Introduction

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

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

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

ADA position statement. An official point of view or belief of the ADA. Position statements are issued on scientific or medical issues related to diabetes. They may be authored or unauthored and are published in ADA journals and other scientific/medical publications as appropriate. Position statements must be reviewed and approved by the Professional Practice Committee and, subsequently, by the Executive Committee of the Board of Directors. ADA position statements are typically based on a systematic review or other review of published literature. They are reviewed on an annual basis and updated as needed. A list of recent position statements is included on p. S100 of this supplement.

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

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

Systematic review. A balanced review and analysis of the literature on a scientific or medical topic related to diabetes. Effective January 2010, technical reviews are replaced with systematic reviews, for which a priori search and inclusion/exclusion criteria are developed and published. The systematic review provides a scientific rationale for a position statement and undergoes critical peer review before submission to the Professional Practice Committee for approval. A list of past technical reviews is included on page S97 of this supplement.

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

DOI: 10.2337/dc10-S001.

list of recent consensus reports is included on p. S96 of this supplement.

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

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

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

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

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

DUALITIES OF INTEREST

Professional Practice Committee Members

John E. Anderson, MD, is on the speaker's bureau for Amylin/Eli Lilly*, GlaxoSmithKline*, Daichi/Sankyo, and Novo Nordisk.

Joan Bardsley, RN, MBA, CDE, has received research funding from Novo Nordisk*, has received honoraria from Novo Nordisk* and GlaxoSmithKline*, and owns stock in Pfizer* and Amylin.

John B. Buse, MD, PhD, has conducted research and/or consulted under contract between the University of North Carolina and Amylin*, Bayhill Therapeutics, Becton Dickinson*, Bristol-Myers Squibb*, DexCom*, Eli Lilly*, GI Dynamics, GlaxoSmithKline*, Halozyme*, Hoffman-LaRoche*, Interkrin*, Johnson & Johnson*, LipoScience*, Mannkind*, Medtronic*, Merck*, Novartis*, Novo Nordisk*, Osiris*, Pfizer*, sanofi-aventis*, Tolerex*, Transition Therapeutics*, and Wyeth; and owns stock in Insulet*.

Martha Funnell, MS, RN, CDE, has been on the advisory board for Novo Nordisk, Eli Lilly, HDI Diagnostics, Intuity Medical, GlaxoSmithKline, and Mannkind and has been a consultant for sanofi-aventis.

Curt D. Furberg, MD, PhD, has been a member of the data safety monitoring committee for Wyeth.

Sheila Y. Garris, MD, FACP, has been a speaker for Takeda, Osient, GlaxoSmithKline, and Novartis and has been a speaker and consultant for Merck, Forrest*, and Daiichi Sankyo.

Silvio E. Inzucchi, MD, has been a consultant/advisor for Takeda, Merck*, Amylin, Daiichi Sankyo, and Medtronic; has accepted honoraria from Novo Nordisk; and has received research funding from Eli Lilly*; Takeda, Merck, Amylin, and Boehringer Ingelheim have provided educational grants* to Yale University for work conducted by him.

Wahida Karmally, DrPH, RD, CDE, CLS, reports no duality of interest.

Antoinette Moran, MD, has been on the advisory committee for Bayer.

Peter D. Reaven, MD, has received research support from Takeda* and Amylin*, is a member of the speaker's bureau for Merck, and is on the advisory panel of and is a board member for Bristol-Myers Squibb.

Guillermo Umpierrez, MD, has received research funding from sanofi-aventis*, Novo Nordisk*, Takeda*, and Eli Lilly*.

Craig Williams, PharmD, has received research funding from Merck* and speaker fees from Merck/Schering Plough and has a relative employed by Pfizer.

David F. Williamson, PhD, reports no duality of interest.

Peter Wilson, MD, has received research funding from GlaxoSmithKline*.

Carol H. Wysham, MD, has been a speaker for Eli Lilly*, Merck, Novo Nordisk, and sanofi-aventis and a consultant and speaker for Amylin Pharmaceuticals*.

American Diabetes Association Staff

M. Sue Kirkman, MD, and Stephanie A. Dunbar, MPH, RD, report no duality of interest.

*Amount >$10,000/year.

Standards of Medical Care in Diabetes—2010

AMERICAN DIABETES ASSOCIATION

Diabetes is a chronic illness that requires continuing medical care and ongoing patient self-management education and support to prevent acute complications and to reduce the risk of long-term complications. Diabetes care is complex and requires 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, general 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 clinical judgment or more extensive evaluation and management of the patient by other specialists as needed. For more detailed information about management of diabetes, refer to references 1–3.

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

These standards of care are revised annually by the ADA multidisciplinary Professional Practice Committee, and new evidence is incorporated. Members of the Professional Practice Committee and their disclosed conflicts of interest are listed in the Introduction. Subsequently, as with all position statements, the standards of care are reviewed and approved by the Executive Committee of ADA's Board of Directors.

Originally approved 1988. Most recent review/revision October 2009.
DOI: 10.2337/dc10-S011

Abbreviations: ABI, ankle-brachial index; ACCORD, Action to Control Cardiovascular Risk in Diabetes; ADAG, A1C-Derived Average Glucose Trial; ADVANCE, Action in Diabetes and Vascular Disease: Preterax and Diamicron Modified Release Controlled Evaluation; ACE, angiotensin converting enzyme; ARB, angiotensin receptor blocker; ACT-NOW, ACTos Now Study for the Prevention of Diabetes; BMI, body mass index; CBG, capillary blood glucose; CFRD, cystic fibrosis–related diabetes; CGM, continuous glucose monitoring; CHD, coronary heart disease; CHF, congestive heart failure; CCM, chronic care model; CKD, chronic kidney disease; CMS, Centers for Medicare and Medicaid Services; CSII, continuous subcutaneous insulin infusion; CVD, cardiovascular disease; DASH, Dietary Approaches to Stop Hypertension; DCCT, Diabetes Control and Complications Trial; DKA, diabetic ketoacidosis; DMMP, diabetes medical management plan; DPN, distal symmetric polyneuropathy; DPP, Diabetes Prevention Program; DPS, Diabetes Prevention Study; DREAM, Diabetes Reduction Assessment with Ramipril and Rosiglitazone Medication; DRS, Diabetic Retinopathy Study; DSME, diabetes self-management education; DSMT, diabetes self-management training; eAG, estimated average glucose; eGFR, estimated glomerular filtration rate; ECG, electrocardiogram; EDIC, Epidemiology of Diabetes Interventions and Complications; ERP, education recognition program; ESRD, end-stage renal disease; ETDRS, Early Treatment Diabetic Retinopathy Study; FDA, Food and Drug Administration; FPG, fasting plasma glucose; GDM, gestational diabetes mellitus; GFR, glomerular filtration rate; HAPO, Hyperglycemia and Adverse Pregnancy Outcomes; ICU, intensive care unit; IFG, impaired fasting glucose; IGT, impaired glucose tolerance; Look AHEAD, Action for Health in Diabetes; MDRD, Modification of Diet in Renal Disease; MNT, medical nutrition therapy; NDEP, National Diabetes Education Program; NGSP, National Glycohemoglobin Standardization Program; NPDR, nonproliferative diabetic retinopathy; OGTT, oral glucose tolerance test; PAD, peripheral arterial disease; PCOS, polycystic ovarian syndrome; PDR, proliferative diabetic retinopathy; PPG, postprandial plasma glucose; RAS, renin-angiotensin system; SMBG, self-monitoring of blood glucose; STOP-NIDDM, Study to Prevent Non-Insulin Dependent Diabetes; SSI, sliding scale insulin; TZD, thiazolidinedione; UKPDS, U.K. Prospective Diabetes Study; VADT, Veterans Affairs Diabetes Trial; XENDOS, XENical in the prevention of Diabetes in Obese Subjects.

I. CLASSIFICATION AND DIAGNOSIS

A. Classification

The classification of diabetes includes four clinical classes:

- type 1 diabetes (results from β-cell destruction, usually leading to absolute insulin deficiency)
- type 2 diabetes (results from a progressive insulin secretory defect on the background of insulin resistance)
- other specific types of diabetes due to other causes, e.g., genetic defects in β-cell function, genetic defects in insulin action, diseases of the exocrine pancreas (such as cystic fibrosis), and drug- or chemical-induced diabetes (such as in the treatment of AIDS or after organ transplantation)
- gestational diabetes mellitus (GDM) (diabetes diagnosed during pregnancy)

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

B. Diagnosis of diabetes

Recommendations

For decades, the diagnosis of diabetes has been based on plasma glucose (PG) criteria, either fasting PG (FPG) or 2-h 75-g oral glucose tolerance test (OGTT) values. In 1997, the first Expert Committee on the Diagnosis and Classification of Diabetes Mellitus revised the diagnostic criteria using the observed association between

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

glucose levels and presence of retinopathy as the key factor with which to identify threshold FPG and 2-h PG levels. The committee examined data from three cross-sectional epidemiologic studies that assessed retinopathy with fundus photography or direct ophthalmoscopy and measured glycemia as FPG, 2-h PG, and HbA_{1c} (A1C). The studies demonstrated glycemic levels below which there was little prevalent retinopathy and above which the prevalence of retinopathy increased in an apparently linear fashion. The deciles of FPG, 2-h PG, and A1C at which retinopathy began to increase were the same for each measure within each population. The analyses helped to inform a then-new diagnostic cut point of ≥126 mg/dl (7.0 mmol/l) for FPG and confirmed the long-standing diagnostic 2-h PG value of ≥200 mg/dl (11.1 mmol/l) (4).

ADA has not previously recommended the use of A1C for diagnosing diabetes, in part due to lack of standardization of the assay. However, A1C assays are now highly standardized, and their results can be uniformly applied both temporally and across populations. In a recent report (5), after an extensive review of both established and emerging epidemiological evidence, an international expert committee recommended the use of the A1C test to diagnose diabetes with a threshold of ≥6.5%, and ADA affirms this decision (6). The diagnostic test should be performed using a method certified by the National Glycohemoglobin Standardization Program (NGSP) and standardized or traceable to the Diabetes Control and Complications Trial (DCCT) reference assay. Point-of-care A1C assays are not sufficiently accurate at this time to use for diagnostic purposes.

Epidemiologic datasets show a relationship between A1C and the risk of retinopathy similar to that which has been shown for corresponding FPG and 2-h PG thresholds. The A1C has several advantages to the FPG, including greater convenience, since fasting is not required; evidence to suggest greater preanalytical stability; and less day-to-day perturbations during periods of stress and illness. These advantages must be balanced by greater cost, limited availability of A1C testing in certain regions of the developing world, and incomplete correlation between A1C and average glucose in certain individuals. In addition, the A1C can be misleading in patients with certain forms of anemia and hemoglobinopathies. For patients with a hemoglobinopathy but normal red cell turnover, such as sickle cell trait, an A1C assay without interference from abnormal hemoglobins should be used (an updated list of A1C assays and whether abnormal hemoglobins impact them is available at www.ngsp.org/prog/index3.html). For conditions with abnormal red cell turnover, such as pregnancy or anemias from hemolysis and iron deficiency, the diagnosis of diabetes must use glucose criteria exclusively.

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

Just as there is <100% concordance between the FPG and 2-h PG tests, there is not perfect concordance between A1C and either glucose-based test. Analyses of National Health and Nutrition Examination Survey (NHANES) data indicate that, assuming universal screening of the undiagnosed, the A1C cut point of ≥6.5% identifies one-third fewer cases of undiagnosed diabetes than a fasting glucose cut point of ≥126 mg/dl (7.0 mmol/l) (E. Gregg, personal communication). However, in practice, a large portion of the diabetic population remains unaware of their condition. Thus, the lower sensitivity of A1C at the designated cut point may well be offset by the test's greater practicality, and wider application of a more convenient test (A1C) may actually increase the number of diagnoses made.

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

Table 2—*Criteria for the diagnosis of diabetes*

1.	A1C ≥6.5%. The test should be performed in a laboratory using a method that is NGSP certified and standardized to the DCCT assay.*
	OR
2.	FPG ≥126 mg/dl (7.0 mmol/l). Fasting is defined as no caloric intake for at least 8 h.*
	OR
3.	Two-hour 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.*
	OR
4.	In a patient with classic symptoms of hyperglycemia or hyperglycemic crisis, a random plasma glucose ≥200 mg/dl (11.1 mmol/l).

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

agnostic threshold, the diagnosis of diabetes is confirmed.

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

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

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

C. Categories of increased risk for diabetes

In 1997 and 2003, The Expert Committee on the Diagnosis and Classification of Diabetes Mellitus (4,7) recognized an intermediate group of individuals whose glucose levels, although not meeting criteria for diabetes, are nevertheless too high to be considered normal. This group was defined as having impaired fasting glucose (IFG) (FPG levels of 100 mg/dl [5.6 mmol/l] to 125 mg/dl [6.9 mmol/l]) or impaired glucose tolerance (IGT) (2-h OGTT values of 140 mg/dl [7.8 mmol/l] to 199 mg/dl [11.0 mmol/l]).

Individuals with IFG and/or IGT have been referred to as having pre-diabetes, indicating the relatively high risk for the future development of diabetes. IFG and IGT should not be viewed as clinical entities in their own right but rather risk factors for diabetes as well as cardiovascular disease (CVD). IFG and IGT are associated with obesity (especially abdominal or visceral obesity), dyslipidemia with high triglycerides and/or low HDL cholesterol, and hypertension. Structured lifestyle intervention, aimed at increasing physical activity and producing 5–10% loss of body weight, and certain pharmacological agents have been demonstrated to prevent or delay the development of diabetes in people with IGT (see Table 7). It should be noted that the 2003 ADA Expert Committee report reduced the lower FPG cut point to define IFG from 110 mg/dl (6.1 mmol/l) to 100 mg/dl (5.6 mmol/l), in part to make the prevalence of IFG more similar to that of IGT. However, the World Health Organization (WHO) and many other diabetes organizations did not adopt this change.

As the A1C becomes increasingly used to diagnose diabetes in individuals with risk factors, it will also identify those at high risk for developing diabetes in the future. As was the case with the glucose measures, defining a lower limit of an intermediate category of A1C is somewhat arbitrary, since risk of diabetes with any measure or surrogate of glycemia is a continuum extending well into the normal ranges. To maximize equity and efficiency of preventive interventions, such an A1C cut point, should balance the costs of false negatives (failing to identify those who are going to develop diabetes) against the costs of false positives (falsely identifying and then spending intervention resources on those who were not going to develop diabetes anyway).

Linear regression analyses of nationally representative U.S. data (NHANES 2005–2006) indicate that among the nondiabetic adult population, an FPG of 110 mg/dl corresponds to an A1C of 5.6%, while an FPG of 100 mg/dl corresponds to an A1C of 5.4%. Receiver operating curve analyses of these data indicate that an A1C value of 5.7%, compared with other cut points, has the best combination of sensitivity (39%) and specificity (91%) to identify cases of IFG (FPG ≥100 mg/dl [5.6 mmol/l]) (R.T. Ackerman, Personal Communication). Other analyses suggest that an A1C of 5.7% is associated with diabetes risk similar to that of the high-risk participants in the Diabetes Prevention Program (DPP) (R.T. Ackerman, personal communication). Hence, it is reasonable to consider an A1C range of 5.7–6.4% as identifying individuals with high risk for future diabetes and to whom the term pre-diabetes may be applied (6).

As is the case for individuals found to have IFG and IGT, individuals with an A1C of 5.7–6.4% should be informed of their increased risk for diabetes as well as CVD and counseled about effective strategies to lower their risks (see IV. PREVENTION/DELAY OF TYPE 2 DIABETES). As with glucose measurements, the continuum of risk is curvilinear, so that as A1C rises, the risk of diabetes rises disproportionately. Accordingly, interventions should be most intensive and follow-up should be particularly vigilant for those with an A1C >6.0%, who should be considered to be at very high risk. However, just as an individual with a fasting glucose of 98 mg/dl (5.4 mmol/l) may not be at negligible risk for diabetes, individuals with an A1C <5.7% may still be at risk, depending on the level of A1C and presence of other risk factors, such as obesity and family history.

Table 3—*Categories of increased risk for diabetes**

FPG 100–125 mg/dl (5.6–6.9 mmol/l) [IFG]
2-h PG on the 75-g OGTT 140–199 mg/dl (7.8–11.0 mmol/l) [IGT]
A1C 5.7–6.4%

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

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

1. Testing should be considered in all adults who are overweight (BMI ≥25 kg/m^2*) and have additional risk factors:
   - physical inactivity
   - first-degree relative with diabetes
   - members of a high-risk ethnic population (e.g., African American, Latino, Native American, Asian American, Pacific Islander)
   - women who delivered a baby weighing >9 lb or were diagnosed with GDM
   - hypertension (≥140/90 mmHg or on therapy for hypertension)
   - HDL cholesterol level <35 mg/dl (0.90 mmol/l) and/or a triglyceride level >250 mg/dl (2.82 mmol/l)
   - women with polycystic ovary syndrome
   - A1C ≥5.7%, IGT, or IFG on previous testing
   - other clinical conditions associated with insulin resistance (e.g., severe obesity, acanthosis nigricans)
   - history of CVD
2. In the absence of the above criteria, testing diabetes should begin at age 45 years
3. If results are normal, testing should be repeated at least at 3-year intervals, with consideration of more frequent testing depending on initial results and risk status.

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

Table 3 summarizes the categories of increased risk for diabetes.

II. TESTING FOR DIABETES IN ASYMPTOMATIC PATIENTS

Recommendations

- Testing to detect type 2 diabetes and assess risk for future diabetes in asymptomatic people should be considered in adults of any age who are overweight or obese (BMI ≥25 kg/m^2) and who have one or more additional risk factors for diabetes (Table 4). In those without these risk factors, testing should begin at age 45 years. (B)
- If tests are normal, repeat testing should be carried out at least at 3-year intervals. (E)
- To test for diabetes or to assess risk of future diabetes, either A1C, FPG , or 2-h 75-g OGTT are appropriate. (B)
- In those identified with increased risk for future diabetes, identify and, if appropriate, treat other CVD risk factors. (B)

For many illnesses there is a major distinction between screening and diagnostic testing. However, for diabetes the same tests would be used for "screening" as for diagnosis. Type 2 diabetes has a long asymptomatic phase and significant clinical risk markers. Diabetes may be identified anywhere along a spectrum of clinical scenarios ranging from a seemingly low-risk individual who happens to have glucose testing, to a higher-risk individual who the provider tests because of high suspicion of diabetes, to the symptomatic patient. The discussion herein is primarily framed as testing for diabetes in individuals without symptoms. Testing for diabetes will also detect individuals at increased future risk for diabetes, herein referred to as pre-diabetic.

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

Type 2 diabetes is frequently not diagnosed until complications appear, and approximately one-fourth of all people with diabetes in the U.S. may be undiagnosed. Although the effectiveness of early identification of pre-diabetes and diabetes through mass testing of asymptomatic individuals has not been proven definitively (and rigorous trials to provide such proof are unlikely to occur), pre-diabetes and diabetes meet established criteria for conditions in which early detection is appropriate. Both conditions are common, are increasing in prevalence, and impose significant public health burdens. There is a long presymptomatic phase before the diagnosis of type 2 diabetes is usually made. Relatively simple tests are available to detect preclinical disease (9). Additionally, the duration of glycemic burden is a strong predictor of adverse outcomes, and effective interventions exist to prevent progression of pre-diabetes to diabetes (see IV. PREVENTION/DELAY OF TYPE 2 DIABETES) and to reduce risk of complications of diabetes (see VI. PREVENTION AND MANAGEMENT OF DIABETES COMPLICATIONS).

Recommendations for testing for diabetes in asymptomatic undiagnosed adults are listed in Table 4. Testing should be considered in adults of any age with BMI ≥25 kg/m^2 and one or more risk factors for diabetes. Because age is a major risk factor for diabetes, testing of those without other risk factors should begin no later than at age 45 years.

Either A1C, FPG, or 2-h OGTT is appropriate for testing. The 2-h OGTT identifies people with either IFG or IGT and thus more people at increased risk for the development of diabetes and CVD. It should be noted that the two tests do not necessarily detect the same individuals (10). The efficacy of interventions for primary prevention of type 2 diabetes (11–17) has primarily been demonstrated among individuals with IGT, but not for individuals with IFG (who do not also have IGT) or those with specific A1C levels.

The appropriate interval between tests is not known (18). The rationale for the 3-year interval is that false negatives will be repeated before substantial time elapses, and there is little likelihood that an individual will develop significant complications of diabetes within 3 years of a negative test result.

Because of the need for follow-up and discussion of abnormal results, testing should be carried out within the health care setting. Community screening outside a health care setting is not recommended because people with positive tests may not seek, or have access to, appropriate follow-up testing and care. Conversely, there may be failure to ensure appropriate repeat testing for individuals who test negative. 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 (19,20).

B. Testing for type 2 diabetes in children

The incidence of type 2 diabetes in adolescents has increased dramatically in the last decade, especially in minority populations (21), although the disease remains rare in the general pediatric population (22). Consistent with recommendations for adults, children and youth at increased risk for the presence or the development of type 2 diabetes should be tested within the health care setting (23). The recommendations of the ADA consensus statement on type 2 diabetes in

Table 5—*Testing for type 2 diabetes in asymptomatic children*

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

children and youth, with some modifications, are summarized in Table 5.

C. Screening for type 1 diabetes

Generally, people with type 1 diabetes present with acute symptoms of diabetes and markedly elevated blood glucose levels, and most cases are diagnosed soon after the onset of hyperglycemia. However, evidence from type 1 diabetes prevention studies suggests that measurement of islet autoantibodies identifies individuals who are at risk for developing type 1 diabetes. Such testing may be appropriate in high-risk individuals, such as those with prior transient hyperglycemia or those who have relatives with type 1 diabetes, in the context of clinical research studies (see, for example, http://www2.diabetestrialnet.org). Widespread clinical testing of asymptomatic low-risk individuals cannot currently be recommended, as it would identify very few individuals in the general population who are at risk. Individuals who screen positive should be counseled about their risk of developing diabetes. Clinical studies are being conducted to test various methods of preventing type 1 diabetes or reversing early type 1 diabetes in those with evidence of autoimmunity.

III. DETECTION AND DIAGNOSIS OF GDM

Recommendations

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

For many years, GDM has been defined as any degree of glucose intolerance with onset or first recognition during pregnancy (4). Although most cases resolve with delivery, the definition applied whether the condition persisted after pregnancy and did not exclude the possibility that unrecognized glucose intolerance may have antedated or begun concomitantly with the pregnancy. This definition facilitated a uniform strategy for detection and classification of GDM, but its limitations were recognized for many years. As the ongoing epidemic of obesity and diabetes has led to more type 2 diabetes in women of childbearing age, the number of pregnant women with undiagnosed type 2 diabetes has increased (24). After deliberations in 2008–2009, the International Association of Diabetes and Pregnancy Study Groups (IADPSG), an international consensus group with representatives from multiple obstetrical and diabetes organizations, including ADA, recommended that high-risk women found to have diabetes at their initial prenatal visit using standard criteria (Table 2) receive a diagnosis of overt, not gestational, diabetes.

Approximately 7% of all pregnancies (ranging from 1 to 14% depending on the population studied and the diagnostic tests used) are complicated by GDM, resulting in more than 200,000 cases annually.

Because of the risks of GDM to the mother and neonate, screening and diagnosis are warranted. Current screening and diagnostic strategies, based on the 2004 ADA position statement on GDM (25), are outlined in Table 6.

Results of the Hyperglycemia and Adverse Pregnancy Outcomes (HAPO) study (26), a large-scale (~25,000 pregnant women) multinational epidemiologic study, demonstrated that risk of adverse maternal, fetal, and neonatal outcomes continuously increased as a function of maternal glycemia at 24–28 weeks, even within ranges previously considered normal for pregnancy. For most complications there was no threshold for risk. These results have led to careful reconsideration of the diagnostic criteria for GDM. The IADPSG recommended that all women not known to have prior diabetes undergo a 75-g OGTT at 24–28 weeks of gestation. The group developed diagnostic cut points for the fasting, 1-h, and 2-h PG measurements that conveyed an odds ratio for adverse outcomes of at least 1.75 compared with women with the mean glucose levels in the HAPO study.

At the time of this update to the Standards of Medical Care in Diabetes, ADA is planning to work with U.S. obstetrical organizations to consider adoption of the IADPSG diagnostic criteria and to discuss the implications of this change. While this change will significantly increase the prevalence of GDM, there is mounting evidence that treating even mild GDM reduces morbidity for both mother and baby (27).

Because women with a history of GDM have a greatly increased subsequent risk for diabetes (28), they should be screened for diabetes 6–12 weeks postpartum, using nonpregnant OGTT criteria, and should be followed up with subsequent screening for the development of diabetes or pre-diabetes, as outlined in II. TESTING FOR DIABETES IN ASYMPTOMATIC PATIENTS. Information on the National Diabetes Education Program (NDEP) campaign to prevent type 2 diabetes in women with GDM can be found at http://ndep.nih.gov/media/NeverTooEarly_Tipsheet.pdf.

IV. PREVENTION/DELAY OF TYPE 2 DIABETES

Recommendations

- Patients with IGT (A), IFG (E), or an A1C of 5.7–6.4% (E) should be referred to an effective ongoing support program for weight loss of 5–10% of body weight and an increase in physical activity of at least 150 min/week of moderate activity such as walking.
- Follow-up counseling appears to be important for success. (B)
- Based on potential cost savings of diabetes prevention, such counseling should be covered by third-party payors. (E)
- In addition to lifestyle counseling, metformin may be considered in those who are at very high risk for developing diabetes (combined IFG and IGT plus

Table 6—*Screening for and diagnosis of GDM*

Carry out diabetes risk assessment at the first prenatal visit.

Women at very high risk should be screened for diabetes as soon as possible after the confirmation of pregnancy. Criteria for very high risk are:

- Severe obesity
- Prior history of GDM or delivery of large-for-gestational-age infant
- Presence of glycosuria
- Diagnosis of PCOS
- Strong family history of type 2 diabetes

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

All women of greater than low risk of GDM, including those above not found to have diabetes early in pregnancy, should undergo GDM testing at 24–28 weeks of gestation. Low-risk status, which does not require GDM screening, is defined as women with ALL of the following characteristics:

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

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

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

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

To make a diagnosis of GDM, at least two of the following plasma glucose values must be found:

- Fasting ≥95 mg/dl
- 1-h ≥180 mg/dl
- 2-h ≥155 mg/dl
- 3-h ≥140 mg/dl

other risk factors such as A1C >6%, hypertension, low HDL cholesterol, elevated triglycerides, or family history of diabetes in a first-degree relative) and who are obese and under 60 years of age. (E)

- Monitoring for the development of diabetes in those with pre-diabetes should be performed every year. (E)

Randomized controlled trials have shown that individuals at high risk for developing diabetes (those with IFG, IGT, or both) can be given interventions that significantly decrease the rate of onset of diabetes (11–17). These interventions include intensive lifestyle modification programs that have been shown to be very effective (58% reduction after 3 years) and use of the pharmacologic agents metformin, α-glucosidase inhibitors, orlistat, and thiazolidinediones, each of which has been shown to decrease incident diabetes to various degrees. A summary of major diabetes prevention trials is shown in Table 7.

Two studies of lifestyle intervention have shown persistent reduction in the role of conversion to type 2 diabetes with 3 years (29) to 14 years (30) of postintervention follow-up.

Based on the results of clinical trials and the known risks of progression of pre-diabetes to diabetes, an ADA Consensus Development Panel (36) concluded that people with IGT and/or IFG should be counseled on lifestyle changes with goals similar to those of the DPP (5–10% weight loss and moderate physical activity of ~30 min/day). Regarding the more difficult issue of drug therapy for diabetes prevention, the consensus panel felt that metformin should be the only drug considered for use in diabetes prevention. For other drugs, the issues of cost, side effects, and lack of persistence of effect in some studies led the panel to not recommend use for diabetes prevention. Metformin use was recommended only for very-high-risk individuals (those with combined IGT and IFG who are obese and have at least one other risk factor for diabetes) who are under 60 years of age. In addition, the panel highlighted the evidence that in the DPP, metformin was most effective compared with lifestyle in individuals with BMI ≥35 kg/m^2 and those under age 60 years.

V. DIABETES CARE

A. Initial evaluation

A complete medical evaluation should be performed to classify the diabetes, detect the presence of diabetes complications, review previous treatment and glycemic control in patients with established diabetes, assist in formulating a management plan, and provide a basis for continuing care. Laboratory tests appropriate to the evaluation of each patient's medical condition should be performed. A focus on the components of comprehensive care (Table 8) will assist the health care team to ensure optimal management of the patient with diabetes.

B. Management

People with diabetes should receive medical care from a physician-coordinated team. Such teams may include, but are not limited to, physicians, nurse practitioners, physician's assistants, nurses, dietitians, pharmacists, and mental health professionals with expertise and a special interest in diabetes. It is essential in this collaborative and integrated team approach that individuals with diabetes assume an active role in their care.

