Position of the Academy of Nutrition and Dietetics: Interventions for the Treatment of Overweight and Obesity in Adults

ABSTRACT

It is the position of the Academy of Nutrition and Dietetics that successful treatment of overweight and obesity in adults requires adoption and maintenance of lifestyle behaviors contributing to both dietary intake and physical activity. These behaviors are influenced by many factors; therefore, interventions incorporating more than one level of the socioecological model and addressing several key factors in each level may be more successful than interventions targeting any one level and factor alone. Registered dietitian nutritionists, as part of a multidisciplinary team, need to be current and skilled in weight management to effectively assist and lead efforts that can reduce the obesity epidemic. Using the Academy of Nutrition and Dietetics' Evidence Analysis Process and Evidence Analysis Library, this position paper presents the current data and recommendations for the treatment of overweight and obesity in adults. Evidence on intrapersonal influences, such as dietary approaches, lifestyle intervention, pharmacotherapy, and surgery, is provided. Factors related to treatment, such as intensity of treatment and technology, are reviewed. Community-level interventions that strengthen existing community assets and capacity and public policy to create environments that support healthy energy balance behaviors are also discussed.
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POSITION STATEMENT

It is the position of the Academy of Nutrition and Dietetics that successful treatment of overweight and obesity in adults requires adoption and maintenance of lifestyle behaviors contributing to both dietary intake and physical activity. These behaviors are influenced by many factors; therefore, interventions incorporating more than one level of the socioecological model and addressing several key factors in each level may be more successful than interventions targeting any one level and factor alone.

THE PURPOSE OF THIS ARTICLE is to provide an update to the 2009 position paper on adult weight management and incorporate the revised Academy's evidence-based adult weight-management guidelines from the Evidence Analysis Library (EAL) and the 2013 American Heart Association, American College of Cardiology, and The Obesity Society (AHA/ACC/TOS) Guideline for the Management of Overweight and Obesity in Adults.[1] The scope of the paper has been expanded to include a socioecological approach and provide evidence regarding community-based and policy-level interventions designed to reduce the prevalence of overweight and obesity in communities in the United States. Within those areas in which various interventions are described, included evidence focuses as much as possible on systematic reviews and/or meta-analyses, randomized controlled trials (RCTs), and other evidence-based guidelines.

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In 2012, 34.9% of adults in the United States were obese and another 33.6% were overweight.[2] The high prevalence of overweight and obesity in the United States negatively affects the health of the population, as obese individuals are at increased risk for developing several chronic diseases, such as type 2 diabetes, cardiovascular disease (CVD), and certain forms of cancer.[1,3] Because of its impact on health, medical costs, and longevity, reducing obesity is considered to be a public health priority.[4]

Weight loss of only 3% to 5% that is maintained has the ability to produce clinically relevant health improvements (eg, reductions in triglycerides, blood glucose, and risk of developing type 2 diabetes).[1] Larger weight loss reduces additional risk factors of CVD (eg, low-density and high-density

This Academy position paper includes the authors' independent review of the literature in addition to systematic review conducted using the Academy's Evidence Analysis Process and information from the Academy's Evidence Analysis Library (EAL). Topics from the EAL are clearly delineated. For a detailed description of the methods used in the Evidence Analysis Process, go to www.andevidencelibrary.com/eaprocess.

Recommendations are assigned a rating by an expert work group based on the grade of the supporting evidence and the balance of benefit vs harm. Recommendation ratings are Strong, Fair, Weak, Consensus, or Insufficient Evidence.

Recommendations can be worded as conditional or imperative statements. Conditional statements clearly define a specific situation and most often are stated as an "if, then" statement, while imperative statements are broadly applicable to the target population without restraints on their pertinence.

Evidence-based information for this and other topics can be found at www.andevidencelibrary.com and subscriptions for nonmembers can be purchased at www.andevidencelibrary.com/store.cfm.

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lipoprotein cholesterol and blood pressure) and decreases the need for medication to control CVD and type 2 diabetes. Thus, a goal of weight loss of 5% to 10% within 6 months is recommended.[1]

EAL Recommendation: "The registered dietitian nutritionist (RDN) should collaborate with the individual regarding a realistic weight-loss goal such as one of the following: up to 2 lb per week, up to 10% of baseline body weight, or a total of 3% to 5% of baseline weight if cardiovascular risk factors (hypertension, hyperlipidemia, and hyperglycemia) are present." **(Rating: Strong, Imperative)**

GOALS OF ADULT OBESITY TREATMENT

While intentional weight loss of at least 3% to 5% improves some clinical parameters,[1] to sustain these improvements, this degree of weight loss needs to be maintained. While there is no standard definition for length of time for maintenance of weight loss for it to be considered successful, duration of 1 year is often used.[5] While long-term weight-loss maintenance is one of the challenges in obesity treatment, it is possible. For example, the Look AHEAD (Action for Health in Diabetes) trial, an RCT with >5,000 adults with type 2 diabetes, reported that 39.3% of the 825 participants who received a lifestyle intervention (consisting of a reduced-energy dietary and physical activity prescription, and a cognitive behavioral intervention) who lost at least 10% of their body weight at year 1 maintained at least a 10% weight loss at year 8, and another 25.8% maintained a 5% to <10% weight loss at year 8.[6]

To achieve a reduction in weight that can be sustained over time and improve cardiometabolic health, obesity treatment ideally produces changes in lifestyle behaviors that contribute to both sides of energy balance in adults. Thus, the diet should be altered so that reductions in excessive energy intake and enhancements in dietary quality occur, so that the likelihood of achieving recommendations provided in the 2010 Dietary Guidelines for Americans (DGA)[7] is increased. Along with changes in dietary intake, obesity treatment should encourage increases in physical activity in order to increase energy expenditure, in the minimum to meet the 2008 Physical Activity Guidelines for Americans (150 minutes per week of moderate-intensity, or 75 minutes per week of vigorous-intensity physical activity)[8] and ideally to meet the American College of Sports Medicine's Position Stand for weight-loss maintenance (>250 minutes/wk of moderate-intensity physical activity),[9] and enhance cardiovascular fitness. Preservation of changes in lifestyle behaviors is required to achieve successful weight-loss maintenance.[10]

FACTORS INFLUENCING FOOD INTAKE

Eating behavior is generally believed to be influenced by both internal and external cues.[11,12] Internally, two systems have been identified that assist with regulating intake.[11] The first system is the homeostatic system, in which neural, nutrient, and hormonal signals allow communication between the gut, pancreas, liver, adipose tissue, brainstem, and hypothalamus. The arcuate nucleus of the hypothalamus integrates these signals and regulates hunger, satiation, and satiety in response to the signals via higher cortical centers that influence the sympathetic and parasympathetic nervous system, gastric motility and hormone secretion, and other processes relevant to energy homeostasis. The second internal system is the hedonic system, which is influenced by the hedonic ("liking") and rewarding ("wanting") qualities of food and is regulated by the corticolimbic system.[11,12] It is through the hedonic system that environmental cues influence consumption.[11,12] The hedonic system does have a strong impact on intake, as is demonstrated in situations when eating occurs after reports of satiation and when there is no nutrition need (eg, the dessert effect).[12] It is believed that cross talk does occur between these two internal systems; however, little is known about this process.[11]

Many external factors influence consumption, but environmental variables that appear to greatly influence intake are food availability and variety and energy density and portion size of food.[12] Research has found that when availability, variety, energy density, and portion size increase, intake is heightened.[12] The increased intake appears to be outside of awareness, is not associated with enhanced satiation, and compensation does not appear to occur over time.

FACTORS INFLUENCING ENGAGING IN MODERATE- TO VIGOROUS-INTENSITY PHYSICAL ACTIVITY

As with food intake, there are internal and external factors that influence how much moderate- to vigorous-intensity physical activity (MVPA) one engages in. Internally, physical limitations and discomfort and beliefs about how MVPA influences health have been related to amount of MVPA achieved.[13] Mood and, specifically, core affective valence (eg, good/bad feelings) in response to engaging in MVPA are related to future physical activity.[14] Also as engaging in regular MVPA involves consistently making decisions to engage in a behavior that requires costs to achieve the long-term cumulative health benefits, it is theorized that strong executive control and optimized brain structures supporting executive functioning (ie, dorsolateral prefrontal cortex) is an important internal factor.[15]

The social and physical environments are also believed to be factors that influence engaging in MVPA. How supportive other individuals are to MVPA efforts and the potential interaction with others who are active are external factors that can promote physical activity.[13] Different physical environmental dimensions, such as walkability, land use, public transportation availability, safety, and aesthetics, in residential and/or work neighborhoods have also been shown to influence physical activity.[16] Finally, within a home or work setting, the option of engaging in sedentary behaviors, especially those that are screen-based, can also influence MVPA.[17]

SOCIOECOLOGICAL MODEL OF OBESITY INTERVENTION

The socioecological model provides a framework that proposes that multiple levels of influence can impact energy-balance behaviors and weight outcomes. Levels of influence include intrapersonal factors, community and organizational factors, and government and public policies.[18]

Intrapersonal-Level Obesity Intervention

The vast majority of research forming an evidence-based approach to obesity treatment has focused on intervention at the individual level, in which treatment targets intrapersonal-level factors that assist with changing energy balance behaviors. The nutrition care process, which includes nutrition assessment, diagnosis, intervention, monitoring, and evaluation, represents an intrapersonal-level of focus. The Academy's evidence-based adult weight-management guidelines from the EAL focus on obesity treatment at the intrapersonal level, incorporating the nutrition care process within its recommendations.

Assessment. As with any nutrition assessment, applicable information that can assist in the development of a nutrition diagnosis and intervention for obesity is essential (see Figure 1 for suggested data to collect for assessment). Determining body mass index (BMI; calculated as kg/m^2) is often the first step of obesity treatment, as it identifies whether a client is overweight or obese. Using the current criterion for overweight and obesity, individuals with a BMI ≥25.0-29.9 (overweight) or ≥30 (obese) should be identified and provided with obesity treatment.[1] Other anthropometric and medical measures, such as waist circumference, blood pressure, lipids, and glucose, should be taken to assess for cardiovascular risk.[1] This will assist with matching obesity treatment benefits with risk profiles and making appropriate referrals.[1]

EAL Recommendation: "The RDN, in collaboration with other health care professionals, administrators, and/or public policy decision-makers, should ensure that all adult patients have the following measurements at least annually: height and weight to calculate BMI; and waist circumference to determine risk of CVD, type 2 diabetes, and all-cause mortality." **(Rating: Fair, Imperative)**

EAL Recommendation: "The RDN, in collaboration with other health care professionals, administrators, and public policy decision makers, should ensure that overweight or obese adults are referred to an RDN for medical nutrition therapy (MNT)." **(Rating: Fair, Imperative)**

Once an RDN initiates the nutrition care process, data about the client (see Figure 1) should be collected to assist in individualizing MNT. An assessment can include, but is not limited to, dietary intake; social history, including living or housing situation and socioeconomic status; and motivation for weight management. Resting metabolic rate should be determined, and that, combined with activity level and calculation of usual dietary intake in terms of energy and nutrient content, can assist with developing dietary parameters that may be appropriate to target during intervention. In the EAL, physical activity is listed with food- and nutrition-related history, and level of physical activity is required to estimate energy needs. To assist with assessing physical activity, "A Physical Activity Toolkit for Registered Dietitians: Utilizing Resources of Exercise is Medicine," was developed by the Weight Management and Sports, Cardiovascular, and Wellness Nutrition dietetic practice groups, in collaboration with the American College of Sports Medicine.

EAL Recommendation: "The RDN should assess the following data in order to individualize the comprehensive weight-management program for overweight and obese adults: food- and nutrition-related history; anthropometric measures; biochemical data, medical tests and procedures; nutrition-focused physical findings; and client history." **(Rating: Strong, Imperative)**

EAL Recommendation: "The RDN should assess the energy intake and nutrient content of the diet." **(Rating: Strong, Imperative)**

EAL Recommendation: "If indirect calorimetry is available, the RDN should use a measured resting metabolic rate (RMR) to determine energy needs in overweight or obese adults." **(Rating: Consensus, Conditional)**

EAL Recommendation: "If indirect calorimetry is not available, the RDN should use the Mifflin-St. Jeor equation using actual weight to estimate RMR in overweight or obese adults." **(Rating: Strong, Conditional)**

EAL Recommendation: "The RDN should multiply the RMR by one of the following physical activity factors to estimate total energy needs: sedentary (1.0 or more to less than 1.4); low active (1.4 or more to less than 1.6); active (1.6 or more to less than 1.9); and very active (1.9 or more to less than 2.5)." **(Rating: Consensus, Imperative)**

EAL Recommendation: "The RDN should assess motivation, readiness and self-efficacy for weight management based on behavior change theories and models (such as cognitive-behavioral therapy, transtheoretical model, and social cognitive theory/social learning theory)." **(Rating: Fair, Imperative)**

Dietary Intervention. As treating obesity requires achieving a state of negative energy balance, all efficacious dietary interventions for obesity treatment must decrease consumption of energy. There are many dietary approaches that can reduce energy intake, with some approaches more greatly reducing intake than others. However, the degree of weight loss generally reflects the size of the decrease in energy intake achieved. Thus, the reduction in energy intake is the primary factor to address in a dietary intervention for obesity treatment.[1] As many dietary approaches reduce energy intake, a client's preference and health and nutrient status should be taken into consideration when a dietary intervention for obesity treatment is prescribed.[1] See Figure 2 for dietary interventions and a summary of the evidence-base regarding ability to produce weight loss or not, or whether evidence is lacking for conclusions to be drawn.

EAL Recommendation: "During weight loss, the RDN should prescribe an individualized diet, including patient preferences and health status, to achieve and maintain nutrient adequacy and reduce caloric intake, based on one of the following caloric reduction strategies: 1,200 kcal to 1,500 kcal/day for women and 1,500 to 1,800 kcal/day for men; energy deficit of approximately 500 kcal/day or 750 kcal/day; one of the evidence-based diets that restricts certain food types (such as high-carbohydrate foods, low-fiber foods, or high-fat foods) in order to create an energy deficit by reduced food intake." **(Rating: Strong, Imperative)**

EAL Recommendation: "For weight loss, the RDN should advise overweight

Assess	Monitor and Evaluate
Food- and nutrition-related history	
• Beliefs and attitudes, including food preferences and motivation • Food environment, including access to fruits and vegetables • Dietary behaviors, including eating out and screen time • Diet experience, including food allergies and dieting history • Medications and supplements • Physical activity	• Beliefs and attitudes, including motivation • Food environment, including access to fruits and vegetables • Dietary behaviors, including eating out and screen time • Medications and supplements • Physical activity
Anthropometric measurements	
• Height, weight, body mass index • Waist circumference • Weight history • Body composition	• Weight, body mass index • Waist circumference • Weight history • Body composition
Biochemical data, medical tests, and procedures	
• Glucose and endocrine profile • Lipid profile	• Glucose and endocrine profile • Lipid profile
Nutrition-focused physical findings	
• Ability to communicate • Affect • Amputations • Appetite • Blood pressure • Body language • Heart rate	• Affect • Appetite • Blood pressure • Body language • Heart rate
Client history	
• Appropriateness of weight management in certain populations (such as eating disorders, pregnancy, receiving chemotherapy) • Client and family medical and health history • Social history, including living or housing situation and socioeconomic status	

Figure 1. Data needed to assess, monitor, and evaluate a comprehensive weight-management program from the Academy of Nutrition and Dietetics' Evidence Analysis Library.

Diet	Investigated using RCTs[a] with evidence considered supportive for weight loss	Investigated using RCTs with evidence considered non-supportive for weight loss	Lacking investigation for weight loss using RCTs
Small, food-based			
Increasing fruits and vegetables		X	
Decreasing sugar-sweetened beverages	X		
Decreasing fast food			X
Portion control	X		
Larger-, energy-, macronutrient- and/or dietary pattern-based			
Energy-focused			
Low-calorie diet	X		
Meal replacement/structured meal plans	X		
Very-low-calorie diet	X		
Macronutrient-focused			
Low-carbohydrate	X		
Low glycemic index/load without energy restriction		X	
High protein with energy restriction	X		
Dietary-pattern focused			
Energy density			X
DASH[b] with energy restriction	X		
Mediterranean with energy restriction	X		
Dietary-timing focused			
Eating frequency			X
Timing of eating			X
Breakfast consumption			X

Figure 2. Evidence-base for dietary interventions for weight loss in adults. Sources include 2013 American Heart Association, American College of Cardiology, and the Obesity Society Guideline for the Management of Overweight and Obesity in Adults and the Academy of Nutrition and Dietetics' Evidence Analysis Library. [a]RCTs=randomized controlled trials; [b]DASH=Dietary Approaches to Stop Hypertension.

or obese adults that as long as the target reduction in calorie level is achieved, many different dietary approaches are effective." **(Rating: Strong, Imperative)**

EAL Recommendation: "During weight maintenance, the RDN should prescribe an individualized diet (including patient preference and health status) to maintain nutrient adequacy and reduce caloric intake for maintaining a lower body weight." **(Rating: Strong, Imperative)**

EAL Recommendation: "For weight maintenance, the RDN should advise overweight and obese adults that as long as the target reduction in calorie level is achieved, many different dietary approaches are effective." **(Rating: Strong, Imperative)**

Small, food-based changes. It has been proposed that small behavior changes, those that shift energy balance by 100 to 200 kcal/day, may be helpful for weight management.[19] It is important to recognize that this degree of energy deficit is much smaller than what is currently recommended to produce clinically relevant weight loss.[1] It is hypothesized that small behavior changes, such as reducing intake of sugar-sweetened beverages (SSB), may be more feasible and sustainable than larger behavior changes, such as changing macronutrient composition of the diet.

Fruits and vegetables. Within the context of promoting healthy diets, the increased consumption of fruits and vegetables has gained recognition, in large part due to the findings of the DASH (Dietary Approaches to Stop Hypertension) and DASH-Sodium RCTs.[20,21] Increasing fruits and vegetables is a dietary change that can reduce dietary energy density, enhance satiation, and assist with decreasing overall energy intake, particularly if fruits and vegetables are consumed instead of other foods higher in energy density.[22] Those RCTs that have examined the influence of solely increasing fruits and vegetables with no other dietary changes on weight management have generally not produced weight loss.[23]

SSB. Reducing SSB should be helpful for weight management if compensation to the reduction in energy consumed from SSB does not occur and if energy-containing beverages are not consumed in place of SSB when SSB are reduced. While few studies have examined the effect of solely reducing SSB on weight loss, an RCT conducted by Tate and colleagues[24] found that replacing caloric beverages with water or diet beverages resulted in weight losses of 2% to 2.5% during a 6-month period. While concerns have been raised about increases in hunger, which may increase overall energy intake when non-nutritive sweetened foods and beverages are consumed, a recent RCT found that consumption of at least 24 oz of non-nutritive sweetened beverages during a 12-week behavioral weight-loss intervention reduced subjective feelings of hunger as compared with a 24-oz water consumption comparison.[25]

Fast food. Food prepared away from home, in particular fast food, comprises an increasing amount of the American diet and contributes to the epidemic of obesity.[26] Fast food is generally high in energy density and commonly purchased in large portion sizes, thereby contributing to excessive energy intake.[26] Due to the relationship between fast food and increased energy intake, in the context of a weight-loss dietary regimen, avoidance or reduction of the frequency of consumption of foods away from home is typically recommended. However, no RCT has been conducted to examine whether reducing fast food alone, with no other changes in the diet, produces weight loss.

At this time, research conducted in the area of small, food-based changes indicates that only changes in SSB, and no other small food-based change, can assist with weight management. It is important to note that the weight loss found with reducing SSB alone, while statistically significant, is below the amount of weight loss that is recommended to improve cardiometabolic health.[1]

Portion-control changes. RDNs have long endorsed skills that include portion control for lifelong weight management.[27] Portion control can be accomplished in a variety of different ways, including using packages containing a defined amount of energy (eg, complete meals, individual food items); portion-controlled utensils where food is delivered in specific serving sizes; or communication strategies such as MyPlate, developed as an adjunct to the DGA,[7] to assist with consuming appropriate serving sizes of specific foods. The EAL's Relationship of Single Serving Portion Size Meals and Weight Management Project states that single-serving portion-sized meals are a tool that can be used as a part of a weight-management program. This project's key findings were that eating one or more single-serving portion-sized meals per day as part of a weight-management program resulted in a reduction of energy intake and weight loss in adults.

Larger, energy, macronutrient, and/or dietary pattern-based changes. Dietary approaches that target larger nutrient (eg, energy and/or macronutrient) and or dietary pattern-based changes (eg, Mediterranean diet) are predominantly considered efficacious for weight loss and produce the recommended amount of weight loss,[1] as many RCTs investigating these diets have shown that they reduce energy intake enough (500 kcal/day to 750 kcal/day) so that the degree of negative energy balance achieved produces at least a 3% reduction in percent body weight.[1] These dietary interventions have either an explicit energy goal per day or provide an ad libitum approach without a formal energy goal that still produces a reduction in energy intake, usually by restriction or elimination of specific foods and/or food groups, or provision of prescribed foods (eg, meal replacement).[1] Outcomes indicate that all of the larger, energy, macronutrient, and/or dietary pattern-based approaches produce a weight loss of about −4 to −12 kg at 6-month follow-up.[1] After 6 months, slow weight regain occurs, and at 1 year, total weight loss is −4 to −10 kg, and at 2 years, total weight loss is at −3 to −4 kg.[1] As this is the pooled effect of the weight loss achieved with the energy, macronutrient and/or dietary pattern-based change diets, the individual weight-loss outcomes for each diet described in this paper are not reported (except for the very-low-calorie diet [VLCD] as this diet has a lower energy prescription than all other diets; meal replacements, as they are a specific form

of the low-calorie diet [LCD] and their weight loss is included to allow comparison with the LCD; and timing of eating, as this diet was not included in the AHA/ACC/TOS Guideline for the Management of Overweight and Obesity in Adults).[1]

Although no one diet approach that targets larger nutrients or dietary patterns is considered to be more efficacious than another diet approach, some of the diets have differential effects on cardiometabolic outcomes and dietary quality. While research in these differential effects is limited, available research on cardiometabolic outcomes specific to a diet intervention, after controlling for effects attributable to weight loss, and diet quality are described here for the corresponding diet. If measures of cardiometabolic outcomes and diet quality are not reported on in a section, this indicates that there is very little evidence available to report about the influence of the diet alone on these parameters.

Energy focused. Two of the most widely investigated dietary prescriptions for weight loss are the LCD and the VLCD. Along with varying in energy goals, these two diets differ in the amount of structure they provide.

LCD. An LCD is usually >800 kcal/day, and typically ranges from 1,200 to 1,600 kcal/day.[28] Structure can be increased in the LCD with the use of a meal plan, in which all food choices and portion sizes for these choices for all meals and snacks are provided. Use of meal replacements, usually liquid shakes and bars, containing a known amount of energy and macronutrient content also increase structure in the LCD diet. These methods of increasing structure in the diet are believed to be helpful for adherence to an LCD because they reduce problematic food choices, and decrease challenges with making decisions about what to consume. In addition, meal replacements can enhance dietary adherence via portion control, limiting dietary variety, and convenience.[28-30] Meal plans and the partial meal-replacement plan, which prescribes two portioned-controlled, vitamin/mineral-fortified meal replacements per day, with a reduced energy meal and snack composed of conventional foods, may produce greater short-term weight loss as compared with an LCD composed of traditional foods.[28,31] For example, a meta-analysis of six studies comparing an LCD composed of conventional foods or meal replacements found a 2.54 kg and 2.43 kg greater weight loss in the meal-replacement group for the 3-month and 1-year follow-ups, respectively.[28]

EAL Recommendation: "For weight loss and weight maintenance, the RDN should recommend portion control and meal replacements or structured meal plans as part of a comprehensive weight-management program." **(Rating: Strong, Imperative)**

VLCD. A VLCD provides ≤800 kcal/day and provide a high degree of dietary structure (VLCDs are commonly consumed as liquid shakes).[32,33] The VLCD is designed to preserve lean body mass; usually 70 to 100 g/day of protein or 0.8 to 1.5 g protein/kg of ideal body weight are prescribed.[32] VLCDs are considered to be appropriate only for those with a BMI ≥30, and are increasingly used with individuals before having bariatric surgery to reduce overall surgical risks in those with severe obesity.[32] A meta-analysis of six RCTs comparing weight-loss outcomes of VLCDs to LCDs found that although VLCDs produce significantly greater weight loss in the short-term (4 months), −16.1%±1.6% vs −9.7%±2.4% of initial weight, there was no difference in weight loss between the diets in long-term follow-up (>1 year), VLCD = −6.3%±3.2%; LCD = −5.0%±4.0%).[32]

Macronutrient focused. Many RCTs have been conducted to help determine which mix of macronutrients best promotes weight loss, while including other positive metabolic benefits. What is important to recognize about macronutrient-focused diet prescriptions is that when one macronutrient is altered, there will be a change in the other macronutrients. Thus, prescriptions for macronutrient-focused diets have often targeted changing one macronutrient, allowing the other two macronutrients to change as different food choices are made. The name of the macronutrient-focused diet is usually based on the one macronutrient that is targeted for change.

Low carbohydrate. A low-carbohydrate diet is commonly defined as consuming no more than 20 g of carbohydrate per day.[34,35] Energy and other macronutrients are not restricted in low-carbohydrate diets. Once a desired weight is achieved, carbohydrate intake can increase to 50 g per day.[36]

While amount of weight loss achieved is not considered to be different between a low-carbohydrate and low-fat, LCD especially over 12 months or longer, research does suggest that these diets may produce differences in cardiometabolic outcomes during weight loss.[1] For example, a low-fat, LCD produces a greater reduction in low-density lipoprotein cholesterol than a low-carbohydrate diet, while a low-carbohydrate diet produces a greater reduction in triglycerides and a larger increase in high-density lipoprotein cholesterol than a low-fat, LCD.[1]

• ***Low-glycemic index/glycemic load.*** There is currently no standard definition of a low-glycemic index or low-glycemic load diet. The effectiveness of a low-glycemic index diet without restriction of energy intake on weight loss is fairly poor.[37] With regard to cardiometabolic outcomes, a recent RCT found that when coupled with energy restriction, a low-glycemic index diet controlled glucose and insulin metabolism more effectively than a high-glycemic index, low-fat diet.[38]

High protein. A high-protein diet is commonly defined as consuming at least 20% energy from protein, with no standard amount defined for fat or carbohydrate.[39] For weight loss, high-protein diets also include an energy restriction. A high-protein diet is often achieved through consumption of conventional foods, but high-protein, portion-controlled liquid and solid meal-replacement products can also be used on a high-protein diet.

Dietary pattern focused. Dietary pattern–focused prescriptions emphasize the importance of the overall diet by providing recommendations about types of foods to consume, rather than providing recommendations about amount of energy or macronutrients, to consume.[7,40] The DGA promotes adopting an eating pattern to assist with weight management and reduce

disease risk.[7] As these diets focus on types of foods to consume and may not produce greater weight loss than other types of diets, they enhance consumption of foods that are generally considered beneficial in the diet and enhance overall dietary quality.[41,42]

Energy density. Energy density is the ratio of energy of a food to the weight of a food (kcal/g). Energy density is largely determined by the water content (higher water content lowers energy density), but is also affected by the fiber and fat content (more fiber lowers energy density and less fat lowers energy density) of foods and beverages consumed. As low-energy density foods have fewer kilocalories per gram weight, low-energy density foods allow consumption of a greater weight of food relative to energy consumed, which may assist with appetite control and reducing energy intake.[22,43]

Basic eating research has found that serving meals with foods low in energy density results in decreased meal energy intake.[22] For example, one study reduced energy density by 20% for entrées served at breakfast, lunch, and dinner, on three different days, using three different methods (reducing fat, increasing fruits and vegetables, or adding water to entrées), with a different method used to reduce energy density each day. With the reduction in energy density, energy intake per day decreased, ranging from −396±44 kcal/day to −230±35 kcal/day, with the largest decrease occurring when fat was reduced in entrées.[44]

Few RCTs have been conducted to examine the effect of a low-energy density diet on weight loss and currently there is no standard method known to best reduce energy density in the diet.[45] Results from these trials about weight loss are mixed, and this may be a consequence of the methods used to reduce dietary energy density, the degree of reduction in energy density achieved, and whether or not energy restriction was included. To better understand how recommendations to reduce energy density can be implemented, guidelines need to be developed regarding what is considered to be low-energy density and high-energy density (currently no definition exists), how best to lower energy density of the diet, and how dietary energy density should be calculated (ie, as energy density is greatly influenced by water, dietary energy density varies greatly depending on whether and how beverages are included in calculations and no standard calculation has been determined).[46]

DASH. DASH is a dietary pattern that was developed to reduce hypertension in individuals with moderate to high blood pressure. DASH encourages the consumption of fruits, vegetables, whole grains, nuts, legumes, seeds, low-fat dairy products, and lean meats and limits consumption of sodium, in addition to caffeinated and alcoholic beverages.[47] A daily energy limit is not a component of the original DASH diet, but when one is provided with the DASH diet, weight loss occurs.[48,49] The DASH diet combined with weight loss significantly enhances reductions in blood pressure above that achieved by weight loss alone.[49]

Mediterranean. There is not a standard definition for the Mediterranean diet, but generally the Mediterranean diet reflects the dietary patterns of Crete, Greece and southern Italy in the early 1960s.[50] The traditional Mediterranean diet was focused on plant-based foods (eg, fruits, vegetables, grains, nuts, seeds), minimally processed foods, olive oil as the primary source of fat, dairy products, fish, and poultry consumed in low to moderate amounts, and minimal amount of red meat.[51] As with the DASH diet, the Mediterranean diet can be prescribed with or without an energy restriction, but if weight loss is desired, it does appear that an energy-restriction component is needed.[52] In addition, the Mediterranean diet may improve cardiovascular risk factors, such as blood pressure, blood glucose, and lipids, more so than a low-fat diet,[53,54] but more research is needed in this area.

In summary, there are several dietary approaches that target larger nutrient (eg, energy and/or macronutrient) and or dietary pattern–based changes (eg, Mediterranean diet) that can produce the recommended amount of weight loss.[1] At this time, as long as the diet helps to reduce energy intake by 500 to 750 kcal/day, there is no one diet that falls into this category that has been shown to be more efficacious than another at producing clinically meaningful weight loss.

Dietary-timing focused. While research on dietary interventions for obesity have predominantly focused on food choices that impact energy, macro- and micronutrient, and food group intake,[55] dietary interventions can also address factors that influence the overall timing of the diet (eg, frequency of consumption, timing of consumption, and breakfast consumption). It is important to note that research on the effect of timing of intake on obesity treatment outcomes is very limited.

Eating frequency. Eating frequency is commonly defined as the number of eating occasions (meals and snacks) occurring per day. A greater number of eating occasions consumed increases overall eating frequency. At this time, there is no standardized definition of what constitutes an eating occasion.[56] Common parameters used to define an eating occasion include amount of energy consumed, type of substance ingested (eg, food or beverage), and the amount of time that has elapsed since the start of the previous eating occasion.[56,57] Few RCTs have been conducted that examine the influence of eating frequency on weight loss, and those that have been conducted have not found that a higher eating frequency produces greater weight loss.[56]

Timing of eating. When and how much energy you eat during the day can also be important for weight management. Potentially consuming more energy earlier in the day, rather than later in the day, can assist with weight management.[55] The mechanism of action by which timing of eating might assist with weight management is by influencing circadian rhythm.[55] Potentially, eating a greater amount earlier in the day may assist with synchronization of peripheral oscillators with the suprachiasmatic nucleus, assisting with maintenance of an appropriate circadian rhythm.[55]

There is only one RCT that has been conducted to examine timing of energy intake and weight loss.[58] In this 12-week intervention, the overweight and obese women with metabolic

syndrome who were randomized to the group that consumed most of their energy earlier in the day lost more weight (−8.7±1.4 kg vs −3.6±1.5 kg).

Breakfast consumption. One dietary pattern factor that has been proposed to influence weight status is regular consumption of breakfast.[59] Similar to eating frequency, there is no standardized definition of breakfast, but common parameters that are believed to be important in defining breakfast include time of day of consumption, time of consumption after ending daily sleep, and types of foods and beverages consumed at breakfast. Only three RCTs have examined the influence of breakfast consumption on weight loss, with all trials being of short duration (≤16 weeks), and no investigation found greater weight loss with breakfast consumption.[60-62]

Overall, the results of intervention research examining the effect of dietary-timing focused interventions do not suggest that increasing eating frequency or consuming breakfast improve weight-loss outcomes, but consuming most of an individual's energy earlier in the day may enhance weight loss.

EAL Recommendation: "For weight loss and weight maintenance, the RDN should individualize the meal pattern to distribute calories at meals and snacks throughout the day, including breakfast." **(Rating: Fair, Imperative)**

Activity Intervention. Activity interventions are designed to enhance energy expenditure, which assists with the achievement of negative energy balance that is required for weight loss. However, it is important to recognize that activity interventions may assist with weight management via other mechanisms that are not well understood (eg, sparing of fat-free mass with weight loss, enhanced ability for energy regulation, and ability to buffer the negative effects of stress on weight).[63] Traditionally, activity interventions have focused on increasing MVPA, as this type of activity has higher energy expenditure than other activities (eg, light physical activity) and also improves cardiovascular health. Recently, focus has turned to the role of sedentary behaviors and obesity treatment.

Physical activity. MVPA is defined as activity that is ≥3.0 metabolic equivalent units (METs; a MET of 1 is generally considered the RMR).[9] There is a large body of research, including RCTs, examining the influence of MVPA on obesity treatment.[9] While increasing MVPA alone is not believed to be the best strategy for weight loss and produces less weight loss than decreasing energy intake, the combination of increasing MVPA with decreasing energy intake produces the largest weight loss.[9,64] For example, a recent meta-analysis of diet or exercise interventions vs combined behavioral weight-management programs found at 12 months that the combined program had greater weight loss than the diet-only programs (mean difference in weight loss achieved for combined behavioral weight management vs diet only was −1.72 kg) and the exercise-only programs (mean difference in weight loss achieved for combined behavioral weight management vs exercise only was −6.29 kg).[64] However, for weight-loss maintenance, research has consistently demonstrated that a high level of MVPA is imperative.[9] The difference in the roles of MVPA for weight loss and weight-loss maintenance is believed to be due to the degree of energy deficit required. Weight loss requires a larger energy deficit (approximately −500 to −1,000 kcal/day for 1 to 2 lb of weight loss per week), which is challenging to achieve via increased MVPA alone. For weight-loss maintenance, equilibrium of energy intake to expenditure is needed; thus, higher levels of MVPA allow energy intake to be greater, which may help long-term adherence to dietary goals. The current recommendation for physical activity is a minimum of 30 minutes of moderate-intensity activity on most days of the week (150 min/wk).[8] However, higher levels of MVPA (>250 min/week) are recommended for weight-loss maintenance.[9] To enhance cardiovascular outcomes associated with increasing MVPA, ideally minutes spent in MVPA is accumulated in bouts of at least 10 minutes.[8]

EAL Recommendation: "For weight loss the RDN should encourage physical activity as part of a comprehensive weight-management program, individualized to gradually accumulate 150 to 420 minutes or more of physical activity per week, depending on intensity, unless medically contraindicated." **(Rating: Consensus, Imperative)**

EAL Recommendation: "For weight maintenance the RDN should encourage physical activity as part of a comprehensive weight-management program, individualized to gradually accumulate 200 to 300 minutes or more of physical activity per week, depending on intensity, unless medically contraindicated." **(Rating: Consensus, Imperative)**

Sedentary behavior. Sedentary behavior is defined as sitting activities with a very low level of energy expenditure (<1.5 METs).[65] Sedentary behavior occurs in a variety of domains (ie, leisure, occupation, transportation, and recreation), and includes working/playing on the computer or tablet, driving a car, and watching television (TV). Given that greater time spent in sedentary behavior, independent of time performing MVPA, has been associated with increased risk of obesity,[66] it is now recommended that sedentary behavior, particularly leisure screen time (eg, TV watching; computer and tablet use), be reduced in adults to improve weight and health status.[66,67]

There are several mechanisms by which reducing sedentary behavior may assist with weight management. The first is through increasing energy expenditure. Research indicates that when time engaged in sedentary behavior is reduced, while little to none of the newly acquired free time is reallocated to MVPA, a significant amount of time is reallocated to light physical activity (1.5 to 2.9 METs).[68,69] The reallocation of time spent in sedentary behavior to light physical activity may increase overall energy expenditure due to light physical activity's higher MET values as compared with sedentary behavior. The second mechanism is through reducing food consumption. Eating appears to be a complementary behavior to some sedentary behaviors, particularly TV watching.[70] As TV watching is reduced, energy consumed while watching TV decreases, thus

lowering intake.[69] Few RCTs have examined reducing sedentary behavior during obesity treatment, and the two trials that have were of a small sample size (<15 participants) and of short duration (8 weeks), and did not find significantly greater weight loss with the conditions that prescribed reducing sedentary behavior to <10 hours/week of TV watching (comparison was an intervention that prescribed increasing MVPA to 200 minutes/wk).[69]

The research on activity interventions demonstrate that increasing MVPA is an important behavioral target in weight management, particularly in weight-loss maintenance. Additional research is required to understand if reducing sedentary behavior should also be a behavioral target in obesity treatment interventions.

Behavior-Change Intervention. Behavior-change theories and models provide an evidence-based approach for changing energy-balance behaviors that are important for obesity treatment.[71] At this time, it is not known what is the best combination of behavior-change strategies and techniques to apply in treating obesity.[72] Instead, it is believed that a variety of strategies from different behavior change theories can be applied to assist with changing behaviors.[71] Evidence-based interventions for behavior change have developed from behavioral theory, which is a theoretical framework that proposes that with the use of learning principles, such as classical and operant conditioning, healthy behaviors can be learned.

Cognitive behavioral therapy. Cognitive behavioral therapy (CBT) uses a directive, action-oriented approach and provides skills to help individuals learn to develop functional thoughts and behaviors.[71] CBT proposes that thoughts, feelings, and behaviors interact to impact health outcomes. Cognitive and behavioral strategies are emphasized to effect change. Commonly used strategies in CBT include self-monitoring, goal setting, problem-solving and preplanning, stimulus control, cognitive restructuring, and relapse prevention. Two widely recognized obesity intervention trials, the Diabetes Prevention Program (DPP) and the Look AHEAD trial, provide examples of the use of CBT in assisting with changing eating and activity behaviors.[73,74] In DPP, the lifestyle intervention received a reduced-energy diet and a physical activity prescription within the context of a CBT intervention.[74] In DPP, during the 2.8 mean years of follow-up, the lifestyle intervention lost 5.6 kg of weight, which was significantly greater than the other two conditions (placebo=−0.1 kg; metformin=−2.1 kg).[74] As mentioned previously, Look AHEAD produced significant weight-loss outcomes in the condition that received the CBT intervention, with significant weight loss reported across time, even up to 8 years follow-up (lifestyle intervention with CBT=−4.7%±0.2%; education comparison=−2.1%±0.2% of initial weight).[6] The materials for the CBT intervention for both DPP and Look AHEAD are available and accessible to the public (DPP: https://dppos.bsc.gwu.edu/web/dppos/dpp; Look AHEAD: www.lookaheadtrial.org/public/home.cfm). RDNs played a large role in intervention in Look AHEAD.[75]

Motivational interviewing. Motivational interviewing focuses on the style of interaction between a practitioner and client. Motivational interviewing emphasizes collaboration, evocation, and autonomy.[76] Collaboration guides practitioners to be "supportive partners" rather than "persuasive experts," which contrasts with the prescriptive, expert-driven style commonly used in dietary interventions. Evocation encourages the practitioner to draw out the client's personal motives and values regarding behavior change. Finally, autonomy emphasizes a client's personal choice, in which the responsibility and decisions about behavior changes fall under the client's, rather than practitioner's, control. Motivational interviewing emphasizes that the intervention for obesity would be driven by the client, rather than the practitioner. Using this approach, motivational interviewing is believed to enhance motivation and self-efficacy, which are considered to be key for changing, and sustaining, behavior change.[76] Motivational interviewing has an additional benefit, in that it can be delivered at a low intensity (ie, shorter and less frequent dosages).[77] For example, a review of 10 RCTs examining motivational interviewing and obesity treatment found that participants receiving a median amount of 60 minutes of motivational interviewing in an encounter, with number of encounters ranging from one to five or more, reduced BMI by 0.72 more so than participants only receiving usual care.[77]

Acceptance and commitment therapy. A "third wave" of behavioral therapy has developed, which is based on the use of acceptance-based strategies. These strategies shift the focus from reducing the occurrence of aversive internal thoughts and feelings to being able to experience these thoughts and feelings to assist with promotion of behavior that is congruent with personal values.[78] It is believed that these approaches enhance mindfulness, which can enhance understanding of the personal decision that one makes and reduce mindless behavior.[78] One acceptance-based approach that has recently been examined for improving obesity treatment is Acceptance and Commitment Therapy (ACT). While few RCTs have examined ACT and obesity treatment, ACT appears to produce an amount of weight loss similar to CBT and may produce greater weight loss in those more susceptible to eating cues (eg, have greater food-related thoughts and feelings when exposed to external food cues), disinhibited eating, or emotional eating.[78]

The research on behavior change interventions demonstrates that CBT and motivational interviewing effectively change eating and physical activity behaviors so that meaningful weight loss occurs. However, not all individuals respond to obesity treatment, even when CBT and/or motivational interviewing are implemented; thus, additional strategies, such as ACT, continue to be developed to assist with behavior change in obesity treatment.

EAL Recommendation: "For weight loss and weight maintenance, the RDN should incorporate one or more of the following strategies for behavior change: self-monitoring; motivational interviewing; structured meal plans and meal replacements and portion control; goal setting; and problem solving." **(Rating: Strong, Imperative)**

EAL Recommendation: "For weight loss and weight maintenance, the RDN may consider using the following

behavior therapy strategies: cognitive restructuring; contingency management; relapse prevention techniques; slowing the rate of eating; social support; stress management; and stimulus control and cue reduction." **(Rating: Fair, Imperative)**

Comprehensive Lifestyle Intervention. Obesity treatment incorporating a dietary prescription that results in an energy deficit of at least 500 kcal/day, a physical activity prescription of at least 150 minutes of MVPA per week, and a structured behavior-change intervention is classified as a lifestyle intervention.[1] Combining all three components—diet, physical activity, and behavioral strategies—in intervention produces greater weight loss than an intervention that uses these same components singularly. The lifestyle interventions of DPP and Look AHEAD that produced significant weight loss are examples of a comprehensive lifestyle intervention.[73,74]

EAL Recommendation: "For weight loss and weight maintenance, the RDN should include the following components as part of a comprehensive weight-management program: reduced-calorie diet, increasing physical activity, use of behavioral strategies." **(Rating: Strong, Imperative)**

Intensity of Intervention. According to the 2013 AHA/ACC/TOS Guideline for the Management of Overweight and Obesity in Adults, frequency of contact appears to be an important characteristic of intervention for weight-loss outcomes.[1] Comprehensive, lifestyle intervention, delivered on site, with face-to-face contact, providing an average of one to two treatment sessions per month (eg, 6 to 12 sessions in 6 months), produces about 2 to 4 kg of weight loss in 6 to 12 months, which is significantly greater than usual care (minimal intervention control group).[1] Comprehensive, lifestyle intervention delivered at a high intensity (≥14 sessions in 6 months) produces greater weight loss relative to usual care than the weight loss that occurs with comprehensive, lifestyle intervention delivered at low-to-moderate intensity (eg, intervention delivered in ≤12 session in 6 months) relative to usual care.[1]

EAL Recommendation: "For weight loss, the RDN should prescribe at least 14 MNT encounters (either individual or group) over a period of at least 6 months." **(Rating: Strong, Imperative)**

"For weight maintenance, the RDN should prescribe at least monthly MNT encounters over a period of at least 1 year." **(Rating: Strong, Imperative)**

eHealth in Intervention. Interventions that can be delivered without face-to-face contact with the use of technology are believed to have the capability to decrease intervention costs and increase the reach of the intervention for those who are in need of treatment.[79] The development of efficacious technology-based weight-loss interventions are thought to have the potential for great public health impact.[79]

Computer-based interventions. The first modern technology-based intervention developed for weight loss was computer-based programs, in which various aspects of the Internet were used. These programs include those with an intervention website, which provided many different Internet-based features (posted education materials, tracking systems, discussion boards, chat rooms, e-mails), or more e-mail–based programs in which interventionists interacted with participants via e-mail. A Cochrane Review of computer-based programs for weight loss found that for interventions lasting 6 months, computer-based interventions produced greater weight loss than minimal interventions (−1.5 kg).[79] However, face-to-face interventions produced greater weight loss than computer-based interventions (−2.1 kg).[79] Only one study in the review reported the cost-effectiveness ratio, thus conclusions could not be drawn about this aspect of computer-based programs.[79] In agreement with this, the 2013 AHA/ACC/TOS Guidelines state that comprehensive interventions delivered onsite by a trained interventionist produce larger weight loss than comprehensive interventions delivered by the Internet or e-mail.[1]

Smartphone-based interventions. Unlike computers, smartphones are usually carried by users everywhere they go and are almost always on. These features of use provide the ability for real-time, on-demand interaction. Thus, it is believed that smartphones provide the opportunity for frequent and interactive feedback, tailored messaging (via text or e-mails), and immediate access to social support.[80] Interactive applications, "apps," can assist with decision making on behaviors, as they can provide timely feedback on health behaviors in real time.[80] Smartphones are theorized to have the ability to maintain important components of face-to-face interaction (eg, accountability, feedback, social support) without face-to-face time.[80] As this is a new area of research in weight management, it is not clear at this time how efficacious these programs will be, but it is believed that these types of programs will outperform computer-based interventions.[80]

Supplements. In a 2009 systematic review of the efficacy and safety of herbal medicines used for obesity treatment, Hasani-Ranjbar and colleagues[81] reported on weight change and body composition outcomes in 17 RCTs. Compounds containing ephedra, *Cissus quandrangularis*, ginseng, bitter melon, and zingiber were found to be helpful in significantly reducing body weight (summary data were not included in the review); however, supplements containing ephedra and bofutsushosan (an oriental herbal medicine) were found to have some adverse effects. Food-based supplements, such as caffeine, carnitine, calcium, choline, chromium, lecithin, fucoxanthin, garcinia cambogia, capsaicin (cayenne pepper), green tea extracts, kelp, taurine, conjugated linoleic acid, psyllium, pyruvate, leucine, forskolin, β-sitosterol, and tea, have been labeled "fat burners" and have been proposed to increase weight loss by increasing fat metabolism.[82] However, according to Jeukendrup and Randall, only caffeine and green tea have shown enhanced fat oxidation, but the effect of the increased fat oxidation on weight management is not clear. All other proposed food-based supplements lack sufficient evidence of increased fat metabolism at this time.[82] In 2013, Hasani-Ranjbar and colleagues[83] reported on another 33 RCTs using herbal- and food-based supplements and suggested that the efficacy and safety of these supplements is still mostly unknown and long-term RCTs are needed to enhance our understanding of the role of supplements and obesity treatment.

One helpful resource regarding supplements comes from the National Center for Complementary and Alternative Medicine, which houses a variety of fact sheets on a number of herbal- and food-based supplements (http://nccam.nih.gov/health/atoz.htm).

Commercial Programs. Commercial programs are weight-loss programs that are usually not delivered by a health care provider and can provide various options of types of support for weight loss to consumers. Options can include face-to-face programs, prepackaged food, and Internet-based programs. Little research has been conducted on commercial options for weight loss, but what has been conducted suggests that commercial-based, comprehensive weight-loss interventions delivered in face-to-face formats have produced an average weight loss of 4.8 to 6.6 kg at 6 months when conventional foods are consumed and 6.6 to 10.1 kg at 12 months with use of prepackaged food, and that these weight losses are greater than minimal-treatment control interventions.[1] This suggests that commercial programs that provide comprehensive programs may be a viable option for treatment.

Medications. Comprehensive lifestyle interventions are efficacious at producing weight loss, however, there is large variability in the ability to implement and maintain changes recommended in these interventions. For those that have difficulty losing weight (BMI ≥30 or BMI ≥27 with obesity-related medical issues, such as high blood pressure, high cholesterol, or type 2 diabetes),[84] medications may be helpful for achieving weight loss. There are three medications for obesity treatment approved for long-term use (up to 2 years).[85]

Orlistat. Orlistat is a lipase inhibitor that causes dietary fat to be excreted as oil in the stool and is recommended to be taken with a diet containing 30% fat. The nonprescription dose of orlistat provides approximately 80% of the weight loss seen with the prescription dose. Orlistat is not absorbed to any significant degree and the side effects relate to the fat in the stool, including abdominal cramps, flatus with discharge, oily spotting, and fecal incontinence. Due to the potential loss of fat-soluble vitamins, orlistat should be taken with a vitamin supplement. A meta-analysis concluded that weight loss with orlistat (60 to 120 mg three times/day) was 2.9 kg greater than placebo at 12 months.[86]

Lorcaserin. Lorcaserin is an agonist of the serotonin (5-HT) 2c receptor in the hypothalamus and enhances feelings of satiety. Lorcaserin at a dose of 10 mg twice a day resulted in a 3.3% greater weight loss than placebo.[85] Lorcaserin was well tolerated with side effects in >5% reported as headaches, dizziness, fatigue, nausea, dry mouth, and constipation. Lorcaserin is a Drug Enforcement Administration schedule IV drug, with low potential for abuse.[85]

Phentermine/topiramate. Phentermine, an appetite suppressant, causes a decrease in food intake by stimulating the release of norepinephrine in the hypothalamus. A controlled-released formulation of phentermine/topiramate, a schedule IV drug, is approved for the treatment of obesity. The dosage begins at a low dose for 14 days (3.75 mg phentermine/23 mg topiramate extended-release once a day), transitions to a mid-dose (double the low dose), and then to a high dose (mid-dose twice a day) if weight loss is not achieved after 12 weeks. If 5% weight loss is still not achieved after 12 weeks on the high dose, the medications should be discontinued. Weight loss was 3.5%, 6.2%, and 9.3% greater than placebo in the low, mid, and high doses, respectively.[87,88] Adverse events occurring in >5% of patients include paresthesias, dizziness, dysguesia, insomnia, constipation, and dry mouth. See the section on sleeve gastrectomy for the EAL recommendation for the use of medication.

Surgery. While comprehensive lifestyle interventions are considered the mainstay of all weight-management treatment, for patients who are unable to achieve or maintain weight loss that improves health or for obese patients at high medical risk, adjunctive treatments are needed.[1] Bariatric surgery is an option that is increasingly used in those individuals with extreme obesity, or with those with a lower BMI but with obesity-related comorbid conditions.[1]

Laparoscopic gastric banding. The lap-band does not permanently alter the anatomy of the gastrointestinal tract, but instead places a thin, inflatable band around the top of the stomach to create a new and smaller stomach pouch. This surgery requires extensive follow-up to make sure the band is properly adjusted. Ten-year follow-up of lap-band surgery indicates maximum weight loss was about 20% at 1 to 2 years, with maintenance of 15% weight loss at 10 years.[89] Popularity of the lap-band has decreased in the United States, primarily due to inferior weight loss, complexity of follow-up, a lower remission rate to diabetes, and a greater need for reoperation due to complications.

Gastric bypass. The bypass, long considered the gold standard obesity operation, permanently alters the anatomy of the gastrointestinal tract. In the bypass, a small pouch is created at the top of the stomach and a part of the small intestine, the jejunum, is attached to a small hole in the pouch. Thus, the surgery allows food to bypass part of the stomach and small intestine. The bypass results in a typical weight loss of 35% at 1 to 2 years, which has been shown to be maintained at 30% weight loss at 10 years.[89] The bypass has the highest mortality rate, rate of complications, and the most severe metabolic abnormalities of the three surgeries. With the bypass, there is greater need for protein, iron and vitamin supplementation, and monitoring of calcium and vitamin D levels.[90]

Sleeve gastrectomy. The sleeve, the newest of the three bariatric procedures, permanently alters the anatomy of the stomach because a portion of the stomach is removed, producing a tube-shaped stomach or sleeve, and now has data on more than 5 years of follow-up. The sleeve is gaining in popularity, as it produces similar weight loss and remission of type 2 diabetes (80% of patients with diabetes before surgery are able to control their blood glucose levels 5 years after bariatric surgery)[91] as occurs with the bypass, but at lower cost, with lower rates of complications and mortality.[90,92,93] Metabolic complications with the sleeve are also fewer than with the bypass, however, recommendations still include vitamin

supplementation and monitoring of iron, calcium, and vitamin D levels.

For bariatric surgery, the 2013 AHA/ACC/TOS Guideline states that for individuals who are obese, weight loss at 2 to 3 years after bariatric surgery ranges from 20% to 35% of initial weight, with a greater weight loss of 14% to 37% for bariatric surgery as compared with nonsurgical comparators.[12]

EAL Recommendation: "For weight loss and weight maintenance, the RDN should implement MNT and coordinate care with an interdisciplinary team of health professionals (may include specialized RDNs, nurses, nurse practitioners, pharmacists, physicians, physician assistants, physical therapists, psychologists, social workers, and so on) especially for patients with obesity-related comorbid conditions. Coordination of care may include collaboration on use of US Food and Drug Administration–approved weight-loss medications; and appropriateness of bariatric surgery for people who have not achieved weight-loss goals with less invasive weight loss-methods." **(Rating: Consensus, Imperative)**

Monitoring and Evaluation. To determine effectiveness of any intervention implemented, outcomes need to be monitored over time and evaluated for degree of success achieved. See Figure 1 for suggested areas to monitor and evaluate for effectiveness of a comprehensive weight-management program.

EAL Recommendation: "The RDN should monitor and evaluate the effectiveness of the comprehensive weight-management program for overweight and obese adults, through the following data: food and nutrition-related history; anthropometric measurements; biochemical data, medical tests, and procedures; and nutrition-focused findings." **(Rating: Strong, Imperative)**

If weight loss is not occurring at the expected rate, total energy needs may need to be reassessed.

EAL Recommendation: "For weight loss and weight maintenance, the RDN should monitor and evaluate total energy needs and consider one of the following (if necessary): re-measure RMR using indirect calorimetry; recalculate Mifflin-St. Jeor equation; or reapply a new physical activity factor to RMR to estimate total energy needs." **(Rating: Consensus, Imperative)**

Community-Level Obesity Intervention

Within the socioecological model framework, community-level obesity interventions focus on utilizing and strengthening existing community assets and capacity in changing energy balance behaviors that can produce weight loss. These types of interventions generally focus on increasing capacity for providing and enhancing access to intervention, with community-based organizations and/or interventionists providing the intervention, and/or altering the community environment to assist with promoting energy-balance behaviors helpful for weight management.

One example of a community-level intervention focusing on increasing capacity for providing and increasing access to intervention is the use of YMCAs as a site for delivering intervention. For example, a comprehensive lifestyle intervention modeled after the DPP delivered to community members at high risk for diabetes by YMCA employees produced 6% weight loss at 6 months.[94] A review of faith-based interventions designed for African-American females, which are implemented in faith-based settings in the community and are also designed to increase capacity for providing and access to intervention, also found significant reductions in anthropometric measures across reviewed studies (for studies reporting change in weight, the range of change in weight was −3.6 to −9.8 lb).[95] Another example that increases capacity and access to intervention and that often has a focus on changing the environment is worksite wellness programs. A review of worksite wellness weight-management programs found that those programs that focused on strategies to increase physical activity and change dietary intake were generally successful at assisting with weight maintenance or producing modest weight loss (for studies reporting change in BMI the range of change was −0.14 to −1.4).[96]

For changing the community environment, it is hypothesized that environments with a greater density of fast-food outlets and/or lower density of farmers' markets or other types of markets with fresh produce encourage dietary intakes that are high in energy density and, thus, contribute to excessive energy intake and obesity.[97] In addition, it is proposed that environments with reduced access for physical activity (few greenways, parks, and sidewalks) produce inactivity, which also contributes to obesity.[98] Most of the research in this area is observational, so it is not clear at this time whether changing these environmental factors will reduce the prevalence of obesity.[98] When communities implement these environmental changes to assist with lowering the prevalence of obesity, a "natural experiment" is created, and evaluation is needed to understand how these environmental changes influence weight.

EAL Recommendation: "The RDN should recommend use of community resources, such as local food sources, food assistance programs, support systems, and recreational facilities." **(Rating: Strong, Imperative)**

Policy-Level Obesity Intervention

Policy-level obesity interventions are generally framed as interventions developed at the federal, state, or local government level that implement broad changes that are believed to help change energy-balance behaviors that can produce weight loss. The broad changes are designed to influence everyone for whom the policy has been developed. Two policy-level interventions that are believed to be helpful for reducing the prevalence of obesity include menu labeling and taxing the cost of certain foods. Menu labeling is under Section 4205 of the Patient Protection and Affordable Health Care Act (www.gpo.gov/fdsys/pkg/BILLS-111hr3590enr/pdf/BILLS-111hr3590enr.pdf). Ideally, consumers can use the labeling information on menus to make choices that could assist with reducing intake, provided they are motivated to do so.[99,100] Menu labeling does seem to influence purchasing decisions that cause a reduction in overall energy purchased in some, but not all, consumers in some types of restaurants.[101] For example, women were found to decrease mean amount of energy per purchase at coffee chain restaurants but men did not, and mean amount of energy per purchase did not decrease in burger and sandwich restaurants.[101] More research is needed to

understand what factors influence purchasing decisions in restaurants for menu labeling to have a broader impact.

Another policy-level intervention gaining momentum is creating a tax that can be levied on unhealthy foods (eg, non-nutrient-dense, energy-dense foods) to help reduce their consumption. The tax could also potentially be combined with a plan to subsidize healthier foods, thus potentially increasing consumption of healthy foods. It is not clear at this time how this type of policy would influence eating behavior and obesity, but the little research conducted in this area suggests that small excise taxes are unlikely to affect obesity rates and that while higher excise taxes are likely to reduce obesity in at-risk populations, higher excise taxes are believed to be less politically palatable or sustainable.[102]

RESPONSIBILITIES OF FOOD AND NUTRITION PRACTITIONERS

To address obesity, it is believed that interventions are needed that can incorporate multiple levels of the socioecological model that can be sustained for many years.[103] Thus, interventions for obesity need to address changing individual-level energy balance behaviors; be delivered in many settings to increase accessibility to intervention; influence the environment in which clients live, work, and play; and impact on policy that can assist with providing a context for supporting engagement in energy-balance behaviors within the population to improve weight management.

Understanding the Socioecological Model

Although obesity is a result of a chronic imbalance of energy intake and energy expenditure, it is now recognized that these individual-level behaviors are influenced by determinants at multiple levels, which enhances understanding that individual choices are shaped by the wider context in which they occur.[103] Thus, ecological models—models that incorporate multiple levels or systems—of health promotion are increasingly promoted to address chronic health conditions.[104] For RDNs to be included in the development, implementation, and evaluation of these interventions, an understanding of the SEM is required. Interventions with a SEM approach will target change at one or more levels, either directly or indirectly, through multilevel, multisectoral interventions.[104] For example, an intervention designed to reduce overweight and obesity in adults might be developed in which a state enacts a law targeting worksites to ensure that worksite cafeterias provide nutrition information about available food choices to employees and provides financial incentives to companies to encourage the development of worksite wellness programs; a company with several worksites develops a wellness program that screens employees for health risks, refers employees who are overweight or obese to an on-site RDN, and provides financial incentives to employees to encourage improving improve weight status; and the worksite RDN provides MNT, incorporating employees' individualized needs and preferences, to referred employees and incorporates family members into sessions to assist with changing the home environment and increasing family support. This approach incorporates several levels of the socioecological model, allowing them to intersect, and enhance overall weight-management outcomes. To develop an ecological approach, developing collaborative partnerships among all stakeholders is key[104] and should be encouraged within the field of nutrition.

Addressing Health Disparities

The prevalence of overweight and obesity continues to remain higher in non-Hispanic black adults and Hispanic adults, as compared with non-Hispanic white adults, indicating a health disparity.[2] To address these disparities, a greater understanding of the multilevel factors associated with energy balance is needed. While energy balance is influenced by a multitude of individual-level factors (eg, genetics, biology, individual behavior, and individual-level social determinants), research suggests that contextual aspects of social determinants, particularly those related to environmental factors, are important to address, as pervasive socioeconomic and racial inequalities found within environmental contexts may underlie obesity disparities.[105] This suggests that interventions containing multiple levels of the socioecological model will be more effective at reducing health disparities.

Addressing Weight Bias

Individuals with overweight and obesity can encounter weight bias in health care settings by health professionals.[106] Weight bias is demonstrated when health care professionals have beliefs that those with obesity are lazy, noncompliant to intervention, and lack self-control.[106] Those experiencing weight bias from health care professionals are more likely to avoid health screenings, cancel appointments, demonstrate maladaptive eating behaviors, and experience poorer outcomes when receiving treatment for overweight or obesity.[107,108] Thus, RDNs should ensure that health care experiences for individuals with overweight or obesity are free of weight bias. Ensuring that RDNs understand the complex etiology of obesity, thus that there are contributors to obesity that are outside of personal control, and the difficulties around achieving significant, sustainable weight loss, may increase empathy regarding the challenges of obesity treatment and reduce weight bias.[108]

Scope of Practice

Integrated ecological-based interventions will provide solutions that cover multiple jurisdictions, requiring a wide range of skills.[103] No one profession will be able to provide all skills required for the development, implementation, and evaluation of these interventions to address obesity. Thus, rather than acting independently, RDNs will need to develop relationships with others to be involved in the SEM approach. These relationships will include traditional health care partners, such as physicians, pharmacists, and psychologists, but also nontraditional partners, such as city planners, architects, and legislators. Within these relationships, the role of the RDN is to provide expertise in the area of nutrition, which includes MNT and related areas, community and public health nutrition, foodservice systems, school

nutrition, and sustainable resilient healthy food and water systems.[109]

REIMBURSEMENT FOR OBESITY TREATMENT INVOLVING MNT

Reimbursement for MNT provided by RDNs is essential to the field of dietetics.[110] The Patient Protection and Affordable Health Care Act provides coverage for nutrition services in the area of obesity counseling for adults.[111] However, the role of the RDN in providing nutrition services covered by the Patient Protection and Affordable Health Care Act is open to interpretation by those paying for these services.[110] In addition, the Centers for Medicare & Medicaid Services provides coverage for Intensive Behavioral Counseling for Obesity for eligible Medicare beneficiaries.[112] As with Patient Protection and Affordable Health Care Act, the role of the RDN in Intensive Behavioral Counseling for Obesity is not covered. While RDNs are not specifically designated as the sole providers of MNT under these reimbursement strategies, RDNs can provide services and receive reimbursement. Third-party payers use a standardized numeric coding set, and within this system the MNT codes, which include those for obesity, describe the services of RDN. The diagnostic codes are usually determined by the referring physician, as it is not within the scope of practice for a RDN to make a medical diagnosis.[110] However, the exception to this is in the case of BMI codes, as BMI represents a mathematical calculation based on measurements that are within the RDN's scope of practice to perform.[113] In a recent survey of coding practices of RDNs collected by the Academy, of those RDNs who completed the survey, obesity was the second highest disease or condition from which reimbursement was received from third-party payers.[110] Only diabetes was ranked higher than obesity for receiving reimbursement from third-party players from responding RDNs.[110]

ROLE OF THE RDN AND NUTRITION AND DIETETICS TECHNICIAN, REGISTERED, IN TREATMENT OF OVERWEIGHT AND OBESITY IN ADULTS

Changing dietary intake so that a reduction in energy intake occurs is a key component of obesity treatment.[1] Thus, the expertise of the RDN and nutrition and dietetics technician, registered (NDTR) is essential for the development, implementation, and evaluation of any intervention designed to reduce overweight and obesity.

MNT

The Academy's definition of MNT is broader than other entities.[114] MNT, as defined by the Academy, is an individualized approach to disease management that incorporates the nutrition care process and is provided by an RDN.[114] Thus, when treatment for overweight and obesity is being delivered at the individual level, the role of the RDN, along with the NDTR, is to provide evidence-based intervention that incorporates the nutrition care process.

Multidisciplinary Teams

As stated earlier, interventions for overweight and obesity that incorporate any level of the socioecological model will require an intervention that includes more than just a focus on dietary intake. A multidisciplinary approach to disease treatment, especially in the case of obesity and chronic disease, is recommended.[115] The type of intervention will designate what other disciplines should be involved, and what other training an RDN and NDTR may benefit from.

Medicare and Intensive Behavioral Counseling

The Centers for Medicare & Medicaid Services approved the provision of intensive behavioral counseling for obesity when delivered by qualified primary care and other select practitioners.[112] Intensive behavioral counseling includes a maximum of 22 face-to-face sessions over 12 months, but a weight-loss goal of 3 kg must be met by 6 months in order for counseling sessions to continue to 12 months. Frequency of contact is one face-to-face visit every week for the first month, one face-to-face visit every other week for months 2 to 6, and one face-to-face visit every month for months 7 to 12 if the weight-loss goal has been met. Each visit is to include the five As approach adopted by the US Preventive Services Task Force. The five As are: 1) assess: ask about behavioral health risk(s) and factors affecting choice of behavior change goals or methods; 2) advise: provide specific and personalized behavior change advice; 3) agree: collaboratively select appropriate treatment goals and methods that take into account the client's values and motivation to changes; 4) assist: aid the client in achieving goals by incorporating behavior change techniques, supplemented with adjunctive medical treatments when appropriate; and 5) arrange: schedule follow-up sessions so that ongoing assistant and support can be provided.

While RDNs are not specifically outlined as a practitioner for delivery of intensive behavioral counseling, if an RDN provides care under conditions specified under the regulation, services can be billed by the one of the specified providers. RDNs developing relationships with the specified providers (general practice, family practice, internal medicine, obstetrics/gynecology, pediatric medicine, geriatric medicine, nurse practitioner, certified clinical nurse specialist, and physician assistant) may create avenues for RDNs to provide treatment for obesity that is reimbursed.

Wadden and colleagues[116] conducted a systematic review of behavioral counseling for overweight and obese primary care patients from RCTs published between 1980 and 2014, finding no studies in which primary care practitioners delivered counseling that followed the Centers for Medicare & Medicaid Services guidelines. However, the investigators found that trained interventionists (eg, those trained in lifestyle intervention, which included RDNs) succeeded in producing weight loss within patients from primary care.

Advocacy

To address the obesity epidemic, interventions need to include larger environmental and policy changes, or public health initiatives, that will provide opportunities to support and behaviors that assist with weight management.[117] These types of strategies have shown previous success at addressing public health concerns (eg, reducing smoking, increasing seat belt use).[118] To develop these strategies, advocacy from RDNs and NDTRs is

required. One advocacy effort in the area of obesity that is particularly focused on nutrition is having accessible healthy and affordable foods, which is especially important to address health disparities.[119] To assist RDNs and NDTRs with advocacy, the Academy has developed the Grassroots Manager. The Grassroots Manager assists RDNs with communicating with their legislators, elected officials, and others who may have the ability to influence policy and legislation that can assist with reducing obesity.

Outcome Data

The role of diet in obesity treatment is established. However, the role of food and nutrition practitioners in obesity treatment is not well documented, thus the need to include an RDN and NDTR in planning or implementing obesity treatment is not clear to all stakeholders. RDNs and NDTRs can assist with documenting the importance of their role in obesity treatment by collecting outcomes related to dietary change and health status. Comparison of outcomes can be made between interventions including RDNs and those not, and with the relationship between frequency of contact with RDNs and outcomes. Thus, to support establishing the role of RDNs and NDTRs in obesity treatment, all practitioners are encouraged to collect and examine outcomes data. To help increase capacity in this effort, RDNs and NDTRs are encouraged to develop partnerships with others that may have skills that are needed in documenting the importance of the RDN in obesity treatment.

CONCLUSIONS

The high prevalence of overweight and obesity in the United States negatively affects the health of the population, thus reducing the prevalence of overweight and obesity is considered to be a public health priority.[4] Weight loss of only 3% to 5% that is maintained has the ability to produce clinically relevant health improvement, with larger amounts of weight loss reducing additional risk factors for CVD. Successful treatment of overweight and obesity in adults requires the ability of adopting and maintaining lifestyle behaviors, which contribute to both sides of the energy-balance equation. Lifestyle behaviors are influenced by several factors at differing levels of the socioecological model, which include factors at the intrapersonal, community and organizational, and government and public level.[18] To address obesity, it is proposed that several factors at differing levels need to be targeted to assist with the development and maintenance of behaviors that are necessary for weight loss and successful weight-loss maintenance.[18] The RDN and NDTR, as part of a multidisciplinary team, need to be current and skilled in weight management to effectively assist and lead efforts that can reduce the obesity epidemic. Due to the many factors and levels of the socioecological model that need to be addressed, these teams will include traditional health care partners, but also nontraditional partners. Within these relationships the role of the RDN is to provide expertise in the area of nutrition, which includes MNT and related areas, community and public health nutrition, foodservice systems, school nutrition, and sustainable resilient healthy food and water systems.[109]

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REVIEW

Bariatric Surgery Evolution from the Malabsorptive to the Hormonal Era

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Abstract While bariatric procedures continued to evolve and develop since the 1950s, their classification has not matched this evolution. The procedures are commonly classified into restrictive, malabsorptive, or combined. In this day and age, we recognize different mechanisms of action of the bariatric procedures. This article aims to review and update the old classifications based on our current understanding of the hormonal aspects of the various bariatric procedures and the role of gut hormones in weight loss and treatment of the associated metabolic comorbidities. The article suggests the need for a new classification of the bariatric procedures, based on the mechanism of action, involving the hormonal aspects of the procedure.

Keywords Gut hormones · Ghrelin · GLP-1 · Peptide YY · Gastric bypass · Sleeve gastrectomy · Gastric band

Background

In 1954, Kremen et al. presented the jejunoileal bypass (JIB) that was being performed from the 1950s through the 1970s. Bariatric surgery history reveals that a Swedish surgeon by the name of Dr. Victor Henriksson had performed a similar procedure 2 years earlier where he excised the redundant bowel rather than bypassing it. Evidence of an earlier similar procedure by Dr. Richard Varco exists, however this report was not published and patient records were lost. Overall, the JIB constructed a short common channel and was complicated by electrolyte disturbance, diarrhea, vitamin deficiency, protein–calorie malnutrition, kidney stones, toxic overgrowth of bacteria in the bypassed intestine, and hepatic failure [1–4]. Another form of intestinal bypass was the jejunocolic bypass (JCB) where ten patients were reported by Payne et al. However significant postoperative morbidities as uncontrollable diarrhea, dehydration, and electrolyte disturbance led Payne and Dewind to subsequently advise against this procedure [5].

Bariatric surgery continued to evolve in the hands of the field pioneers such as Dr. Nicola Scopinaro (University of Genoa, Italy), who founded the biliopancreatic diversion (BPD) in the 1970s. The surgery involved performing a gastrectomy and constructing a short common channel. Scopinaro's BPD offered excellent weight loss but carried the disadvantages of stromal ulcers, diarrhea, protein malnutrition, anemia, and vitamin deficiency [6]. Subsequently it was modified to the BPD/duodenal switch (BPD/DS) procedure. The original duodenal switch was performed by Dr. DeMeester to treat bile reflux gastritis. Subsequently, Scopinaro's BPD and DeMeester's DS, combined with a sleeve gastrectomy (SG), were performed by Dr. Hess in the 1980s as BPD/DS; it was published by Marceau et al. in 1993 [7].

In 1967, Dr. Edward E. Mason, from the University of Iowa, created the gastric bypass (GBP). Other restrictive procedures were also performed including different forms of gastroplasty in the 1980s and the gastric band in the 1990s [8]. Interestingly, the classification of the different bariatric procedures generally categorizes the operations as restrictive [adjustable gastric band (AGB), SG, vertical banded gastroplasty (VBG)], malabsorptive (BPD, JIB, JCB), or combined (BPD/DS, GBP).

In this day and age, we recognize different mechanisms of action of the bariatric procedures. This article aims to

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review and update the old classifications based on our current understanding of the hormonal aspects of the various bariatric procedures and the role of gut hormones in weight loss and treatment of the associated metabolic comorbidities. The article suggests the need for a new classification of the bariatric procedures, based on the mechanism of action, involving the hormonal aspects of the procedure.

Methods

An extensive literature review was conducted via the US National Library of Medicine (PubMed) studying the mechanism of weight loss of different bariatric procedures and their effect on the various gut hormones.

Discussion

Gut hormones are mostly secreted from the fundus of the stomach, pancreas, proximal, and distal small intestines. They exert their effect via the hypothalamus (Table 1).

