Executive Summary of the Clinical Guidelines on the Identification, Evaluation, and Treatment of Overweight and Obesity in Adults

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 a major contributor to preventive 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; weight in kilograms divided by the square of height in meters) of 25 to 29.9 and obesity as a BMI of 30 or greater. However, overweight and obesity are not mutually exclusive, since obese persons are also overweight. A BMI of 30 is about 13.5 kg overweight and is equivalent to a weight of 99.5 kg in a person whose height is 1.8 m and to a weight of 84 kg in one whose height is 1.7 m. The number of overweight and obese men and women has risen since 1960; in the past decade, the percentage of people in these categories has increased to 54.9% of adults aged 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, cultural, 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 (NHLBI) 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 consists 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 5 meetings of the full panel and 2 additional meetings of the executive committee composed of the panel chair and 4 panel members.

The San Antonio Cochrane Center, San Antonio, Tex, assisted the panel in the literature abstraction and in organizing the data into appropriate evidence tables. The center pre-tested 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 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 on the basis of 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 that ranges from A to D. Table 1 summarizes the categories of evidence by their source and provides a definition for each category.

### 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 triglyceride levels and increases high-density lipoprotein cholesterol (HDL-C) levels, and generally produces some reduction in total serum cholesterol and low-density lipoprotein cholesterol (LDL-C) levels. Weight loss reduces blood glucose levels in overweight and obese persons without diabetes, and weight loss also reduces blood glucose levels and hemoglobin A1c levels 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.

### What Treatments Are Effective?

A variety of effective options exist for the management of overweight and obese patients, including dietary therapy approaches such as controlled-energy (low-calorie) diets and lower-fat diets; altering physical activity patterns; behavior therapy techniques; pharmacotherapy; surgery; and combinations of these techniques. (As of September 1997, the Food and Drug

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**Table 1. Evidence Categories**

<table>
<thead>
<tr>
<th>Evidence Category</th>
<th>Sources of Evidence</th>
<th>Definition</th>
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<tbody>
<tr>
<td>A</td>
<td>Randomized controlled trials (RCTs) (rich body of data)</td>
<td>Evidence is from end points 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 requires substantial numbers of studies involving substantial numbers of participants.</td>
</tr>
<tr>
<td>B</td>
<td>RCTs (limited body of data)</td>
<td>Evidence is from end points 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.</td>
</tr>
<tr>
<td>C</td>
<td>Nonrandomized trials, observational studies</td>
<td>Evidence is from outcomes of uncontrolled or nonrandomized trials or from observational studies.</td>
</tr>
<tr>
<td>D</td>
<td>Panel consensus judgment</td>
<td>Expert judgment is based on the panel’s synthesis of evidence from 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).</td>
</tr>
</tbody>
</table>
The BMI, Body Mass Index.

... also needs to be given to the patient’s and overall risk status. Consideration of the patient’s BMI, waist circumference, and associated disease risk factors in most adults with a BMI of greater than 88 cm (35 in). Administration [FDA] requested the voluntary withdrawal from the market of dexfenfluramine hydrochloride and fenfluramine hydrochloride because of 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 hydrochloride 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 3 trials].

**CLINICAL GUIDELINES**

Treatment of the overweight or obese patient is a 2-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, the clinician should 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 obesity and to monitor changes in body weight. In addition, measurements of body weight alone can be used to determine efficacy of weight loss therapy. The BMI is calculated as weight in kilograms divided by height in meters squared. (To estimate BMI using nonmetric measurements, use the following formula: [weight (pounds)/height (inches)]2 × 703.) Weight classifications by BMI, selected for use in this report, are shown in Table 2. A conversion table of heights and weights resulting in selected BMI units is provided in Table 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 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: high-risk cutoff for men is waist circumference greater than 102 cm (>40 in), and for women greater than 88 cm (>35 in).

