

CLINICAL GUIDELINES  
ON THE  
IDENTIFICATION,  
EVALUATION, AND  
TREATMENT OF  
OVERWEIGHT AND  
OBESITY IN ADULTS

*Executive Summary*



# EXECUTIVE SUMMARY

## Introduction:

An estimated 97 million adults in the United States are overweight or obese, a condition that substantially raises their risk of morbidity from hypertension, dyslipidemia, type 2 diabetes, coronary heart disease, stroke, gallbladder disease, osteoarthritis, sleep apnea and respiratory problems, and endometrial, breast, prostate, and colon cancers. Higher body weights are also associated with increases in all-cause mortality. Obese individuals may also suffer from social stigmatization and discrimination. As the second leading cause of preventable death in the United States today, overweight and obesity pose a major public health challenge.

Overweight is here defined as a body mass index (BMI) of 25 to 29.9 kg/m<sup>2</sup> and obesity as a BMI of  $\geq 30$  kg/m<sup>2</sup>. However, overweight and obesity are not mutually exclusive, since obese persons are also overweight. A BMI of 30 is about 30 lb overweight and equivalent to 221 lb in a 6'0" person and to 186 lb in one 5'6". The number of overweight and obese men and women has risen since 1960; in the last decade the percentage of people in these categories has increased to 54.9 percent of adults age 20 years or older.

Overweight and obesity are especially evident in some minority groups, as well as in those with lower incomes and less education.

Obesity is a complex multifactorial chronic disease that develops from an interaction of genotype and the environment. Our understanding of how and why obesity develops is incomplete, but involves the integration of social, behavioral, cul-

tural, physiological, metabolic and genetic factors.

While there is agreement about the health risks of overweight and obesity, there is less agreement about their management. Some have argued against treating obesity because of the difficulty in maintaining long-term weight loss and of potentially negative consequences of the frequently seen pattern of weight cycling in obese subjects. Others argue that the potential hazards of treatment do not outweigh the known hazards of being obese. The intent of these guidelines is to provide evidence for the effects of treatment on overweight and obesity. The guidelines focus on the role of the primary care practitioner in treating overweight and obesity.

## Evidence-Based Guidelines.

To evaluate published information and to determine the most appropriate treatment strategies that would constitute evidence-based clinical guidelines on overweight and obesity for physicians and associated health professionals in clinical practice, health care policy makers, and clinical investigators, the National Heart, Lung, and Blood Institute's Obesity Education Initiative in cooperation with the National Institute of Diabetes and Digestive and Kidney Diseases convened the Expert Panel on the Identification, Evaluation, and Treatment of Overweight and Obesity in Adults in May 1995. The guidelines are based on a systematic review of the published scientific literature found in MEDLINE from January 1980 to September 1997 of topics identified by the panel as key to extrapolating the data related to the obesity evidence model.

Evidence from approximately 394 randomized controlled trials (RCTs) was considered by the panel.

The panel is comprised of 24 members, 8 ex-officio members, and a methodologist consultant. Areas of expertise contributed to by panel members included primary care, epidemiology, clinical nutrition, exercise physiology, psychology, physiology, and pulmonary disease. There were four meetings of the full panel and two additional meetings of the executive committee comprised of the panel chair and four panel members.

The San Antonio Cochrane Center assisted the panel in the literature abstraction and in organizing the data into appropriate evidence tables. The center pretested and used a standardized 25-page form or “Critical Review Status Sheet” for the literature abstraction. Ultimately, 236 RCT articles were abstracted and the data were then compiled into individual evidence tables developed for each RCT. The data from these RCTs served as the basis for many of the recommendations contained in the guidelines.

The panel determined the criteria for deciding on the appropriateness of an article. At a minimum, studies had to have a time frame from start to finish of at least 4 months. The only exceptions were a few 3-month studies related to dietary therapy and pharmacotherapy. To consider the question of long-term maintenance, studies with outcome data provided at approximately 1 year or longer were examined. Excluded were studies in which self-reported weights by subjects were the only indicators used to measure weight loss. No exclusions of studies were made by study size. The panel weighed the evidence based on a thorough examination of the threshold or magnitude of the treatment effect. Each evidence statement (other than those with no available evidence) and each recommendation is categorized by a level of evidence which ranges from A to D. Table ES-1

summarizes the categories of evidence by their source and provides a definition for each category.

- **Who is at Risk?** All overweight and obese adults (age 18 years of age or older) with a BMI of  $\geq 25$  are considered at risk. Individuals with a BMI of 25 to 29.9 are considered overweight, while individuals with a BMI  $\geq 30$  are considered obese. Treatment of overweight is recommended only when patients have two or more risk factors or a high waist circumference. It should focus on altering dietary and physical activity patterns to prevent development of obesity and to produce moderate weight loss. Treatment of obesity should focus on producing substantial weight loss over a prolonged period. The presence of comorbidities in overweight and obese patients should be considered when deciding on treatment options.
- **Why Treat Overweight and Obesity?** Obesity is clearly associated with increased morbidity and mortality. There is strong evidence that weight loss in overweight and obese individuals reduces risk factors for diabetes and cardiovascular disease (CVD). Strong evidence exists that weight loss reduces blood pressure in both overweight hypertensive and nonhypertensive individuals; reduces serum triglycerides and increases high-density lipoprotein (HDL)-cholesterol; and generally produces some reduction in total serum cholesterol and low-density lipoprotein (LDL)-cholesterol. Weight loss reduces blood glucose levels in overweight and obese persons with and without diabetes; and weight loss also reduces blood glucose levels and HbA1c in some patients with type 2 diabetes. Although there have been no prospective trials to show changes in mortality with weight loss in obese patients, reductions in risk factors would suggest that development of type 2 diabetes and CVD would be reduced with weight loss.

## EVIDENCE CATEGORIES

Evidence Category	Sources of Evidence	Definition
A	Randomized controlled trials (rich body of data)	Evidence is from endpoints of well-designed RCTs (or trials that depart only minimally from randomization) that provide a consistent pattern of findings in the population for which the recommendation is made. Category A therefore requires substantial numbers of studies involving substantial numbers of participants.
B	Randomized controlled trials (limited body of data)	Evidence is from endpoints of intervention studies that include only a limited number of RCTs, post-hoc or subgroup analysis of RCTs, or meta-analysis of RCTs. In general, Category B pertains when few randomized trials exist, they are small in size, and the trial results are somewhat inconsistent, or the trials were undertaken in a population that differs from the target population of the recommendation.
C	Nonrandomized trials Observational studies	Evidence is from outcomes of uncontrolled or nonrandomized trials or from observational studies.
D	Panel Consensus Judgment	Expert judgment is based on the panel's synthesis of evidence from experimental research described in the literature and/or derived from the consensus of panel members based on clinical experience or knowledge that does not meet the above-listed criteria. This category is used only in cases where the provision of some guidance was deemed valuable but an adequately compelling clinical literature addressing the subject of the recommendation was deemed insufficient to justify placement in one of the other categories (A through C).