Gastric Fundus

The gastric fundus secretes ghrelin which is a 28-amino acid peptide that is produced from pre-proghrelin. This specifically occurs in the X/A-like cells of the gastric glands and small intestine. Post-translational modification takes place where the third amino acid residue (serine) is covalently linked to octanoate [9]. This acylation is carried out by the enzyme gastric *o*-acyltransferase [10]. Clearance occurs via the enzymes butyrylcholinesterase and lysophospholipase-I [11]. Ghrelin, which is commonly known as the "hunger hormone," increases before meals and decreases quickly after [12]. Ghrelin levels tend to fluctuate according to the individual's eating habits; for example, the routine of missing a specific meal might eliminate the ghrelin spike during that time of the day [13]. Research showed that sleep deprivation increases the ghrelin circulating levels leading to weight gain, therefore maintaining healthy sleeping habits has an important positive effect on weight loss [14]. Ghrelin exerts its effects via the GHS-R1a receptor. The effect of ghrelin in weight gain has been repeatedly demonstrated in the medical literature; a study by Wren et al. showed that intravenous infusion in humans caused a 28 % increase in calorie intake [15]. While this is considered an unfavorable effect in the field of bariatric surgery, ghrelin might have useful applications in cachexia or other malnourishment conditions; for example, Nagaya et al. showed that a 3-week treatment with ghrelin improved muscle wasting and functional capacity in patients with COPD [16]. Obese patients were found to have derangements in ghrelin levels, being usually lower without the usual spikes and do not fall rapidly in response to meal. The lower levels in obese patients might suggest superior sensitivity to ghrelin. The discovery of ghrelin and its role in weight gain has laid the foundation of the concept of "hormonal bariatric surgery" with GBP being one of the superior hormonal procedures with a 72 % reduction in the ghrelin levels. This effect is very noticeable after surgery where patients commonly mention that they "do not feel hungry" for prolonged periods of time. This represents a major role of bariatric surgery in contrast to conventional diet that was found to increase the ghrelin levels and subsequently increases the appetite with an adverse metabolic effect [17].

Recent pharmaceutical research has been aiming at antagonizing ghrelin to achieve an effect similar to the "hormonal bariatric procedures." Blocking ghrelin receptors using GHS-R1a antagonists showed paradoxical effects with increase in oral intake and weight gain [18]. Another product, NOX-B11, was shown to decrease food intake in rats but has not been investigated in humans [19]. A study by Zorilla et al., in 2006, focused on the synthesis of an anti-ghrelin vaccine, which resulted in weight loss in rats [20], but similar effects in human subjects were not demonstrated [21]. Other studies targeted different steps in the ghrelin pathway such as inhibiting gastric *o*-acyltransferase to reduce the circulating acyl ghrelin or lowering ghrelin levels via somatostatin infusion [22].

Table 1 Gut hormones' effect via the hypothalamus

Source	Hormone(s)	Effect
Distal GI (L cells)	Peptide YY GLP-1 Oxyntomodulin	Increased satiety
Pancreas (F cells)	Pancreatic polypeptide Amylin	Increased satiety
Gastric fundus	Ghrelin	Increased hunger
Proximal small intestine (I cells)	Cholecystokinin	Increased satiety

Pancreas

The F cells of the pancreas secrete pancreatic polypeptide (PP) and amylin.

Pancreatic Polypeptide

PP levels increase after food intake, reaching its peak level within 30 minutes and remain elevated for several hours [23]. It exerts its effect via the Y4 receptors, and its degradation mechanism is unknown to date. Some studies demonstrated lower fasting levels in obese individuals [24].

Amylin

Amylin is a polypeptide composed of 37 amino acids; it is released with insulin inhibiting glucagon secretion. This might be of clinical significance in patients with type II diabetes mellitus [25]. The amylin receptor has not been identified. Animal studies demonstrated a favorable effect of amylin administration with decrease in food intake for 1 week [26]. However, in their endeavors to implement amylin as an anti-obesity medication, researchers face the major obstacle of its tendency to form toxic amyloid fibrils. As a result, pharmaceutical research resorted to amylin analogues such as pramlintide that resulted in 12.7 % weight loss over 24 weeks. Another analogue, davalintide, is currently being investigated for the possibility of weekly injections [27].

Proximal Small Intestine

The I cells of the proximal small intestine secrete cholecystokinin (CCK). CCK secretion is stimulated by food intake reaching its peak level in 25 minutes. It remains elevated for approximately 3 hours before inactivation by the enzyme tripeptidyl peptidase II. The importance of CCK as an anti-obesity agent has not been established [28].

Distal Small Intestine

The L cells of the distal small intestine secrete peptide YY (PYY), oxyntomodulin, and glucagon-like peptide 1 (GLP-1).

Peptide YY

PYY is a 36-amino acid polypeptide. The major circulating form, PYY3-36, removes the tyrosine and proline residues by the enzyme dipeptidyl peptidase IV (DPP-IV) [29]. The PYY3-36 degradation mechanism is still unknown [30]. Food intake and exercise stimulate the release of PYY that peaks within 2 hours, exerting its effect via the Y2 receptors in the central nervous system and remains elevated for several hours [31]. A pharmaceutical trial aimed at administering PYY as an anti-obesity agent such as PYY3-36 nasal spray; however, the trial was terminated in 2008 secondary to unsatisfactory weight loss [32]. Human trials of obinepitide (PYY3-36 and PP analogue) showed decrease in food intake for 9 hours when given subcutaneously once a day [33].

Oxyntomodulin

This polypeptide consists of 37 amino acids, 29 of which mimic the structure of glucagon [34]. Oxyntomodulin release is stimulated by food intake, peaks within 30 minutes, and remains elevated for several hours. Clearance occurs via the same degradation mechanism of PYY, which is the enzyme DPP-IV. Oxyntomodulin exerts its effect via acting on GLP-1 receptor [35]. In 2008, a pharmaceutical trial by Thiakis Ltd. (London, UK) implemented oxyntomodulin analogue (TKS1225) as a weight loss agent. No results have been released to the date of writing this manuscript.

Glucagon-Like Peptide 1

The active major circulating forms of this polypeptide are GLP-17-37 and GLP-17-36 that are produced from cleavage at the N-terminus of the GLP-1 polypeptide [36]. Secondary to the relatively similar polypeptide structure of oxyntomodulin and GLP-1, there is some resemblance in their metabolic pathways. Not only that GLP-1 is stimulated by food intake and peaks within 30 min, but also, similar to oxyntomodulin, degradation occurs via DPP-IV which paradoxically increases the anorectic effect of PYY [37].

GLP-1 analogues have tremendous pharmaceutical applications especially in the treatment of diabetes mellitus. Byetta (Amylin Pharmaceuticals, San Diego, CA) is currently used as an oral hypoglycemic. It is presently being investigated as an anti-obesity medication. Another compound, Victoza (Novo

Table 2 Advantages of hormonal bariatric procedures

	Secreted from	Acts on	Effect on satiety	Roux-Y gastric bypass	DS/BPD	Sleeve gastrectomy	Adjustable gastric band
Ghrelin	Fundus	V, BS, HT	↓	↓	↓	↓	↑
GLP-1	L cells	V, BS, HT	↑	↑	↑	↑	No Δ
GIP	K cells	β-cells	?	↓ or no Δ	↓ or no Δ	↑	No Δ
PYY	L cells	V, BS, HT	↑	↑	↑	↑	No Δ
Pancreatic polypeptide	F cells	V, BS	↑	↑	↑	↑	?
Amylin	B cells	BS, HT	↑	↓	?	↑	No Δ
CCK	I cells	V, BS, HT	↑	No Δ	?	↑	?
Oxyntomodulin	L cells	HT	↑	↑	?	?	?

V vagus, *BS* brain stem, *HT* hypothalamus

Nordisk, Denmark), showed significant glycemic control and weight loss in human trials. Januvia (Merck and Co., Whitehouse Station, NJ) inhibits the degradation enzyme DPP-IV. While glycemic control was successful, the weight loss results of Januvia were not consistent [38].

Hormonal Bariatric Surgery

While extensive efforts are being exerted by different pharmaceutical companies to alter the levels of the gut hormones aiming to achieve successful and durable weight loss, hormonal bariatric procedures have already offered the patients this excellent advantage (Table 2). Multiple studies emphasized the effect of bariatric surgery at the hormonal level.

A prospective cross-sectional study from the UK, by Pournaras et al., investigated the effect of GBP on the gut hormones in 34 patients. The study showed that there was higher postprandial PYY response and Increased GLP-1 response (P=0.189). The effect was sustained over 2 years [39].

Another European study by Kotidis et al. measured the fasting ghrelin, leptin, and adiponectin levels in 13 patients who underwent BPD/DS and achieved a successful weight loss. The levels were measured before the surgery and 18 months postoperatively. The authors demonstrated decrease in circulating ghrelin level from 1.44±0.77 to 0.99±0.35 ng/ml (P=0.019). There was decrease in leptin level from 1.81±0.38 to 1.65±0.32 ng/ml (P=0.196) and rise in adiponectin level from 37.85±11.24 to 39.84±16.27 μg/ml (P=0.422). The authors concluded that the effect on ghrelin was secondary to the sleeve gastrectomy part of the procedure [40].

Another study from the University of Minnesota was published in 2010 where Beckman et al. conducted an extensive literature review including 45 published articles aiming at analyzing the changes in the gut hormones after GBP. The authors concluded that GBP leads to increase in the levels of GLP-1 and PYY while ghrelin levels decrease [41].

Evolving evidence in the medical literature demonstrates the role of the SG as a hormonal bariatric procedure. A study published in 2010 by Bohdjalian et al. included 26 patients that were followed for 5 years. The authors found that ghrelin levels decreased from 593±52 to 219±23 pg/ml 1 year after the surgery. The study also found a slight increase of ghrelin to 257±23 pg/ml at 5 years compared to the first postoperative year; however, this was insignificant [42].

A recent prospective study by Tzovaras et al. considered that SG should not be considered as a pure restrictive procedure. The study included 31 patients with median age of 38 years and median BMI of 45.6 kg/m^2. Oral glucose challenge was used to provoke dumping syndrome before the surgery then 6 weeks after. While none of the patients had preoperative dumping symptoms, 29 % developed distinct dumping symptoms and 16 % developed symptoms suggestive of dumping syndrome postoperatively [43].

More evidence continues to appear in the medical literature demonstrating the hormonal effects of bariatric surgeries. A study published by Lee et al. in 2011 compared the effect of GBP and SG on gut hormones. This prospective study included 16 patients in each arm and measured various gut hormones 2 years after the surgery in 13 patients from each arm. The authors concluded that both procedures exerted positive varying hormonal effects on the hindgut [44].

Conclusion

While it is a common understanding that bariatric procedures execute their effects via restriction and/or malabsorption, there is considerable evidence in the medical literature demonstrating the hormonal impact of those procedures through their effect on the gut hormones. The hormonal mechanism of action should be included in classifying the various bariatric procedures in addition to the well-known restrictive and malabsorption means. A proposed new classification would include the AGB in the restrictive group as, to date, there are conflicting data about the hormonal aspects of this procedure. The SG has traditionally been classified as a restrictive operation, but its hormonal impact has been established which would categorize it as a restrictive/hormonal rather than purely restrictive procedure. As for the GBP, differentiation between proximal and distal variations should be recognized, because while a distal GBP creates a short common channel and induces malabsorption, this is not entirely true for a proximal GBP that generally bypasses the duodenum and 1 or 2 ft of the proximal jejunum constructing a long common channel. It seems to be more appropriate to place the proximal GBP in the same category of the SG procedure (i.e., restrictive/hormonal). As for the distal GBP, it has a significant malabsorptive component resembling the BPD/DS, giving both procedures a triple mechanism of action including restrictive, hormonal, and malabsorptive in the proposed classification.

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Pharmacological Management of Obesity: An Endocrine Society Clinical Practice Guideline

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Objective: To formulate clinical practice guidelines for the pharmacological management of obesity.

Participants: An Endocrine Society-appointed Task Force of experts, a methodologist, and a medical writer. This guideline was co-sponsored by the European Society of Endocrinology and The Obesity Society.

Evidence: This evidence-based guideline was developed using the Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) system to describe the strength of recommendations and the quality of evidence.

Consensus Process: One group meeting, several conference calls, and e-mail communications enabled consensus. Committees and members of the Endocrine Society, the European Society of Endocrinology, and The Obesity Society reviewed and commented on preliminary drafts of these guidelines. Two systematic reviews were conducted to summarize some of the supporting evidence.

Conclusions: Weight loss is a pathway to health improvement for patients with obesity-associated risk factors and comorbidities. Medications approved for chronic weight management can be useful adjuncts to lifestyle change for patients who have been unsuccessful with diet and exercise alone. Many medications commonly prescribed for diabetes, depression, and other chronic diseases have weight effects, either to promote weight gain or produce weight loss. Knowledgeable prescribing of medications, choosing whenever possible those with favorable weight profiles, can aid in the prevention and management of obesity and thus improve health. **(*J Clin Endocrinol Metab* 100: 342–362, 2015)**

Summary of Recommendations

1.0 Care of the patient who is overweight or obese

1.1 We recommend that diet, exercise, and behavioral modification be included in all obesity management approaches for body mass index (BMI) ≥ 25 kg/m^2 and that other tools such as pharmacotherapy (BMI ≥ 27 kg/m^2 with comorbidity or BMI over 30 kg/m^2) and bariatric surgery (BMI ≥ 35 kg/m^2 with comorbidity or BMI over 40 kg/m^2) be used as adjuncts to behavioral modification

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Abbreviations: ACE, angiotensin-converting enzyme; AED, antiepileptic drug; ARB, angiotensin receptor blocker; BID, twice a day; BMI, body mass index; BP, blood pressure; CCK, cholecystokinin; CI, confidence interval; DPP-4, dipeptidyl peptidase IV; ER, extended release; GLP-1, glucagon-like peptide-1; H1, histamine; HbA1c, glycated hemoglobin; POMC, proopiomelanocortin; PYY, peptide YY; QD, every day; RCT, randomized controlled trial; SC, subcutaneous; SGLT, sodium-glucose-linked transporter; SNRI, serotonin-norepinephrine reuptake inhibitor; SSRI, selective serotonin reuptake inhibitor; T2DM, type 2 diabetes; TID, three times a day.

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to reduce food intake and increase physical activity when this is possible. Drugs may amplify adherence to behavior change and may improve physical functioning such that increased physical activity is easier in those who cannot exercise initially. Patients who have a history of being unable to successfully lose and maintain weight and who meet label indications are candidates for weight loss medications. (1|⊕⊕⊕⊕)

1.2 In order to promote long-term weight maintenance, we suggest the use of approved[1] weight loss medication (over no pharmacological therapy) to ameliorate comorbidities and amplify adherence to behavior changes, which may improve physical functioning and allow for greater physical activity in individuals with a BMI $\geq$ 30 kg/m^2 or in individuals with a BMI of $\geq$ 27 kg/m^2 and at least one associated comorbid medical condition such as hypertension, dyslipidemia, type 2 diabetes (T2DM), and obstructive sleep apnea. (2|⊕⊕◯◯)

1.3 In patients with uncontrolled hypertension or a history of heart disease, we recommend against using the sympathomimetic agents phentermine and diethylpropion. (1|⊕⊕⊕◯)

1.4 We suggest assessment of efficacy and safety at least monthly for the first 3 months, then at least every 3 months in all patients prescribed weight loss medications. (2|⊕⊕◯◯)

1.5 If a patient's response to a weight loss medication is deemed effective (weight loss $\geq$ 5% of body weight at 3 mo) and safe, we recommend that the medication be continued. If deemed ineffective (weight loss $<$ 5% at 3 mo) or if there are safety or tolerability issues at any time, we recommend that the medication be discontinued and alternative medications or referral for alternative treatment approaches be considered. (1|⊕⊕⊕⊕)

1.6 If medication for chronic obesity management is prescribed as adjunctive therapy to comprehensive lifestyle intervention, we suggest initiating therapy with dose escalation based on efficacy and tolerability to the recommended dose and not exceeding the upper approved dose boundaries. (2|⊕⊕◯◯)

1.7 In patients with T2DM who are overweight or obese, we suggest the use of antidiabetic medications that have additional actions to promote weight loss (such as glucagon-like peptide-1 [GLP-1] analogs or sodium-glucose-linked transporter-2 [SGLT-2] inhibitors), in addition to the first-line agent for T2DM and obesity, metformin. (2|⊕⊕⊕◯)

1.8 In patients with cardiovascular disease who seek pharmacological treatment for weight loss, we suggest using medications that are not sympathomimetics such as lorcaserin and/or orlistat. (2|⊕◯◯◯)

2.0 Drugs that cause weight gain and some alternatives

2.1 We recommend weight-losing and weight-neutral medications as first- and second-line agents in the management of a patient with T2DM who is overweight or obese. Clinicians should discuss possible weight effects of glucose-lowering medications with patients and consider the use of antihyperglycemic medications that are weight neutral or promote weight loss. (1|⊕⊕⊕◯)

2.2 In obese patients with T2DM requiring insulin therapy, we suggest adding at least one of the following: metformin, pramlintide, or GLP-1 agonists to mitigate associated weight gain due to insulin. The first-line insulin for this type of patient should be basal insulin. This is preferable to using either insulin alone or insulin with sulfonylurea. We also suggest that the insulin therapy strategy be considered a preferential trial of basal insulin prior to premixed insulins or combination insulin therapy. (2|⊕⊕⊕◯)

2.3 We recommend angiotensin-converting enzyme (ACE) inhibitors, angiotensin receptor blockers (ARBs), and calcium channel blockers rather than β-adrenergic blockers as first-line therapy for hypertension in patients with T2DM who are obese. (1|⊕⊕⊕⊕)

2.4 When antidepressant therapy is indicated, we recommend a shared decision-making process that provides patients with quantitative estimates of the expected weight effect of the antidepressant to make an informed decision about drug choice. Other factors that need to be taken into consideration include the expected length of treatment. (1|⊕⊕⊕◯)

2.5 We recommend using weight-neutral antipsychotic alternatives when clinically indicated, rather than those that cause weight gain, and the use of a shared decision-making process that provides patients with quantitative estimates of the expected weight effect of the alternative treatments to make an informed decision about drug choice. (1|⊕⊕⊕◯)

2.6 We recommend considering weight gain potential in choosing an antiepileptic drug (AED) for any given patient, and the use of a shared decision-making process that provides patients with quantitative estimates of the expected weight effect of the drugs to make an informed decision about drug choice. (1|⊕⊕⊕◯)

2.7 In women with a BMI $>$ 27 kg/m^2 with comorbidities or BMI $>$ 30 kg/m^2 seeking contraception, we suggest oral contraceptives over injectable medications due to

[1] Approval in the United States is based on FDA determination. Approval in Europe is based on EMA determination.

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weight gain with injectables, provided that women are well-informed about the risks and benefits (ie, oral contraceptives are not contraindicated). (2|⊕◯◯◯)

2.8 We suggest monitoring the weight and waist circumference of patients on antiretroviral therapy due to unavoidable weight gain, weight redistribution, and associated cardiovascular risk. (2|⊕⊕⊕◯)

2.9 We suggest the use of nonsteroidal anti-inflammatory drugs and disease-modifying antirheumatic drugs when possible in patients with chronic inflammatory disease like rheumatoid arthritis because corticosteroids commonly produce weight gain. (2|⊕⊕⊕◯)

2.10 We suggest the use of antihistamines with less central nervous system activity (less sedation) to limit weight gain. (2|⊕⊕◯◯)

3.0 Off-label use of drugs approved for other indications for chronic obesity management

3.1 We suggest against the off-label use of medications approved for other disease states for the sole purpose of producing weight loss. A trial of such therapy can be attempted in the context of research and by healthcare providers with expertise in weight management dealing with a well-informed patient. (Ungraded Best Practice Recommendation)

Method of Development of Evidence-Based Clinical Practice Guidelines

The Clinical Guidelines Subcommittee (CGS) of the Endocrine Society deemed the pharmacological management of obesity a priority area in need of practice guidelines and appointed a Task Force to formulate evidence-based recommendations. The Task Force followed the approach recommended by the Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) group, an international group with expertise in the development and implementation of evidence-based guidelines (1). A detailed description of the grading scheme has been published elsewhere (2). The Task Force used the best available research evidence to develop the recommendations. The Task Force also used consistent language and graphical descriptions of both the strength of a recommendation and the quality of evidence. In terms of the strength of the recommendation, strong recommendations use the phrase "we recommend" and the number 1, and weak recommendations use the phrase "we suggest" and the number 2. Cross-filled circles indicate the quality of the evidence, such that ⊕◯◯◯ denotes very low quality evidence; ⊕⊕◯◯, low quality; ⊕⊕⊕◯, moderate quality; and ⊕⊕⊕⊕, high quality. The Task Force has confidence that persons who receive care according to the strong recommendations will derive, on average, more good than harm. Weak recommendations require more careful consideration of the person's circumstances, values, and preferences to determine the best course of action. Linked to each *recommendation* is a description of the *evidence* and the *values* that panelists considered in making the recommendation; in some instances, there are *remarks,* a section in which panelists offer technical suggestions for testing conditions, dosing, and monitoring. These technical comments reflect the best available evidence applied to a typical person being treated. Often this evidence comes from the unsystematic observations of the panelists and their values and preferences; therefore, these remarks should be considered suggestions.

The Endocrine Society maintains a rigorous conflict-of-interest review process for the development of clinical practice guidelines. All Task Force members must declare any potential conflicts of interest, which are reviewed before they are approved to serve on the Task Force and periodically during the development of the guideline. The conflict-of-interest forms are vetted by the CGS before the members are approved by the Society's Council to participate on the guideline Task Force. Participants in the guideline development must include a majority of individuals without conflicts of interest in the matter under study. Participants with conflicts of interest may participate in the development of the guideline, but they must have disclosed all conflicts. The CGS and the Task Force have reviewed all disclosures for this guideline and resolved or managed all identified conflicts of interest.

Conflicts of interest are defined as remuneration in any amount from the commercial interest(s) in the form of grants; research support; consulting fees; salary; ownership interest (eg, stocks, stock options, or ownership interest excluding diversified mutual funds); honoraria or other payments for participation in speakers' bureaus, advisory boards, or boards of directors; or other financial benefits. Completed forms are available through the Endocrine Society office.

Funding for this guideline was derived solely from the Endocrine Society, and thus the Task Force received no funding or remuneration from commercial or other entities.

A systematic review was commissioned by the Endocrine Society to quantify weight gain and weight loss associated with a discrete list of drugs chosen a priori by this guideline Task Force (3). The systematic review compared a list of 54 commonly used drugs chosen a priori by the Task Force (drugs suspected of having weight implications) that were compared to placebo in randomized controlled trials. For trials to be included, the length of treatment had to be ≥ 30 days. The outcome of interest for the review was weight change (expressed in absolute and rel-

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ative terms). The Task Force also used evidence derived from existing systematic reviews, randomized trials, and observational studies on the management of medications for other conditions that may result in weight gain. Economic analyses and cost effectiveness studies were not reviewed or considered as a basis for the recommendations. Drugs associated with weight gain and suggested alternatives are presented in Supplemental Table 1.

In several of the recommendations, we used evidence derived from randomized clinical trials about the benefits of shared decision making in terms of improving patients' knowledge, reducing decisional conflict and regret, and enhancing the likelihood of patients making decisions consistent with their own values (4). Although there is abundant evidence for the value of shared decision making across several clinical scenarios, specific evidence for obesity management is scant. This highlights a limitation of the existing literature and poses a challenge for implementing a specific strategy for shared decision making in managing obesity.

Medical management of the disease of obesity

The Task Force agrees with the opinion of prominent medical societies that current scientific evidence supports the view that obesity is a disease (5).

Weight loss produces many benefits including risk factor improvement, prevention of disease, and improvements in feeling and function. Greater weight loss produces greater benefits, but modest (5 to 10%) weight loss, such as that produced by lifestyle modifications and medications, has been shown to produce significant improvements in many conditions (5, 6).

Medications used for the management of conditions other than obesity can contribute to or exacerbate weight gain in susceptible individuals. Many of these conditions are also associated with obesity. Healthcare providers can help patients prevent or attenuate weight gain by appropriately prescribing medications that would promote weight loss or minimize weight gain when treating these conditions. Healthcare providers can help selected patients successfully lose weight by appropriately prescribing weight loss medications or in some cases surgical intervention as an adjunct to lifestyle change.

This guideline will target how providers can use medications as an adjunct to lifestyle change therapy to promote weight loss and maintenance. It will also address how prescribers can prevent or attenuate weight gain when prescribing for diabetes, depression, and chronic diseases often associated with obesity. The evidence review addresses medications with a weight loss indication, as well as those medications that affect weight when prescribed for a nonobesity indication, ie, that have been associated with significant weight gain and increase in risk of comorbidities or with weight loss.

Clinical encounter with the patient who is overweight or obese

There are a number of steps a clinician should take in the clinical encounter.

- Annual and symptom-based screening for major chronic conditions associated with obesity in all adult patients with a BMI of 30 kg/m^2 or above. These include T2DM, cardiovascular disease, hypertension, hyperlipidemia, obstructive sleep apnea, nonalcoholic fatty liver disease, osteoarthritis, and major depression.
- Timely adherence to national cancer screening guidelines with the understanding that individuals who are obese are at increased risk for many malignancies (7).
- Identification of contributing factors, including family history, sleep disorders, disordered eating, genetics, and environmental or socioeconomic causes.
- Identification of and appropriate screening for secondary causes of obesity (Table 1). These need not be automatically screened for unless the history and/or physical examination suggests the diagnosis or suspicion of the diagnosis.
- Adherence to the AHA/ACC/TOS Guideline for the Management of Overweight and Obesity in Adults (8), which was updated in 2013 and includes recommendations for assessment and treatment with diet and exercise, as well as bariatric surgery for appropriate candidates.
- Identification of medications that contribute to weight gain. Prescribe drugs that are weight neutral or that promote weight loss when possible.
- Formulation of a treatment plan based on diet, exercise, and behavior modifications as above.

Rationale for pharmacological treatment of obesity

The challenge of weight reduction

If permanent weight loss could be achieved exclusively with behavioral reductions in food intake and increases in energy expenditure, medications for obesity would not be needed. Weight loss is difficult for most patients, and the patient's desire to restrict food and energy intake is counteracted by adaptive biological responses to weight loss (9–12). The fall in energy expenditure (out of proportion to reduction in body mass) and increase in appetite that are observed after weight loss are associated with changes in a range of hormones (12–14). Some of these changes represent adaptive responses to weight loss and result in al-

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Table 1. Causes of Obesity

Primary Causes
Genetic causes
Monogenic disorders
Melanocortin-4 receptor mutation
Leptin deficiency
POMC deficiency
Syndromes
Prader-Willi
Bardet-Biedl
Cohen
Alström
Froehlich
Secondary Causes
Neurological
Brain injury
Brain tumor
Consequences of cranial irradiation
Hypothalamic obesity
Endocrine
Hypothyroidism[a]
Cushing syndrome
GH deficiency
Pseudohypoparathyroidism
Psychological
Depression[b]
Eating disorders
Drug-Induced
Tricyclic antidepressants
Oral contraceptives
Antipsychotics
Anticonvulsants
Glucocorticoids
Sulfonylureas
Glitazones
β blockers

[a] Controversial whether hypothyroidism causes obesity or exacerbates obesity.

[b] Depression associated with overeating or binging.

tered physiology that promotes weight regain. Other changes reflect improvements in dysfunctional hormonal systems that occur as a patient moves from being obese to being closer to a healthy weight. These latter changes underlie many of the health benefits of weight loss.

No approved weight loss medication appears to promote long-term thermogenesis. These medications promote weight loss through effects on appetite, increasing satiety, and decreasing hunger, perhaps by aiding in resisting food cues or by reducing caloric absorption (14).

As discussed above, weight loss is usually associated with a reduction in total energy expenditure that is out of proportion to changes in lean body mass; the primary determinant of resting energy expenditure appears to persist indefinitely as long as the reduced weight is maintained. Clinically, this means that the individual must reduce energy intake or increase energy expenditure indefinitely to sustain weight loss.

Neuroendocrine dysregulation of energy intake and energy expenditure in obesity

Signals to appetite and controlling centers within the central nervous system and in particular the hypothalamus and the brainstem come from the gut, adipose tissue, liver, and pancreas (Figure 1). Distention of the gastrointestinal tract is communicated to the brain. In the process of food intake, gut hormones are secreted that signal satiety in the hindgut primarily; these include most notably peptide YY (PYY; secreted in ileum and colon) and cholecystokinin (CCK; in duodenum), but also gastric inhibitory polypeptide (K cells in duodenum and jejunum) and GLP-1 (L cells in ileum), which are primarily secreted in response to glucose and promote insulin release from the pancreas as well as satiety. Ghrelin is produced in the stomach, and it is unique among gut hormones in that it is orexigenic and levels increase with time since the last meal. These hormones signal areas in the hindbrain and arcuate nucleus, as do insulin and leptin. Leptin is secreted from adipose tissue, and circulating levels are proportional to fat mass. It is an anorectic hormone, which exerts its effects by inhibiting neuropeptide Y/Agouti-related peptide neurons and activating pro-opiomelanocortin (POMC)/cocaine amphetamine-related transcript neurons in the arcuate nucleus, resulting in decreased food intake and increased energy expenditure, although the increase in energy expenditure has been disputed in leptin-deficient humans treated with leptin (15).

Obesity in humans is almost universally associated with high leptin levels and failure to respond to exogenous leptin; thus, leptin analogs have not been found to be useful so far in the treatment of obesity. In humans, many other cues such as reward and emotional factors play a role in food intake aside from hunger, and another pathway is responsible for reward-associated feeding behavior. Increased hunger and decreased satiety after weight loss are associated with an increase in the 24-hour profile of circulating levels of the orexigenic hormone ghrelin and reductions in the levels of the anorexigenic hormones PYY, CCK, leptin, and insulin. These changes in appetite-related hormones appear to persist for at least 1 year after weight reduction and may remain altered indefinitely in a manner that promotes increased energy intake and ultimately weight regain (14, 16–23)

Mechanisms of action of pharmacological agents

With the exception of orlistat, medications indicated for obesity target appetite mechanisms. The medications available for obesity treatment work primarily in the arcuate nucleus to stimulate the POMC neurons, which promote satiety. Some of the medications discussed in Section 1.0 are serotoninergic, dopaminergic, or norepinephrine-

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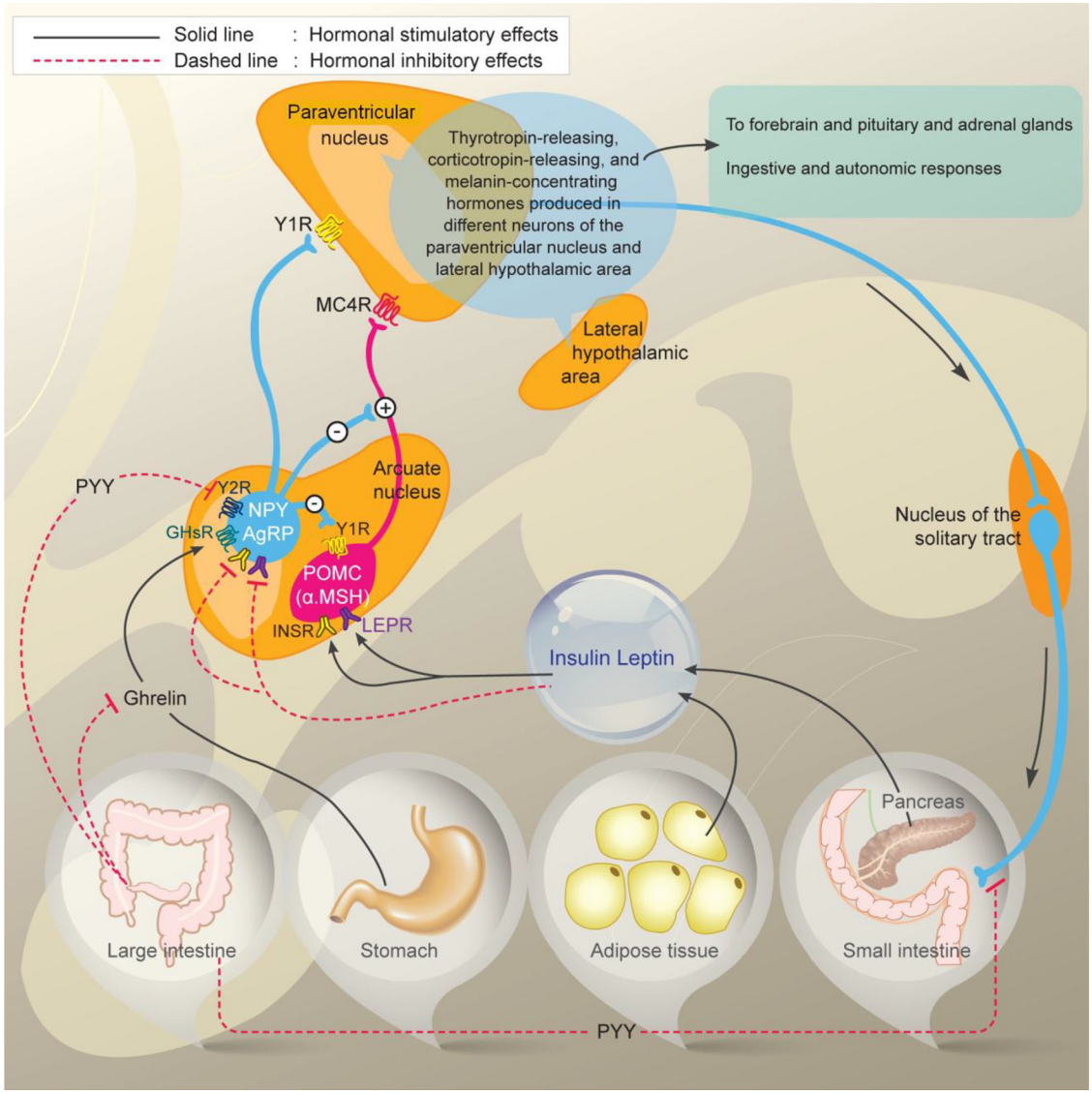

Figure 1. Interactions among hormonal and neural pathways that regulate food intake and body-fat mass. α-MSH, α-melanocyte-stimulating hormone; GHsR, GH secretagogue receptor; INSR, insulin receptor; LEPR, leptin receptor; MC4R, melanocortin receptor type 4; Y1R, Y1 receptor; Y2R, Y2 receptor. [Adapted from J. Korner and R. L. Leibel: To eat or not to eat - how the gut talks to the brain. *N Engl J Med*. 2003;349:926–928 (24), with permission. © Massachusetts Medical Society.]

releasing agents/reuptake inhibitors (Figure 2) (24). Phentermine is primarily a noradrenergic and possibly dopaminergic sympathomimetic amine. Lorcaserin is a serotonin agent specifically stimulating the serotonin type 2c receptor (25). The combination of phentermine and topiramate, which is a neurostabilizer and antiseizure medication, seems to be additive (26); however, it is unclear how topiramate enhances appetite suppression. Bupropion is a dopamine and norepinephrine reuptake inhibitor (27), which stimulates POMC neurons. In combination with naltrexone, buproprion enhances efficacy due to the release of feedback inhibition of POMC neurons that naltrexone potentiates. GLP-1 agonists also affect the POMC neurons and cause satiety (18). Orlistat blocks absorption of 25 to 30% of fat calories and is not appreciably absorbed systemically (28, 29). Another class of medications is associated with weight loss without an effect on appetite. This class is the SGLT-2 inhibitors for T2DM, which promote weight loss by preventing the reabsorption of glucose as well as water in the renal tubules (30).

1.0 Care of the patient who is overweight or obese

1.1 We recommend that diet, exercise, and behavioral modification be included in all overweight and obesity management approaches for BMI $\geq$ 25 kg/m^2 and that other tools such as pharmacotherapy (BMI $\geq$ 27 kg/m^2 with comorbidity or BMI over 30 kg/m^2) and bariatric surgery (BMI $\geq$ 35 kg/m^2 with comorbidity or BMI over

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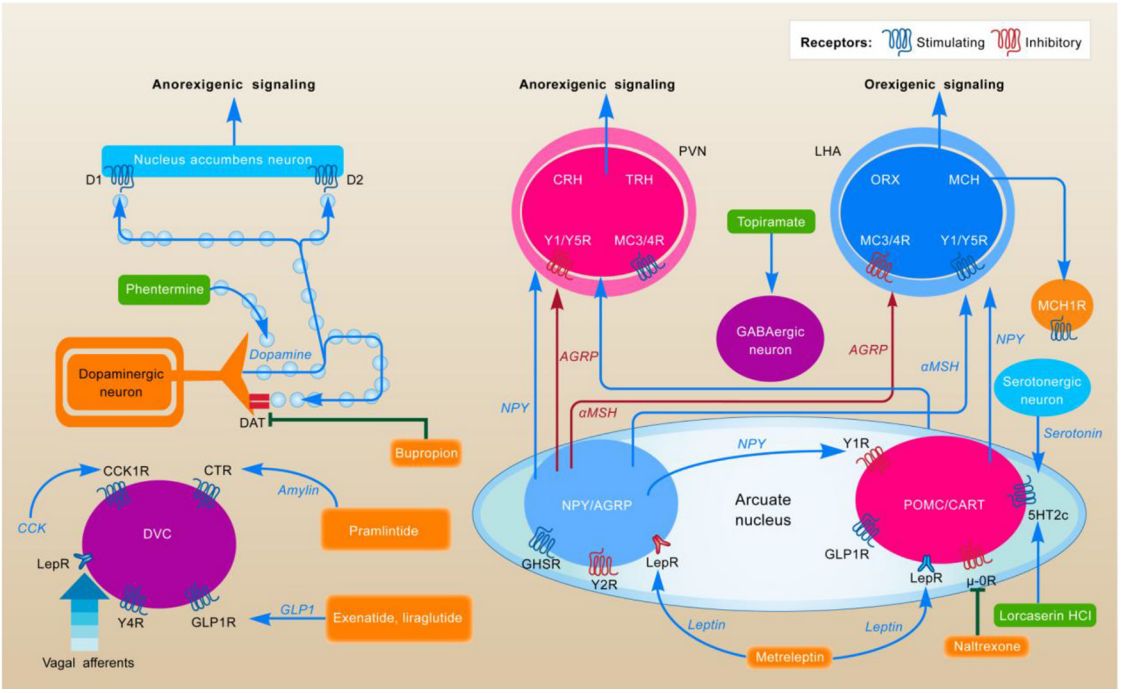

Figure 2. Antiobesity agents and their mechanism of action. AGRP, Agouti-related peptide; CART, cocaine amphetamine-related transcript; CCK1R, CCK1 receptor; GLP1R, GLP-1 receptor; CTR, calcitonin receptor; D1, dopamine 1 receptor; D2, dopamine 2 receptor; DAT, dopamine active transporter; DVC, dorsal vagal complex; GHSR, GH secretagogue receptor; LepR, leptin receptor; MC3/4R, melanocortin receptor type 3/4; MCH1R, melanin-concentrating hormone 1 receptor; NPY, neuropeptide Y; PVN, paraventricular nucleus; Y1/Y5R, Y1/Y5 receptor; Y2R, Y2 receptor; Y4R, Y4 receptor; αMSH, α melanocyte-stimulating hormone; μ-OR, μ-opioid receptor. [Adapted from G. W. Kim et al: Antiobesity pharmacotherapy: new drugs and emerging targets. *Clin Pharmacol Ther*. 2014;95:53–66 (25), with permission. © American Society for Clinical Pharmacology and Therapeutics.

40 kg/m^2) be used as adjuncts to behavioral modification to reduce food intake and increase physical activity when this is possible. Drugs may amplify adherence to behavior change and may improve physical functioning such that increased physical activity is easier in those who cannot exercise initially. Patients who have a history of being unable to successfully lose and maintain weight and who meet label indications are candidates for weight loss medications. (1|⊕⊕⊕⊕) (Table 2 and Supplemental Table 1)

Evidence and relevant values

Weight loss medications reinforce behavioral strategies to create negative energy balance. Most weight loss medications affect appetite and, as a result, promote adherence

Table 2. Advantages and Disadvantages Associated with Weight Loss Medications

Drug	Advantages	Disadvantages
Phentermine	Inexpensive ($) Greater weight loss[a]	Side effect profile No long-term data[b]
Topiramate/phentermine	Robust weight loss[a] Long-term data[b]	Expensive ($$$) Teratogen
Lorcaserin	Side effect profile Long-term data[b]	Expensive ($$$)
Orlistat, prescription	Nonsystemic Long term data[b]	Less weight loss[a] Side effect profile
Orlistat, over-the-counter	Inexpensive ($)	Less weight loss[a] Side effect profile
Natrexone/bupropion	Greater weight loss[a] Food addiction Long-term data[b]	Side effect profile Mid-level price range ($$)
Liraglutide	Side effect profile Long-term data[b]	Expensive ($$$) Injectable

[a] Less weight loss = 2–3%; greater weight loss = >3–5%; robust weight loss = >5%.

[b] Long term is 1–2 years.

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Table 3. Comorbid Conditions in Obesity and Evidence for Amelioration With Weight Reduction

Comorbidity	Improvement After Weight Loss	First Author, Year (Ref)
T2DM	Yes	Cohen, 2012 (132); Mingrone, 2012 (133)[a]; Schauer, 2012 (134); Buchwald, 2009 (135)
Hypertension	Yes	Ilane-Parikka, 2008 (136); Phelan, 2007 (137); Zanella, 2006 (138)
Dyslipidemia and metabolic syndrome	Yes	Ilane-Parikka, 2008 (136); Phelan, 2007 (137); Zanella, 2006 (138)
Cardiovascular disease	Yes	Wannamethee, 2005 (139)
NAFLD	Variable outcomes	Andersen, 1991 (140); Huang, 2005 (141); Palmer, 1990 (142); Ueno, 1997 (143)
Osteoarthritis	Yes	Christensen, 2007 (144); Fransen, 2004 (145); Huang, 2000 (146); Messier, 2004 (147); van Gool, 2005 (148)
Cancer	Yes	Adams, 2009 (149); Sjöström, 2009 (150)
Major depression	Insufficient evidence	
Sleep apnea	Yes	Kuna, 2013 (151)

Abbreviation: NAFLD, nonalcoholic fatty liver disease.

[a] This study showed that weight gain within the normal-weight BMI category (ie, increase from 23 to 25 kg/m^2) increased risk of T2DM 4-fold.

to the diet. The medication that blocks fat absorption reinforces avoidance of high-fat (energy-dense) foods, in addition to promoting malabsorption of fat calories. Medications act to amplify the effect of the behavioral changes to consume fewer calories. They do not "work on their own." To get maximal efficacy, obesity drugs should be used as adjuncts to lifestyle change therapy, and in some cases weight loss is limited without lifestyle change. Whatever baseline behavioral treatment is given, the effect of the drug will be static (33, 34). Just as increasing the dose of medication increases weight loss, increasing the intensity of behavioral modification increases weight loss (33). Patients should be made aware that lifestyle changes are needed when using a weight loss medication and that the addition of a weight loss medication to a lifestyle program will likely result in greater weight loss (6, 35–38).

In making this recommendation, the Task Force acknowledges the variation in the strength of evidence for the different lifestyle interventions and pharmacological interventions for obesity. However, the strong recommendation for reserving pharmacological interventions as an adjunct therapy also depends on values and preferences, with an emphasis on avoiding the side effects, burden, and cost of medications while promoting a healthier lifestyle that has benefit beyond weight loss.

1.2 In order to promote long-term weight maintenance, we suggest the use of approved (see Footnote 1) weight loss medications (over no pharmacological therapy) to ameliorate comorbidities and amplify adherence to behavior changes, which may improve physical functioning and allow for greater physical activity in individuals with a BMI $\geq$ 30 kg/m^2 or in individuals with a BMI of $\geq$ 27 kg/m^2 and at least one associated comorbid medical condition such as hypertension, dyslipidemia, T2DM, and obstructive sleep apnea. (2|⊕⊕◯◯)

Evidence

Caloric restriction through diet and behavior modification has been shown to produce modest but effective weight loss for controlling comorbid medical problems such as diabetes, hypertension, and obstructive sleep apnea (39, 40) (Table 3). Moreover, the adjunctive use of weight loss medication can produce even greater weight loss and cardiometabolic improvements (36, 37, 41–45). Although all of these medications and others have been shown to be effective as adjunctive treatment, none have been shown to be effective on their own. The systematic reviews conducted to support the 2013 AHA/ACC/TOS Guideline for the Management of Overweight and Obesity in Adults (8) evaluated the observational literature about the association of various BMI cutoffs and the incidence of death and cardiovascular disease. That guideline adopted the arbitrary BMI cutpoints of $\geq$ 30 kg/m^2 ($\geq$27 kg/m^2 with medical related comorbidity) that had been determined by the U.S. Food and Drug Administration (FDA) and listed on the package inserts of FDA-approved obesity medications. Our Task Force adopted these cutpoints, realizing that they are arbitrary and only low-quality evidence supports associations determined by these cutpoints. Nevertheless, we had to use cutpoints to provide patients and clinicians with specific implementable and practical recommendations.

The only medication available in the European Union for chronic obesity management is orlistat. We encourage additional scrutiny of medications available in the United States by the European Medicines Agency (EMA) and the

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funding of additional long-term clinical trials in the European Union and elsewhere to study the safety and efficacy of these medications, with the goal of providing access to medications for chronic obesity management to patients in need across the world.

1.3 In patients with uncontrolled hypertension or a history of heart disease, we recommend against using sympathomimetic agents phentermine and diethylpropion. (1|⊕⊕⊕◯) (Table 4)

Evidence

The product labels for medications approved for chronic weight management (46–49) include contraindications and cautions based on clinical data submission on > 1500 individuals treated with each medication before approval. These contraindications are detailed in Table 4. Prescribers should be familiar with these product labels in order to avoid contraindications and to judiciously choose patients based on product cautions.

For the sympathomimetic agents phentermine and diethylpropion, regulatory approval was given based on a smaller clinical profile and without a cardiovascular outcomes study. There is thus a lack of evidence on safety for these products across broad populations. In making a strong recommendation, the panel placed a high value on avoiding harm and a lower value on potential short-term weight loss.

Implementation remarks

Because phentermine and diethylpropion are associated with elevations in mean blood pressure (BP) and pulse rate in treated populations, we do not advocate their prescription in patients with a history of cardiovascular disease, and we suggest caution and careful monitoring in patients with hypertension history. Thus, caution is advised in prescribing these agents in patients with hypertension, history of cardiac arrhythmia, or seizures. A serotonin receptor agonist such as lorcaserin would be a better choice in a patient with these conditions.

Another example is the patient with obesity and depression on a selective serotonin reuptake inhibitor (SSRI) or serotonin-norepinephrine reuptake inhibitor (SNRI). In these patients, lorcaserin would not be the best choice due to the potential for serotonin syndrome. A better choice would be phentermine/topiramate or phentermine alone. Orlistat is likely to be safe in all instances due to its mechanism of action. Other cautionary instances are outlined in Table 4.

1.4 We suggest assessment of efficacy and safety at least monthly for the first 3 months, then at least every 3 months in all patients prescribed weight loss medications. (2|⊕⊕◯◯)

Evidence

Diet, behavior modification, and, if appropriate, pharmacotherapy have been shown to be safe and effective in producing modest but effective weight loss and amelioration of comorbid medical problems. To promote maximum effectiveness, frequent assessments are indicated to assess effectiveness of the treatment, ensure accountability, and monitor safety and efficacy of the weight loss medications. The more accountable patients are to weight loss programs, the better the outcomes that are expected. Moreover, any adverse side effects of the weight loss medications can be detected early and rectified (8). The AHA/ACC/TOS Guideline for the Management of Overweight and Obesity in Adults reviewed randomized clinical trials on weight loss interventions and determined that the best weight loss outcomes occur with frequent face-to-face visits (16 visits per year on average) (8, 38).

1.5 If a patient's response to a weight loss medication is deemed effective (weight loss ≥ 5% of body weight at 3 mo) and safe, we recommend that the medication be continued. If deemed ineffective (weight loss < 5% at 3 mo) or if there are safety or tolerability issues at any time, we recommend that the medication be discontinued and alternative medications or referral for alternative treatment approaches be considered. (1|⊕⊕⊕⊕)

Evidence

Weight loss medications do not change the underlying physiology of weight regulation in any permanent way. Trials of weight loss medication that have used a crossover design have demonstrated that the weight loss effects of these medications are only sustained as long as they are taken and these same benefits occur on introducing the medication in patients previously treated with lifestyle alone. Historically, patients and providers thought that weight loss medications could be used to produce an initial weight loss that could subsequently be sustained by behavioral means. The available evidence does not support this view. Much as antihypertensive medications lower BP to a new steady state with BP rising to baseline levels upon discontinuing medication, weight loss medications promote weight loss to a new steady state with gradual weight gain typically occurring when medications are stopped (50, 51).

1.6 If medication for obesity management is prescribed as adjunctive therapy to comprehensive lifestyle intervention, we suggest initiating therapy with dose escalation based on efficacy and tolerability to the recommended

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Table 4. Pharmacotherapy for Obesity in the United States (December 2014)

Drug (Generic)	Dosage	Mechanism of Action	Weight Loss Above Diet and Lifestyle Alone, Mean Weight Loss, % or kg[a]; Duration of Clinical Studies	Status	Common Side Effects	Contraindications
Phentermine resin	AdipexP (37.5 mg), 37.5 mg/d Ionamin (30 mg), 30–37.5 mg/d	Norepinephrine-releasing agent	3.6 kg (7.9 lb); 2–24 wk	Approved in 1960s for short-term use (3 mo)	Headache, elevated BP, elevated HR, insomnia, dry mouth, constipation, anxiety Cardiovascular: palpitation, tachycardia, elevated BP, ischemic events Central nervous system: overstimulation, restlessness, dizziness, insomnia, euphoria, dysphoria, tremor, headache, psychosis Gastrointestinal: dryness of the mouth, unpleasant taste, diarrhea, constipation, other gastrointestinal disturbances Allergic: urticaria Endocrine: impotence, changes in libido	Anxiety disorders (agitated states), history of heart disease, uncontrolled hypertension, seizure, MAO inhibitors, pregnancy and breastfeeding, hyperthyroidism, glaucoma, history of drug abuse, sympathomimetic amines
Diethylpropion	Tenuate (75 mg), 75 mg/d	Norepinephrine-releasing agents	3.0 kg (6.6 lb); 6–52 wk	FDA approved in 1960s for short-term use (3 mo)	See phentermine resin	See phentermine resin
Orlistat, prescription (120 mg)	120 mg TID	Pancreatic and gastric lipase inhibitor	2.9–3.4 kg (6.5–7.5 lb), 2.9–3.4%; 1 y	FDA approved in 1999 for chronic weight management	Decreased absorption of fat-soluble vitamins, steatorrhrea, oily spotting, flatulence with discharge, fecal urgency, oily evacuation, increased defecation, fecal incontinence	Cyclosporine (taken 2 h before or after orlistat dose), chronic malabsorption syndrome, pregnancy and breastfeeding, cholestasis, levothyroxine, warfarin, antiepileptic drugs
Orlistat, over-the-counter (60 mg)	60–120 mg TID	Pancreatic and gastric lipase inhibitor	2.9–3.4 kg (6.5–7.5 lb), 2.9–3.4%; 1 y	FDA approved in 1999 for chronic weight management	See Orlistat, prescription	See Orlistat, prescription
Lorcaserin (10 mg)	10 mg BID	5HT2c receptor agonist	3.6 kg (7.9 lb), 3.6%; 1 y	FDA approved in 2012 for chronic weight management	Headache, nausea, dry mouth, dizziness, fatigue, constipation	Pregnancy and breastfeeding **Use with caution:** SSRI, SNRI/MAOI, St John's wort, triptans, buproprion, dextromethorphan
Phentermine (P)/ topiramate (T)	3.75 mg P/23 mg T ER QD (starting dose) 7.5 mg P/46 mg T ER daily (recommended dose) 15 mg P/92 mg P/T ER daily (high dose)	GABA receptor modulation (T) plus norepinephrine-releasing agent (P)	6.6 kg (14.5 lb) (recommended dose), 6.6% 8.6 kg (18.9 lb) (high dose), 8.6%; 1 y	FDA approved in 2012 for chronic weight management	Insomnia, dry mouth, constipation, paraesthesia, dizziness, dysgeusia	Pregnancy and breastfeeding, hyperthyroidism, glaucoma, MAO inhibitor, sympathomimetic amines
Naltrexone/ bupropion	32 mg/360 mg 2 tablets QID (high dose)	Reuptake inhibitor of dopamine and norepinephrine (bupropion) and opioid antagonist (naltrexone)	4.8%; 1y (Ref. 79)	FDA approved in 2014 for chronic weight management	Nausea, constipation, headache, vomiting, dizziness	Uncontrolled hypertension, seizure disorders, anorexia nervosa or bulimia, drug or alcohol withdrawal, MAO inhibitors
Liraglutide	3.0 mg injectable	GLP-1 agonist	5.8 kg; 1 y (Ref. 30, 31)	FDA approved in 2014 for chronic weight management	Nausea, vomiting, pancreatitis	Medullary thyroid cancer history, multiple endocrine neoplasia type 2 history

Abbreviations: GABA, γ-aminobutyric acid; HR, heart rate; MAO, monoamine oxidase (Ref. 46–49).

[a] Mean weight loss in excess of placebo as percentage of initial body weight or mean kilogram weight loss over placebo.

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dose and not exceeding the upper approved dose boundaries. (2|⊕⊕◯◯)

Evidence

For the medications approved for long-term treatment for obesity, the recommended doses are as follows: orlistat, 120 mg three times a day (TID); phentermine/topiramate, 7.5 mg/46 mg every day (QD); lorcaserin, 10 mg twice a day (BID); naltrexone/bupropion, 8 mg/90 mg, 2 tablets BID; and for liraglutide, 3.0 mg SC QD (46–49).

For orlistat, the drug is available over the counter at a dosage of 60 mg TID. This dosage has been shown to produce greater weight loss than placebo (52). The recommended prescription dosage is 120 mg TID. Given the favorable safety profile and weight loss efficacy of orlistat at 120 mg TID, it is the preferred dose for prescription (47). There is no evidence from clinical trials using dosages higher than 120 mg TID that efficacy is greater at higher dosages, and prescribers should not exceed 120 mg TID. Orlistat, 120 mg TID, has been studied and approved for treatment of adolescents with obesity (58–60).

For phentermine/topiramate extended release (ER), it is necessary to escalate the dose when starting the medication. The clinical trial data support starting at a dosage of 3.75 mg/23 mg QD and maintaining this for at least 2 weeks. If the patient tolerates the medication, an increase to 7.5 mg/46 mg is in order. Because of the more favorable tolerability profile in clinical studies of the 7.5 mg/46 mg dose, further escalation is only recommended for patients who have not lost 3% of their body weight at 12 weeks. In that case, the dose can be increased to 11.25 mg/69 mg, and then to 15 mg/92 mg. The product label recommends a gradual reduction of dose over 3–5 days because of the observation of seizures occurring when topiramate was stopped abruptly in patients with epilepsy (41, 43, 61).

For lorcaserin, the recommended dosage is 10 mg BID. In clinical trials, lorcaserin 10 mg QD produced nearly as much weight loss as 10 mg BID (42, 44, 45).

Naltrexone/bupropion is available in 8mg/90mg combination tablets. One tablet should be started in the morning and in 1 week 1 tablet added before dinner. As tolerated, the dose should be increased to 2 tablets in the morning the 3rd week, and 2 tablets before the evening meal the 4th week to the maximum of 2 tablets twice daily. If side effects such as nausea develop during dose escalation, the dose should not be increased further until tolerated. If a patient has not lost more than 5% of body weight at 12 weeks, naltrexone/bupropion should be discontinued (79, 93).

Liraglutide should be initiated at a dose of 0.6 mg daily by SC injection. The dose can be increased by 0.6 mg per week up to a maximum of 3.0 mg. If side effects such as nausea develop during dose escalation, the dose should not be increased further until tolerated (31).

There are no comparative data of different doses of phentermine and other sympathomimetics used as a single agent. Therefore, the once-daily doses of 30 mg phentermine (37.5 mg as resin) or 75 mg tenuate should not be exceeded.

1.7 In patients with T2DM who are overweight or obese, we suggest the use of antidiabetic medications that have additional actions to promote weight loss (such as GLP-1 analogs or SGLT-2 inhibitors) in addition to the first-line agent for T2DM and obesity, metformin (63). (2|⊕⊕⊕◯)

Evidence

Individuals with obesity and T2DM may have the dual benefit of weight loss and glycemic control while prescribed a regimen including one or more of three currently available drug classes: metformin, the GLP-1 agonists (exenatide, liraglutide), and the new class of SGLT-2 inhibitors. For the goal of clinically significant weight loss, trials comparing GLP-1 agonists and other antihyperglycemic agents have shown weight loss in some subjects in higher ranges between 5.5 and 8 kg (62). Although other agents including metformin and SGLT-2 inhibitors produce more modest weight loss, ie, in the 1- to 3-kg range in most studies, these agents have not been studied in the setting of concomitant behavioral therapy, and the full weight loss potential is therefore not yet known. In summary, because a subset of diabetes patients may have substantial weight loss on certain diabetes agents that also lower blood glucose, most patients with diabetes should try one or more of these before being considered for additional medications designed for the specific goal of weight loss. The most substantial evidence supports a trial of GLP-1 agonists (see recommendation 2.1).

1.8 In patients with cardiovascular disease who seek pharmacological treatment for weight loss, we suggest using medications that are not sympathomimetics, such as lorcarserin and/or orlistat. (2|⊕◯◯◯)

Evidence

Because patients with a prior history of cardiovascular disease may be susceptible to sympathetic stimulation, agents without cardiovascular signals (increased BP and pulse) should be used preferentially. For patients with established cardiovascular disease who require medication for weight loss, orlistat and lorcaserin should be used. These drugs have a lower risk of increased BP than phentermine and topiramate ER. Lorcaserin showed a reduc-

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tion in pulse and BP greater than placebo in randomized placebo-controlled trials (44).

2.0 Drugs that cause weight gain and some alternatives

A variety of prescription medications have been associated with weight gain. Drug-induced weight gain is a preventable cause of obesity. For all patients, and particularly for patients who have a BMI > 27 kg/m^2 with comorbidities or BMI > 30 kg/m^2, the desired level of clinical efficacy for a chosen therapy should be balanced against side effects, including the likelihood of weight gain. In cases where there are no acceptable therapeutic alternatives, the minimal dose required to produce clinical efficacy may prevent drug-induced weight gain. Patients' initial weight status, the presence of risk factors for cardiovascular disease, diabetes, and other obesity-related health complications, as well as the benefits of pharmacological therapies warrant careful consideration when prescribing a first-line therapy or change in medication.

2.1 We recommend weight-losing and weight-neutral medications as first- and second-line agents in the management of a patient with T2DM who is overweight or obese. (1|⊕⊕⊕◯)

Evidence

The effect of metformin for promoting mild weight loss is likely due to multiple mechanisms (63). However, in animal models, metformin mediates a phenotypic shift away from lipid accretion through AMP-activated Protein Kinase-Nicotinamide phosphoribosyltransferase-Sirtuin 1-mediated changes in metabolism supporting treatment for obesity (64). GLP-1 agonists such as exenatide and liraglutide have also been shown to promote mild weight loss. Pramlintide is an amylin analog that promotes weight loss by increasing satiety and decreasing food intake (65, 66). Dipeptidyl peptidase IV (DPP-4) inhibitors appear to be weight neutral or may lead to minimal weight change. α-Glucosidase inhibitors such as acarbose and miglitol may be weight neutral or lead to a small change in weight (152, 153).

Clinicians should discuss possible weight effects of glucose-lowering medications with patients and consider the use of antihyperglycemic medications that are weight neutral or promote weight loss.

Weight gain is often associated with many diabetes therapies. Patients can gain as much as 10 kg in a relatively short period (3 to 6 mo) after initiating treatment with insulin, sulfonylureas, and other insulin secretagogues like glitinides and thiazolidinediones. Participants in the Diabetes Prevention Program with impaired glucose tolerance who took metformin (850 mg BID) lost 2.1 kg compared with a weight loss of 0.1 kg in the placebo group (69). A recent study comparing sitagliptin plus metformin with pioglitazone in drug-naive patients with T2DM showed that the sitagliptin-metformin combination resulted in weight loss (-1.4 kg) whereas pioglitazone led to weight gain (3.0 kg) (70). A retrospective analysis of exenatide (n = 6280), sitagliptin (n = 5861), and insulin (n = 32 398) indicated that exenatide-treated subjects lost an average of 3.0 kg, sitagliptin-treated subjects lost 1.1 kg, and insulin-treated subjects gained 0.6 kg (71).

In a 1-year trial comparing two doses of liraglutide (1.2 and 1.8 mg) with glimepiride 8 mg, subjects lost 2.05 and 2.45 kg in the 1.2- and 1.8-mg groups, respectively, compared with a 1.12-kg weight gain in the glimepiride group. Glycated hemoglobin (HbA1c) significantly ($P = .0014$) decreased by 0.84% with liraglutide 1.2 mg and by 1.14% with liraglutide 1.8 mg ($P < .0001$) compared to 0.51% with glimepiride (72). An analysis of 17 randomized placebo-controlled trials showed that all GLP-1 agonists reduced HbA1c levels by about 1% (62). The DPP-4 inhibitors sitagliptin and vildagliptin have also been shown in a meta-analysis of 25 studies to lower HbA1c by approximately 0.7 and 0.6%, respectively, in comparison with placebo (73).

A recent review of direct comparisons with active glucose-lowering agents in drug-naive patients demonstrated that DPP-4 inhibitors reduce HbA1c slightly less than metformin (by approximately 0.28) and provide similar glucose-lowering effects as a thiazolidinedione. DPP-4 inhibitors have better gastrointestinal tolerability than metformin yet are weight neutral (74, 75). Another meta-analysis found that an increase in body weight (1.8 to 3.0 kg) was observed with most second-line therapies, the exceptions being DPP-4 inhibitors, α-glucosidase inhibitors, and GLP-1 analogs ($+0.6$ to -1.8 kg) (76). Pramlintide, indicated as an adjunct to insulin, may also aid with weight loss. A meta-analysis demonstrated a weight loss of -2.57 kg for those taking pramlintide vs the control groups (77).

The SGLT-2 inhibitors dapagliflozin and canagliflozin are a new class of antidiabetic drugs that reduce renal glucose reabsorption in the proximal convoluted tubule, leading to increased urinary glucose excretion (78). A recent systematic review and meta-analysis (79) looks at not only the effect of these medications on glycemic indices but also their effects on body weight. Compared with placebo, the mean percentage change in body weight from baseline in eight studies of > 12 weeks comparing the SGLT-2 inhibitor to placebo was -2.37% (95% confidence interval [CI], -2.73 to -2.02). Canagliflozin appears to produce slightly more weight loss on average because three studies with dapagliflozin vs placebo showed mean loss of -2.06% of initial body weight (95% CI, -2.38 to

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−1.74), and five studies of canagliflozin vs placebo showed −2.61% loss (95% CI, −3.09 to −2.13); however, this was not statistically significant. This analysis may underestimate the weight loss effects of these drugs because studies of 12 weeks were included. In 52-week observations, there is no weight regain after maximal loss at 24 weeks.

In addition, because weight-sparing medications are unique in that they do not independently cause hypoglycemia, they have a lower potential for hindering an exercise program. Exercise adjustment is generally necessary only with insulin and with medications that can promote endogenous insulin secretion despite decreasing glucose levels, such as the sulfonylurea and glinide classes of agents (80). Hence, prioritizing metformin, incretin-based medications, and SGLT-2s as therapeutic strategies can reduce exercise-related hypoglycemia and potentially increase the safety and efficacy of exercise in patients with diabetes, thus supporting this important weight-reduction strategy (67, 68).

2.2 In obese patients with T2DM requiring insulin therapy, we suggest adding at least one of the following: metformin, pramlintide, or GLP-1 agonists to mitigate associated weight gain due to insulin. The first-line insulin for this type of patient should be basal insulin. This is preferable to using either insulin alone or insulin with a sulfonylurea. We also suggest that the insulin therapy strategy be considered a preferential trial of basal insulin prior to premixed insulins or combination insulin therapy. (2|⊕⊕⊕◯)

Evidence

Insulin remains the most effective agent to control serum glucose (81). However, multiple large studies typically show weight gain associated with insulin use, either as monotherapy or in combination with oral antidiabetic agents (82–85). Treatment with both metformin and insulin, or when metformin is prescribed in addition to an insulin program, yields similar glycemic benefit to insulin alone without excessive additional weight gain, as shown by meta-analyses and randomized trials (86–88).

Amylin analogs are FDA approved for use in combination with existing insulin treatment. A dose-finding study with pramlintide added to a variety of insulin regimens showed weight loss (−1.4 kg) in treatment groups (89), with HbA1c reductions of 0.62 to 0.68% in the 120-μg dose group. Additionally, weight gain was prevented when pramlintide was added to the basal insulins glargine or detemir. Other studies have found more substantial weight loss of over 3 kg with the use of pramlintide (90).

Other weight-sparing regimens have been studied, including the combination of basal insulin with the weight-neutral DPP-4 inhibitor sitagliptin (91) and weight-reducing combination therapy with liraglutide and metformin. Buse et al (92) investigated the addition of exenatide or placebo to regimens of insulin glargine alone, or in combination with metformin or pioglitazone or both, in adult T2DM patients with HbA1c of 7.1 to 10.5%. Despite superior HbA1c reduction, weight also decreased by 1.8 kg in the exenatide group compared with an increase of 1.0 kg in the placebo group (between-group difference, −2.7 kg; 95% CI, −3.7 to −1.7).

Finally, some weight benefits have been seen with the basal insulin analogs relative to biphasic and prandial insulin analog regimens. The Treating To Target in Type 2 Diabetes trial in patients receiving metformin/ sulfonylurea compared the initiation of basal insulin detemir (twice daily, if required) to that of biphasic insulin aspart BID or prandial insulin aspart TID. Basal insulin use was associated with the least weight gain at 1 year (+1.9 vs +4.7 vs +5.7 kg, detemir vs biphasic vs prandial, respectively) (93), and the weight advantage persisted during the 3-year trial (94).

2.3 We recommend ACE inhibitors, ARBs, and calcium channel blockers rather than β-adrenergic blockers as first-line therapy for hypertension in patients with T2DM who are obese. (1|⊕⊕⊕⊕)

Evidence

Angiotensin is overexpressed in obesity, directly contributing to obesity-related hypertension, providing support for the use of an ACE inhibitor as a first-line agent. Calcium channel blockers are also effective in the treatment of obesity-related hypertension and have not been associated with weight gain or adverse changes in lipids. ACE inhibitors and ARBs have not been associated with weight gain or insulin resistance and provide renal protection in diabetes (95).

If required, selective or nonselective β-blockers with a vasodilating component such as carvedilol and nebivolol are recommended because these agents appear to have less weight gain potential and less of an impact on glucose and lipid metabolism than other nonselective β-blockers (96, 97).

A study in patients taking metoprolol tartrate compared with those taking carvedilol for hypertension showed a mean weight gain of 1.19 kg, suggesting that weight gain is not a class effect of the β-adrenergic blockers (98). A meta-analysis of body weight changes in a series of randomized controlled hypertension trials of at least 6-month duration showed that body weight was higher in the β-blocker group, with a median difference of 1.2 kg between the β-blocker group and the control group (97). The Second Australian National Blood Pressure Trial re-

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ported slightly better cardiovascular outcomes in hypertensive men treated with a regimen that began with an ACE inhibitor compared with a regimen starting with a diuretic (95).

2.4 When antidepressant therapy is indicated, we recommend a shared decision-making process that provides patients with quantitative estimates of the expected weight effect of the antidepressant to make an informed decision about drug choice. Other factors that need to be taken into consideration include the expected length of treatment. (1|⊕⊕⊕◯)

Evidence

The antidepressants vary considerably with respect to their long-term weight gain potential. Serretti and Mandelli (99) evaluated the relative risk of weight gain associated with drugs within the major classes of antidepressant medications in a recent meta-analysis. Paroxetine is considered to be the SSRI associated with the greatest long-term increase in body weight (100), amitriptyline is the most potent inducer of weight gain among the tricyclic antidepressants (99), and mirtazapine (a noradrenergic and specific serotoninergic antidepressant) is also associated with weight gain in the long term (101). Other specific tricyclics that have been associated with weight gain include nortriptyline (102), whereas the effect of imipramine seems to be neutral (99). SSRIs such as fluoxetine and sertraline have been associated with weight loss during acute treatment (4–12 wk) and with weight neutrality in the maintenance (>4 mo) phase (99). No significant effect could be observed for citalopram or escitalopram on body weight (99). Among the serotonin and norepinephrine reuptake inhibitors, venlafaxine and duloxetine have been reported to slightly increase body weight over long-term treatment, although long-term data for venlafaxine are scarce (99). Bupropion selectively inhibits reuptake of dopamine and, to a lesser extent, norepinephrine. It is the only antidepressant that consistently causes weight loss (103). It was originally approved both for treating depression and for inducing smoking cessation. During clinical trials, it suppressed appetite and food cravings and significantly decreased body weight (103). The commissioned systematic review accompanying this guideline (3) was only able to demonstrate weight gain with amitriptyline (1.8 kg) and mirtazapine (1.5 kg) and weight loss with bupropion (−1.3 kg) and fluoxetine (−1.3 kg). The evidence for weight changes with other antidepressants was of lower quality.

2.5 We recommend using weight-neutral antipsychotic alternatives when clinically indicated, rather than those that cause weight gain, and the use of a shared decision-making process that provides patients with quantitative estimates of the expected weight effect of the alternative treatments to make an informed decision about drug choice. (1|⊕⊕⊕◯)

Evidence

Although better tolerated than the older antipsychotics, many of the new atypical antipsychotic agents have weight gain as a side effect (104). This weight gain is of clinical concern because it impedes patient compliance and has deleterious health consequences (104, 105) in patients who are often overweight or obese to begin with. The differential effect of atypical antipsychotics on histamine (H1) receptors, anticholinergic effects, and serotonin type 2C antagonistic effects may explain differences in weight gain among the drugs. Henderson et al (106) demonstrated that weight gain associated with clozapine treatment continued for as long as 46 months and was accompanied by a significant increase in triglyceride levels and a 37% increase in the incidence of T2DM over the 5-year period of observation. A randomized trial investigating the effectiveness of five antipsychotic medications found that a weight gain of > 7% from baseline occurred in 30% of those taking olanzapine, 16% for quetiapine, 14% for risperidone, 12% for perphenazine, and 7% of those taking ziprasidone (107). Allison and Casey (104) noted that patients lost weight when switched from olanzapine to ziprasidone, and this weight loss was associated with improvements in their serum lipid profile and glucose tolerance. In a 6-week, double-blind trial, patients were randomly assigned to receive ziprasidone (n = 136) or olanzapine (n = 133). Body weight increased significantly in those taking olanzapine (3.6 kg) compared with those taking ziprasidone (1.0 kg) (108). A review of nine randomized controlled trials comparing ziprasidone with amisulpride, clozapine, olanzapine, quetiapine, and risperidone showed that ziprasidone produced less weight gain than olanzapine (five RCTs; n = 1659; mean difference, −3.82; 95% CI, −4.69 to −2.96), quetiapine (two randomized controlled trials [RCTs]; n = 754; relative risk, 0.45; 95% CI, 0.28 to 0.74), or risperidone (three RCTs; n = 1063; relative risk, 0.49; 95% CI, 0.33 to 0.74). Ziprasidone was also associated with less cholesterol increase than olanzapine, quetiapine, and risperidone (109). Finally, a review of 34 trials of antipsychotics in youth with psychotic and bipolar disorders found that weight gain ranged from 3.8 to 16.2 kg with olanzapine, 0.9 to 9.5 kg with clozapine, 1.9 to 7.2 kg with risperidone, 2.3 to 6.1 kg with quetiapine, and 0 to 4.4 kg with aripiprazole (110). Despite the variable effects on weight gain among the antipsychotic agents, the prediabetes ef-

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fect may be similar via weight-independent mechanisms (111).

2.6 We recommend considering weight gain potential in choosing an AED for any given patient, and the use of a shared decision-making process that provides patients with quantitative estimates of the expected weight effect of the drugs to make an informed decision about drug choice. (1|⊕⊕⊕◯)

Evidence

AEDs associated with weight loss are felbamate, topiramate, and zonisamide. AEDs associated with weight gain are gabapentin, pregabalin, valproic acid, vigabatrin, and carbamazepine. Weight-neutral AEDs are lamotrigine, levetiracetam, and phenytoin. In clinical practice, it is critical to weigh patients regularly, and AED selection should be based on each patient's profile without sacrificing therapeutic efficacy (112).

Valproic acid has been shown to cause weight gain in both adults and children (113). A retrospective study of long-term weight gain in adult epileptic patients on valproic acid mono- or polytherapy showed that mild-to-moderate weight gain (5 to 10% of baseline weight) was shown in 24% of patients, whereas marked weight gain (>10% gain of baseline weight) was shown in 47% of patients (114). A study of patients taking gabapentin for 12 months or more showed that of 44 patients, 57% gained more than 5% of their baseline body weight; of these, 10 patients (23%) gained more than 10% of their baseline weight (115). Our commissioned systematic review (3) suggested weight gain with gabapentin (2.2 kg after 1.5 mo of use) and divalproex (relative risk for weight gain, 2.8; 95% CI, 1.30, 6.02). Carbamazepine is an older AED and has also been associated with weight gain, although not as significant as valproic acid or gabapentin (116). A study of 66 patients taking AEDs showed that 66.7% of those on carbamazepine had gained an average of 1.5 kg at a 6- to 8-month follow-up visit (117).

