Complete Summary

GUIDELINE TITLE

Massachusetts guidelines for adult diabetes care.

BIBLIOGRAPHIC SOURCE(S)

Diabetes Prevention and Control Program, Diabetes Guidelines Work Group. Massachusetts guidelines for adult diabetes care. Boston (MA): Massachusetts Department of Public Health; 2005 Jun. 39 p. [110 references]

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: Diabetes Guidelines Work Group, Diabetes Prevention and Control Program. Massachusetts guidelines for adult diabetes care. Boston (MA): Massachusetts Department of Public Health; 2003 Jun. 27 p.

**** REGULATORY ALERT ****

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.

- February 26, 2008, Avandia (rosiglitazone): A new Medication Guide for Avandia must be provided with each prescription that is dispensed due to the U.S. Food and Drug Administration's (FDA's) determination that this medication could pose a serious and significant public health concern.
- November 14, 2007, Avandia (rosiglitazone): New information has been added to the existing boxed warning in Avandia's prescribing information about potential increased risk for heart attacks.
- August 14, 2007, Thiazolidinedione class of antidiabetic drugs: Addition of a boxed warning to the updated label of the entire thiazolidinedione class of antidiabetic drugs to warn of the risks of heart failure.
- May 2, 2007, Antidepressant drugs: Update to the existing black box warning on the prescribing information on all antidepressant medications to include warnings about the increased risks of suicidal thinking and behavior in young adults ages 18 to 24 years old during the first one to two months of treatment.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

- Type 1 diabetes mellitus
- Type 2 diabetes mellitus
- Impaired fasting glucose (IFG)
- Impaired glucose tolerance (IGT)
- Gestational diabetes mellitus (GDM)

GUIDELINE CATEGORY

Counseling
Diagnosis
Evaluation
Management
Prevention
Risk Assessment
Screening
Treatment

CLINICAL SPECIALTY

Endocrinology
Family Practice
Internal Medicine
Preventive Medicine

INTENDED USERS

Advanced Practice Nurses
Allied Health Personnel
Managed Care Organizations
Nurses
Physician Assistants

Physicians
Public Health Departments

GUIDELINE OBJECTIVE(S)

- To develop uniform guidelines that apply to adults with diabetes regardless of their insurer
- To help eliminate any confusion brought about by differences in guidelines disseminated by individual third party payers
- To assist health care professionals in systematizing the care provided to people with diabetes

TARGET POPULATION

Community-dwelling adults in Massachusetts with diabetes mellitus

INTERVENTIONS AND PRACTICES CONSIDERED

Screening/Diagnosis

1. Testing for diabetes in asymptomatic adults
2. Laboratory diagnostic testing
    - Fasting plasma glucose (FPG) (preferred)
    - Casual plasma glucose (CPG)
    - 2 hour oral glucose tolerance test (OGTT)

Treatment/Management

General Management

1. Review of medications and doses
2. Weight/body mass index (BMI)
3. Blood pressure
4. Laboratory testing, including hemoglobin A1C, fasting/random glucose, urine microalbumin, fasting lipid profile, creatinine, thyroid function tests, and electrocardiogram (EKG)

Type 2 Diabetes Treatment Approach

1. Self-management counseling
2. Medical nutrition therapy
3. Physical activity
4. Weight reduction
5. Use of oral glucose lowering agents or insulin if necessary (monotherapy or combination therapy)
6. Ameliorate associated cardiovascular risk factors (hypertension, smoking, dyslipidemia)

Diabetes Medications

1. Oral medications

- Sulfonylureas (first or second generation)
- Meglitinides
- Alpha-glucosidase inhibitors
- Biguanides
- Thiazolidinediones

2. Insulin
    - Very short acting
    - Short acting
    - Intermediate acting
    - Long acting
3. Incretin mimetic, if indicated

Prevention

Prevention or Delay of Type 2 Diabetes

1. Screening patients at high risk of diabetes
2. Fasting blood glucose (FBG) test (preferred) or 2-hour oral glucose tolerance test (OGTT)
3. Lifestyle modifications (medical nutrition therapy, increasing physical activity, follow-up weight loss and physical activity counseling)
4. Monitoring for the development of diabetes every 1 to 2 years
5. Drug therapy to prevent diabetes is not recommended until more information is known about its cost effectiveness.

Prevention of Diabetes-Related Complications

1. Cardiovascular risk reduction
    - Assessment of cardiovascular risk based on lipoprotein levels
    - Treatment based on low-density lipoprotein (LDL) levels
        - Lifestyle changes, including medical nutrition therapy, physical activity, smoking cessation, and weight loss if indicated
        - Pharmacotherapy, including statins, angiotensin-converting enzyme (ACE) inhibitors, beta-blockers, aspirin therapy
2. Hypertension
    - Blood pressure measurement at each visit
    - Lifestyle modifications, including weight loss, exercise, smoking cessation, reduction of salt and alcohol intake
    - Pharmacotherapy, including ACE inhibitors, angiotensin II receptor blockers (ARBs), beta blockers, diuretics, and calcium channel blockers
3. Diabetic nephropathy
    - Screening for microalbuminuria via spot collection, 24 hour collection, or timed collection
    - Hypertension control
4. Foot-related conditions associated with ulcers and amputations
    - Assessment of risk factors
    - Comprehensive foot examination
    - Management of at-risk patients and referral to specialist
5. Smoking-related complications
    - Screening
    - Counseling on smoking cessation

- Pharmacotherapy, including nicotine replacement, bupropion, and nortriptyline

6. Psychosocial issues
    - Screening
    - Referral to specialist
7. Retinopathy
    - Comprehensive eye exam
    - Referral to specialist
    - Laser therapy
8. Periodontal disease management
    - Comprehensive oral examination
    - Oral hygiene instruction
    - Referral for dental evaluation and follow-up

Counseling/Education

1. Medical Nutrition Therapy
2. Diabetes Self Management
3. Smoking cessation
4. Psychosocial adjustment
5. Sexuality
6. Preconception/pregnancy

MAJOR OUTCOMES CONSIDERED

Not stated

METHODOLOGY

METHODS USED TO COLLECT/SELECT 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

Expert Consensus (Committee)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

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

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

External Peer Review
Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

The guidelines were developed by a Work Group convened by the Massachusetts Department of Public Health Diabetes Prevention and Control Program and its Advisory Board. The Work Group was comprised of clinicians, representatives from managed care organizations, the Primary Care Clinician Plan, the Massachusetts League of Community Health Centers, the Massachusetts Medical Society, and MassPRO. Their recommendations were incorporated into the final version.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Diagnosis and Classification of Diabetes Mellitus

Criteria for Testing for Diabetes in Asymptomatic Adults

Testing for diabetes should be considered for all individuals age 45 and older, particularly in those with a body mass index (BMI) $\geq$ 25kg/m^2, and, if normal, should be repeated at 3-year intervals. Testing should be considered at a younger age, or be carried out more frequently, in individuals who are overweight (BMI $\geq$ 25 kg/m^2)* and have additional risk factors:

- Are habitually physically inactive
- Have a first-degree relative with diabetes
- Are members of a high-risk ethnic population (African-American, Hispanic, Native American, Asian-American, Pacific Islander)
- Have delivered a baby weighing >9 pounds or were diagnosed with gestational diabetes mellitus (GDM)
- Are hypertensive (blood pressure $\geq$140/90 mmHg)
- Have a high density lipoprotein (HDL) cholesterol level $\leq$ 35 mg/dL, and/or a triglyceride level $\geq$ 250 mg/dL
- Have polycystic ovary syndrome (PCOS)
- Had impaired glucose tolerance (IGT) or impaired fasting glucose (IFG) on previous testing
- Have other conditions associated with insulin resistance (acanthosis nigricans)
- Have a history of vascular disease

*May not be applicable for all ethnic groups.

