

# MASSACHUSETTS GUIDELINES FOR ADULT DIABETES CARE 2009

## TABLE OF CONTENTS

<b>Introduction</b> .....	<b>1</b>
<b>Grading of Evidence</b> .....	<b>2</b>
<b>Diagnosis of Diabetes Mellitus and Pre-diabetes</b> .....	<b>3</b>
Criteria for Testing for Diabetes and Pre-diabetes in Asymptomatic Adults .....	3
Criteria for the Diagnosis of Diabetes and Pre-diabetes in Nonpregnant Adults.....	4
<b>Classification of Diabetes Mellitus and Pre-diabetes</b> .....	<b>5</b>
<b>Prevention or Delay of Type 2 Diabetes</b> .....	<b>6</b>
<b>Treatment Approach Principles for Type 2 Diabetes</b> .....	<b>8</b>
Diabetes Self-Management Education .....	11
Medical Nutrition Therapy .....	14
Physical Activity Guidelines.....	17
Pharmacological Therapy for Type 2 Diabetes.....	19
Algorithm for the Metabolic Management of Type 2 Diabetes.....	20
Summary of Glucose-Lowering Interventions .....	21
Diabetes Medications.....	22
Algorithm for Initiation and Adjustment of Insulin.....	23
<b>Cardiovascular Risk-Reduction Guidelines</b> .....	<b>24</b>
Summary of Lipid-Lowering Therapy .....	24
Lipid-Lowering Decision Tree in Type 2 Diabetes.....	26
Pharmacological Therapy.....	27
Coronary Heart Disease.....	28
Aspirin Therapy in Diabetes .....	29
<b>Hypertension</b> .....	<b>30</b>
<b>Nephropathy</b> .....	<b>32</b>
<b>Retinopathy</b> .....	<b>36</b>
<b>Neuropathy</b> .....	<b>37</b>
Foot Inspection and Monofilament Guide.....	40
<b>Periodontal Disease</b> .....	<b>42</b>
<b>Immunizations</b> .....	<b>43</b>
<b>Tobacco Use and Diabetes</b> .....	<b>44</b>
<b>Psychosocial Issues</b> .....	<b>46</b>
<b>Inpatient Glucose Control</b> .....	<b>48</b>
 <b>Appendix</b>	
<b>Commonly Used Antidiabetic Agents</b> .....	<b>(A)</b>

## INTRODUCTION

Both national studies and state data indicate that people with diabetes do not receive recommended levels of preventive care, leaving wide gaps between current recommendations and actual practice. *The Massachusetts Guidelines for Adult Diabetes Care* were developed as a way to improve diabetes care in the Commonwealth. The *Guidelines* highlight and summarize essential components of quality diabetes management, and offer accompanying tools for use in the primary care setting. These *Guidelines* are neither intended to replace the clinical judgment of primary care providers, nor are they intended to preclude more extensive evaluation and management of the patient by other specialists as needed.

The *Guidelines* were developed by a Work Group convened by the Massachusetts Department of Public Health's Diabetes Prevention and Control Program and its Advisory Board. The Work Group was comprised of clinicians, representatives from managed care organizations, the Primary Care Clinician Plan, Joslin Diabetes Center, the Massachusetts College of Pharmacy and Health Sciences, the Massachusetts League of Community Health Centers, the Massachusetts Medical Society, MassPRO, and the University of Massachusetts Amherst. First developed in 1999, the *Guidelines* are based on the American Diabetes Association's (ADA) Clinical Practice Recommendations, and are reviewed and revised by the Work Group every two years.

The *Guidelines* are a cooperative effort among many partners. This unique collaboration eliminates the confusion brought about by slight differences in guidelines developed by each managed care organization. The *Guidelines* are not intended to serve as a description of benefits or coverage; coverage may vary by insurer.

The 2009 *Guidelines* have been updated and include statements on:

- Screening and diagnosing diabetes and pre-diabetes  
Lifestyle intervention and/or pharmacological treatment for IFG and IGT
- New target threshold for preprandial plasma glucose
- Estimated average glucose
- Physical activity and resistance training
- Management of hyperglycemia in individuals with type 2 diabetes
- Cardiovascular treatment recommendations and goals
- Stages of kidney disease
- Medications to treat symptomatic distal polyneuropathy
- Immunizations
- Inpatient glucose management

We have also added a grading system developed by the American Diabetes Association and updated the **Commonly Used Oral Antidiabetic Agents** tables (now in Appendix A).

In addition to the 2009 Guidelines, the following tools are available:

**Guidelines for Adult Diabetes Care  
(laminated summary)**

This summary of the *Guidelines* highlights basic medical care for people with diabetes. We suggest you post them in each exam room as a reminder of recommendations for care.

**Determining Body Mass Index (BMI)**

Obesity substantially raises the risk of morbidity from type 2 diabetes and other diseases. The BMI describes relative weight for height and is significantly correlated with total body fat content. The BMI may be used to assess overweight and obesity and to monitor changes in body weight.

**Flow Sheet for Diabetes Care**

The flow sheet reflects the recommendations found on the *Guidelines for Adult Diabetes Care* laminated summary. It can be copied or modified for use in your practice and included in patients' charts. Diabetes medications, exams, and test results can be documented over time to track diabetes management.

**Diabetes Care Card (patient wallet card)**

The Diabetes Care Card allows people to track their diabetes care and personal goals. The wallet card has space to record test results and services received over four visits. Encourage your patients to bring this card to each office visit.

## GRADING OF EVIDENCE

The *Massachusetts Guidelines for Adult Diabetes Care* are based on the Clinical Practice Recommendations of the American Diabetes Association (ADA). A grading system developed by the ADA was utilized for the recommendations. The level of supportive evidence is noted in parentheses after each recommendation using the letters A, B, C, or E.

(A): Clear evidence from well-conducted, generalizable, randomized controlled trials.

(B): Supportive evidence from well-conducted cohort studies.

(C): Supportive evidence from poorly controlled or uncontrolled studies.

(E): Expert consensus or clinical experience.

Recommendations with an "A" rating are based on large well-designed clinical trials or well-done meta-analyses. Generally, these recommendations have the best chance of improving outcomes when applied to the population to which they are appropriate. Recommendations with lower levels of evidence may be equally important but are not as well supported. Expert opinion (E) is a separate category for recommendations in which there is as yet no evidence from clinical trials, in which clinical trials may be impractical, or in which there is conflicting evidence.<sup>1</sup>

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<sup>1</sup> American Diabetes Association. *Clinical practice recommendations. Introduction. Diabetes Care* 32, S1-S2, 2009.

# DIAGNOSIS OF DIABETES MELLITUS AND PRE-DIABETES

## Criteria for Testing for Diabetes and Pre-diabetes in Asymptomatic Adults

Testing for diabetes should be considered for all individuals aged 45 and older. Testing should be considered at a younger age in individuals who are overweight (BMI  $\geq 25\text{kg/m}^2$  or BMI  $\geq 23\text{kg/m}^2$  for Asian individuals)<sup>2</sup> and with any of the additional risk factors:<sup>3</sup>

- Habitually physically inactive
- First-degree relative with type 2 diabetes
- Members of a high-risk ethnic population (African American, Latino, Native American, Asian American, Pacific Islander)
- Delivered a baby weighing > 9 lbs. or have been diagnosed with Gestational Diabetes Mellitus (GDM)
- Hypertensive ( $\geq 140/90$  mmHg, or on therapy for hypertension)
- High-density lipoprotein (HDL) cholesterol level  $\leq 35$  mg/dl and/or a triglyceride level  $\geq 250$  mg/dl
- Polycystic ovarian syndrome (PCOS)
- Impaired Glucose Tolerance (IGT) or Impaired Fasting Glucose (IFG) on previous testing
- Other conditions associated with insulin resistance (acanthosis nigricans)
- History of vascular disease
- A waist circumference > 102 cm (40”) for men and > 88 cm (35”) for women<sup>4</sup>
- Medication use that may predispose to diabetes (e.g., steroids, atypical antipsychotics, protease inhibitors)

If normal, testing should be repeated at three-year intervals, with consideration of more frequent testing depending on initial results and risk status.

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<sup>2</sup> National Obesity Forum, Weisell R. Body mass index as indicator of obesity. *Asia Pac J Clin Nutri*: 11 (Supplement 8); S681-S684, 2002. <http://www.nationalobesityforum.org.uk>

<sup>3</sup> American Diabetes Association. *Standards of medical care in diabetes. Diabetes Care* 32 (Supplement 1): S13-S61, 2009.

<sup>4</sup> Balkau B, et al. Waist Circumference, Cardiovascular Disease, and Diabetes Mellitus in 168,000 Primary Care Patients in 63 Countries. *Circulation* 116:1942-1951, 2007.

## Criteria for the Diagnosis of Diabetes and Pre-diabetes in Nonpregnant Adults

*In the absence of unequivocal hyperglycemia, these criteria should be confirmed by repeat testing on a different day.*

	<b>Fasting Plasma Glucose (FPG)* (preferred)</b>	<b>Casual Plasma Glucose (CPG)**</b>	<b>Oral Glucose Tolerance Test (OGTT)***</b>
<b>Diabetes Mellitus</b>	FPG $\geq$ 126 mg/dl	Casual Plasma Glucose $\geq$ 200 mg/dl plus symptoms of diabetes	Two-hour Plasma Glucose (2-h PG) $\geq$ 200 mg/dl
<b>Pre-diabetes</b>	Impaired Fasting Glucose (IFG) FPG $\geq$ 100 and < 126 mg/dl		Impaired Glucose Tolerance (IGT) 2-h PG $\geq$ 140 and < 200 mg/dl
<b>Normal</b>	FPG < 100 mg/dl		2-h PG < 140 mg/dl

\* A FPG via venipuncture is the preferred diagnostic test due to its ease of administration, convenience, acceptability to patients, and lower cost. Fasting is defined as no caloric intake for at least 8 hours.

\*\* Casual is defined as any time of day without regard to time since last meal. Symptoms are the classic ones of polyuria, polydipsia, and unexplained weight loss. There are currently no guidelines for interpreting CPG values that fall between 140-199 mg/dl. For values in this range, options include routine monitoring of FBGs or alternatively, testing with OGTT.

\*\*\* OGTT should be performed using a glucose load containing the equivalent of 75 g anhydrous glucose dissolved in water. The OGTT is not recommended for routine clinical use, but may be necessary when evaluating patients with IFG or when diabetes is still suspected despite an FPG < 126 mg/dl.

The term A1C is used to represent tests of average glycemic control such as glycosylated or glycated hemoglobin (HbA1c). The A1C test measures average blood glucose over the preceding 2 to 3 months and is used to monitor glucose control in patients with diabetes. The test should be performed in all patients with diabetes at initial assessment and then routinely as part of continuing care. The A1C test can be performed non-fasting, without regard to time since last meal.

An International Expert Committee has recently proposed that hemoglobin A<sub>1c</sub> (A1C) assays be considered as the principal means of screening and diagnosing type 2 diabetes, essentially replacing fasting blood glucose (FBG) and the oral glucose tolerance test (OGTT). At the time of this printing, however, the criteria for diagnosing diabetes remain as listed.

## CLASSIFICATION OF DIABETES MELLITUS AND PRE-DIABETES

Not all classifications of diabetes are discussed here. For further information on other types, see the American Diabetes Association reference below.<sup>5</sup>

### **Type 1**

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

### **Type 2**

Individuals with type 2 diabetes have insulin resistance and relative insulin deficiency. Over time, the potential for absolute deficiency exists. Primary treatment centers on beta cell preservation and improving insulin resistance via weight loss, improved nutrition, and increased age-appropriate physical activity. Type 2 diabetes commonly goes undiagnosed for years because it is often asymptomatic in its early stages. Individuals with undiagnosed type 2 diabetes are at increased risk for developing macro- and microvascular complications.

### **Gestational Diabetes Mellitus (GDM)**

GDM, which typically occurs following the 24th week of pregnancy, is defined as any degree of glucose intolerance with onset or first recognition during pregnancy. It does not exclude the possibility that unrecognized glucose intolerance may have preceded, or begun concomitantly with the pregnancy. Six weeks or more after the pregnancy ends, a woman with GDM should be tested to rule out type 1 or type 2 diabetes or pre-diabetes. Women with GDM and their children have a higher risk for development of type 2 diabetes later in life.

### **Pre-diabetes**

Both Impaired Glucose Tolerance (IGT) and Impaired Fasting Glucose (IFG) have been categorized as pre-diabetes and are risk factors for future diabetes and cardiovascular disease. IFG has been defined as a fasting plasma glucose of  $\geq 100$  mg/dl but  $< 126$  mg/dl. IGT is defined as a 2-hour oral glucose tolerance test value (OGTT) of  $\geq 140$  mg/dl, but  $< 200$  mg/dl.

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<sup>5</sup> American Diabetes Association (Position Statement). *Diagnosis and classification of diabetes mellitus. Diabetes Care 32 (Supplement 1): S62-S67, 2009.*

# PREVENTION OR DELAY OF TYPE 2 DIABETES

## Summary

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

Several well-designed studies have shown that individuals at high risk for developing type 2 diabetes can be given lifestyle modification interventions that significantly delay or prevent the onset of diabetes.<sup>6</sup> The Diabetes Prevention Program (DPP) was a randomized clinical trial conducted in 27 sites across the United States. DPP results showed that lifestyle intervention was nearly twice as effective as a glucose-lowering medication (metformin) in delaying or preventing the onset of diabetes in individuals at risk.<sup>7</sup> Study populations often had other recognized risk factors for diabetes including obesity, a prior history of gestational diabetes, or a positive family history of diabetes.<sup>8</sup>

These studies have shown that modest weight loss (5-10% of body weight) and regular physical activity can reduce the rate of progression of IGT to type 2 diabetes. The following lifestyle modifications should be the first treatment modality to employ in persons at high risk:

- Reduced-calorie, reduced-fat meal planning
- Increased moderate intensity physical activity

Such interventions also provide a variety of other health benefits in addition to delaying diabetes. At every opportunity, health care providers are encouraged to stress the benefits of weight loss and physical activity for overweight or sedentary patients.

