

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. Refer patients with significant or a positive ABI for further vascular assessment and consider exercise, medications, and surgical options (126).

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. 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. Patients at low risk may benefit from education on foot care and footwear.

For a detailed review of the evidence and further discussion, see the ADA technical review and position statement in this area (127,128).

Problems involving the feet, especially ulcers and wound care, may require care by a podiatrist, orthopedic surgeon, or rehabilitation specialist experienced in the management of individuals with diabetes. For a complete discussion on wound care, see the ADA consensus statement on diabetic foot wound care (129).

Recommendations

- A multidisciplinary approach is recommended for persons with foot ulcers and high-risk feet, especially those with a history of prior ulcer or amputation. (A)
- The foot examination can be accomplished in a primary care setting and should include the use of a Semmes-Weinstein monofilament, tuning fork, palpation, and a visual examination. (B)
- Educate all patients, especially those with risk factors, including smoking, or prior lower-extremity complications, about the risk and prevention of foot problems and reinforce self-care behavior. (B)
- Refer high-risk patients to foot care specialists for ongoing preventive care and life-long surveillance. (C)
- Initial screening for PAD should include a history for claudication and an assessment of the pedal pulses. Consider obtaining an 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)
- Perform a comprehensive foot examination annually on patients with diabetes to identify risk factors predictive of ulcers and amputations. Perform a visual inspection of patients' feet at each routine visit. (E)

VII. DIABETES CARE IN SPECIFIC POPULATIONS

A. Children and adolescents

1. Type 1 diabetes. Although approximately three-quarters of all cases of type 1 diabetes are diagnosed in individuals younger than 18 years of age, historically, ADA recommendations for management of type 1 diabetes have pertained most directly to adults with type 1 diabetes. 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 all are essential in developing and implementing an optimal diabetes regimen. Although current recommendations for children and adolescents are less likely to be based on evidence derived from rigorous research 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 "Care of Children and Adolescents with Type 1 Diabetes" (34). The following represents a summary of recommendations and guidelines pertaining specifically to the care and management of children and adolescents that are included in that document.

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, although this may not always be possible. 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 be 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, psychologic, 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*. 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 younger than 6 or 7 years of age have a form of "hypoglycemic unawareness," in that counterregulatory mechanisms are immature, and young children lack the cognitive capacity to recognize and respond to hypoglycemic symptoms, placing them at greater risk for hypoglycemia and its sequelae. In addition, 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

Table 9—*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 (<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 hypoglycemia • Developmental and psychological issues
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 disparity between preprandial blood glucose values and A1C levels				

*A lower goal (<7.0%) is reasonable if it can be achieved without excessive hypoglycemia

achieved for older patients and current ADA recommendations for patients in general (130).

In selecting glycemic goals, the benefits of achieving a lower A1C must be weighed against the unique risks of hypoglycemia and the disadvantages of targeting a higher, although more achievable goal that may not promote optimal long-term health outcomes. Age-specific glycemic and A1C goals are presented in Table 9.

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

i. Nephropathy

Recommendations

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

ii. Hypertension

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 3 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 3 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.

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 within 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, 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)

iii. Dyslipidemia

Recommendations

Screening

- Prepubertal children: a fasting lipid profile should be performed on all children >2 years of age at the time of diagnosis (after glucose control has been established) if there is a family history of hypercholesterolemia (total cholesterol >240 mg/dl) or a history of a cardiovascular event before age 55 years, or if family history is unknown. If family history is not of concern, then the first lipid screening should be performed at puberty (>12 years). If values fall are within the accepted risk levels (LDL <100 mg/dl; 2.6 mmol/l), a lipid profile should be repeated every 5 years. (E)
- Pubertal children (>12 years old): a fasting lipid profile should be performed at the time of diagnosis (after glucose control has been established). If values fall within the accepted risk levels (LDL <100 mg/dl; 2.6 mmol/l), the measurement should be repeated every 5 years. (E)
- If lipids are abnormal, annual monitoring is recommended in both age-groups. (E)