The fasting plasma glucose (FPG) is the preferred diagnostic test due to its ease of administration, convenience, acceptability to patients, and lower cost.

Diagnostic Criteria for Diabetes

An FPG $\geq$126 mg/dL (confirmed by testing on two different occasions) is diagnostic for diabetes. If the FPG is <126 and there is a high suspicion of diabetes, the oral glucose tolerance test (OGTT) may be performed. These criteria are for diagnosis and are not treatment criteria or goals.

The hemoglobin A1c (A1C) is not recommended for diagnosis at this time.

Criteria for the Diagnosis of Diabetes in Non-Pregnant Adults

	Fasting Plasma Glucose (FPG)[1] (preferred)	**Casual Plasma Glucose[2]**	**Oral Glucose Tolerance Test (OGTT)[3]**
Diabetes Mellitus	FPG $\geq$126 mg/dL (7.0 mmol/L)	Casual plasma glucose $\geq$200 mg/dL (11.1 mmol/L) plus symptoms of diabetes	Two-hour plasma glucose (2hPG) $\geq$ 200 mg/dL
Prediabetes	Impaired Fasting Glucose (IFG) FPG $\geq$100 and <126 mg/dL		Impaired Glucose Tolerance (IGT) 2hPG $\geq$140 and <200 mg/dL
Normal	FPG <100 mg/dL		2hPG <140 mg/dL

[1]The FPG is the preferred test for diagnosis, but any one of the three listed is acceptable. Fasting is defined as no caloric intake for at least 8 hours.
[2]Casual is defined as any time of day without regard to time since last meal. Symptoms are the classic ones of polyuria, polydipsia, and unexplained weight loss. There are currently no guidelines for interpreting CPG values that fall between 140-199 mg/dL. For values in this range, a follow-up FPG to rule out diabetes can be considered.
[3]OGTT should be performed using a glucose load containing the equivalent of 75 g anhydrous glucose dissolved in water. The OGTT is not recommended for routine clinical use, but may be necessary when evaluating patients with IFG or when diabetes is still suspected despite an FPG<126.

Classification of Diabetes

Type 1

Type 1 diabetes most often results from a cellular mediated autoimmune destruction of the beta cells of the pancreas. Patients with this form of diabetes are dependent upon insulin for survival and are at risk for ketoacidosis. Type 1 commonly occurs in childhood and adolescence but may occur at any age.

Type 2

Individuals with type 2 diabetes have insulin resistance and relative, rather than absolute, insulin deficiency. Primary treatment centers on weight loss, improved nutrition, and increased age-appropriate physical activity. Oral agents may become necessary if the initial treatment is unsuccessful. These patients do not need insulin to survive but may require insulin over time for optimal management, especially if oral agents become ineffective. Type 2 diabetes commonly goes undiagnosed for years because it is often asymptomatic in its early stages. Individuals with undiagnosed type 2 diabetes are at increased risk for developing macro- and microvascular complications.

Impaired Fasting Glucose (IFG) and Impaired Glucose Tolerance (IGT)

IFG has been defined as an FPG of $\geq$100 mg/dL but <126 mg/dL. IGT is defined as a 2-hour oral glucose tolerance test (OGTT) value of $\geq$140 mg/dL but <200 mg/dL. Both IFG and IGT have been categorized as prediabetes and are risk factors for future diabetes and cardiovascular disease. Recent studies have shown that modest weight loss and regular physical activity can reduce the rate of progression of IGT to type 2 diabetes.

Gestational Diabetes Mellitus (GDM)

GDM, which typically occurs following the 24th week, is defined as any degree of glucose intolerance with onset or first recognition during pregnancy*. The definition applies regardless of whether insulin or only dietary modification is used for treatment. Gestational diabetes mellitus complicates approximately 4% of all pregnancies in the U.S.; however, the prevalence is higher among some minority groups. Six weeks or more after the pregnancy ends, a woman with GDM should be tested to rule out type 1 or 2 diabetes or IFG/IGT. Women with GDM have a higher risk for type 2 diabetes later in life.

* Hyperglycemia occurring during the early part of pregnancy is generally indicative of type 1 diabetes or undiagnosed type 2 diabetes.

Goals for Glycemic Control**

	Normal	Goal
Preprandial Plasma Glucose	<100 mg/dL	90-130 mg/dL
Peak Postprandial Plasma Glucose	<120 mg/dL	<180 mg/dL
Hemoglobin A1C	<6%	<7%**

**More stringent goals, including a normal A1C of <6%, can be considered in individual patients and during pregnancy.

Points to remember when setting glycemic goals:

- Individualize goals.
- Target postprandial glucose if A1C values are not optimal and preprandial glucose goals are met.
- A lower A1C is associated with lower rates of microvascular complications as well as myocardial infarction and cardiac death; however, there is a greater risk of hypoglycemia.
- Patients with frequent or severe hypoglycemia may require less intensive glycemic goals.
- Children, pregnant women, and elderly individuals require special considerations when setting glycemic goals.

Prevention or Delay of Type 2 Diabetes

Summary

Hyperglycemia that does not meet the diagnostic criteria for diabetes is referred to as Impaired Fasting Glucose (IFG) or Impaired Glucose Tolerance (IGT).

IFG: Fasting blood glucose 100 mg/dL to 125 mg/dL

IGT: 2 hour value 140 mg/dL to 199 mg/dL

During the last 10 years, five well designed randomized controlled studies have evaluated the effect of various lifestyle modification strategies and/or utilization of glucose-lowering drugs to prevent or delay the onset of type 2 diabetes. The results of these studies clearly demonstrate that patients at high risk for diabetes can be identified early in the disease progression, prior to exhibiting blood glucose values diagnostic for diabetes. It is also evident that type 2 diabetes can be delayed and possibly prevented.

In these prevention trials, lifestyle modification using low calorie, low fat diets and increased physical activity (generally 150 minutes per week) resulted in a 5 to 10% weight loss. These lifestyle approaches successfully and consistently prevented the onset of diabetes. In the Diabetes Prevention Program, the lifestyle intervention was nearly twice as effective as a glucose lowering medication (metformin) in preventing the onset of diabetes among persons with elevated fasting and post-load plasma glucose levels. Overall, the data suggest that lifestyle modification should be the first treatment modality to employ in persons at high risk. Such interventions also provide a variety of other health benefits in

addition to delaying diabetes. Further studies are underway to evaluate the cost-effectiveness of intervention. At this time however, the known financial burden resulting from diabetic complications suggests that an attempt to prevent diabetes is worthwhile. Health care providers are encouraged to stress the benefits of weight loss and physical activity for overweight or sedentary patients at every opportunity.