## Recommendations:

- Patients with IGT (A) or IFG (E) should be referred to an effective ongoing support program for weight loss of 5-10% of body weight and for increasing physical activity to at least 150 minutes per week of moderate activity such as walking.
- In addition to lifestyle counseling, metformin may be considered in those individuals at very high risk of developing diabetes. (E)

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<sup>6</sup> American Diabetes Association (Position Statement). *Diagnosis and classification of diabetes mellitus. Diabetes Care 32 (Supplement 1): S62-S67, 2009.*

<sup>7</sup> *Diabetes Prevention Program (DPP): Knowler WC, et al. Reduction in the incidence of type 2 diabetes with lifestyle intervention or metformin. N Engl J Med 346: 393-403, 2002.*

<sup>8</sup> *Nathan DM, et al. Consensus statement. Impaired fasting glucose and impaired glucose tolerance. Implications for care. Diabetes Care 30:753-759, 2007.*

## PREVENTION OR DELAY OF TYPE 2 DIABETES

### Treatment Recommendations for Individuals with IFG, IGT, or Both<sup>9</sup>

Population	Treatment
IFG or IGT	Lifestyle modification (i.e., 5–10% weight loss and moderate intensity physical activity of at least 150 minutes/week or 30 minutes each day, 5 times per week)
Individuals with IFG and IGT and any of the following: <ul style="list-style-type: none"> <li>• &lt; 60 years of age</li> <li>• BMI <math>\geq</math> 35 kg/m<sup>2</sup></li> <li>• Family history of diabetes in first-degree relatives</li> <li>• Elevated triglycerides</li> <li>• Reduced HDL cholesterol</li> <li>• Hypertension</li> <li>• A1C &gt; 6.0%*</li> </ul>	Lifestyle modification (as above) and consider the addition of metformin**

\* Some providers may use A1C to monitor for progression to diabetes.

\*\*Recommended dosing for metformin: 500-850 mg twice per day, based on gastrointestinal tolerance.

Recent trials have evaluated the use of medications, such as metformin and thiazolidinediones (TZDs), to address insulin resistance in delaying or preventing the development of type 2 diabetes. Given current cost estimates, use of insulin sensitizer medications such as metformin as a first line of defense should be given consideration, contraindications notwithstanding. Some of the manufacturers of thiazolidinediones have reported observational data of an increased risk of fractures (arm, hand, and ankle and foot of 9.30%, 5.09%, and 3.47 % respectively) as compared to metformin and glyburide in women taking these agents for three or more years.<sup>10,11</sup> See **Commonly Used Antidiabetic Medications** in **Appendix A** for additional information on these medications.

<sup>9</sup> Nathan DM, et al. Consensus statement. Impaired fasting glucose and impaired glucose tolerance. Implications for care. *Diabetes Care* 30:753-759, 2007.

<sup>10</sup> The U.S. Food and Drug Administration, [http://www.fda.gov/medwatch/safety/2007/Avandia\\_GSK\\_Ltr.pdf](http://www.fda.gov/medwatch/safety/2007/Avandia_GSK_Ltr.pdf)

<sup>11</sup> The U.S. Food and Drug Administration, <http://www.fda.gov/medwatch/safety/2007/safety07.htm#Actos>

## TREATMENT APPROACH PRINCIPLES FOR TYPE 2 DIABETES

### Treatment Goals

Optimal treatment for type 2 diabetes incorporates a multiple risk factor approach, including self-management education and ongoing support, medical nutrition therapy (MNT), physical activity, weight reduction if appropriate, and the use of glucose-lowering oral agents or insulin. Careful consideration needs to be given to ameliorating associated risk factors such as hypertension, smoking, and dyslipidemia. When possible, care should be provided by a coordinated team that may include physicians, nurse practitioners, physician assistants, diabetes educators, community health workers, nurses, dietitians, pharmacists, social workers, mental health, and other professionals with expertise and special interest in diabetes.

### Recommendations:

- Perform the A1C test at least two times a year in patients who are meeting treatment goals and who have stable glycemic control. (E)
- Perform the A1C test quarterly in patients whose therapy has changed or who are not meeting glycemic goals. (E)
- Having lab results available at the time of the visit is advantageous and may allow for timely decisions on therapy changes. (E) The use of point-of-care testing may facilitate this process. However, as with all point-of-care testing, accuracy may be equipment- and user-dependent.

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

Both the A1C test and patient self-monitoring of blood glucose (SMBG) may be used to assess effectiveness of the management plan on glycemic control. Achievement of desired glucose targets requires education in self-management techniques, including:

- SMBG
- Recognition, treatment, and prevention of hypoglycemia
- Prevention, early detection, and treatment of chronic complications
- MNT (see page 14 for definition and description)
- Regular physical activity
- Reinforcement, continuing education, and ongoing support

Patients with frequent or severe hypoglycemia may require less intensive glycemic goals. Children, pregnant women, and elderly individuals require special consideration when setting glycemic goals.

## TREATMENT APPROACH PRINCIPLES FOR TYPE 2 DIABETES

**Goals for Glycemic Control in Nonpregnant Adults\***

	<b>Normal</b>	<b>Goal</b>
<b>Preprandial Plasma Glucose</b>	< 100 mg/dl	70-130 mg/dl
<b>Peak Postprandial (2-hour) Plasma Glucose</b>	< 120 mg/dl	< 180 mg/dl
<b>A1C</b>	< 6%	< 7%

\* More stringent goals, including a normal A1C of < 6%, can be considered in individual patients and for women who are planning to become pregnant or who are pregnant. Conversely, less stringent goals may be appropriate depending on age and comorbid conditions.

Clinical trials, such as the Diabetes Control and Complications Trial (DCCT), the United Kingdom Prospective Diabetes Study (UKPDS), and the microvascular evidence from the ADVANCE (Action in Diabetes and Vascular Disease: Preterax and Diamicon MR Controlled Evaluation) trial suggest a small but incremental benefit in microvascular outcomes with A1C values closer to normal. Therefore, for selected individual patients, providers might reasonably suggest even lower A1C goals than the general goal of < 7%, if this can be achieved without significant hypoglycemia or other adverse effects of treatment. Such patients might include those with short duration of diabetes and long life expectancy.<sup>12</sup>

### **Points to remember when setting glycemic goals:**

- Individualize goals based on: duration of diabetes, age/life expectancy, comorbid conditions, known cardiovascular disease (CVD) or advanced microvascular complications, and hypoglycemia unawareness.
- If preprandial glucose goals are within target, but A1C values are still not optimal, target postprandial glucose.
- A lower A1C is associated with lower rates of microvascular complications; however, there is a greater risk of hypoglycemia.<sup>13</sup>
- For patients with frequent or severe hypoglycemia, less intensive glycemic control may be preferable.
- Children, pregnant women, and elderly individuals require special consideration when setting glycemic goals.
- Avoid rapid decline in glycemia when prior adverse control was substantial or prolonged.

For those patients who fail to reach target A1C goals after repeated attempts with their primary care providers, an endocrinologist may be consulted. Patients with recurrent hypoglycemia, hypoglycemia unawareness, or nocturnal hypoglycemia; patients on pump therapy or continuous glucose monitoring systems (CGMS); pregnant women and geriatric patients may benefit from consultation with an endocrinologist.

<sup>12</sup> American Diabetes Association. *Standards of Medical Care in Diabetes. Diabetes Care 32 (Supplement 1): S13-S61, 2009.*

<sup>13</sup> Stratton IM, et al. *Association of glycaemia with macrovascular and microvascular complications of type 2 diabetes (UKPDS 35): Prospective observational study. BMJ 321:405-412, 2000.*

## TREATMENT APPROACH PRINCIPLES FOR TYPE 2 DIABETES

To assist in improving patients' understanding of the A1C, the ADA and the American Association of Clinical Chemists have determined that the correlation between A1C levels and mean plasma glucose levels based on data from the A1C-Derived Average Glucose (ADAG) trial support the reporting of the measured A1C as estimated average glucose (eAG). The interpretation of the A1C should provide patients with a more useful index of chronic glycemia. A recently published consensus guideline has endorsed reporting A1C values along with the calculated eAG level.<sup>14,15</sup>

### *Estimated average glucose (eAG)<sup>16</sup>*

A1C (%)	Mean plasma glucose mg/dl
6	126
7	154
8	183
9	212
10	240
11	269
12	298

To convert A1C to eAG:  
 $28.7 \times \text{A1C} - 46.7 = \text{eAG (in mg/dl)}$

A calculator for converting A1C results into eAG, in either mg/dl or mmol/l is available at: <http://professional.diabetes.org/eAG>.

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<sup>14</sup> Nathan DM, et al. Translating the A1C into estimated average glucose values. *Diabetes Care* 31:1473–1478, 2008.

<sup>15</sup> American Diabetes Association. Standards of Medical Care in Diabetes. *Diabetes Care* 32 (Supplement 1): S13-S61, 2009.

<sup>16</sup> *Ibid.*

# DIABETES SELF-MANAGEMENT EDUCATION

## Purpose

Diabetes Self-Management Education (DSME) should be offered throughout the life span of those diagnosed with diabetes and pre-diabetes. Families and support systems are encouraged to participate. The main aims of DSME are to provide patients with the management skills necessary to achieve optimal control of their diabetes, and to assist them in becoming effective, self-directed decision makers for their own diabetes care, health, and well-being. Without comprehension of the relationship between blood glucose readings, meal planning, and physical activity, patients with diabetes will be hindered in their ability to achieve optimal blood glucose control, and are at higher risk for long-term complications. A referral to a Certified Diabetes Educator (CDE) or clinician who has expertise in culturally competent DSME is strongly recommended. A CDE may be a nurse, physician, dietitian, social worker, exercise physiologist, or pharmacist.<sup>17</sup>

National standards for DSME have been established by the American Diabetes Association (ADA) to define quality diabetes self-management education that can be implemented in diverse settings and will facilitate improvement in health care outcomes. Standards are reviewed and updated on a regular basis, so the most current standards should be accessed on the ADA website.<sup>18</sup>

## Goals for DSME

- Prevent type 2 diabetes
- Prevent the acute complications of diabetes, hyperglycemia, and hypoglycemia
- Prevent or delay the chronic complications of diabetes
- Promote healthy birth outcomes through preconception counseling, monitoring, and support during and after pregnancy
- Enhance patient participation in the diabetes treatment
- Plan and improve patient confidence in self-management skills
- Enhance psychosocial adjustment to living with a chronic disease
- Decrease health care costs by reducing the need for expensive hospital stays and the treatment of complications
- Maximize quality of life in a cost-effective manner

A referral for a face-to-face educational assessment is recommended. This allows for an appropriate educational treatment plan to be outlined. DSME is offered at both basic and advanced training levels. Consideration should be given to the patient for dealing with psychosocial aspects of the diagnosis. Literacy and cultural issues that may impact training should also be evaluated. Advances in treatment options are continuing. DSME should be offered annually after initial diagnosis. Ongoing training should ensure that patients are current in changing technology and self-management behavioral strategies.

National standards require that the following areas be covered in DSME: Assessment of knowledge and needs of individuals with pre-diabetes and diabetes will determine which of the content areas are to be provided.<sup>19</sup>

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<sup>17</sup> National Certification Board for Diabetes Educators, <http://www.ncbde.org>

<sup>18</sup> American Diabetes Association, <http://www.diabetes.org>

<sup>19</sup> Funnell MM, et al. National Standards for Diabetes Self-Management Education. *Diabetes Care* 32:S87-S94, 2009.

# DIABETES SELF-MANAGEMENT EDUCATION

## Diabetes Disease Process

### Overview

- Benefits of optimal diabetes control and factors that influence it
- Effects of insulin resistance, deficiency, and excess
- Treatment of insulin resistance through weight loss, physical activity, and medication
- Nature of diabetes in terms of chronicity and metabolism
- Differences between type 1 diabetes, type 2 diabetes, pre-diabetes, and gestational diabetes, if indicated
- Balance of meals, physical activity, and medication, if prescribed

### Nutrition

- Basic vs. advanced training (i.e., basic food groups vs. carbohydrate to insulin ratio)

### Physical activity

- Impact of physical activity on blood glucose, lipid levels, hypertension, weight, and stress reduction
- Frequency, level, and benefits of physical activity
- Impact of physical activity on hyperglycemia, ketosis, and hypoglycemia
- Physical activity planning appropriate to age, ability, interest, and willingness
- Potential impact of physical activity on long-term diabetes complications and skills for avoiding injury

## Medications

### Oral Medication Management

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

### Insulin Management

- Action, dosage, onset/peak/duration, pre-filling, mixing, injecting, site selection, storage, syringe/needle/lancet disposal, travel guidelines, adjustments for sick and well days
- Recommendations for syringe reuse: techniques, benefits, and risks
- Pump use, if appropriate
- Use of Glucagon, if appropriate

### Injectable medication, if prescribed

- Influences of other medications on blood glucose and possible interactions with oral diabetes and other medications

### Monitoring/using results

- Blood glucose meter selection and orientation
- Time(s) to check blood glucose/rationale
- Recording and interpreting results, encouraging dialogue with clinician
- Establish A1C targets
- Use of SMBG to adjust the treatment plan based on approved guidelines
- Disposal of syringes, needles, lancets, and other contaminated materials
- Urinary and blood ketone testing, if appropriate
- Use of advanced technology: Continuous Glucose Monitoring System (CGMS), if appropriate

# DIABETES SELF-MANAGEMENT EDUCATION

## Acute complications

- Hypoglycemia and hyperglycemia recognition, causes, treatment, and prevention
- Diabetes management during illness
- Trauma, surgery, and/or severe acute illness
- Planning skills for scheduled procedures and surgeries
- Potential changes in blood glucose monitoring
- Meal planning changes: short- and long-term where applicable (e.g., surgeries, illness > 1-2 days)
- Potential changes in medication (e.g., addition of insulin to oral medications or insulin initiation, times, and frequency of insulin doses)
- Signs and symptoms of acute changes in status of diabetes control (e.g., Diabetic Ketoacidosis [DKA], dehydration, Hyperosmolar Hyperglycemic State [HHS])
- Importance of strict glycemic control during:
  - Pre-surgical preparation
  - Recovery period

## Complications prevention and recognition

- Self-foot care, early detection of problems, and importance of timely access to care
- Early recognition of eye disease and need for complete eye exam
- Impact of lipids; importance of monitoring annually, or every two years if values fall within accepted risk levels
- Importance of blood pressure control; need for regular monitoring
- Identification of the symptoms, treatment, and major factors contributing to the development of complications
- Preventing kidney disease, peripheral vascular disease, cardiovascular disease, periodontal disease, and neuropathy
- Importance of pneumonia vaccine and yearly flu vaccine
- Smoking cessation
- Use of aspirin if not contraindicated

## Goal setting and problem solving

## Psychosocial adjustment

- Assess adjustment to lifestyle changes; screen for depression, eating disorders, and cognitive impairment; refer to counseling as needed
- Develop psychosocial skills and incorporate into routine care to support emotional well-being
- Ongoing support

## Preconception care, pregnancy, and GDM (if applicable)

Women who are pregnant and have diabetes, whether preexisting or GDM, have a goal of delivering a healthy baby after gestation. In order to accomplish this goal, it is critical for the mother's glucose levels to be within the target range, before pregnancy for those with preexisting diabetes and during pregnancy for all women. The treatment plan will include MNT, as well as physical activity and insulin as needed. The treatment plan will need to be adjusted throughout the course of the pregnancy and frequent monitoring will be required.<sup>20</sup>

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<sup>20</sup> Funnell MM, et al. National standards for diabetes self-management education. *Diabetes Care* 30:1630-1637, 2007.

