NGC banner

Guideline Summary NGC-8221

Guideline Title

Standards of medical care in diabetes. VI. Prevention and management of diabetes complications.

Bibliographic Source(s)

American Diabetes Association (ADA). Standards of medical care in diabetes. VI. Prevention and management of diabetes complications. Diabetes Care 2011 Jan;34(Suppl 1):S27-38.

Guideline Status

Note: This guideline has been updated. The National Guideline Clearinghouse (NGC) is working to update this summary.

FDA Warning/Regulatory Alert

Note from the National Guideline Clearinghouse: This guideline references a drug(s) for which important revised regulatory and/or warning information has been released.

- March 1, 2012 – Statins and HIV or Hepatitis C drugs : The U.S. Food and Drug Administration (FDA) notified healthcare professionals of updates to the prescribing information concerning interactions between protease inhibitors and certain statin drugs. Protease inhibitors and statins taken together may raise the blood levels of statins and increase the risk for muscle injury (myopathy). The most serious form of myopathy, called rhabdomyolysis, can damage the kidneys and lead to kidney failure, which can be fatal.

- February 28, 2012 – Statin drugs : The U.S. Food and Drug Administration (FDA) has approved important safety label changes for the class of cholesterol-lowering drugs known as statins. The changes include removal of routine monitoring of liver enzymes from drug labels. Information about the potential for generally non-serious and reversible cognitive side effects and reports of increased blood sugar and glycosylated hemoglobin (HbA1c) levels has been added to the statin labels. The lovastatin label has been extensively updated with new contraindications and dose limitations when it is taken with certain medicines that can increase the risk for muscle injury.

- November 9, 2011 – Trilipix (fenofibric acid) : The U.S. Food and Drug Administration (FDA) notified healthcare professionals the cholesterol-lowering medicine Trilipix (fenofibric acid) may not lower a patient's risk of having a heart attack or stroke. FDA reviewed the data from the Action to Control Cardiovascular Risk in Diabetes (ACCORD) Lipid trial. The ACCORD Lipid trial found no significant difference in the risk of experiencing a major adverse cardiac event between the group treated with fenofibrate plus simvastatin compared with simvastatin alone. Information from the trial has been added to the Important Limitations of Use and Warnings and Precautions sections of the Trilipix physician label and to the patient Medication Guide.

- June 8, 2011 – Zocor (simvastatin) : The U.S. Food and Drug Administration (FDA) notified healthcare professionals that it is recommending limiting the use of the highest approved dose of the cholesterol-lowering medication simvastatin (80 mg) because of increased risk of muscle damage. FDA is requiring changes to the simvastatin label to add new contraindications (should not be used with certain medications) and dose limitations for using simvastatin with certain medicines.

Scope

Disease/Condition(s)

Complications of diabetes mellitus, including:

- Cardiovascular disease (CVD)
  - Hypertension
  - Dyslipidemia
  - Coronary heart disease (CHD)
- Nephropathy
- Retinopathy
- Neuropathy
  - Distal symmetric polyneuropathy (DPN)
  - Autonomic neuropathy
- Foot ulceration

Guideline Category

Counseling

Diagnosis

Evaluation

Management

Prevention

Risk Assessment

Screening

Treatment

Clinical Specialty

Cardiology

Endocrinology

Family Practice

Geriatrics

Internal Medicine

Nephrology

Neurology

Nursing

Obstetrics and Gynecology

Ophthalmology

Optometry

Pediatrics

Podiatry

Preventive Medicine

Intended Users

Advanced Practice Nurses

Allied Health Personnel

Dietitians

Health Care Providers

Health Plans

Hospitals

Managed Care Organizations

Nurses

Optometrists

Pharmacists

Physician Assistants

Physicians

Podiatrists

Public Health Departments

Guideline Objective(s)

- To provide recommendations for the prevention and management of diabetes complications
- To provide clinicians, patients, researchers, payers, and other interested individuals with the components of diabetes care, treatment goals, and tools to evaluate the quality of care