Screening Recommendations

Screen patients who are at high risk for diabetes:

- Age $\geq$45
- BMI $\geq$25 kg/m^2 (BMI $\geq$23 kg/m^2 for Asian individuals)
- 1st degree relative with diabetes
- Habitual physical inactivity
- African-American, Hispanic, Native American, Asian American, Pacific Islander
- History of gestational diabetes or delivering a baby weighing >9 lbs
- History of hypertension ($\geq$140/90 mmHg)
- HDL cholesterol level $\leq$35 mg/dL and/or a triglyceride level $\geq$250 mg/dL
- Polycystic ovary syndrome
- Acanthosis nigricans
- History of vascular disease

Testing

- Use either the FBG test or the 2-hour oral glucose tolerance test.
- The FBG test is preferred due to convenience, lower cost, and ease of administration.
- In those positive for IFG or IGT, screen for additional cardiovascular disease risk factors (e.g., tobacco use, hypertension, dyslipidemia). Provide treatment as appropriate.

Treatment

- Refer patients with IFG or IGT for medical nutrition therapy for counseling on weight loss, as well as instruction for increasing physical activity.
- Provide for follow-up weight loss and physical activity counseling.
- Monitor for the development of diabetes every 1 to 2 years.

Lifestyle Modifications

- Individuals at high risk for developing diabetes need to become aware of the benefits of modest weight loss and participating in regular physical activity.

Pharmacological

- Drug therapy should not be routinely used to prevent diabetes until more information is known about its cost effectiveness.

Type 2 Diabetes Treatment Approach Principles

Optimal treatment for type 2 diabetes incorporates a multiple risk factor approach including self-management counseling, medical nutrition therapy, physical activity, weight reduction if appropriate, and the use of oral glucose lowering agents or insulin if necessary. Careful consideration needs to be given to ameliorating associated cardiovascular risk factors such as hypertension, smoking, and dyslipidemia.

When setting treatment goals for individuals with type 2 diabetes, it is important to assess the risk for severe hypoglycemia and consider the person's ability to comprehend the regimen. Consider as well other factors that may optimize or minimize the treatment's benefit including: advanced age, end-stage renal disease (ESRD), advanced cardiovascular or cerebrovascular disease, or other comorbidities that may lead to reduced life span.

Achievement of normal or near normal blood glucose levels requires education in self-management techniques including:

- Self monitoring of blood glucose
- Recognition, treatment, and prevention of hypoglycemia
- Prevention, early detection, and treatment of chronic complications
- Medical nutrition therapy
- Regular physical activity
- Reinforcement and continuing education

For individuals who have been unable to achieve optimal blood glucose control through dietary changes and regular physical activity, the use of a single antidiabetic oral agent is recommended. *Sulfonylureas*, *metformin*, *meglitinides*, *alpha-glucosidase inhibitors*, and *thiazolidinediones* are all approved by the U.S. Food and Drug Administration (FDA) for monotherapy. The choice of a particular agent must depend, however, on the individual's characteristics. Appropriate diet and exercise should be maintained even if the diabetes is being managed pharmacologically. See the original guideline document for an algorithm to assist in the choice of a pharmaceutical agent.

In case of monotherapy failure, combination therapies may be attempted. If, despite the use of oral agent combination therapy glycemic control is not achieved or maintained, insulin must be used, either alone or in combination with an indicated oral drug regimen. The total daily insulin doses range from 0.4 to 1.2 U/kg/day. For insulin resistant patients, doses of >1.5 U/kg/day may be required.

Choice of specific agents should be based on self-monitoring of blood glucose (SMBG) profiles and physician preference. Remember to evaluate the patient's cardiac, renal, and hepatic function as appropriate for each oral agent. The choice of an additional agent depends on the patient's SMBG patterns and clinical scenario. See the original guideline document for information comparing the oral antidiabetic agents.

There are several recent or ongoing clinical trials comparing the effect of combining a thiazolidinedione with metformin and/or a sulfonylurea. From a clinical perspective, these studies suggest a relatively small difference in glucose control for any particular two-combination regimen. The adverse effect of a particular course of therapy may determine which combination regimen is chosen

for a specific patient. Individual concerns over hypoglycemia, gastrointestinal (GI) side effects, or edema may "tip the scale" away from one permutation towards another.

Possible considerations for selecting various combination regimens include:

- Adding a thiazolidinedione to current therapy may be helpful in patients with high triglycerides and low HDL.
- Adding metformin may be helpful in patients with an elevated low-density lipoprotein (LDL).
- Adding a meglitinide may be helpful if post-prandial glucoses are elevated.
- Combining a thiazolidinedione with metformin may be helpful in patients with albuminuria.
- Weight gain may increase when adding a thiazolidinedione and sulfonylurea together.
- Meglitinide therapy improves post-prandial glucose control when added to metformin.
- Meglitinide therapy combined with an alpha-glucosidase inhibitor could potentiate risk for post-prandial hypoglycemia.
- Metformin therapy combined with an alpha-glucosidase inhibitor could potentiate gastrointestinal side effects.

See the original guideline document for an algorithm on combination therapy in type 2 diabetes.

Diabetes Medications

See the table beginning on page 9 in the original guideline document for a list of medications and dosages available for the treatment of diabetes, including first- and second-generation sulfonylureas, meglitinides, alpha-glucosidase inhibitors, biguanides, thiazolidinediones, insulin (very short acting, short acting, intermediate acting, and long acting), and incretin mimetic.

Cardiovascular Risk Reduction Guidelines

Summary of Lipid-Lowering Therapy

Patients with diabetes have one of the highest risks of cardiovascular disease (CVD) and are likely to benefit the most from early intervention with cardioprotective drugs. Lipid abnormalities are known to be more prevalent in patients with type 2 diabetes, contributing to higher rates of CVD. Attention to reducing modifiable cardiac risk factors as well as lowering LDL cholesterol, raising HDL cholesterol, and lowering triglycerides has been shown to reduce macrovascular disease and mortality, particularly for those who have had prior cardiovascular events. Aggressive treatment of diabetic dyslipidemia will reduce the risk of coronary heart disease (CHD) in patients with diabetes.

Screening Recommendations

- Annual testing for lipid disorders. More often if necessary to reach goal levels.

- Test every two years for those with low risk profiles (LDL <100 mg/dL, HDL >50 mg/dL, and triglycerides <150 mg/dL).

Lifestyle Modifications

Specific lifestyle changes aimed at lowering lipid profiles are recommended for all patients with diabetes. Lifestyle intervention should include medical nutrition therapy (MNT), increased physical activity, smoking cessation, and weight loss if indicated. Nutrition therapy should be tailored to the individual patient and focus on the reduction of saturated fat, cholesterol, and transunsaturated fat intake.

Treatment Recommendations and Goals

Pharmacological Therapy

The first priority of pharmacological therapy is to lower LDL cholesterol to a target goal of <100 mg/dL or to achieve a reduction in LDL of 30 to 40%. For LDL lowering, statins (atorvastatin, lovastatin, pravastatin, simvastatin, fluvastatin, and rosuvastatin) are the drugs of choice. Other drugs that lower LDL include nicotinic acid, ezetimibe, bile acid sequestrants, and fenofibrate.

See the original guideline document for dosage and LDL reduction information for statins and for a lipid lowering decision tree in type 2 diabetes.