# MEDICAL NUTRITION THERAPY

## Summary

Medical nutrition therapy (MNT), defined as nutritional diagnostic, therapeutic, and counseling services provided by a registered dietitian or nutrition professional for the purpose of managing diabetes, is an integral component of assisting patients in acquiring and maintaining the knowledge, skills, and behaviors to successfully meet the challenges of daily diabetes self-management.<sup>21</sup>

The *2006 Nutrition Recommendations and Interventions for Diabetes*, published by the ADA, identifies three categories of MNT: primary prevention to reduce the risk of or delay the onset of diabetes; nutrition management for blood glucose control; and management and prevention in the treatment of comorbidities.<sup>22</sup> Adequate nutrition advice or an individualized meal plan will assist patients in achieving optimal blood glucose control. Meeting nutrition-related goals requires a coordinated team effort that includes the person with diabetes. A referral to a registered dietitian skilled in the complexities of diabetes management is strongly recommended.

## Recommendations:

- People with pre-diabetes or diabetes should receive individualized MNT as needed to achieve treatment goals, preferably provided by a registered dietitian familiar with components of diabetes MNT. (B)
- Weight loss is recommended for all overweight or obese individuals who have or are at risk for diabetes. (A)
- For weight loss, either low-carbohydrate or low-fat, calorie-restricted diets may be effective in the short-term (up to 1 year) (A).
- For patients on low-carbohydrate diets, monitor lipid profiles, renal function, and protein intake (in those with nephropathy) and adjust hypoglycemic therapy as needed. (E)<sup>23</sup>

Motivational interviewing, a counseling technique shown to be beneficial in behavioral change, should be utilized in working with clients to modify nutritional intake.<sup>24,25</sup>

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<sup>21</sup> Centers for Medicare and Medicaid Services. *Medical nutrition therapy services: overview*. <http://www.cms.hhs.gov/medicalnutritiontherapy>.

<sup>22</sup> American Diabetes Association (Position Statement). *Nutrition recommendations and interventions for diabetes*. *Diabetes Care* 31:S61-S78, 2008.

<sup>23</sup> American Diabetes Association. *Standards of medical care in diabetes*. *Diabetes Care* 32 (Supplement 1): S13-S61, 2009.

<sup>24</sup> West DS, et al. *Motivational Interviewing improves weight loss in women with type 2 diabetes*. *Diabetes Care* 30:1081-1087, 2007.

<sup>25</sup> Channon et al. *A multicenter randomized controlled trial of motivational interviewing in teenagers with diabetes*. *Diabetes Care* 30: 1390-1395, 2007.

# MEDICAL NUTRITION THERAPY

## Goals for MNT

- Achieve and maintain near normal blood glucose levels as well as optimal lipid levels, blood pressure, and recommended body weight.
- Prevent and treat the acute and long-term complications of diabetes.
- Improve overall health through optimum nutrition and physical activity.
- Address individual needs, considering cultural preferences, lifestyle, and ability to change.
- Maintain the pleasure of eating by only limiting food choices when indicated by scientific evidence.
- Delay the onset of diabetes in patients with pre-diabetes.
- Provide for the needs of special populations:
  - Youth with type 1 or type 2 diabetes
  - Pregnant and lactating women
  - Older adults
  - Active individuals treated with drugs that may potentially cause hypoglycemia (insulin and insulin secretagogues and meglitinides) to ensure safety during activity
  - Individuals at risk for developing diabetes
  - Individuals with deteriorating renal or cardiac function
  - Individuals with deteriorating visual acuity

## Basic Education

For patients newly diagnosed with diabetes or pre-diabetes, or patients not recently educated, basic survival skills should include:

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

## Advanced MNT topics should include:

- Weight loss strategies, including reduction in energy intake and/or increase in physical activity, if indicated; consideration of medications and/or bariatric surgery for those with a BMI > 35
- Amount (grams) and type of carbohydrate in food and influence on blood glucose levels
- Use of meal replacements, if desired
- Glycemic index
- Sources of nutrients and their effects on blood glucose and lipid levels
- Carbohydrate counting
- Label reading and grocery shopping guidelines
- Dining out
- Reduced dietary energy from saturated fat (< 7% of total energy); intake of *trans* fat should be minimized
- Use of sugar-containing foods, dietetic foods, and sweeteners
  - Sugar alcohols and nonnutritive sweeteners are safe when consumed within the acceptable daily intake levels established by the Food and Drug Administration (FDA)

## MEDICAL NUTRITION THERAPY

- Alcohol guidelines
  - If adults with diabetes choose to use alcohol, daily intake should be limited to a moderate amount (one drink per day or less for adult women and two drinks per day or less for adult men)
- Using blood glucose monitoring for glucose pattern control
- Adjusting meal times
- Adjusting food for physical activity
- Special occasions, holidays
- Travel, schedule changes
- Vitamin and mineral supplementation
  - Routine supplementation with antioxidants, such as vitamins E and C and carotene, is not advised because of lack of evidence of efficacy and concern related to long-term safety
  - Benefit from chromium supplementation in people with diabetes or obesity has not been conclusively demonstrated, and therefore cannot be recommended

### **Ongoing Nutrition Education**

Ongoing nutrition education is recommended for patients recently diagnosed with diabetes or pre-diabetes who have been taught basic survival skills. Patients who may benefit from nutrition education include those who have not received current nutrition education, who are having difficulty with diabetes management, or who are experiencing changes in lifestyle, medication, weight, or childbearing status. Follow-up sessions should focus on increasing the patient's knowledge, skills, and flexibility as he or she gains experience living with diabetes.

### **A weight loss program should include:**

- Individualized counseling
- Structured, intensive lifestyle education
- Promotion of healthy food choices and physical activity

# PHYSICAL ACTIVITY

## Summary

Physical activity is an important component of a healthy lifestyle that can help to prevent diabetes and its complications. The use of the term “physical activity” is preferred to “exercise” because it includes the spectrum of options from mild (e.g., walking or light housekeeping) to moderate (e.g., brisk walking, dancing, swimming, bicycling) to vigorous (e.g., jogging, bicycling uphill, swimming multiple laps). The metabolic effects of physical activity are generally measurable up to 24-48 hours after a single session. Therefore, repeated sessions of physical activity (generally 5-7 times per week) are recommended to achieve ongoing benefits.<sup>26, 27</sup>

## Recommendations for Physical Activity:

- People with diabetes should be advised to perform at least 150 minutes/week of physical activity (50-70% of maximum heart rate). (A)
- In the absence of contraindications, people with type 2 diabetes should be encouraged to perform resistance training three times per week; targeting all major muscle groups.<sup>28</sup> (A)

Moderate-intensity activity for about 150 minutes a week has been shown to substantially lower the risk of heart disease in people with diabetes.<sup>29</sup> For individuals whose goals are weight loss, 300 minutes (5 hours) or more of moderate-intensity activity a week has even greater benefit.<sup>30</sup> Health care providers should work with their patients with diabetes to adapt physical activity so that it is appropriate for their condition.

Recommendations for screening asymptomatic patients with diabetes for coronary artery disease (CAD) before starting on a program of physical activity remain unclear. A recent ADA Consensus Statement on this issue concluded that routine screening is not recommended and providers should use clinical judgment in this area, including encouraging high-risk patients to start with short periods of low-intensity physical activity and increase the duration and intensity gradually.<sup>31</sup> Providers should also assess patients with diabetes for conditions that might contraindicate certain types of physical activity or predispose to injury.

Conditions that may contraindicate moderate to vigorous activity include:

- Uncontrolled hypertension
- Peripheral neuropathy (risk for lower extremity injury)
- Severe autonomic neuropathy or hypoglycemia unawareness
- Pre-proliferative or proliferative retinopathy or macular edema (risk for retinal detachment or vitreous hemorrhage)
- Blood glucose concentration  $\geq 250$  mg/dl with ketones or  $\geq 300$  mg/dl without ketones

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<sup>26</sup> Sigal RJ, et al. Physical activity/exercise and type 2 diabetes. *Diabetes Care* 27:2518-2539, 2004.

<sup>27</sup> Department of Health and Human Services: Physical activity and health: A report of the Surgeon General. Atlanta, GA, Centers for Disease Control and Prevention, 1996.

<sup>28</sup> American Diabetes Association. Standards of medical care in diabetes. *Diabetes Care* 32 (Supplement 1): S13-S61, 2009.

<sup>29</sup> Sigal RJ, et al. Physical activity/exercise and type 2 diabetes. *Diabetes Care* 27:2518-2539, 2004.

<sup>30</sup> U.S. Department of Agriculture, <http://www.mypyramid.gov>

<sup>31</sup> Bax JJ, et al. Screening for coronary artery disease in patients with diabetes. *Diabetes Care* 30: 2729–2736, 2007.

## PHYSICAL ACTIVITY

### Goals for Physical Activity

The overall goals of physical activity are to improve glycemic control, maintain a healthy weight, decrease cardiovascular risk, reduce blood pressure, improve balance to prevent falls, reduce stress, and improve well being. These goals should address the individual's preferred method of becoming more physically active. Aerobic activity should be distributed over at least three days per week with no more than two days between activities.

For substantial health benefits, adults should aim for:

- 150 minutes per week of moderately intense physical activity, or
- 75 minutes per week of vigorously intense physical activity, or
- Some combination of the two.

For more extensive health benefits, adults should aim for:

- 300 minutes per week of moderately intense physical activity, or
- 150 minutes of vigorously intense physical activity, or
- Some combination of both.<sup>32</sup>

### Resistance Training

Resistance exercise has been shown to improve insulin sensitivity to about the same extent as aerobic exercise.<sup>33,34</sup> Studies have shown that either aerobic or resistance training alone improves glycemic control in type 2 diabetes, but the improvements are greatest with combined aerobic and resistance training.<sup>35</sup>

- The goal is three times per week targeting all major muscle groups. Start by identifying a weight that cannot be lifted more than 8-10 times. Use this weight and gradually increase to three sets of 8-10 repetitions.
- Resistance training is not recommended for people with significant retinopathy due to risk of retinal detachment or vitreous hemorrhage.

### Basic Education

- Relationship of physical activity to change in blood glucose levels
- Impact of physical activity on risk for hypoglycemia (especially in patients taking sulfonylureas, meglitinides, or insulin preparations). Added carbohydrate should be ingested if pre-exercise glucose is < 100 mg/dl
- Potential for impact of physical activity on blood glucose levels up to 12-24 hours after completion
- Types of physical activity
- Injury prevention

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<sup>32</sup> U.S. Department of Health and Human Services. 2008 Physical Activity Guidelines for Americans: <http://www.health.gov/paguidelines/guidelines/chapter7.aspx>

<sup>33</sup> Dunstan DW, et al. High-intensity resistance training improves glycemic control in older patients with type 2 diabetes. *Diabetes Care* 25: 1729–1736, 2002.

<sup>34</sup> Castaneda C, et al. A randomized controlled trial of resistance exercise training to improve glycemic control in older adults with type 2 diabetes. *Diabetes Care* 25: 2335–2341, 2002.

<sup>35</sup> Sigal RJ, et al. Effects of aerobic training, resistance training, or both on glycemic control in type 2 diabetes. *Annals of Internal Med* 147: 357–369, 2007.

## PHARMACOLOGICAL THERAPY FOR TYPE 2 DIABETES

The ADA and the European Association for the Study of Diabetes published a consensus statement on the approach to management of hyperglycemia in individuals with type 2 diabetes. Highlights of this approach are: intervention at the time of diagnosis with metformin in combination with lifestyle changes (MNT and physical activity), and continuing timely augmentation of therapy with additional agents (including early initiation of insulin therapy) as a means of achieving and maintaining recommended levels of glycemic control (i.e., A1C < 7% for most patients). The overall objective is to achieve and maintain glycemic control and to change interventions when therapeutic goals are not being met.<sup>36,37</sup>

The U.S. Food and Drug Administration (FDA) has approved many classes of oral agents for monotherapy (see **Algorithm for the Metabolic Management of Type 2 Diabetes** on page 20). The choice of a particular agent must depend, however, on the individual's characteristics, self-monitoring of blood glucose (SMBG) profiles, clinical scenario, cost-effectiveness, and physician preferences. Before initiating therapy, renal status and hepatic function should be evaluated. Appropriate nutrition and physical activity should be maintained even if the diabetes is being managed pharmacologically. This suggested treatment approach reflects current thinking; however, changes will continue to be made in this recommended algorithm as the science evolves.

In the case of monotherapy not achieving target glycemic goals, combinations of oral agents or injectable therapies should be attempted. The adverse effect profile of a particular course of therapy may determine which combination regimen is chosen for a specific patient. Individual concerns over hypoglycemia, gastrointestinal (GI) side effects, or edema may tip the scale away from one permutation towards another. Cardiac, renal, and hepatic function should be evaluated as appropriate for each oral agent. The table on the following page compares the oral antidiabetic agents. Insulin can be used either alone or in combination with an indicated oral/injectable drug regimen.

New drugs to treat diabetes are in development and in various stages of approval by the FDA. Since 2007, the FDA has been concerned about cardiovascular side effects of diabetes drugs, due to increased risk of heart attacks associated with rosiglitazone (Avandia®).<sup>38</sup> The FDA now requires manufacturers to evaluate cardiovascular risks for all new drugs for diabetes before approval. Some new medications, saxagliptin (Onglyza®) and liraglutide (Victoza®), may not need to meet this requirement, as they were under development prior to the new regulation.