Table ES-1

- **What Treatments Are Effective?** A variety of effective options exist for the management of overweight and obese patients, including dietary therapy approaches such as low-calorie diets and lower-fat diets; altering physical activity patterns; behavior therapy techniques; pharmacotherapy\*; surgery; and combinations of these techniques.

**Clinical Guidelines**

Treatment of the overweight or obese patient is a two-step process: assessment and treatment management. Assessment requires determination of the degree of overweight and overall risk status. Management includes both reducing excess body weight and instituting other measures to control accompanying risk factors.

**Assessment:** When assessing a patient for risk status and as a candidate for weight loss therapy, consider the patient’s BMI, waist circumference, and overall risk status. Consideration also needs to be given to the patient’s motivation to lose weight.

- **Body Mass Index.** The BMI, which describes relative weight for height, is significantly correlated with total body fat content. The BMI should be used to assess overweight and obese-

ty and to monitor changes in body weight. In addition, measurements of body weight alone can be used to determine efficacy of weight loss therapy. BMI is calculated as weight (kg)/height squared (m<sup>2</sup>). To estimate BMI using pounds and inches, use: [weight (pounds)/height (inches)<sup>2</sup>] x 703. Weight classifications by BMI, selected for use in this report, are shown in Table ES- 2. A conversion table of heights and weights resulting in selected BMI units is provided in Table ES-3.

- **Waist Circumference.** The presence of excess fat in the abdomen out of proportion to total body fat is an independent predictor of risk factors and morbidity. Waist circumference is positively correlated with abdominal fat content. It provides a clinically acceptable measurement for assessing a patient’s abdominal fat content before and during weight loss treatment. The sex-specific cutoffs noted on the next page can be used to identify increased relative risk for the development of obesity-associated risk factors in most adults with a BMI of 25 to 34.9 kg/m<sup>2</sup>:

CLASSIFICATION OF OVERWEIGHT AND OBESITY BY BMI		
	Obesity Class	BMI (kg/m <sup>2</sup> )
Underweight		<18.5
Normal		18.5 – 24.9
Overweight		25.0 – 29.9
Obesity	I	30.0 – 34.9
	II	35.0 – 39.9
Extreme Obesity	III	≥40

Table ES-2

\* As of September 1997, the Food and Drug Administration (FDA) requested the voluntary withdrawal from the market of dexfenfluramine and fenfluramine due to a reported association between valvular heart disease and the use of dexfenfluramine or fenfluramine alone or combined with phentermine. The use of these drugs for weight reduction, therefore, is not recommended in this report. Sibutramine is approved by FDA for long-term use. It has limited but definite effects on weight loss and can facilitate weight loss maintenance (Note: FDA approval for orlistat is pending a resolution of labeling issues and results of Phase III trials.)

## HIGH RISK

Men > 102 cm (> 40 in)

Women > 88 cm (> 35 in)

These waist circumference cutpoints lose their incremental predictive power in patients with a BMI  $\geq 35$  kg/m<sup>2</sup> because these patients will exceed the cutpoints noted above. Table ES-4 adds the disease risk of increased abdominal fat to the disease risk of BMI. These categories denote *relative* risk, not *absolute* risk; that is, relative to risk at normal weight. They should not be equated with absolute risk, which is determined by a summation of risk factors. They relate to the need to institute weight loss therapy and do not directly define the required intensity of modification of risk factors associated with obesity.

- **Risk Status.** Assessment of a patient's absolute risk status requires examination for the presence of:

*Disease conditions:* established coronary heart disease (CHD), other atherosclerotic diseases, type 2 diabetes, and sleep apnea; patients with these conditions are classified as being at very high risk for disease complications and mortality.

*Other obesity-associated diseases:* gynecological abnormalities, osteoarthritis, gallstones and their complications, and stress incontinence.

*Cardiovascular risk factors:* cigarette smoking, hypertension (systolic blood pressure  $\geq 140$  mm Hg or diastolic blood pressure  $\geq 90$  mm Hg, or the patient is taking antihypertensive agents), high-risk LDL-cholesterol ( $\geq 160$  mg/dL), low HDL-cholesterol ( $< 35$  mg/dL), impaired fasting glucose (fasting plasma glucose of 110 to 125 mg/dL), family history of

premature CHD (definite myocardial infarction or sudden death at or before 55 years of age in father or other male first-degree relative, or at or before 65 years of age in mother or other female first-degree relative), and age (men  $\geq 45$  years and women  $\geq 55$  years or postmenopausal). Patients can be classified as being at high absolute risk if they have three of the aforementioned risk factors. Patients at high absolute risk usually require clinical management of risk factors to reduce risk.

Patients who are overweight or obese often have other cardiovascular risk factors.

Methods for estimating *absolute risk* status for developing cardiovascular disease based on these risk factors are described in detail in the National Cholesterol Education Program's *Second Report of the Expert Panel on the Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults* (NCEP's ATP II) and the *Sixth Report of the Joint National Committee on Prevention, Detection,*

*Evaluation, and Treatment of High Blood Pressure* (JNC VI). The intensity of intervention for cholesterol disorders or hypertension is adjusted according to the absolute risk status estimated from multiple risk correlates.

These include both the risk factors listed above and evidence of end-organ damage present in hypertensive patients. Approaches to therapy for cholesterol disorders and hypertension are described in ATP II and JNC VI, respectively. In overweight patients, control of cardiovascular risk factors deserves equal emphasis as weight reduction therapy.

Reduction of risk factors will reduce the risk for cardiovascular disease whether or not efforts at weight loss are successful.