Treatment

- Treatment should be based on fasting lipid levels (mainly LDL) obtained after glucose control is established. (E)
- Initial therapy should consist of optimization of glucose control and MNT aimed at a decrease in the amount of saturated fat in the diet. (E)
- The addition of pharmacologic lipid-lowering agents is recommended for LDL >160 mg/dl (4.1 mmol/l) and is also recommended in patients who have LDL cholesterol values 130–159

mg/dl (3.4–4.1 mmol/l) based on the patient's CVD risk profile, after failure of MNT and lifestyle changes. (E)
- The goal of therapy is an LDL value <100 mg/dl (2.6 mmol/l). (E)

iv. Retinopathy

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, as well as experience in counseling the pediatric patient and family on the importance of early prevention/intervention.

Recommendations
- The first ophthalmologic examination should be obtained once the child is 10 years of age or older 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)

c. *Other issues*. A major issue deserving emphasis in this age-group is that of "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.

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. Information should be supplied to school personnel, so that they may be made aware of the diagnosis of diabetes in the student and of the signs, symptoms, and treatment of hypoglycemia. In most cases it is imperative that blood glucose testing be performed at the school or day care setting before lunch and when signs or symptoms of abnormal blood glucose levels are present. Many children may require support for insulin administration by either injection or continuous subcutaneous insulin injection (CSII) before lunch (and often also before breakfast) at school or in day care. For further discussion, see the ADA position statement "The Care of Children With Diabetes in the School and Day Care Setting" (131) and the National Diabetes Education Program (NDEP) publication "*Helping the Student with Diabetes Succeed: A Guide for School Personnel*" (National Diabetes Education Program, 2003, www.ndep.nih.gov).

2. Type 2 diabetes. Finally, the incidence of type 2 diabetes in children and adolescents has been shown to be increasing, especially in ethnic minority populations (132,133). 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 otherwise straightforward 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. The ADA consensus statement "Type 2 Diabetes in Children and Adolescents" (8) provides guidance to the prevention, screening, and treatment of type 2 diabetes, as well as its comorbidities in young people.

B. Preconception care

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 above which the risk begins or below which it disappears. However, malformation rates above the 1–2% background rate seen in nondiabetic pregnancies appear to be limited to pregnancies in which first trimester A1C concentrations are >1% above the normal range.

Preconception care of diabetes appears to reduce the risk of congenital malformations. Five nonrandomized studies have 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 (134–138). 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 by patients rather than randomized. Thus, it is impossible to be certain that the lower malformation rates resulted fully from improved diabetes care. Nonetheless, the overwhelming 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 is in good metabolic control and 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. Teams may vary but should include a diabetologist, an internist or a family physician, an obstetrician, a diabetes educator, a dietitian, a social worker, and other specialists as necessary. The goals of preconception care are to *1*) integrate the patient into the management of her diabetes, *2*) achieve the lowest A1C test results possible without excessive hypoglycemia, *3*) assure effective contraception until stable and acceptable glycemia

is achieved, and 4) identify, evaluate, and treat long-term diabetic complications such as retinopathy, nephropathy, neuropathy, hypertension, and CAD.

For further discussion, see the ADA technical review and position statement on this subject (139,140).

Recommendations

- A1C levels should be normal or as close to normal as possible (<1% above the upper limits of normal) 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. They 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)
- Among the drugs commonly used in the treatment of patients with diabetes, statins are pregnancy category X and should be discontinued before conception if possible. ACE inhibitors and ARBs are category C in the first trimester (maternal benefit may outweigh fetal risk in certain situations) but category D in later pregnancy and should generally be discontinued before pregnancy. Among the oral antidiabetic agents, metformin and acarbose are classified as category B and all others as category C; potential risks and benefits of oral antidiabetic agents in the preconception period must be carefully weighed, recognizing that sufficient data are not available to establish the safety of these agents in pregnancy. They should generally be discontinued in pregnancy. (E)