The management plan should be formulated as a collaborative therapeutic alliance among the patient and family, the physician, and other members of the health care team. A variety of strategies and techniques should be used to provide adequate education and development of problem-solving skills in the various aspects of diabetes management. Implementation of the management plan requires that each aspect is understood and agreed to by the patient and the care providers and that the goals and treatment plan are reasonable. Any plan should recognize diabetes self-management education (DSME) and on-going diabetes support as an integral component

Table 7—*Therapies proven effective in diabetes prevention trials*

Study (ref.)	*n*	Population	Mean age (years)	Duration (years)	Intervention (daily dose)	Incidence in control subjects (%/year)	Relative risk reduction (%) (95% CI)	3-Year number needed to treat*
Lifestyle								
Finnish DPS (12)	522	IGT, BMI ≥25 kg/m^2	55	3.2	I-D&E	6	58 (30–70)	8.5
DPP (11)	2,161†	IGT, BMI ≥24 kg/m^2, FPG >5.3 mmol/l	51	3	I-D&E	10.4	58 (48–66)	6.9
Da Qing (13)	259†	IGT (randomized groups)	45	6	G-D&E	14.5	38 (14–56)	7.9
Toranomon Study (31)	458	IGT (men), BMI = 24 kg/m^2	~55	4	I-D&E	2.4	67 ($P < 0.043$)‡	20.6
Indian DPP (17)	269†	IGT	46	2.5	I-D&E	23	29 (21–37)	6.4
Medications								
DPP (11)	2,155†	IGT, BMI >24 kg/m^2, FPG >5.3 mmol/l	51	2.8	Metformin (1,700 mg)	10.4	31 (17–43)	13.9
Indian DPP (17)	269†	IGT	46	2.5	Metformin (500 mg)	23	26 (19–35)	6.9
STOP NIDDM (15)	1,419	IGT, FPG >5.6 mmol/l	54	3.2	Acarbose (300 mg)	12.4	25 (10–37)	9.6
XENDOS (32)	3,277	BMI >30 kg/m^2	43	4	Orlistat (360 mg)	2.4	37 (14–54)	45.5
DREAM (16)	5,269	IGT or IFG	55	3.0	Rosiglitazone (8 mg)	9.1	60 (54–65)	6.9
Voglibose Ph-3 (33)	1,780	IGT	56	3.0 (1-year Rx)	Vogliobose (0.2 mg)	12.0	40 (18–57)	21 (1-year Rx)
ACT-NOW (34)	602	IGT or IFG	52	2.6	Pioglitizone (45 mg)	6.8	81 (61–91)	6.3

Modified and reprinted with permission (35). Percentage points: *Number needed to treat to prevent 1 case of diabetes, standardized for a 3-year period to improve comparisons across studies. †Number of participants in the indicated comparisons, not necessarily in entire study. ‡Calculated from information in the article. ACT-NOW, ACTos Now Study for the Prevention of Diabetes; DPP, Diabetes Prevention Program; DPS, Diabetes Prevention Study; DREAM, Diabetes Reduction Assessment with Ramipril and Rosiglitazone Medication; STOP NIDDM, Study to Prevent Non-Insulin Dependent Diabetes; XENDOS, Xenical in the prevention of Diabetes in Obese Subjects. I, individual; G, group; D&E, diet and exercise.

of care. In developing the plan, consideration should be given to the patient's age, school or work schedule and conditions, physical activity, eating patterns, social situation and cultural factors, and presence of complications of diabetes or other medical conditions.

C. Glycemic control

1. Assessment of glycemic control

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

a. Glucose monitoring

Recommendations

- SMBG should be carried out three or more times daily for patients using multiple insulin injections or insulin pump therapy. (A)
- For patients using less frequent insulin injections, noninsulin therapies, or medical nutrition therapy (MNT) alone, SMBG may be useful as a guide to the success of therapy. (E)
- To achieve postprandial glucose targets, postprandial SMBG may be appropriate. (E)
- When prescribing SMBG, ensure that patients receive initial instruction in, and routine follow-up evaluation of, SMBG technique and using data to adjust therapy. (E)
- Continuous glucose monitoring (CGM) in conjunction with intensive insulin regimens can be a useful tool to lower A1C in selected adults (age ≥25 years) with type 1 diabetes (A).
- Although the evidence for A1C lowering is less strong in children, teens, and younger adults, CGM may be helpful in these groups. Success correlates with adherence to ongoing use of the device. (C)
- CGM may be a supplemental tool to SMBG in those with hypoglycemia unawareness and/or frequent hypoglycemic episodes. (E)

The ADA consensus and position statements on SMBG provide a comprehensive review of the subject (37,38). Major clinical trials of insulin-treated patients that demonstrated the benefits of intensive glycemic control on diabetes complications have included SMBG as part of multifactorial interventions, suggesting that SMBG is a component of effective therapy. SMBG allows patients to evaluate their individual response to therapy and assess whether glycemic targets are being achieved. Results of SMBG can be useful in preventing hypoglycemia and adjusting medications (particularly prandial insulin doses), MNT, and physical activity.

Table 8—*Components of the comprehensive diabetes evaluation*

Medical history
- Age and characteristics of onset of diabetes (e.g., DKA, asymptomatic laboratory finding)
- Eating patterns, physical activity habits, nutritional status, and weight history; growth and development in children and adolescents
- Diabetes education history
- Review of previous treatment regimens and response to therapy (A1C records)

Current treatment of diabetes, including medications, meal plan, physical activity patterns, and results of glucose monitoring and patient's use of data
- DKA frequency, severity, and cause
- Hypoglycemic episodes
  - Hypoglycemia awareness
  - Any severe hypoglycemia: frequency and cause
- History of diabetes-related complications
  - Microvascular: retinopathy, nephropathy, neuropathy (sensory, including history of foot lesions; autonomic, including sexual dysfunction and gastroparesis)
  - Macrovascular: CHD, cerebrovascular disease, PAD
  - Other: psychosocial problems*, dental disease*

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

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

Referrals
- Annual dilated eye exam
- Family planning for women of reproductive age
- Registered dietitian for MNT
- DSME
- Dental examination
- Mental health professional, if needed

* See appropriate referrals for these categories.

The frequency and timing of SMBG should be dictated by the particular needs and goals of the patient. SMBG is especially important for patients treated with insulin in order to monitor for and prevent asymptomatic hypoglycemia and hyperglycemia. For most patients with type 1 diabetes and pregnant women taking insulin, SMBG is recommended three or more times daily. For these populations, significantly more frequent testing may be required to reach A1C targets safely without hypoglycemia. The optimal frequency and timing of SMBG for patients with type 2 diabetes on noninsulin therapy is unclear. A meta-analysis of SMBG in non–insulin-treated patients with type 2 diabetes concluded that some regimen of SMBG was associated with a reduction in A1C of 0.4%. However, many of the studies in this analysis also included patient education with diet and exercise counseling and, in some cases, pharmacologic intervention, making it difficult to assess the contribution of SMBG alone to improved control (39). Several recent trials have called into question the clinical utility and cost-effectiveness of routine SMBG in non–insulin-treated patients (40–42).

Because the accuracy of SMBG is instrument and user dependent (43), it is important to evaluate each patient's monitoring technique, both initially and at regular intervals thereafter. In addition, optimal use of SMBG requires proper 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, and these skills should be reevaluated periodically.

CGM through the measurement of interstitial glucose (which correlates well with PG) is available. These sensors require calibration with SMBG, and the latter are still recommended for making acute treatment decisions. CGM devices also have alarms for hypo- and hyperglycemic excursions. Small studies in selected patients with type 1 diabetes have suggested that CGM use reduces the time spent in hypo- and hyperglycemic ranges and may modestly improve glycemic control. A larger 26-week randomized trial of 322 type 1 diabetic patients showed that adults age 25 years and older using intensive insulin therapy and CGM experienced a 0.5% reduction in A1C (from ~7.6 to 7.1%) compared with usual intensive insulin therapy with SMBG (44). Sensor use in children, teens, and adults to age 24 years did not result in significant A1C lowering, and there was no significant difference in hypoglycemia in any group. Importantly, the greatest predictor of A1C lowering in this study for all age-groups was frequency of sensor use, which was lower in younger age-groups. In a smaller randomized controlled trial of 129 adults and children with baseline A1C <7.0%, outcomes combining A1C and hypoglycemia favored the group using CGM, suggesting that CGM is also beneficial for individuals with type 1 diabetes who have already achieved excellent control with A1C <7.0% (45). Although CGM is an evolving technology, emerging data suggest that it may offer benefit in appropriately selected patients who are motivated to wear it most of the time. CGM may be particularly useful in those with hypoglycemia unawareness and/or frequent episodes of hypoglycemia, and studies in this area are ongoing.

b. A1C

Recommendations

- Perform the A1C test at least two times a year in patients who are meeting treatment goals (and who have stable glycemic control). (E)

- Perform the A1C test quarterly in patients whose therapy has changed or who are not meeting glycemic goals. (E)
- Use of point-of-care testing for A1C allows for timely decisions on therapy changes, when needed. (E)

Because A1C is thought to reflect average glycemia over several months (43) and has strong predictive value for diabetes complications (11,46), A1C testing should be performed routinely in all patients with diabetes, at initial assessment and then as part of continuing care. Measurement approximately every 3 months determines whether a patient's glycemic targets have been reached and maintained. For any individual patient, the frequency of A1C testing should be dependent on the clinical situation, the treatment regimen used, and the judgment of the clinician. Some patients with stable glycemia well within target may do well with testing only twice per year, while unstable or highly intensively managed patients (e.g., pregnant type 1 diabetic women) may be tested more frequently than every 3 months. The availability of the A1C result at the time that the patient is seen (point-of-care testing) has been reported to result in increased intensification of therapy and improvement in glycemic control (47,48).

The A1C test is subject to certain limitations. Conditions that affect erythrocyte turnover (hemolysis, blood loss) and hemoglobin variants must be considered, particularly when the A1C result does not correlate with the patient's clinical situation (43). In addition, A1C does not provide a measure of glycemic variability or hypoglycemia. For patients prone to glycemic variability (especially type 1 diabetic patients, or type 2 diabetic patients with severe insulin deficiency), glycemic control is best judged by the combination of results of SMBG testing and the A1C. The A1C may also serve as a check on the accuracy of the patient's meter (or the patient's reported SMBG results) and the adequacy of the SMBG testing schedule.

Table 9 contains the correlation between A1C levels and mean PG levels based on data from the international A1C-Derived Average Glucose (ADAG) trial using frequent SMBG and CGM in 507 adults (83% Caucasian) with type 1, type 2, and no diabetes (49). ADA and the American Association of Clinical Chemists have determined that the correlation ($r = 0.92$) is strong enough to justify reporting both an A1C result and an estimated average glucose (eAG) result when a clinician orders the A1C test. In previous versions of the Standards of Medical Care in Diabetes, the table describing the correlation between A1C and mean glucose was derived from relatively sparse data (one seven-point profile over 1 day per A1C reading) in the primarily Caucasian type 1 participants in the DCCT (50). Clinicians should note that the numbers in the table are now different, as they are based on ~2,800 readings per A1C in the ADAG trial.

Table 9—*Correlation of A1C with average glucose*

	Mean plasma glucose	
A1C (%)	mg/dl	mmol/l
6	126	7.0
7	154	8.6
8	183	10.2
9	212	11.8
10	240	13.4
11	269	14.9
12	298	16.5

These estimates are based on ADAG data of ~2,700 glucose measurements over 3 months per A1C measurement in 507 adults with type 1, type 2, and no diabetes. The correlation between A1C and average glucose was 0.92 (49). A calculator for converting A1C results into estimated average glucose (eAG), in either mg/dl or mmol/l, is available at http://professional.diabetes.org/eAG.

In the ADAG trial, there were no significant differences among racial and ethnic groups in the regression lines between A1C and mean glucose, although there was a trend toward a difference between Africans/African Americans participants and Caucasians that might have been significant had more Africans/African Americans been studied. A recent study comparing A1C to CGM data in 48 type 1 diabetic children found a highly statistically significant correlation between A1C and mean blood glucose, although the correlation ($r = 0.7$) was significantly lower than in the ADAG trial (51). Whether there are significant differences in how A1C relates to average glucose in children or in African American patients is an area for further study. For the time being, the question has not led to different recommendations about testing A1C or different interpretations of the clinical meaning of given levels of A1C in those populations.

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

2. Glycemic goals in adults

- Lowering A1C to below or around 7% has been shown to reduce microvascular and neuropathic complications of type 1 and type 2 diabetes. Therefore, for microvascular disease prevention, the A1C goal for nonpregnant adults in general is <7%. (A)
- In type 1 and type 2 diabetes, randomized controlled trials of intensive versus standard glycemic control have not shown a significant reduction in CVD outcomes during the randomized portion of the trials. Long-term follow-up of the DCCT and UK Prospective Diabetes Study (UKPDS) cohorts suggests that treatment to A1C targets below or around 7% in the years soon after the diagnosis of diabetes is associated with long-term reduction in risk of macrovascular disease. Until more evidence becomes available, the general goal of <7% appears reasonable for many adults for macrovascular risk reduction. (B)
- Subgroup analyses of clinical trials such as the DCCT and UKPDS, and evidence for reduced proteinuria in the Action in Diabetes and Vascular Disease: Preterax and Diamicron Modified Release Controlled Evaluation (ADVANCE) trial suggest a small but incremental benefit in microvascular outcomes with A1C values closer to normal. Therefore, for selected individual patients, providers might reasonably suggest even lower A1C goals than the general goal of <7%, if this can be achieved without significant hypoglycemia or other adverse effects of treatment. Such patients might include those with short duration of diabetes, long life expectancy, and no significant CVD. (B)
- Conversely, less-stringent A1C goals than the general goal of <7% may be appropriate for patients with a history of severe hypoglycemia, limited life expectancy, advanced microvascular or macrovascular complications, and extensive comorbid conditions and those with longstanding diabetes in whom the general goal is difficult to attain de-

spite diabetes self-management education, appropriate glucose monitoring, and effective doses of multiple glucose-lowering agents including insulin. (C)

Glycemic control is fundamental to the management of diabetes. The DCCT, a prospective, randomized, controlled trial of intensive versus standard glycemic control in patients with relatively recently diagnosed type 1 diabetes, showed definitively that improved glycemic control is associated with significantly decreased rates of microvascular (retinopathy and nephropathy) as well as neuropathic complications (53). Follow-up of the DCCT cohorts in the Epidemiology of Diabetes Interventions and Complications (EDIC) study has shown persistence of this effect in previously intensively treated subjects, even though their glycemic control has been equivalent to that of previous standard arm subjects during follow-up (54,55).

In type 2 diabetes, the Kumamoto study (56) and the UKPDS (57,58) demonstrated significant reductions in microvascular and neuropathic complications with intensive therapy. Similar to the DCCT-EDIC findings, long-term follow-up of the UKPDS cohort has recently demonstrated a "legacy effect" of early intensive glycemic control on long-term rates of microvascular complications, even with loss of glycemic separation between the intensive and standard cohorts after the end of the randomized controlled trial (59). The more recent Veterans Affairs Diabetes Trial (VADT) in type 2 diabetes also showed significant reductions in albuminuria with intensive (achieved median A1C 6.9%) compared with standard glycemic control but no difference in retinopathy and neuropathy (60,61).

In each of these large randomized prospective clinical trials, treatment regimens that reduced average A1C to 7% (1% above the upper limits of normal) were associated with fewer markers of long-term microvascular complications; however, intensive control was found to increase the risk of severe hypoglycemia and led to weight gain (46,60,62).

Epidemiological analyses of the DCCT and UKPDS (46,53) demonstrate a curvilinear relationship between A1C and microvascular complications. Such analyses suggest that, on a population level, the greatest number of complications will be averted by taking patients from very poor control to fair or good control. These analyses also suggest that further lowering of A1C from 7 to 6% is associated with further reduction in the risk of microvascular complications, albeit the absolute risk reductions become much smaller. The ADVANCE study of intensive versus standard glycemic control in type 2 diabetes found a statistically significant reduction in albuminuria with an A1C target of <6.5% (achieved median A1C 6.3%) compared with standard therapy achieving a median A1C of 7.0% (63). Given the substantially increased risk of hypoglycemia (particularly in those with type 1 diabetes, but also in the recent type 2 diabetes trials described below), the concerning mortality findings in the Action to Control Cardiovascular Risk in Diabetes (ACCORD) trial described below and the relatively much greater effort required to achieve near-normoglycemia, the risks of lower targets may outweigh the potential benefits on microvascular complications on a population level. However, selected individual patients, especially those with little comorbidity and long life expectancy (who may reap the benefits of further lowering glycemia below 7%) may, at patient and provider judgment, adopt glycemic targets as close to normal as possible as long as significant hypoglycemia does not become a barrier.

Whereas many epidemiologic studies and meta-analyses (64,65) have clearly shown a direct relationship between A1C and CVD, the potential of intensive glycemic control to reduce CVD has been less clearly defined. In the DCCT, there was a trend toward lower risk of CVD events with intensive control (risk reduction 41%, 95% CI 10–68%), but the number of events was small. However, 9-year post-DCCT follow-up of the cohort has shown that participants previously randomized to the intensive arm had a 42% reduction ($P = 0.02$) in CVD outcomes and a 57% reduction ($P = 0.02$) in the risk of nonfatal myocardial infarction (MI), stroke, or CVD death compared with participants previously in the standard arm (66). The benefit of intensive glycemic control in this type 1 diabetic cohort has recently been shown to persist for up to 30 years (67).

The UKPDS trial of type 2 diabetes observed a 16% reduction in cardiovascular complications (combined fatal or nonfatal MI and sudden death) in the intensive glycemic control arm, although this difference was not statistically significant ($P = 0.052$), and there was no suggestion of benefit on other CVD outcomes such as stroke. In an epidemiologic analysis of the study cohort, a continuous association was observed such that for every percentage point lower median on-study A1C (e.g., 8–7%), there was a statistically significant 18% reduction in CVD events, again with no glycemic threshold. A recent report of 10 years of follow-up of the UKPDS cohort described, for the participants originally randomized to intensive glycemic control compared with those randomized to conventional glycemic control, long-term reductions in MI (15% with sulfonylurea or insulin as initial pharmacotherapy, 33% with metformin as initial pharmacotherapy, both statistically significant) and in all-cause mortality (13 and 27%, respectively, both statistically significant) (59).

Because of ongoing uncertainty regarding whether intensive glycemic control can reduce the increased risk of CVD events in people with type 2 diabetes, several large long-term trials were launched in the past decade to compare the effects of intensive versus standard glycemic control on CVD outcomes in relatively high-risk participants with established type 2 diabetes. In 2008, results of three large trials (ACCORD, ADVANCE, and VADT) suggested no significant reduction in CVD outcomes with intensive glycemic control in these populations. Details of these three studies are shown in Table 10, and their results and implications are reviewed more extensively in a recent ADA position statement (52).

The ACCORD study randomized 10,251 participants with either history of a CVD event or significant CVD risk to a strategy of intensive glycemic control (target A1C <6.0%) or standard glycemic control (A1C target 7.0–7.9%). Investigators used multiple glycemic medications in both arms. From a baseline median A1C of 8.1%, the intensive arm reached a median A1C of 6.4% within 12 months of randomization, while the standard group reached a median A1C of 7.5%. Other risk factors were treated aggressively and equally in both groups. The intensive glycemic control group had more use of insulin in combination with multiple oral agents, significantly more weight gain, and more episodes of severe hypoglycemia than the standard group.

In early 2008, the glycemic control arm of ACCORD was halted on the recommendation of the study's data safety monitoring board due to the finding of an increased rate of mortality in the intensive arm compared with the standard arm

Table 10—*Comparison of the three trials of intensive glycemic control and CVD outcomes*

	ACCORD	ADVANCE	VADT
Participant characteristics			
n	10,251	11,140	1,791
Mean age (years)	62	66	60
Duration of diabetes (years)	10	8	11.5
History of CVD (%)	35	32	40
Median baseline A1C (%)	8.1	7.2	9.4
On insulin at baseline (%)	35	1.5	52
Protocol characteristics			
A1C goals (%) (I vs. S)*	<6.0 vs. 7.0–7.9	≤6.5 vs. "based on local guidelines"	<6.0 (action if >6.5) vs. planned separation of 1.5
Protocol for glycemic control (I vs. S)*	Multiple drugs in both arms	Multiple drugs added to gliclizide vs. multiple drugs with no gliclizide	Multiple drugs in both arms
Management of other risk factors	Embedded blood pressure and lipid trials	Embedded blood pressure trial	Protocol for intensive treatment in both arms
On-study characteristics			
Achieved median A1C (%) (I vs. S)	6.4 vs. 7.5	6.3 vs. 7.0	6.9 vs. 8.5
On insulin at study end (%) (I vs. S)*	77 vs. 55*	40 vs. 24	89 vs. 0.74
Weight changes (kg)			
Intensive glycemic control arm	+3.5	−0.1	+7.8
Standard glycemic control arm	+0.4	−1.0	+3.4
Severe hypoglycemia (participants with one or more episodes during study) (%)			
Intensive glycemic control arm	16.2	2.7	21.2
Standard glycemic control arm	5.1	1.5	9.9
Outcomes			
Definition of primary outcome	Nonfatal MI, nonfatal stroke, CVD death	Microvascular plus macrovascular (nonfatal MI, nonfatal stroke, CVD death) outcomes	Nonfatal MI, nonfatal stroke, CVD death, hospitalization for heart failure, revascularization
HR for primary outcome (95% CI)	0.90 (0.78–1.04)	0.9 (0.82–0.98); macrovascular 0.94 (0.84–1.06)	0.88 (0.74–1.05)
HR for mortality findings (95% CI)	1.22 (1.01–1.46)	0.93 (0.83–1.06)	1.07 (0.81–1.42)

*Insulin rates for ACCORD are for any use during the study. I, intensive glycemic control; S, standard glycemic control. Abridged from ref. 52.

(1.41 vs. 1.14%/year, hazard ratio 1.22, 95% CI 1.01–1.46), with a similar increase in cardiovascular deaths. The primary outcome of ACCORD (MI, stroke, or cardiovascular death) was lower in the intensive glycemic control group due to a reduction in nonfatal MI, although this finding was not statistically significant when the study was terminated (68). Of note, prespecified subset analyses showed that participants with no previous CVD event and those who had a baseline A1C <8% had a statistically significant reduction in the primary CVD outcome, although overall mortality was not reduced in these groups.

The cause of excess deaths in the intensive group of the ACCORD has been difficult to pinpoint (and is discussed in some detail in a 2009 ADA position statement [52]). However, exploratory analyses of the mortality findings of ACCORD (evaluating variables including weight gain, use of any specific drug or drug combination, and hypoglycemia) were reportedly unable to identify a clear explanation for the excess mortality in the intensive arm. At the 69th Scientific Sessions of the American Diabetes Association, the ACCORD investigators presented additional analyses showing no increase in mortality in participants who achieved A1C levels <7% or in those who lowered their A1C quickly after trial enrollment. In fact, the converse was observed: those at highest risk for mortality were participants in the intensive arm with the highest A1C levels.

The ADVANCE study randomized participants to a strategy of intensive glycemic control (with primary therapy being the sulfonylurea gliclizide and additional medications as needed to achieve a target A1C of ≤6.5%) or to standard therapy (in which any medication but gliclizide could be used and the glycemic target was according to "local guidelines"). ADVANCE participants

were slightly older than those in ACCORD and VADT and had similar high CVD risk. However, they had an average duration of diabetes that was 2 years shorter, lower baseline A1C (median 7.2%), and almost no use of insulin at enrollment. The median A1C levels achieved in the intensive and standard arms were 6.3 and 7.0%, respectively, and maximal separation between the arms took several years to achieve. Use of other drugs that favorably impact CVD risk (aspirin, statins, and angiotensin enzyme inhibitors) was lower in ADVANCE than in ACCORD or VADT.

The primary outcome of ADVANCE was a combination of microvascular events (nephropathy and retinopathy) and major adverse cardiovascular events (MI, stroke, and cardiovascular death). Intensive glycemic control significantly reduced the primary end point, although this was due to a significant reduction in the microvascular outcome, primarily development of macroalbuminuria, with no significant reduction in the macrovascular outcome. There was no difference in overall or cardiovascular mortality between the intensive compared with the standard glycemic control arms (63).

VADT randomized participants with type 2 diabetes uncontrolled on insulin or maximal dose oral agents (median entry A1C 9.4%) to a strategy of intensive glycemic control (goal A1C <6.0%) or standard glycemic control, with a planned A1C separation of at least 1.5%. Medication treatment algorithms were used to achieve the specified glycemic goals, with a goal of using similar medications in both groups. Median A1C levels of 6.9 and 8.4% were achieved in the intensive and standard arms, respectively, within the 1st year of the study. Other CVD risk factors were treated aggressively and equally in both groups.

The primary outcome of VADT was a composite of CVD events. The cumulative primary outcome was nonsignificantly lower in the intensive arm. There were more CVD deaths in the intensive arm than in the standard arm, but the difference was not statistically significant (60). Post hoc subgroup analyses suggested that duration of diabetes interacted with randomization such that participants with duration of diabetes less than about 12 years appeared to have a CVD benefit of intensive glycemic control while those with longer duration of disease prior to study entry had a neutral or even adverse effect of intensive glycemic control. Other exploratory analyses suggested that severe hypoglycemia within the past 90 days was a strong predictor of the primary outcome and of CVD mortality (69).

All three of these trials were carried out in participants with established diabetes (mean duration 8–11 years) and either known CVD or multiple risk factors suggesting the presence of established atherosclerosis. Subset analyses of the three trials suggested a significant benefit of intensive glycemic control on CVD in participants with shorter duration of diabetes, lower A1C at entry, and/or absence of known CVD. The DCCT-EDIC study and the long-term follow-up of the UKPDS cohort both suggest that intensive glycemic control initiated soon after diagnosis of diabetes in patients with a lower level of CVD risk may impart long-term protection from CVD events. As is the case with microvascular complications, it may be that glycemic control plays a greater role before macrovascular disease is well developed and minimal or no role when it is advanced. Consistent with this concept, data from an ancillary study of VADT demonstrated that intensive glycemic control was quite effective in reducing CVD events in individuals with less atherosclerosis at baseline (assessed by coronary calcium) but not in people with more extensive baseline atherosclerosis (70).

The benefits of intensive glycemic control on microvascular and neuropathic complications are well established for both type 1 and type 2 diabetes. ADVANCE and VADT have added to that evidence base by demonstrating a significant reduction in the risk of new or worsening albuminuria with intensive glycemic control. The lack of significant reduction in CVD events with intensive glycemic control in ACCORD, ADVANCE, and VADT should not lead clinicians to abandon the general target of an A1C <7.0% and thereby discount the benefit of good control on serious and debilitating microvascular complications.

The evidence for a cardiovascular benefit of intensive glycemic control primarily rests on long-term follow-up of study cohorts treated early in the course of type 1 and type 2 diabetes as well as subset analyses of ACCORD, ADVANCE, and VADT. A recent group-level meta-analysis of the three trials suggests that glucose lowering has a modest (9%) but statistically significant reduction in major CVD outcomes, primarily nonfatal MI, with no significant increase in mortality. A prespecified subgroup analysis suggested that major CVD outcome reduction occurred in patients without known CVD at baseline (HR 0.84 [95% CI 0.74–0.94]) (71). Conversely, the mortality findings in ACCORD and subgroup analyses of VADT suggest that the potential risks of very intensive glycemic control may outweigh its benefits in some patients, such as those with very long duration of diabetes, known history of severe hypoglycemia, advanced atherosclerosis, and advanced age/frailty. Certainly, providers should be vigilant in preventing severe hypoglycemia in patients with advanced disease and should not aggressively attempt to achieve near-normal A1C levels in patients in whom such a target cannot be reasonably easily and safely achieved.

Recommended glycemic goals for nonpregnant adults are shown in Table 11. The recommendations are based on those for A1C values, with listed blood glucose levels that appear to correlate with achievement of an A1C of <7%. The issue of pre- versus postprandial SMBG targets is complex (72). Elevated postchallenge (2-h OGTT) glucose values have been associated with increased cardiovascular risk independent of FPG in some epidemiological studies. In diabetic subjects, some surrogate measures of vascular pathology, such as endothelial dysfunction, are negatively affected by postprandial hyperglycemia (73). It is clear that postprandial hyperglycemia, like preprandial hyperglycemia, contributes to elevated A1C levels, with its relative contribution being higher at A1C levels that are closer to 7%. However, outcome studies have clearly shown A1C to be the primary predictor of complications, and landmark glycemic control trials such as the DCCT and UKPDS relied overwhelmingly on preprandial SMBG. Additionally, a randomized controlled trial in patients with known CVD found no CVD benefit of insulin regimens targeting postprandial glucose compared with those targeting preprandial glucose (74). For individuals who have premeal glucose values within target but A1C values above target, a reasonable recommendation for postprandial testing and targets is monitoring postprandial plasma glucose (PPG) 1–2 h after the start of the meal and treatment aimed at reducing PPG values to <180 mg/dl to help lower A1C.

As noted above, less stringent treatment goals may be appropriate for adults with limited life expectancies or advanced

Table 11 —*Summary of glycemic recommendations for non-pregnant adults with diabetes*

A1C	<7.0%*
Preprandial capillary plasma glucose	70–130 mg/dl (3.9–7.2 mmol/l)
Peak postprandial capillary plasma glucose†	<180 mg/dl (<10.0 mmol/l)
Key concepts in setting glycemic goals:	
• A1C is the primary target for glycemic control	
• Goals should be individualized based on:	
• duration of diabetes	
• age/life expectancy	
• comorbid conditions	
• known CVD or advanced microvascular complications	
• hypoglycemia unawareness	
• individual patient considerations	
• More or less stringent glycemic goals may be appropriate for individual patients	
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.

vascular disease. Glycemic goals for children are provided in VII.A.1.a. Glycemic control. Severe or frequent hypoglycemia is an absolute indication for the modification of treatment regimens, including setting higher glycemic goals.