*Other risk factors:* physical inactivity and high serum triglycerides ( $> 200$  mg/dL). When these factors are present, patients can be considered to have incremental absolute risk above that estimated from the preceding risk factors. Quantitative risk contribution is

**SELECTED BMI UNITS CATEGORIZED BY INCHES (CM) AND POUNDS (KG).**

Height in inches (cm)	BMI 25 kg/m <sup>2</sup>	BMI 27 kg/m <sup>2</sup>	BMI 30 kg/m <sup>2</sup>
	Body weight in pounds (kg)		
58 (147.32)	119 (53.98)	129 (58.51)	143 (64.86)
59 (149.86)	124 (56.25)	133 (60.33)	148 (67.13)
60 (152.40)	128 (58.06)	138 (62.60)	153 (69.40)
61 (154.94)	132 (59.87)	143 (64.86)	158 (71.67)
62 (157.48)	136 (61.69)	147 (66.68)	164 (74.39)
63(160.02)	141 (63.96)	152 (68.95)	169 (76.66)
64 (162.56)	145 (65.77)	157 (71.22)	174 (78.93)
65 (165.10)	150 (68.04)	162 (73.48)	180 (81.65)
66 (167.64)	155 (70.31)	167 (75.75)	186 (84.37)
67 (170.18)	159 (72.12)	172 (78.02)	191 (86.64)
68 (172.72)	164 (74.39)	177 (80.29)	197 (89.36)
69 (175.26)	169 (76.66)	182 (82.56)	203 (92.08)
70 (177.80)	174 (78.93)	188 (85.28)	207 (93.90)
71 (180.34)	179 (81.19)	193 (87.54)	215 (97.52)
72 (182.88)	184 (83.46)	199 (90.27)	221 (100.25)
73 (185.42)	189 (85.73)	204 (92.53)	227 (102.97)
74 (187.96)	194 (88.00)	210 (95.26)	233 (105.69)
75 (190.50)	200 (90.72)	216 (97.98)	240 (108.86)
76 (193.04)	205 (92.99)	221(100.25)	246 (111.59)

Metric conversion formula =  
weight (kg)/height (m)<sup>2</sup>

Example of BMI calculation:  
A person who weighs 78.93 kilograms and is  
177 centimeters tall has a BMI of 25:

$$\text{weight (78.93 kg)/height (1.77 m)}^2 = 25$$

Non-metric conversion formula =  
[weight (pounds)/height (inches)<sup>2</sup>] x 703

Example of BMI calculation:  
A person who weighs 164 pounds and is  
68 inches (or 5' 8") tall has a BMI of 25:

$$[\text{weight (164 pounds)/height (68 inches)}^2] \times 703 = 25$$

Table ES-3

not available for these risk factors, but their presence heightens the need for weight reduction in obese persons.

- **Patient Motivation.** When assessing the patient’s motivation to enter weight loss therapy, the following factors should be evaluated: reasons and motivation for weight reduction; previous history of successful and unsuccessful weight loss attempts; family, friends, and work-site support; the patient’s understanding of the causes of obesity and how obesity contributes to several diseases; attitude toward physical activity; capacity to engage in physical activity; time availability for weight loss intervention; and financial considerations. In addition to considering these issues, the health care practitioner needs to heighten a patient’s motivation for weight loss and prepare the patient for treatment. This can be done by enumerating the dangers accompany-

ing persistent obesity and by describing the strategy for clinically assisted weight reduction. Reviewing the patients’ past attempts at weight loss and explaining how the new treatment plan will be different can encourage patients and provide hope for successful weight loss.

**Evaluation and Treatment:** The general goals of weight loss and management are: (1) at a minimum, to prevent further weight gain; (2) to reduce body weight; and (3) to maintain a lower body weight over the long term. The overall strategy for the evaluation and treatment of overweight and obese patients is presented in the Treatment Algorithm on the next page. This algorithm applies only to the assessment for overweight and obesity and subsequent decisions based on that assessment. It does not include any initial overall assessment for cardiovascular risk factors or diseases that are indicated.

### CLASSIFICATION OF OVERWEIGHT AND OBESITY BY BMI, WAIST CIRCUMFERENCE AND ASSOCIATED DISEASE RISKS

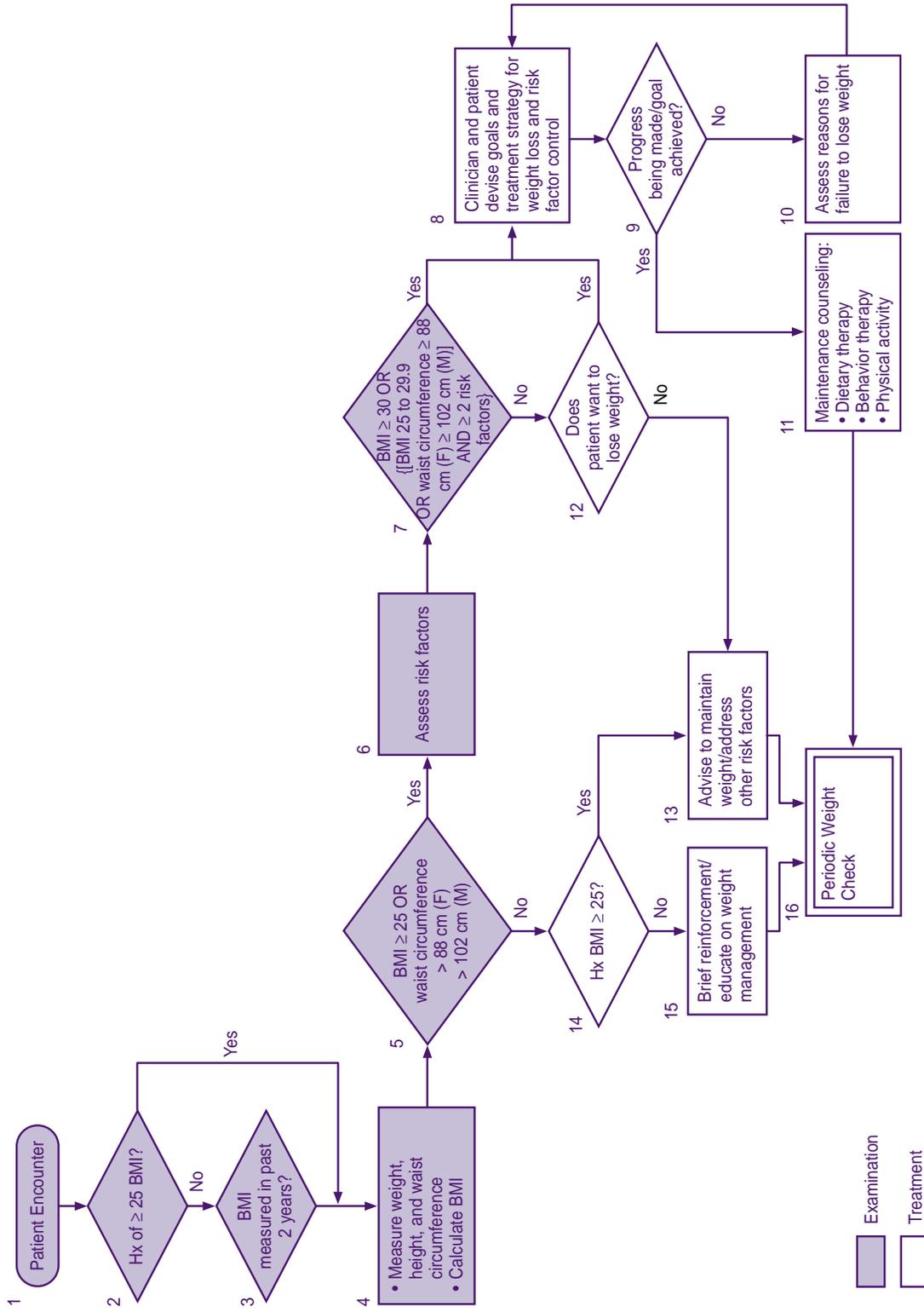
	BMI (kg/m <sup>2</sup> )	Obesity Class	Disease Risk* Relative to Normal Weight and Waist Circumference	
			Men ≤ 102 cm (≤ 40 in) Women ≤ 88 cm (≤ 35 in)	> 102 cm (> 40 in) > 88 cm (> 35 in)
Underweight	<18.5		—	—
Normal <sup>†</sup>	18.5 – 24.9		—	—
Overweight	25.0 – 29.9		Increased	High
Obesity	30.0 – 34.9	I	High	Very High
	35.0 – 39.9	II	Very High	Very High
Extreme Obesity	≥40	III	Extremely High	Extremely High