C. Older individuals

Diabetes is an important health condition for the aging population; at least 20% of patients over the age of 65 years have diabetes. The number of older individuals with diabetes can be expected to grow rapidly over the coming decades. A recent publication, "Guidelines for Improving the Care of the Older Person with Diabetes," (141) contains evidence-based guidelines produced in conjunction with the American Geriatric Society. This document contains an excellent discussion of this area, and specific guidelines and language from it have been incorporated below. Unfortunately, there are no long-term studies in individuals >65 years of age demonstrating the benefits of tight glycemic control, blood pressure, and lipid control. 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 care of older adults with diabetes is complicated by their clinical and functional heterogeneity. Some older individuals developed diabetes in middle age and face years of comorbidity; others who are newly diagnosed may have had years of undiagnosed comorbidity or few complications from the disease. Some older adults with diabetes are frail and have other underlying chronic conditions, substantial diabetes-related comorbidity, or limited physical or cognitive functioning, but other older adults with diabetes have little comorbidity and are active. Life expectancies are also highly variable for this population. Clinicians caring for older adults with diabetes must take this heterogeneity into consideration when setting and prioritizing treatment goals.

All this having been said, patients who can be expected to live long enough to reap the benefits of long-term intensive diabetes management (~10 years) and who are active, cognitively intact, and willing to undertake the responsibility of self-management should be encouraged to do so and be treated using the stated goals for younger adults with diabetes.

There is good evidence from middle-aged and older adults suggesting that multidisciplinary interventions that provide education on medication use, monitoring, and recognizing hypo- and hyperglycemia can significantly improve glycemic control. Although control of hyperglycemia is important, in older individuals with diabetes, greater reductions in morbidity and mortality may result from control of all cardiovascular risk factors rather than from tight glycemic control alone. There is strong evidence from clinical trials of the value of treating hypertension in the elderly. There is less evidence for lipid-lowering and aspirin therapy, although as diabetic patients have such an elevated risk for CVD, aggressive management of lipids and aspirin use when not contraindicated are reasonable interventions.

As noted above, for patients with advanced diabetes complications, life-limiting comorbid illness, or 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. Patients with poorly controlled diabetes may be subject to acute complications of diabetes, including hyperglycemic hyperosmolar coma. Older patients can be treated with the same drug regimens as younger patients, but special care is required in prescribing and monitoring drug therapy. Metformin is often contraindicated because of renal insufficiency or heart failure. Sulfonylureas and other insulin secretagogues can cause hypoglycemia. Insulin can also cause hypoglycemia as well as require good visual and motor skills and cognitive ability of the patient or a caregiver. Thiazolidinediones should not be used in patients with CHF (New York Heart Association [NYHA] Class III and IV). Drugs should be started at the lowest dose and titrated up gradually until targets are reached or side effects develop. As well as regards blood pressure and lipid management, the potential benefits must always be weighed against potential risks.

VIII. DIABETES CARE IN SPECIFIC SETTINGS

A. Diabetes care in the hospital

The management of diabetes in the hospital is extensively reviewed in the ADA Technical Review, "Management of diabetes and hyperglycemia in hospitals" by Clement et al. (142). This review forms the basis for these guidelines. In addition, the American Association of Clinical Endocrinologists held a conference on this topic (143), and the recommendations from this meeting (144) were also carefully reviewed and discussed in the formulation of the guidelines, which follow. The management of diabetes in the hospital is generally considered secondary in importance compared with the condition that prompted admission.

Patients with hyperglycemia fall into 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. The prevalence of diabetes in hospitalized adults is conservatively estimated at 12–25%, depending on the thoroughness used in identifying patients. Patients presenting to hospitals may have unrecognized diabetes or hospital-related hyperglycemia. Using the A1C test may be a valuable case-finding tool for identifying diabetes in hospitalized patients.

A rapidly growing body of literature supports targeted glucose control in the hospital setting with potential for improved mortality, morbidity, and health care economic outcomes. Hyperglycemia in the hospital may result from stress, decompensation of type 1 diabetes, type 2 diabetes, or other forms of diabetes and/or may be iatrogenic due to administration or withholding of pharmacologic agents, including glucocorticoids, vasopressors, etc. Distinction between decompensated diabetes and stress hyperglycemia is often not made.

