

General

Guideline Title

Clinical practice guidelines for healthy eating for the prevention and treatment of metabolic and endocrine diseases in adults: cosponsored by the American Association of Clinical Endocrinologists/the American College of Endocrinology and the Obesity Society.

Bibliographic Source(s)

Gonzalez-Campoy JM, St. Jeor ST, Castorino K, Ebrahim A, Hurley D, Jovanovic L, Mechanick JI, Petak SM, Yu YH, Harris KA, Kris-Etherton P, Kushner R, Molini-Blandford M, Nguyen QT, Plodkowski R, Sarwer DB, Thomas KT, American Association of Clinical Endocrinologists, American College of Endocrinology, The Obesity Society. Clinical practice guidelines for healthy eating for the prevention and treatment of metabolic and endocrine diseases in adults: cosponsored by the American Association of Clinical Endocrinologists/the American College of Endocrinology and the Obesity Society. Endocr Pract. 2013 Sep-Oct;19(Suppl 3):1-82. [721 references] PubMed

Guideline Status

This is the current release of the guideline.

Regulatory Alert

FDA Warning/Regulatory Alert

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

• April 8, 2016 – Metformin-containing Drugs : The U.S. Food and Drug Administration (FDA) is requiring labeling changes regarding the recommendations for metformin-containing medicines for diabetes to expand metformin's use in certain patients with reduced kidney function. The current labeling strongly recommends against use of metformin in some patients whose kidneys do not work normally. FDA concluded, from the review of studies published in the medical literature, that metformin can be used safely in patients with mild impairment in kidney function and in some patients with moderate impairment in kidney function.

Recommendations

Major Recommendations

The levels of evidence (1-4) and the recommendation grades (A-D) are defined at the end of the "Major Recommendations" field.

Executive Summary of Recommendations

Clinical questions are labeled "Q". Recommendations are labeled "R". Recommendation grades are based on four intuitive levels: (grades A [strong], B [intermediate], and C [weak]) or expert opinion when there is a lack of conclusive clinical evidence (grade D). The "best evidence" rating level (BEL), which corresponds to the best conclusive evidence found in the discussion section in the appendix, accompanies the recommendation grades in the Executive Summary.

Q1. What Is Healthy Eating?

Q1.1. General Recommendations for Healthy Eating and Disease Prevention

R1: All patients should be instructed on healthy eating and on proper meal planning by qualified health care professionals (Grade A, BEL 1). Essential macronutrients and micronutrients, fiber, and water should be provided by well-chosen foods and beverages that can be enjoyed and constitute a healthy eating pattern. Macronutrients should be recommended in the context of a calorie-controlled meal plan (Grade A, BEL 1). All patients should also be counseled on other ways to achieve a healthy lifestyle, including regular physical activity (150 minutes or more per week), ways to avoid a sedentary lifestyle, appropriate sleep time (6 or more hours every night), and budgeting time for recreation or play, stress reduction, and happiness (Grade A, BEL 1).

Q1.2. Healthy Macronutrient Intake

R2: In a healthy eating meal plan, carbohydrates should provide 45% to 65% of ingested energy, with due diligence to limit simple sugars or foods that have a high glycemic index (GI). Regardless of the macronutrient mix, total caloric intake must be appropriate for individual weight management goals. Patients should consume 6 to 8 servings of carbohydrates (one serving is 15 grams of carbohydrate) per day with at least half (3 to 4 servings) being from high-fiber, whole-grain products (Grade A, BEL 1). Consumption of fruits (especially berries) and vegetables (especially raw) (≥4.5 cups per day) will increase fiber, increase phytonutrient intake, and facilitate calorie control (Grade B, BEL 2). Patients should be instructed to consume whole grains in place of refined grains, which will add fiber and micronutrients to meals and help lower blood pressure (BP) (Grade A, BEL 1).

R3: Protein from both plant and animal sources (15% to 35% of calories depending on total intake) can replace a portion of saturated fat and/or refined carbohydrates in the meal plan to help improve blood lipids and BP (Grade A, BEL 1). The meal plan should include a maximum of 6 ounces per day of reduced-fat animal protein to increase the nutrient-to-calorie ratio (Grade B, BEL 1). Reduced-fat dairy (2 to 3 servings per day) should be recommended as a source of high-quality protein for patients who are not intolerant or allergic to lactose because it lowers BP and helps reduce weight while also providing important micronutrients (Grade A, BEL 1). Plant protein (e.g., pulses, including beans, lentils, and some nuts; and certain vegetables, including broccoli, kale, and spinach) should be emphasized in meal planning, as it is not commonly consumed in Western meals; plant proteins confer many health benefits, including improved blood lipid levels and BP (Grade B, BEL 2).

R4: Patients should be counseled to consume unsaturated fats from liquid vegetable oils, seeds, nuts, and fish (including omega-3 fatty acids) in place of high-saturated fat foods (butter and animal fats), providing 25% to 35% of daily calories to reduce the risk for cardiovascular disease (CVD) (Grade A, BEL 1). It should be recommended that patients consume natural foods high in monounsaturated fat, such as olive oil in the Mediterranean dietary pattern, since this is strongly associated with improved health outcomes (Grade A, BEL 1). It should be recommended that patients eat at least 2 servings of cold-water, fatty fish (such as salmon or mackerel) every week because they contain greater amounts of eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA) (Grade B, BEL 2).

Q1.3. Healthy Micronutrient Intake

R5: With the exception of proven therapies for documented specific vitamin deficiency states or diseases, or pregnancy, there are insufficient data to recommend supplemental vitamin intake above the recommended dietary allowances (RDA) (Grade D, BEL 4). Vitamin E supplementation to decrease cardiovascular (CV) events or cancer is not recommended (Grade B, BEL 2). Lifelong regular follow-up and individualized therapy are recommended in diseases known to cause intestinal malabsorption (e.g., after malabsorptive bariatric surgery, ileo-colic resection, short bowel syndrome, celiac disease, inflammatory bowel disease, exocrine pancreatic insufficiency, chronic kidney disease [CKD], and chronic liver disease) to detect and treat vitamin and mineral deficiencies (Grade B, BEL 2).

R6: Vitamin B_{12} levels should be checked periodically in older adults and patients on metformin therapy (Grade A, BEL 1). With the exception of early treatment of patients with neurologic symptoms, pernicious anemia, or malabsorptive bariatric surgery requiring parenteral (intramuscular or subcutaneous) vitamin B_{12} replacement, patients with vitamin B_{12} deficiency can generally be treated with oral vitamin B_{12} (1,000 μ g per day of oral crystalline cobalamin) and may benefit from increasing the intake of vitamin B_{12} in food (Grade A, BEL 1).

