Complete Summary

GUIDELINE TITLE

VA/DoD clinical practice guideline for the management of diabetes mellitus.

BIBLIOGRAPHIC SOURCE(S)

Veterans Health Administration, Department of Defense. VA/DoD clinical practice guideline for the management of diabetes mellitus. Washington (DC): Veterans Health Administration, Department of Defense; 2003 Sep. Various p.

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: Management of diabetes mellitus in the primary care setting. Washington (DC): Department of Veterans Affairs (U.S.); 1999 Dec. 147 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.

COMPLETE SUMMARY CONTENT

** REGULATORY ALERT **
SCOPE
METHODOLOGY - including Rating Scheme and Cost Analysis
RECOMMENDATIONS
EVIDENCE SUPPORTING THE RECOMMENDATIONS
BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

CONTRAINDICATIONS
QUALIFYING STATEMENTS
IMPLEMENTATION OF THE GUIDELINE
INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES
IDENTIFYING INFORMATION AND AVAILABILITY
DISCLAIMER

SCOPE

DISEASE/CONDITION(S)

Diabetes mellitus

GUIDELINE CATEGORY

Diagnosis
Evaluation
Management
Prevention
Screening
Treatment

CLINICAL SPECIALTY

Endocrinology
Family Practice
Internal Medicine

INTENDED USERS

Advanced Practice Nurses
Dietitians
Health Care Providers
Nurses
Pharmacists
Physician Assistants
Physicians

GUIDELINE OBJECTIVE(S)

- To promote evidence-based management of individuals with diabetes
- To identify the critical decision points in management of patients with diabetes mellitus, such as glycemic control, evaluation of the eyes and feet, and early recognition and treatment of comorbid conditions including hypertension, hyperlipidemia, and renal disease
- To allow flexibility so that local policies or procedures, such as those regarding referrals to or consultation with diabetes teams, ophthalmology, optometry, podiatry, nephrology, and endocrinology (lipids), can be accommodated
- To decrease the development of complications

- To improve local management of patients with diabetes and thereby improve patient outcomes
- To update the 1999 Veterans Affairs/Department of Defense (VA/DoD) guideline on management of diabetes mellitus

TARGET POPULATION

Veterans with diabetes mellitus or at risk for diabetes mellitus and its complications

INTERVENTIONS AND PRACTICES CONSIDERED

Core Assessment

1. Biochemical tests for diagnosis, including fasting blood sugar and random/casual blood sugar
2. Evaluation of symptoms and risk factors
3. Assessment of the risk of maternal fetal complications and screening of pregnant women for autoimmune thyroid disease, hypertension, and renal disease
4. Identification of comorbid conditions and/or complications requiring special attention
5. Referral of pediatric patients
6. Patient stabilization (medically, psychologically, and socially)
7. Annual medical evaluation including: patient/family history, physical examination, laboratory tests, nutritional assessment, educational assessment)
8. Determination of diabetes type (Type 1 or 2, age, body mass index [BMI], urinary ketones)
9. Consideration of aspirin therapy to prevent cardiovascular disease
10. Management of hypertension (Note: for complete management see VA/DoD guideline at www.oqp.med.va.gov/cpg/cpg.htm or www.qmo.amedd.army.mil.)
    - Angiotensin-converting enzyme inhibitor
    - Angiotensin receptor blockers
    - Calcium channel blockers
    - Beta-blockers
    - Diuretics
11. Evaluation and management of lipids
    - Screening for lipid abnormalities (fasting lipid profile)
    - Lifestyle counseling
    - Drug therapy when indicted (statins, niacin, bile acid resin, fibrates)

Screening and Prevention

1. Recognizing risk factors for developing diabetes mellitus
2. Obtaining fasting plasma glucose in patients with risk factors
3. Counseling for interventions to prevent diabetes mellitus (e.g., lifestyle modifications, weight loss)
4. Repeated screening at regular intervals

Glycemic Control

1. Assessment of glycemic control (HbA_1c), and the determination of optimal target HbA_1c using risk stratification criteria
2. Adjustment of HbA_1c target and target range according to individual risk, benefit and preference
3. Identification of high risk patients and patients requiring insulin therapy
4. Insulin replacement therapy (Type 1)
5. Pharmacological therapy (Type 2)
    - Sulfonylureas
    - Biguanides (metformin)
    - Insulin
    - Alpha-glucosidase inhibitor (miglitol, acarbose)
    - Thiazolidinediones (rosiglitazone, pioglitazone)
    - Repaglinide
6. Follow-up and patient monitoring
7. Patient education and practices to improve patient adherence
8. Referral to specialist, if necessary

Eye Care

1. Assessment of ocular risk factors and referral of high risk patients expediently for a dilated eye examination
2. Follow-up eye examination intervals
3. Patient education, including: the need for periodic eye examination, compliance, and the significance of new visual symptoms

Foot Care

1. Visual inspection and peripheral sensation testing at routine primary care visits, and annual foot risk assessment to identify patients at high risk for the development of foot ulcers and lower extremity amputations
2. Assessment of limb threatening conditions (e.g., systematic infection, acute ischemia or rest pain, foot ulceration, puncture wound, ingrown toenail, hemorrhagic callous with or without cellulites)
3. Wound assessment and the identification of any minor wound or lesion that can be treated by primary care physician
4. Referral to foot care specialist, when necessary
5. Patient and family foot education

Kidney Function Assessment/Treatment

1. Screening for renal disease (microalbuminuria; macroalbuminuria, microhematuria, renal insufficiency, nephropathy)
    - Routine urinalysis
    - Serum creatinine
    - Spot urine for albumin and creatinine
    - 24-hour urine for creatinine and protein
    - Random urine for protein/creatinine or albumin/creatinine ratio
2. Referral or consultation, if necessary
3. Evaluate for retinopathy and refer, if necessary
4. Treatment of transient causes of proteinuria
5. Reevaluation for nondiabetic causes of elevated creatinine
6. Counseling patient on reduced protein diet

7. Identification of hypertensive patients who may benefit from hypertension control management
8. Drug therapy (ACE inhibitors) and periodic reevaluation (3 to 6 months)

Self-Management and Education

1. Education on basic concepts, core competency (survival skills), self-management, nutrition, and/or other patient needs
2. Referral for comprehensive diet consultation, risk-focused intervention, or to appropriate specialist
3. Assessment of patient's knowledge and self-management skills

MAJOR OUTCOMES CONSIDERED

- Blood glucose level
- Blood pressure
- Vision change
- Rates of foot wounds
- Lipid levels
- Identification of renal disease
- Level of patient knowledge of disease

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

The guideline developer performed a Medline literature search, dated March 1997 through March 1999, covering areas of diabetes, hypertension, lipid management, renal disease, foot and eye care, and diabetes education.

2003 Update

Eighteen researchable questions and associated key terms were developed by the Working Group after orientation to the seed guidelines and to goals that had been identified by the Working Group. The questions specified: (adapted from the Evidence-Based Medicine (EBM) toolbox, Centre for Evidence-Based Medicine.

- Population - characteristics of the target patient population
- Intervention - exposure, diagnostic, or prognosis
- Comparison - intervention, exposure, or control used for comparison
- Outcome -outcomes of interest

These specifications served as the preliminary criteria for selecting studies.

Published, peer-reviewed, randomized controlled trials (RCTs) were considered to constitute the strongest level of evidence in support of guideline

recommendations. This decision was based on the judgment that RCTs provide the clearest, scientifically sound basis for judging comparative efficacy. The Working Group made this decision recognizing the limitations of RCTs, particularly considerations of generalizability with respect to patient selection and treatment quality. Meta-analyses that included random controlled studies were also considered to be the strongest level of evidence, as well as reports of evidence-based systematic reviews.

A systematic search of the literature was conducted. It focused on the best available evidence to address each key question and ensured maximum coverage of studies at the top of the hierarchy of study types: evidence-based guidelines, meta-analyses, and systematic reviews. When available, the search sought out critical appraisals already performed by others that described explicit criteria for deciding what evidence was selected and how it was determined to be valid. The sources that have already undergone rigorous critical appraisal include Cochrane Reviews, Best Evidence, Technology Assessment, and EPC reports.

The search continued using well-known and widely available databases that were appropriate for the clinical subject. In addition to Medline/PubMed, the following databases were searched: Database of Abstracts of Reviews of Effectiveness (DARE) and Cochrane Central Register of Controlled Trials (CCTR). For Medline/PubMed, limits were set for language (English), date of publication (1999 through May 2002), and type of research (RCT and meta-analysis). For the CCTR, limits were set for date of publication (1990 through 2002).

Once definitive reviews or clinical studies that provided valid relevant answers to the question were identified, the search ended. The search was extended to studies/reports of lower quality (observational studies) only if there were no high quality studies.

Exclusion criteria included reviews that omitted clinical course or treatment. Some retrieved studies were rejected on the basis of published abstracts, and a few were rejected after the researchers scanned the retrieved citation for inclusion criteria. Typical exclusions included studies with physiological endpoints or studies of populations that were not comparable to the population of interest (e.g., studies of diabetes in children or pregnancy).

The results of the search were organized and reported using reference manager software. At this point, additional exclusion criteria were applied. The bibliographies of the retrieved articles were hand-searched for articles that may have been missed by the computer search. Additional experts were consulted for articles that may also have been missed.

Literature Review and Inclusion Criteria

As a result of the original and updated literature reviews, more than 180 articles were identified for possible inclusion. These articles formed the basis for formulating the guideline recommendations. The literature search for the guideline update was validated by: (1) comparing the results to a search conducted by the independent research and appraisal team; (2) a review of the database by the expert panel; and (3) requesting articles pertaining to special topics from the experts in the working group.

It is important to note that due to application of article screening criteria in the updated guideline, some of the studies that were included in the original guideline were not included in the updated analyses.

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

Note: The quality rating procedure used in the 2003 update was different from the rating scale used in the development of the original guideline in 1999. Where adjustments to the update process were made, articles from the original process were re-graded to reflect the changed rating scale (e.g., the level of recommendation was assigned for each evidence, based on study design and significance of the quality of the evidence).

Quality of Evidence

I: Evidence obtained from at least one properly done randomized controlled trial.

II-1: Evidence obtained from well designed controlled trails without randomization.

II-2: Evidence obtained from well designed cohort or case-control analytic study

II-3: Evidence obtained from multiple time series; dramatic results of uncontrolled experiments

III: Opinion of respected authorities, case reports, and expert committees.

Overall Quality

Good: High grade evidence (I or II-1) directly linked to health outcome

Fair: High grade evidence (I or II-1) linked to intermediate outcome; or grade evidence (II-2 or II-3) directly linked to health outcome

Poor: Level III evidence or no linkage of evidence to health outcome

Net Effect of Intervention

Substantial:

- More than a small relative impact on a frequent condition with a substantial burden of suffering, or
- A large impact on an infrequent condition with a significant impact on the individual patient level

Moderate:

- A small relative impact on a frequent condition with a substantial burden of suffering, or
- A moderate impact on an infrequent condition with a significant impact on the individual patient level

Small:

- A negligible relative on a frequent condition with a substantial burden of suffering, or
- A small impact on an infrequent condition with a significant impact on the individual patient level

Zero or Negative:

- Negative impact on patients, or
- No relative impact on either a frequent condition with a substantial burden of suffering, or
- An infrequent condition with a significant impact on the individual patient level

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

A group of clinician reviewers and other researchers in health care, with experience in evidence-based appraisal, independently read and coded each article that met inclusion criteria. Each article was turned into a one-page summary of the critical appraisal by the research team and added to a central electronic database. Clinicians from the Center for Evidence-Based Practice at the State University of New York, Upstate Medical University, Department of Family Medicine [SUNY] contributed several of the appraisal reports. Each of the evidence reports covered:

- Summary of findings
- Methodology
- Search terms
- Resources searched
- Summary table of findings
- Critical appraisal of each study

Quality ratings were made for each evidence using the grading scale presented in the field "Rating Scheme for the Strength of the Evidence."

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

The original 1997 Veterans Health Administration (VHA) guidelines represented a "seed document" that was updated from January-June, 1999. As with the original workgroup, the charge of the VHA/Department of Defense (DoD) group was to provide evidence-based action recommendations whenever possible. Major clinical randomized controlled trials and observational studies published from March 1997 through March 1999 in the relevant areas were identified by the literature search and reviewed by the expert panel. Each reference cited was critically appraised for scientific merit, clinical relevance, and applicability to the populations served by the Federal health care system. Recommendations were based on the expert panels' opinion and clinical experience only when scientific evidence was unavailable from the current literature.

2003 Update

The development of the 2003 Diabetes Mellitus Guideline Update (version 3.0) was initiated in March 2002 and continued through January 2003. The development process followed the steps described in "Guideline for Guideline," an internal working document of VHA's National Clinical Practice Guideline Council, which requires an ongoing review of the work in progress.

The Offices of Quality and Performance and Patient Care Service, in collaboration with the network Clinical Managers, the Deputy Assistant Under Secretary for Health, and the Medical Center Command of the DoD identified clinical leaders to champion the guideline development process. During a preplanning conference call, the clinical leaders defined the scope of the guideline and identified a group of clinical experts from the VA and DoD that formed the Guideline Development Working Group.

At the start of the update process, the clinical leaders, guideline panel members, outside experts, and experts in the field of guideline and algorithm development were consulted to determine which aspects of the 1999 guideline required updating. These consultations resulted in the following recommendations that guided the update efforts: (1) update any recommendations from the original guideline likely to be effected by new research findings; (2) provide information and recommendations on health systems changes relevant to diabetes care; (3) address content areas and models of treatment for which little data existed during the development of the original guideline; and (4) review the performance and lessons learned since the implementation of the original guideline.

The Working Group participated in a face-to-face session to reach a consensus about the guideline recommendations and to prepare a draft document. The draft was revised by the experts through numerous conference calls and individual contributions to the document.

This 2003 Guideline Update is the product of many months of diligent effort and consensus building among knowledgeable individuals from the Department of Veterans Affairs (VA), Department of Defense (DoD), academia, and guideline facilitators from the private sector. An experienced moderator facilitated the multidisciplinary Working Group. The list of participants is included in the introduction to the guideline update.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Note: The quality rating procedure used in the 2003 update was different from the rating scale used in the development of the original guideline in 1999. Where adjustments to the update process were made, articles from the original process were re-graded to reflect the changed rating scale (e.g., the level of recommendation was assigned for each evidence, based on study design and significance of the quality of the evidence)

Final Grade of Recommendation is determined according to the following chart:

	The net benefit of the intervention			
Quality of Evidence	**Substantial**	**Moderate**	**Small**	**Zero or Negative**
Good	**A**	**B**	**C**	**D**
Fair	**B**	**B**	**C**	**D**
Poor	**I**	**I**	**I**	**I**

A – A strong recommendation that the intervention is always indicated and acceptable

B – A recommendation that the intervention may be useful/effective.