2.7 In women with a BMI > 27 kg/m^2 with comorbidities or BMI > 30 kg/m^2 seeking contraception, we suggest oral contraceptives over injectable medications due to weight gain with injectables, provided that women are well-informed about the risks and benefits (ie, oral contraceptives are not contraindicated). (2|⊕◯◯◯)

Evidence

Contraceptive drugs are available in different dosages and formulations and are composed of progestins alone or in combination with estrogens. Some progestins have androgenic/antiandrogenic properties. The research on contraceptives and weight gain is conflicting, and the studies conducted so far are difficult to compare because of the different formulations of contraceptives containing variable doses of estrogens, and with the progestins having different androgenic/antiandrogenic profiles. Moreover, randomized controlled trials comparing hormonal contraceptive methods with a placebo usually raise ethical issues. As recently documented by Gallo et al (118), only four trials included a placebo group or no intervention group, and no evidence has been found to support the association between combination (estrogen plus a progestin) hormonal contraception and weight change. In addition, the same authors, by examining 79 trials of combination contraceptives, concluded that no substantial difference in weight could be found. Moreover, discontinuation of combination contraceptives because of weight change did not differ between groups where this was studied (118).

There is limited evidence of weight gain when using progestin-only contraceptives. Mean gain was less than 2 kg for most studies up to 12 months (119). However, it should be noted that most of the trials were conducted in normal-weight women and excluded obese subjects.

Remarks

Selected studies have reported an increase in contraceptive failure in women with a BMI > 27 kg/m^2. Data on this issue are conflicting but should be discussed with the appropriate patients on an individual basis.

2.8 We suggest monitoring the weight and waist circumference of patients on antiretroviral therapy due to unavoidable weight gain, weight redistribution, and associated cardiovascular risk. (2|⊕⊕⊕◯)

Evidence

Treatments for human immunodeficiency disease include administration of antiretroviral therapy and protease inhibitors. Although effective for suppressing HIV viral activity, which should be associated with appropriate weight gain, such treatments are associated with increased deposition of visceral adipose tissue (120) and lipodystrophy (121). One study of 10 HIV patients treated with protease inhibitor-containing regimens found that patients gained an average of 8.6 kg ($P = .006$) after 6 months (120).

2.9 We suggest the use of nonsteroidal anti-inflammatory drugs and disease-modifying antirheumatic drugs when possible in patients with chronic inflammatory disease like rheumatoid arthritis because corticosteroids commonly produce weight gain. (2|⊕⊕⊕◯)

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Evidence

When possible, chronic steroid therapy should be avoided in the treatment of chronic inflammatory disease to avoid weight gain in individuals who are overweight or obese. Weight gain and its effects on comorbidities should be considered among the commonly known side effects of glucocorticoid therapy. This is particularly important in rheumatic diseases because, for example, obesity in the setting of osteoarthritis leads to more severe disability and reduced exercise capacity, ambulatory capacity, and quality of life (122). A systematic review reported that, based on data from four RCTs in rheumatoid arthritis, glucocorticoids cause a weight increase of 4 to 8% (123, 124). An additional study showed that, when compared with sulfasalazine, glucocorticoid therapy was associated with a 1.7-kg weight gain after 1 year of treatment (125, 126), and another showed a 2.0-kg weight gain after 24 weeks in patients taking prednisone (127).

2.10 We suggest the use of antihistamines with less central nervous system activity (less sedation) to limit weight gain. (2|⊕⊕◯◯)

Evidence

Research is inconclusive regarding differences in the weight gain potential of sedating vs nonsedating antihistamines because weight has rarely been an outcome in studies of antihistamines, but it appears that the more potent the antihistamine, the greater the potential for weight gain (128). A recent study demonstrated that the odds ratio for being overweight was increased in prescription H1 antihistamine users (129). Furthermore, a study using data from the 2005–2006 National Health and Nutrition Examination Survey found that prescription H1 antihistamine users had a significantly higher weight, waist circumference, and insulin concentration than matched controls (129).

3.0 Off-label use of drugs approved for other indications for chronic obesity management

3.1 We suggest against the off-label use of medications approved for other disease states for the sole purpose of producing weight loss. A trial of such therapy can be attempted in the context of research and by healthcare providers with expertise in weight management dealing with a well-informed patient. (Ungraded Best Practice Recommendation)

Evidence

A variety of drug classes approved for other uses have been utilized off-label by some prescribers to promote weight loss in patients who are obese. Categories of drugs used may include the antiseizure medication topiramate as well as zonisamide, metformin, GLP-1 agonists such as exenatide and liraglutide, the antidepressant bupropion, as well as drugs for attention deficit hyperactivity disorder such as methylphenidate, and thyroid hormones. Combination treatments of these drugs also represent off-label use, although they have been utilized by some practitioners. Physicians without expertise in weight management or endocrinology are advised against prescribing off-label medications.

If a provider chooses to prescribe a medication for weight loss that is not FDA approved for this indication or is not approved for chronic administration, at minimum they should advise patients that this approach has not been evaluated for safety and efficacy and is not approved by the FDA. This discussion as well as details of the risks and benefits of the treatment approach that were presented to the patient should be documented in the medical record. The provider should discuss medications that are FDA approved for weight loss with the patient and document why an off-label medication was chosen over one of these. Practices such as selling weight loss medications out of the office should be avoided because they could be interpreted as representing a conflict of interest for the provider.

Long-term prescribing of phentermine

Although phentermine is FDA approved for weight loss, it is not approved for long-term use. This presents a conundrum for clinicians because it is clear that weight regain will likely occur once the medication is stopped. One approach that has been tried to avoid this situation is intermittent therapy (130). Although this approach appears to work and might be appropriate when a patient is intermittently exposed to environmental factors that promote weight gain, it is not a logical way to prescribe given what is understood about the effects of weight loss medications on weight regulation. The question then is whether or not it is reasonable to prescribe phentermine off-label long term. In making this decision with a patient, direction and guidance provided by State Medical Boards and local laws always take precedence. However, in the many locations where these sources have not provided clear advice, clinicians are left to make their own best professional judgments.

Phentermine is currently the most widely prescribed weight loss medication, and it is likely that much of this prescribing is off label. This is likely a reflection of the low cost of phentermine as compared to other weight loss medications. There currently are no long-term data on safety or efficacy, although recent data on 269 patients treated long term with phentermine suggest that the addiction potential is low (131). In addition, recent data on single and combination agents for weight loss document phen-

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termine 15 mg alone as able to induce over 7% weight loss at 6 months (26). There currently is minimal evidence of any serious long-term side effects when phentermine is used alone for weight loss. Given the wide clinical prescribing of phentermine for more than 20 years and the lack of evidence of serious side effects, even in the absence of long-term controlled safety and efficacy data, it seems reasonable for clinicians to prescribe phentermine long term as long as the patient: 1) has no evidence of serious cardiovascular disease; 2) does not have serious psychiatric disease or a history of substance abuse; 3) has been informed about weight loss medications that are FDA approved for long-term use and told that these have been documented to be safe and effective whereas phentermine has not; 4) does not demonstrate a clinically significant increase in pulse or BP when taking phentermine; and 5) demonstrates a significant weight loss while using the medication. These aspects of care should be documented in the patient's medical record, and the off-label nature of the prescribing should be documented at each visit. Medication should be started at 7.5 or 15 mg/d initially and only increased if the patient is not achieving clinically significant weight loss. Patients should be followed at least monthly during dose escalation and then at least every 3 months when on a stable dose.

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Metabolic and weight-loss effects of a long-term dietary intervention in obese patients[1–3]

Herwig H Ditschuneit, Marion Flechtner-Mors, Timothy D Johnson, and Guido Adler

ABSTRACT

Background: Obesity is a chronic disease that has become one of the most serious health problems in Western society.

Objective: We assessed the long-term effects of an energy-restricted diet combined with 1 or 2 daily meal replacements on body weight and biomarkers of disease risk in 100 obese patients.

Design: Phase 1 consisted of a 3-mo, prospective, randomized, parallel intervention study of 2 dietary interventions to reduce weight. The energy-restricted diet (5.2–6.3 MJ/d) consisted of conventional foods (group A) or an isoenergetic diet with 2 meals and 2 snacks replaced daily by energy-controlled, vitamin-and-mineral-supplemented prepared foods (group B). Phase 2 consisted of a 24-mo, case-control, weight-maintenance study with an energy-restricted diet and 1 meal and 1 snack replaced daily for all patients.

Results: Total weight loss (as a percentage of initial body weight) was 5.9 ± 5.0% in group A and 11.3 ± 6.8% in group B ($P < 0.0001$). During phase 1, mean weight loss in group B ($n = 50$) was 7.1 ± 3.5 kg, with significant reductions in plasma triacylglycerol, glucose, and insulin concentrations ($P < 0.0001$). Group A patients ($n = 50$) lost an average of 1.3 ± 2.2 kg with no significant improvements in these biomarkers. During phase 2, both groups lost on average an additional 0.07% of their initial body weight every month ($P < 0.01$). During the 27-mo study, both groups experienced significant reductions in systolic blood pressure and plasma concentrations of triacylglycerol, glucose, and insulin ($P < 0.01$).

Conclusion: These findings support the hypothesis that defined meal replacements can be used for successful, long-term weight control and improvements in certain biomarkers of disease risk. *Am J Clin Nutr* 1999;69:198–204.

KEY WORDS Weight loss, biomarkers, disease risk, meal replacements, obesity, humans

INTRODUCTION

Persons with a body mass index (in kg/m^2) >27 have significant increases in age-related mortality (1, 2). Morbidity also increases because of the obesity-induced incidence of diabetes, coronary artery disease, and hypertension (3, 4). Clinical studies have suggested that minimal, sustained weight loss can reduce or eliminate these obesity-related disorders (3–8). Unfortunately, long-term outcome data show that most persons who lose weight regain the weight lost within 5 y (9) and that in those with abnormal biomarkers at the beginning of weight loss, these disease-associated risk factors are reestablished (9).

More recent evidence indicates that dietary interventions lasting 2 y that include the use of energy-controlled, nutrient-dense meal replacements remain a viable, practical, safe, and effective alternative to pharmacologic intervention (10). McCarron et al (11) found that patients who ate nutritionally balanced, prepackaged meals received greater clinical benefits and nutritional completeness and showed better compliance than did those following a self-selected food plan. Reductions in body weight were also associated with improvements in biomarkers of disease and obesity-related comorbidities (11). However, this study was limited in duration to 10 wk.

The present study was designed to test the hypothesis that meal replacements are a useful tool for sustained weight loss and that minimal, sustained weight loss will maintain improvements in biomarkers of disease risk. The study was 27 mo in duration and consisted of 2 phases. The first 3-mo phase was designed to test the efficacy of 2 modes of energy restriction on body weight loss and associated measures of obesity risk factors for disease, eg, blood pressure and plasma, triacylglycerol, glucose, and insulin concentrations. The second phase included the same patients for an additional 24 mo of weight maintenance to further test the hypothesis that moderate, sustained weight loss could sustain the improvements in the obesity risk factors for disease.

SUBJECTS AND METHODS

Subjects

The study patients were referred to the Obesity Center at the University Hospital of Ulm for obesity management. All patients

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[2] Supported in part by a grant from Slim•Fast Foods Company, West Palm Beach, FL. The company also provided meal- and snack-replacement products free of charge.

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had been treated by the referring practitioner with energy-restricted diets for ≥3 mo. Dissatisfaction with the degree of weight loss was the primary reason for transfer to the University Center.

The study was carried out according to the principles of the Helsinki Declaration and the protocol was approved by the Freiburg Ethics Committee International (Freiburg, Germany). Participants were informed that the purpose of the first phase of the study (phase 1) was to compare 2 diet plans for their ability to promote weight loss, whereas the purpose of the second phase of the study (phase 2) was to evaluate a single diet plan for long-term weight maintenance and improvement in blood indexes, eg, glucose homeostasis and blood lipid profiles associated with disease.

Exclusion criteria

Individuals with a history or presence of significant disease, endocrine disorders, psychiatric diseases, alcohol or drug abuse, or abnormal laboratory test results of clinical significance were excluded. In addition, women were excluded if they were lactating, pregnant, or wished to become pregnant.

Inclusion criteria

Patients were men and women aged >18 y whose body mass indexes were >25.0 and ≤40.0 and who gave their informed consent to participate. Patients indicated their willingness to be randomly assigned to study groups and to follow the program protocol, which included monthly hospital visits for physical examinations and review of diet records. One hundred patients met the inclusion criteria, agreed to be randomly assigned to study groups, and adhered to the study protocol.

Study design

The study was divided into 2 phases. Phase 1 (3 mo of weight loss) was a randomized, parallel intervention trial in which patients were randomly assigned to 1 of 2 dietary treatments (group A or B) by a computer-generated identification number. In phase 2 (24 mo of weight loss and weight maintenance), all patients were prescribed the same diet. Patients were analyzed according to their original group assignment. The patients were encouraged to maintain their usual level of physical activity throughout both phases of the study.

Dietary intervention

The dietary intervention during phase 1 was structured such that a staff nutritionist explained the diet plan in detail and counseled participants by using personalized sample menus and recipes and instruction in maintenance of a food diary. Throughout the study, patients were prescribed a balanced diet providing 5.2–6.3 MJ/d (1200–1500 kcal/d) and 19–21% of energy as protein, 48–54% of energy as carbohydrate, and 25–34% of energy as fat. Three meals (breakfast, lunch, and dinner) and 2 snacks (1 between breakfast and lunch and 1 between lunch and dinner) were recommended. The nutritionist provided monthly, personalized instructions by using food exchange lists and food diaries to equalize the prescribed energy intakes between groups A and B. Individual preferences for various food items were integrated into the diet plan.

During phase 1, the 3-mo weight-loss period, group A was prescribed a diet in which all meals and snacks were prepared from self-selected, conventional foods. Group B was prescribed similar self-selected diets, except that 2 of the 3 main meals (breakfast, lunch, or dinner) were replaced with meal-replacement shakes, soups, or hot chocolate (Slim•Fast; Slim•Fast Foods Company, West Palm Beach, FL). Each meal replacement contained 0.84–1.05 MJ energy, 14.0–17.0 g protein, 27.0–33.5 g carbohydrate, 5.0–6.6 g fat, and 4.5–6.5 g fiber and was supplemented with essential vitamins and minerals. In place of snacks, patients were provided with 2 nutrition snack bars (Slim•Fast) per day containing 0.38–0.46 MJ energy, 1.4–1.7 g protein, 16.1–18.1 g carbohydrate, 2.4–3.9 g fat, and 1.1 g fiber.

In phase 2, all patients were seen monthly and continued to receive the same instructions while following their food plans. The energy content of the prescribed diet was the same in both groups, and all patients were instructed to replace one meal and one snack with the energy-controlled, nutrient-dense meal and snack replacements.

Dietary records

At the initial visit, patients were instructed on food selection, meal portion control, and recording of daily dietary intakes. Accurate daily recording was stressed and daily food diaries were maintained for 7 consecutive days during the 2-wk period before each visit. Food quantities were recorded by using household measurements. Records were reviewed with each patient and analyzed monthly by the nutritionist. Nutrient calculations were carried out by using the German Food Code BLS and the NUTRILOG program (GiV, Göttingen, Germany).

Data collection

At each monthly visit, anthropometric data, blood pressure, and side effects were recorded. Weight measurements to the nearest 0.1 kg were taken by using the same precision scale with patients dressed only in underwear. Waist and hip circumferences were measured to the nearest 0.5 cm by using a nonstretchable tape measure. Waist circumference was measured midway between the lower rib margin and the iliac crest; hip circumference was measured at the widest point of the trochanter and buttocks area. The waist-to-hip circumference ratio was calculated. Blood pressure was measured on the upper right arm by using a mercury column manometer to the nearest 5 mm Hg at 0800 with the patient in a supine position and after the patient had rested for ≥10 min. Measurements were made at each visit under similar conditions. At baseline, 3 mo, and every 12 mo thereafter, blood samples were taken at ≈0800, ≥10 h after the previous meal. Biochemical measurements were done by standard methods in the Department of Clinical Chemistry at University Hospital.

Statistics

Comparisons of baseline values between the 2 groups, within a sex, were calculated by using a two-sample *t* test (12). Values are given as means ± SDs, unless stated otherwise. For phase 1, a linear regression model was fit for percentage weight change and absolute body weight with sex and group as covariates. The sex-by-group interaction was also considered. Treatment group was the only significant predictor of percentage weight change and absolute body weight.

For all secondary outcome variables, a two-sample *t* test was used to compare the 2 groups. A paired *t* test was also used to test whether there were significant changes from baseline to 3 mo for each group within a sex (12).

Generalized estimating equations [GEEs (13, 14)] were used to analyze phase 2 of the study. An unstructured, working corre-

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lation matrix was assumed for the GEE algorithm for all outcomes except percentage weight change, for which a compound, symmetric structure was assumed. GEEs are a method of analyzing longitudinal data that do not rely on distributional assumptions. Furthermore, they give robust estimates of parameters and their SEs. For each outcome of interest, a GEE model was fit with sex, group, time, and baseline outcome as main effects and all interactions between sex, group, and time. All outcomes were measured at 3, 15, and 27 mo with the exception of anthropometric characteristics, which were measured monthly.

Thirty-seven patients did not complete phase 2 of the trial. If these dropouts were informative, then regression estimates may have been biased. Because all patients completed phase 1 of the study, a linear regression model for percentage weight change at 3 mo with sex, group, and dropouts (dropouts are defined as those who did not complete phase 2) as main effects was built. There was no significant difference in weight loss at 3 mo between dropouts and those who completed both phases of the study. Because dropping out did not appear to depend on relative success or failure in phase 1 of the study, the phase 2 analyses were performed on an available case basis.

RESULTS

Fifty patients were randomly assigned to group A (control group) and 50 patients to group B (meal-replacement group). Baseline characteristics of the 100 study patients are given in **Table 1**. There were no significant differences between the 2 groups in sex distribution, age, body weight, or body mass index.

TABLE 1
Clinical characteristics of subjects enrolled in the control group (group A) and the meal-replacement group (group B)[1]

	Group A		Group B	
	Women (n = 41)	Men (n = 9)	Women (n = 38)	Men (n = 12)
Age (y)	46.8 ± 11.2	45.5 ± 12.0	44.3 ± 9.8	46.5 ± 9.5
Body weight (kg)	90.6 ± 9.4	101.7 ± 12.3	89.1 ± 12.1	103.7 ± 12.9
BMI (kg/m^2)	33.9 ± 3.0	33.1 ± 4.1	33.1 ± 4.1	33.0 ± 3.7
Waist-to-hip ratio	0.87 ± 0.09	0.95 ± 0.12	0.86 ± 0.10	0.95 ± 0.09
SBP (mm Hg)	140 ± 14	136 ± 12	137 ± 15	142 ± 14
DBP (mm Hg)	83 ± 7	81 ± 4	81 ± 6	83 ± 5

[1] $\bar{x}$ ± SD. SBP, systolic blood pressure; DBP, diastolic blood pressure. There were no significant differences between groups.

Phase 1

Weight changes

All 100 patients completed phase 1 of the study and body weight was reduced in both groups after 3 mo (**Table 2**). In group A, men lost 1.1 ± 2.6 kg and women lost 1.2 ± 2.1 kg; in group B, men lost 8.4 ± 3.9 kg and women lost 6.8 ± 3.3 kg (two-sample t test). After 3 mo, women in group A and men and women in group B had significantly lower body weights than at baseline ($P < 0.001$). Between-group differences by sex were significant only for women: women in group B lost significantly more weight than did women in group A ($P < 0.001$). The combined mean body weight loss for group A (41 women, 9 men) was 1.3 ± 2.2 kg, whereas that for group B (38 women, 12 men) was 7.1 ± 3.5 kg ($P < 0.001$).

Food diaries

At baseline, reported energy intakes were 7.52 ± 0.85 and 7.59 ± 0.35 MJ/d for groups A and B, respectively. At the end of phase 1, reported energy intakes were 6.96 ± 0.36 and 6.17 ± 0.18 MJ/d. Although there was a trend for decreased energy intake by group and sex, reductions in energy intake were significant only for men in group B.

Baseline fat intakes for groups A and B were 37.6% and 36.0% of energy intake, respectively. At the end of phase 1, estimated fat intake was reduced to 32.9% in group A and 26.4% in group B (both $P < 0.05$).

Biomarkers for disease risk

Changes in key biomarkers for disease risk as they related to changes in body weight for women and men are shown in Table 2. Although body weight loss in women in group A was significant, there were no significant changes in biomarkers with the exception of serum cholesterol, which decreased by 0.2 mmol/L. In contrast, women in group B had a 5-fold greater weight loss than women in group A and showed significant improvements in plasma triacylglycerol, blood glucose, and insulin concentrations.

Men in group A showed no significant changes in weight or biomarkers. Men in group B, on the other hand, experienced significant weight loss and concomitant reductions in plasma triacylglycerol, blood glucose, and insulin concentrations. In addition, both women and men in group B experienced a significant improvement in systolic blood pressure.

Phase 2

Weight changes

During the next 24 mo (phase 2), patient attrition occurred and at the end of this phase 37 patients had dropped out. These patients (19 in group A and 18 in group B) withdrew because of clinical events (n = 6), social or domestic events (n = 7), unwillingness to comply with the protocol (n = 13), or unknown reasons (n = 11). The clinical events were 4 surgical interventions (2 bone fractures, 1 tendon rupture, and 1 inguinal hernia) and 2 infectious diseases (1 respiratory and 1 urinary tract infection).

No reported adverse events were attributable to the dietary regimen. Patient complaints included headache (n = 10), loss of hair (n = 4), abdominal discomfort (diarrhea, gas, and constipation; n = 7), back pain (n = 3), depressed mood (n = 2), cold intolerance (n = 2), and influenza syndrome (n = 32). These complaints were transient.

The mean body weight of the patients remaining at each milestone measurement is reported in **Table 3**. No significant sex differences were found with GEEs; hence, the phase 2 data were combined in Table 3. Both groups experienced additional weight loss over the 24 mo, with time as a significant covariate. In group A, body weight was reduced from 91.4 ± 11.6 to 85.0 ± 11.8 kg and in group B from 85.5 ± 13.4 to 82.2 ± 13.4 kg. On average, both groups lost weight at the rate of 0.07 ± 0.03% ($P < 0.01$) of their initial body weight every month from 3 to 27 mo. For those 63 patients who completed the 27-mo study, this equaled an additional weight loss of 4.2 ± 3.7 kg for group A and 3.0 ± 6.4 kg for group B. There was also a significant group effect ($P < 0.0001$) during phase 2. Group B lost and maintained an average of 5.34% more of their body weight than did group A. There was no group-by-time interaction.

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TABLE 2
Anthropometric and biochemical measurements in obese subjects during phase 1 of treatment with an energy-restricted diet (5.2–6.3 MJ)[1]

	Women		Men	
	Baseline	3 mo	Baseline	3 mo
Body weight (kg)				
Group A	90.6 ± 9.4	89.4 ± 10.4[2]	101.7 ± 12.3	100.5 ± 13.0
Group B	89.1 ± 12.1	82.3 ± 12.0[2,3]	104.1 ± 13.1	95.2 ± 13.1[2]
Waist-to-hip ratio				
Group A	0.87 ± 0.09	0.85 ± 0.13	0.95 ± 0.12	0.95 ± 0.13
Group B	0.86 ± 0.15	0.84 ± 0.13	0.95 ± 0.09	0.93 ± 0.11
SBP (mm Hg)				
Group A	141 ± 16	142 ± 16	136 ± 15	134 ± 14
Group B	139 ± 18	130 ± 14[2,3]	142 ± 15	132 ± 10[2]
DBP (mm Hg)				
Group A	84 ± 8	82 ± 6	82 ± 8	80 ± 4
Group B	82 ± 8	80 ± 5	83 ± 7	82 ± 3
Triacylglycerol (mmol/L)				
Group A	1.96 ± 1.10	1.93 ± 1.10	2.92 ± 2.03	3.16 ± 2.50
Group B	2.00 ± 1.07	1.57 ± 0.74[2]	2.94 ± 1.48	2.29 ± 1.70[2]
Cholesterol (mmol/L)				
Group A	5.97 ± 1.00	5.78 ± 1.01[2]	6.17 ± 0.61	6.12 ± 0.97
Group B	5.75 ± 1.02	5.70 ± 0.94	6.07± 0.97	6.09 ± 0.66
HDL cholesterol (mmol/L)				
Group A	1.33 ± 0.34	1.30 ± 0.30	1.02 ± 0.15	0.96 ± 0.16
Group B	1.40 ± 0.41	1.34 ± 0.46	1.04 ± 0.28	1.15 ± 0.33
Blood glucose (mmol/L)				
Group A	5.05 ± 0.78	5.08 ± 0.77	5.01 ± 1.05	5.06 ± 0.88
Group B	4.96 ± 0.28	4.55 ± 0.69[2,3]	5.11 ± 1.02	4.74 ± 0.99[2]
Insulin (pmol/L)				
Group A	129.5 ± 45.8	128.6 ± 59.7	172.3 ± 60.3	171.6 ± 65.9
Group B	128.5 ± 51.7	78.9 ± 23.4[2,3]	143.5 ± 53.6	100.8 ± 34.9[2,3]

[1] $\bar{x}$ ± SD. Group A: n = 41 F, 9 M; group B: n = 38 F, 12 M. Group A received the energy-restricted diet only; group B received the energy-restricted diet with 2 meals and 2 snacks replaced by energy-controlled, nutrient-dense meal-replacement products. SBP, systolic blood pressure; DBP, diastolic blood pressure.

[2] Significantly different from baseline, $P < 0.001$ (paired t test).

[3] Significantly different from group A, $P < 0.001$ (two-sample t test).

Food diaries

Energy intakes in group A were 7.15 ± 0.48 MJ/d at 3 mo, 6.50 ± 0.42 MJ/d at 15 mo, and 6.72 ± 0.35 MJ/d at 27 mo. Energy intakes in group B also changed little during this period: 5.96 ± 0.27 MJ/d at 3 mo, 6.28 ± 0.36 MJ/d at 15 mo, and 6.60 ± 0.29 MJ/d at 27 mo.

Biomarkers for disease risk

Changes in important biomarkers for disease risk as they related to changes in body weight during phase 2 are shown in Table 3. The results are reported for baseline and 3, 15, and 27 mo. With use of GEEs (13, 14), further decreases in systolic and diastolic blood pressure were noted during phase 2 in both groups; group B had significantly lower blood pressure than did group A at baseline ($P < 0.001$).

Serum triacylglycerol concentrations decreased significantly over time in both groups ($P < 0.01$). Values in group A fell from 2.13 ± 1.34 mmol/L at baseline to 1.77 ± 0.62 mmol/L at 27 mo. Values in group B were 2.23 ± 1.24 and 1.40 ± 0.49 mmol/L at the same time points. Significant group effects were apparent and may have been related to the degree of weight loss. Total serum cholesterol decreased similarly over time in both groups. There were no significant changes in concentrations of HDL cholesterol.

In group B, insulin concentrations did not change significantly after the initial weight-loss phase, whereas in group A, insulin concentrations decreased at 12 mo and remained unchanged for the balance of the study. By 27 mo, GEEs showed that blood glucose concentrations in groups A and B had decreased by an average of 0.56 and 0.59 mmol/L ($P < 0.001$).

Phase 1 and phase 2 percentage weight changes

Weight-loss data were analyzed as a percentage of initial body weight on an available case basis (**Figure 1**). Expressed in this manner, there were no differences by sex. After 3 mo, there was a 1.5 ± 2.6% decrease in group A and a 7.8 ± 3.7% decrease in group B; this difference between groups was highly significant ($P < 0.001$, Figure 1, months 0–3). At 15 mo (12 mo of phase 2), group A had lost 3.9 ± 5.5% of their original weight and group B had lost 9.5 ± 5.6%. The total percentage loss by the end of the study (phases 1 and 2) was 5.9 ± 5.0% for group A and 11.3 ± 6.8% for group B. According to the percentage of total weight lost, 7 of 50 patients (14%) in group A and 21 of 50 patients (42%) in group B had reduced their body weight by >10% of their initial weight.

DISCUSSION

In this study, we compared energy-controlled meal and snack replacements with a standard weight-loss diet for 3 mo (Table 2). During the subsequent 24 mo, daily meal replacements were

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TABLE 3
Anthropometric and biochemical measurements for phase 1 and phase 2 of treatment with an energy-restricted diet (5.2–6.3 MJ)[1]

	Phase 1		Phase 2	
	Baseline (n = 100)	3 mo (n = 100)	15 mo (n = 78)	27 mo (n = 63)
Body weight (kg)[2,3]				
Group A	92.7 ± 10.8	91.4 ± 11.6	87.5 ± 12.1	85.0 ± 11.8
Group B	92.6 ± 13.7	85.5 ± 13.4	84.3 ± 13.8	82.2 ± 13.4
Waist-to-hip ratio				
Group A	0.90 ± 0.10	0.86 ± 0.21	0.85 ± 0.24	0.84 ± 0.18
Group B	0.89 ± 0.12	0.86 ± 0.18	0.85 ± 0.20	0.85 ± 0.19
SBP (mm Hg)[2,3]				
Group A	140 ± 14	141 ± 16	135 ± 12	138 ± 13
Group B	139 ± 15	130 ± 13	123 ± 11	124 ± 12
DBP (mm Hg)[4]				
Group A	83 ± 6	82 ± 5	78 ± 5	80 ± 6
Group B	82 ± 6	80 ± 5	76 ± 5	78 ± 5
Triacylglycerol (mmol/L)[2,3]				
Group A	2.13 ± 1.34	2.15 ± 1.50	1.65 ± 0.53	1.77 ± 0.62
Group B	2.23 ± 1.24	1.75 ± 1.09	1.58 ± 0.41	1.40 ± 0.49
Cholesterol (mmol/L)[3,5]				
Group A	6.01 ± 0.94	5.84 ± 1.00	5.45 ± 0.93	5.69 ± 0.60
Group B	5.83 ± 1.01	5.79 ± 0.89	5.51 ± 0.53	5.35 ± 0.95
HDL cholesterol (mmol/L)				
Group A	1.27 ± 0.33	1.24 ± 0.31	1.24 ± 0.26	1.18 ± 0.17
Group B	1.31 ± 0.41	1.30 ± 0.44	1.24 ± 0.30	1.39 ± 0.77
Glucose (mmol/L)[2,3]				
Group A	5.05 ± 0.85	5.07 ± 0.79	4.55 ± 0.40	4.52 ± 0.42
Group B	4.97 ± 0.87	4.58 ± 0.74	4.75 ± 0.63	4.40 ± 0.39
Insulin (pmol/L)[3,5,6]				
Group A	134.6 ± 50.4	139.1 ± 63.2	93.1 ± 28.4	98.8 ± 30.0
Group B	132.0 ± 53.1	84.9 ± 30.4	96.2 ± 48.0	81.8 ± 30.2

[1] $\bar{x}$ ± SD. SBP, systolic blood pressure; DBP, diastolic blood pressure. During phase 1, group A received the energy-restricted diet only and group B received the energy-restricted diet with 2 meals and 2 snacks replaced by energy-controlled, nutrient-dense meal-replacement products; during phase 2, both groups received the energy-restricted diet and 1 meal and 1 snack were replaced by energy-controlled, nutrient-dense meal-replacement products.
[2] Significant treatment effect based on the generalized estimating equation, $P < 0.01$.
[3] Significant time effect based on the generalized estimating equation, $P < 0.01$.
[4] Significant sex-by-group interaction, $P < 0.01$.
[5] Significant group-by-time interaction, $P < 0.01$.
[6] Significant sex-by-time interaction, $P < 0.01$.

evaluated in all patients for maintenance of weight loss (Figure 1). Changes in weight and biomarkers of disease risk were measured throughout the 27-mo study (Table 3).

The first 3 mo (phase 1) was a prospective, randomized, parallel intervention study in which patients in both the control group (group A) and meal-replacement group (group B) lost weight. Although the same energy intake was prescribed in both groups, group B lost significantly more weight. There were no dropouts during phase 1, an unusual finding in most weight-loss studies. Weekly visits to the clinic and excellent support from the clinical staff may have played a contributory role in this zero dropout rate. Heber et al (10), in a study using minimal intervention with the same meal replacements and diet strategy as in the present study, found a high approval rating for appetite satisfaction (≥78%) and taste (≥96%). These factors may have played a similar role in the present study.

During phase 2, all patients were prescribed the same diet of one meal replacement and one nutrition bar as a snack; the original randomization was maintained for reporting the results. In both groups, the average weight lost was maintained, with additional losses over the next 2 y (Figure 1). Although weight loss in group B was greater than in group A during phase 1, the rate of weight loss between the groups was not significantly different during phase 2. Once the meal-replacement therapy was initiated, group A patients experienced an average weight loss of 3.8 ± 5.0% of their initial body weight after 15 mo and 4.7 ± 5.5% by the end of the study (Figure 1). Percentage weight losses at comparable time points for group B were 8.5 ± 6.1% and 9.4 ± 7.1%. Because both patient groups were provided the same meal-replacement therapy and dietary guidelines during phase 2, the lack of significant difference in the rate of weight loss was expected.

Seven-day food diaries showed a decline in energy intake from baseline, with the greatest decline observed in group B during phase 1. However, when the diary data were compared with change in body weight, it appeared that patients reported less than they consumed. Furthermore, they became less compliant in accurate reporting of food consumption as the study progressed. This tendency to underreport food intake has been documented by other investigators involved in dietary intervention studies (15, 16). For this reason, body weight loss and the link between this and changes in biomarkers was emphasized rather than the report of dietary intake.

Several biomarkers of disease risk were monitored throughout the 27-mo study and links were observed between weight loss and

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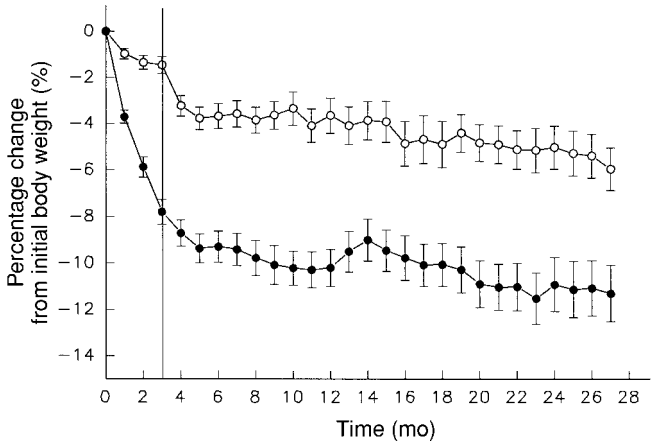

FIGURE 1. Mean (±SEM) percentage change from initial body weight in obese patients during 27 mo of treatment with an energy-restricted diet containing 5.2–6.3 MJ/d. Data were analyzed on an available case basis. During the first 3 mo (phase 1), patients were randomly assigned to receive the energy-restricted diet only (group A, ○) or to receive the energy-restricted diet with 2 meals and 2 snacks replaced by energy-controlled, nutrient-dense meal-replacement products (group B, ●). During the next 24 mo (phase 2), all patients received the energy-restricted diet and 1 meal and 1 snack were replaced by energy-controlled, nutrient-dense meal-replacement products.

improvement in biomarker values. During phase 1, patients in group A showed no significant improvement in the measured biomarkers, but did show subsequent improvement with further weight loss (Tables 2 and 3). Group B sustained improvements in biomarkers throughout the 27-mo study period. In a similar study, patients lost an average of 7.5 kg in 12 wk without experiencing significant changes in their lipid profiles (10). However, these patients weighed less at the start of the intervention and had plasma lipid concentrations within the normal range. The lack of elevated plasma lipids might explain the difference in responses between the study by Heber et al (10) and the present one.

In longitudinal clinical trials, dropouts are cause for concern because they may bias the interpretation of study results. To reduce the likelihood of bias while maximizing the data available, we analyzed weight changes at 3 mo and showed that there was no significant difference in body weight losses or percentage weight-loss data between the patients who dropped out and those who completed the full 2-y study. Hence, the phase 2 data were analyzed on an available case basis. Because the test of dropouts versus those who completed the study was performed with the 3-mo data, it is possible that the patients who dropped out of the study during the following 2 y might be informative. This is highly unlikely, however, because the reasons for patients dropping out of the study did not appear to be related to poor weight control performance.

The most relevant finding was the significant improvement in biomarkers of disease risk with the sustained reduction in body weight over a 27-mo period. This study supports previous findings (17–23) that a modest, sustained weight loss can have long-term health benefits as measured by improvements in biomarkers of disease risk. This dietary intervention, which lasted 2 y, gave results comparable with drug treatment (24–26) but without the adverse events and with only minimal, transient gastrointestinal side effects. In addition, the 8% weight-loss standard, recently established for dietary management of obesity with low-energy diets (27), was attained in the group receiving the meal replacements for the full 27 mo of this study.

It is often difficult to select and prepare energy-restricted diets for long-term weight control that include all of the required nutrients at recommended intakes. The use of meal replacements coupled with a variety of low-fat foods for a sensible food plan may have helped our patients adhere to the energy-reduced diet. This strategy not only promotes versatility but also supports the continuation of healthy eating patterns, which is necessary for permanent lifestyle changes. Other benefits of the meal replacements cited by Heber et al (10) include convenience, low cost, and the relatively minimal time needed for professional intervention. In conclusion, long-term dietary interventions in obese patients that include the use of nutrient-dense meal-replacement products were effective in improving long-term weight control in addition to blood pressure and metabolic biomarkers of comorbid disease.

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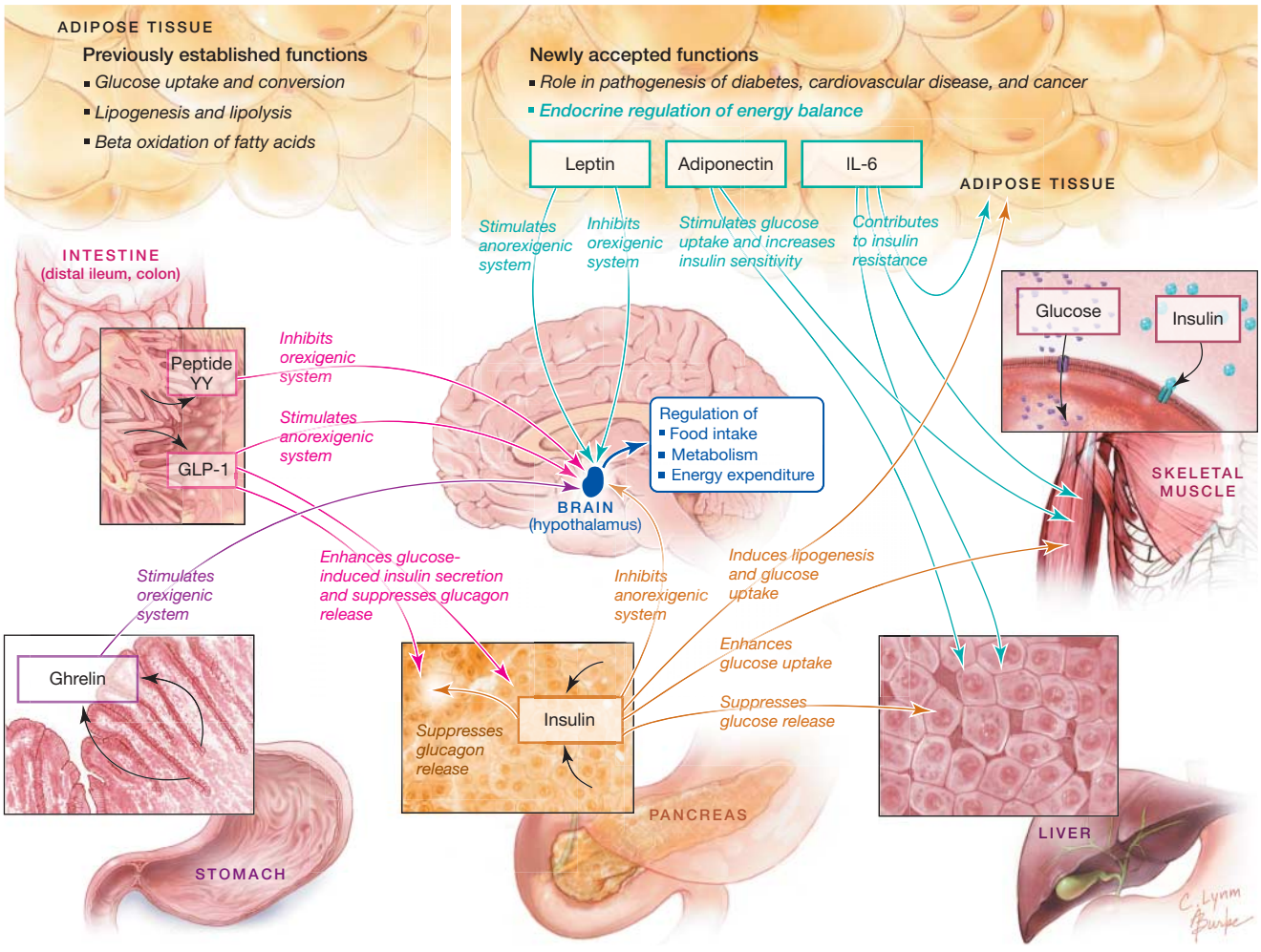
AT FIRST SIGHT, THE ADIPOCYTE APPEARS TO BE FULLY occupied by a droplet of fat. It is difficult even to see the nucleus or any other structure responsible for the metabolic activity of cells, let alone to suggest that the adipocyte is a professional secretory cell. This benign appearance misled investigators for decades into believing that fat cells were passive storage organs that simply esterify dietary lipids upon consumption of a meal and release free fatty acids upon fasting. Over the past decade, it has become apparent that fat cells are metabolically much more active than anticipated. While the role of the adipocyte in postprandial glucose disposal is well understood, its roles in lipogenesis, glyceroneogenesis, and mitochondrial beta oxidation are increasingly appreciated. Adipose tissue is an important endocrine tissue intricately involved in the regulation of energy balance, as well as in the pathogenesis of diabetes, cardiovascular disease, and cancer, through its ability to sequester potentially toxic lipid species and to secrete a vast array of lipid and hormonal products (referred to as adipokines). This week's cover and cover story figure feature the special role of adipose tissue among the complex relationships involved in the network of energy balance.

Leptin is secreted from fat proportionate to the amount of lipids contained in an adipocyte. For unknown reasons, more leptin is secreted from women's fat cells than from men's, given the same amount of lipid content. Secreted leptin enters the brain (especially the hypothala-



Neuroendocrine and Endocrine Pathways of Obesity. Once a cell thought to be a simple, passive storehouse for lipids, the adipocyte is now known to be marvelously complex. It senses the body's energy state and sends signals to many organs, coordinating their function. The solution for the obesity epidemic might lie in better understanding adipocyte biology.

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mus), where it acts on several groups of nerve cell groups to regulate a number of physiologic processes. Leptin activates some neurons and inhibits other classes of neurons to inhibit food intake, to promote an enhanced metabolic rate and energy expenditure, and to regulate the levels of glucose and insulin in the blood. Leptin levels decline during fasting, and leptin deficiency induces a characteristic set of starvation responses that include increased appetite and reduced energy expenditure. Obese individuals have high leptin levels; thus, leptin deficiency is not a cause of obesity in the vast majority of humans. On the contrary, obesity is thought to induce leptin "resistance" in the brain, which means that the signals conveyed by increasing leptin levels to reduce food intake and body weight are no longer heard at the level of these key neuronal groups in the brain.

Adiponectin is also secreted by adipose tissue, but, in contrast to leptin, adiponectin levels decline with increasing obesity. This is especially true for central obesity, which is associated with lower levels of adiponectin than is observed for peripheral obesity. Many positive metabolic aspects have been attributed to adiponectin, which is widely appreciated as a hepatic insulin sensitizer, an anti-inflammatory factor, as well as a potent cytoprotective factor for cardiac myocytes and pancreatic beta cells.

Another adipokine is interleukin 6 (IL-6), which is secreted by fat cells in proportion to the amount of fat. Tissue macrophages in adipose tissue also contribute to the local increase in IL-6 levels. Beyond its immune modulatory role, IL-6 can directly cause insulin resistance by interfering with insulin receptor signal transduction. Visceral adipose tissue–derived IL-6 is directly released into the portal vein and potently drives production of C-reactive protein in the liver.

Glucagon-like peptide-1 (GLP-1), produced in ileal L-cells in the gut, exerts important effects on pancreatic beta cells by enhancing glucose-induced insulin secretion, while suppressing glucagon release in alpha cells. It acts on many additional organs, including the brain, where it induces a reduction in food intake.

Insulin exerts its effects on muscle and adipocytes by enhancing glucose disposal to these tissues and by suppressing hepatic glucose release. Effects in these cells are not only achieved through direct insulin signaling in these tissues, but are also mediated in part by insulin action on the brain. This action is thought to play a key role in regulating whole-body glucose homeostasis. An additional very important function of insulin is related to its paracrine effects on alpha cells in the pancreas, in which insulin potently suppresses glucagon release. Glucagon stimulates glucose secretion from the hepatocyte, and it is thought that an important consequence of loss of insulin production relates to unopposed glucagon action under these conditions that leads to hyperglycemic excursions.

Ghrelin is secreted by cells in the stomach. Ghrelin levels increase following fasting and prior to meals. When a person is eating, ghrelin levels decline. Ghrelin stimulates food intake by acting on neurons in the brain, including the AgRP/NPY neurons in the hypothalamus.

One key site in the brain that regulates food intake is the hypothalamus. Several nerve cell groups (called nuclei) in the hypothalamus regulate food intake and energy expenditure (ie, metabolic rate). Included in these are groups of neurons called POMC (pro-opiomelanocortin) neurons. POMC neurons are the prototypical anorexigenic neurons and secrete neuropeptides that activate melanocortin receptors to inhibit food intake and regulate insulin levels in the blood and glucose production in the liver. In contrast, neurons that produce neuropeptide Y and AgRP are located next to the POMC neurons. These neurons are the prototypical orexigenic neurons and block the actions of POMC neurons at downstream neurons expressing melanocortin receptors. Both sets of these neurons are direct targets of leptin and neurotransmitters like serotonin that regulate feeding. The latter point is important because the mechanism of locaserin (an antiobesity drug recently approved by the Food and Drug Administration) for inhibiting food intake and reducing body weight is based on its ability to activate serotonin receptors including those expressed by POMC neurons.

Eating is essential for preservation of life. Consequently, systems regulating energy balance and food ingestion are highly regulated and interconnected. Solutions for the current obesity epidemic will arise once we better understand energy balance and how it has become disordered by the modern, 21st-century environment.

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RESEARCH
Review

Lifestyle Weight-Loss Intervention Outcomes in Overweight and Obese Adults with Type 2 Diabetes: A Systematic Review and Meta-Analysis of Randomized Clinical Trials

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ABSTRACT

The majority of people with type 2 diabetes are overweight or obese, and weight loss is a recommended treatment strategy. A systematic review and meta-analysis was undertaken to answer the following primary question: In overweight or obese adults with type 2 diabetes, what are the outcomes on hemoglobin A1c (HbA1c) from lifestyle weight-loss interventions resulting in weight losses greater than or less than 5% at 12 months? Secondary questions are: What are the lipid (total cholesterol, low-density lipoprotein cholesterol, high-density lipoprotein cholesterol, and triglycerides) and blood pressure (systolic and diastolic) outcomes from lifestyle weight-loss interventions resulting in weight losses greater than or less than 5% at 12 months? And, what are the weight and metabolic outcomes from differing amounts of macronutrients in weight-loss interventions? Inclusion criteria included randomized clinical trial implementing weight-loss interventions in overweight or obese adults with type 2 diabetes, minimum 12-month study duration, a 70% completion rate, and an HbA1c value reported at 12 months. Eleven trials (eight compared two weight-loss interventions and three compared a weight-loss intervention group with a usual care/control group) with 6,754 participants met study criteria. At 12 months, 17 study groups (8 categories of weight-loss intervention) reported weight loss <5% of initial weight (−3.2 kg [95% CI: −5.9, −0.6]). A meta-analysis of the weight-loss interventions reported nonsignificant beneficial effects on HbA1c, lipids, or blood pressure. Two study groups reported a weight loss of ≥5%: a Mediterranean-style diet implemented in newly diagnosed adults with type 2 diabetes and an intensive lifestyle intervention implemented in the Look AHEAD (Action for Health in Diabetes) trial. Both included regular physical activity and frequent contact with health professionals and reported significant beneficial effects on HbA1c, lipids, and blood pressure. Five trials (10 study groups) compared weight-loss interventions of differing amounts of macronutrients and reported nonsignificant differences in weight loss, HbA1c, lipids, and blood pressure. The majority of lifestyle weight-loss interventions in overweight or obese adults with type 2 diabetes resulted in weight loss <5% and did not result in beneficial metabolic outcomes. A weight loss of >5% appears necessary for beneficial effects on HbA1c, lipids, and blood pressure. Achieving this level of weight loss requires intense interventions, including energy restriction, regular physical activity, and frequent contact with health professionals. Weight loss for many overweight or obese individuals with type 2 diabetes might not be a realistic primary treatment strategy for improved glycemic control. Nutrition therapy for individuals with type 2 diabetes should encourage a healthful eating pattern, a reduced energy intake, regular physical activity, education, and support as primary treatment strategies.
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TYPE 2 DIABETES AFFECTS APPROXIMATELY 11% OF US adults and 8% of adults worldwide[1,2]; an additional 37% of US adults have prediabetes (51% of those aged 65 years or older).[1] For both conditions, overweight and obesity are major risk factors.[3] Professional organizations and medical care providers recommend weight loss as a primary strategy for glycemic control. For example, the

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American Diabetes Association recommends weight loss for all overweight or obese individuals who have or are at risk for diabetes.[3] Weight-loss therapies include lifestyle interventions (eg, nutrition therapy, increased physical activity, education, and support), weight-loss medications, and bariatric surgery. For individuals with prediabetes, strong evidence exists for the benefits of modest weight loss, regular physical activity, and continued education and support for the prevention or delay of type 2 diabetes.[4] In those with newly diagnosed type 2 diabetes, a large retrospective cohort study also found that individuals who lost approximately 10% of their body weight after diabetes diagnosis were more likely to achieve glycemic control and blood pressure targets, despite weight regain, 4 years later compared with individuals with stable or weight gain trajectories.[5] However, the feasibility and health benefits of weight loss greater than or less than 5% in overweight or obese individuals with type 2 diabetes are unclear. Unanswered are questions about the amount of weight loss needed to achieve beneficial outcomes, achievability of needed weight loss, and types of weight-loss interventions that result in beneficial outcomes on hemoglobin A1c (HbA1c), lipids, and blood pressure. The ideal macronutrient composition of weight-loss interventions is also controversial.

The 2013 American Heart Association/American College of Cardiology/The Obesity Society Guideline for the Management of Overweight and Obesity reported that in overweight and obese adults with type 2 diabetes, a 2% to 5% weight loss from lifestyle interventions results in lowering of HbA1c by 0.2% to 0.3% and that weight loss of 5% to 10% is associated with HbA1c reductions of 0.6% to 1.0%.[6] This summary of weight-loss benefits in individuals with type 2 diabetes was based on a 2004 systematic review[7] and a Norris and colleagues 2005 Cochrane Review and meta-analysis[8,9] of weight-loss intervention studies in adults with type 2 diabetes with a follow-up of 1 to 5 years, as well as 1- and 4-year results of the Look AHEAD (Action for Health in Diabetes) trial.[10,11] All but two of the weight-loss studies in the reviews and meta-analysis were published before 2000; therefore, an update on this data is important, which is undertaken in this review and meta-analysis.

Randomized clinical trials and observational studies have shown that medical nutrition therapy for type 2 diabetes effectively improves glycemic control as well as other metabolic outcomes.[12] However, weight loss is not the primary goal of the nutrition therapy interventions in these studies, although it is sometimes reported. In individuals with type 2 diabetes, a variety of nutrition therapy interventions resulted in positive metabolic outcomes, with a common focus of the interventions being a reduced energy intake.[12] However, as the disease progresses and insulin deficiency becomes more prominent, glucose-lowering medications, including insulin, generally need to be added to nutrition therapy to achieve desired glycemic control. At this point, prevention of weight gain, rather than weight loss, often becomes a goal of nutrition therapy.

Registered dietitian nutritionists and medical care professionals routinely provide weight-loss advice to overweight and obese adults with diabetes. There remain uncertainties, however, regarding benefits from various lifestyle weight-loss intervention on improving glycemic control and other metabolic outcomes. Therefore, a systematic review and meta-analysis was undertaken to determine the role of lifestyle weight-loss intervention in nutrition therapy for type 2 diabetes. The primary question was: In overweight or obese adults with type 2 diabetes, what are the outcomes on HbA1c from lifestyle weight-loss intervention resulting in weight losses greater than or less than 5% at 12 months? Secondary questions are: What are the lipid (total cholesterol, LDL-cholesterol [LDL-C], HDL-cholesterol [HDL-C], and triglycerides [TG]) and blood pressure (systolic [SBP] and diastolic [DBP]) outcomes from weight-loss intervention resulting in weight losses greater than or less than 5% at 12 months? And, what are the weight and metabolic outcomes from differing amounts of macronutrients in lifestyle weight-loss intervention in individuals with type 2 diabetes?

RESEARCH DESIGN AND METHODS

Literature Search and Inclusion Criteria

The PubMed online database and Cochrane Library, along with the references of selected articles, were searched to retrieve related abstracts. Medical subject headings used in the online search included “Diabetes Mellitus, Type 2” and “Weight Loss” and “Randomized Clinical Trial” (publication type) and (“2000/01/01” [publication date]: “2014/03/01” [publication date]) and English [language]. As noted, articles were reviewed from January 1, 2000 to March 1, 2014. The year 2000 was selected to begin the search as studies published before that date are included in the 2013 American Heart Association/American College of Cardiology/The Obesity Society Guideline for the Management of Overweight and Obesity in Adults.[6] Study inclusion criteria were the following: a randomized clinical trial $\geq$1 year in duration; lifestyle weight-loss intervention implemented in overweight or obese adults with type 2 diabetes; program completion rate of $\geq$70%; and a 1-year HbA1c value reported. Only studies using lifestyle interventions (ie, diet and/or physical activity) were included, as they are the primary therapies recommended for weight loss in individuals with diabetes. Trials using weight-loss medications or bariatric surgery were not included. The review protocol was not registered. All studies initially identified from the database search were screened by reviewing the abstract. Studies that did not meet all eligibility criteria after review of the abstract or full-text were excluded from additional consideration in this review. From title and abstract analysis, 51 articles were selected for detailed review. After the analysis of the articles, 40 were excluded because they did not meet all of the study criteria (Figure 1).

Data Extraction

Two reviewers independently abstracted relevant data from the full-text articles of studies meeting all study criteria. The original study authors were contacted for additional information where needed in two studies. Changes from participants’ mean baseline data to 12 months from weight-loss intervention study groups on study outcomes were assessed. The primary end points were the weighted mean differences in weight loss, both actual (kilograms) and percentage of weight loss, from the weight-loss interventions and resulting effect on HbA1c. Secondary end points were the weighted mean differences on blood lipid

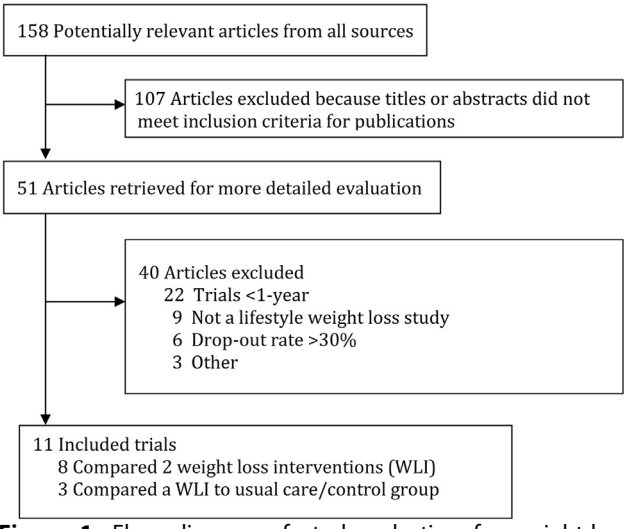

Figure 1. Flow diagram of study selection for weight-loss intervention clinical trials in overweight/obese adults with type 2 diabetes.

levels (total cholesterol [TC], LDL-C, HDL-C, and TG) and blood pressure (SPB and DBP) also from baseline to 12 months from lifestyle weight-loss intervention study groups. Weight-loss interventions implementing differing macronutrient compositions and their weighted mean differences in weight loss and HbA1c outcomes were also secondary end points. Study-specific macronutrients were described qualitatively.

Studies were broken down by weight-loss intervention and resulting mean weight loss in kilograms and percentages and mean change in HbA1c. Weight-loss trials were divided into studies with <5% mean weight loss at 12 months, studies with ≥5% weight loss at 12 months, and usual care/control studies. Data were pooled from study groups in similar categories of weight-loss intervention. For weight-loss intervention studies comparing differing macronutrient compositions data were extracted on reported mean percentages of macronutrient intake, reported mean daily calorie intake and mean daily calorie deficit, mean weight loss (kilograms and percentages), and mean changes in HbA1c, lipids, and blood pressure at 12 months. Given that all studies in this review were randomized controlled trials with similar populations and of similar duration, a formal assessment of bias using an evidence grading system was not used. Study quality is discussed in general terms in the Discussion section.

Statistical Analysis

Meta-analyses were performed using PROC MIXED in SAS 9.3 (SAS Institute, Inc). Each study group of a given trial was treated as a random effect to account for heterogeneity of study populations. Study variances were supplied under the PARMS statement. Forest plots were developed in Microsoft Excel.[13] Effect sizes were estimated for 12-month changes in weight, HbA1c, TC, LDL-C, HDL-C, TG, SBP, and DBP by weight loss category. Similarly, effect sizes were estimated by macronutrient composition for changes in weight and HbA1c.

RESULTS

Literature Search and Study Characteristics

The literature review identified 158 citations for screening. Of these, 51 articles were reviewed with 40 excluded because they did not meet study eligibility criteria. Thirty-one did not meet the criteria for study length, completion rate, study design, or 12-month laboratory data being reported; 6 involved weight-loss drug therapy and 3 bariatric surgery. Eleven randomized clinical trials with a completion rate of ≥70% and 12-month HbA1c outcomes data (Figure 1) fulfilled all eligibility criteria.[10,14-23]

Mean baseline data for study participants, weight-loss intervention interventions, mean weight loss (kilograms and percentages), baseline and mean HbA1c outcomes, and group (<5% or ≥5% weight loss at 12 months or control/usual care) are summarized in Table 1. Across the 11 weight-loss intervention studies (22 study groups), there were 6,754 participants. Nine studies (17 study groups) with 1,365 participants reported weight loss <5% of baseline weight[14-23]; two trials (two study groups) with 2,678 participants reported weight loss ≥5% of baseline weight[10,20]; and 2,711 participants were in the usual care/control study groups (three trials, three study groups).[10,14,15] The mean baseline weight of participants with weight losses <5% was 98.4 kg (range=85.7 to 107.1 kg), for participants with weight losses ≥5% 99.9 kg (range=86 to 100.5 kg), and for participants in the usual care/control study groups 100.6 kg (range=96 to 106.7 kg).

Three of the 11 studies compared a weight-loss intervention with a usual care/control group[10,14,15] and eight of the studies compared two different weight-loss interventions,[16-23] resulting in a total of 19 weight-loss intervention study groups (Table 1). The authors identified 10 categories of weight-loss intervention that were implemented in the 19 weight-loss intervention study groups: meal replacements used for two or more meals per day and as an adjunct to a reduced-energy diet[14,16]; reduced energy intake to achieve a 5% weight loss or a recommended daily caloric deficit of 500 kcal below estimated caloric needs[15,16]; group behavioral weight-management focusing on changes in lifestyle with a strong emphasis on goal setting and problem solving[17]; high-carbohydrate diets with >55% of recommended energy intake from carbohydrate[18,21,22]; low-carbohydrate diets with ≤25% of recommended energy intake from carbohydrate[19,23]; low-fat diets with <30% of recommended energy intake from fat[19,20,23]; high-monounsaturated fat diet with 20% of recommended energy intake from monounsaturated fat[18]; high-protein diets with 30% of recommended energy intake from protein[21,22]; Mediterranean-style diet rich in vegetables, whole grains, olive oil, and energy intake restricted to 1,500 kcal/day for women and 1,800 kcal/day for men, and 150 minutes of weekly physical activity[20]; and intensive lifestyle intervention in which meal replacements or structured food plan and 175 minutes of weekly physical activity were prescribed and participants received frequent follow-up and support using a variety of contact methods.[10,11]

Participants in 7 of the 11 trials reported actual food intake through the use of food records, primarily 3-day food diaries.[14,18-23] Actual food intakes were not reported in three studies.[15-17] Participants in the Look AHEAD trial completed a questionnaire at years 1 and 4 that included

Table 1. Overweight/obese adults with type 2 diabetes lifestyle weight-loss intervention studies[a]

Author(s), year	Subjects enrolled (n [%] of completers)	Mean baseline weight (kg)	Mean baseline age (y)	Sex (% male)	Weight-loss interventions	Mean kg Weight Loss (%)			Hemoglobin A1c (%)		
						6 mo	12 mo	Final or 4 y	Mean baseline	12 mo % change	Final or 4-y % Change
Study groups with <5% weight loss at 12 mo											
Meal replacements											
Metz and colleagues, 2000[14]	56 (41 [80])	96	54.6±9.0[b]	45	Meal replacements (prepared meal plan)	5.5±6.4[b] (5.7)	3.0±5.4[b] (3.1)		8.8±1.4[b]	−0.2±1.5[b]	
Li and colleagues, 2005[16]	52 (46 [88])	93	54.4±9.3[b]	59	Soy-based meal replacement	5.3±0.6[c] (5.6)	4.4±0.8[c] (4.7)		7.6±1.4[c]	−0.3	
Pooled data	108 (87 [81])					5.4 (5.7)	3.7 (3.9)				
Reduced energy intake											
Wolf and colleagues, 2004[15]	73 (54 [74])	107.1±25.5[b]	53.3±8.6[b]	38	Individualized meal plan; weight loss goal 5% of initial weight	4.0 (5.6 to 2.5)[d] (3.7)	2.4 (4.1 to 0.6)[d] (2.2)		7.9±1.6[c]	−0.2±1.4[c]	
Li and colleagues, 2005[16]	52 (36 [70])	93	56.6±10.4[b]	67	Daily caloric deficit of 500 kcal/day of estimated calorie needs	2.9±0.7[c] (3.1)	2.4±0.8[c] (2.5)		7.5±1.7[c]	−0.2	
Pooled data	125 (90 [72])					3.6 (3.4)	2.4 (2.3)				
Group behavioral weight management											
West and colleagues, 2007[17]	109 (103 [94])	97±17[b]	54±10[b]	0	Group behavioral weight management	4.7±0.5[c] (4.8)	4.8±0.6[c] (4.9)	18 mo 3.5±0.6[c] (3.6)	7.5±1.4[c]	−0.6±0.1[c]	18 mo −0.1±0.1[c]
West and colleagues, 2007[17]	108 (99 [92])	97±16[b]	52±10[b]	0	Group behavioral weight management plus motivational interviewing	3.1±0.5[c] (3.1)	2.7±0.6[c] (2.7)	18 mo 1.7±0.6[c] (1.7)	7.6±1.4[c]	−0.4±0.0[c]	18 mo −0.2±0.1[c]
Pooled data	217 (202 [93])					3.7 (4.0)	3.8 (3.9)				
High CHO,[e] ≥55% of kcal from CHO											
Brehm and colleagues, 2009[18]	62 (52 [85])	102.1±2.0[c]	56.5±0.8[c]	37	60% CHO, 15% protein, 25% fat; 200 to 300 kcal/day less than daily kcal requirements	3.8±2.0[c] (3.7)	3.8±0.6[c] (3.7)		7.2±0.1[c]	−0	18 mo (−0)
Larsen and colleagues, 2011[21]	46 (44 [96])	95.5 (91.5-99.6)[d]	56.8 (55.8-61.7)[d]	39	55% CHO, 15% protein, 30% fat; 30% energy restriction for 3 mo followed by 9 mo energy balance	3.1 (3.2)	2.2±4.3[b] (2.3)		7.8±0.6[b]	−0.3±1.0[b]	

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Table 1. Overweight/obese adults with type 2 diabetes lifestyle weight-loss intervention studies[a] (*continued*)

Author(s), year	Subjects enrolled (n [%] of completers)	Mean baseline weight (kg)	Mean baseline age (y)	Sex (% male)	Weight-loss interventions	Mean kg Weight Loss (%)			Hemoglobin A1c (%)		
						6 mo	12 mo	Final or 4 y	Mean baseline	12 mo % change	Final or 4-y % Change
Study groups with <5% weight loss at 12 mo											
Krebs and colleagues, 2012[22]	212 (150 [71])	101.9±20.1[b]	58.0±9.2[b]	34	55% CHO, 15% protein, 30% fat; energy intake reduced by 500 kcal/day	3.2 (3.1)	2.4±6.6[b] (2.3)	2 y 2.9 (2.8)	8.0±1.2[b]	−0.2	2 y ↑0.1
Pooled data	320 (246 [77])					3.3 (3.2)	2.6 (2.6)				
Low-CHO, ≤25% of kcal from CHO											
Davis and colleagues, 2009[19]	55 (45 [82])	93.6±18[b]	54±6[b]	18	20 to 25 g daily CHO for 2 weeks; Atkins diet thereafter	4.8±3.5[b] (5.1)	3.1±4.8[b] (3.3)		7.5±1.5[b]	−0.0±0.9[b]	
Guldbrand and colleagues, 2012[23]	30 (26 [87])	91.4±19[b]	61.2±9.5[b]	47	20% CHO, 30% protein, 50% fat; 1,600 kcal/day for women, 1,800 kcal/day for men	3.9 (4.3)	1.9±2.0[b]	2 y 2.0 (2.2)	7.5±3.1[b]	−0.2	2 y −0
Pooled data	85 (71 [84])					4.4 (4.7)	2.6 (2.8)				
Low-fat, <30% kcal from fat											
Davis and colleagues, 2009[19]	50 (40 [80])	101±19[b]	53±7[b]	26	25% fat; modeled after the Diabetes Prevention Program	4.4±5.3[b] (4.4)	3.1±5.8[b] (3.0)		7.4±1.4[b]	↑0.2±1.4[b]	
Esposito and colleagues, 2009[20]	107 (97 [91])	85.7±9.9[b]	51.9±10.7[b]	49	<30% fat; based on American Heart Association guidelines; 1,500 kcal/day for women and 1,800 kcal/day for men; physical activity goal of 175 min/wk	Not reported	4.2±3.5[b] (4.9)	4 y 3.2±1.9[b] (3.7)	7.8±0.0[b]	−0.6±0.6[b]	4 y −0.5±0.4[g]
Guldbrand and colleagues, 2012[23]	31 (28 [90])	98.8±2.1[b]	62.7±11[b]	42	30% fat, 50% CHO, 20% protein; 1,600 kcal/day for women and 1,800 kcal/day for men	4.6 (4.7)	3.9±5.9[b] (4.3)	2 y 2.9 (2.9)	7.2±2.9[b]	↑0.1	2 y ↑0.2
Pooled data	188 (165 [88])					4.5 (4.5)	3.9 (4.3)				

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Table 1. Overweight/obese adults with type 2 diabetes lifestyle weight-loss intervention studies[a] (*continued*)

Author(s), year	Subjects enrolled (n [%] of completers)	Mean baseline weight (kg)	Mean baseline age (y)	Sex (% male)	Weight-loss interventions	Mean kg Weight Loss (%)			Hemoglobin A1c (%)		
						6 mo	12 mo	Final or 4 y	Mean baseline	12 mo % change	Final or 4-y % Change
Study groups with <5% weight loss at 12 mo											
High MUFA,[f] 20% of kcal from MUFA											
Brehm and colleagues, 2009[18]	62 (43 [69])	103.7±2.8[c]	56.5±0.8[c]	37	20% MUFA (40% fat), 45% CHO, 15% protein 200 to 300 kcal/day less than daily kcal requirements	4.5 (4.3)	4.0±0.8[c]		7.4±0.1[c]	↑0.1	18 mo ↑0.1
High-Protein, >30% of kcal from protein											
Larsen and colleagues, 2011[21]	53 (48 [90])	94.6 (90.5-98.8)[d]	59.6 (57.5-61.8)[d]	57	30% protein, 40% CHO, 30% fat; 30% energy restriction for 3 mo followed by 9 mo of energy balance	2.8 (3)	2.2±3.8[b] (2.3)		7.9±0.5[b]	−0.3±1.0[b]	
Krebs and colleagues, 2012[22]	207 (144 [70])	103.4±19[b]	57.7±9.9[b]	46	30% protein, 40% CHO, 30% fat; total energy intake reduced by ~500 kcal/day of energy requirements	3.2 (3.1)	3.2±6.6[b] (3.0)	2 y 4.0 (3.9)	8.1±1.2[b]	−0.1	2 y ↑0.1
Pooled data	260 (192 [74])					3.1 (3.1)	2.9 (2.8)				
Pooled data <5% weight loss	n=1,365	98.4					3.2 kg (3.2%)		7.6	−0.2	
Study groups with ≥5% weight loss at 12 mo											
Mediterranean-style Diet											
Esposito and colleagues, 2009[20]	108 (98 [91])	86.0±10.4[b]	52.4±11.2[b]	50	1,500 kcal/day for women and 1,800 kcal/day for men; diet rich in vegetables, whole grains, 30 to 50 g of added olive oil (~50% CHO, >30% fat); PA goal of 175 min/wk	Not reported	6.2±3.2[b] (7.2)	4-y: 3.8±2.0[b] (4.4)	7.7±0.9[b]	−1.2±1.0[b]	4 y −0.9±0.6[b]

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Table 1. Overweight/obese adults with type 2 diabetes lifestyle weight-loss intervention studies[a] (*continued*)

Author(s), year	Subjects enrolled (n [%] of completers)	Mean baseline weight (kg)	Mean baseline age (y)	Sex (% male)	Weight-loss interventions	Mean kg Weight Loss (%)			Hemoglobin A1c (%)		
						6 mo	12 mo	Final or 4 y	Mean baseline	12 mo % change	Final or 4-y % Change
Study groups with ≥5% weight loss at 12 mo											
ILI[g]											
Look AHEAD Trial, 2007; 2010[10,11]	2,570 (2,419 [94])	100.5±19.6[b]	58.6±6.8[b]	41	Portion-controlled diets that included liquid meal replacements and frozen food entrées or structured food plans; goal a minimum weight loss of 7% of initial body weight during 1st year; physical activity goal of 175 min/wk	Not reported	8.6±6.9[b] (8.6)	4-y:4.7 (4.4 to 5.0)[d] (4.7)	7.3±0[c]	−0.6±1.0[c]	4 y −0.2 (0.2 to 0.1)[d]
Pooled data weight loss >5%	n=2,678	99.9					8.5 kg (8.5%)		7.3%	−0.6%	
Usual care/control study groups											
Metz and colleagues, 2000[14]	63 (51 [81])	96	54.0±9.9[b]	40	Macronutrient equivalent diet based on exchange lists	1.5±3.2[b] (1.0)	1.0±3.8[b] (1.0)		8.8±1.2[b]	−0.2±1.3[b]	
Wolf and colleagues, 2004[15]	73 (63 [87])	106.7±24.3[b]	53.4±8.0[b]	42	Received educational materials	1.0 (1.0)	↑0.6 (↑1.0 to ↑2.2)[d] (↑0.5)		7.5±1.5[c]	−0.0±3.0[c]	
Look AHEAD Trial, 2007; 2010[10,11]	2,575 (2,396 [93])	100.8±18.8[b]	58.9±6.9[b]	41	Diabetes support and education; 3 group sessions during 1st year but were not weighed and received no counseling in behavioral strategies	Not reported	0.7±4.8[c] (0.6)	4-y: 1.1 (0.8 to 1.4)[d] (1.1)	7.3±0[c]	−0.1	4 y −0.0 (0.13 to 0.06)[d]
Pooled data	2,711 (2,510 [92])	100.6					0.6 (0.6)		7.4%	−0.1%	

[a]Baseline data were subjects enrolled, weight, age, sex, weight-loss interventions; mean kilogram weight loss (% of weight loss) from baseline; mean hemoglobin A1c (%) at baseline and changes. Weight-loss studies are divided into studies with <5% weight loss at 12 months, studies with ≥5% weight loss at 12 months, and usual care/control studies. Data are pooled from study groups in similar categories of weight-loss interventions.
[b]Values are mean±standard deviation.
[c]Values are mean±standard error of mean.
[d]Values are means or between-group difference (95% CI).
[e]CHO=carbohydrate.
[f]MUFA=monounsaturated fatty acids.
[g]ILI=intensive lifestyle intervention.