### Table 2. Classification of Overweight and Obesity by Body Mass Index (BMI)

<table>
<thead>
<tr>
<th>BMI, kg/m²</th>
<th>Underweight</th>
<th>Normal</th>
<th>Overweight</th>
<th>Obesity, class</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>&lt;18.5</td>
<td>18.5-24.9</td>
<td>25.0-29.9</td>
<td>I 30.0-34.9</td>
</tr>
<tr>
<td></td>
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<td></td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>II 35.0-39.9</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>III (extreme obesity) ≥ 40</td>
</tr>
</tbody>
</table>

### Table 3. Selected Body Mass Index (BMI) Units

<table>
<thead>
<tr>
<th>Height, cm (in)</th>
<th>BMI of 25</th>
<th>BMI of 27</th>
<th>BMI of 30</th>
</tr>
</thead>
<tbody>
<tr>
<td>147.32 (58)</td>
<td>53.98 (119)</td>
<td>58.51 (129)</td>
<td>64.86 (143)</td>
</tr>
<tr>
<td>149.86 (59)</td>
<td>56.25 (124)</td>
<td>60.33 (133)</td>
<td>67.13 (148)</td>
</tr>
<tr>
<td>152.40 (60)</td>
<td>58.06 (128)</td>
<td>62.60 (138)</td>
<td>69.40 (153)</td>
</tr>
<tr>
<td>154.94 (61)</td>
<td>59.87 (132)</td>
<td>64.86 (143)</td>
<td>71.67 (158)</td>
</tr>
<tr>
<td>157.48 (62)</td>
<td>61.69 (136)</td>
<td>66.68 (147)</td>
<td>74.39 (164)</td>
</tr>
<tr>
<td>160.02 (63)</td>
<td>63.96 (141)</td>
<td>68.95 (152)</td>
<td>76.68 (169)</td>
</tr>
<tr>
<td>162.56 (64)</td>
<td>65.77 (145)</td>
<td>71.21 (157)</td>
<td>78.93 (174)</td>
</tr>
<tr>
<td>165.10 (65)</td>
<td>68.04 (150)</td>
<td>73.48 (162)</td>
<td>81.65 (180)</td>
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<tr>
<td>167.64 (66)</td>
<td>70.31 (155)</td>
<td>75.75 (167)</td>
<td>84.37 (186)</td>
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<tr>
<td>170.18 (67)</td>
<td>72.12 (159)</td>
<td>78.02 (172)</td>
<td>86.64 (191)</td>
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<tr>
<td>172.72 (68)</td>
<td>74.39 (164)</td>
<td>80.29 (177)</td>
<td>89.38 (197)</td>
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<td>175.26 (69)</td>
<td>76.66 (169)</td>
<td>82.56 (182)</td>
<td>92.08 (203)</td>
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<td>177.80 (70)</td>
<td>78.93 (174)</td>
<td>85.28 (188)</td>
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<td>180.34 (71)</td>
<td>81.19 (179)</td>
<td>87.54 (193)</td>
<td>97.52 (215)</td>
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<tr>
<td>182.88 (72)</td>
<td>83.46 (184)</td>
<td>90.27 (199)</td>
<td>100.25 (221)</td>
</tr>
<tr>
<td>185.42 (73)</td>
<td>85.73 (189)</td>
<td>92.53 (204)</td>
<td>102.97 (227)</td>
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<tr>
<td>187.96 (74)</td>
<td>88.00 (194)</td>
<td>95.26 (210)</td>
<td>105.69 (233)</td>
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<tr>
<td>190.50 (75)</td>
<td>90.27 (200)</td>
<td>97.98 (216)</td>
<td>108.36 (240)</td>
</tr>
<tr>
<td>193.04 (76)</td>
<td>92.54 (205)</td>
<td>100.25 (221)</td>
<td>111.58 (246)</td>
</tr>
</tbody>
</table>

*To calculate BMI: metric conversion formula = weight (kilograms)/[height (meters)]² and nonmetric conversion formula = weight (pounds)/[height (inches)]² × 703.