Target Population

Patients with type 1 or type 2 diabetes mellitus, including pregnant women

Interventions and Practices Considered

Risk Assessment / Screening / Diagnosis

1. Blood pressure (systolic and diastolic)
2. Serum low-density lipoprotein (LDL) cholesterol, high-density lipoprotein (HDL) cholesterol, and triglyceride concentrations
3. Coronary heart disease screening, including risk factor assessment
4. Annual testing for microalbuminuria and measurement of serum creatinine to estimate glomerular filtration rate (GFR) and stage the level of chronic kidney disease (CKD)
5. Dilated and comprehensive eye exam including retinal photography
6. Screening for distal symmetric polyneuropathy and cardiovascular autonomic neuropathy, with electrophysiological testing, as needed
7. Foot examination
8. Screening for peripheral arterial disease (PAD), including history of claudication, pedal pulses, and ankle-brachial index

Management / Treatment / Prevention

1. Patient education
   - Lifestyle modification (e.g., diet, weight loss, physical activity, smoking cessation)
   - Foot care
2. Drug therapy
   - Angiotensin-converting enzyme (ACE) inhibitors
   - Angiotensin receptor blockers (ARBs)
   - Beta-blockers
   - Diuretics
   - Calcium channel blockers (CCBs)
   - Statins
   - Fibrates
   - Niacin
   - Combination drug therapy
   - Antiplatelet agents, including aspirin and clopidogrel
   - Medications for relieving symptoms of polyneuropathy
3. Laser therapy to reduce the risk of vision loss
4. Referral to specialist

Monitoring

1. Renal function tests
2. Serum potassium levels
3. Glomerular filtration rate

Major Outcomes Considered

- Lipid levels
- Cardiovascular events
- Morbidity and mortality associated with cardiovascular disease
- Progression of microalbuminuria to macroalbuminuria
- Glomerular filtration rate (GFR)
- Retinopathy and vision loss
- Neuropathy
- Foot ulcers or amputation
- Efficacy and cost-effectiveness of interventions

Methodology

Methods Used to Collect / Select the Evidence

Searches of Electronic Databases

Description of Methods Used to Collect / Select the Evidence

Not stated

Number of Source Documents

Not stated

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

American Diabetes Association's Evidence Grading System for Clinical Practice Recommendations

A

Clear evidence from well-conducted, generalizable, randomized controlled trials that are adequately powered, including:

- Evidence from a well-conducted multicenter trial
- Evidence from a meta-analysis that incorporated quality ratings in the analysis

Compelling nonexperimental evidence (i.e., "all or none" rule developed by the Centre for Evidence-Based Medicine at Oxford)

Supportive evidence from well-conducted randomized controlled trials that are adequately powered, including:

- Evidence from a well-conducted trial at one or more institutions
- Evidence from a meta-analysis that incorporated quality ratings in the analysis

B

Supportive evidence from well-conducted cohort studies, including:

- Evidence from a well-conducted prospective cohort study or registry
- Evidence from a well-conducted meta-analysis of cohort studies

Supportive evidence from a well-conducted case-control study

C

Supportive evidence from poorly controlled or uncontrolled studies, including:

- Evidence from randomized clinical trials with one or more major or three or more minor methodological flaws that could invalidate the results
- Evidence from observational studies with high potential for bias (such as case series with comparison 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

Methods Used to Analyze the Evidence

Review of Published Meta-Analyses

Systematic Review

Description of the Methods Used to Analyze the Evidence

Not stated

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

Not stated

Rating Scheme for the Strength of the Recommendations

Recommendations have been assigned ratings of A, B, or C, depending on the quality of evidence (see "Rating Scheme for the Strength of the Evidence"). 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.

Cost Analysis

- A number of large randomized clinical trials have demonstrated the efficacy and cost-effectiveness of brief counseling in smoking cessation, including the use of quit lines and in the reduction of tobacco use.

- Consultation with a nephrologist when stage 4 chronic kidney disease (CKD) develops has been found to reduce cost, improve quality of care, and keep people off dialysis longer.
- The use of retinal photography with remote reading by experts has great potential in areas where qualified eye care professionals are not available, and may also enhance efficiency and reduce costs when the expertise of ophthalmologists can be utilized for more complex examinations and for therapy.