\* Disease risk for type 2 diabetes, hypertension, and CVD.

† Increased waist circumference can also be a marker for increased risk even in persons of normal weight.

Table ES-4

## Treatment Algorithm\*



\* This algorithm applies only to the assessment for overweight and obesity and subsequent decisions based on that assessment. It does not reflect any initial overall assessment for other conditions and diseases that the physician may wish to do.

■ **Goals of Weight Loss and Management.**

The *initial goal* of weight loss therapy is to reduce body weight by approximately 10 percent from baseline. If this goal is achieved, further weight loss can be attempted, if indicated through further evaluation.

A *reasonable time line* for a 10 percent reduction in body weight is 6 months of therapy. For overweight patients with BMIs in the typical range of 27 to 35, a decrease of 300 to 500 kcal/day will result in weight losses of about ½ to 1 lb/week and a 10 percent loss in 6 months. For more severely obese patients with BMIs > 35, deficits of up to 500 to 1,000 kcal/day will lead to weight losses of about 1 to 2 lb/week and a 10 percent weight loss in 6 months. Weight loss at the rate of 1 to 2 lb/week (calorie deficit of 500 to 1,000 kcal/day) commonly occurs for up to 6 months. After 6 months, the rate of weight loss usually declines and weight plateaus because of a lesser energy expenditure at the lower weight.

Experience reveals that lost weight usually will be regained unless a weight maintenance program consisting of dietary therapy, physical activity, and behavior therapy is continued indefinitely.

After 6 months of weight loss treatment, efforts to maintain weight loss should be put in place. If more weight loss is needed, another attempt at weight reduction can be made. This will require further adjustment of the diet and physical activity prescriptions.

For patients unable to achieve significant weight reduction, prevention of further weight gain is an important goal; such patients may also need to participate in a weight management program.

■ **Strategies for Weight Loss and Weight Maintenance.**

*Dietary Therapy:* A diet that is individually planned and takes into account the patient's overweight status in order to help create a deficit of 500 to 1,000 kcal/day should be an integral part of any weight loss program.

Depending on the patient's risk status, the low-calorie diet (LCD) recommended should be consistent with the NCEP's Step I or Step II Diet (see page 74 of the guidelines).

Besides decreasing saturated fat, total fats should be 30 percent or less of total calories. Reducing the percentage of dietary fat alone will not produce weight loss unless total calories are also reduced. Isocaloric replacement of fat with carbohydrates will reduce the percentage of calories from fat but will not cause weight loss. Reducing dietary fat, along with reducing dietary carbohydrates, usually will be needed to produce the caloric deficit needed for an acceptable weight loss. When fat intake is reduced, priority should be given to reducing saturated fat to enhance lowering of LDL-cholesterol levels. Frequent contacts with the practitioner during dietary therapy help to promote weight loss and weight maintenance at a lower weight.

*Physical Activity:* An increase in physical activity is an important component of weight loss therapy, although it will not lead to substantially greater weight loss over 6 months. Most weight loss occurs because of decreased caloric intake. Sustained physical activity is most helpful in the prevention of weight regain. In addition, it has a benefit in reducing cardiovascular and diabetes risks beyond that produced by weight reduction alone. For most obese patients, exercise should be initiated slowly, and the intensity should be increased gradually. The exercise can be done all at one time or intermittently over the day. Initial activities may be walking or swimming at a slow pace. The patient can start by walking 30 minutes for 3 days a week and can build to 45 minutes of more intense walking

at least 5 days a week. With this regimen, an additional expenditure of 100 to 200 calories per day can be achieved. All adults should set a long-term goal to accumulate at least 30 minutes or more of moderate-intensity physical activity on most, and preferably all, days of the week. This regimen can be adapted to other forms of physical activity, but walking is particularly attractive because of its safety and accessibility. Patients should be encouraged to increase “every day” activities such as taking the stairs instead of the elevator. With time, depending on progress and functional capacity, the patient may engage in more strenuous activities. Competitive sports, such as tennis and volleyball, can provide an enjoyable form of exercise for many, but care must be taken to avoid injury. Reducing sedentary time is another strategy to increase activity by undertaking frequent, less strenuous activities.

*Behavior Therapy:* Strategies, based on learning principles such as reinforcement, that provide tools for overcoming barriers to compliance with dietary therapy and/or increased physical activity are helpful in achieving weight loss and weight maintenance. Specific strategies include self-monitoring of both eating habits and physical activity, stress management, stimulus control, problem solving, contingency management, cognitive restructuring, and social support.

*Combined Therapy:* A combined intervention of behavior therapy, an LCD, and increased physical activity provides the most successful therapy for weight loss and weight maintenance. This type of intervention should be maintained for at least 6 months before considering pharmacotherapy.

*Pharmacotherapy:* In carefully selected patients, appropriate drugs can augment LCDs, physical activity, and behavior therapy in weight loss. Weight loss drugs that have

been approved by the FDA for long-term use can be useful adjuncts to dietary therapy and physical activity for some patients with a BMI of  $\geq 30$  with no concomitant risk factors or diseases, and for patients with a BMI of  $\geq 27$  with concomitant risk factors or diseases. The risk factors and diseases considered important enough to warrant pharmacotherapy at a BMI of 27 to 29.9 are hypertension, dyslipidemia, CHD, type 2 diabetes, and sleep apnea. Continual assessment by the physician of drug therapy for efficacy and safety is necessary.