### Table 4. Classification of Overweight and Obesity by Body Mass Index (BMI), Waist Circumference, and Associated Disease Risk

<table>
<thead>
<tr>
<th>Disease Risk† Relative to Normal Weight and Waist Circumference</th>
<th>Men, &lt;102 cm; Women, &lt;88 cm</th>
<th>Men, &gt;102 cm; Women, &gt;88 cm</th>
</tr>
</thead>
<tbody>
<tr>
<td>BMI, kg/m²</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Underweight</td>
<td>&lt;18.5</td>
<td>...</td>
</tr>
<tr>
<td>Normal†</td>
<td>18.5-24.9</td>
<td>...</td>
</tr>
<tr>
<td>Overweight</td>
<td>25.0-29.9</td>
<td>Increased</td>
</tr>
<tr>
<td>Obesity, class</td>
<td></td>
<td></td>
</tr>
<tr>
<td>I</td>
<td>30.0-34.9</td>
<td>High</td>
</tr>
<tr>
<td>II</td>
<td>35.0-39.9</td>
<td>Very high</td>
</tr>
<tr>
<td>III (extreme obesity)</td>
<td>≥ 40</td>
<td>Extremely high</td>
</tr>
</tbody>
</table>

*Disease risk for type 2 diabetes, hypertension, and cardiovascular disease. Ellipses indicate that no risk at these levels of BMI was assigned.

†Increased waist circumference can also be a marker for increased risk even in persons of normal weight.
These waist circumference cutoff points lose their incremental predictive power in patients with a BMI of 35 or greater because these patients will exceed the cutoff points noted above. Table 4 presents the associated disease risks of increased abdominal fat relative to BMI. These categories denote relative risk, not absolute risk; ie, 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, 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 of ≥140 mm Hg or diastolic blood pressure of ≥90 mm Hg, or the patient is taking antihypertensive agents), high-risk LDL-C (≥4.13 mmol/L [≥160 mg/dL]), low HDL-C (<0.90 mmol/L [<35 mg/dL]), impaired fasting glucose level (6.1-6.9 mmol/L [110-125 mg/dL]), family history of premature coronary heart disease (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 ≥45 years and women ≥55 years or postmenopausal). Patients can be classified as being at high absolute risk if they have 3 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 CVD based on these risk factors are described in detail in the National Cholesterol Education Program’s (NCEP) Second Report of the Expert Panel on the Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults 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 CVD whether or not efforts at weight loss are successful.
Box 1: A patient encountered is defined as any interaction with a health care practitioner (generally a physician, nurse practitioner, or physician’s assistant) that provides the opportunity to assess a patient’s weight status and provide advice, counseling, or treatment. Box 2: The practitioner must seek to determine whether the patient has ever been overweight. While a technical definition is provided, a simple question such as “Have you ever been overweight?” will accomplish the same goal. Questions directed toward weight history, dietary habits, physical activities, and medications may provide useful information. Box 3: For those who have not been overweight, a 2-year interval is appropriate for the reassessment of body mass index (BMI). While this time span is not evidence-based, it is believed to be a reasonable compromise between the need to identify weight gain at an early stage and the need to limit the time, effort, and cost of repeated measurements. Box 4: Weight must be measured so that the BMI can be calculated. Most charts are based on weights obtained with the patient wearing undergarments and no shoes. BMI can be manually calculated (weight in kilograms divided by the square of height in meters), but is more easily obtained from a nomogram. Waist circumference is important because evidence suggests that abdominal fat is a particularly strong determinant of cardiovascular risk in those with a BMI of 25 to 29.4. Increased waist circumference can also be a risk factor even in persons of normal weight. A nutritive index will also help to assess the diet-related and physical activity contribution to weight gain in patients. Box 5: “BMI = 25, or waist circumference > 88 or > 102 cm”—These cutoffs divide overweight from normal weight and are consistent with other national and international guidelines. The relation between weight and mortality is J-shaped, and evidence suggests that the right side of the “J” begins to rise at a BMI of 25. Waist circumference is incorporated as an “or” factor because some patients with BMI lower than 25 will have disproportionate abdominal fat, and this increases their cardiovascular risk despite their low BMI. These abdominal circumference values are not necessary for patients with a BMI of 35 or greater. Box 6: Risk assessment for cardiovascular disease (CVD) and diabetes in a person with evident obesity will include screening for coronary heart disease (CHD), type 2 diabetes, and sleep apnea. However, sibutramine should not be used in patients with a history of hypertension, CHD, congestive heart failure, arrhythmias, or history of stroke. Certain patients may be candidates for weight loss surgery. Each component of weight loss therapy can be introduced briefly. The selection of weight loss methods should be made in the context of patient preferences, analysis of past failed attempts, and consideration of the available resources. Box 9: During the acute weight loss period and at 6-month and 1-year follow-up visits, the patients should be weighed, BMI calculated, and progress assessed. If at any time it appears that the program is failing, a reassessment should take place to determine the reasons (see box 10). If pharmacotherapy is being used, appropriate monitoring for adverse effects is recommended. If a patient can achieve the recommended 10% reduction in body weight in 6 months to 1 year, this change in weight can be considered good progress. The patient can then enter the phase of weight maintenance and long-term monitoring. If the patient is not able to lose or gain weight or has evidence that some component is overemphasized and the therapy cannot always be attributed to degree of compliance. Once a limit of weight loss has been obtained, the practitioner is responsible for long-term monitoring of weight factors and for encouraging the patient to maintain a reduced weight level. Box 10: If a patient fails to achieve the recommended 10% reduction in body weight in 6 months or 1 year, a reevaluation is required. A critical question is whether the level of motivation is high enough to continue clinical therapy. If motivation is high (patient is concerned and feels that weight loss is important), the therapist should continue. If motivation is low (patient is not concerned and feels that weight loss is not important), the protocol should be reviewed and the patient referred to a more structured approach. Box 11: Weight loss management requires ongoing therapy for the remainder of the patient’s life. For those who have not been overweight, a 2-year interval is appropriate for the reassessment of body mass index (BMI). While this time span is not evidence-based, it is believed to be a reasonable compromise between the need to identify weight gain at an early stage and the need to limit the time, effort, and the cost of repeated measurements.

