VA/DoD CLINICAL PRACTICE GUIDELINE FOR

SCREENING AND MANAGEMENT OF OVERWEIGHT AND OBESITY

Department of Veterans Affairs

Department of Defense

QUALIFYING STATEMENTS

The Department of Veterans Affairs (VA) and The Department of Defense (DoD) guidelines are based upon the best information available at the time of publication. They are designed to provide information and assist decision-making. They are not intended to define a standard of care, and should not be construed as one. Neither should they be interpreted as prescribing an exclusive course of management.

Variations in practice will inevitably and appropriately occur when clinicians take into account the needs of individual patients, available resources, and limitations unique to an institution or type of practice. Every healthcare professional making use of these guidelines is responsible for evaluating the appropriateness of applying them in the setting of any particular clinical situation.

Version 1.0 – 2006

Prepared by:

THE MANAGEMENT OF OVERWEIGHT AND OBESITY

Working Group

With support from:

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&

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Version 1.0 – 2006

Based on evidence reviewed until February 2005

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INTRODUCTION

The VA/DoD clinical practice guideline (CPG) for the screening and management of overweight and obesity provides an evidence-based approach in the screening and management of overweight and obese patients for the purpose of providing improved clinical outcomes.

The guideline was developed under the auspices of the Veterans Health Administration (VHA) and the Department of Defense (DoD) pursuant to directives from the Department of Veterans Affairs (VA). VHA and DoD define clinical practices guidelines as:

"Recommendations for the performance or exclusion of specific procedures or services derived through a rigorous methodological approach that includes:

- Determination of appropriate criteria, such as effectiveness, efficacy, population benefit, or patient satisfaction; and
- Literature review to determine the strength of the evidence in relation to these criteria."

Overweight and obesity deplete physical health and well-being, drive huge and growing healthcare costs, and are major contributors to premature morbidity and mortality. A debate over the number of deaths attributable to obesity can obscure the important costs of obesity in terms of reduction in quality of life and the impact of comorbid conditions that are enhanced by obesity. The Centers for Disease Control and Prevention (CDC) cites a study that estimates that health costs attributed to overweight and obesity may be upwards of $78.5 billion. In addition, overweight and obesity are associated with increased all-cause mortality rates and increased morbidity rates of hypertension, diabetes, dyslipidemia, and coronary artery disease among many other comorbid conditions. The epidemic growth in the percent of the population that is either overweight or obese portends ominously for the future.

Overweight is defined as a body mass index (BMI) of 25 to 29.9 kg/m^2. An individual with a BMI of 30 kg/m^2 or more is defined as obese. According to NHANES, approximately 64 percent of Americans are overweight and 30 percent are obese. A DoD survey in 2002 reported that, while the active duty military population has a much lower obesity prevalence (13 percent) than the American population at large, more than 62 percent of active duty men and 34 percent of active duty women self-report as overweight according to accepted BMI criteria. The active duty prevalence of overweight and obesity has steadily increased since 1995 when the DoD began surveying height and weight data. For the active duty population, overweight and obesity can have important negative effects on individual operational readiness including decreased exercise tolerance, increased risk of heat injury, increased rates of musculoskeletal injury, and abnormal sleep physiology with excessive daytime sleepiness and impaired vigilance.

The adult non-active duty population served by the Military Health System appears to more closely mirror the civilian population. According to an NQMP study on the prevalence of obesity in the direct care system, the rate of obesity among non-active duty users of military treatment facilities is 34 percent, somewhat higher than the NHANES rate. Overweight and obesity affect the VHA beneficiary population even more significantly. Among veterans at VA medical facilities, it is estimated that 68 percent of the male population and 73 percent of the female population are overweight with 37 percent of males and 33 percent of females meeting the criteria for obesity.

Obesity is a complex and chronic disease that develops from an interaction between the individual's genotype and the environment. The fundamental basis of obesity is an imbalance between energy intake and energy expenditure; when energy intake exceeds output, weight gain results. In either instance, the risk of cardiovascular disease (CVD) increases as individuals gain weight, further emphasizing the gravity of the healthcare dilemma posed by the explosive increase in the prevalence of overweight/obesity in the population at large.

Though there are several ways to estimate body fat, most of which are not readily available or convenient in the clinical setting, BMI is recommended as a practical screening tool to determine overweight and obesity. Based on an almost linear increasing relationship between BMI and mortality in adults with a BMI of 30 and above, all adults with BMI greater than 30 kg/m^2 should be offered weight loss treatment. For adults with a BMI 25 to 29.9 kg/m^2 (overweight) the relationship between body weight and mortality is less clearly defined. In addition to BMI, measurement of waist circumference (WC) has been shown to be an independent predictor of disease risk and is more closely linked to adverse health outcomes than BMI. WC may also be used to guide the management of overweight adults.