At the present time, sibutramine is available for long-term use. (Note: FDA approval of orlistat is pending a resolution of labeling issues and results of Phase III trials.) It enhances weight loss modestly and can help facilitate weight loss maintenance. Potential side effects with drugs, nonetheless, must be kept in mind. With sibutramine, increases in blood pressure and heart rate may occur. Sibutramine should not be used in patients with a history of hypertension, CHD, congestive heart failure, arrhythmias, or history of stroke. With orlistat, fat soluble vitamins may require replacement because of partial malabsorption. All patients should be carefully monitored for these side effects.

*Weight Loss Surgery:* Weight loss surgery is one option for weight reduction in a limited number of patients with clinically severe obesity, i.e., BMIs  $\geq 40$  or  $\geq 35$  with comorbid conditions. Weight loss surgery should be reserved for patients in whom efforts at medical therapy have failed and who are suffering from the complications of extreme obesity. Gastrointestinal surgery (gastric restriction [vertical gastric banding] or gastric bypass [Roux-en Y]) is an intervention weight loss option for motivated subjects with acceptable operative risks. An integrated program must be in place to provide guidance on diet, phys-

ical activity, and behavioral and social support both prior to and after the surgery.

- **Adapt Weight Loss Programs To Meet the Needs of Diverse Patients.** Standard treatment approaches for overweight and obesity must be tailored to the needs of various patients or patient groups. Large individual variation exists within any social or cultural group; furthermore, substantial overlap among subcultures occurs within the larger society. There is, therefore, no “cookbook” or standardized set of rules to optimize weight reduction with a given type of patient. However, to be more culturally sensitive and to incorporate patient characteristics in obesity treatment programs: consider and adapt the setting and staffing for the program; consider how the obesity treatment program integrates into other aspects of patient health care and self care; and expect and allow for program modifications based on patient responses and preferences.

The issues of weight reduction after age 65 involve such questions as: does weight loss reduce risk factors in older adults; are there risks associated with obesity treatment that are unique to older adults; and does weight reduction prolong the lives of older adults? Although there is less certainty about the importance of treating overweight at older ages than at younger ages, a clinical decision to forgo obesity treatment in older adults should be guided by an evaluation of the potential benefit of weight reduction and the reduction of risk for future cardiovascular events.

In the obese patient who smokes, smoking cessation is a major goal of risk factor management. Many well-documented health benefits accompany smoking cessation, but a major obstacle to cessation has been the attendant weight gain observed in about 80

percent of quitters. This weight gain averages 4.5 to 7 lb, but in 13 percent of women and 10 percent of men, weight gain exceeds 28 lb. Weight gain that accompanies smoking cessation has been quite resistant to most dietary, behavioral, or physical activity interventions.

The weight gained with smoking cessation is less likely to produce negative health consequences than would continued smoking. For this reason, smoking cessation should be strongly advocated regardless of baseline weight. Prevention of weight gain through diet and physical activity should be stressed. For practical reasons, it may be prudent to avoid initiating smoking cessation and weight loss therapy simultaneously. If weight gain ensues after smoking cessation, it should be managed vigorously according to the guidelines outlined in this report. Although short-term weight gain is a common side effect of smoking cessation, this gain does not rule out the possibility of long-term weight control.

#### Summary of Evidence-Based Recommendations

### **A** ADVANTAGES OF WEIGHT LOSS

The recommendation to treat overweight and obesity is based not only on evidence that relates obesity to increased mortality but also on RCT evidence that weight loss reduces risk factors for disease. Thus, weight loss may not only help control diseases worsened by obesity, it may also help decrease the likelihood of developing these diseases. The panel reviewed RCT evidence to determine the effect of weight loss on blood pressure and hypertension, serum/plasma lipid concentrations, and fasting blood glucose and fasting insulin. Recommendations focusing on these conditions underscore the advantages of weight loss.

#### 1. Blood Pressure

To evaluate the effect of weight loss on blood pressure and hypertension, 76 articles reporting RCTs were considered for inclusion in these

guidelines. Of the 45 accepted articles, 35 were lifestyle trials and 10 were pharmacotherapy trials. There is strong and consistent evidence from these lifestyle trials in both overweight hypertensive and nonhypertensive patients that weight loss produced by lifestyle modifications reduces blood pressure levels. Limited evidence exists that decreases in abdominal fat will reduce blood pressure in overweight nonhypertensive individuals, although not independent of weight loss, and there is considerable evidence that increased aerobic activity to increase cardiorespiratory fitness reduces blood pressure (independent of weight loss). There is also suggestive evidence from randomized trials that weight loss produced by most weight loss medications, except for sibutramine, in combination with adjuvant lifestyle modifications will be accompanied by reductions in blood pressure. Based on a review of the evidence from the 45 RCT blood pressure articles, the panel makes the following recommendation:

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*Weight loss is recommended to lower elevated blood pressure in overweight and obese persons with high blood pressure. Evidence Category A.*

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## 2. Serum/Plasma Lipids

Sixty-five RCT articles were evaluated for the effect of weight loss on serum/plasma concentrations of total cholesterol, LDL-cholesterol, very low-density lipoprotein (VLDL)-cholesterol, triglycerides, and HDL-cholesterol. Studies were conducted on individuals over a range of obesity and lipid levels. Of the 22 articles accepted for inclusion in these guidelines, 14 RCT articles examined lifestyle trials while the remaining 8 articles reviewed pharmacotherapy trials. There is strong evidence from the 14 lifestyle trials that weight loss produced by lifestyle modifications in overweight individuals is accompanied by reductions in serum triglycerides and by increas-

es in HDL-cholesterol. Weight loss generally produces some reductions in serum total cholesterol and LDL-cholesterol. Limited evidence exists that a decrease in abdominal fat correlates with improvements in lipids, although the effect may not be independent of weight loss, and there is strong evidence that increased aerobic activity to increase cardiorespiratory fitness favorably affects blood lipids, particularly if accompanied by weight loss. There is suggestive evidence from the eight randomized pharmacotherapy trials that weight loss produced by weight loss medications and adjuvant lifestyle modifications, including caloric restriction and physical activity, does not result in consistent effects on blood lipids. The following recommendation is based on the review of the data in these 22 RCT articles:

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*Weight loss is recommended to lower elevated levels of total cholesterol, LDL-cholesterol, and triglycerides, and to raise low levels of HDL-cholesterol in overweight and obese persons with dyslipidemia. Evidence Category A.*