Other risk factors: physical inactivity and high serum triglyceride levels (>2.26 mmol/L [>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 not available for these risk factors, but their presence heightens the need for weight reduction in these persons.

Patient Motivation. When assessing the patient’s motivation to begin 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 workplace 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 accompanying persistent obesity and by describing the strategy for clinically assisted weight

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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 Figure. This treatment 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. Each step (designated by a box) in this process is described.

Goals of Weight Loss and Management

• The initial goal of weight loss therapy is to reduce body weight by approximately 10% 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% 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 1255 to 2092 kJ/d (300-500 kcal/d) will result in weight losses of about 0.23 to 0.45 kg/wk and a 10% loss in 6 months. For more severely obese patients with BMIs greater than 35, deficits of up to 2092 to 4184 kJ/d (500-1000 kcal/d) will lead to weight losses of about 0.45 to 0.90 kg/wk and a 10% weight loss in 6 months. Weight loss at the rate of 0.45 to 0.90 kg/wk (energy deficit of 2092-4184 kJ/d) occurs safely 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 to help create a deficit of 2092 to 4184 kJ/d (500-1000 kcal/d) should be an integral part of any weight loss program. A patient may choose a diet of 4184 to 5021 kJ/d (1000-1200 kcal/d) for women and 5021 to 6276 kJ/d (1200-1500 kcal/d) for men. Depending on the patient’s risk status, the controlled-energy diet (low-calorie diet or LCD) recommended should be consistent with the NCEP’s Step I or Step II diet. Besides decreasing intake of saturated fat, total fats should be 30% or less of total energy intake. Reducing the percentage of dietary fat alone will not produce weight loss unless total energy intake is also reduced. Isoenergetic replacement of fat with carbohydrates will reduce the energy fraction from fat but will not cause weight loss. Reducing intake of dietary fat, along with reducing dietary carbohydrates, usually will be needed to produce the energy 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-C 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 substan-

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controlled-energy diet (or 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 controlled-energy diets (or LCD), 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 30 or greater with no concomitant risk factors or diseases, and for patients with a BMI of 27 or greater 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, coronary heart disease, type 2 diabetes, and sleep apnea. Continual assessment by the physician of drug therapy for efficacy and safety is necessary.