The Rationale for the Treatment of Overweight and Obesity

There is a growing body of evidence that links overweight and obesity with an increased risk of several chronic health conditions, reduced quality of life, and early mortality. Overweight and obese adults are at greater risk for developing hypertension, diabetes, dyslipidemia, cardiovascular disease, stroke, obstructive sleep apnea, and some types of cancers. Overweight and obese women are at increased risk for developing infertility and menstrual irregularities. The accepted goal of weight loss is to prevent or reduce obesity-associated morbidity and mortality by improving cardiovascular and metabolic risk factors. Indeed, clinical studies have demonstrated that weight loss improves blood pressure, cholesterol, glycemic control, and obstructive sleep apnea and reduces incident hypertension and type 2 diabetes. However, there currently is no direct evidence from prospective clinical trials demonstrating that weight loss reduces cardiovascular morbidity and mortality.

While direct evidence is lacking, most experts agree that epidemiological studies generally support that weight loss "that reduces blood pressure and cholesterol will reduce the number of deaths from heart disease and stroke." Furthermore, we now have strong evidence that modest weight loss among overweight and obese adults will reduce the incidence and severity of diabetes, a chronic condition that is linked to significant morbidity, mortality, and healthcare costs. Thus, in conclusion, intentional weight loss among overweight and obese adults is likely to be beneficial, although the method of weight loss (i.e., diet, exercise, drugs, and surgery) and the age at which it occurs may be important determinants of its overall efficacy. The goal of this guideline is to identify those patients who are likely to benefit from weight loss, based on high-quality evidence from clinical trials, and provide detailed information to clinicians on how to prescribe and monitor the success of such interventions.

Obesity Research

In developing this guideline, the Working Group drew heavily from the following guideline sources, which are referenced respectively throughout the guideline:

- National Heart, Lung, and Blood Institute in cooperation with National Institute of Diabetes and Digestive and Kidney Diseases (1998). Obesity Education Initiative. Clinical guidelines on the identification, evaluation, and treatment of overweight and obesity in adults: the Evidence Report. NIH publication no. 98-4083. Bethesda, MD: U.S. Department of Health and Human Services, United States Public Health Service, National Institutes of Health. [referenced as: NHLBI, 1998]
- U.S. Preventive Services Task Force. Screening for Obesity in Adults: Recommendations and Rationale. November 2003. Agency for Health Care Research and Quality, Rockville, MD. http://www.ahrq.gov/clinic/3rduspstf/obesity/obesrr.htm. [referenced as: USPSTF, 2003]
- Pharmacologic and Surgical Management of Obesity in Primary Care: A Clinical Practice Guideline from the American College of Physicians. Annals of Internal Medicine, 2005;142(7):525-531. [referenced as: ACP, 2005]

The following three major systematic reviews served as the main source for the review of the evidence by the Working Group:

- Avenell A., Broom J., Poobalan A., Aucott L., Stearns S.C., Smith W.C.S., et al. Systematic review of the long-term effects and economic consequences of treatments for obesity and implications for health improvement. Health Technol Assess, 2004 May;8(21):iii-iv, 1-182. [referenced as: Avenell et al., 2004]
- McTigue K.M., Harris R., Hemphill B., Lux L., Sutton S., Bunton A.J., & Lohr K.N. Screening and interventions for obesity in adults: summary of the evidence for the U.S. Preventive Services Task Force. Ann Intern Med, 2003 Dec 2;139(11):933-49. [referenced as: McTigue et al., 2003]
- Shekelle P.G., Morton S.C., Maglione M.A., Suttorp M., Tu W., Li Z., et al. Pharmacological and Surgical Treatment of Obesity. Evidence Report/Technology Assessment No. 103. (Prepared by the Southern California–RAND Evidence-Based Practice Center, Santa Monica, CA, under contract Number 290-02-0003.) AHRQ Publication No. 04-E028-2. Rockville, MD: Agency for Health Care Research and Quality. July 2004. [referenced as: Shekelle et al., 2004]

The Working Group also systematically reviewed studies investigating dietary, lifestyle changes, exercise interventions, pharmacologic, and surgical weight loss strategies to assess the weight loss efficacy and the effects of weight loss on mortality, CVD, quality of life and comorbidity.

The Working Group recognized certain limitations in determining the applicability of findings from these studies to everyday clinical practice in the VHA and DoD healthcare system. Specifically, weight loss studies have methodological limitations that restrict the applicability of findings to unselected obese people assessed in everyday clinical practice. These limitations include inadequate study duration, large proportions of subjects lost to follow-up, a lack of an appropriate usual care group, and a lack of patient-related health outcomes in high-risk individuals. In addition, some treatment strategies are more difficult to investigate in research designed as randomized controlled trials (RCTs). For patients facing the decision of such extreme surgery and providers who recommend and perform these surgeries, a double-blind random design raises profound concerns. Thus, the highest level of evidence grading is lacking in these important areas (e.g., exercise and behavioral modification). Research addressing more aggressive strategies such as bariatric surgery raises difficult ethical questions for investigators recruiting patients to treatment or control groups.

Furthermore, the Working Group recognized that the availability of the different treatment modalities varies at clinics and medical centers. This is especially true with regard to weight loss medications (sibutramine and orlistat) and bariatric surgery. There is strong evidence to suggest that medications and surgery are valuable assets in treating overweight and obesity; however, the availability of these resources may determine the extent of their use in confronting the obesity epidemic.

