

Capital Health

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Diabetes Clinical Practice Guideline

**Based on American Diabetes Association Position Statement:
Standards of Medical Care in Diabetes 2019**

Approved by CHP Quality Improvement Committee: 9/8/09, 5/10/11, 3/12/13, 3/10/15, 03/14/17,
3/6/18, 3/12/2019

Standards of Medical Care for Patients with Diabetes Mellitus

Criteria for Diagnosis: two abnormal test results from the same sample:

1. A1C \geq 6.5% (preferred) **OR**
 2. Fasting plasma glucose \geq 126 mg/dL
- Criteria may also include:**
3. 2-hour plasma glucose \geq 200 mg/dl during an oral glucose tolerance test, **OR**
 4. Symptoms of hyperglycemia or hyperglycemic crisis and random plasma glucose \geq 200mg/dL

Prevention or Delay of Type 2 Diabetes

- Refer patients with Prediabetes to an intensive behavioral lifestyle interventional program based on the Diabetes Prevention Program to achieve and maintain a 7% weight loss and moderate physical activity to at least 150 minutes per week. (Evidence A) Technology-assisted interventions may be effective. (Evidence B)
- Metformin therapy for prevention of type 2 diabetes should be considered in those with prediabetes, especially for those with a BMI of \geq 35 kg/m², those aged <60 years, and women with prior gestational diabetes. (Evidence A)
- Diabetes self-management education and support programs may be appropriate venues for people with prediabetes. (Evidence B)

Comprehensive Medical Evaluation, initial and ongoing (Evidence B)

Medical History

- Age and characteristics of diabetes onset
- Eating patterns, physical activity habits, eating behavior, BMI history, sleep behaviors, substance use, social support
- Complementary and alternative medicine use, vaccination history and needs
- Diabetes education history/needs to include health apps and online education
- Presence of common co-morbidities, psychosocial problems and dental issues
- Review of previous treatment regimens and response to therapy; include A1C history
- Current treatment of diabetes, including medications, medication taking-behavior.
 - o Results of glucose monitoring and patient's use of data
 - o Insulin pump settings, as indicated
- Assess eating pattern, and psychosocial conditions to include anxiety, depression, and cognitive impairment, and disordered eating. Refer for further assessment or intervention if warranted
- Hypoglycemic risk and episodes
 - o hypoglycemia awareness
 - o any severe hypoglycemia: frequency and cause
- History of increased blood pressure, abnormal lipids
- History of diabetes-related complications and common comorbidities
 - o microvascular: retinopathy, nephropathy, neuropathy (sensory, including history of foot lesions; autonomic, including sexual dysfunction and gastroparesis)
 - o macrovascular: CHD, cerebrovascular disease, PAD

- presence of hemoglobinopathies or anemias
- dental, eye, and specialty visits
- For women of childbearing capacity, review contraception and preconception planning

Physical examination

- Height, weight and BMI; growth development in children and adolescents
- Blood pressure determination, including orthostatic measurements when indicated
- Fundoscopic examination (refer to eye specialist)
- Thyroid palpation
- Skin examination (for acanthosis nigricans, lipodystrophy, insulin injection or infusion set insertion sites)
- Comprehensive foot examination:
 - Inspection – skin integrity, ulcers, condition of toenails, foot deformity, callous
 - palpation of dorsalis pedis and posterior tibial pulses – refer to ABI if diminished
 - determination of proprioception, vibration, and monofilament sensation

Laboratory evaluation

- A1C, if results not available within past 3 months
- If not performed or available within past year:
 - Lipid profile, including total, LDL and HDL cholesterol and triglycerides
 - Liver function tests
 - Test for urine albumin excretion with spot urine albumin-to-creatinine ratio
 - Serum creatinine and calculated eGFR
 - Thyroid-stimulating hormone in Type 1 diabetes
 - Vitamin B12 if on Metformin (when indicated)
 - Serum potassium levels in patients on ACE inhibitors, ARBs, or diuretics
 - Morning Serum Testosterone level in men with diabetes who have symptoms or signs of hypogonadism (Evidence B)