**See Appendix A: Commonly Used Diabetes Medications**

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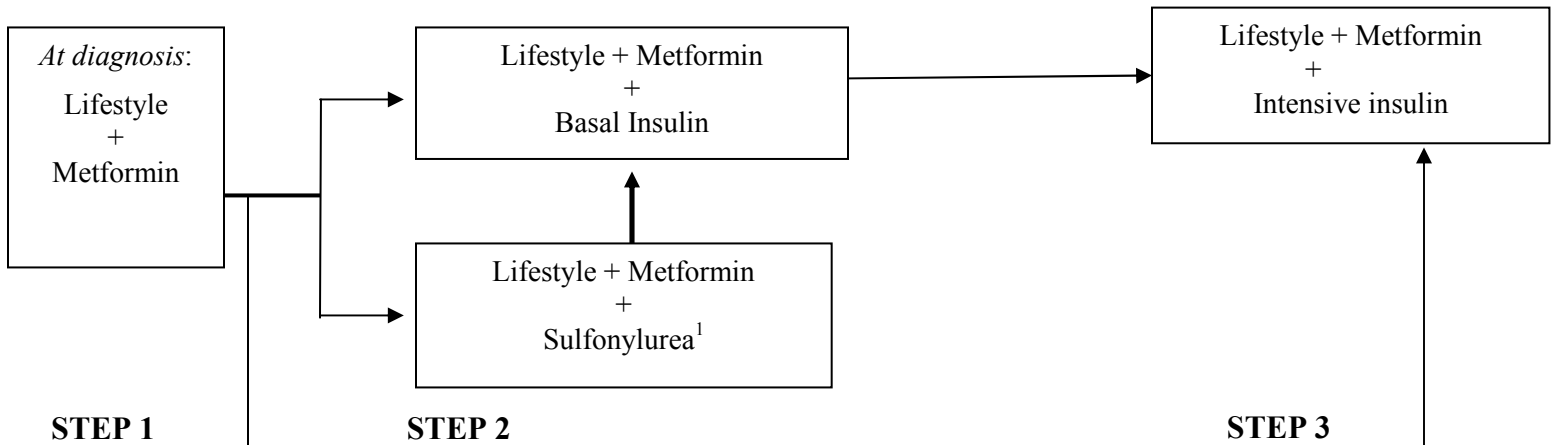
<sup>36</sup> American Diabetes Association. *Standards of Medical Care in Diabetes. Diabetes Care 32 (Supplement 1): S13-S61, 2009.*

<sup>37</sup> Nathan DM, et al. *Medical management of hyperglycemia in type 2 diabetes: a consensus algorithm for the initiation and adjustment of therapy: a consensus statement of the American Diabetes Association and the European Association for the Study of Diabetes. Diabetes Care 32: 193–203, 2009.*

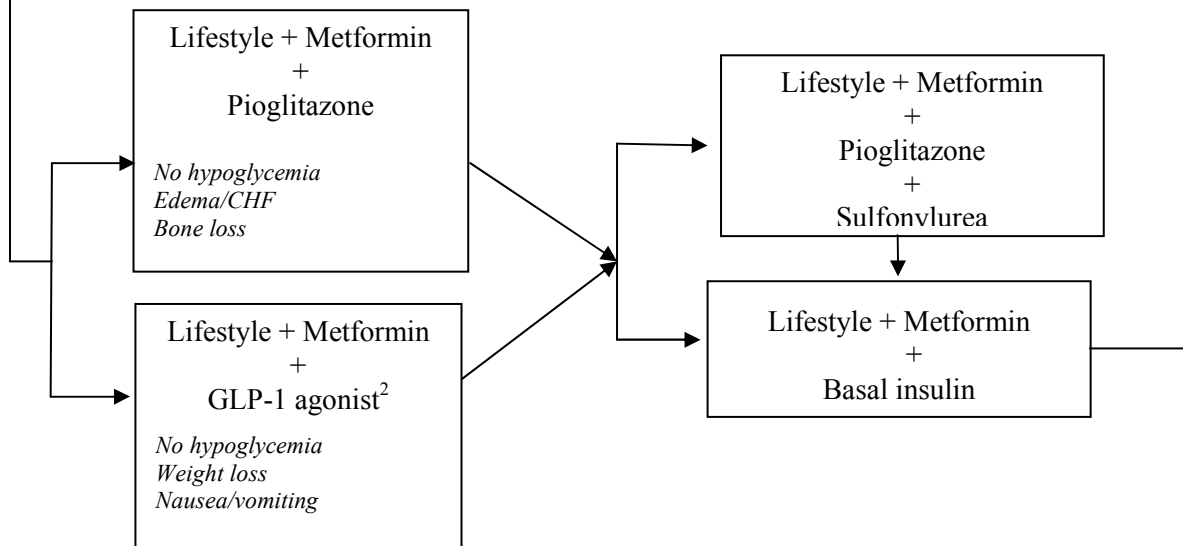
<sup>38</sup> [http://www.fda.gov/cder/drug/InfoSheets/HCP/rosiglitazone200707HCP.htm#2007\\_5](http://www.fda.gov/cder/drug/InfoSheets/HCP/rosiglitazone200707HCP.htm#2007_5)

## Metabolic Management of Type 2 Diabetes

### Tier 1: well-validated core therapies



### Tier 2: Less well-validated therapies



Reinforce lifestyle interventions at every visit and check A1C every 3 months until A1C is < 7%, and then at least every 6 months. The interventions should be changed if A1C is  $\geq 7\%$ .

Renal dysfunction is considered a contraindication to metformin use because it may increase the risk of lactic acidosis, an extremely rare (less than 1 case per 100,000 treated patients) but potentially fatal complication. However, recent studies have suggested that metformin is safe unless the estimated glomerular filtration rate falls to < 30 ml/min.

<sup>1</sup>Sulfonylureas other than glyburide or chlorpropamide

<sup>2</sup>Insufficient clinical use to be confident regarding safety

Adapted from: Nathan D, et al. Medical management of hyperglycemia in type 2 diabetes: A consensus algorithm for the initiation and adjustment of therapy. *Diabetes Care* 32:193-203, 2009.

## SUMMARY OF GLUCOSE-LOWERING INTERVENTIONS<sup>39</sup>

Intervention	Expected decrease in A1C with monotherapy (%)	Advantages	Disadvantages
<b>Tier 1: well-validated core</b>			
Step 1: initial therapy			
Lifestyle to decrease weight and increase activity	1.0–2.0	Broad benefits	Insufficient for most within first year
Metformin	1.0–2.0	Weight neutral	GI side effects, contraindicated with renal insufficiency
Step 2: additional therapy			
Insulin	1.5–3.5	No dose limit, rapidly effective, improved lipid profile	One to four injections daily, monitoring, weight gain, hypoglycemia, analogues are expensive
Sulfonylurea	1.0–2.0	Rapidly effective	Weight gain, hypoglycemia (especially with glibenclamide or chlorpropamide)
<b>Tier 2: less well-validated</b>			
TZDs	0.5–1.4	Improved lipid profile (pioglitazone), potential decrease in Myocardial Infarction (pioglitazone)	Fluid retention, CHF, weight gain, bone fractures, expensive, potential increase in Myocardial Infarction (rosiglitazone)
GLP-1 agonist	0.5–1.0	Weight loss	Two injections daily, frequent GI side effects, long-term safety not established, expensive
Other therapy			
α-Glucosidase inhibitor	0.5–0.8	Weight neutral	Frequent GI side effects, three times/day dosing, expensive
Glinide	0.5–1.5 <sup>a</sup>	Rapidly effective	Weight gain, three times/day dosing, hypoglycemia, expensive
Pramlintide	0.5–1.0	Weight loss	Three injections daily, frequent GI side effects, long-term safety not established, expensive
DPP-4 inhibitor	0.5–0.8	Weight neutral	Long-term safety not established, expensive

<sup>39</sup> Nathan D, et al. Medical management of hyperglycemia in type 2 diabetes: A consensus algorithm for the initiation and adjustment of therapy. Massachusetts Guidelines for Adult Diabetes Care \* Revised June 2009  
Diabetes Prevention and Control Program \* Diabetes Guidelines Work Group

# DIABETES MEDICATIONS

## Insulin Considerations

### The use of insulin requires the following considerations:

- The onset, peak, and duration of any insulin preparation may vary depending on injection site, exercise, depth of injection, and other variables. Hypoglycemia is a side effect of insulin, and patients must be instructed on the risks as well as appropriate treatments for hypoglycemia.
- Reduced hyperglycemia and an improvement in glucose toxicity will occur in patients with type 2 diabetes, given sufficient doses of insulin. Individuals with moderately controlled type 2 diabetes, defined as a fasting plasma glucose  $\geq 140$  and  $\leq 200$  mg/dl, will often show sufficient response to a single or twice-daily dose of insulin.
- Insulin therapy often results in weight gain as a result of improved blood glucose utilization. Attention should be given to lifestyle adjustments, such as modifications to diet and implementing an exercise program, which can counteract insulin-induced weight gain.<sup>40</sup>
- Individuals with uncontrolled type 2 diabetes, defined as a fasting plasma glucose of  $\geq 200$  mg/dl, or those who have proved not responsive to the above-mentioned regimens, may require frequent insulin dosing. This usually requires the addition of short-acting insulin before meals.
- The total daily insulin doses for type 2 diabetes may range from 0.4 - 1.2 U/kg/day. Be aware that in insulin-resistant patients, doses of  $> 1.5$  U/kg/day may be required.
- Total daily dosage for people with type 1 diabetes may range from 0.3 - 0.8 U/kg/day.
- The degree of glucose-lowering effect is dose-related. Studies have demonstrated a lowering of fasting glucose of up to 190 mg/dl from baseline in patients with type 2 diabetes treated with insulin.
- Insulin can be delivered via syringe, pen, or pump.<sup>41</sup>

Insulins listed in the medications chart in **Appendix A** are U-100. In some cases U-500, which contains 500 units of insulin per ml instead of 100 units per ml (other insulins), may be used. This may be an option for patients requiring very high doses of insulin (i.e.,  $\geq 200$  units per day). Using this high-potency alternative allows injections of smaller volumes, but increases the potential for serious hypoglycemia. Extreme caution in dosing is advised.<sup>42</sup>

## Continuous Glucose Monitoring Systems (CGMS)

An endocrinologist may be consulted for evaluation and possible use of CGMS in appropriately selected patients. Candidates for CGMS are patients who have: hypoglycemia unawareness, recurrent hypoglycemia (E), or nocturnal hypoglycemia; who are geriatric or pregnant; are on pump therapy; or are on insulin and failing treatment.<sup>43</sup>

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*Diabetes Care* 32:193-203, 2009.

<sup>41</sup> Carver C. *Insulin Treatment and the Problem of Weight Gain in Type 2 Diabetes. The Diabetes Educator* 32: 910-917, 2006.

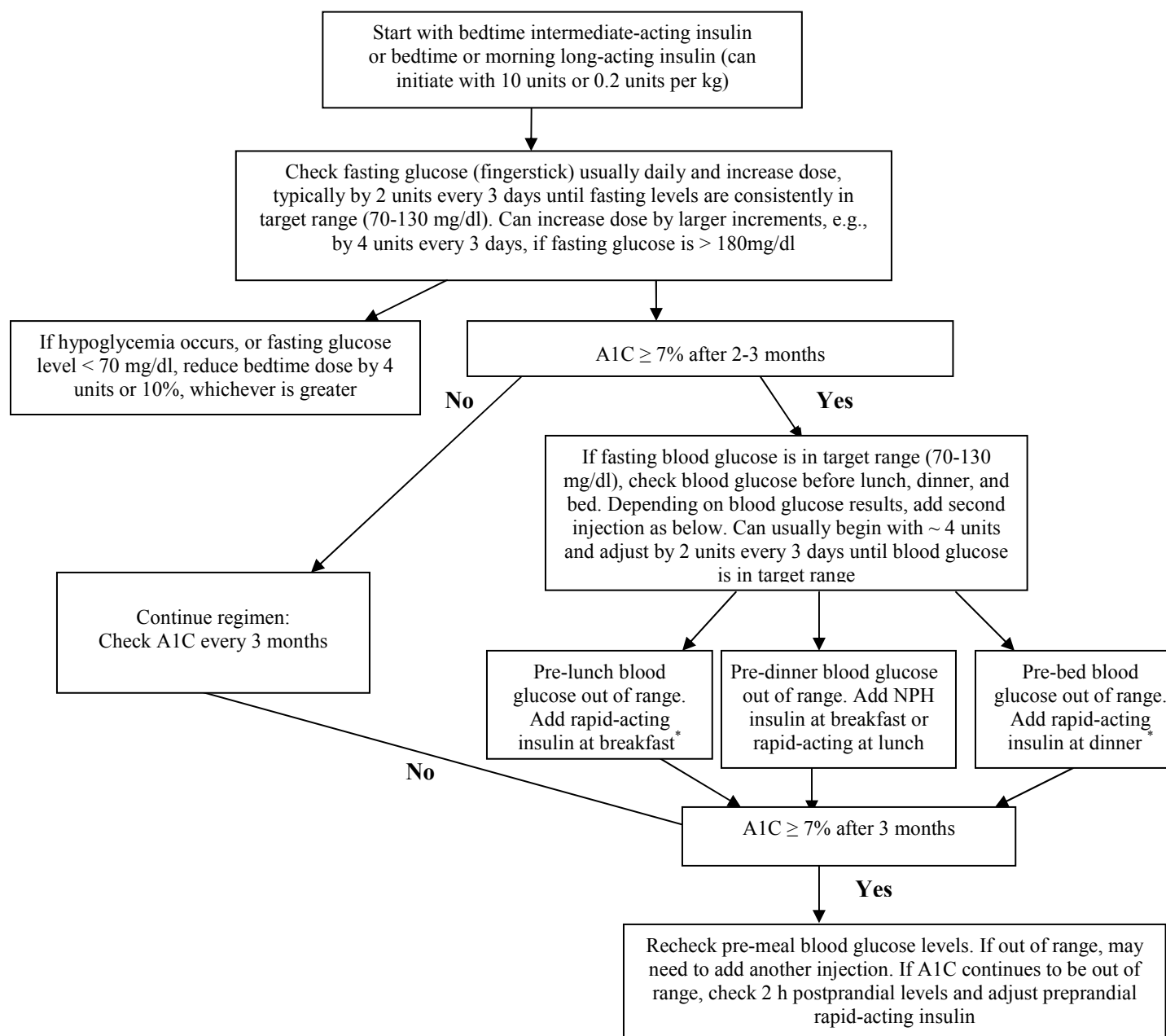
<sup>41</sup> White Jr. JR.. *The pharmacological reduction of blood glucose in patients with type 2 diabetes mellitus. Clinical Diabetes* 16:1998.

<sup>42</sup> Cochrane E, et al. *The use of U-500 in patients with extreme insulin resistance. Diabetes Care* 28: 1240-1244, 2005.

<sup>43</sup> *The Juvenile Diabetes Research Foundation Continuous Glucose Monitoring Study Group. Continuing glucose monitoring and intensive treatment of type 1 diabetes. NEJM* 359: 1464-1476, 2008.