Implementation

The guideline algorithms are designed to be adapted to the individual facility's needs and resources. Clinicians can use the algorithms to determine appropriate interventions and timing of care for their patients and to better stratify obese and overweight patients and optimize healthcare utilization. There is no intent to restrict providers from using their clinical expertise in the care of an individual patient. The guideline's recommendations should facilitate, not replace, clinical judgment.

This guideline has been developed to assist VHA and DoD facilities to implement processes of care that are evidence-based. The guideline is designed to achieve maximum functionality and independence and improve patient/family quality of life. The recommendations may provide facilities lacking organized weight management care a structured approach to confront the challenges in facing the obesity epidemic and assure that veterans and active duty personnel who can benefit from weight

reduction will have access to comparable care, regardless of geographic location. It is also meant to encourage each Veterans Integrated Services Network (VISN) or DoD medical treatment facility (MTF), or other care access sites in developing innovative plans, to remove barriers that prevent patients from gaining prompt access to preventive care and inhibit primary care providers, specialists, and allied health professionals from working together.

Although this guideline represents the best evidence-based practice on the date of its publication, it is certain that medical practice is evolving and that this evolution will require continuous updating of published information. New technologies and on-going research will assuredly improve weight management care in the future. This guideline can assist in identifying priorities for research efforts and allocation of resources. As a result of implementing evidence-based practice, followed by data collection and assessment, new practice-based evidence may emerge.

The guideline addresses screening and management for adult populations. Obesity in childhood and adolescence is a significant and compelling issue that requires a guideline dedicated to that age group.

A systematic approach was used to develop this guideline update. It is described in detail in Appendix A.

REFERENCES

2002 Survey of Health Related Behaviors. http://www.tricare.osd.mil/main/news/2002WWFinalReport.pdf

Clinical Guidelines on the Identification, Evaluation, and Treatment of Overweight and Obesity in Adults: The Evidence Report. National Heart, Lung and Blood Institute in Cooperation with the National Institute of Health. NIH Publication No. 98-4083, September 1998.

Das, S., Kinsinger, L., et al. Obesity Prevalence Among Veterans at Veterans Affairs Medical Facilities. American Journal of Preventative Medicine. 2005;28:291-294.

Department of Health and Human Services Centers for Disease Control and Prevention: http://www.cdc.gov/nccdphp/dnpa/obesity/economic_consequences.htm

NHANES - National Center for Health Statistics National Health and Nutrition Examination Survey: http://www.cdc.gov/nchs/nhanes.htm

NQMP Study: Prevalence of Obesity in the Direct Care System, 2003: http://www.nqmp.info/ed/content/factsheet/download/ss_obesity_03.pdf

Reaven G., Abbasi F., and McLaughlin T. Obesity, Insulin Resistance, and Cardiovascular Disease. Recent Progress in Hormone Research, 2004;59:207-223.

KEY POINTS ADDRESSED BY THE GUIDELINE

1. Routine primary care screening for overweight and obesity.
2. Assessment of risk factors and obesity-associated conditions influenced by weight.
3. Evidence-based strategies for weight loss and weight maintenance for patients who are overweight or obese.
4. Promotion of lifestyle changes (diet and exercise) in persons with normal weight to prevent weight gain.
5. Advice for persons who are overweight (BMI of 25-29.9 kg/m^2) without obesity-associated conditions, to maintain or lose weight and prevent weight gain.
6. The involvement of patients in their education, goal setting, and decision-making process.
7. Strategies to achieve sustained weight loss by creating an energy deficit (when energy expenditure is greater than caloric intake).
8. The combination of dietary therapy, increased physical activity, and behavioral modification therapy as the key components of weight loss therapy.
9. Weight loss drug therapy as an adjunct to long-term diet and physical activity for patients who are obese (BMI $\geq$ 30 kg/m^2), or are overweight with a BMI $\geq$ 27 kg/m^2 and present with obesity-associated conditions.
10. Weight loss (bariatric) surgery as an option for patients with extreme obesity (BMI $\geq$40 kg/m^2) or a BMI of $\geq$ 35 kg/m^2 with one or more obesity-associated conditions in whom other methods of weight loss treatment have failed.

Summary of the Available Evidence for Key Recommendations

	Strong level of evidence	Limited level of evidence	Unknown efficacy or insufficient evidence
Screening	• BMI correlates with disease risk	• BMI relates to fat distribution • Waist circumference is related to disease and fat distribution	–
Weight Loss	• Combination of diet therapy, physical activity, and behavioral modification leads to weight loss • Weight loss improves glycemic control, dyslipidemia, and blood pressure	• Weight loss improves sleep apnea, metabolic syndrome, and osteoarthritis	• Weight loss effect on cardiovascular disease • Weight loss effect on survival
Diet Therapy	• Calorie restriction results in weight loss • Adherence to diet is more important than the specific diet choice	• Low fat or low carbohydrate diets may be better for weight loss	• Diet based on glycemic index • Protein-sparing diet
Physical Activity	• Physical activity and restricted calorie diet leads to weight loss • Physical activity increases fitness and reduces cardiovascular risk • Physical activity should be for at least 30 minutes most days of the week	• Physical activity is essential to maintain weight • Multiple intermittent bursts of exercise are effective • Lifestyle physical activities are as good as structured exercise	–
Behavioral Therapy	• Behavioral modification enables compliance with diet and exercise programs • Multiple behavioral modification strategies should be used • High intensity of the intervention is essential	• Group behavioral modification has better results than individual	• Which behavioral modification technique is better
Pharmaco-therapy	• Orlistat and sibutramine may lead to weight loss • Orlistat improves glycemic control, dyslipidemia, and blood pressure • Drugs have adverse effects	• Sibutramine improves secondary outcomes (cholesterol, and glycemic control)	• Long-term safety and effectiveness
Surgery	• Surgery is effective for reducing weight in patients with extreme obesity (BMI $\geq$ 40 kg/m^2) or $\geq$ 35 kg/m^2 with comorbid conditions.	• Surgery may improve comorbid conditions (glycemic control, dyslipidemia and blood pressure)	• Preoperative selection and assessment criteria • Long-term safety and effectiveness

