

## CHAPTER 18-- DIETARY TREATMENT OF OBESITY

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### 1. INTRODUCTION

NHANES data reveals that 33% of U.S. adults are overweight, (BMI of 25-29), over 35% are obese (BMI 30 or higher) and over 6% are extremely obese (BMI greater than or equal to 40.0) (1). Obesity is a chronic medical condition requiring long-term therapy (2, 3-5). If left untreated, overweight and obesity can increase the risk degenerative diseases such as diabetes, hypertension, dyslipidemia, coronary artery disease, and metabolic syndrome, and orthopedic problems. In addition, obesity can promote the development of various negative psychological effects, and can diminish one's quality of life (6).

Self-initiated approaches to weight reduction are often ineffective. We all long for a quick and easy remedy to cure it, when in fact, there is no sure cure. The only effective method to keep off excess weight is through life-long weight management and obesity prevention, involving physical activity, balanced with a healthy diet (3;5). Health professionals can help people become more effective at maintaining a healthy weight, or losing weight when necessary.

Although 1998 NIH guidelines recommend that healthcare professionals advise obese patients to lose weight, the proportion of obese patients who reported being counseled by a healthcare professional has declined since 1994 (7). Yet the fact remains that a modest (10%) weight reduction in obese people is an attainable goal, and often results in clinical improvements of several health-related parameters, even if the individual remains clinically obese (3;8;9). This information should encourage health professionals to advise weight loss for obese patients and that they need not be overwhelmed by their inability to meet excessively ambitious, or unrealistic, weight loss goals (8;10). Smaller amounts of weight loss can still bring considerable health and social benefits.

There is a great deal of misinformation about obesity in many countries today, including the USA. According to a survey by the Natural Marketing Institute, 59% of the general population would benefit from losing weight. Of them, 26% used weight loss products in the past year, 21% used prescriptions, 18% used over the counter medications and 11% used weight loss dietary

supplements to maintain and/or manage their weight (11). Only some of these strategies are effective, as we will see in this chapter.

Weight management counseling of overweight and obese patients deserves reconsideration and reemphasis by health professionals because it carries potential for health benefits. Obese patients receiving weight reduction advice from their physicians are significantly more likely to embark on weight loss attempts than those who do not. Yet less than 42% of obese individuals reported that they received weight loss recommendations from their physicians (12). These findings underscore the need for increased health professional involvement in obesity treatment (4;10;13). When physicians are appropriately aware of, and include recommendations for lifestyle changes in counseling their obese patients, results are promising (12;14). Even more importantly, they should stress achievement and maintenance of a healthy weight before obesity becomes apparent.

The 2010 Dietary Guidelines for Americans (Table 1) provides assistance in maintaining and achieving a healthy weight as well as reducing risk of chronic, diet-related diseases through promoting health and a healthy eating pattern (15). MyPlate.gov (Figure 1) and the Dietary Approaches to Stop Hypertension (DASH) recommendations (Table 2) also provide specific guidance on food selection to assure a healthful diet. The 2008 Physical Activity Guidelines for Americans provide science-based guidance to help Americans, ages six and older, improve their health through appropriate forms of physical activity (Table 3). These guidelines are all useful for prevention of weight gain and maintenance of a healthy weight for the weight loss phase of weight control, different physical activity recommendations are involved, and these are discussed in this chapter.

This chapter focuses on steps health professionals can take to help their patients manage their weights more effectively, or to lose weight by dietary means when that is necessary.

Table 1. Dietary Guidelines for Americans, 2010 (15)		
Risk Intervention and Goals	Key Recommendations	Special Population Recommendations
<b>Adequate nutrients within calorie needs</b>	<p>Consume a variety of nutrient-dense foods/beverages with the basic food groups</p> <p>Limit intake of saturated and trans fats, cholesterol, added sugars, salt, and alcohol.</p> <p>Balance intake of calories with energy needs</p>	<p><i>Adults age &gt;50</i> should consume vitamin B12 fortified foods or a supplement in crystalline form</p> <p><i>Women of childbearing age who may become pregnant</i> should consume foods rich in heme-iron and/or iron-rich plant foods with food rich in vitamin C to enhance absorption</p> <p><i>Women in the first trimester</i> should also consume adequate folic acid via dietary supplement, fortified sources of food containing folic acid as well as other foods naturally high in folic acid</p> <p><i>Older adults, people with dark skin, and those not exposed to sufficient sunlight</i> should consume extra vitamin D from vitamin D fortified foods and/or supplements</p>

<b>W e i g h t M a n a g e m e n t</b>	<p>Maintain body weight in a healthy range by balancing calories with energy expended</p> <p>Prevent gradual weight gain by making small decreases in food/beverage calories in combination with increases in physical activity</p>	<p><i>Overweight adults:</i> strive for slow, steady weight loss by decreasing calories and increasing physical activity while maintaining adequate nutrient intake</p> <p><i>Overweight children</i> place on a weight-reduction diet only after consultation with a healthcare provider; reduce the rate of weight gain while allowing growth and development</p> <p><i>Pregnant women</i> ensure weight gain is appropriate as specified by healthcare provider, since optimal total pregnancy weight gain varies from person to person (14).</p> <p><i>Breastfeeding women:</i> moderate weight loss is acceptable and does not compromise of the nursing infant's weight gain</p> <p><i>Overweight adults and children with chronic diseases and/or on medications:</i> consult a healthcare provider before starting weight reduction to obtain a weight loss plan that ensures other health problems are managed appropriately.</p>
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<p><b>Physical Activity</b></p>	<p>Engage in regular physical activity and reduce sedentary activities to promote overall health, psychological well-being and a healthy body weight</p> <p>Reduce the risk of chronic diseases in adulthood by engaging in at least 30 minutes of moderate-intensity physical activity on most days of the week</p> <p>Greater health benefits can be obtained by engaging in physical activity that is more vigorous or for a longer duration</p> <p>Manage unhealthy body weight gain by engaging in about 60 minutes of moderate-to-vigorous intensity activity on most days per week while not exceeding caloric requirements</p> <p>Sustain weight loss by engaging in at least 60-90 minutes of daily moderate-intensity physical activity while not exceeding caloric requirements</p> <p>Achieve over-all physical fitness by including a variety of exercises (cardiovascular, stretching, resistance, and calisthenics)</p>	<p><i>Children and adolescents:</i> engage in at least 60 minutes of physical activity on most, preferably all, days of the week</p> <p><i>Pregnant women:</i> engage in 30 minutes or more of moderate intensity physical activity most days of the week if no medical or obstetric complications are present; avoid falls and abdominal trauma</p> <p><i>Breastfeeding women:</i> there are no adverse effects from acute or regular exercise</p> <p><i>Older adults:</i> participate in regular physical activity to help reduce functional declines associated with age</p>
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<b>Food Groups to Encourage</b>	<p>Consume a sufficient amount of fruits and vegetables while staying within energy needs; two cups of fruit and 2 1/2 cups of vegetables per day are recommended for a reference 2,000-calorie intake, with higher or lower amounts depending on the calorie level</p> <p>Choose a variety of fruits and vegetables each day. In particular, select from all five vegetable subgroups (dark green, orange, legumes, starchy vegetables, and other vegetables) several times a week</p> <p>Consume 3 or more ounce-equivalents of whole-grain products per day, with the rest of the recommended grains coming from enriched or whole-grain products. In general, at least half the grains should come from whole grains</p> <p>Consume 3 cups per day of fat-free or low-fat milk or equivalent milk products.</p>	<p><i>Children and adolescents:</i> consume whole-grain products often; at least half the grains should be whole grains</p> <p><i>Children 2 to 8 years:</i> consume 2 cups per day of fat-free or low-fat milk or equivalent milk products</p> <p><i>Children 9 years of age and older:</i> consume 3 cups per day of fat-free or low-fat milk or equivalent milk products</p>
<b>Fats</b>	<p>Consume less than 10% of calories from saturated fat and less than 300 mg/day of cholesterol</p> <p>Limit intake of fats and oils high in saturated and trans-fatty acids; keep trans-fatty acid intake as low as possible</p>	<p><i>Children ages 2 to 3 :</i> keep total fat intake between 30%-35% of total calories</p> <p><i>Children and adolescents ages 4 to 18 :</i> consume 25% - 35% of total calories from fat with most fats coming from sources of polyunsaturated and monounsaturated fatty acids (i.e. fish, nuts and vegetable oils)</p>

	<p>Consume 20% - 35% of total calories from fat; emphasize polyunsaturated and monounsaturated fatty acids (i.e. fish, nuts, vegetable oils)</p> <p>Choose and prepare meat, poultry, dry beans and milk or milk-products that are lean, low-fat or fat-free</p>	
<b>Carbohydrates</b>	<p>Choose fiber-rich fruits, vegetables, and whole grains often</p> <p>Choose and prepare foods and beverages with little added sugars or caloric sweeteners, such as amounts suggested by the USDA Food Guide and the DASH Eating Plan</p> <p>Reduce the incidence of dental caries by practicing good oral hygiene and consuming sugar - and starch-containing foods and beverages less frequently</p>	
<b>Sodium and Potassium</b>	<p>Consume potassium-rich foods daily such as fruits and vegetables while choosing and preparing foods with little salt</p> <p>Consume less than 2,300 mg (about 1 tsp) of sodium per day</p>	<p><i>Middle-aged and older adults, African Americans, and people with hypertension aim to consume less than 1,500 mg of sodium per day and meet potassium recommendation of 4,700 mg per day with food.</i></p>

<b>Alcohol</b>	Those who choose to drink alcohol should do so in moderation; defined as 1 drink per day for women; 2 drinks per day for men	Those engaging in activities that require attention, skill or coordination such as driving or operating machinery: avoid alcohol consumption  Those under the legal drinking age and women who are pregnant should avoid alcohol consumption.
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<b>Food Safety</b>	<p>To avoid microbial foodborne illness, clean hands, food contact surfaces, and fruits and vegetables</p> <p>Meat and poultry should not be washed or rinsed</p> <p>Separate raw, cooked, and ready-to-eat foods while shopping, preparing, or storing foods</p> <p>Cook foods to a safe temperature to kill microorganisms</p> <p>Chill (refrigerate) perishable food promptly and defrost foods properly</p> <p>Avoid raw (unpasteurized) milk or any products made from unpasteurized milk, raw or partially cooked eggs or foods containing raw eggs, raw or undercooked meat and poultry, unpasteurized juices, and raw sprouts</p>	<p><i>Infants and young children, pregnant women, older adults, and those who are immunocompromised DO not eat or drink raw (unpasteurized) milk or any products made from unpasteurized milk, raw or partially cooked eggs or foods containing raw eggs, raw or undercooked meat and poultry, raw or undercooked fish or shellfish, unpasteurized juices, and raw sprouts.</i></p> <p><i>Pregnant women, older adults, and those who are immunocompromised eat only deli meats and frankfurters that have been reheated to steaming hot.</i></p>
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**Table 2. Dietary Approaches to Stop Hypertension (DASH) Diet Recommendations (17)**

**The number of daily servings in a food group vary depending on caloric needs<sup>a</sup>**

Food Group	1,200 calories	1,400 calories	1,600 calories	1,800 calories	2,000 calories	2,600 calories	3,100 calories	Serving Sizes
Grains	4-5	5-6	6	6	6-8	10-11	12-13	1 slice bread 1 oz dry cereal <sup>b</sup> ½ cup cooked rice, pasta or cereal <sup>b</sup>
Vegetables	3-4	3-4	3-4	4-5	4-5	5-6	6	1 cup raw leafy vegetable ½ cup cut-up raw or cooked vegetable ½ cup vegetable juice
Fruits	3-4	4	4	4-5	4-5	5-6	6	1 medium fruit ¼ cup dried fruit ½ cup fresh, frozen or canned fruit ½ cup fruit juice
Fat-free or low-fat milk and milk products	2-3	2-3	2-3	2-3	2-3	3	3-4	1 cup milk or yogurt 1½ oz cheese
Lean meats, poultry and fish	3 or less	3-4 or less	3-4 or less	6 or less	6 or less	6 or less	6-9	1 oz cooked meats, poultry or fish 1 egg
Nuts, seeds, and legumes	3 per week	3 per week	3 -4 per week	4 per week	4-5 per week	1	1	1/3 cup or 1½ oz nuts 2 Tbsp peanut butter

								2 Tbsp or ½ oz seeds ½ cup cooked legumes (dried beans, peas)
<b>Fats and oils</b>	1	1	2	2-3	2-3	3	4	1 tsp soft margarine 1 tsp vegetable oil 1 Tbsp mayonnaise 1 Tbsp salad dressing
<b>Sweets and sugars</b>	3 or less per week	3 or less per week	3 or less per week	5 or less per week	5 or less per week	Less than 2	Less than 2	1 Tbsp sugar 1 Tbsp jelly or jam ½ cup sorbet, gelatin dessert 1 cup lemonade
<b>Maximum sodium limit<sup>d</sup></b>	2,300 mg/day	2,300 mg/day	2,300 mg/day	2,300 mg/day	2,300 mg/day	2,300 mg/day	2,300 mg/day	

#### Footnotes Dietary Approaches to Stop Hypertension (DASH) Diet Recommendations

- a. Eating patterns from 1,200 to 1,800 calories meet the nutritional needs of children 4 to 8 years old. Patterns from 1,600 to 3,100 calories meet the nutritional needs of children 9 years and older as well as adults.
- b. Serving sizes vary between ½ \_cup and 1¼ \_cups, depending on cereal type. Check product's Nutrition Facts label.

**Table 3. 2008 Physical Activity Guidelines for Americans (18)**

Population/Focus Area	Key Guidelines
<b>Children and Adolescents</b>	<p>Children and adolescents” 60 minutes (1 hour) or more of physical activity daily.</p> <ul style="list-style-type: none"> <li>• <b>Aerobic:</b> Most of the 60 or more minutes a day should be either moderate- or vigorous-intensity aerobic physical activity, and should include vigorous-intensity physical activity at least 3 days a week.</li> <li>• <b>Muscle-strengthening:</b> As part of their 60 or more minutes of daily physical activity, children and adolescents should include muscle-strengthening physical activity on at least 3 days of the week.</li> <li>• <b>Bone-strengthening:</b> As part of their 60 or more minutes of daily physical activity, children and adolescents should include bone-strengthening physical activity on at least 3 days of the week.</li> </ul> <p>Encourage young people to participate in physical activities that are appropriate for their age, that are enjoyable, and that offer variety.</p>
<b>Adults</b>	<ul style="list-style-type: none"> <li>• All adults should avoid inactivity. Some physical activity is better than none, and adults who participate in any amount of physical activity gain some health benefits.</li> <li>• For substantial health benefits, adults should do at least 150 minutes (2 hours and 30 minutes) a week of moderate-intensity, or 75 minutes (1 hour and 15 minutes) a week of vigorous-intensity aerobic physical activity, or an equivalent combination of moderate- and vigorous intensity aerobic activity. Aerobic activity</li> </ul>

	<p>should be performed in episodes of at least 10 minutes, and preferably, it should be spread throughout the week.</p> <ul style="list-style-type: none"> <li>• For additional and more extensive health benefits, adults should increase their aerobic physical activity to 300 minutes (5 hours) a week of moderate intensity, or 150 minutes a week of vigorous intensity aerobic physical activity, or an equivalent combination of moderate- and vigorous-intensity activity. Additional health benefits are gained by engaging in physical activity beyond this amount.</li> <li>• Adults should also do muscle-strengthening activities that are moderate or high intensity and involve all major muscle groups on 2 or more days a week, as these activities provide additional health benefits.</li> </ul>
<b>Older Adults</b>	<p>The <i>Key Guidelines for Adults</i> also apply to older adults. In addition, the following Guidelines are for older adults:</p> <ul style="list-style-type: none"> <li>• When older adults cannot complete 150 minutes of moderate-intensity aerobic activity a week because of chronic conditions, they should be as physically active as their abilities and conditions allow.</li> <li>• Older adults should include exercises that maintain or improve balance if they are at risk of falling.</li> <li>• Older adults should determine their level of effort for physical activity relative to their level of fitness.</li> <li>• Older adults with chronic conditions should understand whether and how their conditions affect their ability to do regular physical activity safely.</li> </ul>
<b>Safe Physical Activity</b>	<p>To perform physical activity safely and reduce the risk of injuries and other adverse events, people should:</p> <ul style="list-style-type: none"> <li>• Understand the risks but remember that physical activity is safe for almost everyone.</li> <li>• Choose types of physical activity that are appropriate for their current fitness level and health goals, because some activities are safer than others.</li> <li>• Increase physical activity gradually over time when more activity is necessary to meet guidelines or health goals. Inactive people should “start low and go slow,” gradually increasing how often and how long activities are done.</li> </ul>

	<ul style="list-style-type: none"> <li>• Protection: using appropriate gear and sports equipment, looking for safe environments, following rules and policies, and making sensible choices about when, where, and how to be active.</li> <li>• Those with chronic conditions or symptoms should be under the care of a health-care provider and should consult the health-care provider about the types and amounts of activity appropriate for them.</li> </ul>
<b>Women During Pregnancy and the Postpartum Period</b>	<ul style="list-style-type: none"> <li>• Healthy women who are not already highly active or doing vigorous-intensity activity should complete at least 150 minutes of moderate-intensity aerobic activity a week during pregnancy and the postpartum period. Preferably, this activity should be spread throughout the week.</li> <li>• Pregnant women who habitually engage in vigorous-intensity aerobic activity or who are highly active can continue physical activity during pregnancy and the postpartum period, provided that they remain healthy and discuss with their health-care provider how and when activity should be adjusted over time.</li> </ul>
<b>Adults with Disabilities</b>	<ul style="list-style-type: none"> <li>• Adults with disabilities, who are able to do so, should complete at least 150 minutes a week of moderate-intensity, or 75 minutes a week of vigorous-intensity aerobic activity, or an equivalent combination of moderate- and vigorous-intensity aerobic activity. Aerobic activity should be performed in episodes of at least 10 minutes, and preferably, it should be spread throughout the week.</li> <li>• Adults with disabilities, who are able to do so should also do muscle-strengthening activities of moderate or high intensity that involve all major muscle groups on 2 or more days a week, as these activities provide additional health benefits.</li> <li>• When adults with disabilities are not able to meet the Guidelines, they should engage in regular physical activity according to their abilities and should avoid inactivity.</li> <li>• Adults with disabilities should consult their health-care providers about the amounts and types of physical activity that are appropriate for their abilities.</li> </ul>
<b>Chronic Medical Conditions</b>	<ul style="list-style-type: none"> <li>• Adults with chronic conditions can obtain important health benefits from regular physical activity.</li> <li>• When adults with chronic conditions perform activity according to their abilities, physical activity is safe.</li> </ul>

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|  | <ul style="list-style-type: none"><li>• Adults with chronic conditions should be under the care of a health-care provider. People with chronic conditions and symptoms should consult their health-care provider about the types and amounts of activity appropriate for them.</li></ul> |
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## 2. RATIONALE FOR DIETARY TREATMENT

Over two-thirds of adults in the United States are currently overweight or obese (19). The percent of overweight and obese people has risen to this point over the past several decades, among men and women, all ethnic groups, all ages, and all education levels. From 1960 to 2010, the prevalence of obesity in the United States more than doubled, going from 13.4% to 36.1% in adults ages 20 to 74, although the prevalence of overweight remained relatively stable (20). In recent years the trend has begun to level off, with one large study finding no significant differences in the incidence of obesity in adults between 2003-2004 and 2011-2012 (21). However, the incidence of both overweight and obesity remain high, and with the medical costs for an obese person averaging \$1,429 more per year (in 2008 dollars) than a normal weight person, attention to weight control and maintenance remains paramount for medical practitioners (22).

Weight control has health advantages, and therefore maintaining or achieving a healthy weight is important for all Americans. Obesity is associated with an increase in mortality rates. Obese individuals have an increased risk of death of at least 20% for all-cause and CVD associated mortality (23). Excess weight might contribute to as much as 41% of uterine cancers, and 10% of gallbladder, kidney, liver, and colon cancers (. In weight control prevention it is especially paramount because once weight and adiposity have surpassed healthy levels, they are difficult to reduce. Therefore, it is important for health professionals to monitor the weights of all their patients and to provide anticipatory guidance so that those who are already at healthy weights remain so. The 2010 Dietary Guidelines for Americans ([Table 1](#)) stress maintenance of a body weight within a healthy range by balancing calories from foods and beverages with calories expended, by preventing gradual weight gain over time, by making small decreases in foods and beverages, and by increasing physical activity. However, this is easier said than done. The chapter will assist health professionals in operationalizing these recommendations.

## 3. EVALUATING OVERWEIGHT AND OBESITY

This section outlines a stepwise approach for assessing overweight and obesity.

### 3.1 Assess Body Fat Burden and Health Status

Before any patient is placed on a reducing diet, where caloric intake is greatly reduced, often alongside increases in energy expenditure, medical assessment of weight, fat distribution, and health risks is essential.

### 3.2 Measure Body Mass Index (BMI) as an Indirect Measure of Body Fat Burden

Weight should be measured, without clothing, on electronic scales, which provide accurate weights even for heavy patients. Scales should be calibrated to ensure accuracy. Height is best measured with a wall-mounted stadiometer or against a wall rather than on beam-balance scales, which are unsteady and unreliable. Body fat is difficult to measure directly and accurately in clinical practice. Therefore, body mass index (BMI), which is highly correlated with total body fat and future health risks, is recommended as the best surrogate method of capturing body fat, although it can overestimate body fat in individuals with high muscle mass. BMI can be calculated using the following formulas (24):

$$\text{BMI} = (\text{weight lbs} \div \text{height inches}^2) \times 703 \text{ or } \text{BMI} = \text{weight kilograms} \div \text{height meters}^2 \text{ (24)}$$

Table 4 presents the National Institutes of Health (NIH) classification of BMI values for adults (24). These values are based on abundant data associating higher BMI levels with higher health risks. Although individuals with the same BMI often differ somewhat in the amount of body fat they have, this is still a useful approximation that can be performed quickly and inexpensively in clinical settings.

Table 4. Classification of Weight Status by Body Mass Index (BMI) (24)	
Classification	BMI (kilogram/m <sup>2</sup> )
Underweight	<18.5
Normal weight	18.5-24.9
Overweight	25-29.9
Obesity Class 1	30-34.9
Obesity Class 2	35-39.9
Extreme Obesity Class 3	>40

Individuals with a BMI under 18.5 are classified as underweight, whereas those with a BMI over 25 are considered overweight; those over BMI 30 are classified as class 1 obesity, those over BMI 35 as class 2 obesity, and those over BMI 40 as extreme, or class 3, obesity. In general, the orthopedic and metabolic hazards increase with increasing BMI. Tracking changes in BMI, as well as body weight itself, are easy to use tools for monitoring body composition over time, identifying those at risk for developing overweight and obesity, and monitoring the success of those undergoing weight loss therapy.



### 3.3 Measure Waist Circumference to Quantify Risks Related to Body Fat Distribution

The distribution of fat on the body, as well as its sheer amount, also alters risk of some metabolic disorders. The reasons for this are becoming clear as the role of adipose tissue as an endocrine organ is more fully understood. Excess abdominal fat in the viscera, characterized by an accumulation of fat centrally (sometimes referred to as android "apple" or abdominal fat distribution or ectopic fat) is associated with greater risk of certain chronic degenerative diseases than is a peripheral fat deposition pattern (gynoid "pear" or lower body fat pattern).

Although the causal associations between certain diseases and body fat distribution are still a matter of debate (28;27), measuring waist circumference in addition to BMI is still clinically useful in assessing risk posed by body fat distribution (24;5;28-31).

Visceral and subcutaneous fat are difficult to measure accurately in office practice. Waist circumference, taken at the level of the umbilicus (belly button) with a plastic or other type of non-stretchable measuring tape, is a reasonable proxy for assessing the likely size of visceral fat deposits and the extent of abdominal obesity. Waist circumference is easier to measure and more straightforward to interpret than are waist-to-hip ratios. It is generally used as the standard in assessing central vs. peripheral fatness. The cut-points for increased risk are a waist circumference of greater than 35 inches (>88cm) in women, or greater than 40 inches (>102cm) in men (24; 31). Although the usefulness of these absolute cut-offs have been questioned due to the many possible confounding variables in their relationship with health, monitoring changes over time is advocated (32). Measuring waist circumference is most useful for defining risk in obese patients with BMI 25-35 kg/m<sup>2</sup>. Obese patients with BMIs over 35 kg/m<sup>2</sup> already have elevated risk, so waist circumference measurements may be less necessary for them (31).

Table 5 shows how risks of weight related conditions such as type 2 diabetes, hypertension, and cardiovascular disease increase with greater BMI and waist circumference. Patients with high waist circumference may need increased monitoring and treatment of blood pressure, unhealthy blood lipid profiles, and other cardiovascular risk factors. Physical inactivity and smoking increase health risk still further. They act synergistically and apparently increase the severity of the other risk factors present as well as increasing risks themselves in other ways. Elevated serum triglycerides and lower HDL are other markers for increased cardiovascular risk that increase with high waist circumference.

Table 5. Classification of Risk of Type 2 Diabetes, Hypertension and Cardiovascular Disease Associated with Weight and Fat Distribution	
Classification of Fatness Status by BMI and Waist Circumference	Increase in Disease Risk for Type 2 Diabetes, Hypertension and Cardiovascular Disease Over Normal Weight and Waist Circumference

	<i>Waist circumference Women &lt;35 inches Men &lt; 40 inches</i>	<i>Waist circumference Women &gt;35 inches Men &gt; 40 inches</i>
Underweight (BMI <18.5)	---	---
Normal (BMI (18.5-24.9)	---	---
Overweight (BMI 25-29.9)	Increased	High
Obese Class 1 (BMI 30-34.9)	High	Very high
Obese Class 2 (BMI 35-39.9)	Very high	Very high
Extreme Obesity Class 3 (BMI >40)	Extremely high	Extremely high

### 3.4 Document Other Risk Factors and Comorbidities That Increase Risk and Have Other Implications for Therapy

The presence of risk factors or already clinically apparent diseases further increases the health risk of obesity over that evident with high BMI and high waist circumference alone. [Table 6](#) describes different conditions that further add to the adverse health effects of overweight and obesity itself (24). Weight loss can help lower elevated blood pressure, blood glucose, both total and low-density lipoprotein levels (LDL), plasma cholesterol and triglyceride levels, and raise high density lipoprotein (HDL) cholesterol levels in those with abnormally high values. Other modalities of treatment, including pharmacologic therapy, may also be necessary to bring some patients into healthy ranges.

<b>Table 6. Risk Factors and Comorbidities that Increase the Risks of Morbidity from Overweight and Obesity (24)</b>	
<b>Level of Risk</b>	<b>Conditions</b>
High Absolute Risk	Established coronary heart disease or other atherosclerotic disease Type 2 diabetes Sleep Apnea

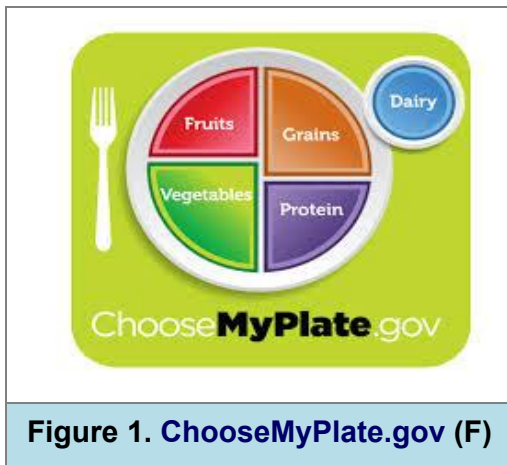
High absolute Risk if 3 or More of These Risk Factors are Present	Hypertension Cigarette smoking High low-density lipoprotein cholesterol Low high density lipoprotein cholesterol Impaired fasting glucose Family history of early cardiovascular disease Age: >45 in men or >55 in women
Increased Risk	Increased surgical risk Psychological disorders such as depression Osteoarthritis Hirsutism (presence of excess body and facial hair) Gallstones Stress incontinence Gynecologic problems such as amenorrhea and menorrhagia

### 3.5 Determine if the Patient is a Candidate for Weight Loss

All individuals with a BMI over 30, and those with a BMI between 25-29.9 with a high waist circumference or one or more of the risk factors listed in [Table 6](#), are potential candidates for weight reduction. Patients who have a BMI between 25-29.9, but who do not have any risk factors or comorbidities should be counseled to avoid further weight gain (23). The goal of weight control is both the reduction of weight and the maintenance of healthy body weight over the long term. Weight loss should be achieved through a

high-intensity lifestyle intervention, which is discussed further in section 4.2, if possible (23). If the patient is not open to weight loss, at least prevention of further weight gain should be attempted. Those with very high BMIs (over 35) are unlikely to be able to achieve sufficient fat loss on a usual low calorie diet of 1,200 to 1,500 calories without regimes that must continue for many months. They should be referred for care to a multidisciplinary team specializing in obesity for treatment with very low calorie diets, and possibly pharmacology or surgery (23).

Some individuals whose weights are at healthy levels and who are without weight associated health problems also may wish to lose weight. These patients need to have their concerns about diet addressed, but should not embark on reducing diets since there are no medical indications for them to do so. They should encouraged to maintain their weight within a healthy range, and counseled to follow dietary recommendations from ChooseMyPlate.gov (Figure 1), the Dietary Approaches to Stop Hypertension (DASH) eating plan (Table 2), or the Dietary Guidelines for Americans (Table 1).



**Figure 1. ChooseMyPlate.gov (F)**

#### **4. CHOOSE TREATMENT OPTIONS**

The following section covers the various means of treating obesity, including dietary changes, medications, and/or surgical options. Diet plays a critical role in all of these options.

##### **4.1 Assess the Patient's Readiness and Willingness to Lose Weight**

The previous sections provide the rationale for assessment of the health risks associated with obesity, the potential health benefits accruing from weight loss, and the importance of then maintaining a healthy body weight. Weight control requires behavioral change, which cannot happen without patient buy-in to the process. Therefore, the health risks of overweight and obesity need to be communicated, and patient readiness to change needs to be established. Table 7 outlines the various stages of behavior

change as conceptualized by Kushner based on Prochaska's model of behavior change, often referred to as the *Transtheoretical Model of Behavior Change* (6). It is important to note many patients will not progress through the outlined stages linearly, but rather will go back and forth repeatedly among stages. Therefore, timing is important and the clinician must watch for an appropriate time to bring up or follow through on the issue.

**Table 7. Trans-theoretical Model of Behavior Change (6)**

Stage	Characteristics	Patient Verbal Cues
Pre-contemplation	Unaware of problem, no interest in change	"I'm not really interested in weight loss. It's not a problem."
Contemplation	Aware of the problem, beginning to think of changing	"I need to lose weight but with all that's going on in my life right now, I'm not sure if I can."
Preparation	Realizes benefits of making changes and thinking about how to make change	"I have to lose weight, and I'm planning to do that."
Action	Actively taking steps toward achieving the behavioral goal, but only for a brief period (less than 6 months)	"I'm doing my best. This is harder than I thought."
Maintenance	Initial treatment and behavioral goals reached and sustained for a longer period of time (e.g., more than 6 months)	"I've learned a lot through this process."

Often, those who are at highest health risk due to obesity are unaware of how serious their weight-related problems are, or are in deep denial about them. The consequences of excess weight, including long-term implications, must therefore be raised and carefully explained. Helping patients to draw connections between the short-and long-term health consequences of their current weight, and the implications this will have on things they care about, such as their family or the ability to participate in activities they enjoy, may aid in empowering patients to progress through the various stages of behavior change.

Once patient readiness and willingness to lose weight has been established, a plan of attack needs to be jointly devised with the patient. Some patients are ready to start a treatment program immediately, and the patient and counselor are able to begin setting goals together right away. Other patients have reservations or other issues keeping them from reaching the action stage needed to embark upon their weight loss goals, making it important for the counselor to address these road-blocks before moving on. For

patients who are not ready to act, the issue should be deferred and brought up again at the next visit, rather than dropping the subject entirely. Some groups of patients are unable or unwilling to embark on a weight reduction program at all. Even patients who are unwilling to embark on a reducing diets may be willing to take steps to avoid further weight gain, or may be willing to work on other risk factors such as smoking cessation or increasing physical activity. These activities should be encouraged. For those who are ready and raring to go, a referral to a registered dietitian should be provided where the subject can be addressed in-depth

#### 4.2 Decide if Dietary Treatment is the Appropriate Option

Weight reduction with dietary treatment is in order for virtually all patients with a BMI over 30, as well as those with a BMI of 25-29.9 with comorbidities. A dietary approach to weight loss should be executed in the context of comprehensive lifestyle intervention whenever possible. This type of intervention involves frequent, in-person encounters with a trained interventionist in an individual or group setting, and incorporates a moderately reduced calorie diet, increases in physical activity, and the use of behavioral techniques to facilitate adherence to recommendations. The gold standard is a comprehensive, high-intensity, on-site program with greater than 14 sessions in 6 months, provided either in a group or individually, by a trained interventionist, and lasting for at least 1 year. When a comprehensive lifestyle intervention is not feasible, other dietary-based approaches, such as electronically based programs and commercial programs, which will be discussed in further detail later, can be appropriate alternatives (23).

For some patients, however, a low calorie (hypocaloric) diet alone may not be enough to prompt significant and lasting weight loss (34). For patients who have failed to lose on a comprehensive lifestyle program, for those with a BMI greater than 30, or greater than 27 if one or more comorbidities are present, and who are likely to have little success with a purely dietary approach on the basis of a history of many failures, other steps may be in order. This is especially important for those with class 2 (BMI>35) and 3 (BMI > 40) obesity, referral to a multidisciplinary obesity treatment team for adjunctive therapies (i.e., very low calorie diets, pharmacological treatment, and/or gastric bypass surgery) is warranted (23).

#### 4.3 Decide if Drugs will be Useful Adjunctive Therapy to the Reducing Diet

Prescription drugs are one form of adjunctive therapy that may be considered for those with a BMI greater than 30, or a BMI of 27 and above if one or more comorbidities are present, who are unable to lose weight with dietary measures alone. Weight loss drugs are only adjuncts to, rather than substitutes for, reducing diets, however, and a reducing diet will still be necessary. Without a hypocaloric diet, drugs are unlikely to be effective. The addition of weight loss medication to a dietary-based weight loss regimen can help patients lose up to 10% of their initial body weight, with most weight loss occurring in the first six months (35).

Table 8 provides an overview of prescription medications that are available. Note that none are totally free of side effects.

Table 8. Prescription Medications Available in the United States for Weight Loss (35 )			
Generic Name + (Trade Name)	Food and Drug Administration Approval for Weight Loss	Drug Type	Side Effects Reported

Orlistat (Prescription: Xenical™)	Yes; long term for adults and children age 12 and older	Lipase Inhibitor	Gastrointestinal issues (cramping, diarrhea, oily spotting)
<i>*OTC Brand: Alli™</i>	<i>*Alli™</i> for adults only		Do not take with cyclosporine
Lorcaserin (Belviq™)	Yes; long term for adults	Serotonin Receptor Antagonist	Headache, dizziness, nausea, fatigue, dry mouth  Do not take with Selective Serotonin Reuptake Inhibitors (SSRIs) or Monoamine Oxidase Inhibitors (MAOIs)
Phentermine-Topiramate (Qsymia™)	Yes; long term for adults  Contraindicated in women who are pregnant or may become pregnant	Appetite Suppressant/Seizure Treatment	Tingling of hands and feet, trouble sleeping, taste alterations, dry mouth constipation, dizziness, birth defects
Bupropion – Naltrexone (Contrave™)	Yes; long term for adults	Depression Treatment/Alcohol and Opioid Abuse Treatment	Nausea, constipation, headache, vomiting, dizziness, insomnia, dry mouth, diarrhea, increased blood pressure and heart rate, seizures, suicidal thoughts and behaviors
Phentermine (Adipex-P™, Suprenza™, Zantryl™)	Yes; short term (up to 12 weeks) for adults	Appetite Suppressant	Increased blood pressure and heart rate, sleeplessness, nervousness
Diethylpropion (Tenuate™)	Yes; short term (up to 12 weeks) for adults	Appetite Suppressant	Dizziness, headache, sleeplessness, nervousness
Phendimetrazine (Bontril PDM™, Adipost™, Melfiat™)	Yes; short term (up to 12 weeks) for adults	Appetite Suppressant	Sleeplessness, nervousness

Benzphetamine (Didrex™)	Yes; short term (up to 12 weeks) for adults	Appetite Suppressant	Restlessness, anxiety, sleeplessness, headache
Bupropion (Wellbutrin™)	No	Depression Treatment	Dry mouth, insomnia
Topiramate (Topamax™)	No	Seizure Treatment	Numbness of skin, change in taste
Zonisamide (Zonegran™)	No	Seizure Treatment	Drowsiness, dry mouth, dizziness, headache, nausea
Metformin (Glucophage™)	No	Diabetes Treatment	Weakness, dizziness, metallic taste, nausea
Byetta (Exenatide™, Bydureon™)	No	Diabetes Treatment	Nausea

Many of the Food and Drug Administration (FDA)-approved weight-loss medications are approved only for short-term use (short term is usually interpreted to mean use up to 12 weeks), although some physicians still prescribe them for longer periods of time (35). Only four prescription drugs are currently approved for long-term use in weight reduction: Orlistat (Xenical™), Lorcaserin (Belviq™), Phentermine-Topiramate (Qsymia™), and Bupropion–Naltrexone (Contrave™).