Regarding goals for glycemic control for women with GDM, recommendations from the Fifth International Workshop-Conference on Gestational Diabetes (75) are to target maternal capillary glucose concentrations of:

- Preprandial ≤95 mg/dl (5.3 mmol/l) and either
  - 1-h postmeal ≤140 mg/dl (7.8 mmol/l)

  or
  - 2-h postmeal ≤120 mg/dl (6.7 mmol/l)

For women with preexisting type 1 or type 2 diabetes who become pregnant, a recent consensus statement (76) recommends the following as optimal glycemic goals, if they can be achieved without excessive hypoglycemia:

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

3. Approach to treatment

a. Therapy for type 1 diabetes. The DCCT clearly showed that intensive insulin therapy (three or more injections per day of insulin or continuous subcutaneous insulin infusion [CSII] or insulin pump therapy) was a key part of improved glycemia and better outcomes (53,66). At the time of the study, therapy was carried out with short- and intermediate-acting human insulins. Despite better microvascular outcomes, intensive insulin therapy was associated with a high rate in severe hypoglycemia (62 episodes per 100 patient-years of therapy). Since the time of the DCCT, a number of rapid-acting and long-acting insulin analogs have been developed. These analogs are associated with less hypoglycemia with equal A1C lowering in type 1 diabetes (77,78).

Recommended therapy for type 1 diabetes therefore consists of the following components: *1*) use of multiple dose insulin injections (3–4 injections per day of basal and prandial insulin) or CSII therapy; *2*) matching of prandial insulin to carbohydrate intake, premeal blood glucose, and anticipated activity; and *3*) for many patients (especially if hypoglycemia is a problem), use of insulin analogs. There are excellent reviews available that guide the initiation and management of insulin therapy to achieve desired glycemic goals (3,77,79).

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

b. Therapy for type 2 diabetes. The ADA and the European Association for the Study of Diabetes (EASD) published a consensus statement on the approach to management of hyperglycemia in individuals with type 2 diabetes (80) and a subsequent update (81). Highlights of this approach include: intervention at the time of diagnosis with metformin in combination with lifestyle changes (MNT and exercise) and continuing timely augmentation of therapy with additional agents (including early initiation of insulin therapy) as a means of achieving and maintaining recommended levels of glycemic control (i.e., A1C <7% for most patients). The overall objective is to achieve and maintain glycemic control and to change interventions when therapeutic goals are not being met.

The algorithm took into account the evidence for A1C lowering of the individual interventions, their additive effects, and their expense. The precise drugs used and their exact sequence may not be as important as achieving and maintaining glycemic targets safely. Medications not included in the consensus algorithm, owing to less glucose-lowering effectiveness, limited clinical data, and/or relative expense, still may be appropriate choices for individual patients to achieve glycemic goals. Initiation of insulin at the time of diagnosis is recommended for individuals presenting with weight loss or other severe hyperglycemic symptoms or signs.

D. Medical nutrition therapy

General recommendations

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

Energy balance, overweight, and obesity

- In overweight and obese insulin-resistant individuals, modest weight loss has been shown to reduce insulin resistance. Thus, weight loss is recommended for all overweight or obese individuals who have or are at risk for diabetes. (A)
- For weight loss, either low-carbohydrate or low-fat calorie-restricted diets

may be effective in the short-term (up to 1 year). (A)
- For patients on low-carbohydrate diets, monitor lipid profiles, renal function, and protein intake (in those with nephropathy) and adjust hypoglycemic therapy as needed. (E)
- Physical activity and behavior modification are important components of weight loss programs and are most helpful in maintenance of weight loss. (B)

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

Dietary fat intake in diabetes management
- Saturated fat intake should be <7% of total calories. (A)
- Reducing intake of *trans* fat lowers LDL cholesterol and increases HDL cholesterol (A); therefore intake of *trans* fat should be minimized (E).

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

Other nutrition recommendations
- Sugar alcohols and nonnutritive sweeteners are safe when consumed within the acceptable daily intake levels established by the Food and Drug Administration (FDA). (A)
- If adults with diabetes choose to use alcohol, daily intake should be limited to a moderate amount (one drink per day or less for adult women and two drinks per day or less for adult men). (E)
- Routine supplementation with antioxidants, such as vitamins E and C and carotene, is not advised because of lack of evidence of efficacy and concern related to long-term safety. (A)
- Benefit from chromium supplementation in people with diabetes or obesity has not been conclusively demonstrated and therefore cannot be recommended. (C)
- Individualized meal planning should include optimization of food choices to meet recommended dietary allowances (RDAs)/dietary reference intakes (DRIs) for all micronutrients. (E)

MNT is an integral component of diabetes prevention, management, and self-management education. In addition to its role in preventing and controlling diabetes, ADA recognizes the importance of nutrition as an essential component of an overall healthy lifestyle. A full review of the evidence regarding nutrition in preventing and controlling diabetes and its complications and additional nutrition-related recommendations can be found in the ADA position statement, Nutrition Recommendations and Interventions for Diabetes, published in 2006 and updated for 2008 (82). Achieving nutrition-related goals requires a coordinated team effort that includes the active involvement of the person with pre-diabetes or diabetes. Because of the complexity of nutrition issues, it is recommended that a registered dietitian who is knowledgeable and skilled in implementing nutrition therapy into diabetes management and education be the team member who provides MNT.

Clinical trials/outcome studies of MNT have reported decreases in A1C at 3–6 months ranging from 0.25 to 2.9% with higher reductions seen in type 2 diabetes of shorter duration. Multiple studies have demonstrated sustained improvements in A1C at 12 months and longer when a registered dietitian provided follow-up visits ranging from monthly to three sessions per year (83–90). Meta-analyses of studies in nondiabetic, free-living subjects report that MNT reduces LDL cholesterol by 15–25 mg/dl (91) or by up to 16% (92), while clinical trials support a role for lifestyle modification in treating hypertension (92,93).

Because of the effects of obesity on insulin resistance, weight loss is an important therapeutic objective for overweight or obese individuals with pre-diabetes or diabetes (94). Short-term studies have demonstrated that moderate weight loss (5% of body weight) in subjects with type 2 diabetes is associated with decreased insulin resistance, improved measures of glycemia and lipemia, and reduced blood pressure (95); longer-term studies (≥52 weeks) showed mixed effects on A1C in adults with type 2 diabetes (96–99), and results were confounded by pharmacologic weight loss therapy. A systematic review of 80 weight loss studies of ≥1 year duration demonstrated that moderate weight loss achieved through diet alone, diet and exercise, and meal replacements can be achieved and maintained over the long term (4.8–8% weight loss at 12 months [100]). The multifactorial intensive lifestyle intervention used in the DPP, which included reduced intake of fat and calories, led to weight loss averaging 7% at 6 months and maintenance of 5% weight loss at 3 years, associated with a 58% reduction in incidence of type 2 diabetes (11). Look AHEAD (Action for Health in Diabetes) is a large clinical trial designed to determine whether long-term weight loss will improve glycemia and prevent cardiovascular events in subjects with type 2 diabetes. One-year results of the intensive lifestyle intervention in this trial show an average of 8.6% weight loss, significant reduction of A1C, and reduction in several CVD risk factors (101). When completed, the Look AHEAD study should provide insight into the effects of long-term weight loss on important clinical outcomes.

The optimal macronutrient distribution of weight loss diets has not been established. Although low-fat diets have traditionally been promoted for weight loss, several randomized controlled trials found that subjects on low-carbohydrate diets (<130 g/day of carbohydrate) lost more weight at 6 months than subjects on low-fat diets (102,103); however, at 1 year, the difference in weight loss between the low-carbohydrate and low-fat diets was not significant and weight loss was modest with both diets. Another study of overweight women randomized to one of four diets showed significantly more weight loss at 12 months with the Atkins low-carbohydrate diet than with higher-carbohydrate diets (104). Changes in serum triglyceride and HDL

cholesterol were more favorable with the low-carbohydrate diets. In one study, those subjects with type 2 diabetes demonstrated a greater decrease in A1C with a low-carbohydrate diet than with a low-fat diet (103). A recent meta-analysis showed that at 6 months, low-carbohydrate diets were associated with greater improvements in triglyceride and HDL cholesterol concentrations than low-fat diets; however, LDL cholesterol was significantly higher with the low-carbohydrate diets (105). In a 2-year dietary intervention study, Mediterranean and low-carbohydrate diets were found to be effective and safe alternatives to a low-fat diet for weight reduction in moderately obese participants (99).

The RDA for digestible carbohydrate is 130 g/day and is based on providing adequate glucose as the required fuel for the central nervous system without reliance on glucose production from ingested protein or fat. Although brain fuel needs can be met on lower-carbohydrate diets, long-term metabolic effects of very-low-carbohydrate diets are unclear, and such diets eliminate many foods that are important sources of energy, fiber, vitamins, and minerals that are important in dietary palatability (106).

Although numerous studies have attempted to identify the optimal mix of macronutrients for meal plans of people with diabetes, it is unlikely that one such combination of macronutrients exists. The best mix of carbohydrate, protein, and fat appears to vary depending on individual circumstances. For those individuals seeking guidance as to macronutrient distribution in healthy adults, DRIs may be helpful (106). It must be clearly recognized that regardless of the macronutrient mix, the total caloric intake must be appropriate to the weight management goal. Further, individualization of the macronutrient composition will depend on the metabolic status of the patient (e.g., lipid profile and renal function) and/or food preferences. Plant-based diets (vegan or vegetarian) that are well planned and nutritionally adequate have also been shown to improve metabolic control (107,108).

The primary goal with respect to dietary fat in individuals with diabetes is to limit saturated fatty acids, *trans* fatty acids, and cholesterol intake so as to reduce risk for CVD. Saturated and *trans* fatty acids are the principal dietary determinants of plasma LDL cholesterol. There is a lack of evidence on the effects of specific fatty acids on people with diabetes; therefore, the recommended goals are consistent with those for individuals with CVD (92,109).

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

Reimbursement for MNT

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

E. Bariatric surgery

Recommendations

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

Gastric reduction surgery, either gastric banding or procedures that involve bypassing or transposing sections of the small intestine, when part of a comprehensive team approach, can be an effective weight loss treatment for severe obesity, and national guidelines support its consideration for people with type 2 diabetes who have BMI >35 kg/m^2. Bariatric surgery has been shown to lead to near or complete normalization of glycemia in ~55–95% of patients with type 2 diabetes, depending on the surgical procedure. A meta-analysis of studies of bariatric surgery reported that 78% of individuals with type 2 diabetes had complete "resolution" of diabetes (normalization of blood glucose levels in the absence of medications) and that the resolution rates were sustained in studies that had follow-up exceeding 2 years (110). Resolution rates are lower with procedures that only constrict the stomach and higher with those that bypass portions of the small intestine. Additionally, there is a suggestion that intestinal bypass procedures may have glycemic effects that are independent of their effects on weight.

A recent randomized controlled trial compared adjustable gastric banding to the "best available" medical and lifestyle therapy in subjects with type 2 diabetes diagnosed <2 years before randomization and with BMI 30–40 kg/m^2 (111). In this trial, 73% of surgically treated patients achieved "remission" of their diabetes, compared with 13% of those treated medically. The latter group lost only 1.7% of body weight, suggesting that their therapy was not optimal. Overall the trial had 60 subjects, and only 13 had a BMI <35 kg/m^2, making it difficult to generalize these results to diabetic patients who are less severely obese or with longer duration of diabetes.

Bariatric surgery is costly in the short term and has some risks. Rates of morbidity and mortality directly related to the surgery have been reduced considerably in recent years, with 30-day mortality rates now 0.28%, similar to those of laparoscopic cholecystectomy (112). Longer-term concerns include vitamin and mineral deficiencies, osteoporosis, and rare but often severe hypoglycemia from insulin hypersecretion. Cohort studies attempting to match subjects suggest that the procedure may reduce longer-term mortality rates (113), and it is reasonable to postulate that there may be recouping of costs over the long term. However, studies of the mechanisms of glycemic improvement, long-term benefits and risks, and cost-effectiveness of bariatric surgery in individuals with type 2 diabetes will require

well-designed, randomized clinical trials with optimal medical and lifestyle therapy of diabetes and cardiovascular risk factors as the comparators.

F. Diabetes self-management education

Recommendations

- People with diabetes should receive DSME according to national standards when their diabetes is diagnosed and as needed thereafter. (B)
- Effective self-management and quality of life are the key outcomes of DSME and should be measured and monitored as part of care. (C)
- DSME should address psychosocial issues, since emotional well-being is associated with positive diabetes outcomes. (C)
- Because DSME can result in cost-savings and improved outcomes (B), DSME should be reimbursed by third-party payors. (E)

DSME is an essential element of diabetes care (114–120), and national standards for DSME (121) are based on evidence for its benefits. Education helps people with diabetes initiate effective self-management and cope with diabetes when they are first diagnosed. Ongoing DSME and support also help people with diabetes maintain effective self-management throughout a lifetime of diabetes as they face new challenges and as treatment advances become available. DSME helps patients optimize metabolic control, prevent and manage complications, and maximize quality of life in a cost-effective manner (122).

DSME is the on-going process of facilitating the knowledge, skill, and ability necessary for diabetes self-care (121). This process incorporates the needs, goals, and life experiences of the person with diabetes. The overall objectives of DSME are to support informed decision-making, self-care behaviors, problem-solving, and active collaboration with the health care team and to improve clinical outcomes, health status, and quality of life in a cost-effective manner (121).

Current best practice of DSME is a skills-based approach that focuses on helping those with diabetes make informed self-management choices. DSME has changed from a didactic approach focusing on providing information, to a more theoretically based empowerment model that focuses on helping those with diabetes make informed self-management decisions. Care of diabetes has shifted to an approach that is more patient centered and places the person with diabetes at the center of the care model working in collaboration with health care professionals. Patient-centered care is respectful of and responsive to individual patient preferences, needs, and values and ensures that patient values guide all decision making (123).

1. Evidence for the benefits of DSME

Multiple studies have found that DSME is associated with improved diabetes knowledge and self-care behavior (115); improved clinical outcomes such as lower A1C (116,117,119,120,124), lower self-reported weight (115), improved quality of life (118,125), and healthy coping (126); and lower costs (127). Better outcomes were reported for DSME interventions that were longer and included follow-up support (115,128–131), that were culturally (132) and age appropriate (133,134) and tailored to individual needs and preferences (114), and that addressed psychosocial issues (114,115, 119,135). Both individual and group approaches have been found effective (136–138). There is growing evidence for the role of community health workers and peer (139) and lay leaders (140) in delivering DSME and support in addition to the core team (141).

Diabetes education is associated with increased use of primary and preventive services and lower use of acute, inpatient hospital services (127). Patients who participate in diabetes education are more likely to follow best practice treatment recommendations, particularly among the medicare population, and to have lower Medicare and commercial claim costs (142).

2. National Standards for DSME

The National Standards for DSME are designed to define quality diabetes self-management education and to assist diabetes educators in a variety of settings to provide evidence-based education (121). The standards, most recently revised in 2007, are reviewed and updated every 5 years by a task force representing key organizations involved in the field of diabetes education and care.

3. Reimbursement for DSME

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

G. Physical activity

Recommendations

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

ADA technical reviews on exercise in patients with diabetes, currently being updated, have summarized the value of exercise in the diabetes management plan (143,144). 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 (11–13). Structured exercise interventions of at least 8 weeks' duration have been shown to lower A1C by an average of 0.66% in people with type 2 diabetes, even with no significant change in BMI (145). Higher levels of exercise intensity are associated with greater improvements in A1C and fitness (146).

1. Frequency and type of exercise

The U.S. Department of Health and Human Services' Physical Activity Guidelines for Americans (147) suggest that adults over age 18 years perform 150 min/week of moderate-intensity or 75 min/week of vigorous aerobic physical activity or an equivalent combination of the two. In addition, the guidelines suggest that adults also do muscle-strengthening activities that involve all major muscle groups two or more days per week. The guidelines suggest that adults over age 65 years, or those with disabilities, follow the adult guidelines if possible or (if this is not possible) be as physically active as they are able. Studies included in the meta-analysis of effects of exercise interventions on glycemic control (145) had a mean number of sessions per week of 3.4, with a mean of 49 min/session. The DPP lifestyle intervention, which included 150 min/week of moderate intensity exercise, had a beneficial effect on glycemia in those with pre-diabetes. Therefore, it seems reasonable to recommend that peo-

ple with diabetes try to follow the physical activity guidelines for the general population.

Progressive resistance exercise improves insulin sensitivity in older men with type 2 diabetes to the same or even to a greater extent as aerobic exercise (148). Clinical trials have provided strong evidence for the A1C-lowering value of resistance training in older adults with type 2 diabetes (149,150) and for an additive benefit of combined aerobic and resistance exercise in adults with type 2 diabetes (151).

2. Evaluation of the diabetic patient before recommending an exercise program

Prior guidelines have suggested that before recommending a program of physical activity, the provider should assess patients with multiple cardiovascular risk factors for coronary artery disease (CAD). As further discussed in VI.A.5. Coronary heart disease screening and treatment, the area of screening asymptomatic diabetic patients for CAD remains unclear, and a recent ADA consensus statement on this issue concluded that routine screening is not recommended (152). Providers should use clinical judgment in this area. Certainly, high-risk patients should be encouraged to start with short periods of low-intensity exercise and to increase the intensity and duration slowly.

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

3. Exercise in the presence of nonoptimal glycemic control

a. Hyperglycemia. When people with type 1 diabetes are deprived of insulin for 12–48 h and are ketotic, exercise can worsen hyperglycemia and ketosis (153); therefore, vigorous activity should be avoided in the presence of ketosis. However, it is not necessary to postpone exercise simply based on hyperglycemia, provided the patient feels well and urine and/or blood ketones are negative.

b. Hypoglycemia. In individuals taking insulin and/or insulin secretagogues, physical activity can cause hypoglycemia if medication dose or carbohydrate consumption is not altered. For individuals on these therapies, added carbohydrate should be ingested if pre-exercise glucose levels are <100 mg/dl (5.6 mmol/l) (154,155). Hypoglycemia is rare in diabetic individuals who are not treated with insulin or insulin secretagogues, and no preventive measures for hypoglycemia are usually advised in these cases.

4. Exercise in the presence of specific long-term complications of diabetes

a. Retinopathy. In the presence of proliferative diabetic retinopathy (PDR) or severe non-proliferative diabetic retinopathy (NPDR), vigorous aerobic or resistance exercise may be contraindicated because of the risk of triggering vitreous hemorrhage or retinal detachment (156).

b. Peripheral neuropathy. Decreased pain sensation in the extremities results in increased risk of skin breakdown and infection and of Charcot joint destruction. Prior recommendations have advised non–weight-bearing exercise for patients with severe peripheral neuropathy. Studies have shown that moderate-intensity walking may not lead to increased risk of foot ulcers or reulceration in those with peripheral neuropathy (157). All individuals with peripheral neuropathy should wear proper footwear and examine their feet daily for early detection of lesions. Anyone with a foot injury or open sore should be restricted to non–weight-bearing activities.

c. Autonomic neuropathy. Autonomic neuropathy can increase the risk of exercise-induced injury or adverse events through decreased cardiac responsiveness to exercise, postural hypotension, impaired thermoregulation, impaired night vision due to impaired papillary reaction, and unpredictable carbohydrate delivery from gastroparesis predisposing to hypoglycemia (158). Autonomic neuropathy is also strongly associated with CVD in people with diabetes (159,160). People with diabetic autonomic neuropathy should undergo cardiac investigation before beginning physical activity more intense than that to which they are accustomed.

d. Albuminuria and nephropathy. Physical activity can acutely increase urinary protein excretion. However, there is no evidence that vigorous exercise increases the rate of progression of diabetic kidney disease and likely no need for any specific exercise restrictions for people with diabetic kidney disease (161).

H. Psychosocial assessment and care

Recommendations

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

Psychological and social problems can impair the ability of the individual (162–164) or the family to carry out diabetes care tasks and therefore compromise health status. There are opportunities for the clinician to assess psychosocial status in a timely and efficient manner so that referral for appropriate services can be accomplished.

Key opportunities for screening of psychosocial status occur at diagnosis, during regularly scheduled management visits, during hospitalizations, at discovery of complications, or when problems with glucose control, quality of life, or adherence are identified. Patients are likely to exhibit psychological vulnerability at diagnosis and when their medical status changes, i.e., the end of the honeymoon period, when the need for intensified treatment is evident, and when complications are discovered (164).

Issues known to impact self-management and health outcomes include but are not limited to: attitudes about the illness, expectations for medical management and outcomes, affect/mood, general and diabetes-related quality of life, diabetes-related distress (165), resources (financial, social, and emotional) (166), and psychiatric history (167,168). Screening tools are available for a number of these areas (135). Indications for referral to a mental health specialist familiar with diabetes management may include gross noncompliance with medical regimen (by self or others) (168), depression with the possibility of self-harm (169,170), debilitating anxiety (alone or with depression), indications of an eating disorder, or cognitive functioning that

significantly impairs judgment. It is preferable to incorporate psychological assessment and treatment into routine care rather than waiting for identification of a specific problem or deterioration in psychological status (135). Although the clinician may not feel qualified to treat psychological problems, using the patient-provider relationship as a foundation for further treatment can increase the likelihood that the patient will accept referral for other services. It is important to establish that emotional well-being is part of diabetes management.

I. When treatment goals are not met

For a variety of reasons, some people with diabetes and their health care providers do not achieve the desired goals of treatment (Table 11). Rethinking the treatment regimen may require assessment of barriers including income, health literacy, diabetes distress, depression, and competing demands, including those related to family responsibilities and dynamics. Other strategies may include culturally appropriate and enhanced DSME, comanagement with a diabetes team, referral to a medical social worker for assistance with insurance coverage, or change in pharmacological therapy. Initiation of or increase in SMBG, utilization of CGM, frequent contact with the patient, or referral to a mental health professional or physician with special expertise in diabetes may be useful. Providing patients with an algorithm for self-titration of insulin doses based on SMBG results may be helpful for type 2 patients who take insulin (171).

J. Intercurrent illness

The stress of illness, trauma, and/or surgery frequently aggravates glycemic control and may precipitate diabetic ketoacidosis (DKA) or nonketotic hyperosmolar state, life-threatening conditions that require immediate medical care to prevent complications and death (172). Any condition leading to deterioration in glycemic control necessitates more frequent monitoring of blood glucose and (in ketosis-prone patients) urine or blood ketones. Marked hyperglycemia requires temporary adjustment of the treatment program and, if accompanied by ketosis, vomiting, or alteration in level of consciousness, immediate interaction with the diabetes care team. The patient treated with noninsulin therapies or MNT alone may temporarily require insulin. Adequate fluid and caloric intake must be assured. Infection or dehydration are more likely to necessitate hospitalization of the person with diabetes than the person without diabetes.

The hospitalized patient should be treated by a physician with expertise in the management of diabetes. For further information on management of patients with hyperglycemia in the hospital, see VIII.A. Diabetes care in the hospital. For further information on management of DKA or nonketotic hyperosmolar state, refer to the ADA consensus statement on hyperglycemic crises (173).

K. Hypoglycemia

Recommendations

- Glucose (15–20 g) is the preferred treatment for the conscious individual with hypoglycemia, although any form of carbohydrate that contains glucose may be used. If SMBG 15 min after treatment shows continued hypoglycemia, the treatment should be repeated. Once SMBG glucose returns to normal, the individual should consume a meal or snack to prevent recurrence of hypoglycemia. (E)
- Glucagon should be prescribed for all individuals at significant risk of severe hypoglycemia, and caregivers or family members of these individuals should be instructed in its administration. Glucagon administration is not limited to health care professionals. (E)
- Individuals with hypoglycemia unawareness or one or more episodes of severe hypoglycemia should be advised to raise their glycemic targets to strictly avoid further hypoglycemia for at least several weeks to partially reverse hypoglycemia unawareness and reduce risk of future episodes. (B)

Hypoglycemia is the leading limiting factor in the glycemic management of type 1 and insulin-treated type 2 diabetes (174). Treatment of hypoglycemia (PG <70 mg/dl) requires ingestion of glucose- or carbohydrate-containing foods. The acute glycemic response correlates better with the glucose content than with the carbohydrate content of the food. Although pure glucose is the preferred treatment, any form of carbohydrate that contains glucose will raise blood glucose. Added fat may retard and then prolong the acute glycemic response (175). Ongoing activity of insulin or insulin secretagogues may lead to recurrence of hypoglycemia unless further food is ingested after recovery.

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

Prevention of hypoglycemia is a critical component of diabetes management. Teaching people with diabetes to balance insulin use, carbohydrate intake, and exercise is a necessary but not always sufficient strategy. In type 1 diabetes and severely insulin-deficient type 2 diabetes, the syndrome of hypoglycemia unawareness, or hypoglycemia-associated autonomic failure, can severely compromise stringent diabetes control and quality of life. The deficient counter-regulatory hormone release and autonomic responses in this syndrome are both risk factors for and are caused by hypoglycemia. A corollary to this "vicious cycle" is that several weeks of avoidance of hypoglycemia has been demonstrated to improve counterregulation and awareness to some extent in many patients (174,176,177). Hence, patients with one or more episodes of severe hypoglycemia may benefit from at least short-term relaxation of glycemic targets.

L. Immunization

Recommendations

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

Influenza and pneumonia are common, preventable infectious diseases associated with high mortality and morbidity in the elderly and in people with chronic diseases. Though there are limited studies reporting the morbidity and mortality of influenza and pneumococcal pneumonia specifically in people with diabetes, observational studies of patients with a variety of chronic illnesses, including diabetes, show that these conditions are associated with an increase in hospitalizations for influenza and its complications. People with diabetes may be at increased risk of the bacteremic form of pneumococcal infection and have been reported to have a high risk of nosocomial bacteremia, which has a mortality rate as high as 50% (178).

Safe and effective vaccines are available that can greatly reduce the risk of serious complications from these diseases (179,180). In a case-control series, influenza vaccine was shown to reduce diabetes-related hospital admission by as much as 79% during flu epidemics (179). There is sufficient evidence to support that people with diabetes have appropriate serologic and clinical responses to these vaccinations. The Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices recommends influenza and pneumococcal vaccines for all individuals with diabetes (http://www.cdc.gov/vaccines/recs/). For a complete discussion on the prevention of influenza and pneumococcal disease in people with diabetes, consult the technical review and position statement on this subject (178,181).

VI. PREVENTION AND MANAGEMENT OF DIABETES COMPLICATIONS

A. Cardiovascular disease

CVD is the major cause of morbidity and mortality for individuals with diabetes and the largest contributor to the direct and indirect costs of diabetes. The common conditions coexisting with type 2 diabetes (e.g., hypertension and dyslipidemia) are clear risk factors for CVD, and diabetes itself confers independent risk. Numerous studies have shown the efficacy of controlling individual cardiovascular risk factors in preventing or slowing CVD in people with diabetes. Large benefits are seen when multiple risk factors are addressed globally (182,183). Risk for coronary heart disease and CVD in general can be estimated using multivariable risk factor approaches, and such a strategy may be desirable to undertake in adult patients prior to instituting preventive therapy.

1. Hypertension/blood pressure control

Recommendations

Screening and diagnosis

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

Goals

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

Treatment

- Patients with a systolic blood pressure 130–139 mmHg or a diastolic blood pressure 80–89 mmHg may be given lifestyle therapy alone for a maximum of 3 months, and then if targets are not achieved, patients should be treated with the addition of pharmacological agents. (E)
- Patients with more severe hypertension (systolic blood pressure ≥140 mmHg or diastolic blood pressure ≥90 mmHg) at diagnosis or follow-up should receive pharmacologic therapy in addition to lifestyle therapy. (A)
- Lifestyle therapy for hypertension consists of weight loss if overweight, DASH-style dietary pattern including reducing sodium and increasing potassium intake, moderation of alcohol intake, and increased physical activity. (B)
- Pharmacologic therapy for patients with diabetes and hypertension should be paired with a regimen that includes either an ACE inhibitor or an angiotensin II receptor blocker (ARB). If one class is not tolerated, the other should be substituted. If needed to achieve blood pressure targets, a thiazide diuretic should be added to those with an estimated glomerular filtration rate (GFR) (see below) ≥30 ml · min/1.73 m^2 and a loop diuretic for those with an estimated GFR <30 ml · min/1.73 m^2. (C)
- Multiple drug therapy (two or more agents at maximal doses) is generally required to achieve blood pressure targets. (B)
- If ACE inhibitors, ARBs, or diuretics are used, kidney function and serum potassium levels should be closely monitored. (E)
- In pregnant patients with diabetes and chronic hypertension, blood pressure target goals of 110–129/65–79 mmHg are suggested in the interest of long-term maternal health and minimizing impaired fetal growth. ACE inhibitors and ARBs are contraindicated during pregnancy. (E)

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

a. Screening and diagnosis. Measurement of blood pressure in the office should be done by a trained individual and should follow the guidelines established for nondiabetic individuals: measurement in the seated position, with feet on the floor and arm supported at heart level, after 5 min of rest. Cuff size should be appropriate for the upper arm circumference. Elevated values should be confirmed on a separate day. Because of the clear synergistic risks of hypertension and diabetes, the diagnostic cutoff for a diagnosis of hypertension is lower in people with diabetes (blood pressure ≥130/80 mmHg) than in those without diabetes (blood pressure ≥140/90 mmHg) (184).