Executive Summary

Obesity is recognized as a chronic disease resulting from a combination of biological and environmental factors. Obesity is a significant health problem that deserves the same attention and long-term intervention as other serious, chronic health conditions.

Effective treatment produces substantial health benefits in the form of reduced blood pressure and cholesterol levels and improved glycemic control. Even modest weight reduction in obese and overweight individuals can reduce the risk factors for diabetes and cardiovascular disease (CVD), in addition to other health benefits including increased longevity. Unfortunately, many healthcare professionals do not aggressively address the issue of obesity with their patients. BMI and WC determinations can be performed easily and they aid in assessing a patient's risk for developing obesity related morbidity and the urgency of achieving weight loss.

A successful weight loss program is based primarily on proper dietary guidelines, increased physical activity, and behavioral modification therapy strategies. A weight maintenance program should follow the weight loss period to prevent weight regain. Drug therapy, as an adjunct to these measures, can provide effective long-term weight loss and weight maintenance. Orlistat and sibutramine, both are currently FDA-approved for weight loss treatment, have been shown to be safe and effective when used over periods of up to four years and two years, respectively. For extreme cases of obesity, bariatric surgery may produce dramatic weight loss.

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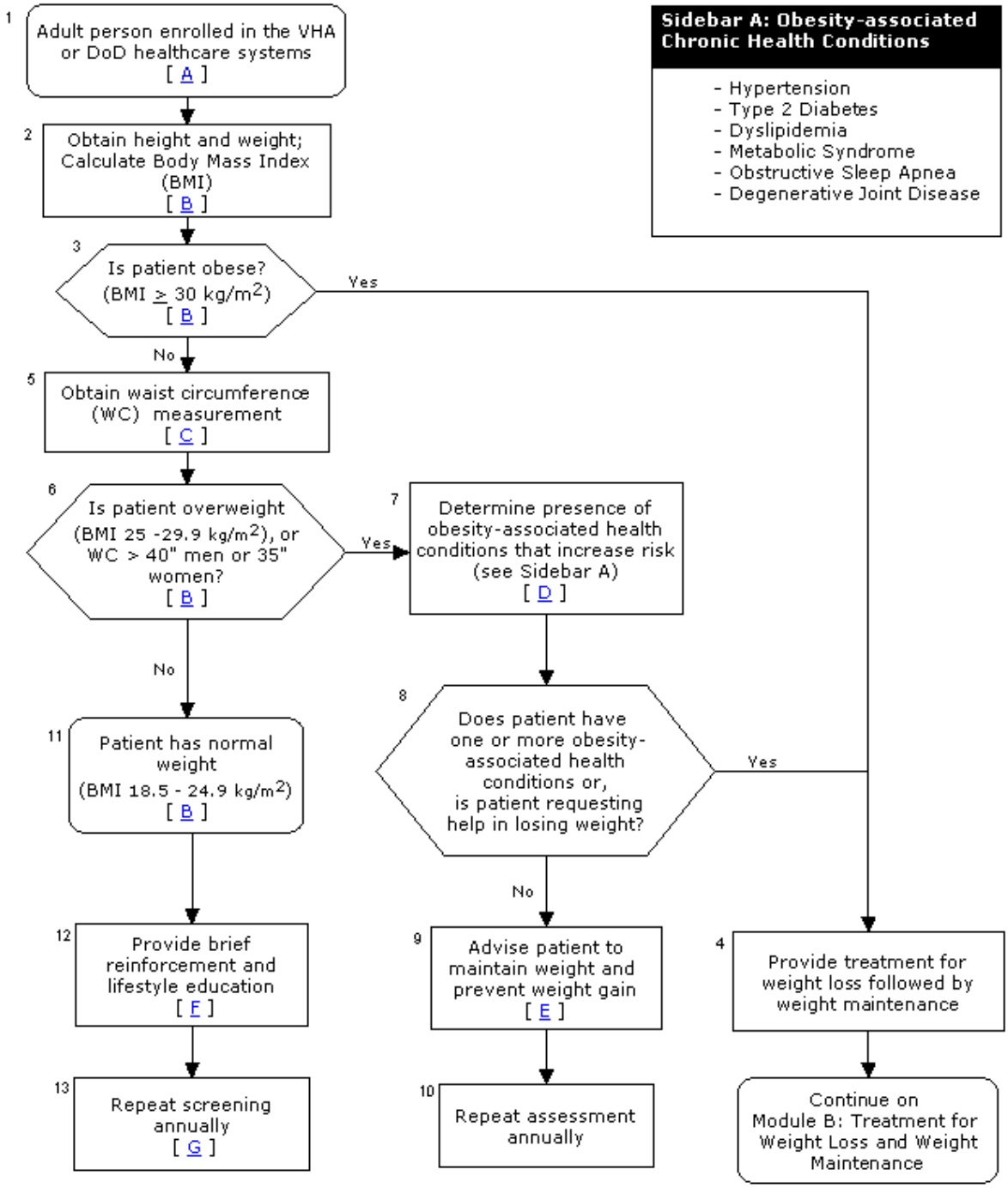
The Working Group acknowledges the advice and support provided by Tom Wadden, PhD and Richard Atkinson, MD in reviewing the content of the guideline.