Method of Guideline Validation

Internal Peer Review

Description of Method of Guideline Validation

The recommendations were reviewed and approved by the Professional Practice Committee and, subsequently, by the Executive Committee of the Board of Directors.

Recommendations

Major Recommendations

Note: This guideline has been updated. The National Guideline Clearinghouse (NGC) is working to update this summary. The recommendations that follow are based on the previous version of the guideline.

The evidence grading system for clinical practice recommendations (A–C, E) is defined at the end of the "Major Recommendations" field.

Cardiovascular Disease (CVD)

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

Goals

- A goal systolic blood pressure <130 mm Hg is appropriate for most patients with diabetes. (C)
- Based on patient characteristics and response to therapy, higher or lower systolic blood pressure targets may be appropriate. (B)
- Patients with diabetes should be treated to a diastolic blood pressure <80 mm Hg. (B)

Treatment

- Patients with a systolic blood pressure of 130 to 139 mm Hg or a diastolic blood pressure of 80 to 89 mm Hg may be given lifestyle therapy alone for a maximum of 3 months and then, if targets are not achieved, be treated with addition of pharmacologic agents. (E)
- Patients with more severe hypertension (systolic blood pressure ≥140 mm Hg or diastolic blood pressure ≥90 mm Hg) 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, Dietary Approaches to Stop Hypertension (DASH)-style dietary pattern including reducing sodium and increasing potassium intake, moderation of alcohol intake, and increased physical activity. (B)
- Pharmacologic therapy for patients with diabetes and hypertension should be paired with a regimen that includes either an angiotensin-converting enzyme (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 (eGFR) ≥30 mL/min/1.73 m^2 and a loop diuretic for those with an eGFR <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 to 129/65 to 79 mm Hg 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 (low-density lipoprotein [LDL] cholesterol <100 mg/dL, high-density lipoprotein [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 omega-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 cardiovascular disease (CVD) (A)

- Without CVD who are over the age of 40 and have one or more other CVD risk factors (A)

- For patients at lower risk than 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 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% to 40% from baseline is an alternative therapeutic goal. (A)

- Triglyceride levels <150 mg/dL (1.7 mmol/L) and HDL cholesterol >40 mg/dL (1.0 mmol/L) in men and >50 mg/dL (1.3 mmol/L) in women are desirable. 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 outcomes studies for either CVD outcomes or safety. (E)

- Statin therapy is contraindicated in pregnancy. (E)

Summary of Recommendations for Glycemic, Blood Pressure, and Lipid Control for Most Adults with Diabetes

- A1C <7.0%*
- Blood pressure <130/80 mm Hg†
- Lipids
  - LDL cholesterol <100 mg/dL (<2.6 mmol/L)‡

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

†Based on patient characteristics and response to therapy, higher or lower systolic blood pressure targets may be appropriate.

‡In individuals with overt CVD, a lower LDL cholesterol goal of 70 mg/dL (1.8 mmol/L), using a high dose of a statin, is an option.

Antiplatelet Agents

- Consider aspirin therapy (75 to 162 mg/day) as a primary prevention strategy in those with type 1 and 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)

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

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

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

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

- Combination therapy with aspirin (75 to 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 (CHD) Screening and Treatment

Screening

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

Treatment

- In patients with known CVD, ACE inhibitor (C), 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, beta-blockers should be continued for at least 2 years after the event. (B)

- Longer-term use of beta-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 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 glomerular filtration rate (GFR) and stage the level of chronic kidney disease (CKD), if present. (E)