Referrals

- Eye Care professional for annual dilated eye exam
- Family planning for women of reproductive age
- Registered dietician for medical nutrition therapy
- Diabetes Self-Management Education (DSME)/ Diabetes Self-Management Support (DSMS)
- Dentist for comprehensive dental and periodontal examination
- Mental health professional, if indicated

Goals of care should include shared decision-making, involving educated and informed patients and/or family/caregiver(s)

Lifestyle Management

Self-Management Education and Support

- All people with diabetes should participate in diabetes self-management education to facilitate the knowledge, skills, and ability necessary for diabetes self-care. Diabetes self-management support is additionally recommended to assist with implementing and sustaining skills and behaviors needed for ongoing self-management. (Evidence B)

- Self-management education and support should be patient centered, may be given in group of individual settings or using technology, and should be communicated with the entire diabetes care team (Evidence A)

Medical Nutrition Therapy (MNT)

- Individuals with prediabetes or diabetes should receive individualized MNT to achieve treatment goals, preferably by a registered dietician familiar with the components of diabetes MNT. (Evidence A)
- Weight loss (>5%) achievable by the combination of reduction of calorie intake and lifestyle modification benefits individuals with diabetes or prediabetes who are overweight or obese. Intervention programs to facilitate weight loss are recommended (Evidence A)
- For individuals on a flexible insulin program, education on carbohydrate counting (Evidence A), and in some cases fat and protein gram estimation (Evidence B), to determine mealtime insulin dosage, can improve glycemic control.
- For individuals on a fixed daily insulin dose, having a consistent pattern of carbohydrate intake with respect to time and amount can improve glycemic control and reduce the risk of hypoglycemia (Evidence B)
- Individuals with diabetes and those at risk should avoid sugar-sweetened beverages (including fruit juices) to control weight and reduce their risk of cardiovascular disease (CVD) and fatty liver (Evidence B) and should minimize the consumption of foods with added sugar that have the capacity to displace healthier, more nutrient-dense food choices (Evidence A)
- Ingested protein appears to increase insulin response without increasing plasma glucose, so carbohydrate sources high in protein should be avoided when trying to treat or prevent hypoglycemia (Evidence B)
- An eating plan emphasizing elements of a Mediterranean-style diet rich in monounsaturated and polyunsaturated fats may be considered to improve glucose metabolism and lower CVD risk and can be an effective alternative to a diet low in total fat but relatively high in carbohydrates. (Evidence B)
- Eating foods rich in long-chain fatty acids, such as fatty fish (EPA and DHA) and nuts and seeds (ALA) is recommended to prevent or treat CVD (Evidence B). However, evidence does not support a beneficial role for the routine use of n-3 dietary supplements (Evidence A).
- Alcohol consumption may place people with diabetes at increased risk for hypoglycemia, especially if taking insulin or insulin secretagogues. Education and awareness regarding the recognition and management of delayed hypoglycemia are warranted (Evidence B)
- Sodium should be limited to <2,300 mg/day, although further restriction may be indicated for those with both diabetes and hypertension (evidence B)
- Nonnutritive sweeteners as a substitute for caloric sweeteners have the potential to reduce overall calorie and carbohydrate intake and low calorie or nonnutritive sweetened beverages may serve as a short-term replacement strategy. Overall, people are encouraged to decrease both sweetened and nonnutritive-sweetened beverages and use alternatives, with an emphasis on water intake (Evidence B)
- A variety of eating patterns are acceptable for the management of type 2 diabetes and prediabetes (Evidence B)

Diabetes Self-Management Education (DSME) and Support (DSMS)

- All people with diabetes should participate in diabetes self-management education to facilitate the knowledge, skills, and ability necessary for diabetes self-care and in diabetes self-management support to assist with implementing and sustaining skills and behaviors needed for ongoing self-management (Evidence B)
- Self-management education and support should be patient centered, may be given in group or individual settings or by using technology, and should help guide clinical decisions (Evidence A)