R7: The prevalence of vitamin D deficiency and insufficiency warrants case finding by measurement of 25-hydroxyvitamin D (25[OH]D) levels in populations at risk, including institutionalized elderly patients, people with hyperpigmented skin, and people with obesity (Grade B BEL 2). Older adults, people with increased skin pigmentation, and those exposed to insufficient sunlight should increase vitamin D intake from vitamin D-fortified

foods and/or supplements to at least 800 to 1,000 international units (IU) daily (Grade A, BEL 1).

Q2. What Nutritional Recommendations Are Appropriate for Weight Management?

Q2.1. Approach to Overweight and Obesity

R8: Overweight and obesity should be managed as a long-term chronic disease (Grade A, BEL 1). Overweight and obesity should be managed using a multidisciplinary team approach (Grade A, BEL 1). Nutrition counseling for overweight and obesity should be aimed to decrease fat mass and also to correct adipose tissue dysfunction (adiposopathy) (Grade A, BEL 1). Adult feeding behavior is solidly rooted from childhood, so it is important to counsel adult patients to include their families, especially their children, in healthy eating behavior changes (Grade B, BEL 2). Nutrition counseling should be culturally, linguistically, and educationally provided to meet individual patient needs (Grade D, BEL 4).

R9: The weight-loss goal for overweight or obese patients is 5% to 10% of current body weight over the ensuing 6 to 12 months. This goal is perennial until an acceptable body mass index (BMI) is achieved (Grade A, BEL 1). Combined therapy utilizing a low-calorie meal plan (LCMP), increased physical activity, behavior therapy, and appropriate pharmacotherapy provides the most successful intervention for weight loss and weight maintenance and is also recommended as an adjunct to bariatric surgery (Grade A, BEL 2. Expert panel experience and consensus).

Q2.2. Behavior Modification

R10: Sustained behavior modification must be achieved for long-term success with weight management. Food and activity recordkeeping should be recommended to help patients achieve the best results (Grade A, BEL 1). Behavioral group therapy is a cost-effective way of providing nutrition counseling to patients and should be incorporated into weight management treatment programs (Grade B, BEL 2). Use of portion-controlled prepackaged meals should be considered as a way to achieve a lower caloric intake (Grade A, BEL 1).

Q2.3. Low-Calorie Meal Plans

R11: When first treating a patient with overweight or obesity, emphasis should be placed on maintaining a healthy meal plan and avoiding fad diets while including food choices from all major food groups (Grade A, BEL 2). A healthy, LCMP with a deficit of 500 to 1,000 kcal/day should be an integral part of any program aimed at achieving a total weight-loss rate of 1 to 2 pounds/week (which may include lean muscle mass as well as fat mass weight loss) (Grade A, BEL 1). All meal plans of <1,200 kcal/day should be carefully selected so that nutrient requirements are met. When particular food groups are severely restricted or omitted, the use of dietary supplements to meet nutrient requirements should be implemented (Grade D, BEL 4).

Q2.4. Very Low-Calorie Meal Plans

R12: Very low-calorie meal plans (VLCMPs) (\leq 800 kcal/day or \sim 6 to 10 kcal/kg), which can produce weight losses up to 1.5 to 2.5 kg/week and up to 20 kg in 12 to 16 weeks, may be recommended for patients with a BMI >30 kg/m² who have significant comorbidities or who have failed other nutritional approaches to weight loss (Grade B, BEL 2). VLCMP treatment requires nutritional supplementation and medical monitoring for complications, including electrolyte imbalances, hepatic transaminase elevation, and gallstone formation, and the duration of treatment should not exceed 12 to 16 weeks (Grade A, BEL 1).

Q3. What Nutritional Recommendations Are Appropriate for Cardiovascular Health?

Q3.1. Nutritional Strategies for Excess Fat Mass and Adiposopathy

R13: All patients at risk for CVD should implement healthy eating patterns, which provide calorie control, adequate nutrients, beneficial bioactive compounds, and result in weight loss or weight maintenance (Grade D, BEL 4). To help control calorie intake, patients should eat meals that are low in energy density (Grade A, BEL 1). All patients should also be advised to increase caloric expenditure to at least 150 minutes of moderate-intensity activity every week (e.g., running) (Grade A, BEL 1). Successful weight loss and maintenance to decrease CV risk must include both a change in meal plan as well as frequent physical activity (Grade A, BEL 1).

Q3.2. Nutritional Strategies for Dyslipidemia

R14: The therapeutic lifestyle changes (TLC) meal plan with viscous fiber and plant sterols and stanols is recommended for individuals with elevated low-density-lipoprotein cholesterol (LDL-C) (Grade A, BEL 1). The Mediterranean meal plan (or a TLC meal plan that provides 30 to 35% of calories from total fat with an emphasis on mono- and polyunsaturated fatty acids [PUFAs]) is recommended for individuals who have abnormal non-LDL-C lipid values (Grade A, BEL 1).

Q3.3. Nutritional Strategies for Hypertension

R15: Attaining and maintaining a healthy body weight is recommended to prevent and treat hypertension. Obese and overweight individuals should accomplish a 10% weight loss to decrease their BP (Grade A, BEL 1). All patients should be counseled to adhere to the Dietary Approaches to Stop Hypertension (DASH) meal plan, which is high in fruits, vegetables, whole grains, and reduced-fat dairy (Grade A, BEL 1). Sodium intake should be reduced to <2,300 mg/day, and potassium intake should be increased to >4,700 mg/day with implementation of a DASH-type meal plan (Grade A, BEL 1). Sodium intake should be further reduced (<1,500 mg/day; or 3,800 mg/day of table salt) for people age 51 years and above, all people who are African American, regardless of age, and for patients who have hypertension, DM, or CKD (Grade A, BEL 1).

Q4. What Nutrient Sources Should Be Limited for Cardiovascular Health?

R16: Added sugars should be limited to <100 calories per day for women and <150 calories per day for men (Grade A, BEL 1). Sugar-sweetened beverage (SSB) intake should be reduced as an effective way to reduce added sugar intake (Grade B, BEL 2). Saturated fat intake should be limited to <7% for reduction of CVD risk (Grade A, BEL 1). It is recommended that processed red meat intake be limited to less than 2 servings per week and that lean or very lean red meat cuts be consumed while controlling for saturated fat intake (Grade B, BEL 2). Whole grain products should be substituted for refined grain products when possible, such that at least one-half of daily servings of grains are from whole grains (Grade B, BEL 2).

Q5. What Nutritional Recommendations Are Appropriate for Diabetes Mellitus?

Q5.1. Patient Nutrition Education

R17: Medical nutrition therapy provided by a physician, physician extender, registered dietician (RD), and/or certified diabetes educator (CDE) is recommended for all patients with DM (Grade A, BEL 1). Patients with DM who experience difficulty achieving glycemic targets should keep a personal food diary (Grade D, BEL 4).