C – A recommendation that the intervention may be considered

D – A recommendation that a procedure may be considered not useful/effective, or may be harmful.

I – Insufficient evidence to recommend for or against – the clinician will use clinical judgment

COST ANALYSIS

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

METHOD OF GUIDELINE VALIDATION

Comparison with Guidelines from Other Groups
Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Version 1.0 of the Veterans Health Administration (VHA) Guidelines was reviewed at a joint meeting of the National Diabetes Education Program (NDEP) Steering Committee and the Diabetes Mellitus Federal Interagency Coordinating Committee (DMICC) on October 21, 1997.

The original 1997 VHA guidelines represented a "seed document" that was updated and adapted by the joint VHA/DoD Diabetes Guideline Development Group over a six-month period from January-June, 1999.

This version was compared with the most recent guidelines published by other professional organizations, notably those of the American Diabetes Association, National Kidney Foundation (NKF), Joint National Council VI on Hypertension (JNC-VI), and National Cholesterol Education Program (NCEP). A summary comparing recommendations from VHA/DoD Diabetes Clinical Guidelines with other currently published guidelines is included in Table 2 in the original guideline document.

2003 Update

The final draft was reviewed by experts from the Department of Veterans Affairs (VA) and Department of Defense (DoD) internal medicine, endocrinology, and primary care. The draft was also reviewed by diabetes educators and other professionals involved in diabetes education teams. Their feedback was integrated into the final draft.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

The recommendations for the management of diabetes in the primary care setting are organized into 7 major algorithms. Each algorithm, the objectives and recommendations or annotations that accompany it, and the evidence supporting the recommendations are presented below. The quality of evidence **(QE)** grading (I-III); **overall quality** (Good, Fair, Poor); and final grade of recommendations **(R)** (A-D, I) are provided for specific statements. These grades, along with "net effect of the interventions" are defined at the end of the "Major Recommendations" field.

Note: A list of all abbreviations is provided at the end of the "Major Recommendations" field.

Core Algorithm

Module D - Core

The core module provides an overview of the important components of diabetes care that should be considered at each visit and the interventions that should be performed at appropriate intervals. This module will assist the provider to organize and prioritize a care plan for persons with diabetes mellitus (DM).

A. **Patient with Diabetes Mellitus**

Diabetes mellitus is a state of absolute or relative insulin deficiency resulting in hyperglycemia. This algorithm applies to adults only (age ≥17), both type 1 and type 2 (formerly referred to as insulin-dependent and non-insulin dependent diabetes mellitus), but not to gestational diabetes mellitus (GDM).

Biochemical Criteria for Diagnosis

The criterion for the diagnosis of DM is either two fasting plasma glucose (FPG) readings with results ≥126 mg/dL or two random blood sugars with values ≥200 mg/dL, if symptoms of DM are present.

Oral glucose tolerance testing is no longer recommended in clinical practice. Hemoglobin A_1c (HbA_1c) measurement is not recommended as a screening test. An individual with a casual plasma glucose level ≥200 mg/dL but without symptoms should have his or her fasting blood glucose measured.

Individuals with impaired glucose homeostasis have an increased risk of developing DM and should receive counseling regarding weight control, exercise, and future screening.

Diagnosis of Diabetes Mellitus

Status	Fasting Plasma Glucose (FPG) Preferred Level (a), (b)	Casual Plasma Glucose(c)
Diabetes mellitus	FPG >126 mg/dL (7.0 mmol/L)	Casual plasma glucose ≥200 mg/dL (11.1 mmol/L) plus symptoms of diabetes
Impaired glucose homeostasis	Impaired fasting glucose (IFG) FPG ≥110; <126 mg/dL	
Normal	FPG <110 mg/dL	

a. Fasting is defined as no caloric intake for at least 8 hours.
b. FPG is the preferred test for diagnosis, but either of the two listed is acceptable. In the absence of unequivocal hyperglycemia with acute

metabolic decompensation, one of these two tests should be used on a different day to confirm the diagnosis.

c. Casual means any time of day without regard to time since last meal; classic symptoms include polyuria, polydipsia, and unexplained weight loss.

Patients with one or more of the following risk factors have a higher risk to be diagnosed with diabetes:

- Age $\geq$45 years
- Family history (parents or siblings with DM)
- High-density lipoprotein cholesterol (HDL-C) level $\leq$40 mg/dL (0.90 mmol/L) and triglyceride (TG) level $\geq$250 mg/dL (2.82 mmol/L)
- History of gestational diabetes mellitus (GDM); or women delivering babies weighing >9 pounds
- Hypertension (blood pressure $\geq$140/90 mmHg)
- Obesity ($\geq$20 percent above ideal body weight, or body mass index [BMI] $\geq$25 kg/m^2)
- Habitual physical inactivity
- History of impaired fasting glucose (IFG) or impaired glucose tolerance (IGT)
- Race/ethnicity: African American, Hispanic American, Native American, Asian American, Pacific Islander.

Oral glucose tolerance testing (OGTT) is no longer recommended in clinical practice because it is an imprecise test with poor reproducibility. Nonetheless, it would be of value to list the criteria for the diagnosis of diabetes using the OGTT for those providers who decide to continue to use the OGTT. The World Health Organization suggests continued use of the OGTT for patients with blood glucose values in the "uncertain range." Also, the OGTT does seem to better predict macrovascular complications.

OGTT diagnostic criteria (per American Diabetes Association [ADA]):

- Normal glucose tolerance: 2-h postload glucose (2-h PG) <140 mg/dL (7.8 mmol/l)
- Impaired glucose tolerance: 2-h PG 140 (7.8 mmol/l) and <200 mg/dL (11.1 mmol/l)
- Provisional diagnosis of diabetes (the diagnosis must be confirmed): 2-h PG 200 mg/dL (11.1 mmol/l)

B. **Refer to Pediatric Diabetes Management**

Objective

Provide appropriate management for diabetic children.

Annotation

Approximately three-fourths of all newly diagnosed cases of type 1 DM occur in children (below the age of 18). Children's health care needs are different

from those of adults in several ways. Providing health care to children not only must involve meeting their physical needs but must address their changing developmental stages. It is important to remember that young children have a limited ability to communicate their needs and to indicate if they are in pain and therefore should not be expected to understand specific clinical interactions.

Primary care providers should refer children with diabetes for consultative care to a team with expertise in providing care to children. Members of this team must have knowledge of and experience in meeting the medical, psychosocial, and developmental needs of children. The team should include, at a minimum, a pediatrician, certified diabetes educator, registered nurse, registered dietitian, and social worker, all with expertise and specialized training in the comprehensive care of the child with diabetes.

C. **Is Patient a Female of Reproductive Potential?**

Objective

Assess the risk of maternal fetal complications should unintended pregnancy occur and to implement prevention strategies.

Annotation

Primary care providers should strongly recommend to all patients with preexisting diabetes that they plan and prepare for each pregnancy. Primary care providers should also counsel all diabetic female patients of reproductive potential on the need for optimal glycemic control.

Because of the high risk nature of the diabetic pregnancy and the need for intensive multidisciplinary monitoring and patient support, referral of women with diabetes to an expert high risk perinatal team at the earliest possible opportunity must be considered as the standard of care. Ideally, such referral should be made during the period of planned conception.

D. **Identify Comorbid Conditions**

Objective

Evaluate DM management in the context of the patient's total health status.

Annotation

DM may not be the patient's only disease, nor is it necessarily the condition that needs to be prioritized for immediate treatment. Persons with DM are at risk of multiple comorbid conditions including:

- Coronary artery disease (CAD)
- Peripheral vascular disease (PVD)
- Hypertension (HTN)
- Hyperlipidemia

The following are examples of conditions that affect the management of DM:

- Chronic obstructive pulmonary disease (COPD)
- Substance use disorder (SUD)
- Depression

Among the more frequently encountered precipitating factors resulting in secondary diabetes are:

- Pancreatic disease (e.g., due to alcoholism, pancreatic insufficiency secondary to chronic pancreatitis, malignancy, hemochromatosis)
- Drug induced disease (especially thiazide diuretics, steroids, phenytoin)
- Cushing´s Disease
- Acromegaly

E. **Is the Patient Medically, Psychologically, and Socially Stable?**

Objective

Stabilize the patient before initiating long-term disease management.

Annotation

- Urgent or semi-urgent medical conditions, including hypo- or hyperglycemia, must be treated before long-term disease management principles are applied.
- The urgency of medical treatment, including the necessity for hospitalization, will depend upon the presence of ketoacidosis, dehydration, hyperosmolarity, infections, etc.
- Psychiatric illness and marked socioeconomic hardship (e.g., homelessness, absence of support system or reliable transportation, and unemployment.) pose significant barriers to diabetic management. If such circumstances are identified, involvement of mental health, social services, and case management professionals may enhance patient compliance with treatment and follow-up.
- The determination of stability is up to the judgment of the provider.

F. **Identify/Update Related Problems from the Medical Record, History, Physical Examination, Laboratory Tests, Nutritional and Educational Assessment**

Objective

Obtain and document a complete medical evaluation for the patient with DM annually.

Annotation

In addition to a general medical examination, a complete evaluation of patients with DM will include:

- Information regarding the onset and duration of DM
- History of hospitalization for diabetic events
- Review of glycemic control
- Measurement of serum lipids
- Identification of foot complications
- Identification of eye complications
- Screening for hypertension
- Screening for kidney disease
- Identification of macrovascular disease
- Identification of neurovascular disease
- Assessment of psychosocial status (including family support)
- Appraisal of self-management skills

On a follow-up visit, the evaluation should focus on updating of new information and/or changes to the patient record. The components of evaluation are summarized in the table below.

Evaluation of the Diabetic Patient

Evaluation Component	History-Patient/Family	Physical Examination
Glycemia	• Home glucose monitoring records • Hyperglycemia • Ketoacidosis • Hypoglycemia • Lifestyle • Nutrition • Current and past medications Also consider secondary etiologies: • Cushing's disease • Acromegaly • Hemochromatosis • Medications	• Weight • Height • Body mass index (BMI) is calculated by dividing the patient's weight in kg by the patient's height, in meters squared.
Foot	Symptoms of neuropathy: pain, paresthesia Symptoms of peripheral vascular disease Symptoms of systemic or local infection Previous episodes of foot complications:	Visual inspection including: • Nails • Web spaces • Ulcers • Calluses • Deformities Palpation of pulses and determination of sensation--consider using a 5.07

Evaluation Component	History-Patient/Family	Physical Examination
	• Foot deformity • Skin breakdown • Ulcers • Amputations	monofilament
Eye	• Changes in vision • Laser treatment • Glaucoma • Dilated retinal exam by eye care provider within last year	Visual acuity, if changes in vision are reported
Kidney	• Known history of diabetic disease • Family history of hypertension and renal disease	Edema
Hypertension	• Previous diagnosis of hypertension • Current and previous medications	Blood pressure
Coronary and peripheral arterial disease/hyperlipidemia	Atherosclerotic disease: • Myocardial infarction (MI)/angina • Stroke • Transient ischemic attack (TIA) • Claudication • Surgical history of revascularization Atherosclerotic risks other than diabetes: • Smoking history • Family history	Cardiac examination: • Heart • Peripheral circulation including pulses and bruits • Cutaneous or tendinous xanthomata

Evaluation Component	History-Patient/Family	Physical Examination
	• Previous diagnosis of hyperlipidemia; triglycerides Current and previous medications: • Aspirin • Estrogen therapy • Hypolipidemics	
Neurovascular	Sensory state of: • Hands and feet	• Interosseous muscle wasting • Deep tendon reflexes
Self-management education	Knowledge, understanding, and self-described behaviors: • Use of medication • Goals of treatment • Diet and self management skills • What to do in case of complications	Observation: • Home glucose monitoring if indicated • Foot self-examination
Other	• Dental history and oral exam • Dental and gingival health	Oral examination
	• Infections • Insulin injection sites • Immunizations: flu, pneumovax	N/A

Educational Assessment

The following questions were developed based on expert opinion and are believed to reflect the patient's general knowledge and ability to adequately self-manage his or her diabetes.

- Is there anything you do or have been advised to do because of your diabetes that you have difficulty with or are unable to do?
- Do you know what to do when your sugar is high/low (describe both hyperglycemia and hypoglycemia symptoms)? Who and when do you call?
- Do you remember your target goals: HbA_1c, low-density lipoprotein (LDL), weight, exercise, blood pressure?
- Which food affects your blood sugar the most: chicken breast, salad, or potato?

The patient´s inability to answer these questions indicates possible deficiency in knowledge and self-management skills. Module M (Self-Management/Education) provides the clinician with additional assessment information and action plans.

Patients with DM who have more immediate medical or psychiatric problems should still have an educational need assessment done. This evaluation is to determine whether they have sufficient skills to manage their glycemic control during a period of concurrent illness, with a goal of avoiding symptomatic hypo- or hyperglycemia.

G. **Determine and Document if Diabetes Mellitus is Type 1 or 2 (if Not Already Done)**

Objective

Determine what treatment components are needed for a particular patient.

Annotation

Patients with type 1 DM are insulinopenic (i.e., virtually absent insulin secretion), often due to autoimmune or toxic (e.g., alcohol) destruction of the pancreatic beta cells. Patients with type 2 DM have underlying insulin resistance and relative insulin deficiency.

In a primary care setting, the patient's age at the time diabetes is diagnosed, plus the BMI, and level of urinary ketones, are usually sufficient to classify the patient.

Clinical Classification of DM

	Likely Type 1	**Indeterminate**	**Likely Type 2**
Age	<30 years	30–40 years	>40 years
BMI	<25 BMI*	25–27	>27
Urinary ketones	Moderate to large	Low to moderate	None to low

* For Asian/Pacific Islanders the BMI threshold should be 23.

The increasing prevalence of obesity has translated to an earlier onset for type 2 diabetes. Therefore, using age alone as a discriminator for the diagnosis of type 1 or type 2 diabetes may be misleading.

H. Consider Aspirin Therapy

Objective

Prevent cardiovascular disease.

Recommendations

1. Prescribe aspirin therapy (75 to 325 mg/day) for all adult patients with type 2 diabetes and evidence of cardiovascular disease.
2. Consider beginning aspirin therapy (75 to 325 mg/day) for primary prevention in patients age 40 with type 2 diabetes and one or more other cardiovascular risk factors.
3. Consider individual evaluation for aspirin therapy for patients age 30 to 40 years with type 2 DM, particularly those with other cardiovascular risk factors or with type 1 DM and long duration of disease.