Orlistat is available for both prescription (Xenical™) and over-the-counter at a lower dose as Alli™. Over-the-counter Alli™ is available only to adults aged 18 and older, and is a half-dose version of prescription Orlistat (<http://www.myalli.com>) (35). Orlistat operates at the level of the gut to inhibit pancreatic lipase, blocking the absorption of about one third of fat consumed. Use over one to two years can lead to a weight loss of five to seven pounds (35). Adherence to a reduced calorie diet with less than 30% calories from fat is necessary while on either Orlistat or Ali. Both Orlistat and Ali's disadvantages include fat malabsorption, sometimes accompanied by anal leakage, and decreased absorption of fat-soluble vitamins. Because of this decrease in fat-soluble vitamin absorption, patients taking either version of the drug should be advised to take a multivitamin supplement containing fat-soluble vitamins to ensure adequate nutritional status (35). Dietetic counseling is helpful in managing weight loss.

Lorcaserin (Belvique™) is another weight loss drug approved for long term use and is available by prescription only. Studies evaluating its effectiveness found that 47% of those who used the drug lost at least 5% of their initial body weight (35). Qsymia™ is another long-term weight loss drug that was approved by the FDA in 2012. Qsymia™ is a combination of an appetite suppressant, phentermine, and a seizure medication, topiramate. Studies found that after 1 year using the recommended dose of the drug, 62% of patients lost greater than 5% of their initial body weight (35). Contrave™ is the newest long-term drug to treat



obesity, and was approved in September 2014. Contrave™ is a combination of bupropion, an antidepressant, and naltrexone, a medication used to treat alcohol and opioid dependence. Studies showed that after 1 year, 42% of the non-diabetic patients tested lost at least 5% of their initial body weight. (36). With all long-term weight loss drugs, if at least 5% of initial body weight is not lost by 12 weeks, use of the drug should be discontinued as it is unlikely to be effective later, and therefore the risks outweigh the putative benefits (35).

Phentermine (Suprenza™), phendimetrazine (Adipost™), diethylpropion (Tenuate™), and benzphetamine (Didrex™) are modestly effective prescribed anorectic agents approved for short-term use (12 weeks in a 12 month period) by the Food and Drug Administration (FDA) (35). Phentermine and diethylpropion are widely prescribed, as they are relatively inexpensive (approximately \$30 for a one-month supply), and provide slight stimulatory effects. However, little research has been done on their long-term side-effects (39).

The off-label use of bupropion (Wellbutrin™), a drug originally approved by the FDA for aiding in smoking cessation, has become popular in the past few years for weight control. Bupropion enhances norepinephrine and weakly blocks dopamine reuptake and is being studied for the treatment of obesity. Bupropion could be considered if a patient presenting with obesity wanted to quit smoking as well and lose weight (38). Short term side effects most often reported are agitation, dry mouth, insomnia, headache, nausea, constipation, and tremor. However, its long-term effects on weight loss are not clear, and its use must be accompanied by a low-calorie diet if it is to help in weight loss.

Topiramate (Topamax™) and zonisamide (Zonegran™) are anticonvulsants that were originally approved to treat epilepsy. They are also sometimes used off-label for their weight-loss effects. However, adverse effects have also been reported, most commonly difficulty with memory, parathesia, difficulty concentrating, and mood problems. These drugs are approved by the FDA for epilepsy only, and not for weight loss (38).

Metformin (Glucophage™) is a diabetes medication that may promote small amounts of weight loss in people with obesity and type 2 diabetes. One study found that patients treated with metformin for diabetes lost 2kg more at 6 months compared to placebo, and maintained at 1 kg at 4 years follow-up. It is unclear, however, if weight loss on metformin is related to improved glucose tolerance or the drug itself (40).

Byetta™ (exenatide) and pramlintide are sometimes used in treating the comorbidities of obesity. Both compounds affect the gastrointestinal hormones that regulate glucose homeostasis, gastric emptying, and satiety. Exenatide (Byetta™) is used as an adjunctive therapy for improving glycemic control in patients with type 2 diabetes who also take metformin or sulfonylurea. Pramlintide is an adjunctive therapy for patients with type 1 or type 2 diabetes who use insulin at mealtimes. Usually patients with diabetes gain weight with better glucose control, however, with these drugs, better blood glucose control is often associated with weight loss, at least in preliminary studies. The most common side effect of these medications is nausea (38).

Major disappointments have resulted as research on the once promising class of drugs known as cannabinoid (CB<sub>1</sub>) receptor antagonists has continued. Rimonabant (Acomplia™) was the first CB<sub>1</sub> receptor blocker approved for use in the world. Its

suggested use was for patients with a BMI of 30 or more, in conjunction with exercise and diet, to aid in weight loss. CB<sub>1</sub> receptors are located in the brain, gastrointestinal tract, adipose tissue, heart, pituitary, and adrenal glands, and if they are stimulated, these receptors increase appetite. Blockage of these receptors is thought to decrease appetite. However, the FDA ruled that Rimonabant carried too much risk to be approved for use in the United States, with side effects including nausea, anxiety, diarrhea, and depressed mood that, in severe cases, led to suicide (38). In 2009, the European Medicines Agency (EMA) also concluded that the benefits of Rimonabant no longer outweighed the risks, and marketing authorization for the drug in the European Union was officially revoked (43). Investigation into the cannabinoid (CB<sub>1</sub>) receptor antagonist class of drugs has since ceased (39).

Other areas of research for future weight loss drugs include drugs combining appetite suppressants and those that affect addiction, drugs affecting gut hormones that influence appetite, drugs that work to shrink the blood vessels supplying fat cells, drugs targeting genes associated with obesity, and manipulation of gut bacteria (35).

Sibutramine (Meridia™) was a commonly used obesity drug first introduced in 1997. However, it was voluntarily withdrawn from US markets by its manufacturer in 2010 after clinical trial data indicated that the drug increased the risk for heart attack and stroke. It should not be prescribed or used for the treatment of obesity (44).

Some of the surprisingly positive effects with weight loss drugs are due the fact that the medications are not what they seem to be but rather adulterated and contain undeclared drugs. The FDA releases an extensive list of tainted weight loss products, many of which contain undeclared drugs (Table 9) (44). If patients are taking any of these contaminated products, they should be advised to stop immediately. Table 9 provides a comprehensive list of these tainted products on the market from 2011 onwards, along with the undeclared pharmaceutical/chemical included in the product. There are also other drugs that may be added although they are no longer available for distribution through legitimate sources because of adverse and sometimes fatal side effects including Fen-Phen™, Redux™, Pondimin™, fenfluramine, Meridia™, and dexfenfluramine.

<b>Table 9. FDA's List of Tainted Weight Loss Products (45)</b> <i>The Undeclared Drug/Chemical Ingredient is Listed in parentheses after Each Product</i>		
1 Day Diet (Sibutramine)	7 Days Herbal Slim (Sibutramine)	24 Ince (Sibutramine)
A-Slim 100% Natural Slimming Capsule (Sibutramine)	Acai Berry Soft Gel ABC (Sibutramine)	Advanced (Sibutramine)
Advanced Blue (Sibutramine)	Advanced Slim 5 (Sibutramine)	Asset Bee Pollen (Sibutramine)

Asset Bold (Sibutramine)	Asset Extreme (Sibutramine)	Asset Extreme Plus (Sibutramine)
B-Perfect (Sibutramine)	Be Inspired (Sibutramine)	Beautiful Slim Body (Sibutramine)
Bella Vi Insane Amp'd/Bella Vi Amp'd Up (Sibutramine)	Best Line Suplemento Alimenticio (Sibutramine)	Best Share Green Coffee: Brazilian Slimming Coffee (Sibutramine)
Bethel 30 (Sibutramine)	Body Beauty 5 Days Slimming Coffee (Sibutramine)	Botanical Slimming Soft Gel (Sibutramine)
Burn 7 (Sibutramine)	Celerite Slimming Capsules (Sibutramine)	Citrus Fit Gold (Sibutramine)
DaiDaiHuaJiaoNang (Sibutramine and Phenolphthalein)	Diet Master (Sibutramine)	Dr. Mao Slimming Capsules (Sibutramine)
Dr. Ming's Chinese Capsule (Sibutramine)	Dream Body Slimming Capsule (Sibutramine)	Extreme Body Slim (Sibutramine)
Fat Zero (Sibutramine and Phenolphthalein)	Fruit & Plant Slimming (Sibutramine)	Fruit Plant Lossing Fat Capsule (Sibutramine)
Goodliness Fat-Reducing Capsules (Sibutramine)	Hot Detox (Sibutramine)	Infinity (Sibutramine)
Instant Slim/ Shou Fu Ti Tun Guo Xiang Xing Jian Fei Jiao Nang (Sibutramine)	Ja Dera 100% Natural Weight Loss Supplement (Sibutramine)	Japan Hokkaido Slimming Weight Loss Pills (Sibutramine, Benzocaine, Phenolphthalein and Diclofenac)
Japan Rapid Weight Loss Diet Pills Green (Phenolphthalein)	Japan Rapid Weight Loss Diet Pills Yellow (Sibutramine and Phenolphthalein)	Japan Weight Loss Blue (Sibutramine, Analogs of Sibutramine, and Ephedrine Alkaloids)
Jimpnness Beauty Fat Loss Capsules (Sibutramine)	La Jiao Shou Shen (Sibutramine)	Leisure 18 Slimming Coffee (Sibutramine)
Lingzhi Cleansed Slim Tea (Sibutramine)	Lipo 8 Burn Slim (Sibutramine)	Lishou (Sibutramine)

Lite Fit USA (Sibutramine)	Lose Weight Coffee (Sibutramine)	LX1 (DMAA)
Magic Slim (Sibutramine)	Magic Slim Tea (Sibutramine)	Magic Slim Weight Reduction Capsule (Sibutramine)
MAXILOSS Weight Advanced (Sibutramine)	MAXILOSS Weight Advanced Blue (Sibutramine)	Meizi Evolution (Sibutramine)
Meizitang Citrus (Sibutramine)	Mix Fruit Slimming (Sibutramine)	Natural Body Solution (Sibutramine)
New You (Phenolphthalein)	P57 Hoodia (Sibutramine)	Pai You Guo Slim Tea (Sibutramine and Phenolphthalein)
Paiyouji Plus (Sibutramine)	Perfect Body Solutions (Sibutramine)	PhentraBurn Slimming Capsules (Sibutramine)
Sheng Yuan Fang (Sibutramine)	Slender Slim 11 (Sibutramine)	Slim Forte Slimming Capsule/Slim Forte Double Power Slimming Capsule (Sibutramine)
Slim Forte Slimming Coffee (Sibutramine)	Slim Max (Sibutramine)	Slim Trim U (Sibutramine)
Slim Xtreme Herbal Slimming Capsule (Sibutramine)	SLIMDIA Revolution (Sibutramine)	SlimEasy Herbs Capsule (Sibutramine)
SlimExtra Herbal Capsule (Sibutramine)	Slimming Diet (Sibutramine)	Slimming Diet Berry Plus (Sibutramine)
Strawberry Balance (Sibutramine)	Super Slim (Sibutramine)	Super Slimming (Sibutramine)
Sport Burner (Fluoxetine)	Tengda (Sibutramine)	Thinogenics (Sibutramine)
Toxin Discharged Tea (Fluoxetine)	Trim-Fast Slimming Softgel (Sibutramine)	Ultimate Formula Bee Pollen Capsules (Sibutramine)
Vitaccino Coffee (Sibutramine)	XIYOUJI QINGZHI CAPSULE (Sibutramine)	Zi Xiu Tang Bee Pollen Capsules (Sibutramine)

Drugs for weight loss are of limited efficacy, some patients cannot afford them, and all of them have side effects. About one fourth of all individuals who are prescribed medications will not have the expected response (39). Patients who are likely to respond to

drugs tend to do so within the first month of therapy. If they fail to lose four pounds (1.8 kilograms) in the first four weeks, the drug is unlikely to be effective, and it may be appropriate to discontinue its use. A loss of four pounds within the first four weeks generally predicts weight loss of at least 5% body weight by six months of therapy, if the diet and drug continue to be used (39).

Dietary supplements purported to be helpful in weight loss are discussed in [section 9.7.3 \(Dietary Supplements and Weight Loss\)](#). No supplement currently on the market is both safe and effective for weight loss.

#### 4.4 Rule Surgical Options In or Out

Surgical options such as adjustable gastric banding, or more invasive techniques such as Roux-Y gastric bypass, sleeve gastrectomy or biliopancreatic diversion with duodenal switch surgery are recommended only for patients classified as Obesity class 2 or above (BMI >35), or as Obesity class 1 (BMI >30) with comorbidities (23). Patients who opt for the surgical route must adhere to certain dietary recommendations before the surgery is performed to show they are able to follow a hypocaloric diet. After surgery, food intake is altered and meals must be smaller because gastric capacity is considerably limited (46). Patients will be required to adhere to a strict, multi-stage diet post-surgery to heal and adjust to new gut physiology short term, as well as to promote weight loss long-term. A post-operative weight reduction surgery diet used in one hospital is shown in [Table 10](#), but there is no standard, widely accepted protocol for diet therapy post-bypass at present. Dietary restrictions must continue indefinitely after surgery to prevent weight regain, and patients will require lifelong use of appropriate vitamin and mineral supplementation to prevent deficiencies. Failure to adhere to a hypocaloric diet through such strategies as consuming large amounts of alcoholic or sugar sweetened beverages, melted ice cream, and many small but calorically dense meals will result in weight and fat gain.

While data suggests that bariatric surgery is more successful than non-surgical interventions, in promoting greater long-term weight loss and inducing initial remission of type-2 diabetes, there is a lack of evidence assessing the long-term risks, complications, and costs of bariatric surgery (238). It is important to note that post-surgery, patients are at risk for many nutritional deficiencies, which can negatively impact overall health, even in the context of weight loss. In one recent study that followed patients who had lost weight more than 50 lbs prior to body contouring procedures, those that had lost more than 100 lbs were more likely to suffer complications, with the effect being greater in those who had lost over 100 lbs from bariatric surgery compared to non-surgical means. Among patients who had bariatric surgery, the risk was highest for those who had had gastric bypass, and lowest in those who had had a lap-band or gastric sleeve (239).

**Table 10. Post Gastric Bypass Surgery Diet Used in Tufts Medical Center (47)**

Stage 1	One ounce of water per hour, typically in the hospital on the day of surgery
Stage 2	Non-caloric clear liquids, usually in the hospital the day after surgery (e.g., sugar-free Jell-O, flat diet soda, diet juice)

Stage 3	<ol style="list-style-type: none"> <li>1) 3-4 small meals per day, each consisting of a high-protein, no added sugar shake, such as Isopure or Sugar-Free Carnation® Instant Breakfast™</li> <li>2) Water or non-caloric, non-carbonated clear liquids between meals</li> <li>3) Goals of this stage are to drink 64 oz fluid per day 50-60 grams of protein a day for women and 60-70 grams of protein per day for men</li> <li>4) This stage lasts 2-3 weeks</li> </ol>
Stage 4	<ol style="list-style-type: none"> <li>1) Small portions of moist, ground/pureed foods.</li> <li>2) Begin supplementing with a multivitamin plus minerals, Vitamin D with calcium (specifically calcium acetate), and sublingual Vitamin B<sub>12</sub></li> <li>3) Aim for 60-70 grams of protein per day</li> <li>4) This stage lasts 4-5 weeks</li> </ol>
Stage 5	<ol style="list-style-type: none"> <li>1) Small portions of low-fat (&lt;3-5 grams per serving) or low-sugar (&lt;14 grams per serving) solid foods</li> <li>2) At least 64 ounces of fluid per day</li> <li>3) Aim for 60-80 grams of protein</li> <li>4) Continue to take supplements</li> <li>5) Follow this 6-8 weeks after surgery and follow up with a Registered Dietitian</li> </ol>

**Note:** Post Gastric Bypass Surgery Diet Used in Tufts Medical Center is adapted with permission from Melissa Page MS, RD, LDN, Weight and Wellness Center, Tufts Medical Center, Boston, MA.

There are many tools aid in accessing obesity and

well as in determining appropriate treatment options. One such tool is the *American Society of Bariatric Physicians Obesity Algorithm* (292). Another useful tool is the algorithm in the “2013 Guideline for the Management of Overweight and Obesity in Adults,” which was created by the *American College of Cardiology/American Heart Association Task Force on Practice Guidelines* and *The Obesity Society* (23).

available to practitioners to its related health risks, as

## 5. SET GOALS

Goal setting is an important part of achieving weight loss. This section outlines steps in goal setting that are successful for weight loss/ or weight maintenance.

### 5.1 Clarify Reasonable Goals

In 1998 the National Institutes of Health (NIH) issued guidelines recommending that healthcare professionals advise obese patients to lose weight. Evaluating the effect of these guidelines somewhat later, one study examined the proportion of obese patients and those that actually received advice between 1994 and 2000. The proportion of patients that were obese and received advice to lose weight from physicians during routine medical check-ups decreased from 42.3% in 1994 to 40.3% in 2000. Among those that did receive advice to lose weight had 2.8 odds of trying to lose the weight opposed to those who did not receive any advice (48). In addition to the NIH guidelines, in 2003, the U.S. Preventative Services Task Force (USPSTF) recommends that clinicians screen all adult patients for obesity and offer intensive multi-component behavioral intervention to those affected individuals. Primary care physicians play a critical role in screening adults for obesity and providing appropriate treatment (49). Even with these national recommendations and guidelines, it is still a challenge for healthcare providers to manage obesity (50). Another challenge is who is to pay for it, since many insurance plans do not, and many of those who are obese do not have the money to pay for treatment out-of-pocket. In 2009, less than 50% of obese patients received weight loss advice from physicians, citing many barriers to counseling and intensive treatment of obesity (50). This study concluded that there is a general lack of consensus about the best approach to weight loss; however, this can be improved if counseling skills are developed early during training of physicians in treating obesity (50).

As demonstrated in the study mentioned above, those patients who received advice to lose weight were almost three times more likely to attempt weight loss, so it is important for health professionals to discuss weight loss with their obese patients. The approach used by health professionals when treating obese patients and helping them to set goals is most effective when it is non-judgmental, respectful, and empathetic. This allows patients to feel comfortable with discussing their weight. The focus should

be on an acceptable weight to achieve better health outcomes rather than simply reaching a lower body weight (51-53). Furthermore, health professionals must always keep in mind that overweight or obese patients might be hesitant to broach the topic of weight loss, but indeed want assistance in discussing, setting and achieving weight loss. By speaking and working with patients as partners in reaching their weight goal, health care providers can play a big hand in improving their patients' health.

Understandably patients do not like the terms "obesity," "fatness," or "excess fat," and are more receptive to terms such as, "weight" and "excess weight." It may be difficult for health care providers to bring up the topic of weight loss, but for more tips and advice, healthcare providers can visit The National Institutes of Health's Weight Control Information Network (WIN) at <http://win.niddk.nih.gov/publications/talking.htm> for more information on discussing obesity with patients and for some examples of how to bring up the topic of weight loss with patients.

Determining whether a patient is motivated to lose weight is pertinent and the first order of business, since patient involvement and investment are essential for weight loss success. If a patient is not ready to engage in weight loss, discuss the importance of weight maintenance and physical activity at visits until the patient is ready to begin weight loss therapy (24). Once the patient expresses the desire to lose weight, determine the patient's weight-related goals and ascertain that goals are realistic and attainable. Agreeing on realistic goals facilitates maintenance of weight loss (54). Unrealistic goals should be discussed and made into more achievable ones. Additionally, patients need to be reassured that the counselor, or healthcare provider, is interested in their health as individuals. Providers should not assume that all of their obese patients' health problems are weight-related (55), nor should they fail to treat these other problems even if the patients refuse treatment for the obesity. The health care professional's job is to reduce health risks and improve quality of life to the greatest extent possible within patients' wishes (56).

On their own, patients often choose to lose weight using drastic measures, such as fasting or very, very low calorie diets, to get fast results even though there is no evidence that they are the best for losing weight. Healthy weight loss is key for long-term weight maintenance (54;57). Intensive, very low-calorie diets (VLCDs; e.g.,  $\leq 800$  calories per day and especially  $< 500$  calories) produce significantly greater initial weight loss, however, these results are often not maintained over time (58). In a study done in 2008, participants were enrolled in a program designed to help maintain weight loss. Participants all initially lost weight using one of three methods, VLCD, commercial programs or a self-guided approach. At the start of the study, those who had used a VLCD lost up to 24% of highest body weight in the last two year compared to those in the commercial programs and self-guided approaches who lost 17%. Results showed that those who used a VLCD regained significantly more weight than the other two groups by six months in the weight maintenance program. However, those who had lost weight using a self-guided method were able to maintain their initial weight loss with great success (58). It should be emphasized that the primary reason for losing weight is for better health outcomes; therefore, weight loss should occur by using healthy methods, ones that can be maintained throughout life. Concentrating on improving health outcomes and other risk factors rather than simply on weight loss is vital.

Once it is established the patient is motivated, health professionals should begin by working with the patient to set realistic, achievable, and sustainable weight loss goals (57). From the medical perspective, an ideal weight goal is one that will maximize health related effects while minimizing disruption to the patient's quality of life. This allows the patient to incorporate dietary



changes into daily life and therefore incorporate them into their lifestyle to maintain weight loss. Physicians have access to measurements of weight-related risk factors that will be improved if weight is lost. Therefore they are uniquely qualified to define and communicate what a "healthier" weight should be for the patient. Nurse practitioners, registered dietitians, physician assistants, and others should reinforce the message the physician gives, and carry out the actual therapy.

There is no single target weight that will meet every one's goals. Optimal weight reduction targets vary depending on the patient's weight and co-morbidities. Progress toward healthier weight goals should involve a gradual approach that minimizes health risks and is timed to the patient's level of readiness. Excess emphasis on aesthetic and cosmetic aspects of weight loss should be avoided. Most patients may have unrealistic ideas of how much better they will look with weight loss so it is important to stress the health advantages of even modest weight loss (i.e. a half-pound per week) (59). While some cosmetic improvement is possible with a weight loss of five to ten pounds, it rarely meets the patients' expectations, which can be discouraging. Patients need to have a realistic weight loss target set for themselves, which they have developed during counseling session with a health professional. In time, greater weight loss may be possible if realistic goals are adopted, met, and sustained. The aesthetic and cosmetic effects of weight loss are "extra benefits." The primary medical concern is to help the patient lose enough weight to improve or maintain his/her health.

## **5.2 Adopt Realistic Goals that Include Health Objectives**

A healthy target for loss is usually to achieve a weight loss of one-half to two pounds of body weight each week over six months (24 weeks), leading to a decrease of 5 to 10% in body weight from baseline. For example a 250 pound, 5'6" woman with a BMI of 40 that lost 12.5 pounds over six months, would have a 5% weight loss, and an ending BMI of 38.5. A 10% weight loss would result in a BMI of 36.3. The goal is to maintain this weight loss over time, and that is never easy. A weight loss of 5 to 10% is achievable and moderate enough to decrease some obesity-related risk factors, such as type 2 diabetes, hypertension, cardiovascular disease, and sleep apnea (9).

The recommendation of dieting for six months rather than a longer amount of time is a practical one because after about six months, most patients have great difficulty sustaining adherence to any diet, particularly if it is very rigorous. Weight plateaus as energy intake fluctuates and resting metabolic rate and energy output decrease. After six months of weight loss, patients should focus on maintenance of the weight loss through a combination of diet therapy, physical activity, and behavior modification. If successful, after several months they can start a weight loss cycle again. When patients do not engage in a weight management program that includes all three components, the risk they will regain all or some of the weight increases (57;60). Most individuals regain one-third of their lost weight in one year, and nearly half return to their original weight within five years (54). The more frequently a patient has contact with his/her health care provider, the weight loss and maintenance outcomes tend to be more successful (57).

### 5.3 Define Achievable Successful Outcomes for Weight Reduction with the Patient

Patient weight goals depend on their motivation and their perception of health risks, in addition to other aspects of their lives unrelated to health outcomes. Some patients simply are not motivated to lose weight, or they may be motivated but unwilling or unable to make any changes at present. It is unreasonable to provide an unmotivated patient a weight loss goal that they do not wish to achieve. Instead it would be beneficial to come to an agreement about the steps the patient is willing to take to begin to improve their health. One of the newer techniques used in counseling is “*motivational interviewing*” (MI); an egalitarian, empathetic approach to counseling. It uses specific strategies, such as reflective listening, positive affirmation, and agenda setting to engage the patient in health behavior changes that will facilitate weight loss. The goal in MI is to assist individuals to work through their ambivalence about behavior change and to find what motivates them internally. Patients understandably often have strong aversions to the weight loss process, so MI counselors reflect the patient’s doubts and work through those with the patient. The process also provides opportunities for the patient to voice concerns about remaining overweight or gaining even more weight, which might serve as motivation to begin losing weight or gaining more control of their weight. MI can be more effective than the counselor simply stating facts to counter the beliefs and doubts of the patient and often enables patients to develop their own reasons and plans for change. Individuals are more likely to accept and act upon their own choices and opinions when they voice them themselves (30).

For patients who are already motivated, the weight loss process can begin much faster because the patient is already willing to make changes. However, it is important to check what they think they will accomplish and when. Their patients’ weight loss targets are often unrealistically low and their time frames unrealistically short (e.g., targets of 25% or more of body weight in a few weeks rather than many months). Numerous studies have shown that obese individuals hope to lose 25 to 35% of their initial weight within a year or less after beginning obesity treatment. Realistically, patients lose only 5 to 15% of their initial weight over a year after beginning any kind of obesity treatment. Unfortunately, many dieters still maintain unrealistic standards even when they are repeatedly informed that their goals may be unrealistic (61).

For example, in one recent assessment, the before-treatment weight loss goals of 45 obese women were assessed, and the women were randomized into a behaviorally based weight-loss program over 48 weeks. While 8 to 10% of weight loss would have been a success from a medical perspective, the women identified a loss of 32% of their body weight as ideal. At the conclusion of their 48-week treatment, the women lost an average of 16% of their total body weight. Even though their weight loss was more than medically expected, the women collectively considered this loss to be “disappointing” (54). This study illustrated how most patients’ ideal weight loss goals are unrealistic and often two to three times what most patients achieve (62). For these types of patients, counseling on more realistic targets and time frames is helpful.

Because patient weight goals are often very different from those of their healthcare providers, health professionals must clearly understand patient expectations for treatment and understand the rationale behind these patient expectations. It may be necessary to work with the patient to re-evaluate changes in expectations over the course of treatment (54). Providing patients with verbal and written information on how much weight they can expect to lose with obesity treatment is helpful in communicating

and setting realistic weight loss goals (61). When patients' ideals of drastic weight loss are not met within their preferred time frame it leads to disappointment and frustration, so these dramatic goals must be addressed at the onset of treatment. It is also important to praise patients once they begin to make positive behavior changes. It helps them feel as though their efforts have been acknowledged and motivates them to maintain their new habits and continue to lose weight or stop gaining more weight. Health professionals should be sure to frequently remind their patients of the health benefits that a 5 to 10% weight loss will offer.

#### **5.4 Define Dieting Success in Broader Terms than Weight Loss Alone**

Definitions of success are always patient-specific, but health professionals should emphasize the importance of health outcomes rather than how the patient would like to look as their definition of weight loss success. The definition of successful obesity treatment includes goals other than weight loss, and these broader health goals need to be communicated to patients. The reduction of risk factors and co-morbidities, even if weight is not lost, is a "success" from the health standpoint. For some patients, prevention of further weight gain after years of a slow, steady increase in weight is "progress." The maintenance of a reduced weight, even if it is still within the range of obesity as clinically defined, is also a "success". Some outcomes to focus on include improved metabolic profiles such as, lower blood pressure, serum cholesterol, or fasting blood glucose. The following health behavior changes also denote success: increased daily physical activity and fitness; greater healthfulness of eating patterns, such as more consumption of fruits, vegetables and fiber; and reduction in dietary fat. Changes in specific unhealthful habits such as smoking, or overindulgence in alcoholic beverages, are also reasonable measures of success that may help enhance self-esteem, self-efficacy, quality of life and functional capacity (24;5).

#### **5.5 Set an Individualized "Healthier Weight" Target with the Patient**

Patients can be unreasonably hard on themselves and fear that losing weight requires drastic measures. An initial healthy weight goal of 1-2 BMI units often requires much less extreme measures than patients think. For example, a 5'4" woman weighing 250 pounds with a BMI of 43 losing 5% of her body weight, or 12.5 pounds, will have an ending BMI of 41. This amount of weight loss could take up to 25 weeks, if she loses one-half a pound per week. Weight loss of one-half a pound to two pounds per week is reasonable and offers the best chance for long-term success, but for extremely heavy people, this may take many months or years. However, as mentioned before, weight loss of even 10% of initial body weight, if sustained, significantly reduces risks of coronary heart disease and other co-morbidities (9;63). Obese patients often expect to lose 25% to 35% of their initial weight over the first year of obesity treatment. Dieters often maintain these expectations even when they are repeatedly informed that their goals are likely unrealistic—even with pharmacological treatment, so the message needs to be repeated (61).

#### **5.6 A Reasonable Target: 10% Loss of Body Weight over 6 Months**

A 10% weight loss target can be achieved in most patients with a caloric deficit of 500 to 1,000 calories per day, leading to losses of one pound to two pounds per week. For women, a weight reduction plan of eating approximately 1,000 to 1,200 calories per day is suitable. According to the National Institutes of Health and the National Heart, Lung, and Blood Institute, a 1,200 - 1,600 calorie allowance for men or women who weigh 165 pounds, or more, and who exercise regularly is recommended. These calorie

amounts along with increased physical activity and behavioral modification will likely produce a caloric deficit to achieve the targeted weight loss plan of one to two pounds per week (64). With a caloric deficit of 500 to 1000 calories per day, if followed with perfect adherence, after six months, weight loss of 26 to 52 pounds would be expected. However, in reality, losses are usually between 20 to 25 pounds, since adherence is never perfect (65).

A decrease of one BMI unit usually represents a loss of 10 to 15 pounds, but the exact amount depends on height and weight. A decrease in two BMI units over six months is another way of stating a weight loss goal. Reductions of this magnitude in weight usually decrease several weight-related risk factors such as blood glucose and blood pressure, which should result in better overall health. In addition, patients' clothing is likely to fit better and their appearance should be trimmer. If further weight reduction is necessary after 10% of initial body weight is lost, it can be attempted with an increased calorie deficit after prior weight loss has been maintained for several months. Medical nutrition therapy for obesity should last at least six months or until weight loss goals are achieved. After that it is vital to begin a weight maintenance program that includes the same three components used for initial weight loss, diet, physical activity, and behavior change to help prevent weight regain and maintain the patient's new, healthy lifestyle (57). In addition, the patient should have a strong social support network of encouraging friends and family, and/ or participate in a group where others are also undergoing weight loss treatment. With a strong social support network it is easier for patients to continue his/her healthier lifestyle (66).

### **5.7 Set an Increased Physical Activity Goal**

Physical activity is important in weight loss. Physical activity and exercise are not synonymous. Both are desirable but the first is essential. If left on their own, most dieters become more sedentary during weight loss, especially if diets are very low in calories. This is because a markedly negative energy balance reduces exercise tolerance, the body's maximal power output and increases the body's sense of perceived exertion (67). Therefore, conscious efforts to increase physical activity while dieting should be attempted. However, physical activity alone, without a reduction of calories, only induces modest reductions in body weight. Few studies to date have incorporated enough physical activity to achieve even a 5% weight loss using a physical activity intervention alone. When physical activity is paired with energy restriction, it has a synergistic effect on weight loss. Despite its modest effects on weight loss, physical activity is also essential for improving health-related outcomes relevant to many obesity related co-morbidities (e.g., heart disease, type 2 diabetes, and possibly some cancers)(68). Physical activity is also vital in preventing weight regain and may enhance quality of life (69). There is a strong association between physical activity at follow-up and maintenance of weight loss. Data from the National Weight Control Registry, a registry of more than 3,000 individuals who have successfully maintained at least a 30-pound weight loss for a minimum of one year, shows that 90% of the individuals report that physical activity is crucial to their long-term weight maintenance. They report expending, on average, 2,700 calories per week in exercise, the energy equivalent of walking four miles seven days a week (70).

## 5.8 Individualize the Diet and Other Aspects of the Treatment Program

Evidence-based reviews of successful weight control techniques increasingly emphasize the importance of individualized, multidisciplinary care in addition to realistic goals that are focused on health-outcomes and making permanent lifestyle changes, including an increase in physical activity (65;71).

The specific factors that induce a chronically positive energy balance differ among individuals. Daily lifestyle, environment, resources, and social situations may vary considerably. Weight loss strategies must, therefore, be individualized in order to promote adherence and success (5). No single diet works for everyone. Different dietary approaches for maximizing adherence are successful to varying degrees in different individuals. If asked, patients can usually identify some strategies that have worked for them in the past and health professionals can build a program starting with these strategies as starting points. Previous pitfalls can also be identified and the new weight loss strategy can be tailored to avoid them. Candidates for weight reduction should discuss the approach that best suits their needs with their physician, dietitian, or other health professional. In addition to energy content, individual food selections, meal frequency and many other factors can be tailored to make the diet better suited for the individual. Some factors to consider include the diet's cost, convenience, how it approaches treatment of co-existing health conditions, and whether it assists patients in adopting strategies for healthful life-long weight maintenance (72;73).

Many overweight patients have already tried many times to lose weight on their own. For example, in the United States 50 – 70% of US adults are trying to lose weight (74). Self-directed efforts are usually motivated by aesthetic or social rather than health-related reasons. The goals they adopt are often unrealistically ambitious, the information they obtain on weight management is often inaccurate, and the motivation and support they receive is often inadequate. Solo efforts often fail and lead to discouragement and a sense of futility (75). The vital role of health professionals is to provide motivation, information, counseling, and support for patients to be successful.

Throughout weight loss patients must be counseled on sound eating patterns. Some dietary education topics that should be discussed to help them are listed in Table 11. The National Institutes of Health ([www.nutrition.gov](http://www.nutrition.gov)), the American Dietetic Association ([www.eatright.org](http://www.eatright.org)) and other organizations, provide materials, checklists, guidelines, menus, and recipes to assist in such patient education (4;48). Resources for health professionals and for patients can also be accessed at websites such as myplate.gov, the American Heart Association (<http://www.americanheart.org/>), American Diabetes Association (<http://www.diabetes.org/>), the American Cancer Society (<http://www.cancer.org/>), and the American Dietetic Association (<http://www.eatright.org/>).

**Table 11. Checklist of Nutrition Education Topics that are Helpful to Cover in Counseling Patients on Weight Management (15;57)**

### Dietary Interventions

- Energy values of different foods
- Food Composition (calories, fats, carbohydrate, fiber, protein)
- The Dietary Guidelines for Americans
- Portion control and standard serving size (individualized)
- Meal planning and food preparation
- Recipe modification
- Avoiding over consumption of foods with high energy content but little nutritional value
- Hydration status and limiting alcohol consumption
- Discuss health risks of obesity and rapid weight loss (monitor health with a team of healthcare providers)

### Physical Activity

- Increases in physical activity (individualized)

### Behavior Change

- Reading nutrition labels
- Cooking more meals at home
- New habits of food purchasing
- Mealtime strategies to avoid overeating

- Eating strategies for restaurants and social situations
- Awareness of physiological hunger and satiety cues
- Awareness of eating and emotions
- Establishing achievable short-term and medium-term goals
- Tracking intake and physical activity to keep accountability and records of progress
- Seeking support

Patients should maintain daily records of their food and beverage intake; this helps to cue them to restrain themselves, and also the record is a visual reminder that it is important to watch one's intake. Some may also wish to include their mood at the time they ate in order to help in recognizing reasons for eating beyond hunger. Record keeping often increases awareness of consumption, and promotes dietary adherence. Patients should be encouraged to review food records each week and to identify any patterns related to eating and behavior that they can work on for the next week.

## **6. PLAN THE WEIGHT REDUCTION (ENERGY DEFICIT PHASE) OF WEIGHT CONTROL**

This section will cover guidelines for the calorie-deficit phase of weight loss.