## DIABETES MEDICATIONS

### Initiation and Adjustment of Insulin Regimens<sup>44</sup>



**Initiation and adjustment of insulin regimens.** Insulin regimens should be designed taking lifestyle and meal schedule into account. The algorithm can only provide basic guidelines for initiation and adjustment of insulin.

\* Premixed insulins, combining rapid- and longer-acting insulin in a single injection, are not recommended during adjustment of doses; however, they can be used conveniently, usually before breakfast and/or dinner, if the proportional adjustments of rapid- and intermediate-acting insulins are the same as the fixed proportions available.

<sup>44</sup> Nathan D, et al. Medical Management of Hyperglycemia in Type 2 Diabetes: A Consensus Algorithm for the Initiation and Adjustment of Therapy. *Diabetes Care* 32:193-203, 2009.

## CARDIOVASCULAR RISK-REDUCTION GUIDELINES

### Summary of Lipid-Lowering Therapy

Diabetes has been classified as a coronary equivalent and patients with diabetes should be treated as if they have underlying cardiovascular disease (CVD). They are likely to benefit from early intervention with lifestyle modification and cardio-protective drugs, if necessary.

Evidence from clinical trials published over the past decade suggests that broad-based treatment of dyslipidemia, hypertension, microalbuminuria, and hypercoagulability (as well as interventional cardiology and cardiovascular surgery during acute coronary syndrome) can improve the event-free survival rate in people with diabetes who already have clinical CVD.<sup>45</sup>

### Recommendations:

- Annual fasting test for lipid disorders. More often if necessary to reach goal levels. (E)
- Testing every two years is adequate for those with low-density lipoprotein (LDL), high-density lipoprotein (HDL), and triglycerides (TG) within the target levels listed below. (E)
- Lifestyle modification focusing on reduction of saturated fat, trans fat, and cholesterol intake; weight loss (if indicated) and increased physical activity should be recommended to improve lipid profile. (A)
- Statin therapy should be added to lifestyle therapy, regardless of baseline lipid levels, for patients with diabetes with overt CVD (A) and for patients without CVD who are over the age of 40 and have one or more other CVD risk factors. (A)
- In patients without overt CVD and under age 40, or those with multiple CVD risk factors, statin therapy should be considered in addition to lifestyle therapy if LDL cholesterol remains above 100 mg/dl. (E)
- In individuals without overt CVD, the primary goal is an LDL cholesterol goal of < 100 mg/dl. (A)
- In individuals with overt CVD, a lower LDL cholesterol goal of < 70 mg/dl, using a high dose of a statin, is an option. (B)
- If patients treated with drugs do not reach targets on maximal tolerated statin therapy, a reduction in LDL cholesterol of ~ 30-40% from baseline is an alternative therapeutic goal. (A)
- Triglyceride levels < 150 mg/dl and HDL cholesterol > 40 mg/dl in men and > 50 mg/dl in women are desirable. However, LDL cholesterol-targeted statin therapy remains the preferred strategy. (C)
- Statin therapy is contraindicated in pregnancy. (E)

### Lifestyle Modifications

Specific lifestyle changes aimed at improving lipid profiles are recommended for all patients with diabetes. Lifestyle intervention should include MNT, increased physical activity, smoking cessation, and weight loss, if indicated. MNT should be tailored to the individual patient and focus on the reduction of saturated fat, cholesterol, and *trans* fat intake.<sup>46</sup>

According to the American Dietetic Association's Evidence Analysis Library, there is fair evidence to support the use of omega-3 fatty acids in decreasing the risk of death from cardiac events and non-fatal myocardial infarctions (MI). If not contraindicated, omega-3 fatty acids can be added to the diet. They can be from both marine and

<sup>45</sup> Remuzzi, G, et al. *Prevention and Treatment of Diabetic Renal Disease in Type 2 Diabetes: The BENEDICT study. J Am Soc Nephrol 17: S90-S97, 2006.*

<sup>46</sup> Grundy SM, et al. *Implications of recent clinical trials for the National Cholesterol Education Program Adult Treatment Panel III Guidelines. Circulation 110:237-239, 2004.*

## CARDIOVASCULAR RISK-REDUCTION GUIDELINES

plant sources: two 4-oz servings of fish per week (preferably fatty fish such as mackerel, salmon, herring, trout, sardines, or tuna) and plant-based foods containing 1.5 g alpha-linolenic acids (1 Tbsp canola or walnut oil, 0.5 Tbsp ground flax seed, < 1 tsp flax seed oil). The FDA does warn that fatty fish can be high in methylmercury and should be limited accordingly in women who are or may become pregnant, nursing mothers, and young children.<sup>47</sup>

<b>Target Levels of Risk Factors in Patients with Diabetes</b>		
<b>First priority</b>		
	LDL cholesterol (mg/dl)	Non-HDL cholesterol (mg/dl)
Highest-risk patients, including those with: diabetes plus one or more additional major CVD risk factors	< 70	< 100
High-risk patients, including those with: diabetes but no other major CVD risk factors	< 100	< 130
<b>Second priority</b>		
Triglycerides	< 150 mg/dl	
HDL cholesterol	> 40 mg/dl (male); > 50 mg/dl (female)	

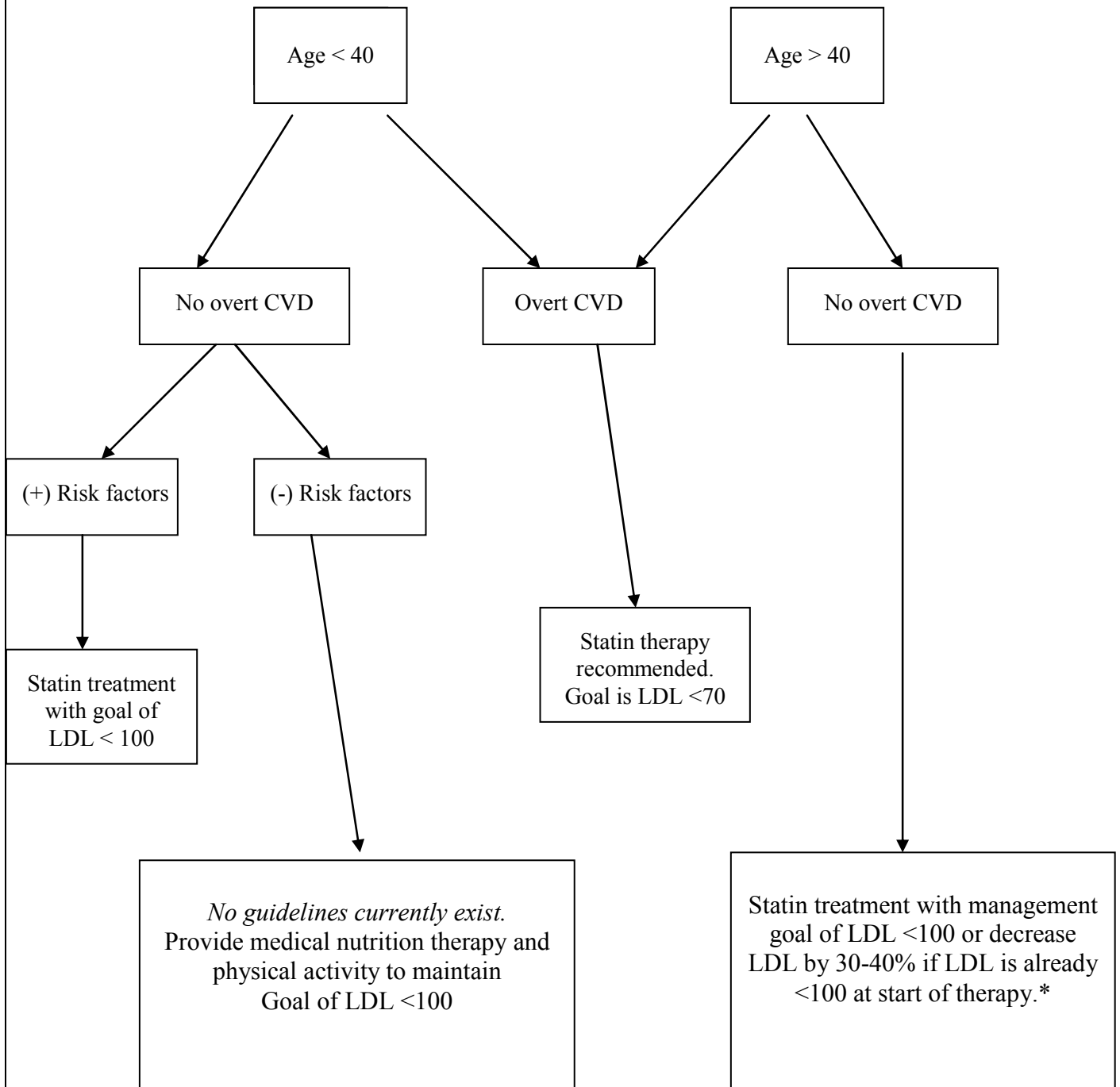
Non-HDL cholesterol (total cholesterol minus HDL cholesterol) reflects the concentration of cholesterol within all lipoprotein particles currently considered atherogenic. The Adult Treatment Panel III (ATP III) proposed that in individuals with hypertriglyceridemia (which would include many with diabetes), non-HDL cholesterol levels are a secondary goal of therapy after targeting LDL cholesterol levels. Many studies have demonstrated that non-HDL cholesterol is a better predictor of CVD risk than is LDL cholesterol and this may be especially true of statin-treated patients. Additional benefits of non-HDL cholesterol measurement are its lack of additional expense in patients already getting lipid panel measurements and that it can be calculated from nonfasting samples.<sup>48</sup>

See: **Lipid-Lowering Decision Tree in Type 2 Diabetes** on page 26.

<sup>47</sup> U.S. Food and Drug Administration, Center for Food Safety and Nutrition, <http://www.cfsan.fda.gov/~dms/admehg3.html>

<sup>48</sup> *Ibid.*

## Lipid-Lowering Decision Tree in Type 2 Diabetes



\*Based on randomized studies for type 2 diabetes- may or may not be applicable for type 1 diabetes

## PHARMACOLOGICAL THERAPY

Statins are the preferred drugs for LDL reduction. Other drugs that lower LDL include nicotinic acid, ezetimibe (18% reduction), bile acid sequestrants (15-30%), and fibric acid derivatives (fenofibrate and gemfibrozil 5-20%). Niacin and fibric acid derivatives are used primarily for TG lowering.

Liver function should be evaluated before the start of pharmacotherapy, and post initiation, as directed by package insert.

Current Available Statin Therapies for Lipid Disorders			
Generic Name	Trade Name®	Dose (mg)*	LDL % Reduction**
atorvastatin <sup>49,50</sup>	Lipitor	10-80	29-45%
Fluvastatin	Lescol	20-80	17-25%
Lovastatin	Mevacor	10-80	16-29%
Pravastatin	Pravachol	10-80	16-27%
rosuvastatin	Crestor	5-40	33-46%
Simvastatin	Zocor	5-80	19-36%
colesevelam***	Welchol	3750	~ 20%

**Highlighted drugs are available as generic formulations**

\* All of these statins are available at doses up to 80 mg except for rosuvastatin. For every doubling of the dose above starting dose, an approximate 6% decrease in LDL cholesterol level can be obtained.<sup>51</sup>

\*\* Estimated LDL reductions were obtained from U.S. FDA package inserts for each drug.

\*\*\* Colesevelam, traditionally used as a cholesterol lowering agent by binding intestinal bile acids, may be used as add-on therapy in type 2 diabetes. It lowers LDL by ~ 20% and A1C by ~ 0.5%. Other bile acid resins lower blood glucose as well, but colesevelam is better tolerated. Colesevelam may increase triglycerides, so caution is needed if TG level is over 300 mg/dl. Colesevelam should be avoided if TG level is over 500 mg/dl. Colesevelam is available as 625 mg tablets and should be dosed either 3 tablets twice a day or 6 tablets once a day. Other drugs and vitamins should be given at least 4 hours before colesevelam.

<sup>49</sup> Raikou M, et al. Cost-effectiveness of primary prevention of cardiovascular disease with atorvastatin in type 2 diabetes: Results from the Collaborative Atorvastatin Diabetes Study (CARDS). *Diabetologia*. 50:733-40, 2007.

<sup>50</sup> Ray KK, et al. Early and late benefits of high-dose atorvastatin in patients with acute coronary syndromes. Results from PROVE IT-TIMI 22 Trial. *J Am Coll Cardiol* 46:1405-1410, 2005.

<sup>51</sup> Buse JB, et al. Primary prevention of cardiovascular diseases in people with diabetes mellitus: A scientific statement from the American Heart Association and the American Diabetes Association. *Diabetes Care* 30:162-172, 2007.

## CORONARY HEART DISEASE

Cardiovascular risk factors should be assessed at least annually in people with diabetes. For patients without clear or suggestive symptoms of coronary artery disease, a risk factor-based approach is recommended, evaluating for dyslipidemia, hypertension, smoking, a positive family history of premature coronary disease, or the presence of micro- or macroalbuminuria. A recent study, however, concluded that the presence of traditional and emerging cardiac risk factors failed to identify a significant percentage of patients with silent ischemia.<sup>52</sup>

### Recommendations:

- In patients with known CVD: angiotensin-converting enzyme (ACE) inhibitor (C), aspirin (A), and statin therapy (A) (if not contraindicated) should be used to reduce risk of cardiovascular events.
- In patients > 40 years of age with another cardiovascular risk factor (hypertension, premature family history, dyslipidemia, microalbuminuria, cardiac autonomic neuropathy, or smoking) aspirin and statin therapy (if not contraindicated) should be used to reduce the risk of cardiovascular events. (B)
- A beta-blocker, if not contraindicated, should be added for patients with a prior myocardial infarction. (A)
- Screening tests such as a stress electrocardiogram (ECG), and/or stress echocardiography, and/or perfusion imaging may be beneficial for those with: 1) typical or atypical cardiac symptoms, and/or 2) an abnormal resting electrocardiogram. (E)

Other considerations with less clear evidence:

- A risk factor evaluation aimed at stratifying patients by 10-year risk should be considered. (B)
- Metformin is contraindicated in patients with acute or unstable heart failure, however may be used in patients with stable CHF if renal function is normal. (C)
- In patients with CHF, thiazolidinediones use is contraindicated. (C)
- Use caution in prescribing thiazolidinediones for patients with preexisting edema or heart disease. (E)

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<sup>52</sup> Wackers FJ, et al. Detection of ischemia in asymptomatic diabetic subjects. *Diabetes Care* 27:1954-1961, 2004.