Home blood pressure self-monitoring and 24-h ambulatory blood pressure monitoring may provide additional evidence of "white coat" and masked hypertension and other discrepancies between office and "true" blood pressure, and studies in nondiabetic populations show that home measurements may correlate better with CVD risk than office measurements (185,186). However, the preponderance of the clear evidence of benefits of treatment of hypertension in people with diabetes is based on office measurements.

b. Treatment goals. Randomized clinical trials have demonstrated the benefit (reduction of coronary heart disease [CHD] events, stroke, and nephropathy) of lowering blood pressure to <140 mmHg systolic and <80 mmHg diastolic in individuals with diabetes (184,187–189). Epidemiologic analyses show that blood pressure >115/75 mmHg is associated with increased cardiovascular event rates and mortality in individuals with diabetes (184,190,191). Therefore, a target blood pressure goal of <130/80 mmHg is reasonable if it can be achieved safely. The ongoing ACCORD trial is designed to determine whether blood pressure lowering to systolic blood pressure <120 mmHg provides greater cardiovascular protection than a systolic blood pressure level of <140 mmHg in patients with type 2 diabetes (192).

c. Treatment strategies. Although there are no well-controlled studies of diet and exercise in the treatment of hypertension in individuals with diabetes, the Dietary Approaches to Stop Hypertension (DASH) study in nondiabetic individuals has shown antihypertensive effects similar to those of pharmacologic monotherapy. Lifestyle therapy consists of reducing sodium intake (to <1,500 mg/day) and excess body weight; increasing consumption of fruits, vegetables (8–10 servings/day), and low-fat dairy products (2–3 servings/day); avoiding excessive alcohol consumption (no more than two servings per day in men and no more than one serving per day in women); and increasing activity levels (184,193). These nonpharmacological strategies may also positively affect glycemia and lipid control. Their effects on cardiovascular events have not been established. An initial trial of nonpharmacologic therapy may be reasonable in diabetic individuals with mild hypertension (systolic 130–139 mmHg or diastolic 80–89 mmHg). If the blood pressure is ≥140 mmHg systolic and/or ≥90 mmHg diastolic at the time of diagnosis, pharmacologic therapy should be initiated along with nonpharmacologic therapy (184).

Lowering of blood pressure with regimens based on a variety of antihypertensive drugs, including ACE inhibitors, ARBs, β-blockers, diuretics, and calcium channel blockers, has been shown to be effective in reducing cardiovascular events. Several studies suggested that ACE inhibitors may be superior to dihydropyridine calcium channel blockers in reducing cardiovascular events (194–196). However, a variety of other studies have shown no specific advantage to ACE inhibitors as initial treatment of hypertension in the general hypertensive population, but rather an advantage on cardiovascular outcomes of initial therapy with low-dose thiazide diuretics (184,197,198).

In people with diabetes, inhibitors of the renin-angiotensin system (RAS) may have unique advantages for initial or early therapy of hypertension. In a nonhypertension trial of high-risk individuals including a large subset with diabetes, an ACE inhibitor reduced CVD outcomes (199). In patients with congestive heart failure (CHF), including diabetic subgroups, ARBs have been shown to reduce major CVD outcomes (200–203), and in type 2 patients with significant nephropathy, ARBs were superior to calcium channel blockers for reducing heart failure (204–206). Though evidence for distinct advantages of RAS inhibitors on CVD outcomes in diabetes remains conflicting (187,207), the high CVD risks associated with diabetes, and the high prevalence of undiagnosed CVD, may still favor recommendations for their use as first-line hypertension therapy in people with diabetes (184). Recently, the blood pressure arm of the ADVANCE trial demonstrated that routine administration of a fixed combination of the ACE inhibitor perindopril and the diuretic indapamide significantly reduced combined microvascular and macrovascular outcomes, as well as CVD and total mortality. The improved outcomes also could have been due to lower achieved blood pressure in the perindopril-indapamide arm (208). In addition, the ACCOMPLISH (Avoiding Cardiovascular Events in Combination Therapy in Patients Living with Systolic Hypertension) trial showed a decrease in morbidity and mortality in those receiving benazapril and amlodipine versus benazapril and hydrochlorothiazide. The compelling benefits of RAS inhibitors in diabetic patients with albuminuria or renal insufficiency provide additional rationale for use of these agents (see below, VI.B. Nephropathy screening and treatment).

An important caveat is that most patients with hypertension require multidrug therapy to reach treatment goals, especially diabetic patients whose targets are lower. Many patients will require three or more drugs to reach target goals (184). If blood pressure is refractory to optimal doses of at least three antihypertensive agents of different classifications, one of which should be a diuretic, clinicians should consider an evaluation for secondary forms of hypertension.

During pregnancy in diabetic women with chronic hypertension, target blood pressure goals of 110–129 mmHg systolic and 65–79 mmHg diastolic are reasonable, as they contribute to long-term maternal health. Lower blood pressure levels may be associated with impaired fetal growth. During pregnancy, treatment with ACE inhibitors and ARBs is contraindicated, since they can 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 (209).

2. Dyslipidemia/lipid management

Recommendations

Screening

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

Treatment recommendations and goals

- Lifestyle modification focusing on the reduction of saturated fat, *trans* fat, and cholesterol intake; increase of n-3 fatty acids, viscous fiber, and plant stanols/sterols; weight loss (if indicated); and increased physical activity should be recommended to improve the lipid profile in patients with diabetes. (A)
- Statin therapy should be added to lifestyle therapy, regardless of baseline lipid levels, for diabetic patients:
  - with overt CVD. (A)
  - without CVD who are over the age of 40 years and have one or more other CVD risk factors. (A)
- For patients at lower risk than described above (e.g., without overt CVD and under the age of 40 years), statin therapy should be considered in addition to lifestyle therapy if LDL cholesterol remains >100 mg/dl or in those with multiple CVD risk factors. (E)
- In individuals without overt CVD, the

Table 12—*Reduction in 10-year risk of major CVD endpoints (CHD death/non-fatal MI) in major statin trials, or sub-studies of major trials, in diabetic subjects* (N = *16,032*)

Study (ref.)	CVD prevention	Statin dose and comparator	Risk reduction	Relative risk reduction	Absolute risk reduction	LDL cholesterol reduction
4S-DM (211)	2°	Simvastatin 20–40 mg vs. placebo	85.7 to 43.2% (50%)	42.5%	186 to 119 mg/dl	36%
ASPEN 2° (216)	2°	Atorvastatin 10 mg vs. placebo	39.5 to 24.5% (34%)	12.7%	112 to 79 mg/dl	29%
HPS-DM (212)	2°	Simvastatin 40 mg vs. placebo	43.8 to 36.3% (17%)	7.5%	123 to 84 mg/dl	31%
CARE-DM (213)	2°	Pravastatin 40 mg vs. placebo	40.8 to 35.4% (13%)	5.4%	136 to 99 mg/dl	27%
TNT-DM (214)	2°	Atorvastatin 80 mg vs. 10 mg	26.3 to 21.6% (18%)	4.7%	99 to 77 mg/dl	22%
HPS-DM (212)	1°	Simvastatin 40 mg vs. placebo	17.5 to 11.5% (34%)	6.0%	124 to 86 mg/dl	31%
CARDS (234)	1°	Atorvastatin 10 mg vs. placebo	11.5 to 7.5% (35%)	4.0%	118 to 71 mg/dl	40%
ASPEN 1° (216)	1°	Atorvastatin 10 mg vs. placebo	9.8 to 7.9% (19%)	1.9%	114 to 80 mg/dl	30%
ASCOT-DM (215)	1°	Atorvastatin 10 mg vs. placebo	11.1 to 10.2% (8%)	0.9%	125 to 82 mg/dl	34%

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

primary goal is an LDL cholesterol <100 mg/dl (2.6 mmol/l). (A)
- In individuals with overt CVD, a lower LDL cholesterol goal of <70 mg/dl (1.8 mmol/l), using a high dose of a statin, is an option. (B)
- If drug-treated patients do not reach the above targets on maximal tolerated statin therapy, a reduction in LDL cholesterol of ~30–40% from baseline is an alternative therapeutic goal. (A)
- Triglycerides levels <150 mg/dl (1.7 mmol/l) and HDL cholesterol >40 mg/dl (1.0 mmol/l) in men and >50 mg/dl (1.3 mmol/l) in women, are desirable. However, LDL cholesterol–targeted statin therapy remains the preferred strategy. (C)
- If targets are not reached on maximally tolerated doses of statins, combination therapy using statins and other lipid-lowering agents may be considered to achieve lipid targets but has not been evaluated in outcome studies for either CVD outcomes or safety. (E)
- Statin therapy is contraindicated in pregnancy. (E)

a. Evidence for benefits of lipid-lowering therapy. Patients with type 2 diabetes have an increased prevalence of lipid abnormalities, contributing to their high risk of CVD. Over the past decade or more, multiple clinical trials have demonstrated significant effects of pharmacologic (primarily statin) therapy on CVD outcomes in subjects with CHD and for primary CVD prevention (210). Analyses of diabetic subgroups of larger trials (211–215) and trials specifically in subjects with diabetes (216,217) showed significant primary and secondary prevention of CVD events with and without CHD deaths in diabetic populations. As shown in Table 12, and similar to findings in nondiabetic subjects, reduction in "hard" CVD outcomes (CHD death and nonfatal MI) can be more clearly seen in diabetic subjects with high baseline CVD risk (known CVD and/or very high LDL cholesterol levels), but overall the benefits of statin therapy in people with diabetes at moderate or high risk for CVD are convincing.

Low levels of HDL cholesterol, often associated with elevated triglyceride levels, are the most prevalent pattern of dyslipidemia in people with type 2 diabetes. However, the evidence base for drugs that target these lipid fractions is significantly less robust than that for statin therapy (217). Nicotinic acid has been shown to reduce CVD outcomes (218), although the study was done in a nondiabetic cohort. Gemfibrozil has been shown to decrease rates of CVD events in subjects without diabetes (219,220) and in a diabetic subgroup of a larger trial (219). However, in a large trial specific to diabetic patients, fenofibrate failed to reduce overall cardiovascular outcomes (221).

Table 13—*Summary of recommendations for glycemic, blood pressure, and lipid control for adults with diabetes*

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

*Referenced to a nondiabetic range of 4.0–6.0% using a DCCT-based assay. †In individuals with overt CVD, a lower LDL cholesterol goal of <70 mg/dl (1.8 mmol/l), using a high dose of a statin, is an option.

b. Dyslipidemia treatment and target lipid levels. For most patients with diabetes, the first priority of dyslipidemia therapy (unless severe hypertriglyceridemia is the immediate issue) is to lower LDL cholesterol to a target goal of <100 mg/dl (2.60 mmol/l) (222). Lifestyle intervention, including MNT, increased physical activity, weight loss, and smoking cessation, may allow some patients to reach lipid goals. Nutrition intervention should be tailored according to each patient's age, type of diabetes, pharmacological treatment, lipid levels, and other medical conditions and should focus on the reduction of saturated fat, cholesterol, and *trans* unsaturated fat intake and increases in n-3 fatty acids, viscous fiber (such as in oats, legumes, citrus), and plant stanols/sterols. Glycemic control can also beneficially modify plasma lipid levels, particularly in patients with very high triglycerides and poor glycemic control.

In those with clinical CVD or who are over age 40 years and have CVD risk factors, pharmacological treatment should be added to lifestyle therapy regardless of baseline lipid levels. Statins are the drugs of choice for lowering LDL cholesterol.

In patients other than those described above, statin treatment should be considered if there is an inadequate LDL cholesterol response to lifestyle modifications and improved glucose control or if the patient has increased cardiovascular risk

(e.g., multiple cardiovascular risk factors or long duration of diabetes). Very little clinical trial evidence exists for type 2 diabetic patients under the age of 40 years and for type 1 diabetic patients of any age. In the Heart Protection Study (lower age limit 40 years), the subgroup of 600 patients with type 1 diabetes had a proportionately similar reduction in risk as patients with type 2 diabetes although not statistically significant (212). Although the data are not definitive, consideration should be given to lipid-lowering goals for type 1 diabetic patients similar to those for type 2 diabetic patients, particularly if other cardiovascular risk factors are present.

c. Alternative LDL cholesterol goals. Virtually all trials of statins and CVD outcome have tested specific doses of statins against placebo, other doses of statin, or other statins, rather than aiming for specific LDL cholesterol goals (223). As can be seen in Table 10, placebo-controlled trials generally achieved LDL cholesterol reductions of 30–40% from baseline. Hence, LDL cholesterol lowering of this magnitude is an acceptable outcome for patients who cannot reach LDL cholesterol goals due to severe baseline elevations in LDL cholesterol and/or intolerance of maximal, or any, statin doses. Additionally, for those with baseline LDL cholesterol minimally >100 mg/dl, prescribing statin therapy to lower LDL cholesterol to ~30–40% from baseline is probably more effective than prescribing just enough to get LDL cholesterol slightly <100 mg/dl.

Recent clinical trials in high-risk patients, such as those with acute coronary syndromes or previous cardiovascular events (224–226), have demonstrated that more aggressive therapy with high doses of statins to achieve an LDL cholesterol of <70 mg/dl led to a significant reduction in further events. Therefore, a reduction in LDL cholesterol to a goal of <70 mg/dl is an option in very-high-risk diabetic patients with overt CVD (227).

In individual patients, LDL cholesterol lowering with statins is highly variable, and this variable response is poorly understood (228). Reduction of CVD events with statins correlates very closely with LDL cholesterol lowering (229). When maximally tolerated doses of statins fail to significantly lower LDL cholesterol (<30% reduction from patients baseline), the primary aim of combination therapy should be to achieve additional LDL cholesterol lowering. Niacin, fenofibrate, ezetimibe, and bile acid sequestrants all offer additional LDL cholesterol lowering. The evidence that combination therapy provides a significant increment in CVD risk reduction over statin therapy alone is still elusive.

d. Treatment of other lipoprotein fractions or targets. Severe hypertriglyceridemia may warrant immediate therapy of this abnormality with lifestyle and usually pharmacologic therapy (fibric acid derivative or niacin) to reduce the risk of acute pancreatitis. In the absence of severe hypertriglyceridemia, therapy targeting HDL cholesterol or triglycerides has intuitive appeal but lacks the evidence base of statin therapy (186). If the HDL cholesterol is <40 mg/dl and the LDL cholesterol is 100–129 mg/dl, gemfibrozil or niacin might be used, especially if a patient is intolerant to statins. Niacin is the most effective drug for raising HDL cholesterol. It can significantly increase blood glucose at high doses, but recent studies demonstrate that at modest doses (750–2,000 mg/day), significant improvements in LDL cholesterol, HDL cholesterol, and triglyceride levels are accompanied by only modest changes in glucose that are generally amenable to adjustment of diabetes therapy (230,231).

Combination therapy with a statin and a fibrate or a statin and niacin may be efficacious for treatment of all three lipid fractions, but this combination is associated with an increased risk for abnormal transaminase levels, myositis, or rhabdomyolysis. The risk of rhabdomyolysis is higher with higher doses of statins and with renal insufficiency and seems to be lower when statins are combined with fenofibrate than gemfibrozil (232). Several ongoing trials may provide much-needed evidence for the effects of combination therapy on cardiovascular outcomes.

In 2008, a consensus panel convened by ADA and the American College of Cardiology (ACC) recommended a greater focus on non-HDL cholesterol and apo lipoprotein B (apo B) in patients who are likely to have small LDL particles, such as people with diabetes (233). The consensus panel suggested that for statin-treated patients in whom the LDL cholesterol goal would be <70 mg/dl (non-HDL cholesterol <100 mg/dl), apo B should be measured and treated to <80 mg/dl. For patients on statins with an LDL cholesterol goal of <100 mg/dl (non-HDL cholesterol <130 mg/dl), apo B should be measured and treated to <90 mg/dl.

For a summary of recommendations for glycemic, blood pressure, and lipid control for adults with diabetes, see Table 13.

3. Antiplatelet agents

Recommendations

- Consider aspirin therapy (75–162 mg/day) as a primary prevention strategy in those with type 1 or type 2 diabetes at increased cardiovascular risk (10-year risk >10%). This includes most men >50 years of age or women >60 years of age who have at least one additional major risk factor (family history of CVD, hypertension, smoking, dyslipidemia, or albuminuria). (C)
- There is not sufficient evidence to recommend aspirin for primary prevention in lower risk individuals, such as men <50 years of age or women <60 years of age without other major risk factors. For patients in these age-groups with multiple other risk factors, clinical judgment is required. (C)
- Use aspirin therapy (75–162 mg/day) as a secondary prevention strategy in those with diabetes with a history of CVD. (A)
- For patients with CVD and documented aspirin allergy, clopidogrel (75 mg/day) should be used. (B)
- Combination therapy with ASA (75–162 mg/day) and clopidogrel (75 mg/day) is reasonable for up to a year after an acute coronary syndrome. (B)

ADA and the American Heart Association (AHA) have, in the past, jointly recommended that low-dose aspirin therapy be used as a primary prevention strategy in those with diabetes at increased cardiovascular risk, including those who are over 40 years of age or those with additional risk factors (family history of CVD, hypertension, smoking, dyslipidemia, or albuminuria) (235). These recommendations were derived from several older trials that included small numbers of patients with diabetes.

Aspirin has been shown to be effective in reducing cardiovascular morbidity and mortality in high-risk patients with previous MI or stroke (secondary prevention). Its net benefit in primary prevention among patients with no previous cardiovascular events is more controversial, both for patients with and without a history of diabetes (236). The U.S. Preventive Services Task Force recently updated its evidence base and recommendations about aspirin use for primary pre-

vention (237,238). The Task Force recommended encouraging aspirin use in men 45–79 and women 55–79 years of age and not encouraging aspirin use in younger adults and did not differentiate based on the presence or absence of diabetes.

Two recent randomized controlled trials of aspirin specifically in patients with diabetes failed to show a significant reduction in CVD end points, raising further questions about the efficacy of aspirin for primary prevention in people with diabetes (239,240). In 2009, ADA AHA, and ACC convened a group of experts to review and synthesize the available evidence and use this information to create an updated recommendation. Their report, including analyses in addition to those described below, will be published in early 2010.

The ATT (Anti-Thrombotic Trialists') collaborators recently published an individual patient-level meta-analysis of the six large trials of aspirin for primary prevention in the general population (236). These trials collectively enrolled over 95,000 participants, including almost 4,000 with diabetes. Overall, they found that aspirin reduced the risk of vascular events by 12% (RR 0.88 [95% CI 0.82–0.94]). The largest reduction was for nonfatal MI (0.77 [0.67–0.89]). Aspirin had little effect on CHD death (0.95 [0.78–1.15]) or total stroke (0.95 [0.85–1.06]). The net effect on total stroke reflected a relative reduction in risk of ischemic stroke (−14%) and a relative increased risk of hemorrhagic stroke (+32%). There was some evidence of a difference in aspirin effect by sex. Aspirin reduced CHD events in men (0.77 [0.67–0.89]) but not in women (0.95 [0.77–1.17]). Conversely, aspirin had no effect on stroke in men (1.01 [0.74–1.39]) but reduced stroke in women (0.77 [0.59–0.99]). These potential differences in effect by sex were of borderline statistical significance, were affected strongly by the results of one trial, and cannot be considered definitive. Notably, sex differences in aspirin's effects have not been observed in studies of secondary prevention (236). In the six trials examined by the ATT collaborators, the effect of aspirin on major vascular events was similar for patients with and without diabetes (0.88 [0.67–1.15] and 0.87 [0.79–0.96], respectively). The CI was wider for those with diabetes because of their smaller number.

Based on the currently available evidence, aspirin appears to have a modest effect on ischemic vascular events with the absolute decrease in events depending on the underlying CVD risk. The main adverse effects appear to be an increased risk of gastrointestinal bleeding. The excess risk may be as high as 1–5 per 1,000 per year in real-world settings. In adults with CVD risk greater than 1% per year, the number of CVD events prevented will be similar to or greater than the number of episodes of bleeding induced, although these complications do not have equal effects on long-term health (241).

Average daily dosages used in most clinical trials involving patients with diabetes ranged from 50–650 mg but were mostly in the range of 100–325 mg/day. There is little evidence to support any specific dose, but using the lowest possible dosage may help reduce side effects (242). Although platelets from patients with diabetes have altered function, it is unclear what, if any, impact that finding has on the required dose of aspirin for cardioprotective effects in the patient with diabetes. Many alternate pathways for platelet activation exist that are independent of thromboxane A_2 and thus not sensitive to the effects of aspirin (243). Therefore, while "aspirin resistance" appears higher in diabetic patients when measured by a variety of ex vivo and in vitro methods (platelet aggrenometry, measurement of thromboxane B_2), these observations alone are insufficient to empirically recommend at this time that higher doses of aspirin be used in the diabetic patient (244–246).

Aspirin use for secondary prevention continues to have a strong evidence base and is recommended. Until further evidence is available, low-dose (75–162 mg/day) aspirin use for primary prevention is reasonable for adults with diabetes and no previous history of vascular disease who are at increased CVD risk (10-year risk of CVD events >10%) and who are not at increased risk for bleeding. This generally includes most men over age 50 years and women over age 60 years who also have one or more of the following major risk factors: smoking, hypertension, dyslipidemia, family history of premature CVD, and albuminuria.

Aspirin should not be recommended for those at low CVD risk (women under age 60 years and men under age 50 years with no major CVD risk factors; 10-year CVD risk <5%), as the low benefit is offset by the incidence of significant bleeding. Clinical judgment should be used for those at intermediate risk (younger patients with one or risk factors or older patients with no risk factors; those with 10-year CVD risk 5–10%) until further research is available. Use of aspirin in patients under the age of 21 years is contraindicated due to the associated risk of Reye's syndrome.

Clopidogrel has been demonstrated to reduce CVD events in diabetic individuals (247). It is recommended as adjunctive therapy in the 1st year after an acute coronary syndrome or as alternative therapy in aspirin-intolerant patients.

4. Smoking cessation

Recommendations

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

Issues of smoking and diabetes are reviewed in detail in the ADA technical review (248) and position statement (249) on this topic. A large body of evidence from epidemiological, case-control, and cohort studies provides convincing documentation of the causal link between cigarette smoking and health risks. Cigarette smoking contributes to one of every five deaths in the U.S. and is the most important modifiable cause of premature death. Much of the prior work documenting the impact of smoking on health did not separately discuss results on subsets of individuals with diabetes, suggesting that the identified risks are at least equivalent to those found in the general population. Other studies of individuals with diabetes consistently found a heightened risk of CVD and premature death among smokers. Smoking is also related to the premature development of microvascular complications of diabetes and may have a role in the development of type 2 diabetes.

A number of large randomized clinical trials have demonstrated the efficacy and cost-effectiveness of smoking cessation counseling in changing smoking behavior and reducing tobacco use. The routine and thorough assessment of tobacco use is important as a means of preventing smoking or encouraging cessation. Special considerations should include assessment of level of nicotine dependence, which is associated with difficulty in quitting and relapse (250,251).

5. Coronary heart disease screening and treatment

Recommendations

Screening

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

Treatment

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

Screening for CAD is reviewed in a recently updated consensus statement (93). To identify the presence of CAD in diabetic patients without clear or suggestive symptoms, a risk factor–based approach to the initial diagnostic evaluation and subsequent follow-up has intuitive appeal. However, recent studies concluded that using this approach fails to identify which patients will have silent ischemia on screening tests (159,252).

Candidates for cardiac testing include those with *1*) typical or atypical cardiac symptoms and *2*) an abnormal resting electrocardiogram (ECG). The screening of asymptomatic patients remains controversial, especially since intensive medical therapy, indicated in diabetic patients at high risk for CVD, has an increasing evidence base for providing equal outcomes to invasive revascularization, including in diabetic patients (253,254). There is also recent preliminary evidence that silent myocardial ischemia may reverse over time, adding to the controversy concerning aggressive screening strategies (255). Finally, a recent randomized observational trial demonstrated no clinical benefit to routine screening of asymptomatic patients with type 2 diabetes and normal ECGs (256). Despite abnormal myocardial perfusion imaging in more than one in five patients, cardiac outcomes were essentially equal (and very low) in screened versus unscreened patients. Accordingly, the overall effectiveness, especially the cost-effectiveness, of such an indiscriminate screening strategy is in question.

In all patients with diabetes, cardiovascular risk factors should be assessed at least annually. These risk factors include dyslipidemia, hypertension, smoking, a positive family history of premature coronary disease, and the presence of micro- or macroalbuminuria. Abnormal risk factors should be treated as described elsewhere in these guidelines. Patients at increased CHD risk should receive aspirin and a statin, and ACE inhibitor, or ARB therapy if hypertensive, unless there are contraindications to a particular drug class. While clear benefit exists for ACE inhibitor and ARB therapy in patients with nephropathy or hypertension, the benefits in patients with CVD in the absence of these conditions is less clear, especially when LDL cholesterol is concomitantly controlled (257,258).

B. Nephropathy screening and treatment

Recommendations

General recommendations

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

Screening

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

Treatment

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

Diabetic nephropathy occurs in 20–40% of patients with diabetes and is the single leading cause of end-stage renal disease (ESRD). Persistent albuminuria in the range of 30–299 mg/24 h (microalbuminuria) has been shown to be the earliest stage of diabetic nephropathy in type 1 diabetes and a marker for development of nephropathy in type 2 diabetes. Microalbuminuria is also a well-established marker of increased CVD risk (259,260). Patients with microalbuminuria who progress to macroalbuminuria (≥300 mg/24 h) are likely to progress to ESRD (261,262). However, a number of interventions have been demonstrated to re-

duce 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 (263,264) and type 2 (57,58) diabetes. The UKPDS provided strong evidence that control of blood pressure can reduce the development of nephropathy (187). In addition, large prospective randomized studies in patients with type 1 diabetes have demonstrated that achievement of lower levels of systolic blood pressure (<140 mmHg) resulting from treatment using ACE inhibitors provides a selective benefit over other antihypertensive drug classes in delaying the progression from micro- to macroalbuminuria and can slow the decline in GFR in patients with macroalbuminuria (205,206,265). In type 2 diabetes with hypertension and normoalbuminuria, RAS inhibition has been demonstrated to delay onset of microalbuminuria (266).

In addition, ACE inhibitors have been shown to reduce major CVD outcomes (i.e., MI, stroke, and death) in patients with diabetes (199), thus further supporting the use of these agents in patients with microalbuminuria, a CVD risk factor. ARBs do not prevent microalbuminuria in normotensive patients with type 1 or type 2 diabetes (267,268); however, ARBs have been shown to reduce the rate of progression from micro- to macroalbuminuria as well as ESRD in patients with type 2 diabetes (269–271). Some evidence suggests that ARBs have a smaller magnitude of rise in potassium compared with ACE inhibitors in people with nephropathy (272,273). It is important to note that both ACE inhibitors and ARBs reduce loss of kidney function in people with diabetic nephropathy, above and beyond any such effect attributable to a reduction in systemic blood pressure. Combinations of drugs that block the renin-angiotensin-aldosterone system (e.g., an ACE inhibitor plus an ARB, a mineralocorticoid antagonist, or a direct renin inhibitor) have been shown to provide additional lowering of albuminuria (274–277). However, the long-term effects of such combinations on renal or cardiovascular outcomes have not yet been evaluated in clinical trials.

Other drugs, such as diuretics, calcium channel blockers, and β-blockers, should be used as additional therapy to further lower blood pressure in patients already treated with ACE inhibitors or ARBs (204) or as alternate therapy in the rare individual unable to tolerate ACE inhibitors or ARBs.

Table 14—*Definitions of abnormalities in albumin excretion*

Category	Spot collection (μg/mg creatinine)
Normal	<30
Microalbuminuria	30–299
Macroalbuminuria (clinical)	≥300

Studies in patients with varying stages of nephropathy have shown that protein restriction helps slow the progression of albuminuria, GFR decline, and occurrence of ESRD (278–281). Protein restriction should be considered particularly in patients whose nephropathy seems to be progressing despite optimal glucose and blood pressure control and use of ACE inhibitor and/or ARBs (281).

Assessment of albuminuria status and renal function

Screening for microalbuminuria can be performed by measurement of the albumin-to-creatinine ratio in a random spot collection (preferred method); 24-h or timed collections are more burdensome and add little to prediction or accuracy (282,283). Measurement of a spot urine for albumin only, whether by immunoassay or by using a dipstick test specific for microalbumin, without simultaneously measuring urine creatinine, is somewhat less expensive but susceptible to false-negative and -positive determinations as a result of variation in urine concentration due to hydration and other factors.

Abnormalities of albumin excretion are defined in Table 14. 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.

Information on presence of abnormal urine albumin excretion in addition to level of GFR may be used to stage CKD. The National Kidney Foundation classification (Table 15) is primarily based on GFR levels and therefore differs from other systems, in which staging is based primarily on urinary albumin excretion (284). Studies have found decreased GFR in the absence of increased urine albumin excretion in a substantial percentage of adults with diabetes (285,286). Epidemiologic evidence suggests that a substantial fraction of those with CKD in the setting of diabetes have little or no detectable albuminuria (285). Serum creatinine should therefore be measured at least annually in all adults with diabetes, regardless of the degree of urine albumin excretion.

Serum creatinine should be used to estimate GFR and to stage the level of CKD, if present. Estimated GFR (eGFR) is commonly co-reported by laboratories or can be estimated using formulae such as the Modification of Diet in Renal Disease (MDRD) study equation (287). Recent reports have indicated that the MDRD is more accurate for the diagnosis and stratification of CKD in patients with diabetes than the Cockcroft-Gault formula (288). GFR calculators are available at http://www.nkdep.nih.gov.

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

Complications of kidney disease correlate with level of kidney function. When the eGFR is less than 60 ml · min/1.73 m^2, screening for anemia, malnutrition, and metabolic bone disease is indicated. Early vaccination against Hepatitis B is indicated in patients likely to progress to end-stage kidney disease.

Consider referral to a physician experienced in the care of kidney disease when there is uncertainty about the etiology of kidney disease (active urine sediment, absence of retinopathy, or rapid decline in GFR), difficult management issues, or advanced kidney disease. The threshold for referral may vary depending on the frequency with which a provider encounters diabetic patients with significant kidney disease. Consultation with a nephrologist when stage 4 CKD develops has been

Table 15—*Stages of CKD*

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

*Kidney damage defined as abnormalities on pathologic, urine, blood, or imaging tests. Adapted from ref. 283.

found to reduce cost, improve quality of care, and keep people off dialysis longer (289,290). However, nonrenal specialists should not delay educating their patients about the progressive nature of diabetic kidney disease, the renal preservation benefits of aggressive treatment of blood pressure, blood glucose, and hyperlipidemia, and the potential need for renal replacement therapy.