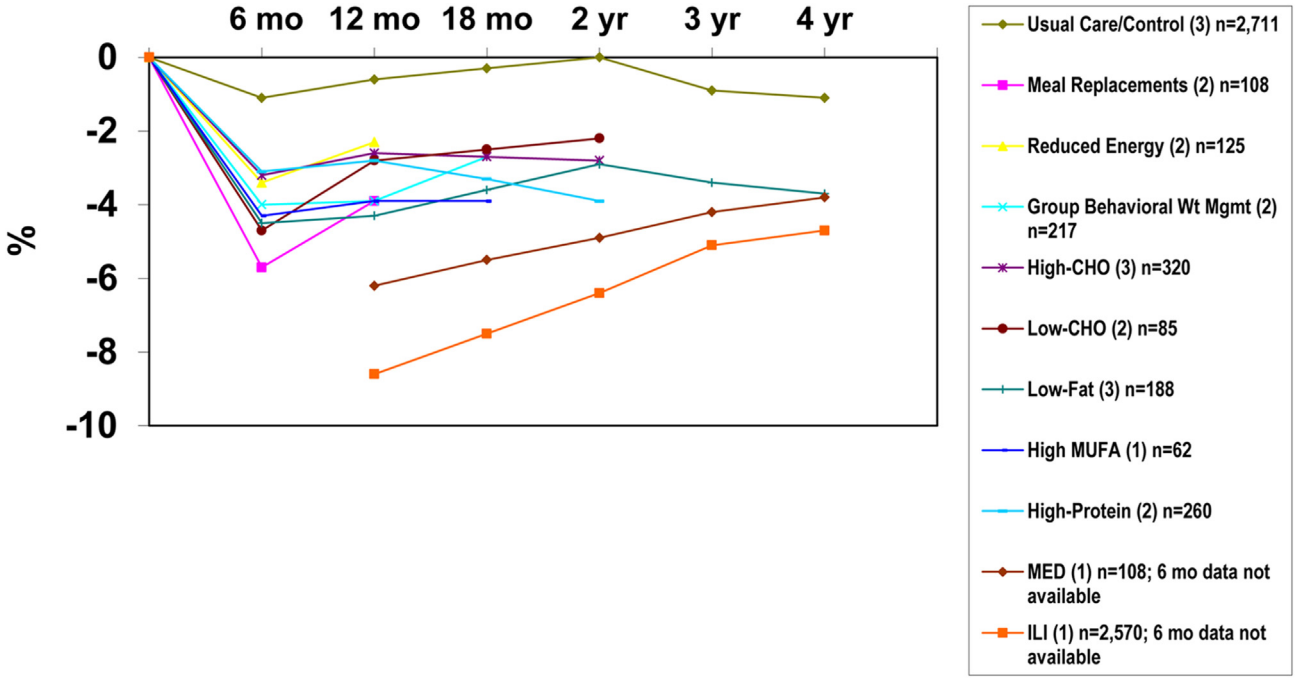

Figure 2. Mean percentage of weight loss/maintenance in individuals with type 2 diabetes from 11 studies of weight-loss interventions (19 weight-loss intervention study groups with 10 categories of weight-loss intervention; n=6,754).

Study group	12-month difference	SE[a]	Weight (%)	Mean difference (95% CI)
Brehm[18] High MUFA[b]	0.1	0.10	9.4%	0.1 (-0.09, 0.29)
Brehm[18] High CHO[c]	0	0.11	6.7%	0 (-0.21, 0.21)
Davis[19] Low CHO	-0.02	0.13	5.1%	-0.02 (-0.28, 0.24)
Davis[19] Low Fat	0.24	0.22	2.1%	0.24 (-0.19, 0.67)
Esposito[20] Low-fat	-0.6	0.06	11.2%	-0.6 (-0.71, -0.48)
Gulbrand[23] Low Fat	0.1	0.52	0.5%	0.1 (-0.92, 1.12)
Gulbrand[23] Low CHO	-0.2	0.57	0.4%	-0.2 (-1.3, 0.9)
Krebs[22] High Protein	-0.1	0.10	2.5%	-0.1 (-0.3, 0.1)
Krebs[22] High CHO	-0.2	0.10	2.5%	-0.2 (-0.39, 0)
Larsen[21] High CHO	-0.28	0.15	4.0%	-0.28 (-0.56, 0)
Larsen[21] High Protein	-0.23	0.15	3.3%	-0.23 (-0.52, 0.06)
Li[16] Meal Replacements	-0.3	0.07	19.5%	-0.3 (-0.43, -0.16)
Li[16] Reduced Energy Intake	-0.15	0.08	19.5%	-0.15 (-0.29, 0)
Metz[14] Meal Replacements	-0.24	0.24	1.8%	-0.24 (-0.7, 0.22)
West[17] Group + Motivational Interviewing	-0.44	0.08	5.9%	-0.44 (-0.6, -0.27)
West[17] Group Behavioral	-0.62	0.11	3.4%	-0.62 (-0.84, -0.39)
Wolf[15] Reduced Energy Intake	-0.2	0.19	2.1%	-0.2 (-0.57, 0.17)
12-month Wt loss <5%	**-0.224**			**-0.224 (-0.64, 0.19)**
Esposito[20] Med-Style	-1.25	0.09	44.3%	-1.25 (-1.42, -1.07)
Look AHEAD[10] Intensive Lifestyle	-0.64	0.02	55.7%	-0.64 (-0.67, -0.6)
12-month Wt loss ≥5%	**-0.91**			**-0.91 (-2.3, 0.48)**
Look AHEAD [10] Diabetes Education	-0.12	0.02	60.2%	-0.12 (-0.15, -0.08)
Metz[14] Usual Care	-0.2	0.18	28.0%	-0.2 (-0.55, 0.15)
Wolf[15] Usual Care	0	0.25	11.8%	0 (-0.49, 0.49)
Usual Care/Control	**-0.128**			**-0.128 (-1.56, 1.31)**
Test for heterogeneity: Q=2.39, df=21, I^2=777%				

Figure 3. Forest plot for hemoglobin A1c (HbA1c) (%) change from baseline to 12 months in weight-loss intervention trials in overweight and obese adults with type 2 diabetes. [a]SE=standard error. [b]MUFA=monounsaturated fatty acids. [c]CHO=carbohydrate.

Study group	12-month difference	SE[a]	Weight (%)	Mean difference (95% CI)
Brehm[18] High MUFA[b]	3	7.17	1.2%	3 (-11.04, 17.04)
Brehm[18] High CHO[c]	2	4.90	2.2%	2 (-7.59, 11.59)
Davis[19] Low CHO	3.9	4.38	3.1%	3.9 (-4.69, 12.49)
Davis[19] Low Fat	-5.9	4.28	3.7%	-5.9 (-14.29, 2.49)
Esposito[20] Low-fat	-5.8	0.67	62.1%	-5.8 (-7.11, -4.48)
Gulbrand[23] Low Fat	0	6.95	1.8%	0 (-13.62, 13.62)
Gulbrand[23] Low CHO	-7.8	7.07	1.8%	-7.8 (-21.64, 6.04)
Krebs[22] High Protein	-3.9	2.32	3.3%	-3.9 (-8.44, 0.64)
Krebs[22] High CHO	-1.5	2.28	3.3%	-1.5 (-5.95, 2.95)
Larsen[21] High CHO	0.4	5.75	1.8%	0.4 (-10.87, 11.67)
Larsen[21] High Protein	-5.9	3.76	3.6%	-5.9 (-13.27, 1.47)
Li[16] Meal Replacements	-10.76	6.80	1.3%	-10.76 (-24.08, 2.56)
Li[16] Reduced Energy Intake	-5.3	3.80	5.2%	-5.3 (-12.74, 2.14)
Metz[14] Meal Replacements	6.2	4.09	3.2%	6.2 (-1.81, 14.21)
Wolf[15]Reduced Energy Intake	-1.8	3.90	2.4%	-1.8 (-9.43, 5.83)
12-month Wt loss <5%				**-4.39 (-15.47, 6.69)**
Esposito[20] Med-Style	-15.1	1.48	100.0%	-15.1 (-18.01, -12.18)
12-month Wt loss ≥5%				**-15.1 (-46.43, 16.23)**
Metz[14] Usual Care	1	6.51	59.6%	1 (-11.76, 13.76)
Wolf[15] Usual Care	9	6.01	40.4%	9 (-2.77, 20.77)
Usual Care/Control				**4.24 (-64.36, 72.83)**

Test for heterogeneity: Q=0.970, df=17, I^2=1652%

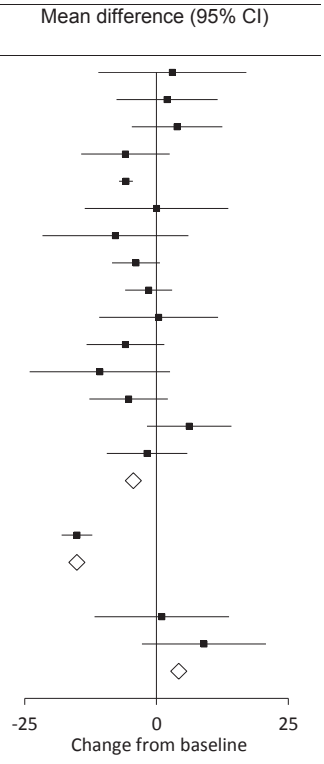

Figure 4. Forest plot for total cholesterol (mg/dL) change from baseline to 12 months in weight-loss intervention trials in overweight and obese adults with type 2 diabetes. To convert mg/dL cholesterol to mmol/L, multiply mg/dL by 0.026. To convert mmol/L cholesterol to mg/dL, multiply mmol/L by 38.7. Cholesterol of 193 mg/dL=5.00 mmol/L. [a]SE=standard error. [b]MUFA=monounsaturated fatty acids. [c]CHO=carbohydrate.

questions on reducing calorie and fat intake and use of meal replacements; no data from food records were reported.[24]

Although physical activity was suggested or encouraged in several studies,[15,17,18,19,21] only three weight-loss intervention (Mediterranean-style, intensive lifestyle intervention, and one low-fat diet)[10,20] study groups recommended, measured, and reported adherence to physical activity. Four trials did not mention physical activity.[14,16,22,23] Changes in glucose-lowering, lipid, or BP medications can also have an effect on weight-loss intervention outcomes. General decreases in medications at 12 months were reported in seven studies.[10,15,16,19-21,23] Only one study reported an increase in medications at 12 months; the Look AHEAD control study group reported an increase in lipid medications.[25] Four trials did not report on medication changes.[14,17,18,22]

Duration of diabetes can also impact weight-loss intervention outcomes. Participants in the Mediterranean-style diet group were newly diagnosed with type 2 diabetes[20] and participants in the Look AHEAD trial had a mean (±standard deviation) duration of diabetes of 6.8±6.5 years.[26] Only two other trials, all with weight losses <5%, reported on duration of diabetes (range=8.6 to 9.8 years).[21,23]

Data Analysis

Weight Changes. Data from 17 study groups with weight losses <5% at 12 months were pooled into eight categories of weight-loss intervention; the reported average weight losses ranged from 1.9 to 4.8 kg (2.0% to 4.9%).[14-23] Two study groups, the Mediterranean-style diet and intensive lifestyle intervention (Look AHEAD trial), reported weight losses ≥5% at 12 months; weight loss of 6.2±3.2 kg and 8.6±6.9 kg (7.2% and 8.6%), respectively.[10,20] Figure 2 illustrates the mean percentages of weight loss/maintenance from the 10 weight-loss intervention categories and the usual care/control group. Six-month weight changes from baseline in the Mediterranean-style and intensive lifestyle intervention groups were not available. Pooled weight loss from weight-loss intervention groups indicated some maintenance of weight loss, even over several years of follow-up.

Hemoglobin A1c. The overall estimated change in HbA1c at 12 months for the eight categories of weight-loss intervention with weight loss <5% was a decrease of 0.2% (95% CI: −0.6, 0.2), which was not significant compared with baseline (P=0.2787) (Figure 3).[14-23] Two weight-loss intervention study groups reporting ≥5% weight loss at 12 months had significant improvements in HbA1c. The Mediterranean-style diet study group in newly diagnosed patients reported a decrease in HbA1c of 1.2% (95% CI: −1.4, −1.1) at 12 months from a baseline of 7.8% (P<0.0001).[20] The intensive lifestyle intervention in the Look AHEAD trial reported a decrease of 0.6% (95% CI: −0.7, −0.6) at 12 months from a baseline of 7.3% (P<0.0001).[10,26]

Study group	12-month difference	SE[a]	Weight (%)	Mean difference (95% CI)
Brehm[18] High MUFA[b]	0	7.00	2.7%	0 (-13.71, 13.71)
Brehm[18] High CHO[c]	-3	4.60	5.2%	-3 (-12.02, 6.02)
Davis[19] Low CHO	-1.5	3.64	9.7%	-1.5 (-8.62, 5.62)
Davis[19] Low Fat	-7	4.03	8.9%	-7 (-14.9, 0.9)
Gulbrand[23] Low Fat	-3.9	4.87	7.9%	-3.9 (-13.43, 5.63)
Gulbrand[23] Low CHO	-7.7	6.35	4.8%	-7.7 (-20.15, 4.75)
Krebs[22] High Protein	-0.3	2.26	7.4%	-0.3 (-4.73, 4.13)
Krebs[22] High CHO	-3	2.22	7.4%	-3 (-7.35, 1.35)
Larsen[21] High CHO	1.7	4.40	6.6%	1.7 (-6.91, 10.31)
Larsen[21] High Protein	-2	3.13	11.1%	-2 (-8.13, 4.13)
Li[16] Meal Replacements	-6.1	6.21	3.3%	-6.1 (-18.27, 6.07)
Li[16] Reduced Energy Intake	8.76	4.22	9.0%	8.76 (0.48, 17.03)
Metz[14] Meal Replacements	7	3.74	8.1%	7 (-0.32, 14.32)
Wolf[15] Reduced Energy Intake	1.6	3.81	7.8%	1.6 (-5.86, 9.06)
12-month Wt loss <5%				**-0.67 (-16.87, 15.53)**
Look AHEAD[10]Intensive Lifestyle	-4.44	0.54	100.0%	-4.44 (-5.49, -3.38)
12-month Wt loss ≥5%				**-4.44 (-61.49, 52.61)**
Look AHEAD[10] Diabetes Education	-3.7	0.54	35.5%	-3.7 (-4.76, -2.63)
Metz[14] Usual Care	-0.3	3.84	42.3%	-0.3 (-7.83, 7.23)
Wolf[15] Usual Care	3.7	4.41	22.3%	3.7 (-4.95, 12.35)
Usual Care/Control				**-0.62 (-34.7, 33.47)**

Test for heterogeneity: Q=0.43, df=17, I^2=3826%

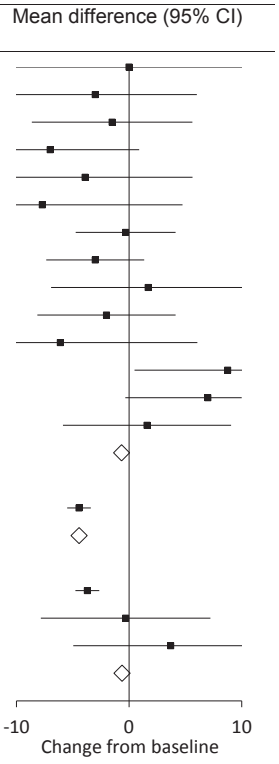

Figure 5. Forest plot for low-density lipoprotein cholesterol (mg/dL) change from baseline to 12 months in weight-loss intervention trials in overweight and obese adults with type 2 diabetes. To convert mg/dL cholesterol to mmol/L, multiply mg/dL by 0.026. To convert mmol/L cholesterol to mg/dL, multiply mmol/L by 38.7. Cholesterol of 193 mg/dL=5.00 mmol/L. [a]SE=standard error. [b]MUFA=monounsaturated fatty acids. [c]CHO=carbohydrate.

Lipids. Ten of the studies measured baseline and 12-month lipid levels.[10,14-16,18-23] Changes in TC were estimated from 16 study groups with reported TC and variance (measures at baseline were used if not reported at 12 months) (Figure 4). For weight loss <5%, the meta-analysis reported a decrease of 4.4 mg/dL (95% CI: −15.5, 6.7) (0.11 mmol/L [95% CI: −0.40, 0.17]), which was not significant from baseline (P=0.4117).[14-16,18-23] The Mediterranean-style diet study group (weight loss ≥5%) reported a significant decrease in TC at 12 months (15.1 mg/dL [95% CI: −18.0, −12.2; P<0.01]) (0.39 mmol/L [95% CI: −0.47, −0.32]).[20]

Changes in LDL-C were estimated from 15 study groups with reported LDL-C and variance (Figure 5). For study groups with a weight loss <5%, the meta-analysis reported a decrease of 0.7 mg/dL (95% CI: −16.9, 15.5) (0.02 mmol/L [95% CI: −0.44, 0.40]), which was not significant from baseline (P=0.9309).[14,15,18-23] The intensive lifestyle intervention study group (weight loss ≥5%) reported a significant decrease in LDL-C at 12 months of −4.4 mg/dL (95% CI: −5.5, −3.4; P<0.001) (0.11 mmol/L [95% CI: −0.14, −0.09]).[10,26]

Changes in HDL-C were estimated from 17 study groups with reported HDL-C and variance (Figure 6). For weight loss <5%, estimated change from 15 study groups reported an increase of 1.2 mg/dL (95% CI: −0.4, 2.8) (0.03 mmol/L [95% CI: −0.01, 0.07]), which was not significant from baseline (P=0.1245).[14-16,18-23] Both the Mediterranean-style diet and intensive lifestyle intervention reported significant increases in HDL-C of 3.9 mg/dL (95% CI: 1.2, 6.6; P<0.01) (0.10 mmol/L [95% CI: 0.03, 0.17]) and 3.4 mg/dL (95% CI: 2.8, 3.9; P<0.0001) (0.09 mmol/L [95% CI: 0.07, 0.10]), respectively.[10,20,26]

Changes in TG were estimated from 17 study groups with reported TG and variance (Figure 7). Estimated change for weight loss <5% from 15 study groups was a decrease of 16.9 mg/dL (95% CI: −89.0, 55.1) (0.19 mmol/L [95% CI: −1.01, 0.62]), which was not significant from baseline (P=0.6232).[14-16,18-23] Both the Mediterranean-style and intensive lifestyle intervention study groups reported significant decreases in TG, 39.0 mg/dL (95% CI: −56.4, −21.6; P<0.001) (0.44 mmol/L [95% CI: −0.64, −0.24]) and 29.3 mg/dL (95% CI: −32.8, −25.8; P<0.0001) (0.33 mmol/L [95% CI: −0.37, −0.29]), respectively.[10,20,26]

Blood Pressure. Eight of the trials (14 weight-loss intervention study groups) reported the effect of weight loss on blood pressure (Figures 8 and 9).[10,14,18-23] For weight loss <5% a nonsignificant decrease from baseline to 12 months in SBP of 2.2 mm Hg (95% CI: −5.8, 1.3)[14,18-23] and a nonsignificant decrease in DBP of 3.5 mm Hg (95% CI: −9.8, 2.7)[14,18-23] were reported. The Mediterranean-style diet and intensive lifestyle intervention study groups reported favorable decreases in SBP at 12 months, 2.3 mm Hg (95% CI: −2.9, −1.7; P<0.01) and 9.9 mm Hg (95% CI: −13.9, −5.9; P<0.0001), respectively, as well as for DBP, 4.0 mm Hg (95% CI: −9.9, 1.9;

Study group	12-month difference	SE[a]	Weight (%)	Mean difference (95% CI)
Brehm[18] High MUFA[b]	5	1.20	0.9%	5 (2.64, 7.35)
Brehm[18] High CHO[c]	5	0.71	2.2%	5 (3.6, 6.39)
Davis[19] Low CHO	6.2	1.55	0.5%	6.2 (3.16, 9.23)
Davis[19] Low Fat	2.3	1.28	0.9%	2.3 (-0.21, 4.81)
Esposito[20] Low-fat	1	0.08	89.4%	1 (0.84, 1.15)
Gulbrand[23] Low Fat	3.1	2.01	0.5%	3.1 (-0.84, 7.04)
Gulbrand[23] Low CHO	4.3	2.34	0.3%	4.3 (-0.28, 8.88)
Krebs[22] High Protein	1.1	0.69	0.8%	1.1 (-0.25, 2.45)
Krebs[22] High CHO	0.7	0.68	0.8%	0.7 (-0.62, 2.02)
Larsen[21] High CHO	2.9	1.31	0.7%	2.9 (0.32, 5.47)
Larsen[21] High Protein	3.1	1.55	0.4%	3.1 (0.05, 6.14)
Li[16] Meal Replacements	-0.97	10.00	0.0%	-0.97 (-20.56, 18.62)
Li[16] Reduced Energy Intake	2.26	5.10	0.1%	2.26 (-7.74, 12.26)
Metz[14] Meal Replacements	1.9	0.73	2.1%	1.9 (0.47, 3.32)
Wolf[15] Reduced Energy Intake	0.5	1.74	0.4%	0.5 (-2.91, 3.91)
12-month Wt loss <5%				**1.22 (-0.37, 2.82)**
Esposito[20] Med-Style	3.9	1.36	74.5%	3.9 (1.22, 6.57)
Look AHEAD[10] Intensive Lifestyle	3.37	0.27	25.5%	3.37 (2.84, 3.89)
12-month Wt loss ≥5%				**3.76 (-10.62, 18.15)**
Look AHEAD[10] Diabetes Education	1.35	0.14	36.0%	1.35 (1.07, 1.62)
Metz[14] Usual Care	0.3	0.89	53.7%	0.3 (-1.44, 2.04)
Wolf[15] Usual Care	-0.9	1.64	10.3%	-0.9 (-4.11, 2.31)
Usual Care/Control				**0.55 (-8.26, 9.37)**
Test for heterogeneity: Q=1.46, df=19, I^2=1200%				

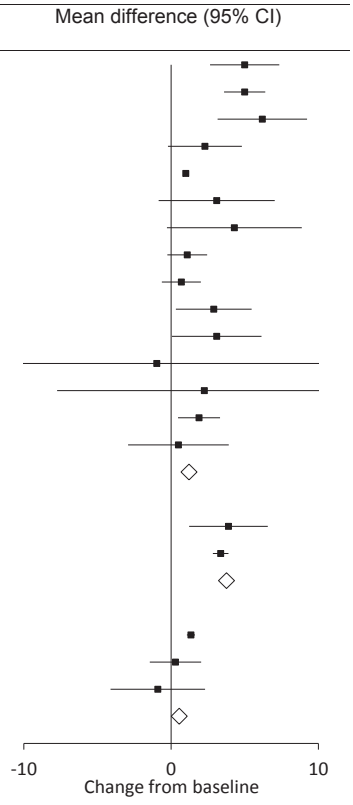

Figure 6. Forest plot for high-density lipoprotein cholesterol (mg/dL) change from baseline to 12 months in weight-loss intervention trials in overweight and obese adults with type 2 diabetes. To convert mg/dL cholesterol to mmol/L, multiply mg/dL by 0.026. To convert mmol/L cholesterol to mg/dL, multiply mmol/L by 38.7. Cholesterol of 193 mg/dL=5.00 mmol/L. [a]SE=standard error. [b]MUFA=monounsaturated fatty acids. [c]CHO=carbohydrate.

$P<0.001$) and 3.1 mm Hg (95% CI: −3.4, −2.8; $P<0.0001$), respectively.[10,11,20,26]

Macronutrient Composition and Outcomes

Five trials compared lifestyle weight-loss intervention with differing macronutrient compositions (high-monounsaturated fat vs high-carbohydrate,[18] low-carbohydrate vs low-fat,[19,23] and high-protein vs high-carbohydrate[21,22]; Table 2). All five trials reported that 12-month weight changes did not differ statistically between study groups and decreases ranged from 2.5 to 4.0 kg. Meta-analysis of high-carbohydrate, low-carbohydrate, low-fat, or high-protein diets and their effects on changes in HbA1c, lipids, and BP from baseline to 12 months were all nonsignificant (data not shown). Food records were completed by participants in all five trials and were used to measure adherence to diet recommendations. Although the reported macronutrient composition shifted from baseline toward the recommended carbohydrate, protein, or fat percentages at 12 months, the total daily caloric intake was relatively similar (range=1,440 to 1,810 kcal) across the various macronutrient weight-loss intervention groups.

DISCUSSION

Of the 19 lifestyle weight-loss intervention study groups included in this review, 17 (8 weight-loss intervention categories) reported a weight loss at 12 months of <5% of initial weight. A meta-analysis of the weight-loss intervention reported nonsignificant beneficial effects on HbA1c, lipids, and BP. Only two study groups with 12-month weight losses of ≥5% (the Mediterranean-style diet in the Esposito trial[20] and the intensive lifestyle intervention in the Look AHEAD trial[10]) had significant decreases in HbA1c, as well as significant improvements in lipids and BP. Both study groups recommended and measured physical activity and participants had frequent contact with health professionals (registered dietitian nutritionists were the primary counselors in these trials).

In the meta-analysis, the 17 lifestyle weight-loss intervention study groups with <5% weight loss had nonsignificant HbA1c changes at 12 months; however, individually, 6 did report significant improvements in HbA1c: 1 meal replacement,[14] 1 high-carbohydrate,[21] 1 low-fat,[20] 1 high-protein,[21] and 2 study groups of the Group Behavioral Weight Management trial in which the HbA1c improvements at 12 months were not maintained to 18 months.[17] Nonsignificant changes in HbA1c were reported from 11 weight-loss intervention groups: meal replacements,[16] reduced energy intake,[15,16] high carbohydrate,[18,22] low carbohydrate,[19,23] low-fat,[19,23] high monounsaturated fat,[18] and high protein.[22]

Previous evidence documenting the effectiveness of weight loss in individuals with type 2 diabetes and improved glycemic control has been mixed. A review of long-term (1 year or longer in duration) weight-loss trials used to develop

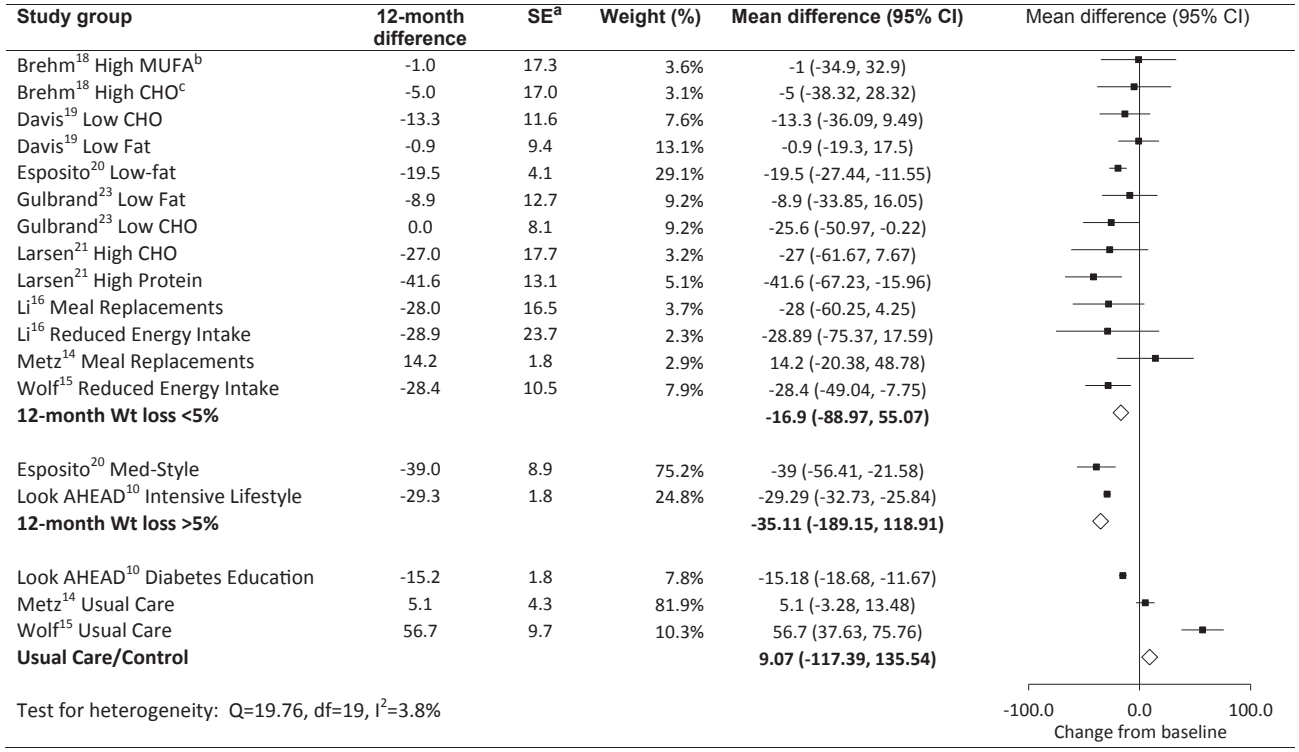

Figure 7. Forest plot for triglycerides (mg/dL) change from baseline to 12 months in weight-loss intervention trials in overweight and obese adults with type 2 diabetes. To convert mg/dL triglyceride to mmol/L, multiply mg/dL by 0.0113. To convert mmol/L triglyceride to mg/dL, multiply mmol/L by 88.6. Triglyceride of 159 mg/dL=1.80 mmol/L. [a]SE=standard error. [b]MUFA=monounsaturated fatty acids. [c]CHO=carbohydrate.

practice guidelines for diabetes reported inconsistent improvements in HbA1c for individuals who achieved modest weight loss.[27] A meta-analysis and Cochrane review of weight-loss intervention in participants with type 2 diabetes with long-term follow-up reported a 12-month weight loss of approximately 3.1% (range=−4.5 to −1.7) and decreases in HbA1c of approximately 0.3% (range=−0.8 to 0.2) from weight-loss intervention; the weight loss was significant at $P<0.05$, but the effect on HbA1c was not significant.[8,9] The 2013 American Heart Association/American College of Cardiology/The Obesity Society Guideline also reported that weight losses <5% lowered HbA1c by 0.2% to 0.3% and weight losses ≥5% lowered HbA1c by 0.6% to 1.0%, but did not report the statistical significance of these data.

Compared with individuals without diabetes, it is generally more difficult for individuals with diabetes to lose and/or maintain weight loss.[8,28,29] Seventeen of the 19 study groups reported weight losses <5% (1.9 to 4.8 kg; mean of 3.2%) at 12 months; and in a systematic review of weight-loss intervention (diet alone, diet and exercise, and meal replacements) in individuals primarily without diabetes, the mean weight loss at 12 months was 4.5 to 7.5 kg (5% to 8%).[30]

Several factors may contribute to the quality of the studies and inconsistent outcomes across weight-loss studies in individuals with diabetes. First, the lifestyle weight-loss intervention may have been implemented too late in the disease process. The progressive nature of type 2 diabetes has been well documented[31]; therefore, a weight-loss intervention implemented earlier in the disease process as was done in the Mediterranean-style study group may be more effective, especially if implemented before some diabetes medications (eg, insulin secretagogues) are needed that have weight-gain side effects.[32] Secondly, the majority of lifestyle weight-loss intervention may not have been intense enough to produce the weight loss necessary to improve metabolic outcomes. Individuals in the intensive lifestyle intervention study group were seen weekly for the first 6 months and three times per month for the next 6 months; during years 2 through 4, participants were seen individually at least once a month, contacted another time each month by telephone or e-mail, and offered a variety of ancillary group classes. And thirdly, energy restriction is reported to be at least as important, if not more important, than weight loss for improving glycemic control. In general, glucose levels improve rapidly when energy intake is reduced, even before much weight is lost.[5] In addition, weight loss plateaus because of compensatory physiological mechanisms, despite continued maintenance of reduced energy intake.[29,33-35] A reduced energy intake may maintain improved outcomes but does not continue to produce weight loss.[36] A variety of nutrition therapy interventions focusing on reduced energy intake have been shown to improve HbA1c levels and other outcomes. These include reduced energy/fat intake, portion control and healthy food choices, carbohydrate counting, simplified meal plans,[12] as well as a variety of eating patterns.[37]

The ideal macronutrient percentages for weight loss have been an area of controversy. Low-carbohydrate and/or high-protein diets have been recommended for better

Study group	12-month difference	SE[a]	Weight (%)	Mean difference (95% CI)
Brehm[18] High MUFA[b]	-2.0	2.3	1.3%	-2 (-6.5, 2.5)
Brehm[18] High CHO[c]	-1.0	1.0	5.4%	-1 (-2.99, 0.99)
Davis[19] Low CHO	2.0	2.1	1.2%	2 (-2.12, 6.12)
Davis[19] Low Fat	-1.8	3.2	0.6%	-1.8 (-8.06, 4.46)
Esposito[20] Low-fat	-2.0	0.2	80.3%	-2 (-2.36, -1.63)
Gulbrand[23] Low Fat	-10.0	2.3	1.7%	-10 (-14.57, -5.42)
Gulbrand[23] Low CHO	-8.0	2.7	1.3%	-8 (-13.36, -2.63)
Krebs[22] High Protein	-0.2	1.1	1.1%	-0.2 (-2.44, 2.04)
Krebs[22] High CHO	-1.3	1.1	1.1%	-1.3 (-3.52, 0.92)
Larsen[21] High CHO	-0.8	1.7	2.3%	-0.8 (-4.03, 2.43)
Larsen[21] High Protein	-5.0	1.6	2.2%	-5 (-8.09, -1.9)
Metz[14] Meal Replacements	-8.8	1.7	1.7%	-8.8 (-12.05, -5.54)
12-month Wt loss <5%				**-2.24 (-5.83, 1.34)**
Esposito[20] Med-Style	-2.3	0.3	43.4%	-2.32 (-2.9, -1.73)
Look AHEAD[10] Intensive Lifestyle	-9.9	2.1	56.6%	-9.9 (-13.94, -5.85)
12-month Wt loss >5%				**-5.24 (-13.77, 3.3)**
Look AHEAD[10] Diabetes Education	-7.0	0.3	92.8%	-7.03 (-7.61, -6.44)
Metz[14] Usual Care	-5.1	0.4	7.2%	-5.1 (-5.89, -4.3)
Usual Care/Control				**-6.61 (-27.56, 14.34)**

Test for heterogeneity: Q=1.74, df=15, I^2=762%

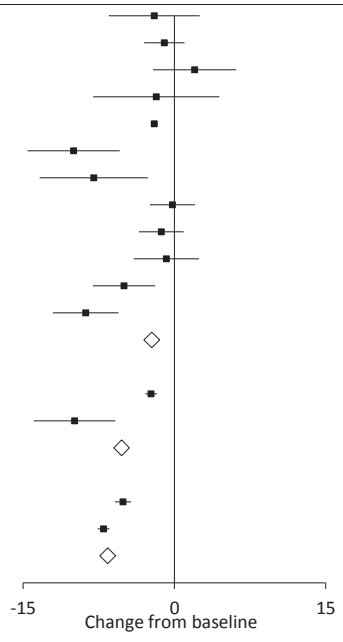

Figure 8. Forest plot for systolic blood pressure (mm Hg) change from baseline to 12 months in weight-loss intervention trials in overweight and obese adults with type 2 diabetes. [a]SE=standard error. [b]MUFA=monounsaturated fatty acids. [c]CHO=carbohydrate.

weight-loss outcomes in individuals with diabetes.[38,39] To better determine macronutrient composition of weight-loss intervention, a secondary question reviewed five trials comparing different macronutrient percentages and their outcomes. As noted, all study groups reported a similar decrease in caloric intake of approximately 300 kcal, a caloric

Study group	12-month difference	SE[a]	Weight (%)	Mean difference (95% CI)
Brehm[18] High MUFA[b]	-5.0	1.4	10.0%	-5 (-7.74, -2.25)
Brehm[18] High CHO[c]	-4.0	1.6	6.3%	-4 (-7.13, -0.86)
Davis[19] Low CHO	-2.9	1.4	9.5%	-2.9 (-5.64, -0.15)
Davis[19] Low Fat	-2.2	1.8	6.2%	-2.2 (-5.79, 1.39)
Esposito[20] Low-fat	-3.0	4.0	0.5%	-3 (-10.84, 4.84)
Gulbrand[23] Low Fat	-8.0	1.6	10.4%	-8 (-11.16, -4.83)
Gulbrand[23] Low CHO	-6.0	2.0	6.9%	-6 (-9.93, -2.06)
Krebs[22] High Protein	-0.1	0.9	7.5%	-0.1 (-1.78, 1.58)
Krebs[22] High CHO	-0.5	0.8	7.5%	-0.5 (-2.15, 1.15)
Larsen[21] High CHO	0.6	1.7	6.6%	0.6 (-2.66, 3.86)
Larsen[21] High Protein	0.2	1.5	6.7%	0.2 (-2.81, 3.21)
Metz[14] Meal Replacements	-5.1	0.9	21.9%	-5.1 (-6.8, -3.39)
12-month Wt loss <5%				**-3.53 (-9.80, 2.73)**
Esposito[20] Med-Style	-4.0	3.0	6.2%	-4 (-9.88, 1.88)
Look AHEAD[10] Intensive Lifestyle	-3.1	0.2	93.8%	-3.07 (-3.37, -2.76)
12-month Wt loss >5%				**-3.13 (-19.13, 12.87)**
Look AHEAD[10] Diabetes Education	-1.6	0.2	40.0%	-1.64 (-1.94, -1.33)
Metz[14] Usual Care	-3.8	1.0	60.0%	-3.8 (-5.69, -1.9)
Usual Care/Control				**-2.94 (-13.31, 7.44)**

Test for heterogeneity: Q=0.90, df=15, I^2=1568%

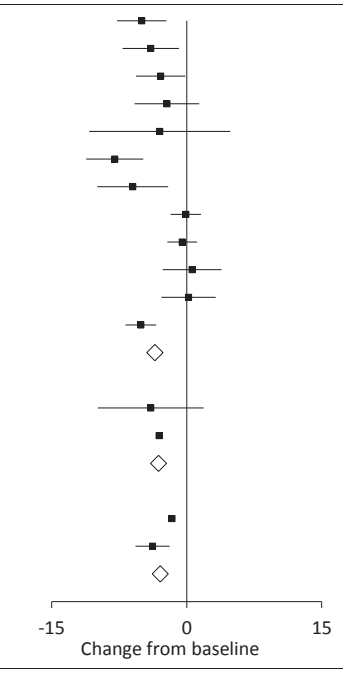

Figure 9. Forest plot for diastolic blood pressure (mm Hg) change from baseline to 12 months in weight-loss intervention trials in overweight and obese adults with type 2 diabetes. [a]SE=standard error. [b]MUFA=monounsaturated fatty acids. [c]CHO=carbohydrate.

Table 2. Lifestyle weight-loss intervention trials in overweight and obese adults with type 2 diabetes comparing differing macronutrient compositions: Recommended and reported macronutrient percentages and daily calorie intake, mean weight loss, and mean change in hemoglobin A1c levels at 12 months

Weight-loss intervention	Author(s), no. of subjects	Recommended macronutrient (carbohydrate, protein, fat), % and daily calorie deficit	Reported macronutrient intake at 12 mo (carbohydrate, protein, fat), %	Reported kcal/day intake at 12 mo (calorie deficit)	Weight loss, kg, mean±SD[a] at 12 mo (%)	Change in hemoglobin A1c, % mean±SD at 12 mo
High CHO[b]	Brehm and colleagues,[18] n=62	60, 15, 25; −200 to 300 kcal/day	54, 18, 28	1,550 (−330)	−3.8±4.3 (3.7)	0±0.8
	Larsen and colleagues,[21] n=46	55, 15, 30; 3-mo −30% kcal (~1,500 kcal/day), 9-mo energy balance	49, 19, 32	1,580 (−610)	−2.2±4.3 (2.3)	−0.3±1.0
	Krebs and colleagues,[22] n=212	55, 15, 30; −500 kcal/day	48, 21, 31	1,620 (−255)	−2.4 ± 6.6 (2.3)	−0.2±1.1
Low CHO	Davis and colleagues,[19] n=50	20 to 25 g/day CHO for 2 wk; Atkins diet thereafter	33, 23, 44	1,640±600 (−340)	−3.1±4.8 (3.3)	0±0.9
	Gulbrand and colleagues,[23] n=30	20, 30, 50; 1,600 kcal/day for women, 1,800 kcal/day for men	28, 24, 48	1,440 (−250)	−1.9±12.0 (2.0)	−0.2±1.4
Low fat	Davis and colleagues,[19] n=50	25 fat; modeled after the Diabetes Prevention Program	50, 19, 31	1,810±590 (−50)	−3.1±5.8 (3.0)	+0.2±1.5
	Gulbrand and colleagues,[23] n=31	50, 20, 30; 1,600 kcal for women, 1,800 kcal for men	48, 20, 32	1,580 (−225)	−3.9±5.9 (4.3)	+0.1±0.9
High protein	Larsen and colleagues,[21] n=53	40, 30, 30; 3-mo −30% kcal (~1,500 kcal/day), 9-mo energy balance	42, 27, 31	1,590 (−530)	−2.2±3.8 (2.3)	−0.2±1.1
	Krebs and colleagues,[22] n=207	40, 30, 30; −500 kcal/day	45, 22, 33	1,730 (−150)	−3.2±6.6 (3.0)	−0.1±1.0
High MUFA[c]	Brehm and colleagues,[18] n=62	45, 15, 40 (20 MUFA); 200 to 300 kcal/day	46, 16, 38 (14 MUFA)	1,550 (−350)	−4.0±5.2 (3.9)	+0.1±0.8

[a]SD=standard deviation.
[b]CHO=cholesterol.
[c]MUFA=monounsaturated fatty acids.

intake of approximately 1,600 kcal, and a weight loss of approximately 3 kg. Of concern are the low-carbohydrate diets that report 46% of caloric intake from fat,[19,23] with one trial reporting 20% of total caloric intake from saturated fats.[19] In studies conducted in individuals without diabetes, high-fat diets, especially diets high in saturated fat, consumed long term are reported to contribute to insulin resistance.[40-42] The effect on insulin sensitivity of high-fat and high-saturated fat intakes, especially in reduced-energy diets in individuals with diabetes, is an area of research that requires additional studies.

Of interest, are two studies that did not meet study criteria because of high drop-out rates. Iqbal and colleagues[43] compared the effects of a low-carbohydrate (30 g/day) vs a low-fat diet (≤30% calories from fat and 500 kcal/day deficit) for 24 months in obese individuals with diabetes. No clinically significant changes in weight, HbA1c, or lipids were reported at any of the time points. Caloric intake and macronutrient intake also did not differ significantly between groups at any point, suggesting that low-carbohydrate diets may be difficult to sustain. Similarly, Brinkworth and colleagues[44] did not find significant differences between groups of obese individuals with type 2 diabetes in weight, glycemic control, or lipids in a 64-week randomized controlled trial that compared energy-restricted high-protein to high-carbohydrate diets. Therefore, it can be concluded that a reduced total energy intake is more readily achieved and important than changes in macronutrient distributions and should be prioritized in lifestyle weight-loss intervention.

As with all systematic reviews and meta-analyses, we are limited to abstracting the data reported in the primary studies. It is difficult to account for the potential bias of published studies that favor successful interventions and for enrolling participants most likely to be successful. Community or clinical weight-management programs are likely to experience a higher drop-out rate and with fewer subjects achieving weight and metabolic goals. However, if one assumes that the tendency to enroll subjects likely to be successful is evenly distributed across all intervention types, then the intervention comparison analyses would be appropriate. Furthermore, there are, of course, individual variations in response to lifestyle weight-loss intervention and the conclusions from this analysis only reflect mean responses in the study groups.

Although 7 of the 11 trials did report study participants' food/nutrient intake, 4 did not. Self-reported food intake has well-recognized limitations as under-reporting of energy intake often is common.[45] Periodic recording of food intake also may not accurately reflect the intake over the duration of the study. Of concern is that food/nutrient intake was not reported in the largest of the weight-loss trials, the Look AHEAD Study.

Other limitations of the study data are that not all studies reported participants' duration of diabetes and medication changes. Future weight-loss studies in individuals with type 2 diabetes should focus on methods to more accurately measure adherence to nutrition therapy recommendations, the role of weight loss across the continuum of diabetes, and the interactions of lifestyle changes and medications.

The strength of this study is the inclusion of studies of ≥12 months of follow-up and required completion rate. Weight-loss intervention studies of shorter-term interventions (≤6 months) often report beneficial outcomes that are not maintained long term. Because diabetes is a chronic and progressive disease, nutrition therapy recommendations, including those for weight loss, just as for medications, must change as the disease changes. Weight loss is an important strategy for the prevention or delay of type 2 diabetes and can also be beneficial in individuals with newly diagnosed diabetes, but as insulin deficiency becomes more prominent, the amount of weight that is typically lost in weight-loss programs might not improve metabolic outcomes.

CONCLUSIONS

For overweight or obese individuals with type 2 diabetes, a weight loss of at least 5% improved glucose, lipids, and blood pressure control over 12 months. This amount of weight loss was atypical in the majority of the lifestyle weight-loss interventions reported, shown primarily in the intense, comprehensive, and sustained patient-contact protocol, such as those in the Look AHEAD trial. Such interventions may be impractical in most health care settings today and more translation research is needed to optimize weight-loss intervention for individuals with diabetes. Until more evidence emerges, nutrition therapy for overweight and obese individuals with type 2 diabetes should continue to focus primarily on encouraging a healthful eating pattern with careful attention to reduced portion sizes, energy intake, and participation in regular physical activity to improve metabolic outcomes.[12,27,36] To the extent that weight loss is included as part of the nutrition therapy intervention, a balanced emphasis should be given to realistic goals and expectations in relation to weight-loss and metabolic outcomes.

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Academy of Nutrition and Dietetics: Standards of Practice and Standards of Professional Performance for Registered Dietitian Nutritionists (Competent, Proficient, and Expert) in Adult Weight Management

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ABSTRACT

Weight management encompasses the inter-relationship of nutrition, physical activity, and health behavior change. Nutrition is key for the prevention and treatment of obesity and chronic disease and maintenance of overall health. Thus, the Weight Management Dietetic Practice Group, with guidance from the Academy of Nutrition and Dietetics Quality Management Committee, has developed Standards of Practice and Standards of Professional Performance for Registered Dietitian Nutritionists (RDNs) in Adult Weight Management as a resource for RDNs working in weight management. This document allows RDNs to assess their current skill levels and to identify areas for further professional development in this expanding practice area. This document describes the current standards for weight management practice for RDNs. The Standards of Practice represent the four steps in the Nutrition Care Process as applied to the care of patients/clients. The Standards of Professional Performance consist of six domains of professionalism: Quality in Practice, Competence and Accountability, Provision of Services, Application of Research, Communication and Application of Knowledge, and Utilization and Management of Resources. Within each standard, specific indicators provide measurable action statements that illustrate how the standard can be applied to practice. The indicators describe three skill levels (competent, proficient, and expert) for RDNs working in weight management. The Standards of Practice and Standards of Professional Performance are complementary resources for the Registered Dietitian Nutritionist in weight management.
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Editor's note: Figures 1 and 2 that accompany this article are available online at www.andjrnl.org.

THE WEIGHT MANAGEMENT Dietetic Practice Group (WM DPG) of the Academy of Nutrition and Dietetics (Academy), under the guidance of the Academy Quality Management Committee, has developed Standards of Practice (SOP) and Standards of Professional Performance (SOPP) for Registered Dietitian Nutritionists (RDNs) in Adult Weight Management. These documents build on the Academy's Revised 2012 SOP in Nutrition Care and SOPP for RDs.[1] The Academy of Nutrition and Dietetics/Commission on Dietetic Registration's (CDR) Code of Ethics[2] along with the Academy's Revised 2012 SOP in Nutrition Care and SOPP for RDs[1] are tools within the Scope of Practice in Nutrition and Dietetics[3] and Scope of Practice for the RD[4] that guide the practice and performance of RDNs in all settings.

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All registered dietitians are nutritionists—but not all nutritionists are registered dietitians. The Academy's Board of Directors and Commission on Dietetic Registration have determined that those who hold the credential Registered Dietitian (RD) may optionally use "Registered Dietitian Nutritionist" (RDN) instead. The two credentials have identical meanings. In this document, the expert working group has chosen to use the term RDN *to refer to both registered dietitians and registered dietitian nutritionists.*

Approved November 2014 by the Quality Management Committee of the Academy of Nutrition and Dietetics (Academy) and the Executive Committee of the Weight Management Dietetic Practice Group of the Academy. ***Scheduled review date: September 2019.*** *Questions regarding the Standards of Practice and Standards of Professional Performance for Registered Dietitian Nutritionists in Adult Weight Management may be addressed to Academy quality management staff - Sharon McCauley, MS, MBA, RDN, LDN, FADA, FAND, director, Quality Management, at quality@eatright.org.*

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The scope of practice in nutrition and dietetics is composed of statutory and individual components, includes the Code of Ethics, and encompasses the range of roles, activities, and regulations within which RDNs perform. For credentialed practitioners, scope of practice is typically established within the practice act and interpreted and controlled by the agency or board that regulates the practice of the profession in a given state.[3] An RDN's statutory scope of practice may delineate the services an RDN is authorized to perform in a state where a practice act or certification exists.

The RDN's individual scope of practice is determined by education, training, credentialing, and demonstrated and documented competence to practice. Individual scope of practice in nutrition and dietetics has flexible boundaries to capture the breadth of the individual's professional practice. The Scope of Practice Decision Tool, which is an online, interactive tool, permits an RDN to answer a series of questions to determine whether a particular activity is within his or her scope of practice. The tool is designed to assist an RDN in critically evaluating personal knowledge, skill, and demonstrated competence with criteria resources.[5]

The Centers for Medicare and Medicaid Services, Department of Health and Human Services, Final Rule effective July 11, 2014 for Hospital Conditions of Participation now allows a hospital and its medical staff the option of granting RDNs or other clinically qualified nutrition professionals ordering privileges for therapeutic diets and nutrition-related services, including nutrition supplements and enteral and parenteral nutrition if consistent with State law. RDNs in hospital settings interested in obtaining ordering privileges must review State practice acts (eg, licensure, certification, and title protection) and state health care facility regulations to determine whether there are any barriers that must be addressed. An RDN interested in obtaining ordering privileges should review the state analysis and regulation for a brief breakdown of each state's relevant law and practice tips that outline the regulations and implementation steps for ordering privileges (www.eatright.pro/resources/advocacy/quality-health-care/consumer-protection-and-licensure/learn-about-the-CMS-rule-on-therapeutic-diet-orders).

Medical staff oversight of an RDN(s) occurs in one of two ways. A hospital has the regulatory flexibility to appoint an RDN(s) to the medical staff and grant the RDN(s) specific nutrition ordering privileges, or can authorize the ordering privileges without appointment to the medical staff. The RDN ordering privileges must be ensured through the hospital's medical staff rules, regulations, and bylaws, or other facility-specific process (http://www.gpo.gov:80/fdsys/pkg/FR-2014-05-12/pdf/2014-10687.pdf).

The Academy's Revised 2012 SOP in Nutrition Care and SOPP for RDs[1] reflect the minimum competent level of nutrition and dietetics practice and professional performance for RDNs. These standards serve as blueprints for the development of focus area SOP and SOPP for RDNs in competent, proficient, and expert levels of practice. The SOP in Nutrition Care is composed of four standards representing the four steps of the Nutrition Care Process (NCP) as applied to the care of patients/clients.[6] The SOPP consist of standards representing six domains of professionalism: Quality in Practice, Competence and Accountability, Provision of Services, Application of Research, Communication and Application of Knowledge, and Utilization and Management of Resources. The SOP and SOPP for RDNs are designed to promote the provision of safe, effective, and efficient food and nutrition services, facilitate evidence-based practice, and serve as a professional evaluation resource.

These focus area standards for RDNs in weight management provide a guide for self-evaluation and expanding practice, a means of identifying areas for professional development, and a tool for demonstrating competence in delivering weight management nutrition and dietetic services. They are used by RDNs to assess their current level of practice and to determine the education and training required to maintain currency in their focus area and advancement to a higher level of practice. In addition, the standards may be used to assist RDNs in transitioning their knowledge and skills to a new focus area of practice. Like the SOP in Nutrition Care and SOPP for RDs,[1] the indicators (ie, measureable action statements that illustrate how each standard can be applied in practice) (see Figures 1 and 2 available online at www.andjrnl.org) for the SOP and SOPP for RDNs in Adult Weight Management were developed with input and consensus of content experts representing diverse practice and geographic perspectives. The SOP and SOPP for RDNs in Adult Weight Management were reviewed and approved by the Executive Committee of the WM DPG and the Academy Quality Management Committee.

THREE LEVELS OF PRACTICE

The Dreyfus model[7] identifies levels of proficiency (novice, advanced beginner, competent, proficient, and expert) (refer to Figure 3) during the acquisition and development of knowledge and skills. The first two levels are components of the required didactic education (novice) and supervised practice experience (advanced beginner) that precede credentialing for nutrition and dietetics practitioners. Upon successfully attaining the RDN, a practitioner enters professional practice at the competent level and manages his or her professional development to obtain individual professional goals. This model is helpful in understanding the levels of practice described in the SOP and SOPP for RDNs in Adult Weight Management. In Academy focus areas, these three levels are represented as competent, proficient, and expert practice levels.

Competent Practitioner

In nutrition and dietetics, a competent practitioner is an RDN who is either just starting practice after having obtained RDN registration by CDR, or an experienced RDN who has recently assumed responsibility to provide nutrition services in a new focus area. A focus area is defined as an area of nutrition and dietetics practice that requires focused knowledge, skills, and experience.[8] A competent practitioner who has obtained RDN status and is starting in professional employment acquires additional on-the-job skills and engages in tailored continuing education to further enhance knowledge and skills obtained in formal education. An RDN starts with technical training and professional interaction for advancement and expanding breadth of competence. A general practice RDN may include responsibilities across several areas of practice, including, but not limited to: community, clinical, consultation and business, research, education, and food and nutrition management.[8] The

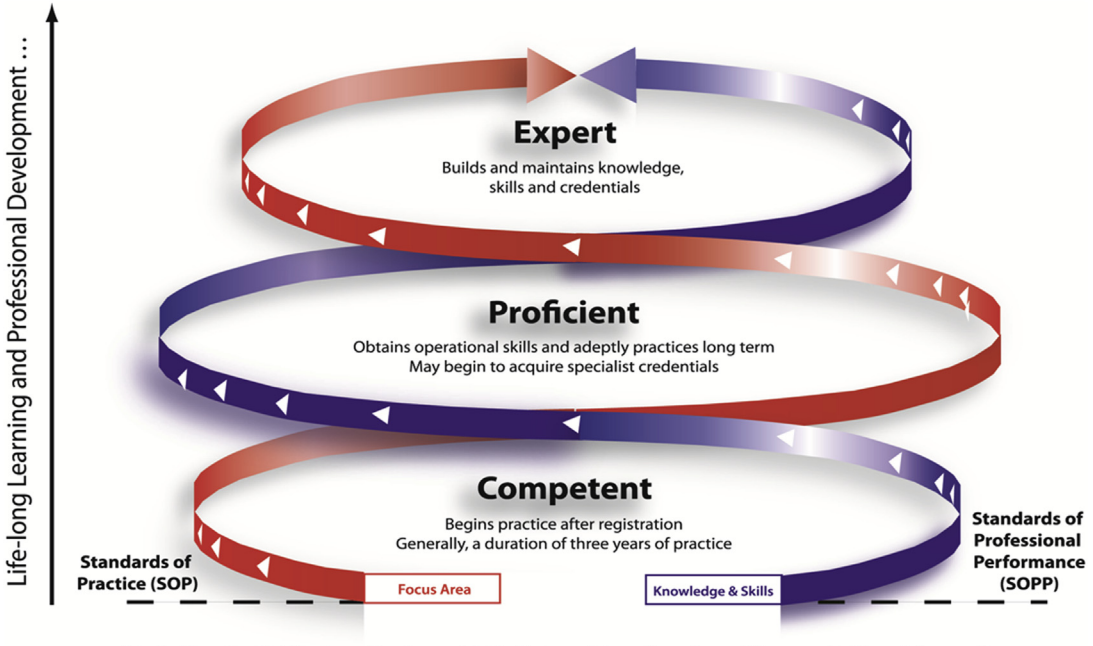
Standards of Practice are authoritative statements that describe practice demonstrated through nutrition assessment, nutrition diagnosis (problem identification), nutrition intervention (planning, implementation) and outcomes monitoring and evaluation (four separate standards), and the responsibilities for which registered dietitian nutritionists (RDNs) are accountable. The Standards of Practice for RDNs in Adult Weight Management presuppose that the RDN uses critical thinking skills; analytical abilities; theories; best-available research findings; current accepted nutrition, dietetics, and medical knowledge; and the systematic holistic approach of the nutrition care process as they relate to the application of the standards. Standards of Professional Performance for RDNs in Adult Weight Management are authoritative statements that describe behavior in the professional role, including activities related to Quality in Practice; Competence and Accountability; Provision of Services; Application of Research; Communication and Application of Knowledge; and Utilization and Management of Resources (six separate standards).

Standards of Practice and Standards of Professional Performance are evaluation resources with complementary sets of standards—both serve to describe the practice and professional performance of RDNs. All indicators may not be applicable to all RDNs' practice or to all practice settings and situations. RDNs operate within the directives of applicable federal and state laws and regulations, as well as policies and procedures established by the organization in which they are employed. To determine whether an activity is within the scope of practice of the RDN, the practitioner compares his or her knowledge, skill, and competence with the criteria necessary to perform the activity safely, ethically, legally, and appropriately. The Academy's Scope of Practice Decision Tool, which is an online, interactive tool, is specifically designed to assist practitioners with this process.

The term patient/client *is used in the Standards of Practice as a universal term as these Standards relate to direct provision of nutrition care and services. Patient/client could also mean client/patient, resident, participant, consumer, or any individual or group who receives weight management services.* Customer *is used in the Standards of Professional Performance as a universal term. Customer could also mean client/patient, client/patient/customer, participant, consumer, or any individual, group, or organization to which the RDN provides services. These services are provided to adults 19 years and older. These Standards of Practice and Standards of Professional Performance are not limited to the clinical setting. In addition, it is recognized that the family and caregiver(s) of patients/clients, including individuals with special health care needs, play critical roles in overall health and are important members of the team throughout the assessment and intervention process. The term* appropriate *is used in the standards to mean: Selecting from a range of best-practice or evidence-based possibilities, one or more of which would give an acceptable result in the circumstances.*

Each standard is equal in relevance and importance and includes a definition, a rationale statement, indicators, and examples of desired outcomes. A standard is a collection of specific outcome-focused statements against which a practitioner's performance can be assessed. The rationale statement describes the intent of the standard and defines its purpose and importance in greater detail. Indicators are measurable action statements that illustrate how each specific standard can be applied in practice. Indicators serve to identify the level of performance of competent practitioners and to encourage and recognize professional growth.

Standard definitions, rationale statements, core indicators, and examples of outcomes found in the Academy of Nutrition and Dietetics Revised 2012 Standards of Practice in Nutrition Care and Standards of Professional Performance for RDs have been adapted to reflect three levels of practice (competent, proficient, and expert) for RDNs in Adult Weight Management (see figure below). In addition, the core indicators have been expanded to reflect the unique competence expectations for the RDN providing adult weight management.



Adapted from the *Dietetics Career Development Guide*. For more information, please visit www.eatright.org/futurepractice

Figure 3. Standards of Practice and Standards of Professional Performance for Registered Dietitian Nutritionists (RDNs) (Competent, Proficient, and Expert) in Adult Weight Management.

competent RDN could complete the CDR Level I Certificate of Training in Adult Weight Management to gain more knowledge in nutrition, physical activity, and behavior change strategies in weight management (http://www.cdrnet.org/products/continuing-professional-development-education).

Proficient Practitioner

A proficient practitioner is an RDN who is generally 3 or more years beyond entry into the profession, has obtained operational job performance skills, and is successful in the RDN's chosen focus area of practice.[8] The proficient practitioner demonstrates additional knowledge, skills, and experience in a focus area of nutrition and dietetics practice. An RDN may acquire specialist credentials, if available, to demonstrate proficiency in a focus area of practice. The proficient RDN could complete the CDR Level II Certificate of Training in Adult Weight Management to gain advanced knowledge in nutrition, physical activity, and behavior change strategies in weight management (http://www.cdrnet.org/products/continuing-professional-development-education).

Expert Practitioner

An expert practitioner is an RDN who is recognized within the profession and has mastered the highest degree of skill in, or knowledge of, a certain focused or generalized area of nutrition and dietetics through additional knowledge, experience, or training.[8] An expert practitioner exhibits a set of characteristics that include leadership and vision and demonstrates effectiveness in planning, achieving, evaluating, and communicating targeted outcomes. An expert practitioner may have an expanded or specialist role, or both, and may possess an advanced credential, if available, in a focus area of practice. Generally, the practice is more complex and the practitioner has a high degree of professional autonomy and responsibility.

These Standards, along with the Academy/CDR Code of Ethics,[2] answer the questions: Why is an RDN uniquely qualified to provide weight management nutrition and dietetics services? What knowledge, skills, and competencies does an RDN need to demonstrate for the provision of safe, effective, and quality weight management care and service at the competent, proficient, and expert levels?

OVERVIEW

Over the last several decades, overweight and obesity have reached epidemic proportions; currently there are more than 78 million obese adults in the United States.[9] Obesity is associated with increased incidence of cardiovascular disease risk factors, including hypertension, dyslipidemia, and stroke; type 2 diabetes; gall bladder disease; osteoarthritis; sleep apnea; respiratory problems; and some cancers.[10] In addition, obesity is associated with other negative factors, including increased cost of health care and psychosocial issues.[11] Obese patients incur 46% increased inpatient costs, 27% more physician visits and outpatient costs, and 80% increased spending on prescription drugs compared to nonobese individuals.[11] Several lifestyle factors, including poor dietary habits and low levels of physical activity, are strongly associated with the increase in rates of obesity in the United States.[10,12]

Weight management, as a specialty, addresses all aspects of body weight, including assessment of body weight, lifestyle, cultural and socioeconomic factors, other morbidities, and behavior change issues, such as readiness to change. This information provides the basis for the RDN to determine weight loss and health goals, caloric and nutrient needs, and appropriate intervention strategies. The latest guideline released for the management of overweight and obese adults, 2013 American Heart Association (AHA)/American College of Cardiology (ACC)/The Obesity Society (TOS) Guideline for the Management of Overweight and Obesity in Adults[10] describes evidence-based recommendations for obesity management. The AHA/ACC/TOS guideline gives "strong" recommendations for diet strategies for weight loss that include prescribing a diet to achieve reduced calorie intake for obese and overweight individuals as part of a comprehensive lifestyle intervention; and lifestyle interventions and counseling that is delivered by a nutrition professional, RDN, or a trained interventionist (ie, RDN, psychologist, exercise specialist, health counselor, or professional in training).[10] The Academy updated the Adult Weight Management Evidence-Based Nutrition Practice Guideline in 2014.[13] The Academy recommendations align with the AHA/ACC/TOS guideline, particularly for referral of overweight or obese individuals to the RDN for intensive counseling and behavioral interventions to promote sustained weight loss and reduce known risk factors for diet-related chronic disease. In addition, the US Preventive Services Task Force "recommends screening all adults for obesity. Clinicians should offer or refer patients with a body mass index (BMI) of 30 kg/m^2 or higher to intensive, multicomponent behavioral interventions."[14] The importance of attaining optimal weight status is emphasized in several recent US Department of Health and Human Services and US Department of Agriculture documents, including the 2010 Dietary Guidelines for Americans[15] and Healthy People 2020.[16] In 2005, the Institute of Medicine issued Dietary Reference Intakes for energy intake related to weight loss and obesity prevention,[17] and in 2012, outlined a national weight-loss plan that includes five key recommendations for reducing obesity.[18] Medical nutrition therapy (MNT) for weight management has demonstrated efficacy for weight loss and weight maintenance.[19] Thus, RDNs are well positioned to assist individuals and organizations in integrating nutrition, lifestyle changes, and weight management to promote overall health and wellness.

Weight Management Dietetic Practice Group

In 1978, the Academy (then the American Dietetic Association) introduced DPGs for Academy members who wish to connect with other members within their areas of professional interest and/or practice. Initially, the field of weight management was included within other DPGs, notably Sports, Cardiovascular, and Wellness Nutrition. In 2003, the WM DPG was formed, acknowledging that RDNs needed a professional resource group that specialized in obesity and weight management. Two subunits were identified in the specialty practice areas of Pediatric Weight Management and Bariatric Surgery. Membership quickly grew to more than 5,000. The vision of the WM DPG is "to optimize the nation's health through weight and lifestyle management." The mission is "to empower

members to be the nation's weight management and lifestyle change leaders."

The initial priority of the WM DPG was to provide quality continuing education in obesity and weight management through its newsletter, annual symposia, and website (www.wmdpg.org). The robust website houses recorded webinars, newsletter articles, professional resources, and member directory. In 2014, a third specialty area, Coaching, was launched as a special interest group. As more national attention is being given to the importance of integrating weight management into health management policy, the WM DPG has prioritized more involvement in public policy and the development of a credential—interprofessional certified specialist in obesity and weight management.

Scope of Practice for the Registered Dietitian Nutritionist in Adult Weight Management

The Scope of Practice for the RD[4] describes the weight management practice area of nutrition and dietetics performed by RDNs who apply evidence-based knowledge in weight management to address the diverse nutritional needs of individuals. Weight management RDNs provide MNT in direct patient/client care and design, implement, and manage safe and effective nutrition strategies that enhance lifelong health, fitness, and optimal weight management. They assess, educate, and counsel what, how much, and when to consume foods and fluids to maintain health and appropriate body weight and body composition. Valued for their ability to positively impact behavior and promote lifestyle change, weight management RDNs assist individuals in implementing nutrition plans that will enable them to achieve their goals. In addition, weight management RDNs generate and analyze data to monitor and evaluate the effectiveness of their interventions.

Weight management RDNs use the SOP SOPP for RDNs in Adult Weight Management to assess their knowledge, skills, and competencies to provide safe, effective, quality weight management care and services. Weight management RDNs may work as members of interdisciplinary teams to integrate nutrition effectively into the patient's/client's weight management plan. Additional members of interdisciplinary teams may include, but are not limited to, any of the following: physician, bariatric physician, mid-level providers, physical therapist, physiologist, psychologist, pharmacist, nurse, certified athletic trainer, or RDN specializing in sports nutrition and/or eating disorder therapy.

Evidence-Based Weight Management Practice

Several factors determine an individual's body weight, including genetics, energy balance (caloric intake and expenditure), psychosocial issues, disease states, and certain medications. There is strong evidence that in order to decrease body weight, there needs to be an adjustment in energy intake, energy output, or a combination of both.[20]

Overall health and disease risk factors can be decreased with relatively small amounts of weight loss. The 2013 AHA/ACC/TOS guideline[10] recommends "a realistic and meaningful weight loss goal as an important first step," and that a sustained weight loss of as little as 3% to 5% of body weight may lead to clinically meaningful reductions in some cardiovascular disease risk factors. The guideline recommends as an initial goal, the loss of 5% to 10% of baseline weight within 6 months. Weight management becomes health management, as it can improve overall health and risk factors related to chronic diseases, such as cardiovascular disease and type 2 diabetes.

Evidence-based weight management strategies facilitate safe and effective weight loss and maintenance. The key to optimal weight management is an individualized and personalized approach. Once the individual's nutrient needs and goals are established, the weight management RDN develops a plan that includes appropriate quantity and quality of food and fluid intake, and dietary supplements when appropriate. Other factors, such as daily schedule demands, environmental factors, available resources, and cultural influences, are part of the plan. The weight management RDN must be well versed in patient/client counseling and behavior change techniques. According to the 2009 Position of the Academy of Nutrition and Dietetics: Weight Management, the goals for weight management are not just about losing pounds on the scale, but must include the development of healthful lifestyles with behavior modification and an emphasis on overall fitness and health.[19] Goals for weight management practice may include prevention of weight gain, varying degrees of improvements in physical and emotional health, attainable and maintainable weight loss, and improvements in eating, exercise, and other health behaviors.

Weight management RDNs educate individuals regarding energy, nutrient, and fluid intake to facilitate weight loss, and other aspects of healthful living, including physical activity,[20] menu planning, recipe modification, grocery shopping, and food preparation and storage. Weight management RDNs have traditionally worked in inpatient and outpatient hospital settings, worksite wellness programs, fitness facilities, private practice, and in colleges and universities.

The weight management industry in the United States is a multibillion-dollar industry with few evidence-based products and programs. This provides an opportunity for the RDN to offer guidance on food and nutrition applicable to goals for health, fitness, and body weight. Weight management RDNs are relied upon for evidence-based weight management strategies and to help guide evaluation of safety, effectiveness, quality, and application of weight management products and services.

Expanded practice areas for weight management RDNs include providing nutrition guidance for individuals whose occupations require weight restrictions and/or maintenance of specified physical conditioning or body weight or composition. Examples include military personnel,[21] law enforcement officers, and firefighters.

Demand is increasing for weight management RDNs to be employed in private companies that are interested in improving the health of their employees. Weight management RDNs provide nutrition expertise in program and product development and in testing and monitoring, and evaluation of programs in the market place. Weight management RDNs in private practice are increasingly using web tools and social media to interact with

patients/clients and the public. Weight management RDNs are hired by researchers to participate in various components of research investigations and programs. Weight management RDNs use MNT for overweight or obese individuals diagnosed with medical conditions (eg, diabetes, cardiovascular disease, cancer, gluten intolerance, food allergies, Crohn's disease, eating disorders) and in situations such as various forms of paralysis, cancer treatment, pre and post bariatric surgery, and post amputation from traumatic injuries.

Employers seeking the skills of weight management RDNs use the SOP SOPP for RDNs in Adult Weight Management to develop job descriptions, such as for weight management positions, competency assessment tools, and descriptions for clinical ladders. The Scope of Practice in Nutrition and Dietetics,[3] Scope of Practice for the RD,[4] and the SOP and SOPP for RDNs in Adult Weight Management role descriptions are components of a comprehensive approach that assists weight management RDNs in gauging their level of practice and developing a pathway for advancement. They define weight management nutrition and dietetics practice, document skill levels, and establish benchmarks. Weight-management nutrition and dietetics is a growing and demanding practice area that requires integration of MNT, nutrition science, exercise principles, behavior change principles, and corresponding research into a variety of settings in which individuals need to manage their weight and/or want to improve their overall health and wellness.[22]

ACADEMY STANDARDS OF PRACTICE AND STANDARDS OF PROFESSIONAL PERFORMANCE FOR REGISTERED DIETITIAN NUTRITIONISTS (COMPETENT, PROFICIENT, AND EXPERT) IN ADULT WEIGHT MANAGEMENT

An RDN can use the Academy SOP and SOPP for RDNs (Competent, Proficient, and Expert) in Adult Weight Management (see the website exclusive Figures 1 and 2, available online at www.andjrnl.org, and Figure 3) to:

- identify the competencies needed to provide weight management nutrition and dietetics care and services;
- self-assess whether he or she has the appropriate knowledge base and skills to provide safe and effective weight management nutrition and dietetics care and service for their level of practice;
- identify the areas in which additional knowledge and skills are needed to practice at the competent, proficient, or expert level of weight management nutrition and dietetics practice;
- provide a foundation for public and professional accountability in weight management nutrition and dietetics care and service;
- support efforts for strategic planning and assist management in the planning of weight management nutrition and dietetics services and resources;
- enhance professional identity and communicate the nature of weight management nutrition and dietetics care and services;
- guide the development of weight management nutrition and dietetics-related education and continuing education programs, job descriptions, and career pathways; and
- assist educators and preceptors in teaching students and interns the knowledge, skills, and competencies needed to work in weight management nutrition and dietetics, and the understanding of the full scope of this focus area of practice.

APPLICATION TO PRACTICE

All RDNs, even those with significant experience in other practice areas, must begin at the competent level when practicing in a new setting or new focus area of practice. At the competent level, an RDN in weight management is learning the principles that underpin this focus area and is developing skills for safe and effective weight management practice. This RDN, who may be an experienced RDN or may be new to the profession, has a breadth of knowledge in nutrition and dietetics and may have proficient or expert knowledge/practice in another focus area. However, the RDN new to the focus area of weight management may experience a steep learning curve while becoming familiar with the body of knowledge and available resources to support weight management–related nutrition and dietetics practice.

At the proficient level, an RDN has developed a deeper understanding of weight management practice and is better equipped to apply evidence-based guidelines and best practices than at the competent level. This RDN is also able to modify practice according to unique situations (eg, integrating the care of multiple chronic diseases into the nutrition care plan). The RDN at the proficient level may possess a specialist credential.

At the expert level, an RDN thinks critically about weight management nutrition and dietetics, demonstrates a more intuitive understanding of weight management nutrition and dietetics care and services, displays a range of highly developed clinical and technical skills, and formulates judgments acquired through a combination of education, experience, and critical thinking. Essentially, practice at the expert level requires the application of composite nutrition and dietetics knowledge, with practitioners drawing not only on their clinical experience, but also on the experience of the weight management RDNs in various disciplines and practice settings. Expert RDNs with extensive experience have the ability to see the significance and meaning of weight management nutrition and dietetics within a contextual whole, are fluid and flexible, and have considerable autonomy in practice. They not only develop and implement weight management nutrition and dietetics services, they also manage, drive, and direct clinical care, conduct and collaborate in research, accept organization leadership roles, engage in scholarly work, guide interdisciplinary teams, and lead practice advancement.

Indicators for the SOP (Figure 1, available online at www.andjrnl.org) and SOPP (Figure 2, available online at www.andjrnl.org) for RDNs in Adult Weight Management are measurable action statements that illustrate how each standard can be applied in practice. Within the SOP and SOPP for RDNs in Adult Weight Management, an "X" in the competent column indicates that an RDN who is caring for patients/clients is expected to complete this activity and/or seek assistance to learn how to perform at the

level of the standard. A competent RDN in weight management could be an RDN starting practice after registration or an experienced RDN who has recently assumed responsibility to provide weight management care for patients/clients.