Coronary Heart Disease

Cardiovascular risk factors should be assessed at least annually. For patients without clear or suggestive symptoms of coronary artery disease, a risk factor-based approach is recommended, evaluating for dyslipidemia, hypertension, smoking, a positive family history of premature coronary disease, or the presence of micro- or macroalbuminuria. A recent study, however, concluded that the presence of traditional and emerging cardiac risk factors failed to identify a significant percentage of patients with silent ischemia.

Recommendations

- An angiotensin-converting enzyme (ACE) inhibitor, unless contraindicated, is recommended for patients >55 years of age with one cardiovascular risk factor (independent of hypertensive status).
- A beta-blocker should be considered for patients with a prior myocardial infarction or for those undergoing major surgery.
- Screening tests such as a stress electrocardiogram (ECG) and/or stress echocardiography, and/or perfusion imaging may be beneficial for asymptomatic patients.
- A risk factor evaluation aimed at stratifying patients by 10-year risk should be considered.
- Metformin is contraindicated in patients with treated heart failure.
- Use caution in prescribing thiazolidinediones for patients with preexisting edema, concurrent insulin therapy, heart failure, or other heart diseases.

Aspirin Therapy in Diabetes

Both men and women with diabetes have a two- to four-fold increased risk of dying from the complications of cardiovascular disease. Evidence suggests that aspirin therapy should be prescribed as a secondary prevention strategy and, if no contraindications exist, should also be used as a primary prevention strategy in men and women with diabetes who are at high risk (over 40 or with other CVD risk factors). Use of aspirin has not been studied in individuals under the age of 30.

Recommendations

- Use aspirin therapy (75 to 162 mg/day) as a secondary prevention strategy in diabetic men and women with a history of myocardial infarction, vascular bypass procedure, stroke or transient ischemic attack, peripheral vascular disease, claudication, and/or angina.
- Use aspirin therapy (75 to 162 mg/day) as a primary prevention strategy in men and women with type 2 diabetes at increased cardiovascular risk, including those over 40 years of age or who have additional risk factors (family history of CVD, hypertension, smoking, dyslipidemia, albuminuria).
- Use aspirin therapy as a primary prevention strategy in men and women with type 1 diabetes at increased cardiovascular risk, including those over 40 years of age or who have additional risk factors (family history of CVD, hypertension, smoking, dyslipidemia, albuminuria).
- People with aspirin allergy, bleeding tendency, anticoagulant therapy, recent gastrointestinal bleeding, and clinically active hepatic disease are not candidates for aspirin therapy. Other antiplatelet agents may be a reasonable alternative for high-risk patients with contraindications to aspirin therapy.
- Aspirin therapy should not be recommended for patients under the age of 21 years because of the increased risk of Reye's syndrome associated with aspirin use in this population.

Hypertension

Summary

Hypertension contributes to the development and progression of chronic complications of diabetes. The primary goal of therapy for adults should be to decrease blood pressure to <130/80 mmHg. Epidemiological analysis of the United Kingdom Prospective Diabetes Study (UKPDS) showed a continuous relationship between the level of systolic blood pressure and the risk of stroke, diabetes-related deaths, heart failure, microvascular complications, and visual loss.

Screening Recommendations

- Measure blood pressure at every routine visit. Patients with systolic blood pressure (SBP) $\geq$130 mmHg or diastolic blood pressure (DBP) $\geq$80 mmHg require confirmation on a separate day.
- Orthostatic readings should be performed when clinically indicated. (Orthostatic measurement is recommended to rule out autonomic neuropathy. Orthostatic hypotension is defined as a fall in the SBP of 20 to 30 mmHg or DBP of 10 to 15 mmHg after two to three minutes of standing.)

Cardiovascular autonomic neuropathy is common in patients with diabetes and can cause falsely low or high readings depending on the position of the patient when the blood pressure is taken. Blood pressure and pulse should ideally be measured both in the supine and standing position leaving two minutes in between readings. Two or more determinations in each position should be obtained using an appropriately sized cuff. If the first two readings differ by more than 5 mmHg, additional readings should be obtained and averaged.

Lifestyle Modifications

Changes such as weight loss, exercise, smoking cessation, and prudent reduction of salt and alcohol should be a major aspect of treatment of hypertension. A maximum three-month trial of lifestyle/behavioral modification is recommended for those with a SBP 130 to 139 mmHg or a DBP of 80 to 89 mmHg.

Treatment

If target levels are not reached by the end of three months, pharmacological therapy should be instituted. Patients with SBPs of $\geq$140 mmHg or DBPs $\geq$90mmHg should receive prescriptions for both antihypertensive medication as well as lifestyle changes.

Treatment Categories

Systolic	Diastolic	Comment
<130 mmHg	<80 mmHg	Target blood pressure
130 to 139 mmHg	80 to 89 mmHg	Lifestyle changes alone (maximum 3 months), then add drug therapy
$\geq$140 mmHg	$\geq$90 mmHg	Lifestyle changes plus drug therapy

Benefit of Aggressive Treatment

Aggressive treatment of even mild-to-moderate hypertension is beneficial. Continued reduction of blood pressure into the normal range reduces strokes, diabetes-related deaths, heart failure, and microvascular complications, including retinopathy, nephropathy, and possibly neuropathy. Both systolic and diastolic hypertension markedly accelerate the progression of diabetic nephropathy. Control of hypertension has been demonstrated conclusively to reduce the rate and progression of nephropathy and to reduce the complications of cerebrovascular disease and cardiovascular disease (CVD).

Pharmacological Therapy

Initial drug therapy should begin with any currently recommended antihypertensive medication known to reduce CVD events in patients with diabetes (ACE inhibitors, angiotensin II receptor blockers [ARBs], beta-blockers, diuretics, and calcium channel blockers). Patients with SBPs of $\geq$140 mmHg or DBPs $\geq$90 mmHg should receive prescriptions for antihypertensive medication, as well as lifestyle and behavioral changes.

- All patients with diabetes and hypertension should be treated with ACE inhibitors, or ARBs if ACE inhibitors are not tolerated. Add a thiazide diuretic if needed to reach target blood pressure.
- Monitor renal function and serum potassium levels when using ACE inhibitors, ARBs, or diuretics.
- Multiple drug therapy utilizing two or more agents at proper doses is often necessary to reach target levels.
- Clinical trials provide evidence that ACE inhibitors and ARBs have an additional impact on nephropathy. Refer to the section on Nephropathy.
- The addition of a beta-blocker should be considered for those who have had a recent myocardial infarction (MI).
- In pregnant patients with diabetes and chronic hypertension, target goals of 110 to 129/65 to 79 mmHg are suggested. ARBs and ACE inhibitors are contraindicated during pregnancy and should be discontinued in women planning pregnancy due to their teratogenic effect.
- In elderly patients blood pressure should be lowered gradually.

Nephropathy

Summary

The earliest clinical evidence of nephropathy is the appearance of low but abnormal levels of albumin in the urine, referred to as microalbuminuria. Microalbuminuria, a harbinger of renal failure (types 1 and 2) and cardiovascular complications (type 1) in diabetes, is an albumin concentration in the urine that is greater than normal (but is not detectable with common urine dipstick assays for protein).