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## 3. Blood Glucose

To evaluate the effect of weight loss on fasting blood glucose and fasting insulin levels, 49 RCT articles were reviewed for inclusion in these guidelines. Of the 17 RCT articles accepted, 9 RCT articles examined lifestyle therapy trials and 8 RCT articles considered the effects of pharmacotherapy on weight loss and subsequent changes in blood glucose. There is strong evidence from the nine lifestyle therapy trials that weight loss produced by lifestyle modification reduces blood glucose levels in overweight and obese persons without diabetes, and weight loss reduces blood glucose levels and HbA<sub>1c</sub> in some patients with type 2 diabetes; there is suggestive evidence that decreases in abdominal fat will improve glucose tolerance in overweight individ-

uals with impaired glucose tolerance, although not independent of weight loss; and there is limited evidence that increased cardiorespiratory fitness improves glucose tolerance in overweight individuals with impaired glucose tolerance or diabetes, although not independent of weight loss. In addition, there is suggestive evidence from randomized trials that weight loss induced by weight loss medications does not appear to improve blood glucose levels any better than weight loss through lifestyle therapy in overweight persons both with and without type 2 diabetes. Based on a full review of the data in these 17 RCT articles, the panel makes the following recommendation:

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*Weight loss is recommended to lower elevated blood glucose levels in overweight and obese persons with type 2 diabetes. Evidence Category A.*

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energy X-ray absorptiometry), but no trial data exist to indicate that one measure of fatness is better than any other for following overweight and obese patients during treatment. Since measuring body fat by these techniques is often expensive and is not readily available, a more practical approach for the clinical setting is the measurement of BMI; epidemiological and observational studies have shown that BMI provides an acceptable approximation of total body fat for the majority of patients. Because there are no published studies that compare the effectiveness of different measures for evaluating changes in body fat during weight reduction, the panel bases its recommendation on expert judgment from clinical experience:

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*Practitioners should use the BMI to assess overweight and obesity. Body weight alone can be used to follow weight loss, and to determine efficacy of therapy. Evidence Category C.*

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## **B** MEASUREMENT OF DEGREE OF OVERWEIGHT AND OBESITY

Patients should have their BMI and levels of abdominal fat measured not only for the initial assessment of the degree of overweight and obesity, but also as a guide to the efficacy of weight loss treatment. Although there are no RCTs that review measurements of overweight and obesity, the panel determined that this aspect of patient care warranted further consideration and that this guidance was deemed valuable. Therefore, the following four recommendations that are included in the Treatment Guidelines were based on nonrandomized studies as well as clinical experience.

1. **BMI To Assess Overweight and Obesity**  
There are a number of accurate methods to assess body fat (e.g., total body water, total body potassium, bioelectrical impedance, and dual-

### 2. **BMI To Estimate Relative Risk**

In epidemiological studies, BMI is the favored measure of excess weight to estimate relative risk of disease. BMI correlates both with morbidity and mortality; the relative risk for CVD risk factors and CVD incidence increases in a graded fashion with increasing BMI in all population groups. Moreover, calculating BMI is simple, rapid, and inexpensive, and can be applied generally to adults. The panel, therefore, makes this recommendation:

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*The BMI should be used to classify overweight and obesity and to estimate relative risk of disease compared to normal weight. Evidence Category C.*

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### 3. Assessing Abdominal Fat

For the most effective technique for assessing abdominal fat content, the panel considered measures of waist circumference, waist-to-hip ratio (WHR), magnetic resonance imaging (MRI), and computed tomography. Evidence from epidemiological studies shows waist circumference to be a better marker of abdominal fat content than WHR, and that it is the most practical anthropometric measurement for assessing a patient's abdominal fat content before and during weight loss treatment. Computed tomography and MRI are both more accurate but impractical for routine clinical use. Based on evidence that waist circumference is a better marker than WHR—and taking into account that the MRI and computed tomography techniques are expensive and not readily available for clinical practice—the panel makes the following recommendation:

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*The waist circumference should be used to assess abdominal fat content. Evidence Category C.*

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### 4. Sex-Specific Measurements

Evidence from epidemiological studies indicates that a high waist circumference is associated with an increased risk for type 2 diabetes, dyslipidemia, hypertension, and CVD. Therefore, the panel judged that sex-specific cutoffs for waist circumference can be used to identify increased risk associated with abdominal fat in adults with a BMI in the range of 25 to 34.9. These cutpoints can be applied to all adult ethnic or racial groups. On the other hand, if a patient is very short, or has a BMI above the 25 to 34.9 range, waist cutpoints used for the general population may not be applicable. Based on the evidence from nonrandomized studies, the panel makes this recommendation:

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*For adult patients with a BMI of 25 to 34.9 kg/m<sup>2</sup>, sex-specific waist circumference cutoffs should be used in conjunction with BMI to identify increased disease risks. Evidence Category C.*

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## **C** GOALS FOR WEIGHT LOSS

The general goals of weight loss and management are to reduce body weight, to maintain a lower body weight over the long term, and to prevent further weight gain. Evidence indicates that a moderate weight loss can be maintained over time if some form of therapy continues. It is better to maintain a moderate weight loss over a prolonged period than to regain from a marked weight loss.

### 1. Initial Goal of Weight Loss from Baseline

There is strong and consistent evidence from randomized trials that overweight and obese patients in well-designed programs can achieve a weight loss of as much as 10 percent of baseline weight. In the diet trials, an average of 8 percent of baseline weight was lost. Since this average includes persons who did not lose weight, an individualized goal of 10 percent is reasonable. The panel, therefore, recommends that:

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*The initial goal of weight loss therapy should be to reduce body weight by approximately 10 percent from baseline. With success, further weight loss can be attempted if indicated through further assessment. Evidence Category A.*

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### 2. Amount of Weight Loss

Randomized trials suggest that weight loss at the rate of 1 to 2 lb/week (calorie deficit of 500 to 1,000 kcal/day) commonly occurs for up to 6 months.

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*Weight loss should be about 1 to 2 lb/week for a period of 6 months, with the subsequent strategy based on the amount of weight lost. Evidence Category B.*

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## **D** HOW TO ACHIEVE WEIGHT LOSS

The panel reviewed relevant treatment strategies designed for weight loss that can also be used to foster long-term weight control and prevention of weight gain. The consequent recommendations emphasize the potential effectiveness of weight control using multiple interventions and strategies, including dietary therapy, physical activity, behavior therapy, pharmacotherapy, and surgery, as well as combinations of these strategies.