At present, sibutramine is available for long-term use. It enhances weight loss modestly and can help facilitate weight loss maintenance. Potential adverse effects with drug use, 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, coronary heart disease, congestive heart failure, arrhythmias, or history of stroke. With orlistat (FDA approval pending), fat-soluble vitamins may require replacement because of partial malabsorption. All patients should be carefully monitored for these adverse effects.

Weight Loss Surgery. Weight loss surgery is one option for weight reduction in a limited number of patients with clinically severe obesity, ie, BMI of 40 or greater or BMI of 35 or greater 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, physical activity, and behavioral and social support both before and after the surgery.

Adaptation of Weight Loss Programs for 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, clinicians should (1) consider and adapt the setting and staffing for the program, (2) consider how the obesity treatment program integrates into other aspects of patient health care and self-care, and (3) expect and allow for program modifications based on patient responses and preferences.

The issues of weight reduction after the age of 65 years 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 forego 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% of quitters. This weight gain averages 2 to 3 kg, but in 13% of women and 10% of men, weight gain exceeds 12.7 kg. 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. 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

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 and plasma lipid concentrations, and fasting blood glucose and fasting insulin levels. Recommendations focusing on these conditions underscore the advantages of weight loss.

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
effects blood lipid levels, particularly if accompanied by weight loss. There is suggestive evidence from the 8 pharmacotherapy RCTs that weight loss produced by weight loss medications and adjuvant lifestyle modifications, including energy restriction and physical activity, does not result in consistent effects on blood lipid levels. The following recommendation is based on the review of the data in these 22 RCT articles: **Weight loss is recommended to lower elevated levels of total cholesterol, LDL-C, and triglycerides, and to raise low levels of HDL-C in overweight and obese persons with dyslipidemia (Evidence Category A).**

**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 examined lifestyle therapy trials and 8 considered the effects of pharmacotherapy on weight loss and subsequent changes in blood glucose levels. There is strong evidence from the 9 lifestyle therapy trials that weight loss produced by lifestyle modifications reduces blood glucose levels in overweight and obese persons without diabetes, and weight loss reduces blood glucose levels and hemoglobin A1c levels in some patients with type 2 diabetes. There is suggestive evidence that decreases in abdominal fat will improve glucose tolerance in overweight individuals 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, although not independent of weight loss. In addition, there is suggestive evidence from RCTs that weight loss induced by use of 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: **Weight loss is recommended to lower elevated blood glucose levels in overweight and obese persons with type 2 diabetes (Evidence Category A).**

**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 4 recommendations that are included in the Treatment Guidelines were based on nonrandomized studies and clinical experience.

**BMI to Assess Overweight and Obesity.** There are a number of accurate methods to assess body fat (eg, total body water, total body potassium, bioelectrical impedance, and dual-energy X-ray absorptiometry), but no trial data exist to indicate that one measure of fatness is better than any other for monitoring overweight and obese patients during treatment. Because 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 most 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: **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).**

**BMI to Estimate Relative Risk.** In epidemiological studies, BMI is the favored measure of excess weight to estimate relative risk of disease. The BMI correlates both with morbidity and mortality; the relative risk for CVD risk factors and CVD incidence increases in a graded fashion.

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**Serum/Plasma Lipids.** Sixty-five RCT articles were evaluated for the effect of weight loss on concentrations of serum and plasma total cholesterol, LDL-C, very low-density lipoprotein cholesterol, triglycerides, and HDL-C. Studies were conducted on individuals with a range of obesity and lipid levels. Of the 22 articles accepted for inclusion in these guidelines, 14 RCT articles examined lifestyle trials, and 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 triglyceride levels and by increases in HDL-C levels. Weight loss generally produces some reductions in serum total cholesterol and LDL-C levels. Limited evidence exists that a decrease in abdominal fat correlates with improvement in lipid levels, 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 lipid levels, particularly...
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: The BMI should be used to classify overweight and obesity and to estimate relative risk of disease compared with normal weight (Evidence Category C).