Q5.2. Caloric and Protein Intake

R18: Patients with DM should consume total daily calories at amounts sufficient to attain or maintain a normal BMI of 18.5 to 24.9 kg/m², which is generally in the 15 to 30 kcal/kg/day range, depending on level of physical activity (Grade A, BEL 1). Patients with DM should consume protein in the 0.8 to 1.0 g/kg/day range, and protein should account for about 15 to 35% of the total calorie consumption for the day (Grade C, BEL 3).

Q5.3. Carbohydrate Intake

R19: Medical nutrition therapy should be implemented to control the glycemic response to meals and to achieve hemoglobin A1c (A1c) and blood glucose levels as close to the target range as possible without risk to the individual patient (Grade A, BEL 1). Carbohydrates should account for about 45% to 65% of the total caloric consumption for the day, including low-fat dairy products and sucrose (Grade C, BEL 3). Patients with DM should consume carbohydrate primarily from unprocessed carbohydrates, which are provided by a target of 8 to 10 servings per day of vegetables (particularly raw), fruits, and legumes, with due diligence to limit simple sugars or foods that have a high GI (Grade A, BEL 1). Regardless of the macronutrient mix, total caloric intake must be appropriate for individual weight management goals. Patients with DM should consume 20 to 35 g of fiber from raw vegetables and unprocessed grains (or about 14 g of fiber per 1,000 kcal ingested) per day (the same as the general population) (Grade B, BEL 2). Patients with type 1 DM (T1DM), or insulin-treated type 2 DM (T2DM) should synchronize insulin dosing with carbohydrate intake (Grade A, BEL 1). Patients with T2DM treated with short-acting oral hypoglycemic agents (nateglinide, repaglinide) should also synchronize carbohydrate intake with administration of these medications (Grade A, BEL 1). Patients with DM may safely consume artificial sweeteners within the guidelines of the U.S. Food and Drug Administration (FDA) (Grade D, BEL 4).

Q5.4. Fat Intake

R20: For patients with DM, total fat intake should account for about 30% of the total daily calories (Grade B, BEL 2). Consumption of saturated fat should be less than 7% of total daily calories regardless of the serum total cholesterol level, and PUFAs should be up to 10% of the total daily calories (examples of food sources include vegetable oils high in n-6 PUFA, soft margarine, salad dressings, mayonnaise, and some nuts and seeds) (Grade B, BEL 2). The n-3 PUFAs are most desirable, and dietary recommendations for EPA and DHA can be achieved with two or more servings of fresh fish per week (Grade B, BEL 2). In patients with DM, monounsaturated fatty acids (MUFAs) should be up to 15 to 20% of the total daily calories (Grade B, BEL 2). Dietary cholesterol should be less than 200 mg/day (Grade A, BEL 1). Patients with DM should avoid consumption of trans fats (Grade C, BEL 3).

Q5.5. Other Nutritional Recommendations

R21: There is insufficient evidence to specifically recommend a "low-GI" meal plan in patients with DM (Grade D, BEL 4). There is insufficient evidence to support the routine use of antioxidants, chromium, magnesium, and/or vanadium in patients with DM (Grade C, BEL 3).

R22: Patients with DM who choose to drink alcohol should ingest it with food and limit intake to 2 servings per day for men or 1 serving per day for women. Alcohol intake should not be increased for any purported beneficial effect (Grade D, BEL 4). There is insufficient evidence, based on long-term risks and benefits, to support the use of fad diets in patients with DM (Grade D, BEL 4).

Q5.6. Diabetes Mellitus Prevention

R23: There is insufficient evidence to support nutrition changes to specifically prevent T1DM (Grade D, BEL 4). However, women with a personal or family history of T1DM who may be HLA-DR3 and DR4 carriers should be counseled on the medical evidence suggesting that the use of infant formula derived from cow's milk in the first 6 months of life increases a baby's risk of T1DM by stimulating antibody formation to the beta-cells (Grade B, BEL 2). Patients at high risk for the development of T2DM should implement lifestyle interventions to achieve a minimum of 7% weight loss followed by weight maintenance, and a minimum of 150 minutes of weekly physical activity, similar in intensity to brisk walking (Grade A, BEL 1).

Q6. What Nutritional Recommendations Are Appropriate for Chronic Kidney Disease?

Q6.1. General Approach

R24: Patients with CKD should have a meal plan low in protein, sodium, potassium, and phosphorus, which slows the progression of kidney disease (Grade A, BEL 1). All patients with CKD should receive nutrition education by qualified health care professionals (Grade A, BEL 1).

Q6.2. Protein Requirements

R25: In CKD stages 1, 2, or 3, protein intake should be limited to 12 to 15% of daily calorie intake or 0.8 g of high-biological-value (HBV) protein/kg body weight/day (Grade A, BEL 1). In CKD stage 4, protein intake should be reduced to 10% of daily calorie intake or 0.6 g of high-quality protein/kg body weight/day, provided an essential amino acid (EAA) deficiency does not occur (Grade A, BEL 1). For nondialyzed CKD patients with a glomerular filtration rate (GFR) <25 mL/min, 0.6 g of protein/kg body weight/day should be prescribed, with at least 50% of the protein intake from HBV sources to ensure a sufficient amount of EAAs (Grade A, BEL 1). For patients with CKD stage 5 or patients on renal replacement therapy (RRT), protein intake should be 1.3 g/kg/day (peritoneal dialysis) or 1.2 g/kg/day (hemodialysis) (Grade A, BEL 1). Urinary protein losses in the nephrotic syndrome should be replaced, and a low-normal protein dietary reference intake (DRI) of 0.8 to 1.0 g/kg body weight/day should be recommended (Grade C, BEL 3).

R26: Patients with CKD stages 1, 2, or 3 should ingest 35 kcal/kg body weight/day in order to maintain neutral nitrogen balance and to prevent catabolism of stored proteins for energy needs (Grade B, BEL 2). Patients with CKD and a GFR <25 mL/min should ingest 35 kcal/kg body weight/day if they are younger than age 60 years or 30 to 35 kcal/kg body weight/day if they are age 60 years or above (Grade B, BEL 2).

Q6.3. Electrolytes

R27: All patients with CKD, regardless of CKD stage, should limit sodium intake to 2.0 g/day (Grade A, BEL 1). When potassium levels are elevated, potassium intake (including salt substitutes) should be limited to 2 to 3 g/day (Grade A, BEL 1). When diarrhea or vomiting is present, potassium intake should be liberalized and provided with meals that include a variety of fruits, vegetables, and grains (Grade D, BEL 4).