Screening

When to Screen

- Type 2 diabetes: at diagnosis and yearly thereafter.
- Type 1 diabetes: after five years of disease duration and yearly thereafter.
- Yearly testing is recommended even if the patient has previously screened positive for microalbuminuria and/or is currently taking ACE inhibitors or ARBs in order to provide monitoring and to ensure adequate control of microalbuminuria.

Screening Tests

Most authorities recommend the analysis of a spot sample for the albumin-to-creatinine ratio. Additional options, including a 24-hour urine collection or a timed collection, are rarely necessary for screening, but do provide a more complete evaluation. Due to the variability in albumin excretion, 2 of 3 samples done in a 3- to 6-month period should show elevated levels before diagnosing microalbuminuria. If normal, repeat yearly. Random spot collection (preferred):

- Normal <30 micrograms/mg creatinine
- Microalbuminuria 30 to 299 micrograms/mg creatinine
- Clinical albuminuria $\geq$300 micrograms/mg creatinine

Several factors may influence the albumin excretion rate. Screening should be postponed in the following situations: exercise within 24 hours, marked hypertension or hyperglycemia, infection, hematuria, fever, or heart failure.

Hypertension and Nephropathy

To reduce the risk or slow the progression of nephropathy, optimal glucose and blood pressure control are recommended. Both systolic and diastolic hypertension markedly accelerate the progression of diabetic nephropathy. Control of hypertension--regardless of agent used--has been demonstrated conclusively to reduce the rate and progression of nephropathy and to reduce the complications of cerebrovascular disease and cardiovascular disease. Refer also to the Cardiovascular and Hypertension sections in the original guideline document.

Pharmacological Therapy

For patients with both micro- and macroalbuminuria, either ACE inhibitors or ARBs should be used except during pregnancy. To assess hyperkalemia, serum potassium levels should be monitored in patients treated with either class of medication. Clinical trials reveal the following observations:

- In patients with type 1 diabetes and microalbuminuria and hypertension, ACE inhibitors delay the progression of nephropathy.
- For type 2 patients with both hypertension and microalbuminuria, both ACE inhibitors and ARBs delay the progression to macroalbuminuria.
- In type 2 patients who have hypertension, macroalbuminuria, and renal insufficiency, ARBs delay the progression of nephropathy.
- Dihydropyridine calcium channel blockers (DCCBs) are less likely to slow the progression of nephropathy compared with ACE inhibitors or ARBs. DCCBs should be used only as an additional therapy in patients already treated with ACE inhibitors or ARBs.
- The UKPDS demonstrated beta-blockers to be as effective as ACE inhibitors in reducing negative outcomes.
- For patients with albuminuria or nephropathy who cannot tolerate ACE inhibitors and/or ARBs, consider using beta-blockers, diuretics, or non-DCCBs. Non-DCCBs may reduce albuminuria in diabetic patients including during pregnancy.
- Due to their teratogenic potential, caution is advised when using either ACE inhibitors or ARBs in women of childbearing age.

Foot Inspection and Monofilament Use Guide

Summary

Foot ulcers and amputations resulting from neuropathy and/or peripheral vascular disease are major causes of disability and morbidity among people with diabetes. The risk of ulcers or amputations is increased in people who have had diabetes $\geq$10 years, are male, have poor glucose control, smoke, or have cardiovascular, retinal, or renal complications. Early recognition of problems and risk factor management can delay or prevent unfavorable outcomes.

Screening

Risk Identification

The following conditions are associated with an increased risk for amputation:

- Peripheral neuropathy with loss of protective sensation
- Altered biomechanics
- Evidence of increased pressure (hemorrhage under a callus, erythema)
- Bony deformity
- Peripheral vascular disease (PVD)
- History of ulcers or amputation in the other limb
- Severe nail pathology

Risk Category

Low Risk

All of the following:

- Intact protective sensation
- Pedal pulses present
- No severe deformity
- No prior foot ulcer
- No amputation

High Risk

One or more of the following:

- Loss of protective sensation
- Absent pedal pulses
- Severe foot deformity
- History of foot ulcer
- Prior amputation

Recommendations

- Perform a visual foot inspection at each primary care visit.
- Conduct an annual comprehensive foot exam. The exam may take place in the primary care setting and should include a visual inspection and palpation for pulses as well as a sensory evaluation using a tuning fork or a Semmes-Weinstein monofilament (see original guideline document for instructions on the use of the Semmes-Weinstein monofilament and tuning fork).
- Provide self-care education to all patients, especially those with risk factors such as smoking or prior lower extremity complications.
- Refer high-risk patients to a foot care specialist for ongoing preventive care.
- Screen for peripheral artery disease (PAD) by assessing the pedal pulses and evaluating for a history of claudication. Consider obtaining an ankle-brachial index (ABI) as many patients with PAD are asymptomatic.

- Refer patients with significant claudication or a positive ABI for further vascular assessment.
- Offer a multidisciplinary approach for patients with foot ulcers and high-risk feet.

Medical Nutrition Therapy

Purpose

Medical Nutrition Therapy (MNT) is an integral component in assisting patients in acquiring and maintaining the knowledge, skills, and behaviors to successfully meet the challenges of daily diabetes self-management. Adequate nutrition advice or an individualized meal plan will assist patients in achieving optimal blood glucose control. Achieving nutrition-related goals requires a coordinated team effort that includes the person with diabetes. A referral to a registered dietitian skilled in the complexities of diabetes management is strongly recommended.

Goals

- Achieve and maintain near normal blood glucose levels as well as optimal lipid levels, blood pressure, and recommended body weight.
- Prevent and treat the acute and long-term complications of diabetes.
- Improve overall health through optimum nutrition and physical activity.
- Address individual needs, considering cultural preferences, lifestyle, and ability to change.
- Provide for the needs of special populations:
    - Youth with type 1 or type 2 diabetes
    - Pregnant and lactating women
    - Older adults
    - Individuals treated with insulin and insulin secretagogues
    - Individuals at risk for developing diabetes
    - Individuals with deteriorating renal function

Basic Education

For newly diagnosed patients or patients not recently educated about their diabetes. Basic survival skills should include:

- Relationship of food and meals to blood glucose levels, medication, and activity
- Monitoring of total grams of carbohydrate intake
- Basic food/meal plan guidelines
- Consistent times each day for meals and snacks
- Recognition, prevention, and treatment of hypoglycemia
- Sick day management
- Self-monitoring of blood glucose

Essential Education for Ongoing Nutrition Self-Management

Ongoing education is recommended for patients recently diagnosed with diabetes who have been taught basic survival skills or those who have not received current

nutrition education. Others who may benefit from nutrition self-management education include patients having difficulties with diabetes management or those experiencing changes in lifestyle, medication, weight, or childbearing status. Follow-up sessions should focus on increasing the patient's knowledge, skills, and flexibility as he or she gains experience living with diabetes.

Topics include:

- Weight loss strategies, including reduction in energy intake and/or increase in physical activity, if indicated
- Amount (grams) and type of carbohydrate in blood and influence on blood glucose levels
- Sources of nutrients and their effect on blood glucose and lipid levels
- Carbohydrate counting
- Label reading and grocery shopping guidelines
- Dining out
- Modifying fat intake
- Use of sugar-containing foods, dietetic foods, and sweeteners
- Alcohol guidelines
- Using blood glucose self-monitoring for glucose pattern control
- Adjusting meal times
- Adjusting food for exercise
- Special occasions, holidays
- Travel, schedule changes
- Vitamin and mineral supplementation

Low carbohydrate diets (restricting total CHO to <130 g/day) are not recommended in the management of diabetes.