Module A: Screening for Overweight and Obesity



12/3/2006

MODULE A

SCREENING FOR OVERWEIGHT AND OBESITY

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ANNOTATIONS

A. Adult Person Enrolled in the VHA or DoD Healthcare Systems

DEFINITION

Any adult eligible for care in the Veterans Health Administration (VHA) or the Department of Defense (DoD) healthcare delivery system should be screened and if necessary, treated for overweight or obesity as described in this guideline. (See Module B: Treatment for Weight Loss and Weight Maintenance)

DISCUSSION

In this guideline, an adult is defined as an individual age 18 years or older. This guideline is not directed to the treatment of children, adolescents (less than age 18), or pregnant/lactating women. Patients with existing comorbid conditions should be managed in consultation with appropriate specialists or existing practice guidelines. The U.S. Preventive Services Task Force (USPSTF), National Institutes of Health (NIH), and the World Health Organization (WHO) all currently recommend that providers screen all adults for overweight and obesity using body mass index (BMI) (McTigue et al., 2003, NHLBI, 1998; USPSTF, 2003; WHO, 2000).

B. Obtain Height and Weight; Calculate Body Mass Index (BMI)

OBJECTIVE

Screen all adults for overweight or obesity.

BACKGROUND

Though there are several ways to estimate body fat (e.g., skin-fold calipers, hydrodensitometry, dual energy X-ray absorptiometry, and bioelectrical impedance), most are not readily available or convenient in the clinical setting. The body mass index (BMI) is recommended as a practical screening tool to determine overweight and obesity in adult populations due to its ease of obtaining and use.

In this guideline, overweight and obesity are defined according to the 1998 NHLBI classification (see Table 1). The classification is based primarily on the associations between BMI, chronic disease, and mortality. The relation between BMI and disease risk varies among individuals and among different populations. For example, individuals who are short in stature or who have a relatively high muscular mass may fall into the overweight category by BMI but may not be at increased risk of obesity-associated conditions. Therefore, this classification must be viewed as a broad generalization.

For the BMI Calculation Chart, see Appendix B. Additional BMI calculators and tables can be accessed at: http://www.cdc.gov/nccdphp/dnpa/bmi/.

When obtaining weight and height, healthcare providers should be sensitive to the needs of obese patients. Many obese patients require appropriate sized blood pressure cuffs, wide-based armless chairs, and scales that measure individuals greater than 350 pounds.

Table 1: Classification of Overweight and Obesity by BMI and Associated Disease Risk (*)

Classification	BMI (kg/m^2)	Disease Risk with Normal Waist Circumference	Disease Risk with Excessive Waist Circumference
Underweight	< 18.5	–	–
Normal	18.5 – 24.9	–	–
Overweight	25.0 – 29.9	Increased	Moderate
Obese I	30.0 – 34.9	Moderate	Severe
Obese II	35.0 – 39.9	Severe	Very Severe
Obese III	≥ 40.0	Very Severe	Very Severe

** Disease risk for obesity-associated conditions*

RECOMMENDATIONS

1. Adult patients should have their BMI calculated from their height and weight to establish a diagnosis of overweight or obesity. [B]

2. Obese patients (BMI ≥ 30 kg/m^2) should be offered weight loss treatment. [B]
(See Module B: Treatment for Weight Loss and Weight Maintenance)

3. Overweight patients (BMI between 25 and 29.9 kg/m^2) or patients with increased waist circumference (> 40 inches for men; > 35 inches for women) should be assessed for the presence of obesity-associated conditions that are directly influenced by weight, to determine the benefit they might receive from weight loss treatment. [B]

4. Normal weight patients (BMI between 18.5 and 24.9 kg/m^2) should be provided with education regarding healthy lifestyle behaviors, advised of their BMI and their weight range margins, and instructed to return for further evaluation should those margins be exceeded. [Expert Opinion]

DISCUSSION

Presently, there is no precise clinical definition of obesity, based on the degree of excess body fat that places an individual at increased health risk. General consensus exists for an indirect measure of body fat, called the weight for height index or body mass index (BMI). The BMI is an easily obtained and reliable measurement for overweight and obesity and is defined as a person's weight (in kilograms) divided by the square of the person's height (in meters). If weight is measured in pounds and inches, the BMI is calculated as [weight (in pounds)/height (in inches)^2]x 703 (McTigue et al., 2003; NHLBI, 1998, Qeutelet, 1869). Obesity cut-offs based on mortality risk are defined in body mass index units of kilograms per meter squared (kg/m^2) (WHO, 2000).