Evidence

	Recommendation	Sources	Quality of Evidence (QE)	Overall Quality	Recommendation Grade (R)
1	Aspirin therapy for patients with type 2 DM and evidence of large vessel disease	Collins et al., 1994; de Gaetano, 2001	**I**	**Good**	**A**
2	Aspirin therapy for patients with type 2 DM	Collins et al., 1994; de Gaetano, 2001; "Aspirin effects," 1992	**I**	**Fair**	**B**
3	Aspirin therapy for younger patients (age 30 to 40)	Working Group Consensus	**III**	**Poor**	**I**

	Recommendation	Sources	Quality of Evidence (QE)	Overall Quality	Recommendation Grade (R)
	with type 2 DM or with type 1 DM and other cardiovascular risk factors				
4	Aspirin therapy for patients age <40 with type 1 diabetes, in particular, those with longer duration of disease	Working Group Consensus	**III**	**Poor**	**I**

I. Review All Diabetes-Related Complications and Set Priorities

Objective

Identify DM-related complications requiring special attention.

Recommendations

1. If the individualized HbA_1c is not on target, refer to Module G – Glycemic Control.
2. If systolic blood pressure (SBP) >140 or diastolic blood pressure (DBP) is >80 mmHg, refer to the VA/DoD Clinical Practice Guideline for the Management of Hypertension. (Also see Annotation J).
3. If a lipids-evaluation was not done within one year or the patient has elevated cholesterol or lipids, refer to the VA/DoD Clinical Practice Guideline for the Management of Dyslipidemia (Lipids). (Also see Annotation K).
4. If a renal evaluation was not done within one year or the patient has micro-/macroalbuminuria or elevated creatinine, refer to Module R – Renal Disease.
5. If an eye evaluation was not done within two years, the patient has symptoms, or a previous exam showed a high risk for visual loss or retinopathy, refer to Module E – Eye Care.
6. If a foot-risk assessment was not done within one year or the patient has risk factors or an active lesion, refer to Module F – Foot Care.
7. If the patient needs additional nutritional or lifestyle education, refer to Module M – Self Management and Education.
8. If the patient is a candidate for an **influenza vaccine**, administer it in season.
9. Administer **pneumonia vaccine**, if indicated. (See VA/DoD Preventive Index Guideline).

10. If the patient is using tobacco, refer to the VA/DoD Clinical Practice Guideline for the Management of Tobacco Use Cessation.

Summary of the Management of Hypertension in Diabetes Mellitus

For complete management of hypertension see: VA/DoD Clinical Practice Guideline for the Diagnosis and Management of Hypertension in the Primary Care Setting at www.oqp.med.va.gov/cpg/cpg.htm or www.qmo.amedd.army.mil.

Patients with Diabetes with SBP >140 or DBP >80 mm Hg

Recommendations

1. Patients with diabetes with hypertension (BP > 140/90 mm Hg) or with isolated hypertension (ISH) (defined as pretreatment SBP greater than 140 and DBP less than 90) should:
    - Begin antihypertensive therapy with an angiotensin converting enzyme inhibitor (ACEI)
    - Switch to an angiotensin receptor blocker (ARB) if ACEI induced side-effects occur
    - Use other agents as necessary to achieve BP target <140/80 mm Hg
2. Patients with diabetes with SBP less than 139 and DBP between 80 and 89 with or without microalbuminuria would benefit from ACEI therapy. However, there is no clinical trial evidence that pinpoints the target level of BP.
3. In patients with diabetes with renal insufficiency (i.e., serum creatinine >1.5 mg/dL) or proteinuria (i.e., >1 g/24h) there are some data suggesting that further BP lowering (<125/75 mm Hg) may further slow progression of renal disease. Lower BP should be achieved, if feasible and practical, depending on the tolerance of medications and side effects of BP lowering.

Evidence – General Recommendations

	Recommendation	**Sources**	**Quality of Evidence (QE)**	**Overall Quality**	**Recommendation Grade (R)**
1	Treatment of HTN in patients with diabetes to retard progression of macrovascular complications and DM	Epstein & Sowers, 1992; Gaede et al., 1999; Hansson et al.,	**I**	**Good**	**A**

	Recommendation	Sources	Quality of Evidence (QE)	Overall Quality	Recommendation Grade (R)
		1998; UKPDS 38, 1998			
2	Target BP of <140/80 mm Hg for patients with diabetes with HTN, due to high risk for cardiovascular disease	Gaede et al., 1999; Hansson et al, 1998; Lindholm et al., 2002; UKPDS 38, 1998	**I**	**Good**	**A**
3	Consideration of lower BP targets (<125/75 mm Hg) to slow the progression of renal disease for patients with diabetes with elevated serum creatinine and/or urinary protein excretion above 1 g/day	Lazarus et al., 1997	**II-2**	**Fair**	**B**

Evidence – General Therapeutic Recommendations

	Recommendation	Sources	Quality of Evidence (QE)	Overall Quality	Recommendation Grade (R)
1	Antihypertensive therapy with ACEI for patients with diabetes with BP >140/80 mm Hg. Switch to ARB if	Andersen et al., 2000; Hansson et al, 1998; "Effects of	**I**	**Good**	**A**

	Recommendation	Sources	Quality of Evidence (QE)	Overall Quality	Recommendation Grade (R)
	ACEI-induced side-effects occur, then use other agents to achieve BP target <140/80 mm Hg	ramipril," 2000; Lacourciere et al., 2000; Lindholm et al., 2002; Mogensen et al., 2000; Muirhead et al., 1999; Nielsen et al., 1997			

Evidence – Specific Therapeutic Recommendations

	Recommendation	Sources	Quality of Evidence (QE)	Overall Quality	Recommendation Grade (R)
1	ACEI for normotensive patients with type 1 DM and proteinuria and for patients with type 2 DM and microalbuminuria or a high risk for cardiovascular disease	"Effects of ramipril," 2000; Lewis et al., 1993	**I**	**Good**	**A**
2	Consideration of ACEI for normotensive patients with type 1 DM	Laffel, McGill, & Gans , 1995; Viberti et al., 1994	**I**	**Fair**	**B**

	Recommendation	Sources	Quality of Evidence (QE)	Overall Quality	Recommendation Grade (R)
3	Treatment with ARBs for patients with type 2 DM and nephropathy, microalbuminuria, or HTN and left ventricular hypertrophy	Brenner et al., 2001; Lewis et al., 2001; Lindholm et al., 2002; Mogensen et al., 2000; Parving et al., 2001	**I**	**Good**	**A**
4	Combination ACEI and nondihydropyridine calcium channel blocker (NCCB) to provide renal protection in patients with inadequate response to an ACEI alone	Bakris et al., 1998; Vivian & Goebig, 2001	**II-2**	**Fair**	**B**
5	Diuretics to enhance the BP lowering effects of other antihypertensive agents	Brenner et al., 2001; Curb et al., 1996; Lewis et al., 2001; Lindholm et al., 2002	**I**	**Good**	**A**

Evidence – Therapeutic Cautions

	Recommendation	Sources	Quality of Evidence (QE)	Overall Quality	Recommendation Grade (R)

	Recommendation	Sources	Quality of Evidence (QE)	Overall Quality	Recommendation Grade (R)
1	Use caution in prescribing long-acting dihydropyridine calcium channel blockers (DHCCBs) without an ACEI or ARB because of the risk of less renal protection and/or adverse cardiovascular outcomes	Estacio et al., 1998; Lewis et al., 2001; Opie & Schall, 2002; Pahor et al., 2000; Tatti et al., 1998	**I**	**Good**	**A**

Summary of the Management of Lipids in Diabetes Mellitus

For complete management of lipids see: VA/DoD Clinical Practice Guideline for the Diagnosis and Management of Dyslipidemia in the Primary Care Setting at www.oqp.med.va.gov/cpg/cpg.htm or www.qmo.amedd.army.mil.

Diabetes Patient With No Lipids Evaluation Within One Year Or Elevated Cholesterol Or Lipids

Recommendations

1. Patients with diabetes and patients with established coronary heart disease (CHD) should be screened for lipid abnormalities. A fasting lipid profile is required at least once every two years (triglycerides and HDL-C or LDL-C).
2. All patients with diabetes should be given lifestyle counseling. Lifestyle change is indicated in all patients with LDL-C >100 mg/dL. Strategies include diet (dietary/nutritional management of fat and/or cholesterol intake or medical nutrition therapy [MNT] consult), exercise, smoking cessation, cessation of excessive use of alcohol, and weight control.
3. Patients with diabetes with elevated triglyceride (TG) level should receive drug therapy. Elevated TG level (>400 mg) may be due to poor glycemic control. The most common secondary causes of hypertriglyceridemia are alcohol, diabetes, and hypothyroidism. Addressing these underlying conditions can improve or normalize triglyceride levels and failing to address these conditions can render therapy ineffective. Once glycemic control is improved, the TG level should be reassessed.

4. Patients with diabetes who do not reach LDL target and whose LDL-C level is >130 mg/dL should begin pharmacotherapy.

Dyslipidemia Drug Therapy Recommendations

Lipid Disorder	Monotherapy	Efficacy		Considerations
LDL-C Initial	Statins	LDL -22 to -60%		• Use statins with caution in hepatic disease. • Niacin is contraindicated in hepatic disease and relatively contraindicated in DM, gout, and history of complicated/active peptic ulcer disease. • Resins may increase TG.
Alternate	Niacin	-13 to -21%		
	Bile acid resin (resin)	-10 to -20%		
LDL-C and TG Initial	Niacin	LDL -13 to -21%	TG -10 to -24%	• For high TG, use fibrates or niacin. • For high LDL, use statins.
	or statin	-22 to -60%	-06 to -37%	
Alternate	Fibrates	+10 to -35%	-32 to -53%	
LDL and HDL	Niacin	LDL -13 to -21%	HDL +10 to +24%	• No preferences in terms of efficacy.
	or statin	-22 to -60%	+2 to +12%	
	or fibrates	+10	+2 to	

Lipid Disorder	Monotherapy	Efficacy		Considerations
		to -35%	+34%	
TG 400–1000 mg/dL	Consider gemfibrozil if HDL-C < 40 mg/dL[a]			• For high TG, use direct LDL-C measurement or non-HDL-C as lipid disorder to guide therapy.

Adapted from PBM-MAP, 1997.
[a] Rubins et al., 1999.

For CHD/Atherosclerotic Cardiovascular [ASCVD] Patients

For patients with known CHD/ASCVD who have HDL <40 mg/dL, pharmacotherapy with gemfibrozil is recommended (Rubins et al., 1999).

Dyslipidemia Drug Therapy Recommendations

Lipid Disorder	Monotherapy	Efficacy		Considerations
LDL-C >130 mg/dL and HDL-C <40 mg/dL	Gemfibrozil	LDL +10 to –35%	HDL +2 to 34%	• Outcome data for secondary prevention only.

Adapted from PBM-MAP, 1997.

Evidence

	Recommendation	Sources	Quality of Evidence (QE)	Overall Quality	Recommendation Grade (R)
1	Lifestyle modification	Ebrahim & Davey	**I**	**Good**	**A**

	Recommendation	Sources	Quality of Evidence (QE)	Overall Quality	Recommendation Grade (R)
		Smith, 1999; Wilson et al., 1998			
2	Primary prevention	Downs et al., 1998; Shepherd et al., 1995	**I**	**Good**	**A**
3	Secondary prevention	"Randomised trial of cholesterol lowering," 1994; Canner et al., 1986; Frick et al., 1987; Leng, Price, & Jepson, 2000; "Executive summary of the Third Report," 2001; Campeau et al., 1997; Sacks et al., 1996	**I**	**Good**	**A**
4	Treatment of low HDL	Gordon et al., 1989; Rubins et al., 1999	**I**	**Good**	**A**

Module S – Screening And Prevention

A. **Screening for Diabetes Mellitus**

Objective

Diagnose type 2 diabetes mellitus (DM) at a stage early enough that effective treatment can minimize the risk of severe microvascular and macrovascular complications.

Recommendations

1. Screening for DM, at 1 to 3 year intervals, should be considered at 1 to 3 year intervals in adults age ≥45.
2. Screening younger non-pregnant adults who have hypertension or dyslipidemia or multiple other recognized risk factors for diabetes should be considered. Risk factors include history of impaired glucose tolerance (IGT), BMI >25 kg/m2, sedentary lifestyle, first-degree relative with DM, history of gestational DM or large (>9 lb) birth weight infants, hypertension, HDL cholesterol <35 mg/dL (0.90 mmol/l) and/or fasting serum triglycerides >250 mg/dL (2.82 mmol/l), history of polycystic ovarian syndrome, member of a high risk ethnic population, IGT or IFG on previous testing, or other clinical conditions associated with insulin resistance.
3. Fasting plasma glucose (FPG) is the preferred screening test for DM and is also a component of diagnostic testing. DM is diagnosed if the value is ≥126 mg/dL on at least two occasions (see Module D, Annotation A). A normal FPG is <110 mg/dL. An FPG ≥110 and <126 mg/dL (7.0 mmol/l) is an indication for retesting, which should be done on a different day.
4. Although not recommended as a first-line screening test, casual non-fasting plasma glucose >200 mg/dL (on at least two occasions) is sufficient to diagnose DM, and <110 mg/dL is sufficient to exclude it. Random (non-fasting) plasma glucose in the range 111 to 199 mg/dL should be followed up with a fasting plasma glucose.
5. Lifestyle modification in patients with impaired fasting glucose (IFG)/impaired glucose tolerance (IGT) should be considered.

Evidence

	Recommendation	**Sources**	**Quality of Evidence (QE)**	**Overall Quality**	**Recommendation Grade (R)**
1	Screening of high risk persons >age 45 for DM	"The cost-effectiveness of screening," 1998; Rao, 1999; Tuomilehto et al., 2001	**II-2**	**Good**	**C**
2	Screening of persons age <45	ADA, 2002; Working	**III**	**Fair/Poor**	**C**

	Recommendation	Sources	Quality of Evidence (QE)	Overall Quality	Recommendation Grade (R)
	with DM risk factors	Group Consensus			
3	Screening using fasting plasma glucose (FPG) test	ADA, 2002; Engelgau, Narayan, & Herman, 2000	**III; II-3**	**Fair**	**B**

Prevention of Diabetes

Objective

Prevent or delay the onset of type 2 DM in high risk patients.

Recommendations

1. Patients with IGT (i.e., a FPG >110 mg/dL and <126 mg/dL) should be counseled about prevention of DM. Intensive lifestyle interventions to prevent diabetes include both regular aerobic exercise and a calorie-restricted diet to promote and maintain weight loss.
2. Patients with a BMI >25 are at high-risk for DM and should achieve and sustain weight loss of 5 percent or more.
3. Modification of lifestyle may be beneficial for all patients and may be considered in patients with risk factors for diabetes (other than IGT).