### **6.1 General Principles**

For an individual already overweight, successful weight control first requires a hypo-caloric phase during which dietary intake is decreased while energy output is increased (or at least not decreased). This phase is referred to as the "weight loss" "energy deficit" or "hypo-caloric phase" of weight loss.

The essential components of weight loss, regardless of type of diet, are decreased energy intake, increased energy output through physical activity, behavioral modification and alterations in the environment that foster all of these measures. Although this chapter focuses on dietary measures in the treatment of obesity, all reasonable weight control programs should also include physical activity and behavioral modification.

## **6.2 Size of Caloric Deficit Needed to Lose Weight**

Obesity results from the accumulation of excessive body fat, which is stored as adipose tissue. An energy deficit of approximately 3,500 calories is required to lose one pound of fat. However, there are several factors that can influence this particular number. These include compensatory changes in resting metabolism, the energy cost of work, and discretionary physical activity, which can sometimes alter this figure by 100 to 200 calories. Over the long-term, this relationship of 3,500 calories per pound of fat holds up quite well. Thus, it is the size of the energy deficit between basal energy needs and the energy output that determines the slope of decline in adipose tissue over time. How well this energy deficit is maintained throughout the weight loss period is dependent on a multitude of factors (76). In addition, creating a calorie deficit using this rule of 3,500 calories per pound may not be applicable to everyone. Work by Dr. Kevin Hall has shown that initial body fat as well as the magnitude of weight loss can influence the applicability of this rule (76).

As previously mentioned, a reduction of 500 to 1,000 calories per day is recommended to achieve a weight loss of approximately one to two pounds of body weight per week (i.e. -3,500 to -7,000 calories total). Cutting down on alcohol, dietary fats and/or sugary caloric carbohydrates is a practical way to produce this deficit (70).

## **6.3 Goal of the Energy Deficit Phase**

The goal of dietary treatment of obesity during the weight loss (energy deficit) phase is to decrease body fat stores without unduly depleting lean body mass or otherwise compromising health. Lean body mass includes skeletal muscle and vital organs. During weight loss, some lean muscle tissue is always lost in combination with the fat loss, but the goal is to keep this loss to a minimum (64). While weight is shed, body stores of other nutrients such as water, vitamins, minerals and electrolytes must be maintained. Fortunately, dietary strategies are available to minimize loss of lean tissue and other nutrients.

A systematic review found that increased lean tissue is lost if the energy deficit of the diet is too large in combination with rapid weight loss. In contrast, inclusion of exercise (both cardiovascular and resistance) and adequate dietary protein ( $\geq 60$  grams per day, ranging from 0.8 g - 1.5 g per kg of body weight) helps to minimize lean tissue loss (73). These dietary strategies should be incorporated into dietary treatment plans to minimize lean body mass reduction and maximize fat loss.

## **7. TROUBLESHOOT DIET FAILURES**

There are many factors that contribute to patients losing less weight than expected. This section describes how health professionals can work with these patients and address the issues that are coming into play.



## **7.1 Keep Food Records: Food Intake Varies from Day to Day and it is Easy to Forget to Diet Every Day**

People vary in their eating patterns from day to day. Weight reduction prescriptions are such that the patient should aim for a caloric deficit of approximately 500 calories per day, which would achieve weight loss of about one pound per week. This can seem like somewhat of an abstract since the patient may not know how many calories he/she is eating in the first place. Since most people vary in their food intake from day to day, they have difficulty recognizing if they are eating less than they were previously. For this reason, simply urging patients to "eat less" of certain foods in general, is unlikely to produce clinically significant weight loss. Specific advice is more appropriate and easier for the patient to achieve. Examples of specific actions that decrease caloric intake include, cutting down portion sizes of high calorie, frequently consumed foods; avoiding appetizers; eliminating a second cocktail; replacing a second serving of steak at dinner with vegetables; or ordering roasted, baked, grilled, or steamed foods instead of fried, deep fried, sautéed, or creamed items when dining out.

Patients should also be advised to increase their intake of foods that are low in totally calories while also increasing the fiber content of their foods and replacing high-fat food with minimally processed, carbohydrates or proteins. A diet rich in food that is low in energy density, such as fruits, vegetables, and soups, will reduce caloric intake while also promoting satiety. This strategy is thought to be superior to a fat and portion restricted diet. A 2010 study evaluated the energy density of daily intake for three different groups. One group comprised overweight adults, another was of normal weight adults and the third consisted of weight loss maintainers (who had lost  $\geq 10\%$  of maximum body weight and kept it off for  $\geq 5$  years). Dietary intake was collected via three 24-hour phone dietary recalls and energy density was calculated using three different methods. Results showed that those in the weight loss maintainer group consumed significantly less energy per day (49). When the energy density of food is decreased, but the volume of food remains the same, calories consumed will decrease. In one study, the energy density of foods was lowered by 30%, consequently, daily energy intake also decreased by 30% (77).

Providing calorie recommendations, and instructions to keep food and physical activity records, will help patients see what factors influence their weight. Patients who record their daily food intake (i.e., food item, portion, calories, time of eating, and fat grams, if desired) as well as their physical activity for the day, are more successful in weight loss and weight maintenance efforts than those who do not (78). Some patients find it helpful to write down their emotions during their meal times to help assess whether the patient is eating out of emotion or out of hunger. The National Weight Control Registry data indicates that frequent self-monitoring of caloric intake and weight helps patients to maintain their new lower weight (79).

Patients who are able to self-monitor are more successful in weight loss efforts than those who do not self-monitor. Self-monitoring fosters awareness, an essential initial step in behavioral change. The Handbook of Assessment Methods for Eating Behaviors and Weight-Related Problems states that, "It is well established that self-monitoring or recording daily intakes via food records is a useful tool in weight loss programs" (80). Furthermore, the interplay among awareness, self-observation, recording, and self-evaluation can enhance self-management by improving how individuals attend to their health. A common

denominator among all successful weight losers is self-monitoring (57;78;79;81). Patients who use food records report they have a heightened awareness of their eating behaviors, they recognize the need to make significant dietary changes and they are more able to “stay on track.” In addition, their label reading, fat and calorie counting, and portion determination skills are improved (81). These are all important skills that overweight or obese individuals need to lose weight and/or maintain their weight at lower levels. These are also skills for making healthier lifestyle choices throughout the rest of their lives, thus improving their overall health.

## **7.2 Self-reports of Energy Intake are Almost Always Underestimated**

The average, healthy, adult, American male consumes approximately 2,800 calories per day, and the average female about 1,800 calories. Yet, such intakes are seldom accurately reported in a diet recall or food log. Usually, the recall or food log will show a much lower calorie intake. Reporting energy intakes is difficult, even for individuals who have been trained to do so accurately. In other words, people are widely unaware of what or how much they are eating on a daily basis. Even small omissions or inaccurate portion size reports could subtract hundreds of calories from the total calorie consumption of the day. Several days of observation are necessary to achieve accurate calorie intake since energy balance is achieved over weeks, not days. Thus, a report from any given day is certain to have a considerable amount of random as well as probably systematic error when used to estimate usual calorie intake.

Underreporting of energy intakes is common and usually off by a large margin (20%) in virtually every patient, and particularly so among the overweight population (82). Objective biomarkers of energy output such as doubly labeled water indicate that underreporting could be as great as 1,200 calories per day in very obese persons (83;84). Subjective reports of energy intake are often so low that if they were actually true, those patients should be losing weight. But in fact, they are gaining weight. It is biologically impossible to gain weight on a hypo-caloric diet, so underreporting must be considered (85).

The most common problem arising from these errors is that patients' actual weight loss is usually less than was desired. This could be a result of underreporting and underestimating intake. Typically, when overweight people report their intakes by recall, they often underestimate their intakes by 30 to 40%. These patients are likely to make similar mistakes in underestimating their intakes on reducing diets because of difficulties in portion size judgment, forgetting, the social desirability of reporting adherence to the prescribed regimen, and other factors. This can be explained by the “flat-slope phenomenon,” which describes how individuals with a high intake of food tend to underreport their intake while those with a low intake of food tend to over report (48). For example, many people underestimate or forget that their very large food intake on weekends “counts”; or they forget to count alcohol, snacks, or something they may have had a second helping of. Thus, on a 1,200-calorie diet, actual consumption may be 2,600 calories or more on some days, and weight loss understandably slows.

Methods for assisting dieters in minimizing diet recall errors would be to use household measures or weighing scales to determine the portion size consumed more accurately, in addition to the use of food diaries. Portion-controlled liquid meal replacements,

frozen low calorie entrees, and other foods that are fixed in portion sizes might also be helpful in not only portion control but also in reporting that intake because the portion size is usually labeled (see [10.3 Formulas and Meal Replacements](#)).

Consistency in reporting intake does not necessarily mean that the reported intake is accurate, which is especially true for those who are morbidly obese. Underreporting is also especially pronounced among women, smokers, and those of low educational and socioeconomic status (83). In addition, those who underreport tend to be consistent under-reporters, and so they are difficult to detect since the records are all similar (83). In spite of these limitations, patients who keep food journals or diaries, are more successful in losing and/or maintaining weight loss than those who do not (78). Additionally, self-reports are useful for the patient and counselor alike to obtaining clues on dietary patterns that may be helpful in working through barriers to weight loss.

### **7.3 Remind Patients to Stay Active: Self-reports of Energy Output Tend to be Over Estimated**

Self-reports of energy output as measured by physical activity questionnaires have been validated using doubly labeled water methods. Some lengthy questionnaires used for research purposes are quite accurate at estimating physical activity (86). However, the shorter questionnaires, used clinically, are not accurate for individuals (87). As is the case with dietary recalls, physical activity questionnaires may be useful for self-monitoring, but should not be used for prescribing or assessing energy intakes or outputs exactly. Motion sensors (pedometers or accelerometers) have become popular in recent years. Accelerometers and pedometers provide objective physical activity measurements and are sensitive to walking (88). Either is a worthwhile purchase to help in self-monitoring of physical activity.

Accelerometers measure the body's acceleration in one direction for long periods. In contrast to the pedometer, an accelerometer distinguishes between different walking speeds and intensities. Many accelerometers also record the amount of steps taken, allowing comparison with pedometers. Accelerometers have been validated as accurate forms of measurement in regards to steps counted (88). On the other hand, pedometers are less expensive because they measure only step count and not walking speed so this may be a better option for someone who is not willing or able to purchase an accelerometer. Unfortunately, pedometers are less sensitive to detecting steps if a person is walking slowly (e.g., less than two miles per hour). When walking at this slow of a pace, pedometers underestimate step count by approximately 50 to 90%. However, if a person is walking above 3.5 miles per hour, most pedometers approach 100% accuracy in step count (89). If a patient chooses to purchase a pedometer, piezoelectric pedometers are best because they are more accurate than spring-levered pedometers. This is especially true for obese or elderly individuals, who are more likely to walk at a slower pace, because these pedometers measure slow walking speeds more accurately (89;90).

If a motion sensor, either a pedometer or accelerometer, has a calorie counter built in, it could be inaccurate. Rather than focusing on the calories burned according to the motion sensor, patients should focus on the number of steps walked per day. Goals of a

certain number of steps each day can be prescribed and patients are able to monitor their progress on their own. One common step count goal is 10,000 steps per day. However, most patients need to work up to that number so they should set smaller, more achievable goals until they feel they can reach the ultimate goal of 10,000 steps. The basic point is that if the patient can be induced to walk 10,000 steps a day or to gradually increase the number of steps he walks no matter how low it is, progress is being made, and the finer points of absolute accuracy can be disregarded. The ability for patients to quantify physical activity in a tangible way fosters commitment, encourages performance, provides a realistic goal, and eventually may provide a feeling of self-accomplishment.

### **7.3.1 Compensatory Decreases in Energy Output Occur on Most Reducing Diets**

Unconscious compensatory decreases in physical activity usually occur on reducing diets, particularly if diets are at a very restricted calorie level. These decreases in physical activity result in slower weight loss. As a rule of thumb, if a person is decreasing calorie intake by 500 calories, there is a corresponding decrease in energy output of about 165 calories. This is a result of decreased resting metabolic rate, decreased discretionary physical activity and a decreased in energy used moving the body, which results in only a 335-calorie deficit rather than a 500-calorie deficit. So, the caloric deficit may be less than anticipated and actual weight loss becomes less than desired (91). Energy balance seems to be more strongly preserved during energy deprivation than during energy surplus, which impedes weight loss to a greater extent (92-94). This retarding effect on weight loss may be due to compensatory slowing down of resting basal metabolic rate, decreased non-obligatory physical activity and decreased thermogenesis. By including physical activity during the weight loss phase, these alterations can be alleviated to some extent, through greater energy output and preservation of lean tissue (10). Health professionals can use this information as an additional incentive for patients to maintain physical activity.

### **7.3.2 Physical Activity Guidelines for Americans who are Overweight**

All weight loss programs should include physical activity. According to the 2008 Physical Activity Guidelines for Americans, recommendations for weight loss include engaging in 45 to 75 minutes of moderate-intensity activity per day. This can include activities such as, walking at least three miles per hour, participating in water aerobics, ballroom dancing, or gardening. Alternatively, individuals could instead participate in 22 minutes of vigorous activity per day, such as swimming, jogging, jumping rope, or hiking. Once an individual loses weight, physical activity and exercise are still important for maintaining weight loss. For weight maintenance, 60 minutes of moderate activity per day or 30 minutes of vigorous activity per day is recommended. In addition, weight resistance activities, which involve all the major muscle groups, are recommended for two or more days per week. If these recommendations cannot be achieved, it is helpful to stress to the patient that some activity is better than none. These national recommendations should be used as goals but it may take time to reach those goals. It is a good idea to start where the patient feels comfortable and confident that they can accomplish their goals before overwhelming them with requirements of great amounts of exercise.

## **7.4 Remind Patients that Shifts in Water Balance May Obscure True Decreases in Body Fat and Overestimate Fat-related Weight Loss**

Dramatic decreases in weight often occur on reducing diets, particularly in the first few weeks. This is especially true for those on severely hypo-caloric regimes (with deficits of 1,000 calories per day), those on ketogenic diets, and those on very low carbohydrate diets (95;96). The type of fluid shift (loss or increase of fluid) depends on the caloric level and macronutrient composition of each diet. For example, high protein, low carbohydrate diets increase obligatory urine volume due to greater urinary loads of nitrogen, ketones, and other solutes (particularly sodium, if they are low in sodium), and will result in increased fluid losses. Increased loss of lean tissue is also associated with large fluid losses because of loss of nitrogen from tissues, such as muscle, along with water, which comprises most of the lean tissue. Fluid losses are also more apparent on hypocaloric regimes that are very low in carbohydrate (<100 grams/day and especially <50 grams of carbohydrate), since they are insufficient to replete glycogen stores, and glycogen consists largely of carbohydrate and water. Shifts in water balance may cause very dramatic deviations from the usual linear slope of weight loss. They may also cause rapid weight accumulation over just a few days if there is a period of non-adherence. This is a result of the body storing glycogen and water when the dieter eats a large carbohydrate load after a period of carbohydrate deprivation. Fluid accumulates rapidly because for every gram of glycogen that gets stored, three grams of water are stored with it. Thus, gains or losses of glycogen are associated with large changes in body water balance and water weight. These shifts can be sudden and alarming to patients (96).

### **7.4.1 Weight Loss Varies with Water Balance Shifts**

Water balance and weight often shift during the initial period of weight loss programs, particularly on very low carbohydrate diets. As glycogen stores are depleted in response to reduced carbohydrate intake, there is an increase in fluid loss, which produces an initial and often dramatic weight loss. However, the steep rate of initial weight loss will not continue. Patients should be reminded that one-half to one pound per week of fat loss is a realistic, achievable goal that will improve their health. Additionally, they should be told that it is difficult to continue losing weight at such a rapid pace. Since glycogen stores are likely depleted, and the initial diuresis has already been achieved, there is less water weight to lose. A recent position paper on Weight Management concluded,

### **7.4.2 Remind Patients that Fat Loss and Weight Loss Do Not Always Track over the Short Run, Although They Do Over the Long Run**

In the long term, fat loss and weight loss closely parallel each other. However, this is not necessarily true at the beginning of obesity treatment. The amount of weight that is lost over time, particularly in the beginning (the first several days) depends not only on the energy deficit from metabolic needs, but also on adherence to the weight reduction plan (76). Additionally, shifts in water balance may be considerable over the short run. These shifts can make it seem as though more fat is being lost than in reality. It is important to educate patients about these patterns so they are aware of what is happening to their body as they go through their weight loss program.

## 8. SET THE CALORIC LEVEL OF THE REDUCING DIET

If a caloric level of a weight-reducing diet is to be set, the two general approaches include calculated-deficit and fixed-calorie diets. With calculated deficit diets, current daily caloric needs of the patient are either measured or estimated, and the deficit is derived by subtracting from those needs (70). Fixed-calorie diets have a pre-determined recommendation for total daily caloric intake, based on caloric levels that produce weight loss in clinical trials (70). Fixed-calorie diets include low-calorie diets (LCD) and very-low-calorie diets (VLCD). Calculated-deficit and fixed-calorie approaches are discussed in this section. Another approach, in which an *ad libitum* diet designed to produce a caloric deficit through restriction or elimination of particular foods, is described in section 9.

### 8.1 Calculated-Deficit Diets

From the clinical standpoint, hypocaloric diets must be defined in terms of the energy needs of the individual and the deficit that will be created, since it is the size of the energy deficit that will determine the physiological effects expected. Ideally, energy needs should be based on resting metabolic rate (RMR), while taking into account level of physical activity. If possible, RMR should be measured (e.g., with indirect calorimetry) (70), since it can vary significantly from prediction calculations in obese individuals (97). Products such as the MedGem™ indirect calorimeter can be used in an office environment to quickly, easily, and accurately estimate a patient's RMR (98), although caution should be used, since it may over-estimate RMR in overweight individuals [Anderson et al., 2014]. However, "if RMR cannot be measured, then the Mifflin-St. Jeor equation using actual weight is the most accurate for estimating RMR for overweight and obese individuals" (57;70). According to the Academy of Nutrition and Dietetics Evidence Analysis Library (EAL), the Mifflin-St. Jeor equation accurately predicted RMR using actual body weight within +/- 10% of measured RMR in 70% of obese individuals (57). Of the remaining 30%, 9% were overestimations and 21% were underestimations. Table 12 presents this equation. The individual error range was a maximum overestimate of 15% to a maximum underestimate of 20%" (24). While the Harris-Benedict and WHO equations are often used in clinical practice with reasonable accuracy, results have been mixed regarding their applications to individuals who are overweight or obese.

After calculating the patient's RMR, his/her RMR should be multiplied by an appropriate physical activity factor to provide a baseline daily caloric level for weight maintenance. Once a baseline caloric level is configured, the patient's recommended calorie intake should be reduced to facilitate weight loss. Reducing the calorie level by 500 calories is a common strategy to yield a weight loss of approximately one pound per week, although reductions of up to 750 calories per day are sometimes used (31). Another approach is to reduce current caloric intake by 30% (31). However, depending on the patient's BMI and current intake, a larger reduction in calories may be needed, as described in the following sections. Calculations for estimating energy needs and various physical activity factors are provided in [Table 12](#).

**Table 12. Estimating Resting Metabolic Rate Using the Mifflin-St. Jeor Equation (15;57;70)**

Males >19 years old

$$\text{RMR} = (9.99 \times \text{actual weight}^*) + (6.25 \times \text{height}^*) - (4.92 \times \text{age}) + 5$$

\*use weight in kilograms (kilogram), height in centimeters (cm).

Females >19 years old

$$\text{RMR} = (9.99 \times \text{actual weight}^*) + (6.25 \times \text{height}^*) - (4.92 \times \text{age}) - 161$$

\*use weight in kilograms (kilogram), height in centimeters (cm).

**Activity Factors for Different Physical Activity Levels**

	<b>Sedentary</b> Light physical activity associated with typical day-to-day life.	<b>Low Active</b> Walking about 1.5 to 3 miles per day at 3 to 4 miles per hour, in addition to the light physical activity associated with typical day-to-day life.	<b>Active</b> Walking > 3 miles per day at 3 to 4 miles per hour, in addition to light physical activity associated with typical day-to-day life: 60 minutes of at least moderate intensity physical activity	<b>Very Active</b> Walking more than 7.5 miles per day at 3 to 4 miles per hour, in addition to light physical activity associated with typical day-to-day life: 60 minutes of at least moderate to vigorous intensity physical activity
Males	1.00	1.11	1.25	1.48
Females	1.00	1.12	1.27	1.45

The major determinant of weight loss on reducing diets is size of the *actual*, and not the prescribed, caloric deficit. Thus, if energy needs can be measured or estimated with reasonable accuracy, then a calculated caloric deficit would be the preferred method



(70). Once caloric needs for current weight maintenance are determined, the deficit can be calculated by subtracting 500-750 calories, or with a 30% caloric reduction. Diets that reduce caloric intake relative to energy expenditure result in weight loss, regardless of macronutrient composition (31).

Recent advances in methodology such as mathematical modeling have demonstrated the amount of weight loss may not be as high as one might predict based on energy balance alone (99). This is due largely to metabolic slowing that occurs with weight loss, even after accounting for declines in lean tissue (100). As weight is lost, total energy expenditure declines; so fewer calories are needed to maintain weight (101). Thus, ideally, RMR should be measured periodically as weight is lost, and caloric intake recommendations adjusted accordingly. Physical activity may ameliorate some of this decline, but not all (100).

## **8.2 Low-Calorie Diets (LCDs): 1,000 to 1,200 Calories for Females, 1,200 to 1,600 Calories for Males**

The caloric level of the diet requires attention first and foremost; after this, other characteristics of the diet can be considered. Diets that reduce caloric intake to about 1,200 to 1,500 calories in women, and 1,500 to 1,800 calories in men will result in weight loss if they are adhered to perfectly, regardless of their macronutrient composition (102; 31). This is because such caloric levels will result in a caloric deficit for most overweight and obese adults. The National Institutes of Health have recommended low calorie diets of 1,000 to 1200 calories for women, and 1,200 to 1,600 calories per day for men, although adherence may be difficult with lower caloric intake (24;65). Either way, the rationale is that on such regimens, a deficit of approximately 500 to 1,000 calories per day will be created, which should result in a slow progressive weight loss of one to two pounds per week. Two sample menus and other materials at 1,200 and 1,600 calories and many aids to assist the physician are provided in the NIH monograph (65). The [ChooseMyPlate.gov](https://www.choosemyplate.gov) website also provides such materials and worksheets that can be accessed by consumers, and guide them daily through their weight loss.

It is important to recognize that when using fixed calorie reducing diet plans, that even with perfect adherence, individuals will vary greatly in their weight loss. This is because their resting energy needs and physical activity, and thus energy outputs, often differ markedly, and may fluctuate even within an individual.

The National Institute of Health's Obesity Initiative sponsored an evidence based review of low calorie diets (65). It found that on average, diets such as these reduced body weight by an average of 8% over three to 12 months of treatment, and that the losses were accompanied by decreases in abdominal fat, which is the type of adipose tissue deposition that is associated with highest chronic disease risk. However, no improvements were noted in cardio-respiratory fitness as measured by  $\text{VO}_2$  max unless the dieters also increased their physical activity (24).



There are many pre-packaged meals on the market that fit into the low-calorie diet category, including Healthy Choice®, Lean Cuisine®, and Smart Ones®. Some patients find them useful for one or more meals a day since they provide a measured and moderate amount of calories per meal. Weight Watchers®™, Jenny Craig®™, and NutriSystem™ are more structured commercial programs that also can provide pre-packed, pre-portioned food options. See Tables 21 and 23 for a list of these programs and products.

### **8.3 Very-Low-Calorie Diets (VLCDs): ≤ 800 Calories**

VLCDs supply 800 calories or less, a total of 50 to 80 grams of protein, 100% of the Reference Daily Intake (RDI) for vitamins and minerals per day, and are designed to produce very rapid weight loss while still preserving lean body mass (39). VLCDs are prescribed as a form of intensive diet therapy, which require close medical supervision, and should not be used long-term. They are intended to induce quick and significant weight loss of about 3-5 pounds weekly, or 14 to 21 kilograms over a short time (11-14 weeks). VLCD's are sometimes used to provide a jump-start to further obesity treatment. This is typically done through meal-replacement liquid diets (6), as described below. Any diet, regardless of its caloric level, that provides less than half of an individual's energy needs can be considered a VLCD for that individual. However, virtually all adults have energy needs that exceed 1,000 calories per day, and therefore any diet below 500 calories, and for most individuals, diets below 800 calories, are VLCDs. Depending on a person's caloric requirements, other regimens that are higher in calories may also be VLCD for some people with very high energy needs using this same rule of thumb; for example, a 1,200 calorie diet prescribed to a man whose usual intake is 3,000 calories would also qualify as a VLCD.

#### **8.3.1 Uses and Candidates for Therapy**

These VLCDs are reserved for special uses and for individuals at high risk because of their potential for greater adverse metabolic effects and the consequent need for more extensive medical monitoring. Possible side effects range from fatigue, constipation, nausea, or diarrhea to more serious risks such as ketoacidosis and gallstones (section 8.3.4). VLCDs are often used when the health risks from obesity are particularly acute and threatening so that it is imperative to lose weight. Other individuals can usually reduce just as well on a LCD with less risk and discomfort (103). According to the National Task Force on the Prevention and Treatment of Obesity, VLCDs in patients with BMIs >30 are usually effective in promoting significant short-term weight loss, in addition to improving coexisting obesity-related conditions (e.g., obstructive sleep apnea, poorly-controlled type 2 diabetes, hypertriglyceridemia) (104). However, these diets require close metabolic monitoring (~at least every 2 weeks), and should only be prescribed and adjusted under the supervision of a physician specializing in obesity care. Medical contraindications include recent myocardial infarction, cardiac conduction disorders, history of cardiovascular disease, renal or hepatic disease, cancer, type 1 diabetes, and pregnancy. Behavioral contraindications to their use include bulimia nervosa, major depression, bipolar disorder, substance abuse, and acute psychiatric illness. The advantages of the VLCD for patients include a rapid improvement in

blood pressure, blood glucose, serum lipids and often-psychological status. For those who require surgery, the rapid loss of weight may reduce some of the surgical risks associated with obesity.

### **8.3.2 Formulations Available**

The hallmarks of the VLCD are the low calorie level and a relatively high percent of protein; which is at least 0.8 grams, but up to 1.5 grams per kilogram of ideal body weight (39;105). Protein needs are elevated on VLCD because in the hypocaloric state, the efficiency of protein utilization for maintaining the body's lean cell mass is lessened since some of the amino acids are metabolized to produce glucose. Also, very heavy people who often are candidates for therapy have a larger lean body mass, and thus more lean tissue, as well as much more fat than their smaller peers. Even after adjustment for their greater fatness, total protein needs, which are most highly associated with the size of the lean body mass, are elevated. Therefore, higher protein levels may help to preserve protein nutritional status, although this remains to be demonstrated. VLCDs also have extremely low fat content and relatively low carbohydrate levels, making them ketogenic. Without special formulation or supplementation, the VLCD is deficient in several vitamins and minerals, specifically potassium, calcium, iron, zinc, vitamin C, vitamin B6, copper, and possibly other nutrients.

There are two major types of VLCDs currently in use; commercial and "home-made" preparations. The commercial preparations include powdered products that are rich in egg- or milk-based proteins, are mixed with water, and consumed four to five times per day. The commercial products must provide at least 70 grams of protein by law, and often contain much higher amounts of high quality protein (70 to 100 grams), 50 to 100 grams carbohydrate, and up to 15 grams fat per day, plus vitamins and minerals in amounts to meet the Recommended Dietary Allowances (RDA). These products are formulated under FDA regulatory specifications. They are convenient and have a predictable and adequate composition when used as directed. Their major disadvantage compared to home preparations is their higher cost. The formulas or prepackaged meals are relatively choice-free and help dieters avoid contact with conventional foods, which in some cases may facilitate dietary adherence and remove temptation.

Several commercial weight loss programs are available that provide an entire program of commercially prepared VLCDs plus the other essential aspects of a sound weight control program, including dietetic advice, exercise, behavioral modification, and supervision during the VLCD and post VLCD phases. The choices include the programs of HMR™ (Health Management Resources), Optifast™ (Novartis Nutrition), and Medifast™. These programs employ health professionals who are trained in weight management, and a structured program that encourages adherence. The major disadvantage is that they are expensive (\$3,000 to \$34,000 for 26 to 28 weeks), and costs may not be covered by health insurance (105). Also, there is the uncertainty that the weight that is lost will remain so over the long run. Therefore a serious psychological as well as economic investment of effort in long-term weight management is also mandatory. See [Table 13](#) for available program details.

**Table 13. Medically Supervised Meal Replacement Programs**

<b>Program/Product and Company</b>	<b>Description</b>	<b>Is product medically supervised?</b>
HMR™ (Health Management Resources)	The HMR Decision-Free™ Clinic Weight-Loss Program: food provided includes shakes, puddings, soups, entrees, bars, and multigrain hot cereals.	Yes
Medifast™	Provides special meal-plans for women, men, patients with diabetes, seniors, and teens. Six meals per day are prescribed, and foods offered include shakes, bars, soups, scrambled eggs, oatmeal, chili, puddings, and hot and cold drinks. All products are suitable for people with type 2 diabetes.	Yes
Optifast™ (Novartis Nutrition)	Comes as a powder to be mixed with water or as a liquid ready-to drink beverage. Patients are prescribed 5 packets of formula every 3-4 hours per day, in place of meals.	No

The "home made" VLCD regimens are sometimes referred to as "protein-sparing fasts", or "protein sparing modified fasts" (PSMF). This is a misnomer since they do not "spare" protein except in contrast to a total fast. They are usually based on lean meat, fish or poultry and a few other foods plus supplements of two to three grams of potassium chloride and a multivitamin/multimineral supplement in amounts approximating the Recommended Dietary Allowances (RDA). Without such supplementation, they may be nutritionally inadequate. When patients are provided with appropriate dietetic counseling and health supervision by a physician who is experienced in the use of VLCDs and other aspects of a complete weight reduction program, these formulations are also safe and generate rapid weight loss. The extremely hypocaloric versions of VLCDs (e.g., less than or equal to 800 calories per day), which are low in carbohydrate and sodium, promote a mild ketosis that gradually leads to diuresis and rapid weight loss in the first several days on the diet.

### **8.3.3 Use of Very-Low-Calorie Diets (VLCDs)**

Evaluation of general health and cardiac status is important prior to the institution of a VLCD. Evaluation of medication dosages and physician monitoring during the regimen are also important, since with weight loss dosing may need to be adjusted. Many practitioners begin the regimen with a two to four week low calorie diet (LCD) phase to assess the ability to comply with a

restrictive regimen, and to begin the weight loss process. This is followed by a 12 to 16 week VLCD phase; the regimen is limited to this amount of time to avoid excessive loss of lean tissue. The VLCD phase is then followed by a 12 to 14 week refeeding phase of transitioning back to usual foods and gradually increasing caloric levels. The goal is to increase calories from healthful foods up to 1,200 to 1,500 calories per day, increasing caloric intake by 100 to 150 calories per day (39). This helps to avoid rapid weight changes due to refeeding with restoration of glycogen stores and shifts in water balance. The refeeding phase also provides a time for assisting the dieter to plan a maintenance diet on conventional foods and to solidify a physical activity schedule. VLCD are most effective when administered as part of a more general weight control program that includes physical activity, nutrition education, behavioral modification and attention to decreasing other risk factors. If additional weight loss is needed, it is recommended that several months elapse before another VLCD phase is instituted (106). Although lean tissue is lost on most weight reduction diets, this is a particular risk on VLCD, since greater energy restrictions are associated with more lean tissue losses (73).

### **8.3.4 Safety of Very-Low-Calorie Diets (VLCDs)**

The VLCD induces semi-starvation, which has both benefits and risks to the patient. Occasionally, with inadequate commercial products, such as one sold in the 1970's that consisted of hydrolyzed collagen (an incomplete protein consisting solely of the amino acid glycine) with inadequate amounts of electrolytes, vitamins and minerals, deaths occurred (107). Today, commercial products are better regulated and are nutritionally complete by law; however, the potential for misuse still exists. Some physiological effects are inevitable on VLCDs. On VLCDs mild ketosis occurs and increases risks of dehydration, although dehydration can be avoided by ample fluid intake. Patients on VLCDs should drink at least two liters of non-caloric liquids per day (preferably water) to make up for decreased food intake and to prevent dehydration. Avoidance of caffeinated beverages is sometimes recommended, as they can further the risk of dehydration, although moderate use is not prohibited (39). Electrolyte imbalances may occur, and so may nutrient deficiencies if measures are not taken to prevent them on "home-made" VLCD, by use of appropriate supplements. Minor side effects that occur, even with appropriate physician monitoring of cardiac and general health status, include fatigue, dizziness (due to orthostatic hypotension), muscle cramps, gastrointestinal distress (constipation and/or diarrhea), and cold intolerance. The risk of cholelithiasis (gallstones) is increased, and seems to be particularly high when weight loss is very rapid (e.g., >1.5 kilograms/week). The risk of cholelithiasis can be decreased by administering ursodeoxycholic acid, including a moderate amount of fat in the diet, and limiting the amount of weight loss to 1.5 kilograms per week (105).

### **8.3.5 Effectiveness of Very-Low-Calorie Diets (VLCDs)**

Because these VLCDs are so low in energy, they usually produce a greater initial weight loss than LCDs. Patients who completed a comprehensive VLCD program including lifestyle modification lost an average of 15 to 25% of initial weight within three to four months (105). However, in comparisons of VLCDs with energy levels of approximately 800 calories versus diets at lower caloric

levels of 400 to 500 calories, the lower VLCDs did not necessarily result in greater weight loss, perhaps because compensatory reductions in resting energy expenditure, discretionary physical activity, and the lack of adherence on the lower calorie regimes thwarted weight loss (108).

There seems to be little difference in outcomes between commercial and properly formulated homemade VLCDs. The NIH expert panel review of existing studies found that preservation of weight loss over the long-term (e.g., >1 year) was not different on VLCD from that of LCD since most patients gained back 30 to 50% of the lost weight. Studies of VLCDs vary in their long-term results, but weight regain is common (~3.1-3.7 kg during 21-38 weeks afterwards) (31). Combining a VLCD with behavior therapy, physical activity, and active physician follow-up may help to prevent this weight regain, and lend to greater weight loss (109). As such, the long-term advantages of VLCDs in weight control are unclear. Although weight gain is common after cessation of VLCDs, individual clinicians may decide that the expense and quick initial weight loss are worth it for the patient (39).

#### **8.4 Fasting and Alternate Day Fasting**

Total fasting is contraindicated for weight reduction because it causes excessive breakdown of lean tissue and ketosis. Also, the compensatory decreases in resting metabolism and physical activity on total fasts are profound and counterproductive, since they lower energy output (24;5).

Short-term modified alternate-day fasting (ADF) is a relatively new dietary strategy that has not yet received enough research attention to support the effectiveness of its use. On typical ADF diets, patients consume 25% of their energy needs on the fast day, and food intake *ad libitum* the next day. Many of the ADF studies do not include control groups that undertake other dietary approaches to weight loss, plus the sample sizes have been small (15-64 subjects) and the durations short (8-12 weeks) (110; 111; 112; 113; 114). However, results to date show similar weight loss and improvements in metabolic factors as compared to studies using other dietary approaches to weight loss, as well as good adherence. For example, Varady et al found that ADF was a viable diet option, helping obese patients not only to lose weight, but to also decrease their risk of coronary artery disease (CAD) (110). Emerging evidence suggests that the relative contribution of fat and carbohydrate in ADF diets does not have an impact on weight and blood lipid profiles (115). An alternative fasting regimen that has become popular among some dieters is two days of fast followed by five days of usual eat. Further research is needed with larger samples, dietary control groups, and longer durations before ADF's widespread use for weight loss purposes, however.

An alternative intermittent fasting regimen that has become popular among some dieters is two non-consecutive days of fasting and five unrestrictive days of usual eating each week. This "5:2 Diet", developed by Dr. Michael Mosley in the United Kingdom, has spread widely throughout Europe, and now the United States. For the two fast days, men are to eat no more than 600 kcals, and women 500 kcals. Usually this consists of a very light breakfast and dinner with little or no lunch. Anecdotally, weight loss

has been similar to other dietary approaches to weight loss (~2 pounds/week) for short terms (~6 weeks). However, research is lacking on this specific type of diet, so its long-term safety and efficacy has not been tested, and its appropriateness in varying populations is currently unknown

## **9. CONSIDER THE COMPOSITION OF THE REDUCING DIET**

The composition of the reducing diet is important because it may influence both the composition of the weight that is lost and nutritional status. Several published overviews of some popular diets and the basic principles that must be considered in weight control can provide more information (72;91;102;116). Over the past several decades, the potential of varying dietary composition for purposes of weight loss has been studied extensively, yet not one universally optimal diet for all patients has emerged. “A variety of dietary approaches can produce weight loss in overweight and obese individuals” (31). The challenge for practitioners is to identify which diet would be most suited for each individual patient. This may be based on previous dieting experiences, personal food preferences, lifestyle, and other factors (57).