R28: Phosphate intake should be limited to 800 mg/day for patients with stage 3, 4, or 5 CKD (Grade A, BEL 1). All patients with CKD and hyperphosphatemia should get 2,000 mg/day of total calcium intake (binders plus calcium in meals) (Grade A, BEL 1).

R29: All patients with CKD who have hyperphosphatemia and secondary hyperparathyroidism should be treated with oral vitamin D to bring the total serum 25(OH)D level to greater than 30 ng/mL (Grade A, BEL 1). If the intact parathyroid hormone (PTH) level remains elevated above treatment goal despite a serum 25(OH)D level higher than 30 ng/mL, treatment with an active form of vitamin D is indicated (Grade A, BEL 1).

R30: Patients with stage 3, 4, or 5 CKD should receive oral ferrous sulfate, 325 mg three times a day, in order to maintain transferrin saturation >20% and serum ferritin >100 ng/mL (Grade A, BEL 1).

Q6.4. Renal Replacement Therapy

R31: For patients with end-stage kidney disease (ESKD) on RRT, potassium intake should be limited to 3 to 4 g/day (peritoneal dialysis) or 2 to 3 g/day (hemodialysis) (Grade A, BEL 1). Patients with DM and ESKD who are on RRT should be routinely queried regarding their eating habits, home glucose monitoring, and frequency and severity of hypoglycemia (Grade C, BEL 3).

Q7. What Nutritional Recommendations Are Appropriate for Bone Health?

Q7.1. Calcium

R32: Total elemental calcium intake should be 1,000 mg/day for premenopausal women and men and 1,200 to 1,500 mg/day for postmenopausal women, preferentially from food sources (Grade A, BEL 1). Excessive amounts of elemental calcium intake, in the range of 2,000 mg/day, may increase the risk of kidney stones and other side effects and should therefore be actively discouraged (Grade A, BEL 1). A calcium intake greater than 1,500 mg/day is associated with an increased risk of advanced prostate cancer and should be discouraged (Grade B, BEL 2). Calcium supplements should be used if a patient's meal plan does not provide adequate calcium intake (Grade A, BEL 1). Calcium citrate should be recommended instead of calcium carbonate for patients with achlorhydria, history of gastric surgery, and those being treated with proton-pump inhibitors or H2-receptor blockers (Grade B, BEL 2). For best absorption, calcium supplements should be limited to no more than 500 mg of elemental calcium per dose, since there is decreasing absorption with increasing doses (Grade A, BEL 1). A 24-hour urine calcium collection should be measured in patients with osteoporosis or patients at risk for bone loss in order to check calcium adequacy and test for hypercalciuria or malabsorption (Grade B, BEL 2).

Q7.2. Vitamin D

R33: Serum 25(OH)D should be measured in individuals at risk for vitamin D deficiency (e.g., elderly, institutionalized, or malnourished patients) and in those with known osteopenia or osteoporosis (Grade A, BEL 1). Vitamin D should be supplemented to keep the plasma 25(OH)D level greater than 30 ng/mL (Grade A, BEL 1). For most patients, a daily intake of at least 1,000 to 2,000 IU of ergocalciferol (D₂) or cholecalciferol (D₃) should be adequate (Grade A, BEL 1). For patients with advanced renal failure in whom renal activation of vitamin D is impaired, calcitriol should be dosed to allow for adequate intestinal absorption of calcium (Grade A, BEL 1).

Q8. What Nutritional Recommendations Are Appropriate for Pregnancy and Lactation?

Q8.1. Pregnancy Planning

R34: Prior to pregnancy, women should be encouraged to achieve a normal BMI (Grade A, BEL 1). Elevated fasting blood glucose prior to pregnancy should prompt screening for DM and initiation of a healthy eating meal plan and lifestyle modification (Grade A, BEL 1). Any chronic diseases, including DM, thyroid disorders, and rheumatologic disorders should be optimally controlled prior to conception with a focus on appropriate nutrition and physical activity (Grade D, BEL 4).

Q8.2. Pregnancy

R35: The appropriate individual caloric intake should be calculated based on prepregnancy and current (pregnant) BMI (Grade D, BEL 4). Pregnant women who are vegetarian or vegan must be referred to a RD specializing in pregnancy to assist in meal planning and appropriate use of dietary supplements (Grade D, BEL 4). Women who are pregnant should consume 1.1 g/kg of protein per day in the second and third trimesters (Grade B, BEL 2). During pregnancy, less than 10% of calories should be derived from saturated fats and less than 10% should be derived from PUFAs, with the remainder from MUFAs (Grade D, BEL 4). *Trans* fatty acids should be avoided during a pregnancy since they may have adverse effects on fetal development (Grade B, BEL 2).

R36: Daily ingestion of a prenatal vitamin (PNV) is recommended for all women during pregnancy (Grade A, BEL 1). All women in their childbearing years should consume 400 μ g/day of folic acid, and once pregnancy is confirmed, the intake should be adjusted to 600 μ g/day (Grade B, BEL 2). Intake of vitamin A over 10,000 IU a day is teratogenic, so women should be advised against excessive supplementation (Grade B, BEL 2). All pregnant women should ingest a minimum of 250 μ g of iodine daily (Grade B, BEL 2).

R37: Women who have DM and/or are insulin resistant should adjust the percentage of ingested carbohydrate during pregnancy to obtain proper glycemic control (Grade B, BEL 2). Women with gestational DM (GDM) should: (1) adhere to the recommendations for healthy eating for all pregnant women, (2) allow for appropriate weight gain during pregnancy (i.e., 2 to 5 pounds in the first trimester and 0.5 to 1 pound per week thereafter), (3) avoid concentrated sweets and "fast foods," and (4) eat small, frequent meals with protein, having only one starch with breakfast and choosing high-fiber foods with lower fat content (Grade C, BEL 3).

R38: Patients should be instructed to consume less than 300 mg of caffeine (3 cups of coffee) per day during pregnancy, since caffeine can increase the incidence of miscarriage and stillbirth when consumed in larger quantities (Grade B, BEL 2).

Q8.3. Lactation

R39: Whenever possible, exclusive breastfeeding is recommended for at least the first 6 months of life (Grade A, BEL 1). All women should be instructed on breastfeeding, made aware of community resources about breastfeeding, and counseled to adjust their meal plans to meet nutritional needs during lactation (Grade A, BEL 1). All pregnant and lactating women should ingest a minimum of 250 μ g of iodine daily (Grade B, BEL 2). During breastfeeding, basal insulin requirements decrease. Women who breastfeed should be advised to either lower their basal insulin dose (or basal insulin infusion rate if on an insulin pump) or eat a carbohydrate-containing snack prior to breastfeeding (Grade D, BEL 4).

Q9. What Nutritional Recommendations Are Appropriate for the Elderly?