Although BMI is commonly used to identify obesity, there are questions regarding how accurately BMI can determine body composition and identify obese from non-obese individuals. In a study by Frankenfield et al. (2001) obesity was defined as body fat of at least 25 percent of total body mass for men and at least 30 percent for women. Obesity based on body fat was always present in subjects with a BMI of at least 30 kg/m^2. However, 30 percent of men and 46 percent of women with a BMI below 30 kg/m^2 had obesity levels of body fat. The greatest variability in the prediction of percentage of body fat and body fat divided by height (m^2) from regression equations using BMI was at a BMI below 30 kg/m^2. In conclusion, using impedance derived body fat mass as the criterion, people with a BMI of at least 30 kg/m^2 are obese. However, significant numbers of people with a BMI below 30 kg/m^2 are also obese and thus misclassified by BMI. These results suggest that evaluation of body fat by measurement

of WC may be a more appropriate way to assess obesity in people with a BMI below 30 kg/m^2. (See Annotation C)

Whereas little evidence exists from prospective studies showing that weight loss improves long-term morbidity and mortality, strong evidence suggests that obesity is associated with increased morbidity and mortality and that weight loss in obese persons reduces important disease risk factors (NHLBI, 1998). In adults, disease risk increases independently with increasing BMI and excess abdominal fat. Cardiovascular and other obesity related disease risks increase significantly when BMI exceeds 25 kg/m^2.

Obesity-- Overall, mortality begins to increase with BMI levels greater than 25 kg/m^2 and increases most dramatically as BMI levels surpass 30 kg/m^2. An almost linear relationship between BMI and mortality is found in adults with a BMI of 30 kg/m^2 or above (obese) (WHO, 2000). A largely linear relationship is found between body weight and conditions such as coronary heart disease (CHD), hypertension, and type 2 diabetes mellitus (Must et al., 1999; WHO, 2000). Based on these clear relationships, all adults with a BMI of 30 kg/m^2 or above should be offered weight loss treatment.

Overweight-- For adults with a BMI of 25 to 29.9 kg/m^2 (overweight), the relationship between body weight and mortality is less clearly defined (Heiat, 2003; Heiat et al., 2001; Strawbridge et al., 2000). Furthermore, some adults with a BMI lower than 30 will have a disproportionate amount of abdominal fat which increases their cardiovascular risk despite their low BMI (NHLBI, 1998). Waist circumference (WC) measurements greater than 40 inches (102 cm) in men and 35 inches (88 cm) in women do indicate an increased risk of obesity related comorbidities.

Most overweight individuals are considered at increased risk for developing obesity-associated morbidities such as hypertension and type 2 diabetes (Must et al., 1999; WHO, 2000). Thus, the decision to refer overweight patients for weight loss treatment should be made in the context of assessments of obesity-associated conditions that are known to increase health risks and patient preferences. (NHLBI, 1998). (See Annotation D)

While there is evidence that the BMI level associated with increased disease risk differs between ethnic groups, (Fernandez et al., 2003; Mozumdar & Roy, 2004; Tzamakoukas, et al., 1994) more data are needed to generate clear ethnic group specific cut-points for treatment of overweight (NHLBI, 1998).

Notably, there is also an on-going debate surrounding the mortality implications for overweight in those over 65 years of age. Numerous studies have demonstrated that overweight individuals over 65 years of age do not have a higher risk of death than their normal weight peers (Heiat et al., 2003). Thus, among those over 65 years of age, the relationship between BMI and mortality risk is best described as a ‘‘U-shaped curve, with a large, flat bottom and a right curve that does not begin to rise significantly until BMI is greater than 31 to 32 kg/m^2’’ (Heiat et al., 2001).

Normal weight-- In general, the lowest mortality risk is associated with a BMI between 18.5 and 24.9 kg/m^2 (normal weight). These individuals should be advised to maintain their current body weight since weight gain, even within the normal range, may be associated with increased risk of chronic medical conditions (WHO, 2000).

EVIDENCE

	Recommendation	Sources of Evidence	QE	Overall Quality	SR
1.	Adult patients should have their BMI calculated from their height and weight.	McTigue et al., 2003 NHLBI, 1998 USPSTF, 2003 WHO, 2000	I	Fair	B
2	Overweight adults (BMI between 25 and 29.9 kg/m^2) should be assessed for other risk factors to determine if they need treatment for overweight.	Heiat, 2003 Heiat et al., 2003 McTigue et al., 2003 NHLBI, 1998 Strawbridge et al., 2000 USPSTF, 2003 WHO, 2000	I	Fair	B
3.	Obese patients should be offered weight loss treatment.	Heiat et al., 2001 McTigue et al., 2003 NHLBI, 1998 WHO, 2000	I	Good	B

QE = Quality of Evidence; SR = Strength of Recommendation (see Appendix A)

C. Obtain Waist Circumference Measurement

OBJECTIVE

Assess person's body fat distribution.