Diabetes Self-Management Training

Purpose

The main aims of diabetes education are to provide patients with the management skills necessary to achieve optimal control of their diabetes and to assist them in becoming effective self-directed decision makers for their own diabetes care, health, and well-being. Without comprehension of the relationship between home blood glucose readings, meal planning, and physical activity, patients with diabetes will be hindered in their ability to achieve optimal blood glucose control, and be at higher risk for long term complications. A referral to a nurse or other clinician who has expertise in culturally competent diabetes self-management education is strongly recommended.

Goals

- Prevent the acute complications of diabetes, hyperglycemia, and hypoglycemia.
- Prevent or delay the chronic complications of diabetes.
- Promote healthy birth outcomes through preconception counseling, monitoring, and support during and following pregnancy.
- Enhance patient participation in the clinician's diabetes treatment plan and improve patient confidence in self-management skills.

- Enhance psychological adjustment to living with a chronic disease.
- Decrease health care costs by reducing the need for expensive hospital stays and the treatment of complications.

Basic Education (Survival Skills)

Overview

- Nature of diabetes in terms of chronicity and metabolism
- Differences between type 1 and type 2 diabetes
- Balance of meals, physical activity, and medication, if prescribed

Exercise

- Impact of exercise on blood glucose, lipid levels, hypertension, weight, and stress reduction

Acute Complications

- Hypoglycemia recognition, causes, treatment, and prevention
- Hyperglycemia recognition, causes, treatment, and prevention
- Sick day management

Oral Medication Management

- Action, side effects, timing of dose(s), interactions

Insulin Management

- Action, dosage, onset/peak/duration, pre-loading, mixing, injecting, site selection, storage, syringe disposal
- Use of Glucagon, if appropriate

Psychosocial

- Assess adjustment to lifestyle change, screen for depression, refer to counseling as needed

Self-Monitoring

- Blood glucose meter selection and orientation
- Time(s) to check blood sugar/rationale
- Recording and interpretation of results, encouraging dialogue with clinician
- Disposal of lancets and contaminated materials
- Performance of urinary ketone testing, if appropriate

Continuing Education

Overview

- Benefits of optimal diabetes control and factors that influence it
- Effects of insulin resistance, deficiency, and excess
- Treatment of insulin resistance through weight loss, activity, and medication

Exercise

- Exercise planning appropriate to age, ability, interest, and willingness
- Complication avoidance during exercise

Oral Medication Management

- Action times and maximum dose
- Influences of other medications on blood glucose and possible interactions with oral diabetes medications

Insulin Management

- Methods of storing and adjusting insulin during travel
- Syringe reuse: techniques, benefits, and risks
- Traveling with diabetes, transporting supplies, and medication adjustment

Self-Monitoring

- Use of self-monitoring of blood glucose to adjust the treatment plan based on approved guidelines
- Establish glycated hemoglobin targets

Complication Prevention and Recognition

- Self foot care, early detection of problems, and importance of timely access to care
- Early recognition of eye disease and need for complete eye exam annually
- Impact of lipids, importance of monitoring annually or every two years if values fall within accepted risk levels
- Importance of blood pressure control, need for regular monitoring
- Identification of the symptoms, treatment, and major factors of preventing kidney disease, peripheral vascular disease, cardiovascular disease, periodontal disease, and neuropathy
- Importance of pneumonia vaccine and yearly flu vaccine
- Smoking cessation

Smoking and Diabetes

Summary

Patients with diabetes who smoke have a heightened risk of morbidity and premature death due to macrovascular complications. Smoking is also related to the premature development of microvascular disease and may have a role in the development of type 2 diabetes. The cardiovascular burden of diabetes in combination with smoking is not being consistently presented to people with

diabetes. Only about half of the smokers with diabetes have been advised to quit smoking by their health care providers.

Screening Recommendations

- Ask about smoking at every visit.
- For adults who have never smoked, flag the record to avoid repeat questions.
- For adults who have previously smoked, check for relapse.
- For children and adolescents who do not smoke, continue to ask at every visit.

Treatment Recommendations

Include smoking cessation counseling and other forms of treatment as a part of routine diabetes care. Remember the "5 A's":

- **A**sk about smoking at every visit.
- **A**ssess readiness to quit among current tobacco users.
- Assess current level of nicotine dependence.
- **A**dvise all smokers of the importance of quitting, describing the added risks of smoking and diabetes.
- **A**ssist those ready to quit:
    - Establish a quit date.
    - Provide a referral to a smoking cessation program such as QuitWorks (a stop-smoking service for Massachusetts residents).
    - Provide a referral to behavioral counseling if needed.
    - Offer pharmacological supplements if appropriate.
- **A**rrange a follow-up phone call soon after the quit date.

For those who have quit:

- Encourage maintenance.
- Review benefits of cessation.
- Anticipate threats to maintenance, such as weight gain, depression, prolonged withdrawal.

Pharmacological Therapy

- As with the general population, pharmacological agents increase smoking cessation rates when used in conjunction with behavioral interventions.
- Nicotine replacement therapy for 4 to 6 weeks is helpful for those with a moderate to severe nicotine dependence.
- Bupropion or nortriptyline is useful in decreasing the desire to smoke and allaying depression as well.

See the original guideline document for a smoking intervention model.

Psychosocial Issues

Psychosocial issues may prevent people with diabetes from adhering to the recommended medical regimen. Stressors such as family nonsupport, eating

disorders, insufficient financial or social resources, and cognitive impairment may impact a patient's ability to carry out necessary diabetes care tasks. In addition to obtaining a history of previous psychiatric treatment, it is important in achieving optimal outcomes to provide timely identification of issues that may impact or be symptomatic of depression.

In particular, depression in people with diabetes requires careful management due to its severe impact on comorbid conditions as well as on the individual's quality of life. Depression is known to affect glycemic control and micro/macrovascular complications. In addition, depressive symptoms play a more important role in mortality among people with diabetes than in those without. For adults with diabetes, the presence of two or more coexisting chronic conditions, particularly coronary artery disease, chronic arthritis, and stroke, increase the chances of developing major depression.

Compared to diabetic patients who are not depressed, those who are depressed require more costly care. These differences are partly related to non-adherence to medication regimens and worsened self-care skills. Depressive symptoms impact subsequent physical symptoms of poor glucose control by influencing patients' ability to adhere to their self-care regimen.

Although the primary clinician may not feel qualified to treat psychological problems, utilizing the patient-provider relationship as a foundation for further treatment can increase the likelihood that the patient will accept referral for other services.

Screening

- It is important to include psychosocial evaluation as an integral component of the initial assessment for a patient with diabetes. Other opportunities for screening will occur during regularly scheduled management visits, as well as at times of medical status change such as the occurrence of a hospitalization, the development of a complication, or when problems with glucose control are identified.
- Screening should include but is not limited to: psychiatric history, affect/mood, quality of life attitudes, medical management expectations, availability of and ability to access financial, social, and emotional resources.
- Screening for depression, eating disorders, and cognitive impairment is needed when adherence to the medical regimen is poor.