09.1. Healthy Eating for Energy Balance and Toward an Ideal Body Weight

R40: As people age, they should implement healthy eating to maintain an ideal body weight, since both overweight and underweight lead to increased morbidity and mortality (Grade A, BEL 1). In the elderly with sarcopenia and decreased basal metabolic rate, formulating a meal plan should include caloric reduction to maintain energy balance and to prevent fat-weight gain (Grade B, BEL 2). To constrain caloric overconsumption in the elderly while also ensuring micronutrient adequacy, quality foods low in calories and containing adequate amounts of HBV protein sources to provide EAAs and essential fatty acids (EFAs) and rich in micronutrients and fiber should be ingested routinely (Grade B, BEL 2). Quality food high in proteins, minerals, and vitamins but low in saturated fat, cholesterol, and *trans* fat (such as lean meat, fish, poultry, eggs, and dry beans and nuts) should be recommended for overweight or obese elderly patients to provide adequate protein intake without carrying a high risk for CVD (Grade A, BEL 1). Older adults should consume more of the nutrient-dense whole-grain foods, such as brown rice, whole-wheat breads, and whole-grain and fortified cereals to meet carbohydrate needs. Conversely, the consumption of refined starch-based foods such as processed potato, white bread, pasta, and other commercial products made of refined wheat flour should be limited to decrease the risk of obesity and DM (Grade B, BEL 2). Dehydration is a more prevalent condition in the elderly, and thirst sensation may be compromised with aging, therefore habitual fluid intake (about 2 quarts per day or eight 8-ounce glasses) is recommended (Grade B, BEL 2).

R41: On an individual basis, ingestion of nutrition supplements between meals should be recommended for undernourished elderly patients (Grade B, BEL 2). Energy and nutrient-dense foods, or manipulation of energy and nutrient density of the meal plan, should be recommended for the frail elderly to promote weight gain and improve clinical outcomes (Grade A, BEL 1). Food safety, including the prevention of food spoilage, should be provided for all elderly patients (Grade D, BEL 4).

Q9.2. Healthy Eating to Prevent Micronutrient Deficiency in Older Adults

R42: To ensure adequacy of a wide variety of micronutrients, a daily mix of nutrient-dense foods, including fruits and vegetables, should be recommended (Grade B, BEL 2). In the elderly, pills should not be used as a substitute for meals (Grade D, BEL 4). The elderly should consume at least 3 daily servings of calcium-rich foods (Grade A, BEL 1). In the elderly, case finding for vitamin D and vitamin B_{12} deficiencies is reasonable given their high prevalence with advancing age (Grade B, BEL 2). It is appropriate to recommend a daily multivitamin (MVI) to complement food intake in older adults who cannot achieve adequate micronutrient intake otherwise (Grade B, BEL 2). Surveillance to prevent toxicity from excess ingestion of vitamin pills is appropriate for the elderly (Grade C, BEL 3).

Q9.3. Healthy Eating for the Frail Elderly

R43: Community nutrition assistance programs that provide individuals with home-delivered meals should be recommended for frail elderly patients still living independently (Grade A, BEL 1). Barriers to healthy eating in the elderly should be actively found and addressed, including provision of direct feeding assistance where self-feeding is not adequate, treatment of depression, group meals for institutionalized patients, correcting oral and dental problems leading to difficulties with eating, chewing or swallowing, addressing social isolation, rectifying polypharmacy, and treating underlying diseases (Grade B, BEL 2). Physicians treating geriatric patients should make every effort to reduce the number of medications to achieve better medication adherence and to allow for better nutritional care (Grade D, BEL 4).

Definitions:

2010 American Association of Clinical Endocrinologists (AACE) Protocol for Production of Clinical Practice Guidelines. Step I: Evidence Rating

1	Meta-analysis of randomized controlled trials (MRCT)
1	Randomized controlled trials (RCT)
2	Meta-analysis of nonrandomized prospective or case-controlled trials (MNRCT)
2	Nonrandomized controlled trial (NRCT)
2	Prospective cohort study (PCS)
2	Retrospective case-control study (RCCS)
3	Cross-sectional study (CSS)
3	Surveillance study (registries, surveys, epidemiologic study, retrospective chart review, mathematical modeling of database) (SS)
3	Consecutive case series (CSS)
3	Single case reports (SCR)

1 = strong evidence; 2 = intermediate evidence; 3 = weak evidence; 4 = no evidence.

Adapted from Mechanick et al. Endocr Pract. 2010;16:270-283.

2010 American Association of Clinical Endocrinologists (AACE) Protocol for Production of Clinical Practice Guidelines. Step III: Grading of Recommendations – How Different Evidence Levels Can Be Mapped to the Same Recommendation Grade^a

Best Evidence Level	Subjective Factor Impact	Two-thirds Consensus	Mapping	Recommendation Grade
1	None	Yes	Direct	A
2	Positive	Yes	Adjust up	A
2	None	Yes	Direct	В
1	Negative	Yes	Adjust down	В
3	Positive	Yes	Adjust up	В
3	None	Yes	Direct	С
2	Negative	Yes	Adjust down	С
4	Positive	Yes	Adjust up	С
4	None	Yes	Direct	D
3	Negative	Yes	Adjust down	D
1, 2, 3, 4	NA	No	Adjust down	D

aStarting with the left column, best evidence levels (BELs), subjective factors, and consensus map to recommendation grades in the right column. When subjective factors have little or no impact ("none"), then the BEL is directly mapped to recommendation grades. When subjective factors have a strong impact, then recommendation grades may be adjusted up ("positive" impact) or down ("negative" impact). If a two-thirds consensus cannot be reached, then the recommendation grade is D. not applicable (NA) regardless of the presence or absence of strong subjective factors, the absence of a two-thirds consensus mandates a recommendation grade D.

Adapted from Mechanick et al. Endocr Pract. 2010;16:270-283.