C. Retinopathy screening and treatment

Recommendations

General recommendations

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

Screening

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

Treatment

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

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

In addition to duration of diabetes, other factors that increase the risk of, or are associated with, retinopathy include chronic hyperglycemia (291), the presence of nephropathy (292), and hypertension (293). Intensive diabetes management with the goal of achieving near normoglycemia has been shown in large prospective randomized studies to prevent and/or delay the onset and progression of diabetic retinopathy (53,57,58). Lowering blood pressure has been shown to decrease the progression of retinopathy (187). Several case series and a controlled prospective study suggest that pregnancy in type 1 diabetic patients may aggravate retinopathy (294,295); laser photocoagulation surgery can minimize this risk (295).

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

The DRS (296) showed that panretinal photocoagulation surgery reduced the risk of severe vision loss from PDR from 15.9% in untreated eyes to 6.4% in treated eyes. The benefit was greatest among patients whose baseline evaluation revealed high-risk characteristics (chiefly disc neovascularization or vitreous hemorrhage). Given the risks of modest loss of visual acuity and contraction of the visual field from panretinal laser surgery, such therapy is primarily recommended for eyes with PDR approaching or having high-risk characteristics.

The ETDRS (297) established the benefit of focal laser photocoagulation surgery in eyes with macular edema, particularly those with clinically significant macular edema, with reduction of doubling of the visual angle (e.g., 20/50–20/100) from 20% in untreated eyes to 8% in treated eyes. The ETDRS also verified the benefits of panretinal photocoagulation for high-risk PDR, but not for mild or moderate NPDR. In older-onset patients with severe NPDR or less-than-high-risk PDR, the risk of severe vision loss or vitrectomy was reduced 50% by early laser photocoagulation surgery at these stages.

Laser photocoagulation surgery in both trials was beneficial in reducing the risk of further vision loss, but generally not beneficial in reversing already diminished acuity. This preventive effect and the fact that patients with PDR or macular edema may be asymptomatic provide strong support for a screening program to detect diabetic retinopathy.

As retinopathy is estimated to take at least 5 years to develop after the onset of hyperglycemia (298), patients with type 1 diabetes should have an initial dilated and comprehensive eye examination within 5 years after the onset of diabetes. Patients with type 2 diabetes who generally have had years of undiagnosed diabetes (299) and who have a significant risk of prevalent diabetic retinopathy at the time of diabetes diagnosis should have an initial dilated and comprehensive eye examination soon after diagnosis. Examinations should be performed by an ophthalmologist or optometrist who is knowledgeable and experienced in diagnosing the presence of diabetic retinopathy and is aware of its management. Subsequent examinations for type 1 and type 2 diabetic patients are generally repeated annually. Less frequent exams (every 2–3 years) may be cost effective after one or more normal eye exams (300–302), while examinations will be required more frequently if retinopathy is progressing.

Examinations can also be done with retinal photographs (with or without dilation of the pupil) read by experienced experts. In-person exams are still necessary when the photos are unacceptable and for follow-up of abnormalities detected. Photos are not a substitute for a comprehensive eye exam, which should be performed at least initially and at intervals thereafter as recommended by an eye care professional. This technology has great potential in areas where qualified eye care professionals are not available and may also enhance efficiency and reduce costs when the expertise of ophthalmologists can be used for more complex examinations and for therapy (303).

Results of eye examinations should be documented and transmitted to the referring health care professional. For a detailed review of the evidence and further discussion of diabetic retinopathy, see the ADA technical review and position statement on this subject (304,305).

D. Neuropathy screening and treatment (306)

Recommendations

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

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

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

1. Diagnosis of neuropathy

a. Distal symmetric polyneuropathy. Patients with diabetes should be screened annually for DPN using tests such as pinprick sensation, vibration perception (using a 128-Hz tuning fork), 10-g monofilament pressure sensation at the distal plantar aspect of both great toes and metatarsal joints, and assessment of ankle reflexes. Combinations of more than one test have >87% sensitivity in detecting DPN. Loss of 10-g monofilament perception and reduced vibration perception predict foot ulcers (306).

b. Diabetic autonomic neuropathy (307). The symptoms and signs of autonomic dysfunction should be elicited carefully during the history and physical examination. Major clinical manifestations of diabetic autonomic neuropathy include resting tachycardia, exercise intolerance, orthostatic hypotension, constipation, gastroparesis, erectile dysfunction, sudomotor dysfunction, impaired neurovascular function, "brittle diabetes," and hypoglycemic autonomic failure.

Cardiovascular autonomic neuropathy, a CVD risk factor (93), is the most studied and clinically important form of diabetic autonomic neuropathy. Cardiovascular autonomic neuropathy may be indicated by resting tachycardia (>100 bpm), orthostasis (a fall in systolic blood pressure >20 mmHg upon standing without an appropriate heart rate response), or other disturbances in autonomic nervous system function involving the skin, pupils, or gastrointestinal and genitourinary systems.

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

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

Table 16—*Table of drugs to treat symptomatic DPN*

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

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

2. Symptomatic treatments

a. Distal symmetric polyneuropathy. The first step in management of patients with DPN should be to aim for stable and optimal glycemic control. Although controlled trial evidence is lacking, several observational studies suggest that neuropathic symptoms improve not only with optimization of control, but also with the avoidance of extreme blood glucose fluctuations. Patients with painful DPN may benefit from pharmacological treatment of their symptoms: many agents have efficacy confirmed in published randomized controlled trials, with several FDA-approved for the management of painful DPN. See Table 16 for examples of agents to treat DPN pain.

b. Diabetic autonomic neuropathy. Gastroparesis symptoms may improve with dietary changes and prokinetic agents such as metoclopramide or erythromycin. Treatments for erectile dysfunction may include phosphodiesterase type 5 inhibitors, intracorporeal or intraurethral prostaglandins, vacuum devices, or penile prostheses. Interventions for other manifestations of autonomic neuropathy are described in the ADA statement on neuropathy (306). As with DPN treatments, these interventions do not change the underlying pathology and natural history of the disease process but may have a positive impact on the quality of life of the patient.

E. Foot care

Recommendations

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

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

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

- previous amputation
- past foot ulcer history
- peripheral neuropathy
- foot deformity
- peripheral vascular disease
- visual impairment
- diabetic nephropathy (especially patients on dialysis)
- poor glycemic control
- cigarette smoking

Many studies have been published proposing a range of tests that might usefully identify patients at risk of foot ulceration, creating confusion among practitioners as to which screening tests should be adopted in clinical practice. An ADA task force was therefore assembled in 2008 to concisely summarize recent literature in this area and recommend what should be included in the comprehensive foot exam for adult patients with diabetes. Their recommendations are summarized below, but clinicians should refer to the task force report (308) for further details and practical descriptions of how to perform components of the comprehensive foot examination.

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

The neurologic exam recommended is designed to identify LOPS rather than early neuropathy. The clinical examination to identify LOPS is simple and requires no expensive equipment. Five simple clinical tests (use of a 10-g monofilament, vibration testing using a 128-Hz tuning fork, tests of pinprick sensation, ankle reflex assessment, and testing vibration perception threshold with a biothesiometer), each with evidence from well-conducted prospective clinical cohort studies, are considered useful in the diagnosis of LOPS in the diabetic foot. The task force agrees that any of the five tests listed could be used by clinicians to identify LOPS, although ideally two of these should be regularly performed during the screening exam—normally the 10-g monofilament and one other test. One or more abnormal tests would suggest LOPS, while at least two normal tests (and no abnormal test) would rule out LOPS. The last test listed, vibration assessment using a biothesiometer or similar instrument, is widely used in the U.S.; however,

identification of the patient with LOPS can easily be carried out without this or other expensive equipment.

Initial screening for PAD should include a history for claudication and an assessment of the pedal pulses. A diagnostic ABI should be performed in any patient with symptoms of PAD. Due to the high estimated prevalence of PAD in patients with diabetes and the fact that many patients with PAD are asymptomatic, an ADA consensus statement on PAD (309) suggested that a screening of ABI be performed in patients over 50 years of age and considered in patients under 50 years of age who have other PAD risk factors (e.g., smoking, hypertension, hyperlipidemia, or duration of diabetes >10 years). Refer patients with significant symptoms or a positive ABI for further vascular assessment and consider exercise, medications, and surgical options (309).

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 LOPS, the importance of foot monitoring on a daily basis, the proper care of the foot including nail and skin care, and the selection of appropriate footwear. Patients with LOPS should be educated on ways to substitute other sensory modalities (hand palpation, visual inspection) for surveillance of early foot problems. Patients' understanding of these issues and their physical ability to conduct proper foot surveillance and care should be assessed. Patients with visual difficulties, physical constraints preventing movement, or cognitive problems that impair their ability to assess the condition of the foot and to institute appropriate responses will need other people, such as family members, to assist in their care.

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

Foot ulcers and wound care may require care by a podiatrist, orthopedic or vascular surgeon, or rehabilitation specialist experienced in the management of individuals with diabetes. For a complete discussion, see the ADA consensus statement on diabetic foot wound care (310).

VII. DIABETES CARE IN SPECIFIC POPULATIONS

A. Children and adolescents

1. Type 1 diabetes

Three-quarters of all cases of type 1 diabetes are diagnosed in individuals <18 years of age. Because children are not simply "small adults," it is appropriate to consider the unique aspects of care and management of children and adolescents with type 1 diabetes. Children with diabetes differ from adults in many respects, including changes in insulin sensitivity related to sexual maturity and physical growth, ability to provide self-care, supervision in child care and school, and unique neurologic vulnerability to hypoglycemia and DKA. Attention to such issues as family dynamics, developmental stages, and physiologic differences related to sexual maturity are all essential in developing and implementing an optimal diabetes regimen. Although recommendations for children and adolescents are less likely to be based on clinical trial evidence, because of current and historical restraints placed on conducting research in children, expert opinion and a review of available and relevant experimental data are summarized in the ADA statement on care of children and adolescents with type 1 diabetes (311).

Ideally, the care of a child or adolescent with type 1 diabetes should be provided by a multidisciplinary team of specialists trained in the care of children with pediatric diabetes. At the very least, education of the child and family should be provided by health care providers trained and experienced in childhood diabetes and sensitive to the challenges posed by diabetes in this age-group. At the time of initial diagnosis, it is essential that diabetes education 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, psychological, and emotional maturity. MNT should be provided at diagnosis, and at least annually thereafter, by an individual experienced with the nutritional needs of the growing child and the behavioral issues that have an impact on adolescent diets, including risk for disordered eating.

a. Glycemic control

Recommendations

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

While current standards for diabetes management reflect the need to maintain glucose control as near to normal as safely possible, special consideration must be given to the unique risks of hypoglycemia in young children. Glycemic goals need to be modified to take into account the fact that most children <6 or 7 years of age have a form of "hypoglycemic unawareness." Their counterregulatory mechanisms are immature and they may lack the cognitive capacity to recognize and respond to hypoglycemic symptoms, placing them at greater risk for severe hypoglycemia and its sequelae. In addition, and unlike the case in adults, young children under the age of 5 years are at risk for permanent cognitive impairment after episodes of severe hypoglycemia (312–314). Extensive evidence indicates that near normalization of blood glucose levels is seldom attainable in children and adolescents after the honeymoon (remission) period. The A1C level achieved in the "intensive" adolescent cohort of the DCCT group was >1% higher than that achieved by adult DCCT subjects and above current ADA recommendations for patients in general. However, the increased frequency of use of basal bolus regimens (including insulin pumps) in youth from infancy through adolescence has been associated with more children reaching ADA blood glucose targets (315,316) in those families in which both parents and the child with diabetes are motivated to perform the required diabetes-related tasks.

In selecting glycemic goals, the benefits on long-term health outcomes of achieving a lower A1C must be weighed against the unique risks of hypoglycemia and the difficulties achieving near-normoglycemia in children and youth. Age-specific glycemic and A1C goals are presented in Table 17.

Table 17—*Plasma blood glucose and A1C goals for type 1 diabetes by age-group*

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

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

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

i. Nephropathy

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

ii. Hypertension

Recommendations
- Treatment of high-normal blood pressure (systolic or diastolic blood pressure consistently above the 90th percentile for age, sex, and height) should include dietary intervention and exercise aimed at weight control and increased physical activity, if appropriate. If target blood pressure is not reached with 3–6 months of lifestyle intervention, pharmacologic treatment should be initiated. (E)
- Pharmacologic treatment of hypertension (systolic or diastolic blood pressure consistently above the 95th percentile for age, sex, and height or consistently >130/80 mmHg, if 95% exceeds that value) should be initiated as soon as the diagnosis is confirmed. (E)
- ACE inhibitors should be considered for the initial treatment of hypertension. (E)
- The goal of treatment is a blood pressure consistently <130/80 or below the 90th percentile for age, sex, and height, whichever is lower. (E)

Hypertension in childhood is defined as an average systolic or diastolic blood pressure 95th percentile for age, sex, and height percentile measured on at least three separate days. "High-normal" blood pressure is defined as an average systolic or diastolic blood pressure ≥90th but <95th percentile for age, sex, and height percentile measured on at least 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.

iii. Dyslipidemia

Recommendations

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

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

People diagnosed with type 1 diabetes in childhood have a high risk of early subclinical (317–319) and clinical (320) CVD. Although intervention data are lacking, the AHA categorizes type 1 diabetic children in the highest tier for cardiovascular risk and recommends both lifestyle and pharmacologic treatment for those with elevated LDL cholesterol levels (321,322). Initial therapy should be with a Step II AHA diet, which restricts saturated fat to 7% of total calories and restricts dietary cholesterol to 200 mg per day. Data from randomized clinical trials

in children as young as 7 months of age indicate that this diet is safe and does not interfere with normal growth and development (323,324).

For children over the age of 10 years with persistent elevation of LDL cholesterol despite lifestyle therapy, statins should be considered. Neither long-term safety nor cardiovascular outcome efficacy has been established for children. However, recent studies have shown short-term safety equivalent to that seen in adults and efficacy in lowering LDL cholesterol levels, improving endothelial function, and causing regression of carotid intimal thickening (325–327). No statin is approved for use under the age of 10 years, and statin treatment should generally not be used in type 1 diabetic children prior to this age.

iv. Retinopathy

Recommendations

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

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

v. *Celiac disease*

Recommendations

- Children with type 1 diabetes should be screened for celiac disease by measuring tissue transglutaminase or antiendomysial antibodies, with documentation of normal serum IgA levels, soon after the diagnosis of diabetes. (E)
- Testing should be repeated if growth failure, failure to gain weight, weight loss, or gastroenterologic symptoms occur. (E)
- Consideration should be given to periodic rescreening of asymptomatic individuals. (E)
- Children with positive antibodies should be referred to a gastroenterologist for evaluation. (E)
- Children with confirmed celiac disease should have consultation with a dietitian and be placed on a gluten-free diet. (E)

Celiac disease is an immune-mediated disorder that occurs with increased frequency in patients with type 1 diabetes (1–16% of individuals compared with 0.3–1% in the general population) (328,329). Symptoms of celiac disease include diarrhea, weight loss or poor weight gain, growth failure, abdominal pain, chronic fatigue, malnutrition due to malabsorption, other gastrointestinal problems, and unexplained hypoglycemia or erratic blood glucose concentrations.

vi. Hypothyroidism

Recommendations

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

Autoimmune thyroid disease is the most common autoimmune disorder associated with diabetes, occurring in 17–30% of patients with type 1 diabetes (330). The presence of thyroid auto-antibodies is predictive of thyroid dysfunction, generally hypothyroidism and less commonly hyperthyroidism (331). Subclinical hypothyroidism may be associated with increased risk of symptomatic hypoglycemia (332) and with reduced linear growth (333). Hyperthyroidism alters glucose metabolism, potentially resulting in deterioration of metabolic control.

c. Self-management. No matter how sound the medical regimen, it can only be as good as the ability of the family and/or individual to implement it. Family involvement in diabetes remains an important component of optimal diabetes management throughout childhood and into adolescence. Health care providers who care for children and adolescents therefore must be capable of evaluating the behavioral, emotional, and psychosocial factors that interfere with implementation and then must work with the individual and family to resolve problems that occur and/or to modify goals as appropriate.

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

2. Type 2 diabetes

The incidence of type 2 diabetes in adolescents is increasing, especially in ethnic minority populations (21). Distinction between type 1 and type 2 diabetes in children can be difficult, since the prevalence of overweight in children continues to rise and since autoantigens and ketosis may be present in a substantial number of patients with features of type 2 diabetes (including obesity and acanthosis nigricans). Such a distinction at the time of diagnosis is critical because treatment regimens, educational approaches, and dietary counsel will differ markedly between the two diagnoses.

Type 2 diabetes has a significant incidence of comorbidities already present at the time of diagnosis (334). It is recommended that blood pressure measurement, a fasting lipid profile, microalbuminuria assessment, and dilated eye examination be performed at the time of diagnosis. Thereafter, screening guidelines and treatment recommendations for hypertension, dyslipidemia, microalbuminuria, and retinopathy in youth with type 2 diabetes are similar to those for youth with type 1 diabetes. Additional problems that may need to be addressed include polycystic ovary disease and the various comorbidities associated with pediatric obesity such as sleep apnea, hepatic steatosis, orthopedic complications, and psychosocial concerns. The ADA consensus statement on this subject (23) provides guidance on the prevention, screening, and treatment of type 2 diabetes and its comorbidities in young people.

B. Preconception care

Recommendations

- A1C levels should be as close to normal as possible (<7%) in an individual patient before conception is attempted. (B)
- Starting at puberty, preconception counseling should be incorporated in the routine diabetes clinic visit for all women of child-bearing potential. (C)
- Women with diabetes who are contemplating pregnancy should be evaluated and, if indicated, treated for diabetic retinopathy, nephropathy, neuropathy, and CVD. (E)
- Medications used by such women should be evaluated prior to conception because drugs commonly used to treat diabetes and its complications may be contraindicated or not recommended in pregnancy, including statins, ACE inhibitors, ARBs, and most noninsulin therapies. (E)

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

Preconception care of diabetes appears to reduce the risk of congenital malformations. Five nonrandomized studies compared rates of major malformations in infants between women who participated in preconception diabetes care programs and women who initiated intensive diabetes management after they were already pregnant. The preconception care programs were multidisciplinary and designed to train patients in diabetes self-management with diet, intensified insulin therapy, and SMBG. Goals were set to achieve normal blood glucose concentrations, and >80% of subjects achieved normal A1C concentrations before they became pregnant (335–339). In all five studies, the incidence of major congenital malformations in women who participated in preconception care (range 1.0–1.7% of infants) was much lower than the incidence in women who did not participate (range 1.4–10.9% of infants). One limitation of these studies is that participation in preconception care was self-selected rather than randomized. Thus, it is impossible to be certain that the lower malformation rates resulted fully from improved diabetes care. Nonetheless, the evidence supports the concept that malformations can be reduced or prevented by careful management of diabetes before pregnancy.

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

Women contemplating pregnancy need to be seen frequently by a multidisciplinary team experienced in the management of diabetes before and during pregnancy. The goals of preconception care are to *1*) involve and empower the patient in the management of her diabetes, *2*) achieve the lowest A1C test results possible without excessive hypoglycemia, *3*) assure effective contraception until stable and acceptable glycemia is achieved, and *4*) identify, evaluate, and treat long-term diabetes complications such as retinopathy, nephropathy, neuropathy, hypertension, and CHD (76).

Among the drugs commonly used in the treatment of patients with diabetes, a number may be relatively or absolutely contraindicated during pregnancy. Statins are category X (contraindicated for use in pregnancy) and should be discontinued before conception, as should ACE inhibitors (340). ARBs are category C (risk cannot be ruled out) in the first trimester but category D (positive evidence of risk) in later pregnancy and should generally be discontinued before pregnancy. Among the oral antidiabetic agents, metformin and acarbose are classified as category B (no evidence of risk in humans) and all others as category C. Potential risks and benefits of oral antidiabetic agents in the preconception period must be carefully weighed, recognizing that data are insufficient to establish the safety of these agents in pregnancy.

For further discussion of preconception care, see the related ADA consensus statement (76) and position statement (341) on preexisting diabetes and pregnancy.

C. Older adults

Recommendations

- Older adults who are functional, are cognitively intact, and have significant life expectancy should receive diabetes care using goals developed for younger adults. (E)
- Glycemic goals for older adults not meeting the above criteria may be relaxed using individual criteria, but hyperglycemia leading to symptoms or risk of acute hyperglycemic complications should be avoided in all patients. (E)
- Other cardiovascular risk factors should be treated in older adults with consideration of the time frame of benefit and the individual patient. Treatment of hypertension is indicated in virtually all older adults, and lipid and aspirin therapy may benefit those with life expectancy at least equal to the time frame of primary or secondary prevention trials. (E)
- Screening for diabetes complications should be individualized in older adults, but particular attention should be paid to complications that would lead to functional impairment. (E)

Diabetes is an important health condition for the aging population; at least 20% of patients over the age of 65 years have diabetes, and this number can be expected to grow rapidly in the coming decades. Older individuals with diabetes have higher rates of premature death, functional disability, and coexisting illnesses such as hypertension, CHD, and stroke than those without diabetes. Older adults with diabetes are also at greater risk than other older adults for several common geriatric syndromes, such as polypharmacy, depression, cognitive impairment, urinary incontinence, injurious falls, and persistent pain.

The American Geriatric Society's guidelines for improving the care of the older person with diabetes (342) have influenced the following discussion and recommendations. The care of older

adults with diabetes is complicated by their clinical and functional heterogeneity. Some older individuals developed diabetes years earlier and may have significant complications; others who are newly diagnosed may have had years of undiagnosed diabetes with resultant complications or may have few complications from the disease. Some older adults with diabetes are frail and have other underlying chronic conditions, substantial diabetes-related comorbidity, or limited physical or cognitive functioning. Other older individuals with diabetes have little comorbidity and are active. Life expectancies are highly variable for this population but often longer than clinicians realize. Providers caring for older adults with diabetes must take this heterogeneity into consideration when setting and prioritizing treatment goals.

There are few long-term studies in older adults that demonstrate the benefits of intensive glycemic, blood pressure, and lipid control. Patients who can be expected to live long enough to reap the benefits of long-term intensive diabetes management and who are active, have good cognitive function, and are willing should be provided with the needed education and skills to do so and be treated using the goals for younger adults with diabetes.

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

Although control of hyperglycemia may be important in older individuals with diabetes, greater reductions in morbidity and mortality may result from control of other cardiovascular risk factors rather than from tight glycemic control alone. There is strong evidence from clinical trials of the value of treating hypertension in the elderly (343,344). There is less evidence for lipid-lowering and aspirin therapy, although the benefits of these interventions for primary and secondary prevention are likely to apply to older adults whose life expectancies equal or exceed the time frames seen in clinical trials.

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

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

D. Cystic fibrosis–related diabetes

Cystic fibrosis-related diabetes (CFRD) is the most common comorbidity in people with cystic fibrosis, occurring in ~20% of adolescents and 40–50% of adults. The additional diagnosis of diabetes in this population is associated with worse nutritional status, more severe inflammatory lung disease, and greater mortality from respiratory failure. For reasons that are not well understood, women with CFRD are particularly vulnerable to excess morbidity and mortality. Insulin insufficiency related to partial fibrotic destruction of the islet mass is the primary defect in CFRD. Genetically determined function of the remaining β-cells and insulin resistance associated with infection and inflammation may also play a role. Encouraging new data suggest that early detection and aggressive insulin therapy have narrowed the gap in mortality between cystic fibrosis patients with and without diabetes and have eliminated the sex difference in mortality.

A consensus conference on CFRD was cosponsored in 2009 by ADA, the Cystic Fibrosis Foundation, and the Lawson Wilkins Pediatric Endocrine Society. Recommendations for the clinical management of CFRD will be found in the consensus report to be published in 2010.

VIII. DIABETES CARE IN SPECIFIC SETTINGS

Diabetes care in the hospital

Recommendations

- All patients with diabetes admitted to the hospital should have their diabetes clearly identified in the medical record. (E)
- All patients with diabetes should have an order for blood glucose monitoring, with results available to all members of the health care team. (E)
- Goals for blood glucose levels
  - Critically ill patients: Insulin therapy should be initiated for treatment of persistent hyperglycemia starting at a threshold of ≤180 mg/dl (10 mmol/l). Once insulin therapy is started, a glucose range of 140–180 mg/dl (7.8–10 mmol/l) is recommended for the majority of critically ill patients. (A) These patients require an intravenous insulin protocol that has demonstrated efficacy and safety in achieving the desired glucose range without increasing risk for severe hypoglycemia. (E)
  - Non–critically ill patients: There is no clear evidence for specific blood glucose goals. If treated with insulin, the premeal blood glucose target should generally be <140 mg/dl (7.8 mmol/l) with random blood glucose <180 mg/dl (10.0 mmol/l), provided these targets can be safely achieved. More stringent targets may be appropriate in stable patients with previous tight glycemic control. Less stringent targets may be appropriate in those with severe comorbidites. (E)
- Scheduled subcutaneous insulin with basal, nutritional, and correction components is the preferred method for achieving and maintaining glucose control in noncritically ill patients. (C) Using correction dose or "supplemental" insulin to correct premeal hyperglycemia in addition to scheduled prandial and basal insulin is recommended. (E)
- Glucose monitoring should be initiated in any patient not known to be diabetic who receives therapy associated with high risk for hyperglycemia, including high-dose glucocorticoid therapy, initiation of enteral or parenteral nutrition, or other medications such as octreotide

or immunosuppressive medications. (B) If hyperglycemia is documented and persistent, treatment is necessary. Such patients should be treated to the same glycemic goals as patients with known diabetes. (E)
- A plan for treating hypoglycemia should be established for each patient. Episodes of hypoglycemia in the hospital should be tracked. (E)
- All patients with diabetes admitted to the hospital should have an A1C obtained if the result of testing in the previous 2–3 months is not available. (E)
- Patients with hyperglycemia in the hospital who do not have a diagnosis of diabetes should have appropriate plans for follow-up testing and care documented at discharge. (E)

The subject of diabetes in the hospital is extensively reviewed in an ADA technical review (345). A recent updated consensus statement by the American Association of Clinical Endocrinologists (AACE) and the ADA (346) form the basis for the discussion and guidelines in this section.

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

- Medical history of diabetes: diabetes 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 management of hyperglycemia in the hospital has logically been considered secondary in importance to the condition that prompted admission (345). However, a body of literature now supports targeted glucose control in the hospital setting for potential improved clinical outcomes. Hyperglycemia in the hospital may result from stress; decompensation of type 1, type 2, or other forms of diabetes; and/or may be iatrogenic due to withholding of antihyperglycemic medications or administration of hyperglycemia-provoking agents such as glucocorticoids or vasopressors.

People with diabetes are more likely to be hospitalized and to have longer lengths of stay than those without diabetes. A recent survey estimated that 22% of all hospital inpatient days were incurred by people with diabetes and that hospital inpatient care accounted for one-half of the $174 billion total U.S. medical expenditures for this disease (347). This is due, in part, to the continued expansion of the worldwide epidemic of type 2 diabetes. In the U.S. alone, there are ~1.6 million new cases of diabetes each year with an overall prevalence of 23.6 million people (7.8% of the population, with one-quarter of cases remaining undiagnosed). An additional 57 million American adults are at high risk for type 2 diabetes (348). While the costs of illness-related stress hyperglycemia are not known, they are likely to be significant given the poor prognosis of such patients (349–352).

There is substantial observational evidence linking hyperglycemia in hospitalized patients (with or without diabetes) to poor outcomes. Cohort studies as well as a few early randomized controlled trials (RCTs) suggested that intensive treatment of hyperglycemia improved hospital outcomes (345,351,352). Interventions to normalize glycemia, however, have had inconsistent results. Indeed, recent trials in critically ill patients have failed to show a significant improvement in mortality with intensive glycemic control (353,354) or have even shown increased mortality risk (355). Moreover, these recent RCTs have highlighted the risk of severe hypoglycemia resulting from such efforts (353–358).

The largest study to date, NICE-SUGAR, a multicenter, multinational RCT, tested the effect of tight glycemic control (target 81–108 mg/dl) on outcomes among 6,104 critically ill participants, the majority of whom (>95%) required mechanical ventilation (355). Ninety-day mortality was significantly higher in the intensive versus the conventional group (target 144–180 mg/dl) (78 more deaths; 27.5 vs. 24.9%, $P = 0.02$) in both surgical and medical patients. Mortality from cardiovascular causes was more common in the intensive group (76 more deaths; 41.6 vs. 35.8%; $P = 0.02$). Severe hypoglycemia was also more common in the intensively treated group (6.8 vs. 0.5%; $P < 0.001$). The precise reason for the increased mortality in the tightly controlled group is unknown. The results of this study lie in stark contrast to a famous 2001 single-center study that reported a 42% relative reduction in intensive care unit (ICU) mortality in critically ill surgical patients treated to a target blood glucose of 80–110 mg/dl. Importantly, the control group in NICE-SUGAR had reasonably good blood glucose management, maintained at a mean glucose of 144 mg/dl, only 29 mg/dl above the intensively managed patients. Accordingly, this study's findings do not disprove the notion that glycemic control in the ICU is important. However, they do strongly suggest that it is not necessary to target blood glucose values <140 mg/dl and that a highly stringent target of <110 mg/dl actually may be dangerous.

In a recent meta-analysis of 26 trials ($N = 13,567$), which included the NICE-SUGAR data, the pooled relative risk (RR) of death with intensive insulin therapy was 0.93 as compared with conventional therapy (95% CI 0.83–1.04) (358). Approximately half of these trials reported hypoglycemia, with a pooled RR of intensive therapy of 6.0 (95% CI 4.5–8.0). The specific ICU setting influenced the findings, with patients in surgical ICUs appearing to benefit from intensive insulin therapy (RR 0.63 [95% CI 0.44–0.91]), while those in other critical care settings did not (medical ICU: 1.0 [0.78–1.28]; "mixed" ICU: 0.99 [0.86–1.12]). It was concluded that overall, intensive insulin therapy increased the risk of hypoglycemia but provided no overall benefit on mortality in the critically ill, although a benefit to patients admitted to the surgical ICU was suggested.