Evidence

	Recommendation	Sources	Quality of Evidence (QE)	Overall Quality	Recommendation Grade (R)
1	Weight loss and exercise counseling of patients with FPG ≥110	Working Group Consensus	**III**	**Poor**	**I**
2	Diet and exercise leading to weight loss to slow progression to	Knowler et al., 2002; Tumilehto	**I**	**Good**	**A**

	Recommendation	Sources	Quality of Evidence (QE)	Overall Quality	Recommendation Grade (R)
	diabetes	et al., 2001; Pan et al., 1997			
3	Weight loss for patients with a BMI >25	Knowler et al., 2002; Tumilehto et al., 2001; Pan et al., 1997	**I**	**Good**	**A**
4	Lifestyle modification for patients with other risk factors	Field et al., 2001; Manson et al., 1992	**II-2**	**Fair**	**B**

Algorithm - Glycemic Control

Module G - Glycemic Control

A. **Patient with Diabetes Mellitus**

Every patient with diabetes mellitus (DM), regardless of its duration, needs to negotiate with his or her provider an appropriate target glycemic goal and then plan a treatment strategy to achieve this goal.

Glycemic control should be reevaluated at every regular interim visit or in the context of visits that relate to other concurrent problems that could affect glycemic control.

B. **Assess Glycemic Control**

Objective

Determine the patient's current level of glycemic control

Recommendations

1. HbA_1c should be measured periodically to assess glycemic control over time.

2. Postprandial plasma glucose (PPG) level should be assessed in patients with:
    a. Elevated HbA_1c (not at target) but a normal fasting plasma glucose level
    b. Frequent troublesome hypoglycemic symptoms during waking active hours
3. The PPG level should be used to modify the therapy. (Working Group Consensus) (**QE – III, Overall Quality – Poor, R – I**)

C. **Determine Recommended Glycemic Control Target Using Risk Stratification Criteria**

Objective

Determine the recommended target based on the patient's absolute risk for developing microvascular complications.

Recommendations

1. Each patient's glycemic target range must be individualized, based on the provider's appraisal of the risk-benefit ratio for that individual.
2. HbA_1c target for any patient with diabetes should be kept <9 percent to avoid symptoms of hyperglycemia.
3. The patient with very mild or no microvascular complications of diabetes, and who is free of major concurrent illnesses and with a reasonable life expectancy, should have an HbA_1c target of <7 percent.
4. The patient with advanced microvascular complications and/or major comorbid illness or short life expectancy is less likely to show survival benefit; therefore, aggressive glucose lowering may not be warranted.
5. Risk of hypoglycemia should be considered in recommending a target goal.

Evidence

	Recommendation	**Sources**	**Quality of Evidence (QE)**	**Overall Quality**	**Recommendation Grade (R)**
1	Progression to nonproliferative retinopathy	Delahanty, Simkins & Camelon, 1993; Klein, 1995; Ohkubo et al., 1995	**I**	**Good**	**A**
2	Progression to	Klein et	**I**	**Fair**	**B**

	Recommendation	Sources	Quality of Evidence (QE)	Overall Quality	Recommendation Grade (R)
	proliferative retinopathy	al., 1994			
3	Progression to microalbuminuria	Delahanty, Simkins & Camelon, 1993, Kawazu et al., 1994; Krolewski et al., 1995; Ohkubo et al., 1995	**I**	**Good**	**A**
4	Progression to proteinuria	Delahanty, Simkins & Camelon, 1993; Ohkubo et al., 1995	**I**	**Good**	**A**
5	Progression to blindness	Delahanty, Simkins & Camelon, 1993; Ohkubo et al., 1995	**I**	**Good**	**A**
6	Progression to end-stage renal disease	Delahanty, Simkins & Camelon, 1993; Klein, 1995 Ohkubo et al., 1995	**I**	**Fair**	**B**
7	Progression to neuropathy	Delahanty, Simkins & Camelon, 1993; "Effect of intensive diabetes,"	**I**	**Good**	**A**

	Recommendation	Sources	Quality of Evidence (QE)	Overall Quality	Recommendation Grade (R)
		1995			
8	Progression to amputations	Klein et al., 1994; Mayfield et al., 1996	**I**	**Fair**	**B**
9	Myocardial infarction, stroke	Abraira et al., 1997; Anderson et al., 1995; Delahanty, Simkins & Camelon, 1993; Klein, 1995; Ohkubo et al., 1995; Singer et al., 1992	**I**	**Good**	**A**
10	Effect of DM on life expectancy	Goodkin, 1975; Panzram, 1987; Singer et al., 1992	**I**	**Fair**	**B**
11	Duration of DM and incidence of end-stage microvascular complications	Humphrey et al., 1989; Klein et al., 1994; Klein, 1995; Palmberg et al., 1981; UKPDS 16, 1995	**I**	**Fair**	**B**
12	Effect of ethnicity	Haffner et	**II-1**	**Fair**	**B**

	Recommendation	Sources	Quality of Evidence (QE)	Overall Quality	Recommendation Grade (R)
	on glycemic target levels	al., 1988; Hamman et al., 1989; Lee et al., 1992; Nelson et al., 1988; Rabb, Gagliano, & Sweeney, 1990			
13	Preexisting retinopathy or microalbuminuria as a risk factor for progression	Delahanty, Simkins & Camelon, 1993; Ohkubo et al., 1995	**I**	**Good**	**A**
14	Progression to microvascular complication (primary laser therapy)		**I**	**Good**	**A**

Determination of Target HbA_1c Level

Major Comorbidity (d) or Physiologic Age	Microvascular Complications		
	Absent or Mild (a)	**Moderate (b)**	**Advanced (c)**
Absent (>15 years of life expectancy)	7 percent (<1 percent above upper normal range)	<8 percent (<2 percent above upper normal range)	<9 percent (<3 percent above upper normal range)
Present (e) 5 to 15 years of	<8 percent (<2 percent	<8 percent (<2 percent	<9 percent (<3 percent

Major Comorbidity (d) or Physiologic Age	Microvascular Complications		
	Absent or Mild (a)	**Moderate (b)**	**Advanced (c)**
life expectancy	above upper normal range)	above upper normal range)	above upper normal range)
Marked (f) <5 years of life expectancy	<9 percent (<3 percent above upper normal range)	<9 percent (<3 percent above upper normal range)	<9 percent (<3 percent above upper normal range)

a. Mild microvascular disease is defined by early background retinopathy, and/or microalbuminuria, and/or mild neuropathy.
b. Moderate microvascular disease is defined by preproliferative (without severe hemorrhage, intraretinal microvascular anomalies [IRMA], or venous bleeding) retinopathy or persistent, fixed proteinuria (macroalbuminuria) and/or demonstrable peripheral neuropathy (sensory loss).
c. Advanced microvascular disease is defined by severe nonproliferative (with severe hemorrhage, IRMA, or venous bleeding) or proliferative retinopathy and/or renal insufficiency (serum creatinine level >2.0 mg/dl) and/or insensate extremities or autonomic neuropathy (e.g., gastroparesis, impaired sweating, orthostatic hypotension).
d. Major comorbidity includes, but is not limited to, any or several of the following conditions: cardiovascular disease, chronic obstructive pulmonary disease, chronic liver disease, stroke, and malignancy.
e. Moderate degree of major comorbid condition
f. Severe degree or end-stage major comorbid condition

D. **Adjust the Glycemic Target According to Patient's Factors**

Objective

Ensure that the recommended target value for HbA_1c can be safely achieved by the patient, taking into consideration individual risk, benefit, and preference

Recommendations

1. Risks of a proposed therapy should be balanced against the potential benefits, based upon the patient's medical, social, and psychological status.

E. **Set a Glycemic Target Range After Discussion with Patient**

Objective

Establish the patient's readiness and willingness to achieve the target.

Recommendations

1. A specific target range of glycemic control should be negotiated by the patient and provider after discussing the risks and benefits of therapy.
2. If necessary, the patient should be referred to an endocrine/diabetes clinic or a case manager to meet glycemic control target goals.

F. **Is Patient High Risk?**

Objective

Identify the high risk patient for whom subspecialty consultation would be appropriate to assist in the development of a treatment plan and/or to supervise ongoing care.

Recommendations

1. The patient with HbA_1c >9.5 percent should be considered for aggressive management on an expedited basis.
2. The patient who is on high-dose multiple agents should be considered for referral.

High risk DM patients include those who:

- Have type 1 DM (especially patients with history of hospitalizations for metabolic complications and/or patients who are receiving intensive insulin therapy)
- Have recurrent episodes of incapacitating hypo- and/or hyperglycemia
- Have poor recognition of hypoglycemia and who have history of severe hypoglycemic reactions (including coma, seizures, or frequent need for emergency resuscitation)
- Have new-onset insulin-requiring DM
- Have visual and/or renal impairment
- Have psychosocial problems (including alcohol or substance abuse) that complicate management
- Have HbA_1c >9.5 percent

G. **Does Patient Require Insulin?**

Objective

Identify the patients for whom insulin treatment is the only viable alternative.

Recommendations

1. The patient with type 1 DM should receive insulin replacement therapy.
2. The patient with type 2 DM or DM of undetermined cause who exhibits significant or rapid weight loss and/or persistent nonfasting ketonuria

has at least severe relative insulin deficiency and will likely require insulin therapy on an indefinite basis.

H. **Institute/Adjust Insulin, Consider Referral**

Objective

Improve/achieve glycemic goals using insulin.

Recommendations

1. All patients with type 1 DM should be referred to a diabetic clinic with multidisciplinary resources (e.g., diabetologist, diabetic nurse, educator/manager, and registered dietitian) for institution and adjustment of insulin therapy.
2. If expeditious referral is not possible, the primary care provider should institute "survival" insulin therapy.
    - Calculate total daily dose (TDD) of 0.5 units/kg body weight/day.
    - Two-thirds of the TDD administered 30 minutes prior to breakfast as two parts human neutral protamine Hagedorn insulin (NPH) insulin and one-part human regular insulin.
    - The remaining third of the TDD can be split equally, as human regular insulin 30 minutes before supper and as human NPH insulin at bedtime.

See Annotation J-3 of the original document, Insulin Therapy.

I. **Assure Appropriate Intervention to Address Patient Adherence**

Objective

Assure proper patient monitoring and contact with the health care team.

Recommendations

1. Patients with diabetes should be assessed for knowledge, performance skills, and barriers to full compliance.
2. If psychosocial, personal, or financial barriers are identified, additional resources should be consulted, as applicable (e.g., mental health, medical social work, or financial counselors).

J. **Initiate/Adjust Therapy**

Objective

Achieve glycemic target goals by the most cost effective and least invasive means.

Recommendations

1. Individual treatment goals must be established with the patient based on the extent of the disease, comorbid conditions, and patient preferences.
2. Institution of diet and exercise is usually the appropriate initial management in patients with new onset type 2 diabetes, depending upon severity of symptoms, psychosocial evaluation, and overall health status. Encourage diet and exercise and lifestyle modification.
3. If treatment goals are not achieved with diet and exercise alone, drug therapy should be initiated.
4. There is no evidence that blood glucose monitoring in stable type 2 DM patients is of clinical benefit. If self-monitoring is to be done, a twice-weekly regimen is usually sufficient. Special situations, such as acute intercurrent illness, frequent hypo- or hyperglycemia, or changes in medication regimen, may justify more frequent monitoring on a temporary basis.

The concept of sequential treatment is commonly employed in clinical management of chronic diseases. The sequential steps for glycemic control therapy are summarized in following Table and in Diagram G1 in the original guideline document.

Sequential Treatment for Type 2 DM

Therapy	**Drugs**	**Expected reduction in HbA1c Over a 2 to 3 month period of follow-up**
Lifestyle modification, diet and exercise	None	
Lifestyle modification, diet and exercise, and Monotherapy with oral agent or insulin	Sulfonylurea or biguanide	1 to 2 percent
Lifestyle modification diet and exercise, and Combination (add a second oral agent)	Sulfonylurea + biguanide Sulfonylurea/biguanide + alpha-glucosidase inhibitor Sulfonylurea/biguanide + thiazolidinedione Biguanide + repaglinide/nateglinide	1 to 2 percent 0.5 to 1 percent 0.7 to 1.75 percent 0.1 to 0.3 percent
Insulin with oral agent	Biguanide + insulin	0.2 to 2.6 percent

Therapy	Drugs	Expected reduction in HbA1c Over a 2 to 3 month period of follow-up
	Thiazolidinedione + insulin Sulfonylurea + insulin	
Insulin	Insulin alone	2 percent
Referral	None	--

J.1 Monotherapy

Recommendations

1. Sulfonylurea as first line for most patients. (Inzucchi, 2002; Johansen, 1999) (**QE – I, Overall Quality – Fair, R – B**)
2. Metformin as first line for overweight patients. (Johansen, 1999; "Effect of intensive blood-glucose," 1998) (**QE – I, Overall Quality – Good, R – A**)
3. Glitazones not preferred as monotherapy. (Chilcott et al., 2001; Ebeling et al., 2001; Malinowski & Bolesta, 2000; Nakamura et al., 2000) (**QE – I, II-1, I, II-1; Overall Quality – Fair; R – B**)

See Appendix G3 of the original document, Pharmacological Therapy.

J.2 Combination Therapy

Recommendations

1. Metformin as add-on therapy to sulfonylurea for failed sulfonylurea treatment, if not contraindicated. (Kirk et al., 1999; "Effect of intensive blood-glucose," 1998) (**QE – I, Overall Quality – Fair, R – B**)
2. Insulin as add-on therapy, if the patient is not within 1.5 percent of the target range. (Raskin et al., 2001; Rosenstock et al, 2002) (**QE – I, Overall Quality – Fair, R – B**)

J.3 Insulin Therapy

Recommendations

1. The patient with type 1 DM should receive insulin replacement therapy.

2. The care of patients with type 1 DM should be individualized, in consultation with a multidisciplinary diabetes care team. If expeditious consultation is not possible, the primary care provider should institute "survival" insulin therapy:
    a. Calculate a total daily dose (TDD) of 0.5 units/kg body weight/day.
    b. Two-thirds of the TDD administered 30 minutes prior to breakfast as two parts human neutral protamine Hagedorn insulin (NPH) insulin and one-part human regular insulin.
    c. Remaining third of the TDD can be split equally, as human regular insulin 30 minutes before supper and as human NPH insulin at bedtime
3. On at least a temporary basis, the use of intermediate- or long-acting insulin for controlling fasting plasma glucose, alone or in addition to oral agents, should be considered for patients with type 2 DM in whom:
    a. Oral agents have proven ineffective, intolerable, or are contraindicated.
    b. Rapid restoration of euglycemia is desirable (e.g., the patient with persistent symptoms of diabetes or with hyperglycemia in perioperative and/or critical care settings).
    c. Pregnancy is desired or has already occurred.
    d. HbA_1c is >1.5 percent above target.
    e. Relative insulin deficiency is suggested by weight loss and persistent, non-fasting ketosis.
4. Although the available intermediate- and long-acting forms of insulin include lente, ultralente, and glargine, NPH should be considered for most patients needing insulin to control fasting hyperglycemia.
5. Insulin glargine may be considered in the following settings:
    a. In the insulin-treated patient with frequent, severe nocturnal hypoglycemia
    b. As a basal insulin for patients on multiple daily insulin injections
6. In patients treated with insulin, regular insulin is recommended for most patients that require mealtime coverage.
7. Dietary counseling and individualized education should accompany initiation or change of mealtime insulin in response to hyperglycemia or hypoglycemia.
8. In patients treated with insulin, alternatives to regular insulin include aspart and lispro and should be considered in the following settings:
    a. Demonstrated requirement for pre-meal insulin coverage due to postprandial hyperglycemia AND concurrent frequent hypoglycemia
    b. Patients using an insulin pump (Note: aspart is FDA-approved for use in an insulin pump: satisfactory outcomes have also been reported using lispro in pumps.)