Clinical Algorithm(s)

None provided

Scope

Disease/Condition(s)

Metabolic and endocrine disorders

Guideline Category

Counseling

Evaluation

Management

Prevention

Risk Assessment

Treatment

Endocrinology Family Practice Geriatrics Internal Medicine Nephrology Nutrition Obstetrics and Gynecology Preventive Medicine **Intended Users** Advanced Practice Nurses Allied Health Personnel Dietitians Nurses Physician Assistants Physicians Guideline Objective(s) To define the standards of care for healthy eating in the management and prevention of metabolic and endocrine disorders **Target Population** Adults with or at risk of metabolic and endocrine diseases **Interventions and Practices Considered** 1. Patient instruction on healthy eating and proper meal planning 2. General counseling for a healthy lifestyle (regular physical activity, avoidance of sedentary lifestyle, appropriate sleep time, budgeting time for

Measurement of vitamin D levels in populations at risk

• Monitoring of vitamin B₁₂ levels and oral supplements if indicated

• Proven therapies for documented specific vitamin deficiency states or diseases, or pregnancy

• Lifelong regular follow-up and individualized therapy (for diseases known to cause intestinal malabsorption)

5. Management of weight and obesity

3. Healthy macronutrient intake

Unsaturated fats4. Healthy micronutrient intake

recreation, play, stress reduction, happiness)

• Proteins (plant and animal sources)

• Carbohydrates (45% to 65% of ingested energy)

Clinical Specialty

Cardiology

- Multidisciplinary team approach
- Behavior modification
- Low and very low-calorie meal plans
- 6. Nutritional management for cardiovascular health, including the development of nutritional strategies for
 - Excess fat mass and adiposopathy
 - Dyslipidemia
 - Hypertension
- 7. Nutritional strategies for diabetes mellitus (DM)
 - Patient nutrition and prevention education
 - Monitoring of caloric, protein, carbohydrate, fat and alcohol intake
- 8. Nutritional strategies for chronic kidney disease (CKD)
 - Protein, sodium, potassium and phosphate limitation
 - Oral vitamin D and ferrous sulfate
- 9. Nutrition management for bone health (calcium supplementation, vitamin D)
- 10. Nutrition management during pregnancy and lactation
 - Healthy eating plan and proper caloric intake
 - Screening for and management of DM
 - Prenatal vitamins (PNV)
 - Limiting caffeine
- 11. Nutritional management in the elderly
 - Healthy eating for energy balance and maintenance of ideal body weight
 - Prevention of micronutrient deficiency
 - Community nutrition assistance programs
 - Overcoming barriers to healthy eating

Note: The following interventions were considered but not recommended or there was insufficient evidence to make a recommendation:

Supplemental vitamin intake above the recommended dietary allowances (RDA)

Vitamin E supplementation to decrease cardiovascular (CV) events or cancer

"Low-Glycemic Index" meal plan or fad diets for DM

Routine use of antioxidants, chromium, magnesium, and/or vanadium for DM

Major Outcomes Considered

- Morbidity (e.g., diabetes mellitus, cardiovascular health, chronic kidney disease, bone health)
- Mortality
- · Overweight and obesity
- Pregnancy planning, pregnancy, and lactation
- Elderly care
- Malnourishment and malabsorption

Methodology

Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Primary Sources)

Hand-searches of Published Literature (Secondary Sources)

Searches of Electronic Databases

The authors each searched PubMed for references published on the subject retroactively, dating back 40 years. Each author used the terms "healthy eating," "nutrition," "meal pattern" and "diet," cross-referenced with the relevant disease state addressed by the individual author's question. Since this was the first-ever reference-graded clinical practice guideline on healthy eating, further references were identified from the reference lists of identified sources.

Number of Source Documents

Not stated

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

2010 American Association of Clinical Endocrinologists (AACE) Protocol for Production of Clinical Practice Guidelines. Step I: Evidence Rating

1	Meta-analysis of randomized controlled trials (MRCT)
1	Randomized controlled trials (RCT)
2	Meta-analysis of nonrandomized prospective or case-controlled trials (MNRCT)
2	Nonrandomized controlled trial (NRCT)
2	Prospective cohort study (PCS)
2	Retrospective case-control study (RCCS)
3	Cross-sectional study (CSS)
3	Surveillance study (registries, surveys, epidemiologic study, retrospective chart review, mathematical modeling of database) (SS)
3	Consecutive case series (CSS)
3	Single case reports (SCR)
4	No evidence (theory, opinion, consensus, or review) (NE)

1 = strong evidence; 2 = intermediate evidence; 3 = weak evidence; 4 = no evidence.

Adapted from Mechanick et al. Endocr Pract. 2010;16:270-283.

Methods Used to Analyze the Evidence

Review of Published Meta-Analyses

Systematic Review

Description of the Methods Used to Analyze the Evidence

Recommendations are assigned evidence level (EL) ratings on the basis of the quality of supporting evidence:

2010 American Association of Clinical Endocrinologists (AACE) Protocol for Production of Clinical Practice Guidelines—Step II: Evidence Analysis and Subjective Factors

Study Design	Data Analysis	Interpretation of Results
Premise correctness	Intent-to-treat	Generalizability

Allocation concealment (randomization) Design Selection bias	Appropriate statistics	Incompleteness Incompleteness
Appropriate blinding		Validity
Using surrogate endpoints (especially in "first-in-its-class" intervention)		
Sample size (beta error)		
Null hypothesis versus Bayesian statistics		

Adapted from Mechanick et al. Endocr Pract. 2010;16:270-283.

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

The American Association of Clinical Endocrinologists (AACE) Board of Directors mandated a clinical practice guideline (CPG) on healthy eating for the prevention and treatment of metabolic and endocrine diseases in adults. The project was approved for co-authorship with The Obesity Society (TOS) by the leadership of both organizations. This CPG was developed in accordance with the AACE Protocol for Standardized Production of Clinical Practice Guidelines – 2010 Update. Reference citations in the text of this document include the reference number, numerical descriptor (evidence level; EL 1-4), and semantic descriptor (see Tables 1 to 4 in the original guideline document). Recommendations are assigned Grade levels based on the supporting clinical evidence and subjective factors. The format of this CPG is based on specific and relevant clinical questions. All primary writers have made disclosures regarding multiplicities of interest. In addition, all primary writers are credentialed experts in the fields of nutrition, endocrinology, or both.

The clinical practice guideline started with a series of questions to be answered by each section author.

- What is healthy eating for adults?
- What is healthy eating for patients with diabetes?
- What is healthy eating for patients with overweight and obesity?
- What is healthy eating in pregnancy?
- What is healthy eating for patients with renal failure?
- What is healthy eating for bone health?
- What is healthy eating for the elderly?

Clinical questions are labeled "Q" and recommendations are labeled "R". Recommendation grades are based on four intuitive levels: (grades A [strong], B [intermediate], and C [weak]) or expert opinion when there is a lack of conclusive clinical evidence (grade D). The "best evidence" rating level (BEL), which corresponds to the best conclusive evidence found in the discussion section in the appendix, accompanies the recommendation grades in the Executive Summary. There are also four intuitive levels of evidence: 1 = strong, 2 = intermediate, 3 = weak, and 4 = no evidence. Comments may be appended to recommendations regarding relevant subjective factors that may have influenced the grading process. The consensus level of experts for each recommendation may also be explicitly provided in appropriate instances. Thus, the process leading to a final recommendation and grade is not dogmatic but rather incorporates a complex expert integration of objective and subjective factors meant to reflect optimal real-life clinical decision-making to enhance patient care. Where appropriate, cascades of recommendations are provided (settings with limited resources, unique patient attributes, etc).