Physical Activity

- Most adults with type 1 (evidence C) and type 2 (evidence B) diabetes should engage in 150 minutes or more of moderate-to-vigorous physical activity per week spread over at least 3 days a week with no more than 2 consecutive days without activity; and they should engage in 2-3 sessions per week of resistant exercise. All adults, particularly those with type 2 diabetes, should decrease the amount of time spent in daily sedentary behavior (evidence B). Flexibility and balance training are recommended 2-3 times per week and may include yoga or tai chi (evidence C)
- All adults, particularly those with type 2 diabetes, should decrease the amount of time spent in daily sedentary behavior (Evidence B)
- Prolonged sitting should be interrupted every 30 minutes for blood glucose benefits, particularly in adults with type 2 diabetes (evidence C)

Smoking cessation

- Advise all patients not to smoke or use tobacco products (Evidence A) or e-cigarettes (Evidence B)
- Include smoking cessation counseling and other forms of treatment as a routine component of diabetes care (Evidence A)

Behavioral Health

- Psychosocial care should be integrated with a collaborative, patient-centered approach and provided to all people with diabetes, with the goals of optimizing health outcomes and health-related quality of life (Evidence A)
- Screen for psychosocial problems such as depression, diabetes-related distress, anxiety, eating disorders, and cognitive impairment at periodic intervals and when there is a change in disease, treatment, or life circumstance. Include caregivers and family members in the assessment as warranted. (Evidence B)
- Older adults (>65 years) with diabetes should be considered a high-priority population for depression screening and treatment and for cognitive status (Evidence B)

Management Plan

Glycemic control:

- A reasonable goal for many non-pregnant adults is <7% (53 mmol/mol). (evidence A) Lowering A1C to below 7% has been shown to reduce microvascular complications of diabetes.
 - Less-stringent A1C goals (such as <8 or 64 mmol/mol) may be appropriate for patients with:
 - a history of severe hypoglycemia
 - limited life expectancy
 - advanced microvascular or macrovascular complications
 - extensive co-morbid conditions
 - long-standing diabetes with a difficult to achieve goal despite diabetes education and

monitoring and effective doses of multiple glucose-lowering agents including insulin (evidence B)

- Preprandial capillary plasma glucose: 80-130 mg/dl
- Peak postprandial capillary plasma glucose: <180 mg/dl
- From the American College of Physicians (March 2018):
 - Goals and target ranges for glycemic control should be personalized based on a discussion of benefits and harms of pharmacotherapy, patients' preferences, patients' general health and life expectancy, treatment burden, and costs of care rather than a fixed target A1c for all
 - Shared decision-making is important in setting A1c goals

A1C

- A1C testing should be performed routinely in all patients with diabetes. The frequency of A1C testing is dependent on the clinical situation, the treatment regimen and the clinician's judgment.
- A1C testing is subject to limitations. In conditions that affect red blood cell turnover (such as hemolytic and other anemias, recent blood transfusions, use of drugs that stimulate erythropoiesis, HIV, ESRD, and pregnancy/postpartum) and in hemoglobin variants, options include more frequent use of SMBG, CGM use, fructosamine, and 1,5-anhydroglucitol

Diabetes Technology

Self-monitoring of blood glucose (SMBG)

- Patients on multiple-dose insulin (MDI), or insulin pump therapy should perform self-monitoring blood glucose (SMBG) prior to meals and snacks, occasionally postprandial, at bedtime, prior to exercise, when they suspect low blood glucose, after treating low blood glucose until they are normoglycemic, and prior to critical tasks such as driving. (Evidence B)
- When prescribed as part of a broad educational program, SMBG may help to guide treatment decision and/or self-management for patients taking less frequent insulin injections (evidence B) or noninsulin therapies (evidence B)
- When prescribing SMBG, ensure that patients receive ongoing instruction and regular evaluation of SMBG techniques and results, as well as their ability to use SMBG data to adjust therapy. (Evidence E)
- When used properly, continuous glucose monitoring (CGM) in conjunction with intensive insulin regimens is a useful tool to lower A1c in adults with type 1 diabetes who are not meeting glycemic targets and should be used as close to daily as possible for maximal benefit (Evidence A)
- Automated insulin delivery systems may be considered in youth (>7 years) and adults with type 1 diabetes to improve glycemic control (Evidence B)