Evidence

	Recommendation	Sources	Quality of Evidence (QE)	Overall Quality	Recommendation Grade (R)
1	Individualized care, in consultation with a diabetes care team for patients with type 1 DM	Working Group Consensus	**III**	**Poor**	**I**
2	Intermediate- or long-acting insulin to control testing plasma glucose	Gerich, 2002	**II-2**	**Fair**	**B**
3	NPH for most patients	Pieber, Eugene-Jolchine, & Derobert, 2000; Raskin et al., 2000; Ratner et al., 2000; Rosenstock, Park, & Zimmerman, 2000; Yki-Jarvinen, Dressler, & Ziemen, 2000	**II-1**	**Good**	**B**
4	Insulin glargine in consultation with a diabetes specialist	Working Group Consensus	**III**	**Poor**	**I**
5	Insulin glargine for frequent or severe nocturnal hypoglycemia	Ratner et al, 2000; Rosenstock et al., 2001; Yki-Jarvinen, Dressler, & Ziemen, 2000	**II-1**	**Good**	**B**
6	Insulin glargine for	Working	**III**	**Poor**	**I**

	Recommendation	Sources	Quality of Evidence (QE)	Overall Quality	Recommendation Grade (R)
	a multiple injection alternative	Group Consensus			
7	First-line regular insulin	Home et al., 1998; Home, Lindholm, & Riis, 2000; Raskin et al., 2000; Tamas et al., 2001	**I**	**Fair**	**B**
8	Short-acting insulin analog use for postprandial hyperglycemia with concurrent frequent hypoglycemic events on regular insulin therapy	Home et al., 1998; Home, Lindholm, & Riis, 2000; Raskin et al., 2000; Tamas et al., 2001	**I**	**Fair**	**B**
9	Insulin analogs for pump therapy	Bode & Strange, 2001; Hanaire-Broutin et al., 2000; Raskin et al., 2001	**I**	**Fair**	**B**

K. **Determine If There Are Side Effects or Contraindications to Current Treatment**

Objective

Modify therapy due to side effects of drug therapy.

Recommendations

1. The patient with recurrent or severe hypoglycemia should be evaluated for precipitating factors that may be easily corrected (e.g., missed meals, exercise, incorrect administration of insulin-dosage or timing).

See Appendix G3 of the original document, Pharmacological Therapy.

L. Are There Problems with Patient Adherence?

Objective

Identify barriers to full adherence to the prescribed treatment regimen.

Recommendations

1. If the patient does not achieve his/her target range, the provider should identify barriers to patient adherence to the treatment regimen (e.g., miscommunication, lack of education or understanding, financial/social/psychological barriers, and cultural beliefs).
2. If barriers are identified, referral to a case manager or behavioral/financial counselor should be considered as appropriate.

See Module M, Appendix M-6, Patient Self-management and Knowledge Needs Assessment, in the original guideline document.

M. Should Glycemic Control Target Be Adjusted?

Objective

Determine whether the recommended glycemic control goal remains appropriate for the patient.

Recommendation

1. Treatment goals should be periodically reassessed based upon patient specific factors, including changes in the patient's health status, adverse drug reactions, adherence to therapy, and preferences.

N. Follow-Up

Objective

Maintain glycemic control and ensure proper patient monitoring by the health care team.

Recommendations

1. The patient should be scheduled for appropriate follow-up to evaluate response, tolerability to therapy, goal reassessment, and management of acute and chronic problems.
2. The frequency of primary care provider visits for the patient with diabetes who is meeting treatment goals and who has no unstable chronic complications should be individualized.

3. When there is a sudden change in health status or when changes are made to the treatment regimen, follow-up within one month or sooner may be appropriate.

Algorithm – Kidney Function

Module R - Kidney Function

A. **Patient with Diabetes Mellitus And No Kidney Evaluation in the Past 12 Months**

Patients with type 1 diabetes mellitus (DM) should be screened for kidney disease after puberty and at a minimum of every five years. Patients with type 2 DM should be screened for kidney disease at the time of DM diagnosis, since the onset of type 2 DM occurs on average 10 years before a clinical diagnosis is made (Harris, 1995).

Patients being treated with an angiotensin converting enzyme inhibitor (ACEI) or angiotensin receptor blocker (ARB), because of either a prior diagnosis of microalbuminuria (or other medical problems such as CHF or hypertension), may still require an annual assessment of their kidney function to monitor onset or progression of their nephropathy and adjust treatment accordingly. For example, the new onset of nephropathy in a patient with diabetes and hypertension on ACEI might prompt a lower blood pressure control goal for that individual patient.

Recommendation/Evidence

1. Annual reevaluations of life expectancy. (Working Group Consensus) (**QE – III, Overall Quality – Poor, R – I**)
2. If probable life expectancy has increased significantly from the previous year (due to improvements in comorbidities), consider the appropriateness of screening for nephropathy. (Bennet et al., 1995; Gall et al., 1991; Mogensen, 1987; Ordonez & Hiatt, 1989) (**QE – II-1, Overall Quality – Poor, R – C**)

B. **Screen For Microalbuminuria: Measure Albumin-To-Creatinine Ratio In A Random Spot Urine OR 24-Hour Urine Collection For Protein And Creatinine**

Objective

Quantify the amount of proteinuria.

Recommendations

1. Patients with diabetes who have a probable life expectancy of >5 years should be screened for elevated urinary albumin or protein excretion using the cut-points adopted [Table R-1 below] from the American Diabetes Association.

2. The use of urine "strips" is not the recommended screening method, because they do not take into account possible errors resulting from alterations in urine concentration.
3. The preferred method for nephropathy screening is a random spot urine sample to measure the albumin-to-creatinine ratio. A 24-hour urine collection for protein and creatinine may also be used, but is more cumbersome for patients and prone to collection errors.
4. Because of variability in urinary albumin excretion, two of three specimens collected within a 3- to 6-months period should be abnormal before diagnosing microalbuminuria.
5. Heavy exercise (within 24 hours of urine collection), urinary tract infection, acute febrile illnesses, and heart failure may transiently increase urinary albumin excretion and thus, screening should be postponed in these situations to avoid false positive determination. Patients should be instructed not to exercise the day before providing a urine specimen.
6. The Working Group does not recommend stopping an ACEI or ARB prior to screening, even though these drugs may decrease urinary albumin excretion.

Table R-1. Definitions of Abnormalities in Albumin Excretion. (ADA, 2002)

Condition	24-Hour Urine Collection (mg/24h)	Random Urine Alb/Cr Ratio (micrograms/mg creatinine)	Timed Urine Collection (micrograms/min)
Normal	≤30	<30	≤20
Microalbuminuria	30–300	30–300	20–200
Macroalbuminuria	≥300	≥300	≥200

Evidence

	Recommendation	Sources	Quality of Evidence (QE)	Overall Quality	Recommendation Grade (R)
1	Strip testing (not recommended)	Kouri et al., 1991	**II**	**Fair**	**B**
2	A random urine for protein/Cr ratio or Alb/Cr ratio	Ginsberg et al., 1983; Rodby et	**II**	**Fair**	**B**

	Recommendation	Sources	Quality of Evidence (QE)	Overall Quality	Recommendation Grade (R)
		al., 1995; Toto et al., 1997			
3	Postponement of urinary screening for albuminuria if patient has done heavy exercise or has a UTI, acute febrile illness, or heart failure	ADA, 1997; Bennett et al., 1995	**III**	**Poor**	**I**
4	Stopping an ACE inhibitor prior to urinary screening (not recommended)	Working Group Consensus	**III**	**Poor**	**I**

C. **Obtain Serum Creatinine And Estimate Glomerular Filtration Rate (eGFR)**

Objective

Detect presence of reduced kidney function, and identify patients at risk for progressive kidney failure, uremic complications, and high risk for cardiovascular disease.

Recommendation

1. Serum creatinine level should be used to estimate the GFR to identify patients at risk and develop appropriate management plans.

D. **Is Urine Alb/Cr >30 mg/mg Confirmed?**

Objective

Establish a diagnosis of early diabetic nephropathy and ensure that albuminuria is persistent, not transient, before committing the patient to treatment.

Recommendations

1. Patients with diabetes with urine albumin/creatinine levels of ≥30 mg/mg in the random specimen should repeat the test to ensure that the level was not transiently elevated (by heavy exercise, urinary tract infection, acute febrile illness, or heart failure).
2. If a second test is ≥30 mg/mg, the patient has persistent microalbuminuria; if the second test is <30mg/mg, repeat the test a third time.

Evidence

	Recommendation	Sources	Quality of Evidence (QE)	Overall Quality	Recommendation Grade (R)
1	Multiple urinary measurements	Murray, 1996	**I**	**Fair**	**B**
2	Urine Alb/Cr ration ≥30 mg/mg—screening criteria for microalbuminuria	ADA, 2002; Bennett et al., 1995	**II**	**Fair**	**B**

E. **Is Urine Alb/Cr ratio >300 mg/mg or 24-Hour Urine Protein >300 mg/24 h?**

Objective

Help distinguish diabetic from nondiabetic kidney nephropathy.

Recommendation

1. Persons with diabetes and macroalbuminuria (i.e., urine Alb/creatinine ratio ≥300 mg/mg or 24-hour urine protein ≥300 mg/d) should be assessed for level of kidney function as these levels of albuminuria indicate established to advanced diabetic renal disease.

F. **Is Diabetic Nephropathy Suspected? (Can a Nondiabetic Kidney Disease Be Excluded?)**

Objective

Collect additional evidence confirming the diagnosis of diabetic nephropathy. Clinicians should assess whether the patient has had the typical course and features of diabetic kidney disease.

Recommendations

1. Document the course of the albuminuria. It would be unusual to go from having normal urine to macroalbuminuria in less than one year in diabetic kidney disease.
2. Document that blood pressure has been rising. As diabetic kidney disease progresses from micro to macroalbuminuria, the blood pressure usually rises.
3. Document the presence of other diabetic complications such as retinopathy. All patients with diabetes with macroalbuminuria should undergo an eye exam to confirm the diagnosis of retinopathy (findings include microaneurysm, flame hemorrhage, and soft/hard exudates) (see Module E, Eye Care) because >90 percent of patients with macroalbuminuria from diabetes will also have at least mild retinopathy.
4. If the course has been atypical (i.e., rapidly progressive or no evidence of retinopathy), refer or consult with nephrology for further work-up.

G. **Is Serum Creatinine >1.4 mg/dL Or eGFR <60 mL/min (Kidney Function Abnormal)?**

Objective

Evaluate individuals with reduced kidney function to identify potential etiologies for kidney disease other than diabetes.

Recommendations

1. Consider alternative explanations for reduced kidney function including prerenal, renal, and postrenal causes.
2. Obtain renal ultrasound in all patients with reduced kidney function except those whose reduced kidney function is easily resolved.
3. Consider obtaining other tests and referral to specialists in nephrology or urology as indicated.

H. **Refer to Nephrology**

Objective

Obtain consultation from a nephrologist regarding the need for further work-up, potentially including renal biopsy

Recommendation

1. Primary care providers should consult with or refer to a nephrologist when a patient has macroalbuminuria with normal creatinine but other features inconsistent with the sole diagnosis of diabetic nephropathy. These atypical features include absence of diabetic retinopathy on dilated eye exam, rapidly progressive course, short duration of diabetes, small kidneys on ultrasound, red blood cell casts in the urine, and/or lack of increase in blood pressure concurrent with increasing albuminuria.

2. Patients with diabetes with reduced kidney function may have electrolyte disturbances, anemia, or bone disease. Also, these patients´ kidney failure may progress and they may need dialysis or evaluation for renal transplantation. For these reasons, an initial evaluation by nephrology for confirmation of diagnosis, optimal management of kidney disease, and appropriate timing of dialysis access is recommended for patients with chronic kidney disease or for acute kidney disease that does not rapidly resolve (see the VA/DoD Clinical Practice Guideline on Pre-ESRD). (Working Group Consensus) (**QE – III, Overall Quality – Poor, R – I**)

I. **Start/Adjust Treatment With ACEI; If Adverse Effects To ACEI, Change To ARB; Check Serum Potassium Prior To Starting ACEI and Repeat In 2 To 4 Weeks**

Objective

Reduce albuminuria and ensure that ACEIs or ARBS do not induce or aggravate hyperkalemia.

Recommendation

1. Start/adjust treatment with ACEIs.

Evidence

	Recommendation	Sources	Quality of Evidence (QE)	Overall Quality	Recommendation Grade (R)
1	Begin ACEI treatment with onset of persistent microalbuminuria in both Type 1 and 2 diabetic patients, even in the absence of hypertension.	Lovell, 2001	**I**	**Good**	**A**
2	Check serum potassium and creatinine prior to starting ACEI and in 2 to 4 weeks.	Bennett et al., 1995	**II-2**	**Fair**	**C**

J. **Is HbA1c >8% Or Blood Pressure >140/80?**

Objective

Identify persons who may benefit from intensified blood pressure management.

Recommendation

1. If the patient´s macroalbuminuria is not improving, or diabetes and/or blood pressure is not controlled, consider a change in treatment.

Evidence

	Recommendation	Sources	Quality of Evidence (QE)	Overall Quality	Recommendation Grade (R)
1	Patients with diabetes with elevated serum creatinine and/or urinary protein excretion above 1 gm/d may benefit from lower BP targets (<125/75 mm Hg) to slow the progression of renal disease.	Lazarus et al., 1997	**II-2**	**Fair**	**B**
General Therapeutic Recommendations					
2	Antihypertensive therapy for patients with diabetes with BP >140/80 mm Hg should start with ACEI. Switch to ARB if ACEI-induced side-effects occur, then use other agents to achieve BP target <140/80 mm Hg.	Andersen et al., 2000; Hansson et al, 1998; "Effects of ramipril," 2000; Lacourciere et al., 2000; Lindholm et al., 2002; Mogensen et al., 2000; Muirhead	**I**	**Good**	**A**

	Recommendation	Sources	Quality of Evidence (QE)	Overall Quality	Recommendation Grade (R)
		et al., 1999; Nielsen et al., 1997			
Specific Therapeutic Recommendations					
3	ACEI should be used in normotensive patients with type 1 DM and proteinuria, and in patients with type 2 DM and microalbuminuria or a high risk for cardiovascular disease.	"Effects of ramipril," 2000; Lewis et al., 1993	**I**	**Good**	**A**
4	Consider ACEI for normotensive patients with type 1 DM	Laffel, McGill, & Gans, 1995; Viberti et al., 1994	**I**	**Fair**	**B**

K. **Monitor Urine Protein-To-Creatinine Ratio And Estimated GFR; Adjust Treatment And Follow-Up Annually**

Objective

Decide if kidney disease is progressing on the current regimen that includes ACEI, blood pressure control, and glycemic control.