Dietary composition on reducing diets should be geared towards decreasing risks of nutrient inadequacy and diet-related chronic diseases. Accordingly, the diet should be adequate in all nutrients, to prevent deficiencies, while following dietary guidelines for health, performance (cognitive and physical), and well-being (24;117). Consumption of vegetables, legumes, fruits, whole grains, lean sources of protein, and water should be encouraged, with emphasis on balance and moderation (33). Diets that promote extreme restriction or unusually high intakes of any macronutrient or food should be limited to a short amount of time. Recommendations for healthful composition of weight reducing diets are outlined in the 2010 Dietary Guidelines for Americans (Table 1) and discussed further in this section.

Several studies have concluded that a reduced calorie diet results in clinically meaningful weight loss regardless of what macronutrients are emphasized (31, 118; 119). For example, in a study with 811 overweight adults placed on one of four diets, the best predictor of weight loss was dietary adherence. The targeted percentages of energy derived from fat, protein, and carbohydrates in the four diets were 20, 15, and 65%; 20, 25, and 55%; 40, 15, and 45%; and 40, 25, and 35%. After six months individuals lost an average of six kilograms, 7% of their initial body weight, and after 12 months they started to regain weight. At the end of the two-year study there were no differences in the amount of weight lost amongst participants. Changes from baseline differed among the different diet groups by less than 0.5 kilograms of body weight, and less than 0.5 centimeters at the waist. However, all of the diets reduced risk factors for cardiovascular disease and diabetes at both six months and two years (120). Similarly, a systematic review of long term randomized controlled trials comparing the Atkins, Weight Watchers, Zone, and South Beach diets showed similar modest weight loss with all four approaches [Atallah et al., 2014].

According to the most recent Guidelines for Managing Overweight and Obesity in Adults (31), which is supported by a systematic evidence review by several expert panels, clinically-meaningful weight loss can be achieved through various dietary strategies. The best predictor of weight loss is adherence to a diet that produces a negative caloric balance. Thus, practitioners and patients are challenged to work together to find the option that will best help the patient to adhere. The 15 dietary strategies identified by the expert panel are listed in the table below (31). They all produced caloric deficit, but either through prescribed calorie levels, through restriction or elimination of foods or food groups, or through targeting food groups or providing foods. The expert panel concluded that the strength of the evidence was high for these studies.

<b>Table 14: Fifteen dietary strategies identified by an expert panel as having sufficient empirical evidence to recommend for weight loss (31).</b>		
<b><u>Prescribed Calorie Deficit</u><sup>^</sup></b>	<b>Caloric Deficit through Restriction/Elimination</b>	<b>Caloric Deficit through Targeting Food Groups or Food Provision</b>
Lacto-ovo-vegetarian	High protein (30%) Zone-type (40% carbohydrate) with 5 meals daily	European Association for the Study of Diabetes Guidelines
Low calorie	Low carbohydrate (initially <20g/day)	High protein (25%), moderated carbohydrates (45%)
Low glycemic load	Low fat (10-25%) vegan-style	Moderate protein (12%), higher carbohydrate (58%)
Low fat (<30%), high dairy & fiber	Low fat (~20%)	High or low glycemic load meals
Macronutrient targeted*	Low glycemic load	
Mediterranean-style		
AHA-style step 1		

<sup>^</sup>Calorie prescription was either calculated or fixed, as described in section 8

\*Macronutrients have ranged 15-25% protein, 20-40% fat, and 55-65% carbohydrate in these studies

## 9.1 Macronutrient Distribution

As described above, the macronutrient composition of the diet does not appear to play a major role in overall weight loss; reduced-calorie diets result in clinically meaningful weight loss regardless of which macronutrients they emphasize (121; 118).



There is one exception: over the short term, low carbohydrate diets are ketogenic, and may cause a greater loss of body water than body fat (at least in the first few days of the diet). Water weight is regained when the diet ceases, or when carbohydrate intake increases. In this case, glycogen stores, which hold water, are regained. Generally, when any reducing diet is maintained over the long term, if it remains hypocaloric, it will result in a loss of body fat – regardless of the distribution of macronutrients.

Although weight loss is caused by many reduced-calorie diets, the nutritional adequacy of different calorie levels and macronutrient composition for weight loss diets varies (122). The lower the reducing diet is in calories, and the more its composition differs from usual levels, the greater the risk of nutrient inadequacy. For the most part, moderate fat, balanced macronutrient reduction diets are nutritionally adequate. Very low-fat diets tend to be deficient in vitamins E, B12, calcium, iron and zinc. High fat, low carbohydrate diets are nutritionally inadequate, and require supplementation to make them nutritionally adequate in many nutrients (96;123;124). They are often low in fiber, so constipation may occur. In this case, fiber supplements and ample water intake may be recommended. Dietary supplements used on weight reduction diets should be within RDA levels and below upper safe limits.

Metabolic parameters may improve on some various popular diets including decreased blood pressure, blood lipids, blood sugar, and serum insulin, related to energy restriction and weight loss, regardless of the macronutrient composition of the diet. However, there are some differences. Moderate fat, balanced nutrient reduction diets lower low-density lipoprotein (LDL) cholesterol, normalize plasma triglycerides, and normalize ratios of HDL/total cholesterol. High fat, very low carbohydrate diets result in ketosis. Low and very low-fat diets (e.g., 15-20% of calories) reduce low-density lipoprotein (LDL) cholesterol, and after a transient rise in triglycerides, may also decrease plasma triglyceride levels. Low carbohydrate diets (e.g., <100 grams of carbohydrate) that result in weight loss may also cause a decrease in blood lipids, blood glucose and insulin levels, and blood pressure. However, these diets are often high in saturated fat, total fat, and in dietary cholesterol, and low in plant-based nutrients such as fiber, so variability in metabolic responses may be seen, due in part to genetic predisposition. Moreover, these diets are ketogenic, often causing signs and symptoms such as diuresis, dizziness, halitosis, fatigue, weakness, hypotension, and malaise.

Hunger may vary on the different diets, and also from one individual to the next, but little objective evidence is available for comparing different reducing diets on their anti-hunger effects. Many factors affect hunger, appetite and subsequent food intake, including interactions between physiological and non-physiological factors. Schoeller and Buchholz speculate that a greater consumption of protein may increase satiety, which in turn results in better adherence to hypocaloric diets, however, substantial long-term evidence to support this supposition is lacking (124), and more research is needed in this area.

Long-term dietary adherence is likely to be a function primarily of psychological and lifestyle issues rather than macronutrient composition itself. At present little is known about the nutritional or other characteristics of diets that maximize adherence. It is likely that "one size does not fit all" in this respect, so the importance of individualization is underscored.



## 9.2 Protein

This section outlines dietary protein needs during weight reduction. The Recommended Dietary Allowance for protein is 0.8 grams per kilogram per day, but most Americans eat about 1.2 grams per kilogram per day, or approximately 15% of their total caloric intakes from protein. For people in energy balance and at a stable weight, the World Health Organization (WHO) recommends that dietary protein should account for approximately 10 to 15% of energy intake (125).

### 9.2.1 Protein Needs During Weight Reduction

Protein requirements tend to rise on hypocaloric diets, especially on VLCDs when protein is burned for energy. Thus, protein needs increase so that loss of lean body mass can be minimized. This is because when energy intakes are insufficient, glucogenic amino acids are used to maintain blood glucose levels and other ketogenic amino acids must be used for energy, so overall protein requirements increase. Fortunately, the hormonal milieu in hypocaloric states spares nitrogen to some extent and causes preferential use of fat for energy. However, fatty acids cannot be converted to blood glucose, so glucogenic amino acids are needed for this. Inevitably, as adipose tissue is mobilized some lean tissue is lost and consequently some nitrogen is also lost. Losses of water, calcium, phosphorus, potassium, and vitamins follow the loss of lean tissue. Excess losses of lean body mass can be hazardous, affecting cardiovascular function, exercise tolerance, and possibly immune responses, and thus should be avoided. As mentioned previously, excess loss of lean tissue can result from energy deficits that are too great (73).

As a rule of thumb, a minimum of 65 to 70 grams of protein is needed daily. On a VLCD, 1.5 grams of high quality protein per kilogram of ideal body weight per day is desirable, with intakes no less than, and preferably more than, 65 to 70 grams daily. Intakes may need to be even higher if the dieter suffers from certain diseases or is physically stressed, since nitrogen losses may be more extreme in these states. On diets providing 600 to 1,200 calories per day, daily protein intake should be at least one gram per kilogram ideal body weight per day. Reducing diets over 1,200 calories per day should supply at least 0.8 grams per kilogram ideal body weight, and more if the individual is physically active. Levels should remain this high after weight loss has stopped and maintenance has begun.

### 9.2.2 High Protein Weight Loss Diets

High protein reducing diets are those that provide more than 1.6 grams per kilogram of desirable weight per day. Self-prescribed high protein reducing diets vary in their composition from about 28 to 65% of energy, providing 71 to 163 grams of protein per day. They are currently popular as a new strategy for losing weight, and are usually quite low in their carbohydrate content. Some are clearly ketogenic, and severely limit carbohydrates to below 50 grams per day. Examples include the *Doctor's Quick Weight Loss*

*Diet* (126) *The Dukan Diet* (126), *Dr. Atkins™' Diet Revolution* (127), *The 17 Day Diet* (231), and various iterations of the Paleo Diet, which is discussed in more detail below. Diets that are extremely high in protein should not be undertaken for long periods of time, since their long-term safety has not been sufficiently examined.

Other diets are extremely high in protein, very low in carbohydrate and ketogenic, but also very high in fat, such as *Protein Power* (128). Two other high protein diets with enough carbohydrate so that they are not likely to be ketogenic are *The Zone* (129) and *Sugar Busters* (130).

Many high protein diets include elaborate instructions that prescribe strict, structured eating schedules, and involve limited food variety and dietary flexibility. The high protein diets that are ketogenic also induce quick initial weight loss because of their low caloric level, and their diuretic effect owing to glycogen depletion, and sodium and water loss. They may also be associated with decreased appetite due to the high protein intake, since protein may show to be particularly satiating (131;132). Ketosis has long been said to reduce appetite, although little data supports this. Nonetheless, for some patients these constraints may help them to achieve and maintain low calorie intakes over the short run.

Popular high protein reducing regimens are not risk-free, however. Many of these diets advocate very high intakes of protein from meat and other foods that are also often high in saturated fat, cholesterol and sodium while they are low in dietary fiber, antioxidants, potassium, calcium, magnesium, and some vitamins. The purine content of meat, poultry, seafood, eggs, seeds, and nuts is high, and can increase uric acid levels and risk of gout in susceptible persons. The high protein load may also increase urinary calcium loss if it is not buffered (133). In patients with diabetic nephropathy, very high protein diets may speed progression, although the data are not definitive (134). Because many high protein diets are often by default low in carbohydrate, they also can cause an increase in ketosis. Finally, these diets do not necessarily promote greater long-term weight loss as compared to other options (135;136; 118).

## **9.3 Fat**

This section outlines dietary fat needs during weight reduction.

### **9.3.1 Fat Needs During Weight Reduction**

Even on reducing diets, the human body needs small amounts (e.g., three to six grams) of essential fatty acids (linoleic or arachidonic acid). Some fat is also necessary as a carrier for the fat-soluble vitamins A, D, E, and K. Therefore the diet should not be devoid of fat. However, because fat is calorically dense, it is often decreased on reducing diets to reduce energy intake while increasing bulk.

### 9.3.2 Moderate to Low-Fat Balanced Deficit Reducing Diets

In general, levels of dietary fat, saturated fat, trans fat, polyunsaturated fat, monounsaturated fat, and cholesterol should follow guidelines from the American Heart Association (AHA) on weight reduction diets. While lower levels may be appropriate in some cases, they amply meet requirements while supporting cardiovascular health (24).

Weight reduction diets that are moderate to low in fat (20 to 30% of calories) are called "balanced deficit" diets because they maintain a reasonable balance among macronutrients similar to that recommended in [MyPlate](#), [DASH](#), and the [Dietary Guidelines for Americans](#) (15; 117). They tend to achieve most of the caloric deficit by reducing fat from the typical level in North American Diets of about 34% or more of calories to 20 to 30% fat, 15% protein, and 55 to 65% of calories from carbohydrates. Some examples of balanced deficit diets are the Weight Watchers® Diet (25% fat, 20% protein, and 55% carbohydrate, with 26 grams of dietary fiber), Jenny Craig®, the National Cholesterol Education Program Step 1 diet (25% fat), diets based on the MyPlate, the DASH diet, the Shape up and Drop 10 diet of Shape Up! America (33), and the Nutrisystem® diet. Popular diet books using this approach include *The Biggest Loser Diet* (232), *The Mayo Clinic Diet* (233), and *The Engine 2 Die* (234). These dietary patterns have been extensively reviewed and appear to be effective for weight reduction on low calorie diets for most individuals.

### 9.3.3 Very Low-Fat Reducing Diets (<20% Fat Calories)

Very low-fat diets such as the Pritikin Diet (137), the Ornish Diet (138), and *The Spark Solution Diet* (235) have been advocated not only for weight reduction, but also for improving cardiovascular risk profiles. The Ornish Diet, which is very low in fat (13% of calories) and saturated fat, very high in carbohydrate (81% of calories) and very high in fiber (38 grams), is part of a program that includes nonsmoking, exercise and behavior modification. It was shown to reduce some cardiovascular risk factors in a limited long term study (138). For those who can adhere to the Ornish regime it may be helpful. However, it may not be appropriate for all populations, such as diabetics.

### 9.3.4 High Fat Diets for Weight Reduction (55 to 65% Fat)

High fat reducing diets are also usually low or very low in carbohydrate (<200 grams carbohydrate per day). Some current examples include Dr. Atkins™' Diet Revolution (127), Protein Power (128), the Carbohydrate Addicts Diet (139), Dr. Bernstein's Diabetes Solution (140), Life Without Bread (141), the Pennington Diet (141), and the Bulletproof Diet (236). There is some evidence that free-living, overweight people who self-select high fat, low carbohydrate diets consume fewer calories and lose weight (102). This is not because the laws of thermodynamics are violated, but because they have far fewer food options, if they adhere to such rigorous regimens. When high fat, low carbohydrate reducing diets are fed they also tend to cause ketosis and diuresis. They may also result in decreased blood lipids, glucose and insulin, along with and decreased blood pressure, but only if weight is lost. Over the short term (a few days or weeks) high fat, low carbohydrate, ketogenic diets cause a greater loss of body

water than body fat, but water balance is quickly restored when carbohydrate intakes increase or when the diet ends. High fat, low carbohydrate diets are often nutritionally inadequate, so they often require some supplementation with micronutrients and fiber. If such high fat levels are continued on a chronic basis after weight is lost, they may increase dietary risks for coronary artery disease. More research is needed in this area.

## **9.4 Carbohydrates and the Glycemic Index**

The following section reviews carbohydrate needs during weight reduction, and the glycemic index.

### **9.4.1 Carbohydrate Needs in Weight Reduction**

Carbohydrate needs for most individuals are at least 50 grams per day, to fuel the central nervous system, red blood cells, and other glucose-dependent tissues. If carbohydrate intake fall below this, than gluconeogenesis is likely to ensue. The carbon source for gluconeogenesis cannot be fatty acids, so in these cases, amino acids are used to maintain blood glucose and fuel glucose-dependent tissues. At least 100 grams carbohydrate, and preferably carbohydrate within the Acceptable Macronutrient Distribution Ranges (AMDR) of 45 to 65% of total energy intake, should be provided for diets that are over 800 calories per day. Under experimental conditions, both hypocaloric diets very high in sugars (mono-and di-saccharides) and diets very high in starches (digestible polysaccharides) that are equi-caloric have similar weight loss effects (143;144). However, from the practical standpoint, since many products that are high in sugar are calorically dense and often are also high in calories, added fat, and low in fiber, vitamins and minerals; sugars are usually limited on reducing diets. Additionally, high sugar diets may increase some cardiovascular risk factors (145). From the physiological standpoint, “added” sugar, and sugar inherently in the foods, are similar in their caloric contributions.

Individuals assigned to a low-carbohydrate, high-protein diets do lose more weight at six months than those on low-fat, reduced-energy diet. However, this difference is no longer significant at 12 months (70;116;120). An evidence review from the Academy of Nutrition and Dietetics concluded that, “An individualized, reduced calorie diet is the basis of the dietary component of a comprehensive weight management program. Reducing dietary fat and/or carbohydrates is a practical way to create a caloric deficit of 500 to 1,000 kcal below estimated energy needs and should result in a weight loss of one to two pounds per week” (70). Whether an individual dieter reduces fat or carbohydrate does not matter. If calories are similar, in the long run, weight loss amounts to reducing caloric intake. Concerns regarding an increase in cardiovascular risks with low-carbohydrate diets now do not appear to be as problematic as first thought (70). If an obese person loses weight, cardiovascular risk factors usually improve (31).

#### **9.4.2 Low Carbohydrate Diets (<100 grams Carbohydrate)**

Diets providing less than 100 grams of carbohydrate per day, and especially those with less than 50 grams carbohydrates per day, are ketogenic. Ketosis can be a problem on some popular diets that are very low in carbohydrates, such as Dr. Atkins™' Diet Revolution (127), Protein Power (128), The Dukan Diet (126), Dr. Bernstein's Diabetes Solution (140), The Bulletproof Diet (236), and the Pennington Diet (142). Also, VLCs containing fewer than 100 grams of carbohydrate per day are ketogenic and may lead to excessive protein breakdown to maintain blood glucose levels unless protein intakes are increased. When the body must rely on catabolism of protein to preserve blood glucose levels via gluconeogenesis, the catabolism of the protein is accompanied by loss of water. For every gram of protein (or glycogen) that is broken down, three grams of water are released, causing rapid weight loss but also a state of relative dehydration (95). Relative dehydration caused by ketosis and failure to drink adequate amounts of fluids is not only undesirable for health reasons, it reduces exercise tolerance (67). It also does not address the primary purpose of the weight-reducing strategy, which is to decrease excess adipose tissue and not water weight. One main concern with studies to date on low carbohydrate diets is that most of them do not include exercise. Since exercise tolerance declines with low carbohydrate intakes and reduced glycogen stores, more research is needed in this area before such diets can be recommended.

#### **9.4.3 Low Glycemic Index Diets**

The Glycemic Index (GI) was originally developed for the therapy of diabetes, but it has gained popularity in weight management. The GI describes the blood glucose response resulting from consumption of a defined amount of carbohydrate (usually 50 grams) from a given food, relative to the response of the same amount of carbohydrate from a control food (usually white bread)(146). In brief, the GI is an alternative system for classifying carbohydrate-containing foods according to their postprandial blood glucose responses to portions containing standardized amounts of carbohydrates (30). Since the GI is based on standardized portions, glycemic load (GL), the product of GI and carbohydrate amount, is used to evaluate the effect of meals/snacks—differing in both quality and quantity of carbohydrates—on postprandial glycemia (30).

The basic premise is that more moderate blood glucose and metabolic responses from low-GI foods and a low GL will sustain satiety and energy balance to a greater extent than would high-GI foods and a high GL load. The GI may be important in regulating hunger, voluntary energy intake, and satiety. A high-GI meal or snack may compromise glucose uptake following a subsequent meal—a phenomenon known as the “second-meal effect.” The underlying mechanism likely involves decreased insulin sensitivity with increased concentrations of circulating free fatty acids during the late postprandial phase. With regard to a high-GI meal or snack, it is thought that, “the drop in blood glucose during the middle postprandial phase may increase the preference for high-GI foods, leading to repeated cycles of excess hunger followed by hyperphagia that may last for several hours

following restoration of euglycemia. These vicious cycles, exacerbated by the second-meal effect may contribute to disappointing long-term weight control with conventional low-fat diet prescriptions that emphasize the importance of consuming starchy foods” (30). Hence, low-GI foods are thought to help minimize blood glucose fluctuations, hunger hormones, and increase satiety.

Some, but not all, studies have conducted a follow-up period at 12 months showing that overweight or obese individuals on low-GI diets lose slightly more weight (1-3 kg) than those on high-GI diets or conventional energy restricted weight loss diets (147). Beyond short term weight loss, low-GI diets have also shown to decrease fasting glucose and insulin levels, reduce circulating triglycerides, and improve blood pressure (30;148;149). Thus, low-GI and low-GL diet plans may help some individuals lose weight, typically one to two BMI units, and help improve metabolic parameters and risk of cardiovascular disease. (148). The effects of low GI carbohydrates may also help to prevent excess weight gain, although more research must be done on their longer-term efficacy (150-152).

Consumption of whole grains, legumes, fruits, vegetables, and whole foods that are low in GI, is helpful in meeting fiber goals and may be helpful in weight management. A well balanced, hypocaloric low glycemic index diet may prove to be effective in properly educated, adherent patients who are willing to take the time to learn about high- and low-glycemic foods, and who do not completely exclude healthful high glycemic foods. For example, sausages, ice cream, and chocolate cake with frosting are all low GI foods, while parsnips, carrots, bananas, dates and potatoes tend to be high GI foods. This underscores the point that more than just GI must be considered in food choices and patients need to be educated accordingly. Since GI is not listed on food labels in most countries, and since many factors influence it, such as cooking, ripeness, and the other foods consumed at the same meal, this dietary approach may pose a challenge for some patients. Any reducing diet must be viewed as a whole. In the USA nutrient fact labels are available on most processed foods, and provide information on carbohydrate content. Therefore the GI does not offer much additional information. However labeling of carbohydrate subtypes is not done in some countries, and use of the GI is popular. As seen in the table at the beginning of this section, diets with altered GI have been applied in cases where calories were prescribed, where food was provided, and where intake was limited, and all produced similar results to other dietary approaches. However, data are limited in US populations. In summary, diets based on the GI may offer some patients benefits in terms of short and long-term weight loss, but the perpetuity of the regimen remains in question.

#### **9.4.4 Paleo Diet**

The Paleo Diet has gained considerable popularity among consumers in recent years, although no large-scale scientific study has thoroughly investigated it yet, especially for the purposes of weight loss. This dietary approach suggests that individuals consume only foods and beverages that presumably made up the diets of Paleolithic humans (153). Thus, all processed foods and beverages are eliminated in addition to grains, dairy, and legumes. Allowed foods include meats, fish, poultry, vegetables, fruits, and nuts (not peanuts). Deficits in caloric intake are achieved through elimination of large amounts of usually-consumed food

types. Advantages are that this diet tends to be high in nutrients that come from vegetables and fruits (e.g. vitamin C), and it is low in sodium and glycemic index / load (154). However, it is low in calcium, and high in cholesterol (154). While it provides satiety, many subjects find adherence difficult, due to the restriction of so many foods and beverages. To date, most studies have only tested this diet short term (10 days to 3 months), with low subject numbers (9-20), sometimes lacking control groups, and without a concurrent exercise prescription (155; 154; 156; 157). Weight loss has been comparable to other similar dietary approaches (156), and improvements have been noted for several risk factors of cardiovascular disease and type 2 diabetes (154; 157), even without weight loss (155). Patients attempting this diet while on warfarin treatment should consult their physician or dietitian due to the high vitamin K coming from the abundance of vegetables (153). More work is needed to determine long-term outcomes and adherence for this diet. Particular attention should be given to bone and gastrointestinal health, since dairy, cereal fibers, and legumes are missing from this diet [158; 159; 160].

#### **9.4.5 High-Fructose Corn Syrup and Weight**

High-fructose corn syrup (HFCS) does not contribute to overweight or obesity any differently than do other energy sources (161). HFCS has been blamed for the obesity epidemic mainly due to the association between American's increases in weight along with the increase in HFCS in our food supply since the 1970s, but similar associations are also present with bottled water sales. However, association is not causation. In 2004, Bray et al (162) hypothesized that HFCS was a direct causative factor for obesity. However, to date, there is no scientific evidence supporting this theory. As stated in White's article from *The American Journal of Clinical Nutrition*, "The HFCS-obesity hypothesis of Bray et al relies heavily on the positive association between increasing HFCS use and obesity rates in the United States. However, Bray et al treated this association in isolation, offering no perspective on trends in total caloric intake or added sweeteners use in comparison with use of other dietary macronutrients."

HFCS was introduced to the food industry in the late 1960s and was well received because it is stable in acidic foods and beverages, is easily transportable and is sweet. HFCS can be pumped from delivery vehicles to storage and mixing tanks, requiring only simple dilution before use. Furthermore, it has remained relatively inexpensive. Its sweetness mirrored that of sugar. Contrary to popular belief, HFCS is not sweeter than sucrose. The forms of HFCS in the food supply are HFCS-55 and HFCS-42 with 55% fructose and 42% glucose, and 42% fructose and 53% glucose, respectively. The remaining carbohydrates are free glucose, maltose, and maltotriose. A similar ratio of fructose to glucose as in HFCS is also in honey, invert sugar, fruit, and fruit juices (163). Table sugar or sucrose is composed of 50% fructose and 50% glucose. Hence, the ratio of glucose to fructose in both HFCS and sucrose is essentially 1 to 1. Furthermore, HFCS and sucrose both contain four calories per gram. Existing theoretical and empirical evidence suggests that fructose-induced problems are not more related to HFCS than sucrose intake (164). Total caloric intake is positively associated with BMI, independent of sugar intake (165). However, the World Health



Organization and U.S. Dietary Guidelines recommend avoidance of excess added sugars due to their 'empty calories', which may dilute dietary quality, and also may elevate some cardiometabolic risk factors (117; 145),

HFCS is not a direct cause of the obesity epidemic in the United States. To date, there is no evidence linking these two factors (161;166;167). As Forshee et al concluded, "Evidence from ecological studies linking HFCS consumption with rising BMI rates is unreliable. Evidence from epidemiologic studies and randomized controlled trials is inconclusive. Based on the currently available evidence, an expert panel concluded that HFCS does not appear to contribute to overweight and obesity any differently than do other energy sources" (161).

## **9.5 Water**

This section discusses water and electrolyte needs during weight reduction.

### **9.5.1 Water Needs on Reducing Diets Vary**

Ample fluid intake is important on weight reduction diets to prevent dehydration, especially if diets are ketogenic, very low in calories, or being undertaken in hot climates or with physical exertion. As mentioned earlier, losses of body glycogen and protein are accompanied by losses of body water. Intake of low-calorie or calorie-free fluids such as water should be emphasized (168). Water needs go up with increases in physical activity, not only due to sweat losses, but also due to increased water losses due to respiration (67). The fatigue that some dieters associate with hypocaloric diets is often due in part to dehydration, especially if they have also increased their physical activity and exercise regimes dramatically. Body water losses of as little as 2% have been associated with decreased physical and mental performance, and impaired thermoregulation (168). Some dieters may be in a state of mild dehydration much of the time, and this is unnecessary and may detract from quality of life. General water recommendations average approximately 2.7 liters (91 ounces) per day for women and 3.7 liters (125 ounces) per day for men. This includes total water intake from all beverages and water in foods. It has been estimated that 20% of total water consumption comes from solid foods (169). A fluid intake plan should be incorporated in every weight loss regimen. Non-caloric sources of fluid should be emphasized; pure water and seltzers tend to be great choices.

## **9.6 Electrolytes**

Under normal circumstances on a well-balanced diet that is not overly restrictive with energy, electrolyte balance is maintained. If an individual may be losing excess electrolytes due to high sweat or urine losses, electrolytes can usually be replaced with normal



foods (67). The American diet is overly abundant in sodium. Potassium is not so abundant but can be obtained in fruits and vegetables. Examples of foods that are high in both sodium and potassium include tomato sauces and vegetable soups. Electrolyte levels are of particular concern on VLCD, since occasionally cardiac arrhythmias have resulted from hypokalemia on such regimens (105). Since hypokalemia can be fatal, electrolyte levels must always be monitored on VLCD.

## 9.7 Vitamins and Minerals

The next section outlines vitamin and mineral needs during weight reduction.

### 9.7.1 Vitamin and Mineral Needs During Weight Reduction

Vitamin and mineral nutrition is critical during weight reduction and maintenance. The amounts of nutrients specified in Recommended Dietary Allowance (RDA) for an individual's age and sex must continue to be met, even on reducing diets for all other nutrients (See [Table 15](#) and [Table 16](#)). The lower the diet is in calories, the more likely it is that essential vitamins, minerals and electrolytes such as potassium, copper, magnesium, Vitamin E, Vitamin B6, folic acid, iron, and calcium are likely to be low. As a rule of thumb, diets below 1,200 calories per day are likely to require vitamin and mineral supplements in amounts approximating the Recommended Dietary Allowances (15). Above 1,200 calories per day, women in reproductive age groups may still need iron, calcium, and folic acid supplements, since their needs for these nutrients are high, but most other nutrient needs can be met by a well-balanced diet that follows the Dietary Guidelines for Americans (15). For this reason, foods with high micronutrient density, but low energy density are especially important to include on a reducing diet. They include fruits, vegetables, legumes, and lightly processed whole grains. [Table 15](#), [Table 16](#), [Table 17](#), and [Table 18](#) present the current DRIs for vitamins, minerals and tolerable upper levels (UL) for these same nutrients.

Table 15. Dietary Reference Intakes (DRIs): Recommended Intakes for Individuals, Vitamins (292) Food and Nutrition Board, Institute of Medicine, The National Academies												
Life Stage Group	Vitamin A	Vitamin C	Vitamin D	Vitamin E	Vitamin K	Thiamin	Riboflavin	Niacin	Vitamin B6	Folate	Vitamin B12	Pantothenic Acid

	(µg/d) <sup>a</sup>	(mg/d)	(µg/d) <sup>b,c</sup>	(mg/d) <sup>d</sup>	(µg/d)	(mg/d)	(mg/d)	(mg/d) <sup>e</sup>	(mg/d)	(µg/d) <sup>f</sup>	(µg/d)	Acid (mg/d)
Infants												
0–6 mo	400*	40*	10	4*	2.0*	0.2*	0.3*	2*	0.1*	65*	0.4*	1.7*
7–12 mo	500*	50*	10	5*	2.5*	0.3*	0.4*	4*	0.3*	80*	0.5*	1.8*
Children												
1–3 y	300	15	15	6	30*	0.5	0.5	6	0.5	150	0.9	2*
4–8 y	400	25	15	7	55*	0.6	0.6	8	0.6	200	1.2	3*
Males												
9–13 y	600	45	15	11	60*	0.9	0.9	12	1.0	300	1.8	4*
14–18 y	900	75	15	15	75*	1.2	1.3	16	1.3	400	2.4	5*
19–30 y	900	90	15	15	120*	1.2	1.3	16	1.3	400	2.4	5*
31–50 y	900	90	15	15	120*	1.2	1.3	16	1.3	400	2.4	5*
51–70 y	900	90	15	15	120*	1.2	1.3	16	1.7	400	2.4 <sup>h</sup>	5*
> 70 y	900	90	20	15	120*	1.2	1.3	16	1.7	400	2.4 <sup>h</sup>	5*
Females												

9–13 y	<b>600</b>	<b>45</b>	<b>15</b>	<b>11</b>	60*	<b>0.9</b>	<b>0.9</b>	<b>12</b>	<b>1.0</b>	<b>300</b>	<b>1.8</b>	4*
14–18 y	<b>700</b>	<b>65</b>	<b>15</b>	<b>15</b>	75*	<b>1.0</b>	<b>1.0</b>	<b>14</b>	<b>1.2</b>	400 <sup>i</sup>	<b>2.4</b>	5*
19–30 y	<b>700</b>	<b>75</b>	<b>15</b>	<b>15</b>	90*	<b>1.1</b>	<b>1.1</b>	<b>14</b>	<b>1.3</b>	400 <sup>i</sup>	<b>2.4</b>	5*
31–50 y	<b>700</b>	<b>75</b>	<b>15</b>	<b>15</b>	90*	<b>1.1</b>	<b>1.1</b>	<b>14</b>	<b>1.3</b>	400 <sup>i</sup>	<b>2.4</b>	5*
51–70 y	<b>700</b>	<b>75</b>	<b>15</b>	<b>15</b>	90*	<b>1.1</b>	<b>1.1</b>	<b>14</b>	<b>1.5</b>	<b>400</b>	2.4 <sup>h</sup>	5*
> 70 y	<b>700</b>	<b>75</b>	<b>20</b>	<b>15</b>	90*	<b>1.1</b>	<b>1.1</b>	<b>14</b>	<b>1.5</b>	<b>400</b>	2.4 <sup>h</sup>	5*
<b>Pregnancy</b>												
≤ 18 y	<b>750</b>	<b>80</b>	<b>15</b>	<b>15</b>	75*	<b>1.4</b>	<b>1.4</b>	<b>18</b>	<b>1.9</b>	600 <sup>j</sup>	<b>2.6</b>	6*
19–30 y	<b>770</b>	<b>85</b>	<b>15</b>	<b>15</b>	90*	<b>1.4</b>	<b>1.4</b>	<b>18</b>	<b>1.9</b>	600 <sup>j</sup>	<b>2.6</b>	6*
31–50 y	<b>770</b>	<b>85</b>	<b>15</b>	<b>15</b>	90*	<b>1.4</b>	<b>1.4</b>	<b>18</b>	<b>1.9</b>	600 <sup>j</sup>	<b>2.6</b>	6*
<b>Lactation</b>												
≤ 18 y	<b>1,200</b>	<b>115</b>	<b>15</b>	<b>19</b>	75*	<b>1.4</b>	<b>1.6</b>	<b>17</b>	<b>2.0</b>	<b>500</b>	<b>2.8</b>	7*
19–30 y	<b>1,300</b>	<b>120</b>	<b>15</b>	<b>19</b>	90*	<b>1.4</b>	<b>1.6</b>	<b>17</b>	<b>2.0</b>	<b>500</b>	<b>2.8</b>	7*
31–50 y	<b>1,300</b>	<b>120</b>	<b>15</b>	<b>19</b>	90*	<b>1.4</b>	<b>1.6</b>	<b>17</b>	<b>2.0</b>	<b>500</b>	<b>2.8</b>	7*

**NOTE:** This table (taken from the DRI reports, see [www.nap.edu](http://www.nap.edu)) presents Recommended Dietary Allowances (RDAs) in **bold type** and Adequate Intakes (AIs) in ordinary type followed by an asterisk (\*). An RDA is the average daily intake level sufficient; sufficient to meet the nutrient requirements of nearly all (97-98 percent) healthy individuals in a group. It is calculated from an Estimated Average Requirement (EAR) when scientific evidence is not available to establish an EAR, and thus calculate an RDA, an AI is usually developed. For healthy breastfed infants, the AI is the mean intake. The AI for other life stage and gender groups is believed to cover needs of all individuals in the group, but lack of data prevent being able to specify with confidence the percentage of individuals covered by this intake.

<sup>a</sup> As retinol activity equivalents (RAEs). 1 RAE = 1 µg retinol, 12 µg β-carotene, 24 µg α-carotene, or 24 µg β-cryptoxanthin. To calculate RAEs of provitamin A carotenoids in foods, divide the REs by 2. For preformed vitamin A in foods or supplements and for provitamin A supplements, 1 RE = 1 RAE.

<sup>b</sup> Calciferol. 1 µg calciferol = 40 IU vitamin D.

<sup>c</sup> Under the assumption of minimal sunlight.

<sup>d</sup> As α-tocopherol. α-Tocopherol includes *RRR*-α-tocopherol, the only form of α-tocopherol that occurs naturally in foods, and the *2R*- and *2S*-forms of α-tocopherol (*RRR*-, *RSR*-, *RRS*-, and *RSS*-α-tocopherol) that occur in fortified foods and supplements. It does not include the *2S*-stereoisomeric forms of α-tocopherol (*SRR*-, *SSR*-, *SRS*-, and *SSS*-α-tocopherol), also found in fortified foods and supplements.

<sup>e</sup> As niacin equivalents (NE). 1 mg of niacin = 60 mg of tryptophan; 0–6 months = preformed niacin (not NE).

<sup>f</sup> As dietary folate equivalents (DFE). 1 DFE = 1 µg food folate = 0.6 µg of folic acid from fortified food or as a supplement consumed with a meal or of a supplement taken on an empty stomach.

<sup>g</sup> Although AIs have been set for choline, there are few data to assess whether a dietary supply of choline is needed at all stages of life. It may be that the choline requirement can be met by endogenous synthesis at some of these stages.

<sup>h</sup> Because 10 to 30 percent of older people may malabsorb food-bound B<sub>12</sub>, it is advisable for those older than 50 years to meet their requirement by consuming foods fortified with B<sub>12</sub> or a supplement containing B<sub>12</sub>.

<sup>i</sup> In view of evidence linking inadequate folate intake with neural tube defects in the fetus, it is recommended that all women capable of becoming pregnant consume 400 µg from supplements or fortified foods in addition to intake of food folate from a varied diet.