Obesity Management

- High intensity interventions (>16 sessions in 6 months) focusing on diet, physical activity, and behavioral strategies to achieve a 500-750 kcal/day energy deficit should be prescribed for patients

with type 2 diabetes who are overweight or obese and ready to achieve weight loss. Diets should be individualized. (Evidence A)

- Short-term (3-month) interventions that use very low calorie diets (≤ 800 kcal/day) and total meal replacements may be prescribed for carefully selected patients in medical care settings with close medical monitoring. Such programs must incorporate long-term weight maintenance counseling (Evidence B)
- Weight-loss medications are effective as adjunct to diet, physical activity, and behavioral counseling for selected patients with type 2 diabetes and BMI ≥ 27 kg/m². Potential benefits must be weighed against the potential risks, and the medication should be discontinued if the response to the therapy is $<5\%$ weight loss after 3 months or if there are significant safety or tolerability issues at any time. (Evidence A)
- Metabolic surgery should be recommended as an option to treat type 2 diabetes in appropriate surgical candidates with BMI ≥ 40 kg/m² (≥ 37 kg/m² in Asian Americans) who do not achieve durable weight loss and improvements in comorbidities with reasonable nonsurgical methods or as an option for adults with BMI 35-39 kg/m² (32-37 kg/m² in Asian Americans) who do not achieve weight loss and improvements in comorbidities with reasonable nonsurgical methods (Evidence A)
 - People presenting for metabolic surgery should receive a comprehensive readiness and mental health assessment (Evidence B)

Pharmacologic therapy for Type 2 diabetes

- Metformin is the preferred initial pharmacological agent for type 2 diabetes (Evidence A)
- Metformin should be continued when used in combination with other agents, including insulin, if not contraindicated and if tolerated (Evidence A)
- Among patients with type 2 diabetes who have established atherosclerotic cardiovascular disease, sodium-glucose cotransporter 2 inhibitors, or glucagon-like peptide 1 receptor agonists with demonstrated cardiovascular disease benefit are recommended as part of the antihyperglycemic regimen (Evidence A)
- In most patients who need the greater glucose-lowering effect of an injectable medication, glucagon-like peptide 1 receptor agonists are preferred to insulin (Evidence B)
- Intensification of treatment for patients with type 2 diabetes not meeting treatment goals should not be delayed (Evidence B)

Cardiovascular disease and Risk Management

- Measure blood pressure at every routine visit (Evidence B). Most people with diabetes and hypertension should be treated to a systolic blood pressure goal of <140 mmHg and a diastolic blood pressure goal of <90 mmHg. (Evidence A). All hypertensive patients with diabetes should monitor their blood pressure at home (Evidence B)
- Pharmacological therapy for patients with diabetes and hypertension should be with drug classes demonstrated to reduce cardiovascular events to include ACE inhibitors, angiotensin receptor blockers (ARBs), thiazide-line diuretics, or dihydropyridine calcium channel blockers (Evidence A)
- An ACE inhibitor or angiotensin receptor blocker, at the maximally tolerated dose indicated for

blood pressure treatment, is the recommended first line treatment for hypertension in patients with diabetes and urinary albumin-to-creatinine ratio ≥ 300 (Evidence A) or 30-299 mg/g creatinine (Evidence B). If one class is not tolerated, the other should be substituted (Evidence B)