Recommendations

1. Persons with diabetes should be monitored annually for kidney function (estimated GFR) and protein-to-creatinine ratio.
2. Reevaluate the current treatment regimen (i.e., ACEIs, blood pressure control, and glycemic control) for patients with diabetes with progressing kidney disease.

Evidence

	Recommendation	Sources	Quality of Evidence (QE)	Overall Quality	Recommendation Grade (R)
1	Reevaluation of the current treatment regimen of patients with progressive kidney disease	"Consensus development conference," 1994; ADA, 1995; "Position statement," 1997; ADA, 2002; Bennett et al., 1995; Gall et al., 1991; Ordonez & Hiatt, 1989; Ravid et al., 1993	**II-1; III; II-2; II-1**	**Fair**	**B**
2	Monitor at one year	Working Group Consensus	**III**	**Poor**	**I**

L. **Consider Counseling Patient On Reduced Protein Diet**

Objective

Advise the patient that lowering protein intake may have a positive effect on the progression of his/her kidney disease.

Recommendation

1. Consider counseling patients with diabetes with macroalbuminuria (diabetic nephropathy) to reduce daily dietary protein allowance to 0.8 g-1/kg body wt-1/day-1 (~10 percent of calories).

Evidence

	Recommendation	Sources	Quality of Evidence (QE)	Overall Quality	Recommendation Grade (R)
1	Reduction of daily	ADA,	**II-1**	**Fair**	**C**

	Recommendation	Sources	Quality of Evidence (QE)	Overall Quality	Recommendation Grade (R)
	dietary protein allowance to 0.8 g-1/kg body wt-1/day-1 (~10 percent of calories) in Type 1 DM with macroalbuminuria	2002; Ciavarella et al., 1987; Evanoff et al., 1989; Walker et al., 1989; Waugh & Addlesee, 1997; Zeller et al., 1991	**II** **III**		

M. **Are There Side Effects To ACEI Treatment?**

Objective

Screen the patient for contraindications to ACEI use.

Recommendations

1. Persons with diabetes should be assessed for contraindications to ACEI use.

N. **Stop ACEI Treatment; Change to ARB**

Objective

Ascertain if there are side effects that warrant discontinuation of the ACEI.

Recommendations

1. Change ACEI to ARB if patient has an ACEI-induced cough. Angioedema risk may be lower with ARB vs. ACEI, but providers should use great caution if ARB is prescribed to a patient with a history of angioedema associated with ACEI use.
2. ACEI and ARB may cause similar rates of hyperkalemia and abrupt reduction of kidney function.

Evidence

	Recommendation	Sources	Quality of Evidence (QE)	Overall Quality	Recommendation Grade (R)
1	Switch to ARB if an ACEI-induced cough occurs.	Andersen et al., 2000; Hansson et al, 1998; Lacourciere et al., 2000; Lindholm et al., 2002; Mogensen et al., 2000; Muirhead et al., 1999; Nielsen et al., 1997	**I**	**Good**	**A**

O. **Monitor Random Urine Protein-To-Creatinine Ratio And Serum Creatinine (eGFR) Every 6 Months; Adjust Treatment And Follow-Up, As Indicated**

Objective

Decide whether the kidney disease is progressing on the current dose of ACEI.

Recommendations

1. Patients with diabetes on ACEIs should have a spot urine for Alb/Cr ratio at 6 months from initiation of ACEI.
2. If albuminuria is progressing or the estimated GFR is continuing to decline, consider increasing the ACEI to the maximum recommended dose, while reinforcing glycemic control and a low-protein diet.

Evidence

	Recommendation	Sources	Quality of Evidence (QE)	Overall Quality	Recommendation Grade (R)

	Recommendation	Sources	Quality of Evidence (QE)	Overall Quality	Recommendation Grade (R)
1	Increase ACEI to maximal dose as long as nephropathy is progressing.	Lovell et al., 2001	**I**	**Good**	**A**
2	Add other anti-hypertensives to maximal ACEI dose if nephropathy is still progressing.	ADA, 2002; Parving et al., 2001; UKPDS 39, 1998	**I**	**Good**	**A**

Algorithm - Eye Care

Module E - Eye Care

A. **Has Patient's Vision Changed Recently?**

Objective

Identify patients with diabetes mellitus (DM) in need of urgent referral to an eye care provider.

Recommendation

1. Patients with an acute change in vision (i.e., occurring within a 48–72 hours period) or change in ocular function should be urgently referred to an eye care provider.

B. **Reassess Need for Eye Examination within One Year**

Objective

Establish the timing of the initial ocular evaluation for patients with early-onset DM.

Recommendation

Diabetic patients (type 1) with early onset (age <30 years) should begin annual evaluations when the duration of the diabetes diagnosis is greater than 3 years.

Evidence

	Recommendation	Sources	Quality of Evidence (QE)	Overall Quality	Recommendation Grade (R)
1	Annual evaluations to begin when the duration of the diabetes diagnosis is >3 years	Klein et al., "The Wisconsin epidemiologic study of diabetic retinopathy. II & III," 1984; Malone et al., 2001	**I**	**Fair**	**B**

C. **Is Any Ocular Risk Factor Present?**

Objective

Identify patients at risk for advanced retinopathy or rapid progression of preexisting diabetic eye disease.

Recommendations

1. All diabetic patients should be screened for high risk indicators for advanced retinopathy.
2. Patients are defined as high-risk if they have at least one of the following risk factors:
    - DM for 15 years or more
    - Any evidence of diabetes nephropathy (including microproteinuria)
    - Lower extremity amputation related to DM
    - History of any diabetic retinopathy
    - Pregnancy and preexisting diabetes

Evidence

	Recommendation	Sources	Quality of Evidence (QE)	Overall Quality	Recommendation Grade (R)
1	Screening of all diabetic patients	Klein, Klein, & Moss,	**II-2**	**Fair**	**B**

	Recommendation	Sources	Quality of Evidence (QE)	Overall Quality	Recommendation Grade (R)
	for high risk indicators for advanced retinopathy	1992; Klein et al., "The Wisconsin epidemiologic study of diabetic retinopathy. II," 1984; Klein, Moss, & Klein, 1993; Mayfield et al., 1996; Savage et al, 1996			
2	Existence of at least one of the listed risk factors is sufficient to define the patient as high risk.	Working Group Consensus	**III**	**Poor**	**C**

D. **Refer for Eye Examination within 3 Months**

Objective

Ensure that high risk patients are expediently referred.

Recommendations

1. Patients at high risk for ocular complications should receive a comprehensive dilated eye examination within three months of diagnosis by an ophthalmologist or optometrist knowledgeable and experienced in detecting diabetic eye disease.
2. A dilated fundus examination or validated fundus imaging technique should be used to detect retinopathy, with interpretation by a qualified, experienced reader.
3. Retinal imaging techniques cannot substitute for a comprehensive eye exam for other eye problems, when indicated. Periodic comprehensive eye examinations by a trained eye specialist should be scheduled based on the individual patient's risk factors for ocular disease, other than diabetic retinopathy.

Evidence

	Recommendation	Sources	Quality of Evidence (QE)	Overall Quality	Recommendation Grade (R)
1	Comprehensive dilated eye examination within three months of diagnosis by ophthalmologist or optometrist knowledgeable and experienced in detecting diabetic eye disease	Klein et al., "The Wisconsin epidemiologic study of diabetic retinopathy. II & III," 1984; UKPDS 38, 1998	**II-1**	**Fair**	**C**
2	Dilated fundus examination and fundus photography to detect retinopathy	Javitt & Aiello, 1996; Javitt et al., 1994; Javitt, Canner, & Sommer, 1989; Nathan et al., 1991; Vijan, Hofer, & Hayward, 2000	**I**	**Good**	**B**
3	Periodic comprehensive eye examinations	Working Group Consensus	**III**	**Poor**	**I**

E. **Is Patient Newly Diagnosed DM Type 2 or on Insulin?**

Objective

Screen for retinopathy in newly diagnosed patients with type 2 diabetes or those on insulin.

Recommendations

1. Patients who have not had a dilated eye exam within the past 12 months and are newly diagnosed with type 2 DM or on insulin for established diabetes should have a dilated fundus examination performed within 3 months. (Klein et al., "The Wisconsin Epidemiologic Study II," 1984; Klein et al., "The Wisconsin Epidemiologic Study II," 1984; Klein et al., 1989) (**QE – II-1. Overall Quality – Fair, R – C**).

Evidence

	Recommendation	Sources	Quality of Evidence (QE)	Overall Quality	Recommendation Grade (R)
1	Dilated eye examination performed within 3 months for newly diagnosed patients with type 2 DM	Klein et al., "The Wisconsin epidemiologic study of diabetic retinopathy. II & III," 1984; Klein et al., 1989	**II-1**	**Fair**	**C**

F. **Follow-Up Examination Yearly or According to Eye Care Provider-Recommended Schedule**

Objective

Establish a follow-up interval for patients who may be at moderate to high risk for retinopathy development or progression.

Recommendations

1. Patients who have ocular risk factors, are on insulin, or who have had retinopathy detected on a previous examination should have a fundus examination at least yearly with the precise examination interval determined by the eye care specialist.

Evidence

	Recommendation	Sources	Quality of Evidence (QE)	Overall Quality	Recommendation Grade (R)
1	At least annual evaluation for patients who had retinopathy detected on previous examinations, have ocular risk	Javitt, Canner, & Sommer, 1989; Javitt et al., 1994;	**I**	**Fair**	**B**

	Recommendation	Sources	Quality of Evidence (QE)	Overall Quality	Recommendation Grade (R)
	factors, or are on insulin	Dasbach, 1991; Morisaki et al., 1994; Chen et al., 1995; Klein et al., 1994 & 1989; Kohner et al., 2001; Savage et al., 1997; Stratton et al., 2001; Vijan, Hofer, & Hayward, 2000			

G. **Is There Evidence Of Retinopathy On Past Examination?**

Objective

Establish a follow-up interval for patients who have had retinopathy detected on a previous examination.

Recommendation

1. Patients who have had retinopathy detected on previous examinations should be seen at least annually. The eye care provider should determine the optimal screening intervals based on the patient´s severity of retinopathy and risk factors associated with retinopathy progression.

H. **Follow-Up Examination Every Two Years; Consider More Frequent Screening If Patient Is At Increased Risk For Progression Of Retinopathy**

Objective

Establish a follow-up interval for patients who have had no retinopathy detected on previous examinations and who do not require insulin for control.

Recommendations

1. Patients who have had no retinopathy on all previous examinations should be screened for retinopathy at least every other year (biennial screening).
2. More frequent screening should be considered in patients with clinical findings associated with an increased rate of progression or prevalence of retinopathy. These clinical findings include poorly controlled hypertension, chronic severe hyperglycemia, recent initiation or intensification of insulin therapy, or other known microvascular disease (albuminuria or neuropathy).

Evidence

	Recommendation	**Sources**	**Quality of Evidence (QE)**	**Overall Quality**	**Recommendation Grade (R)**
1	At least biennial screening exams (every other year) for retinopathy for patients who had no retinopathy on all previous examinations	Kohner et al., 1999 & 2001; Stratton et al., 2001; Vijan, Hofer, & Hayward, 2000	**II-1**	**Good**	**B**
2	Consideration of more frequent screening in patients with risk factors associated with an increased rate of progression or prevalence of retinopathy	Agardh et al., 1994; Henricsson et al., 1997; Javitt, Canner, & Sommer, 1989; Javitt et al., 1994; Klein et al., 1989 & 1994; Savage et al., 1997; Vijan, Hofer, &	**I**	**Fair**	**C**

	Recommendation	Sources	Quality of Evidence (QE)	Overall Quality	Recommendation Grade (R)
		Hayward, 2000			

Algorithm - Foot Care

Module F - Foot Care

A. **Perform and Document Visual Inspection of Feet**

Objective

Examine the patient´s feet for any abnormal findings.

Recommendation

1. The patients feet should be visually inspected for:
    - Breaks in the skin
    - Erythema
    - Trauma
    - Pallor on elevation
    - Dependent rubor
    - Changes in the size or shape of the foot
    - Nail deformities
    - Extensive callous
    - Tinea pedis
    - Pitting edema

Evidence

	Recommendation	Sources	Quality of Evidence (QE)	Overall Quality	Recommendation Grade (R)
1	Visual inspection of the feet at every routine primary care visit	ADA, 2002; Working Group Consensus	**III**	**Poor**	**I**

B. **Perform Foot Risk Assessment**

Objective

Identify the patient at risk for lower extremity (LE) ulcers and amputations.

Recommendation

1. A foot risk assessment must be performed and documented at least once a year. A complete foot risk assessment includes:
    - Evaluation of the skin for breakdown
    - Assessment of protective sensation using the Semmes-Weinstein 5.07 monofilament
    - Evaluation for lower extremity (LE) arterial disease
    - Evaluation for foot deformity
    - Prior history of ulcers or amputations

In addition, the patient's footwear should be evaluated.

Evidence

	Recommendation	**Sources**	**Quality of Evidence (QE)**	**Overall Quality**	**Recommendation Grade (R)**
1	Foot risk assessment	ADA, 2002; Mayfield et al., 1998 & 2000	**II** **III**	**Fair**	**B**

C. **Are Any Limb-Threatening Conditions Present?**

Objective

Identify a limb-threatening condition that may require immediate attention, referral, or hospitalization.

Recommendation

1. Evaluation should be performed for limb-threatening conditions, such as systemic infection, acute ischemia/rest pain, foot ulceration, puncture wound, ingrown toenail, and hemorrhagic callous with or without cellulitis.

Evidence

	Recommendation	Sources	Quality of Evidence (QE)	Overall Quality	Recommendation Grade (R)
1	Assessment of peripheral vascular disease	Carrington et al., 2001; Orchard & Strandness, 1993	**II-1, III**	**Fair**	**B**
2	Evaluation for acute ischemia or rest pain	Orchard & Strandness, 1993	**III**	**Poor**	**I**
3	Evaluation for foot ulceration	ADA, 2002; Brodsky & Schneidler, 1991; Caputo et al., 1994; Eckman et al., 1995; Reiber, Boyko, & Smith, 1995	**III**	**Poor**	**I**
4	Evaluation for ingrown toenail	Giacalone, 1997	**II-1**	**Fair**	**B**

D. **Refer To Appropriate Level Of Care For Evaluation And Treatment**

Objective

Determine the appropriate intervention.