1. Blood glucose targets

a. *General medicine and surgery*. Observational studies suggest an association between hyperglycemia and increased mortality. General medical and surgical patients with a blood glucose value(s) >220 mg/dl (12.2 mmol/l) have higher infection rates (145).

When admissions on general medicine and surgery units were studied, patients with new hyperglycemia had significantly increased in-hospital mortality than patients with known diabetes. In addition, length of stay was higher for the new hyperglycemia group, and both the patients with new hyperglycemia and those with known diabetes 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) (146).

b. *CVD and critical care*. The relationship of blood glucose levels and mortality in the setting of acute myocardial infarction (AMI) has been reported. A meta-analysis 15 previously published studies comparing in-hospital mortality and CHF in both hyper- and normoglycemic patients with and without diabetes. In subjects without known diabetes whose admission blood glucose was 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 was 180 mg/dl (10 mmol/l), risk of death was moderately increased compared with patients who had diabetes but no hyperglycemia on admission (147). In another study (148), admission blood glucose values were analyzed in consecutive patients with AMI. Analysis revealed an independent association of admission blood glucose and mortality. The 1-year mortality rate was 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). Finally, in the first Diabetes and Insulin-Glucose Infusion in Acute Myocardial Infarction (DIGAMI) study, (51,149) insulin-glucose infusion followed by subcutaneous insulin treatment in diabetic patients with AMI was examined. Intensive subcutaneous insulin therapy for 3 or more months improved long-term survival (51). Mean blood glucose in the intensive insulin intervention arm was 172.8 mg/dl (9.6 mmol/l) (vs. 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.

c. *Cardiac surgery*. Attainment of targeted glucose control in the setting of cardiac surgery is associated with reduced mortality and risk of deep sternal wound infections in cardiac surgery patients with diabetes (150,151) and supports the concept that perioperative hyperglycemia is an independent predictor of infection in patients with diabetes (152), with the lowest mortality in patients with blood glucose <150 mg/dl (8.3 mmol/l) (150,153).

d. *Critical care*. A mixed group of patients with and without diabetes admitted to a surgical ICU were randomized to receive intensive insulin therapy (target blood glucose 80–110 mg/dl [4.4–6.1]) The mean blood glucose of 103 mg/dl (5.7 mmol/l) had reduced mortality during the ICU stay and decreased overall in hospital mortality (52). Subsequent analysis demonstrated that for each 20 mg/dl (1.1 mmol/l), glucose was elevated >100 mg/dl (5.5 mmol/l), and the risk of ICU death increased. 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).

e. *Acute neurological disorders*. Hyperglycemia is associated with worsened outcomes in patients with acute stroke and head injury, as evidenced by the large number of observational studies in the literature (154–156) A meta-analysis identified an admission blood glucose >110 mg/dl (6.1 mmol/l) for increased mortality for acute stroke (157).

2. Treatment options

a. *Oral diabetes agents*. No large studies have investigated the potential roles of various oral agents on outcomes in hospitalized patients with diabetes. While the various classes of oral agents are commonly used in the outpatient setting with good response, their use in the inpatient setting presents some specific issues.

- Sulfonylureas and meglitinides—The long action and predisposition to hypoglycemia in patients not consuming their normal nutrition serve as relative contraindications to routine use of sulfonylureas in the hospital for many patients (158). Sulfonylureas do not generally allow rapid dose adjustment to meet the changing inpatient needs. Sulfonylureas also vary in duration of action between individuals and likely vary in the frequency with which they induce hypoglycemia While the two available meglitinides, repaglinide and neteglinide, theoretically would produce less hypoglycemia than sulfonyl-

ureas, lack of clinical trial data for these agents would preclude their use.