Treatment

- In the treatment of the nonpregnant patient with micro- and 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 to 1.0 g/kg body wt/day in individuals with diabetes and the earlier stages of CKD and to 0.8 g/kg body wt/day in the later stages of CKD may improve measures of renal function (e.g., urine albumin excretion rate and GFR) and is recommended. (B)
- When ACE inhibitors, ARBs, or diuretics are used, monitor serum creatinine and potassium levels for the development of acute kidney disease and hyperkalemia. (E)
- Continued monitoring of urine albumin excretion to assess both response to therapy and progression of disease is recommended. (E)
- When eGFR <60 ml/min/1.73 m^2, evaluate and manage potential complications of CKD. (E)
- Consider referral to a physician experienced in the care of kidney disease when there is uncertainty about the etiology of kidney disease (heavy proteinuria, active urine sediment, absence of retinopathy, rapid decline in GFR), 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 to 3 years) may be considered following one or more normal eye exams. Examinations will be required more frequently if retinopathy is progressing. (B)
- High-quality fundus photographs can detect most clinically significant diabetic retinopathy. Interpretation of the images should be performed by a trained eye care provider. While retinal photography may serve as a screening tool for retinopathy, it is not a substitute for a comprehensive eye exam, which should be performed at least initially and at intervals thereafter as recommended by an eye care professional. (E)
- Women with pre-existing diabetes who are planning pregnancy or who have become pregnant should have a comprehensive eye examination and be counseled on the risk of development and/or progression of diabetic retinopathy. Eye examination should occur in the first trimester with close follow-up throughout pregnancy and for 1 year postpartum. (B)

Treatment

- Promptly refer patients with any level of macular edema, severe 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 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 (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 loss of protective sensation and structural abnormalities, or have history of prior lower-extremity complications to foot care specialists for ongoing preventive care and life-long surveillance. (C)
- Initial screening for peripheral arterial disease (PAD) should include a history for claudication and an assessment of the pedal pulses. Consider obtaining an ankle-brachial index (ABI), as many patients with PAD are asymptomatic. (C)
- Refer patients with significant claudication or a positive ABI for further vascular assessment and consider exercise, medications, and surgical options. (C)

Definitions:

American Diabetes Association's Evidence Grading System for Clinical Practice Recommendations

A

Clear evidence from well-conducted, generalizable, randomized controlled trials that are adequately powered, including:

- Evidence from a well-conducted multicenter trial
- Evidence from a meta-analysis that incorporated quality ratings in the analysis

Compelling nonexperimental evidence (i.e., "all or none" rule developed by the Centre for Evidence-Based Medicine at Oxford)

Supportive evidence from well-conducted randomized controlled trials that are adequately powered, including:

- Evidence from a well-conducted trial at one or more institutions
- Evidence from a meta-analysis that incorporated quality ratings in the analysis

B

Supportive evidence from well-conducted cohort studies, including:

- Evidence from a well-conducted prospective cohort study or registry
- Evidence from a well-conducted meta-analysis of cohort studies

Supportive evidence from a well-conducted case-control study

C

Supportive evidence from poorly controlled or uncontrolled studies, including:

- Evidence from randomized clinical trials with one or more major or three or more minor methodological flaws that could invalidate the results
- Evidence from observational studies with high potential for bias (such as case series with comparison 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

Clinical Algorithm(s)

None provided

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of supporting evidence is identified and graded for each recommendation (see the "Major Recommendations" field).

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Prevention and appropriate management of diabetes complications

Potential Harms

- Combination therapy with a statin and a fibrate or statin and niacin may be efficacious for patients needing treatment for all three lipid fractions, but this combination is associated with an increased risk for abnormal transaminase levels, myositis, or rhabdomyolysis. The risk of rhabdomyolysis is higher with higher doses of statins and with renal insufficiency and seems to be lower when statins are combined with fenofibrate than gemfibrozil.
- The main adverse effect of aspirin appears to be an increased risk of gastrointestinal bleeding. The excess risk may be as high as 1 to 5 per 1,000 per year in real-world settings.
- Measurement of 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.

Contraindications

Contraindications

- During pregnancy, treatment with angiotensin-converting enzyme (ACE) inhibitors and angiotensin receptor blockers (ARBs) is contraindicated, since they can cause fetal damage.
- Statin therapy is contraindicated in pregnancy.
- Thiazolidinedione treatment should be avoided in patients with symptomatic heart failure.
- Metformin should be avoided in unstable or hospitalized patients with congestive heart failure.
- Aspirin therapy is contraindicated in patients under the age of 21 years because of the associated risk of Reye's syndrome.

Qualifying Statements

Qualifying Statements

- 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 American Diabetes Association, 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.
- 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.