An "X" in the proficient column indicates that an RDN who performs at this level has a deeper understanding of weight management nutrition and dietetics and has the ability to modify therapy to meet the needs of patients/clients in various situations (eg, caring for a patient/client with multiple chronic diseases and bariatric surgery). An "X" in the expert column indicates that the RDN who performs at this level possesses a comprehensive understanding of weight management nutrition and dietetics and a highly developed range of skills and judgments acquired through a combination of experience and education. The expert RDN builds and maintains the highest level of knowledge, skills, and behaviors including leadership, vision, and credentials.

Standards and indicators presented in Figures 1 and 2 (available at www.andjrnl.org) in boldface type originate from the Academy's Revised 2012 SOP in Nutrition Care and SOPP for RDs[1] and should apply to RDNs in all three levels. Several indicators developed for this focus area not in boldface type are identified as applicable to all levels of practice. Where an "X" is placed in all three levels of practice, it is understood that all RDNs in weight management are accountable for practice within each of these indicators. However, the depth with which an RDN performs each activity will increase as the individual moves beyond the competent level. Several levels of practice are considered in this document; thus, taking a holistic view of the SOP and SOPP for RDNs in Adult Weight Management is warranted. It is the totality of individual practice that defines the level of practice and not any one indicator or standard.

RDNs should review the SOP and SOPP in Adult Weight Management at regular intervals to evaluate their individual focus area knowledge, skill, and competence. Regular self-evaluation is important because it helps identify opportunities to improve and/or enhance practice and professional performance. This self-appraisal also enables weight management RDNs to better utilize these Standards in CDR's *Professional Development Portfolio* process and each of its five steps for reflection, self-assessment, planning, improvement, and commitment to lifelong learning[23] (see Figure 4). RDNs are encouraged to pursue additional training, regardless of practice setting, to maintain currency and to expand individual scope of practice within the limitations of the legal scope of practice, as defined by State law. RDNs are expected to practice only at the level at which they are competent, and this will vary depending on education, training, and experience.[24] RDNs are encouraged to pursue additional knowledge and skill training, and collaboration with other RDNs in weight management to promote consistency in practice and

How to Use the *Standards of Practice (SOP) and Standards of Professional Performance (SOPP) for Registered Dietitian Nutritionists (RDNs) (Competent, Proficient, and Expert) in Adult Weight Management* as part of the *Professional Development Portfolio* Process[a]	
1. Reflect	Assess your current level of practice and whether your goals are to expand your practice or maintain your current level of practice. Review the SOP and SOPP for RDNs in Adult Weight Management document to determine what you want your future practice to be, and assess your strengths and areas for improvement. These documents can help you set short- and long-term professional goals.
2. Conduct learning needs assessment	Once you have identified your future practice goals, you can review the SOP and SOPP for RDNs in Adult Weight Management document to assess your current knowledge, skills, behaviors, and define what continuing professional education is required to achieve the desired level of practice.
3. Develop learning plan	Based on your review of the SOP and SOPP for RDNs in Adult Weight Management, you can develop a plan to address your learning needs as they relate to your desired level of practice.
4. Implement learning plan	As you implement your learning plan, keep reviewing the SOP and SOPP for RDNs in Adult Weight Management document to reassess knowledge, skills, and behaviors and your desired level of practice.
5. Evaluate learning plan process	Once you achieve your goals and reach or maintain your desired level of practice, it is important to continue to review the SOP and SOPP for RDNs in Adult Weight Management document to reassess knowledge, skills, and behaviors and your desired level of practice.
[a]The Commission on Dietetic Registration *Professional Development Portfolio* process is divided into five interdependent steps that build sequentially upon the previous step during each 5-year recertification cycle and succeeding cycles.	

Figure 4. Case examples of Standards of Practice and Standards of Professional Performance for Registered Dietitian Nutritionists (RDNs) (Competent, Proficient, and Expert) in Pediatric Nutrition.

Role	*Examples of use of SOP and SOPP documents by RDNs in different practice roles*
Clinical practitioner	The hospital employing a registered dietitian nutritionist (RDN) in general clinical practice has changed the coverage assignment for the RDN to include services for patients/clients in the weight management setting. The RDN reviews available resources regarding weight management for this patient population. The RDN recognizes a need for specific knowledge and/or skills that are not familiar. The RDN reviews the Standards of Practice (SOP) and Standards of Professional Performance (SOPP) to evaluate individual skills and competencies for providing care to individuals with weight management concerns. The RDN sets his or her goals to improve competency in this area of practice before beginning to provide patient care to this population independently.
Manager	A manager who oversees a number of RDNs providing weight management counseling to individuals with a variety of medical conditions in the weight management clinic considers the SOP and SOPP when determining work assignments, when determining expertise needed at the program level, and when assisting staff in evaluating competency and needs for additional knowledge and/or skills in weight management. The manager recognizes the SOP and SOPP as important tools for staff to use to assess their own competencies and as the basis for identifying personal performance plans.
Practitioner returning to employment or private practice	After several years out of clinical practice, an RDN decides to return to active practice. The RDN plans to start a private practice and would like one of the focus areas to be individuals who require weight management counseling and education. Before accepting referrals, the RDN uses the SOP and SOPP as an evaluation tool to determine the knowledge and skills needed to competently provide quality weight management counseling and education.
Public health or community nutrition practitioner	An RDN working in a community health nutrition program notices an increase in the number of clients who are near or above the body mass index for overweight and obesity. The RDN uses the SOP and SOPP to evaluate the level of competence needed to provide quality weight management to these individuals, identity areas for education and skill building, and to determine what level of practitioner to refer individuals who are found to require a level of care higher than the RDN can competently provide.
Researcher	An RDN working in a research setting is awarded a grant to demonstrate the role of the RDN and the impact of weight management provided by the RDN on health outcomes. The RDN uses the SOP and SOPP to assist with design of the research protocol.
Nutrition and dietetics educator	An RDN develops tools (eg, handouts, presentations, workshops, social networking tools) for targeted populations (eg, corporate wellness settings, outpatient clinics, bariatric centers, health and wellness fair attendees) that reflect application of the SOP SOPP for RDNs in Adult Weight Management.
Other settings	An RDN is interested is working with an online weight management company and takes a position with a commercial online weight management company. The RDN reviews the SOP and SOPP for RDNs in Adult Weight Management to determine the knowledge, skills, and competencies needed to implement the nutrition care process (eg, assess, diagnose, implement a care plan, monitor, and evaluate) with overweight or obese individuals. The RDN develops a plan for education and skill development and incorporates it into his or her Professional Development Portfolio. An RDN employed by or consulting in occupational settings (eg, police academy, military, national guard, police or fire department) uses the SOP and SOPP for RDNs in Adult Weight Management as a guide for delivering weight management and dietetics care in nontraditional settings (eg, law enforcement, military training/combat, emergency response).

Figure 5. Case examples of Standards of Practice (SOP) and Standards of Professional Performance (SOPP) for Registered Dietitian Nutritionists (RDNs) (Competent, Proficient, and Expert) in Adult Weight Management.

performance and continuous quality improvement. See Figure 5 for case examples of how RDNs in different roles, at different levels of practice, may use the SOP and SOPP in Adult Weight Management.

In some instances, components of the SOP and SOPP for RDNs in Adult Weight Management do not specifically differentiate between proficient-level and expert-level practice. In these areas, it was the consensus of the content experts that the distinctions are subtle, captured in the knowledge, experience, and intuition demonstrated in the context of practice at the expert level, which combines dimensions of understanding, performance, and value as an integrated whole.[25] A wealth of knowledge is embedded in the experience, discernment, and practice of expert-level RDN practitioners. The knowledge and skills acquired through practice will continually expand and mature. The indicators will be refined as expert-level RDNs systematically record and document their experience using the concept of clinical exemplars. Clinical exemplars include a brief description of the need for action and the process used to change the outcome. The experienced practitioner observes clinical events, analyzes them to make new connections between events and ideas, and produces a synthesized whole. Clinical exemplars provide outstanding models of the actions of individual weight management RDNs in clinical settings and the professional activities that have enhanced patient/client care.[26,27]

FUTURE DIRECTIONS

The SOP and SOPP for RDNs in Adult Weight Management are innovative and dynamic documents. Future revisions will reflect changes and advances in practice, dietetics education programs, and outcomes of practice audits. The authors acknowledge that the three practice levels may require more clarity and differentiation in content and role delineation, and that competency statements that better characterize differences among the practice levels are needed. Creation of this clarity, differentiation, and definition are the challenges of today's weight management RDNs to better serve tomorrow's practitioners and their patients, clients, and customers.

Weight management is increasingly considered as a specialty career track to address the unique needs of the obesity epidemic. The Academy Council on Future Practice, upon petitioning from WM DPG and the Diabetes Care and Education DPG, has requested CDR develop a new interprofessional specialist credential—Board Certified Specialist in Obesity and Weight Management (CSOWM). This credential will reflect the attainment of specialty knowledge, experience, and skills, therefore, elevating the role of the RDN in obesity and weight management.

CONCLUSIONS

RDNs face complex situations every day. Addressing the unique needs of each situation and applying standards appropriately is essential to providing safe, timely, person-centered quality care and service. All RDNs are advised to conduct their practice based on the most recent edition of the Code of Ethics, the Scope of Practice in Nutrition and Dietetics, the Scope of Practice for the RDN and the SOP in Nutrition Care and SOPP for RDNs. The SOP and SOPP for RDNs in Adult Weight Management are complementary documents and are key resources for RDNs at all knowledge and performance levels. These standards can and should be used by weight management RDNs in daily practice to consistently improve and appropriately demonstrate competency and value as providers of safe and effective nutrition and dietetics care and services. These standards also serve as a professional resource for self-evaluation and professional development for RDNs specializing in weight management practice. Just as a professional's self-evaluation and continuing education process is an ongoing cycle, these standards are also a work in progress and will be reviewed and updated every 5 years. Current and future initiatives of the Academy, as well as advances in weight management care and services, will provide information to use in these updates and in further clarifying and documenting the specific roles and responsibilities of RDNs at each level of practice. As a quality initiative of the Academy and the WM DPG, these standards are an application of continuous quality improvement and represent an important collaborative endeavor.

These standards have been formulated to be used for individual self-evaluation and the development of practice guidelines and specialist credentials, but not for disciplinary actions, or determinations of negligence or misconduct. These standards do not constitute medical or other professional advice, and should not be taken as such. The information presented in these standards is not a substitute for the exercise of professional judgment by the health care professional. The use of the standards for any other purpose than that for which they were formulated must be undertaken within the sole authority and discretion of the user.

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STATEMENT OF POTENTIAL CONFLICT OF INTEREST

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Standard 1: Nutrition Assessment
The registered dietitian nutritionist (RDN) uses accurate and relevant data and information to identify nutrition-related problems.

Rationale:
Nutrition assessment is the first of four steps of the Nutrition Care Process. Nutrition assessment is a systematic process of obtaining, verifying, and interpreting data in order to make decisions about the nature and cause of nutrition-related problems. It is initiated by referral and screening of individuals or groups for nutrition risk factors.

Nutrition assessment is conducted using validated tools, the five domains of nutrition assessment and comparative standards as documented in the Nutrition Care Process Terminology (eNCPT). eNCPT is available as an online resource (formerly the *International Dietetics & Nutrition Terminology Reference Manual* [IDNT]). Nutrition assessment is an ongoing, dynamic process that involves not only initial data collection, but also reassessment and analysis of patient/client or community needs. It provides the foundation for nutrition diagnosis, the second step of the Nutrition Care Process.

Refer to the eNCPT online.

Indicators for Standard 1: Nutrition Assessment						
Bold Font Indicators are Academy Core RDN Standards of Practice Indicators				**The "X" signifies the indicators for the level of practice**		
Each RDN:				**Competent**	**Proficient**	**Expert**
1.1	**Anthropometric assessment: Assesses anthropometric measures that may include: height, weight, body mass index (BMI), waist circumference, growth pattern indices/percentile ranks/*z*-scores, and weight history, using:**			**X**	**X**	**X**
	1.1A	Standard procedures and equipment for height, weight, calculation of BMI, and waist circumference		X	X	X
		1.1A1	Scales, stadiometers, skinfold calipers, and other equipment appropriate to target population	X	X	X
		1.1A2	Ethnic-specific criteria when evaluating waist circumference and BMI	X	X	X
	1.1B	Body composition using most appropriate instrument when excess fat and/or excess skin present.			X	X
	1.1C	Body composition with validated instruments, such as magnetic resonance imaging, dual-energy x-ray absorptiometry, and computed tomography, that segment body fat to determine body fat distribution				X
1.2	**Biochemical data, medical tests, and procedure assessment: Assesses laboratory profiles, medical tests, and procedures that may include: acid–base balance, electrolyte, renal, essential fatty acid, gastrointestinal, glucose/endocrine, inflammatory, lipid, metabolic rate, mineral, nutritional anemia, protein, urine, and vitamin/mineral profiles**			**X**	**X**	**X**
	1.2A	Routine diagnostic tests and therapeutic procedures (eg, complete blood count, comprehensive metabolic panel, blood pressure, heart rate, electrocardiogram)		X	X	X
	1.2B	More complex diagnostic tests and therapeutic procedures (endocrine markers, urinary analysis, sleep studies)			X	X
	1.2C	Resting energy expenditure utilizing a room calorimeter or validated indirect calorimetry			X	X

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Figure 1. Standards of Practice for Registered Dietitian Nutritionist (RDNs) in Adult Weight Management.

Indicators for Standard 1: Nutrition Assessment						
Bold Font Indicators are Academy Core RDN Standards of Practice Indicators				**The "X" signifies the indicators for the level of practice**		
Each RDN:				**Competent**	**Proficient**	**Expert**
1.3	**Nutrition-focused physical findings assessment (often referred to as clinical assessment): Assesses findings from evaluation of body systems, muscle and subcutaneous fat wasting, oral health, hair, skin and nails, signs of edema, suck/swallow/breathe ability, appetite, and affect**			**X**	**X**	**X**
	1.3A	Clinical signs of fluid imbalance (eg, skin turgor with dehydration, fatigue, muscle cramps, dark urine, rapid weight change with fluid overload or loss, constipation)		X	X	X
	1.3B	Clinical signs of nutrition-related chronic disease (eg, acanthosis nigricans, waist circumference, BMI)		X	X	X
	1.3C	Clinical signs of undernutrition (eg, dry, brittle, or thinning hair and nails, irritability, inability to concentrate)		X	X	X
	1.3D	Clinical signs of malnutrition, which include disordered eating and eating disorders (eg, hypothermia, bradycardia, lanugo, muscle wasting, tooth erosion, bony protrusions, parotid gland enlargement, gastrointestinal distress)			X	X
	1.3E	Complex health issues (eg, intellectual and/or developmental disabilities)				X
1.4	**Food and nutrition-related history assessment (often referred to as dietary assessment): Assesses**			**X**	**X**	**X**
	1.4A	**Food and nutrient intake, including the composition and adequacy of food and nutrient intake, meal and snack patterns, and food allergies and intolerances**		**X**	**X**	**X**
		1.4A1	Self-reported and/or confirmed food allergy or intolerance (eg, gluten sensitivity/intolerance, lactose intolerance/milk allergy)	X	X	X
		1.4A2	Current and past patient/client use of alcohol, specialized diets, functional foods, and liquid meal replacements.	X	X	X
		1.4A3	Changes in appetite or usual intake as a result of deliberate weight-control measures, medical conditions, illnesses, and injuries	X	X	X
		1.4A4	Changes in appetite or usual intake as a result of psychological factors (eg, depression, anxiety, PTSD[a])	X	X	X
		1.4A5	Changes in appetite or usual intake related to chronic disease, psychiatric disease (eg, bipolar disorder, dissociative identity disorder), or psychotropic medications		X	X
	1.4B	**Food and nutrient administration, including current and previous diets and diet prescriptions and food modifications, eating environment, and enteral and parenteral nutrition administration**		**X**	**X**	**X**
		1.4B1	Occupational influences on eating patterns (eg, meal/snack access; night, split, extended shifts)	X	X	X

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Figure 1. *(continued)* Standards of Practice for Registered Dietitian Nutritionist (RDNs) in Adult Weight Management.

Indicators for Standard 1: Nutrition Assessment						
Bold Font Indicators are Academy Core RDN Standards of Practice Indicators				**The "X" signifies the indicators for the level of practice**		
Each RDN:				**Competent**	**Proficient**	**Expert**
		1.4B2	Home influences on eating patterns (eg, budget, time, food preferences) and responsibilities related to meal planning, purchasing, and preparation	X	X	X
		1.4B3	Social environment (eg, social interactions around meals and the influence of others on eating and food choices)	X	X	X
		1.4B4	Lifestyle practices at home, work, and play (eg, food episodes, structure, location, and time of day for meals and snacks)	X	X	X
		1.4B5	Level of support needed for self-directed food selection, attainment, preparation, and intake (eg, support of care providers, adaptive equipment, literacy tools)		X	X
	1.4C	**Medication and dietary and herbal supplement use, including prescription and over-the-counter medications, herbal preparations, and complementary medicine products used**		**X**	**X**	**X**
		1.4C1	Safety and efficacy of dietary and supplement intake (eg, macro- and micronutrients, fiber, bioactive substances, caffeine, herbals) and supplements for weight management	X	X	X
			1.4C1i Reports adverse events to MedWatch, the US Food and Drug Administration Safety Information and Adverse Event Reporting Program	X	X	X
		1.4C2	Actual or potential drug/nutrient interactions	X	X	X
		1.4C3	Nutrition-related side effects (including alterations in absorption, metabolism, or excretion of nutrients) of long-term use of medication		X	X
		1.4C4	Adequacy of vitamin and mineral supplements for the bariatric patient/client		X	X
	1.4D	**Knowledge, beliefs, and attitudes including understanding of nutrition-related concepts, conviction of the truth, and feelings/emotions toward some nutrition-related statement or phenomenon, body image, and preoccupation with food and weight, and readiness to change nutrition-related behaviors**		**X**	**X**	**X**
		1.4D1	Food preparation skills and knowledge	X	X	X
		1.4D2	Eating beliefs and conviction (eg, food combination, avoiding "white foods")	X	X	X
		1.4D3	Underlying or nonapparent barriers or failures that hinder adherence to nutrition therapy		X	X

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Figure 1. *(continued)* Standards of Practice for Registered Dietitian Nutritionist (RDNs) in Adult Weight Management.

Indicators for Standard 1: Nutrition Assessment							
Bold Font Indicators are Academy Core RDN Standards of Practice Indicators					**The "X" signifies the indicators for the level of practice**		
Each RDN:					**Competent**	**Proficient**	**Expert**
	1.4E	**Behavior including patient/client activities and actions, which influence achievement of nutrition-related goals**			**X**	**X**	**X**
		1.4E1	Adherence to goals (eg, self-reported adherence, visit attendance, recall of nutrition goals, self-monitoring, and self-management as agreed upon)		X	X	X
		1.4E2	Knowledge of and ability to eat mindfully (eg, hunger cues, emotions, distractions, monitor/manage eating antecedents such as hunger, mood, location, work/life situations)		X	X	X
		1.4E3	Behaviors associated with disordered eating/eating disorders such as binge eating, use of compensatory behaviors (eg, purging, laxative use)		X	X	X
			1.4E3i	At-risk behaviors, such as perfectionism, fear of eating unhealthy foods		X	X
	1.4F	**Factors affecting access to food that influence intake and availability of a sufficient quantity of safe, healthful food and water, as well as food/nutrition-related supplies**			**X**	**X**	**X**
		1.4F1	Safe, healthful food/meal availability (eg, financial resources, access to farms, markets, and/or groceries; access to appropriate kitchen, pantry, and equipment for safely cooking, serving, and storing food)		X	X	X
		1.4F2	Awareness and use of community resources for food (eg, SNAP[b], food bank, WIC[c], shelters)		X	X	X
	1.4G	**Physical activity, cognitive, and physical ability to engage in specific tasks, such as self-feeding, activities of daily living (ADLs), instrumental activities of daily living (IADLs), and breastfeeding**			**X**	**X**	**X**
	1.4H	**Nutrition-related patient/client-centered measures, including nutrition quality of life, and patient/client perception of his or her nutrition intervention, cultural, ethnic, religious, and lifestyle factors and their impact on life**			**X**	**X**	**X**
		1.4H1	Food-related beliefs, behaviors, and traditions		X	X	X
		1.4H2	Family influences, cultural, ethnic, and religious implications for weight management goals		X	X	X
1.5	**Patient/client history: Assesses current and past information related to personal, medical, family, and social history**				**X**	**X**	**X**
	1.5A	Weight history through childhood, adolescence, and adulthood			X	X	X
		1.5A1	Specific developmental stages when significant weight change occurred		X	X	X
		1.5A2	Life events related to significant weight change (eg, marriage, birth, divorce, death, job changes)		X	X	X

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Figure 1. *(continued)* Standards of Practice for Registered Dietitian Nutritionist (RDNs) in Adult Weight Management.

Indicators for Standard 1: Nutrition Assessment						
Bold Font Indicators are Academy Core RDN Standards of Practice Indicators				**The "X" signifies the indicators for the level of practice**		
Each RDN:				**Competent**	**Proficient**	**Expert**
		1.5A3	Key benchmarks related to weight status (eg, highest/lowest adult weight, usual body weight, pre/post-pregnancy weight)	X	X	X
		1.5A4	Incidence of trauma (eg, sexual, domestic, physical and/or mental) related to significant weight change		X	X
	1.5B	Medical history of health, disease conditions, and other comorbidities		X	X	X
		1.5B1	Metabolic and hormonal conditions that may be associated with weight status (eg, prediabetes, diabetes, polycystic ovary syndrome, thyroid disorders, CVD[d], PVD[e], sleep apnea, and bariatric surgery)	X	X	X
		1.5B2	Weight-related side effects of medications (eg, weight gain associated with anti-inflammatory, antihypertensive, antidepressants, antipsychotics; weight loss associated with diuretics, stimulants, medications taken specifically for weight loss)		X	X
		1.5B3	Medical and surgical procedures, such as amputations and gastrointestinal surgeries that could impact nutrition and weight status		X	X
		1.5B4	Potential physiological and sensory challenges associated with obesity-related diagnosis (eg, altered gastrointestinal function related to hypotonia from cerebral palsy, gastroparesis related to diabetes, limited food acceptance related to sensory issues from autism)		X	X
	1.5C	Family history for weight and related comorbidities		X	X	X
		1.5C1	Family history of bariatric surgery	X	X	X
		1.5C2	Family interaction patterns that supported or hindered weight management	X	X	X
	1.5D	History of previous weight-loss strategies/medical nutrition therapy		X	X	X
		1.5D1	Behavioral and social environmental factors that supported or hindered previous weight loss/maintenance activities	X	X	X
		1.5D2	Components of previous weight loss attempts most and least helpful for patient/client	X	X	X
	1.5E	History of or current indicators of eating disorders (eg, night, binge and/or restrictive eating, purging, excessive exercise)		X	X	X
		1.5E1	Treatment history	X	X	X
	1.5F	History of tobacco, alcohol, and/or drug use, dependency, and treatment		X	X	X

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Figure 1. *(continued)* Standards of Practice for Registered Dietitian Nutritionist (RDNs) in Adult Weight Management.

Indicators for Standard 1: Nutrition Assessment						
Bold Font Indicators are Academy Core RDN Standards of Practice Indicators				**The "X" signifies the indicators for the level of practice**		
Each RDN:				**Competent**	**Proficient**	**Expert**
	1.5G	Level of motivation		X	X	X
		1.5G1	Motivation relative to previous weight loss attempts	X	X	X
		1.5G2	Current stage of change relative to eating and physical activity behaviors	X	X	X
		1.5G3	Patient/client self-efficacy	X	X	X
1.6	**Comparative standards: Identifies and uses comparative standards to estimate energy, fat, protein, carbohydrate, fiber, fluid, vitamin, and mineral needs, as well as recommended body weight, BMI, and desired growth patterns**			**X**	**X**	**X**
	1.6A	**Identifies the most appropriate reference standards (ie, national, state, institutional, and regulatory) based on practice setting, patient/client age, and disease/injury state and compares nutrition assessment data to appropriate criteria, relevant norms, population-based surveys, and standards**		**X**	**X**	**X**
		1.6A1	Clinical practice recommendations for classification and guidelines for overweight and obesity, including BMI and waist circumference (eg, WHO[f] guidelines for classifying level of obesity)	X	X	X
		1.6A2	Recommendations from NHLBI[g] Practical Guide, American Diabetes Association Standards of Medical Care (diabetes.org) as benchmark tools when evaluating physical or clinical findings	X	X	X
	1.6B	Determines adequacy and appropriateness of food, beverage, and nutrient intake (eg, macro- and micronutrients, meal patterns, calories, food allergies) using Dietary Guidelines for Americans and the Dietary Reference Intake		X	X	X
		1.6B1	Determines adequacy of nutrient intake when Dietary Guidelines for Americans do not apply, such as in the bariatric surgery patient		X	X
	1.6C	Determines resting metabolic rate utilizing Mifflin-St Jeor Equation		X	X	X
1.7	**Physical activity habits and restrictions: Assesses physical activity, history of physical activity, and exercise training**			**X**	**X**	**X**
	1.7A	Factors affecting physical activity (eg, age, vision, weight, joint and other health issues, dexterity, amputations, paralysis, medication contraindication)		X	X	X
	1.7B	Factors affecting access to physical activity and environmental safety (eg, physical and climatic, walkability of neighborhood, proximity to parks/green space, access to physical activity facilities/ programs)		X	X	X
	1.7C	Current physical activity level using FITT (Frequency, Intensity, Time, Type) principle		X	X	X

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Figure 1. *(continued)* Standards of Practice for Registered Dietitian Nutritionist (RDNs) in Adult Weight Management.

Indicators for Standard 1: Nutrition Assessment						
Bold Font Indicators are Academy Core RDN Standards of Practice Indicators				**The "X" signifies the indicators for the level of practice**		
Each RDN:				**Competent**	**Proficient**	**Expert**
	1.7D		Current level of physical activity relative to current Physical Activity Guidelines for Americans	X	X	X
	1.7E		Awake time spent sitting or lying down (eg, screen time, sedentary occupation, commute time)	X	X	X
	1.7F		Patient/client knowledge, readiness to learn, barriers, and potential for behavior changes related to physical activity	X	X	X
		1.7F1	Patient/client short- and long-term goals for physical activity	X	X	X
		1.7F2	Potential barriers to success related to ability to meet personal and/or national exercise goals/standards (self-induced, economic, cultural)	X	X	X
		1.7F3	Patient/client self efficacy	X	X	X
	1.7G		Energy expenditure based on physical activity, NEAT (nonexercise activity thermogenesis)		X	X
1.8	**Reviews collected data for factors that affect nutrition and health status**			**X**	**X**	**X**
	1.8A		**Utilizes nutrition assessment data documented by the nutrition and dietetics technician, registered (NDTR) or dietetic technician, registered (DTR) or other health care practitioner**	**X**	**X**	**X**
		1.8A1	Identifies information contributory to weight history in developing nutrition plan of care. Examples are: • Physical activity limitations • Social or living situation • Cultural food habits • Food allergies/intolerances • Disordered eating/eating disorders	X	X	X
		1.8A2	Reviews information on mental health diagnoses as contributes to weight history in developing nutrition plan of care		X	X
	1.8B		Uses complex decision making and experience to draw conclusions from results of tests, procedures, and evaluations in the context of integrated disease management		X	X
		1.8B1	Uses an interdisciplinary approach to identify highly complex issues important in nutrition diagnosis (eg, medical, psychological, behavioral, other therapies)		X	X
1.9	**Organizes and clusters nutrition risk factors, complications, and assessment data to identify possible problem areas for determining nutrition diagnoses**			**X**	**X**	**X**
1.10	**Documents and communicates:**			**X**	**X**	**X**
	1.10A		**Date and time of assessment**	**X**	**X**	**X**

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Figure 1. *(continued)* Standards of Practice for Registered Dietitian Nutritionist (RDNs) in Adult Weight Management.

Indicators for Standard 1: Nutrition Assessment						
Bold Font Indicators are Academy Core RDN Standards of Practice Indicators				**The "X" signifies the indicators for the level of practice**		
Each RDN:				**Competent**	**Proficient**	**Expert**
	1.10B	**Pertinent data (eg, medical, social, behavioral)**		**X**	**X**	**X**
	1.10C	**Comparison to appropriate standards**		**X**	**X**	**X**
	1.10D	**Patient/client perceptions, values, and motivation related to presenting problems**		**X**	**X**	**X**
	1.10E	**Changes in patient/client perceptions, values, and motivation related to presenting problems**		**X**	**X**	**X**
		1.10E1	Ability of patient/client to achieve goals (self-efficacy)	X	X	X
	1.10F	**Reason for discharge/discontinuation or referral if appropriate**		**X**	**X**	**X**

Examples of Outcomes for Standard 1: Nutrition Assessment

- Appropriate assessment tools and procedures (matching assessment method to situation) are implemented
- Assessment tools are applied in valid and reliable ways
- Appropriate and pertinent data are collected
- Effective interviewing methods are utilized
- Data are organized and categorized in a meaningful framework that relates to nutrition problems
- Data are validated
- Use of assessment data leads to the determination that a nutrition diagnosis/problem does or does not exist
- Problems that require consultation with or referral to another provider are recognized
- Documentation and communication of assessment are complete, relevant, accurate, and timely

Standard 2: Nutrition Diagnosis

The registered dietitian nutritionist (RDN) identifies and labels specific nutrition problem(s)/diagnosis(es) that the RDN is responsible for treating.

Rationale:

Nutrition Diagnosis is the second of four steps of the Nutrition Care Process. At the end of the nutrition assessment step, data are clustered, analyzed, and synthesized. This will reveal a nutrition diagnosis category from which to formulate a specific nutrition diagnosis statement.

The nutrition diagnosis demonstrates a link to determining goals for outcomes, selecting appropriate interventions, and tracking progress in attaining expected outcomes. Diagnosing nutrition problems is the responsibility of the RDN.

Refer to the eNCPT online.

Indicators for Standard 2: Nutrition Diagnosis					
Bold Font Indicators are Academy Core RDN Standards of Practice Indicators			**The "X" signifies the indicators for the level of practice**		
Each RDN:			**Competent**	**Proficient**	**Expert**
2.1	**Derives the nutrition diagnosis(es) from the assessment data**		**X**	**X**	**X**
	2.1A	**Identifies and labels the problem**	**X**	**X**	**X**
	2.1B	**Determines etiology (cause/contributing risk factors)**	**X**	**X**	**X**

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Figure 1. *(continued)* Standards of Practice for Registered Dietitian Nutritionist (RDNs) in Adult Weight Management.

Indicators for Standard 2: Nutrition Diagnosis					
Bold Font Indicators are Academy Core RDN Standards of Practice Indicators			**The "X" signifies the indicators for the level of practice**		
Each RDN:			**Competent**	**Proficient**	**Expert**
	2.1C	**Clusters signs and symptoms (defining characteristics)**	**X**	**X**	**X**
	2.1D	Uses complex information and data (eg, biochemical, weight-influencing medications, trauma, and psychological history)		X	X
	2.1E	Uses complex information related to food intake and clinical factors (eg, conditions or disease states such as diabetes, cardiovascular disease, bariatric surgery, pregnancy, lactation, disordered eating, psychiatric illness, and developmental disability)		X	X
	2.1F	Uses complex information related to food intake and clinical complications and their management within the multidisciplinary environment (eg, uncontrolled diabetes, kidney disease, neuropathy)			X
2.2	**Prioritizes and classifies the nutrition diagnosis(es)**		**X**	**X**	**X**
	2.2A	Uses evidence-based protocols and guidelines for obesity to prioritize nutrition diagnosis in order of importance or urgency	X	X	X
	2.2B	Uses experience and clinical judgment in addition to protocols and guidelines for obesity to determine nutrition diagnosis hierarchy for patient/client with complex needs		X	X
	2.2C	Determines the nutrition diagnosis hierarchy for disease states and complications in designing nutrition protocols and guidelines			X
2.3	**Validates the nutrition diagnosis(es) with patients/clients/community, family members, or other health care professionals when possible and appropriate; corroborates right patient/client to right diagnosis**		**X**	**X**	**X**
	2.3A	Provides evidence to substantiate the nutrition diagnosis	X	X	X
2.4	**Documents the nutrition diagnosis(es) using standardized terminology and written statement(s) that include Problem (P), Etiology (E), and Signs and Symptoms (S) (PES statement[s])**		**X**	**X**	**X**
2.5	**Re-evaluates and revises nutrition diagnosis(es) when additional assessment data become available**		**X**	**X**	**X**

Examples of Outcomes for Standard 2: Nutrition Diagnosis

- Nutrition Diagnostic Statements that are:
  - Clear and concise
  - Specific—patient/client or community centered
  - Accurate
  - Based on reliable and accurate assessment data
  - Includes date and time
- Documentation of nutrition diagnosis(es) is relevant, accurate, and timely
- Documentation of nutrition diagnosis(es) is revised and updated as additional assessment data become available

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Figure 1. *(continued)* Standards of Practice for Registered Dietitian Nutritionist (RDNs) in Adult Weight Management.

Standard 3: Nutrition Intervention
The registered dietitian nutritionist (RDN) identifies and implements appropriate, purposefully planned interventions designed with the intent of changing a nutrition-related behavior, risk factor, environmental condition, or aspect of health status for an individual, target group, or the community at large.

Rationale:
Nutrition intervention is the third of four steps of the Nutrition Care Process. It consists of two interrelated components—planning and implementation. Planning involves prioritizing the nutrition diagnoses, conferring with the patient/client and others, reviewing practice guidelines and policies, setting goals, and defining the specific nutrition intervention strategy.

Implementation of the nutrition intervention/plan of care is the action phase that includes carrying out and communicating the intervention/plan of care, continuing data collection, and revising the nutrition intervention/plan of care strategy, as warranted, based on the patient/client response. An RDN implements the interventions or assigns components of nutrition intervention/plan of care to support staff in accordance with applicable laws and regulations. Nutrition intervention/plan of care is ultimately the responsibility of the RDN.

Refer to eNCPT online.

Indicators for Standard 3: Nutrition Intervention					
Bold Font Indicators are Academy Core RDN Standards of Practice Indicators			**The "X" signifies the indicators for the level of practice**		
Each RDN:			**Competent**	**Proficient**	**Expert**
Plans the Nutrition Intervention/Plan of Care					
3.1	**Prioritizes the nutrition diagnosis(es) based on problem severity, safety, patient/client clinical needs, likelihood that nutrition intervention/plan of care will influence problem, and patient/client perception of importance**		**X**	**X**	**X**
	3.1A	Prioritization considerations may include: • Comorbid conditions • Hospitalizations and/or surgery • Lifestyle factors (eg, work schedule, eating environment) • Socioeconomic status (eg, access to food, homelessness) • Food behaviors, food beliefs • Patient/client preferences and goals • Resources and support systems for weight management (eg, family, work, social network)	X	X	X
	3.1B	Stage of change (readiness) stated by patient/client	X	X	X
	3.1C	Challenges that impact nutritional status (eg, genetic disorders, sensory processing disorders, behavioral health issues, pica, disordered eating)		X	X
3.2	**Bases intervention/plan of care on best available research/evidence, evidence-based guidelines and best practices (eg, Academy Position Papers, Academy EAL[h] Adult Weight Management Evidence-Based Nutrition Practice Guideline, National Guidelines-Dietary Guidelines for Americans, AHA/ACC/TOS[i] Guideline for the Management of Overweight and Obesity in Adults)**		**X**	**X**	**X**
	3.2A	Recognizes when it is appropriate to utilize adjusted intervention guidelines for patient/clients (eg, intellectual and/or developmental disabilities, Prader-Willi syndrome, Down syndrome; and patients/clients receiving psychiatric medications)		X	X

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Figure 1. *(continued)* Standards of Practice for Registered Dietitian Nutritionist (RDNs) in Adult Weight Management.

Indicators for Standard 3: Nutrition Intervention						
Bold Font Indicators are Academy Core RDN Standards of Practice Indicators				**The "X" signifies the indicators for the level of practice**		
Each RDN:				**Competent**	**Proficient**	**Expert**
3.3	**Refers to policies and program standards**			**X**	**X**	**X**
3.4	**Confers with patient/client, caregivers, interdisciplinary team, and other health care professionals**			**X**	**X**	**X**
3.5	**Determines patient/client-centered plan, goals, and expected outcomes**			**X**	**X**	**X**
	3.5A	Encourages patient/client to play an active role in goal setting for behavior change		X	X	X
	3.5B	Identifies barriers to successful implementation (eg, patient/client compliance, food availability and preparation issues, social support, readiness to change, financial considerations, realistic expectations, food knowledge and duration of treatment, commitment to process)		X	X	X
	3.5C	Develops and implements strategies to address lapses in commitment or behaviors and identifies recovery strategies			X	X
	3.5D	Communicates to the patient/client physiological processes of weight regulation in helping patient/client set realistic expectations			X	X
3.6	**Develops the nutrition prescription**			**X**	**X**	**X**
	3.6A	Considers the educational needs of the patient/client, including cultural competency and health literacy		X	X	X
		3.6A1	Reviews food access and preparation skills needed to reach goal(s)	X	X	X
	3.6B	Considers general physical activity recommendations for health and fitness based on published, evidence-based population-specific positions and guidelines (eg, Physical Activity Guidelines for Americans, ACSM[j])		X	X	X
	3.6C	Assists medically cleared patient/client with establishing physical activity goals and devising plans for execution		X	X	X
	3.6D	Tailors prescription to meet nutrient and energy needs considering multiple morbidities		X	X	X
		3.6D1	Takes into consideration complexities of the patient/client (eg, bariatric surgery, medication use, metabolic conditions)		X	X
	3.6E	Develops individualized plan of care		X	X	X
3.7	**Defines time and frequency of care, including intensity, duration, and follow-up**			**X**	**X**	**X**
	3.7A	Utilizes guidelines established for MNT[k] and AHA/ACC/TOS recommendations for obesity management		X	X	X
3.8	**Utilizes standardized terminology for describing interventions**			**X**	**X**	**X**

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Figure 1. *(continued)* Standards of Practice for Registered Dietitian Nutritionist (RDNs) in Adult Weight Management.

Indicators for Standard 3: Nutrition Intervention					
Bold Font Indicators are Academy Core RDN Standards of Practice Indicators			**The "X" signifies the indicators for the level of practice**		
Each RDN:			**Competent**	**Proficient**	**Expert**
3.9	**Identifies resources and referrals needed**		**X**	**X**	**X**
	3.9A	Tools to assist patient/client with managing food intake (eg, food guides, computer/tablet/phone apps, portion guides, scales)	X	X	X
	3.9B	Resources to support patient/client with behavior change goals (eg, community support groups, fitness facilities, or programs)	X	X	X
	3.9C	Referrals to programs/providers based on individual patient/client needs (eg, behavioral health, fitness professional, medical weight management program, bariatric specialist)	X	X	X
	3.9D	Resources/referrals for complex needs (eg, behavioral, communication, dysphasia management, skills training for care providers/family, feeding team)		X	X
Implements the Nutrition Intervention/Plan of Care					
3.10	**Collaborates with colleagues, interdisciplinary team, and other health care professionals**		**X**	**X**	**X**
	3.10A	Provides ongoing follow-up documentation to referring physician	X	X	X
	3.10B	Refers to other members of interdisciplinary team when need is outside scope of practice of RDN (eg, exercise physiologist, behavioral health professionals)	X	X	X
	3.10C	Facilitates and fosters active communication, learning, partnerships, and collaboration within the interdisciplinary team and other providers as appropriate		X	X
	3.10D	Directs the interdisciplinary team and others as appropriate			X
3.11	**Communicates and coordinates the nutrition intervention/plan of care**		**X**	**X**	**X**
	3.11A	Ensures that patient/client and, as appropriate, family/significant others/caregivers, understand and can articulate goals and other relevant aspects of plan of care	X	X	X
	3.11B	Communicates plan of care to other health care professionals involved in implementation of the plan	X	X	X
	3.11C	Coordinates care for the patient/client with other members of the health care team (eg, physician, pharmacist, bariatric coordinator, exercise professional, medical weight management coordinator)		X	X

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Figure 1. *(continued)* Standards of Practice for Registered Dietitian Nutritionist (RDNs) in Adult Weight Management.

Indicators for Standard 3: Nutrition Intervention					
Bold Font Indicators are Academy Core RDN Standards of Practice Indicators			**The "X" signifies the indicators for the level of practice**		
Each RDN:			**Competent**	**Proficient**	**Expert**
3.12	**Initiates and individualizes the nutrition intervention/plan of care**		**X**	**X**	**X**
	3.12A	**Utilizes physician/referring practitioner-driven protocols or other facility-specific processes to implement, initiate, or modify orders for diet or nutrition-related services (eg, nutrition supplements, dietary supplements, food texture modifications for dentition or individual preferences, enteral and parenteral nutrition, nutrition-related laboratory tests and medications, and nutrition education and counseling); services are consistent with specialized training where required, competence, approved clinical privileges for order writing, and organization policy**	**X**	**X**	**X**
	3.12B	**Utilizes physician/referring practitioner-driven protocols or other facility-specific processes to manage nutrition support therapies (eg, formula selection, rate adjustments based on energy needs or laboratory results, addition of designated medications and vitamin/mineral supplements to parenteral nutrition solutions or supplemental water for enteral nutrition); services are consistent with specialized training where required, competence, approved clinical privileges for order writing and organization policy**	**X**	**X**	**X**
	3.12C	Addresses topics with patient/client as outlined in nutrition prescription when developing the plan of care (eg, access to food, food preparation capabilities, food selection and preparation, meal planning, portion control, physical activity goals, socioeconomic status, social support, motivation, barriers to change)	X	X	X
	3.12D	Uses a variety of educational and behavioral approaches, tools, and materials as appropriate	X	X	X
	3.12E	Uses advanced behavior change techniques to facilitate patient/client self-management (eg, motivational interviewing, behavior modification, cognitive behavioral skills)		X	X
	3.12F	Uses critical thinking and synthesis skills to guide decision making in complex situations (eg, pre/post bariatric surgery, post−bariatric surgery vitamin deficiencies)		X	X
	3.12G	Uses critical thinking and synthesis skills to guide decision making in complicated, unpredictable situations (eg, uncontrolled diabetes, eating disorders with medical complications, post−bariatric surgery reactive hypoglycemia)			X
3.13	**Assigns activities to NDTR or DTR and other administrative support and technical personnel in accordance with qualifications, organization policies, and applicable laws and regulations**		**X**	**X**	**X**
	3.13A	**Supervises support personnel**	**X**	**X**	**X**
	3.13B	Provides support personnel with information and guidance needed to complete assigned activities	X	X	X

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Figure 1. *(continued)* Standards of Practice for Registered Dietitian Nutritionist (RDNs) in Adult Weight Management.

Indicators for Standard 3: Nutrition Intervention					
Bold Font Indicators are Academy Core RDN Standards of Practice Indicators			**The "X" signifies the indicators for the level of practice**		
Each RDN:			**Competent**	**Proficient**	**Expert**
3.14	**Continues data collection**		**X**	**X**	**X**
	3.14A	Identifies specific data to be collected for the patient/client, including weight change, biochemical, behavioral, and lifestyle factors	X	X	X
	3.14B	Utilizes a prescribed/standardized format for recording data	X	X	X
	3.14C	Utilizes data obtained from validated measures (eg, IWQOL-Lite,[l] WCSS[m])		X	X
3.15	**Follows up and verifies that nutrition intervention/plan of care is occurring**		**X**	**X**	**X**
	3.15A	Reviews plan with patient/client and other health care professionals on a schedule as appropriate based on protocol, patient/client needs, and/or payor considerations	X	X	X
	3.15B	Communicates data with other health care professionals as needed for interdisciplinary care	X	X	X
3.16	**Adjusts nutrition intervention/plan of care strategies, if needed, as response occurs**		**X**	**X**	**X**
	3.16A	Reviews analysis of data trends and modifies plan of care, if indicated	X	X	X
	3.16B	Collaborates with patient/client to modify goals and assigned actions based on new information and/or feedback from the patient/client	X	X	X
	3.16C	Utilizes intervention strategies to encourage greater independence in food choices and empower the patient/client to take control of his or her health and achieve wellness		X	X
	3.16D	Uses critical thinking and synthesis skills in decision making in complex situations and in combining multiple intervention approaches		X	X
	3.16E	Makes adjustments in supportive services as needed (eg, training of direct providers, collaboration with health care professionals)		X	X
	3.16F	Draws on experiential knowledge, clinical judgment, and research about the patient/client population to tailor the strategy in complicated, unpredictable, and dynamic situations			X
3.17	**Documents:**		**X**	**X**	**X**
	3.17A	**Date and time**	**X**	**X**	**X**
	3.17B	**Specific treatment goals and expected outcomes**	**X**	**X**	**X**
	3.17C	**Recommended interventions**	**X**	**X**	**X**
	3.17D	**Adjustments to the plan and justification**	**X**	**X**	**X**
	3.17E	**Patient/client/community receptivity**	**X**	**X**	**X**
	3.17F	**Referrals made and resources used**	**X**	**X**	**X**

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Figure 1. *(continued)* Standards of Practice for Registered Dietitian Nutritionist (RDNs) in Adult Weight Management.

Indicators for Standard 3: Nutrition Intervention					
Bold Font Indicators are Academy Core RDN Standards of Practice Indicators			**The "X" signifies the indicators for the level of practice**		
Each RDN:			**Competent**	**Proficient**	**Expert**
	3.17G	**Patient/client comprehension**	**X**	**X**	**X**
	3.17H	**Barriers to change**	**X**	**X**	**X**
	3.17I	**Other information relevant to providing care and monitoring progress over time**	**X**	**X**	**X**
	3.17J	**Plans for follow up and frequency of care**	**X**	**X**	**X**
	3.17K	**Rationale for discharge or referral if applicable**	**X**	**X**	**X**

Examples of Outcomes for Standard 3: Nutrition Intervention

- Appropriate prioritizing and setting of goals/expected outcomes
- Involves patient/client, care givers, and interdisciplinary team, as appropriate, in developing nutrition intervention/plan of care
- Appropriate individualized patient/client-centered nutrition intervention/plan of care, including nutrition prescription, is developed
- Interdisciplinary collaborations are utilized
- Nutrition interventions/plan of care are delivered and actions are carried out
- Documentation of nutrition intervention/plan of care is:
  - Comprehensive
  - Specific
  - Accurate
  - Relevant
  - Timely
  - Dated and Timed
- Documentation of nutrition intervention/plan of care is revised and updated

Standard 4: Nutrition Monitoring and Evaluation

The registered dietitian nutritionist (RDN) monitors and evaluates indicators and outcomes data directly related to the nutrition diagnosis, goals, and intervention strategies to determine the progress made in achieving desired outcomes of nutrition care and whether planned interventions should be continued or revised.

Rationale:

Nutrition monitoring and evaluation is the fourth step in the Nutrition Care Process. Through monitoring and evaluation, the RDN identifies important measures of change or patient/client outcomes relevant to the nutrition diagnosis and nutrition intervention and describes how best to measure these outcomes.

Nutrition monitoring and evaluation are essential components of an outcomes management system. The aim is to promote uniformity within the profession in evaluating the efficacy of nutrition interventions/plans of care.

Refer to eNCPT online.

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Figure 1. *(continued)* Standards of Practice for Registered Dietitian Nutritionist (RDNs) in Adult Weight Management.

Indicators for Standard 4: Nutrition Monitoring and Evaluation						
Bold Font Indicators are Academy Core RDN Standards of Practice Indicators				**The "X" signifies the indicators for the level of practice**		
Each RDN:				**Competent**	**Proficient**	**Expert**
4.1	**Monitors progress:**			**X**	**X**	**X**
	4.1A	**Assesses patient/client understanding and compliance with nutrition intervention/plan of care**		**X**	**X**	**X**
		4.1A1	Evaluates adherence (eg, eating plan, portion and/or calorie control, S.M.A.R.T. [specific, measureable, attainable, realistic, and timely] goals)	X	X	X
	4.1B	**Determines whether the nutrition intervention/plan of care is being implemented as prescribed**		**X**	**X**	**X**
		4.1B1	Evaluates intervention plan implementation considering special situations (eg, holidays, major life events/changes)	X	X	X
		4.1B2	Evaluates nutritional intervention in the face of complex clinical situations (eg, pre/post bariatric surgery; managing weight with complex conditions such as comorbid conditions, multiple medications, food allergies and intolerances, and cultural factors)		X	X
		4.1B3	Utilizes advanced expertise to identify additional resources and/or avenues of therapy to enhance effectiveness of intervention		X	X
	4.1C	**Evaluates progress or reasons for lack of progress related to problems and interventions**		**X**	**X**	**X**
		4.1C1	Identifies factors that facilitate or impede progress such as: • Emotional, social, cognitive, behavioral, environmental factors • Motivators and incentives to change and/or consequences to change	X	X	X
		4.1C2	Uses multiple resources to assess progress (eg, laboratory and other clinical data, self-monitoring tools, changes in body weight/body composition, pertinent medications/dietary supplements) relative to effectiveness of care plan		X	X
		4.1C3	Identifies any changes to patient's/client's cognitive, physical, environmental status that could interfere with plan of care		X	X
		4.1C4	Identifies problems beyond scope of nutrition that are interfering with the interventions and recommends appropriate adjustments			X
	4.1D	**Evaluates evidence that the nutrition intervention/plan of care is influencing a desirable change in the patient/client behavior or status**		**X**	**X**	**X**
		4.1D1	Monitors factors (eg, physical, social, cognitive, environmental) and interprets laboratory and other data that may reflect a change in the patient/client behavior or status	X	X	X

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Figure 1. *(continued)* Standards of Practice for Registered Dietitian Nutritionist (RDNs) in Adult Weight Management.

Indicators for Standard 4: Nutrition Monitoring and Evaluation						
Bold Font Indicators are Academy Core RDN Standards of Practice Indicators				**The "X" signifies the indicators for the level of practice**		
Each RDN:				**Competent**	**Proficient**	**Expert**
	4.1E	**Identifies positive or negative outcomes**		**X**	**X**	**X**
		4.1E1	Documents progress in meeting desired goals (eg, normalized eating patterns; weight loss/maintenance; improved health, including lowered blood pressure, blood cholesterol, stabilized blood glucose [normalized hemoglobin A1c]; improved physical capabilities, such as movement, improved energy, better sleep patterns)	X	X	X
		4.1E2	Identifies unintended consequences (eg, excessive rate of weight loss) or the use of inappropriate methods of achieving goals	X	X	X
		4.1E3	Identifies potential revision of interventions based on outcomes	X	X	X
		4.1E4	Identifies underlying factors interfering with intervention outcomes and access to resources to determine future treatment recommendations		X	X
		4.1E5	Develops action plan in complex cases based on the effect of all interventions on patient's/client's overall health outcome		X	X
	4.1F	**Supports conclusions with evidence**		**X**	**X**	**X**
		4.1F1	Demonstrates that prescribed intervention is successful/ unsuccessful through documentation of clinical, cognitive, and psychosocial indicators	X	X	X
4.2	**Measures outcomes:**			**X**	**X**	**X**
	4.2A	**Selects the nutrition care outcome indicator(s) to measure**		**X**	**X**	**X**
		4.2A1	Anthropometric measures (eg, weight, BMI, waist circumference, rate of weight change)	X	X	X
		4.2A2	Body composition measures (eg, fat mass)	X	X	X
		4.2A3	Laboratory measures (eg, lipid panel, comprehensive metabolic panel)	X	X	X
		4.2A4	Behavioral measures (eg, activity level, eating behaviors, cognitive functioning, goal attainment)	X	X	X
		4.2A5	Quality of life measures (eg, activity and daily living)	X	X	X
		4.2A6	Gut hormones and gut bacteria measures in the research setting			X
	4.2B	**Uses standardized nutrition care outcome indicator(s)**		**X**	**X**	**X**
4.3	**Evaluates outcomes:**			**X**	**X**	**X**
	4.3A	**Compares monitoring data with nutrition prescription/goals or reference standard (eg, ACC/AHA/TOS Adult Obesity Guidelines)**		**X**	**X**	**X**
	4.3B	**Evaluates impact of the sum of all interventions on overall patient/ client health outcomes**		**X**	**X**	**X**

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Figure 1. *(continued)* Standards of Practice for Registered Dietitian Nutritionist (RDNs) in Adult Weight Management.

Indicators for Standard 4: Nutrition Monitoring and Evaluation						
Bold Font Indicators are Academy Core RDN Standards of Practice Indicators				**The "X" signifies the indicators for the level of practice**		
Each RDN:				**Competent**	**Proficient**	**Expert**
	4.3C		Evaluates the patient/client variance from planned outcomes and incorporates findings into future individualized treatment recommendations	X	X	X
	4.3D		Evaluates patient/client outcomes in relation to program goals	X	X	X
		4.3D1	Evaluates underlying factors interfering with intervention outcomes and access to services (eg, prognosis, psychological factors, resources) and analyzes this impact on future recommendations		X	X
		4.3D2	Reassesses and modifies, if applicable action plan in complex cases based on effects of all interventions on patient's/client's overall health outcomes		X	X
4.4	**Documents**			**X**	**X**	**X**
	4.4A		**Date and time**	**X**	**X**	**X**
	4.4B		**Indicators measured, results, and the method for obtaining measurement**	**X**	**X**	**X**
	4.4C		**Criteria to which the indicator is compared (eg, nutrition prescription/goal or a reference standard)**	**X**	**X**	**X**
	4.4D		**Factors facilitating or hampering progress**	**X**	**X**	**X**
	4.4E		**Other positive or negative outcomes**	**X**	**X**	**X**
	4.4F		**Future plans for nutrition care, nutrition monitoring and evaluation, follow-up, referral, or discharge**	**X**	**X**	**X**

Examples of Outcomes for Standard 4: Nutrition Monitoring and Evaluation

- The patient/client/community outcome(s) directly relate to the nutrition diagnosis and the goals established in the nutrition intervention/plan of care. Examples include, but are not limited to:
  - Nutrition outcomes (eg, change in knowledge, behavior, food, or nutrient intake)
  - Clinical and health status outcomes (eg, change in laboratory values, body weight, blood pressure, risk factors, signs and symptoms, clinical status, infections, complications, morbidity, and mortality)
  - Patient-/client-centered outcomes (eg, quality of life, satisfaction, self-efficacy, self-management, functional ability)
  - Health care utilization and cost-effectiveness outcomes (eg, change in medication, special procedures, planned/unplanned clinic visits, preventable hospital admissions, length of hospitalizations, fewer sick days, lower health care premiums, increased worker productivity, morbidity, and mortality)
- Monitoring reflects use of standardized outcomes measures
- Documentation of nutrition monitoring and evaluation is:
  - Comprehensive
  - Specific
  - Accurate
  - Relevant
  - Timely
  - Dated and timed

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Figure 1. *(continued)* Standards of Practice for Registered Dietitian Nutritionist (RDNs) in Adult Weight Management.

Glossary

Resting energy expenditure (REE)—the amount of energy required for a 24-hour period by the body during resting conditions. It is closely related to, but not identical to, basal metabolic rate.

Acanthosis nigricans—skin condition indicative of high insulin levels characterized by areas of dark, velvety discoloration in body folds and creases, generally affects armpits, groin, and neck.

Lanugo—fine, soft hair.

Bioactive substances—extranutritional constituents that typically occur in small quantities in foods currently studied to evaluate their effects on health. Examples include plant stanol and sterol esters, soy protein, psyllium, and b-glucan.

Bariatric surgery—surgical removal/rearrangement of the stomach and/or small intestines to induce weight loss through restriction, malabsorption, and/or gut hormones (gastric bypass, sleeve gastrectomy, laparoscopic adjustable gastric band).

Self-efficacy—belief in one's ability to succeed in specific situations.

Nonexercise activity thermogenesis (NEAT)—energy expended for activities that are not sleeping, eating, volitional exercise.

Motivational interviewing—a goal-oriented, client-centered counseling style for eliciting behavior change by helping clients to explore and resolve ambivalence about changing selected behaviors.

Behavior modification—an approach used to help individuals develop a set of skills to achieve a healthier weight, including the use of self-monitoring, goal setting, and problem-solving strategies.

Quality of life measures—self-reported measures of one's physical and mental well-being (http://www.cdc.gov/hrqol/concept.htm).

[a]PTSD=post-traumatic stress disorder.

[b]SNAP=Supplemental Nutrition Assistance Program.

[c]WIC=Special Supplemental Nutrition Program for Women, Infants, and Children.

[d]CVD=cardiovascular disease.

[e]PVD=peripheral vascular disease.

[f]WHO=World Health Organization (http://www.who.int/en/).

[g]NHLBI=National Heart, Lung, and Blood Institute (http://www.nhlbi.nih.gov).

[h]EAL=Evidence Analysis Library (http://andeal.org).

[i]AHA/ACC/TOS=American Heart Association/American College of Cardiology/The Obesity Society (http://circ.ahajournals.org/content/early/2013/11/11/01.cir.0000437739.71477.ee).

[j]ACSM=American College of Sports Medicine (http://www.acsm.org).

[k]MNT=medical nutrition therapy.

[l]IWQOL-Lite=Impact of Weight on Quality of Life-Lite Questionnaire (http://link.springer.com/referenceworkentry/10.1007%2F978-0-387-78665-0_12).

[m]WCSS=Weight Control Strategies Scale (http://www.ncbi.nlm.nih.gov/pubmed/23512914).

Figure 1. *(continued)* Standards of Practice for Registered Dietitian Nutritionist (RDNs) in Adult Weight Management.

Standard 1: Quality in Practice
The registered dietitian nutritionist (RDN) provides quality services using a systematic process with identified leadership, accountability, and dedicated resources.

Rationale:
Quality practice in nutrition and dietetics is built on a solid foundation of education, credentialing, evidence-based practice, demonstrated competence, and adherence to established professional standards. Quality practice requires systematic measurement of outcomes, regular performance evaluations, and continuous improvement.

Indicators for Standard 1: Quality in Practice						
Bold Font Indicators are Academy Core RDN Standards of Professional Performance Indicators				**The "X" signifies the indicators for the level of practice**		
Each RDN:				**Competent**	**Proficient**	**Expert**
1.1	**Complies with applicable laws and regulations as related to his/her area(s) of practice**			**X**	**X**	**X**
	1.1A	Complies with federal, state, and local laws and regulations related to weight management and patient/client care (eg, Health Insurance Portability and Accountability Act [HIPAA], food safety)		X	X	X
		1.1A1	Complies with state licensure laws, including continuing education requirements	X	X	X
		1.1A2	Complies with telehealth licensure guidelines (http://www.telehealthresourcecenter.org/toolbox-module/licensure-and-scope-practice)	X	X	X
1.2	**Performs within individual and statutory scope of practice**			**X**	**X**	**X**
	1.2A	Discusses with patient/client the relationship between weight and health, physical activity, behavior change, and disease prevention		X	X	X
1.3	**Adheres to sound business and ethical billing practices applicable to the setting**			**X**	**X**	**X**
	1.3A	Complies with appropriate billing codes for payor and type of nutrition visit (eg, group, individual)		X	X	X
1.4	**Utilizes national quality and safety data (eg, Institute of Medicine, National Quality Forum, Institute for Healthcare Improvement) to improve the quality of services provided and to enhance customer-centered service**			**X**	**X**	**X**
	1.4A	Participates in hospital/agency/institution, and local, state, and national quality improvement initiatives		X	X	X
	1.4B	Leads efforts to maximize weight management services using national quality and safety data			X	X
1.5	**Utilizes a systematic performance improvement model that is based on practice knowledge, evidence, research, and science for delivery of the highest-quality services**			**X**	**X**	**X**
	1.5A	Identifies performance improvement criteria to monitor the delivery of services		X	X	X

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Figure 2. Standards of Professional Performance for Registered Dietitian Nutritionists (RDNs) in Adult Weight Management. Note: The term *customer* is used in this evaluation resource as a universal term. Customer could also mean client/patient, client/patient/customer, participant, consumer, or any individual, group, or organization to which the RDN provides service.

Indicators for Standard 1: Quality in Practice						
Bold Font Indicators are Academy Core RDN Standards of Professional Performance Indicators				**The "X" signifies the indicators for the level of practice**		
Each RDN:				**Competent**	**Proficient**	**Expert**
	1.5B		Serves in a leadership role in developing performance improvement criteria for the delivery of services		X	X
1.6	**Participates in or designs an outcomes-based management system to evaluate safety, effectiveness, and efficiency of practice**			**X**	**X**	**X**
	1.6A		**Involves colleagues and others, as applicable, in systematic outcomes management**	**X**	**X**	**X**
		1.6A1	Selects criteria for data collection, and advocates for and participates in the development of clinical, operational, and financial data collection tools upon which weight management nutrition care–sensitive outcomes can be derived, reported, and used for improvement		X	X
		1.6A2	Serves in leadership role to evaluate benchmarks of weight management based on public health and population-based indicators (eg, Healthy People 2020 Leading Health Indicators)			X
	1.6B		**Utilizes indicators that are specific, measurable, attainable, realistic, and timely (S.M.A.R.T.)**	**X**	**X**	**X**
	1.6C		**Defines expected outcomes**	**X**	**X**	**X**
	1.6D		**Measures quality of services in terms of process and outcome**	**X**	**X**	**X**
		1.6D1	Evaluates aggregate patient/client clinical outcomes (eg, BMI[a], biometric, medication, behavior, fitness changes)	X	X	X
		1.6D2	Evaluates the provision of weight management (eg, staff, patient/client ratio, reimbursement data, and customer satisfaction survey results)		X	X
	1.6E		**Documents outcomes**	**X**	**X**	**X**
1.7	**Identifies and addresses potential and actual errors and hazards in provision of services**			**X**	**X**	**X**
	1.7A		Ensures safe care for the weight management patient/client	X	X	X
		1.7A1	Applies safety guidelines when recommending rate of weight loss and physical activity considerations related to weight	X	X	X
		1.7A2	Ensures infrastructure of examination rooms and equipment is appropriate for individuals with severe obesity (eg, space, chairs, blood pressure cuffs, examination tables, scales)	X	X	X
		1.7A3	Develops protocols to identify, address, and prevent errors and hazards in the delivery of weight management services		X	X

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Figure 2. *(continued)* Standards of Professional Performance for Registered Dietitian Nutritionists (RDNs) in Adult Weight Management. Note: The term *customer* is used in this evaluation resource as a universal term. Customer could also mean client/patient, client/patient/customer, participant, consumer, or any individual, group, or organization to which the RDN provides service.

Indicators for Standard 1: Quality in Practice						
Bold Font Indicators are Academy Core RDN Standards of Professional Performance Indicators				**The "X" signifies the indicators for the level of practice**		
Each RDN:				**Competent**	**Proficient**	**Expert**
	1.7B	Reviews literature for safety and recommended use of prescription weight-loss medications and over-the-counter weight-loss supplements		X	X	X
	1.7C	Collaborates with health care team to identify, address, and prevent errors and hazards in the delivery of weight management services		X	X	X
	1.7D	Tailors protocols to support patient/client care, which account for other medical conditions (eg, diabetes, renal disease)			X	X
	1.7E	Develops protocols to identify, address, and prevent errors and hazards in the delivery of weight management services				X
1.8	**Compares actual performance to performance goals (eg Gap Analysis, SWOT Analysis [Strengths, Weaknesses, Opportunities, and Threats], PDCA Cycle [Plan-Do-Check-Act])**			**X**	**X**	**X**
	1.8A	**Reports and documents action plan to address identified gaps in performance**		**X**	**X**	**X**
	1.8B	Compares individual performance to self-directed goals and expected outcomes		X	X	X
		1.8B1	Compares departmental/organizational performance to goals and expected outcomes		X	X
1.9	**Evaluates interventions to improve processes and services**			**X**	**X**	**X**
	1.9A	Tests interventions to improve processes and services		X	X	X
	1.9B	Benchmarks departmental/organizational performance with national programs and standards			X	X
	1.9C	Guides the development, testing, and redesign of program evaluation systems				X
1.10	**Improves or enhances services based on measured outcomes**			**X**	**X**	**X**
	1.10A	Leads in evaluation of systems, processes, and programs to ensure organization and weight management–related core values and evidence-based practices are followed			X	X
	1.10B	Directs the development and management of systems, processes and programs in weight management for continued quality improvement.				X

Examples of Outcomes for Standard 1: Quality in Practice

- Services are within scope of practice and applicable laws and regulations
- Use of national quality standards and best practices are evident in customer-centered services
- Performance indicators are specific, measurable, attainable, realistic, and timely (S.M.A.R.T.)
- Aggregate outcomes results meet pre-established criteria
- Results of quality improvement activities direct refinement and advancement of practice

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Figure 2. *(continued)* Standards of Professional Performance for Registered Dietitian Nutritionists (RDNs) in Adult Weight Management. Note: The term *customer* is used in this evaluation resource as a universal term. Customer could also mean client/patient, client/patient/customer, participant, consumer, or any individual, group, or organization to which the RDN provides service.

Standard 2: Competence and Accountability
The registered dietitian nutritionist (RDN) demonstrates competence in and accepts accountability and responsibility for ensuring safety and quality in the services provided.

Rationale:
Competence and accountability in practice includes continuous acquisition of knowledge, skills, and experience in the provision of safe, quality customer-centered service.

Indicators for Standard 2: Competence and Accountability					
Bold Font Indicators are Academy Core RDN Standards of Professional Performance Indicators			**The "X" signifies the indicators for the level of practice**		
Each RDN:			**Competent**	**Proficient**	**Expert**
2.1	**Adheres to the Code of Ethics**		**X**	**X**	**X**
2.2	**Integrates the Standards of Practice (SOP) and Standards of Professional Performance (SOPP) into practice, self-assessment, and professional development**		**X**	**X**	**X**
	2.2A	Integrates applicable focus area SOP and SOPP into practice	X	X	X
	2.2B	Utilizes the Standards for RDNs in Adult Weight Management to assess performance at the appropriate level of practice	X	X	X
	2.2C	Utilizes the Standards for RDNs in Adult Weight Management to develop and implement a professional plan to improve the quality of practice and performance and to advance practice	X	X	X
	2.2D	Develops corporate/institutional policies, guidelines, human resource materials (eg, job descriptions, career ladders, acceptable performance level) using the Standards for RDNs in Adult Weight Management as guidelines		X	X
	2.2E	Assigns services to levels of performance (competent, proficient, expert) or practice as outlined in SOP and SOPP			X
2.3	**Demonstrates and documents competence in practice and delivery of customer-centered service**		**X**	**X**	**X**
	2.3A	Documents examples of expanded professional responsibility reflective of a proficient practice role		X	X
	2.3B	Documents examples of expanded professional responsibility reflective of an expert practice role			X
2.4	**Assumes accountability and responsibility for services and behaviors**		**X**	**X**	**X**
	2.4A	**Acknowledges and corrects errors**	**X**	**X**	**X**
	2.4B	Develops and directs policies and procedures that ensure staff accountability and responsibility when serving in a management role		X	X
2.5	**Conducts self-assessment at regular intervals**		**X**	**X**	**X**
	2.5A	**Identifies needs for professional development**	**X**	**X**	**X**
	2.5B	Seeks opportunities for professional development	X	X	X

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Figure 2. *(continued)* Standards of Professional Performance for Registered Dietitian Nutritionists (RDNs) in Adult Weight Management. Note: The term *customer* is used in this evaluation resource as a universal term. Customer could also mean client/patient, client/patient/customer, participant, consumer, or any individual, group, or organization to which the RDN provides service.

Indicators for Standard 2: Competence and Accountability					
Bold Font Indicators are Academy Core RDN Standards of Professional Performance Indicators			**The "X" signifies the indicators for the level of practice**		
Each RDN:			**Competent**	**Proficient**	**Expert**
	2.5C	Applies self-assessment findings to strengthen professional development for consistency with evidence-based guidelines, best practices, and current research findings	X	X	X
2.6	**Designs and implements plans for professional development**		**X**	**X**	**X**
	2.6A	Engages in continuing education opportunities in weight management and related areas according to his/her professional development plan and career goals	X	X	X
	2.6B	Completes focused opportunities in weight management training (eg, Commission on Dietetic Registration [CDR] Certificate of Training in Adult or Childhood and Adolescent Weight Management, Weight Management Dietetic Practice Group Symposium)	X	X	X
	2.6C	Pursues focused opportunities in advanced weight management training (eg, CDR Level 2 Certificate of Training in Adult Weight Management, advanced behavior change skills training) and available weight management certifications		X	X
	2.6D	**Documents professional development activities in career portfolio**	**X**	**X**	**X**
	2.6E	**Documents professional development activities as per organization guidelines**	**X**	**X**	**X**
2.7	**Engages in evidence-based practice and utilizes best practices**		**X**	**X**	**X**
	2.7A	Integrates evidence-based practice and research evidence in delivering quality care utilizing the Academy of Nutrition and Dietetics (Academy), Academy EAL,[b] ACSM,[c] position papers, and best practices	X	X	X
	2.7B	Integrates evidence-based practice and research evidence in delivering professional presentations and publications	X	X	X
	2.7C	Participates in research activities and publication of results to advance evidence and best practices		X	X
	2.7D	Authors original research papers and book chapters to advance evidence and best practices			X
2.8	**Participates in peer review of self and others**		**X**	**X**	**X**
	2.8A	Engages in peer review activities consistent with setting and patient/client population (eg, peer evaluation, peer supervision, clinical chart review, performance evaluations)	X	X	X
	2.8B	Conducts scholarly review of professional articles, chapters, books, programs and guidelines		X	X
	2.8C	Leads an editorial board for review of professional articles, chapters and books			X

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Figure 2. *(continued)* Standards of Professional Performance for Registered Dietitian Nutritionists (RDNs) in Adult Weight Management. Note: The term *customer* is used in this evaluation resource as a universal term. Customer could also mean client/patient, client/patient/customer, participant, consumer, or any individual, group, or organization to which the RDN provides service.

Indicators for Standard 2: Competence and Accountability					
Bold Font Indicators are Academy Core RDN Standards of Professional Performance Indicators			**The "X" signifies the indicators for the level of practice**		
Each RDN:			**Competent**	**Proficient**	**Expert**
2.9	**Mentors others**		**X**	**X**	**X**
	2.9A	Participates in mentoring students and interns	X	X	X
	2.9B	Participates in mentoring for entry-level RDNs and RDNs changing field(s)		X	X
	2.9C	Develops mentoring or internship opportunities for students and professionals in weight management practice		X	X
	2.9D	Mentors RDNs and other health care professionals in analyzing weight management evidence		X	X
	2.9E	Directs and guides the professional development of the RDN through mentoring or supervised practice experiences in weight management			X
2.10	**Pursues opportunities (education, training, credentials) to advance practice in accordance with laws and regulations and requirements of practice setting**		**X**	**X**	**X**
	2.10A	Serves on committees with the Academy and dietetic practice groups (DPGs) to develop programs, tools, and resources in support of assisting the RDN to obtain specialty certification/credential		X	X
	2.10B	Leads efforts to develop or advance education, training, and credential opportunities			X

Examples of Outcomes for Standard 2: Competence and Accountability

- Practice reflects the Code of Ethics
- Practice reflects the Standards of Practice and Standards of Professional Performance
- Competence is demonstrated and documented
- Safe, quality customer-centered service is provided
- Self-assessments are conducted regularly
- Professional development needs are identified
- Directed learning is demonstrated
- Practice reflects evidence-based practice and best practices
- Relevant opportunities (education, training, credentials, certifications) are pursued to advance practice
- Commission on Dietetic Registration recertification requirements are met

Standard 3: Provision of Services

The registered dietitian nutritionist (RDN) provides safe, quality service based on customer expectations and needs, and the mission and vision of the organization/business.

Rationale:

Quality programs and services are designed, executed, and promoted based on the RDN's knowledge, professional experience, and competence in addressing the needs and expectations of the organization/business and its patients/clients.

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Figure 2. *(continued)* Standards of Professional Performance for Registered Dietitian Nutritionists (RDNs) in Adult Weight Management. Note: The term *customer* is used in this evaluation resource as a universal term. Customer could also mean client/patient, client/patient/customer, participant, consumer, or any individual, group, or organization to which the RDN provides service.

Indicators for Standard 3: Provision of Services						
Bold Font Indicators are Academy Core RDN Standards of Professional Performance Indicators				**The "X" signifies the indicators for the level of practice**		
Each RDN:				**Competent**	**Proficient**	**Expert**
3.1	**Contributes to or leads in development and maintenance of programs/ services that address needs of the customer or target population(s)**			**X**	**X**	**X**
	3.1A	**Aligns program/service development with the mission, vision, and service expectations and outputs of the organization/business**		**X**	**X**	**X**
		3.1A1	Develops and manages weight management programs in compliance with evidence-based guidelines and national standards (eg, Academy, TOS,[d] ASMBS[e])		X	X
	3.1B	**Utilizes the needs, expectations, and desired outcomes of the customer (eg, patient/client, administrator, client organization[s]) in program/service development**		**X**	**X**	**X**
		3.1B1	Conducts regular scans of weight management environment for opportunities to deliver additional weight management programs		X	X
	3.1C	**Makes decisions and recommendations that reflect stewardship of time, talent, finances, and environment**		**X**	**X**	**X**
	3.1D	**Proposes programs and services that are customer-centered, culturally appropriate, and minimize health disparities**		**X**	**X**	**X**
	3.1E	Outlines evaluation plan for program effectiveness		X	X	X
3.2	**Promotes public access and referral to credentialed nutrition and dietetics practitioners for quality food and nutrition programs and services**			**X**	**X**	**X**
	3.2A	**Contributes to or designs referral systems that promote access to qualified, credentialed nutrition and dietetics practitioners**		**X**	**X**	**X**
		3.2A1	Evaluates the effectiveness of weight management referral processes and tools		X	X
		3.2A2	Directs and manages referral processes and systems			X
	3.2B	**Refers customers to appropriate providers when requested services or identified needs exceed the RDN's individual scope of practice**		**X**	**X**	**X**
		3.2B1	Builds relationships with other health care practitioners to facilitate collaboration that meets patient/client needs	X	X	X
		3.2B2	Refers to interdisciplinary health care professionals as appropriate	X	X	X
		3.2B3	Refers individual patient/client to a qualified fitness professional (eg, certification by ACSM, ACE,[f] NSCA[g]) for a formal fitness evaluation unless the RDN holds the appropriate exercise certification and demonstrates competence to conduct exercise testing and prescribe exercise regimens	X	X	x

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Figure 2. *(continued)* Standards of Professional Performance for Registered Dietitian Nutritionists (RDNs) in Adult Weight Management. Note: The term *customer* is used in this evaluation resource as a universal term. Customer could also mean client/patient, client/patient/customer, participant, consumer, or any individual, group, or organization to which the RDN provides service.