- Metformin—The major limitation to metformin use in the hospital is a number of specific contraindications to its use, many of which occur in the hospital. All of these contraindications relate to lactic acidosis, a potentially fatal complication of metformin therapy. 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 (159). Recent evidence continues to indicate that lactic acidosis is a rare complication, despite the relative frequency of risk factors (160). However, in the hospital, where the risk for hypoxia, hypoperfusion, and renal insufficiency is much higher, it still seems prudent to avoid the use of metformin in most patients.
- Thiazolidinediones—Thiazolidinediones are not suitable for initiation in the hospital because of their delayed onset of effect. In addition, they do 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.

In summary, each of the major classes of oral agents has significant limitations for inpatient use. Additionally, they provide little flexibility or opportunity for titration in a setting where acute changes demand these characteristics. Therefore, insulin, when used properly, may have many advantages in the hospital setting.

b. *Insulin*. The inpatient insulin regimen must be matched or tailored to the specific clinical circumstance of the individual patient. A recent meta-analysis concluded that insulin therapy in critically ill patients had a beneficial effect on short-term mortality in different clinical settings (161).

- Subcutaneous insulin therapy—Subcutaneous insulin therapy may be used to attain glucose control in most hospitalized patients with diabetes. The components of the daily insulin dose requirement can be met by a variety of types of insulin, depending on the particular hospital situation. Subcutaneous insulin therapy is subdivided into programmed or 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, it is recommended that the appropriate scheduled insulin doses be increased the following day (162) to accommodate the increased insulin needs. There are no studies comparing human regular insulin with rapid-acting analogues for use as correction-dose insulin. However, due to the longer duration with human regular insulin, there is a greater risk of "insulin stacking" when the usual next blood glucose measurement is performed 4–6 h later.

The traditional sliding scale insulin regimens, usually consisting of regular insulin without any intermediate or long-acting insulin, have been shown to be ineffective (162–164). Problems cited with sliding scale insulin regimens are that the sliding scale regimen prescribed on admission is likely to be used throughout the hospital stay without modification (162). Second, sliding scale insulin therapy treats hyperglycemia after it has already occurred, rather than preventing the occurrence of hyperglycemia. This "reactive" approach can lead to rapid changes in blood glucose levels, exacerbating both hyperglycemia and hypoglycemia.

- 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 insulin lispro or aspart 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 in nonpregnant adults, including DKA and nonketotic hyperosmolar state; general preoperative, intraoperative, and postoperative care; the postoperative period following heart surgery organ transplantation or cardiogenic shock and possibly stroke exacerbated hyperglycemia during high-dose glucocorticoid therapy; patients who are not eating (NPO); critical care illness; and as a dose-finding strategy, anticipatory to 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. Algorithms should incorporate the concept that maintenance requirements differ between patients and change over the course of treatment. Although numerous algorithms have been published, there have been no head-to-head comparisons, and thus no single algorithm can be recommended for an individual hospital. Ideally, intravenous insulin algorithms should consider both the glucose level and its rate of change. For all algorithms, frequent bedside glucose testing is required, but the ideal frequency is not known.

- Transition from intravenous to subcutaneous insulin therapy—There are no specific clinical trials examining how to best transition from intravenous to subcutaneous insulin or which patients with type 2 diabetes may be transitioned to oral agents. For those who will require subcutaneous insulin, it is necessary to administer short- or rapid-acting insulin subcutaneously 1–2 h before discontinuation of the intravenous insulin infusion. An intermediate or long-acting insulin must be injected 2–3 h before discontinuing the insulin infusion. In transitioning from intravenous insulin infusion to subcutaneous therapy, the caregiver may order subcutaneous insulin with appropriate duration of action to be administered as a single dose or repeatedly to maintain basal effect until the time of day when the choice of insulin or analog preferred for basal effect normally would be provided.

3. Self-management in the hospital. Self-management in the hospital may be appropriate for competent adult patients who have a stable level of consciousness and reasonably stable known daily insulin requirements, successfully conduct self-management of diabetes at home, have physical skills appropriate to successfully self-administer insulin and perform SMBG, and have adequate oral intake. Appropriate patients are those already

proficient in carbohydrate counting, use of multiple daily injections of insulin 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.