Assessing Abdominal Fat. For the most effective technique for assessing abdominal fat content, the panel considered measures of waist circumference, waist-to-hip ratio, magnetic resonance imaging, and computed tomography. Evidence from epidemiological studies shows waist circumference to be a better marker of abdominal fat content than waist-to-hip ratio, 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 magnetic resonance imaging are more accurate but impractical for routine clinical use. Based on evidence that waist circumference is a better marker than waist-to-hip ratio—and taking into account that the magnetic resonance imaging and computed tomography techniques are expensive and not readily available for clinical practice—the panel makes the following recommendation: The waist circumference should be used to assess abdominal fat content (Evidence Category C).

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 cutoff points 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 cutoff points 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 cutoff points used for the general population may not be applicable. Based on the evidence from nonrandomized studies, the panel makes this recommendation: For adult patients with a BMI of 25 to 34.9, sex-specific waist circumference cutoffs should be used in conjunction with BMI to identify increased disease risks (Evidence Category 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.

Initial Goal of Weight Loss From Baseline. There is strong and consistent evidence from RCTs that overweight and obese patients in well-designed programs can achieve a weight loss of as much as 10% of baseline weight. In the diet trials, an average of 8% of baseline weight was lost. Since this average includes persons who did not lose weight, an individualized goal of 10% is reasonable. The panel, therefore, recommends that: The initial goal of weight loss therapy should be to reduce body weight by approximately 10% from baseline. With success, further weight loss can be attempted if indicated through further assessment (Evidence Category A).

Amount of Weight Loss. Randomized trials suggest that weight loss at the rate of 0.45 to 0.90 kg/wk (energy deficit of 2092-4184 kJ/d) commonly occurs for up to 6 months. The panel makes the following recommendation: Weight loss should be about 0.45 to 0.90 kg/wk for a period of 6 months, with the subsequent strategy based on the amount of weight lost (Evidence Category B).

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 intervensions and strategies, including dietary therapy, physical activity, behavior therapy, pharmacotherapy, and surgery, as well as combinations of these strategies.

Dietary Therapy. The panel reviewed 86 RCT articles to determine the effectiveness of diets on weight loss (including controlled-energy diets [or LCDs], very controlled-energy diets [very low calorie diets or VLCDs], vegetarian diets, American Heart Association dietary guidelines, the NCEP’s Step I diet with energy intake 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% of initial body weight can be obtained over 3 to 12 months with a controlled-energy diet (LCD) and that this weight loss effect is a decrease in abdominal fat; and, although lower-fat diets without targeted energy intake reduction help promote weight loss by producing a reduced energy intake, lower-fat diets with targeted energy reduction promote greater weight loss than lower-fat diets alone. Furthermore, very controlled-energy diets (VLCDs) produce greater initial weight losses than controlled-energy diets (LCDs) (over the long term of >1 year, weight loss is not different from that of the controlled-energy diets [LCDs]). In addition, RCTs suggest that no improvement in cardiorespiratory fitness as measured by maximum oxygen consumption appears to occur in obese adults who lose weight on controlled-energy diets (LCDs) alone without physical activity. The following recommendations are based on the evidence extracted from the 48 accepted articles: (1) Controlled-energy diets (LCDs) are recommended for weight loss in overweight and obese persons (Evidence Category A). Reducing fat as part of a controlled-energy diet (LCD) is a practical way to reduce calories. (Evidence Category A). (2) Reducing dietary fat alone without reducing energy intake is not sufficient for weight loss. However, reducing intake of dietary fat, along with reducing intake of dietary carbohydrates, can facilitate energy reduction (Evi-
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 (maximum oxygen consumption). Thirteen of these articles were accepted for inclusion in these guidelines. A review of these articles reveals strong evidence that physical activity alone, ie, 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 controlled 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: (1) Physical activity is recommended as part of a comprehensive weight loss therapy and weight control program because it: (a) modestly contributes to weight loss in overweight and obese adults (Evidence Category A), (b) may decrease abdominal fat (Evidence Category B), (c) increases cardiorespiratory fitness (Evidence Category A), and (d) may help with maintenance of weight loss (Evidence Category C). (2) 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).
based on the evidence from these articles: The combination of a reduced-energy diet and increased physical activity is recommended because it produces weight loss that may also result in decreases in abdominal fat and increases in cardiorespiratory fitness (Evidence Category A).