Recommendations

1. Patients with limb-threatening conditions should be referred to the appropriate level of care for evaluation and treatment.
2. If the patient´s symptoms limit his/her lifestyle, a vascular specialist should determine the appropriateness of surgical intervention on a patient-specific basis. Justification of vascular procedures should be based on the outcomes of the vascular interventions.

A foot care specialist is defined as a podiatrist, vascular surgeon, orthopedic surgeon, or other health care provider with demonstrated training, competence, and licensure in foot care.

Evidence

	Recommendation	Sources	Quality of Evidence (QE)	Overall Quality	Recommendation Grade (R)
1	Referral for life-threatening conditions	Working Group Consensus	**III**	**Poor**	**I**
2	Referral to a vascular specialist for symptoms that limit lifestyle	Conte et al., 1995; Currie et al., 1995; Lavery et al., 1995	**III, II, III**	**Poor**	**I**

E. **Is Patient at High Risk for Foot Problem?**

Objective

Identify the patient at high risk for LE foot ulcers and amputations.

Recommendations

1. Patients without limb-threatening conditions should be evaluated for their level of risk for LE foot ulcers and amputations.
2. The existence of one of the following characteristics is sufficient to define the patient as high risk for foot problem:
    a. Lack of sensation to Semmes-Weinstein 5.07 monofilament at one or more noncalloused plantar sites
    b. Evidence of LE arterial disease (absence of both dorsalis pedis and tibialis posterior pulses, dependent rubor with pallor on elevation, history of rest pain or claudication, and prior history of LE bypass surgery)
    c. Foot deformities (specifically hammer toes, claw toe, Charcot's arthropathy, bunions, and metatarsal head deformities)
    d. History of foot ulcer or non-traumatic lower-extremity amputation (LEA) at any level
3. The patient at high risk should be referred to a foot care specialist for a more comprehensive evaluation and intensive treatment plan including patient education concerning foot care practices, hygiene, and footwear.

Evidence

	Recommendation	Sources	Quality of Evidence (QE)	Overall Quality	Recommendation Grade (R)
1	Identification of risk factors in the diabetic foot	ADA, 2002; Bailey, Yu, & Rayfield, 1985; Birke & Sims, 1988; Bloomgarden, 2001; Boyko et al., 1996; Carrington et al., 2001; Holewski et al., 1988; Mayfield et al., 1996; Pecoraro, Reiber, & Burgess, 1990; Rith-Najarian, Stolusky & Gohdes, 1992; Sims, Cavanagh, & Ulbrecht, 1988	**III** **III** **III** **III** **II-2** **II** **III** **II** **II** **III** **II**	**Fair**	**B**

F. **Is There a Minor Wound or Lesion?**

Objective

Determine the extent of the injury.

Recommendations

1. Minor lesions or wounds that could possibly be treated by the primary care provider are blisters, erosions, and/or minor cuts that do not extend beyond subcutaneous tissue. Pulses are present, there are no signs of acute infection, and there is no severe lower limb pain and no sign of a worsening lesion.
2. Patients with an ingrown toenail should be referred to a foot specialist for evaluation and treatment (see Annotation C, Ingrown Toenail).

G. **Refer to Foot Care Specialist for Complete Evaluation and Treatment**

Objective

Ensure a more intensive follow-up treatment plan.

Recommendations

1. High risk patients with a minor foot wound or lesion should be promptly referred to a foot care specialist (i.e., podiatrist, vascular surgeon, orthopedic surgeon, and other health care providers with demonstrated training, competence, and licensure in foot care) for evaluation and treatment.
2. Footwear prescriptions should be based upon individual characteristics of foot structure and function.

Evidence

	Recommendation	**Sources**	**Quality of Evidence (QE)**	**Overall Quality**	**Recommendation Grade (R)**
1	Referral to a foot care specialist for high-risk patients with minor foot wounds	Working Group Consensus	**III**	**Poor**	**I**
2	Consideration of a footwear prescription	Bloomgarden, 2001	**III**	**Poor**	**I**

H. **Perform and Document Patient Education for Preventive Foot Care and Footwear**

Objective

Empower the patient to perform proper foot care practices.

Recommendation

1. All patients and their families should receive self-management education for preventive foot care and selection of footwear. Instruction should include recommendations for daily foot inspection and preventive foot care, skin care, and use of emollients, nail care, and treatment for callous.

Evidence

	Recommendation	Sources	Quality of Evidence (QE)	Overall Quality	Recommendation Grade (R)
1	Patient education on specific aspects of care	ADA, 2002; Litzelman et al., 1993; Young et al., 1992	**III, I, III**	**Fair**	**B**
2	Patient instruction on self-foot care	Ahroni, 1993; Barth et al., 1991; Fain & Melkus, 1994; Feste, 1991; Mayfield et al., 1998; Weir, Nathan, & Singer, 1994	**III, II, II, III, II, III**	**Fair**	**B**

I. **Perform Visual Inspection and Peripheral Sensation Evaluation at Each Routine Primary Care Visit**

Objective

Ensure ongoing screening to identify patients at risk for LE ulcers and amputation.

Recommendation

1. Visual inspection and peripheral sensation testing should be performed at each routine primary care visit for all patients (see Annotation A).

J. **Perform Wound Assessment**

Objective

Determine the character and nature of the wound.

Recommendations

1. Patients with diabetes with minor wounds or foot lesions should have a wound assessment.
2. The wound assessment includes:
    a. A review of anatomic, physical, and lesion characteristics including determination or circumference, depth, and involvement of deep structures.
    b. Assessment for signs of infection including necrosis, sinus tracts, exudate, odor, presence of fibrin, and healthy granulation tissue.
    c. Assessment of surrounding areas for signs of edema, cellulitis, or abscess.

K. **Provide Local Wound Care; Offload Pressure and Weight as Indicated**

Objective

Provide care of an uncomplicated minor lesion.

Recommendations

1. Patients with diabetes with uncomplicated minor lesions should receive local wound care. Primary care providers should attempt to offload weight-bearing on the affected extremity.
2. Patients with diabetes with uncomplicated minor lesions must be followed at least monthly.

Evidence

	Recommendation	**Sources**	**Quality of Evidence (QE)**	**Overall Quality**	**Recommendation Grade (R)**
1	Local wound care	"Preventive foot care," 2000; Brodsky & Schneidler, 1991; Caputo et al., 1994; Eckman et al., 1995	**III**	**Poor**	**I**

L. **Has Wound Healed Within 4 Weeks?**

Objective

Determine appropriateness of the treatment outcome.

Recommendation

1. Patients with diabetes treated for an uncomplicated wound should be assessed within four weeks from the initial wound assessment for appropriate reduction in lesion size and depth and appearance of healthy granulating tissue with no evidence of infection.

Evidence

	Recommendation	**Sources**	**Quality of Evidence (QE)**	**Overall Quality**	**Recommendation Grade (R)**
1	Assessment of wound healing progress within 4 weeks	"Preventive foot care," 2000	**III**	**Poor**	**I**

M. **Is There a Minor Foot Problem?**

Objective

Identify minor conditions that could be attended to by the patient and/or family member.

Recommendation

1. Patients with diabetes with minor foot problems (e.g., onychomycosis, painful corn, dry skin, athlete´s foot, minor calluses, uncomplicated nail trimming, and improper foot hygiene) may be treated by a primary care provider in the office or by the patient or family members at home (see Annotation F).

N. **Treat as Appropriate**

Objective

Determine the feasibility of treating the patient at home or in the office of the primary care provider.

Recommendation

1. Assure that patient and family members have received appropriate education regarding preventive foot care.
2. Treat minor foot problems, as appropriate.

Evidence

	Recommendation	Sources	Quality of Evidence (QE)	Overall Quality	Recommendation Grade (R)
1	Treatment of minor foot problems, as appropriate	Ahroni, 1993; Barth et al., 1991; Fain & Melkus, 1994; Feste, 1991; Weir, Nathan, & Singer, 1994	**III, II, III, III, III**	**Poor**	**I**

Algorithm - Self-management and Education

Module M - Self-Management and Education

A. **Is This a Patient with Newly Diagnosed Diabetes Mellitus?**

Module M applies to patients who have been diagnosed with diabetes mellitus (DM) and require diabetes self-management education (DSME) and knowledge and skills to facilitate implementation of their treatment plan.

B. **Provide Information and Education on Basic Concepts, Core Competencies. Document Findings**

Objective

Ensure that patients with diabetes understand the core competencies (survival skills) and other basic information so that they may safely self-manage their diabetes.

Recommendation

1. Ensure that patients newly diagnosed with DM are provided with core competency education (see Appendix M-1: Core Competencies [Survival Skills] for Patients with Diabetes in the original guideline document).

Evidence

	Recommendation	Sources	Quality of Evidence (QE)	Overall Quality	Recommendation Grade (R)
1	Periodic HbA_1c is sufficient to ascertain diabetic control.	Coster et al., 2000; Faas, Schellevis, & Van Eijk, 1997; Harris, 2001; Meier et al., 2002; Oki, Flora, & Isley, 1997; Piette & Glasgow, 2001; Wieland et al., 1997	**II**	**Fair**	**B**

C. **Refer for Comprehensive Self-management and Diet Education**

Objective

Provide or refer for comprehensive DSME and Medical Nutrition Therapy (MNT).

Recommendations

1. Patients newly diagnosed with diabetes should receive comprehensive DSME and education for MNT. The education component should be tailored to the patient´s needs and should be provided through one of the following ways:
    a. Refer to a diabetes self-management education program. This referral can be to either an in-house comprehensive diet consultation—MNT—or a comprehensive DSME program.
    b. An ADA recognized program is recommended, if available (see Appendix M-3: Suggested Points of Contact for Patient Education/Nutrition/Self-Management Programs in the original guideline document).
    c. Conduct education in your clinical setting in the absence of an available comprehensive self -management program. Topics

should be covered by the most qualified health care professionals, knowledgeable in the topic area. A team approach is highly desirable and could include, but is not limited to, a referral to a dietitian, certified diabetes educator, registered nurse, pharmacist, psychologist, exercise physiologist, physical therapist, social worker, endocrinologist, behaviorist, ophthalmologist, optometrist, physician, podiatrist, other health care professionals and paraprofessionals, or other specialized physicians based on the individual patient´s needs. See Appendix M-4: Primary Care Staff Office Diabetes Education Resources and Tools in the original guideline document, for resource materials.

d. Education may take place in either individual or group settings.

2. DSME, including MNT, should be an interactive, collaborative, ongoing process involving patients with diabetes and educators and include the following four-step process:

    a. Assessment of the patient´s educational needs
    b. Identification of the patient´s specific self-management goals
    c. Education and behavioral interventions aimed at meeting the patient´s goals
    d. Evaluation of the patient´s progress towards the goals

Evidence

	Recommendation	Sources	Quality of Evidence (QE)	Overall Quality	Recommendation Grade (R)
1	Provision of comprehensive DSME and MNT education	Coranian & Harstall, 2001; Davidson, Delcher, & Englund, 1979; Franz et al., 1995; Funnel & Haas, 1995; Jacobson, O´Rourke, & Wolf, 1983; Merritt et al., 1983; Miller et al., 2002; Miller & Goldstein, 1972; Norris et al., "Self-management,"	**I** **II-2** **II-2** **III** **III** **III** **I** **III** **I** **I** **I** **III**	**Good** **Fair** **Fair** **Poor** **Poor** **Poor** **Fair** **Poor** **Poor** **Fair** **Fair** **Poor**	**B**

	Recommendation	Sources	Quality of Evidence (QE)	Overall Quality	Recommendation Grade (R)
		2002; Norris, Engelgau, & Narayan, 2001; Rickheim et al., 2002; Rubin, Dietrich, & Hawk, 1998			
2	Individualized and tailored sessions to meet participants´ needs	Arseneau et al., 1994; Conget et al., 1995; Ellison & Rayman, 1998; Miller et al., 2002; Monk et al., 1995; Rachmani et al, 2002; Raji et al., 2002; Schlundt et al., 1994; Travis, 1997	**I** **III** **III** **I** **III** **I** **I** **III** **III**	**Good** **Poor** **Poor** **Fair** **Poor** **Good** **Fair** **Poor** **Poor**	**B**
3	Setting behavioral goals and determining a follow-up schedule with patient	Conget et al., 1995; Garcia and Suarez, 1996; Glasgow et al., 1992; Pascale et al., 1995	**III** **II-3** **I** **I**	**Poor** **Fair** **Good** **Good**	**B**
4	Assessment of patient´s knowledge of DM and understanding about self-care	"Hypoglycemia in the Diabetes," 1997; UKPDS 24, 1998	**I**	**Good**	**A**
5	Provision of specialized referrals when	Aubert et al., 1998; Franz et al., 1995;	**II-1** **II-2** **I**	**Fair** **Fair** **Good**	**B**

	Recommendation	Sources	Quality of Evidence (QE)	Overall Quality	Recommendation Grade (R)
	necessary	Norris et al., "Increasing," 2002; Sikka et al., 1999	**II-2**	**Fair**	
6	Education provided in either individual or group settings	Rickheim et al., 2002	**I**	**Fair**	**B**

D. **Determine Patient's Extent of Knowledge and Self-Management Skill Deficit Based on Treatment Goals**

Objective

Determine the education and skills enhancement needed to enable the patient to self-manage.

Recommendation

1. Assessment of the following factors should be completed to determine the extent of the patient´s educational and skills deficit and his/her ability for self-management: knowledge of the diabetes disease process, treatment goals, management skills, cultural influences, health beliefs/behavior, attitudes, socioeconomic factors and barriers.
2. Results from the assessment of the patient´s learning needs, abilities, preferences, and readiness to learn should be documented.

E. **Does the Patient Need Referral for Further Education or Intervention?**

Objective

Identify patients who are at high risk for diabetes complications or in need of further educational intervention.

Annotation

After explaining the basic concepts, if the provider determines that the patient does not yet understand the concepts or would benefit from a more in-depth, risk-focused education or intervention, a consultation should be requested. Because primary care appointments frequently do not provide adequate time to address background and educational issues, a referral or separate visit(s) to address the patient's needs may be required. Referral may involve sending the patient to the comprehensive DSME program, possibly for a second time. However, it may be necessary to send the patient to another

provider/specialist for individual visit(s) to evaluate and address an often complex combination of educational issues, treatment issues, coordination of care issues, psychosocial issues or financial issues. High risk patients may benefit from these types of referrals. Decisions for referral are based on level-of-risk and extent of educational deficits.