4. Preventing hypoglycemia. Hypoglycemia, especially in insulin-treated patients, is the leading limiting factor in the glycemic management of type 1 and type 2 diabetes (165). In the hospital, multiple additional risk factors for hypoglycemia are present, even among patients who are neither "brittle" nor tightly controlled. Patients who do not have diabetes may experience hypoglycemia in the hospital, in association with factors such as altered nutritional state, heart failure, renal or liver disease, malignancy, infection, or sepsis (166). Patients having diabetes may develop hypoglycemia in association with the same conditions (167). 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, reduction of rate of administration of intravenous dextrose, and unexpected interruption of enteral feedings or parenteral nutrition. Altered consciousness from anesthesia may also alter typical hypoglycemic symptoms.

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

5. Diabetes care providers. Diabetes management may be offered effectively by primary care physicians or hospitalists, but involvement of appropriately trained specialists or specialty teams may reduce length of stay, improve glycemic control, and improve outcomes (168–171). 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 implement intravenous infusion of insulin for the majority of patients having prolonged NPO status, hospitals will need multidisciplinary support for using insulin infusion therapy outside of critical care units.

6. DSME. Teaching diabetes self-management to patients in hospitals is a difficult and challenging task. Patients are hospitalized because they are ill, under increased stress related to their hospitalization and diagnosis, and in an environment that is not conducive to learning. Ideally, people with diabetes should be taught at a time and place conducive to learning: as an outpatient in a nationally recognized program of diabetes education classes.

For the hospitalized patient, diabetes "survival skills" education is generally considered a feasible approach. Patients are taught sufficient information 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 hopefully prevent subsequent episodes of hospitalization.

7. MNT. Even though hospital diets continue to be ordered by calorie levels based on the "ADA diet," it has been recommended that the term "ADA diet" no longer be used (172). Since 1994, the ADA has not endorsed any single meal plan or specified percentages of macronutrients. Current nutrition recommendations advise individualization based on treatment goals, physiologic parameters, and medication usage.

Because of the complexity of nutrition issues, it is recommended that a registered dietitian, knowledgeable and skilled in MNT, serve as the team member who provides MNT. 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 (172).

8. 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. For this reason, the terms bedside and point-of-care glucose monitoring are used interchangeably.

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 controlled with continuous intravenous insulin typically require hourly blood glucose testing until the blood glucose levels are stable, then every 2 h.

Bedside blood glucose testing is usually performed with portable glucose devices that are identical or similar to devices for home SMBG.

Recommendations

- All patients with diabetes admitted to the hospital should be identified in the medical record as having diabetes. (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 <180 mg/dl (10.0 mmol/l). These patients will usually require IV insulin. (B)
  - Noncritically ill patients: premeal blood glucose should be kept as close to 90–130 mg/dl (5.0–7.2 mmol/l) (midpoint of range: 110 mg/dl) as possible given the clinical situation and a postprandial blood glucose level <180 mg/dl. Insulin should be used as necessary. (E)
- Scheduled prandial insulin doses should be given in relation to meals and should be adjusted according to point of care glucose levels. The traditional sliding scale insulin regimens are ineffective and are not recommended. (C)
- 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 for discharge planning 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)

B. Diabetes care in the school and day care setting (131)

There are about 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, children in the school and day care setting still face discrimination. Parents and the health care team should provide school systems and day care providers with the information necessary by developing an individualized "Diabetes Medical Management Plan" including information necessary for children with diabetes to participate fully and safely in the school/day care experience. 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.

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 response to high and low blood glucose levels. This will 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. These school personnel need not be health care professionals.

The student with diabetes should have immediate access to diabetes supplies at all times, with supervision as needed. A student with diabetes should be able to obtain a blood glucose level and respond to the results as quickly and conveniently as possible, minimizing the need for missing instruction in the classroom. Accordingly, a student who is capable of doing so 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. The student's desire for privacy during testing and should also be accommodated.

Recommendations

- An individualized Diabetes Medical Management Plan 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 and in the appropriate response to high and low blood glucose levels. These school personnel need not be health care professionals. (E)
- The student with diabetes should have immediate access to diabetes supplies at all times, with supervision as needed. (E)
- The 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 indicated in the student's Diabetes Medical Management Plan. (E)

C. Diabetes care at diabetes camps (173)

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 camps specialized for children and youth with diabetes is to allow for 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.