Implementation of the Guideline

Description of Implementation Strategy

While numerous interventions to improve adherence to the recommended standards have been implemented, 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 six core elements for the provision of optimal care of patients with chronic disease: 1) delivery system design (moving from a *reactive* to a *proactive* care delivery system, where planned visits are coordinated through a team-based approach; 2) self-management support; 3) decision support (basing care on consistent, effective care guidelines); 4) clinical information systems (using registries that can provide patient-specific and population-based support to the care team); 5) community resources and policies (identifying or developing resources to support healthy lifestyles); and 6) health systems (to create a quality-oriented culture). Alterations in reimbursement that reward the provision of quality care, as defined by the attainment of evidence-based quality measures, will also be required to achieve desired outcome goals. 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. Collaborative, multidisciplinary teams are best suited to provide such care for people with chronic conditions like diabetes and to facilitate patients' performance of appropriate self-management.

A rapidly evolving literature suggests that there are three major strategies to successfully improve the quality of diabetes care delivered by a team of providers. National Diabetes Education Program (NDEP) maintains an online resource (www.betterdiabetescare.nih.gov) to help health care professionals design and implement more effective health care delivery systems for those with diabetes.

Three specific objectives are outlined below.

Objective 1

Provider and team behavior change: Facilitate timely and appropriate intensification of lifestyle and/or pharmaceutical therapy of patients who have not achieved beneficial levels of blood pressure, lipid, or glucose control.

- Clinical information systems including registries that can prospectively identify and track those requiring assessments and/or treatment modifications by the team.
- Electronic medical record-based clinical decision support at the point of care, both personalize and standardize care and can be used by multiple providers
- Use of checklists and/or flow sheets that mirror guidelines.
- Detailed treatment algorithms enabling multiple team members to "treat to target" and appropriately intensify therapy.
- Availability of care or disease management service by nurses, pharmacists, and other providers using detailed algorithms often catalyzing reduction in A1C, blood pressure, and low-density lipoprotein (LDL) cholesterol.

Objective 2

Patient behavior change: Implement a systematic approach to support patients' behavior change efforts as needed including 1) healthy lifestyle (physical activity, healthy eating, nonuse of tobacco, weight management, effective coping, medication taking and management); 2) prevention of diabetes complications (screening for eye, foot, and renal complications; immunizations); and 3) achievement of appropriate blood pressure, lipid, and glucose goals.

- Delivery of high-quality diabetes self-management education (DSME), which has been shown to improve patient self-management, satisfaction, and glucose control.
- Delivery of ongoing diabetes self-management support (DSMS) to ensure that gains achieved during DSME are sustained. National DSME standards call for an integrated approach that includes clinical content and skills, behavioral strategies (goal-setting, problem solving), and addressing emotional concerns in each needed curriculum content area. Provision of continuing education and support (DSMS) improves maintenance of gains regardless of the educational methodology.
- Provision of automated reminders via multiple communication channels to various subgroups of diabetic patients.

Objective 3

Change the system of care: Research on the comprehensive CCM suggests additional strategies to improve diabetes care, including the following:

- Basing care on consistent, evidence-based care guidelines
- Redefining and expanding the roles of the clinic staff
- Collaborative, multidisciplinary teams to provide high-quality care and support patients' appropriate self-management
- Audit and feedback of process and outcome data to providers to encourage population-based care improvement strategies
- Care management, one of the most effective diabetes quality improvement strategies to improve glycemic control
- Identifying and/or developing community resources and public policy that support healthy lifestyles
- Alterations in reimbursement that reward the provision of appropriate and high-quality care and accommodate the need to personalize care goals, providing additional incentives to improve diabetes care

The most successful practices have an institutional priority for quality of care, expanding the role of teams and staff, redesigning their delivery system, activating and educating their patients, and using electronic health record tools. Recent initiatives such as the Patient Centered Medical Home show promise in improving outcomes through coordinated primary care and offer new opportunities for team-based chronic disease care.

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

Implementation Tools

Personal Digital Assistant (PDA) Downloads

Quick Reference Guides/Physician Guides

Slide Presentation

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Living with Illness

Staying Healthy

IOM Domain

Effectiveness

Patient-centeredness

Identifying Information and Availability

Bibliographic Source(s)

American Diabetes Association (ADA). Standards of medical care in diabetes. VI. Prevention and management of diabetes complications. Diabetes Care 2011 Jan;34(Suppl 1):S27-38.

Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

1998 (revised 2011 Jan)

Guideline Developer(s)

American Diabetes Association - Professional Association

Source(s) of Funding

American Diabetes Association (ADA)

Guideline Committee

Professional Practice Committee

Composition of Group That Authored the Guideline

Committee Members: John Anderson, MD; John Buse, MD, PhD; Martha Funnell; Robert Gabbay, MD; Silvio Inzucchi (*Chairman*); Jane Kadohiro, DrPH, APRN, CDE; Daniel Lorber, MD; Michelle Magee, MD; Sunder Mudaliar, MD; Patrick O'Connor, MD, MPH; Peter Reaven, MD; Susan Braithwaite, MD; Guillermo Umpierrez, MD; Stuart Weinzimer, MD; Carol Wysham, MD; Gretchen Youssef, MS, RD, CDE; Judy Fradkin, MD (*Ex officio*); Stephanie Dunbar, RD, MPH (*Staff*); Sue Kirkman, MD (*Staff*)

Financial Disclosures/Conflicts of Interest

All members of the Professional Practice Committee are required to disclose potential conflicts of interest.

Conflict of interest disclosures for the 2010 Professional Practice Committee Members are available from the American Diabetes Association (ADA) Web site (see "Availability of Companion Documents" field).

Guideline Status

Note: This guideline has been updated. The National Guideline Clearinghouse (NGC) is working to update this summary.

Guideline Availability

Electronic copies of the updated guideline: Available from the American Diabetes Association (ADA) Web site.

Print copies: Available from the American Diabetes Association, 1701 North Beauregard Street, Alexandria, VA 22311.

Availability of Companion Documents

The following are available:

- Introduction. Diabetes Care 34:S1-S2, 2011.
- Summary of revisions for the 2011 clinical practice recommendations. Diabetes Care 34:S3, 2011.
- Executive summary: standards of medical care in diabetes. Diabetes Care 34:S4-S10, 2011.
- Professional Practice Committee Members (includes conflict of interest disclosure). Diabetes Care 34:S97-S98, 2011.

Electronic copies: Available from the American Diabetes Association (ADA) Web site.

Print copies: Available from the American Diabetes Association, 1701 North Beauregard Street, Alexandria, VA 22311.

The following are also available:

- Diagnosis and classification of diabetes mellitus. Diabetes Care 2011 Jan; 34(Suppl 1):S62-S69. Electronic copies: Available from the ADA Web site.
- 2011 Standards of medical care in diabetes. Clinical practice recommendations. Slide set. American Diabetes Association; 2011 Jan. 130 p. Electronic copies: Available from the ADA Web site.
- 2011 Standards of medical care in diabetes. Clinical practice recommendations. Personal Digital Assistant (PDA). American Diabetes Association; 2011 Jan. Electronic copies: Available for download from the ADA Web site.

Patient Resources

None available

NGC Status

This summary was completed by ECRI on November 1, 1998. The information was verified by the guideline developer on December 15, 1998. It was updated by ECRI on April 1, 2000, April 2, 2001, March 14, 2002, July 29, 2003, May 26, 2004, July 1, 2005, and March 17, 2006, and April 25, 2007. This summary was updated by ECRI Institute on March 31, 2008. The updated information was verified by the guideline developer on May 15, 2008. This summary was updated by ECRI Institute on January 5, 2010 following the U.S. Food and Drug Administration advisory on Plavix (Clopidogrel). This summary was updated by ECRI Institute on May 20, 2010. The information was verified by the guideline developer on May 25, 2010. This summary was updated by ECRI Institute on February 25, 2011. This summary was updated by ECRI Institute on June 27, 2011 following the U.S. Food and Drug Administration advisory on Zocor (simvastatin). This summary was updated by ECRI Institute on November 22, 2011 following the U.S. Food and Drug Administration (FDA) advisory on Trilipix (fenofibric acid). This summary was updated by ECRI Institute on April 13, 2012 following the U.S. Food and Drug Administration advisories on Statin Drugs and Statins and HIV or Hepatitis C drugs.

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