Rating Scheme for the Strength of the Recommendations

2010 American Association of Clinical Endocrinologists (AACE) Protocol for Production of Clinical Practice Guidelines. Step III: Grading of Recommendations – How Different Evidence Levels Can Be Mapped to the Same Recommendation Grade^a

Best Evidence Level	Subjective Factor Impact	Two-thirds Consensus	Mapping	Recommendation Grade
1	None	Yes	Direct	A

Best Evidence Level	Subjective Pactor Impact	Two-thirds Consensus	Mipsing	Recommendation Grade
2	None	Yes	Direct	В
1	Negative	Yes	Adjust down	В
3	Positive	Yes	Adjust up	В
3	None	Yes	Direct	С
2	Negative	Yes	Adjust down	С
4	Positive	Yes	Adjust up	С
4	None	Yes	Direct	D
3	Negative	Yes	Adjust down	D
1, 2, 3, 4	NA	No	Adjust down	D

aStarting with the left column, best evidence levels (BELs), subjective factors, and consensus map to recommendation grades in the right column. When subjective factors have little or no impact ("none"), then the BEL is directly mapped to recommendation grades. When subjective factors have a strong impact, then recommendation grades may be adjusted up ("positive" impact) or down ("negative" impact). If a two-thirds consensus cannot be reached, then the recommendation grade is D. not applicable (NA) regardless of the presence or absence of strong subjective factors, the absence of a two-thirds consensus mandates a recommendation grade D.

Adapted from Mechanick et al. Endocr Pract. 2010;16:270-283.

Cost Analysis

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

Method of Guideline Validation

External Peer Review

Internal Peer Review

Description of Method of Guideline Validation

This clinical practice guideline (CPG) has been reviewed and approved by the primary writers, other invited experts, the American Association of Clinical Endocrinologists (AACE) Publications and Nutrition Committees, and the AACE Board of Directors prior to submission for peer review in Endocrine Practice. This CPG has also been approved by selected members of The Obesity Society (TOS) prior to submission for peer review in *Obesity*, The Official Journal of TOS.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

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

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Appropriate nutritional treatment and prevention of metabolic and endocrine diseases in adults

Potential Harms

- During vitamin D therapy for secondary hyperparathyroidism, serum calcium and phosphorus levels need to be monitored closely to prevent hypercalcemia and hyperphosphatemia, aiming for calcium and phosphorus levels of <10.2 mg/dL and <4.6 mg/dL, respectively.
- Supplemental calcium should not be given in the setting of hypercalcemia associated with primary hyperparathyroidism, sarcoidosis, vitamin D toxicity, or hypercalcemia of malignancy among other disorders.
- In the Women's Health Initiative, there was an increased risk of kidney stones (17% increase) in those supplemented with calcium and vitamin D.
- Gastrointestinal symptoms (bloating, gas, constipation) can be a problem in some patients taking calcium supplementation. Calcium
 carbonate may be more associated with gastrointestinal symptoms, and changing to calcium citrate may help in some patients. Evaluation for
 lactose intolerance, celiac disease, or lack of sufficient fluid or fiber should be considered in patients with persistent symptoms.
- There was a higher risk of advanced and more aggressive prostate cancer in men with calcium intake above 1,500 mg daily.
- In pregnant women, vitamin A is imperative for fetal eye development and has been known to be deficient in developing countries. In the
 United States, with the combination of balanced nutrition and prenatal vitamins (PNVs), pregnant women are ingesting more than adequate
 amounts. Vitamin A toxicity, which affects organogenesis, should be avoided.
- Phytoestrogens are present in soybeans and can act as endocrine disruptors. Soy protein in concentrated forms (such as supplements) should be used with caution due to its potential estrogenic effects.
- For those who can follow low-calorie restrictions, side effects or complications may develop that warrant close follow-up. The following
 possible side effects should be discussed with patients and expected when entering a weight-loss process: constipation, hypotension, loss of
 muscle mass, cold intolerance, poor wound healing, and psychological symptoms such as depression and irritability.
- Because very low-calorie meal plans (VLCMPs) result in rapid weight loss they can be associated with a number of side effects and
 complications. Minor side effects include headache, fatigue, dizziness, constipation, nausea, diarrhea, hair loss, and cold intolerance. Serious
 complications include volume depletion and cholelithiasis. Studies have shown that 10% to 25% of people on VLCMPs will develop
 gallstones, and some will eventually require surgery.
- Oral iron absorption is best when given without food, typically in between meals; but, this form of therapy is not always well tolerated because of gastrointestinal side effects.

Qualifying Statements

Qualifying Statements

- American Association of Clinical Endocrinologists Medical Guidelines for Clinical Practice are systematically developed statements to assist
 health care professionals in medical decision making for specific clinical conditions. Most of the content herein is based on literature reviews.
 In areas of uncertainty, professional judgment was applied.
- These guidelines are a working document that reflects the state of the field at the time of publication. Because rapid changes in this area are
 expected, periodic revisions are inevitable. The guideline developers encourage medical professionals to use this information in conjunction
 with their best clinical judgment. The presented recommendations may not be appropriate in all situations. Any decision by practitioners to
 apply these guidelines must be made in light of local resources and individual patient circumstances.

Implementation of the Guideline

Description of Implementation Strategy

An implementation strategy was not provided.

Implementation Tools

Slide Presentation

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Getting Better

Living with Illness

Staying Healthy

IOM Domain

Effectiveness

Patient-centeredness

Identifying Information and Availability

Bibliographic Source(s)

Gonzalez-Campoy JM, St. Jeor ST, Castorino K, Ebrahim A, Hurley D, Jovanovic L, Mechanick JI, Petak SM, Yu YH, Harris KA, Kris-Etherton P, Kushner R, Molini-Blandford M, Nguyen QT, Plodkowski R, Sarwer DB, Thomas KT, American Association of Clinical Endocrinologists, American College of Endocrinology, The Obesity Society. Clinical practice guidelines for healthy eating for the prevention and treatment of metabolic and endocrine diseases in adults: cosponsored by the American Association of Clinical Endocrinologists/the American College of Endocrinology and the Obesity Society. Endocr Pract. 2013 Sep-Oct;19(Suppl 3):1-82. [721 references] PubMed

Adaptation

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

Date Released

2013 Sep-Oct

Guideline Developer(s)

American Association of Clinical Endocrinologists - Medical Specialty Society

American College of Endocrinology - Medical Specialty Society

The Obesity Society - Disease Specific Society

Source(s) of Funding

American Association of Clinical Endocrinologists (AACE)

Guideline Committee

American Association of Clinical Endocrinologists/American College of Endocrinology Task Force on Healthy Eating Clinical Practice Guidelines