## ASPIRIN THERAPY IN DIABETES

Both men and women with diabetes have a two- to four-fold increased risk of dying from the complications of cardiovascular disease. Evidence suggests that aspirin therapy should be prescribed as a secondary prevention strategy and, if no contraindications exist, should also be used as a primary prevention strategy in men and women with diabetes who are at high risk (over age 40 or with other CVD risk factors). The use of aspirin has not been studied in individuals under the age of 30.<sup>53</sup>

### Aspirin Therapy Recommendations:

- Use aspirin therapy (75-162 mg/day) as a secondary prevention strategy in men and women with diabetes and a history of myocardial infarction, vascular bypass procedure, stroke or transient ischemic attack, peripheral vascular disease, claudication, and/or angina. (A)
- Use aspirin therapy (75-162 mg/day) as a primary prevention strategy in men and women with type 1 or type 2 diabetes at increased cardiovascular risk, including those over 40 years of age or who have additional risk factors (family history of CVD, hypertension, smoking, dyslipidemia, albuminuria). (C)
- People with aspirin allergy, bleeding tendency, recent gastrointestinal bleeding, and clinically active hepatic disease are not candidates for aspirin therapy. Other antiplatelet agents, such as clopidogrel, may be a reasonable alternative for high-risk patients with contraindications to aspirin therapy. (B)
- Combination therapy with aspirin (75–162 mg/day) and clopidogrel (75 mg/day) is reasonable for up to a year after an acute coronary syndrome. (B)

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<sup>53</sup>American Diabetes Association (Position Statement). Aspirin therapy in diabetes. *Diabetes Care* 27 (Supplement 1): S72-S73, 2004.

# HYPERTENSION

## Summary

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

## Recommendations:

- Patients with diabetes should be treated to a systolic blood pressure (SBP) < 130 mmHg (C) and to a diastolic blood pressure (DBP) < 80 mmHg. (B)
- Patients with SBP of 130-139 mmHg or DBP of 80-89 mmHg may be given lifestyle therapy alone for a maximum of 3 months and then, if targets are not achieved, be treated with the addition of pharmacological agents. (E)
- Patients with more severe hypertension (SBP  $\geq$  140 mmHg or DBP  $\geq$  90 mmHg) at diagnosis or follow-up should receive prescriptions for both antihypertensive medication and lifestyle/behavioral changes.<sup>54,55</sup> (A)
- All patients with diabetes and hypertension should be treated with ACE inhibitors, or angiotensin II receptor blockers (ARBs). If one class is not tolerated, the other should be substituted. Add a thiazide diuretic in those with estimated GFR  $\geq$  30 ml/min per 1.73 m<sup>2</sup> or a loop diuretic for those with estimated GFR < 30 ml/min per 1.73 m<sup>2</sup> if needed to reach target blood pressure. (C)
- Monitor renal function and serum potassium levels when using ACE inhibitors, ARBs, or diuretics. (E)
- Multiple drug therapy utilizing two or more agents at proper doses is often necessary to reach target levels. (B)
- Clinical trials provide evidence that ACE inhibitors and ARBs have an additional impact on nephropathy and CVD.<sup>56</sup> (A) Refer to the section on **Nephropathy and CVD Risk-Reduction (on page 32)**.
- Beta-blockers should be added for those who have had a recent myocardial infarction (MI) if not contraindicated; caution should be used in those with hypoglycemia unawareness. (A)
- In pregnant patients with diabetes and chronic hypertension, target blood pressure goals of 110-129/65-79 mmHg are suggested. ACE inhibitors and ARBs are contraindicated during pregnancy and should be discontinued in women planning pregnancy due to their teratogenic effects. (E)
- In elderly patients, blood pressure should be lowered gradually.

## Benefit of Aggressive Treatment

Control of hypertension has been demonstrated conclusively to reduce the rate and progression of nephropathy and retinopathy, and to reduce the complications of cerebrovascular disease and cardiovascular disease (CVD). Recent data suggests that the addition of amlodipine to an ACE-I may be used instead of an ACE-I and thiazide, as some data suggests improved reduction of cardiovascular outcomes in at-risk patients.<sup>57</sup>

<sup>54</sup> Adler A, et al. Association of systolic blood pressure with macrovascular and microvascular complications of type 2 diabetes (UKPDS 36): Prospective observational study. *BMJ* 321: 412-419, 2000.

<sup>55</sup> Chobanian AV, et al. Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure. National Heart, Lung, and Blood Institute; National High Blood Pressure Education Program Coordinating Committee. *The Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure (JNC 7)*. *Hypertension* 42:1206-52, 2003.

<sup>56</sup> Schrier RW, et al. Appropriate blood pressure control in hypertensive and normotensive type 2 diabetes mellitus: a summary of the ABCD trial. *Nat Clin Pract Nephrol* 3: 428-438, 2007.

<sup>57</sup> Jamerson K, et al. Benazepril plus amlodipine or hydrochlorothiazide for hypertension in high-risk-patients. *NEJM* 359: 2417-2428, 2008.

## HYPERTENSION

### Lifestyle Modifications

The Dietary Approaches to Stop Hypertension (DASH) diet, which encourages the intake of fruits, vegetables, whole grains, poultry, fish, and low-fat dairy products, particularly when combined with sodium restriction, has been associated with substantial improvements in blood pressure.<sup>58</sup> Weight loss, increased physical activity, smoking cessation, and prudent reduction of sodium and alcohol should be major components of treatment of hypertension. A maximum three-month trial of lifestyle/behavioral modification is recommended for those with a SBP of 130-139 mmHg or a DBP of 80-89 mmHg.

Treatment Categories		
Systolic	Diastolic	Comment
< 130 mmHg	< 80 mmHg	Target blood pressure
130-139 mmHg	80-89 mmHg	Lifestyle changes alone (maximum 3 months), then add drug therapy
≥ 140 mmHg	≥ 90 mmHg	Lifestyle changes plus drug therapy

### Blood Pressure Measurement:

- Measure blood pressure at every routine visit. Patients with SBP ≥ 130 mmHg or DBP ≥ 80 mmHg require confirmation on a separate day. (C)
- Measure blood pressure in a seated position, with feet flat on the floor and arm supported at heart level after 5 minutes of rest.<sup>59</sup> (A)
- Orthostatic measurement is recommended to identify autonomic neuropathy. (E)

Cardiovascular autonomic neuropathy is common in patients with diabetes and can cause falsely low or high blood pressure readings, depending on the position of the patient when the blood pressure is taken.<sup>60</sup> Blood pressure and pulse should ideally be measured both in the supine and standing position, leaving two minutes between readings. Two or more determinations in each position should be obtained using an appropriately sized cuff. If the first two readings differ by more than 5 mmHg, additional readings should be obtained and averaged. Orthostatic hypotension is defined as a fall in SBP of at least 20 mmHg or a fall in DBP of at least 10 mmHg within three minutes of standing up.<sup>61,62</sup>

<sup>58</sup> Buse JB, et al. Primary prevention of cardiovascular diseases in people with diabetes mellitus: A scientific statement from the American Heart Association and the American Diabetes Association. *Diabetes Care* 30:162-172, 2007.

<sup>59</sup> Chobanian AV, et al. The Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure *JAMA* 289:2560-2571, 2003.

<sup>60</sup> Maser RE, et al. Diabetic autonomic neuropathy and cardiovascular risk: The Pittsburgh Epidemiology of Diabetes Complications Study III. *Arch Intern Med* 150:1218-1222, 1990.

<sup>61</sup> The Consensus Committee of the American Autonomic Society and the American Academy of Neurology. Consensus statement on the definition of orthostatic hypotension, pure autonomic failure, and multiple system atrophy. *Neurology* 46: 1470-1471,1996.

<sup>62</sup> Arauz-Pacheco C, et al. The treatment of hypertension in adult patients with diabetes. *Diabetes Care* 25: 134-147, 2002.

# NEPHROPATHY

## Summary

The earliest clinical evidence of nephropathy is microalbuminuria, the appearance of low but abnormal levels of albumin in the urine. A harbinger of renal failure and cardiovascular complications in diabetes, microalbuminuria is an albumin concentration in the urine that is greater than normal but is not detectable with common urine dipstick assays for protein.

## When to Screen

- Type 2 diabetes: assess urine albumin excretion at diagnosis and yearly thereafter. (E)
- Type 1 diabetes: assess urine albumin excretion after five years of disease duration and yearly thereafter. (E)
- Serum creatinine should be measured annually for the estimation of glomerular filtration rate (GFR) and to stage the level of chronic kidney disease.<sup>63</sup> (E)

## Screening Tests

### Urine Albumin:Creatinine Ratio

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

Random spot collection (preferred):

- Normal: < 30 µg/mg creatinine
- Microalbuminuria: 30-299 µg/mg creatinine
- Macroalbuminuria: ≥ 300 µg/mg creatinine

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

### Serum Creatinine

Serum creatinine should be measured annually for the estimation of glomerular filtration rate (GFR) in all adults with diabetes regardless of the degree of urinary albumin excretion. The serum creatinine alone should not be used as a measure of kidney function but instead used to estimate GFR and estimate the level of chronic kidney disease. The use of prediction equations to estimate GFR from serum creatinine and other variables (age, sex, race, and body size) is recommended by the National Kidney Foundation as a cost-effective method of diagnosis and stratification of chronic kidney disease. If the GFR is low, check the parathyroid hormone (PTH) and vitamin D levels to rule out secondary hyperparathyroidism. Consider referral to a physician experienced in the care of diabetic renal disease when the estimated GFR has fallen to < 60 ml/min per 1.73 m<sup>2</sup>, or if difficulties occur in the management of hypertension or hyperkalemia.

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<sup>63</sup> American Diabetes Association. *Standards of Medical Care in Diabetes. Diabetes Care* 32 (Supplement 1): S13-S61, 2009.

## NEPHROPATHY

### Calculation of Glomerular Filtration Rate

#### Cockcroft-Gault Equation<sup>64</sup>

$$\frac{(140 - \text{Age}) \times \text{Weight (Kg)}}{72 \times \text{Creatinine (mg/dL)}} \times K$$

K is a constant.  
For males, K = 0.139; for females, K = 0.118

Online resource for estimating GFR:

National Kidney Disease Education Program (NKDEP): <http://www.nkdep.nih.gov>

PDA downloadable resource for GFR: The National Kidney Disease Education Program, the National Institutes of Health: [http://nkdep.nih.gov/professionals/gfr\\_calculators/gfr\\_application.htm](http://nkdep.nih.gov/professionals/gfr_calculators/gfr_application.htm)

#### Stages of Kidney Disease<sup>65</sup>

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

\* Kidney damage is defined as abnormalities on pathologic urine, blood or imaging tests.

<sup>64</sup> Rigalleau V, et al. Estimation of glomerular filtration rate in diabetic subjects. *Diabetes Care*, 28:838-843, 2005.

<sup>65</sup> American Diabetes Association. *Standards of Medical Care in Diabetes. Diabetes Care* 32 (Supplement 1): S13-S61, 2009.

# NEPHROPATHY

## Nephropathy and Hypertension

To reduce the risk or slow the progression of nephropathy, optimal glucose and blood pressure control are recommended. Both systolic and diastolic hypertension markedly accelerate the progression of diabetic nephropathy. Control of hypertension has been demonstrated to reduce the rate and progression of nephropathy and to reduce the complications of cerebrovascular disease and CVD disease. Refer also to the **Cardiovascular (page 24) and Hypertension (page 30)** sections of these Guidelines.

## Pharmacological Therapy

### Recommendations:

- For patients with both micro- and macroalbuminuria, either angiotensin-converting enzyme (ACE) inhibitors or Angiotensin II Receptor Blockers (ARBs) should be used except during pregnancy. To assess hyperkalemia and acute kidney disease, serum potassium levels and serum creatinine should be monitored in patients treated with either class of medication. (E)
- Continued assessment of albumin excretion after diagnosis of microalbuminuria and institution of ACE inhibitor or ARB therapy and blood pressure control is unclear. Continued surveillance can assess both response to therapy and progression of disease. Some suggest that reducing abnormal albuminuria (> 30 mg/g) to the normal or near-normal range may improve renal and cardiovascular prognosis, but this approach has not been formally evaluated in prospective trials.<sup>66</sup> (E)

Clinical trials reveal the following observations:

- In patients with type 1 diabetes with microalbuminuria and hypertension, ACE inhibitors delay the progression of nephropathy. (A)
- For patients with type 2 diabetes with both hypertension and microalbuminuria, both ACE inhibitors and ARBs delay the progression to macroalbuminuria. (A)
- In patients with type 2 diabetes who have hypertension, macroalbuminuria, and renal insufficiency, ARBs delay the progression of nephropathy. (A)
- Dihydropyridine calcium channel blockers (DCCBs) are less likely to slow the progression of nephropathy compared with ACE inhibitors or ARBs. DCCBs should be used only as an additional therapy in patients already treated with ACE inhibitors or ARBs.<sup>67</sup> (A)
- For patients with albuminuria or nephropathy who cannot tolerate ACE inhibitors and/or ARBs, consider using beta-blockers, diuretics, or non-DCCBs. Non-DCCBs may reduce albuminuria in patients with diabetes including during pregnancy. (A)
- Due to their teratogenic potential, caution is advised when using either ACE inhibitors or ARBs in women of childbearing age.

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<sup>66</sup> American Diabetes Association. *Standards of Medical Care in Diabetes*. *Diabetes Care* 32 (Supplement 1): S13-S61, 2009.

<sup>67</sup> Berl T, et al. *Cardiovascular outcomes in the Irbesartan Diabetic Nephropathy Trial of patients with type 2 diabetes and overt nephropathy*. *Annals of Internal Medicine* 138; 542-554, 2003.

# NEPHROPATHY

## Kidney Disease and Medical Nutrition Therapy

Medicare and other payors provide coverage of MNT for beneficiaries diagnosed with diabetes or renal disease (except for those receiving dialysis) when provided by a registered dietitian or nutrition professional who meets the provider qualifications. A referral by the beneficiary's treating physician indicating a diagnosis of diabetes or renal disease is required. Medicare provides coverage for 3 hours of MNT in the first year and 2 hours in subsequent years.