Examples of conditions that may warrant risk-focused intervention are:

- Elevated HbA_1c (3 percent above the upper limit of normal or >9.5 percent)
- Uncontrolled hypertension (>140/90)
- Serum creatinine level >2 mg/dL
- High risk feet
- Pregnancy; or planned pregnancy; or woman of child bearing age
- Poor eyesight
- Severe psychosocial or economic barriers
- Advanced age
- Intensive insulin therapy
- Recurrent hypoglycemia or hypoglycemia unawareness
- Recent hospitalization for diabetic ketoacidosis (DKA) or severe hyperglycemia

The need for risk-focused interventions may also have been identified through other modules of this guideline.

Any deficiencies in the critical areas reviewed in the medical history (see Module D) may indicate patient knowledge needs in multiple areas and should trigger a referral for comprehensive DSME.

F. **Refer as Appropriate for Comprehensive Self-Management and Diet Education or Risk-Focused Intervention or to a Case Manager or Appropriate Specialist**

Objective

Determine which referrals are appropriate based on the patient's needs and availability of providers, programs, and benefit coverage.

Recommendations

1. Patients at high risk may have needs beyond educational deficits and should be referred for focused attention by other services. Possible referrals could include, but are not limited to, the following: dietitian, medical nutrition therapist, certified diabetes educator or comprehensive DSME Program, case manager, registered nurse, pharmacist, psychologist, exercise physiologist, physical therapist, social worker, endocrinologist, ophthalmologist, optometrist, physician, podiatrist, behaviorist, other health care professionals, or paraprofessionals.
2. A case manager is a valuable resource for providing ongoing, detailed coordination of care for high risk patients.

Evidence

	Recommendation	Sources	Quality of Evidence (QE)	Overall Quality	Recommendation Grade (R)
1	Provision of specialized referrals when necessary	Aubert et al., 1998; Franz et al., 1995; Norris, "Increasing," 2002; Sikka et al., 1999	**II-1** **II-2** **I** **II-2**	**Fair** **Fair** **Good** **Fair**	**B**

G. **Reassess and Follow-Up as Indicated**

Objective

Identify the frequency of patient appointments needed to evaluate educational effectiveness or reinforce education/self-management skills.

Recommendations

1. When knowledge deficits continue to exist or a large number of lifestyle changes are necessary, frequent follow-up may be indicated.
2. Recently learned diabetes skills or information should be reevaluated no longer than 3 months after initial instruction. One possible method involves follow-up at earlier time points (e.g., 1 month).
3. When appropriate, single behavioral goals should be identified and prioritized to increase the likelihood of the patient adopting lifestyle changes necessary to achieve treatment goals.

H. **Does the Patient Want More Information?**

Objective

Address patient's desire (motivation) for additional information.

Annotation

Patients often hear of developments in diabetes or have specific questions regarding newer treatment modalities. They may also decide they want to improve their glycemic control or their life style.

I. **Provide Materials or Patient Reference List or Refer as Needed**

Objective

Provide additional information in response to patients' questions about new treatments or advanced self-management skills that have been communicated from other persons with diabetes or the media.

Annotation

If the patient requests additional information it may not be essential for the caregiver to intervene professionally or refer to a specialist. Appendix M-7, List of Patient References: Diabetes Resources in the original guideline document may provide the patient with adequate information.

Definitions:

Quality of Evidence

I: Evidence obtained from at least one properly done randomized controlled trial.

II-1: Evidence obtained from well designed controlled trails without randomization.

II-2: Evidence obtained from well designed cohort or case-control analytic study

II-3: Evidence obtained from multiple time series study; dramatic results of uncontrolled experiment

III: Opinions of respected authorities, case reports and expert committees.

Overall Quality

Good: High grade evidence (I or II-1) directly linked to health outcome

Fair: High grade evidence (I or II-1) linked to intermediate outcome; or grade evidence (II-2 or II-3) directly linked to health outcome

Poor: Level III evidence or no linkage of evidence to health outcome

Net Effect of Intervention

Substantial:

- More than a small relative impact on a frequent condition with a substantial burden of suffering, or
- A large impact on an infrequent condition with a significant impact on the individual patient level

Moderate:

- A small relative impact on a frequent condition with a substantial burden of suffering, or

- A moderate impact on an infrequent condition with a significant impact on the individual patient level

Small:

- A negligible relative on a frequent condition with a substantial burden of suffering, or
- A small impact on an infrequent condition with a significant impact on the individual patient level

Zero or Negative:

- Negative impact on patients, or
- No relative impact on either a frequent condition with a substantial burden of suffering, or
- An infrequent condition with a significant impact on the individual patient level

Final Grade of Recommendation is determined according to the following chart:

	The net benefit of the intervention			
Quality of Evidence	**Substantial**	**Moderate**	**Small**	**Zero or Negative**
Good	**A**	**B**	**C**	**D**
Fair	**B**	**B**	**C**	**D**
Poor	**I**	**I**	**I**	**I**

Rating Scheme for the Strength of Recommendations

A – A strong recommendation that the intervention is always indicated and acceptable

B – A recommendation that the intervention may be useful/effective.

C – A recommendation that the intervention may be considered

D – A recommendation that a procedure may be considered not useful/effective, or may be harmful.

I – Insufficient evidence to recommend for or against – the clinician will use clinical judgment

Abbreviations

ACEI – angiotensin converting enzyme inhibitor
ADA – American Diabetes Association
Alb/Cr – urine albumin/creatinine ration
ARB – angiotensin receptor blocker
ASCVD – atherosclerotic cardiovascular disease
BMI – body mass index
BP – blood pressure
CABG – coronary artery bypass grafting
CAD – coronary artery disease
CCB – calcium channel blocker
CHD – coronary heart disease
CHF – congestive heart failure
COPD – chronic obstructive pulmonary disease
CVD – cardiovascular disease
DBP – diastolic blood pressure
DCCT – Diabetic Control and Complication Trial
DHCCB – dihydropyridine calcium channel blockers
DKA – diabetic ketoacidosis
DM – diabetes mellitus
DoD – Department of Defense
DPP – NIH-funded Diabetes Prevention Program
DSME – diabetes self-management education
EKG – electrocardiogram
ESRD – end stage renal disease
ETDRS – Early Treatment Diabetic Retinopathy Study
FBS – fasting blood glucose
FPG – fasting plasma glucose
g – gram
GDM – gestational diabetes mellitus
GFR – glomerular filtration rate
GU – genitourinary
HbA_1c – hemoglobin marker (A_1c)
HDL – high density lipoproteins
HDL-C – high density lipoproteins – cholesterol
HTN – hypertension
IFG – impaired fasting glucose
IGT – impaired glucose tolerance
IRMA – intraretinal microvascular anomalies
ISH – isolated hypertension
JNC VI – Sixth Report of the Joint National Committee on Detection, Evaluation and Treatment of High Blood Pressure
LDL – low density lipoproteins
LDL-C – low density lipoproteins – cholesterol
LE – lower extremity
LE – level of evidence
LEA – lower extremity amputation
mg/dL – milligrams per deciliter
MI – myocardial infarction
mmols/dL – millimoles per deciliter
MNT – medical nutrition therapy
NCCB – nondihydropyridine calcium channel blocker
NCEP – National Cholesterol Education Program
NPH – neutral protamine Hagedorn insulin

OGTT – oral glucose tolerance test
PG – postload glucose
PPG – postprandial glucose
PVD – peripheral vascular disease
RCT – randomized controlled trial
SBP – systolic blood pressure
SFU – sulfonylurea
SMBG – self-monitoring blood glucose
SME – self-management education
SR – strength of recommendation
SUD – substance use disorder
TDD – total daily dose
TG – triglycerides
TIA – transient ischemic attack
UKPDS – United Kingdom Prospective Diabetes Study
UTI – urinary tract infection
VA – Veterans Affairs
VHA – Veterans Health Administration
WESDR – Wisconsin Epidemiological Study of Diabetic Retinopathy

CLINICAL ALGORITHM(S)

Algorithms are provided in the original guideline document for:

- Core Algorithm
- Screening and Prevention
- Glycemic Control
- Eye Care
- Foot Care
- Renal Disease
- Self-management and Education

EVIDENCE SUPPORTING THE RECOMMENDATIONS

REFERENCES SUPPORTING THE RECOMMENDATIONS

References open in a new window

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is specified and graded for most recommendations (see "Major Recommendations").

The majority of the literature supporting the science for these guidelines is referenced throughout the original document and is based upon key randomized controlled trials and longitudinal studies published from 1992 through May 2002. Following the independent review of the evidence, a consensus meeting was held to discuss discrepancies in ratings and formulate recommendations. Where existing literature was ambiguous or conflicting, or where scientific data was lacking on an issue, recommendations were based on the clinical experience of

the Working Group. These recommendations are indicated in the evidence tables as based on "Working Group Consensus".

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

- Despite the high prevalence and even higher direct and indirect economic costs of diabetes, there is now incontrovertible scientific evidence that effective antihyperglycemic, antihypertensive, and hypolipidemic treatment produces substantial outcomes benefit.
- In addition, preventive care for diabetes can delay, if not prevent, a significant percentage of the instances of vision loss, chronic renal failure, foot ulcers and lower extremity amputations, as well as admissions for metabolic control.

POTENTIAL HARMS

General Side Effects of Pharmacotherapy

- Side effects of pharmacological therapy can include drug-drug interactions, hypoglycemia, and specific adverse drug effects. Patients may experience side effects from medications if adjustments are not made when patients undergo medical or surgical procedures, have a change in their condition, or develop an intercurrent illness.
- Patients may develop contraindications to continued use of a previously successful maintenance medication. Examples would include newly recognized renal insufficiency or severe congestive heart failure in a patient treated with metformin.
- Refer to the original guideline document for further details regarding specific medications.

CONTRAINDICATIONS

CONTRAINDICATIONS

Absolute contraindications to angiotensin-converting enzyme inhibitors (ACEI) include:

- Pregnancy
- Hyperkalemia (advanced renal insufficiency or hyporeninemic hypoaldosteronism)
- Known allergy to ACEI
- Angioedema with prior ACEI use

Relative contraindications include:

- Known bilateral renal artery stenosis

Niacin is contraindicated in patients with hepatic disease and relatively contraindicated in patients with diabetes mellitus, gout, and history of complicated/active peptic ulcer disease.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

- It should be recognized that this series of algorithms, as is true for most, cannot be used as a linear guideline for the recognition and management of diabetes mellitus and is not intended to supersede the clinical judgment of the provider caring for an individual.
- There is no intent to prevent practitioners from using their best judgment in the care of an individual patient. Rather, the intent is to establish verifiable treatment objectives for veterans with diabetes that will lead to a reduction in limb loss, visual loss, chronic renal insufficiency, and cardiovascular disease.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

Explicit indicators to measure implementation system wide are a part of the Veterans Health Administration´s (VHA's) performance measurement system and are described in the Technical Manual on the Department of Veterans Affairs (VA's) Web site.

IMPLEMENTATION TOOLS

Clinical Algorithm
Patient Resources
Pocket Guide/Reference Cards
Quality Measures
Resources

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

RELATED NQMC MEASURES

- Diabetes mellitus: percent of patients with a diagnosis of diabetes mellitus having HbA1c testing performed during the past year.
- Diabetes mellitus: percent of patients with a diagnosis of diabetes mellitus having HbA1c less than 7.
- Diabetes mellitus: percent of eligible patients with a diagnosis of diabetes mellitus having a nephropathy screening test during the past year or documented evidence of nephropathy.
- Diabetes mellitus: percent of patients with diabetes mellitus having full lipid panel in the past year.
- Diabetes mellitus: percent of patients with diabetes mellitus and blood pressure less than 130/80 mm Hg.

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)

Veterans Health Administration, Department of Defense. VA/DoD clinical practice guideline for the management of diabetes mellitus. Washington (DC): Veterans Health Administration, Department of Defense; 2003 Sep. Various p.

ADAPTATION

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

DATE RELEASED

1999 Dec (revised 2003 Sep)

GUIDELINE DEVELOPER(S)

Department of Defense - Federal Government Agency [U.S.]
Veterans Health Administration - Federal Government Agency [U.S.]

SOURCE(S) OF FUNDING

United States Government

GUIDELINE COMMITTEE

The Management of Diabetes Mellitus Working Group

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: Management of diabetes mellitus in the primary care setting. Washington (DC): Department of Veterans Affairs (U.S.); 1999 Dec. 147 p.

GUIDELINE AVAILABILITY

Electronic copies available from the Department of Veterans Affairs (VA) Web site.

Print copies: Department of Veterans Affairs, Veterans Health Administration, Office of Quality and Performance (10Q) 810 Vermont Ave. NW, Washington, DC 20420.

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- VA/DOD clinical practice guideline for the management of diabetes mellitus (DM) in primary care. Guideline Summary. Washington (DC): Department of Veterans Affairs (U.S.); 2003 Mar. See the related QualityTool summary on the Health Care Innovations Exchange Web site.
- VA/DOD clinical practice guideline for the management of diabetes mellitus (DM) in primary care. Core pocket card. Washington (DC): Department of Veterans Affairs (U.S.); 2003.
- VA/DOD clinical practice guideline for the management of diabetes mellitus (DM) in primary care. Glycemic control medication pocket card. Washington (DC): Department of Veterans Affairs (U.S.); 2003. See the related QualityTool summary on the Health Care Innovations Exchange Web site.
- VA/DOD clinical practice guideline for the management of diabetes mellitus (DM) in primary care. Key points. Washington (DC): Department of Veterans Affairs (U.S.); 2003. See the related QualityTool summary on the Health Care Innovations Exchange Web site.

Electronic copies available from the Department of Veterans Affairs (VA) Web site.

The following is also available:

- Putting clinical practice guidelines to work [online tutorial]. Available from the Department of Veterans Affairs Web site.

Print copies: Department of Veterans Affairs, Veterans Health Administration, Office of Quality and Performance (10Q) 810 Vermont Ave. NW, Washington, DC 20420.

See also the following related QualityTool summaries on the Health Care Innovations Exchange Web site:

- Management of diabetes mellitus in primary care algorithm D: core
- Management of diabetes mellitus in primary care algorithm E: eye care
- Management of diabetes mellitus in primary care algorithm F: foot care
- Management of diabetes mellitus in primary care algorithm G: glycemic control
- Management of diabetes mellitus in primary care algorithm M: self-management and education
- Diabetes mellitus algorithm R: kidney function
- Diabetes mellitus algorithm S: screening and prevention
- Department of Veterans Affairs/Department of Defense (VA/DoD) clinical practice guideline for the management of diabetes mellitus in primary care pocket guide: recommended followup

PATIENT RESOURCES

The following is available:

- Diabetes self-management health tips. Washington (DC): Department of Veterans Affairs (U.S.); 2003. 2 p.

Electronic copies available in Portable Document Format (PDF) from the Department of Veterans Affairs (VA) Web site. See the related QualityTool summary on the Health Care Innovations Exchange Web site.

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.

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