Indicators for Standard 3: Provision of Services						
Bold Font Indicators are Academy Core RDN Standards of Professional Performance Indicators				**The "X" signifies the indicators for the level of practice**		
Each RDN:				**Competent**	**Proficient**	**Expert**
		3.2B4	Refers individual/client to a qualified behavioral health specialist/psychologist, as appropriate, when individual/client elicits or demonstrates behaviors beyond the RDN's expertise	X	X	x
		3.2B5	Establishes and maintains networks to support overall care of the patient/client		X	X
		3.2B6	Supports referral resources with curriculum and training regarding the complex needs of severely obese patients/clients			X
	3.2C	**Monitors effectiveness of referral systems and modifies as needed to achieve desirable outcomes**		**X**	**X**	**X**
		3.2C1	Manages, evaluates, and updates the nutrition referral process		X	X
		3.2C2	Directs and coordinates referral process and systems			X
		3.2C3	Designs referral process and systems			X
3.3	**Contributes to or designs customer-centered services**			**X**	**X**	**X**
	3.3A	**Assesses needs, beliefs/values, goals, and resources of the customer**		**X**	**X**	**X**
		3.3A1	Identifies current weight management messages, trends, and programs influencing customer base (eg, popular diets, supplements, fitness programs)	X	X	X
		3.3A2	Incorporates goal setting and behavior change strategies (eg, stages of change, motivational interviewing) in program design	X	X	X
		3.3A3	Leads in utilizing, evaluating, and communicating the effectiveness of different theoretical frameworks for interventions (eg, health belief model, social cognitive theory/social learning theory, stages of change [transtheoretical theory])			X
	3.3B	**Utilizes knowledge of the customer's/target population's health conditions, cultural beliefs, and business objectives/services to guide design and delivery of customer-centered services**		**X**	**X**	**X**
		3.3B1	References weight management resources (eg, CDC's[h] obesity data maps and trends, religious and cultural practices, community centers health programming, and local fitness programs)	X	X	X
		3.3B2	Directs, manages, and updates systematic processes to identify, track and monitor utilization of patient/client resources		X	X

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Figure 2. *(continued)* Standards of Professional Performance for Registered Dietitian Nutritionists (RDNs) in Adult Weight Management. Note: The term *customer* is used in this evaluation resource as a universal term. Customer could also mean client/patient, client/patient/customer, participant, consumer, or any individual, group, or organization to which the RDN provides service.

Indicators for Standard 3: Provision of Services						
Bold Font Indicators are Academy Core RDN Standards of Professional Performance Indicators				The "X" signifies the indicators for the level of practice		
Each RDN:				Competent	Proficient	Expert
	3.3C	**Communicates principles of disease prevention and behavioral change appropriate to the customer or target population**		**X**	**X**	**X**
		3.3C1	Recognizes patient/client cultural beliefs regarding weight status in relationship to health	X	X	X
		3.3C2	Designs tools to communicate disease prevention and behavioral change principles		X	X
	3.3D	**Collaborates with the customers to set priorities, establish goals, and create customer-centered action plans to achieve desirable outcomes**		**X**	**X**	**X**
		3.3D1	Confirms that weight management plans are reflective of evidence-based approaches	X	X	X
	3.3E	**Involves customers in decision making**		**X**	**X**	**X**
3.4	**Executes programs/services in an organized, collaborative, and customer-centered manner**			**X**	**X**	**X**
	3.4A	**Collaborates and coordinates with peers, colleagues, and within interdisciplinary teams**		**X**	**X**	**X**
		3.4A1	Collaborates with community programming and resources as needed	X	X	X
		3.4A2	Serves as a consultant for issues related to nutrition for weight management		X	X
		3.4A3	Directs efforts to improve collaboration between patients/clients and other care providers			X
	3.4B	**Participates in or leads in the design, execution, and evaluation of programs and services (eg, nutrition screening system, medical and retail foodservice, electronic health records, interdisciplinary programs, community education) for customers**		**X**	**X**	**X**
		3.4B1	Develops and delivers weight management programs and services that integrate nutrition with exercise, health promotion, and wellness	X	X	X
		3.4B2	Plans and implements systems of weight management services using evidence-based guidelines and best practices		X	X
		3.4B3	Directs systems of weight management services			X
	3.4C	**Develops or contributes to design and maintenance of policies, procedures, protocols, standards of care, technology resources, and training materials that reflect evidence-based practice in accordance with applicable laws and regulations**		**X**	**X**	**X**
		3.4C1	Leads the process of developing, monitoring, evaluating, and improving protocols, guidelines, and practice tools			X

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Figure 2. *(continued)* Standards of Professional Performance for Registered Dietitian Nutritionists (RDNs) in Adult Weight Management. Note: The term *customer* is used in this evaluation resource as a universal term. Customer could also mean client/patient, client/patient/customer, participant, consumer, or any individual, group, or organization to which the RDN provides service.

Indicators for Standard 3: Provision of Services						
Bold Font Indicators are Academy Core RDN Standards of Professional Performance Indicators				**The "X" signifies the indicators for the level of practice**		
Each RDN:				**Competent**	**Proficient**	**Expert**
	3.4D	**Participates in or develops process for clinical privileges required for enhanced activities and expanded roles consistent with state practice acts, federal and state regulations, organization policies, and medical staff rules, regulations and bylaws; enhanced activities include but not limited to implementing physician-driven protocols or other facility-specific processes, initiating or modifying orders for therapeutic diets, nutrition supplements, dietary supplements, enteral and parenteral nutrition, nutrition-related laboratory tests and medications, and adjustments to fluid therapies or electrolyte replacements; expanded roles and nutrition-related services include but not limited to initiating and performing bedside swallow screenings, insertion and monitoring of nasogastric or nasoenteric feeding tubes, and indirect calorimetry measurements**			**X**	**X**	**X**
		3.4D1	Develops programs, protocols, and policies based on evidence- or consensus-based guidelines, best practices, trends, and national and international guidelines		X	X
		3.4D2	Directs the development of programs, protocols, and policies based on evidence- or consensus-based guidelines, best practices, trends, and national and international guidelines			X
	3.4E	**Complies with established billing regulations and adheres to ethical billing practices**		**X**	**X**	**X**
		3.4E1	Develops tools to monitor adherence to billing regulations and ethical billing practices		X	X
	3.4F	**Communicates with the interdisciplinary team and referring party consistent with the HIPAA rules for use and disclosure of patient's/client's personal health information (PHI)**		**X**	**X**	**X**
		3.4F1	Develops tools to monitor adherence to HIPAA rules and/or address breaches in the protection of PHI		X	X
3.5	**Utilizes support personnel appropriately in the delivery of customer-centered care in accordance with laws, regulations, and organization policies**			**X**	**X**	**X**
	3.5A	**Assigns activities, including direct care to patients/clients, consistent with the qualifications, experience, and competence of support personnel**		**X**	**X**	**X**
		3.5A1	Determines capabilities/expertise of support staff in working with patients/clients to determine tasks that may be delegated		X	X
	3.5B	**Supervises support personnel**		**X**	**X**	**X**

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Figure 2. *(continued)* Standards of Professional Performance for Registered Dietitian Nutritionists (RDNs) in Adult Weight Management. Note: The term *customer* is used in this evaluation resource as a universal term. Customer could also mean client/patient, client/patient/customer, participant, consumer, or any individual, group, or organization to which the RDN provides service.

Indicators for Standard 3: Provision of Services						
Bold Font Indicators are Academy Core RDN Standards of Professional Performance Indicators				**The "X" signifies the indicators for the level of practice**		
Each RDN:				**Competent**	**Proficient**	**Expert**
		3.5B1	Trains support personnel and evaluates their competence		X	X
3.6	**Designs and implements food delivery systems to meet the needs of customers**			**X**	**X**	**X**
	3.6A		**Collaborates on or designs food delivery systems to address nutrition status, health care needs, and outcomes, and to satisfy the cultural preferences and desires of target populations (eg, health care patients/clients, employee groups, visitors to retail venues)**	**X**	**X**	**X**
		3.6A1	Evaluates effectiveness of foodservice planning and delivery for patient/clients to identify areas for improvement		X	X
	3.6B		**Participates in, consults with others, or leads in developing menus to address health and nutritional needs of target population(s)**	**X**	**X**	**X**
		3.6B1	Collaborates on the calorie and nutrient level of menus and items for purchase (eg, concession stands, vending machines, cafeteria menu items) in health care and community settings to allow target population to meet weight targets	X	X	X
	3.6C		**Participates in, consults, or leads interdisciplinary process for determining nutritional supplements, dietary supplements, enteral and parenteral nutrition formularies, and delivery systems for target population(s)**	**X**	**X**	**X**
		3.6C1	Provides guidance regarding products in formulary in accordance to best practices (eg, ASMBS, A.S.P.E.N.[i])	X	X	X
		3.6C2	Recommends enteral nutrition in accordance with best practices for the patient post-bariatric surgery		X	X
		3.6C3	Recommends nutritional supplements, dietary supplements, and/or medical foods in accordance with best practices for the patient post-bariatric surgery		X	X
3.7	**Maintains records of services provided**			**X**	**X**	**X**
	3.7A		**Documents according to organization policy, standards, and system including electronic health records**	**X**	**X**	**X**
	3.7B		**Implements data management systems to support data collection, maintenance, and utilization**	**X**	**X**	**X**
	3.7C		**Uses data to document outcomes of services (eg, staff productivity, cost/benefit, budget compliance, quality of services) and provide justification for maintenance or expansion of services**	**X**	**X**	**X**

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Figure 2. *(continued)* Standards of Professional Performance for Registered Dietitian Nutritionists (RDNs) in Adult Weight Management. Note: The term *customer* is used in this evaluation resource as a universal term. Customer could also mean client/patient, client/patient/customer, participant, consumer, or any individual, group, or organization to which the RDN provides service.

Indicators for Standard 3: Provision of Services						
Bold Font Indicators are Academy Core RDN Standards of Professional Performance Indicators				**The "X" signifies the indicators for the level of practice**		
Each RDN:				**Competent**	**Proficient**	**Expert**
		3.7C1	Collects data and documents outcomes and compares against targets and evidence-based/best practices	X	X	X
		3.7C2	Analyzes and communicates value of nutrition services in relation to patient/client and organization outcomes/goals		X	X
		3.7C3	Directs and manages systematic processes to identify, track, and update patient/client resources; documents patient/client use of weight management and health care services			X
	3.7D	**Uses data to demonstrate compliance with accreditation standards, laws, and regulations**		**X**	**X**	**X**
		3.7D1	Prepares and presents reports for institution and accrediting bodies		X	X
3.8	**Advocates for provision of quality food and nutrition services as part of public policy**			**X**	**X**	**X**
	3.8A	**Communicates with policy makers regarding the benefit/cost of quality food and nutrition services**		**X**	**X**	**X**
		3.8A1	Advocates with state and national congressional representatives regarding benefit/cost of weight management services on health care costs (eg, responds to Academy Action Alerts and other calls to action via Grassroots Manager, letters, emails, and/or phone calls)	X	X	X
		3.8A2	Influences policy and lawmakers for weight management issues		X	X
		3.8A3	Reviews, revises, and introduces policy, statutes, administrative rules/regulations impacting the population with obesity			X
	3.8B	**Advocates in support of food and nutrition programs and services for populations with special needs**		**X**	**X**	**X**
		3.8B1	Participates in patient/client advocacy activities, such as support groups at the local level and the Obesity Action Coalition at the national level	X	X	X
		3.8B2	Advocates for policies that reduce discrimination based on weight status	X	X	X
		3.8B3	Takes leadership role and initiates advocacy/activities; authors articles and delivers presentations		X	X

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Figure 2. *(continued)* Standards of Professional Performance for Registered Dietitian Nutritionists (RDNs) in Adult Weight Management. Note: The term *customer* is used in this evaluation resource as a universal term. Customer could also mean client/patient, client/patient/customer, participant, consumer, or any individual, group, or organization to which the RDN provides service.

Examples of Outcomes for Standard 3: Provision of Services

- Program/service design and systems reflect organization/business and customer needs and expectations
- Customers participate in establishing goals and customer-focused action plans
- Customers' needs are met
- Customers are satisfied with services and products
- Evaluations reflect expected outcomes
- Effective screening and referral services are established
- Customers have access to food assistance
- Customers have access to food and nutrition services
- Support personnel are supervised when providing nutrition care to customers
- Ethical billing practices are utilized

Standard 4: Application of Research

The registered dietitian nutritionist (RDN) applies, participates in or generates research to enhance practice. Evidence-based practice incorporates the best available research/evidence in the delivery of nutrition and dietetics services.

Rationale:

Application, participation, and generation of research promote improved safety and quality of nutrition and dietetics practice and services.

Indicators for Standard 4: Application of Research					
Bold Font Indicators are Academy Core RDN Standards of Professional Performance Indicators			**The "X" signifies the indicators for the level of practice**		
Each RDN			**Competent**	**Proficient**	**Expert**
4.1	**Accesses and reviews best available research/evidence for application to practice**		**X**	**X**	**X**
	4.1A	Reads major peer-reviewed publications in obesity and weight management; uses evidence-based guidelines, practice guidelines, and related resources	X	X	X
	4.1B	Demonstrates understanding of research design and methodology, data collection, interpretation of results, application, and use of the EAL	X	X	X
	4.1C	Demonstrates understanding of current research, trends, and epidemiological surveys in obesity, weight management, and related areas	X	X	X
	4.1D	Interprets current research in weight management and related areas and applies to professional practice as appropriate	X	X	X
	4.1E	Identifies key health and performance questions and uses systematic methods to apply evidence-based guidelines to answer questions and inform decisions		X	X
	4.1F	Utilizes the EAL and other evidence-based resources as a resource when writing or reviewing research papers		X	X

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Figure 2. *(continued)* Standards of Professional Performance for Registered Dietitian Nutritionists (RDNs) in Adult Weight Management. Note: The term *customer* is used in this evaluation resource as a universal term. Customer could also mean client/patient, client/patient/customer, participant, consumer, or any individual, group, or organization to which the RDN provides service.

Indicators for Standard 4: Application of Research					
Bold Font Indicators are Academy Core RDN Standards of Professional Performance Indicators			**The "X" signifies the indicators for the level of practice**		
Each RDN			**Competent**	**Proficient**	**Expert**
	4.1G	Contributes expertise and critical thinking skills when a reviewer for original research and/or evidence-based guidelines relevant to obesity and weight management		X	X
	4.1H	Functions as a primary or senior author of research, and academic and/or organization's position and practice papers or other scholarly work			X
4.2	**Utilizes best available research/evidence as the foundation for evidence-based practice**		**X**	**X**	**X**
	4.2A	Follows evidence-based practice guidelines (eg, EAL, Academy, AHA/ACC/TOS[j]) to provide safe, effective quality care for overweight/obese individuals	X	X	X
	4.2B	Reviews the available scientific literature for guidance in situations where evidence-based practice guidelines for weight management are not established and consults with more experienced practitioner for guidance as needed	X	X	X
	4.2C	Analyzes and applies the available scientific literature in situations where evidence-based practice guidelines for weight management are not established		X	X
	4.2D	Utilizes advanced training, available research, and emerging theories to manage complex cases (eg, uncontrolled type 1 and type 2 diabetes, multiple morbidities, postoperative bariatric surgery complications) in target populations			X
4.3	**Integrates best-available research/evidence with best practices, clinical and managerial expertise, and customer values**		**X**	**X**	**X**
	4.3A	Directs the integration of evidence-based guidelines into policies and procedures for weight management practice			X
4.4	**Contributes to the development of new knowledge and research in nutrition and dietetics**		**X**	**X**	**X**
	4.4A	Participates in efforts to extend research to practice through journal clubs, professional supervision, and the Academy's Dietetics Practice-Based Research Network	X	X	X
	4.4B	Participates in scholarly writing, including but not limited to, professional articles, chapters, books		X	X
	4.4C	Participates in development and/or implementation and reporting of practice-based research		X	X
	4.4D	Participates in updating the EAL in weight management and related areas		X	X
	4.4E	Develops EAL questions in weight management			X

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Figure 2. *(continued)* Standards of Professional Performance for Registered Dietitian Nutritionists (RDNs) in Adult Weight Management. Note: The term *customer* is used in this evaluation resource as a universal term. Customer could also mean client/patient, client/patient/customer, participant, consumer, or any individual, group, or organization to which the RDN provides service.

Indicators for Standard 4: Application of Research					
Bold Font Indicators are Academy Core RDN Standards of Professional Performance Indicators			**The "X" signifies the indicators for the level of practice**		
Each RDN			**Competent**	**Proficient**	**Expert**
	4.4F	Initiates research related to obesity and weight management as the primary investigator or co-investigator with other members of the multidisciplinary research team			X
	4.4G	Serves as advisor, preceptor, and/or committee member for graduate level research			X
	4.4H	Uses evidence-based guidelines, best practices, and clinical experience to generate new knowledge and programs in weight management			X
4.5	**Promotes research through alliances and collaboration with food and nutrition and other professionals and organizations**		**X**	**X**	**X**
	4.5A	Identifies research issues/questions	X	X	X
	4.5B	Collaborates with interdisciplinary and/or interorganizational teams to perform and disseminate nutrition research related to weight management		X	X
	4.5C	Leads interdisciplinary and/or interorganizational research activities			X

Examples of Outcomes for Standard 4: Application of Research

- Customers receive appropriate services based on the effective application of best available research/evidence
- Best available research/evidence is used as the foundation of evidence-based practice
- Evidence-based practice, best practices, clinical and managerial expertise, and customer values are integrated in the delivery of nutrition and dietetic services

Standard 5: Communication and Application of Knowledge
The registered dietitian nutritionist (RDN) effectively applies knowledge and expertise in communications.

Rationale:
The RDN works with and through others to achieve common goals by effective sharing and application of their unique knowledge, skills, and expertise in food, nutrition, dietetics, and management services.

Indicators for Standard 5: Communication and Application of Knowledge					
Bold Font Indicators are Academy Core RDN Standards of Professional Performance Indicators			**The "X" signifies the indicators for the level of practice**		
Each RDN:			**Competent**	**Proficient**	**Expert**
5.1	**Communicates current, evidence-based knowledge related to a particular aspect of the profession of nutrition and dietetics**		**X**	**X**	**X**
	5.1A	Contributes weight management expertise to other health care providers, the community, and outside agencies	X	X	X
	5.1B	Translates evidence-based research to weight management practice		X	X

(continued on next page)

Figure 2. *(continued)* Standards of Professional Performance for Registered Dietitian Nutritionists (RDNs) in Adult Weight Management. Note: The term *customer* is used in this evaluation resource as a universal term. Customer could also mean client/patient, client/patient/customer, participant, consumer, or any individual, group, or organization to which the RDN provides service.

Indicators for Standard 5: Communication and Application of Knowledge						
Bold Font Indicators are Academy Core RDN Standards of Professional Performance Indicators				**The "X" signifies the indicators for the level of practice**		
Each RDN:				**Competent**	**Proficient**	**Expert**
	5.1C		Evaluates obesity-related public health trends and epidemiological reports related to obesity prevention and treatment (eg, CDC, WHO[k]), as well as underlying etiologies as applies to weight management practice		X	X
	5.1D		Consults as a expert on complex weight management issues with other health care professionals, organizations, and community			X
5.2	**Communicates and applies best-available research/evidence**			**X**	**X**	**X**
	5.2A		**Demonstrates critical thinking and problem-solving skills when communicating with others**	**X**	**X**	**X**
	5.2B		Demonstrates flexibility and innovation to effectively communicate and apply complex ideas		X	X
5.3	**Selects appropriate information and most effective method or format when communicating information and conducting nutrition education and counseling**			**X**	**X**	**X**
	5.3A		**Utilizes communication methods (eg, oral, print, one-on-one, group, visual, electronic, and social media) targeted to the audience**	**X**	**X**	**X**
	5.3B		**Uses information technology to communicate, manage knowledge, and support decision making**	**X**	**X**	**X**
		5.3B1	Uses electronic health records within the worksite as appropriate	X	X	X
		5.3B2	Identifies web-based weight management tools/resources	X	X	X
		5.3B3	Develops and updates web-based weight management tools/resources		X	X
		5.3B4	Leads in the advancement of technology/informatics in weight management			X
5.4	**Integrates knowledge of food and nutrition with knowledge of health, social sciences, communication, and management in new and varied contexts**			**X**	**X**	**X**
	5.4A		Leads the integration of scientific knowledge and experience in weight management into practice for complex problems or in new research methodologies			X
5.5	**Shares current, evidence-based knowledge, information with patients/clients, colleagues, and the public**			**X**	**X**	**X**
	5.5A		**Guides patients/clients, students, and interns in the application of knowledge and skills**	**X**	**X**	**X**
		5.5A1	Participates as a preceptor or mentor to dietetic students/ interns	X	X	X
		5.5A2	Contributes to the education and professional development of students through formal and informal mentoring/teaching	X	X	X

(continued on next page)

Figure 2. *(continued)* Standards of Professional Performance for Registered Dietitian Nutritionists (RDNs) in Adult Weight Management. Note: The term *customer* is used in this evaluation resource as a universal term. Customer could also mean client/patient, client/patient/customer, participant, consumer, or any individual, group, or organization to which the RDN provides service.

Indicators for Standard 5: Communication and Application of Knowledge						
Bold Font Indicators are Academy Core RDN Standards of Professional Performance Indicators				**The "X" signifies the indicators for the level of practice**		
Each RDN:				**Competent**	**Proficient**	**Expert**
		5.5A3	Contributes to the education and professional development of RDNs, and weight management and/or health care professionals through formal and informal mentoring/ teaching		X	X
		5.5A4	Develops formal, structured mentor and preceptor programs in weight management		X	X
	5.5B	**Assists individuals and groups to identify and secure appropriate and available resources and services**		**X**	**X**	**X**
		5.5B1	Recommends current, evidence-based weight management educational resources (eg, Academy, US Department of Agriculture Choose My Plate at http://www.choosemyplate.gov, NHLBI,[l] Weight Management DPG website at http://www.wmdpg.org)	X	X	X
	5.5C	**Utilizes professional writing and verbal skills in communications**		**X**	**X**	**X**
	5.5D	Participates as an invited reviewer, author, and/or presenter at meetings and media outlets			X	X
	5.5E	Functions as a content expert for business, industry, and national organizations				X
5.6	**Establishes credibility and contributes as a resource within the interdisciplinary health care and management team promoting food and nutrition strategies that enhance health and quality of life outcomes of target populations**			**X**	**X**	**X**
	5.6A	Communicates with the interdisciplinary team to promote the use of evidence-based guidelines that integrate food and nutrition with weight management and health		X	X	X
	5.6B	Consults with physicians and other health care professionals (eg, psychologists, CDEs,[m] physical therapists, social workers, nurses)		X	X	X
	5.6C	Promotes the use of the EAL and evidence-based guidelines to integrate food, nutrition, and lifestyle behaviors with weight management and health practices		X	X	X
	5.6D	Leads interdisciplinary collaborations at a systems level				X
5.7	**Communicates performance improvement and research results through publications and presentations**			**X**	**X**	**X**
	5.7A	Presents evidence-based weight management research and information to community groups and colleagues		X	X	X
	5.7B	Presents evidence-based weight management research and information at professional meetings and conferences (eg, local, regional, national, international)			X	X
	5.7C	Authors authoritative articles in weight management and related areas			X	X

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Figure 2. *(continued)* Standards of Professional Performance for Registered Dietitian Nutritionists (RDNs) in Adult Weight Management. Note: The term *customer* is used in this evaluation resource as a universal term. Customer could also mean client/patient, client/patient/customer, participant, consumer, or any individual, group, or organization to which the RDN provides service.

Indicators for Standard 5: Communication and Application of Knowledge					
Bold Font Indicators are Academy Core RDN Standards of Professional Performance Indicators			**The "X" signifies the indicators for the level of practice**		
Each RDN:			**Competent**	**Proficient**	**Expert**
	5.7D	Serves in a leadership role for weight management–related scholarly work (eg, reviewer, editor, editorial advisory board) and in program planning and conferences (eg, local, regional, national, international)		X	X
	5.7E	Translates research findings for incorporation into development of policies, procedures, and guidelines for weight management and dietetics at national and international levels			X
	5.7F	Directs collation of research data (eg, position papers, practice papers, meta-analysis, review articles) into publications and presentations			X
5.8	**Seeks opportunities to participate in and assume leadership roles in local, state, and national professional and community-based organizations**		**X**	**X**	**X**
	5.8A	Functions as a weight management and nutrition resource as an active member of local/state/national organizations	X	X	X
	5.8B	Participates in local and regional health/weight management coalitions and projects	X	X	X
	5.8C	Serves in leadership roles in weight management–related state and national organizations; and public and/or industry advisory boards		X	X
	5.8D	Identifies new opportunities for leadership and crosses discipline boundaries to promote nutrition and dietetics in a broader context		X	X
	5.8E	Serves and advocates in leadership role on committees and/or for publications (eg, editor, editorial advisory board member, column editor) or within business/industry-related or other national weight management programs			X
	5.8F	Proactively seeks opportunities for leadership development and positions, and is identified as an expert related to weight management issues			X

Examples of Outcomes for Standard 5: Communication and Application of Knowledge

- Expertise in food, nutrition, and management is demonstrated and shared
- Information technology is used to support practice
- Individuals and groups:
  - Receive current and appropriate information and customer-centered service
  - Demonstrate understanding of information received
  - Know how to obtain additional guidance from the RDN
- Leadership is demonstrated through active professional and community involvement

Standard 6: Utilization and Management of Resources

The registered dietitian nutritionist (RDN) uses resources effectively and efficiently.

Rationale:

The RDN demonstrates leadership through strategic management of time, finances, facilities, supplies, technology, and human resources.

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Figure 2. *(continued)* Standards of Professional Performance for Registered Dietitian Nutritionists (RDNs) in Adult Weight Management. Note: The term *customer* is used in this evaluation resource as a universal term. Customer could also mean client/patient, client/patient/customer, participant, consumer, or any individual, group, or organization to which the RDN provides service.

Indicators for Standard 6: Utilization and Management of Resources						
Bold Font Indicators are Academy Core RDN Standards of Professional Performance Indicators				**The "X" signifies the indicators for the level of practice**		
Each RDN:				**Competent**	**Proficient**	**Expert**
6.1	**Uses a systematic approach to manage resources and improve operational outcomes**			**X**	**X**	**X**
	6.1A	Recognizes and utilizes existing resources (eg, educational/training tools and materials, staff time) as needed in the provision of weight management-related nutrition services		X	X	X
	6.1B	Implements administratively sound programs (eg, Nutrition Care Process protocols, food quality and food safety, weight counseling, and education)		X	X	X
	6.1C	Collaborates with administrative, medical, and foodservice staffs in strategic planning and to secure resources and services to achieve desired outcomes			X	X
	6.1D	Directs or manages business and strategic planning for the design and delivery of nutrition services in weight management–related programs in various setting (eg, clinic, hospital, corporate, military, community programs, schools)				X
6.2	**Quantifies management of resources in the provision of nutrition and dietetic services with the use of standardized performance measures and benchmarking as applicable**			**X**	**X**	**X**
	6.2A	Manages effective delivery of weight management nutrition programs (eg, budget, staff, facility, supplies)		X	X	X
		6.2A1	Utilizes business skills relating to budget management, inventory tracking, ordering and distribution, negotiations for compensation and additional resources	X	X	X
		6.2A2	Collaborates with stakeholders on development of marketing plan to successfully deliver weight management programs		X	X
		6.2A3	Directs operational review reflecting evaluation of performance and benchmarking data to manage resources and modifications to design and delivery of nutrition services for weight management			X
6.3	**Evaluates safety, effectiveness, productivity, and value while planning and delivering services and products**			**X**	**X**	**X**
	6.3A	Participates in evaluation and selection of tools and new products (eg, nutritional supplements, dietary supplements, medical foods, food/meals, web-based programs, and monitoring systems)		X	X	X
	6.3B	Evaluates safety, effectiveness, and value of programs in meeting the needs of target population			X	X
	6.3C	Utilizes facility data and outcomes to enhance program outcomes			X	X
	6.3D	Seeks administration/advisory board support for program enhancements that meet organizational goals				X

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Indicators for Standard 6: Utilization and Management of Resources					
Bold Font Indicators are Academy Core RDN Standards of Professional Performance Indicators			**The "X" signifies the indicators for the level of practice**		
Each RDN:			**Competent**	**Proficient**	**Expert**
6.4	**Participates in quality assurance and performance improvement (QAPI) and documents outcomes and best practices relative to resource management**		**X**	**X**	**X**
	6.4A	Participates in QAPI activities to evaluate and report outcomes of delivery of services against goals and performance targets (eg, budgeted vs actual hours, actual vs budgeted revenue, actual vs projected patient/client volumes)	X	X	X
	6.4B	Anticipates outcomes and consequences of various approaches; recommends/modifies program to achieve targeted outcomes		X	X
6.5	**Measures and tracks trends regarding patient/customer, employee, and stakeholder satisfaction in the delivery of products and services**		**X**	**X**	**X**
	6.5A	Analyzes data for effective and efficient use of resources and customer satisfaction		X	X
	6.5B	Communicates the need for change based on collected data		X	X
	6.5C	Implements, monitors, and evaluates changes based on collected data			X

Examples of Outcomes for Standard 6: Utilization and Management of Resources

- Documentation of resource use is consistent with operation
- Data are used to promote, improve, and validate services
- Desired outcomes are achieved and documented
- Resources are effectively and efficiently managed

Glossary:

Dietary Supplement—a dietary supplement is a product taken by mouth that contains a "dietary ingredient" intended to supplement the diet. The "dietary ingredients" in these products may include: vitamins, minerals, herbs or other botanicals, amino acids, and substances such as enzymes, organ tissues, glandulars, and metabolites. http://www.fda.gov/Food/DietarySupplements/QADietarySupplements/default.htm#what_is.

Physical Activity (PA) Guidelines for Americans—evidence-based physical activity guidelines set by the Physical Activity Guidelines Advisory Committee; http://www.health.gov/PAGuidelines/.

Healthy People 2020 Leading Health Indicators—a set of indicators selected to communicate national high-priority health issues and actions that can be taken to address them; http://www.healthypeople.gov/2020/default.aspx.

Evidence Analysis Library—the Academy of Nutrition and Dietetics Evidence Analysis Library (EAL) website houses systematic reviews and practice guidelines related to the topics of food and nutrition; https://www.andeal.org/.

Informatics—the science of managing, storing, and communicating information. Health informatics focuses on the application of information science within the health care arena. Refer to Practice Paper of the Academy of Nutrition and Dietetics: Nutrition Informatics, 2012; http://www.eatrightstore.org/search?keyword-informatics.

Medical food—food which is formulated to be consumed or administered enterally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation. http://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/medicalfoods/default.htm.

Nutritional supplement—a nutritional supplement is a food item consumed to manage calories, protein or other nutrient(s) to enhance nutritional quality; the supplement could be a meal replacement, a part of a meal or consumed as a snack. Examples: Commercial ready-to-use beverages or powdered products to be reconstituted with milk/milk substitute or water, portion-controlled meals, puddings, soups or bars.

[a]BMI=body mass index.

[b]EAL=Evidence Analysis Library (http://www.andeal.org).

[c]ACSM=American College of Sports Medicine (http://www.acsm.org).

[d]TOS=The Obesity Society (http://www.obesity.org).

[e]ASMBS=American Society for Metabolic and Bariatric Surgery (http://asmbs.org).

[f]ACE=American Council on Exercise (http://www.acefitness.org).

[g]NSCA=National Strength and Conditioning Association (http://www.nsca.com/Home/).

[h]CDC=Centers for Disease Control and Prevention (http://www.cdc.gov).

[i]A.S.P.E.N.=American Society for Parenteral and Enteral Nutrition (http://www.nutritioncare.org).

[j]AHA/ACC/TOS=American Heart Association, American College of Cardiology, The Obesity Society (http://circ.ahajournals.org/content/early/2013/11/11/01.cir.0000437739.71477.ee).

[k]WHO=World Health Organization (http://www.who.int/en/).

[l]NHLBI=National Heart, Lung, and Blood Institute (www.nhlbi.nih.gov).

[m]CDEs=Certified Diabetes Educators (www.ncbde.org).

Figure 2. *(continued)* Standards of Professional Performance for Registered Dietitian Nutritionists (RDNs) in Adult Weight Management. Note: The term *customer* is used in this evaluation resource as a universal term. Customer could also mean client/patient, client/patient/customer, participant, consumer, or any individual, group, or organization to which the RDN provides service.

ELSEVIER

Surgery for Obesity and Related Diseases 9 (2013) 159–191

SURGERY FOR OBESITY AND RELATED DISEASES

AACE/TOS/ASMBS Guidelines

Clinical Practice Guidelines for the Perioperative Nutritional, Metabolic, and Nonsurgical Support of the Bariatric Surgery Patient—2013 Update: Cosponsored by American Association of Clinical Endocrinologists, The Obesity Society, and American Society for Metabolic & Bariatric Surgery ☆

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☆ These Guidelines are endorsed by the European Association for the Study of Obesity (EASO), International Association for the Study of Obesity (IASO), International Society for the Perioperative Care of the Obese Patient (ISPCOP), Society American Gastrointestinal Endoscopic Surgeons (SAGES), American College of Surgery (ACS), and International Federation for the Surgery of Obesity and Metabolic Disorders (IFSO).

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Abbreviations AACE, American Association of Clinical Endocrinologists; ACS, American College of Surgery; ASMBS, American Association of Metabolic and Bariatric Surgery; BAC, blood alcohol content; BED, binge eating disorder; BEL, best evidence level; BMI, body mass index; BPD-DS, biliopancreatic diversion with duodenal switch; CCS, clinical case series; CK, creatine kinase; CPAP, continuous positive airway pressure; CPG, clinical practice guidelines; CSS, cross-sectional study; CT, computerized tomography; CVD, cardiovascular disease; DCCP, diabetes comprehensive care plan; DVT, deep venous thrombosis; DXA, dual-energy x-ray absorptiometry; EL, evidence level; EN, enteral nutrition; FDA, U.S. Food and Drug Administration; GERD, gastrointestinal reflux disease; HDL, high-density lipoprotein; ICU, intensive care unit; LABS, longitudinal assessment of bariatric surgery; LAGB, laparoscopic adjustable gastric band; LDL, low-density lipoprotein; LSG, laparoscopic sleeve gastrectomy; MI, myocardial infarction; MNRCT, meta-analysis of nonrandomized controlled trials; MRCT, meta-analysis of randomized controlled trials; NAFLD, nonalcoholic fatty liver disease; NASH, nonalcoholic steatohepatitis; NE, no evidence; NIH, National Institutes of Health; OHS, obesity hypoventilation syndrome; OSA, obstructive sleep apnea; OS-MRS, obesity surgery mortality risk score; PTH, parathyroid hormone; PCOS, polycystic ovary syndrome; PCS, prospective cohort study; PE, pulmonary embolism; PN, parenteral nutrition; PPI, proton pump inhibitor; RCT, randomized controlled trial; RML, rhabdomyolysis; RYGB, Roux-en-Y gastric bypass; SCR, single case report; SG, sleeve gastrectomy; SOS, Swedish Obesity Subjects; SS, surveillance survey; T2D, type 2 diabetes mellitus; TOS, The Obesity Society; TSH, thyroid-stimulating hormone; UGI, upper gastrointestinal; VTE, venous thromboembolism.

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Abstract The development of these updated guidelines was commissioned by the AACE, TOS, and ASMBS Board of Directors and adheres to the AACE 2010 protocol for standardized production of clinical practice guidelines (CPG). Each recommendation was re-evaluated and updated based on the evidence and subjective factors per protocol. Examples of expanded topics in this update include: the roles of sleeve gastrectomy, bariatric surgery in patients with type-2 diabetes, bariatric surgery for patients with mild obesity, copper deficiency, informed consent, and behavioral issues. There are 74 recommendations (of which 56 are revised and 2 are new) in this 2013 update, compared with 164 original recommendations in 2008. There are 403 citations, of which 33 (8.2%) are EL 1, 131 (32.5%) are EL 2, 170 (42.2%) are EL 3, and 69 (17.1%) are EL 4. There is a relatively high proportion (40.4%) of strong (EL 1 and 2) studies, compared with only 16.5% in the 2008 AACE-TOS-ASMBS CPG. These updated guidelines reflect recent additions to the evidence base. Bariatric surgery remains a safe and effective intervention for select patients with obesity. A team approach to perioperative care is mandatory with special attention to nutritional and metabolic issues. (Surg Obes Relat Dis 2013;9:159-191.) © 2013 American Society for Metabolic and Bariatric Surgery. All rights reserved.

Keywords: Bariatric surgery; Obesity; Metabolic surgery; Diabetes surgery; Metabolic syndrome; Clinical practice guidelines; Best practice guidelines; Weight loss surgery

Outline

Introduction

Obesity continues to be a major public health problem in the United States, with more than one third of adults considered obese in 2009–2010, as defined by a body mass index (BMI) $\geq$30 kg/m^2 (1 [EL 3, SS]). Obesity has been associated with an increased hazard ratio for all-cause mortality (2 [EL 3, SS]), as well as significant medical and psychological co-morbidity. Indeed, obesity is not only a chronic medical condition but should be regarded as a bona fide disease state (3 [EL 4, NE]). Nonsurgical management can effectively induce 5%–10% weight loss and improve health in severely obese individuals (4 [EL 1, RCT]) resulting in cardiometabolic benefit. Bariatric surgery procedures are indicated for patients with clinically severe obesity. Currently, these procedures are the most successful and durable treatment for obesity. Furthermore, although overall obesity rates and bariatric surgery procedures have plateaued in the United States, rates of severe obesity are still increasing and now there are approximately 15 million people in the United States with a BMI $\geq$40 kg/m^2 (1 [EL 3, SS]; 5 [EL 3, SS]). Only 1% of the clinically eligible population receives surgical treatment for obesity (6 [EL 3, SS]). Given the potentially increased need for bariatric surgery as a treatment for obesity, it is apparent that clinical practice guidelines (CPG) on the subject keep pace and are kept current.

Since the 2008 TOS/ASMBS/AACE CPG for the perioperative nutritional, metabolic, and nonsurgical support of the bariatric surgery patient (7 [EL 4; CPG]), significant data have emerged regarding a broader range of available surgeries for the treatment of obesity. A PubMed computerized literature search (performed on December 15, 2012) using the search term "bariatric surgery" reveals a total of 14,287 publications with approximately 6800 citations from 2008 to 2012. Updated CPG are therefore needed to guide clinicians in the care of the bariatric surgery patient.

What are the salient advances in bariatric surgery since 2008? The sleeve gastrectomy (SG; laparoscopic SG [LSG]) has demonstrated benefits comparable to other bariatric procedures and is no longer considered investigational (8 [EL 4, NE]). A national risk-adjusted database positions SG between the laparoscopic adjustable gastric band (LAGB) and laparoscopic Roux-en-Y gastric bypass (RYGB) in terms of weight loss, co-morbidity resolution, and complications (9 [EL 2, PCS]). The number of SG procedures has increased with greater third-party payor

coverage (9 [EL 2, PCS]). Other unique procedures are gaining attention, such as gastric plication, electrical neuromodulation, and endoscopic sleeves, but these procedures lack sufficient outcome evidence and therefore remain investigational and outside the scope of this CPG update.

There is also emerging data on bariatric surgery in specific patient populations, including those with mild to moderate obesity, type 2 diabetes (T2D) with class I obesity (BMI 30–34.9 kg/m^2), and patients at the extremes of age. Clinical studies have demonstrated short-term efficacy of LAGB in mild to moderate obesity (10 [EL 1, RCT]; 11 [EL 2, PCS]; 12 [EL 2, PCSA]; 13 [EL 3, SS]), leading the Food and Drug Administration (FDA) to approve the use of LAGB for patients with a BMI of 30 to 35 kg/m^2 with T2D or other obesity-related co-morbidities (14 [EL 4, NE]). Although controversial, this position was incorporated by the International Diabetes Federation, which proposed eligibility for bariatric procedures in a subset of patients with T2D and a BMI of 30 kg/m^2 with suboptimal glycemic control despite optimal medical management (15 [EL 4, NE]). Thus, the term *metabolic surgery* has emerged to describe procedures intended to treat T2D as well as reduce cardiometabolic risk factors. In 1 study, metabolic surgery was shown to induce T2D remission in up to 72% of subjects at 2 years; however, this number was reduced to 36% at 10 years (16 [EL 2, PCS]). In a more recent study, patients who underwent RYGB sustained diabetes remission rates of 62% at 6 years (17 [EL 2, PCS]). The overall long-term effect of bariatric surgery on T2D remission rates is currently not well studied. Additionally, for patients who have T2D recurrence several years after surgery, the legacy effects of a remission period on their long-term cardiovascular risk is not known. The mechanism of T2D remission has not been completely elucidated but appears to include an incretin effect (SG and RYGB procedures) in addition to caloric restriction and weight loss. These findings potentially expand the eligible population for bariatric and metabolic surgery.

Another area of recent interest is the use of bariatric surgery at the extremes of age. Historically, the 1991 National Institutes of Health (NIH) consensus criteria stipulated that treatment of obesity with bariatric surgery is limited to adults (18 [EL 4, NE]). Until 2003, $<$.7% of bariatric procedures were performed in adolescents (age $<$20 years) (19 [EL 3, SS]). However, in academic centers alone, the number of bariatric procedures in adolescents nearly doubled from 2002–2006 to $>$100 cases per year in 2007–2009 (20 [EL 3, SS]). Morbidity and mortality in this 2007–2009 cohort were 2.9% and 0%, respectively (20 [EL 3, SS]).

Advanced age $>$45 years has also been cited as a risk factor for bariatric surgery in some series; however, the data have been conflicting. Prospective data collected from a single academic center demonstrated that patients age $\geq$55 years had a 3-fold mortality compared with younger patients (21 [EL 3, SS]). However, recent American College of Surgeons National Surgical Quality Improvement Program (ACS NSQIP) data of 48,378 patients failed to reveal advanced age to be associated with statistically significant mortality compared with controls (22 [EL 3, SS]). Although many bariatric programs have established arbitrary cutoff levels for age at 65–70 years, other programs primarily consider overall health risks and physiological status.

The Obesity Surgery Mortality Risk Score (OS-MRS) by DeMaria et al. (23,24) identified 5 preoperative risk factors that predicted increased risk of 30-day morbidity and mortality after RYGB. These included advanced age ($\geq$45 years), "super-obesity" (BMI $\geq$50 kg/m^2), hypertension, male gender, and pulmonary embolism (PE) or surrogate (23 [EL 3, SS]; 24 [EL 3, SS]). However, a more recent multicenter study of 4776 patients who underwent bariatric surgery failed to replicate the OS-MRS (25 [EL 2, PCS]). The Longitudinal Assessment of Bariatric Surgery (LABS) data did find that a history of thrombophilia (deep venous thrombosis [DVT] and PE), obstructive sleep apnea (OSA), or functional status to be independently predictive of 30-day adverse outcomes, including death (25 [EL 2, PCS]). Age and gender, however, were not predictors of death in the LABS analysis (25 [EL 2, PCS]). Moreover, 30-day mortality for RYGB and LAGB occurred in only .3% of procedures, less than had been reported previously (25 [EL 2, PCS]).

Despite the known complications of bariatric surgery, overall mortality has improved since 2008. Data reported from the Swedish Obese Subjects (SOS) study, a large prospective observational study of $>$2000 patients who underwent bariatric surgery, demonstrated a mortality hazard ratio (HR) of .71, 10 years following bariatric surgery compared with matched obese controls (17 [EL 2, PCS]). More recent data from this cohort followed for up to 20 years demonstrated a HR of .47 in cardiovascular death (including stroke and myocardial infarction) among surgical subjects compared with obese controls (26 [EL 2, PCS]). In another cohort, all-cause mortality was reduced by 40% 7 years after RYGB, compared with the control group, and cause-specific mortality in the surgery group decreased by 56% for coronary artery disease, by 92% for T2D, and by 60% for cancer (27 [EL 2, RCCS]).

As the prevalence of obesity has grown in the United States, so too has the number of bariatric operations for the surgical treatment of obesity. Promising pharmacological (including biological) treatments are on the horizon, but at present, bariatric surgery remains superior to nonsurgical treatments in terms of short-term benefits in surrogate markers of metabolic disease. Durability of benefit in terms of pertinent clinical outcomes will be the endpoints of current prospective trials. An enriched evidence base, expanding eligible patient populations, and safer, innovative surgical treatments for obesity will likely result in a greater number of obese patients undergoing surgery.

Table 1
2010 American Association of Clinical Endocrinologists Protocol for Production of Clinical Practice Guidelines–Step I: Evidence Rating*

Numerical descriptor (evidence level)	Semantic descriptor (reference methodology)
1	Meta-analysis of randomized controlled trials (MRCT)
1	Randomized controlled trail (RCT)
2	Meta-analysis of nonrandomized prospective or case-controlled trails (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) (SS)
3	Consecutive case series (CCS)
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.

This CPG update aims to keep pace with the evidenced based literature, and along with the accompanying checklist (28 [EL 4]), assist physicians and allied health professionals with both routine and difficult clinical decision making.

Methods

The Boards of Directors for the American Association of Clinical Endocrinologists (AACE), The Obesity Society (TOS), and the American Society for Metabolic & Bariatric Surgery (ASMBS) approved this update of the 2008 AACE, TOS, and ASMBS Medical Guidelines for Clinical Practice for the Perioperative Nutritional, Metabolic, and Nonsurgical Support of the Bariatric Surgery Patient (2008 AACE-TOS-ASMBS CPG; 7). These CPG expired in 2011 per the National Guideline Clearinghouse (http://www.guideline.gov/content.aspx?id=13022&search=bariatric+aace) (29 [EL 4, NE]). Selection of the co-chairs, primary writers, and reviewers, as well as the logistics for creating this evidence based CPG were conducted in strict adherence with the AACE Protocol for Standardized Production of Clinical Practice Guidelines—2010 Update (30 [EL 4, CPG]); Tables 1–4. This updated CPG methodology has the advantage of greater transparency, diligence, and detail for mapping the strength of evidence and expert opinion into a final graded recommendation. Nevertheless, as with all white papers, there is an element of subjectivity that must be recognized by the reader when interpreting the information.

The Executive Summary is reorganized by clinical questions and provides updated recommendation numbers (R1, R2, R3, … R100) with original recommendation numbers in parentheses, and an appended "-r," indicating substantive

Table 2
2010 American Association of Clinical Endocrinologists 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)	Appropriate statistics	Logical
Selection bias		Incompleteness
Appropriate blinding		Validity
Using surrogate end points (especially in "first-in-its-class" intervention)		
Sample size (beta error)		
Null hypothesis versus Bayesian statistics		

Table 3
2010 American Association of Clinical Endocrinologists Protocol for Production of Clinical Practice Guidelines–Step III: Grading of Recommendations; How Different Evidence Levels can be Mapped to the Same Recommendation Grade*

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	B
1	Negative	Yes	Adjust down	B
3	Positive	Yes	Adjust up	B
3	None	Yes	Direct	C
2	Negative	Yes	Adjust down	C
4	Positive	Yes	Adjust up	C
4	None	Yes	Direct	D
3	Negative	Yes	Adjust down	D
1,2,3,4	NA	No	Adjust down	D

*Starting with the left column, best evidence levels (BEL), subjective factors, and condensus 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. NA=not applicable (regardless of the presence or absence of strong subjective factors, the absence of a two-thirds consensus mandates a recommendation grade D).

Table 4
2010 American Association of Clinical Endocrinologists Protocol for Production of Clinical Practice Guidelines–Step IV: Examples of Qualifiers That May Be Appended to Recommendations

Cost-effectiveness
Risk-benefit analysis
Evidence gaps
Alternative physician preferences (dissenting opinions)
Alternative recommendations ("cascades")
Resource availability
Cultural factors
Relevance (patient-oriented evidence that matters)

content or grading revision, or "-NEW," indicating new content. In many cases, recommendations have been condensed for clarity and brevity. In other cases, recommendations have been expanded for more clarity for complex decision making. The relevant evidence base, supporting tables, and figures for the updated recommendations follow the Executive Summary. The reader is encouraged to refer to the 2008 AACE-TOS-ASMBS CPG (7 [EL 4, CPG]) for background material not covered in this update.

Executive summary

There are 74 recommendations in this 2013 update, compared with 164 original recommendations in 2008. There are 56 revised recommendations and 2 new recommendations (R30 and R59) in this 2013 update. Consensus among primary writers was obtained for each of the recommendations.

Q1. Which patients should be offered bariatric surgery?

R1(1)-r. Patients with a BMI $\geq$40 kg/m^2 without coexisting medical problems and for whom bariatric surgery would not be associated with excessive risk should be eligible for 1 of the procedures **(Grade A; BEL 1).**

R2(2/3)-r. Patients with a BMI $\geq$35 kg/m^2 and 1 or more severe obesity-related co-morbidities, including T2D, hypertension, hyperlipidemia, obstructive sleep apnea (OSA), obesity-hypoventilation syndrome (OHS), Pickwickian syndrome (a combination of OSA and OHS), nonalcoholic fatty liver disease (NAFLD) or nonalcoholic steatohepatitis (NASH), pseudotumor cerebri, gastroesophageal reflux disease (GERD), asthma, venous stasis disease, severe urinary incontinence, debilitating arthritis, or considerably impaired quality of life, may also be offered a bariatric procedure. Patients with BMI of 30–34.9 kg/m^2 with diabetes or metabolic syndrome may also be offered a bariatric procedure although current evidence is limited by the number of subjects studied and lack of long-term data demonstrating net benefit.

- **Grade A, BEL 1 for BMI $\geq$35 kg/m^2 and therapeutic target of weight control and improved biochemical markers of cardiovascular disease [CVD] risk**
- **Grade B, BEL 2 for BMI $\geq$30 kg/m^2 and therapeutic target of weight control and improved biochemical markers of CVD risk**
- **Grade C, BEL 3 for BMI $\geq$30 kg/m^2 and therapeutic target of glycemic control in T2D and improved biochemical markers of CVD risk.**

R3(4)-r. There is insufficient evidence for recommending a bariatric surgical procedure specifically for glycemic control alone, lipid lowering alone, or cardiovascular disease risk reduction alone, independent of BMI criteria **(Grade D).**

Q2. Which bariatric surgical procedure should be offered?

R4(5/6/7)-r. The best choice for any bariatric procedure (type of procedure and type of approach) depends on the individualized goals of therapy (e.g., weight loss and/or metabolic [glycemic] control), available local-regional expertise (surgeon and institution), patient preferences, and personalized risk stratification **(Grade D).** At this time, there is still insufficient evidence to generalize in favor of one bariatric surgical procedure for the severely obese population **(Grade D).** In general, laparoscopic bariatric procedures are preferred over open bariatric procedures due to lower early postoperative morbidity and mortality **(Grade B; BEL 2).** Laparoscopic adjustable gastric banding (LAGB), laparoscopic sleeve gastrectomy (LSG), laparoscopic Roux-en-Y gastric bypass (RYGB), and laparoscopic biliopancreatic diversion BPD, BPD/duodenal switch (BPD-DS), or related procedures are primary bariatric and metabolic procedures that may be performed in patients requiring weight loss and/or metabolic control **(Grade A; BEL 1).** Physicians should exercise caution when recommending BPD, BPD-DS, or related procedures because of the greater associated nutritional risks related to the increased length of bypassed small intestine **(Grade A; BEL 1).** Investigational procedures may be considered for selected patients based on available institutional review board (IRB) approved protocols, suitability for clinical targets and individual patient factors, and only after a careful assessment balancing the importance for innovation, patient safety, and demonstrated effectiveness **(Grade D).**

Q3. How should potential candidates for bariatric surgery be managed preoperatively?

R5(8). All patients should undergo preoperative evaluation for obesity-related co-morbidities and causes of obesity, with special attention directed to those factors that could affect a recommendation for bariatric surgery (see Preoperative Checklist in Table 5) **(Grade A; BEL 1).**

R6(9). The preoperative evaluation must include a comprehensive medical history, psychosocial history, physical examination (see Table 16 in ref [6]), and appropriate laboratory testing to assess surgical risk (Table 6) **(Grade A; BEL 1).**

R7(10). The medical necessity for bariatric surgery should be documented **(Grade D).**

R8(11/12)-r. Because informed consent is a dynamic process, there should be a thorough discussion with the patient regarding the risks and benefits, procedural options, choices of surgeon and medical institution, and the need for long-term follow-up and vitamin supplementation (including costs required to maintain appropriate follow-up) **(Grade D).** Patients should also be provided with educational materials and access to preoperative educational sessions at prospective bariatric surgery centers **(Grade**

Table 5
Preoperative Checklist for Bariatric Surgery*

√	Complete H & P (obesity-related co-morbidities, causes of obesity, weight/BMI, weight loss history, commitment, and exclusions related to surgical risk)
√	Routine labs (including fasting blood glucose and lipid panel, kidney function, liver profile, lipid profile, urine analysis, prothrombin time/INR, blood type, CBC)
√	Nutrient screening with iron studies, B_{12} and folic acid (RBC folate, homocysteine, methylmalonic acid optional), and 25-vitamin D (vitamins A and E optional); consider more extensive testing in patients undergoing malabsorptive procedures based on symptoms and risks
√	Cardiopulmonary evaluation with sleep apnea screening (ECG, CXR, echocardiography if cardiac disease or pulmonary hypertension suspected; DVT evaluation if clinically indicated)
√	GI evaluation (H pylori screening in high-prevalence areas; gallbladder evaluation and upper endoscopy if clinically indicated)
√	Endocrine evaluation (A_{1c} with suspected or diagnosed prediabetes or diabetes; TSH with symptoms or increased risk of thyroid disease; androgens with PCOS suspicion (total/bioavailable testosterone, DHEAS, Δ_4-androstenedione); screening for Cushing's syndrome if clinically suspected (1 mg overnight dexamethasone test, 24-hour urinary free cortisol, 11 PM salivary cortisol)
√	Clinical nutrition evaluation by RD
√	Psychosocial-behavioral evaluation
√	Document medical necessity for bariatric surgery
√	Informed consent
√	Provide relevant financial information
√	Continue efforts for preoperative weight loss
√	Optimize glycemic control
√	Pregnancy counseling
√	Smoking cessation counseling
√	Verify cancer screening by primary care physician

*See text for abbreviations.

Table 6
Postoperative Checklist for Bariatric Surgery*

	Checklist Item	LAGB	LSG	RYGB	BPDDS
Early postoperative care					
√	monitored telemetry at least 24 hr if high risk for MI	√	√	√	√
√	protocol-derived staged meal progression supervised by RD	√	√	√	√
√	healthy eating education by RD	√	√	√	√
√	multivitamin plus minerals (# tablets for minimal requirement)	1	2	2	2
√	calcium citrate, 1200–1500 mg/d	√	√	√	
√	vitamin D, at least 3000 units/d, titrate to >30 ng/mL	√	√	√	√
√	vitamin B_{12} as needed for normal range levels	√	√	√	√
√	maintain adequate hydration (usually >1.5 L/d PO)	√	√	√	√
√	monitor blood glucose with diabetes or hypoglycemic symptoms	√	√	√	√
√	pulmonary toilet, spirometry, DVT prophylaxis	√	√	√	√
√	if unstable, consider pulmonary embolus (PE), intestinal leak (IL)	PE	PE	PE/IL	PE/IL
√	if rhabdomyolysis suspected, check CPK	√	√	√	√
Follow-up					
√	visits: initial, interval until stable, once stable (months)	1,1–2,12	1,3–6,12	1,3,6–12	1,3,6
√	monitor progress with weight loss and evidence of complications each visit	√	√	√	√
√	SMA-21, CBC/plt with each visit (and iron at baseline and after as needed)	√	√	√	√
√	avoid nonsteroidal antiinflammatory drugs	√	√	√	√
√	adjust postoperative medications	√	√	√	√
√	consider gout and gallstone prophylaxis in appropriate patients	√	√	√	√
√	need for antihypertensive therapy with each visit	√	√	√	√
√	lipid evaluation every 6–12 months based on risk and therapy	√	√	√	√
√	monitor adherence with physical activity recommendations	√	√	√	√
√	evaluate need for support groups	√	√	√	√
√	bone density (DXA) at 2 years	√	√	√	√
√	24-hour urinary calcium excretion at 6 months and then annually	√	√	√	√
√	B_{12} (annually; MMA and HCy optional; then q 3–6 months if supplemented)	√	√	√	√
√	folic acid (RBC folic acid optional), iron studies, 25-vitamin D, iPTH	x	x	√	√
√	vitamin A (initially and q 6–12 months thereafter)	x	x	optional	√
√	copper, zinc, and selenium evaluation with specific findings	x	x	√	√
√	thiamine evaluation with specific findings	√	√	√	√
√	consider eventual body contouring surgery	√	√	√	√

*see text for abbreviations; based on general obesity-related risks, GI functional anatomy, and clinical endpoints after specific bariatric surgical procedures.

D). Consent should include experience of the surgeon with the specific procedure offered and whether the hospital has an accredited bariatric surgery program **(Grade D).**

R9(13)-r. Financial information should be provided, and the bariatric surgery program should be able to provide all necessary clinical material for documentation so that third-party payor criteria for reimbursement are met **(Grade D).**

R10(14)-r. Preoperative weight loss can reduce liver volume and may help improve the technical aspects of surgery in patients with an enlarged liver or fatty liver disease and is therefore encouraged before bariatric surgery **(Grade B; BEL 1; downgraded due to inconsistent results).** Preoperative weight loss or medical nutritional therapy may also be used in selected cases to improve co-morbidities, such as reasonable preoperative glycemic targets **(Grade D)**.

Q4. What are the elements of medical clearance for bariatric surgery?

R11(15–17)-r. Preoperative glycemic control should be optimized using a diabetes comprehensive care plan, including healthy dietary patterns, medical nutrition therapy, physical activity, and as needed, pharmacotherapy **(Grade A; BEL 1).** Reasonable targets for preoperative glycemic control, which may be associated with improved bariatric surgery outcomes, include a hemoglobin A_{1c} value of 6.5%–7.0% or less, a fasting blood glucose level of $\leq$110 mg/dL, and a 2-hour postprandial blood glucose concentration of $\leq$140 mg/dL (http://www.aace.com/sites/default/files/DMGuidelinesCCP.pdf) **(Grade A; BEL 1).** More liberal preoperative targets, such as an A_{1c} of 7%–8%, should be considered in patients with advanced microvascular or macrovascular complications, extensive co-morbid conditions, or long-standing diabetes in which the general goal has been difficult to attain despite intensive efforts (Grade A; BEL 1). In patients with $A_{1c} > 8\%$ or otherwise uncontrolled diabetes, clinical judgment determines the need for bariatric surgery **(Grade D).**

R12(18/19)-r. Routine screening for primary hypothyroidism before bariatric surgery is not recommended **(Grade D).** Patients at risk for primary hypothyroidism should have screening serum thyroid-stimulating hormone (TSH) level **(Grade B; BEL 2).** Patients found to be hypothyroid should be treated with L-thyroxine monotherapy **(Grade A; BEL 1).**

R13(20/21)-r. A fasting lipid panel should be obtained in all patients with obesity **(Grade A; BEL 1).** Treatment should be initiated according to the National Cholesterol Education Program Adult Treatment Panel III guidelines (see http://www.nhlbi.nih.gov/guidelines/cholesterol/ and https://www.aace.com/files/lipid-guidelines.pdf) **(Grade D).**

R14(22–24)-r. Candidates for bariatric surgery should avoid pregnancy preoperatively and for 12 to 18 months postoperatively **(Grade D).** Women who become pregnant after bariatric surgery should be counseled and monitored for appropriate weight gain, nutritional supplementation, and for fetal health **(Grade C; BEL 3).** All women of reproductive age should be counseled on contraceptive choices following bariatric surgery **(Grade D).** Patients with RYGB or malabsorptive procedures should be counseled in nonoral contraceptive therapies **(Grade D).** Patients who do become pregnant following bariatric surgery should have nutritional surveillance and laboratory screening for deficiency every trimester, including iron, folate and B_{12}, calcium, and fat soluble vitamins **(Grade D).** Patients who become pregnant post-LAGB should have band adjustments as necessary for appropriate weight gain for fetal health **(Grade B; BEL 2).**

R15(25). Estrogen therapy should be discontinued before bariatric surgery (1 cycle of oral contraceptives in premenopausal women; 3 weeks of hormone replacement therapy in postmenopausal women) to reduce the risks for postoperative thromboembolic phenomena **(Grade D).**

R16(26). Women with PCOS should be advised that their fertility status might be improved postoperatively **(Grade D).**

R17(28). Case-by-case decisions to screen for rare causes of obesity should be based on specific historical and physical findings **(Grade D).**

R18(29–31). Noninvasive cardiac testing beyond an electrocardiogram is determined on the basis of the individual risk factors and findings on history and physical examination **(Grade B).** Patients with known heart disease may require a formal cardiology consultation before bariatric surgery **(Grade D)**. Patients at risk for heart disease should undergo evaluation for perioperative β-adrenergic blockade **(Grade A; BEL 1).**

R19(32/33)-r. In patients considered for bariatric surgery, chest radiograph and standardized screening for obstructive sleep apnea (with confirmatory polysomnography if screening tests are positive) should be considered. **(Grade C, BEL 3)**. Patients with intrinsic lung disease or disordered sleep patterns should have a formal pulmonary evaluation, including arterial blood gas measurement, when knowledge of the results would alter patient care **(Grade C; BEL 3).**

R20(34/157)-r. Tobacco use should be avoided at all times by all patients. In particular, patients who smoke cigarettes should stop, preferably at least 6 weeks before bariatric surgery **(Grade A; BEL 2, upgraded by consensus).** Also, tobacco use should be avoided after bariatric surgery given the increased risk for of poor wound healing, anastomotic ulcer, and overall impaired health **(Grade A; BEL 1).**

R21(35/36)-r. Patients with a history of deep venous thrombosis (DVT) or cor pulmonale should undergo an appropriate diagnostic evaluation for DVT **(Grade D).** A prophylactic vena caval filter may present a greater risk than benefit in patients with a history of prior PE or DVT given

the risks of filter-related complications including thrombosis **(Grade C; BEL 3).**

R22(37). Clinically significant gastrointestinal symptoms should be evaluated before bariatric surgery with imaging studies, upper gastrointestinal (UGI) series, or endoscopy **(Grade D).**

R23(38)-r. Abdominal ultrasound is not recommended as a routine screen for liver disease **(Grade C, BEL 3).** Abdominal ultrasound is indicated to evaluate symptomatic biliary disease and elevated liver function tests. In patients with increased liver function tests (2 to 3 times the upper limit of normal), abdominal ultrasonography and a viral hepatitis screen may be considered **(Grade D).** Consideration can be made for liver biopsy at the time of surgery to document steatohepatitis and/or cirrhosis that may otherwise be unknown due to normal appearance and/or liver function tests **(Grade D).**

R24(39)-r. Routine screening for the presence of Helicobacter pylori before bariatric surgery may be considered in high-prevalence areas **(Grade C; BEL 3).**

R25(40)-r. Before bariatric surgery, prophylactic treatment for gouty attacks should be considered in patients with a history of gout **(Grade C, BEL 3).**

R26(41). There are insufficient data to warrant preoperative assessment of bone mineral density with dual-energy x-ray absorptiometry (DXA) outside formal CPG recommendations by the National Osteoporosis Foundation (www.nof.org) **(Grade D).**

R27(42/43)-r. A psychosocial-behavioral evaluation, which assesses environmental, familial, and behavioral factors, should be required for all patients before bariatric surgery **(Grade C; BEL 3).** Any patient considered for bariatric surgery with a known or suspected psychiatric illness, or substance abuse, or dependence, should undergo a formal mental health evaluation before performance of the surgical procedure **(Grade C; BEL 3).** Following RYGB, high-risk groups should eliminate alcohol consumption due to impaired alcohol metabolism and risk of alcohol use disorder postoperatively **(Grade C; BEL 3).**

R28(44)-r. All patients should undergo evaluation of their ability to incorporate nutritional and behavioral changes before and after bariatric surgery **(Grade C; BEL 3).**

R29(45)-r. All patients should undergo an appropriate nutritional evaluation, including micronutrient measurements, before any bariatric surgical procedure. In comparison with purely restrictive procedures, more extensive perioperative nutritional evaluations are required for malabsorptive procedures **(Grade A; BEL 1).**

R30(NEW). Patients should be followed by their primary care physician and have age and risk appropriate cancer screening before surgery. **Grade C; BEL 3).**

Q5. How can early postoperative care be optimized?

R31(46–53/90/91)-r. A low-sugar clear liquid meal program can usually be initiated within 24 hours after any of the bariatric procedures, but this diet and meal progression should be discussed with the surgeon and guided by the registered dietician (RD) **(Grade C; BEL 3).** A consultation for postoperative meal initiation and progression should be arranged with a dietician who is knowledgeable of the postoperative bariatric diet. **(Grade A, BEL 1).** Patients should receive education in a protocol-derived staged meal progression based on their surgical procedure **(Grade D).** Patients should be counseled to eat 3 small meals during the day and chew small bites of food thoroughly before swallowing (**Grade D).** Patients should adhere with principles of healthy eating, including at least 5 daily servings of fresh fruits and vegetables **(Grade D).** Protein intake should be individualized, assessed, and guided by an RD, in reference to gender, age, and weight **(Grade D).** A minimal protein intake of 60 g/d and up to 1.5 g/kg ideal body weight per day should be adequate; higher amounts of protein intake—up to 2.1 g/kg ideal body weight per day—need to be assessed on an individualized basis **(Grade D).** Concentrated sweets should be eliminated from the diet after RYGB to minimize symptoms of the dumping syndrome, as well as after any bariatric procedure to reduce caloric intake **(Grade D).** Crushed or liquid rapid-release medications should be used instead of extended-release medications to maximize absorption in the immediate postoperative period **(Grade D).**

R32(54/89/93)-r. After consideration of risks and benefits, patients with, or at risk for, demonstrable micronutrient insufficiencies or deficiencies should be treated with the respective micronutrient **(Grade A, BEL 2, upgraded by consensus)**. Minimal daily nutritional supplementation for patients with RYGB and LSG all in chewable form initially (i.e., 3 to 6 months), should include 2 adult multivitamin plus mineral (each containing iron, folic acid, and thiamine) supplements **(Grade B, BEL 2)**, 1200 to 1500 mg of elemental calcium (in diet and as citrated supplement in divided doses) **(Grade B, BEL 2)**, at least 3000 international units of vitamin D (titrated to therapeutic 25-hydroxyvitamin D levels >30 ng/ml) **(Grade A, BEL 1)**, and vitamin B_{12} (parenterally as sublingual, subcutaneous, or intramuscular preparations, or orally, if determined to be adequately absorbed) as needed to maintain B12 levels in the normal range **(Grade B; BEL 2)**. Total iron provided should be 45–60 mg via multivitamins and additional supplements. Minimal daily nutritional supplementation for patients with LAGB should include 1 adult multivitamin plus mineral (including iron, folic acid, and thiamine) **(Grade B, BEL 2)**, 1200 to 1500 mg of elemental calcium (in diet and as citrated supplement in divided doses) **(Grade B, BEL 2)**, at least 3000 international units of vitamin D (titrated to therapeutic 25-dihydroxyvitamin D

levels). Alternatively, in lieu of routine screening with relatively costly biochemical testing, the above routine micronutrient supplementation may be initiated preoperatively **(Grade D)**.

R33(55)-r. Fluids should be consumed slowly, preferably at least 30 minutes after meals to prevent gastrointestinal symptoms, and in sufficient amounts to maintain adequate hydration (more than 1.5 liters daily) **(Grade D).**

R34(56/92)-r. Nutrition support (enteral nutrition [EN; tube feeds] or parenteral nutrition [PN]) should be considered in bariatric surgery patients at high nutritional risk (e.g., Nutrition Risk Score [NRS 2002] ≥ 3); PN should be considered in those patients who are unable to meet their needs using their gastrointestinal tract for at least 5–7 days with noncritical illness or 3–7 days with critical illness (**Grade D).** In patients with severe protein malnutrition and/or hypoalbuminemia, not responsive to oral or EN protein supplementation, PN should be considered **(Grade D).**

R35(57)-r. In patients with T2D, periodic fasting blood glucose concentrations should be determined **(Grade A; BEL 1).** Preprandial, 2-hour postprandial, and bedtime reflectance meter glucose (RMG; "fingerstick") determinations in the home setting should also be encouraged, depending on the patient's ability to test, the level of glycemic control targeted, use of oral agents or insulin, and overall care plan **(Grade A; BEL 1).** RMG determinations should also be performed if symptoms of hypoglycemia occur **(Grade A; BEL 1).**

R36(58–61)-r. In patients with diabetes, the use of all insulin secretagogues (sulfonylureas and meglitinides) should be discontinued and insulin doses should be adjusted postoperatively (due to low calorie intake) to minimize the risk for hypoglycemia **(Grade D).** Antidiabetic medications should be withheld if the T2D is in remission following bariatric surgery **(Grade D).** Metformin may be continued postoperatively until prolonged clinical resolution of diabetes is demonstrated by normalized glycemic targets (including fasting and postprandial blood glucose and HbA_{1c}). Insulin therapy, using a rapid-acting insulin analogue (insulin lispro, aspart, or glulisine) before meals and a basal long-acting insulin analogue (insulin glargine or detemir) should be used to attain glycemic targets (140–180 mg/dL) in nonintensive care unit hospitalized patients **(Grade D).** In the intensive care unit, intravenous regular insulin, as part of a standard intensive insulin therapy protocol, should be used to control hyperglycemia to a 140–180 mg/dL blood glucose target **(Grade D).** Antidiabetic medications that improve insulin sensitivity (metformin), as well as incretin-based therapies, should be considered in outpatients not reaching glycemic targets. **(Grade D).** Endocrinology consultation should be considered for patients with uncontrolled hyperglycemia **(Grade D).**

R37(62)-r. Patients with high perioperative risk for myocardial infarction should be managed in a monitored telemetry setting for at least the first 24 hours postoperatively **(Grade D).**

R38(64)-r. Pulmonary management includes aggressive pulmonary toilet and incentive spirometry, oxygen supplementation to avoid hypoxemia, and early institution of continuous positive airway pressure (CPAP) when clinically indicated (**Grade C, BEL 3).**

R39(65/66)-r. Prophylaxis against deep venous thrombosis (DVT) is recommended for all patients **(Grade B; BEL 2).** Prophylactic regimens after bariatric surgery include sequential compression devices **(Grade C; BEL 3),** as well as subcutaneously administered unfractionated heparin or low-molecular-weight heparin given within 24 hours after bariatric surgery **(Grade B; BEL 2).** Extended chemoprophylaxis after hospital discharge should be considered for high-risk patients, such as those with history of DVT **(Grade C, BEL 3).** Early ambulation is encouraged **(Grade C; BEL 3).**

R40(67–71)-r. Respiratory distress or failure to wean from ventilatory support should raise suspicion and prompt an evaluation for an acute postoperative complication, such as pulmonary embolus (PE) or anastomotic leak **(Grade D).** In the clinically stable patient, UGI studies (water-soluble contrast followed by thin barium) or computed tomography (CT) may be considered to evaluate for anastomotic leaks in suspected patients **(Grade C; BEL 3).** Exploratory laparotomy or laparoscopy is justified in the setting of high clinical suspicion for anastomotic leaks despite a negative study **(Grade C; BEL 3).** The presence of a new sustained pulse rate of more than 120 beats/min for longer than 4 hours, tachypnea, hypoxia, or fever, should raise concern for an anastomotic leak **(Grade D).** A selected Gastrografin upper gastrointestinal (UGI) study in the absence of abnormal signs or symptoms may be considered to identify any subclinical leaks before discharge of the patient from the hospital, although routine studies are not cost effective. **(Grade C; BEL 3).** C-reactive protein (CRP) testing should be considered if a postoperative leak is suspected.

R41(72–75)-r. Patients should have adequate padding at pressure points during bariatric surgery **(Grade D).** When rhabdomyolysis (RML) is suspected, creatine kinase (CK) levels should be determined, urine output monitored, and adequate hydration ensured **(Grade C; BEL 3).** The risk for RML increases as BMI increases (particular with BMI >55–60 kg/m^2); therefore, screening CK levels may be tested in these higher risk groups **(Grade D)**.

Q6. How can optimal follow-up of bariatric surgery be achieved?