It is very clear that the management of hyperglycemia in the hospital presents unique challenges that stem from variations in a patient's nutritional status and level of consciousness, the practical limitations of intermittent glycemic monitoring, and the ultimate importance of patient safety. Accordingly, reasonable glucose targets in the hospital setting are modestly higher than may be routinely advised in patients with diabetes in the outpatient setting. The following recommendations represent a synthesis of the evidence base over the past decade and are somewhat less stringent than prior recommendations of the ADA Standards of Medical Care in Diabetes. For a comprehensive review of these data, the reader is referred to the latest consensus statement from AACE and ADA on inpatient management of hyperglycemia (346).

1. Glycemic targets in hospitalized patients

a. Definition of glucose abnormalities in the hospital setting. Hyperglycemia has been defined as any blood glucose >140 mg/dl (7.8 mmol/l). Levels that are significantly and persistently above this may require treatment in hospitalized patients. In patients without a previous diagnosis of diabetes, elevated blood glucose may be due to "stress hyperglycemia," a condition that can be established by a review of prior records or measurement of an A1C. A1C values >6.5% suggest that diabetes preceded hospitalization (359). Hypoglycemia has been defined as any blood glucose <70 mg/dl (3.9 mmol/l). This is the standard definition in outpatients and correlates with the initial threshold for the release of counterregulatory hormones (177). Severe hypoglycemia in hospitalized patients has been defined by many as <40 mg/dl (2.2 mmol/l), although this is lower than the ~50 mg/dl (2.8 mmol/l) level at which cognitive impairment begins in normal individuals (177,360,361). As with hyperglycemia, hypoglycemia among inpatients is also associated with adverse short- and long-term outcomes. Early recognition and treatment of mild to moderate hypoglycemia (40 and 69 mg/dl [2.2 and 3.8 mmol/l]) can prevent deterioration to a more severe episode with potential adverse sequelae (361,362).

i. Critically ill patients. Based on the weight of the available evidence, for the majority of critically ill patients in the ICU setting, insulin infusion should be used to control hyperglycemia, with a starting threshold of ≤180 mg/dl (10.0 mmol/l). Once intravenous insulin is started, the glucose level should be maintained between 140 and 180 mg/dl (7.8 and 10.0 mmol/l). Greater benefit may be realized at the lower end of this range. Although strong evidence is lacking, somewhat lower glucose targets may be appropriate in selected patients. However, targets <110 mg/dl (6.1 mmol/l) are not recommended. Use of insulin infusion protocols with demonstrated safety and efficacy, resulting in low rates of hypoglycemia, are highly recommended.

ii. Noncritically ill patients. With no prospective, RCT data to inform specific glycemic targets in noncritically ill patients, recommendations are based on clinical experience and judgment. For the majority of noncritically ill patients treated with insulin, premeal glucose targets should generally be <140 mg/dl (7.8 mmol/l) with random blood glucose <180 mg/dl (10.0 mmol/l), as long as these targets can be safely achieved. To avoid hypoglycemia, consideration should be given to reassessing the insulin regimen if blood glucose levels fall below 100 mg/dl (5.6 mmol/l). Modification of the regimen is required when blood glucose values are <70 mg/dl (3.9 mmol/l), unless the event is easily explained by other factors (such as a missed meal, etc.).

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

Clinical judgment, combined with ongoing assessment of the patient's clinical status, including changes in the trajectory of glucose measures, severity of illness, nutritional status, or concurrent use of medications that might affect glucose levels (e.g., steroids, octreotide) must be incorporated into the day-to-day decisions regarding insulin dosing (363).

2. Treatment options in hospitalized patients

In the hospital setting, insulin therapy is the preferred method of glycemic control in majority of clinical situations (346). In the ICU, intravenous infusion is the preferred route of insulin administration. Outside of critical care units, subcutaneous insulin is used much more frequently. Oral agents have a limited role in the inpatient setting.

a. Intravenous insulin infusions. In the critical care setting, continuous intravenous insulin infusion has been shown to be the most effective method for achieving specific glycemic targets (346). Because of the very short half-life of circulating insulin, intravenous delivery allows rapid dosing adjustments to address alterations in patients' status.

Intravenous insulin is ideally administered via validated written or computerized protocols that allow for predefined adjustments to the insulin infusion rate according to glycemic fluctuations and insulin dose. An extensive review of the merits and deficiencies of published protocols is beyond the intent of this statement, and the reader is referred to several available reports and reviews (364–366). Continued education of staff with periodic ongoing review of patient data are critical for successful implementation of any insulin protocol (364–366).

Patients who receive intravenous insulin infusion will usually require transition to subcutaneous insulin when they begin eating regular meals or are transferred to lower intensity care. Typically, a percentage (usually 75–80%) of the total daily intravenous infusion dose is proportionately divided into basal and prandial components (see below). Importantly, subcutaneous insulin must be given 1–4 h prior to discontinuation of intravenous insulin to prevent hyperglycemia (367).

b. Subcutaneous insulin. Scheduled subcutaneous insulin is the preferred method for achieving and maintaining glucose control in non-ICU patients with diabetes or stress hyperglycemia. The recommended components of inpatient subcutaneous insulin regimens include a basal, nutritional, and supplemental (correction) component (345,346,368). Each component can be met by one of several available insulin products, depending on the particular hospital situation. The reader is referred to several recent publications and reviews that describe currently available insulin preparations and protocols (366–370).

A topic that deserves particular attention is the persistent overuse of what has been branded as sliding scale insulin (SSI) for management of hyperglycemia. The term "correction insulin," which refers to the use of additional short or rapid-acting insulin with scheduled insulin doses to treat blood glucose above desired targets, is preferred (345). Prolonged therapy with SSI as the sole regimen is ineffective in the majority of patients (and potentially dangerous in type 1 diabetes) (370–375).

c. Noninsulin agents. These agents are inappropriate in the majority of hospitalized patients because they are less titratable than insulin in the short tem and are meant to be used in patients eating on a regular meal schedule. Continuation of these agents may be appropriate in selected stable patients who are expected to consume meals at regular intervals. Specific caution is required with metformin, due to the possibility that a contraindication may develop during the hospitalization, such as renal insufficiency, unstable hemodynamic status, or need for an imaging study that requires a radio-contrast dye (345,376). Injectable noninsulin therapies such as exenatide and pramlint-

ide have limitations similar to those of oral agents in the hospital setting.

d. Specific clinical situations

i. Insulin pumps. Patients who use CSII pump therapy in the outpatient setting can be candidates for diabetes self-management in the hospital, provided that they have the mental and physical capacity to do so (346,368). It is important that nursing personnel document basal rates and bolus doses on a regular basis (at least daily). The availability of hospital personnel with expertise in CSII therapy is essential.

ii. Enteral nutrition. Hyperglycemia is a common side effect of inpatient enteral nutrition therapy (377). A recent report using a combination of basal insulin with correction insulin achieved a mean glucose value of 160 mg/dl (8.9 mmol/l). Similar results were achieved in the group randomized to receive SSI alone; however, 48% of patients required the addition of intermediate-acting insulin to achieve glycemic targets (373).

iii. Parenteral nutrition. The high glucose load in standard parenteral nutrition frequently results in hyperglycemia, which is associated with a higher incidence of complications and mortality in critically ill ICU patients (378). Insulin therapy is highly recommended, with glucose targets as defined previously by severity of illness.

iv. Glucocorticoid therapy. Hyperglycemia is a common complication of corticosteroid therapy (363). Several approaches have been proposed for treatment of this condition, but there are no published protocols or studies that investigate the efficacy of these approaches. A reasonable approach is to institute glucose monitoring for at least 48 h in all patients receiving high dose glucocorticoid therapy and initiate insulin as appropriate. In patients who are already being treated for hyperglycemia, early adjustment of insulin doses is recommended. Importantly, during steroid tapers, insulin dosing should be proactively adjusted to avoid hypoglycemia.

v. Hypoglycemia prevention. Hypoglycemia, especially in insulin-treated patients, is the leading limiting factor in the glycemic management of type 1 and type 2 diabetes (174). In the hospital, multiple additional risk factors for hypoglycemia are present, even among patients who are neither "brittle" nor tightly controlled. Patients with or without diabetes may experience hypoglycemia in the hospital in association with altered nutritional state, heart failure, renal or liver disease, malignancy, infection, or sepsis (379,379,380). Additional triggering events leading to iatrogenic hypoglycemia include sudden reduction of corticosteroid dose, altered ability of the patient to self-report symptoms, reduction of oral intake, emesis, new NPO status, inappropriate timing of short- or rapid-acting insulin in relation to meals, reduction of rate of administration of intravenous dextrose, and unexpected interruption of enteral feedings or parenteral nutrition.

Despite the preventable nature of many inpatient episodes of hypoglycemia, institutions are more likely to have nursing protocols for the treatment of hypoglycemia than for its prevention. Tracking such episodes and analyzing their causes are important quality improvement activities.

3. Diabetes care providers in the hospital

Inpatient diabetes management may be effectively provided by primary care physicians, endocrinologists, or hospitalists. Involvement of appropriately trained specialists or specialty teams may reduce length of stay, improve glycemic control, and improve outcomes (381–384). In the care of diabetes, implementation of standardized order sets for scheduled and correction-dose insulin may reduce reliance on sliding-scale management. A team approach is needed to establish hospital pathways. To achieve glycemic targets associated with improved hospital outcomes, hospitals will need multidisciplinary support to develop protocols for subcutaneous insulin therapy that effectively and safely achieve glycemic targets (385).

4. Self-management in the hospital

Self-management of diabetes in the hospital may be appropriate for competent adult patients who have a stable level of consciousness, have reasonably stable daily insulin requirements, successfully conduct self-management of diabetes at home, have physical skills needed to successfully self-administer insulin and perform SMBG, have adequate oral intake, and are proficient in carbohydrate counting, use of multiple daily insulin injections, or insulin pump therapy and sick-day management. The patient and physician, in consultation with nursing staff, must agree that patient self-management is appropriate under the conditions of hospitalization. For patients conducting self-management in the hospital, it is imperative that basal, prandial, and correction doses of insulin and results of bedside glucose monitoring be recorded as part of the patient's hospital medical record. While many institutions allow patients on insulin pumps to continue these devices in the hospital, others express concern regarding use of a device unfamiliar to staff, particularly in patients who are not able to manage their own pump therapy. If a patient is too ill to self-manage either multiple daily injections or CSII, then appropriate subcutaneous doses can be calculated on the basis of their basal and bolus insulin needs during hospitalization, with adjustments for changes in nutritional or metabolic status.

5. DSME in the hospital

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

For the hospitalized patient, diabetes "survival skills" education is generally a feasible approach. Patients and/or family members receive sufficient information and training to enable safe care at home. Those newly diagnosed with diabetes or who are new to insulin and/or blood glucose monitoring need to be instructed before discharge. Those patients hospitalized because of a crisis related to diabetes management or poor care at home need education to prevent subsequent episodes of hospitalization. An assessment of the need for a home health referral or referral to an outpatient diabetes education program should be part of discharge planning for all patients.

6. MNT in the hospital

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

an inpatient team member. The dietitian is responsible for integrating information about the patient's clinical condition, eating, and lifestyle habits and for establishing treatment goals in order to determine a realistic plan for nutrition therapy (386,387).

7. Bedside blood glucose monitoring

Bedside blood glucose monitoring using point-of-care glucose meters is performed before meals and bedtime in the majority of inpatients who are eating usual meals. In patients who are receiving continuous enteral or parenteral nutrition, glucose monitoring is optimally performed every 4–6 h. In patients who are receiving cycled enteral or parenteral nutrition, the schedule for glucose monitoring can be individualized but should be frequent enough to detect hyperglycemia during feedings and risk of hypoglycemia when feedings are interrupted (374,376). More frequent blood glucose testing ranging from every 30 min to every 2 h is required for patients on intravenous insulin infusions.

Safe and rational glycemic management relies on the accuracy of blood glucose measurements using point-of-care blood glucose meters, which have several important limitations. Although the FDA allows a ±20% error for glucose meters, questions about the appropriateness of this criterion have been raised (388). Glucose measures differ significantly between plasma and whole blood, terms which are often used interchangeably and can lead to misinterpretation. Most commercially available capillary glucose meters introduce a correction factor of ~1.12 to report a "plasma-adjusted" value (389).

Significant discrepancies between capillary, venous, and arterial plasma samples have been observed in patients with low or high hemoglobin concentrations, hypoperfusion, and the presence of interfering substances (389,390). Analytical variability has been described with several point-of-care meters (391). Any glucose result that does not correlate with the patient's status should be confirmed through conventional laboratory sampling of PG.

While laboratory measurement of PG has less variability and interference, multiple daily phlebotomies are not practical. The use of indwelling lines as the sampling source also poses risks for infection. Studies performed using continuous interstitial glucose monitoring systems in the critical care setting (392) currently are limited by the lack of reliability in the hypoglycemic range as well as by cost.

8. Discharge planning

It is important to anticipate the postdischarge antihyperglycemic regimen in all patients with diabetes or newly discovered hyperglycemia. The optimal program will need to consider the type and severity of diabetes, the effects of the patient's illness on blood glucose levels, and the capacities and desires of the patient. Smooth transition to outpatient care should be ensured, especially in those new to insulin therapy or in whom the diabetes regimen has been substantially altered during the hospitalization. All patients in whom the diagnosis of diabetes is new should have, at minimum, "survival skills" training prior to discharge.

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

- level of understanding related to the diagnosis of diabetes
- SMBG and explanation of home blood glucose goals
- definition, recognition, treatment, and prevention of hyperglycemia and hypoglycemia
- identification of health care provider who will provide diabetes care after discharge
- information on consistent eating patterns
- when and how to take blood glucose–lowering medications including insulin administration (if going home on insulin)
- sick-day management
- proper use and disposal of needles and syringes

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

IX. STRATEGIES FOR IMPROVING DIABETES CARE

— The implementation of the standards of care for diabetes has been suboptimal in most clinical settings. A recent report (393) indicated that only 57.1% of adults with diagnosed diabetes achieved an A1C of <7%, only 45.5% had a blood pressure <130/80 mmHg, and just 46.5% had a total cholesterol <200 mg/dl. Most distressing was that only 12.2% of people with diabetes achieved all three treatment goals.

While numerous interventions to improve adherence to the recommended standards have been implemented, the challenge of providing uniformly effective diabetes care has thus far defied a simple solution. A major contributor to suboptimal care is a delivery system that too often is fragmented, lacks clinical information capabilities, often duplicates services, and is poorly designed for the delivery of chronic care. The chronic care model (CCM) includes five core elements for the provision of optimal care of patients with chronic disease: delivery system design, self-management support, decision support, clinical information systems, and community resources and policies. Redefinition of the roles of the clinic staff and promoting self-management on the part of the patient are fundamental to the successful implementation of the CCM (394). Collaborative, multidisciplinary teams are best suited to provide such care for people with chronic conditions like diabetes and to empower patients' performance of appropriate self-management. Alterations in reimbursement that reward the provision of quality care, as defined by the attainment of quality measures developed by such programs as the ADA/National Committee for Quality Assurance Diabetes Provider Recognition Program, will also be required to achieve desired outcome goals.

In recent years, numerous health care organizations, ranging from large health care systems such as the U.S. Veteran's Administration to small private practices, have implemented strategies to improve diabetes care. Successful programs have published results showing improvement in process measures such as measurement of A1C, lipids, and blood pressure. Effects on in important intermediate outcomes, such as mean A1C for populations, have been more difficult to demonstrate (395–397), although examples do exist (398–402), often taking more than 1 year to manifest (394). Features of successful

programs reported in the literature include

- Delivery of DSME: increases adherence to standard of care and educating patients on glycemic targets and improves the percentage of patients who reach goal A1C (142,403)
- Adoption of practice guidelines, with participation of health care professionals in the process of development: Guidelines should be readily accessible at the point of service, preferably as computerized reminders at the point of care. 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: successful at improving adherence to standards of care
- Systems changes: such as provision of automated reminders to health care professionals and patients and audit and feedback of process and outcome data to providers
- Quality improvement programs combining continuous quality improvement or other cycles of analysis and intervention with provider performance data
- Practice changes: such as availability of point of care testing of A1C, scheduling planned diabetes visits, clustering of dedicated diabetes visits into specific times within a primary care practice schedule, or group visits and/or visits with multiple health care professionals on a single day
- Tracking systems with either an electronic medical record or patient registry: 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 (404).
- Availability of case or (preferably) care management services (405): Nurses, pharmacists, and other nonphysician health care professionals using detailed algorithms working under the supervision of physicians have demonstrated the greatest reduction in A1C and blood pressure (406,407).

Evidence suggests that these individual initiatives work best when provided as components of a multifactorial intervention. When practices are compared, those that address more of the CCM elements demonstrate lower A1C levels and lower cardiovascular risk scores (408). The most successful practices have an institutional priority for quality of care, involve all of the staff in their initiatives, redesign their delivery system, activate and educate their patients, and use electronic health record tools (409,410).

NDEP maintains an online resource (www.betterdiabetescare.nih.gov) to help health care professionals design and implement more effective health care delivery systems for those with diabetes.

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

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Summary of Revisions for the 2010 Clinical Practice Recommendations

Beginning with the 2005 supplement, the Clinical Practice Recommendations contained only the "Standards of Medical Care in Diabetes" and selected other position statements. This change was made to emphasize the importance of the "Standards" as the best source to determine American Diabetes Association recommendations. The position statements in the supplement are updated yearly. Position statements not included in the supplement will be updated as necessary and republished when updated. A list of the position statements not included in this supplement appears on p. S100.

Additions to the "Standards of Medical Care in Diabetes"

- A section on cystic fibrosis–related diabetes has been added.

Revisions to the "Standards of Medical Care in Diabetes"

In addition to many small changes related to new evidence since the previous version, the following sections have undergone major changes:

- The section "Diagnosis of diabetes" has been revised to include the use of A1C to diagnose diabetes, with a cut point of ≥6.5%.
- The section previously titled "Diagnosis of pre-diabetes" has been renamed "Categories of increased risk for diabetes." In addition to impaired fasting glucose and impaired glucose tolerance, an A1C range of 5.7–6.4% has been included as a category of increased risk for future diabetes.
- The section "Detection and diagnosis of GDM" has been revised to discuss potential future changes in the diagnosis based on international consensus.
- The section "Diabetes self-management education" has been extensively revised to reflect new evidence.
- The section "Antiplatelet agents" has been extensively revised to reflect recent trials questioning the benefit of aspirin for primary cardiovascular disease prevention in moderate- or low-risk patients. The recommendation has changed to consider aspirin therapy as a primary prevention strategy in those with diabetes at increased cardiovascular risk (10-year risk >10%). This includes men >50 years of age or women >60 years of age with at least one additional major risk factor.
- The section "Retinopathy screening and treatment" has been updated to include a recommendation on use of fundus photography as a screening strategy.
- The section "Diabetes care in the hospital" has been extensively revised to reflect new evidence calling into question very tight glycemic control goals in critically ill patients.
- The section "Strategies for improving diabetes care" has been extensively revised to reflect newer evidence.

DOI: 10.2337/dc10-S003

Executive Summary: Standards of Medical Care in Diabetes—2010

Current criteria for the diagnosis of diabetes

- A1C ≥6.5%: The test should be performed in a laboratory using a method that is National Glycohemoglobin Standardization Program (NGSP) certified and standardized to the Diabetes Control and Complications Trial (DCCT) assay.
- FPG ≥126 mg/dl (7.0 mmol/l): Fasting is defined as no caloric intake for at least 8 h.
- 2-h plasma glucose ≥200 mg/dl (11.1 mmol/l) during an oral glucose tolerance test (OGTT): The test should be performed as described by the World Health Organization using a glucose load containing the equivalent of 75 g anhydrous glucose dissolved in water.
- In a patient with classic symptoms of hyperglycemia or hyperglycemic crisis: a random plasma glucose ≥200 mg/dl (11.1 mmol/l).

Testing for diabetes in asymptomatic patients

- Testing to detect type 2 diabetes and assess risk for future diabetes in asymptomatic people should be considered in adults of any age who are overweight or obese (BMI ≥25 kg/m^2) and who have one or more additional risk factors for diabetes (see Table 4 of Standards of Medical Care in Diabetes—2010). In those without these risk factors, testing should begin at age 45 years. (B)
- If tests are normal, repeat testing should be carried out at least at 3-year intervals. (E)
- To test for diabetes or to assess risk of future diabetes, A1C, FPG , or 2-h 75-g OGTT are appropriate. (B)
- In those identified with increased risk for future diabetes, identify and, if appropriate, treat other cardiovascular disease (CVD) risk factors. (B)

Detection and diagnosis of gestational diabetes mellitus

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

Prevention of type 2 diabetes

- Patients with IGT (A), IFG (E), or an A1C of 5.7–6.4% (E) should be referred to an effective ongoing support program for weight loss of 5–10% of body weight and increase in physical activity to at least 150 min/week of moderate activity such as walking.
- Follow-up counseling appears to be important for success. (B)
- Based on potential cost savings of diabetes prevention, such counseling should be covered by third-party payors. (E)
- In addition to lifestyle counseling, metformin may be considered in those who are at very high risk for developing diabetes (combined IFG and IGT plus other risk factors such as A1C >6%, hypertension, low HDL cholesterol, elevated triglycerides, or family history of diabetes in a first-degree relative) and who are obese and under 60 years of age. (E)
- Monitoring for the development of diabetes in those with pre-diabetes should be performed every year. (E)

Glucose monitoring

- Self-monitoring of blood glucose (SMBG) should be carried out three or more times daily for patients using multiple insulin injections or insulin pump therapy. (A)
- For patients using less frequent insulin injections, noninsulin therapies, or medical nutrition therapy (MNT) alone, SMBG may be useful as a guide to the success of therapy. (E)
- To achieve postprandial glucose targets, postprandial SMBG may be appropriate. (E)
- When prescribing SMBG, ensure that patients receive initial instruction in, and routine follow-up evaluation of, SMBG technique and their ability to use data to adjust therapy. (E)
- Continuous glucose monitoring (CGM) in conjunction with intensive insulin regimens can be a useful tool to lower A1C in selected adults (age >25 years) with type 1 diabetes. (A)
- Although the evidence for A1C-lowering is less strong in children, teens, and younger adults, CGM may be helpful in these groups. Success correlates with adherence to ongoing use of the device. (C)
- CGM may be a supplemental tool to SMBG in those with hypoglycemia unawareness and/or frequent hypoglycemic episodes. (E)

A1C

- Perform the A1C test at least two times a year in patients who are meeting treatment goals (and who have stable glycemic control). (E)
- Perform the A1C test quarterly in patients whose therapy has changed or who are not meeting glycemic goals. (E)
- Use of point-of-care testing for A1C allows for timely decisions on therapy changes, when needed. (E)

Glycemic goals in adults

- Lowering A1C to below or around 7% has been shown to reduce microvascular and neuropathic complications of type 1 and type 2 diabetes. Therefore, for microvascular disease prevention, the A1C goal for nonpregnant adults in general is <7%. (A)
- In type 1 and type 2 diabetes, randomized controlled trials of intensive versus standard glycemic control have not shown a significant reduction in CVD outcomes during the randomized portion of the trials. Long-term follow-up of the DCCT and UK Prospective Dia-

DOI: 10.2337/dc10-S004

betes Study (UKPDS) cohorts suggests that treatment to A1C targets below or around 7% in the years soon after the diagnosis of diabetes is associated with long-term reduction in risk of macrovascular disease. Until more evidence becomes available, the general goal of <7% appears reasonable for many adults for macrovascular risk reduction. (B)
- Subgroup analyses of clinical trials such as the DCCT and UKPDS and evidence for reduced proteinuria in the ADVANCE trial suggest a small but incremental benefit in microvascular outcomes with A1C values closer to normal. Therefore, for selected individual patients, providers might reasonably suggest even lower A1C goals than the general goal of <7%, if this can be achieved without significant hypoglycemia or other adverse effects of treatment. Such patients might include those with short duration of diabetes, long life expectancy, and no significant CVD. (B)
- Conversely, less stringent A1C goals than the general goal of <7% may be appropriate for patients with a history of severe hypoglycemia, limited life expectancy, advanced microvascular or macrovascular complications, or extensive comorbid conditions and those with longstanding diabetes in whom the general goal is difficult to attain despite diabetes self-management education, appropriate glucose monitoring, and effective doses of multiple glucose-lowering agents including insulin. (C)

Medical nutrition therapy

General recommendations

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

Energy balance, overweight, and obesity

- In overweight and obese insulin-resistant individuals, modest weight loss has been shown to reduce insulin resistance. Thus, weight loss is recommended for all overweight or obese individuals who have or are at risk for diabetes. (A)
- For weight loss, either low-carbohydrate or low-fat calorie-restricted diets may be effective in the short-term (up to 1 year). (A)
- For patients on low-carbohydrate diets, monitor lipid profiles, renal function, and protein intake (in those with nephropathy) and adjust hypoglycemic therapy as needed. (E)
- Physical activity and behavior modification are important components of weight loss programs and are most helpful in maintenance of weight loss. (B)

Primary prevention of diabetes

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

Dietary fat intake in diabetes management

- Saturated fat intake should be <7% of total calories. (A)
- Reducing intake of *trans* fat lowers LDL cholesterol and increases HDL cholesterol (A); therefore, intake of *trans* fat should be minimized. (E)

Carbohydrate intake in diabetes management

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

Other nutrition recommendations

- Sugar alcohols and nonnutritive sweeteners are safe when consumed within the acceptable daily intake levels established by the Food and Drug Administration (FDA). (A)
- If adults with diabetes choose to use alcohol, daily intake should be limited to a moderate amount (one drink per day or less for adult women and two drinks per day or less for adult men). (E)
- Routine supplementation with antioxidants, such as vitamins E and C and carotene, is not advised because of lack of evidence of efficacy and concern related to long-term safety. (A)
- Benefit from chromium supplementation in people with diabetes or obesity has not been conclusively demonstrated and, therefore, cannot be recommended. (C)
- Individualized meal planning should include optimization of food choices to meet recommended dietary allowances (RDAs)/dietary reference intakes (DRIs) for all micronutrients. (E)

Bariatric surgery

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

Diabetes self-management education

- People with diabetes should receive diabetes self-management education (DSME) according to national standards when their diabetes is diagnosed and as needed thereafter. (B)
- Effective self-management and quality

of life are the key outcomes of DSME and should be measured and monitored as part of care. (C)
- DSME should address psychosocial issues, since emotional well-being is associated with positive diabetes outcomes. (C)
- Because DSME can result in cost-savings and improved outcomes (B), DSME should be reimbursed by third-party payors. (E)

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

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

Hypoglycemia
- Glucose (15–20 g) is the preferred treatment for the conscious individual with hypoglycemia, although any form of carbohydrate that contains glucose may be used. If SMBG 15 min after treatment shows continued hypoglycemia, the treatment should be repeated. Once SMBG glucose returns to normal, the individual should consume a meal or snack to prevent recurrence of hypoglycemia. (E)
- Glucagon should be prescribed for all individuals at significant risk of severe hypoglycemia, and caregivers or family members of these individuals instructed in its administration. Glucagon administration is not limited to health care professionals. (E)
- Individuals with hypoglycemia unawareness or one or more episodes of severe hypoglycemia should be advised to raise their glycemic targets to strictly avoid further hypoglycemia for at least several weeks, to partially reverse hypoglycemia unawareness and reduce risk of future episodes. (B)

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

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

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

Treatment
- Patients with a systolic blood pressure of 130–139 mmHg or a diastolic blood pressure of 80–89 mmHg may be given lifestyle therapy alone for a maximum of 3 months, and then if targets are not achieved, be treated with addition of pharmacological agents. (E)
- Patients with more severe hypertension (systolic blood pressure ≥140 or diastolic blood pressure ≥90 mmHg) at diagnosis or follow-up should receive pharmacologic therapy in addition to lifestyle therapy. (A)
- Lifestyle therapy for hypertension consists of: weight loss if overweight, DASH-style dietary pattern including reducing sodium and increasing potassium intake, moderation of alcohol intake, and increased physical activity. (B)
- Pharmacologic therapy for patients with diabetes and hypertension should be with a regimen that includes either an ACE inhibitor or an angiotensin receptor blocker (ARB). If one class is not tolerated, the other should be substituted. If needed to achieve blood pressure targets, a thiazide diuretic should be added to those with an estimated glomerular filtration rate (GFR) (see below) ≥30 ml/min per 1.73 m^2 and a loop diuretic for those with an estimated GFR <30 ml/min per 1.73 m^2. (C)
- Multiple drug therapy (two or more agents at maximal doses) is generally required to achieve blood pressure targets. (B)
- If ACE inhibitors, ARBs, or diuretics are used, kidney function and serum potassium levels should be closely monitored. (E)
- In pregnant patients with diabetes and chronic hypertension, blood pressure target goals of 110–129/65–79 mmHg are suggested in the interest of long-term maternal health and minimizing impaired fetal growth. ACE inhibitors and ARBs are contraindicated during pregnancy. (E)

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

Treatment recommendations and goals
- Lifestyle modification focusing on the reduction of saturated fat, *trans* fat, and cholesterol intake; increase of n-3 fatty acids, viscous fiber, and plant stanols/sterols; weight loss (if indicated); and increased physical activity should be recommended to improve the lipid profile in patients with diabetes. (A)
- Statin therapy should be added to lifestyle therapy, regardless of baseline lipid levels, for diabetic patients:
  - with overt CVD. (A)
  - without CVD who are over the age of 40 years and have one or more other CVD risk factors. (A)