- Multiple-drug therapy is generally required to achieve blood pressure targets. However, combinations of ACE inhibitor and angiotensin receptor blockers and combinations of ACE inhibitors or angiotensin receptor blockers with direct renin inhibitors should not be used (Evidence A)
 - For patients treated with an ACE inhibitor or ARB or diuretic, serum creatinine/eGFR and serum potassium levels should be monitored at least annually (Evidence B)
- For patients with blood pressure $>120/80$ mmHg, lifestyle interventions consist of weight loss if overweight or obese, a DASH (Dietary Approaches to Stop Hypertension) style diet, reducing dietary sodium, increasing dietary potassium, moderation of alcohol, and increased physical activity (Evidence B)
- For patient of all ages with diabetes and overt atherosclerotic cardiovascular disease, (CVD) high intensity Statin therapy should be added to lifestyle therapy. (Evidence A)
- For patients with diabetes aged 40-75 years (Evidence A) and >75 years (Evidence B) without additional atherosclerotic CVD risk factors, consider using moderate-intensity Statin and lifestyle therapy
- Combination therapy (Statin/fibrate and niacin/Statin) has not been shown to improve atherosclerotic CVD outcomes and is generally not recommended. Statin/niacin therapy may increase the risk of stroke (Evidence A)
- For patients with diabetes and atherosclerotic cardiovascular disease, if LDL cholesterol is ≥ 70 mg/dL on maximally tolerated statin dose, consider adding additional LDL-lowering therapy (such as ezetimibe or PCSK9 inhibitor) after evaluating the potential for further atherosclerotic cardiovascular disease risk reduction, drug-specific adverse effects, and patient preferences. Ezetimibe may be preferred due to lower cost (Evidence A)
- Statin therapy is contraindicated in pregnancy (Evidence B)

Antiplatelet Therapy

- Use aspirin therapy (75-162 mg/day) as a secondary prevention strategy in those with diabetes and a history of CVD. (Evidence A)
- For those with a documented aspirin allergy, clopidogrel (75 mg/day) should be used (Evidence B)
- Aspirin therapy (75-162 mg/day) may be considered as a primary prevention strategy in those with type 1 or type 2 diabetes who are at increased cardiovascular risk and are not at increased risk of bleeding (Evidence C)

Older Adults

- Screen for cognitive impairment and depression in adults aged 65 and older at initial visit and annually as appropriate (Evidence B)
- Adjust glycemic targets and pharmacologic interventions to avoid hypoglycemia (Evidence B)
- Avoid overtreatment (Evidence B)
- Simplify complex regimens if it can be achieved within the individualized A1c target (Evidence B)

Microvascular Complications and Foot Care

Diabetic Kidney Disease

- To reduce the risk or slow the progression of diabetic kidney disease, optimize glucose control and blood pressure control. (Evidence A)
- At least once a year, quantitatively assess urinary albumin and eGFR in patients with type 1 diabetes with duration of ≥ 5 years and all patients with type 2 diabetes and in all patients with comorbid hypertension. (Evidence B)
- For people with nondialysis-dependent chronic kidney disease, dietary protein intake should be approximately 0.8g/kg body weight per day (the recommended daily allowance). For patients on dialysis, higher levels of dietary protein intake should be considered (Evidence B)
- Treat all non-pregnant patients with diabetes and hypertension and urinary albumin excretion >300 mg/day or eGFR <60 mL/min/1.73m² with ACE inhibitors or ARBs. (Evidence A)
- Patients should be referred for evaluation for renal replacement treatment if they have an eGFR of <30 mL/min/1.73 m²
- Promptly refer to a physician experienced in the care of kidney disease for uncertainty about the etiology of kidney disease, difficult management issues, and rapidly progressing kidney disease (Evidence B)

Retinopathy

- To reduce the risk or slow the progression of retinopathy, optimize glucose control and blood pressure control (Evidence A)
- Adults with type 1 diabetes should have an initial dilated and comprehensive eye examination by an ophthalmologist or optometrist within 5 years after the onset of diabetes (Evidence B)
- Patients with type 2 diabetes should have an initial dilated and comprehensive eye examination by an ophthalmologist or optometrist at the time of the diagnosis of diabetes (Evidence B)
- If there is no evidence of retinopathy for one or more eye exams, then exams every 1-2 years may be considered (Evidence B)
- Telemedicine programs that use validated retinal photography with remote readings by an ophthalmologist or optometrist and timely referral for a comprehensive eye examination when indicated can be an appropriate screening strategy for diabetic retinopathy (Evidence B)
- If diabetic retinopathy is present, subsequent examination for patients with type 1 and 2 diabetes should be repeated more frequently by an ophthalmologist or optometrist (Evidence B)
- Promptly refer patients with any level of macular edema, severe nonproliferative diabetic retinopathy or any proliferative diabetic retinopathy to an ophthalmologist who is knowledgeable and experienced in the management and treatment of diabetic retinopathy (Evidence A)
- The presence of retinopathy is not a contraindication to aspirin therapy for cardio protection as this therapy does not increase the risk of retinal hemorrhage (Evidence A)