### Nutrition Recommendations for People with Diabetes and Kidney Disease

- Protein: 0.8-1.0 g/kg body wt/day. Several small studies suggest that vegetable or soy protein sources may protect kidney function compared with red-meat sources. Reduction of protein intake to 0.8 g/kg body wt/day in the later stages may improve measures of renal function. Regardless of the level of protein intake, 50% to 75% of the protein should be of high biological value, derived predominantly from lean poultry, fish, and soy- and vegetable-based proteins.
- Energy: 35 kcal/kg (high in complex carbohydrate), unless patient is obese
- Fat: < 30% of total calories:
  - Polyunsaturated fatty acid  $\leq$  10%
  - Fish oil may be useful for IgA nephropathy (12 g/day)
- Cholesterol: < 200 mg/day
- Sodium: 1,000-2,000 mg/day
- Potassium: Individualize based on labs
- Phosphorus: < 12 mg/kg/day
- Calcium: 1,000-1,500 mg/day, not to exceed 2,000 mg
- Vitamins/minerals: Dietary Reference Intakes for B-complex and vitamin C, individualize vitamin D and iron
- Fluid restriction: May be indicated because of the high incidence of edema in nephrotic syndrome

## RETINOPATHY

Diabetic retinopathy is estimated to be the most frequent cause of new cases of blindness among adults aged 20-74 years in the United States. The prevalence of retinopathy is strongly related to the duration of diabetes. Follow-up from the Diabetes Prevention Program (DPP) indicated nearly 8% of people with pre-diabetes (IGT and IFG) already had evidence of retinopathy.<sup>68</sup> Intensive diabetes management with the goal of achieving near normal glycemia has been shown to prevent and/or delay the onset of diabetic retinopathy. High blood pressure is an established risk factor for the development of macular edema and is linked to the presence of proliferative diabetic retinopathy. Nephropathy is also associated with retinopathy. Patients with diabetic retinopathy or macular edema are often asymptomatic. Early diagnosis and prompt application of laser photocoagulation surgery is useful in preventing vision loss, but generally not beneficial in reversing already diminished acuity.<sup>69</sup>

### Screening Recommendations:

- An ophthalmologist or optometrist who is knowledgeable and experienced in diagnosing the presence of diabetic retinopathy and is aware of its management should perform comprehensive eye exams. (E)
- Adults with type 1 diabetes should have an initial dilated and comprehensive eye examination within 5 years of the diagnosis of diabetes. (B)
- Adults with type 2 diabetes should have an initial dilated and comprehensive eye examination shortly following the diagnosis of diabetes. (B)
- Subsequent examinations for patients with type 1 and type 2 diabetes should be repeated annually. A qualified eye care professional may recommend less frequent exams (i.e., every 2 years).<sup>70</sup> (B)
- Examinations will be required more frequently if retinopathy is progressing. (B)
- Women with preexisting diabetes should have a comprehensive eye exam when planning pregnancy and should be counseled on the risk of development and/or progression of diabetic retinopathy.<sup>71</sup> (B)
- Women with diabetes who become pregnant should have a comprehensive eye exam in the first trimester with close follow-up at intervals determined by retinopathy status throughout pregnancy and for one year postpartum. (B)
- Retinal screening is not necessary for women who develop gestational diabetes because these women are not at increased risk for diabetic retinopathy. (B)
- In general, small doses of aspirin are safe for preventative therapy in patients with retinopathy; when in doubt, consult a diabetic eye disease specialist. (A)
- Anyone with a change or loss of vision requires prompt referral to an eye care specialist. (A)

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<sup>68</sup> National Institutes of Health and American Diabetes Association. *Diabetic Retinopathy Occurs in Pre-Diabetes*. NEWSROOM June 10-14, 2005.

<sup>69</sup> American Diabetes Association (Position Statement). *Retinopathy in diabetes*. *Diabetes Care* 27 (Supplement 1): S84-S87, 2004.

<sup>70</sup> American Diabetes Association. *Standards of Medical Care in Diabetes*. *Diabetes Care* 32 (Supplement 1): S13-S61, 2009.

<sup>71</sup> Kitzmiller JL, et al. *Managing preexisting diabetes for pregnancy. Summary of evidence and consensus recommendations for care*. *Diabetes Care* 31:1060-1079, 2008.

# NEUROPATHY

## Summary

Neuropathy is a disorder of the peripheral nervous system resulting in loss of nerve fibers affecting many bodily functions. There are several syndromes of diabetic neuropathy, the most common being autonomic neuropathy and distal symmetric polyneuropathy (DPN). The diabetic neuropathies are heterogeneous with diverse clinical manifestations. Specific treatment for the underlying nerve damage is currently not available. Improved glycemic control may slow progression but rarely reverses neuronal loss. Effective symptomatic treatments are available for the manifestations of DPN and autonomic neuropathy. Early recognition and appropriate management of neuropathy in the patient with diabetes is important for a number of reasons:

- Non-diabetic neuropathies may be present in patients with diabetes and may be treatable.
- A number of treatment options exist for symptomatic diabetic neuropathy.
- Up to 50% of DPN may be asymptomatic and patients are at risk of insensate injury to their feet.
- Autonomic neuropathy may involve every system in the body.
- Cardiovascular autonomic neuropathy causes substantial morbidity and mortality.

## Diabetic Autonomic Neuropathy Recommendations:

- Patients with diabetes should be screened for presenting signs and symptoms of diabetic autonomic neuropathy as part of the initial history and review of systems and at least annually thereafter (B).
- Screening for signs and symptoms of cardiovascular autonomic neuropathy should be instituted at diagnosis of type 2 diabetes and five years after the diagnosis of type 1 diabetes. (E)

## Signs and Symptoms of Autonomic Neuropathy

<p><b>Cardiac</b></p> <ul style="list-style-type: none"> <li>• Resting tachycardia (&gt;100 bpm)</li> <li>• Exercise intolerance</li> <li>• Orthostatic hypotension (a fall in systolic blood pressure &gt; 20 mmHg or diastolic blood pressure &gt; 10 mmHg upon standing)</li> </ul>	<p><b>Genitourinary Tract</b></p> <ul style="list-style-type: none"> <li>• Recurrent urinary tract infections</li> <li>• Pyelonephritis</li> <li>• Incontinence</li> <li>• Palpable bladder</li> <li>• Loss of penile erection</li> <li>• Retrograde ejaculation</li> <li>• Sexual dysfunction in female</li> </ul>
<p><b>Gastrointestinal</b></p> <ul style="list-style-type: none"> <li>• Esophageal enteropathy/Gastroparesis</li> <li>• Constipation</li> <li>• Diarrhea</li> <li>• Fecal incontinence</li> </ul>	<p><b>Other Symptoms</b></p> <ul style="list-style-type: none"> <li>• Hyper- or hypohidrosis (inability to sweat or excessive sweating)</li> <li>• Impaired neurovascular function</li> <li>• Hypoglycemia unawareness</li> </ul>

## Treatment for Autonomic Neuropathy

The first step towards the goal of slowing the progress of diabetic neuropathies is to achieve and maintain optimal glycemic control. Improving labile blood glucose values may have an impact on symptoms as well. A number of pharmacological agents are used to treat the symptoms of autonomic neuropathies such as gastroparesis, bladder dysfunction, and sexual dysfunction. Although they do not change the underlying pathology of the disease, they may improve the patient's quality of life.

## NEUROPATHY

### Distal symmetric polyneuropathy (DPN)

Foot ulcers and amputations resulting from neuropathy and/or peripheral vascular disease (PVD) are major causes of disability and morbidity among people with diabetes. The risk of ulcers or amputations is increased in people who have had diabetes for 10 or more years; are male; have poor glucose control; smoke; or have cardiovascular, retinal, or renal complications. Early recognition of problems and risk factor management can delay or prevent unfavorable outcomes.<sup>72</sup>

#### DPN Recommendations:

- Conduct a comprehensive foot exam at least annually. The exam may take place in the primary care setting and should include a visual inspection and palpation for pulses as well as a sensory evaluation using a tuning fork or a Semmes-Weinstein monofilament. (B) See **Monofilament and Tuning Fork Instructions** (pages 40-41).
- Perform a visual foot inspection at every visit for patients who have neuropathy. (E)
- Provide self-care education to all patients, especially those with risk factors such as smoking or prior lower extremity complications. (B)
- Refer patients who have loss of protective sensation and structural abnormalities, or who have a prior history of lower-extremity complications to a podiatrist for ongoing preventive care. (C)
- Screen for peripheral artery disease (PAD) by assessing the pedal pulses and evaluating for a history of claudication. Consider obtaining an ankle-brachial index (ABI), as many patients with PAD are asymptomatic. (C)
- Refer patients with significant claudication or a positive ABI for further vascular assessment. (C)
- Offer a multidisciplinary approach for patients with foot ulcers and high-risk feet. (B)

#### Screening

<p>Low Risk</p> <p>All of the following:</p> <ul style="list-style-type: none"> <li>• Intact protective sensation</li> <li>• Pedal pulses present</li> <li>• No severe deformity</li> <li>• No prior foot ulcer</li> <li>• No amputation</li> </ul>	<p>High Risk: associated with an increased risk for amputation</p> <p>One or more of the following:</p> <ul style="list-style-type: none"> <li>• Smoking</li> <li>• Peripheral neuropathy with loss of protective sensation</li> <li>• Altered biomechanics</li> <li>• Evidence of increased pressure (hemorrhage under a callus, erythema)</li> <li>• Bony deformity</li> <li>• PVD</li> <li>• History of ulcers or amputation of the other limb</li> <li>• Severe nail pathology</li> <li>• Absent pedal pulses</li> </ul>
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<sup>72</sup> Boulton et al. *Comprehensive Foot Examination and Risk Assessment. A report of the Task Force of the Foot Care Interest Group of the American Diabetes Association, with endorsement by the American Association of Clinical Endocrinologists. Diabetes Care 31:1679-1685, 2008.*

## NEUROPATHY

### Symptomatic Treatments

- Aim for stable and optimal glycemic control.
- Avoid extreme blood glucose fluctuations.
- Some patients many need pharmacological treatment for pain associated with distal symmetric polyneuropathy (DNP).

**Table of drugs to treat symptomatic DPN<sup>73</sup>**

Class	Examples	Typical doses <sup>*</sup>
Tricyclic drugs	amitriptyline	10-75 mg at bedtime
	nortriptyline	25-75 mg at bedtime
	imipramine	25-75 mg at bedtime
Anticonvulsants	gabapentin	300-1,200 mg t.i.d.
	carbamazepine	200-400 mg t.i.d.
	pregabalin <sup>†</sup>	100 mg t.i.d.
5-hydroxytryptamine and norepinephrine uptake inhibitor	duloxetine <sup>†</sup>	60-120 mg daily
Substance P inhibitor	capsaicin cream	0.025-0.075% applied t.i.d. or q.i.d.

\* Dose response may vary; initial doses should be low and titrated up.

<sup>†</sup> Has FDA indication for treatment of painful diabetic neuropathy.

Many agents have efficacy confirmed in published randomized controlled trials. The choices of treatment will depend on contraindications as well as reimbursement. Doses should be started low and titrated to efficacy. Particular care should be given to adverse effects in the elderly. Capsaicin is effective but requires up to 4 weeks to show an effect.

<sup>73</sup> American Diabetes Association. *Standards of Medical Care in Diabetes. Diabetes Care* 32 (Supplement 1): S13-S61, 2009.

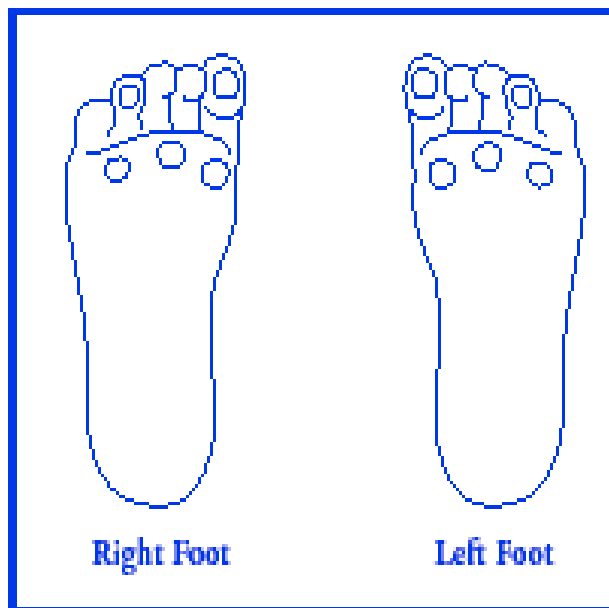
# NEUROPATHY

## Foot Inspection and Monofilament Guide

### Assessing for Loss of Protective Sensation

#### Use of the Semmes-Weinstein monofilament

- Have the patient look away or close his or her eyes.
- Hold the filament perpendicular to the skin.
- Avoiding any ulcers, calluses, or sores, touch the monofilament to the skin until it bends. Hold in place for approximately 1.5 seconds, then gently remove it.
- Randomly test the sites shown on the diagram below.
- Elicit a response from the patient at each site. Lack of sensation at any site may indicate diabetic neuropathy.<sup>74</sup>
- Non-disposable monofilaments may be cleaned with 1:10 sodium hypochlorite (household bleach) solution if contaminated with blood or body fluids.



<sup>74</sup> Boulton AJM, et al. *Comprehensive Foot Examination and Risk Assessment: A report of the Task Force of the Foot Care Interest Group of the American Diabetes Association, with endorsement by the American Association of Clinical Endocrinologists. Diabetes Care 31: 1679-168, 2008.*

## NEUROPATHY

### Tuning fork instructions

- Strike a 128 Hz tuning fork (hard enough to make a noise).
- Place the vibrating tuning fork on the dorsum of the great toe, just proximal to the nail bed.
- With the hand that is not holding the tuning fork, place a finger on the plantar surface of the same toe.
- Have the patient close his or her eyes and inform you when vibration is no longer perceived.
- Gauge the difference between when the patient stops feeling the vibrating tuning fork and when you stop sensing vibration. Severe sensory loss is indicated when feeling the vibration stops almost immediately.
- If the patient and the examiner stop feeling the vibration at nearly the same moment, vibratory perception is considered normal.
- Intermediate losses can be judged as mild or moderate loss of perception.
- Some clinicians recommend counting how long the patient perceived the vibration and use 10 seconds as the cut-off for normal perception.

## MONOFILAMENT RESOURCES

All monofilaments are 5.07 (10 gm.)