<sup>j</sup> It is assumed that women will continue consuming 400 µg from supplements or fortified food until their pregnancy is confirmed and prenatal care, which ordinarily occurs after the end of the periconceptional period—the critical time for formation of the neural tube.

**Sources:** *Dietary Reference Intakes for Calcium, Phosphorus, Magnesium, Vitamin D, and Fluoride (1997); Dietary Reference Intakes for Vitamin C, Riboflavin, Niacin, Vitamin B<sub>6</sub>, Folate, Vitamin B<sub>12</sub>, Pantothenic Acid, Biotin, and Choline (1998); Dietary Reference Intakes for Vitamin A, Selenium, and Carotenoids (2000); Dietary Reference Intakes for Vitamin A, Vitamin K, Arsenic, Boron, Chromium, Copper, Iodine, Iron, Manganese, Molybdenum, Nickel, Silicon, Vanadium, and Zinc (2001); and Dietary Reference Intakes for Calcium and Vitamin D (2011).* These reports were accessed via [www.nap.edu](http://www.nap.edu).

**Table 16. Dietary Reference Intakes (DRIs): Recommended Intakes for Individuals, Elements (293)**  
Food and Nutrition Board, Institute of Medicine, National Academies

<b>Life Stage Group</b>	<b>Calcium</b> (mg/d)	<b>Chromium</b> (µg/d)	<b>Copper</b> (µg/d)	<b>Fluoride</b> (mg/d)	<b>Iodine</b> (µg/d)	<b>Iron</b> (mg/d)	<b>Magnesium</b> (mg/d)	<b>Manganese</b> (mg/d)	<b>Molybdenum</b> (µg/d)	<b>Phosphorus</b> (mg/d)	<b>Selenium</b> (µg/d)	<b>Zinc</b> (mg/d)
<b>Infants</b>												
0–6 mo	200*	0.2*	200*	0.01*	110*	0.27*	30*	0.003*	2*	100*	15*	2*
7–12 mo	260*	5.5*	220*	0.5*	130*	11	75*	0.6*	3*	275*	20*	3
<b>Children</b>												
1–3 y	700	11*	340	0.7*	90	7	80	1.2*	17	460	20	3
4–8 y	1000	15*	440	1*	90	10	130	1.5*	22	500	30	5
<b>Males</b>												
9–13 y	1,300	25*	700	2*	120	8	240	1.9*	34	1,250	40	8
14–18 y	1,300	35*	890	3*	150	11	410	2.2*	43	1,250	55	11
19–30 y	1,000	35*	900	4*	150	8	400	2.3*	45	700	55	11
31–50 y	1,000	35*	900	4*	150	8	420	2.3*	45	700	55	11

51–70 y	1,000	30*	900	4*	150	8	420	2.3*	45	700	55	11
> 70 y	1,200	30*	900	4*	150	8	420	2.3*	45	700	55	11
Females												
9–13 y	1,300	21*	700	2*	120	8	240	1.6*	34	1,250	40	8
14–18 y	1,300	24*	890	3*	150	15	360	1.6*	43	1,250	55	9
19–30 y	1,000	25*	900	3*	150	18	310	1.8*	45	700	55	8
31–50 y	1,000	25*	900	3*	150	18	320	1.8*	45	700	55	8
51–70 y	1,200	20*	900	3*	150	8	320	1.8*	45	700	55	8
> 70 y	1,200	20*	900	3*	150	8	320	1.8*	45	700	55	8
Pregnancy												
≤ 18 y	1,300	29*	1,000	3*	220	27	400	2.0*	50	1,250	60	12
19–30 y	1,000	30*	1,000	3*	220	27	350	2.0*	50	700	60	11
31–50 y	1,000	30*	1,000	3*	220	27	360	2.0*	50	700	60	11
Lactation												

≤ 18 y	<b>1,300</b>	44*	<b>1,300</b>	3*	<b>290</b>	<b>10</b>	<b>360</b>	2.6*	<b>50</b>	<b>1,250</b>	<b>70</b>	<b>13</b>
19–30 y	<b>1,000</b>	45*	<b>1,300</b>	3*	<b>290</b>	<b>9</b>	<b>310</b>	2.6*	<b>50</b>	<b>700</b>	<b>70</b>	<b>12</b>
31–50 y	<b>1,000</b>	45*	<b>1,300</b>	3*	<b>290</b>	<b>9</b>	<b>320</b>	2.6*	<b>50</b>	<b>700</b>	<b>70</b>	<b>12</b>

**NOTE:** This table (taken from the DRI reports, see [www.nap.edu](http://www.nap.edu)) presents Recommended Dietary Allowances (RDAs) in **bold type** and Adequate Intakes (AIs) in ordinary type followed by an asterisk (\*). An RDA is the average daily intake level sufficient; sufficient to meet the nutrient requirements of nearly all (97-98 percent) healthy individuals in a group. It is calculated from an Estimated Average Requirement (EAR). If sufficient scientific evidence is not available to establish an EAR, and thus calculate an RDA, an AI is usually developed. For healthy breastfed infants, the AI is the mean intake. The AI for other life stage and gender groups is believed to cover needs of all individuals in the group, but lack of data or uncertainty in the data prevent being able to specify with confidence the percentage of individuals covered by this intake.

**SOURCES:** *Dietary Reference Intakes for Calcium, Phosphorus, Magnesium, Vitamin D, and Fluoride (1997); Dietary Reference Intakes for Thiamin, Riboflavin, Niacin, Vitamin B<sub>6</sub>, Folate, Vitamin B<sub>12</sub>, Pantothenic Acid, Biotin, and Choline (1998); Dietary Reference Intakes for Vitamin C, Vitamin E, Selenium, and Carotenoids (2000); Dietary Reference Intakes for Vitamin A, Vitamin K, Arsenic, Boron, Chromium, Copper, Iodine, Iron, Manganese, Molybdenum, Nickel, Silicon, Vanadium, and Zinc (2001); and Dietary Reference Intakes for Calcium and Vitamin D (2011).* These reports may be accessed via [www.nap.edu](http://www.nap.edu).

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**Table 17. Dietary Reference Intakes (DRIs): Tolerable Upper Intake Levels (UL<sup>a</sup>) for Vitamins(293)**

Food and Nutrition Board, Institute of Medicine, National Academies

Life Stage	Vitamin A	Vitamin C	Vitamin D	Vitamin E	Vitamin K	Thiamin	Riboflavin	Niacin	Vitamin B <sub>6</sub>	Folate	Vitamin B <sub>12</sub>	Pantothenic Acid	Biotin	Choline	Carotenoids <sup>e</sup>
------------	-----------	-----------	-----------	-----------	-----------	---------	------------	--------	------------------------	--------	-------------------------	------------------	--------	---------	--------------------------

<b>Group</b>	(µg/d) <sup>b</sup>	(mg/d)	(µg/d)	(mg/d) <sup>c</sup> <sub>,d</sub>	---	---	---	(mg/d) <sup>d</sup>	(mg/d)	(µg/d) <sub>d</sub>	---	---	---	(g/d)	---
<b>Infants</b>															
0-6 mo	600	ND <sup>f</sup>	25	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND
7-12 mo	600	ND	38	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND	ND
<b>Children</b>															
1-3 y	600	400	63	200	ND	ND	ND	10	30	300	ND	ND	ND	1.0	ND
4-8 y	900	650	75	300	ND	ND	ND	15	40	400	ND	ND	ND	1.0	ND
<b>Males, Females</b>															
9-13 y	1,700	1,200	100	600	ND	ND	ND	20	60	600	ND	ND	ND	2.0	ND
14-18 y	2,800	1,800	100	800	ND	ND	ND	30	80	800	ND	ND	ND	3.0	ND
19-70 y	3,000	2,000	100	1,000	ND	ND	ND	35	100	1,000	ND	ND	ND	3.5	ND
> 70 y	3,000	2,000	100	1,000	ND	ND	ND	35	100	1,000	ND	ND	ND	3.5	ND
<b>Pregnancy</b>															
≤ 18 y	2,800	1,800	100	800	ND	ND	ND	30	80	800	ND	ND	ND	3.0	ND



19-50 y	3,000	2,000	100	1,000	ND	ND	ND	35	100	1,000	ND	ND	ND	3.5	ND
<b>Lactation</b>															
≤ 18 y	2,800	1,800	100	800	ND	ND	ND	30	80	800	ND	ND	ND	3.0	ND
19-50 y	3,000	2,000	100	1,000	ND	ND	ND	35	100	1,000	ND	ND	ND	3.5	ND

<sup>a</sup> **NOTE:** A Tolerable Upper Limit (UL) is the highest level of daily nutrient intake that is likely to pose no risk of adverse health effects to almost all individuals in the general population. Unless otherwise specified, the UL represents total intake from food, water, and supplements. Due to lack of suitable data, ULs could not be established for vitamin K, thiamin, riboflavin, vitamin B<sub>12</sub>, pantothenic acid, biotin, or carotenoids. In the absence of ULs, extra caution may be warranted in consuming levels above recommended intakes. Members of the general population should be advised not to routinely exceed the UL. The UL is not meant to apply to individuals who are treated with the nutrient under medical supervision or to individuals with predisposing conditions that modify their sensitivity to the nutrient.

<sup>b</sup> As preformed vitamin A only.

<sup>c</sup> As  $\beta$ -tocopherol; applies\ any form of supplemental  $\beta$ -tocopherol.

<sup>d</sup> The ULs for vitamin E, niacin, and folate apply to synthetic forms obtained from supplements, fortified foods, or a combination of the two.

<sup>e</sup>  $\beta$ -Carotene supplements are advised only to serve as a provitamin A source for individuals at risk of vitamin A deficiency.

<sup>f</sup> ND = Not determinable due to lack of data of adverse effects in this age group and concern with regard to lack of ability to handle excess amounts. Source of intake should be from food only to prevent high levels of intake.

**Sources:** *Dietary Reference Intakes for Calcium, Phosphorous, Magnesium, Vitamin D, and Fluoride (1997); Dietary Reference Intakes for Thiamin, Riboflavin, Niacin, Vitamin B<sub>6</sub>, Folate, Vitamin B<sub>12</sub>, Pantothenic Acid, Biotin, and Choline (1998); Dietary Reference Intakes for Vitamin C, Vitamine E, Selenium, and Carotenoids (2000); Dietary Reference Intakes for Vitamin A, Vitamin K, Arsenic, Boron, Chromium, Copper, Iodine, Iron, Manganese, Molybdenum, Nickel, Silicon, Vanadium, and Zinc (2001); and Dietary Reference Intakes for Calcium and Vitamin D (2011).* These reports may be accessed via [www.nap.edu](http://www.nap.edu).

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**Table 18. Dietary Reference Intakes (DRIs): Tolerable Upper Intake Levels (UL<sup>a</sup>), Elements(293)**  
Food and Nutrition Board, Institute of Medicine, National Academies

Life Stage Group	Arsenic <sup>b</sup>	Boron	Calcium	Chromium	Copper	Fluoride	Iodine	Iron	Magnesium	Manganese	Molybdenum	Nickel	Phosphorus	Selenium	Silicon <sup>d</sup>	Vanadium	Zinc
	---	(mg/d)	(mg/d)	---	(µg/d)	(mg/d)	(µg/d)	(mg/d)	(mg/d) <sup>c</sup>	(mg/d)	(µg/d)	(mg/d)	(g/d)	(µg/d)	---	(mg/d) <sup>e</sup>	(mg/d)
<b>Infants</b>																	
0-6 mo	ND <sup>f</sup>	ND	1000	ND	ND	0.7	ND	40	ND	ND	ND	ND	ND	45	ND	ND	4
7-12 mo	ND	ND	1500	ND	ND	0.9	ND	40	ND	ND	ND	ND	ND	60	ND	ND	5
<b>Children</b>																	
1-3 y	ND	3	2500	ND	1,000	1.3	200	40	65	2	300	0.2	3	90	ND	ND	7
4-8 y	ND	6	2500	ND	3,000	2.2	300	40	110	3	600	0.3	3	150	ND	ND	12
<b>Males, Females</b>																	
9-13 y	ND	11	3000	ND	5,000	10	600	40	350	6	1,100	0.6	4	280	ND	ND	23
14-18 y	ND	17	3000	ND	8,000	10	900	45	350	9	1,700	1.0	4	400	ND	ND	34
19-30 y	ND	20	2500	ND	10,000	10	1,100	45	350	11	2,000	1.0	4	400	ND	1.8	40

31-50 y	ND	20	2500	ND	10,000	10	1,100	45	350	11	2,000	1.0	4	400	ND	1.8	40
51 - 70 y	ND	20	2000	ND	10,000	10	1,100	45	350	11	2,000	1.0	4	400	ND	1.8	40
>70 y	ND	20	2000	ND	10,000	10	1,100	45	350	11	2,000	1.0	3	400	ND	1.8	40
<b>Pregnancy</b>																	
≤ 18 y	ND	17	3000	ND	8,000	10	900	45	350	9	1,700	1.0	3.5	400	ND	ND	34
19-50 y	ND	20	2500	ND	10,000	10	1,100	45	350	11	2,000	1.0	3.5	400	ND	ND	40
<b>Lactation</b>																	
≤ 18 y	ND	17	3000	ND	8,000	10	900	45	350	9	1,700	1.0	4	400	ND	ND	34
19-50 y	ND	20	2500	ND	10,000	10	1,100	45	350	11	2,000	1.0	4	400	ND	ND	40

<sup>a</sup> **NOTE:** A Tolerable Upper Limit (UL) is the highest level of daily nutrient intake that is likely to pose no risk of adverse health effects to almost all individuals in the general population. Unless otherwise specified, the UL represents total intake from food, water, and supplements. Due to lack of suitable data, ULs could not be established for vitamin K, thiamin, riboflavin, vitamin B<sub>12</sub>, pantothenic acid, biotin, or carotenoids. In the absence of ULs, extra caution may be warranted in consuming levels above recommended intakes. Members of the general population should be advised not to routinely exceed the UL. The UL is not meant to apply to individuals who are treated with the nutrient under medical supervision or to individuals with predisposing conditions that modify their sensitivity to the nutrient.

<sup>b</sup> Although the UL was not determined for arsenic, there is no justification for adding arsenic to food or supplements.

<sup>c</sup> The ULs for magnesium represent intake from a pharmacological agent only and do not include intake from food and water.

<sup>d</sup> Although silicon has not been shown to cause adverse effects in humans, there is no justification for adding silicon to supplements.

<sup>e</sup> Although vanadium in food has not been shown to cause adverse effects in humans, there is no justification for adding vanadium to food and vanadium supplements should be used with caution. The UL is based on adverse effects in laboratory animals and this data could be used to set a UL for adults but not children and adolescents.

<sup>f</sup> ND = Not determinable due to lack of data of adverse effects in this age group and concern with regard to lack of ability to handle excess amounts. Source of intake should be from food only to prevent high levels of intake.

**Sources:** *Dietary Reference Intakes for Calcium, Phosphorous, Magnesium, Vitamin D, and Fluoride (1997); Dietary Reference Intakes for Thiamin, Riboflavin, Niacin, Vitamin B<sub>6</sub>, Folate, Vitamin B<sub>12</sub>, Pantothenic Acid, Biotin, and Choline (1998); Dietary Reference Intakes for Vitamin C, Vitamine E, Selenium, and Carotenoids (2000); Dietary Reference Intakes for Vitamin A, Vitamin K, Arsenic, Boron, Chromium, Copper, Iodine, Iron, Manganese, Molybdenum, Nickel, Silicon, Vanadium, and Zinc (2001); and Dietary Reference Intakes for Calcium and Vitamin D (2011).* These reports may be accessed via [www.nap.edu](http://www.nap.edu).

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### 9.7.2 Calcium Supplementation, Dietary Dairy Intake, and Weight Loss

Some studies in the past have suggested that calcium supplementation and/or supplementation of dairy products in the diet play a direct role in the prevention and treatment of obesity. However, not all data support this hypothesis, and several studies found that calcium or dairy consumption do not aid in weight loss (170), nor does calcium supplementation have an effect in preventing weight gain (171-173).

In a review evaluating 49 randomized clinical trials assessing the effect of dairy product or calcium supplement consumption, 41 studies showed no effect, two reported weight gain, one showed a lower rate of gain, and five showed it was effective as an aide in weight loss (170).

Major et al found that calcium plus vitamin D supplementation enhanced the beneficial effect of weight loss on the lipid profile; however, it had no effect on weight itself (174). There is also some evidence that high calcium or high dairy intakes during weight loss spare lean tissue loss to a greater extent than lower levels, although the evidence is not conclusive at this time.

### 9.7.3 Dietary Supplements and Weight Loss

Currently over half of the adult population uses dietary supplements (175). Most reported the motivation for using them was to increase over health even though less than a quarter of those supplements taken were recommended by a physician or healthcare provider (175). Retail sales of weight-loss supplements were estimated to be over \$25.177 billion in 2008, including meal replacements (176).

**Table 19. Common Ingredients in Weight Loss Dietary Supplements\* (294)**

<b>Ingredient</b>	<b>Purported Mechanism</b>	<b>Research Findings</b>	<b>Safety+</b>
Bitter orange (synephrine)	Increased energy expenditure and lipolysis; mild appetite suppressant	Small clinical trials of poor methodological quality demonstrating possible effect on resting metabolic rate and energy expenditure, with inconclusive effects on weight loss	Reported adverse effects include chest pain, anxiety, and increased blood pressure and heart rate
Caffeine (as added caffeine or from guarana, kola nut, yerba mate, or other herbs)	Stimulation of central nervous system; increased thermogenesis and fat oxidation	Short-term clinical trials of combination products showing possible modest effect on body weight or decreased weight gain over time	Safety concerns not usually reported at doses less than 400 mg/day for adults, but there are significant safety concerns at higher doses.  Reported adverse effects include nervousness, jitteriness, vomiting, and tachycardia

Calcium	Increased lipolysis and fat accumulation; decreased fat absorption	Several large clinical trials have shown no effect on body weight, weight loss, or prevention of weight gain	No safety concerns reported at recommended intakes, but constipation, kidney stones, and interference with zinc and iron absorption can occur at intakes above 2,000–2,500 mg for adults
Chitosan	Binding of dietary fat in the digestive tract	Small clinical trials, mostly of poor methodological quality, have shown minimal effect on body weight	Reported adverse effects include flatulence, bloating, constipation, indigestion, nausea, and heartburn
Chromium	Increased lean muscle mass; promotion of fat loss; reduced food intake, hunger levels, and fat cravings	Several clinical trials of varying methodological quality have found minimal effect on body weight and body fat	Reported adverse effects include headache, watery stools, constipation, weakness, vertigo, nausea, vomiting, and urticaria (hives) when taken above recommended intakes (25–45 mcg/day for adults)
<i>Coleus forskohlii</i> (forskolin)	Enhanced lipolysis; reduced appetite	A small number of clinical trials show no effect on body weight	Unknown
Conjugated linoleic acid	Promotion of apoptosis in adipose tissue	Several clinical trials have shown	Reported adverse effects include abdominal

		minimal effect on body weight and body fat	discomfort and pain, constipation, diarrhea, loose stools, dyspepsia, and possible adverse effects on blood lipid profiles
Ephedra (ma huang, ephedrine)	Stimulation central nervous system; increased thermogenesis; reduced appetite	Several short-term clinical trials of good methodological quality, many of ephedra combined with caffeine, have found modest effect on short-term weight loss	<b>Banned as a dietary supplement ingredient</b>  Reported adverse effects include anxiety, mood changes, nausea, vomiting, hypertension, palpitation, stroke, seizures, heart attack, and death
<i>Garcinia cambogia</i> (hydroxycitric acid)	Inhibited lipogenesis; suppressed food intake	Several short-term clinical trials of varying methodological quality have found little to no effect on body weight	Reported adverse effects include headache, nausea, upper respiratory tract symptoms, and gastrointestinal symptoms
Glucomannan	Increased feelings of satiety and fullness; prolonged gastric emptying time	Several clinical trials of varying methodological quality, mostly focused on effects on lipid and blood glucose levels, have found little to no effect on body	Tablet forms may cause esophageal obstructions. Other reported adverse effects include loose stools, flatulence, diarrhea, constipation, and abdominal discomfort

		weight	
Green coffee bean extract ( <i>Coffea arabica</i> , <i>Coffea canephora</i> , <i>Coffea robusta</i> )	Inhibited fat accumulation; modulated glucose metabolism	Few clinical trials of poor methodological quality have suggested possible modest effect on body weight	Reported adverse effects include headache and urinary tract infections
Green tea ( <i>Camellia sinensis</i> ) and green tea extract	Increased energy expenditure and fat oxidation; reduced lipogenesis and fat absorption	Several clinical trials of good methodological quality on green tea catechins with and without caffeine have shown possible modest effect on body weight	Reported adverse effects for green tea extract include constipation, abdominal discomfort, nausea, increased blood pressure, liver damage
Guar gum	Bulking agent in gut; delayed gastric emptying; increased feelings of satiety	Several clinical trials of good methodological quality have found no effect on body weight	Reported adverse effects include abdominal pain, flatulence, diarrhea, nausea, and cramps
Hoodia ( <i>Hoodia gordonii</i> )	Suppressed appetite; reduced food intake	Very little published research in humans, but results from one study suggest no effect on energy intake or body weight	Concern for increased heart rate and blood pressure. Other reported adverse effects include headache, dizziness, nausea, and vomiting



Pyruvate	Increased lipolysis and energy expenditure	Few clinical trials of weak methodological quality suggest possible minimal effect on body weight and body fat	Reported adverse effects include diarrhea, gas, bloating, and possible decreases in high-density lipoprotein levels
Raspberry ketone	Altered lipid metabolism	Studied only in combination with other ingredients. Unable to draw conclusions.	Unknown
White kidney bean ( <i>Phaseolus vulgaris</i> )	Acts as a “starch blocker, interfering with breakdown and absorption of carbohydrates	Few clinical trials, all of poor methodological quality, suggest possible modest effect on body fat, but no effect on body weight	Reported adverse effects include headache, soft stools, flatulence, and constipation
Yohimbe ( <i>Pausinystalia yohimbe</i> , yohimbine)	Hyperadrenergic effects	Very little research has been done on yohimbe for weight-loss, with insufficient evidence to draw firm conclusions.	Significant safety concerns reported, with adverse effects including headache, anxiety, agitation, hypertension, and tachycardia

\*Table adapted from *The ODS Fact Sheet on Dietary Supplements for Weight Loss* (294)

+Listed in order of severity, with the most severe reported side effects listed last.

In 2001, MetaboLife® 356, an Ephedra-containing combination supplement, was the top selling dietary supplement. It reached \$70 million in sales, but it was also responsible for 64 percent of all herb-related adverse events reported to the U.S. Poison Control Center during that same year (175;177). Ephedra, or Ma Huang, is the common name for the herb that was used in many of these weight loss supplements. It is an herb used in traditional Chinese Medicine (TCM). Its use in weight reduction though, is not a common practice in TCM. Americans used this supplement as a weight loss aid from the mid 1990's, up until 2004, when it was banned by the FDA (178;179).

The NIH sponsored a thorough systematic review of the safety and efficacy of Ephedra through the Agency of Healthcare Research and Quality's (AHRQ) Evidence Based Practice Center at the University of Southern California, which conducted the study. It concluded that the use of Ephedra, with or without caffeine, correlated with a small but nonetheless statistically significant increase in weight loss over six months, (almost equal to 0.9 kilograms per month more than with the placebo). The weight lost by those taking Ephedra in combination with caffeine exceeded weight lost by prescription medications in two head-to-head randomized, double-blinded clinical trials (178). There were no studies that measured the long-term effects (more than 6 months) of Ephedra use, and the problem was that the supplement was not safe. Adverse effects of the supplement in the AHRQ study included two to three times more nausea, vomiting, psychiatric symptoms such as anxiety and change in mood, autonomic hyperactivity, and palpitations when compared with placebo. Serious adverse events (SAE's) were defined as specified by FDA criteria. SAEs were reported to the FDA, and adverse event reports from a manufacturer of Ephedra-containing dietary supplements were also evaluated in the RAND/Southern California systemic review. These reports raised concern about the safety of dietary supplements containing Ephedra due to the number of deaths, myocardial infarctions, cerebrovascular accidents, seizures, and serious psychiatric illnesses in young adults, data was sufficient to warrant concern (178).

The FDA concluded in 2004 that Ephedra-containing products were not to be recommended for weight loss. There was unreasonable risk for illness and injury when taking such dietary supplements. Thus, the sale of dietary supplements containing Ephedra has been prohibited in the United States since April 2004 (178). Ephedra like supplements such as Citrus aurantium (Bitter orange) may also pose risk.

The latest information on dietary supplements and weight loss can be found at [www.ods.nih.gov](http://www.ods.nih.gov).

## **9.8 Fiber**

The next section outlines dietary fiber needs during weight reduction.

### **9.8.1 Fiber Needs in Reducing Diets**

Dietary fiber is chemically similar to carbohydrate in most of its forms but it is virtually non-caloric because the human body lacks the enzymes to break the fiber's glycosidic bonds. Some short-term experimental and several cross-sectional studies suggest that an increased dietary fiber intake reduces weight gain. In contrast, fiber is not effective as a weight loss aid (180). Fiber should be included in reducing diets at levels of about 25 to 38 grams per day to facilitate laxation. Both soluble and insoluble dietary fiber may also modify hunger and help to sustain satiety, but again experimental evidence is not conclusive (10;181;182). Inclusion of five or more servings of fruits and vegetables daily, with plenty of whole grain breads and cereals helps to meet both soluble and insoluble fiber goals on reducing diets. On a VLCD, it is also important to include at least some fiber. As dietary fiber intakes increase, water requirements also increase, so intakes of fluid should also be substantial. Adequate fiber and water are essential for maintaining a soft stool and normal laxation. Ample fiber intakes are associated with reduced risk of several chronic diseases (183).

## **9.9 Energy-Dense Beverages, Alcohol, and Energy-Free Artificially and Naturally Sweetened Beverages**

Currently, it is estimated that the mean intake of "added" sugars in the American diet is about 15.8% of total energy, and that the largest source of these added sugars is from calorically sweetened beverages such as soft drinks, fruit aides, and other sweetened beverages, accounting for 47% of total added sugars in the diet (184;185). The term "energy-dense beverage" encompasses a wide variety of beverages, including sugar sweetened soda, fruit drinks, juice, lemonade, sweetened iced tea, milk and soy beverages, and alcohol. Alcohol is especially calorie dense (7 Cal/gm, vs 4 for sugars), and it also may bypass satiety mechanisms and lead to a lack of ability to control eating. Curiously, in recent years it has been neglected in spite of the fact that many adults (and unfortunately some younger people) drink alcohol on a regular basis.

### **9.9.1 Energy-Dense Beverages**

When compared to water or energy-free beverages, consumption of energy-containing beverages tends to increase total energy intake from meals (184). Although the evidence is not highly conclusive, it is argued that: 1) consumption of an isocaloric beverage compared to consumption of solid food prior to a meal increases food intake, 2) solid foods enhance satiety hormones more than energy-dense beverages, and 3) energy-dense beverages are often comprised largely of refined carbohydrates, which stimulate fewer satiety signals than unprocessed carbohydrates, fat or protein (184). More research is needed on this issue to validate each of these assumptions. It should be noted that alcohol is also energy dense and bypasses satiety mechanisms. This is discussed below further in section [9.9.2 Alcohol](#).

*The Beverage Guidance Panel* recommends that the average person limit daily consumption of caloric, sweetened beverages without nutritional benefits (soft drinks, fruit drinks, fruit cocktails, fruit aids, and sweetened teas and coffees) to eight ounces per day. Caloric, nutrient-dense beverage consumption (milk, soy and 100% fruit and vegetable juices) should be kept to a minimum

(186). In the United States, a regular, 12-ounce can of calorically sweetened soda provides approximately 150 calories, typically in the form of high-fructose corn syrup. These calories, if not balanced with exercise or a caloric reduction in other areas of one's diet, could gradually lead weight gain over time (187).

While there may be health benefits to consuming energy and nutrient dense beverages such as milk and 100% fruit juice, the additional energy provided by these energy-dense beverages must be offset by an increase in energy expenditure or a decrease in other areas of energy consumption in order for weight loss or weight maintenance goals to be achieved. Any energy-dense beverages included in the diet should also be nutrient dense, such as various forms of milks (e.g. dairy, soy) and 100% fruit juices (which should be limited to about one serving per day). Most other caloric beverages, such as sodas, fruit drinks, sweetened coffees and teas provide calories with little or no vitamins, minerals, or other nutrients. For this reason, energy-dense beverages are generally not recommended for patients attempting to lose weight.

### **9.9.2 Alcohol**

Alcohol (ethanol) contains approximately seven calories per gram, providing more energy per unit of weight than either carbohydrate or protein (each providing about four calories per gram), but less than fat (about 9 calories per gram). Alcoholic beverages are a source of non-nutritive energy, or “empty calories”. If protein, carbohydrate and/or fat are consumed at the same time as alcohol is ingested, their oxidation will be suppressed (most notably fat oxidation), since alcohol is preferentially oxidized, and the other macronutrients balance through the sparing effect of alcohol on fat oxidation. This may lead to increased fat storage.

In addition to alcohol's influence on macronutrient metabolism, chronic extremely excess intake of alcohol also interferes with the absorption and utilization of several vitamins and minerals. Alcohol in excess also impairs nutrient absorption by damaging the stomach and intestinal lining, disabling the transport of some nutrients into the blood. Chronic overconsumption of alcohol can also lead to fatty liver, dyslipidemia, and further weight gain, and should be discouraged.

Another important consideration concerning alcohol's influence on energy balance is its effects on energy intake. Alcohol is positioned at the bottom of the hierarchy of satiating efficiency of metabolic fuels consumed by humans (10). Generally, satiety provided by fuels is ranked from lowest to highest: alcohol, fat, carbohydrate (depending on type), and protein (188). Alcohol energy is additive to the diet, producing no compensation in energy intake under most ad-libitum situations, and in fact, some research suggests that alcohol may stimulate appetite (189;190). For these reasons, alcohol consumption is usually contraindicated on weight-loss diets.

### **9.9.3 Low and No Calorie Sweeteners**

These ingredients are variously called low and no calorie sweeteners, non-nutritive sweeteners, sugar substitutes, reduced calorie sweeteners, or artificial sweeteners). They are added to foods and beverages to provide sweetness without adding significant amounts of sugar and calories to the product. They are also used as flavorings to mask the bitter taste of drugs <http://www.caloriecontrol.org/sweeteners-and-lite/sugar-substitutes>.

Low calorie sweeteners are appealing because they satisfy our innate preference for sweetness without the associated calories consuming sugar would have. They do not contribute to dental caries, may help to make low calorie diets more palatable, and assist compliance. These low calorie sweeteners are consumed by approximately one fifth of U.S. adults (191). In human studies, data have been conflicting on whether they are associated with weight loss (192). However, the draft conclusions of the 2015 Dietary Guidelines Scientific Advisory Committee concluded that there was moderate and generally consistent evidence from randomized clinical trials conducted in adults and children supporting the contention that replacement of sugar-containing sweeteners with low calorie sweeteners reduces calorie intake, body weight and adiposity. However evidence was judged only limited from long-term observational studies in children and adults that there was an association between low calorie sweeteners and body weight compared to sugar containing sweeteners. The Committee further concluded in its draft statement that there was only limited long-term observational study evidence in adults that there was an association between low calorie sweeteners and risk of type 2 diabetes.

The FDA has approved seven non-nutritive sweeteners for use in foods and beverages in the United States to date. Most are regulated as food additives, including acesulfame-potassium (Acesulfame-K, Ace-K, Sunett, Sweet One), aspartame (Equal, NutraSweet), saccharin (Necta Sweet, Sugar Twin, Sweet 'N Low), sucralose (Splenda), and two products that are used largely as ingredients rather than as table top sweeteners, neotame, and most recently, advantame. Cylamate is not sold in the United States but is sold in many other countries as a tabletop sweetener. The FDA granted stevia leaf, often called "sweet leaf", a plant-derived sweetener, (PureVia, Sun Crystals, and Truvia Generally Recognized As Safe (GRAS) status. It is derived from stevia leaves by steeping them in water and purifying to extract to obtain only high purity rebaudioside A. The ingredient is sold under the trade name Rebiana and is the major source of sweetness in the Truvia sweetener brand. , Also GRAS is the product *Fruit-Sweetness*<sup>™</sup> is a non-caloric fruit concentrate sweetener derived from the monk fruit, a traditional fruit originating in Southeast Asia (193). The sweeteners have a variety of different chemical structures, as shown in Table 20, and summarized elsewhere (<http://www.caloriecontrol.org/sweeteners-and-lite/sugar-substitutes>). They also vary widely in their sweetness and in their most common uses. The most commonly consumed source of these products is as a sweetener to beverages either provided by sachets of the different products, that are added to the drink or as an ingredient in a variety of "diet" soft drinks and colas. The sweeteners used in foods and beverages are listed on the ingredient list for those who prefer a specific ingredient.

There is little evidence that low calorie sweeteners in and of themselves can cause patients to lose weight; their use must always be coupled with a hypocaloric diet. The low calorie sweeteners may make reducing diets more palatable and encourage compliance, but this remains to be demonstrated conclusively (194-195). During weight maintenance, water and other non-caloric beverages or, low calorie sweetened beverages are a preferable alternative to high calorie beverages, such as regular soft drinks, sweet teas, other sugary drinks and alcohol. Some recommend that adults consume no more than 32 ounces of low calorie sweetened beverages per day, but there is little evidence supporting such recommendations (186). If an individual wishes to reduce his/her exposure to a particular low calorie sweetener, both consuming less or choosing a variety of low calorie sweeteners are useful strategies to consider

### **9.9.3.1 SAFETY OF LOW CALORIE SWEETENERS**

The safety of low-calorie sweeteners has been evaluated by several bodies, including the US Food and Drug Administration (FDA), the Joint Expert Committee of Food Additives (JECFA) of the United Nations Food and Agricultural Organization (FAO), the World Health Organization (WHO), the Scientific Committee on Food (SCF) of the European Commission, and the European Food Safety Authority (EFSA) (242, 254). In the United States, the use of sweeteners is regulated by FDA under the 1958 Food Additives Amendment of the Food, Drug and Cosmetic Act of 1938 (249). Currently, two low calorie nutritive sweeteners sugar alcohols (mannitol and xylitol) and six non-nutritive sweeteners (aspartame, acesulfame-K, saccharin, sucralose, neotame, advantame) are approved as food additives by the FDA (242), and two additional “natural” sweeteners, extracts of stevia and monk fruit, are approved as GRAS.

An Acceptable Daily Intake (ADI) is established for all FDA-approved low-calorie sweeteners. It represents the amount of each sweetener that can be safely ingested daily by a human over a lifetime without risk based on animal toxicity studies. The ADI is expressed as milligrams per kilogram of body weight. The ADI is not a maximum intake level. It is a conservative estimate of the level-- a hundredth of the maximum level-- at which no observed adverse effect is seen in feeding studies of toxicity in experimental animals (243). Consumption of these low-calorie sweeteners at levels below the ADI is considered by the FDA to be safe for the entire population, including children and pregnant women (246). Exceptions for particularly vulnerable populations, such as individuals who suffer from phenylketonuria (a rare metabolic disorder), who should not consume aspartame-sweetened products, are listed in the table, and on the product label.

Low-calorie sweeteners such as stevia and monk fruit extracts that are GRAS are also acceptable only for specified uses in specified amounts that are in line with traditional uses of these ingredients in human diets over the course of history. Generally Recognized as Safe (GRAS); substances are those that scientific experts have agreed are safe for use in appropriate amounts in

foods and beverages, based largely on traditional use. They do not require the extensive testing required by FDA for food additives, but are permitted to be used only at specified levels (244). Also, some other compounds with sweet tastes, including thaumatin, neohesperidine, and glycyrrhizin are GRAS when used in small amounts for an intended use as flavor enhancers, but not as sweeteners.