Behavior Therapy. Thirty-six RCTs were reviewed to evaluate whether behavior therapy provides additional benefit beyond other weight loss approaches, and 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% over a period of 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 interventions with the greatest intensity appear to be associated with the greatest weight loss. Long-term follow-up results of patients undergoing behavior therapy show a return to baseline weight for the majority of subjects in the absence of continued behavior intervention. Randomized controlled trials suggest that behavior therapy, when used in combination with other weight loss approaches, provides additional benefits in assisting patients to lose weight in the short term, ie, 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: **Behavior therapy is a useful adjunct when incorporated into treatment for weight loss and weight maintenance (Evidence Category B).**

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: **Practitioners need to assess the patient’s motivation to begin 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).**

**Summary of Lifestyle Therapy.** There is strong evidence that combined interventions of a controlled-energy diet (LCD), increased physical activity, and behavior therapy provide the most successful therapy for weight loss and weight maintenance. The panel makes the following recommendation: **Weight loss and weight maintenance therapy should use the combination of controlled-energy diets (LCDs), increased physical activity, and behavior therapy (Evidence Category A).**

**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 a combination of phentermine and fenfluramine results in weight loss in obese adults when used for 6 months to 1 year. Strong evidence also indicates that use of appropriate weight loss drugs can augment diet, physical activity, and behavior therapy in weight loss. Adverse 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 30 or greater with no concomitant obesity-related risk factors or diseases, as well as for patients with a BMI of 27 or greater 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: **Weight loss drugs approved by the FDA for long-term use may be useful (Evidence Category B).**

Weight loss surgery is an option for carefully selected patients with clinically severe obesity (BMI ≥40 or ≥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: **Weight loss surgery is an option for carefully selected patients with clinically severe obesity (BMI ≥40 or ≥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).**

**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 (3-5 years). In fact, most people 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.

Randomized controlled trials 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: **(1) After successful weight loss, the likelihood of weight loss maintenance is enhanced by a program consisting of dietary therapy, physical activity, and behavior therapy that 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). (2) A weight maintenance program should be a priority after the initial 6 months of weight loss therapy (Evidence Category B).**

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: **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).

**Special Treatment Groups**

The needs of special patient groups must be addressed when considering treatment options for overweight and obesity. The guidelines focus on 3 such groups including smokers, older adults, and diverse patient populations.

**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: 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).

**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 CVD risk factors in older and younger adults. Therefore, in the panel’s judgment: A clinical decision to forego 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).

**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 2 RCTs, 4 cross-sectional studies, and 4 intervention studies, as well as additional published literature on treatment approaches with diverse patient populations, the panel recommends the following: 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).

**CONCLUSIONS**

The clinical guidelines evidence report was reviewed by 115 health experts at major medical and professional societies. It has been endorsed by the coordinating committees of the NCEP and the National High Blood Pressure Education Program, the North American Association for the Study of Obesity, the National Institute of Diabetes and Digestive and Kidney Diseases National Task Force on the Prevention and Treatment of Obesity, and the American Heart Association. These groups represent 54 professional societies, government agencies, and consumer organizations. An abbreviated practical guide based on the evidence report will be distributed to primary care physicians in the United States and to other interested health care practitioners. “The Clinical Guidelines on the Identification, Evaluation, and Treatment of Overweight and Obesity in Adults: Evidence Report” is published as the September 1998 supplement to the Journal of Obesity Research and is available on the NHLBI Web site at http://www.nhlbi.nih.gov/nhlbi/ nhlbi.htm or by writing to the NHLBI Information Center, PO Box 30105, Bethesda, MD 20824-0105.

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