Neuropathy

- All patients should be screened for diabetic peripheral neuropathy (DPN) starting at diagnosis of type 2 diabetes and 5 years after the diagnosis of type 1 diabetes and at least annually thereafter using simple clinical tests such as 10-g monofilament. (Evidence B)
- Optimize glycemic control to prevent or delay the development of DPN and cardiovascular autonomic neuropathy (CAN) in patients with type 1 diabetes (Evidence A) and to slow the

- progression of neuropathy in some patients with type 2 diabetes (Evidence B)
- Assess and treat patients to reduce pain related to DPN (Evidence B)
- Either pregabalin or duloxetine are recommended as initial pharmacologic treatments for neuropathic pain in diabetes (Evidence A)

Foot Care

- Perform at least an annual comprehensive foot examination to include inspection, assessment of foot and leg pulses and deformities, and testing for loss of protective sensation (10-g monofilament plus any one of the following: vibration using 128-Hz tuning fork, pinprick sensation, ankle reflexes or vibration perception threshold (Evidence B)
- A multidisciplinary approach, including the use of specialized footwear, is recommended for individuals with foot ulcers and high-risk feet to include dialysis patients and those with Charcot foot, prior ulcers, or amputation (Evidence B)
- Provide general foot self-care education to patients with diabetes (Evidence B)
- Recommend specialized therapeutic footwear to high risk patients with diabetes and severe neuropathy, foot deformities, or history of amputation (Evidence B)

Older Adults

- Screening for early detection of cognitive impairment or depression is indicated for adults 65 years of age and older at the initial visit and annually as appropriate (Evidence B)
- Avoid hypoglycemia in older adults by adjusting glycemic targets and pharmacologic interventions (Evidence B) Deintensify complex regimens to reduce the risk of hypoglycemia if it can be achieved with in the individualized A1C target (Evidence B)
- Lifestyle management should focus on optimal nutrition and protein intake and regular exercise to include aerobic activity and resistance training as ability allows (Evidence B)

Immunization

- Annual influenzavaccine (Evidence C)
- Pneumococcal vaccine (Evidence C)
- Hepatitis B vaccine for unvaccinated adults (Evidence C)
- Provide routine vaccinations for children and adults with diabetes by age (Evidence C)

Annual Measurement for Effectiveness of Diabetes Guideline

HEDIS[®] Comprehensive Diabetes Care, Commercial and Medicare populations:

- HbA1c Testing
- Poor HbA1c control (>9%, no result on record, or HbA1c was not done during the measurement year)
- HbA1c Control (<8%)
- HbA1c Control (<7%) for a selected population

- Statin Medication Adherence
- Retinal Eye Exam
- Medical Attention for Nephropathy
- Blood Pressure Controlled <140/90 mm Hg

ADA recommendations are assigned rating of A, B or C depending on the quality of evidence:

- Evidence A- recommendations are based on large well-designed clinical trials or well-done meta-analyses
- Evidence B- recommendations are based on well-conducted cohort studies
- Evidence C- supportive evidence from poorly controlled or uncontrolled studies. There may be evidence from observational studies or conflicting evidence where the weight of the evidence supports the recommendation
- Evidence E- Expert opinion or clinical experience

References:

American Diabetes Association; Standards of Medical Care in Diabetes- 2019; the Journal of Clinical and Applied Research and Education; Volume 42; Supplement 1 January 2019

NCQA; Technical Specifications for Health Plans; HEDIS 2019; Volume 2