R42(78–83/85/88)-r. The frequency of follow up depends on the bariatric procedure performed and the severity of co-morbidities **(Grade D).** Following LAGB, frequent nutritional follow-up and/or band adjustments are important for maximal weight loss **(Grade C; BEL 3).** Significant

weight regain or failure to lose weight should prompt evaluation for (a) decreased patient adherence with lifestyle modification, (b) evaluation of medications associated with weight gain or impairment of weight loss, (c) development of maladaptive eating behaviors, (d) psychological complications, and (e) radiographic or endoscopic evaluation to assess pouch enlargement, anastomotic dilation, formation of a gastrogastric fistula among patients who underwent a RYGB, or inadequate band restriction among patients who underwent a LAGB **(Grade B; BEL 2).** Interventions should first include a multidisciplinary approach, including dietary change, physical activity, behavioral modification with frequent follow up; and then if appropriate, pharmacologic therapy and/or surgical revision **(Grade B; BEL 2).** In those patients with or without complete resolution of their T2D, dyslipidemia, or hypertension, continued surveillance and management should be guided by current clinical practice guidelines for those conditions **(Grade D).** Routine metabolic and nutritional monitoring is recommended after all bariatric surgical procedures **(Grade A; BEL 1).**

R43(84)-r. Patients who have undergone RYGB, BPD, or BPD/DS and who present with postprandial hypoglycemic symptoms that have not responded to nutritional manipulation should undergo an evaluation to differentiate noninsulinoma pancreatogenous hypoglycemia syndrome (NIPHS) from factitious or iatrogenic causes, dumping syndrome, and insulinoma **(Grade C; BEL 3).** In patients with NIPHS, therapeutic strategies include dietary changes (low carbohydrate diet), octreotide, diazoxide, acarbose, calcium channel antagonists, gastric restriction, and reversal procedures, with partial or total pancreatectomy reserved for the rare recalcitrant cases **(Grade C; BEL 3).**

R44(86)-r. Patients should be advised to incorporate moderate aerobic physical activity to include a minimum of 150 minutes per week and goal of 300 minutes per week, including strength training 2 to 3 times per week (see ACSM Position Statement July 2011 http://www.acsm-msse.org/) **(Grade A; BEL 1).**

R45(87)-r. All patients should be encouraged to participate in ongoing support groups after discharge from the hospital **(Grade B; BEL 2).**

R46(94/95/100)-r. In patients who have undergone RYGB, BPD, or BPD/DS, treatment with oral calcium citrate and vitamin D (ergocalciferol [vitamin D_2] or cholecalciferol [vitamin D_3]), is indicated to prevent or minimize secondary hyperparathyroidism without inducing frank hypercalciuria (**Grade C; BEL 3).** In cases of severe vitamin D malabsorption, oral doses of vitamin D_2 or D_3 may need to be as high as 50,000 units 1 to 3 times weekly to daily, and more recalcitrant cases may require concurrent oral administration of calcitriol (1,25-dihydroxyvitamin D) **(Grade D).** Hypophosphatemia is usually due to vitamin D deficiency and oral phosphate supplementation should be provided for mild to moderate hypophosphatemia (1.5 to 2.5 mg/dL) **(Grade D).**

R47(96). In patients with RYGB, BPD, or BPD/DS, bone density measurements with use of axial (spine and hip) dual-energy x-ray absorptiometry (DXA) may be indicated to monitor for osteoporosis at baseline and at about 2 years **(Grade D).**

R48(97/98)-r. Bisphosphonates may be considered in bariatric surgery patients with osteoporosis only after appropriate therapy for calcium and vitamin D insufficiency (**Grade C; BEL 3).** Evaluation should include serum parathyroid hormone (PTH), total calcium, phosphorus, 25-hydroxyvitamin D, and 24-hour urine calcium levels **(Grade C; BEL 3)**. If therapy is indicated, then intravenously administered bisphosphonates should be used, as concerns exist about adequate oral absorption and potential anastomotic ulceration with orally administered bisphosphonates **(Grade C; BEL 3).** Recommended intravenous dosages of bisphosphonates include zoledronic acid, 5 mg once a year, or ibandronate, 3 mg every 3 months **(Grade D).** If concerns about absorption or potential anastomotic ulceration are obviated, oral bisphosphonate administration can be provided; the recommended dosages are alendronate, 70 mg/wk; risedronate, 35 mg/wk or 150 mg/mo; or ibandronate, 150 mg/mo **(Grade C; BEL 3).**

R49(101/102)-r. Management of oxalosis and calcium oxalate stones includes avoidance of dehydration **(Grade D)**, a low oxalate meal plan **(Grade D)**, oral calcium **(Grade B, BEL 1, downgraded due to small evidence base)**, and potassium citrate therapy **(Grade B, BEL 1, downgraded due to small evidence base).** Probiotics containing Oxalobacter formigenes may be used as they have been shown to improve renal oxalate excretion and improve supersaturation levels **(Grade C; BEL 3).**

R50(103/107)-r. There is insufficient evidence to support routine screening for essential fatty acid, vitamin E, or vitamin K deficiencies **(Grade D).**

R51(104/105)-r. Routine screening for vitamin A deficiency, which may present as ocular complications, is recommended after purely malabsorptive bariatric procedures, such as BPD or BPD/DS, and supplementation alone or in combination with other fat-soluble vitamins (D, E, and K) may be indicated in this setting. **(Grade C; BEL 3).**

R52(108). In the presence of an established fat-soluble vitamin deficiency with hepatopathy, coagulopathy, or osteoporosis, assessment of a vitamin K_1 level should be considered **(Grade D).**

R53(76/77/109–112)-r. Anemia without evidence of blood loss warrants evaluation of nutritional deficiencies as well as age appropriate causes during the late postoperative period **(Grade D).** Iron status should be monitored in all bariatric surgery patients **(Grade D).** Treatment regimens include oral ferrous sulfate, fumarate, or gluconate to provide up to 150–200 mg of elemental iron daily **(Grade A; BEL 1).** Vitamin C supplementation may be added simultaneously to increase iron absorption **(Grade C; BEL 3).** Intravenous iron infusion (preferably with ferric

gluconate or sucrose) may be needed for patients with severe intolerance to oral iron or refractory deficiency due to severe iron malabsorption **(Grade D).**

R54(113–116)-r. Baseline and postoperative evaluation for vitamin B_{12} deficiency is recommended in all bariatric surgery and annually in those with procedures that exclude the lower part of the stomach (e.g., LSG, RYGB) **(Grade B; BEL 2).** Oral supplementation with crystalline vitamin B_{12} at a dosage of 1000 μg daily or more may be used to maintain normal vitamin B_{12} levels **(Grade A; BEL 1).** Intranasally administered vitamin B_{12}, 500 μg weekly, may also be considered **(Grade D).** Parenteral (intramuscular or subcutaneous) B_{12} supplementation, 1000 μg/mo to 1000–3000 μg every 6 to 12 months, is indicated if B_{12} sufficiency cannot be maintained using oral or intranasal routes **(Grade C; BEL 3).**

R55(117)-r. Folic acid supplementation (400 μg/d) should be part of a routine mineral-containing multivitamin preparation **(Grade B; BEL 2)** and should be supplemented in all women of childbearing age to reduce the risk of fetal neural tube defects **(Grade A; BEL 1).**

R56(119)-r. Nutritional anemias resulting from malabsorptive bariatric surgical procedures might also involve deficiencies in vitamin B_{12}, folate, protein, copper, selenium, and zinc and should be evaluated when routine screening for iron deficiency anemia is negative **(Grade C; BEL 3).**

R57(120/121)-r. There is insufficient evidence to support routine selenium screening or supplementation after bariatric surgery **(Grade D).** However, selenium levels should be checked in patients with a malabsorptive bariatric surgical procedure who have unexplained anemia or fatigue, persistent diarrhea, cardiomyopathy, or metabolic bone disease **(Grade C; BEL 3).**

R58(122/123)-r. Routine screening for zinc deficiency should occur after malabsorptive bariatric surgical procedures **(Grade C; BEL 3)** and should be routinely supplemented following BPD/BPDDS **(Grade C; BEL 3).** Zinc deficiency should be considered in patients with hair loss, pica, significant dysgeusia, or in male patients with hypogonadism or erectile dysfunction **(Grade D).**

R59(NEW). Copper supplementation (2 mg/d) should be included as part of routine multivitamin with mineral preparation **(Grade D).** Routine copper screening is not indicated following bariatric surgery but should be evaluated in patients with anemia, neutropenia, myeloneuropathy, and impaired wound healing **(Grade D).** In severe deficiency, treatment can be initiated with IV copper (2 to 4 mg/d) × 6 days **(Grade D).** Subsequent treatment or treatment of mild to moderate deficiency can usually be achieved with oral copper sulfate or gluconate 3 to 8 mg/d until levels normalize and symptoms resolve **(Grade D).** Patients being treated for zinc deficiency or using supplemental zinc for hair loss should receive 1 mg of copper for each 8 to 15 mg of zinc as zinc replacement can cause copper deficiency **(Grade C; BEL 3).**

R60(124–129)-r. Thiamine supplementation should be included as part of routine multivitamin with mineral preparation **(Grade D).** Routine thiamine screening is not recommended following bariatric surgery **(Grade C; BEL 3).** Screening for thiamine deficiency and/or empiric thiamine supplementation should be considered in postbariatric surgery patients with rapid weight loss, protracted vomiting, parenteral nutrition, excessive alcohol use, neuropathy or encephalopathy, or heart failure **(Grade D).** Patients with severe thiamine deficiency (suspected or established) should be treated with intravenous thiamine, 500 mg/d, for 3 to 5 days, followed by 250 mg/d for 3 to 5 days or until resolution of symptoms, and then to consider treatment with 100 mg/d, orally, usually indefinitely or until risk factors have resolved **(Grade C; BEL 3).** Mild deficiency can be treated with intravenous thiamine, 100 mg/d, for 7–14 days **(Grade C; BEL 3).** In recalcitrant or recurrent cases of thiamine deficiency without 1 of the above risks, the addition of antibiotics for small intestine bacterial overgrowth should be considered **(Grade C; BEL 3).**

R61(130)-r. Lipid levels and need for lipid-lowering medications should be periodically evaluated **(Grade D).** The effect of weight loss on dyslipidemia is variable and incomplete; therefore, lipid-lowering medications should not be stopped unless clearly indicated **(Grade C; BEL 3).**

R62(131)-r. The need for antihypertensive medications should be evaluated repeatedly **(Grade D).** Because the effect of weight loss on blood pressure is variable, incomplete, and at times transient, antihypertensive medications should not be stopped unless clearly indicated **(Grade D).**

R63(132–135/138)-r. Persistent and severe gastrointestinal symptoms (e.g., nausea, vomiting, abdominal pain, diarrhea, and constipation) warrant evaluation **(Grade C; BEL 3).** Upper endoscopy with small bowel biopsies and aspirates remains the "gold standard" in the evaluation of celiac disease and bacterial overgrowth **(Grade C; BEL 3).** Screening with a stool specimen should be obtained if the presence of Clostridium difficile colitis is suspected **(Grade C; BEL 3).** Persistent steatorrhea after BPD/BPDDS should prompt an evaluation for nutrient deficiencies **(Grade C; BEL 3).**

R64(136/137)-r. Nonsteroidal antiinflammatory drugs should be completely avoided after bariatric surgery, if possible, because they have been implicated in the development of anastomotic ulcerations/perforations. **(Grade C; BEL 3)** and alternative pain medication should be identified before bariatric surgery **(Grade D).**

R65(139–141)-r. Endoscopy may be the preferred procedure for gastrointestinal symptoms suggestive of stricture or foreign body (e.g., suture, staple) as it can be both diagnostic and therapeutic (endoscopic dilation or foreign body removal) **(Grade C; BEL 3).** Evaluation

can also include H pylori testing as a possible contributor to persistent gastrointestinal symptoms after bariatric surgery **(Grade D).** Anastomotic ulcers should be treated with H_2 receptor blockers, proton pump inhibitors (PPI), sucralfate, and if H pylori is identified, triple therapy to include antibiotics, bismuth, and PPI **(Grade C; BEL 3).**

R66(142)-r. Patients who previously underwent a RYGB with a nonpartitioned stomach who develop a gastrogastric fistula or herniation with symptoms of weight regain, marginal ulcer, stricture or gastroesophageal reflux, may benefit from a revisional procedure **(Grade C; BEL 3).**

R67(143/144). Persistent vomiting, regurgitation, and UGI obstruction after LAGB should be treated with immediate removal of fluid from the adjustable band **(Grade D).** Persistent symptoms of gastroesophageal reflux, regurgitation, chronic cough, or recurrent aspiration pneumonia after LAGB raise concern for the band being too tight or the development of an abnormally large gastric pouch above the band or esophageal dilation. These symptoms should prompt immediate referral to a bariatric surgeon **(Grade D).**

R68(145/146)-r. Ultrasound should be used to evaluate patients with right upper quadrant pain for cholecystitis **(Grade D)**. Prophylactic cholecystectomy may be considered with RYGB to prevent gallbladder complications **(Grade B; BEL 2)**. Oral administration of ursodeoxycholic acid, at least 300 mg daily in divided doses, significantly decreases gallstone formation after RYGB and may be considered for use in patients after bariatric surgery who have not had a cholecystectomy **(Grade A; BEL 1).**

R69(147/148)-r. Although uncommon, suspected bacterial overgrowth in the biliopancreatic limb after BPD or BPD/DS should be treated empirically with metronidazole or rifaximin **(Grade C; BEL 3).** For antibiotic-resistant cases of bacterial overgrowth, probiotic therapy with Lactobacillus plantarum 299v and Lactobacillus GG may be considered **(Grade D).**

R70(149–152). Definitive repair of asymptomatic abdominal wall hernias can be deferred until weight loss has stabilized and nutritional status has improved, to allow for adequate healing (12 to 18 months after bariatric surgery) **(Grade D).** Symptomatic hernias that occur after bariatric surgery require prompt surgical evaluation **(Grade C; BEL 3).** Patients with sudden onset, severe cramping periumbilical pain or recurrent episodes of severe abdominal pain anytime after weight loss surgery should be evaluated with an abdominal and pelvic CT scan to exclude the potentially life-threatening complication of a closed loop bowel obstruction **(Grade D).** Exploratory laparotomy or laparoscopy is indicated in patients who are suspected of having an internal hernia because this complication can be missed with upper gastrointestinal (UGI) x-ray studies and CT scans **(Grade C; BEL 3).**

R71(153–156)-r. Body-contouring surgery may be performed after bariatric surgery to manage excess tissue that impairs hygiene, causes discomfort, and is disfiguring **(Grade C; BEL 3).** This surgery is best pursued after weight loss has stabilized (12 to 18 months after bariatric surgery) **(Grade D).**

Q7. What are the criteria for hospital admission after bariatric surgery?

R72(158–162)-r. Severe malnutrition should prompt hospital admission for initiation of nutritional support **(Grade D).** The initiation and formulation of enteral (tube feeding) or parenteral nutrition should be guided by current clinical practice guidelines **(Grade D).** Hospital admission is required for the management of gastrointestinal complications after bariatric surgery in clinically unstable patients **(Grade D).** Surgical management should be pursued for gastrointestinal complications not amenable or responsive to medical therapy **(Grade D).** However, if not dehydrated, most patients can undergo endoscopic stomal dilation for stricture as an outpatient procedure **(Grade D).**

R73(163). Revision of a bariatric surgical procedure can be recommended when serious complications related to previous bariatric surgery cannot be managed medically **(Grade C; BEL 3).**

R74(164). Reversal of a bariatric surgical procedure is recommended when serious complications related to previous bariatric surgery cannot be managed medically and are not amenable to surgical revision **(Grade D).**

Evidence base

This evidence base pertains to the updated recommendations and contains 403 citations, of which 33 (8.2%) are EL 1, 131 (32.5%) are EL 2, 170 (42.2%) are EL 3, and 69 (17.1%) are EL 4. There is a relatively high proportion (40.4%) of strong (EL 1 and 2) studies, compared with only 16.5% in the 2008 AACE-TOS-ASMBS CPG (7 [EL 4, CPG]). The evidence base, supporting tables, and unrevised recommendations for general information may be found in the 2008 AACE-TOS-ASMBS CPG (7 [EL 4, CPG]).

Q1. Which patients should be offered bariatric surgery?

R1(1).The evidence base for recommending bariatric surgery for patients with BMI $\geq$40 kg/m^2 without coexisting medical problems is enriched with recent EL 1–3 studies demonstrating benefit: mortality (31 [EL 1, MRCT]; 32 [EL 1, RCT]), weight loss (33 [EL 1, MRCT]; 34 [EL 1, MRCT]; 35 [EL 2, PCS]; 36 [EL 2, PCS]), diabetes remission (37 [EL 1, MRCT]; 38 [EL 1, RCT]; 39 [EL 1, RCT]; 40 [EL 1, RCT]); improved beta-cell function (41 [EL 1; RCT]); and improved pulmonary function (42 [EL 3; PCS]). Currently, the WHO

classification scheme for obesity, based on BMI, determines diagnostic and therapeutic management. However, BMI is confounded by ethnic differences (43 [EL 2, MNRCT]; 44 [EL 4, NE]) and body composition (44 [EL 4, NE]); (45 [EL 2, CSS], and future improved risk stratification strategies may incorporate other anthropometric measurements, such as waist circumference (46 [EL 3, SS]) or waist-to-hip ratio (43 [EL 2, MNRCT]), co-morbidity and functional status assessments (47 [EL 4 NE]), and body composition technologies (45 [EL 3, CSS]). Factors found to be associated with poor outcome include open procedures, male gender, older age, congestive heart failure, peripheral vascular disease, deep venous thrombosis, PE, obstructive sleep apnea, impaired functional status, and chronic kidney disease (48 [EL 2, PCS]; 49 [EL 3, SS]). Therefore, further studies are needed that utilize new clinical risk-stratification systems to optimize patient selection criteria and consequently, patient outcomes.

R2(2/3). Many recent studies demonstrate benefit for bariatric surgery patients with BMI <35 kg/m^2 in terms of weight loss (10 [EL 1, RCT]; 12 [EL 2, PCS]), diabetes remission, and cardiovascular risk reduction (50 [EL 2, RCT]; 51 [EL 1, RCT]; 52 [EL 2, PCS]; 53 [EL 2, PCS]). This evidence base is supported by additional, though not as strong, studies and post hoc analyses from diverse ethnicities on weight loss (54 [EL 2, PCS]) and T2D improvement (11 [EL 2; PCS]; 55 [EL 3, SS]; 56 [EL 4, NE review and analysis]; 57 [EL 2, PCS]; 58 [EL 3, SS]; 59 [EL 2; PCS]; 60 [EL 2, NRCT]; 61 [EL 2, PCS]; 62 [EL 2; MNRCT]; 63 [EL 2, PCS]; 64 [EL 2, PCS]). As a result, the United States Food and Drug Administration (FDA) approved the LAP-BAND for patients with a BMI of 30–34.9 kg/m^2 with an obesity-related co-morbidity. Moreover, the recent comparative effectiveness, randomized, nonblinded, single-center trial, with 34% of patients with BMI <35 kg/m^2, represents a highly relevant study, even though it cannot yet be generalizable (39 [EL 2, RCT]). A companion paper by Mingrone et al. (40 [EL 2, RCT]) randomized patients with BMI ≥ 35 kg/m^2 and does not apply to this CPG recommendation. Future, well-designed clinical trials that incorporate longer follow-up periods with demonstration of safety in the surgical group, relevant CVD outcomes, and an intensive medical therapy comparator group associated with weight loss, will clarify this CPG recommendation for patients with BMI <35 kg/m^2.

R3(4). There are no compelling studies to date that support recommending a bariatric surgical procedure for the management of T2D alone, in the absence of obesity (BMI <30 kg/m^2).

Q2. Which bariatric surgical procedure should be offered?

R4(5/6/7). Two principal determinants since publication of the 2008 AACE-TOS-ASMBS CPG (7 [EL 4; CPG]) have impacted clinical decision making regarding the choice of a specific bariatric surgery procedure (see Fig. 1 for depictions of the 4 common bariatric surgery procedures). First, the emphasis has shifted from weight loss outcomes to the metabolic effects of bariatric surgery procedures, and second, sufficient data regarding the safety, efficacy, and durability of various procedures, especially the LSG, have been published. The advent of personalized medicine and applicability to obesity genetics and medicine is reviewed by Blakemore and Froguel (65 [EL 4]). Additionally, new procedures have emerged that are still considered investigational but will clearly impact future decision making. The superiority of laparoscopic bariatric surgical procedures, versus open procedures, was further demonstrated by the meta-analysis of Reoch et al. (66 [EL 1, MRCT]).

As the metabolic effects of various bariatric operations become better understood, the traditional classifications of procedures as "restrictive," "malabsorptive," or "combination" procedures have become less functional and less widely accepted. Adjustable gastric banding has clearly been shown to result in improvement or remission of diabetes and metabolic syndrome (50 [EL 2, RCT]), but it appears that these effects may not be related to changes in gut hormones (67 [EL 2, PCS]). The early, weight-independent effects of RYGB, BPD/BPDDS, and LSG on T2D improvement have led many to refer to these procedures as "metabolic" operations (68 [EL 2, NRCT]; 69 [EL 2, PCS]; 70 [EL 2, NRCT]; 71 [EL 4, NE]). In a 2-year period, RYGB was associated with increased achievement of American Diabetes Association (ADA) composite endpoints (38.2% versus 10.5% with routine medical management; $P < .001$; $A_{1c} < 7.0\%$ + LDL-cholesterol <100 mg/dL, and systolic blood pressure [BP] <130 mm Hg) (72 [EL 3, SS]). In recent follow-up reports of the Swedish Obese Subjects (SOS) study at median follow-up of 14.7 years, bariatric surgery was associated with improved T2D prevention and reduced cardiovascular deaths; these results extend the bariatric surgery benefits on surrogate markers to relevant clinical outcomes (26 [EL 2, PCS]; 73 [EL 2, PCS]). Nevertheless, the durability issue of T2D resolution remains at issue since approximately one third of RYGB patients experience relapse (74 [EL 3, SS]). Elevated GLP-1 levels and various other gut hormone changes favoring satiety and glucose metabolism have been demonstrated after RYGB (75 [EL 2, NRCT]; 76 [EL 2, NRCT], 77 [EL 4, NE]; 78 [EL 1, RCT]), BPD (79 [EL 4, NE]; 80 [EL 2, PCS]; 81 [EL 2, PCS]), and LSG (82 [EL 1, RCT]; 83 [EL 2, PCS]; 84 [EL 2, NRCT]). Exclusion of nutrient flow through the duodenum and proximal bowel (RYGB, BPD, BPD/DS) may also play a role in diabetes remission after these procedures, although the precise mechanism for this effect has not been established and requires further study (85 [EL 4, NE]; 86 [EL 4, NE]). Future therapeutic targets based on the various mechanisms of action of these

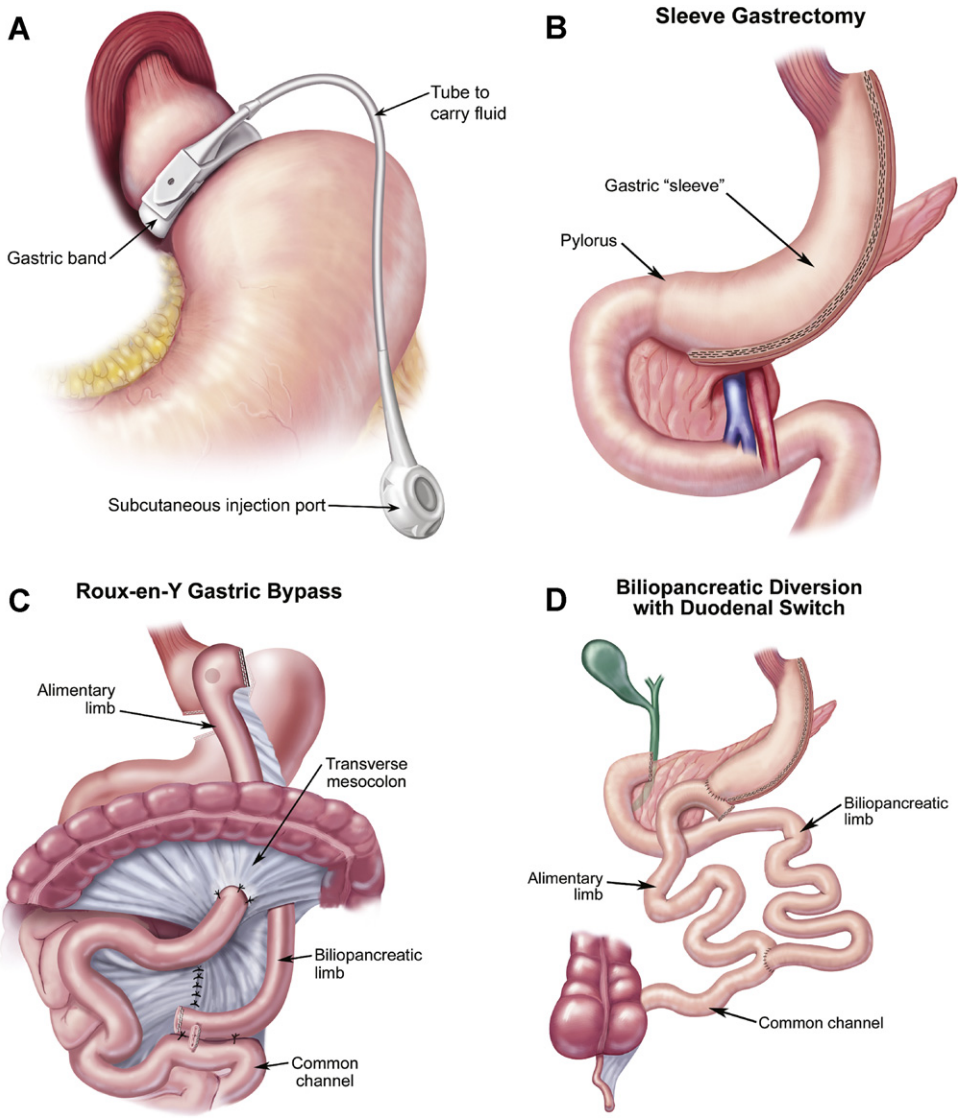

Fig. 1. Common types of bariatric surgery procedures. (A) Adjustable gastric band; (B) sleeve gastrectomy; (C) Roux-en-Y gastric bypass; (D) biliopancreatic diversion with duodenal switch. (Illustrations reprinted with permission from Atlas of Metabolic and Weight Loss Surgery, Jones et al. Cine-Med, 2010. Copyright of the book and illustrations are retained by Cine-Med.)

operations are likely as they become more clearly defined (86 [EL 4, NE]; 87 [EL 4, NE]).

The LSG has become widely accepted as a primary bariatric operation and is no longer considered investigational (see ASMBS statement at http://s3.amazonaws.com/publicASMBS/GuidelinesStatements/PositionStatement/ASMBS-SLEEVE-STATEMENT-2011_10_28.pdf [accessed on May 22, 2012]). The LSG is seldom used as part of a 2-stage risk management strategy for high-risk patients. Because nearly 80% of the stomach is transected and nutrients rapidly pass through a gastric conduit, increased GLP-1 and PYY 3–36 and decreased ghrelin levels result, producing key metabolic effects (78 [EL 1, RCT]; 82 [EL 1, RCT]; 83 [EL 2, PCS]; 84 [EL 2, NRCT]; 88 [EL 1, RCT]). In addition to many recently published case series reporting the short- and medium-term safety and efficacy (weight loss and glycemic status) of the SG, the majority of which were performed laparoscopically (89 [EL 3, SS]; 90 [EL 3, SS]; 91 [EL 2, PCS]; 92 [EL 3, SS]; 93 [EL 3, SS]; 94 [EL 3, SS]; 95 [EL 2, PCS]; 96 [EL 3, SS]; 97 [EL 2, PCS]; 98 [EL 2, PCS]; 99 [EL 3, SS]; 100 [EL 3, SS]; 101 [EL 3, SS]; 102 [EL 2, PCS]), there are now several comparative studies (103 [EL]; 104 [EL]; 105 [EL]; 106 [EL]; 107 [EL]; 108 [EL]; 109 [EL]; 110 [EL]; 111 [EL]; 112 [EL]; 113 [EL]; 114 [EL]; 115 [EL]), 6 randomized controlled trials (78 [EL 1, RCT]; 82 [EL 1, RCT]; 116 [EL 1, RCT]; 117 [EL 1, RCT]; 118 [EL 1, RCT]; 119 [EL 1, RCT]), and meta-analyses (120 [EL 2, MNRCT]; 121 [EL 2, MNRCT]) demonstrating equivalency or superiority to other accepted procedures (RYGB

and LAGB). Analyses of outcomes from large prospective databases have revealed a risk/benefit profile for LSG that is positioned between the LAGB and RYGB (122 [EL 3, SS]; 123 [EL 3, SS]). There is also data demonstrating the durability of LSG at 5 to 9 years with acceptable long-term weight loss in the range of 50%–55% EWL (124 [EL 2, PCS]; 125 [EL 3, SS]; 126 [EL 3, SS]; 127 [EL 3, SS]; 128 [EL 2, PCS]). However, there are still concerns about the overall durability of the LSG procedure in light of a paucity of long-term (>5–10 year) data, major complication rates (approximately 12.1% on average), mortality (up to 3.3% in some studies), and costs (129 [EL 2, MNRCT]).

Gastric plication is an investigational procedure designed to create gastric restriction without the placement of a device or resection of tissue. This procedure is performed laparoscopically and involves infolding the greater curvature of the stomach to tubularize the stomach and create an intraluminal fold. This technique has also been used in combination with a LAGB to help augment early weight loss. There are several short-term studies demonstrating relative safety and effectiveness of greater curvature plication with outcomes intermediate between LAGB and SG (130 [EL 2, PCS]; 131 [EL 2, PCS]; 132 [EL 2, PCS]; 133 [EL 2, PCS]). Notwithstanding the above EL 2 studies, more robust comparative data and conclusive data evaluating the durability of this procedure will be needed before specific recommendations can be made. As new procedures (both surgical and endoscopic) continue to emerge within the field of bariatric surgery, it is important to balance innovation and patient choice with patient safety and demonstrated effectiveness based on clear benchmarks. For now, investigational bariatric procedures should only be recommended within the framework of an institutional review board (IRB), or equivalent, approved clinical research study.

Q3. How should potential candidates for bariatric surgery be managed preoperatively?

R8(11/12). Informed consent for bariatric surgery is a dynamic process of education and comprehension in addition to the disclosure of risks and benefits (134 [EL 3, NE]; 135 [EL 2, PCS]). Educational objectives, active teaching and learning processes, and assessments are recommended (134 [EL 3, NE]; 136 [EL 4, NE]; 137 [EL 4, NE]) and should be communicated at a 6th–8th grade reading level (138 [EL 4, NE]). Multimedia tools for informed consent and patient education show promise for improving comprehension (139 [EL 2, NRCT]). Many programs begin the patients' experience with informational seminars but education should be ongoing. Promotion of realistic expectations is recommended given the tendency for patients to endorse unrealistic expectancies for weight loss (140 [EL 2, PCS]; 141 [EL 3, SS]; 142 [EL 2, PCS]). As a result, the benefits of a proposed bariatric surgery should not be overstated (138 [EL 4, NE]). Accreditation may be awarded by the Unified National Accreditation Program for Bariatric Surgery Centers by the American College of Surgeons (ACS) and ASMBS (http://www.facs.org/news/2012/acs-asmbs0312.html, accessed on September 17, 2012).

R10(14). Cirrhosis (143 [EL 3, SS]) has been associated with adverse outcome following bariatric surgery, including progression to liver transplantation (144 [EL 3, SS]). Preoperative weight loss (targeting 3 kg fat loss [over 2 weeks], 5% excess body weight [EBW] loss, or 10% total weight loss with energy-restricted diets) has been associated with reduction in hepatic volume (145 [EL 2, PCS]), variable perceived and measured facility in operative technique (beneficial: 146 [EL 2, PCS]; equivocal: 147 [EL 1, RCT]), variable effects on short-term (≤1 year; beneficial: 148 [EL 3, SS]; 149 [EL 1, RCT]; 150 [EL 2, PCS], 151 [EL 2, PCS]; not beneficial: 152 [EL 3, SS]) complication rates and weight loss, and no conclusive benefit for long-term outcome parameters. Therefore, recommendations to implement an aggressive preoperative weight loss program to reduce liver volume should not be applied to all patients with hepatomegaly, but rather at the discretion of the bariatric surgery team for a subset of those higher-risk patients (e.g., technically difficult cases, preoperative BMI >50 kg/m^2, etc.) to improve short-term outcomes. Preoperative weight loss with medical nutrition therapy can improve glycemic control and should therefore be utilized in obese patients with diabetes (153 [EL 4]).

Q4. What are the elements of medical clearance for bariatric surgery?

R11(15–17). A diabetes comprehensive care plan (DCCP) has been described in the 2011 AACE CPG (153 [EL 4, NE]); EL 1 reports can be found here supporting preoperative and postoperative glycemic control targets). Importantly, a shorter duration and better glycemic control preoperatively is associated with a higher rate of T2D remission after bariatric surgery (154 [EL 2, PCS]). More liberal targets may be used based on clinical judgment. Risk factors contributing to complications and death after RYGB include T2D, in addition to BMI ≥55 kg/m^2 (main factor), obstructive sleep apnea, and cardiomyopathy (155 EL 2, PCS). Among 468 patients undergoing RYGB, elevated preoperative A_{1c} was associated with elevated postoperative hyperglycemia. Postoperative hyperglycemia is independently associated with wound infections, acute renal failure, and reduced T2D remission rates (156 [EL 3, SS]). Absolute weight loss is negatively correlated with preoperative treatment for T2D ($P = .021$; due to weight gain and orectic effects of insulin and insulin secretagogues), but not with preoperative biomarkers of T2D or insulin resistance (fasting BG, fasting insulin, or homeostatic model assessment [HOMA] index) (157 EL 2, PCS). However, T2D remission rates following RYGB were positively correlated with preoperative C-peptide levels, suggesting that this

biomarker may be used to assist in the selection of patients with obesity-related T2D (158 [EL 2, PCS]).

R12(18/19). Severe obesity is associated with increased TSH levels and subclinical hypothyroidism; following bariatric surgery and weight loss, TSH levels decrease (159 [EL 2, PCS]; 160 [EL 2, PCS]; 161 [EL 3, SS]; 162 [EL 2, PCS]; 163 [EL 3, SS]). Nevertheless, routine screening for primary hypothyroidism simply due to the presence of an obese state is not recommended, whereas aggressive case finding is recommended in at-risk patients (164 [EL 4, NE]). In short, obesity appears to be associated with TSH elevation in the absence of a primary thyroid disease. Notwithstanding the above, many insurance companies require TSH testing before bariatric surgery.

R13(20/21). Preoperative triglyceride levels were positively correlated with nonalcoholic steatohepatitis (NASH) and high-density lipoprotein (HDL) levels were negatively correlated with nonalcoholic fatty liver disease (NAFLD), supporting the utility of lipoprotein profiling preoperatively (165 [EL 2, PCS]). Treatment guidelines are provided in the 2012 AACE CPG for management of dyslipidemia and prevention of atherosclerosis (166 [EL 4, CPG).

R14(22–24). This recommendation is updated based on additional evidence (primary EL 3) related to the harmful effects of various deficiencies (iron, calcium, B_{12}, folic acid, and vitamin D) and teratogens (vitamin A). These studies serve as the basis for position papers (167 [EL 4, position]) and reviews (168 [EL 4, review], 169 [EL 4, review]).

R18(29/31). The evidence base is updated by 2 studies. Cardiopulmonary testing (at least an electrocardiogram and polysomnography) is recommended preoperatively with further testing (echocardiography, spirometry, and arterial blood gases) guided by additional risk factors specific tests (170 [EL 2, PCS]). Continuation of beta-blockers in a cohort comprised of many bariatric surgery patients was associated with fewer cardiac events and improved 90-day mortality rates (171 [EL 3, SS]).

R19(32/33). Obstructive sleep apnea (OSA) is prevalent before bariatric surgery (up to 94%), with a significant number undiagnosed (38%) (172 [EL 3, SS]; 173 [EL 3, SS]; 174 [EL 3, CSS]; 175 [EL 3, SS]; 176 [EL 3, SS]; 177 [EL 3, SS]). Moreover, attempts at predictive modeling, although encouraging, do not appear to have sufficient sensitivity and specificity (173 [EL 3, SS]; 175 [EL 3, SS]; 176 [EL 3, SS]; 178 [EL 3, SS]). Moderate to severe OSA is associated with increased risk for all-cause mortality (179 [EL 3, SS]) and in bariatric surgery patients, with adverse outcomes (180 [EL 2, PCS]). Therefore, routine preoperative screening with polysomnography should be considered, with further diagnostic testing and treatment of appropriate at-risk patients (181 [EL 4, CPG]). Standard preoperative management of overweight/obese patients with OSA using continuous positive airway pressure (CPAP) is recommended (182 [EL 4, review]).

R20(34/157). Recent data supports the association of smoking cigarettes with an increased risk of postoperative marginal ulceration (183 [EL 3, SS]) and pneumonia (184 [EL 3, SS]). The relative risk conferred by cigarette smoking on the incidence of infections in post-bariatric surgery patients undergoing body contouring abdominoplasty is 14, with a cutoff of 8.5 pack-years (185 [EL 3, SS]), and undergoing mastopexy is 3.8, with a cutoff of 6.85 pack-years (186 [EL 3, SS]). Smoking cessation has been recommended at least 6 weeks before bariatric surgery in the evidence-based best practice guidelines by Schumann et al. (181 [EL 4, CPG]). However, the timing specified by this recommendation—that smoking should be stopped at least 6 weeks preoperatively—was not supported by a meta-analysis (187 [EL 2, MNRCT]). Therefore, all smokers should be advised to stop smoking at any time before bariatric surgery, even if it is within 6 weeks before surgery.

R21(35/36). The Bariatric Outcomes Longitudinal Database prospectively evaluated 73,921 patients undergoing bariatric surgery and analyzed venous thromboembolism (VTE) events within 90 days of surgery (188 [EL 3, SS]). The overall risk of VTE after surgery was .42%, and 73% of these events occurred after discharge, most within 30 days after surgery (188 [EL 3, SS]). The risk of VTE was greater in the patients undergoing RYGB than in those undergoing adjustable gastric banding (.55% versus .16%) (188 [EL 3, SS]). VTE was more frequent when the procedure was performed using an open, rather than a laparoscopic approach (1.54% versus .34%) (188 [EL 3, SS]). Patients with a VTE event were older, had higher BMI, and were more likely to have a history of VTE (16.5% versus 3.7%) than patients who did not have a VTE event (188 [EL 3, SS]). The risk of VTE was greater in men (hazard ratio 2.32, 95% confidence interval 1.81–2.98) and in patients with an inferior vena cava filter (hazard ratio 7.66, 95% confidence interval 4.55–12.91) (188 [EL 3, SS]). However, there is evidence suggesting that prophylactic IVC filter placement before RYGB does not prevent PE and may lead to additional complications (189 [EL 3, SS]).

R23(38). In a study limited to obese patients in the eastern region of Saudi Arabia, the prevalence of abnormal liver function tests was low and generally due to nonalcoholic fatty liver disease (NAFLD) (190 [EL 3, SS]). Therefore, routine abdominal ultrasonography is not needed to routinely screen for significant liver disease before bariatric surgery.

R24(39). The reported prevalence range for preoperative H pylori has widened from 8.7% in a German cohort (191 [EL 2, PCS]) to 85.5% in a Saudi cohort of bariatric surgery patients (192 [EL 3, SS]), with other series having intermediate values (193 [EL 3, SS]; 194 [EL 3, SS]; 195 [EL 3, SS]). In 1 retrospective review, preoperative treatment following H pylori screening resulted in reduced incidence of viscus perforation (196 [EL 3, SS]). In another retrospective review of 560 patients undergoing RYGB,

flexible upper endoscopy, testing for H pylori followed by treatment of patients with positive results, was associated with a lower incidence of postoperative marginal ulcers (2.4%), compared with those who did not undergo such screening (6.8%) (197 [EL 3, SS]). However, in a PCSA, Yang et al. (198 [EL 2, PCS]) conclude that gastric ulcers in symptomatic patients following laparoscopic bariatric surgery are related to the surgical procedure and not exposure to H pylori infection. This finding was corroborated by the results of Loewen et al. (199 [EL 3, CCS]). The issue of H pylori screening before bariatric surgery will require a well-designed RCT, but until then, the evidence does not support routine screening (200 [EL 4, opinion]), but aggressive case finding in high-risk patients may be reasonable.

R25(40). In a retrospective, multicenter study of 411 RYGB patients, 7 of 21 with a history of gout suffered an acute gouty attack postoperatively (201 [EL 3, SS]).

R27(42/43). The psychosocial evaluation identifies potential contraindications to surgical intervention, such as substance abuse or poorly controlled psychiatric illness, and identifies interventions that can enhance long-term weight management (202 [EL 4, review]). Even though there are published recommendations regarding the structure and content of mental health evaluations (203 [EL 2, PCS]; 204 [EL 4, CPG]; 205 [EL 2, PCS]), consensus guidelines have yet to be established. Psychologists, psychiatrists, or other mental health professionals typically perform these evaluations, which rely on clinical interviews, as well as questionnaire measures of psychiatric symptoms and/or objective tests of personality or psychopathological conditions (206 [EL 3, SS]). More comprehensive evaluations assess the bariatric surgery knowledge, weight history, eating and physical activity habits, potential obstacles, and resources that may influence postoperative outcomes (203 [EL 2, PCS]; 204 [EL 4, CPG]). Approximately 90% of bariatric surgery programs require their surgical candidates to undergo a mental health evaluation preoperatively (207 [EL 3, SS]; 208 [EL 3]). A substantial proportion of bariatric surgery candidates present themselves in an overly favorable light during the psychological evaluation (209 [EL 3, SS]), and there is low congruence between clinically derived and research-based diagnoses (210 [EL 3, SS]), which may impact accurate assessment.

A lifetime history of substance abuse disorder is more likely in bariatric surgery candidates compared with the general population (211 [EL 3, SS]). In contrast, current alcohol and substance abuse in bariatric surgery candidates is low compared with the general population (211 [EL 3, SS]). The LABS study demonstrated that certain groups including those with regular preoperative alcohol consumption, alcohol use disorder, recreational drug use, smokers, and those undergoing RYGB had a higher risk of postoperative alcohol use disorder (212 [EL 2, PCS]). A web-based questionnaire study indicated that 83% of respondents continued to consume alcohol after RYGB, with 28.4% indicating a problem controlling alcohol (213 [EL 3, SS]). In a prospective study with 13- to 15-year follow-up after RYGB, there was an increase in alcohol abuse (2.6% presurgery to 5.1% postsurgery) but a decrease in alcohol dependence (10.3% presurgery versus 2.6% postsurgery) (214 [EL 2, PCS]). In a survey 6–10 years after RYGB, 7.1% of patients had alcohol abuse or dependence before surgery, which was unchanged postoperatively, whereas 2.9% admitted to alcohol dependence after surgery but not before surgery (215 [EL 3, SS]). Finally, in a retrospective review of a large electronic database, 2%–6% of bariatric surgery admissions were positive for a substance abuse history (216 [EL 3, SS]). Interestingly, 2 studies have demonstrated better weight loss outcomes among patients with a past substance abuse history compared with those without past alcohol or other substance abuses (217 [EL]; 218 [EL 3, SS]).

The pharmacokinetic changes following RYGB include accelerated alcohol absorption (shorter time to reach maximum concentration) (219 [EL 2, NRCT]), higher maximum alcohol concentration (219 [EL 2, NRCT]; 220 [EL 2, PCS]; 221 [EL 2, PCS]), and longer time to eliminate alcohol (220 [EL 2, PCS]; 221 [EL 2, PCS]). In a recent prospective crossover study of RYGB patients, blood alcohol content (BAC) was measured preoperatively and 3 and 6 months postoperatively after 5 oz of red wine to determine peak BAC and time until sober (221 [EL 2, PCS]). The peak BAC in patients at 6 months (.088%) was greater than the preoperative baseline (.024%) with varying intoxication symptoms (221 [EL 2, PCS]). Similar findings have been demonstrated in patients after LSG (222 [EL 2, PCS]). Weight loss and rapid emptying of a gastric pouch contribute to the higher BAC (219 [EL 2, NRCT]) and faster alcohol absorption and lower metabolic clearance (220 [EL 2, PCS]), respectively, for each drink consumed. Overall, from the existing evidence base, it is unclear how long an individual should be abstinent from alcohol, or other substances with abuse potential, before bariatric surgery.

R28(44). Binge eating disorder (BED), night eating syndrome, grazing, and other loss-of-control eating patterns are quite common in bariatric surgery candidates (223 [EL 2, PCS]; 224 [EL 3, SS]; 225 [EL 2, PCS]). Several studies have linked preoperative BED with less excess body weight lost or weight regain during the 2-year postoperative period (226 [EL 3, SS]; 227 [EL 4, NE]; 228 [EL 3, CSS]; 229 [EL 2, PCS]; 230 [EL 3, SS]) Other studies have not found significant differences in weight loss outcomes when comparing patients with and without preoperative BED (231 [EL 2, PCS]; 232 [EL 2, PCS]; 233 [EL 3, SS]). These conflicting findings may be due in part to the wide variation in methodology for determining BED in the studies (234 [EL 4, NE])). However, loss-of-control eating and grazing appear to be linked to weight loss outcomes (223 [EL 2, PCS]; 224 [EL 3, SS]; 235 [EL 3, SS]; 236 [EL 2, PCS]). Perioperative behavioral strategies to improve adherence

with lifestyle modification include long-term patient-provider contact, actual physical activity interventions (enrolling patients in programs), concrete and specific recommendations, and mechanisms to facilitate impulse control and improve mood (237 [EL 4, opinion]). Notwithstanding the above, preoperative interventions have had mixed results (238 [EL 2, PCS]; 239 [EL 2, PCS]). Bulimia nervosa is rare among bariatric surgery candidates and should be considered a contraindication to these surgical procedures (http://www.behavioralhealthce.com/index.php/component/courses/?task=view&cid=70).

R29(45). The EL 3 evidence base supporting the high prevalence rates and need for systematic preoperative assessment and treatment of nutrient insufficiencies/deficiencies is primarily represented by surveillance studies, case series, and case reports. Additions to this evidence base since the 2008 AACE-TOS-ASMBS CPG (7 [EL 4, CPG]) support this recommendation (240 [EL 3, SS]; 241 [EL 3]; 242 [EL 3, SS]; 243 [EL 3, SS]; 244 [EL 3, SS]; 245 [EL 3, SS]; 246 [EL 3, SS]; 247 [EL 3, SS]; 248 [EL 3, SS]; 249 [EL 3, SS]; 250 [EL 3, SS]; 251 [EL 3, SS]; 252 [EL 3, SS]). The length of intestinal bypass is directly related to the extent of risk for nutritional deficiencies (253 [EL 1, RCT]).

R30 (NEW). Obesity is a risk factor for certain malignancies (e.g., endometrial, renal, gallbladder, breast, colon, pancreatic, and esophageal) (254 [EL 4, review], 255 [EL 3, SS], 256 [EL 4, review], 257 [EL 3, SS], 258 [EL 3, SS]), adversely affects clinical outcomes (259 [EL 2, PCS]), and therefore prompts age- and risk-appropriate cancer screening before bariatric surgery. Gagné et al. (260 [EL 3, SS]) found that among 1566 undergoing bariatric surgery, 36 (2.3%) had a history of malignancy, 4 (.3%) were diagnosed during the preoperative evaluation, 2 (.1%) were diagnosed intraoperatively, and another 16 (1%) were diagnosed postoperatively. However, the authors commented that a finding of malignancy per se was not a contraindication to bariatric surgery as long as the life expectancy was reasonable. Subsequently, limited clinical series have described the benefit of preoperative screening for specific cancer histiotypes (261 [EL 3, CCS]) and the protective effect of bariatric surgery (262 [EL 4, review]). Unfortunately, despite this clinical association, awareness and implementation are still lacking (263 [EL 3, SS]).

Q5. How can early postoperative care be optimized?

R31 (46–53/90/91). In an RCT by Sarwer et al. (264 [EL 1, RCT]), regular postoperative dietary counseling by an RD was associated with greater weight loss at 4 and 24 months compared with the control group. Although none of these weight loss differences reached statistical significance, the dietary counseling group reported greater improvements in eating behavior (264 [EL 1, RCT]). The role of the RD in postoperative care is further reviewed by Kulick et al. (265 [EL 4, position]) and Ziegler et al. (266 [EL 4, consensus]). Recommendations for protein intake are variable but studies suggest higher protein levels (80–90 g/d) are associated with reduced loss of lean body mass (267 [EL 4, NE]; 268 [EL 2, PCS]; 269 [EL 3, SS]). Protein intake is generally reduced following surgery (270 [EL 2, PCS]) and adequate intake can be facilitated through the use of protein supplements, though a causal effect of protein supplement use and favorable body composition change has not been demonstrated (271 [EL 2, PCS]). A review of healthy eating principles after RYGB is provided by Moize et al. (272 [EL 4, review]). Medication absorption depends on the a variety of drug-specific factors, but in general rapid- or immediate-release preparations, in liquid form or crushed to facilitate tolerance, are preferable to extended release or enteric-coated preparations (273 [EL 4, review]; 274 [EL 4, review]).

R32(54/89/93). Many patients will require additional micronutrient supplementation in addition to 2 daily multivitamins recommended (275 [EL 2, PCS]; 276 [EL 4, CPG]). The extent and severity of micronutrient undernutrition is related to the extent and severity of disruption of normal gastrointestinal anatomy and physiology (277 [EL 4, review]). Guidelines for treating iron deficiency in bariatric surgery patients are reviewed by Munoz et al. (278 [EL 4, review]). Guidelines for folic acid and B_{12} are based on maintenance of biochemical and functional markers (e.g., homocysteine, RBC folate, and methylmalonic acid) within target ranges (279 [EL 2, PCS]; 280 [EL 3, SCR]). Calcium intake primarily in the form of food is advocated in LAGB given recent reports linking calcium supplementation with increased incidence of MI risk in postoperative women (281 [EL 2, PCS])). Vitamin D dosages of at least and as high as 6000 IU/d are safe and necessary in many postbariatric surgery patients to achieve target blood levels (282 [EL 1, RCT]; 283 [EL 4, position]). The broad recommendation concerning micronutrient undernutrition and management was designated as Grade A based on expert consensus, even though EL 1 studies are lacking for all relevant vitamins and minerals.

R34(56/92). The Nutrition Risk Score 2002 is a validated instrument to identify patients who would benefit from nutrition support (284 [EL 3, SS]). PN is reserved for those patients requiring nutrition support but unable to meet their needs enterally. The timing of nutrition support initiation is based on the clinical setting and has been discussed in various recent CPG (285 [EL 4, CPG]; 286 [EL 4, NE]; 287 [EL 4, CPG]). The application of these evidence-based CPG recommendations in the bariatric surgery patient has been derived from extrapolations from obesity patients in the ICU (288 [EL 4, review]) and limited reviews and case reports, primarily involving postoperative leaks (289 [EL 4, review]; 290 [EL 4, NE]; 291 [EL 3, SS]).

R35(57). This recommendation is consistent with the 2011 AACE DCCP CPG (153 [EL 4, CPG]).

R36(58–61). Recent changes in the recommendations for inpatient and outpatient glycemic control targets are provided in the 2011 AACE DCCP CPG (153 [EL 4, CPG]) and the review by Schlienger et al. (292 [EL 4, review]). An initial tight glycemic control protocol in the hospital following bariatric surgery can be safely implemented, but outcome studies are lacking so no formal recommendation can be made at this time (293 [EL 3, SS]). Metformin may be considered to manage hyperglycemia in the postoperative patient, but caution should be exercised in patients with reduced glomerular filtration rate (GFR) due to a potential increase for lactic acidosis (153 [EL 4, CPG]; 294 [EL 2, PCS]; 295 [EL 2, NRCT]). There are insufficient data regarding the use of incretin-based therapies in the postoperative setting, but they may assist in achieving glycemic and weight targets (296 [EL 3, SCR]).

R38(64). Postoperative CPAP improves arterial blood gas and reduces the need for intubation (297 [EL 4, review]). NSQIP data from 2006–2008 recently published also reports that postoperative pulmonary complications (pneumonia and respiratory failure) can be predicted by various risk factors, accounted for one fifth of complications and significantly increased 30-day mortality after bariatric surgery (298 [EL 3, SS]). Single-institution retrospective series have demonstrated that CPAP after gastric bypass does not result in an increased anastomotic leak rate (299 [EL 3, SS]).

R39(65/66). Although strong evidence is lacking, there is demonstrable benefit with post-hospital discharge extended chemoprophylaxis for selected high-risk patients; this strategy should be considered based on individual patient risks factors, including VTE, activity level at the time of discharge, and bleeding complications (300 [EL 4, CPG]; 301 [EL 3, SS]; 302 [EL 2, PCS]). The BOLD data demonstrated that 73% of VTE events occurred after hospital discharge (303 [EL 3, SS]). The time frame of 24 hours adheres with the Surgical Care Improvement Project (SCIP; http://www.jointcommission.org/surgical_care_improvement_project/).

The use of prophylactic IVC filters is controversial and there are data that prophylactic IVC filters do not prevent thromboembolic events in postbariatric patients and may lead to additional complications. The Michigan Bariatric Collaborative study (N=542 RYGB patients) found that prophylactic IVC filter placement was not associated with a decrease in VTE-related complications, serious complications, or death (OR=2.49; 95% CO .99–6.26) (304 [EL 3, SS]). There was no subgroup of patients in whom IVC filters improved outcomes, and 57% of patients who died or had permanent disability had a fatal PE or IVC-related complication (304 [EL 3, SS]). Additionally, the BOLD data reported that the risk of VTE was greater in patients with an IVC filter (hazard ratio 7.66, 95% confidence interval 4.55–12.91) (303 [EL 3, SS]).

R40(67–71). The principal update concerns leaks following LSG (305 [EL 3, CCS]; 306 [EL 3, SS]; 307 [EL 2, MNRCT]; 308 [EL 3, CCS]; 309 [EL 4, review]; 310 [EL 4, NE]; 311 [EL 4, position]). The varying prevalence of this complication (0%–12%; increased risk associated with smaller bougie size and higher BMI) in the reports cited represents a key factor in the clinical decision making regarding choice of bariatric procedure, technique and setting. There are new reviews regarding the clinical management of leaks but aspects of suspicion, diagnosis, and early exploration have not changed. Recently, an elevated C-reactive protein (CRP) on day 2 following RYGB was associated with intestinal leak (312 [EL 3, SS]). CT imaging provides information regarding the gastric remnant staple line and the jejunojejunostomy that is not obtained with UGI (305 [EL 3, CCS]; 313 [EL 3, SS]; 314 [EL 3, SS]).

R41(72–75). The incidence of postoperative rhabdomyolysis (RLM; CK >1000 IU/L) ranges from 7–30.4% (315 [EL 2, PCS]; 316 [EL 1, RCT]; 317 [EL 2, PCS]) and even though IVF is an effective treatment, this has not been shown to be an effective preventive measure (316 [EL 1, RCT]). Increased BMI (>55–60 kg/m^2) and bypass $>$ -banding were associated with increased RLM incidence (315 [EL 2, PCS]; 261 [EL 2, PCS]) and patients in these higher risk categories may benefit from routine postoperative CK testing (316 [EL 1, RCT]; 317 [EL 2, PCS]).

Q6. How can optimal follow-up of bariatric surgery be achieved?

R42(78–83/85/88). Adherence with follow-up visits (missing $<25\%$ of appointments, cf. $>25\%$) was associated with greater loss of EBW for LAGB but not RYGB patients (318 [EL 3, SS]). This corroborated findings by Shen et al. (319 [EL 3, SS]) that the association of follow-up frequency impacted weight loss success to a greater degree in LAGB patients, compared with RYGB patients. Dixon et al. (320 [EL 3, SS]) found that a follow-up frequency less than 13 times in 2 years for LAGB patients, especially males, was associated with less weight loss (% excess BMI loss); similar findings were noted when patients were motivated by appearance (especially young females) but there were no associations with "readiness-to-change." In another retrospective review of LAGB patients, Weichman et al. (321 [EL 3, SS]) found that <7 follow-up visits per year was associated with less loss of EBW than with ≥ 7 follow-up visits per year.

Binge eating disorder (BED) and grazing are associated with inadequate weight loss or weight regain after RYGB (322 [EL 3, SS]). In a prospective study, Rutledge et al. (323 [EL 2, PCS]) found that the presence of ≥ 2 psychiatric conditions was associated with inadequate weight loss or weight regain after LAGB or RYGB. Efforts should be made to anticipate inadequate weight loss or weight regain by detecting risk factors such as continued disordered eating and psychiatric co-morbidity and then implementing a self-

monitoring strategy in higher-risk patients (324 [EL 3, SS]). Nutritional management of weight regain after RYGB may be successful (low glycemic load, 45% carbohydrate/35% protein/20% fat [about 16 kcal/kg/d], 3 servings/d dairy product, 15 g/d fiber supplement, and micronutrient supplements to avoid deficiencies) (325 [EL 2, PCS]). Though different mechanisms may ultimately account for inadequate weight loss or weight regain after LAGB procedures, conversion to a RYGB appears efficacious for both indications, at least short term (within 12 months) (326 [EL 2, PCS]). In patients with weight regain after RYGB, revisional surgery is most successful if performed within 5 years after the primary procedure (327 [EL 3, SS]). A recent review of revisional bariatric surgery is provided by Kellogg (328 [EL 4, review]). Additional reviews on nutritional and metabolic follow-up strategies are provided by Ziegler et al. (329 [EL 4, review]) and Koch and Finelli (330 [EL 4, review]).

R43(84). Updated algorithms for the evaluation and treatment of postprandial hypoglycemia after bariatric surgery are provided by Ceppa et al. (331 [EL 3, CCS]) and Cui et al. (332 [EL 3, CCS]). The discriminants used in these algorithms include specific hypoglycemic and dumping symptoms, vasomotor and glycemic responses to oral glucose challenge, and formal insulinoma and 72 hour prolonged fasting tests (331 [EL 3, CCS]); (332 [EL 3, CCS]). Interventions for noninsulinoma pancreatogenous hypoglycemia syndrome (NIPHS) include pharmacological therapy (octreotide [332 [EL 3, CCS]; 333 [EL 3, SCR]), diazoxide (332 [EL 3, CCS]; 334 [EL 3, SCR]), acarbose (333 [EL 3, SCR]) and calcium channel antagonists (332 [EL 3, CCS]; 335 [EL 3, SCR]) and surgical procedures (gastric restriction 280 [EL 2, PCS]) and pancreatectomy (336 [EL 2, PCS]; 337 [EL 3, SCR]).

R44(86). Many bariatric surgery patients have negative beliefs and cognitions regarding physical activity; these should be addressed and the benefits and types of physical activity before and after bariatric surgery reinforced (338 [EL 2, PCS]; 339 [EL 2, PCS]). In a retrospective study of 148 RYGB patients, postoperative physical activity was associated with greater EWL loss (OR 3.5; $P < .01$) (340 [EL 3, SS]). These results were corroborated by Hatoum et al. (341 [EL 2, PCS]). In a nonrandomized trial of 15 patients post-RYGB, an exercise program of 75 minutes cardiovascular warmup + strength training + endurance training, 3 times a week for 12 weeks prevented the reduction in static and dynamic muscle strength observed in control patients (342 [EL 2, NRCT]). In a RCT of 21 patients post-RYGB, 12 weeks of aerobic exercise training was associated with improved cardiac autonomic function and pulmonary functional capacity (343 [EL 1, RCT]). In another RCT of 33 patients post-RYGB or gastric banding, 12 weeks of a high-volume exercise (up to 1 hr/d moderate physical activity with increases in additional light physical activity) was associated with increased resting energy expenditure, improved glucose tolerance, and enhanced physical fitness (344 [EL 1, RCT]).

In 1 meta-analysis, Egberts et al. (345 [EL 2, MNRCT]) found that postbariatric surgery patients participating in an exercise program experienced a standardized mean of 3.62 kg greater weight loss compared with minimal exercise groups. In another meta-analysis, Livhits et al. (346 [EL 2, MNRCT]) demonstrated the salutary effects of postoperative exercise, with many of the study designs analyzed incorporating >30 min/d of moderate physical activity. These findings are consistent with the meta-analysis of Jacobi et al. (347 [EL 2, MNRCT]).

R45(87). A number of empirical studies and a meta-analysis demonstrate improved weight loss outcomes in patients who attend support groups following weight loss surgery (348 [EL 2, MNRCT]; 349 [EL 3, SS]). The positive relationship between support group attendance and weight loss has been found in RYGB (340 [EL 3, SS]; 350 [EL 3, SS]) and LAGB (351 [EL 3, SS]) patients. One study has shown a linear relationship between numbers of groups attended and weight loss after controlling for baseline BMI in LAGB patients (352 [EL 3, SS]).

R47(96). In a cross-sectional study of 2 cohorts (before and 12 months after RYGB), Gomez et al. (353 [EL 3, CSS]) found that bone mineral density (BMD) was positively correlated with lean mass preoperatively and postoperatively and with fat mass preoperatively. However, the authors point out that causal mechanisms among body composition, BMD, and neurohumoral axes remain complex and require further study. Even with the bone loss in the hip after bariatric surgery, the data and limitations of dual energy x-ray absorptiometry (DXA) are not conclusive that there is an increased incidence of osteoporosis and increased fracture risk (354 [EL 4, review]). These limitations are compounded further by the weight constraints of most DXA tables (250–275 pounds), although newer and larger machines can accommodate up to 450 pounds (355 [EL 4, review]). Forearm BMD determinations remain an option for preoperative screening and postoperative surveillance.

R49(101/102). Enteric hyperoxaluria is observed after RYGB and BPDDS and related to fat malabsorption (356 [EL 2, PCS]). Therapeutic strategies to manage hyperoxalaturia in bariatric surgery patients include calcium supplementation, increased hydration, limiting dietary oxalate, and adhering with a low fat diet (356 [EL 2, PCS]). Sakhaee et al. (357 [EL 1, RCT]) performed a placebo-controlled RCT in RYGB patients demonstrating that potassium (40 mEq) calcium (800 mg) citrate (100 mEq) supplementation inhibited calcium oxalate agglomeration. Certain probiotics (e.g., VSL#3) have also been found to lower GI oxalate absorption in bariatric surgery patients (358 [EL 2, PCS]), as well as reduce bacterial overgrowth, increase B_{12} availability, and perhaps by altering the

intestinal microbiome, increase weight loss (359 [EL 1, RCT]).

R54(113–116). A meta-analysis of RCT to treat B_{12} deficiency concluded that oral B_{12} therapy (1000–2000 μg/d) was as effective as intramuscular administration in achieving short-term hematological and neurological responses (360 [EL 1, MRCT]).

R58(122–123). Approximately 9% of patients have a zinc deficiency before bariatric surgery and 42% (RYGB) to 92% (BPDDS) after surgery, depending on procedure type (361 [EL 3, SS]). There are abnormalities in zinc (and iron) absorption markers following RYGB, reinforcing the need to monitor these analytes in this setting (251 [EL 3, SS]; 253 [EL 3, SS]; 362 [EL 2, PCS]).

R59(NEW). Approximately 51%–68% of BPD patients demonstrate low copper levels up to 4 years postoperatively (251 [EL 3, SS]; 253 [EL 3, SS]). This contrasts with approximately 4% of RYGB patients postoperatively up to 5 years (253 [EL 3, SS]). Shorter-term (5 years) hypocupremia was associated with reduced leukocyte and granulocyte counts but not with clinical evidence of hematological or neurological disorders (253 [EL 3, SS]).

R60(124–129). Chronic nausea and emesis are associated with thiamine deficiency in bariatric surgery patients. However, Lakhani et al. (363 [EL 3, SS]) found that among RYGB patients developing thiamine deficiency, they also had evidence of small intestine bacterial overgrowth (SIBO), which responded to thiamine 100 mg PO BID for 2 months (on average) and antibiotics (metronidazole, amoxicillin, or rifaximin for 7–10 days each month for 2 months on average). The authors concluded that SIBO impairs the absorption of thiamine, as well as other nutrients.

R61(130). Improvements in serum lipid levels after bariatric surgery have been well documented and are multifactorial in nature (GI absorption, altered dietary patterns, and not weight loss per se). The continued need for lipid-lowering medication, especially statins, unless overtly unnecessary or not possible due to GI symptoms, is emphasized, though the evidence base is fairly limited (364 [EL 3, SS]).

R62(131). Reductions in systolic and diastolic BP can occur within weeks of RYGB and continue up a year (365 [EL 2, PCS]). A nonmatched PCS with 3.4 years follow-up demonstrated significant improvement (RR .59) in metabolic syndrome components, including hypertension in a bariatric surgery group, compared with a medical weight loss program group (366 [EL 2, PCS]). Notwithstanding these results, the determinants of BP changes with obesity and bariatric surgery are complex. Similar to the above **R61** for statins, postoperative antihypertensives should also not be discontinued unless found to be overtly unnecessary (72 [EL 3, SS]). The SOS (367 [EL 2, PCS]) study and recent RCTs (38 [EL 1, RCT]; 39 [EL 2; RCT]; 40 [EL 1, RCT]; 41 [EL 1, RCT]) have failed to demonstrate major or durable improvements in BP (368 [EL 4, NE]). In addition, certain determinants of BP—muscle sympathetic nerve activity and plasma rennin activity—fall with negative energy balance but rebound with weight stability (369 [EL 2, PCS]).

R63(132–135/138). Among 290 bariatric surgery patients, loose stool and malodorous flatus were most frequent after BPD > RYGB, and constipation most frequent after LAGB (370 [EL 3, SS]).

R64(136/137). Nonsteroidal antiinflammatory drugs are associated with gastric and marginal ulcer perforations after RYGB (371 [EL 3, SS]; 372 [EL 3, SS]).

R65(139–141). Endoscopy is study of choice for chronic abdominal pain after bariatric surgery and foreign body removal can be successful (71% with immediate symptomatic improvement in 1 study; 373 [EL 3, SS]). There is no evidence regarding H pylori testing postoperatively to evaluate GI symptoms or complications.

R66(142). Retrospective series and single case reports have demonstrated the effectiveness of revisional surgery for problems related to nonpartitioned stomach after primary RYGB (gastrogastric fistula, staple line disruption) (374 [EL 3, SS]; 375 [EL 3, SS]; 376 [EL 3, SS]; 377 [EL 3, SCR]; 378 [EL 3, SCR]; 379 [EL 3, SCR]). Endoluminal procedures, such as endoscopic plicating and suturing, can be effective treatment for gastrogastric fistulas and staple line failures in selected cases and are less risky than surgical revision. The technology required and endoscopic skill set needed to accomplish these endoluminal procedures, though, are not widely available and are considered as investigational at this time. (380 [EL 3, SS]; 381 [EL 3, SS]; 382 [EL 3, CCS]; 383 [EL 3, SCR], 384 [EL 3, SCR]).

R68(145/146). Ultrasound is conventionally utilized to assess gallstone formation in the postbariatric surgery patient (385 [EL 4, review]). In a comparative cohort study, prophylactic cholecystectomy was feasible in preventing gallbladder complications after RYGB (386 [EL 2, PCS]). A meta-analysis of 5 RCTs, including 521 patients, concluded that ursodeoxycholic acid (300–1200 mg/d) significantly reduces gallstone formation after bariatric surgery (387 [EL 1, MRCT]).

R69(147/148). Rifaximin therapy provides symptom relief in irritable bowel syndrome and may be considered in post-BPD patients with symptoms related to bacterial overgrowth (388 [EL 1, RCT]). Probiotics can reduce bacterial overgrowth and promote weight loss in RYGB patients (359 [EL 1, RCT]).

R70(R149–152). Deferral of definitive repair of an symptomatic hernia depends on the surgeon's judgement based on the patient's clinical status and ease of repair. In 1 study, concomitant ventral hernia repair and RYGB was associated with small bowel obstruction and/or greater length of hospital stay (389 [EL 3, SS]). Whereas in a later study, concomitant mesh repair for ventral hernias and RYGB or LSG was found to be safe (390 [EL 3, SS]). The

diagnostic challenges for internal hernias and small bowel obstructions following RYGB are related to vague symptom reporting and reduced yield with imaging, both as a result of altered GI anatomy (391 [EL 3, SS]).

R71(R153–156). Body-contouring procedures after bariatric surgery are associated with improved well-being and quality of life (392 [EL 3, SS]). However, there is a 21% overall complication rate with abdominoplasty after bariatric surgery (393 [EL 3, SS]). There are alternatives to the traditional amputation-type panniculectomy for skin laxity after bariatric surgery. The potentially longer fleur-de-lis procedure has been reported to have a lower complication rate and improved symptom/cosmetic outcome (394 [EL 3, SS]). A modification to this procedure with high lateral incisions has been used in those patients who still have a BMI >30 kg/m^2 (395 [EL 3, SS]). Circumferential abdominoplasty is another safe and effective body-contouring procedure after bariatric surgery (396 [EL 3, SS]). Mastopexy is also indicated in nearly all female postbariatric surgery patients (397 [EL 3, SS]). In a retrospective review, van der Beek et al. (398 [EL 3, SS]) found that a stable weight for 3 months that is close to normal, typically requiring 12–18 months postoperatively, was associated with a low complication rate.

R72(158–162). The hospital readmission rate is 5.8% for RYGB and 1.2% for banding procedures within 30 days after discharge; the greatest predictors are prolonged length of stay (LOS) (OR 2.3), open surgery (OR 1.8), and pseudotumor cerebri (OR 1.6) for RYGB and prolonged LOS (OR 2.1), history of DVT or PE (OR 2.1), asthma (OR 1.5), and OSA (OR 1.5) (399 [EL 2, PCS]). In another study, publicly funded insurance, wound infections, malaise, and technical complications were associated with readmission after RYGB (400 [EL 3]).

R73(163). The overall incidence of revisional bariatric surgery ranges from 5%–50% with leak rates around 30% (401 [EL 4, review]). As an example, revisional RYGB after LAGB is safe and effective but with less weight loss, on average, compared with primary RYGB procedures (402 [EL 3, SS]). There are many other case reports and small clinical series but, at present, no RCTs to guide decision making for revisional bariatric surgery.

R74(164). Brolin and Asad (396 [EL 3, SS]) conducted a retrospective review of 2573 primary and 252 revisional bariatric surgeries with 13 undergoing reversals. Rationale for the reversals were intractable vomiting or diarrhea, substance abuse, and severe metabolic complications (403 [EL 3, SS]). Reversal could be obviated in about 50% of patients with patient education and follow-up (403 [EL 3, SS]).

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Disclaimer

American Association of Clinical Endocrinologists, The Obesity Society, and American Society for Metabolic & Bariatric Surgery 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. We 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.

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Case Study

Combined Treatment for Obesity and the Metabolic Syndrome

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An interdisciplinary team provides an ideal basis for successful weight management. Nutrition, exercise, behavior therapy, and medical collaborations strengthen the options and expertise that result in quality care for patients. When this ideal situation is not available, registered dietitians (RDs) with weight management certifications or specialized training can be a resource to other professionals. Although states may impose practice limits or provide guidelines concerning the role of RDs and the overlap of health professional interventions, the following cases are written with a team approach in mind and with RDs having a major role in patient management.

CASE 1

Patient Presentation

A 36-year-old Hispanic woman with a history of gestational diabetes diagnosed during pregnancy presented to her physician for a thyroid function test. During pregnancy, the patient closely monitored her blood glucose levels and was able to control her blood glucose with a daily exercise regimen. She has one child, who is now aged 3.5 years, who was delivered by Cesarean section and weighed 9.3 lb at birth. Since the pregnancy she has been healthy, except for a short bout of postpartum depression that has resolved. She is concerned about her steady weight gain since pregnancy (she is 5 ft, 2 in tall and her weight has increased from 145 to 172 lb) and reports that a friend told her that underactive thyroid could cause weight gain. She says, "I wouldn't mind losing weight if I did not believe I would fail." She feels well and has no other complaints.

The physician inquires about the patient's family history and learns that her father had a myocardial infarction at age 53 years and had type 2 diabetes diagnosed at the time of the heart attack. The physician honors the patient's request and initiates a thyroid panel as well as a routine fasting chemistry and lipid panel.

Test Results

- Thyroid stimulating hormone=1.3 (normal [nl] 0.35-3.5)
- Free T4=1.6 (nl 0.8-1.8)
- Total cholesterol=6.37 mmol/L* (nl varies per patient risk factors)
- Low-density lipoprotein (LDL) cholesterol=3.22 mmol/L* (nl varies per patient risk factors)
- High-density lipoprotein (HDL) cholesterol=1.01 mmol/L* (nl varies per patient risk factors)
- Triglyceride=2.54 mmol/L† (nl≤1.7 mmol/L)
- Fasting glucose=6.55 mmol/L‡ (nl≤5.55 mmol/L)

Based on these laboratory values, the physician asks the patient to make another appointment and makes a referral for as-needed individual appointments or professional consultation with other members of the interdisciplinary team, including an RD, a behavior-modification specialist, and an exercise professional.