#### **9.9.3.2. Low calorie sweeteners that are currently approved by FDA:**

**Saccharin**—Sold under the brand names *Sweet 'N Low*®, *Sugar Twin*®, and *Sweet Twin*®, saccharin is a non-nutritive sweetener that is not metabolized by the body and provides no calories. It has been on the market longer than any other low calorie sweetener. It is 300-500 times sweeter than sugar and is heat stable (246), but leaves a bitter metallic aftertaste in the mouth in individuals who have a certain dominant genetic trait. They can be identified by the ability to taste the chemicals ptc (phenylthiocarbamide) and PROP (6 propyl 2 thiouracil) as bitter or metallic. Those compounds do not appear in food but related compounds such as saccharine and possibly some of the Brassica vegetables have related compounds that are also tasted as bitter. About 70 % of Americans taste ptc related compounds in food as bitter, especially if they are not habituated to coffee or tea or non-smokers, and therefore in the USA saccharine is usually blended with other sweeteners in food and beverage products (252). Many Asians are very sensitive to a bitter taste, and formulations of low calorie soft drinks for them may use other sweeteners (247). The ADI for saccharin is 15 mg/kg/day. Studies in the 1970s in rats linked a lifetime exposure to high doses of saccharin to development of bladder cancer. This raised concerns about the safety of saccharin and led to a ban of saccharin in 1977 by the FDA, and great furor since at the time there were few other non-nutritive sweeteners on the market. Later, after the ban was lifted due to Congressional action, FDA required that products containing saccharin must carry a warning label (244). Subsequent human case- control and other studies showed no association between saccharin and bladder cancer development (254). In addition, it was later shown that physiological differences in bladder and urine chemistry between rats and humans were such that the bladder cancer-causing effect was specific only to rats, and that the toxic effect of tumors in rats was evident only with sodium saccharin but not with other forms of saccharin, and only with lifetime exposures to very high dosages of saccharin, equivalent to hundreds of servings per day in humans (247). After these studies were reviewed, in 2000 saccharin was delisted as a potential human carcinogen. However, products containing saccharin must still label saccharin in declarations on their ingredient list. Today, several professional societies, including the American Dietetic Association, American Medical Association, and American Cancer Society state that saccharin is safe and acceptable for use in all populations (242).

**Acesulfame K (Ace-K)**—Under the brand names of *Sunett*® and *SweetOne*®, Ace-K is a combination of an organic acid and potassium. It is excreted from the body unchanged, and therefore does not yield either a net increase in calories or of potassium in humans. It is 200 times sweeter than sugar. It is heat stable, and thus is suitable for cooking and baking (242). Ace-K also

leaves a metallic aftertaste in some people's mouths when it is used by itself, and so it is usually combined with other sweeteners in sweetener blends, especially in carbonated beverages. The ADI for Ace-K is 15 mg/kg/day; for a person of 70 kg that would be about 1050 mg. The typical amount of Ace-K in a 12-oz beverage is 40 mg and in a packet of tabletop sweetener it is 50 mg (257). Long-term human studies found no effects on cancer even at very high consumption levels of Ace-K. There are also no case reports documenting adverse health effects associated with Ace-K. Therefore, FDA permits Ace-K use in all population segments. An Ace-K metabolite, acetoacetamide, is toxic when consumed at very high doses, but the amount of acetoacetamide found in beverages sweetened with Ace-K is negligible. And therefore consumption of beverages sweetened with Ace-K is deemed to be safe (247).

**Sucralose**—Sucralose is sold under the trade name of *Splenda*®. It is a sugar derivative, which replaces 3 hydrogen-oxygen groups on the sugar with 3 chlorine atoms. Although sucralose is derived from sugar, it is not absorbed nor do gut enzymes in humans metabolize sucralose as a carbohydrate. It is non-caloric (251). It is 600 times sweeter than sugar and is highly heat stable. Sucralose is used extensively in foods and beverages because it retains sweetness over a wide range of temperatures and storage conditions (242). The ADI for sucralose is 5 mg/kg/day. Sucralose had no significant effect on blood glucose control in individuals with type 2 diabetes mellitus even at levels 3 times this amount over three months. Extensive research in humans and experimental animals has found no association between sucralose consumption and carcinogenicity or other health concerns (244). Therefore, sucralose appears to be safe and acceptable for human consumption.

**Aspartame**—It is sold under the trade names *NutraSweet*®, *Canderel*®, *Sanecta*®, *TriSweet*®, E951 (for food ingredients), and *Equal*® (for the tabletop sweetener). Aspartame is a synthetic sweetener composed of aspartic acid and phenylalanine (256). It is used both as an ingredient and sold to consumers as a tabletop sweetener. Since it is metabolized to amino acids, aspartame provides 4 calories per gram. It is 160-220 times sweeter than sugar. Due to its intense sweetness, only a tiny amount (e.g. a few mg) is needed to sweeten a food and thus, the energy provided from the compounds is negligible. Aspartame decomposes and loses its sweetness with heat and so it is not suitable for baking and cooking. However, it is used extensively in soft drinks, which account for more than 70% of aspartame consumption in the US (242). An 8-oz diet Coca Cola contains approximately 125 mg of aspartame and 60 mg of phenylalanine (257). The ADI of aspartame is 50 mg/kg/day (or about 3500 mg for a 70 kg individual). Due to the presence of phenylalanine in aspartame, individuals with phenylketonuria (PKU), a recessive inborn error of metabolism should be cautioned about aspartame consumption since they cannot metabolize phenylalanine effectively and the amino acid can accumulate in the blood, causing toxic metabolites and potentially neurological damage (242). Although this adverse effect is unlikely because the amounts of aspartame that are used in foods and as a sweetener is quite small, diet therapy for PKU includes limiting dietary phenylalanine, including aspartame. FDA requires products containing aspartame to carry the warning label "PHENYLKETOURICS: CONTAINS PHENYLALANINE." The plasma response of phenylalanine to ingestion of aspartame varies in people with PKU, but most seem to tolerate the amount of phenylalanine in a single diet soda sweetened with



aspartame (about 104 mg phenylalanine/12-oz can), so an immediate health crisis is unlikely should a person mistakenly drink a diet soda (244). However, caution is still indicated for PKU patients. In contrast, healthy adults show no significant change in plasma level of aspartic acid even with doses of aspartame about 4 times the ADI (4 times ADI is equal to 200 mg/kg/day) (256). In normal humans, plasma phenylalanine increases in a dose-response manner to aspartame dosage in the range of 2-100 mg/kg/day without any observed effects on cognitive function, but individuals with phenylketonuria are different and may be particularly sensitive (258).

Aspartame is perhaps the most controversial sweetener of them all due to early claims in the 1970

S of neurotoxicity in primates, which were later not confirmed, although the unproven claims continue to circulate on the Internet. One comprehensive review study on the safety of low-calorie sweeteners, including aspartame, stated that “much of potential misinformation about aspartame and health seems to be based on misunderstandings or partial scientific truths” (247) some consumers report adverse reactions to aspartame, including headache, facial edema, skin reactions, respiratory problems, seizures, and behavioral and cognitive changes, numerous controlled studies have failed to reproduce these adverse reactions reported. Adding to the controversy, aspartame was claimed by one Italian laboratory to be carcinogenic, but no associations between aspartame consumption and cancer development were found in a review of their data by a panel of experts in the experimental studies in rodents upon which the claim was based, and the studies themselves were criticized as being inadequate (256) Other data reviewed also were negative for adverse effects. The National Cancer Institute at NIH concluded that there was a lack of association between aspartame consumption and increased cancer risk, even at high intake levels after renewing all of the data (259). The European Food Safety Authority (EFSA) panel in 2009 again reviewed all available scientific evidence on the safety of aspartame and concluded that there was no carcinogenic effect nor association with neurobehavioral disorders or other effects from it and that no further revision of the ADI was needed. The most recent statement of EFSA released in 2013 has also confirmed the safety of aspartame (260). Periodic updates will be made available. Current evidence suggests that aspartame is safe at levels below ADI other than for individuals with PKU, and there is no credible evidence showing carcinogenicity, neurotoxicity, and other adverse health outcomes even at levels above ADI.

**Neotame**—Neotame is a relatively new non-nutritive low calorie sweetener, approved by FDA in 2002. It is used as an ingredient and also as a flavor enhancer that can modify other flavors in foods and beverages (246). Neotame is chemically related to aspartame, being composed of aspartic acid, methanol, and phenylalanine. Although they are similar in chemical structure, neotame and aspartame are completely different compounds with different physical and biological properties (247). Neotame is 7000-13000 times sweeter than sugar, thus only an infinitesimal amount is required for sweetening. The ADI for neotame is 2 mg/kg/day in other countries and 18 mg/day in the United States. Although neotame is metabolized into phenylalanine, a PKU warning label is not required for products containing neotame because the amount of neotame to sweeten a food is so tiny, owing to its intense sweetness. Thus, exposure to phenylalanine from neotame is negligible and clinically insignificant (244). In addition,

neotame is not directly metabolized to phenylalanine (252). The blockage of peptidases that break the peptide bond between aspartic acid and phenylalanine decreases the availability of phenylalanine in the bloodstream after neotame ingestion. Some concerns have been raised regarding neotame being neurotoxic due to the structural similarity to aspartame. However, no adverse effects of this sort or of other concerns have been found (258). Therefore, neotame is considered safe and acceptable for use in all populations.

**Advantame** This ingredient is an intense low calorie non-nutritive sweetener approved in 2014. It is used chiefly as a food ingredient, and is not sold over the counter. It was approved in 2014 for use in foods and beverages; USDA must approve uses in meat and poultry as well. It is structurally somewhat similar to aspartame (295).

**Stevia** (Stevioside, Steviol glycosides, Rebaudioside A)—These are sold under the trade names *Truvia*®, *Sun Crystals*®, *PureVia*®, *Sweetleaf Sweetener*®, *Stevia in the Raw*®, and *Enliten*®. Stevia leaves, often called “sweet leaf”, have been used for centuries in Asian and South American countries as non-caloric sweetener and traditional medicine (261). Steviol glycoside is the sweet component derived from leaves of *Stevia rebaudiana*. It is 250-300 times sweeter than sugar. Stevioside extracts have been used for sweetening in pickled vegetables, seafoods, soy sauce, soft drinks, and confectionary (262). Stevia leaves have also been used medicinally in Asia and South Africa for hypertension, hyperglycemia, obesity, and skin disorders, although the evidence for beneficial effects is scanty and none of these therapeutic uses are approved in the US. Stevioside is not metabolized nor absorbed by the digestive tract. The use of steviosides as a food ingredient was not initially approved in the United States although it was in Europe. Rather, it was sold in the US initially as a dietary supplement and therefore it could not be marketed as a sweetener since this was a different intended use. In 2008, FDA granted stevia GRAS status for use as a general-purpose sweetener in addition to use as a dietary supplement (263). Stevioside can now be found as an ingredient in beverages and as tabletop sweeteners. The Joint Expert Committee on Food Additives (JECFA) conducted a thorough scientific review on stevioside and concluded that it was safe for use in food and beverages with no major toxicity risk. The ADI of 0-4 mg/kg/day has recently been established by JECFA (296).

### 9.9.3.2 Nutritive low calorie sweeteners

**Polyols (Sugar alcohols)**—Sugar alcohols (polyols) are considered nutritive sweeteners because they provide some calories in the diet. However, the amount of calories provided per gram is fewer than table sugar (about 2 vs 4 calories/gram) due to the alcohol's incomplete digestion and absorption. The unabsorbed polyols reach the colon and cause subsequent fermentative degradation by intestinal bacteria (297, 248). Most polyols are about half as sweet as sugar. They replace sugar in the products for sweetness and volume, and therefore, products containing them can be labeled as “sugar-free”. Due to the osmotic effect of

unabsorbed polyols in the large intestine, products containing polyols may cause bloating, gas, discomfort, and diarrhea when consumed in excess (e.g. > 50 g/day sorbitol and >20 g/day mannitol). Therefore, these products are required to carry the statement “Excess consumption may have a laxative effect” on the label. Sensitivities to this laxative effect differ among individuals. Children may be particularly sensitive to the laxative effects of polyols due to their smaller body size (244). Tolerance to polyols can be increased somewhat with a gradual increase of intake that allows for adaptation to their laxative effects (264). Polyols may also confer potential health benefits, such as reduction in dental caries, a lower glycemic response when they are used in place of sugar, provision of fewer calories than sugar, and possibly a prebiotic effect (265). The prebiotic effects are presently poorly documented.

There are three subtypes or categories of Polyols

#### **Polyolinosaccharides:**

**1) Erythritol**—Marketed under the brand name *Zerose*, erythritol is found naturally in pears, melons, grapes, and mushrooms. Due to its almost complete absorption and unchanged excretion in urine within 24 hours, erythritol may not have as potent a laxative effect as some of the other polyols. In addition, erythritol provides fewer calories per gram (0.2 calories per gram) than the other polyols (253, 264).

**Sorbitol**—Usually found in sugar-free candies, chewing gums, baked goods, frozen desserts, and toothpaste, sorbitol is non-cariogenic. It is also slowly absorbed in the gut and metabolized independently of insulin (248, 253). Thus, it may be beneficial for individuals with diabetes.

**Mannitol**—Extracted from seaweed, mannitol is poorly absorbed and may cause a stronger laxative effect at a relatively lower dose (10-20 gram) than other polyols (252, 253). It is used as a dusting powder for chewing gum, an ingredient in chocolate-flavored coating agents for ice cream and candies, and in pharmaceuticals. It also cools the mouth and masks bitter tastes.

**Xylitol**—Xylitol is extracted from birch, raspberry, plum, and corn. It is often found in sugar-free gums, cough drops, mints, and oral health products. Several clinical trials have shown that xylitol is more effective in reducing dental caries than any of the other

polyols. In addition, xylitol may even have a caries-preventive and anti-cariogenic effect (4). Due to this, FDA authorizes the health claim that “xylitol does not promote tooth decay” on product labels (256).

## 2) Polyol Disaccharides:

**Maltitol**-- Derived from maltose, maltitol is a food ingredient that is metabolized into glucose and sorbitol by the gut flora. It is used in chocolate candies, jams, baked goods, and ice cream to give texture to products, and sometimes as a fat replacer (<http://www.caloriecontrol.org/sweeteners-and-lite/polyols>).

**Lactitol** —Although it is derived from lactose, lactitol is not hydrolyzed by lactase in small intestine. Instead, it is fermented by the microflora in the large intestine and converted into biomass and short-chain fatty acids. Also, it acts as a prebiotic, stimulating growth of the gut bacteria. The health effects of this are uncertain, but because lactitol is fermented in the colon, it may act as prebiotic and may produce more intestinal discomfort than some of the other products (249, 253). Lactitol is used as an ingredient in bakery products, hard and soft candies, frozen dairy desserts, and chocolate (248)

**Isomalt**—Under the trade name *Palatinit*, isomalt is incompletely metabolized into mannitol, sorbitol, and glucose in small intestine. It is noncariogenic and triggers only a low glycemic response (242). It is approved in most European countries and is added to candies, toffee, fudge, wafers, and cough drops. 90% of the isomalt is fermented further in colon, making it also a potential prebiotic (265). Intakes of 30 grams of isomalt might increase numbers of bifidobacteria in the colon, but evidence is still uncertain on this, and even if it did the effects of increased bifidobacteria on health are not yet well documented.

## 3) Polyol Polysaccharides:

**Hydrogenated starch hydrolysate (HSH)**—HSH is produced by the hydrolysis of corn, wheat, or potato starch. *Lycasin*®, *Hystar*®, *Stabilite*®, and *Roquette's 75/400* are the HSH brands currently available on the market. They are used mostly as bulking agents and food ingredients to provide sweetness, volume, and texture in commercially produced “sugarless” food products. HSH is metabolized into maltitol, sorbitol, and glucose to provide 3 calories per gram (253). The glycemic index of HSH is similar to that of maltitol, and about 40% of it is digested in the intestine (264). Therefore, it may be suitable for individuals with diabetes but this claim needs more evidence to support it.

### 9.9.3.4 Other sweeteners pending approval:

These sweeteners are not yet fully approved by FDA for use in food:

**Cyclamate**—Sold under the trade names *SugarTwin®* and *Sucaryl®*, cyclamate is 30 times sweeter than sugar, provides no calories, and blends well with other sweeteners. Most individuals do not metabolize cyclamate (252). It is approved for use as a tabletop sweetener in more than 50 countries, but re-approval is currently held abeyance and pending in the United States. Cyclamate has been banned in the US since 1969 based on a study suggesting the association between a saccharin/cyclamate blend sweetener and bladder cancer in rats (266). Cyclamate is converted to its metabolite, cyclohexylamine, which is relatively toxic and may cause bladder cancer in rats. High doses of cyclohexylamine cause male infertility in rats, although this effect is not observed in humans (247). Studies since 1969 have found no relationship between cyclamate and bladder cancer in humans, and this is the evidence that is currently being considered by FDA pending re-approval. FDA has stated that animal studies on mice and rats do not implicate cyclamate as a carcinogen.

**Alitame** – Under brand name *Aclame®*, alitame is derived from amino acids alanine and aspartic acid. Only the aspartic acid component is metabolized, to yield 1.4 calories per gram. Since only a minute amount of the sweetener is used as a food ingredient, the energy provided is negligible. It is 2000 times sweeter than sugar and heat stable. Common applications of alitame are commercially produced baked goods, candies, frozen desserts, beverages, and pasteurized foods. Alitame has been approved by several countries and is pending approval in the USA (242, 253).

**Thaumatococcos daniellii**—Sold under trade name *Talin®*, thaumatin is a protein sweetener that occurs naturally in a West African fruit *Thaumatococcus daniellii*. It is 1600 times sweeter than sugar. However, it leaves a licorice-like aftertaste. Its application in food products is very limited due to the delayed appearance and extinction time of the sweet sensation and this licorice aftertaste (249). In the United States, thaumatin is recognized as GRAS as a flavor enhancer (especially in chewing gums), but not as a sweetener. The Joint Expert Committee on Food Additives (JECFA) reviewed the safety of thaumatin and found no toxicity. The ADI for thaumatin is not yet specified (244).

**Neohesperidine dihydrochalcone** – A derivative of bioflavonoids in citrus fruits, neohesperidin dihydrochalcone is 1500 times sweeter than sugar but has different flavor profile. It also leaves a licorice aftertaste. However, it intensifies the mouth feel of juices, and thus has the potential to be used in fruit juice, chewing gums, and mouthwash (242). It is metabolized by the gut flora. Although it is approved in the European countries, it is recognized as GRAS only in amounts for use as a flavor enhancer in the United States, but not for the larger amounts that would be needed for use as a sweetener.

**Glycyrrhizin**—An extract from licorice root, glycyrrhizin is 30 times sweeter than sugar (247). It has limited use as a flavoring agent in some candies and tobacco due to its strong licorice flavor. It is also GRAS in the United States as a flavoring agent, flavor enhancer, and surfactant, but not as a sweetener (249).

#### **9.9.3.5 POSSIBLE HEALTH BENEFITS OF LOW CALORIE SWEETENERS:**

##### **Weight loss and maintenance**

At different times and places overindulgence of various foods has occurred. In the US today many people of all ages indulge in sugary sweet foods and beverages high in calories, and adults also in alcohol. Reduction of food energy from any source, including these sources, will result in weight loss over the long term if other foods are not substituted for it. In 2014 the Obesity Society issued a statement that reduced consumption of sugar-sweetened beverages can reduce total caloric intake and that individuals and especially children and those with weight problems reduce their consumption of sugar sweetened beverages (298). Low calorie sweeteners offer an option other than water for alternative beverages, but the reality remains that in order to lose weight, the dieter must achieve and maintain a negative energy balance (e.g. Energy intake < energy expenditure) without compensating for what is decreased by increasing intakes of other foods or beverages. . Some randomized-controlled studies have shown beneficial effects of low calorie sweeteners in weight management; with a small short-term weight loss (of about 0.2 kg/week) over placebo with the low calorie sweeteners plus a hypocaloric diet, and improved weight maintenance after the weight loss diet is discontinued while others do not (242, 267, 268, 269, 270). Another study found that when the artificial sweetener group (particularly aspartame) was compared to the control it showed a difference of about 5 kg (maintained a weight loss of 5.1 kg longer), when artificial sweeteners were substituted for caloric sweeteners in beverages and with a hypocaloric diet (267). Other studies were not as positive. A review of aspartame's role on weight control in 2006 showed a weight loss of 0.2 kg/week when products sweetened with sucrose was substituted with aspartame (269) in a hypocaloric diet. Another study showed more successful maintenance of weight loss after three years in women who were encouraged to consume aspartame-sweetened products (247).

In the most definitive study to date, of 303 participants who were overweight, during a 12 week weight loss program those who used low calorie sweetened beverages instead of water alone lost more weight than those in the control group (5.95kg vs 4.09 kg) and felt less hungry as well (299). However, in all of these studies, a weight loss regimen was essential as well, and without one it is likely that compensation would occur, wiping out any beneficial effects. The 2004 position statement of the American Dietetic

Association therefore concluded that, “nonnutritive sweeteners have the potential to promote weight loss in overweight and obese individuals”. Low-calorie sweeteners provide sweetness and palatability to food, with only minimal or virtually no food energy calories. Substituting full-calorie products with low-calorie sweetened product results in fewer calories consumed (244). Assuming that there is no eventual calorie compensation in the regulation of food intake that should be helpful, but such compensation may in fact occur over time without a conscious effort on the dieter’s part to reduce intakes especially when people know they are consuming less calories. Calorie reduction may be achieved only when and as long as low-calorie sweeteners replace their full-calorie counterpart without any additional food eaten to compensate for amount of calories saved.

Because excessive sugar intake might contribute to weight gain and obesity, owing to its effects on increasing caloric intake, a reduction in sugar intake through substitution of low-calorie sweeteners has been proposed to help prevent weight gain. The “AmericanOnTheMove” study in 2007 was conducted to investigate the effect of changes in diet and physical activity on excessive weight gain in overweight children. It showed that a replacement of dietary sugar with a low calorie sweetener (sucralose) in the diet might be an effective tool to reduce caloric intake and reach negative energy balance. However, it should be noted that the experimental group in the study was provided with Splenda products and compensation for participation in the study and these may have been added incentives to patients (300). Thus additional work is needed before the finding can be judged to be well established.

The notion that low calorie sweeteners increase hunger or cravings by uncoupling the sensory and hedonic aspects of sweetness from their satiating effects and thus leading to overconsumption of sugary foods has not been borne out in recent studies. The appetite for sweetness does not seem to be increased by their use and there is no increase in appetite or hunger with consumption of low-calorie sweetened foods and beverages. (301)

(242, 272). One American Dietetic Association’s position statement on nonnutritive sweeteners concluded that nonnutritive sweeteners had no effect on appetite, hunger, and fullness in adults at least, based on results from short-term studies (244). A more recent statement of the Academy of Nutrition and Dietetics in 2012 found that the low calorie sweeteners when substituted for nutritive sweeteners might help consumers to limit carbohydrate and energy intakes as a strategy to manage blood glucose or weight. The American Heart Association/ American Diabetes Association stated in 2012 that some data suggested that low calorie sweeteners might be used in a structured diet to replace sources of added sugars, and that this substitution might result in modest energy intake reductions and weight loss.

Low calorie sweeteners are also claimed to increase adherence in weight-loss programs by providing more palatable food choices from low-calorie sweeteners, and increasing satisfaction with the weight-loss diet (243, 246). These findings also need to be replicated, but it does appear that they have a neutral or slightly positive effect when accompanied by a hypocaloric diet.

## **Improved quality of the diet**

When the caloric intake from added sugar exceeds 25% in usual diets, the amount of some micronutrients in the diet may be reduced and diet quality worsened (244). The theory is that by replacing foods and beverages containing added sugar with the ones containing low-calorie sweeteners, calories can be saved for consumption of more nutrient-dense foods and diet quality may be improved. For example, such products might be helpful for elderly who have decreased energy needs and people who are sedentary and thus require lower caloric intake. However, there is no definitive study to date that explores whether the relationship between use of low-calorie sweeteners and diet quality does in fact exist. One study compared nutrient and energy intakes, quantity of food consumed, and the knowledge and practices between the reduced-sugar foods users and the users of the full sugar versions of the same products (273). The study found that users of reduced-sugar products had higher micronutrient intakes as they reported higher fruits, lower intakes of added fat and sugar, and more label reading. However, this study was cross-sectional and only provided information at one point in time but not over time. Better-designed studies are needed to evaluate relationships between the use of low-calorie products and diet quality.

## **Diabetes management**

Type 2 diabetes is common and appears to be on the rise. The cornerstone of dietary therapy remains weight reduction if the patient is obese, and selected medical options including orlistat (Xenical), phentermine/topiramate (Quymia) and lorcaserin (Belviq) to assist weight loss and various other medications to assist in the lowering and control of blood glucose levels. Intensive lifestyle interventions that promote weight loss in patients with type 2 diabetes have better outcomes than standard diabetes support and education, including use of fewer medications, lower health care costs and fewer hospitalizations (302). Since low-calorie sweeteners contain virtually no calories and no carbohydrates, they may help people with diabetes to use less sugar and make more healthful food choices, especially if they are trying to lose weight and control their blood sugar levels. However, weight loss will not occur if the dieter substitutes other foods for those that have been eliminated. The American Diabetes Association recommends the use of artificial sweeteners in a calorie controlled diet that also controls carbohydrate intake as part of medical nutrition therapy for diabetes, to better maintain blood glucose levels near normal and control carbohydrate intake (274).

The European Food Safety Authority (EFSA) reviewed data to substantiate health claims related to ability of low-calorie sweetener to reduce post-prandial glycemic response and the use of low-calorie sweetener and glycemic response in people with impaired



glucose tolerance. It concluded that such a claim was valid, but that there was no causal relationship between replacement of sugar-sweetened foods and beverages with low-calorie sweeteners and maintenance of normal blood glucose levels (275).

The Glycemic Index (GI) is defined as “the incremental area under the blood glucose response curve of 50 grams carbohydrate portion of a test food expressed as a percentage from a standard food taken by the same subject” (265). Foods with low GI value produce only small rise in blood glucose after ingestion, and thus may aid in control of blood sugar. All sugar alcohols are categorized as low-GI foods. In addition, certain sugar alcohols, sorbitol and xylitol, cause slow increase in plasma glucose due to delayed absorption and metabolism in the liver as well as providing low glycemic responses. Therefore, they may be helpful tools for managing blood glucose levels for people with diabetes. A recent systematic review on Stevia proposed the use of stevia (stevioside) as an antihyperglycemic agent. Stevioside may decrease glucose levels by stimulating the production of insulin, based on studies in humans and animals (262). Another recent study on the effects of stevia, aspartame, and sucrose on postprandial glucose and insulin levels found reduction in postprandial blood glucose levels with consumption of stevia before lunch and dinner meals when compared to both aspartame and sucrose (272). However, better-designed studies on humans are needed to determine the effect of stevioside on glucose tolerance and insulinemia. A recent report hypothesized that low calorie sweeteners increased the risk of altered glucose tolerance and diabetes by altering the microbiome in the gut (Suez et al doi:1036/naturea13794). The claim was based on studies in mice fed very large doses of saccharin, aspartame or sucralose sweeteners which the workers claimed altered insulin resistance. However, when one low calorie sweetener, saccharin, was fed to 7 volunteers, blood sugar rose in 4 and did not change or diminished in the other 3. Other studies with larger sample sizes and more rigorous designs have failed to show adverse effects on glucose tolerance (303)

## **Reduction of Dental Caries**

Dental caries is a complex disease, also involving teeth, bacteria, sugar, time, and saliva. Dietary sugar intake increases the risk of developing dental caries. Sugar (especially retentive forms of sugary foods that stay in the mouth) is metabolized by mutans streptococcus and other cariogenic bacteria on the surfaces of unclean teeth into acids, reducing the pH of the enamel and eroding it, causing decay. When the pH level falls below 5.5, tooth enamel demineralizes through the loss of calcium and phosphate ions (245). Demineralization can be reversed at the stage before the cavity is formed. Decreased sugar intake and good dental hygiene are an important strategy for prevention of dental plaque and dental caries. Therefore, substitution of low-calorie sweeteners (which are not fermented by the bacteria in the mouth) for sugar reduces sugar content of the diet, and thus may help prevent the development of dental caries (276). Sugarless gums and sugarless cough drops, mints, and lozenges also are non-cariogenic, which will not cause dental caries.

It is well known that the low calorie nutritive sweeteners, the sugar alcohols, especially xylitol, have anti-cariogenic properties and prevent formation of dental caries. Polyols are generally not substrates for bacteria in dental plaque. They are not metabolized by the bacteria in dental plaque into acids. The lack of acid production prevents against demineralization of teeth and subsequent dental caries formation (245, 265). However, when polyols (especially sorbitol), are consumed in large amounts (for example, more than two sticks of chewing gum in one day) in animal studies, in one animal study, the number of sorbitol-fermenting bacteria in the mouth increased slightly, somewhat reducing this anti-cariogenic effect. Nevertheless, the fermentation of sorbitol remained very slow when compared to that of sucrose (277). Thus, the bacteria in the mouth adapt to restriction of sugar by alternatively metabolizing sorbitol, but the net effect of the substance still remains positive. More research is needed to on these effects in humans.

Plaque formation may also be affected. In addition to their non-carcinogenicity, polyols also slow demineralization of tooth and promote remineralization of teeth that are with early lesion in the demineralization process. Chewing sugar-free gums containing polyols stimulates more saliva flow in the mouth. Saliva, which has high pH, acts as a buffer to acid production and washes away sugar and acids that could accumulate bacteria. In addition, saliva provides calcium and phosphate ions that can remineralize tooth enamel in the initial stage of demineralization before formation of carious lesion (265, 277).

Among all the polyols, xylitol is the most effective in reducing and preventing dental plaque and caries. Xylitol is the least fermentable polyol. Cariogenic bacteria do not ferment it and thus, the pH of dental plaque does not decrease and the enamel is not eroded (245). Xylitol also inhibits the growth of plaque-forming bacteria themselves (particularly the mutans streptococci) because it is a poor substrate for the bacteria. Therefore, can reduce the accumulation of plaque on tooth enamel (277). The structure of xylitol allows it to form a complex with calcium ions (in a chelate-like structure), which can promote remineralization of tooth enamel, resulting in reversal of the early dental caries lesion (250). Xylitol also acts as a bacteriostatic agent, through the conversion of xylitol into xylitol-5-phosphate by some strains of streptococci. Xylitol-6-phosphate degrades cell membrane of the bacteria and thus, reduces plaque quantity and adhesivity (265). Interestingly, xylitol can also help prevent intra-familial transmission of mutans streptococci from mothers to infants through its property to reduce mutans streptococci quantity (250, 277). Infants can be infected with mutans streptococci through oral transmission from mothers. Infants whose mothers chewed xylitol-sweetened gum had lower counts of mutans streptococci. Therefore, xylitol may also help protect against maternal transmission of cariogenic bacteria.

#### **9.9.3.6 POSSIBLE HEALTH CONCERNS:**

## Safety

In the USA the Food and Drug Administration permits the sale of all of the low calorie sweeteners mentioned above. In the European Union, cyclamate is also allowed and considered safe.

The products have been judged to be safe for consumption by pregnant women. However, one low calorie sweetener, aspartame (sold as NutraSweet and Equal), should be avoided in pregnancy by women who are homozygous carriers of phenylketonuria because it is metabolized to phenylalanine. In such women at very high levels phenylalanine crosses into fetal circulation and may increase risks of mental retardation. In pregnant women, there is one report that more than one diet drink per day increased risk of preterm delivery (OR 1.38, 1.15-1.65) but this has not been confirmed (304). However, other investigators have not been able to confirm the finding. The European Food Safety Authority recently conducted a full risk assessment on aspartame in view of concerns on the part of consumers that included both animal and human studies. Its' conclusion, issued in 2013, was that aspartame and its breakdown products were safe for human consumption at current levels of exposure (the ADI for aspartame is 40 mg/kg/day). It added that for patients with phenylketonuria, the ADI was not applicable because they require strict adherence to a diet low in phenylalanine. However threw a no risk to developing fetuses at the current ADI with the exception of women suffering from phenylketonuria. (296). The Dietary Guidelines 2015 Advisory Committee's draft conclusion for its final report concurred with the EFSA Panel and judged the evidence as moderate that aspartame in amounts commonly consumed was safe and posed minimal health risk for healthy individuals without PKU (including those at risk of most cancers, seizures and cognitive/behavioral problems in children and adults) (305).

Other risks are not well documented. For example, in some observational studies, low calorie sweeteners have been found to be associated with risks of metabolic syndrome (306, 307), with type 2 diabetes (308), or with coronary heart disease and kidney disease (309). However, other observational data show that there is an absence of adverse effects. For example, in the CARDIA study, those consuming a healthy diet pattern with diet beverages showed lower risks of elevated glucose and low HDL cholesterol than did others (310). More impressively in a randomized clinical trial, the CHOICE study, it was found that the diet drinks group showed declines in blood pressure and fasting glucose that were no different than those of controls. The goal was to replace caloric beverages with water or diet beverages to assist weight loss in this randomized single center single blind study of 318 overweight or obese adults studied over a 6 month period. The subject received water alone plus a monthly group website class, a low calories sweetened diet beverage along with the monthly group website, or only the website education on weight loss. None of the groups achieved large weight losses; the largest was the diet beverage group with a loss of 2.5% of body weight, and the smallest was the attention control with 1.5% weight loss at 6 months. The group consuming the diet beverage showed a greater likelihood of achieving a 5% weight loss compared to the attention control (OR 2.29, 95% CI 1.05, 5.01 P=0.04) while the

water group did not differ from the control in terms of its likelihood of achieving a 5% weight loss (311, 312). Effects were similar in another study that included weight maintenance. Dieters were given added advice to use the low calorie sweetener aspartame in a yearlong multidisciplinary program of weight loss and two year follow up, while others were not. The differences between the two groups were small but during maintenance the low calorie sweetener users kept more weight off than those who were non-users (267).

Even among those who use many low calorie sweetened foods and beverages, there is little likelihood that they will reach the ADI. For example, one would have to eat 75 low calorie sweetened yoghurts a day for one's entire lifetime to achieve the ADI for one common low calorie sweetener. In children there is a concern that low calorie sweetened beverages might displace milk and 100% juice, although this fear is not well documented by evidence it has led to regulations that do not include low calorie sweeteners as permitted foods in elementary schools. The American Academy of Pediatrics has recommended that nonnutritive sweeteners should not form a "significant part " of a child's diet, and the Academy of Nutrition and Dietetics views them as safe for children within the range of the ADI (244).

Concern has been expressed based on some observational studies, that low calorie sweetened beverages might be associated with long-term weight gain (313, 314), but others show decreased body weight (315), or both increases and decreases (316). However, in a recent met-analysis of 15 randomized controlled trials, which are considered to be superior in assessing causal inference, as well as 9 prospective cohort studies, the correlation between low calorie sweeteners and body weight favored them very clearly over the comparator arms in the randomized studies, and were not significant in the prospective cohort studies (317). The results suggest that other factors, including reverse causation (that is, low calorie sweetener users being more likely to be obese, gaining weight and trying to control their weight gain rather than the sweeteners causing the weight gain may have been present. People who have maintained their weight loss over the long term use fewer sugar sweetened beverages and more low calorie sweetened beverages than to always normal weight persons (318), and in the US National Weight Control Registry long term weight maintainers also used more water, low calorie sweetened beverages and less alcohol and sugary drinks and juices.

### **Increased appetite and intake**

There have been claims of a paradoxical effect of low-calorie sweeteners on appetite stimulation, leading to an increase in food intake. A 1986 study from the United Kingdom (278) compared the effect of water sweetened with aspartame versus plain water on hunger level. Those consuming highly sweetened water rated their hunger level higher than those who consumed only water. However, the study examined only perceived hunger level, which was subjective, and did not really assess participants' actual

food intake. A subsequent study showed no increase in actual food intakes 1 hour after consumption of solutions sweetened with saccharin, aspartame, and acesulfame-K (279).

Another theory of how low-calorie sweeteners might be orexigenic (enhance intake) involves stimulation of food reward pathways in the hypothalamus after ingestion of food (in this case, glucose). Sweetness stimulates the mesolimbic dopaminergic system, producing a feeling of satisfaction and can stimulate food intake (280, 281). Some evidence suggests that such pathway was not observed with ingestion of low-calorie sweeteners. One study using functional magnetic resonance imaging showed longer suppression of this signal in the hypothalamus with glucose ingestion in normal weight men, but found no such effect with sucralose ingestion. Thus, the lack of responsiveness to this signal from consumption of low-calorie sweeteners might theoretically lead to motivation to seek more food (281). However, at present, the evidence is insufficient to conclude that low-calorie sweeteners enhance appetite or food intake, and more research is needed.

Psychobiological signaling between food and the gut as well as energy compensation of meals are two other proposed explanations of how low-calorie sweeteners may lead to overconsumption and weight gain. The psychobiological theory is that low-calorie sweeteners, unlike caloric sweetener, only provide sweetness but not the food energy (282). When sweetness is not accompanied by calories, there is no signal to provoke cephalic phase of digestion in the gut to prepare for arrival of nutrients and to begin the process of energy utilization and thermogenesis. The animal model showed less effective energy regulation through this mechanism, leading to excessive calorie intake and weight gain. In addition, a theory on energy homeostasis has been proposed as another possible mechanism for speculated weight gain from low-calorie sweeteners. Energy compensation, which is the adjustment of energy intake on subsequent meals based on amount of energy consumed on the prior meal, may be disrupted when caloric sweeteners is replaced with low-calorie sweeteners (283). Because low-calorie sweeteners provide only negligible amounts of energy, an upward compensation by increasing intake on subsequent meals is expected. More importantly, some worry that use of low-calorie sweeteners could lead people to believe that they could consume more of other foods to compensate for lower energy from low-calorie sweetened foods and beverages (280). Overall, there is no current evidence on humans to validate any of these theories. However it is clear that inappropriate use of low calorie nutritive or non-nutritive sweeteners that leads those attempting to control their weights to throw all caution in consumption to the winds will nullify any potentially positive effects that they might have.