BACKGROUND

The patient's BMI is recommended to classify overweight and obesity and to estimate relative risk of disease compared to normal weight. WC is considered an indicator of increased disease risk for overweight patients and is the most practical anthropometric measurement for assessing a patient's abdominal fat content before and during weight loss treatment. Gender-specific WC cut-offs should be used in conjunction with BMI to identify increased disease risk.

RECOMMENDATIONS

1. For screening purposes, waist circumference should be obtained in patients with a BMI < 30 kg/m^2 as a predictor of disease risk. [C]

2. The waist circumference measurement should be made with a tape measure placed above the iliac crest and wrapped in a horizontal fashion around the individual's abdomen at the end of a normal expiration.

3. Gender-specific cut-offs should be used as indicators of increased waist circumference. [C]

- Men: waist circumference > 40 inches (102 cm)
- Women: waist circumference > 35 inches (88 cm)

DISCUSSION

The presence of excessive central adiposity, measured by WC, has been shown to be an independent predictor of weight-related comorbidities, regardless of BMI, sex, race, and ethnicity (NHLBI, 1998). Furthermore, in some populations of patients, WC may be a better indicator of CVD risk than BMI alone (Zhu et al., 2005).

Increased WC has been shown to be an important independent predictor of disease risk (Zhu et al., 2005). This additional disease risk likely reflects the ability of WC to act as a surrogate for abdominal, and in particular, visceral fat (Janssen et al., 2002). WC is defined as the length around the abdomen measured above the iliac crest (instructions on standardized measurements can be found on the NHLBI Web site http://www.nhlbi.nih.gov/guidelines/obesity/practgde.htm). Weight loss treatment is recommended for all obese patients (BMI $\geq$ 30 kg/m^2) regardless of WC (McTigue et al., 2003; NHLBI, 1998; WHO, 2000). WC is incorporated as an "or" factor, because some patients with a BMI lower than 30 will have a disproportionate amount of abdominal fat, which increases their cardiovascular risk despite their low BMI (NHLBI, 1998). In addition, decisions regarding management and progress of weight loss may be guided by the measurement of WC for all patients.

Like BMI, clinically relevant cut-offs for WC likely differ by ethnic group.

EVIDENCE

	Recommendation	Sources of Evidence	QE	Overall Quality	SR
1.	Waist circumference should be obtained in patients with BMI < 30 kg/m^2 as a predictor of disease risk.	NHLBI, 1998 Zhu et al., 2005	II-2	Fair	C
2.	Gender-specific WC cut-offs should be used as indicators of increased disease risk: Men > 40 inches (102cm) Women > 35 inches (88cm)	Janssen et al., 2002 NHLBI, 1998 WHO, 2000	III	Poor	C

QE = Quality of Evidence; SR = Strength of Recommendation (see Appendix A)

D. Determine Presence of Obesity-Associated Health Conditions that Increase Risk

OBJECTIVE

Identify patients who are overweight and who will benefit from weight loss treatment.

BACKGROUND

Several clinical practice guidelines (including the VA/DoD guidelines) for the management of chronic diseases recommend lifestyle interventions to promote weight loss in all patients with hypertension, type 2 diabetes, or dyslipidemia. Weight loss has been shown to directly favorably affect outcomes. Aggressive treatment of these conditions in patients who are overweight will likely result in the greatest benefit.

The decision of which overweight patients to treat is multifaceted. In formulating this guideline and considering the reality of limited resources, the Working Group determined treatment priorities by stratifying patients according to their risk of disease. While many medical comorbid conditions are beneficially affected by weight reduction, only a few (hypertension, type 2 diabetes, dyslipidemia, metabolic syndrome and obstructive sleep apnea) have strong evidence that weight loss improves these conditions and that therefore intense weight loss treatment is warranted. (See Table 2)

RECOMMENDATIONS

1. Weight loss treatment should be offered to overweight patients (BMI 25 – 29.9 kg/m^2) with one or more of the obesity-associated conditions that are directly influenced by weight loss (i.e., hypertension, type 2 diabetes, dyslipidemia, metabolic syndrome, obstructive sleep apnea) [B]; or with degenerative joint disease (DJD). [I]

Table 2: Obesity-Associated Chronic Health Conditions

The presence of any of the following conditions that are directly influenced by weight warrants weight loss therapy:

Hypertension
Type 2 Diabetes
Dyslipidemia
Metabolic Syndrome *
Obstructive Sleep Apnea
Degenerative Joint Disease (DJD)

* For a definition of Metabolic Syndrome, see Annotation L, Table 5.

DISCUSSION

There is strong evidence that all obese adults (BMI ≥ 30 kg/m^2) should receive weight loss treatment; however, the evidence base for the treatment of overweight (BMI 25 - 29.9 kg/m^2) is less clearly defined (National Task Force on the Prevention and Treatment of Obesity, 2000). The controversy stems from a growing body of evidence that indicates that a modest amount of excess body weight may not impair survival or quality of life (Arterburn et al., 2004b; Flegal et al., 2005; National Task Force on the Prevention and Treatment of Obesity, 2000). Among adults over 65 years of age, the evidence that overweight is an independent risk factor for mortality is particularly weak (Heiat, 2003; Heiat et al., 2001; Zamboni et al., 2005). Furthermore, no RCT of weight loss treatment have demonstrated a reduction in mortality in overweight adults (McTigue et al., 2003). Given this controversy, this guideline does not routinely recommend intensive weight loss treatment for overweight adults who are otherwise healthy. However, treatment is recommended for overweight adults who have weight-related health conditions for which there is at least grade B evidence that weight loss improves health outcomes. These conditions include hypertension, dyslipidemia, type 2 diabetes, metabolic syndrome, and obstructive sleep apnea.. Given the current state of the evidence, one can not exclude the possibility that weight loss may improve the health of all overweight adults; therefore, overweight individuals who request assistance with weight loss should also be offered weight loss treatment. (See Annotation L for a detailed discussion of the supporting evidence).