- For lower risk patients than the above (e.g., without overt CVD and under the age of 40 years), statin therapy should be considered in addition to lifestyle therapy if LDL cholesterol remains above 100 mg/dl or in those with multiple CVD risk factors. (E)
- In individuals without overt CVD, the primary goal is an LDL cholesterol <100 mg/dl (2.6 mmol/l). (A)
- In individuals with overt CVD, a lower LDL cholesterol goal of <70 mg/dl (1.8 mmol/l), using a high dose of a statin, is an option. (B)
- If drug-treated patients do not reach the above targets on maximal tolerated statin therapy, a reduction in LDL cholesterol of ~30–40% from baseline is an alternative therapeutic goal. (A)
- Triglycerides levels <150 mg/dl (1.7 mmol/l) and HDL cholesterol >40 mg/dl (1.0 mmol/l) in men and >50 mg/dl (1.3 mmol/l) in women are desirable. However, LDL cholesterol–targeted statin therapy remains the preferred strategy. (C)
- If targets are not reached on maximally tolerated doses of statins, combination therapy using statins and other lipid-lowering agents may be considered to achieve lipid targets but has not been evaluated in outcome studies for either CVD outcomes or safety. (E)
- Statin therapy is contraindicated in pregnancy. (E)

Antiplatelet agents

- Consider aspirin therapy (75–162 mg/day) as a primary prevention strategy in those with type 1 or type 2 diabetes at increased cardiovascular risk (10-year risk >10%). This includes most men >50 years of age or women >60 years of age who have at least one additional major risk factor (family history of CVD, hypertension, smoking, dyslipidemia, or albuminuria). (C)
- There is not sufficient evidence to recommend aspirin for primary prevention in lower risk individuals, such as men <50 years of age or women <60 years of age without other major risk factors. In patients in these age-groups with multiple other risk factors, clinical judgment is required. (C)
- Use aspirin therapy (75–162 mg/day) as a secondary prevention strategy in those with diabetes with a history of CVD. (A)
- For patients with CVD and documented aspirin allergy, clopidogrel (75 mg/day) should be used. (B)
- Combination therapy with ASA (75–162 mg/day) and clopidogrel (75 mg/day) is reasonable for up to a year after an acute coronary syndrome. (B)

Smoking cessation

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

Coronary heart disease

Screening

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

Treatment

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

Nephropathy screening and treatment

General recommendations

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

Screening

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

Treatment

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

Retinopathy screening and treatment

General recommendations

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

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

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

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

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

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

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

Hypertension
- Treatment of high-normal blood pressure (systolic or diastolic blood pressure consistently above the 90th percentile for age, sex, and height) should include dietary intervention and exercise, aimed at weight control and increased physical activity, if appropriate. If target blood pressure is not reached with 3–6 months of lifestyle intervention, pharmacologic treatment should be initiated. (E)
- Pharmacologic treatment of hypertension (systolic or diastolic blood pressure consistently above the 95th percentile for age, sex, and height or consistently greater than 130/80 mmHg, if 95% exceeds that value) should be initiated as soon as the diagnosis is confirmed. (E)
- ACE inhibitors should be considered for the initial treatment of hypertension. (E)
- The goal of treatment is a blood pressure consistently $<$130/80 or below the 90th percentile for age, sex, and height, whichever is lower. (E)

Dyslipidemia
Screening
- If there is a family history of hypercholesterolemia (total cholesterol $>$240 mg/dl) or a cardiovascular event before age 55 years, or if family history is unknown, then a fasting lipid profile should be performed on children $>$2 years of age soon after diagnosis (after glucose control has been established). If family history is not of concern, then the first lipid screening should be performed at puberty ($\geq$10 years). All children diagnosed with diabetes at or after puberty should have a fasting lipid pro-

file performed soon after diagnosis (after glucose control has been established). (E)
- For both age-groups, if lipids are abnormal, annual monitoring is recommended. If LDL cholesterol values are within the accepted risk levels (<100 mg/dl [2.6 mmol/l]), a lipid profile should be repeated every 5 years. (E)

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

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

Celiac disease
- Children with type 1 diabetes should be screened for celiac disease by measuring tissue transglutaminase or anti-endomysial antibodies, with documentation of normal serum IgA levels, soon after the diagnosis of diabetes. (E)
- Testing should be repeated if growth failure, failure to gain weight, weight loss, or gastroenterologic symptoms occur. (E)
- Consideration should be given to periodic re-screening of asymptomatic individuals. (E)
- Children with positive antibodies should be referred to a gastroenterologist for evaluation. (E)
- Children with confirmed celiac disease should have consultation with a dietitian and placed on a gluten-free diet. (E)

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

Preconception care
- A1C levels should be as close to normal as possible (<7%) in an individual patient before conception is attempted. (B)
- Starting at puberty, preconception counseling should be incorporated in the routine diabetes clinic visit for all women of child-bearing potential. (C)
- Women with diabetes who are contemplating pregnancy should be evaluated and, if indicated, treated for diabetic retinopathy, nephropathy, neuropathy, and CVD. (E)
- Medications used by such women should be evaluated prior to conception, since drugs commonly used to treat diabetes and its complications may be contraindicated or not recommended in pregnancy, including statins, ACE inhibitors, ARBs, and most noninsulin therapies. (E)

Older adults
- Older adults who are functional, cognitively intact, and have significant life expectancy should receive diabetes care using goals developed for younger adults. (E)
- Glycemic goals for older adults not meeting the above criteria may be relaxed using individual criteria, but hyperglycemia leading to symptoms or risk of acute hyperglycemic complications should be avoided in all patients. (E)
- Other cardiovascular risk factors should be treated in older adults with consideration of the time frame of benefit and the individual patient. Treatment of hypertension is indicated in virtually all older adults, and lipid and aspirin therapy may benefit those with life expectancy at least equal to the time frame of primary or secondary prevention trials. (E)
- Screening for diabetes complications should be individualized in older adults, but particular attention should be paid to complications that would lead to functional impairment. (E)

Diabetes care in the hospital
- All patients with diabetes admitted to the hospital should have their diabetes clearly identified in the medical record. (E)
- All patients with diabetes should have an order for blood glucose monitoring, with results available to all members of the health care team. (E)
- Goals for blood glucose levels:
  - Critically ill patients: Insulin therapy should be initiated for treatment of persistent hyperglycemia starting at a threshold of no greater than 180 mg/dl (10 mmol/l). Once insulin therapy is started, a glucose range of 140–180 mg/dl (7.8 to 10 mmol/l) is recommended for the majority of critically ill patients. (A) These patients require an intravenous insulin protocol that has demonstrated efficacy and safety in achieving the desired glucose range without increasing risk for severe hypoglycemia. (E)
  - Non–critically ill patients: There is no clear evidence for specific blood glucose goals. If treated with insulin, the premeal blood glucose target should generally be <140 mg/dl (7.8 mmol/l) with random blood glucose <180 mg/dl (10.0 mmol/l), provided these targets can be safely achieved. More stringent targets may be appropriate in stable patients with previous tight glycemic control. Less stringent targets may be appropriate in those with severe comorbidites. (E)
- Scheduled subcutaneous insulin with basal, nutritional, and correction. Components is the preferred method for achieving and maintaining glucose control in noncritically ill patients. (C) Using correction dose or "supplemental" insulin to correct premeal hyperglycemia in addition to scheduled prandial and basal insulin is recommended. (E)
- Glucose monitoring should be initiated in any patient not known to be diabetic who receives therapy associated with high risk for hyperglycemia, including high-dose glucocorticoid therapy, initiation of enteral or parenteral nutrition,

or other medications such as octreotide or immunosuppressive medications. (B) If hyperglycemia is documented and persistent, treatment is necessary. Such patients should be treated to the same glycemic goals as patients with known diabetes. (E)

- A plan for treating hypoglycemia should be established for each patient. Episodes of hypoglycemia in the hospital should be tracked. (E)
- All patients with diabetes admitted to the hospital should have an A1C obtained if the result of testing in the previous 2–3 months is not available. (E)
- 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)

Diagnosis and Classification of Diabetes Mellitus

AMERICAN DIABETES ASSOCIATION

DEFINITION AND DESCRIPTION OF DIABETES MELLITUS

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

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

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

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

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

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

CLASSIFICATION OF DIABETES MELLITUS AND OTHER CATEGORIES OF GLUCOSE REGULATION

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

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

Immune-mediated diabetes. This form of diabetes, which accounts for only 5–10% of those with diabetes, previously encompassed by the terms insulin-dependent diabetes, type 1 diabetes, or juvenile-onset diabetes, results from a cellular-mediated autoimmune destruction

Sections on diagnosis revised Fall 2009.
DOI: 10.2337/dc10-S062

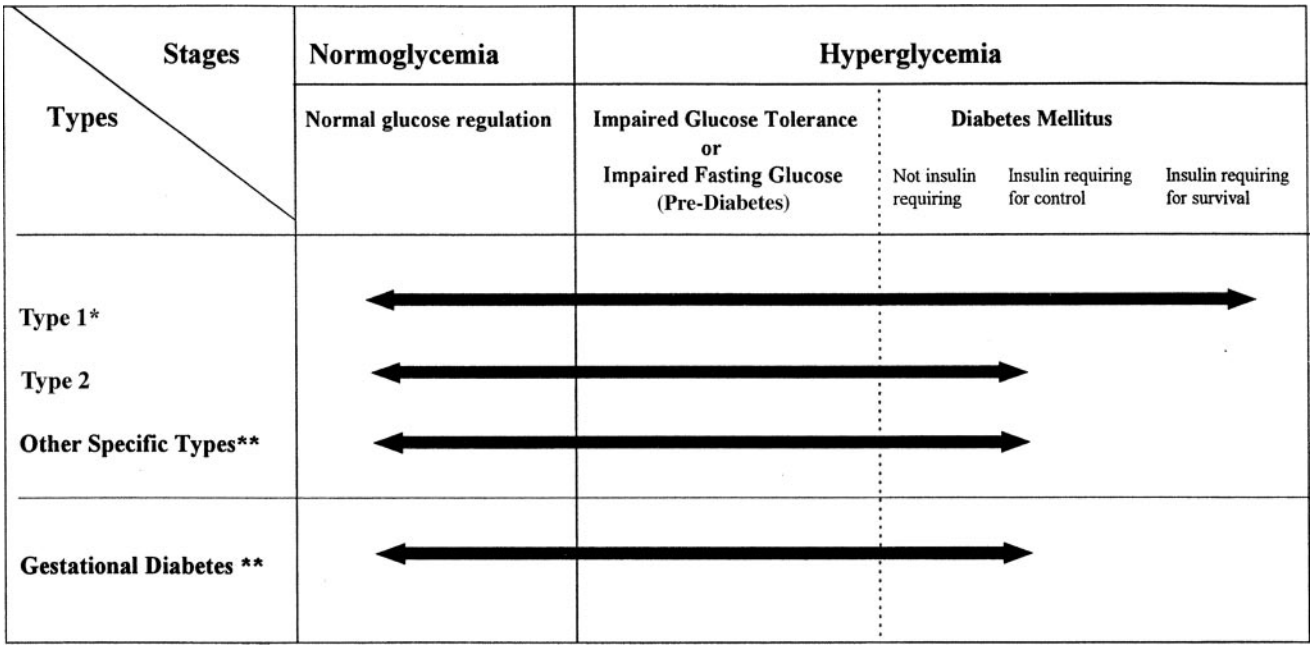

Figure 1—*Disorders of glycemia: etiologic types and stages. *Even after presenting in ketoacidosis, these patients can briefly return to normoglycemia without requiring continuous therapy (i.e., "honeymoon" remission); **in rare instances, patients in these categories (e.g., Vacor toxicity, type 1 diabetes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

of the β-cells of the pancreas. Markers of the immune destruction of the β-cell include islet cell autoantibodies, autoantibodies to insulin, autoantibodies to GAD (GAD65), and autoantibodies to the tyrosine phosphatases IA-2 and IA-2β. One and usually more of these autoantibodies are present in 85–90% of individuals when fasting hyperglycemia is initially detected. Also, the disease has strong HLA associations, with linkage to the DQA and DQB genes, and it is influenced by the DRB genes. These HLA-DR/DQ alleles can be either predisposing or protective.

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

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

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

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

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

Most patients with this form of diabetes are obese, and obesity itself causes some degree of insulin resistance. Patients who are not obese by traditional weight criteria may have an increased percentage of body fat distributed predominantly in the abdominal region. Ketoacidosis seldom occurs spontaneously in this type of diabetes; when seen, it usually arises in association with the stress of another illness such as infection. This form of diabetes frequently goes undiagnosed for many years because the hyperglycemia

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

Other specific types of diabetes

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

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

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

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

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

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

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

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

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

Infections. Certain viruses have been associated with β-cell destruction. Diabetes occurs in patients with congenital rubella, although most of these patients have HLA

Table 1—*Etiologic classification of diabetes mellitus*

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

Patients with any form of diabetes may require insulin treatment at some stage of their disease. Such use of insulin does not, of itself, classify the patient.

and immune markers characteristic of type 1 diabetes. In addition, coxsackievirus B, cytomegalovirus, adenovirus, and mumps have been implicated in inducing certain cases of the disease.

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

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

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

Gestational diabetes mellitus

For many years, GDM has been defined as any degree of glucose intolerance with onset or first recognition during pregnancy. Although most cases resolve with delivery, the definition applied whether or not the condition persisted after pregnancy and did not exclude the possibility that unrecognized glucose intolerance may have antedated or begun concomitantly with the pregnancy. This definition facilitated a uniform strategy for detection and classification of GDM, but its limitations were recognized for many years. As the ongoing epidemic of obesity and diabetes has led to more type 2 diabetes in women

Table 2—*Categories of increased risk for diabetes

FPG 100 mg/dl (5.6 mmol/l) to 125 mg/dl (6.9 mmol/l) [IFG]
2-h PG in the 75-g OGTT 140 mg/dl (7.8 mmol/l) to 199 mg/dl (11.0 mmol/l) [IGT]
A1C 5.7–6.4%

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

of childbearing age, the number of pregnant women with undiagnosed type 2 diabetes has increased.

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

CATEGORIES OF INCREASED RISK FOR DIABETES

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

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

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

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

Compared to the fasting glucose cutpoint of 100 mg/dl (5.6 mmol/l), an A1C cutpoint of 5.7% is less sensitive but more specific and has a higher positive predictive value to identify people at risk for later development of diabetes. A large prospective study found that a 5.7% cutpoint has a sensitivity of 66% and specificity of 88% for the identification of subsequent 6-year diabetes incidence (10). Receiver operating curve analyses of nationally representative U.S. data (NHANES 1999-2006) indicate that an A1C value of 5.7% has modest sensitivity (39-45%) but high specificity (81-91%) to identify cases of IFP (FPG >100 mg/dl) (5.6 mmol/l) or IGT (2-h glucose > 140 mg/dl) (R.T. Ackerman, personal communication). Other analyses suggest that an A1C of 5.7% is associated with diabetes risk similar to the high-risk participants in the DPP (R.T. Ackerman, personal communication). Hence, it is reasonable to consider an A1C range of 5.7 to 6.4% as identifying individuals with high risk for future diabetes and to whom the term pre-diabetes may be applied if desired.

Individuals with an A1C of 5.7–6.4% should be informed of their increased risk for diabetes as well as cardiovascular disease and counseled about effective strategies, such as weight loss and physical activity, to lower their risks. As with glucose measurements, the continuum of risk is curvilinear, so that as A1C rises, the risk of diabetes rises disproportionately.

Accordingly, interventions should be most intensive and follow-up should be particularly vigilant for those with A1C levels above 6.0%, who should be considered to be at very high risk. However, just as an individual with a fasting glucose of 98 mg/dl (5.4 mmol/l) may not be at negligible risk for diabetes, individuals with A1C levels below 5.7% may still be at risk, depending on level of A1C and presence of other risk factors, such as obesity and family history.

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

Table 3—*Criteria for the diagnosis of diabetes*

1. A1C ≥6.5%. The test should be performed in a laboratory using a method that is NGSP certified and standardized to the DCCT assay.*

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.*

OR

4. In a patient with classic symptoms of hyperglycemia or hyperglycemic crisis, a random plasma glucose ≥200 mg/dl (11.1 mmol/l).

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

DIAGNOSTIC CRITERIA FOR DIABETES MELLITUS

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

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

There is an inherent logic to using a more chronic versus an acute marker of dysglycemia, particularly since the A1C is already widely familiar to clinicians as a marker of glycemic control. Moreover, the A1C has several advantages to the FPG, including greater convenience, since fasting is not required, evidence to suggest greater preanalytical stability, and less day-to-day perturbations during periods of stress and illness. These advantages, however, must be balanced by greater cost, the limited availability of A1C testing in certain regions of the developing world, and the incomplete correlation between A1C and average glucose in certain individuals. In addition, the A1C can be misleading in patients with certain forms of anemia and hemoglobinopathies, which may also have unique ethnic or geographic distributions. For patients with a hemoglobinopathy but normal red cell turnover, such as sickle cell trait, an A1C assay without interference from abnormal hemoglobins should be used (an updated list is available at www.ngsp.org/prog/index3.html). For conditions with abnormal red cell turnover, such as anemias from hemolysis and iron deficiency, the diagnosis of diabetes must employ glucose criteria exclusively.

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

Just as there is less than 100% concordance between the FPG and 2-h PG tests, there is not full concordance between A1C and either glucose-based test. Analyses of NHANES data indicate that, assuming universal screening of the undiagnosed, the A1C cut point of ≥6.5% identifies one-third fewer cases of undiagnosed diabetes than a fasting glucose cut point of ≥126 mg/dl (7.0 mmol/l) (cdc website tbd). However, in practice, a large portion of the population with type 2 di-

abetes remains unaware of their condition. Thus, it is conceivable that the lower sensitivity of A1C at the designated cut point will be offset by the test's greater practicality, and that wider application of a more convenient test (A1C) may actually increase the number of diagnoses made.

Further research is needed to better characterize those patients whose glycemic status might be categorized differently by two different tests (e.g., FPG and A1C), obtained in close temporal approximation. Such discordance may arise from measurement variability, change over time, or because A1C, FPG, and postchallenge glucose each measure different physiological processes. In the setting of an elevated A1C but "nondiabetic" FPG, the likelihood of greater postprandial glucose levels or increased glycation rates for a given degree of hyperglycemia may be present. In the opposite scenario (high FPG yet A1C below the diabetes cut point), augmented hepatic glucose production or reduced glycation rates may be present.

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

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

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

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

Diagnosis of GDM

At the time of publication of this statement, the criteria for abnormal glucose tolerance in pregnancy are those of Carpenter and Coustan (11). Recommendations from ADA's Fourth International Workshop-Conference on Gestational Diabetes Mellitus held in March 1997 support the use of the Carpenter/Coustan diagnostic criteria as well as the alternative use of a diagnostic 75-g 2-h OGTT. These criteria are summarized below.

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

This low-risk group comprises women who:

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

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

An FPG level >126 mg/dl (7.0 mmol/l) or a casual plasma glucose >200 mg/dl (11.1 mmol/l) meets the threshold for the diagnosis of diabetes. In the absence of unequivocal hyperglycemia, the diagnosis must be confirmed on a subsequent day. Confirmation of the diagnosis precludes the need for any glucose challenge. In the absence of this degree of hyperglycemia, evaluation for GDM in women with average or high-risk characteristics should follow one of two approaches.

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

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

With either approach, the diagnosis of GDM is based on an OGTT. Diagnostic criteria for the 100-g OGTT are derived from the original work of O'Sullivan and Mahan (12) modified by Carpenter and Coustan (11) and are shown at the top of Table 4. Alternatively, the diagnosis can be made using a 75-g glucose load and the glucose threshold values listed for fasting, 1 h, and 2 h (Table 4, bottom); however,

Table 4—*Diagnosis of GDM with a 100-g or 75-g glucose load*

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

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

this test is not as well validated as the 100-g OGTT.

Results of the Hyperglycemia and Adverse Pregnancy Outcomes study (13), a large-scale (~25,000 pregnant women) multinational epidemiologic study, demonstrated that risk of adverse maternal, fetal, and neonatal outcomes continuously increased as a function of maternal glycemia at 24–28 weeks, even within ranges previously considered normal for pregnancy. For most complications, there was no threshold for risk. These results have led to careful reconsideration of the diagnostic criteria for GDM. The IADPSG recommended that all women not known to have prior diabetes undergo a 75-g OGTT at 24–28 weeks of gestation. The group developed diagnostic cut points for the fasting, 1-h, and 2-h plasma glucose measurements that conveyed an odds ratio for adverse outcomes of at least 1.75 compared with women with the mean glucose levels in the HAPO study.

At the time of publication of this update, ADA is planning to work with U.S. obstetrical organizations to consider adoption of the IADPSG diagnostic criteria and to discuss the implications of this change. While this change will significantly increase the prevalence of GDM, there is mounting evidence that treating even mild GDM reduces morbidity for both mother and baby (14).

Acknowledgments— The American Diabetes Association thanks the following volunteer members of the writing group for the updated sections on diagnosis and categories of increased risk: Silvio Inzucchi, MD; Richard Bergenstal, MD; Vivian Fonseca, MD; Edward Gregg, PhD; Beth Mayer-Davis, MSPH, PhD, RD; Geralyn Spollett, MSN, CDE, ANP; and Richard Wender, MD.

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Diabetes Care in the School and Day Care Setting

AMERICAN DIABETES ASSOCIATION

Diabetes is one of the most common chronic diseases of childhood (1). There are ~186,300 individuals <20 years of age with diabetes in the U.S. Based on 2002–2003 data, the rate of new type 1 diabetes cases was 19.0 per 100,000 children and of type 2 diabetes was 5.3 per 100,000 (2). The majority of these young people attend school and/or some type of day care and need knowledgeable staff to provide a safe school environment. Both parents and the health care team should work together to provide school systems and day care providers with the information necessary to allow children with diabetes to participate fully and safely in the school experience (3,4).

DIABETES AND THE LAW

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

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

Diabetes care in schools

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

To facilitate the appropriate care of the student with diabetes, the school nurse as well as other school and day care personnel must have an understanding of diabetes and must be trained in its management and in the treatment of diabetes emergencies (3,18,19,20,34,36). Knowledgeable trained personnel are essential if the student is to avoid the immediate health risks of low blood glucose and to achieve the metabolic control required to decrease risks for later development of diabetes complications (3,20). Studies have shown that the majority of school personnel have an inadequate understanding of diabetes (21,22). Consequently, diabetes education must be targeted toward day care providers, teachers, and other school personnel who interact with the child, including school administrators, school nurses, coaches, health aides, bus drivers, secretaries, etc. (3,20). Current recommendations and up-to-date resources regarding appropriate care for children with diabetes in the school are universally available to all school personnel (3,23).

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

GENERAL GUIDELINES FOR THE CARE OF THE CHILD IN THE SCHOOL AND DAY CARE SETTING

I. Diabetes Medical Management Plan

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

Originally approved 1998. Revised 2008.
DOI: 10.2337/dc10-S070

specific needs of the child and provide specific instructions for each of the following:

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

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

II. Responsibilities of the various care providers (3)

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

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

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

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

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

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

Diabetes Care Tasks at School: What Key Personnel Need to Know. Alexandria, VA, American Diabetes Association, 2008. Available online at www.diabetes.org/assets/pdfs/schools/forward2008.pdf

Your School & Your Rights: Protecting Children with Diabetes Against Discrimination in Schools and Day Care Centers. Alexandria, VA, American Diabetes Association, 2005 (brochure). Available online at http://www.diabetes.org/your-school-your-rights.*

Children with Diabetes: Information for School and Child Care Providers. Alexandria, VA, American Diabetes Association, 2004 (brochure). Available at http://www.diabetes.org/assets/pdfs/schools/chren-wdiabetes-brochure-caregivers.pdf.*

ADA's *Safe at School* campaign and information on how to keep children with diabetes safe at school. Call 1-800-DIABETES and go to www.diabetes.org/living-with-diabetes/parents-and-kids/diabetes-care-at-school/

American Diabetes Association: *Complete Guide to Diabetes*. Alexandria, VA, American Diabetes Association, 2005. Call 1-800-232–6733.

Raising a Child with Diabetes: A Guide for Parents. Alexandria, VA, American Diabetes Association, 2000. Call 1-800-232–6733.

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School Discrimination Resources. Alexandria, VA, American Diabetes Association, 2006. Available at http://www.diabetes.org/living-with-diabetes/know-your-rights/discrimination/school-discrimination/*

Wizdom: A Kit of Wit and Wisdom for Kids with Diabetes (and their parents). Alexandria, VA, American Diabetes Association, 2000. Order information and select resources available at www.diabetes.org/wizdom.

ADA's *Planet D*, on-line information for children and youth with diabetes. Accessible at http://tracker.diabetes.org/index.php.

*Available in the American Diabetes Association's Education Discrimination Packet by calling 1-800-DIABETES.

the parent/guardian in advance of any expected changes in the school schedule that affect the student's meal times or exercise routine and will remind young children of snack times.

8. Permission for self-sufficient and capable students to carry equipment, supplies, medication, and snacks; to perform diabetes management tasks; and to have cell phone access to reach parent/guardian and health care provider.
9. Permission for the student to see the school nurse and other trained school personnel upon request.
10. Permission for the student to eat a snack anywhere, including the classroom or the school bus, if necessary to prevent or treat hypoglycemia.
11. Permission to miss school without consequences for illness and required medical appointments to monitor the student's diabetes management. This should be an excused absence with a doctor's note, if required by usual school policy.
12. Permission for the student to use the restroom and have access to fluids (i.e., water) as necessary.
13. An appropriate location for insulin and/or glucagon storage, if necessary.
14. A plan for the disposal of sharps based upon an agreement with the student's family, local ordinances, and Universal Precaution Standards.
15. Information on serving size and caloric, carbohydrate, and fat content of foods served in the school (27).

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

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

III. Expectations of the student in diabetes care

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

1. *Toddlers and preschool-aged children*: unable to perform diabetes tasks independently and will need an adult to provide all aspects of diabetes care. Many of these younger children will have difficulty in recognizing hypoglycemia, so it is important that school personnel are able to recognize and provide prompt treatment. However, children in this age range can usually determine which finger to prick, can choose an injection site, and are generally cooperative.
2. *Elementary school–aged children*: depending on the length of diagnosis and level of maturity, may be able to perform their own blood glucose checks, but usually will require supervision. Older elementary school–aged children are generally beginning to self-administer insulin with supervision and understand the effect of insulin, physical activity, and nutrition on blood glucose levels. Unless the child has hypoglycemic unawareness, he or she should usually be able to let an adult know when experiencing hypoglycemia.
3. *Middle school and high school–aged children*: usually able to provide self-care depending on the length of diagnosis and level of maturity but will

always need help when experiencing severe hypoglycemia. Independence in older children should be encouraged to enable the child to make his or her decisions about his or her own care.

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

MONITORING BLOOD GLUCOSE IN THE CLASSROOM

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

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

APPENDIX

Background information on diabetes for school personnel (3)

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

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

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

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

Acknowledgments— The American Diabetes Association thanks the members of the health care professional volunteer writing group for this updated statement: William Clarke, MD; Larry C. Deeb, MD; Paula Jameson, MSN, ARNP, CDE; Francine Kaufman, MD; Georgeanna Klingensmith, MD; Desmond Schatz, MD; Janet H. Silverstein, MD; and Linda M. Siminerio, RN, PhD, CDE.

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Diabetes Management in Correctional Institutions

AMERICAN DIABETES ASSOCIATION

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

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

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

INTAKE MEDICAL ASSESSMENT

Reception screening

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

Intake screening

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

Intake physical examination and laboratory

All potential elements of the initial medical evaluation are included in Table 5 of the ADA's "Standards of Medical Care in Diabetes," referred to hereafter as the "Standards of Care" (4). The essential components of the initial history and physical examination are detailed in Fig. 1. Referrals should be made immediately if the patient with diabetes is pregnant.

Recommendations

- Patients with a diagnosis of diabetes should have a complete medical history and undergo an intake physical examination by a licensed health professional in a timely manner. (E)
- Insulin-treated patients should have a CBG determination within 1–2 h of arrival. (E)
- Medications and MNT should be continued without interruption upon entry into the correctional environment. (E)

SCREENING FOR DIABETES —

Consistent with the ADA Standards of Care, patients should be evaluated for diabetes risk factors at the intake physical and at appropriate times thereafter. Those

Originally approved 1989. Most recent revision, 2008.