Composition of Group That Authored the Guideline

The Obesity Society

Authors: J. Michael Gonzalez-Campoy, MD, PhD, FACE, Medical Director and CEO, Minnesota Center for Obesity, Metabolism, and Endocrinology (MNCOME); Sachiko T. St. Jeor, PhD, RD, Center for Nutrition and Metabolism, Division of Endocrinology, Nutrition, and Metabolism, Department of Internal Medicine, University of Nevada School of Medicine, Reno, Nevada; Kristin Castorino, DO, Internist and Clinical Research Physician specializing in diabetes during pregnancy, Sansum Diabetes Research Institute; Ayesha Ebrahim, MD, FACE, Director of Endocrinology, Minnesota Center for Obesity, Metabolism, and Endocrinology (MNCOME); Dan Hurley, MD, FACE, Division of Endocrinology, Diabetes, Metabolism, Nutrition, College of Medicine, Mayo Clinic; Lois Jovanovic, MD, MACE, CEO and Chief Scientific Officer, Sansum Diabetes Research Institute; Jeffrey I. Mechanick, MD, FACP, FACN, FACE, ECNU, 2013-2014 President, AACE, Clinical Professor of Medicine and Director, Metabolic Support, Division of Endocrinology, Diabetes, and Bone Disease, Icahn School of Medicine at Mount Sinai, New York, New York; Steven M. Petak, MD, JD, MACE, FCLM, Director, Bone Densitometry Unit and Osteoporosis Center, Texas Institute for Reproductive Medicine and Endocrinology; Yi-Hao Yu, MD, PhD, FACE, Medical Director, Weight Loss and Diabetes Center, Endocrinology, Northeast Medical Group, Greenwich Hospital/Yale New Haven Health, and Clinical Associate Professor of Medicine, Drexel University College of Medicine; Kristina A. Harris, Department of Nutritional Sciences, College of Health and Human Development, The Pennsylvania State University; Penny Kris-Etherton, PhD, RD, Department of Nutritional Sciences, College of Health and Human Development, The Pennsylvania State University; Robert Kushner, MD, Professor of Medicine, Northwestern University Feinberg School of Medicine, Chicago, Illinois; Maureen Molini-Blandford, MPH, RD, Center for Nutrition and Metabolism, Division of Endocrinology, Nutrition, and Metabolism, Department of Internal Medicine, University of Nevada School of Medicine, Reno, Nevada; Quang T. Nguyen, DO, Assistant Clinical Professor of Medicine, Center for Nutrition and Metabolism, Division of Endocrinology, Nutrition, and Metabolism, Department of Internal Medicine, University of Nevada School of Medicine, Reno, Nevada, and Adjunct Associate Professor of Endocrinology and Internal Medicine, Touro University Nevada, College of Osteopathic Medicine; Raymond Plodkowski, MD, Center for Nutrition and Metabolism, Division of Endocrinology, Nutrition, and Metabolism, Department of Internal Medicine, University of Nevada School of Medicine, Reno, Nevada; David B. Sarwer, PhD, University of Pennsylvania School of Medicine, Department of Psychiatry, Center for Weight and Eating Disorders; Karmella T. Thomas, RD, Center for Nutrition and Metabolism, Division of Endocrinology, Nutrition, and Metabolism, Department of Internal Medicine, University of Nevada School of Medicine, Reno, Nevada

Financial Disclosures/Conflicts of Interest

- Dr. J. Michael Gonzalez-Campoy reports that he does not have any relevant financial relationships with any commercial interests.
- Dr. Sachiko T. St. Jeor reports that she has received consultant honoraria from Consumer Reports.
- Dr. Kristin Castorino reports that she does not have any relevant financial relationships with any commercial interests.
- Dr. Ayesha Ebrahim reports that she does not have any relevant financial relationships with any commercial interests.
- Ms. Kristina A. Harris reports that she has received salary as an employee from OmegaQuant and research grant support for graduate studies from General Mills Inc.
- Dr. Dan Hurley reports that he does not have any relevant financial relationships with any commercial interests.
- Dr. Lois Jovanovic reports that she does not have any relevant financial relationships with any commercial interests.
- Dr. Penny Kris-Etherton reports that she has received honoraria as a Scientific Advisory Council member from Unilever and McDonald's Global Advisory Council.
- Dr. Robert Kushner reports that he has received advisory board honoraria from Nestle and clinical research grant support from Weight Watchers International, Inc.
- Dr. Jeffrey I. Mechanick reports that he has received honoraria for lecture and program development from Abbott Nutrition (Abbott Laboratories).
- Ms. Maureen Molini-Blandford reports that she does not have any relevant financial relationships with any commercial interests.

- Dr. Quang T. Nguyen reports that he has received speaker honoraria from AstraZeneca, Eli Lilly and Company, and Genzyme Corporation, a Sanofi company.
- Dr. Steven M. Petak reports that he does not have any relevant financial relationships with any commercial interests.
- Dr. Raymond Plodkowski reports that he does not have any relevant financial relationships with any commercial interests.
- Dr. David B. Sarwer reports that he has received consulting fees from Allergan, Inc., BariMD, Inc., BAROnova, Inc., EnteroMedics Inc., and Galderma Laboratories, L.P.
- Ms. Karmella T. Thomas reports that she does not have any relevant financial relationships with any commercial interests.
- Dr. Yi-Hao Yu reports that he does not have any relevant financial relationships with any commercial interests.

Guideline Status

This is the current release of the guideline.

Guideline Availability

Electronic copies: Available from the American Association of Clinical Endocrinologists (AACE) Web site

Print copies: Available from the American Association of Clinical Endocrinologists (AACE), 245 Riverside Avenue, Suite 200, Jacksonville, FL 32202.

Availability of Companion Documents

The following are available:

- Clinical practice guidelines for healthy eating for the prevention and treatment of metabolic and endocrine diseases in adults. Slide presentation. Jacksonville (FL): American Association of Clinical Endocrinologists; 2013. 61 p. Electronic copies: Available from the American Association of Clinical Endocrinologists (AACE) Web site
- American Association of Clinical Endocrinologists protocol for standardized production of clinical practice guidelines. Endocrine Pract 2010;16:270-283. Electronic copies: Available from the AACE Web site ______.

Print copies: Available from the American Association of Clinical Endocrinologists (AACE), 245 Riverside Avenue, Suite 200, Jacksonville, FL 32202

Patient Resources

None available

NGC Status

This NGC summary was completed by ECRI Institute on August 13, 2014. The information was verified by the guideline developer on September 11, 2014. This summary was updated by ECRI Institute on April 15, 2016 following the U.S. Food and Drug Administration advisory on Metformin-containing Drugs.

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