DISCUSSION

Obesity and Risk Classifications

Patient presentations like this one are becoming more common as a result of the obesity epidemic. It illustrates that obesity is a gateway disease to the dysmetabolic syndrome, diabetes, and cardiovascular disease, among others. The patient has several risk factors for the dysmetabolic syndrome, including gestational diabetes. Criteria for the dysmetabolic syndrome are: waist circumference >102 cm or 40 in (men) or >8 cm or 35 in (women),

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**To convert mmol/L cholesterol to mg/dL, multiply mmol/L by 38.7. To convert mg/dL cholesterol to mmol/L, multiply mg/dL by 0.026. Cholesterol of 5.00 mmol/L = 193 mg/dL.*
†To convert mmol/L triglyceride to mg/dL, multiply mmol/L by 88.6. To convert mg/dL triglyceride to mmol/L, multiply mg/dL by 0.0113. Triglyceride of 1.80 mmol/L = 159 mg/dL.
‡To convert mmol/L glucose to mg/dL, multiply μmol/L by 18.0. To convert mg/dL glucose to mmol/L, multiply mg/dL by 0.0555. Glucose of 6.0 mmol/L = 108 mg/dL.

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triglyceride level ≥1.70 mmol/L, low serum HDL level (<1.01 mmol/L for men and <1.3 mmol/L for women), high blood pressure (systolic ≥130 mm Hg or diastolic ≥85 mm Hg), and/or fasting plasma glucose concentration (≥6.11 mmol/L) (1). To make the diagnosis, at least three criteria must be met. This patient has elevated fasting glucose, elevated triglyceride level, and low protective HDL levels and, therefore, meets the criteria. The patient's physical exam should also include a waist circumference measurement, another component of the dysmetabolic syndrome. The patient also has an LDL cholesterol level above the goal for persons with diabetes, according to the National Cholesterol Education Program Third Adult Treatment Panel guidelines (1). Although this patient has the dysmetabolic syndrome and has not yet met the criteria for type 2 diabetes, a goal of LDL cholesterol level <2.6 mmol/L may be ideal due to her multiple risk factors.

Identifying patients with obesity who have the dysmetabolic syndrome is important because it has been shown that nutrition therapy and exercise can reduce or delay the development of type 2 diabetes (2). A Diabetes Prevention Program study (2) focused on subjects with impaired glucose tolerance (subjects with the components of the dysmetabolic syndrome who had a 2-hour glucose tolerance test >7.77 mmol/L). The results showed that subjects in the intensive lifestyle intervention who lost approximately 7% of their body weight and exercised 150 minutes total per week reduced their risk of type 2 diabetes by 58%. The weight management goal for this patient should focus on preventing progression from the dysmetabolic syndrome to type 2 diabetes.

This patient's body mass index (BMI) is 31.5 (measured as kg/m^2) and is classified as class 1 obesity. The first goal of weight management is to decrease total daily energy intake. In general there are three traditional energy goals for overall food intake: weight maintenance, moderate weight loss, and aggressive weight loss. To accomplish each of these goals a clinician can use an isocaloric weight-maintenance diet, a low-energy diet, or a very–low-energy diet, respectively. For most patients a gradual weight loss with a balanced, low-energy diet is appropriate. Patients should be informed that the goal is small, incremental weight losses over time. The current recommended rate of weight loss is between 1 and 2 lb/week (3).

Energy Needs and Prescription

Traditionally, to produce a 1-lb weight loss per week, a 3,500-kcal deficit is needed. Therefore, if the energy deficit is divided by 7 days this yields a 500 kcal/day deficit. If the desired weight loss is 2 lb/week, then the energy deficit must be doubled to 1,000 kcal/day (Schoeller and Buchholz, page S24). The total intake of these low-energy diets is typically 1,000 to 1,500 kcal/day. Diets consisting of 1,000 kcal/day or less may require vitamin and mineral supplementation so a daily multivitamin with minerals is generally recommended (4). Calcium supplementation (Bray and Champagne, page S17) and fiber supplementation (Schoeller and Buchholz, page S24) may be needed to meet needs while consuming lower-energy diets. In addition, B vitamin intake, especially vitamin B-6, B-12, and folic acid, is needed to maintain normal serum homocysteine levels. It is important to limit serum homocysteine for high cardiovascular disease risk. A meta-analysis by Wald and colleagues (5) concluded that a folic acid intake of 800 μg/day would reduce the risk of ischemic heart disease by 16% and stroke by 24% (5). Data from the Nurses' Health Study (6) showed that folate and vitamin B-6 from the diet and supplements protected against coronary heart disease. Also, elevated serum homocysteine levels resulting from low folate intake have been associated with obesity, hyperinsulinism, and insulin resistance in children (7).

Clinicians and patients should set target weights together. An initial goal of a minimum of 7% up to 10% weight loss is appropriate in most cases of persons with the dysmetabolic syndrome. For this patient, a 10% weight loss is approximately 17 lb. This would yield a final weight of 155 lb and a more healthful BMI of 28.4.

The initial energy prescription can begin with current intake, recent weight-gain history, or estimated weight-maintenance needs. The energy evaluation for this patient could begin with a current energy intake of 2,400 kcal/day determined or evaluated from a food record or recall. Alternatively, if one can estimate weight gain over the past month or past 6 months, then excess energy intake can be estimated and addressed. For example, a weight gain of 12 lb in 6 months would represent an added 2 lb/month and 0.5 lb/week and approximately 250 kcal/day of excess intake over needs. This excess, plus maintenance needs, provides a rough estimate of average energy intake. Needs for weight maintenance may be estimated using short methods, such as 25 to 30 kcal/kg body weight, or resting metabolic rate (RMR) with activity estimates. RMR can be directly measured or estimated using equations like the Mifflin-St Jeor equation (8), or the use of charts (9). Based on the Mifflin-St Jeor equation, this patient's resting energy expenditure is 1,426 kcal. This value multiplied by 1.3 for sedentary activity and inclusive of the thermic effect of food provides total needs for weight maintenance of 1,854, or about 1,850 kcal. If the patient's total energy expenditure is 1,850 kcal/day and her intake is 2,400 kcal/day, she will have to reduce intake by 550 kcal/day to maintain weight and then decrease intake by an additional 500 kcal to meet the weight loss goal of 1 lb/week. Her excessive energy intake corresponds with her ongoing weight gain. Thus, a 1,050 kcal/day total deficit or a 1,350 kcal/day diet is needed to lose 1 lb per week based on current intake. To be accurate over time, energy needs should be recalculated based on changing weight. The reduction in energy expended as weight is lost requires a decrease in energy intake and a change in the diet pattern to continue weight losses. To alleviate this situation, Schoeller and Buchholz (page S24) recommends a more sophisticated approach based on averaging weight, the thermic effect of food changes resulting from decreased intake, and weight-change–related physical activity expenditures over a 12-week period. Using this method, the original deficit would be 730 kcal for a 1 lb/week loss or a diet of 1,120 kcal/day or about 1,100 kcal/day.

Diet Composition

Once a weight loss goal has been set and an energy deficit has been established, diet composition is reviewed. There is considerable controversy in the United States regard-

ing the optimal diet type. In the setting of the dysmetabolic syndrome and type 2 diabetes, diets have focused on low carbohydrate intake. Diets with high carbohydrate content can raise serum triglyceride levels and high total carbohydrate intakes are a cultural characteristic common in this patient's ethnic group. High-fiber foods, especially sources of soluble fiber (recommended intake 10 to 25 g/day) should be encouraged to lower LDL cholesterol levels. The glycemic response to food is also often a concern. A number of factors influence the glycemic response to foods, including the type (sugars and starches) and amount of carbohydrate, fiber content, and food preparation. However, contrary to popular belief, studies have shown that the various types of carbohydrate yield similar glycemic responses. Total amount of carbohydrate is the most important determinant of blood sugars (10).

The American Diabetes Association suggests persons with type 2 diabetes can substitute carbohydrate with monounsaturated fat to reduce postprandial glycemia and triglyceridemia (10). It is also reasonable to use this approach for persons with the dysmetabolic syndrome. It should be noted that liberal intake of monounsaturated fat can promote weight gain, so this substitution should only be done when substituting energy from carbohydrates in a monitored weight-management setting. Carbohydrate and monounsaturated fat combined should provide 60% to 70% of total energy. Because Hispanic cultural food patterns are not high in monounsaturated fats, it is important to determine if the patient will accept monounsaturated fats. If the patient does not accept the monounsaturated fats and her triglyceride levels remain elevated with weight loss, n-3 fatty acid supplements might be considered. However, these supplements may increase LDL cholesterol levels; and lab values show that these levels are already elevated for this patient. Encouraging two to three servings of fish per week will provide n-3 fatty acids and can be a substitute for n-3 fatty acid supplementation. Saturated fats should be limited to 7% to 10% of total daily energy intake and total fat intake should be <30% of total energy if weight loss is the goal. Using a goal of 1,100 to 1,350 kcal/day, the recommended 10% saturated fat level results in suggested intake of 12 to 15 g saturated fat per day. However, the goal of 7% saturated fat intake for persons with elevated LDL cholesterol levels results in a suggested intake of 8 to 10 g saturated fat. This is difficult for a patient to convert into foods but, generally, encouraging the lower-fat, lower–saturated-fat meats with limited beef, cheese, and eggs will help the patient meet the 7% level. The total grams of fat would be 37 to 45 g at 30% of 1,100 to 1,350 kcal. Cholesterol should be less than <200 mg/day if the LDL cholesterol level is >2.6 mmol/L*. The patient would be advised to avoid *trans* fatty acids and to increase intake of plant sterols and stanols in margarines and salad dressings to approximately 2 g/day.

Plant sources combined in a dietary plan, known as the portfolio, have produced significant reductions in LDL cholesterol compared to the traditional therapeutic lifestyle changes (TLC) diet and statin cholesterol-lowering drugs (11). The diet consists of 1 oz almonds; 2 g plant sterols from enriched margarine; 35 g soy protein; and 15 g viscous fiber from sources such as oats, barley, eggplant, and okra. A study of 25 patients with hyperlipidemia had a 35% reduction of LDL cholesterol level in 2 weeks of being served the prepared diet, compared with a 12% LDL cholesterol level reduction on the TLC diet (11). The benefit of these plant sources individually has been identified and their inclusion is advocated in the TLC diet.

Protein intake is also a concern in the setting of diabetes because of the potential of promoting nephropathy. If renal function is normal, a protein intake of 15% to 20% of total daily energy intake is acceptable. A diet including more than 20% of energy from protein would not be recommended for a patient with increased cardiovascular risk and diabetes because the dietary saturated fat would usually be higher in high-protein diets (10). Normal protein needs (0.8 g per kg body weight) based on actual weight would result in a recommended intake of approximately 62 g/day. A diet where protein makes up 20% of total intake would result in recommending 55 to 67 g/day protein for persons consuming 1,100 to 1,350 kcal/day. An example of a traditional balanced protein distribution in this energy range would be five to seven servings of starches (15 to 21 g protein), two servings of fat-free dairy (16 g protein), nonstarch vegetables (2 to 4 g protein), two to three servings of fruit (0 g protein), one serving of fat (0 g protein), and 4 to 5 oz meat or meat substitute (28 to 35 g protein). If monounsaturated fats are accepted by the patient, the starch or fruit servings instead of the dairy would be reduced by about one starch/fruit for every 2 tsp added monounsaturated fat. These diet plans can be goals when reviewing the patient's current intake and determining a pattern that the patient will accept.

Behavior Assessment

Intensive counseling and behavior interventions are recommended by the US Preventive Service Task Force for adults with obesity (12). Behavior interventions assist patients to "acquire skills, improve motivation, and develop supports" (12). Patients should be assessed for readiness to change (Berkel and colleagues, page S35). The patient in this case is determined to be at the contemplation phase, based on the statement, "I wouldn't mind losing weight if I did not believe I would fail." She is given information about the relationships among her diet, health, and future health because her understanding of her health condition is limited. A detailed history should be completed, including a review of her weight history, eating patterns, past successes, and a discussion of barriers. Additional factors included in the Nutrition Care Process (13), such as food access, selection, and preparation, are addressed. A "personality lifestyle patterns" approach can be used to determine if there is an initial self-monitoring task that the patient would be willing to complete (Kushner and Blatner, page S53). The patient's willingness to begin self-evaluation and performance on the task provides information about time commitments and efforts in a weight-loss program. In this case, the patient agrees to keep a food record, focus on her snacking patterns, and return in 1 week (Kushner and Blatner, page S53; Berkel and colleagues, page S35). This patient's energy imbalance is most likely related to excessive and high-energy snacks with no regular physical activity, as evidenced by a 25-lb weight gain in 3 years and elevated fasting blood glucose level (13).

At the follow-up appointment the patient reports that she has completed the food record and is now at the action stage in the readiness to change model. She has eliminated her soft-drink intake (Bray and Champagne, page S17), changed her snack patterns over the past 2 weeks, and has had no weight gain. Using motivational interviewing (Kirk and colleagues, page S44) and her initial success at preventing weight gain, the patient and RD discuss the eating pattern together and the patient is encouraged to express her reasons for the changes she has made. Periods when she was vulnerable to overeating and strategies she used to limit portions are discussed. Positive skills are reinforced and new skills are encouraged. She is given an estimate of her energy, fat, and cholesterol intake based on the food record. The patient may choose to work on preventing weight gain or she may choose to make further changes to initiate weight loss (Hill and colleagues, page S63). A goal of a 17-lb loss over 4 to 5 months is agreed upon. The initial energy goal is 1,200 kcal/day and the initial fat intake goal is <40 g/day. The patient agrees to log if she is over or under her pattern for the week, focus on her fat-gram goal, and weigh herself weekly. The patient e-mails her monitoring records to the RD at least weekly (Berkel and colleagues, page S35).

With ongoing intensive counseling, progress will depend on the professional guidance that the patient receives and her commitment to change. For example, at a subsequent appointment, the patient might identify difficulty with the noon meal because she often grabs a bite at fast-food restaurants. She asks for information and a plan to make better choices at fast-food restaurants. Problem solving with the patient and discussion of stimulus control identifies the following options, which are acceptable to the patient: limiting fast-food lunches to 400 to 500 kcal, having a salad at home for dinner on days she eats fast foods, trying purchased meal replacements at noon, and making up a menu of simple meal-replacement foods or frozen entrees that could be purchased for a quick lunch. Over time, it will be important to assess changing psychologic and emotional factors and new barriers to success as her weight and habits change.

Physical Activity Assessment

Adding physical activity to the treatment plan will contribute to decreases in plasma total and LDL cholesterol levels and triglyceride levels. Regular physical activity improves insulin sensitivity and improves glycemic control. Exercise will help limit the typical decrease in HDL cholesterol associated with low-fat diets and weight loss. Due to cardiovascular risk factors, the patient needs to have an exercise stress test before a moderate-intensity exercise program is initiated (14). The patient is approved for exercise, and she plans to join a gym and exercise at home. Upon referral, the team exercise professional assesses the patient for strength, flexibility, balance, and endurance. A plan is written to gradually increase physical activity and to monitor progress toward her goals.

Outcomes

Following 6 months of medical nutrition therapy with increased physical activity and medical follow-up, the patient meets a weight-loss goal of 10% of body weight (weight of 156 lb, BMI 28). Her fasting blood glucose level has decreased to 5.27 mmol/L‡. Her triglyceride level has decreased to 1.36 mmol/L† and her HDL cholesterol level increased to 1.25 mmol/L*, but her total and LDL cholesterol levels remained slightly elevated at 5.46 mmol/L* and 2.8 mmol/L*, respectively. She tells her physician that, because of the expense of the medications, she would prefer to try to reduce her weight further and improve her lipid profile with diet rather than begin medications.

CASE 2

Patient Presentation

The patient is a 45-year-old white man with a medical history of hypercholesterolemia, schizophrenia, and obesity (BMI 36). He comes in because he has noticed a rash on his neck. He describes it as a dark discoloration that has been there for a few years. He does not have the rash on any other part of the body. He has not tried any new soaps, colognes, or aftershave lotions on his neck. The physician does a review of systems. The patient reports that he often gets up in the middle of the night to urinate and is often thirsty. He was told 2 years ago, when he had a cholesterol level measurement done at a health fair, that his cholesterol level was high but he is not sure what the value was. His only current medication is olanzapine, prescribed by a psychiatrist. His schizophrenia is very well controlled and he works as an orderly at a hospital. The patient has a waist circumference of 42 in, he is 6 ft tall, and weighs 250 lb.

The physician inquires about the patient's family history; however, the patient is not in contact with his family. The patient asks if his obesity could be the result of genetic factors. The physician orders routine fasting laboratory tests.

Test Results

- Total cholesterol 5.46 mmol/L*
- LDL cholesterol 4.0 mmol/L*
- HDL cholesterol 0.94 mmol/L*
- Triglyceride 1.67 mmol/L†
- Fasting glucose 5.50 mmol/L‡
- Blood pressure 135/85 mm Hg

Based on these lab results, the physician schedules another appointment with the patient and makes referrals to other members of the interdisciplinary team, including an RD, a behavior specialist, and an exercise professional.

DISCUSSION

Obesity and Risk Classifications

This patient has physical and laboratory findings that suggest the dysmetabolic syndrome. The dark discoloration at his neck is ancanthosis nigricans. This dermatologic condition often occurs at the neck and skin folds and

is seen when insulin resistance and the dysmetabolic syndrome are present. The laboratory findings meet criteria for the dysmetabolic syndrome (low protective HDL cholesterol level, increased waist circumference, and elevated blood pressure).

It is important to note that the medical history and/or lab tests should exclude medical causes for weight gain, such as hypothyroidism and Cushing's syndrome. If the symptoms of hypothyroidism are present (ie, weight gain, constipation, cold intolerance, and fatigue), free T4 and thyroid stimulating hormone levels should be checked. If there are findings that suggest Cushing's syndrome (ie, weight gain, buffalo hump, moon face, hypertension, hypernatremia, or hypokalemia), a 24-hour urine collection for cortisol, or the more recent and convenient bedtime salivary cortisol test, can be considered (Kushner and Blatner, page S53).

The patient's medication history may reveal drugs that cause weight gain. These include steroids, lithium, some antipsychotics (clozapine, olanzapine, risperidone [15]) and some antidepressants (Kushner and Blatner, page S53; Bray and Champagne, page S17). There is some debate as to whether antipsychotic medication causes dysmetabolic syndrome or simply causes weight gain that breaches the threshold for dysmetabolic syndrome and/or type 2 diabetes in susceptible patients. This patient may benefit from changing to a more weight-neutral antipsychotic medication. However, no changes should be made without consultation with the patient's psychiatrist. Antidepressants classified as serotonin selective uptake inhibitors may also have effects on weight gain. A recent study (16) showed that patients with a major depressive disorder treated with paroxetine had a significant weight gain of 3.6%, whereas those treated with sertraline and fluoxetine did not have statistically significant changes in weight. One antidepressant, bupropion, has been shown to cause weight loss in persons treated for depression (17,18).

This patient's weight management plan needs to take into consideration several factors. He should have an LDL cholesterol goal of $\leq$3.38 mmol/L* because of his low HDL cholesterol level and hypertension risk factors. Because the patient is a man aged 45 years, a serum LDL cholesterol goal of $<$2.6 mmol/L* should be considered. Thus, when the diet prescription is formulated, the diet composition should be low in sources of cholesterol and fat. Obesity decreases HDL cholesterol levels, so the net effect of weight loss, when coupled with increased activity, will be improved cardiovascular health resulting from decreased LDL cholesterol level and increased or maintained HDL cholesterol level (1).

The patient's blood pressure meets the criteria for prehypertension as defined by The Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure (19). Optimal blood pressure is defined as a systolic blood pressure of 115 mm Hg and a diastolic blood pressure of 75 mm Hg, with treatment necessary when a patient has a systolic blood pressure of 120 to 139 mm Hg or a diastolic blood pressure of 80 to 89 mm Hg (19). The prehypertensive state requires health-promoting lifestyle modifications, not medications, to prevent cardiovascular disease.

At a BMI of 36, this patient has class II obesity. His ideal body weight, estimated by the short method (5 ft=106 lb)+(6 lb/in$\times$12 in) to be 178 lb$\pm$10% or 161 to 196 lb. He is 54 lb over his ideal weight, or at 128% of his ideal body weight.

Diet Composition

Mineral intake recommendations to positively influence hypertension include limiting daily sodium intake to $<$2,400 mg/day (6 g salt) while increasing food sources of calcium, magnesium, and potassium (19,20). A preponderance of evidence exists for a hypertension-reducing benefit from increasing potassium intake (21). Healthful food choices to provide the preferred mineral balance, including increased dietary potassium, include five or more servings per day of fruits and vegetables, six or more servings of grains per day, and daily intake of two to four servings of low-fat dairy products (19,20). The effect of dietary modifications varies among persons because of genetic factors, age, medications, and other factors. Two recent systematic reviews of the effects of reductions in dietary sodium or salt found minimal effects for white patients with or without hypertension, but greater effects were seen for Asians and African Americans (22) and for maintenance of a lower blood pressure after antihypertensive medications were discontinued (23).

Lifestyle modifications to manage hypertension (19) can decrease systolic blood pressure 5 to 20 mm Hg per 10 kg of weight loss. In addition, decreases of 8 to 14 mm Hg have resulted from adopting the Dietary Approaches to Stop Hypertension (DASH) diet (which is high in fruits and vegetables), decreases of 2 to 8 mm Hg have been shown for dietary sodium restriction, decreases of 4 to 9 mm Hg have resulted from 30 minutes per day of physical activity, and decreases of 2 to 4 mm Hg have been shown from moderate alcohol consumption. In particular, the DASH diet significantly reduced systolic and diastolic blood pressure by 5.5 mm Hg and 3.0 mm Hg more than the control diet among participants whose blood pressure was normotensive (19). In participants with hypertension, the DASH diet without a specific salt restriction reduced systolic and diastolic blood pressure by 11.4 mm Hg and 5.5 mm Hg more, respectively, than the control diet. The DASH diet was lower in fat and higher in vegetables, fruits, and low-fat dairy foods than the control diet and included whole grains, poultry, fish, and nuts. The diet was also rich in calcium, magnesium, and potassium. The control group consumed a typical US diet (low in fruits, vegetables, and dairy products, with average fat content). The addition of a lower salt intake (1,500 mg/day) lowered mean systolic blood pressure by 7.1 mm Hg for participants without hypertension and by 11.5 mm Hg in participants with hypertension (24,25).

The PREMIER Collaborative Research Group (26) compared the implementation of three interventions in a population of 810 adults at four clinical centers. The interventions were "established" (a behavior intervention that implemented established recommendations), "established" + DASH, and advice only. Both the established and the established + DASH interventions resulted in significant weight reduction, improved fitness, and lowered sodium intake. Decreases in the prevalence of hypertension and increases in optimal blood pressure were

highly significant ($P<.001$) for the established + DASH intervention.

The role of increased calcium intake has been reviewed for children (Ritchie and colleagues, page S70) and adults (Hill and colleagues, page S63; Bray and Champagne, page S17). Higher dietary calcium is associated with reduced BMI or reduced incidence of insulin resistance (27). Improvements in weight control are proposed to be more important for patients who have not been using dairy products before beginning a diet.

Energy Needs and Prescription

Because of the numerous difficulties in accurately determining the needs of patients with obesity, this patient's energy needs were assessed using Metabolic Fingerprinting (HealthTech, Newton Upper Falls, MA) and measured resting needs were determined to be 1,800 kcal/day. This is less than the predicted RMR for this patient, indicating a possible genetic difference in his energy metabolism. Using an activity factor of 1.3 for 480 kcal from activity, he would need 2,280 kcal/day for weight maintenance. A reduction of between 500 and 700 kcal/day would result in approximately a 1-lb loss per day. The 1,600 kcal/day level of the Dietary Approaches to Stop Hypertension diet is recommended based on this patient's desire for a structured diet and his need for blood pressure reduction and weight loss. The 2005 Dietary Guidelines for Americans (28), the diet of the American Heart Association, and the Dietary Approaches to Stop Hypertension diet are used as the basis to encourage a diet rich in fruits, vegetables, whole grains, and lean meats. The increase in plant-based foods will decrease the energy density of the foods eaten while increasing intake of calcium, potassium, and magnesium.

Behavior Assessment

The patient's concern about his genetic makeup influencing his obesity is discussed. He is provided information explaining that his metabolic rate and his response to intake changes can be genetically determined (Loos and Rankinen, page S29). One's inability to control genetic makeup, but ability to control environment and other factors contributing to weight gain, is discussed.

The patient says he prefers a very structured diet plan. The Count Calories, Choose Quality Foods, and Exercise Daily concept is introduced (Blackburn and Waltman, page S131). The patient purchases an inexpensive kilocalorie counting program for his personal digital assistant device (Berkel and colleagues, page S35). The medical nutrition therapy protocol for obesity is reviewed, and the patient is provided with menu plans, modified recipes, a fluid intake goal, and goals for weight loss, percent body fat, blood pressure, and waist circumference.

After several weeks of excellent weight losses, the patient complains of hunger during the evening and says he finds the plan increasingly difficult to follow. In accordance with the recommendations of Schoeller and Buchholz (page S24), a higher protein intake (25% to 33% of total daily intake) could increase satiety and compliance.

Weight maintenance is the long-term goal. The patient will be encouraged to recognize that it is normal to have periods of time when he is not losing weight. These periods of stabilized weight allow evaluation of metabolic achievements to decide if further weight reduction is an achievable goal. He will be encouraged to weigh himself weekly and to return for counseling if he has a weight regain of 5 lb. The concept of the energy gap between the kilocalorie intake needed for weight maintenance before weight loss and the kilocalorie intake needed for weight maintenance after weight loss should be discussed (Hill and colleagues, page S63).

Physical Activity

The patient agrees to increase his walking and to wear a pedometer. A pedometer is worn at the patient's waist and provides a measure of activity, including work-related movement. The pedometer will not accurately provide an assessment for strength and flexibility training, but provides particular reinforcement for the walking exercise plans that this patient finds acceptable. A goal of expending 1,000 kcal per week is established and daily activity is self-monitored using a pedometer or exercise log (Bray and Champagne, page S17). The America on the Move Web site (www.americaonthemove.org) is recommended for ideas to increase physical activity (Hill and colleagues, page S63). Contributions to a group marathon tally could be posted to encourage progress (many patients contribute their daily step totals in an attempt to reach 26.2 miles walked).

Outcomes

After 3 months, the patient has lost only 5 lb but has been walking 10,000 steps at least 5 days a week. His blood pressure has decreased to about 115/78 mm Hg as a result of exercise and medication changes, primarily. In consultation with his psychiatrist, a medication change trial is suggested. The patient and his wife have decided that they may need the structure of a meal replacement program with a strong education component to help the patient decrease his energy intake consistently.

CONCLUSION

These cases demonstrate the diversity of approaches to obesity treatment and the value of comprehensive programs. In our experience, patient success improves as the intensity of counseling, self-monitoring, and accountability increase. The goal is always lifelong maintenance of a healthful weight.

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Diabetes Self-Management Education and Support in Type 2 Diabetes: A Joint Position Statement of the American Diabetes Association, the American Association of Diabetes Educators, and the Academy of Nutrition and Dietetics

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DIABETES IS A CHRONIC DISEASE that requires a person with diabetes to make a multitude of daily self-management decisions and to perform complex care activities. Diabetes self-management education and support (DSME/S) provides the foundation to help people with diabetes to navigate these decisions and activities and has been shown to improve health outcomes.[1-7] Diabetes self-management education (DSME) is the process of facilitating the knowledge, skill, and ability necessary for diabetes self-care. Diabetes self-management support (DSMS) refers to the support that is required for implementing and sustaining coping skills and behaviors needed to self-manage on an ongoing basis. (See further definitions in Figure 1.) Although different members of the health care team and community can contribute to this process, it is important for health care providers and their practice settings to have the resources and a systematic referral process to ensure that patients with type 2 diabetes receive both DSME and DSMS in a consistent manner. The initial DSME is typically provided by a health professional, whereas ongoing support can be provided by personnel within a practice and a variety of community-based resources. DSME/S programs are designed to address the patient's health beliefs, cultural needs, current knowledge, physical limitations, emotional concerns, family support, financial status, medical history, health literacy, numeracy, and other factors that influence each person's ability to meet the challenges of self-management.

It is the position of the American Diabetes Association (ADA) that all individuals with diabetes receive DSME/S at diagnosis and as needed thereafter.[8] This position statement focuses on the particular needs of individuals with type 2 diabetes. The needs will be similar to those of people with other types of diabetes (type 1 diabetes, prediabetes, and gestational diabetes mellitus); however, the research and examples referred to in this article focus on type 2 diabetes. The goals of the position statement are ultimately to improve the patient experience of care and education, to improve the health of individuals and populations, and to reduce diabetes-associated per capita health care costs.[9] The use of the diabetes education algorithm presented in this position statement defines when, what, and how DSME/S should be provided for adults with type 2 diabetes.

BENEFITS ASSOCIATED WITH DSME/S

DSME/S has been shown to be cost-effective by reducing hospital admissions and readmissions,[10-12] as well as estimated lifetime health care costs related to a lower risk for complications.[13] Given that the cost of diabetes in the U.S. in 2012 was reported to be $245 billion,[14] DSME/S offers an opportunity to decrease these costs.[11,12] It has been projected that one in three individuals will develop type 2 diabetes by 2050.[15] The US health care system will be unable to afford the costs of care unless incidence rates and diabetes-related complications are reduced.

DSME/S improves hemoglobin A1c (HbA1c) by as much as 1% in people with type 2 diabetes.[3,7,16-20] Besides this important reduction, DSME has a positive effect on other clinical, psychosocial, and behavioral aspects of diabetes. DSME/S is reported to reduce the onset and/or advancement of diabetes complications,[21,22] to improve quality of life[19,23-26] and lifestyle behaviors such as having a more healthful eating pattern and engaging in regular physical activity,[27] to enhance self-efficacy and empowerment,[28] to increase healthy coping,[29] and to decrease the presence of diabetes-related distress[16,30] and depression.[31,32] These improvements

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DSME (Diabetes Self-Management Education)[35]
• The ongoing process of facilitating the knowledge, skill, and ability necessary for diabetes self-care.
• This process incorporates the needs, goals, and life experiences of the person with diabetes or prediabetes and is guided by evidence-based research.
• The overall objectives of DSME are to support informed decision making, self-care behaviors, problem solving, and active collaboration with the health care team and to improve clinical outcomes, health status, and quality of life. Note: The Centers for Medicaid and Medicare Services uses the term "training" instead of "education" when defining the reimbursable benefit (DSMT); the authors of this position statement use the term "education" (DSME) as reflected in the National Standards. In the context of this article, the terms have the same meaning.
Ongoing DSMS (Diabetes Self-Management Support)[35]
• Activities that assist the person with diabetes in implementing and sustaining the behaviors needed to manage his or her condition on an ongoing basis.
• The type of support provided can be behavioral, educational, psychosocial, or clinical.
Patient-Centered Care[69]
• Providing care that is respectful of and responsive to individual patient preferences, needs, and values and ensuring that patient values guide all clinical decisions.
Shared Decision Making
• Eliciting patient perspectives and priorities and presenting options and information so patients can participate more actively in care. Shared decision making is a key component of patient-centered care[43,77] and has been shown to improve clinical, psychosocial, and behavioural outcomes.[78]
Diabetes-Related Distress[29,61]
• This refers to the negative emotional responses (overwhelmed, hopeless, and helpless) and perceived burden related to diabetes.
CDE (Certified Diabetes Educator)[79]
• A health professional who has completed a minimum number of hours in clinical diabetes practice, passed the Certification Examination for Diabetes Educators (administered by the National Certification Board for Diabetes Educators [NCBDE]), and has responsibilities that include the direct provision of diabetes education.
BC-ADM (Board Certified—Advanced Diabetes Management)[80]
• A health care professional who has completed a minimum number of hours in advanced diabetes management, holds a graduate degree, passed the BC-ADM certification exam (administered by the American Association of Diabetes Educators), and has responsibilities of an increased complexity of decision making related to diabetes management and education.

Figure 1. Key definitions.

clearly reaffirm the importance and value-added benefit of DSME. In addition, better outcomes have been shown to be associated with the amount of time spent with a diabetes educator.[3,4,7,11]

This position statement arms health care teams with the information required to better understand the educational process and expectations for DSME and DSMS and their integration into routine care. The ultimate goal of the process is a more engaged and informed patient.[33] It is recommended that all health care providers and/or systems develop processes to guarantee that all patients with type 2 diabetes receive DSME/S services and ensure that adequate resources are available in their respective communities to support these services.

PROVIDING DIABETES EDUCATION AND SUPPORT

Historically, DSME/S has been provided through a formal program where patients and family members participate in an outpatient service conducted at a hospital/health facility. In keeping with evolving health care delivery systems and in meeting the needs of primary care, DSME/S is now being incorporated into office practices, medical homes, and accountable care organizations. Receiving DSME/S in alternative and convenient settings, such as community health centers and pharmacies, and through technology-based programs is becoming more available and affords increased access.

Regardless of the setting, communicating the information and supporting skills that are necessary to promote effective coping and self-management required for day-to-day living with diabetes necessitate a personalized and comprehensive approach. Effective delivery involves experts in educational,

clinical, psychosocial, and behavioral diabetes care.[34,35] Clear communication and effective collaboration among the health care team that includes a provider, an educator, and a person with diabetes are critical to ensure that goals are clear, that progress toward goals is being made, and that appropriate interventions (educational, psychosocial, medical, and/or behavioral) are being used. A patient-centered approach to DSME/S at diagnosis provides the foundation for current and future needs. Ongoing DSME/S can help the person to overcome barriers and to cope with the ongoing demands in order to facilitate changes during the course of treatment and life transitions.

REIMBURSEMENT, NATIONAL STANDARDS, AND REFERRAL

Reimbursement for DSME/S is available from the Centers for Medicare and Medicaid Services (CMS) and many private payers. Additional discipline-specific counseling, such as medical nutrition therapy (MNT) provided by a registered dietitian nutritionist, medication therapy management delivered by pharmacists, and psychosocial counseling offered by mental health professionals, is also reimbursed through CMS and/or third-party payers.[35,36]

In order to be eligible for DSME/S reimbursement, DSME/S programs must be recognized or accredited by a CMS-designated national accreditation organization (NAO). Current NAOs are the ADA and the American Association of Diabetes Educators (AADE). Both bodies assess the quality of programs using criteria established by the National Standards for DSME/S (Figure 2).[35] Currently, CMS reimburses for 10 program hours of initial diabetes education and 2 hours in each subsequent year. Referrals for DSME/S must be made by a health care provider and include specified indicators, such as diabetes type, treatment plan, and reason for referral. Sample referral forms with information needed for reimbursement are available on the ADA website (http://professional.diabetes.org/Recognition.aspx?typ=15&cid=93574) and the AADE website (http://www.diabeteseducator.org/export/sites/aade/_resources/pdf/general/Diabetes_Services_Order_Form_v4.pdf).

According to the National Standards for DSME/S, at least one instructor responsible for designing and planning DSME/S must be a nurse, dietitian, pharmacist, or other trained or credentialed health professional (a certified diabetes educator [CDE] or health care professional with Board Certified-Advanced Diabetes Management [BC-ADM] certification) (Figure 1) who meets specific competency and continuing education requirements.[35] This person is considered the primary instructor. Others can contribute to DSME and provide support with appropriate training and supervision. Trained community health workers, practice-based care managers, peers, and other support persons (eg, family members, social workers, and mental health counselors) have a role in helping to sustain the benefits gained from DSME.[37-41] Such staff/resources can be especially helpful in areas with diverse populations and serve as cultural navigators in health care systems and as liaisons to the community.

1. **Internal structure.** The organizational structure or system that supports self-management education; necessary for sustainability and ongoing self-management education and support.
2. **External input.** Ensures that providers of DSME will seek input from external stakeholders and experts to promote program quality.
3. **Access.** A system of assuring periodic reassessment of the population or community receiving self-management education to ensure that identified barriers to education are addressed.
4. **Program coordination.** The designation of an individual with responsibility for coordinating all aspects of self-management education (even if that person is the solo instructor).
5. **Instructional staff.** Identifies who can participate in the delivery of self-management education, recognizing the unique skill set of all potential providers of self-management education.
6. **Curriculum.** A set of written guidelines, including topics, methods, and tools to facilitate education for all people with diabetes; exactly what is taught will be based on patient's needs, preferences, and readiness.
7. **Individualization.** Instructor(s) will assess the patient to determine an individualized education and support plan focused on behavior change.
8. **Ongoing support.** A follow-up plan for ongoing support will be developed by the patient and instructor; communication among the team regarding goals, outcomes, and ongoing needs is essential.
9. **Participant progress.** Ongoing measurement of patient self-efficacy and success in self-management and achievement of goals; designed to continually assess needed support.
10. **Quality improvement.** Incorporation of systems to continuously look for ways to evaluate DSME/S effectiveness and to identify areas for improvement.

Figure 2. National standards for diabetes self-management education and support (DSME/S): 10 standards. Adapted with permission from Haas et al.[35]

As an alternative to a referral to a formal DSME/S program, office-based health care teams can explore partnerships with educators within their community or assume responsibility for providing and/or coordinating some or all of the patient's diabetes education and support needs. Although this approach requires knowledge, time, and resources to effectively provide education, it offers a unique opportunity to reach patients at the point of care. This position statement and the National Standards for DSME/S are designed to serve as a resource for the health care team. Although reimbursement for education services is somewhat limited, financial benefits can be realized when an office-based program contributes to improved practice processes and patients' achievement of outcomes that can influence mandated quality measures.

DIABETES EDUCATION ALGORITHM

The diabetes education algorithm provides an evidence-based visual depiction of when to identify and refer individuals with type 2 diabetes to DSME/S (Figures 3 and 4; also available as a slide set at professional.diabetes.org/dsmeslides). The algorithm defines four critical time points for delivery and key information on the self-management skills that are necessary at each of these critical periods. The diabetes education algorithm can be used by health care systems, staff, or teams, as well as individuals with diabetes, to guide when and how to refer to and deliver/receive diabetes education.

Guiding Principles and Patient-Centered Care

The algorithm relies on five guiding principles and represents how DSME/S should be provided through patient engagement, information sharing, psychosocial and behavioral support, integration with other therapies, and coordinated care (Figure 5). Associated with each principle are key elements that offer specific suggestions regarding interactions with the patient and topics to address at diabetes-related clinical and educational encounters (Figure 5).

Helping people with diabetes to learn and apply knowledge, skills, and behavioral, problem-solving, and coping strategies requires a delicate balance of many factors. There is an interplay between the individual and the context in which he or she lives, such as clinical status, culture, values, family, and social and community environment. The behaviors involved in DSME/S are dynamic and multidimensional.[42] In a patient-centered approach, collaboration and effective communication are considered the route to patient engagement.[43-45] This approach includes eliciting emotions, perceptions, and knowledge through active and reflective listening; asking open-ended questions; exploring the desire to learn or change; and supporting self-efficacy.[44] Through this approach, patients are better able to

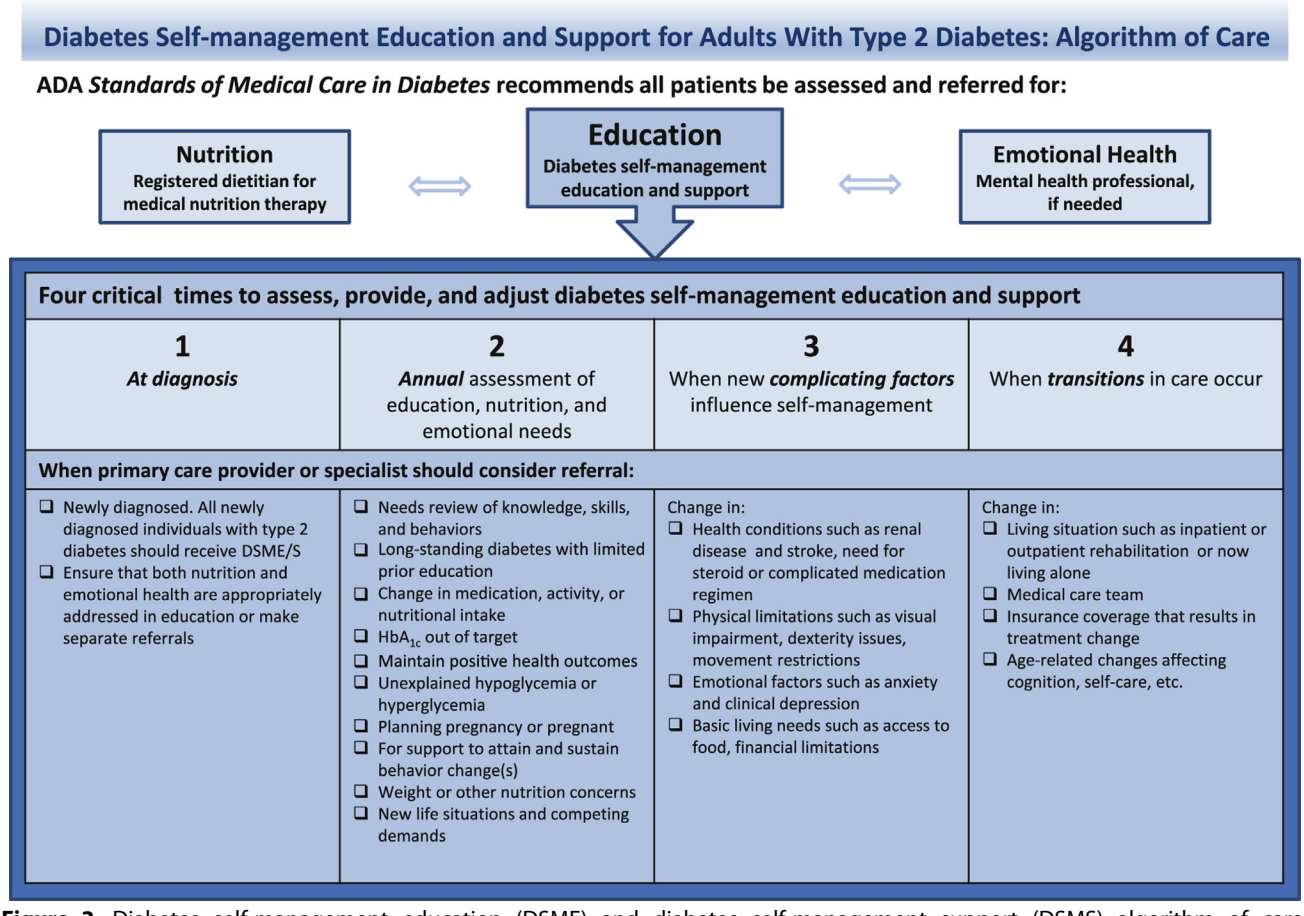

Figure 3. Diabetes self-management education (DSME) and diabetes self-management support (DSMS) algorithm of care. ADA=American Diabetes Association.

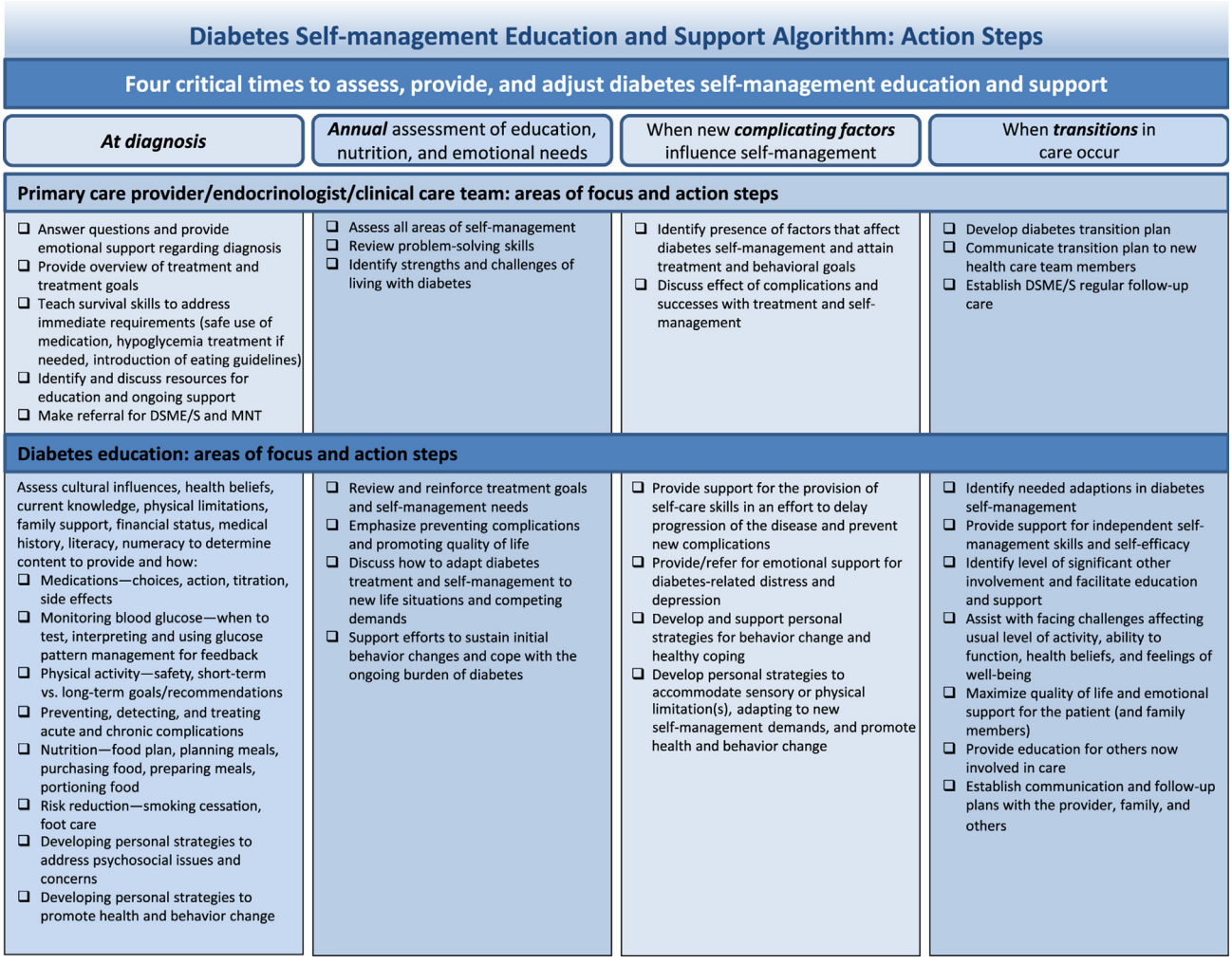

Figure 4. Content for diabetes self-management education (DSME) and diabetes self-management support (DSMS) at four critical time points. MNT=medical nutrition therapy.

explore options, choose their own course of action, and feel empowered to make informed self-management decisions.[45,46] Figure 6 provides a list of patient-centered assessment questions that can be used at diagnosis and at other encounters to guide the education and ongoing support process.

Critical Times to Provide Diabetes Education and Support

There are four critical times to assess, provide, and adjust DSME/S[47]: 1) with a new diagnosis of type 2 diabetes, 2) annually for health maintenance and prevention of complications, 3) when new complicating factors influence self-management, and 4) when transitions in care occur (Figures 3 and 4). Although four distinct time-related opportunities are listed, it is important to recognize that type 2 diabetes is a chronic condition and situations can arise at any time that require additional attention to self-management needs. Whereas patient's needs are continuous (Figure 3), these four critical times demand assessment and, if needed, intensified reeducation and self-management planning and support.

The AADE7 Self-Care Behaviors provide a framework for identifying topics to include at each time: healthy eating, being active, monitoring, taking medication, problem solving, reducing risks, and healthy coping. The educational content listed in each box in Figure 4 is not intended to be all-inclusive, as specific needs will depend on the patient. However, these topics can guide the educational assessment and plan. Mastery of skills and behaviors takes practice and experience. Often a series of ongoing education and support visits are necessary to provide the time for a patient to practice new skills and behaviors and to form habits that support self-management goals.

1. New Diagnosis of Diabetes. The diagnosis of diabetes is often overwhelming.[48] The emotional response to the diagnosis can be a significant barrier for education and self-management. Education at diagnosis should focus on safety concerns (some refer to this as survival-level education) and "what do I need to do once I leave the doctor's office or hospital." To begin the process of coping with the diagnosis and incorporating

Engagement. Provide DSME/S and care that reflects person's life, preferences, priorities, culture, experiences, and capacity.
• Solicit and respond to questions
• Focus on decisions, reasons for the decisions, and results
• Ask about strengths and challenges
• Use shared decision making and principles of patient-centered care to guide each visit
• Engage the patient in a dialogue about current self-management successes, concerns, and struggles
• Engage the patient in a dialogue about therapy and changes in treatment
• Remain "solution neutral" and support patient identifying solution(s)
• Provide support and education to patient's family and caregiver
Information sharing. Determine what the patient needs to make decisions about daily self-management.
• Discuss that DSME/S is an important and essential part of diabetes management
• Describe that DSME/S is needed throughout the life cycle and is on a continuum from prediabetes, newly diagnosed diabetes, health maintenance/follow-up, early to late diabetes complications, and transitions in care related to changes in health status and developmental or life changes
• Avoid being didactic
• Provide "need-to-know" information and avoid providing the encyclopedia on diabetes
• Review that diabetes treatment will change over time
• Provide information to the patient using the above engagement key elements
• Take advantage of "teachable moments" to provide information specific to the patient's care and treatment
• Assess DSME/S patient/family needs for the behavioral and psychosocial aspects of informed decision making
Psychosocial and behavioral support. Address the psychosocial and behavioral aspects of diabetes.
• Assess and address emotional and psychosocial concerns, such as diabetes-related distress and depression
• Present that diabetes-related distress and a range of emotions are common and that stress can raise blood glucose and blood pressure levels
• Discuss that diabetes self-management is challenging but worth the effort
• Support self-efficacy and self-confidence in self-management decisions and abilities
• Support action by the patient to identify self-management problems and develop strategies to solve those problems, including self-selected behavioral goal setting
• Note that it takes about 2-8 months to change a habit/learn/apply behavior
• Address the whole person
• Include family members and/or support system in the educational and ongoing support process
• Refer to community, online, and other resources
Integration with other therapies. Ensure integration and referrals with and for other therapies.
• Ensure access to ongoing medical nutrition therapy
• Recommend additional referrals as needed for behavioral therapy, medication management, physical therapy, etc.
• Address factors that limit the application of diabetes self-management activities
• Advocate for easy access to social services programs that address basic life needs and financial resources
(continued on next page)

Figure 5. Guiding principles and key elements of initial and ongoing diabetes self-management education and support (DSME/S). Adapted from references 45,58,81.

• Identify resources and services that support the implementation of therapies in health care and community settings
Coordination of care across specialty care, facility-based care, and community organizations. Ensure collaborative care and coordination with treatment goals.
• Understand primary care provider and specialist's treatment targets
• Provide overview of DSME/S to referring providers
• Follow medication adjustment protocols or make necessary recommendation to primary care provider
• Correspond with referring provider about education plan, progress toward treatment goals, and needs to coordinate education and support from entire clinical team; ensure documentation in the health record
• Ensure provision of culturally appropriate care
• Use evidence-based decision support
• Use performance data to identify opportunities for improvement

Figure 5. *(continued)* Guiding principles and key elements of initial and ongoing diabetes self-management education and support (DSME/S). Adapted from references 45,58,81.

self-management into daily life, a diabetes educator or someone on the care team should work closely with the individual and his or her family members to answer immediate questions, to address initial concerns, and to provide support and referrals to needed resources.

At diagnosis, important messages should be communicated that include acknowledgment that all types of diabetes need to be taken seriously, complications are not inevitable, and a range of emotional responses is common. Educators should also emphasize the importance of involving family members and/or significant others and of ongoing education and support. The patient should understand that treatment will change over time as type 2 diabetes progresses and that changes in therapy do not mean that the patient has failed. Finally, type 2 diabetes is largely self-managed and DSME and DSMS involve trial and error. The task of self-management is not easy, yet worth the effort.[49]

Other diabetes education topics that are typically covered during the visits at the time of diagnosis are treatment targets, psychosocial concerns, behavior change strategies (eg, self-directed goal setting), taking medications, purchasing food, planning meals, identifying portion sizes, physical activity, checking blood glucose, and using results for pattern management.

At diagnosis of type 2 diabetes, education needs to be tailored to the individual and his or her treatment plan. At a minimum, plans for nutrition therapy and physical activity need to be addressed. Based on the patient's medication and monitoring recommendations, themes such as hypoglycemia identification and treatment, interpreting glucose results, risk reduction, etc, may need to be considered. Patients are supported when personalized education and self-management plans are developed in collaboration with the patients and their primary care provider. Depending on the qualifications of the diabetes educator or staff member facilitating these steps, additional referrals to a registered dietitian nutritionist for MNT, mental health provider, or other specialist may be needed.

Individuals requiring insulin should receive additional education so that the insulin regimen can be coordinated with the patient's eating pattern and physical activity habits.[50,51] Patients presenting at the time of diagnosis with diabetes-related complications or other health issues may need additional or reprioritized education to meet specific needs.

• How is diabetes affecting your daily life and that of your family?
• What questions do you have?
• What is the hardest part right now about your diabetes, causing you the most concern, or most worrisome to you about your diabetes?
• How can we best help you?
• What is one thing you are doing or can do to better manage your diabetes?

Figure 6. Sample questions to guide a patient-centered assessment.[82]

2. Annual Assessment of Education, Nutrition, and Emotional Needs. The health care team and others can help to promote the adoption and maintenance of new diabetes management tasks,[52] yet sustaining these behaviors is frequently difficult. Thus, annual assessments of knowledge, skills, and behaviors are necessary for those who do meet the goals as well as for those who do not.

Annual visits for diabetes education are recommended to assess all areas of self-management, to review behavior change and coping strategies and problem-solving skills, to identify strengths and challenges of living with diabetes, and to make adjustments in therapy.[35,52] The primary care provider or clinical team can conduct this review and refer to a DSME/S program as indicated. More frequent DSME/S visits may be needed when the patient is starting a new diabetes medication or experiencing unexplained hypoglycemia or hyperglycemia, goals and targets are not being met, clinical indicators are worsening, and there is

a need to provide preconception planning. Importantly, the educator is charged with communicating the revised plan to the referring provider.

Family members are an underutilized resource for ongoing support and often struggle with how to best provide this help.[53,54] Including family members in the DSME/S process on at least an annual basis can help to facilitate their positive involvement.[55-57]

Since the patient has now experienced living with diabetes, it is important to begin each maintenance visit by asking the patient about successes he or she has had and any concerns, struggles, and questions. The focus of each session should be on patient decisions and issues—what choices has the patient made, why has the patient made those choices, and if those decisions are helping the patient to attain his or her goals—*not* on perceived adherence to recommendations. Instead, it is important for the patient/family members to determine their clinical, psychosocial, and behavioral goals and to create realistic action plans to achieve those goals. Through shared decision making, the plan is adjusted as needed in collaboration with the patient. To help to reinforce plans made at the visit and support ongoing self-management, the patient should be asked at the close of a visit to "teach-back" what was discussed during the session and to identify one specific behavior to target or prioritize.[58]

3. Diabetes-Related Complications and Other Factors Influencing Self-Management. The identification of diabetes complications or other patient factors that may influence self-management should be considered a critical indicator for diabetes education that requires immediate attention and adequate resources. During routine medical care, the provider may identify factors that influence treatment and the associated self-management plan. These factors may include the patient's ability to manage and cope with diabetes complications, other health conditions, medications, physical limitations, emotional needs, and basic living needs. These factors may be identified at the initial diabetes encounter or may arise at any time. Such patient factors influence the clinical, psychosocial, and behavioral aspects of diabetes care.

The diagnosis of additional health conditions and the potential need for additional medications can complicate self-management for the patient. Diabetes education can address the integration of multiple medical conditions into overall care with a focus on maintaining or appropriately adjusting medication, eating plan, and physical activity levels to maximize outcomes and quality of life. In addition to the introduction of new self-care skills, effective coping, defined as a positive attitude toward diabetes and self-management, positive relationships with others, and quality of life, can be addressed in DSME/S.[29] Additional and focused emotional support may be needed for anxiety, stress, and diabetes-related distress and/or depression.

Diabetes-related health conditions can cause physical limitations, such as visual impairment, dexterity issues, and physical activity restrictions. Diabetes educators can help patients to manage limitations through education and various support resources. For example, educators can help patients to access large-print or talking glucose meters that benefit those with visual impairments and specialized aids for insulin users that can help those with visual and/or dexterity limitations.

Psychosocial and emotional factors have many contributors and include diabetes-related distress, life stresses, anxiety, and depression. In fact, these factors are often considered complications of diabetes and result in poorer diabetes outcomes.[59,60] Diabetes-related distress (see definition in Figure 1) is particularly common, with prevalence rates of 18% to 35% and an 18-month incidence of 38% to 48%.[61] It has a greater impact on behavioral and metabolic outcomes than does depression.[61] Diabetes-related distress is responsive to intervention, including DSME/S and focused attention.[30] Although the National Standards for DSME/S include the development of strategies to address psychosocial issues and concerns,[35] additional mental health resources are generally required to address severe diabetes-related distress, clinical depression, and anxiety.

Social factors, including difficulty paying for food, medications, monitoring and other supplies, medical care, housing, or utilities, negatively affect metabolic control and increase resource use.[62] When basic living needs are not met, diabetes self-management becomes increasingly difficult. Basic living needs include food security, adequate housing, safe environment, and access to medications and health care. Education staff can address such issues, provide information about available resources, and collaborate with the patient to create a self-management plan that reflects these challenges.

If complicating factors are present during initial education or a maintenance session, the DSME/S educators can either directly address these factors or arrange for additional resources. However, complicating factors may arise at any time; providers should be prepared to promptly refer patients who develop complications or other issues for diabetes education and ongoing support.

4. Transitional Care and Changes in Health Status. Throughout the life span, changes in age, health status, living situation, or health insurance coverage may require a reevaluation of the diabetes care goals and self-management needs. Critical transition periods include transitioning into adulthood, hospitalization, and moving into an assisted living facility, skilled nursing facility, correctional facility, or rehabilitation center.

DSME/S affords important benefits to patients during a life transition. Providing input into the development of practical and realistic self-management and treatment plans can be an effective asset for successful navigation of changing situations. A written plan prepared in collaboration with diabetes educators, the patient, family members, and caregivers to identify deficits, concerns, resources, and strengths can help to promote a successful transition. The plan should include personalized diabetes treatment targets; a medical, educational, and psychosocial history; hypo- and hyperglycemia risk factors; nutritional needs; resources for additional support; and emotional considerations.[63,64]

The health care provider can make a referral to a diabetes educator to develop or provide input to the transition plan, provide education, and support successful transitions. The goal

is to minimize disruptions in therapy during the transition, while addressing clinical, psychosocial, and behavioral needs.

MNT AS AN ADJUNCT TO DSME/S PROGRAMS

The National Standards for DSME/S list "incorporating nutritional management into lifestyle" as one of nine core topics in a comprehensive program.[35] Some DSME/S programs include MNT services delivered by a registered dietitian nutritionist, whereas other programs provide basic nutrition guidance and rely on referrals for MNT. DSME/S referral forms often include referral for MNT to help to coordinate care (ADA and AADE referral forms). The ADA publishes nutrition recommendations that detail nutrition therapy goals and nutrition and eating pattern recommendations.[65] All members of the health care team should be versed in the basic principles of diabetes nutrition therapy so that they can facilitate basic meal planning, clarify misconceptions, and/or provide reinforcement of the nutrition plan developed collaboratively by the registered dietitian nutritionist and the patient (Figure 7).

OVERCOMING BARRIERS THAT LIMIT ACCESS AND RECEIPT OF DSME/S

The number of people with type 2 diabetes who receive DSME/S, despite its proven benefits, is low. For example, only 6.8% of individuals with newly diagnosed type 2 diabetes with private health insurance participated in DSME/S within 12 months of diagnosis.[66] Furthermore, only 4% of Medicare participants received DSME/S and/or MNT.[4] To increase the number of individuals with diabetes who receive DSME/S services described in this position statement, it is necessary to consider the barriers that currently limit provision. Barriers are associated with a number of factors including the health system, the individual health care professional, community resources, and the individual with diabetes. Barriers can include a misunderstanding of the necessity and effectiveness of DSME/S, confusion

MNT is an evidence-based application of the Nutrition Care Process provided by the RDN.[a] It includes an individualized nutrition assessment, nutrition diagnosis, intervention and monitoring, and evaluation and is the legal definition of nutrition counseling by an RDN practicing in the United States.[8]
1. Characteristics of MNT reducing HbA1c by 0.5%-2% for type 2 diabetes:
• Series of three to four encounters with an RDN lasting from 45 to 90 min; the RDN should determine if additional encounters are needed
• Series of encounters should begin at diagnosis of diabetes or at first referral to an RDN for MNT for diabetes and should be completed within 3-6 months
• At least one follow-up encounter is recommended annually to reinforce lifestyle changes and to evaluate and monitor outcomes that indicate the need for changes in MNT or medication(s)
2. MNT provides nutrition assessment, nutrition diagnosis, and an intervention and management plan including the creation of individualized food plan and support for the following:
• Individualized modification of food plan/physical activity/medication dosing for improved postprandial control, hypoglycemia prevention, and overall glycemic improvement
• Individualized modification of carbohydrate, protein, fat, and sodium intake and guidance to achieve lipid and blood pressure goals
• Individualized weight management planning and coaching
• Education and support on additional topics to promote flexibility in meal planning, food purchasing/preparation, recipe modification, and eating away from home
• Individualized modification of food plan for managing related complications and comorbidities such as celiac disease, gastroparesis, eating disorders/disordered eating, kidney disease, etc
3. The Centers for Medicaid and Medicare Services reimburses for diabetes MNT when provided by a qualified practitioner (ie, RDN). Many other payers also provide reimbursement. MNT services are included on the American Diabetes Association and American Association of Diabetes Educators DSME/S referral forms. A separate MNT referral form is available from the Academy of Nutrition and Dietetics at: http://www.eatrightpro.org/resource/practice/getting-paid/nuts-and-bolts-of-getting-paid/diabetes-and-renal-disease-resources
[a]The Academy of Nutrition and Dietetics recognizes the use of registered dietitian (RD) and registered dietitian nutritionist (RDN). RD and RDN can only be used by those credentialed by the Commission on Dietetic Registration.

Figure 7. Overview of medical nutrition therapy (MNT).

regarding when and how to make referrals, lack of access to DSME/S services, and patient psychosocial and behavioral factors.[67] Provider misconceptions that can limit access to DSME/S include a misunderstanding of reimbursement issues and the misconception that one or a few initial education visits are adequate to provide patients with the skills needed for lifelong self-management. Lack of or poor reimbursement for DSME/S also can hamper patients' participation. Even when DSME/S programs are operating at peak service, they often struggle to cover costs—making it easy to eliminate programs despite their wider influence on reducing costs and improving health outcomes.[13]

Although people with diabetes report wanting to be actively engaged in their health care, most indicate that they are not actively engaged by their providers and that education and psychological services are not readily available.[68] In order to enhance patient and family engagement in DSME/S, provider communication about the necessity of self-management to achieve treatment and quality-of-life goals and the essential nature of both DSME and ongoing support throughout a lifetime of diabetes is essential (Figure 5).

Removing barriers to access and increasing quality care can be achieved by using data to coordinate care and build workforce capacity.[69] The US health care paradigm is changing with increased attention on primary care practices, technology, and quality measures.[70]

Studies have shown that implementing DSME programs that directly connect with primary care and rely on technology is effective in improving clinical, psychosocial, and behavioral outcomes.[16,71-74] Patients receiving care in these practice settings report more confidence in provider communication and satisfaction with direct access to an educator for information and ongoing support.[16]

Despite the proven value and effectiveness of diabetes education and support services, one of the biggest looming threats to their success is low utilization, which has recently forced many such programs to close. The current reimbursement model and mandate for provider referrals will continue to be limiting factors for access to and participation in DSME/S. The health care community needs processes that support referrals and reimbursement practices, otherwise it will be increasingly more difficult to sustain DSME/S services. Attention to these challenges needs to be met to provide access particularly for areas such as rural and underserved communities.

CONCLUSION

Diabetes is a complex and burdensome disease that requires the person with diabetes to make numerous daily decisions regarding food, physical activity, and medications. It also necessitates that the person be proficient in a number of self-management skills.[35,75,76] In order for people to learn the skills necessary to be effective self-managers, DSME is critical in laying the foundation with ongoing support to maintain gains made during education. Despite proven benefits and general acceptance, the numbers of patients who are referred to and receive DSME/S are disappointingly small. This position statement and algorithm provide the evidence and strategies for the provision of education and support services to all adults living with type 2 diabetes. It is imperative that the health care community, responsible for delivering quality care, mobilizes efforts to address the barriers and explores resources for DSME/S in order to meet the needs of adults living with and managing type 2 diabetes.

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STATEMENT OF POTENTIAL CONFLICT OF INTEREST

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Weight Bias in Healthcare

A Guide for Healthcare Providers Working with Individuals Affected by Obesity

What is Weight Bias?

Weight bias refers to negative stereotypes directed toward individuals affected by excess weight or obesity, which often lead to prejudice and discrimination. Weight bias is evident in many aspects of living such as healthcare, education, employment, the media and more. The prevalence of weight discrimination in the United States is comparable to racial discrimination.

Since the majority of Americans are now affected by excess weight or obesity, this is an important clinical concern, one that no healthcare provider can afford to ignore.

Weight Bias in Healthcare

Research demonstrates that patients affected by obesity frequently feel stigmatized in healthcare settings. Negative attitudes about individuals affected by obesity have been reported by physicians, nurses, dietitians, psychologists, fitness professionals and medical students. Research shows that even healthcare professionals specializing in the treatment of obesity hold negative attitudes.

Bias may have a negative impact on quality of healthcare for individuals affected by obesity. Some studies indicate that these individuals are reluctant to seek medical care and may be more likely to delay seeking treatment or scheduling important preventative services.

How Does This Bias Impact Your Patients?

When patients feel stigmatized they are vulnerable to depression, anxiety and low self-esteem. They are less likely to feel motivated to adopt lifestyle changes, and some may even turn to unhealthy eating patterns impairing weight-loss efforts. The quality of healthcare services which are attempted may also be negatively affected by weight bias.

In addition to avoiding or canceling appointments for prevention or treatment, providers spend less time in those appointments and engage in less health-related discussions with patients affected by obesity when compared with non-overweight patients. Providers themselves admit they do not intervene as much as they know they should.

Thus, the effects of weight bias are far-reaching and can substantially impact an individual's quality of care and desire to manage their weight and health.

OAC
Obesity Action Coalition

An informational piece provided by the Obesity Action Coalition (OAC) and the Rudd Center for Food Policy and Obesity

As a Healthcare Professional, Do You Exhibit Weight Bias?

Research indicates that 46 percent of women affected by obesity reported that small gowns, narrow exam tables and inappropriately sized medical equipment were barriers to receiving healthcare. In addition, 35 percent reported embarrassment about being weighed as a barrier to care.

Doctors, nurses and other health professionals self-report bias and prejudice against patients affected by obesity. The most common stereotypes expressed by health providers include beliefs that patients affected by obesity are:

- *Non-compliant*
- *Dishonest*
- *Lazy*
- *Lacking in self-control*
- *Weak-willed*
- *Unintelligent*
- *Unsuccessful*

Doctors:

Doctors are common sources of stigma. In a study that surveyed more than 2,400 adult women about their experiences of weight bias, 69 percent of respondents reported that doctors were a source of weight bias, and 52 percent reported they had been stigmatized by a doctor on multiple occasions.

As a patient's body mass index (BMI) increases, doctors report less desire to help the patient, are more likely to report that treating the patient is a waste of their time, and express less respect for the patient.

Nurses:

Self-report studies show that nurses view individuals affected by obesity as non-compliant, overindulgent, lazy and unsuccessful.

Studies of self-reported attitudes among nurses indicate that:

- 31 percent "would prefer not to care for individuals affected by obesity"
- 24 percent agreed that individuals affected by obesity "repulsed them"
- 12 percent "would prefer not to touch individuals affected by obesity"

Psychologists:

In studies comparing beliefs about individuals affected by obesity versus "average" weight individuals, psychologists ascribe the following attributes to clients affected by obesity:

- More pathology
- More severe psychological symptoms
- More negative attributes
- Worse prognosis in treatment

How Can You Improve Your Approach to Addressing the Topic of Weight?

Approaching the topic of body weight with patients is a sensitive issue. It can be challenging for providers to discuss health issues related to excess weight while also remaining sensitive to language that may offend patients.

To help facilitate patient-provider interactions that are both productive and positive experiences, it is useful to recognize and implement language about weight that patients prefer and feel comfortable with. Located on the next page, you will see a breakdown of key words that patients affected by obesity found to be stigmatizing, least stigmatizing and more.

Language

Recent research has examined patients' opinions of the kinds of words that health providers use when discussing excess body weight. Specifically, patients were asked their opinions of how stigmatizing, blaming or motivating they perceive different words that doctors use to describe weight. Patients' preferences were as follows:

Least Stigmatizing / Blaming Words	Most Stigmatizing / Blaming Words
• Weight • Unhealthy weight • High BMI	• Fat • Morbidly Obese • Obese

Most motivating for weight loss	Least motivating for weight loss
• Unhealthy Weight • Overweight	• Fat • Morbidly Obese/Chubby

In addition, patients were asked how they would react if a doctor referred to their body weight in a way that made them feel stigmatized. Patients' responses included the following:

I would feel bad about myself.	***42%***
I would be upset/embarrassed.	***41%***
I would talk to my doctor about it.	***24%***
I would seek a new doctor.	***21%***
I would avoid future doctor appointments.	***19%***

It is helpful for providers to be aware of this language, as certain words to describe weight may be hurtful and offensive to patients because of their pejorative connotations.

Using language that is perceived negatively by patients may also jeopardize important discussions about health, and even lead to avoidance of future healthcare.

Prior to initiating conversations about weight with your patients, you may want to ask them what terms they would prefer you use when referring to their weight.

Consider this language in your discussions with patients about their weight:

"Could we talk about your weight today?"
"How do you feel about your weight?"
"What words would you like to use when we talk about weight?"

The Blame Game

In addition to using sensitive language, it is also important to avoid placing blame on patients for their excess weight or difficulties in losing weight. Remember, patients have likely already experienced stigmatizing encounters with health professionals before they enter your office. Most patients have tried to lose weight, repeatedly. Lack of success with weight-loss is much more attributable to the ineffectiveness of current conventional treatment options and biological and genetic factors that contribute to weight regulation, than it is a reflection of personal factors such as discipline or willpower. Therefore, be sure that your medical staff has an accurate understanding of the complex causes and treatment options for obesity and that obesity is the result of multiple complex factors which are complicated by our societal environment making lifestyle change very difficult.

Identify Your Own Biases

Finally, one of the most important strategies to reduce weight bias or prejudice that can unintentionally be communicated to patients is to identify your own personal assumptions and attitudes about weight. You can begin this process by asking yourself the following questions:

- *How do I feel when I work with patients of different body sizes?*
- *Do I make assumptions regarding a person's character, intelligence, abilities, health status or behaviors based only on their weight?*
- *What stereotypes do I have about persons with obesity?*
- *How do my patients affected by obesity feel when they leave my office?*
- *Do they feel confident and empowered, or otherwise?*

Productive and positive discussions with patients about weight-related health will be counterproductive and harmful if bias or blame is present. Addressing the topic of weight with sensitivity will improve provider-patient communication and help empower patients to make positive health behavior changes.

Tips for Discussing Weight

When discussing weight-related health with your patients, it's best to focus on specific lifestyle changes and health behaviors that can be improved, and to emphasize achievable behavioral goals rather than only focusing on weight itself. Examples of achievable, measurable behavioral goals include the following:

- Reducing consumption of sugar-sweetened beverages
- Replacing caloric beverages with water
- Increasing consumption of fruits and vegetables
- Reducing consumption of restaurant foods
- Increasing daily physical activity
- Limiting portion sizes to single servings

It can also be useful to employ motivational interviewing strategies when discussing weight with patients. Motivational interviewing aims to enhance self-efficacy and personal control for behavior change. It uses an interactive, empathic listening style to increase motivation and confidence in patients by specifically emphasizing the discrepancy between personal goals and current health behaviors.

Sample Questions for Your Patients

Here are some examples of questions to ask your patients when assessing ambivalence and motivation for lifestyle changes using a motivational interviewing style:

- How ready do you feel to change your eating patterns and/or lifestyle behaviors?
- How is your current weight affecting your life right now?
- What kinds of things have you done in the past to change your eating?
- What strategies have worked for you in the past?
- How do you feel about changing your eating or exercise behaviors?
- How would you like your health to be different?
- What steps do you feel ready to take to improve your health?

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Part of your goal in motivational interviewing is to help instill optimism and confidence in your patient that he/she can make meaningful behavior changes, and that you are a supportive resource in their efforts.

Be Proactive to Reduce Bias in Your Healthcare Practice

Taking a proactive approach to address and eliminate weight bias in your practice can improve delivery of care for patients affected by obesity. As more than 93 million Americans are affected by the disease of obesity, it important for you as a healthcare professional to provide them with the necessary tools and support to manage their weight and improve their health.

If you would like to learn more about weight bias and stigma, please visit the OAC's Web site at **www.ObesityAction.org** and the UConn Rudd Center for Food Policy and Obesity at **www.uconnruddcenter.org**.

The OAC and the Rudd Center also offer a brochure, titled *Understanding Obesity Stigma*, which further details weight bias in a variety of settings such as education, employment, healthcare and more. To order a free copy, please visit the OAC Web site.

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