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

DOI: 10.2337/dc10-S075

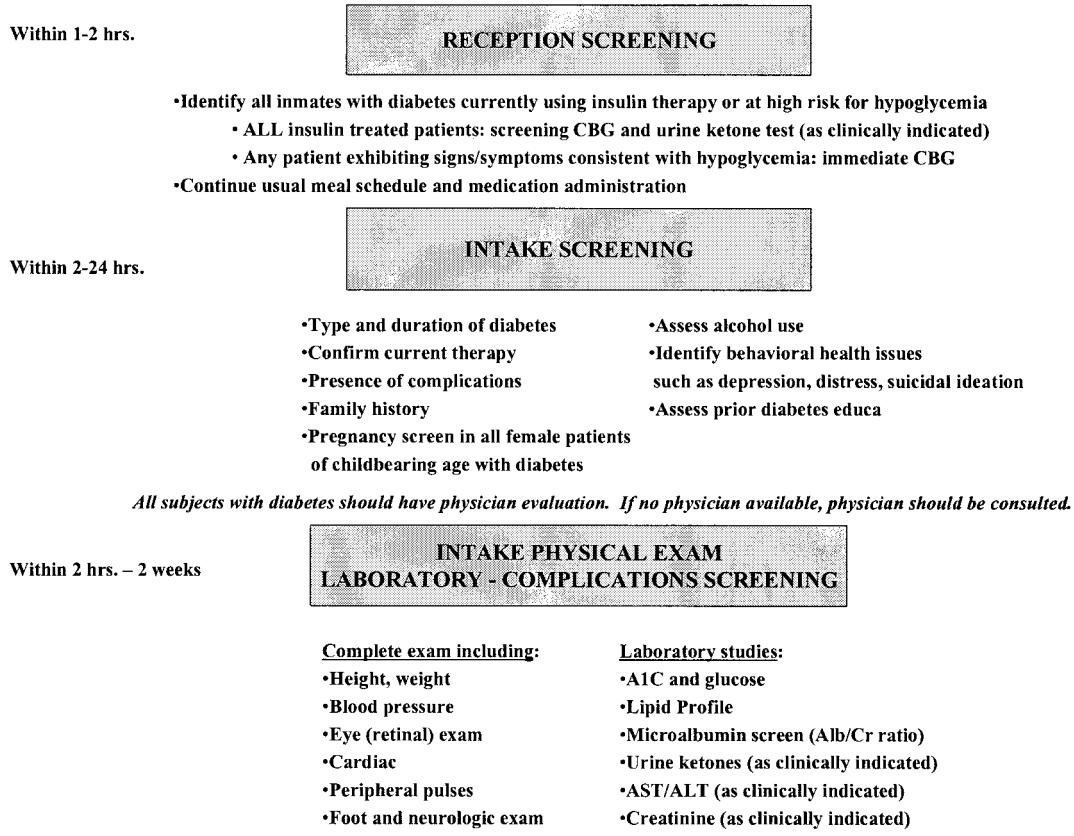

Figure 1—*Essential components of the initial history and physical examination. Alb/Cr ratio, albumin-to-creatinine ratio; ALT, alanine aminotransferase; AST, aspartate aminotransferase.*

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

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

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

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

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

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

Educating the patient, individually or in a group setting, about how carbohydrates and food choices directly affect di-

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

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

*Referenced to a nondiabetic range of 4.0–6.0% using a DCCT-based assay. †In individuals with overt CVD, a lower LDL cholesterol goal of <70 mg/dl (1.8 mmol/l), using a high dose of a statin, is an option.

abetes control is the first step in facilitating self-management. This education enables the patient to identify better food selections from those available in the dining hall and commissary. Such an approach is more realistic in a facility where the patient has the opportunity to make food choices.

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

The use of insulin or oral medications may necessitate snacks in order to avoid hypoglycemia. These snacks are a part of such patients' medical treatment plans and should be prescribed by medical staff.

Timing of meals and snacks must be coordinated with medication administration as needed to minimize the risk of hypoglycemia, as discussed more fully in the MEDICATION section of this document. For further information, see the ADA Position Statement "Nutrition Principles and Recommendations in Diabetes" (7).

URGENT AND EMERGENCY ISSUES

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

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

Hyperglycemia

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

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

Hypoglycemia

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

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

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

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

Recommendations

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

MEDICATION — Formularies should provide access to usual and customary oral medications and insulins necessary to treat diabetes and related conditions. While not every brand name of insulin and oral medication needs to be available, individual patient care requires access to short-, medium-, and long-acting insulins and the various classes of oral medications (e.g., insulin secretagogues, biguanides, α-glucosidase inhibitors, and thiazolidinediones) necessary for current diabetes management.

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

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

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

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

Recommendations

- Formularies should provide access to usual and customary oral medications and insulins to treat diabetes and related conditions. (E)
- Patients should have access to medication at dosing frequencies that are consistent with their treatment plan and medical direction. (E)
- Correctional institutions and police lock-ups should implement policies and procedures to diminish the risk of hypo- and hyperglycemia during off-site travel (e.g., court appearances). (E)

ROUTINE SCREENING FOR AND MANAGEMENT OF DIABETES COMPLICATIONS

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

The following complications should be considered.

- Foot care: Recommendations for foot care for patients with diabetes and no history of an open foot lesion are described in the ADA Standards of Care. A comprehensive foot examination is recommended annually for all patients with diabetes to identify risk factors predictive of ulcers and amputations. Persons with an insensate foot, an open foot lesion, or a history of such a lesion should be referred for evaluation by an appropriate licensed health professional (e.g., podiatrist or vascular surgeon). Special shoes should be provided as recommended by licensed health professionals to aid healing of foot lesions and to prevent development of new lesions.
- Retinopathy: Annual retinal examinations by a licensed eye care professional should be performed for all patients with diabetes, as recommended in the ADA Standards of Care. Visual changes that cannot be accounted for by acute changes in glycemic control require prompt evaluation by an eye care professional.
- Nephropathy: An annual spot urine test for determination of microalbumin-to-creatinine ratio should be performed. The use of ACE inhibitors or angiotensin receptor blockers is recommended for all patients with albuminuria. Blood pressure should be controlled to <130/80 mmHg.
- Cardiac: People with type 2 diabetes are at a particularly high risk of coronary artery disease. Cardiovascular disease risk factor management is of demonstrated benefit in reducing this complication in patients with diabetes. Blood pressure should be measured at every routine diabetes visit. In adult patients, test for lipid disorders at least annually and as needed to achieve goals with treatment. Use aspirin therapy (75–162 mg/day) in all adult patients with diabetes and cardiovascular risk factors or known macrovascular disease. Current national standards for adults with diabetes call for treatment of lipids to goals of LDL ≤100, HDL >40, triglycerides <150 mg/dl and blood pressure to a level of <130/80 mmHg.

MONITORING/TESTS OF GLYCEMIA

— Monitoring of CBG is a strategy that allows caregivers and peo-

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

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

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

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

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

Recommendations

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

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

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

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

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

Recommendations

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

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

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

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

Before the transfer, the health care staff should review the patient's medical record and complete a medical transfer

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

Survival skills	Daily management issues
• hypo-/hyperglycemia	• disease process
• sick day management	• nutritional management
• medication	• physical activity
• monitoring	• medications
• foot care	• monitoring
	• acute complications
	• risk reduction
	• goal setting/problem solving
	• psychosocial adjustment
	• preconception care/pregnancy/gestational diabetes management

summary that includes the patient's current health care issues. At a minimum, the summary should include the following.

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

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

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

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

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

Recommendations

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

SHARING OF MEDICAL INFORMATION AND RECORDS

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

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

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

CHILDREN AND ADOLESCENTS WITH DIABETES

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

Nutrition and activity

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

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

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

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

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

SUMMARY AND KEY POINTS

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

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

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

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Diabetes and Employment

AMERICAN DIABETES ASSOCIATION

As of 2007, approximately 23.6 million Americans have diabetes (1), most of whom are or wish to be participating members of the workforce. Diabetes usually has no impact on an individual's ability to do a particular job, and indeed an employer may not even know that a given employee has diabetes. In 1984, the American Diabetes Association adopted the following position on employment:

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

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

I. EVALUATING INDIVIDUALS WITH DIABETES FOR EMPLOYMENT

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

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

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

Role of diabetes health care professionals

When questions arise about the medical fitness of a person with diabetes for a particular job, a health care professional with expertise in treating diabetes should perform an individualized assessment. The involvement of the diabetes health care professional should occur before any adverse employment decision, such as failure to hire or promote or termination. A health professional who is familiar with the person with diabetes and who has expertise in treating diabetes is best able to perform such an assessment. In some situations and in complex cases, an endocrinologist or a physician who specializes in treating diabetes or its complications is the best qualified health professional to assume this responsibility (4). The individual's treating physician is generally the health care professional with the best knowledge of an individual's diabetes. Thus, even when the employer utilizes its own physician to perform the evaluation, the opinions of the treating physician and other health care professionals with clinical expertise in diabetes should be sought out and carefully considered. In situations where there is disagreement between the opinion of the employee's treating physician and that of the employer's physician, the evaluation should be handed over to an independent health care professional with significant clinical expertise in diabetes.

Individual assessment

A medical evaluation of an individual with diabetes may occur only in limited circumstances (3). Employers may not inquire about an individual's health status—directly or indirectly and regardless of the type of job—before making a job offer, but may require a medical examination or make a medical inquiry once an offer of employment has been extended and before the individual begins the job.

Revised Fall 2009.
DOI: 10.2337/dc10-S082

The job offer may be conditioned on the results of the medical inquiry or examination. An employer may withdraw an offer from an applicant with diabetes only if it becomes clear that he or she cannot do the essential functions of the job or would pose a direct threat (i.e., a significant risk of substantial harm) to health or safety and such threat could not be eliminated with an accommodation (a workplace change that enables a worker with a disability to safely and effectively perform job duties). Another situation in which a medical evaluation is permissible is when a problem potentially related to the employee's diabetes arises on the job and such problem could affect job performance and/or safety. In this situation, a physician may be asked to evaluate the employee's fitness to remain on the job and/or his or her ability to safely perform the job.

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

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

Screening guidelines

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

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

Recommendations

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

II. EVALUATING THE SAFETY RISK OF EMPLOYEES WITH DIABETES

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

Safety concerns

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

Hypoglycemia

Hypoglycemia is defined as a blood glucose level <70 mg/dl (4,6). It is a potential side effect of some diabetes treatments, including insulin and sulfonlyureas. It can usually be effectively self-treated by ingestion of glucose (carbohydrate) and is not often associated with loss of consciousness or a seizure. Severe hypoglycemia, requiring the assistance of another person, is a medical emergency. Symptoms of severe hypogly-

cemia may include confusion or, rarely, seizure or loss of consciousness (6). Most individuals with diabetes never experience an episode of severe hypoglycemia because either they are not on medication that causes it or they recognize the early warning signs and can quickly self-treat the problem by drinking or eating. Also, with self-monitoring of blood glucose levels, most people with diabetes can manage their condition in such a manner that there is minimal risk of incapacitation from hypoglycemia because mildly low glucose levels can be easily detected and treated (4,7).

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

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

Hyperglycemia

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

Aspects of a safety assessment

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

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

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

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

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

Inappropriate assessments

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

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

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

cording a fasting glucose value on a lab report (5). A1C/eAG values provide health care providers with important information about the effectiveness of an individual's treatment regimen (4) but are often misused in assessing whether an individual can safely perform a job. Because they identify only averages and not whether the person had severe extreme blood glucose readings, A1C/eAG results are of no value in predicting short-term complications of diabetes and thus have no use in evaluating individuals in employment situations.

The American Diabetes Association recommends that in most patients A1C levels be kept below 7% (4), or eAG below 154 mg/dl. This recommendation sets a target in order to lessen the chances of long-term complications of high blood glucose levels but does not provide useful information on whether the individual is at significant risk for hypoglycemia or suboptimal job performance and is not a measure of "compliance" with therapy. An A1C or eAG cut off score is not medically justified in employment evaluations and should never be a determinative factor in employment.

"Uncontrolled" or "brittle" diabetes. Sometimes an individual's diabetes is described as "uncontrolled," "poorly controlled," or "brittle." These terms are not well defined and are not relevant to job evaluations. As such, giving an opinion on the level of "control" an individual has over diabetes is not the same as assessing whether that individual is qualified to perform a particular job and can do so safely. Such an individual assessment is the only relevant evaluation.

Recommendations

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

III. ACCOMMODATING EMPLOYEES WITH DIABETES

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

Accommodating daily diabetes management needs

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

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

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

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

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

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

Accommodating complications of diabetes

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

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

It is impossible to provide an exhaustive list of potential accommodations. The key message in accommodating an employee with diabetes is to ensure that ac-

commodations are tailored to the individual and effective in helping the individual perform his or her job. Input from health care professionals who specialize in the particular complication, or from vocational rehabilitation specialists or organizations, may help identify appropriate accommodations.

Recommendations

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

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

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

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

AMERICAN DIABETES ASSOCIATION

Diabetes is a chronic disease that affects >20 million Americans (1) and is characterized by serious, costly, and often fatal complications. The total cost of diagnosed diabetes in the U.S. in 2007 was estimated to be $174 billion (2). To prevent or delay costly diabetes complications and to enable people with diabetes to lead healthy, productive lives, appropriate medical care based on current standards of practice, self-management education, and medication and supplies must be available to everyone with diabetes. This paper is based on technical reviews titled "Diabetes Self-Management Education" (3) and "National Standards for Diabetes Self-Management Education Programs" (4).

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

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

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

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

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

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

Certain principles should guide the creation and enforcement of controls in order to insure that they meet the comprehensive medical needs of people living with diabetes. A wide array of medications and supplies are correlated with improved glycemic outcomes and a reduction in the risk of diabetes-related complications. Because no single diabetes treatment regimen is appropriate for all people with diabetes, providers and patients should have access to a broad array of medications and supplies to develop an effective treatment modality.

The recommendations in this paper are based on the evidence reviewed in the following publications: Diabetes self-management education (Technical Review). *Diabetes Care* 18:1204–1214, 1995; and National standards for diabetes self-management education. *Diabetes Care* 33:S89–S96, 2010.

Approved 1995. Revised 2008.

DOI: 10.2337/dc10-S087

However, the Association also recognizes that there may be a number of medications and/or supplies within any given class. As such, any controls should ensure that all classes of antidiabetic agents with unique mechanisms of action are available to facilitate achieving glycemic goals to reduce the risk of complications. Similar issues operate in the management of lipid disorders, hypertension, and other cardiovascular risk factors, as well as for other diabetes complications. Furthermore, any controls should ensure that all classes of equipment and supplies designed for use with such equipment are available to facilitate achieving glycemic goals to reduce the risk of complications. It is important to note that medical advances are rapidly changing the landscape of diabetes medications and supplies. To ensure that patients with diabetes have access to beneficial updates in treatment modalities, systems of controls must employ efficient mechanisms through which to introduce and approve new products.

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

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

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

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Position Statements

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

Intensive Glycemic Control and Prevention of Cardiovascular Events
Diabetes Care 32:187–192, 2009

Nutrition
Diabetes Care 31 (Suppl. 1):S61–S78, 2008

Generic Drugs
Diabetes Care 30:173, 2007

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

Metabolic Syndrome
Diabetes Care 28:2289, 2005

Neuropathy
Diabetes Care 28:956, 2005

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

Dietary Carbohydrate
Diabetes Care 27:2266, 2004

Weight Management
Diabetes Care 27:2067, 2004

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

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

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

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

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

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

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

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

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

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

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

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

Retinopathy in Diabetes
Diabetes Care 27 (Suppl. 1):S84–S87, 2004

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

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

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

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

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

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

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

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

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

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

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

National Standards for Diabetes Self-Management Education

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

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

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

DEFINITION AND OBJECTIVES

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

GUIDING PRINCIPLES

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

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

STANDARDS

Structure

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

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

Documentation of the organizational structure, mission statement, and goals can lead to efficient and effective provision of DSME. Documentation of an organizational structure that delineates

The previous version of the "National Standards for Diabetes Self-Management Education" was originally published in *Diabetes Care* 23:682–689, 2000. This version received final approval in March 2007.
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DOI: 10.2337/dc10-S089

channels of communication and represents institutional commitment to the educational entity is critical for success (38–42). According to the Joint Commission on Accreditation of Health Care Organizations (JCAHO) (26), this type of documentation is equally important for small and large health care organizations. Health care and business experts overwhelmingly agree that documentation of the process of providing services is a critical factor in clear communication and provides a solid basis from which to deliver quality diabetes education (22,26, 33,35–37). In 2005, JACHO published the *Joint Commission International Standards for Disease or Condition-Specific Care*, which outlines national standards and performance measurements for diabetes and addresses diabetes self-management education as one of seven critical elements (26).

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

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

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

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

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

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

Process

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

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

Expert consensus supports the need for specialized diabetes and educational training beyond academic preparation for the primary instructors on the diabetes team (64,93–97). Certification as a diabetes educator by the National Certification Board for Diabetes Educators (NCBDE) is one way a health professional can demonstrate mastery of a specific body of knowledge, and this certification has become an accepted credential in the diabetes community (98). An additional credential that indicates specialized training beyond basic preparation is board certification in advanced Diabetes Management (BC-ADM) offered by the American Nurses Credentialing Center (ANCC), which is available for master's prepared nurses, dietitians, and pharmacists (48,84,99).

DSME has been shown to be most effective when delivered by a multidisciplinary team with a comprehensive plan of care (7,31,52,100–102). Within the multidisciplinary team, team members work interdependently, consult with one another, and have shared objectives (7,103,104). The team should have a collective combination of expertise in the clinical care of diabetes, medical nutrition therapy, educational methodologies, teaching strategies, and the psychosocial and behavioral aspects of diabetes self-management. A referral mechanism should be in place to ensure that the individual with diabetes receives education from those with appropriate training and credentials. It is essential in this collaborative and integrated team approach that individuals with diabetes are viewed as leaders of their team and assume an active role in designing their educational experience (7,20,31,100–102,104).

Standard 6. *A written curriculum reflecting current evidence and practice guidelines, with*

criteria for evaluating outcomes, will serve as the framework for the DSME entity. Assessed needs of the individual with pre-diabetes and diabetes will determine which of the content areas listed below are to be provided:

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

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

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

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

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

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

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

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

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

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

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

Research suggests that the development of standardized procedures for documentation, training health professionals to document appropriately, and the use of structured standardized forms based on current practice guidelines can improve documentation and may ultimately improve quality of care (100,153–155).

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

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

DSMS is defined as activities to assist the individual with diabetes to implement and sustain the ongoing behaviors needed to manage their illness. The type of support provided can include behavioral, educational, psychosocial, or clinical (13,121–123).

A variety of strategies are available for

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

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

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

Outcomes

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

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

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

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

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

Acknowledgments— Work on this article was supported in part by grant nos. NIH5P60 DK20572 and 1 R18 0K062323 from the National Institute of Diabetes and Digestive and Kidney Diseases of the National Institutes of Health.

The Task Force gratefully acknowledges the assistance and support of Paulina Duker, MPH, APRN-BC, CDE, and Nathanial Clark, MD, CDE, of the American Diabetes Association; Lori Porter, MBA, RD, CAE, of the American Association of Diabetes Educators; and Karmeen Kulkarni, MS, RD, BC-ADM, Past President, Health Care and Education of the American Diabetes Association; Malinda Peeples, MS, RN, CDE, Past President of the American Association of Diabetes Educators; and Carole' Mensing, RN, MA, CDE, for their insights and helpful suggestions.

We also gratefully acknowledge the work of the previous Task Force for the National Standards for DSME: Carole' Mensing, RN, MA, CDE; Jackie Boucher, MS, RD, LD, CDE; Marjorie Cypress, MS, C-ANP, CDE; Katie Weinger, EdD, RN; Kathryn Mulcahy, MSN, RN, CDE; Patricia Barta, RN, MPH, CDE; Gwen Hosey, MS, ARNP, CDE; Wendy Kopher, RN, C, CDE, HTP; Andrea Lasichak, MS, RD, CDE; Betty Lamb, RN, MSN; Mavourneen Mangan, RN, MS, ANP, C, CDE; Jan Norman, RD, CDE; Jon Tanja, BS, MS, RPH; Linda Yauk, MS, RD, LD, CDE; Kimberlydawn Wisdom, MD, MS; and Cynthia Adams, PhD

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159. Two Feathers J, Kieffer EC, Palmisano G, et al: Racial and ethnic approaches to community health (REACH) Detroit partnership: improving diabetes-related outcomes among African American and Latino adults. *Am J Public Health* 95: 1552–1560, 2005
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161. Institute of Healthcare Improvement: How to improve: improvement methods. Available at http://www.ihi.org/IHI/Topics/Improvement/improvementmethods\. Accessed 24 April 2006
162. Bardsley J, Bronzini B, Harriman K, Lumber T: *CQI: A Step by Step Guide for Quality Improvement in Diabetes Education*. Chicago, IL, American Association of Diabetes Educators, 2005
163. Joint Commission Resources: *Cost-Effective Performance Improvement in Ambulatory Care*. Oakbrook Terrace, IL, Joint Commission on Accreditation of Healthcare Organizations, 2003
164. Institute of Healthcare Improvement: Measures: diabetes. Available at http://www.ihi.org/IHI/Topics/ChronicConditions/Diabetes/Measures. Accessed 24 April 2006

Technical Reviews

A technical review is a balanced review and analysis of the literature on a scientific or medical topic related to diabetes. The technical review provides a scientific rationale for a position statement and undergoes critical peer review before submission to the Professional Practice Committee for approval. Effective January 2010, technical reports are replaced with systematic reviews, for which a priori search and inclusion/exclusion criteria are developed and published. Listed below are recent technical reviews.

Economic Analysis of Diabetes Interventions
Klonoff DC, Schwartz DM: An economic analysis of interventions for diabetes. *Diabetes Care* 23:390–404, 2000

Exercise
Sigal RJ, Kenny GP, Wasserman DH, Castaneda-Sceppa C: Physical activity/exercise and type 2 diabetes. *Diabetes Care* 27:2518–2539, 2004

Hospitals
Clement S, Braithwaite SS, Magee MF, Ahmann A, Smith EP, Schafer RG, Hirsh IB: Management of diabetes and hyperglycemia in hospitals. *Diabetes Care* 27: 553–591, 2004

Hyperglycemic Crises
Kitabchi AE, Umpierrez GE, Murphy MB, Barrett EJ, Kreisberg RA, Malone JI, Wall BM: Management of hyperglycemic crises in patients with diabetes. *Diabetes Care* 24:131–153, 2001

Hypertension
Arauz-Pacheco C, Parrott MA, Raskin P: The treatment of hypertension in adult patients with diabetes. *Diabetes Care* 25: 134–147, 2002

Hypoglycemia
Cryer PE, Davis SN, Shamoon H: Hypoglycemia in diabetes. *Diabetes Care* 26: 1902–1912, 2003

Immunizations
Smith SA, Poland GA: Use of influenza and pneumococcal vaccines in people with diabetes. *Diabetes Care* 23:95–108, 2000

Laboratory Analysis
Sacks DB, Bruns DE, Goldstein DE, Maclaren NK, McDonald JM, Parrott M: Guidelines and recommendations for laboratory analysis in the diagnosis and management of diabetes mellitus. *Diabetes Care* 25:750–786, 2002 (Reprinted from *Clin Chem* 48:436–472, 2002)

Neuropathy
Vinik AI, Maser RE, Mitchell BD, Freeman R: Diabetic autonomic neuropathy. *Diabetes Care* 26:1553–1579, 2003

Boulton AJ, Malik RA, Arezzo JC, Sosenko JM: Diabetic somatic neuropathies. *Diabetes Care* 27:1458–1486, 2004

Nutrition Recommendations and Principles
Franz MJ, Bantle JP, Beebe CA, Brunzell JD, Chiasson JL, Garg A, Holzmeister LA, Hoogwerf B, Mayer-Davis E, Mooradian AD, Purnell JS, Wheeler M: Evidence-based nutrition principles and recommendations for the treatment and prevention of diabetes and related complications. *Diabetes Care* 25:148–198, 2002

Pancreas Transplantation
Robertson RP, Davis C, Larsen J, Stratta R, Sutherland DER: Pancreas and islet transplantation for patients with diabetes. *Diabetes Care* 23:112–116, 2000

Retinopathy
Fong DS, Aiello LP, Ferris FL III, Klein R: Diabetic retinopathy. *Diabetes Care* 27: 2540–2553, 2004

Screening for Type 2 Diabetes
Engelgau MM, Narayan KM, Herman WH: Screening for type 2 diabetes. *Diabetes Care* 23:1563–1580, 2000

Tests of Glycemia
Goldstein DE, Little RR, Lorenz RA, Malone JI, Nathan D, Peterson CM, Sacks DB: Tests of glycemia in diabetes. *Diabetes Care* 27:1761–1773, 2004

Consensus Reports

Effective January 2010, prior reports of the types listed below are renamed "consensus reports."

EXPERT COMMITTEE REPORTS

International Expert Committee Report on the Role of the A1C Assay in the Diagnosis of Diabetes
International Expert Committee
Diabetes Care 32:1327–1334, 2009

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

WORKGROUP REPORTS

Comprehensive Foot Examination and Risk Assessment: a Report of the Task Force of the Foot Care Interest Group of the American Diabetes Association, With Endorsement by the American Association of Clinical Endocrinologists
Andrew J.M. Boulton, David G. Armstrong, Stephen F. Albert, Robert G. Frykberg, Richard Hellman, M. Sue Kirkman, Lawrence A. Lavery, Joseph W. LeMaster, Joseph L. Mills, Sr., Michael J. Mueller, Peter Sheehan, and Dane K. Wukich
Diabetes Care 31:1679–1685, 2008

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

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

CONSENSUS STATEMEMENTS

Medical Management of Hyperglycemia in Type 2 Diabetes: A Consensus Algorithm for the Initiation and Adjustment of Therapy: A Consensus Statement of the American Diabetes Association and the European Association for the Study of Diabetes
David M. Nathan, John B. Buse, Mayer B. Davidson, Ele Ferrannini, Rury R. Holman, Robert Sherwin, and Bernard Zinman
Diabetes Care 32:193–203, 2009

American Association of Clinical Endocrinologists and American Diabetes Association Consensus Statement on Inpatient Glycemic Control
Etie S. Moghissi, Mary T. Korytkowski, Monica DiNardo, Daniel Einhorn, Richard Hellman, Irl B. Hirsch, Silvio E. Inzucchi, Faramarz Ismail-Beigi, M. Sue Kirkman, and Guillermo E. Umpierrez
Diabetes Care 32:1119–1131, 2009

Hyperglycemic Crises in Adult Patients With Diabetes
Abbas E. Kitabchi, Guillermo E. Umpierrez, John M. Miles, and Joseph N. Fisher
Diabetes Care 32:1335–1343, 2009

How Do We Define Cure of Diabetes?
John B. Buse, Sonia Caprio, William T. Cefalu, Antonio Ceriello, Stefano Del Prato, Silvio E. Inzucchi, Sue McLaughlin, Gordon L. Phillips II, R. Paul Robertson, Francesco Rubino, Richard Kahn, and M. Sue Kirkman.
Diabetes Care 32:2133–2135, 2009

Management of Hyperglycemia in Type 2 Diabetes: A Consensus Algorithm for the Initiation and Adjustment of Therapy: Update Regarding Thiazolidinediones: a Consensus Statement From the American Diabetes Association and the European Association for the Study of Diabetes
David M. Nathan, John B. Buse, Mayer B. Davidson, Ele Ferrannini, Rury R. Holman, Robert Sherwin, and Bernard Zinman
Diabetes Care 31:173–175, 2008

Lipoprotein Management in Patients With Cardiometabolic Risk: Consensus Statement From the American Diabetes Association and the American College of Cardiology Foundation
John D. Brunzell, Michael Davidson, Curt D. Furberg, Ronald B. Goldberg, Barbara V. Howard, James H. Stein, and Joseph L. Witztum
Diabetes Care 31:811–822, 2008

Managing Preexisting Diabetes for Pregnancy: Summary of Evidence and Consensus Recommendations for Care
John L. Kitzmiller, Jennifer M. Block, Florence M. Brown, Patrick M. Catalano, Deborah L. Conway, Donald R. Coustan, Erica P. Gunderson, William H. Herman, Lisa D. Hoffman, Maribeth Inturrisi, Lois B. Jovanovic, Siri I. Kjos, Robert H. Knopp, Martin N. Montoro, Edward S. Ogata, Pathmaja Paramsothy, Diane M. Reader, Barak M. Rosenn, Alyce M. Thomas, and M. Sue Kirkman
Diabetes Care 31:1060–1079, 2008

Influence of Race, Ethnicity, and Culture on Childhood Obesity: Implications for Prevention and Treatment: A Consensus Statement of Shaping America's Health and the Obesity Society
Sonia Caprio, Stephen R. Daniels, Adam Drewnowski, Francine R. Kaufman, Lawrence A. Palinkas, Arlan L. Rosenbloom, and Jeffrey B. Schwimmer
Diabetes Care 31:2211–2221, 2008

Screening for Coronary Artery Disease in Patients With Diabetes
Jeroen J. Bax, Lawrence H. Young, Robert L. Frye, Robert O. Bonow, Helmut O. Steinberg, and Eugene J. Barrett
Diabetes Care 30:2729–2736, 2007

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

Use of Insulin Pump Therapy in the Pediatric Age-Group: Consensus Statement From the European Society for Paediatric Endocrinology, the Lawson Wilkins Pediatric Endocrine Society, and the International Society for Pediatric and Adolescent Diabetes, Endorsed by the American Diabetes Association and the European Association for the Study of Diabetes

Moshe Phillip, Tadej Battelino, Henry Rodriguez, Thomas Danne, Francine Kaufman for the Consensus forum participants
Diabetes Care 30:1653–1662, 2007

Waist Circumference and Cardiometabolic Risk: a Consensus Statement From Shaping America's Health: Association for Weight Management and Obesity Prevention; NAASO, The Obesity Society; the American Society for Nutrition; and the American Diabetes Association
Samuel Klein, David B. Allison, Steven B. Heymsfield, David E. Kelley, Rudolph L. Leibel, Cathy Nonas, and Richard Kahn
Diabetes Care 30:1647–1652, 2007

Computer Modeling of Diabetes and Its Complications: a Report on the Fourth Mount Hood Challenge Meeting
The Mount Hood 4 Modeling Group
Diabetes Care 30:1638–1646, 2007

Impaired Fasting Glucose and Impaired Glucose Tolerance: Implications for Care
David M. Nathan, Mayer B. Davidson, Ralph A. DeFronzo, Robert J. Heine, Robert R. Henry, Richard Pratley, and Bernard Zinman
Diabetes Care 30:753–759, 2007

Physical Activity/Exercise and Type 2 Diabetes: A Consensus Statement From the American Diabetes Association
Ronald J. Sigal, Glen P. Kenny, David H. Wasserman, Carmen Castaneda-Sceppa, and Russell D. White
Diabetes Care 29:1433–1438, 2006

Diabetic Ketoacidosis in Infants, Children, and Adolescents: A Consensus Statement From the American Diabetes Association
Joseph Wolfsdorf, Nicole Glaser, and Mark A. Sperling
Diabetes Care 29:1150–1159, 2006