**Low calorie sweeteners have no or modest effects on weight loss and weight maintenance unless accompanied by a hypocaloric diet**

A number of studies have been conducted or are now in progress to determine the effects of low-calorie sweetened beverages on

weight changes and metabolic health effects in adults and children in adults, epidemiological studies of children and adolescents are mixed, some showing associations of low calorie sweeteners are associated with increased body weight (319). Two studies (the cross-sectional National Health and Nutrition Examination Survey (NHANES) and the semi-longitudinal San Antonio Heart Study), found positive associations between the use of non-nutritive sweeteners and an increase in body mass index (BMI) (268). However, the design was such that it is not clear if obese people used more low-calorie sweeteners (more likely) or whether low-calorie sweeteners caused them to be obese (less likely). Another longitudinal cohort study found a positive correlation between increased consumption of diet soda and BMI z-scores after two years in 164 elementary school aged children (284). However, the study design again was not such that it could demonstrate a causal relationship between the two, possibly the effects were again due to reverse confounding (e.g. the obese who are most likely to gain weight were those who also used more diet products). Attributes of causal relationships such as strength of association, temporal relationship, consistency of findings, biological plausibility, and strong dose-response relationship, need to be considered when epidemiologic studies of low-calorie sweetener consumption and weight gain are examined. In the few small randomized trials of overweight and obese children, low calorie sweeteners do not or only minimally decrease weight and body mass index (320, 321, 322). Therefore, although there is no strong evidence that use of low-calorie non-nutritive sweeteners (especially in beverages) increases weight, there is also little evidence that it decreases it substantially. However, adding several interventions, such as was done in the 6 month America on the Move study, in which 192 families with at least 1 overweight child were randomized to either an intervention involving increasing physical activity by 2000 steps a day and decreasing sugar by 100 Calories per day with a low calorie sweetener or to a control group which involved only self-monitoring, the two interventions together did show small but greater changes in body mass index for age among the children at month 6 (323).

Another theory to explain the purported association between low-calories sweeteners and weight gain is that lower carbohydrate intake may result in higher fat intake. A reduction in carbohydrate intake by replacing sucrose with low-calorie sweetener is claimed to lead to a higher proportion of energy coming from fat, which in turn may lead to weight gain. However, accumulating evidence does not support the claim that macronutrient shifts occur from the replacement of low-calorie sweeteners and an increased fat intake in the diet (280).

Another potential, but unproven theory based on a study in rats linking low-calorie sweeteners and weight gain is that the gut microflora are altered when they are exposed to low-calories sweeteners. Changes in gut microflora might then trigger inflammatory pathways; promoting insulin resistance, fat accumulation, and weight gain in the individual (286). There is no evidence in humans to support this claim, and the evidence in experimental animals is mixed at best..

### **Development of a “sweet tooth” due to low calorie sweeteners?**

Artificially sweetened and calorically sweetened foods and beverages are claimed to increase the preference for a sweet taste, with an increase in consumption of artificial sweetened beverages may change taste preferences toward sweet foods, especially in children (268). This preference is feared by some to bring about the replacement of healthful foods with sweets, and thus may be associated with lower diet quality in children. However, at present little evidence exists that this is so. In addition, repeated exposure to sweetness could lead to an increased acceptance of sweet sensation as a result of learned behavior and the exposure to sweetness in low-calorie sweetener might establish preference to sweetness in the same manner as other sugars (280).

Low-calorie non-nutritive sweeteners have been shown to activate sweet-taste receptors in the gut in the same manner as sugar does in animal studies. T1R2 and T1R3 are transmembrane sweet-taste receptor proteins found in the gut of both rodents and humans (286, 287). Compounds with a sweet-taste (e.g. sugar and low-calorie sweeteners) bind to these receptors, stimulating signaling pathway to the brain in experimental animals. This leads to changes in electrophysiological patterns in the brain, resulting in preference of sweetness. At present, the evidence that low-calorie sweeteners encourage or exacerbate sweet tooth remains scattered. More research is needed.

What can be said with certainty is that infants and young children do not require low-calorie sweeteners although they are judged as safe by the FDA. The American Dietetic Association (ADA) suggests that parents of children less than 2 years of age discuss use of those products with their pediatricians to ensure that childrens' needs are met (244). Concerns about ensuring that children and adolescents learn good food habits have led some individuals and expert groups to recommend that schools restrict the use of calorically sweetened beverages and high-calorie, low nutrient density sweet foods that are also high in added sugars (288). However, some of those reports have also recommended against the sale of low-calorie sweetened beverages in school, not for safety reasons, but to foster nutrition education. The rationale for doing so is not entirely clear, but nonetheless, many elementary and secondary schools now do not permit non-nutritive sweetened or calorically sweetened beverages in schools. Research is needed to determine if such a prohibition has intended effects on nutrition education, development of a "sweet tooth", dental caries, weight gain or maintenance, overall intakes of sugar, added sugar, or food energy, or other objective standpoints. Also, unintended effects, such as more extensive overall use of the products as gestures of defiance must be assessed.

## **Metabolic Syndrome**

Some large prospective cohort studies found associations between intakes of low-calorie sweeteners and incidence of metabolic syndrome, but the designs were such that cause and effect could not be demonstrated (289). Proponents that such a link is causal suggest that the association is due to deregulation of glucose homeostasis caused by the use of artificial sweeteners. Another, simpler, explanation is a reverse causation. One study on consumption of diet soda in young healthy volunteers before an oral glucose challenge showed an increase in secretion of GLP-1, the anti-hyperglycemic hormone released by intestinal cells, which can alter gastric emptying and secretion of insulin. Whether the low-calorie sweeteners in fact had these effects is not yet clear; the study has not been replicated. The concern raised is that consumption of artificial sweeteners together with foods and drinks containing sugar may lead to increased GLP-1 and insulin secretion, which may result in more rapid sugar absorption and perhaps in turn, could influence blood sugar levels. However, at present, evidence is lacking that this is the case.

Evidence from in vitro and rat studies suggests that low-calorie sweeteners stimulate the sweet-taste receptors in the gut, causing the up-regulation of transporters, sodium-dependent glucose transporter (SGLT 1) and glucose transporter 2 (GLUT 2), on the apical membrane of the small intestine to increase glucose uptake. In addition, low-calorie sweeteners (especially sucralose and saccharin) may also stimulate release of incretin (GLP-1), a gut hormone that stimulates insulin release after ingestion of glucose. This cascade of intestinal uptake transporters, incretin, and insulin release may disrupt glucose homeostasis (286, 287). However, extensive number of studies conducted in humans showed no such effect. Overall, there is no consistent evidence in humans that low-calorie non-nutritive or nutritive sweeteners have adverse effects on insulin release and blood glucose homeostasis.

#### **9.9.3.7 SUMMARY AND RECOMMENDATIONS**

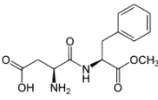
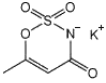
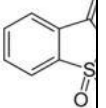
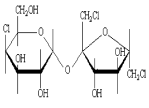
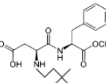
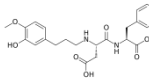
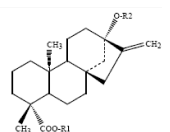
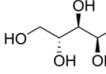
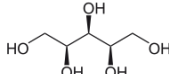
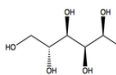
- None of the low-calorie sweeteners permitted by FDA on the US market are necessary in human diets or for human health. However, some consumers enjoy the sweet taste of nutritive or non-nutritive low calorie sweeteners and there is no reason to discourage their use on safety or health grounds.
- All FDA-approved sweeteners are safe for use by the general population, pregnant women (except phenylketonurics), and children (except phenylketonurics) as doses below the Acceptable Daily Intake (ADI). For pregnant women (other than those with PKU) the American Academy of Pediatrics has stated that aspartame is safe for pregnant women and their developing infants. There is also evidence that acesulfame K, sucralose, and the sugar alcohols are safe for pregnant women in small amounts. Little research has been conducted on the safety of saccharin and stevia in pregnant women.
- None of the low-calorie nutritive or non-nutritive sweeteners are perfect substitutes for sugar from the standpoint of taste, mouth feel, and functionality in food processing and preparation, but they are acceptable to many people.
- Most of the nutritive and non-nutritive low-calorie sweeteners are non-cariogenic. Xylitol also appears to have an anti-cariogenic property as well, enhancing remineralization of tooth enamel.



- The best-documented adverse effects with low-calorie sweeteners are from poorly absorbed nutritive low-calorie sweeteners (sugar alcohols) that have laxative effects when consumed in large amounts. A theoretical hazard exists for aspartame with very heavy use of individuals with phenylketonuria (PKU). Other health concerns, such as the fostering of a “sweet tooth” that leads to excessive energy intakes are poorly documented.
- Low calorie sweeteners may be helpful in weight control if they are substituted for some of the caloric sweeteners in the diet and calorie intakes are also reduced. Otherwise, they appear to have little effect. Their use alone without healthful eating, physical activity, and behavior change is unlikely to be helpful in weight management.
- Low-calorie sweeteners contribute little or nothing to the glycemic response and as such may have advantages over caloric sweeteners for individuals who need to control their blood sugar levels.
- There is no current scientific reason to recommend against the use of low calorie sweeteners for those who are trying to lose weight and wish to use them.
- For patients or other users who are concerned about excessive intakes of nutritive or non-nutritive low calorie sweeteners, the best advice is to use several different types of low-calorie sweeteners so that doses of any one compound are low and to always stay below the ADI, or to not use them.

Table 20 is a description of nutritive and nonnutritive low-calorie sweeteners approved by the FDA or recognized as generally recognized as Safe (GRAS). The table describes the following for each non-nutritive and nutritive sweetener; brand name, definition, characteristics, metabolism and excretion, chemical structures, sweetness, calories, ADI, year approved, uses, health benefits, health concerns and additional comments.

Table 20. Nutritive and Non-nutritive low-calorie sweeteners approved by FDA or recognized as Generally Recognized as Safe (GRAS) (242-291).											
	Non-nutritive sweeteners							Nutritive Sweeteners			
Names	Aspartame	Acesulfame-K	Saccharin	Sucralose	Neotame	Advantame	Steviosides	Mannitol	Xylitol	Sorbitol	
Brand names	<i>NutraSweet®</i> , <i>Equal®</i> , <i>others</i>	<i>Sunett®</i> , <i>Sweet One®</i>	<i>Sweet'N Low®</i> , <i>Sweet Twin</i> , <i>Sugar Twin®</i> , <i>Necta Sweet®</i>	<i>Splenda®</i>	<i>Used as ingredient in food products.</i>	<i>Used as an ingredient in food and beverage products</i>	<i>Stevia®</i> , <i>Truvia™</i> , <i>Sun Crystals®</i> , <i>PureVia™</i> , <i>Sweetleaf Sweetener™</i>	<i>Used as ingredient in food products.</i>	<i>XyloSweet</i>	<i>Used as ingredient in food products.</i>	
Definition	Synthetic sweetener composed of aspartic acid and phenylalanine.	A combination of an organic acid and potassium.	Synthetic sweetener in forms of sodium or calcium saccharin.	A sugar derivative by replacing 3 hydroxyl groups with 3 chlorine atoms on the sugar molecule.	Dipeptide methyl ester derived from aspartic acids and phenylalanine.	Synthetic sweetener produced in a 3-step process that ultimately combines aspartame and HMPA	Derived from the leaves of Stevia rebaudiana plant in South America. Known as "sweet leaf."	A hexose alcohol extracted from seaweed.	An intermediate product of carbohydrate metabolism from xylan-containing plants.	A hexose alcohol from hydrogenation of glucose and fructose with nickel catalyst.	
Characteristics	Loses sweetness with high heat.	Highly heat	Highly heat stable	Highly heat stable	Highly heat stable for cooking and baking.	Heat Stable for cooking	Heat stable.	Heat stable. High melting point.	Sweetest of sugar	Heat stable and highly soluble.	

		stable for cooking and baking. Metallic aftertaste.	for cooking and baking. Bitter metallic aftertaste.	for cooking and baking.	Clean sweet sucrose-like taste.	and baking. Clean sweet sucrose like taste. Ultra high potency.	Licorice aftertaste. Enhances sweet and savory flavors. Lacks bulking property.	Non-hygroscopic(does not pick up moisture).	alcohols. Quickly dissolves. Produces cooling effect in the mouth.	Does not cause browning. Humectant (retain moisture).	
	Non-nutritive sweeteners								Nutritive Sweeteners		
Metabolism and Excretion	Broken down into aspartic acid, phenylalanine, and methanol upon digestion. All compounds are metabolized normally, except in individuals with PKU.	Not metabolized and excreted unchanged by kidneys.	Not metabolized and excreted unchanged by kidneys.	Not randomized and excreted by the kidneys and in feces.	Partially absorbed and excreted in feces and urine.		Not absorbed in small intestine. Degraded into steviol by bacteria in the colon, where it is absorbed. Excreted in the feces and urine.	25% is absorbed and excreted in the urine. Unabsorbed portion is fermented by colonic bacteria.	50% absorbed and excreted. Unabsorbed portion is fermented by colonic bacteria.	25% is absorbed and excreted in the urine. Unabsorbed portion is fermented by colonic bacteria.	
Chemical Structures											
Relative sweetness compared to sucrose*	180	200	300	600	7000-13000	20000	200-300	0.5-0.7	1	0.5-0.7	0

Kcal/g	4	0	0	0	0	0	0	1.6	2.4	2.6	0
ADI (mg/kg/d)* *	50	15	5	5	18 mg/day	1970 mg/day	0-4 (as steviol)	Not specified.	Not specified.	Not specified.	N s
ADI for 70kg person / Cans of soda equivalent	3500mg / 28	1050mg / 21	350mg / 4	350mg / 6	18mg / NA	1970 mg/ NA	0 – 280mg / 5	NA / NA	NA / NA	NA / NA	N
Year of approval by FDA and as GRAS.	1981	1988	Prior to 1958. Re-approv ed again in 2000.	1998	2002	2014	GRAS in 2008	1986	1983	GRAS 1982	2
	Non-nutritive sweeteners							Nutritive Sweeteners			
Uses	Tabletop sweetener, ingredients in foods and diet soft drinks. Limited use in bakery products.	Tabletop sweeteners, baked goods, frozen desserts, candies, beverages, cough drops, and breath mints.	Tabletop sweetener, soft drinks, baked goods, jams, chewing gum, canned fruit, candy, dessert toppings, salad dressings.	Tabletop sweetener, beverages, chewing gum, frozen desserts, fruit juices, gelatins.	Flavor enhancer, baked goods, soft drinks, chewing gum, frozen desserts, jams, puddings, gelatins, processed fruits.	Flavor enhancer, baked goods, soft drinks, chewing gum, frozen desserts, jams, puddings, gelatins, processed fruits.	Tabletop sweetener, juices, tea beverages. (Used extensively in Japan for pickles, dried seafoods, and confections).	Dusting powder for chewing gum, ingredient in chocolate-fl avored coating agents for ice cream and confections .	Chewing gum, hard candy, oral health products, cough syrups and cough drops, children’s chewable multivitamins, foods for special dietary needs.	Sugar-free candies, chewing gums, frozen desserts, pastries	E s in f p c b , f c c g c n

Health benefits	Virtually calorie free.	Calorie free.	Calorie free.	Calorie free.	Calorie free.	Calorie Free	Calorie free. Claimed to have a hypoglycemic effect.	Low calorie content. Non-cariogenic. Low glycemic response.	Low calorie content. Reduces dental plaque and caries and may promote tooth remineralization. Low glycemic response.	Low calorie content. Slow absorption and metabolism independently of insulin might benefit for diabetics.	
	Non-nutritive sweeteners							Nutritive Sweeteners			
Health concerns		All should be used at levels below the ADI.						Strong laxative effect at >20 mg/day.		Strong laxative (> 50 mg/day) and also diuretic effects. Flatulence and diarrhea.	
Comment	Requires a label that product contains phenylalanine.				Does not require a label for phenylalanine			Requires a warning label for a possible		Requires a warning label for a possible	

					content due to negligible amount used and low availability of phenylalanine from the neotame.			laxative effect.		laxative effect.	
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\*Relative sweetness as compared to sucrose (table sugar). 1= reference value which is the sweetness of sucrose.

\*\* ADI = Acceptable Daily Intake

\*\*\* Other non-nutritive low-calorie sweeteners (Alitame, Thaumatin, Neohesperidine, and Glycyrrhizin) are not yet approved as both sweeteners and as GRAS in the US. *See text for details.*

<http://beverageinstitute.org/>

### 9.10 Energy Density

Energy density, or caloric density, is defined as the calories provided per unit weight of food eaten (such as calories/gram). When the composition of a diet of usual foods is decreased in fat, the energy density of the diet tends to fall since the total weight of food consumed remains constant, or may increase (196-198) . Some of the beneficial effects of low fat diets in weight loss and maintenance may be due, at least in part, to low energy-density, which may promote satiety. The premise is that if foods bring more weight than calories into the body, gastric distention and intestinal bulking may promote fullness. For example, foods high in water and/or fiber tend to have low energy density, with some that are very high in volume, such as unbuttered popcorn. Their inclusion in a weight reduction diet is advocated by some experts for this reason (10), and because they might increase overall dietary quality (199). As will be discussed later, some evidence suggests that low-energy density, high-volume diets may help people ingest fewer calories and thus may assist with weight loss, although longer-term research is needed (200; 201;199).

### 9.11 Volume of Food

Low energy density is the basis of the “Volumetrics” diet put forth by Dr. Barbara Rolls. This diet is high in fruits, vegetables, cooked whole grains and fibrous foods, which are high in water and bulk, to add volume for satiety without extra calories (285). In a one year study completed by 71 obese women, the low energy density diet group showed slightly better weight loss than a low fat diet group, and reported lower hunger (324). Cross-sectional work has shown that people who maintain large amounts of weight loss over years tend to eat a lower energy density diet than normal weight or obese subjects (201). Some other diets tend to be low in energy density without specifically targeting energy density, through their inclusion of fruits, vegetables, and fibrous foods (199).

## **10 AVAILABLE PROGRAMS**

According to the U.S. Food and Drug Administration (FDA), Americans spent an estimated \$30 billion in 1992 on diet and weight loss programs. Market data, an independent market research and consulting firm, has estimated annual spending on diet and weight loss programs to have reached \$61 billion by 2013 (203). The number of products and programs available to consumers is essentially endless, and the quality of what is available can be questionable. Therefore, patients should be advised to research programs or products they are interested in, and consult with a physician before utilizing any commercial weight loss option.

### **10.1 Registered Dietitians: Dietetic Advice and Individualized Eating Plans**

A registered dietitian is a food and nutrition expert who has met academic and professional requirements including:

- A bachelor’s degree at an accredited university, approved by the [Commission on Accreditation for Dietetics Education \(CADE\)](#) of the [American Dietetic Association \(ADA\)](#).
- Completed an accredited, supervised, experiential practice program (dietetic internship) at a health-care facility, community agency, and/or foodservice corporation, including at least 900 hours of hands-on experience.
- Pass a national examination administered by the [Commission on Dietetic Registration \(CDR\)](#).
- Complete continuing professional education requirements to maintain registration.

Many physicians lack the time that obese patients require for successful weight control therapy. Referral for dietary counseling to a registered dietitian (RD) is useful for many patients, particularly those who have comorbidities that also require medical nutrition therapy. Many registered dietitians also hold certifications in specialized areas of practice, including weight management, providing additional expertise in the management and treatment of obesity (203). They are able to understand more complicated therapeutic dietary recommendations that many patients, especially those with comorbidities, require. Practicing registered dietitians in your area can be located using the website for the Academy of Nutrition and Dietetics at <http://www.eatright.org/>.

#### **10.1.1 Available Programs**

There are over 67,000 registered dietitians in the United States, practicing in hospitals, outpatient centers, health centers, the community, and in private practices, among many other areas of expertise (204). Patients can see a registered dietitian via

patient referrals from physicians for a variety of health problems that require dietary modification, or by self-made appointments. Depending on the area of dietary modification/treatment, health insurance may, or may not, cover the services provided, so patients need to check with their insurance providers before scheduling an appointment. Some formal weight control programs staffed by dietitians are available in hospitals and health centers, where individual counseling is also available.

#### **10.1.2 Candidates for Care**

Dietary advice of a general nature is not enough for patients who have multiple comorbidities requiring medical nutrition therapy (e.g., diabetes, hypertension, coronary artery disease, gastrointestinal disorders, etc.), those on multiple medications, and those with complex and involved health problems that have dietary implications. These patients are prime candidates for dietetic therapy with a dietitian. Patients who have had poor outcomes in weight control efforts on their own, who have special dietary needs or preferences, and who need extensive education and assistance are also particularly likely to benefit.

#### **10.1.3 Advantages**

Registered dietitians are able to read and interpret medical records and are equipped to adopt weight loss prescriptions to the particular needs of patients. Their knowledge of food habits, food preparation, and food products on the market makes them an excellent resource for helping patients to adopt the general weight control prescription to a patient's particular circumstances. A particular advantage of dietetic involvement in patient care is that dietitians often work in medical settings and have access to patient charts, as well as the ability to consult with other health professionals. Registered dietitians are helpful in treating patients on multiple medications, on very-low-calorie diets, and post-gastric bypass counseling. Some dietitians have advanced certification in weight management, and are especially well equipped to counsel patients with complex and involved medical problems. Some insurance companies and health maintenance organizations may pay for obesity treatment when it is part of a larger therapeutic program for conditions such as diabetes if it involves a dietitian who is a certified Medicare provider. Patients should check with their insurance providers about reimbursement.

#### **10.1.4 Disadvantages**

The patient's out-of-pocket costs for dietary counseling from a registered dietitian vary, depending on insurance coverage and the comorbidities that need to be treated/addressed. It is important to note that personal trainers and/or nutritionists do not necessarily have the credentials to be counseling patients on nutrition and dieting. This is particularly true of patients who have comorbidities. Providers should encourage patients seeking counseling on their own to look for the "registered dietitian" credential.

#### **10.1.5 Safety and Effectiveness of Therapy**

Registered dietitians are health professionals who go through extensive schooling and training and are registered in a national registry with specific standards. Licensure is also required in 31 states. Registered dietitians, therefore, have medical, legal, and ethical obligations to their patients. Their own education includes formal educational requirements of at least a baccalaureate degree, a dietetic internship, supervised clinical training, a registration exam, and mandatory continuing education. Dietitians are



trained to read medical charts, to work with physicians and other allied health professionals, and to alert physicians when untoward events arise. Thus, their recommendations regarding weight loss are likely to be safe and evidenced-based. The effectiveness of dietetic counseling, like that of physician counseling for weight control, has seldom been evaluated.

## 10.2 Commercial Weight Loss Programs

Commercial non-medical weight control programs are popular and widely available in the United States and Canada. They will be discussed in detail in the following section.

### 10.2.1 Available Programs

Commercial programs include large chains such as Weight Watchers®, Jenny Craig®, LA Weight Loss Centers®, Nutrisystem®, and many regional ventures. These programs vary, but generally include advice on a structured low calorie diet, exercise, lifestyle modification coupled with group support and/or individual counseling. Oftentimes, there are options for delivery of pre-portioned reduced-calorie meals. Usually the program is administered by a layperson trained by the program who is often a successful program graduate. However, laypersons trained by the company and degree-trained professionals (such as dietitians) may also be on their staff. It should be noted that these programs do not provide physician supervision although they usually require physician sign-off before involvement (105). All of these programs are for-profit entities and charge fees (196). With the growth of the Internet, many programs now offer online support as an adjunct or replacement to more traditional in-person individual or group counseling. A sample of some popular commercial programs is outlined below in Table 21.

**Table 21. Popular Commercial Programs**

Product	Comments
Jenny Craig® (Nestle Nutrition®) ww.jennycraig.com	A commercial program where dieters are paired with trained consultants, often program graduates, who help set goals, plan weekly meal plans, and provide support through in person and phone meetings. The program also includes home-delivered pre-portioned food that provided 3 meals and a dessert or snack each day. The meals are designed to promote 1-2 lbs of weight loss each week using portion control. The plan starts at \$19 per month, plus the cost of food, which ranges from \$16-\$23 per day. A full line of products is also available to be purchased outside the official program in retail outlets. Options in this line range from Complete Meals to Café Steamers. Meals are between 180-410 calories and are available at most local grocers. There are also desert options. These products fulfill American Heart Association heart checklist program criteria, and are lower in sodium than some other brands

<p>Nutrisystem® (Nutrisystem Inc. ®) <a href="http://www.nutrisystem.com">www.nutrisystem.com</a></p>	<p>Participants in the program receive all meals, snacks, and desserts via home delivery. Foods may be chosen a la carte or according to a meal plan with predetermined food choices. Various plans are offered for men and women in different categories: <i>basic</i> for the budget conscious, <i>core</i> for added convenience and variety, <i>select</i> for the most variety, <i>diabetic</i> for diabetics, and <i>vegetarian</i> for vegetarians. Prices vary depending on the plan, but are expensive. One month on the program can cost between \$300 and \$500, and may be more expensive. The program also includes access to an online community and phone counseling. 5-day weight loss kits are also available in retailers such as Wal-Mart® and Costco® for around \$50.00.</p>
<p>Weight Watchers® <a href="http://www.weightwatchers.com">www.weightwatchers.com</a></p>	<p>Weight Watchers uses a group support focus to promote weight loss through attendance at weekly meetings, where members support each other, discuss challenges and successes, and weigh-in. Weight loss is achieved by teaching dieters how to subscribe points to a variety of different foods and eat within a certain point budget each day. For around \$10 per week, dieters can attend meetings and have access to online tools and a mobile app. There is also an online-only self-help version of the Weight Watchers® program which provides a diet plan and fitness information with exercises. Cost is currently around \$20 per month, with an approximately \$30 sign-up fee. However, the often run cost-saving promotions for those willing to sign-up for at least 3 months.</p>
<p>LA Weight Loss Centers® <a href="http://www.laweightloss.com">www.laweightloss.com</a></p>	<p>A 3-part plan that provides meal plans with recipes, snack bars, and dietary supplements. Other tools available include educational material, food diaries, and specialized plates and containers to aid in portion control. The silver plan cost between \$150-\$200 per month, and does not include supplements, while the gold plan costs between \$200-\$250 per month and offers supplements designed by the company called “nutritionals”. Support from counselors is available in-center and online.</p>

Ediets.com <a href="http://www.ediets.com">www.ediets.com</a>	Provides a personalized reducing diet and food list, fitness information, healthy recipes, social networking community, and charts and dieting tools. There are 3 categories of diet plan currently available: the “Vitabot plan”, the “Holly Madison Diet,” and the “Nutrihand plan.” Cost is currently \$9.95 per month. Meal delivery options are also available for \$30 - \$40 per day through “The Chef’s Diet,” which uses a 40-30-30 ratio of carbohydrate, protein, and fat, respectively, and between 1300-1500 calories per day. This option includes 3 meals per day and 2 snacks
Diets.com <a href="http://www.diets.com">www.diets.com</a>	A nutrition and health website with tools to aid in weight loss, healthy living, and wellness. Basic membership is free and includes access to online support groups, articles, and useful tracking tools. However, premium membership, including all of the above in conjunction with a customized diet plan, personalized exercise plan and coping plan, personalized “expert” advice, and individualized weekly self-checklists to help keep dieters on track, is available for around \$40 per month, with those willing to sign-up for 6 months getting the largest discount at just over \$14 per month.

### 10.2.2 Candidates

Overweight and moderately obese persons with few risk factors and few comorbidities are good candidates for these programs. Those who find that they need continued motivation, monitoring, and social support with a structured regimen may particularly benefit from one of these programs.

### 10.2.3 Appropriate Use

These programs are not substitutes for physician concern for or medical monitoring of his or her patients’ weights. They are most successful when the patient’s personal physician continues to provide encouragement and supervision because most commercial weight loss programs provide no or very little physician supervision. The commercial programs are not equipped to deal with patients with multiple involved comorbidities of either a medical or psychological nature. Patients with complex medical issues are better treated by a program and therapists who are more closely connected to the health care system where medical charts and other patient-specific information is available. Registered dietitians and specialized weight control programs operated by medical facilities are more appropriate options in this population.

#### **10.2.4 Advantages**

Most major established commercial chains offer well-crafted, nutritionally adequate, and behaviorally sound programs that, overall, are reasonable therapies. Classes are often held in places of employment or neighborhood centers that are conveniently located. Weight Watchers® offers frozen entrées and other weight control products that are integrated into the program and available in supermarkets, making adherence easier. Jenny Craig® and LA Weight Loss Centers® also offer frozen entrees and various weight control products; however, these are only available through their stores. On the Nutrisystem® program, the customer must eat only Nutrisystem® food for a defined period based on individual needs. Nutrisystem® sends all food items including snacks to the customer via mail.

In a multicenter, randomized, two-year study of 423 subjects with a BMI of 27 to 40 kilogram/m<sup>2</sup> it was shown that a structured commercial weight-loss program was more likely to be effective for managing moderately overweight patients than brief counseling and self-help (205). Individuals were randomly assigned to either a self-help program, consisting of two 20-minute sessions with a nutritionist and provision of printed materials and other self-help resources, or to attendance at meetings of a commercial program (Weight Watchers®). After 26 weeks subjects in the commercial weight-loss program had greater decreases in body weight, BMI, mean waist circumference, and fat mass (205). It is important to discuss commercial program options with individuals so they know their options, but only with individuals who are plausible candidates.

Since it was founded in 1997, most of the large commercial programs have joined the Partnership for Healthy Weight Management, a voluntary association. Members provide, on a voluntary basis, publicly available information to help potential participants meet their needs. Criteria for membership require that programs disclose staff qualifications, essential components of the program, the risks associated with overweight and obesity, other details about the provider's program or product, and program costs.

#### **10.2.5 Disadvantages**

Because they are profit-driven business, the main objective of a commercial weight loss programs may not be driven by patient care. Although most programs require physician approval before participants can enroll, there is no guarantee of the quality of the health assessment that has been carried out prior to enrollment. For some individuals, especially those at very high risk, more intensive medical supervision may be required. The cost of the programs is another obstacle. Many of the poor who are obese do not have the resources to purchase these services and products, even though they might benefit from them. Discounts or waivers of fees for those in financial hardship are rarely available.

Statistics are rarely kept on success rates or long-term adherence. Another problem is maintenance of lost weight and preventing relapse. The companies have become more active in developing programs catering to those who have lost weight to help them maintain their losses in recent years, but incentives to patients for staying in maintenance programs may still not be sufficient. Additionally, very few high-quality studies have assessed the efficacy of commercial weight loss programs and the ones that do provide the best-case scenario for results—as they do not account for participants who have dropped out of the program (206).

The only program that has published high-quality studies to date is Weight Watchers®. The best study on Weight Watchers® determined that participants lost 5% of their initial body weight (about 10 pounds) in 6 months and kept off 3% (about five pounds) at two years (206).

### 10.2.6 Effectiveness and Safety

The major firms provide programs and products that are safe for patients without major comorbidities when directions are followed. However, in spite of the fact that millions of Americans have purchased these services, their effectiveness in bringing about weight loss or sustaining lower weights has rarely been studied with scientific rigor (105).

## 10.3 Formulas and Meal Replacements

In addition to commercial weight loss programs, many meal replacement and formula products for weight control are now available. Patients can purchase these products on their own in supermarkets, drug stores, and online. Unlike very low-calorie diet formulas, which are medical foods that are usually provided as part of a medically supervised treatment program (see Table 13), these products can be purchased by anyone.

### 10.3.1 Available Products

Meal replacements now include not only powders like Slim-Fast® that are mixed with milk or other liquids, but drinks, bars, and frozen entrees. Formulations and nutrient content vary. Most liquid meal replacement products provide about 220 calories per serving and are relatively high in protein, vitamins and minerals, but low in fat (see Table 22 for examples of over-the-counter, ready-to-drink, liquid meal replacements). The health bars and frozen entrees vary in their caloric content, but are generally between 200 and 400 calories, and have more complete profile of nutrients. The entrees include offerings such as Lean Cuisine®, Healthy Choice®, and Smart Ones®, among others (see Table 23 for product listing). All of these pre-packaged entrees share characteristics such as discrete portion sizes that are relatively low in calories (usually 300 calories or less). Generally, all frozen entrees are high in sodium, with at least 500 mg of sodium per serving. Smart Ones® is manufactured by HJ Heinz, and is closely allied with the Weight Watchers® commercial diet program. Its packages are prepared to fit into the food plans for the Weight Watchers® program. All of the meal replacement products are designed to be eaten with additions of conventional foods that supply dietary fiber, other nutrients, additional calories and fluids.

**Table 22. Examples of Caloric Composition of Over the Counter, Ready to Drink, Liquid Meal Replacements for Weight Loss**

	<b>Total calories</b>	<b>Size</b>	<b>Carbohydrates, gm</b>	<b>Protein, gm</b>	<b>Fat, gm</b>

GNC® Total Lean™ Lean Shake™ (GNC®)	170	14 fl oz	6	25	6
EAS® Myoplex® Lite (Abbott®)	170	11 fl oz	20	20	2
Slim-Fast® Protein Meal Shakes (Unilever®)	180	10 fl oz	4	20	9
Atkins™ Advantage® Shakes (Atkins Nutritionals®)	160	11 fl oz	6	15	9
Glucerna® Hunger Smart™ Shake (Abbott®)	180	11.5 fl oz	16	15	8
Carnation® Breakfast Essentials™ No Sugar Added Complete Nutritional Drink (Ready-to-Drink) (Nestle Nutrition®)	250	11 fl oz	16	13	5

Note – Glucerna is formulated for individuals with diabetes or prediabetes

**Table 23. Popular Frozen Entrees**

Product	Comments
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Healthy Choice® (ConAgra Foods®)	A full line of products from Complete Meals to Café Steamers. Meals are between 180-410 calories and are available at most local grocers. There are also desert options. These products fulfill American Heart Association heart checklist program criteria and are lower in sodium than some other brands
Kashi® Frozen Entrées (Kashi®)	A variety of different entrée options are available, many of which are vegetarian. Typically, these entrees range from 250 to 400 calories. They are available in local grocery stores.
Lean Cuisine® (Nestle Nutrition ®)	A wide range of entrees from Panini sandwiches to lasagna. Entrées, including breakfast options, are between 140-400 calories, and are available at many grocery stores.
Smart Ones® (Heinz®)	Smart Ones® products are associated with the Weight Watchers® program, and available at many grocery stores. Entrees range from 180 to 310 calories, and packaging also includes the Weight Watchers® points associated with each item. A small tossed salad and/or fruit may be added to make the meal more complete. There are also snack, desert, and breakfast options available.

### 10.3.2 Candidates

Individuals who are healthy but moderately overweight (BMI 25-30) and who wish to lose less than 5% of their body weight or who wish to use these products for one meal a day to assist in their weight maintenance efforts may find these products helpful. The products provide an easily prepared, generally nutritious, and relatively modest caloric load that can satisfy hunger. For those who are susceptible to environmental triggers (such as being involved in meal preparation or eating in cafeterias or fast food restaurants) and respond by overeating, these products offer a safe and palatable option that lessens temptation.

### 10.3.3 Appropriate Use

Portion controlled liquid meal replacements such as Slim-Fast® or Shakeology (and many other products) are recommended for two meals and a snack with a small meal of conventional foods and low or no calorie beverages. They should not be used as the sole source of nourishment on a diet. The entrée choices are suitable for meals, but their use for multiple meals a day should be cautioned in patients for whom sodium consumption is a concern.

#### **10.3.4 Advantages**

The main advantages of meal replacements are built-in portion and calorie control, widespread availability, convenience composition that is fairly micronutrient dense while remaining low in calories, ease of preparation, and for some of the dry or canned products, portability. Costs of the meal replacements are reasonable, and can simplify food choice decisions. They are lower in calories than many snack or restaurant foods that people who are eating away from home might otherwise consume. They are also convenient, rapidly and easily prepared, and can be eaten anywhere, allowing eaters to avoid “high risk” eating environments.

#### **10.3.5 Disadvantages**

The major disadvantages of these products are their cost, monotony, and limited variety. From a nutritional standpoint, the products vary, but are often quite high in sodium (600 plus milligrams per serving). Only *Healthy Choice*® is low in calories, saturated fat, and also in sodium. As with most strategies, they are ineffective unless they are used as part of an overall low calorie eating plan. If they are used as sole sources of food they would be nutritionally inadequate not only in energy, but several other nutrients and water. Additionally, they might not provide a patient trying to lose weight with practice in planning and preparing their own healthy low-calorie meals for a lifetime of healthy weight management. However, there is little evidence on this part.