<p><b>Lower Extremity Amputation (LEAP) Program</b>            Bureau of Primary Health Care (BPHC)            1-888-ASK-HRSA (275-4772)  <a href="http://www.hrsa.gov/leap/default.htm">www.hrsa.gov/leap/default.htm</a>            Disposable</p>	<p><b>North Coast Medical, Inc.</b>            1-800-821-9319  <a href="http://www.ncmedical.com">www.ncmedical.com</a>            Durable            \$31.95 each            Set of six, assorted sizes: \$146.95</p>
<p><b>Medical Monofilament Manufacturing, LLC</b>            1-508-746-7877  <a href="http://www.medicalmonofilament.com">www.medicalmonofilament.com</a>            Disposable            \$0.29-\$0.39</p>	<p><b>Sammons, Pruss, Rolyan</b>            1-800-558-8633  <a href="http://www.sammonspreston.com">www.sammonspreston.com</a>            Durable            \$29.99 each            Set of five, assorted sizes: \$169.95</p>
<p><b>Mid-Delta Home Health and Hospice</b>            1-800-543-9055  <a href="http://www.middelta.com">www.middelta.com</a>            Durable            \$10.00 each</p>	

# PERIODONTAL DISEASE

## Summary

Periodontal disease is more common among people with diabetes compared to the general population. Almost one-third of people with diabetes have severe periodontal disease with loss of attachment of the gums to the teeth measuring five millimeters or more. Periodontal disease progresses more rapidly and is often more aggressive and difficult to treat in people with diabetes than in people without diabetes.

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

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

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

## Recommendations:<sup>75</sup>

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

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<sup>75</sup> Moore P, et al. *Diabetes and Oral Health Promotion: A Survey of Disease Prevention Behavior. J Am Dent Assoc* 13: 1333-1341, 2000.

## IMMUNIZATIONS

### Summary

People with diabetes, in particular those with end organ complications of cardiac and renal disease, are at high risk for complications, hospitalization, and death from influenza and pneumococcal disease.<sup>76</sup> Vaccines can greatly reduce the risk of serious complications from these diseases. In particular, influenza vaccine has been shown to reduce diabetes-related hospital admissions by as much as 79% during flu epidemics.<sup>77</sup> The CDC and the Advisory Committee on Immunization Practices (ACIP) recommend influenza and pneumococcal vaccines for all individuals with diabetes.<sup>78</sup>

### Recommendations:

- Annually provide an influenza vaccine to all patients with diabetes  $\geq 6$  months of age. (C)
- Administer pneumococcal polysaccharide vaccine to all patients with diabetes  $\geq 2$  years of age. A one-time revaccination is recommended for individuals  $> 64$  years of age previously immunized when they were  $< 65$  years of age if the vaccine was administered  $> 5$  years ago.<sup>79</sup> Other indications for repeat vaccination include nephrotic syndrome, chronic renal disease, and other immunocompromised states. (C)

In addition to influenza and pneumococcal vaccines, early vaccination against hepatitis B is indicated in patients likely to progress to end-stage kidney disease.<sup>80</sup> Zoster vaccine was recently recommended by the ACIP to reduce the risk of shingles and its associated pain in people  $> 60$  years of age.<sup>81</sup> Creation of registries to identify patients with diabetes, and implementation of recall and reminder systems are effective strategies to improve immunization rates.<sup>82</sup>

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<sup>76</sup> American Diabetes Association: *Influenza and pneumococcal immunization in diabetes (Position Statement)*. *Diabetes Care* 27 (Supplement 1):S111–S113, 2004.

<sup>77</sup> Colquhoun AJ, et al. *Effectiveness of influenza vaccine in reducing hospital admissions in people with diabetes*. *Epidemiol Infect* 119: 335–341, 1997.

<sup>78</sup> <http://www.cdc.gov/vaccines/recs/>

<sup>79</sup> American Diabetes Association. *Standards of Medical Care in Diabetes*. *Diabetes Care* 32 (Supplement 1): S13–S61, 2009.

<sup>80</sup> *Ibid.*

<sup>81</sup> *MMWR Recommendations and Reports*. *Prevention of Herpes Zoster: Recommendations of the Advisory Committee on Immunization Practices (ACIP)*, 57(05);1–30, June 6, 2008.

<sup>82</sup> American Diabetes Association: *Influenza and pneumococcal immunization in diabetes (Position Statement)*. *Diabetes Care* 27 (Supplement 1):S111–S113, 2004.

# TOBACCO USE AND DIABETES

## Summary

Patients with diabetes who smoke have a heightened risk of morbidity and premature death due to macrovascular complications. Smoking is also related to the premature development of microvascular disease and may have a role in the development of type 2 diabetes.<sup>83</sup> The cardiovascular burden of diabetes, especially in combination with smoking, needs to be effectively communicated to people with diabetes or to health care providers. There is little evidence that this risk factor is being addressed as consistently and comprehensively as its importance requires.

### Smoking Cessation Recommendations:

- Advise all patients not to smoke. (A)
- Include smoking cessation counseling and other forms of treatment as a routine component of diabetes care.<sup>84</sup> (B)

Prevention and cessation of tobacco use is recommended as an important component of state-of-the-art clinical diabetes care.<sup>85</sup> All patients should be advised not to smoke and smoking cessation counseling and other forms of treatment should be included as a routine component of diabetes care. Tobacco dependence is a chronic condition that often requires repeated intervention by a clinician or team of clinicians and multiple attempts to quit. Many patients relapse several times before quitting for good. Effective treatments exist that can significantly increase rates of long-term abstinence.<sup>86</sup>

It is essential that clinicians and health care delivery systems consistently identify and document tobacco use status and treat every tobacco user seen in a health care setting. Clinicians should offer every patient who uses tobacco at least the brief “5A’s” treatment shown to be effective. The “5A’s” of treating tobacco use and dependence is a useful way of understanding smoking cessation interventions and organizing the clinical team to intervene with patients who smoke.

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<sup>83</sup> Willi C, et al. Active smoking and the risk of type 2 diabetes: a systematic review and meta-analysis. *JAMA* 298(22):2654–2664, 2007.

<sup>84</sup> American Diabetes Association. Standards of Medical Care in Diabetes. *Diabetes Care* 32 (Supplement 1): S13–S61, 2009.

<sup>85</sup> American Diabetes Association (Position Statement). Smoking and diabetes. *Diabetes Care* 27 (Supplement 1): S74–S75, 2004.

<sup>86</sup> Clinical Practice Guideline Treating Tobacco Use and Dependence: 2008 Update. <http://www.ahrq.gov/clinic/tobacco/tobaqrg.pdf>

## TOBACCO USE AND DIABETES

### The “5 A’s” model for treating tobacco use and dependence

#### Ask:

- Identify and document tobacco use status of every patient at every visit.

#### Advise:

- In a clear, strong and personalized manner, urge every tobacco user to quit.
- Provide reasons why quitting is beneficial for people with diabetes.

#### Assess:

- For a current smoker, is the patient willing to make a quit attempt at this time?
- For a former smoker, how recently did you quit and are there any challenges to remaining abstinent?

#### Assist:

- For a patient willing to make a quit attempt, offer medication. Provide or refer for counseling or additional behavioral treatment (see resources below).
- Acknowledge weight management concerns, and discourage smoking as a tool for weight control.
- Acknowledge the possible presence of depression or other mood disorder. Depression can interfere with successful cessation efforts.
- For a patient unwilling to quit at this time, provide motivational interventions designed to increase future quit attempts.
- For the recent quitter and anyone with remaining challenges, provide relapse prevention.

#### Arrange:

- All those receiving the previous A’s should receive follow-up.

While coverage will vary by plan, many health insurance plans, including MassHealth, Commonwealth Care, and Medicare, cover all or some of the cost of FDA-approved prescription and over-the-counter cessation medications. Some plans also provide coverage for counseling support. Members of any health plan may also be referred to free telephone support available through the QuitWorks fax referral program.

### QuitWorks

QuitWorks is a free, evidence-based smoking cessation referral service that links patients who want to quit smoking to the full range of tobacco treatment services offered by the Massachusetts Smoker’s Helpline. QuitWorks [www.quitworks.org](http://www.quitworks.org) was developed by the Massachusetts Department of Public Health in collaboration with all major health plans in Massachusetts.

- Using a simple enrollment form, a physician, nurse, or other clinician can easily and quickly enroll patients who use tobacco, regardless of health insurance status.
- Referring providers will receive faxed information on the services each patient selects and, 6 months later, a report on each patient's quit status.

**Resource:** [The Quick Reference Guide for Clinicians](http://www.ahrq.gov/clinic/tobacco/tobaqrg.pdf) contains strategies and recommendations from the Public Health Service-sponsored Clinical Practice Guideline *Treating Tobacco Use and Dependence: 2008 Update*.  
<http://www.ahrq.gov/clinic/tobacco/tobaqrg.pdf>

## PSYCHOSOCIAL ISSUES

### Summary

Psychological and socioeconomic issues can impair the individual's or family's ability to carry out diabetes care tasks and therefore compromise health status. In particular, depression in people with diabetes requires careful management due to its severe impact on comorbid conditions as well as on the individual's quality of life. In addition to obtaining a history of previous psychiatric treatment, clinicians should assess psychosocial status in a timely and efficient manner so that referral for appropriate services can be accomplished. Stressors such as family issues, insufficient financial or social resources, eating disorders, and cognitive impairment may impact a patient's ability to carry out necessary diabetes care tasks.

### Recommendations:

- Incorporate psychological screening and treatment into routine care rather than waiting for identification of a specific problem or deterioration in psychological status. (E)
- Psychosocial screening and follow-up should include, but is not limited to, attitudes about the illness, expectations for medical management and outcomes, affect/mood, general and diabetes-related quality of life, resources (financial, social, and emotional), and psychiatric history. (E)
- Screen for psychosocial problems such as depression, anxiety, eating disorders, and cognitive impairment when adherence to the medical regimen is poor.<sup>87</sup> (E)

Depression is known to affect glycemic control and micro/macrovacular complications. In addition, depressive symptoms play a more important role in mortality among people with diabetes than in those without diabetes. For adults with diabetes, the presence of two or more coexisting chronic conditions, particularly coronary artery disease, chronic arthritis, and stroke, increase the chances of developing major depression. Compared to patients with diabetes who are not depressed, people with diabetes and depression require more costly care. These differences are partly related to non-adherence to medication regimens and worsened self-care skills. Depressive symptoms impact subsequent physical symptoms of poor glucose control by influencing patients' ability to adhere to their self-care regimen.

Although the clinician may not feel qualified to treat psychological problems, utilizing the patient-provider relationship as a foundation for further treatment can increase the likelihood that the patient will accept referral for other services. It is important to establish that emotional well-being is part of diabetes management.

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<sup>87</sup> American Diabetes Association. *Standards of Medical Care in Diabetes. Diabetes Care 32 (Supplement 1): S13-S61, 2009.*

## PSYCHOSOCIAL ISSUES

The following two questions have shown high sensitivity and specificity:

“During the past month, have you often been bothered by feeling down, depressed, or hopeless?”

“During the past month, have you often been bothered by little interest or pleasure in doing things?”<sup>88</sup>

Treat depression or refer to a mental health specialist for depression treatment.

- Immediately refer to a mental health specialist familiar with diabetes management if self-harm or an eating disorder is suspected. A referral is also recommended if a problem is suspected to be organic in origin or when cognitive function is impaired.

*Resource:*

*PHQ Screeners:* <http://www.phqscreeners.com>

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<sup>88</sup> Arroll B, et al. Screening for depression in primary care with two verbally asked questions: Cross sectional study. *BMJ* 327:1144-1146, 2003.

# INPATIENT GLUCOSE CONTROL

## Summary

People with diabetes are more likely to be hospitalized and to have longer durations of hospital stay than those without diabetes. Hyperglycemia in hospitalized patients has been associated with poor outcomes, such as longer length of stay, increased rates of infections, and in-hospital deaths.<sup>89</sup> Interventions to normalize glycemia, however, have yielded inconsistent results. The ADA and the American Association of Clinical Endocrinologists (AACE) recently issued a joint statement maintaining the need for good glucose management in the hospital setting with revised glucose targets of 140-180 mg/dl in the ICU setting, and between 100-180 mg/dl for most patients admitted to general medical-surgical wards.<sup>90</sup>

## Recommendations:

- All hospitalized patients with diabetes should have their diabetes clearly identified in the hospital record. (E)
- All patients with diabetes should have an order for blood glucose monitoring, with results available to all members of the health care team. (E)
- Scheduled prandial insulin doses should be appropriately timed in relation to meals and should be adjusted to point-of-care glucose levels. (C)
- For patients being treated with insulin in the ICU setting, target glucose levels between 140-180 mg/dl (A)
- For non-critically ill patients treated with insulin, premeal blood glucose target should be < 140 mg/dl in conjunction with random blood glucose values < 180 mg/dl, provided these targets can be safely achieved.<sup>91</sup> (A)

Insulin infusions effectively decrease blood glucose concentrations in intensive care settings and reduce morbidity and mortality in surgical intensive care unit patients. Regimens for intensive insulin therapy should utilize general principles expressed throughout the literature but should also be modified based on specifics of the individual institution. Regimens should be responsive to factors that may rapidly affect the risk for hyper- or hypoglycemia such as:

- Changes in enteral/parenteral feeds (content, rate of delivery, temporary, or permanent cessation)
- Order for NPO
- Prolonged period outside of ICU
- Changes in intravenous glucose solution content
- Use of steroids or pressors (increasing or decreasing doses)
- Sudden changes in clinical status (sepsis, acute renal failure)

Institutions should prepare for transition from ICU to general areas of the hospital by arranging for follow-up glucose testing after intravenous insulin is stopped, and planning for follow-up insulin needs (short-acting during transfer and long-acting during subsequent days). The traditional sliding-scale insulin regimens, when used as monotherapy, have been shown to be ineffective.<sup>92</sup>

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<sup>89</sup> Pomposelli U, et al. Early postoperative glucose control predicts nosocomial infection rate in diabetic patients. *Journal of Parenteral and Enteral Nutrition* 22: 77-81, 1998.

<sup>90</sup> Moghissi ES, et al. American Association of Clinical Endocrinologists and American Diabetes Association. Consensus statement on inpatient glycemic control. *Endocr Pract* 15, May/June 2009. Published ahead of print.

<sup>91</sup> *Ibid.*

<sup>92</sup> American Diabetes Association. *Standards of Medical Care in Diabetes*. *Diabetes Care* 32 (Supplement 1): S13-S61, 2009.

Patients need to be educated that inpatient use of insulin does not commit them to permanent insulin therapy after discharge. Patients with hyperglycemia as inpatients, but without a previous diagnosis of diabetes, should have follow-up fasting glucose testing as outpatients.

For the **Summary of ADA/AACE Recommendations**, see:

[www.aace.com/pub/pdf/guidelines/InpatientGlycemicControlConsensusStatement.pdf](http://www.aace.com/pub/pdf/guidelines/InpatientGlycemicControlConsensusStatement.pdf)