The diabetes camping experience is short term and is most often associated with increased physical activity relative to that experienced while at home. Thus, goals of glycemic control are more related to the avoidance of extremes in blood glucose levels than to the optimization of intensive glycemic control while away at camp.

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 number and timing of injections or basal and bolus dosages given by CSII and type(s) of insulin used.

During camp, a daily record of the camper's progress should be made. All blood glucose levels and insulin dosages should be recorded. 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 when the camper is picked up.

A formal relationship with a nearby medical facility should be secured for each camp so that camp medical staff have the ability to refer to this facility for prompt treatment of medical emergencies. It is imperative that the medical staff is led by someone 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 also have input into the design of the menu and the education program. All camp staff, including medical, nursing, nutrition, and volunteer, should undergo background testing to ensure appropriateness in working with children.

Recommendations

- Each camper should have a standardized medical form completed by his/her family and the physician managing the diabetes. (E)
- It is imperative that the medical staff is led by someone with expertise in managing type 1 and type 2 diabetes, a nursing staff (including diabetes educators and diabetes clinical nurse specialists), and registered dietitians with expertise in diabetes. (E)
- All camp staff, including medical, nursing, nutrition, and volunteer, should undergo background testing to ensure appropriateness in working with children. (E)

D. Diabetes care in correctional institutions (174)

At any given time, over 2 million people are incarcerated in prisons and jails in the U.S. 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.

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.

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 capillary blood glucose (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 medication 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 hypo- or hyperglycemia.

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. 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.

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 patients off-site and the possibility of emergency schedule changes.

Monitoring of CBG is a strategy that allows caregivers and people with diabetes to evaluate diabetes management regimens. The frequency of monitoring will vary by patients' glycemic control and diabetes regimens. 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 individuals with diabetes.

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. Transferring a patient with diabetes from one correctional facility to another requires a coordinated effort as does planning for discharge.

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)
- Correctional staff should be trained in the recognition, treatment, and appropriate referral for hypo- and hyperglycemia. (E)
- Train staff to recognize symptoms and signs of serious metabolic decompensation and to 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)
- Identify patients with type 1 diabetes who are at high risk for DKA. (E)
- 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)
- Include diabetes in correctional staff education programs. (E)
- 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)

IX. HYPOGLYCEMIA AND EMPLOYMENT/LICENSURE (175)

Any person with diabetes, whether insulin treated or noninsulin 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 to 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.

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, oral glucose-lowering agent, and/or insulin), and medical history, particularly in regard to the occurrence of incapacitating hypoglycemic episodes.

Recommendation

- 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)

X. THIRD-PARTY REIMBURSEMENT FOR DIABETES CARE, SELF-MANAGEMENT EDUCATION, AND SUPPLIES (176)

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. 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, such as syringes, strips, and meters, related to the daily care of diabetes must also be reimbursed by third-party payers.

It is recognized that the use of formularies, prior authorization, and related 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. 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.

Medicare and many other third-party payors cover 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 education, as long as the services are not provided on the same date. However, not all Medicare beneficiaries with a diagnosis of diabetes will qualify for both MNT and DSMT benefits. For more information on Medicare policy including follow-up benefits, go to the following link: http://www.diabetes.org/for-health-professionals-and-scientists/recognition/dsmt-mntfaqs.jsp.

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)

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 (177) indicated that only 37% of adults with diagnosed diabetes achieved an A1C of <7%, only 36% had a blood pressure <130/80 and just 48% had a cholesterol level <200 mg/dl. Most distressing was that only 7.3% of diabetes subjects 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 (IOM) 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 activities as the ADA/NCQA 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 website 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 important outcomes such as A1C measurements and blood pressure and lipid determinations as well as process measures such as provision of eye exams. 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.
- System 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 (CQI) 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 either with 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 (*Diabetes Care* 26: 942–943, 2003).
- 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. 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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