#### **10.3.6 Effectiveness and Safety**

These products may be nutritionally inadequate when they are used as the sole sources of food and fluids for many weeks. When the products are used according to directions on the label or in package inserts, they are safe (71). When used as part of a weight loss program these single meal replacements are effective during the weight loss phase (198). They are also valuable additions in the weight maintenance phase, often because the meal replacements provide a low set number of calories in an easy-to-fix-entrée (5), with control over portion size (207).

#### **10.4 Weight Loss Books and Manuals**

In addition to weight loss products, Table 24 provides some examples of popular diet books. Books are difficult to use on one's own because there is little reinforcement. The quality of self-help books on weight control ranges from the sublime to the ridiculous. Among the better, older books currently on the market are the LEARN® Program for Weight Management, which is a sound 15 week course that is usually administered within a treatment program (208). The book is effective when it is part of the treatment program. However, the charges for such a program are considerable, the program is not available in all parts of the country, the effectiveness of self-directed efforts using the book by itself has not been evaluated, and the dietary advice is often vague. Another good book is *Volumetrics* by Barbara Rolls PhD (209), which encourages a diet based on foods that have a low energy density, meaning that they contain few calories per gram of weight. Dr. Rolls' research has shown that foods with large volume but few calories can provide satiety while helping individuals avoid over-consumption of energy. Such foods are usually high in water and fiber, while low in fat. Although the long-term efficacy of this specific diet has yet to be affirmed, the diet is rich in



fruits, vegetables, and other healthful foods (209). The bottom line on diet books is that with few exceptions, the dieter is sure to lose his or her money , but whether weight is lost or not is less certain. Moreover, in spite of the hype there is little evidence that, aside from the few books mentioned above, that the diets “work” and that the authors have discovered a unique new scientific principle that causes weight loss.

**Table 24. Popular Diet Programs and Books (46;230)**

Diet	Brief description	Average Calories Per Day	Composition % of Calories			Claimed Utility (Evidence is usually lacking that the approach is effective)
			%CHO	%Protein	%Fat	
5-Factor Diet Harley Pasternak Ballantine Books, 2009	5 week plan, 5 meals per day, 5 minute preparation time per meal, recipes with only 5 ingredients, 5 cheat days in 5 weeks, and 25 minute workouts 5 days a week for 5 weeks	1300	58	32	10	Weight Loss
The Abs Diet David Zinczenko, Editor-in-Chief of <i>Men's Health</i> Rodale Books, 2005	This diet is based on foundation foods that conform to the	1700	45	25	30	Weight Maintenance

	<p>acronym <i>Abs Diet</i> <i>Power:</i></p> <ul style="list-style-type: none"> <li>• <b>A</b>lmonds and other nuts</li> <li>• <b>B</b>eans and legumes</li> <li>• <b>S</b>pinach and green vegetables</li> <li>• <b>D</b>airy (fat free or low fat)</li> <li>• <b>I</b>ntant Oatmeal</li> <li>• <b>E</b>ggs</li> <li>• <b>T</b>urkey and lean meats</li> <li>• <b>P</b>eanut butter (natural and sugar free)</li> <li>• <b>O</b>live oil</li> <li>• <b>W</b>hole-grain breads and cereals</li> <li>• <b>E</b>xtra protein (whey powder)</li> <li>• <b>R</b>aspberries and other berries</li> </ul>					
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Atkins™ for Life Dr. Robert C. Atkins™, MD St. Martin's Griffin, 2004	A low carbohydrate plan for those who have lost weight with the original Atkins™ Diet. Dieters are advised to cut back on carbohydrates if weight loss stops.	Phase 1: 1540	24	21	55	Weight Maintenance
		Phase 2: 1970	22	22	56	Weight Maintenance
		Phase 3: 2310 Pre-Maintenance	29	19	52	Weight Maintenance
		Phase 4: 2050 Lifetime Maintenance	35	20	44	Weight Maintenance
Eat Right 4 Your Type (The Blood Type Diet) Dr. Peter J. D'Adamo Putnam Adult, 1996	Based on the idea that tailoring one's diet based on blood type (A, B, O, AB) will result in weight loss and overall health.	Blood Type O: 1000	44	29	27	Weight maintenance Overall Health
		Blood Type A: 1150	55	10	34	
		Blood Type B: 1200	55	22	23	
		Blood Type AB: 1200	56	25	20	
Body for Life Bill Phillips, Michael D'Orso William Morrow, 1999	This book focuses primarily on exercise, and recommends 6 small meals per day for 6 weeks,	1270	45	45	10	Exercise and nutrition for quick weight loss

	consisting of lean meats, vegetables, whole grains, healthy fats, and fish in addition to strenuous exercise.					
The New Cabbage Soup Diet Margaret Danbrot St. Martin's Paperbacks, 2004	Very-low calorie diet plan, based on the theory that monotony will cause the person to stop eating. Only food consumed is cabbage soup supplemented occasionally by specific fruits and vegetables	700	57	18	25	Weight Loss
The Cheaters Diet Paul Rivas, MD HCI, 2005	Based on the plate method: 1/2 plate vegetables, 1/4 whole grains, 1/4 lean protein. Dr. Rivas claims that you must cheat on the weekends to "stroke your metabolism and	1200-excessive calories	50	20	30	Weight Maintenance

	boost fat loss.” He suggests eating “whatever you want” from 9am on Saturday to 9pm on Sunday.					
The Diet Solution <a href="http://www.thedietsolutionprogram.com/">http://www.thedietsolutionprogram.com/</a> N/A	Diet that promotes organic and “natural” foods, free of processing, regardless of the macronutrient composition. Excludes soy products.	928	34	20	46	Weight loss
Eat This, Not That! David Zinczenko with Matt Goulding Rodale Books, 2009	Written by the editor-in-chief of <i>Men’s Health</i> magazine, aimed at male readers who eat mainly at fast food restaurants. Attempts to provide readers with alternative options to calorie laden fast food choices.	-	-	-	-	Weight maintenance

Flat Belly Diet Liz Vaccariello and Cynthia Sass Rodale Books, 2009	Premise is to trim calories to 1600, add a mono-unsaturated fatty acid at every meal, eat every four hours, and to perform regular exercise to lose weight and belly fat.	1600	42	25	33	Weight loss
French Women Don't Get Fat Mireille Guiliano Vintage, 2007	Lifestyle changes illustrated through an autobiography of the author	1200-1300	43	22	45	Low Calorie
Change Your Genetic Destiny (The GenoType Diet) Dr. Peter J. D'Adamo with Catherine Whitney Broadway, 2009	An expansion on the concept of the Blood Type Diet, created by naturopathic physician Dr. D'Adamo. Dr. D'Adamo identifies the six "GenoTypes": the Hunter, the Gatherer, the Teacher, the Explorer, the Warrior, and the Nomad. Diet	-	-	-	-	Weight maintenance Overall health

	<p>helps consumers map out their genetic makeup and discover which “GenoType” they are.</p> <p>The theory is that readers can reprogram their gene responses to lose and maintain weight, among other health improvements, by choosing foods that enhance each GenoType, and avoiding foods that do not.</p>					
<p>The New Glucose Revolution: The Authoritative Guide to the Glycemic Index</p> <p>Jennie Brand-Miller, Phd; Thomas Wolever, MD, Phd; Kaye Foster-Powell; Stephen Colagiuri, MD</p> <p>Marlowe and Co., 2006</p>	<p>The theory is that simple carbohydrates cause spikes in blood sugar levels, causing recurrent hunger. Recommends eating low glycemic-index foods (i.e., whole</p>	1200	55	24	21	Weight Maintenance

	grains, protein) to stave off hunger and weight gain.					
Learn Kelly Brownell American Health Publishing Company, 2004	Lifestyle, exercise, attitudes, relationships and nutrition following government recommendations .	1650	55	15	30	Weight Maintenance
Mediterranean	Recommends grains, vegetables, and sources of healthy fats (e.g., olive oil and nuts).	-	45	20	35	Weight Maintenance
The Perricone Prescription Dr. Nicholas Perricone Harper Paperbacks, 2004	Anti-inflammatory foods eaten to reverse aging. Unlimited salmon.	1300	35	39	26	Anti-inflammatory/Overall Health
Pritikin Program for Diet and Exercise Nathan Pritikin Bantam, 1984	Six meals per day, no portion control.	-	80	10	<10	Low fat Vegetarian Weight loss



The Complete Scarsdale Medical Diet  Dr. Herman Tarnower  Bantam, 1982	Artificial sweeteners and appetite suppressants are recommended.	1000	21	46	35	Weight loss
Sensa Weight-Loss Program (The Sprinkle Diet)  Dr. Alan Hirsch, MD, FACP  Hilton Publishing, 2009	Flavorless sprinkles ("Tastanants") sprinkled on food, helps dieters eat less and feel full faster.	-	-	-	-	Weight loss
The Serotonin Power Diet  Judith J. Wurtman, PhD Nina T. Frusztajer, MD  Rodale Books, 2006	The authors claim carbohydrate-rich snack eating will decrease stress and help dieters lose weight by producing more serotonin.	1500	62%	18%	20%	Weight loss
The Sonoma Diet Connie Guttersen RD, PhD Meredith Books, 2005	Influenced by a Mediterranean plant-based diet. This three-phase diet places emphasis on a variety of flavorful, nutrient dense "power foods"	1500 for men	50-55	15-20	30	Low Calorie
		1200 for women	50-55	15-20	30	Low Calorie

	such as almonds, bell peppers, blueberries, broccoli, grapes, olive oil, spinach, strawberries, tomatoes, and whole grains.					
South Beach Diet Dr. Arthur Agatston Rodale, Inc., 2003	3 phase book by Arthur Agatston MD; Low carbohydrate <i>*Phases based on a 140-pound, 40-year-old, lightly active woman</i>	Phase 1: 1850	16	38	46	Low Calorie
		Phase 2: 1450	37	26	40	Low Calorie
		Phase 3: 1750	31	29	40	Low Calorie
The Spectrum Diet Dr. Dean Ornish, MD Ballantine Books, 2008	A lifestyle change; find where you fall on Ornish's food "spectrum" (Group 1 being the healthiest, Group 5, the least healthy) and make changes according to your desired health outcomes (e.g., weight loss, weight maintenance,	1580	70	20	10	Low-fat/vegetarian for overall improved health

	<p>reduced risk of cancer, etc.).</p> <p>Plan calls for regular exercise (aerobic, resistance training, and flexibility), stress management (yoga, meditation), nutrition advice (low-fat, vegetarian), and nurturing relationships.</p>					
<p>Sugar Busters</p> <p>H. Leighton Steward; Morrison C. Bethea, MD; Sam S. Andrews, MD; Luis A. Balart, MD</p> <p>Ballantine Books, 1999</p>	<p>Cut or completely eliminate dietary sugar to trim fat</p>	1200	40	30	30	Weight loss
<p>The Supermarket Diet</p> <p>Janis Jibrin MS, RD</p> <p>Hearst, 2007</p>	<p>Provides shopping lists, meal plans, recipes and snacks. The book begins with a two week boot camp phase. The author helps readers select which</p>	1200-1500	50	20	30	Low Calorie Weight Maintenance

	calorie level is the best fit for them, and how to troubleshoot problems if the calorie level does not seem to be yielding results.					
The Ultimate Weight Solution Dr. Phil McGraw Free Press, 2004	Dr. Phil McGraw authored this 3 phase diet book	Phase 1: 1300	47	36	17	Low Calorie
		Phase 2: 1100	49	32	19	Very low calorie
		Phase 3: 1820	52	27	17	Weight Maintenance
The Volumetrics Weight-Control Plan Barbara Rolls, PhD HarperTorch, 2002	Focuses on satiety and feeling full, by filling up on high volume foods with low energy density (e.g., soup)	1700	61	23	18	Weight loss Weight maintenance
YOU: On a Diet (Revised Edition) Dr. Mehmet Oz and Dr. Michael Roizen Free Press, 2009	Weight loss with an emphasis on waist measurement and its relationship to health.	1700	46	21	33	Weight loss Wight maintenance

<p>The Zone Diet</p> <p>Dr. Barry Sears</p> <p>Thorsons, 1999</p>	<p>Balances carbohydrates, protein, and fat to stabilize the hormones that trigger hunger and weight gain.</p>	1700	40	30	30	Weight loss
<p>The Acid-Alkaline Diet for Optimal Health</p> <p>Christopher Vassey, N.D.</p> <p>Healing Arts Press, 2006</p>	<p>Aims to restore the body's acid-alkaline balance through the use of enzyme supplements, pre- and probiotics, antioxidants, exercise, and a diet high in fruits and vegetables and low in red meat and processed foods.</p>	-	61	17	20	Weight Maintenance/Overall Health Improvement
<p>The Paleo Diet</p> <p>Loren Codain, PhD</p> <p>Houghton Mifflin Harcourt, 2010</p>	<p>Focuses on consuming a diet similar to our Paleolithic ancestors, focusing on lean meats, fruits, and vegetables, and cutting out starchy vegetables,</p>	2,200 (weight maintenance)	23	38	39	Weight Maintenance or Weight Loss (depending on calorie level)

	grains, and processed foods to obtain optimal health.					
The 17 Day Diet Dr. Mike Moreno Free Press, 2011	Diet progresses through 4 cycles, each lasting 17-days, with each cycle employing different calorie levels and foods to promote “body confusion.” The final cycle is a maintenance cycle.	1,062 – 1.177	32-46	33-39	18-24	Wight Loss
Dr. Weil’s Anti-Inflammatory Diet and Pyramid <a href="http://www.drweil.com/drw/u/ART02012/anti-inflammatory-diet">http://www.drweil.com/drw/u/ART02012/anti-inflammatory-diet</a> N/A	Aims to use diet to reduce inflammation by focusing on the consumption of a variety of fresh foods, with a focus on fruits and vegetables, and reducing the consumption of processed foods and fast food.	2000	40-50	20-30	30	Weight Maintenance/Disease Prevention

<p>The Biggest Loser: 6 Weeks to a Healthier You</p> <p>Cheryl Forberg RD, Melissa Roberson, &amp; Lisa Wheeler</p> <p>Rodale Books, 2010</p>	<p>Applies strategies and techniques taught on the “Biggest Loser” TV show into a 6-week plan to help fans at home lose weight.</p>	1500 (varies)	50	30	25	Weight Loss
<p>The DASH Diet Weight Loss Solution</p> <p>Marla Heller, MS, RD</p> <p>Grand Central Life &amp; Style, 2012</p>	<p>Adapts the DASH diet, focusing on fruits and vegetables, low-fat and fat-free dairy, lean meats/fish/poultry, nuts/beans/seeds, heart healthy fats, and limited whole grains, to promote weight loss.</p>	-	55-56	18	26-29	Weight Loss
<p>The Dukan Diet</p> <p>Dr. Pierre Dukan</p> <p>Crown Archtype, 2011</p>	<p>With a focus on lean protein consumption, this diet progresses through 4 phases, to help participants reach and maintain their “true weight.” The 1<sup>st</sup> phase focuses almost entirely on lean protein</p>	-	27-48	33-46	18-23	Weight loss

	consumption, while the remaining phases slowly reintroduce vegetables and grains.					
The Macrobiotic Way Michio Kushi Avery Trade, 2004	Focusing on an individualized approach, this essentially vegetarian diet focuses on whole, natural, foods that are local and organic.	Varies	68	15	17	Weight Maintenance and Health Promotion
The Engine 2 Diet Rip Esselstyn Grand Central Life & Style, 2009	A 4-week plan to lose weight, lower cholesterol, reduce the risk of disease and increase physical fitness by focusing on a plant-powered whole foods diet and a firefighter-inspired exercise program	1850	70	12	23	Weight Loss and Health Promotion



<p>The Spark Solution</p> <p>Becky Hand, RD and Stephanie Romine</p> <p>HarperOne, 2014</p>	<p>A 2-week program that promotes weight loss by providing structured meal plans and exercise routines</p>	1570	57	28	18	
<p>Wheat Belly: Lose the Wheat, lose the Weight, and Find Your Path Back to Health</p> <p>William Davis</p> <p>Rodale Books 2011</p>	<p>Focuses on eliminating all wheat products from the diet. Dr. Davis provides stories of his own practice to illustrate his argument for eliminating wheat as a permanent weight loss solution.</p>					<p>Weight loss</p> <p>Relief from broad spectrum of health and digestive ailments</p>
<p>The Bulletproof Diet</p> <p>Dave Asprey</p> <p>Rodale Books, 2014</p>	<p>Includes a 14-step plan to help its readers eat a diet that is "bulletproof". This book advertises that people can lose up to 1 pound a day by following these steps.</p>	<p>Does not recommend counting calories</p>	5-30	10-30	50-80	

<p>The FastDiet</p> <p>Michael Mosely and Mimi Spencer</p> <p>Atria Books, 2013</p>	<p>Supports eating normally 5 day per week and fasting 2 days per week.</p>	<p>500 calories per day for women and 600 calories per day for men on fasting days.</p>	<p>45</p>	<p>17</p>	<p>40</p>	<p>Weight loss</p>
<p>Eat to Live</p> <p>Joel Furhman, MD</p> <p>Little, Brown, and Company, 2011</p>	<p>Using the notion of nutrient density, this plan begins with a 6-week vegetarian phase focusing on nutrient rich foods, eventually adding in small amount of lean animal protein.</p>	<p>Does not require calorie counting</p>				<p>Weight loss. Limits consumption of animal products to 5-10% of calories and reduces consumption of refined grains even further.</p>
<p>Shred: The Revolutionary Diet</p> <p>Ian Smith, MD</p> <p>St. Martins Press, 2012</p>	<p>A 6-week program using a low-GI diet, meal spacing, meal replacements, and diet confusion. Dieters eat 4 meals or meal replacements and 3 snacks each day.</p>	<p>1400-1700</p>				<p>Weight loss.</p>

<p>The Mayo Clinic Diet</p> <p>The Weigh-loss Experts at the Mayo Clinic</p> <p>Good Books, 2013</p>	<p>A two-part diet focusing on rapid, followed by moderate weight loss, with a focus on building good habits like eating whole grains and breakfast, portion control, and balance, and ending bad habits like eating in front of the TV.</p>	<p>1200 for women</p> <p>1600 for men</p>	57	21	22	Weight Loss
<p>The Plan</p> <p>Lyn-Genet Recitas</p> <p>Grand Central Life and Style, 2013</p>	<p>An elimination diet that claims to help dieters identify trigger-foods that may be causing them to gain weight, feel sick, and age prematurely. Claims everyone has different trigger foods based on body chemistry.</p>					Weight loss; health promotion

The 80/10/10 Diet Dr. Douglas Graham FoodNSport Press, 2006	A raw food diet focusing on high carbohydrate foods, mainly sweet fruits, and only allowing plant-based protein.		80	10	10	Weight loss
The Calorie Myth Johnathan Bailor HarperWave, 2013	Focuses on eating minimal-processed, low-starch, whole foods, and shorter, more intense exercise as the basis of weight loss over calorie counting alone. The plan is high in protein.					Weight loss
The Fast Metabolism Diet Haylie Pomroy Harmony, 2013	A 28-day plan that splits the week into 3 phases, one that is high carbohydrate, one that is high protein, and one that is more balanced.		varies	varies	varies	Weight loss

### 10.5 Web Based Treatment Programs and Resources

The Internet provides some excellent resources for those who want and need more information. However, it also includes sites with questionable recommendations, so individuals should proceed with caution. Web-based resources are discussed below.

### 10.6.1 Available Programs

Two types of programs are available. First are those that primarily provide information. Second are those that counsel the individual and provide low calorie diets and other advice. Sound Internet resources that can help those who are trying to control their weights are listed in Table 25. These fall into the category of informational resources. The reader needs to be aware that not all sites providing advice and information are sound. It is best to trust the sites sponsored by government, professional, and voluntary associations with some standing and expertise in the weight control field. A new entry into the weight loss arena in recent years is the web-based weight control program (210). These are examples of the second type of program. Resources include chat rooms, diet and exercise information, and often products that are for sale. For example, Nutrisystem®.com requires the purchase of prepackaged foods in order to access their web site. The ediets.com website, another weight control program, charges a monthly fee to use its site. It provides shopping lists from which consumers self-select foods, and also it provides general advice.

These web-based commercial offerings vary in their quality, some are very good and others are quite poor.

**Table 25. Internet Resources for Weight Control (210-213)**

Type of Site and Name	Internet address and Comments
<i>Advice and Information on nutrition and weight control</i>	
Academy of Nutrition and Dietetics	<a href="http://www.eatright.org">www.eatright.org</a> This is the website for nutrition professionals. Membership allows entrance to the Journal of the American Dietetic Association and the Evidenced Based Library.
Shape Up! America	<a href="http://www.shapeup.org">www.shapeup.org</a> Provides good yet minimal nutrition education information for patients. Helpful sample menus are provided for 1500 and 2000 calorie diets as well as practical ways to increase physical activity. Founded in 1994, Shape Up America! Is a 501(c)(3) not-for-profit organization committed to raising awareness of obesity as a health issue and to providing responsible information on healthy weight management.

American Obesity Association	<a href="http://www.obesity.org">www.obesity.org</a> Comprehensive website dedicated to obesity. Provides helpful information for patients as well as links to other nutrition/fitness resources. This website also offers information on treatment, prevention, education, various aspects of public policy, and obesity research for professionals.
National Institutes of Health	<a href="http://www.nutrition.gov">www.nutrition.gov</a> Extremely helpful resource for patients and health professionals alike. The website is home to the Dietary Guidelines, MyPyramid which is an interactive diet and physical activity planner, and an abundance of information regarding health and nutrition.
Weight-Control Information Network (WIN)	<a href="http://win.niddk.nih.gov/">http://win.niddk.nih.gov/</a> A helpful information service of the <a href="#">National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)</a> , <a href="#">National Institutes of Health (NIH)</a> for health professionals and the public. WIN was established in 1994 to provide the general public, health professionals, the media, and Congress with up-to-date, science-based information on obesity, weight control, physical activity, and related nutritional issues.
US News and World Report Best Diet Rankings	<a href="http://health.usnews.com/best-diet">http://health.usnews.com/best-diet</a> A helpful resource that ranks and reviews a variety of popular diets for general weight loss, as well as for a variety of diseases and food preferences. The reviews provide a general overview of the diet, a ranking of the diet on several measures, pros and cons of each diet, dos and don'ts for each diet, as well as sample menus with nutritional breakdowns, and expert reviews.
<i>Web-Based Help for Dieters</i>	
WebMD Nutrition Resources	<a href="http://www.webmd.com/diet/default.htm">http://www.webmd.com/diet/default.htm</a> This is an extremely useful resource for patients. The site provides a BMI calculator, calorie counter, diet evaluator, fitness and diet journal, a large food/nutrient

	database, a fiber calculator, helpful articles, videos, and slideshows on eating healthfully, and charts that can be personalized.
Fitday.com	<a href="http://fitday.com/">http://fitday.com/</a> This website is a free online journal that tracks and analyzes food intake, exercise, and weight loss goals.
Caloriescount.com	<a href="http://www.caloriescount.com">www.caloriescount.com</a> This site boasts several online calculators and tools that help the participant keep track of their weight loss, such as the exercise/calories burned calculator and online diet meal plans given the participants appropriate caloric range, which may also be determined from the site. These tools are free of charge.
SparkPeople®	<a href="http://www.sparkpeople.com">www.sparkpeople.com</a> A website with free nutrition, health, and fitness tools, support, and resources, including meal plans, recipes, food and activity trackers, and a mobile act. SparkPeople® boasts a large online social support network, and may particularly help those with a preference towards online community networks. The diet book <i>The Spark Solution</i> was created by those who run the website.

### 10.6.2 Candidates

Those who are overweight or moderately obese with few risk factors, and who need additional support and information after they have been screened by a physician on weight reduction, may find these resources useful. They are not freestanding and need to be administered in conjunction with some additional health and dietary counseling about a hypocaloric diet from a physician or registered dietitian.

### 10.6.3 Advantages

The Internet is widely available at all times of the day or night, at low cost. For example, the US Army has developed a web-based dietary advice program that can be used at Army bases around the world.

### 10.6.4 Disadvantages

High-risk patients, especially those who lack economic resources, may attempt to use these Internet sites for the primary treatment of their condition. Also, some sites provide inappropriate or wrong advice and there is little personal supervision or

support of the dieter. Peer support networks and chat rooms can be beneficial to a patient trying to find support for weight loss, but there is also a risk that peers may provide incorrect advice or promote unsubstantiated weight loss techniques.

#### 10.6.5 Safety and Effectiveness

The safety and effectiveness of internet sites for weight reduction has not been established (105). Only recommended sites should be trusted.

#### 10.7 Voluntary Self-Help Programs

Self-help programs led by laypersons are voluntary programs that charge very low or no fees. National organizations include TOPS Club, Inc.® ([Take Off Pounds Sensibly](#)), OA ([Overeaters Anonymous](#)®), and others. These programs are designed primarily to provide group support to those who have weight problems, rather than to provide and supervise weight reduction diets.

#### 10.8 Mobile Applications for Weight Loss

As people's lives become more mobile, so do the tools that help them lose weight. Calorie tracking programs are available to monitor daily intake, and fitness programs provide sample workouts and activity logs. Other apps are available to promote water consumption and provide tips and support. As with web-based resources, these should be used in conjunction with physician or dietitian-led interventions, and not as a replacement for them. Though research on the efficacy of these programs is still scant, one recent study suggests that combining some form of counseling alongside a smart-phone based platform led to greater results than either counseling or smart-phone use alone (237). Examples of current available apps and the platforms on which they are available are summarized in Table 26.

**Table 26. Mobile Apps to Aid in Weight Loss**

App Name	Cost	Available Platforms	Features
My Fitness Pal	free	Apple, Android, Windows, Blackberry, and online ( <a href="http://www.myfitnesspal.com">http://www.myfitnesspal.com</a> )	Features include a calorie tracker, activity tracker, weight tracker, body measurement tracker, water tracker, extensive food list including restaurants, barcode scanner, breakdown of intake including protein, fat, carbohydrates, fiber, and vitamins and minerals, daily and weekly summaries, ability to add friends, and compatibility with <i>fitbit</i> , <i>map my fitness</i> , and other apps and devices.



Lose It!	Free (premium upgrade for \$39.99/yr)	Apple, Android, and online ( <a href="https://www.loseit.com">https://www.loseit.com</a> )	Features include calorie tracker, activity tracker, weight tracker, barcode scanner, extensive food list with restaurant options, ability to add recipes, breakdown of intake by protein, fat, and carbohydrates, daily and weekly summaries by email, ability to add friends, compatibility with <i>Nike+ fuelband</i> . Premium features include additional compatibility with apps and devices, hydration and sleep trackers, body measurement tracker, and blood glucose and blood pressure trackers.
Mapmyfitness	free (premium upgrade for \$29.99/yr for apple and online)	Apple, Android, Blackberry (limited), and online ( <a href="http://www.mapmyfitness.com">http://www.mapmyfitness.com</a> )	Features include allowing users to track a variety of activities in real time and after the fact, search for and save routes for walking, jogging, biking, and hiking, a food tracker, the ability to play music from music library on phone, add friends and share workouts. “Mapmyrun” and “Mapmyride” are related apps for running and biking respectively. Premium features include training plans, training features, and live location tracking.
Hy	free	Apple	Features include allowing users to set water goals in ml or fl oz, add water consumed in increments of 50 or 100 ml (2 or 4 fl oz), the ability to set reminders to consume water, and facts about the

			importance of water consumption displayed daily.
EaTipster	free	Apple	Features include daily tips on healthy eating from dietitians, ability to save and share tips, and the ability to set reminder for tips

## 11. SUMMARY OF WEIGHT LOSS PHASE

Current guidelines for the composition of weight reducing diets, as discussed above, are outlined in the 2010 Dietary Guidelines for Americans ([Table 1](#)), as well as the MyPlate.gov website.

## 12. WEIGHT MAINTENANCE PHASE OF WEIGHT CONTROL

Once obese individuals have lost weight, their healthier weight and current fat mass must be maintained. This is the weight maintenance phase of weight control. It involves alterations in dietary intake and physical activity from levels that are different to those at the onset of dietary treatment. Energy needs are lower to stay in energy balance than they were prior to weight reduction, even though weight was lost. This is because both fat and lean body mass is lost during the weight reduction phase. With a loss of lean body mass comes a decrease in metabolically active tissue, which then reduces resting metabolism. In addition, it takes less effort for an individual to move with a now lighter body, so the energy cost of physical activity is reduced. The implications are that a slight decrease in energy intake from prior levels and an increase in energy output is necessary during weight maintenance. There is a need for continued attention to these factors by both the physician and patient. Behavior modification is necessary to sustain lifestyle changes developed during the weight reduction phase. It is best initiated during the weight loss phase, and maintained thereafter. All too often the weight maintenance phase is neglected or ignored, and weight is regained over the long term (71). Some factors that seem to be associated with long-term successful weight maintenance include continued regular exercise and to a lesser extent, use of low calorie, low fat diets relatively high in fruits and vegetables. Also, continued self-monitoring of the amount and type of food consumed and of physical activity levels may help (71).

### 12.1 Nutrient Needs

Although energy needs are less during weight maintenance, the requirements for protein, essential fatty acids, carbohydrate, dietary fiber, vitamins and minerals are similar to those of any normal adult. The 2010 Dietary Guidelines for Americans recommend that all Americans, including those who are watching their weight, to adopt the habits listed (see [Table 1](#)).

There is currently much debate about the ideal macronutrient distribution in diets for weight maintenance, but at present very few long-term studies are available on the effects of macronutrient content on weight maintenance. A low-fat, reduced-energy is the best studied diet and the most prescribed for weight maintenance (AND).

### **12.1.2 Carbohydrate**

A recent study of the self-selected diets of free-living American adults found that diets high in carbohydrates (above 55% of calories) were lower in total energy and were associated with lower BMI's than those consuming fewer carbohydrates. The nutrient density (amount of the nutrient per calorie consumed) of those with higher carbohydrate intakes was also higher for vitamins A, Vitamin C, carotene, folate, calcium, magnesium, and iron, but lower in vitamin B-12 and zinc than those with a lower intake of carbohydrates. Also, the high carbohydrate group ate more low-fat foods, grain products and fruits in addition to lower sodium intakes (214). Although individuals who choose to go on a very-low-carbohydrate diet may see increased weight loss within the first six months, these results are not sustained at 12 months (241). It is thought that this diet is not sustainable for long-term weight maintenance and instead, the diet should be a slight reduction in energy all together as well as an increased focus on the reduction of fat (241).

### **12.1.3 Energy Density**

Other studies suggest that energy density of the diet rather than the macronutrient composition of the diet affects energy intake the most (215;216). One review found that low fat, high fiber diets were the most effective in promoting weight loss, and that their effects appeared to be associated with energy density (217). Whether this is true in weight maintenance remains to be determined. There may be macronutrient effects on hunger and satiety that operate through endocrine and metabolic mechanisms such as leptin, insulin, ghrelin, adiponectin and other hormones, which are only now being discovered. These hormones regulate food intake and may be altered. Additionally, the macronutrient composition of habitual diets also affects health risks. Finally, psychological and behavioral factors may make different macronutrient combinations more acceptable to some people. Currently, these topics are the subject of much debate, but research is needed to clarify what and which nutrient composition is optimal. What is currently recommended by the Academy of Nutrition and Dietetics with a strong rating is that an individualized reduced calorie diet is imperative for weight maintenance. By reducing fat, an individual is able to cut out more calories but it is suggested that both fat and carbohydrate be decreased (241).

Other forms of low energy dense diets would be the use of meal replacements or very-low-energy diets. Using meal replacements can be helpful for those who have trouble planning and preparing meals. They can also be helpful for those who experience a large amount of anxiety during meal times. An individual is able to replace one or two meals or snacks with these meal replacements with known nutrient content to help them stay at a calorie deficit of 500 – 1000 cal/day (241). This is something that could be used periodically to help patients get back on track after a relapse of poor food choices and is something that can be maintained long-term. Very-low-energy diets use meal replacement bars or shakes as the sole source of energy during the weight

loss phase, however, this is not suitable for weight maintenance and instead used for quick weight loss and requires additional medical monitoring (241).

### **12.1.3 Fat**

Although much remains to be discovered about the optimal dietary pattern for weight maintenance, a strong case can be made for keeping dietary fat levels below 30% of calories. In studies in which dietary fat was reduced from 35 to 25% of calories with no other recommendations, energy intake was reduced and weight was lost (218). It was estimated that reducing fat by 10% to within the range of 20 to 30% of calories would result in a loss of about 16 grams of body fat a day as a result of reduced energy intake. However, moderation in caloric intake is also necessary. Studies of free-living humans ranging from dietary changes produced only modest body weight losses of about one to three kilograms (182;219;220). Low fat diets consumed on an ad-libitum basis tend to be high in carbohydrate, but LDL cholesterol decreases, plasma triglycerides tend to normalize, and so do HDL/total cholesterol ratios (221). Finally, weight control may be easier (222).

### **12.1.4 Dietary Fiber**

Although the influence of dietary fiber on energy regulation is still not clear, there is evidence that increased dietary fiber intake of about 15 grams appears to be associated with decreased energy intake and body weight of about two kilograms over several months. These effects may even be greater in overweight persons (181). However, these effects are not yet confirmed. Since dietary fiber intake is currently low, only about 15 grams per day in most Americans, and recommendations are for nearly twice that much, increased fiber levels seem to be appropriate, regardless.

### **12.1.4 Vitamins and Minerals**

It is important to meet the current dietary recommendations of 3 – 4 servings of low-fat or non-fat dairy in order to get the daily suggested values of calcium and vitamin D. Research suggests that those with lower calcium intake have increased body weight (241). However, the mechanism by which this works is still unclear.

### **12.1.5 Lessons from Long Term Maintainers: Importance of Increased Physical Activity**

Long-term follow-up of health outcomes demonstrates the need for permanent changes in weight toward healthier levels. The relative lack of effects of temporary downward fluctuations underscores the need for long-term weight maintenance. Data collected from individuals successful at weight loss and maintenance have enhanced our understanding of the most effective strategies in the long-term maintenance of healthier weights and prevention of relapse. Attention to moderation in dietary intake and the maintenance of high levels of physical activity is vital (223-226). Behavioral and attitude adjustments are also important. Encouraging data suggest that behaviors associated with maintenance of weight loss require less effort and become more pleasurable over time (29). In a recent telephone survey, 48% of individuals who had ever lost more than 10% of their body weight had maintained this loss for at least one year, and 26% had maintained for at least 5 years (227). Although these data are self-reported, they suggest progress in the avoidance of relapse and weight gain.

### **13. ADOPT A LONG-TERM EATING PATTERN TO MAINTAIN WEIGHT: ADEQUATE NUTRIENTS WITHIN LOWER CALORIE NEEDS**

Most individuals appear to be aware of and use recommended measures, such as increased physical activity, decreased fat intake, decreased food portions, and decreased energy intakes. The problem is that they do so, but not for enough of the time. However, it is also true that dieting efforts often fail, and weight is often rapidly regained, probably negating predicted health benefits. Chronic dieters tend to be food-preoccupied, distractible, emotional, binge-prone, and unhappy, particularly when the diets are very restrictive (228). It is thus important to foster a healthy, balanced, stable relationship with food and diet. Health professionals can play a vital role in helping patients develop such a relationship.

### **14. CONCLUSIONS: IS DIETING WORTH IT?**

About 39% of women and 21% of men in Western countries have ever tried to lose weight, and approximately 24% of women and 8% of men report that they currently are on a “diet”. In contrast, about 25% of men and 30% of women report that they are watching what they eat to avoid weight gain or to maintain their weights at current levels (229). Hypocaloric diets to induce loss of body fat therefore appear to be a common component of the weight control efforts of many people.

These realities and disadvantages have rightly led to questions about whether dieting is “worth it”, and whether the treatment is worse than the disease. Certainly they suggest that quality of life measures should be included in studies of reducing diets.

This chapter has stressed the role of the dietary treatment of obesity as a part of a comprehensive program of weight control that includes increased physical activity, lifestyle modification, appropriate intakes of nutrients to minimize chronic disease risk, and eating patterns that maximize quality of life. Such dietary treatment in those with mild to moderate obesity helps to decrease risk factors relative to baseline weights after five years. Therefore some health benefit, although it is limited, may be present. However, the health risk/benefit may be negative when dieting entails a cycle of rapid loss followed by equally rapid weight gain. From the standpoint of quality of life and mental health, psychosocial problems do not appear to be inevitable accompaniments of weight loss (184). Therefore, on balance, dietary approaches to obesity management do appear to be worthwhile, if and only if they are viewed as only one component of a long-term weight control program to keep weights and risks at healthier levels. Weight control is “Worth it”!

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