### 1. Dietary Therapy

The panel reviewed 86 RCT articles to determine the effectiveness of diets on weight loss (including LCDs, very low-calorie diets (VLCDs), vegetarian diets, American Heart Association dietary guidelines, the NCEP's Step I diet with caloric restriction, and other low-fat regimens with varying combinations of macronutrients). Of the 86 articles reviewed, 48 were accepted for inclusion in these guidelines. These RCTs indicate strong and consistent evidence that an average weight loss of 8 percent of initial body weight can be obtained over 3 to 12 months with an LCD and that this weight loss effects a decrease in abdominal fat; and, although lower-fat diets without targeted caloric reduction help promote weight loss by producing a reduced caloric intake, lower-fat diets with targeted caloric reduction promote greater weight loss than lower-fat diets alone. Further, VLCDs produce greater initial weight losses than LCDs (over the long term of >1 year, weight loss is not different than that of the LCDs). In addition, randomized trials suggest that no improvement in cardiorespiratory fitness

as measured by  $VO_2$  max appears to occur in obese adults who lose weight on LCDs alone without physical activity. The following recommendations are based on the evidence extracted from the 48 accepted articles:

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*LCDs are recommended for weight loss in overweight and obese persons. Evidence Category A. Reducing fat as part of an LCD is a practical way to reduce calories. Evidence Category A.*

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*Reducing dietary fat alone without reducing calories is not sufficient for weight loss. However, reducing dietary fat, along with reducing dietary carbohydrates, can facilitate caloric reduction. Evidence Category A.*

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*A diet that is individually planned to help create a deficit of 500 to 1,000 kcal/day should be an integral part of any program aimed at achieving a weight loss of 1 to 2 lb/week. Evidence Category A.*

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### 2. Physical Activity

#### *Effects of Physical Activity on Weight Loss*

Twenty-three RCT articles were reviewed to determine the effect of physical activity on weight loss, abdominal fat (measured by waist circumference), and changes in cardiorespiratory fitness ( $VO_2$  max). Thirteen of these articles were accepted for inclusion in these guidelines. A review of these articles reveals strong evidence that physical activity alone, i.e., aerobic exercise, in obese adults results in modest weight loss and that physical activity in overweight and obese adults increases cardiorespiratory fitness, independent of weight loss. Randomized trials suggest that increased physical activity in overweight and obese adults reduces abdominal fat only modestly or not at all, and that regular

physical activity independently reduces the risk for CVD. The panel's recommendation on physical activity is based on the evidence from these 13 articles:

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*Physical activity is recommended as part of a comprehensive weight loss therapy and weight control program because it: (1) modestly contributes to weight loss in overweight and obese adults (Evidence Category A), (2) may decrease abdominal fat (Evidence Category B), (3) increases cardiorespiratory fitness (Evidence Category A), and (4) may help with maintenance of weight loss (Evidence Category C).*

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*Physical activity should be an integral part of weight loss therapy and weight maintenance. Initially, moderate levels of physical activity for 30 to 45 minutes, 3 to 5 days a week, should be encouraged. All adults should set a long-term goal to accumulate at least 30 minutes or more of moderate-intensity physical activity on most, and preferably all, days of the week. Evidence Category B.*

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#### *Effects of Physical Activity and Diet on Weight Loss (Combined Therapy)*

Twenty-three RCT articles were reviewed to determine the effects on body weight of a combination of a reduced-calorie diet with increased physical activity. Fifteen of these articles were accepted for inclusion in the guidelines. These articles contain strong evidence that the combination of a reduced-calorie diet and increased physical activity produces greater weight loss than diet alone or physical activity alone, and that the combination of diet and physical activity improves cardiorespiratory fitness as measured by  $\text{VO}_2$  max in overweight and obese adults

when compared to diet alone. The combined effect of a reduced-calorie diet and increased-physical activity seemingly produced modestly greater reductions in abdominal fat than either diet alone or physical activity alone, although it has not been shown to be independent of weight loss. The panel's following recommendations are based on the evidence from these articles:

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*The combination of a reduced-calorie diet and increased physical activity is recommended since it produces weight loss that may also result in decreases in abdominal fat and increases in cardiorespiratory fitness. Evidence Category A.*

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### 3. Behavior Therapy

Thirty-six RCTs were reviewed to evaluate whether behavior therapy provides additional benefit beyond other weight loss approaches, as well as to compare various behavioral techniques. Of the 36 RCTs reviewed, 22 were accepted. These RCTs strongly indicate that behavioral strategies to reinforce changes in diet and physical activity in obese adults produce weight loss in the range of 10 percent over 4 months to 1 year. In addition, no one behavior therapy appeared superior to any other in its effect on weight loss; multimodal strategies appear to work best and those interventions with the greatest intensity appear to be associated with the greatest weight loss. Long-term follow-up of patients undergoing behavior therapy shows a return to baseline weight for the great majority of subjects in the absence of continued behavioral intervention. Randomized trials suggest that behavior therapy, when used in combination with other weight loss approaches, provides additional benefits in assisting patients to lose weight short-term, i.e., 1 year (no additional benefits are found at 3 to 5 years). The panel found little evidence on the effect of behavior

therapy on cardiorespiratory fitness. Evidence from these articles provided the basis for the following recommendation:

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*Behavior therapy is a useful adjunct when incorporated into treatment for weight loss and weight maintenance. Evidence Category B.*

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There is also suggestive evidence that patient motivation is a key component for success in a weight loss program. The panel, therefore, makes the following recommendation:

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*Practitioners need to assess the patient's motivation to enter weight loss therapy; assess the readiness of the patient to implement the plan and then take appropriate steps to motivate the patient for treatment. Evidence Category D.*

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#### 4. Summary of Lifestyle Therapy

There is strong evidence that combined interventions of an LCD, increased physical activity, and behavior therapy provide the most successful therapy for weight loss and weight maintenance. The panel makes the following recommendation:

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*Weight loss and weight maintenance therapy should employ the combination of LCD's, increased physical activity, and behavior therapy. Evidence Category A.*

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#### 5. Pharmacotherapy

A review of 44 pharmacotherapy RCT articles provides strong evidence that pharmacological therapy (which has generally been studied along

with lifestyle modification, including diet and physical activity) using dexfenfluramine, sibutramine, orlistat, or phentermine/fenfluramine results in weight loss in obese adults when used for 6 months to 1 year. Strong evidence also indicates that appropriate weight loss drugs can augment diet, physical activity, and behavior therapy in weight loss. Adverse side effects from the use of weight loss drugs have been observed in patients. As a result of the observed association of valvular heart disease in patients taking fenfluramine and dexfenfluramine alone or in combination, these drugs have been withdrawn from the market. Weight loss drugs approved by the FDA for long-term use may be useful as an adjunct to diet and physical activity for patients with a BMI of  $\geq 30$  with no concomitant obesity-related risk factors or diseases, as well as for patients with a BMI of  $\geq 27$  with concomitant risk factors or diseases; moreover, using weight loss drugs singly (not in combination) and starting with the lowest effective doses can decrease the likelihood of adverse effects. Based on this evidence, the panel makes the following recommendation:

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*Weight loss drugs approved by the FDA may be used as part of a comprehensive weight loss program, including dietary therapy and physical activity for patients with a BMI of  $\geq 30$  with no concomitant obesity-related risk factors or diseases, and for patients with a BMI of  $\geq 27$  with concomitant obesity-related risk factors or diseases. Weight loss drugs should never be used without concomitant lifestyle modifications. Continual assessment of drug therapy for efficacy and safety is necessary. If the drug is efficacious in helping the patient to lose and/or maintain weight loss and there are no serious adverse effects, it can be continued. If not, it should be discontinued. Evidence Category B.*

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## 6. Weight Loss Surgery

The panel reviewed 14 RCTs that examined the effect of surgical procedures on weight loss; 8 were deemed appropriate. All of the studies included individuals who had a BMI of 40 kg/m<sup>2</sup> or above, or a BMI of 35 to 40 kg/m<sup>2</sup> with comorbidity. These trials provide strong evidence that surgical interventions in adults with clinically severe obesity, i.e., BMIs  $\geq 40$  or  $\geq 35$  with comorbid conditions, result in substantial weight loss, and suggestive evidence that lifelong medical surveillance after surgery is necessary. Therefore, the panel makes the following recommendation:

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*Weight loss surgery is an option for carefully selected patients with clinically severe obesity (BMI  $\geq 40$  or  $\geq 35$  with comorbid conditions) when less invasive methods of weight loss have failed and the patient is at high risk for obesity-associated morbidity or mortality. Evidence Category B.*

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## **E** GOALS FOR WEIGHT LOSS MAINTENANCE

Once the goals of weight loss have been successfully achieved, maintenance of a lower body weight becomes the challenge. Whereas studies have shown that weight loss is achievable, it is difficult to maintain over a long period of time (3 to 5 years). In fact, the majority of persons who lose weight, once dismissed from clinical therapy, frequently regain it—so the challenge to the patient and the practitioner is to maintain the weight loss. Successful weight reduction thus depends on continuing a maintenance program on a long-term basis. In the past, obtaining the goal of weight loss has been considered the end of weight loss therapy. Observation, monitoring, and encouragement of patients who have successfully lost weight should be continued long term. The panel's recommendations on weight

loss maintenance are derived from RCT evidence as well as nonrandomized and observational studies.

### 1. Weight Maintenance Phase

RCTs from the Behavior Therapy section above suggest that lost weight usually will be regained unless a weight maintenance program consisting of dietary therapy, physical activity, and behavior therapy is continued indefinitely. Drug therapy in addition may be helpful during the weight maintenance phase. The panel also reviewed RCT evidence that considered the rate of weight loss and the role of weight maintenance. These RCTs suggest that after 6 months of weight loss treatment, efforts to maintain weight loss are important. Therefore, the panel recommends the following:

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*After successful weight loss, the likelihood of weight loss maintenance is enhanced by a program consisting of dietary therapy, physical activity, and behavior therapy which should be continued indefinitely. Drug therapy can also be used. However, drug safety and efficacy beyond 1 year of total treatment have not been established. Evidence Category B.*

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*A weight maintenance program should be a priority after the initial 6 months of weight loss therapy. Evidence Category B.*

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Strong evidence indicates that better weight loss results are achieved with dietary therapy when the duration of the intervention is at least 6 months. Suggestive evidence also indicates that during dietary therapy, frequent contacts between professional counselors and patients promote weight loss and maintenance. Therefore, the panel recommends the following:

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*The literature suggests that weight loss and weight maintenance therapies that provide a greater frequency of contacts between the patient and the practitioner and are provided over the long term should be utilized whenever possible. This can lead to more successful weight loss and weight maintenance. Evidence Category C.*

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## **F** SPECIAL TREATMENT GROUPS

The needs of special patient groups must be addressed when considering treatment options for overweight and obesity. The guidelines focus on three such groups including smokers, older adults, and diverse patient populations.

### 1. Smokers

Cigarette smoking is a major risk factor for cardiopulmonary disease. Because of its attendant high risk, smoking cessation is a major goal of risk-factor management. This aim is especially important in the overweight or obese patient, who usually carries excess risk from obesity-associated risk factors. Thus, smoking cessation in these patients becomes a high priority for risk reduction. Smoking and obesity together apparently compound cardiovascular risk, but fear of weight gain upon smoking cessation is an obstacle for many patients. Therefore, the panel recommends that:

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*All smokers, regardless of their weight status, should quit smoking. Evidence Category A. Prevention of weight gain should be encouraged and if weight gain does occur, it should be treated through dietary therapy, physical activity, and behavior therapy, maintaining the primary emphasis on the importance of abstinence from smoking. Evidence Category C.*

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### 2. Older Adults

The general nutritional safety of weight reduction at older ages is of concern because restrictions on overall food intake due to dieting could result in inadequate intake of protein or essential vitamins or minerals. In addition, involuntary weight loss indicative of occult disease might be mistaken for success in voluntary weight reduction. These concerns can be alleviated by providing proper nutritional counseling and regular body weight monitoring in older persons for whom weight reduction is prescribed. A review of several studies indicates that age alone should not preclude treatment for obesity in adult men and women. In fact, there is evidence from RCTs that weight reduction has similar effects in improving cardiovascular disease risk factors in older and younger adults. Therefore, in the panel's judgment:

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*A clinical decision to forgo obesity treatment in older adults should be guided by an evaluation of the potential benefits of weight reduction for day-to-day functioning and reduction of the risk of future cardiovascular events, as well as the patient's motivation for weight reduction. Care must be taken to ensure that any weight reduction program minimizes the likelihood of adverse effects on bone health or other aspects of nutritional status. Evidence Category D.*

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### 3. Diverse Patient Populations

Standard obesity treatment approaches should be tailored to the needs of various patients or patient groups. It is, however, difficult to determine from the literature how often this occurs, how specific programs and outcomes are influenced by tailoring, and whether it makes weight loss programs more effective. After reviewing

two RCTs, four cross-sectional studies, and four intervention studies, as well as additional published literature on treatment approaches with diverse patient populations, the panel recommends the following:

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*The possibility that a standard approach to weight loss will work differently in diverse patient populations must be considered when setting expectations about treatment outcomes. Evidence Category B.*

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