Recommendations

- Incorporate psychological screening and treatment into routine care rather than waiting for identification of a specific problem or deterioration in psychological status.
- Treat depression or refer to a mental health specialist for depression treatment.
- Immediately refer to a mental health specialist familiar with diabetes management if self harm or an eating disorder is suspected. A referral is also recommended if a problem is suspected to be organic in origin or when cognitive function is impaired.

Retinopathy

Diabetic retinopathy is estimated to be the most frequent cause of new cases of blindness among adults aged 20 to 74 years. The prevalence of retinopathy is strongly related to the duration of diabetes. Intensive diabetes management with the goal of achieving near normoglycemia has been shown to prevent and/or delay the onset of diabetic retinopathy. High blood pressure is an established risk factor for the development of macular edema and is linked to the presence of proliferative diabetic retinopathy. The presence of nephropathy is also associated with retinopathy. Patients with diabetic retinopathy or macular edema are often asymptomatic. Early diagnosis and prompt application of laser photocoagulation surgery is useful in preventing visual loss, but generally not beneficial in reversing already diminished acuity.

Screening Recommendations

- An ophthalmologist or optometrist who is knowledgeable and experienced in diagnosing the presence of diabetic retinopathy and is aware of its management should perform comprehensive eye exams.
- Adults 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 should have an initial dilated and comprehensive eye examination shortly following the diagnosis of diabetes.
- Subsequent examinations for type 1 and type 2 diabetic patients should be repeated annually.
- A qualified eye care professional may recommend less frequent exams (every 2 to 3 years) in the setting of a normal eye exam.
- Examinations will be required more frequently if retinopathy is progressing.
- Women with preexisting diabetes should have a comprehensive eye examination when planning pregnancy and should be counseled on the risk of development and/or progression of diabetic retinopathy.
- Women with diabetes who become pregnant should have a comprehensive eye examination in the first trimester and close follow-up throughout pregnancy and for 1 year postpartum.
- Retinal screening is not necessary for women who develop gestational diabetes because these women are not at increased risk for diabetic retinopathy.

Treatment Recommendations

- Promptly refer patients with any level of macular edema, severe non-proliferative retinopathy, or any proliferative retinopathy to an ophthalmologist who is knowledgeable and experienced in the management and treatment of diabetic retinopathy.
- Laser therapy is known to reduce the risk of vision loss in patients with high-risk conditions, such as disc neovascularization or vitreous hemorrhage with any retinal neovascularization.

Periodontal Disease

Periodontal disease is more common among people with diabetes. Young adults with diabetes have about twice the risk for periodontal disease than those

without. Almost one-third of people with diabetes has severe periodontal disease with loss of attachment of the gums to the teeth measuring 5 millimeters or more. Periodontal disease progresses more rapidly, is often more aggressive, and difficult to treat in people with diabetes than in people without diabetes.

Defined as a bacterially induced chronic inflammatory process, periodontal disease destroys connective tissue and bone supporting the teeth, leading to tooth loss. Recent research suggests a bi-directional relationship between diabetes and periodontal disease in that people with diabetes are more susceptible, and the presence of periodontal disease can negatively impact glycemic control.

Symptoms of periodontal disease include red, swollen, tender, and bleeding gums, receding gums, evidence of pus upon gum compression, persistent bad breath, loose permanent teeth, change in bite, or change in the fit of dentures. Most individuals with diabetes do not have pain with periodontal disease and some may be asymptomatic.

Concurrent risk factors that increase the chances of developing periodontal disease include: disease duration, poor metabolic control, presence of other long-term complications, smoking, plaque, and hormonal variations as in adolescence, pregnancy, and menopause. Mouth care is often overlooked when managing the other issues associated with diabetes.

Recommendations

- Conduct an oral exam as part of the yearly comprehensive visit.
- Advise patients of the importance of oral hygiene.
- Promptly refer patients with symptoms of periodontal disease for dental evaluation.
- Encourage patients to receive dental follow-up twice a year, and more often if necessary.

Massachusetts Guidelines for Adult Diabetes Care

	Frequency	Description/Comments
History and Physical		
Blood Pressure, Height and Weight	Every 3 to 6 months	If BP >130/80 initiate measures to lower.
Dilated Eye Exam	Annual[1]	Refer to ophthalmologist or optometrist.
Foot Exam	Every 3 to 6 months	Visual exam without shoes and socks every routine diabetes visit
Comprehensive Lower Extremity Sensory Exam	Initial/Annual[2]	Teach protective foot behavior if sensation diminished. Refer to podiatrist if indicated. *See Foot Inspection and Monofilament Use Guide* in the original guideline document.
Dental Exam	Every 6 months	Refer to dentist.
Smoking Status	Ongoing	Check every visit/Encourage

	Frequency	Description/Comments
		smoking cessation. *See Smoking Intervention Model* in the original guideline document.
Labs		
A1C	Every 3 to 6 months[3]	Ideal goal <7.0% or <1% above lab norm[4]. Action required at >8.0%, make changes in regime.
Fasting/Casual Blood Glucose	As indicated	Compare lab results with glucose self-monitoring.
Fasting Lipid Profile	Annual[5]	*See Cardiovascular Risk Reduction Guidelines* in the original guideline document.
Urine Microalbumin/Creatinine	Initial/Annual[6,7]	If abnormal, recheck x2 in a 3-month period, then treat if 2 out of 3 collections show elevated levels.
Serum Creatinine	Initial/As Indicated	
EKG	Initial	If patient is >40 years old or DM ≥10 years
Thyroid Assessment	Initial/As Indicated	Thyroid palpation, thyroid function test(s) if indicated
Recommended Immunizations		
Flu Vaccine	Every fall	
Pneumovax	Recommended once	Also revaccination x1 if ≥65 and first vaccine >5 years ago **and** patient age <65 at time of 1st vaccine
Self-Management		
Review Self-Management Skills	Initial/Ongoing	
Review Treatment Plan	Initial/Ongoing	Check self-monitoring log book, diet, exercise, and meds.
Review Education Plan	Initial/Ongoing	Refer for Diabetes Self-Management Training if indicated.
Counseling		
Review Nutrition Plan	Initial/Ongoing	Refer for medical nutrition therapy if indicated.
Review Physical Activity Plan	Initial/Ongoing	Assess/Prescribe based on patient's health status.
Tobacco Use	Annual/Ongoing	Assess readiness/Counsel cessation/Refer to QuitWorks or other smoking cessation program.
Psychosocial Adjustment	Initial/Ongoing	Suggest diabetes support group/Counsel/Refer
Sexuality/Impotence/Erectile	Annual/Ongoing	Discuss diagnostic evaluation and

	Frequency	Description/Comments
Dysfunction		therapeutic options.
Preconception/Pregnancy	Initial/Ongoing	Need for tight glucose control 3 to 6 months preconception. Consider early referral to OB/GYN.

Abbreviations: BP, blood pressure; A1C, hemoglobin A1c; EKG, electrocardiogram; DM, diabetes mellitus; OB/GYN, obstetrician/gynecologist

[1]Type 1: Initial exam after 3 to 5 years disease duration. Type 2: Initial exam shortly after diagnosis.
[2]Every 3 to 6 months if patient has high-risk foot conditions.
[3]Two times per year for stable glycemic control. Four times per year if change in therapy or if not meeting glycemic goals.
[4]More stringent goals, including a normal A1C of <6% can be considered in individual patients and during pregnancy.
[5]If values fall in lower risk levels, assessment may be repeated every 2 years.
[6]Initial urinalysis at diagnosis of type 2 diabetes. For patients with type 1 diabetes, screen for microalbumin after 5 years of disease duration. Annual microalbumin thereafter.
[7]Type 1: Initial exam to begin with puberty and after 5 years disease duration.

Note: A flow sheet for diabetes care is included in the original guideline document.

CLINICAL ALGORITHM(S)

Algorithms are provided in the original guideline document for:

- New Mild-Moderate Type 2 Diabetes First Line Therapy
- Combination Therapy in Type 2 Diabetes
- Lipid Lowering Decision Tree in Type 2 Diabetes

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of evidence supporting the recommendations is not specifically stated.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Appropriate identification and management of adults who have diabetes mellitus

POTENTIAL HARMS

Refer to the tables on pages 9 through 13 in the original guideline document for information about potential side effects of diabetes medications.

CONTRAINDICATIONS

CONTRAINDICATIONS

Sulfonylureas

All sulfonylureas are contraindicated in diabetic ketoacidosis (DKA).

Second Generation Sulfonylureas

Glyburide/metformin (Glucovance) and *glipizide/metformin (Metaglip)*: Contraindicated in patients with renal insufficiency, chronic metabolic acidosis, or congestive heart failure (CHF).

Alpha-Glucosidase Inhibitors

Acarbose (Precose), miglitol (Glyset): Contraindicated in patients with diabetic ketoacidosis (DKA), inflammatory bowel disease, colonic ulceration, or partial intestinal obstruction. Relatively contraindicated in patients with hepatic failure.

Biguanides

Metformin (Glucophage), metformin extended release (Glucophage XR), glyburide/metformin (Glucovance), and *glipizide/metformin (Metaglip)*: Do not use in patients with impaired renal or hepatic function. Contraindicated in patients with treated heart failure.

Thiazolidinediones

Thiazolidinediones are contraindicated in patients with hepatic or heart failure.

Angiotensin II Receptor Blockers (ARBs) and Angiotensin-converting Enzyme (ACE) Inhibitors

ARBs and ACE inhibitors are contraindicated during pregnancy and should be discontinued in women planning pregnancy due to their teratogenic effect.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

These guidelines are not intended to replace the clinical judgment of primary care providers, nor are they intended to preclude more extensive evaluation and management of the patient by other specialists as needed.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

IMPLEMENTATION TOOLS

Chart Documentation/Checklists/Forms
Clinical Algorithm
Foreign Language Translations
Patient Resources
Pocket Guide/Reference Cards

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)

Diabetes Prevention and Control Program, Diabetes Guidelines Work Group. Massachusetts guidelines for adult diabetes care. Boston (MA): Massachusetts Department of Public Health; 2005 Jun. 39 p. [110 references]

ADAPTATION

These guidelines are based on the following:

- American Diabetes Association. (2005). Standards of medical care. *Diabetes Care* 28 (Supplement 1).

DATE RELEASED

1999 Jun (revised 2005 Jun)

GUIDELINE DEVELOPER(S)

Diabetes Guidelines Work Group - State/Local Government Agency [U.S.]

SOURCE(S) OF FUNDING

This program was partially funded by a cooperative agreement between the Centers for Disease Control and Prevention, Division of Diabetes Translation, and the Massachusetts Department of Public Health, Diabetes Prevention and Control Program.

GUIDELINE COMMITTEE

Diabetes Guidelines Work Group

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

ENDORSER(S)

Baystate Health System - Hospital/Medical Center
Blue Cross Blue Shield of Massachusetts - Managed Care Organization
Boston Medical Center HealthNet Plan - Managed Care Organization
Division of Medical Assistance, Primary Care Clinician (PCC) Plan - State/Local Government Agency [U.S.]
Fallon Health Care System - Managed Care Organization
Harvard Pilgrim Health Care, Inc. - Managed Care Organization
Massachusetts Department of Public Health - State/Local Government Agency [U.S.]
Massachusetts League of Community Health Centers - Hospital/Medical Center
Massachusetts Medical Society - Professional Association
MassHealth Primary Care Clinician (PCC) Plan - State/Local Government Agency [U.S.]
MassPRO - Private Nonprofit Organization
Neighborhood Health Plan - Managed Care Organization
Network Health - Managed Care Organization
Partners/MGH - Managed Care Organization
Tufts Health Plan - Managed Care Organization
University of Massachusetts, Amherst - Academic Institution

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: Diabetes Guidelines Work Group, Diabetes Prevention and Control Program. Massachusetts guidelines for adult diabetes care. Boston (MA): Massachusetts Department of Public Health; 2003 Jun. 27 p.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from the Massachusetts Department of Public Health Web site.

Print copies: Available from the Massachusetts Health Promotion Clearinghouse, The Medical Foundation, 95 Berkeley Street, Boston MA 02116; Fax: (617) 536-8012; Web site: www.maclearinghouse.com.

AVAILABILITY OF COMPANION DOCUMENTS

The following is available:

- 2003 The health of Massachusetts. Impact of diabetes. Boston (MA): Massachusetts Diabetes Health System Coalition, 2003. Electronic copies available in Portable Document Format (PDF) from the Massachusetts Department of Public Health Web site.

Print copies: Available from the Massachusetts Health Promotion Clearinghouse, The Medical Foundation, 95 Berkeley Street, Boston MA 02116; Fax: (617) 536-8012; Web site: www.maclearinghouse.com.

Additionally, a laminated summary of guidelines for adult diabetes care and a flow sheet for diabetes care are available in the original guideline document.

PATIENT RESOURCES

The following are available:

- Diabetes care card (patient wallet card). Boston (MA): Massachusetts Department of Public Health--Diabetes Control Program, 2005. Electronic copies available in Portable Document Format (PDF) from the Massachusetts Department of Public Health Web site. Electronic copies are also available in Chinese, Khmer, Portuguese, Spanish, and Vietnamese in PDF format from the Massachusetts Department of Public Health Web site.
- Additional diabetes brochures are available in a variety of languages in PDF format from the Massachusetts Department of Public Health Web site.

Print copies: Available from the Massachusetts Health Promotion Clearinghouse, The Medical Foundation, 95 Berkeley Street, Boston MA 02116; Fax: (617) 536-8012; Web site: www.maclearinghouse.com.

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

NGC STATUS

This summary was completed by ECRI on April 28, 2001. It was verified by the guideline developer as of May 23, 2001. This summary was updated by ECRI on November 12, 2002, and December 2, 2005. The updated information was verified by the guideline developer on March 22, 2006. This summary was updated by ECRI Institute on September 5, 2007 following the U.S. Food and Drug Administration advisory on the Thiazolidinedione class of antidiabetic drugs. This summary was updated by ECRI Institute on November 9, 2007, following the U.S. Food and Drug Administration advisory on Antidepressant drugs. This summary was updated by ECRI Institute on November 28, 2007 following the U.S. Food and Drug Administration advisory on the Avandia (rosiglitazone maleate)

Tablets. This summary was updated by ECRI Institute on March 10, 2008 following the U.S. Food and Drug Administration advisory on Avandia (rosiglitazone maleate).

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Date Modified: 11/3/2008


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