The Working Group did not find evidence that intensive therapy (i.e., drug therapy) for weight loss directly modifies other vascular conditions such as peripheral vascular disease, abdominal aortic aneurysm, or symptomatic carotid artery disease. Furthermore, no evidence exists to guide weight loss treatment among overweight adults with other major cardiovascular risk factors that are not directly modifiable by weight loss (i.e., male gender, early family history of CAD, advanced age, tobacco use). Some providers may deem it reasonable that the presence of these risk factors should warrant a more aggressive approach; however, based on current evidence, the Working Group cannot routinely recommend weight loss treatment for such patients.

EVIDENCE

	Recommendation	Sources of Evidence	QE	Overall Quality	SR
1.	Overweight adults (BMI between 25 and 29.9 kg/m^2) should be assessed for other risk factors to determine if they need treatment for overweight.	Heiat, 2003 Heiat et al., 2003 McTigue et al., 2003 NHLBI, 1998 Strawbridge et al., 2000 USPSTF, 2003 WHO, 2000	I	Fair	B
2.	Normal weight patients and overweight patients who do not have obesity-associated conditions should be educated to reinforce good lifestyle behaviors.	NHLBI, 1998 WHO, 2000	III	Poor	I

QE = Quality of Evidence; SR = Strength of Recommendation (see Appendix A)

E. Advise Patient to Maintain Weight and Prevent Weight Gain

OBJECTIVE

Promote healthy lifestyles in low-risk patients.

BACKGROUND

Overweight patients (BMI 25 - 29.9 kg/m^2) who do not have associated risk factors may benefit from brief education and advice on a healthy lifestyle with a goal of weight maintenance or mild weight loss. Additional help for weight control, including establishing reasonable goals, setting expectations, and providing a treatment plan may be offered to those patients who want help to lose weight.

RECOMMENDATIONS

1. Overweight patients (BMI 25 - 29.9 kg/m^2) who do not have associated risk factors should be offered brief advice, encouraged to maintain or lose weight, and offered assistance in establishing reasonable weight loss goals as well as diet and exercise plans if they seek help in losing weight. [I]
2. Overweight patients without obesity-associated conditions should be provided with education regarding healthy lifestyle behaviors, be advised of their BMI and their weight range margins and instructed to return for further evaluation should those margins be exceeded. BMI and risk factors should reassessed annually. [Expert Opinion]

DISCUSSION

Brief advice entails educating the patient on healthy lifestyle behaviors. This includes eating a diet balanced in fruits, vegetables, lean protein, whole grains, and low-fat dairy. In addition, moderate daily physical activity is encouraged for weight maintenance and/or mild weight loss.

There is no evidence that intervention may reduce mortality or morbidity of chronic disease in overweight patients without associated risk factors. However, adults who are overweight are at a higher risk for death than individuals with a normal weight (BMI < 25 kg/m^2) and may be at risk for

developing chronic conditions (e.g., hypertension, diabetes, dyslipidemia, cardiovascular disease). Furthermore, as body weight tends to increase with age, young adults who are overweight are at increased risk for gaining weight and becoming obese.

EVIDENCE

	Recommendation	Sources of Evidence	QE	Overall Quality	SR
1.	Brief advice for overweight adults (BMI 25 – 29.9 kg/m^2) without other associated risk factors assists in weight loss and/or weight maintenance.	Working Group Consensus	III	Poor	I

QE = Quality of Evidence; SR = Strength of Recommendation (see Appendix A)

F. Provide Brief Reinforcement and Lifestyle Education

OBJECTIVE

Promote healthy lifestyles for patients with normal weight.

BACKGROUND

Independent of weight or BMI, all adult patients should consistently receive counseling about healthful diet and physical activity in the context of primary care.

RECOMMENDATIONS

1. Patients of normal weight should be praised, encouraged to maintain their normal weight, and educated regarding a healthy lifestyle to include: [Expert Opinion]
    - A balance between caloric intake and energy expenditure
    - A healthy diet emphasizing, whenever possible, fresh fruits and vegetables (see – MyPyramid at http://www.mypyramid.gov)
    - Regular, moderately intense physical activity for more than 30 minutes, five or more days per week
    - Additional healthy lifestyle elements related to weight maintenance that may include tobacco use cessation, limited caffeine intake, sleep hygiene, and stress management

DISCUSSION

The benefits of reinforcing healthy weight messages include:

- Health promotion, primary prevention, and early detection through greater public awareness about healthy lifestyles
- Access to primary prevention programs, and reconsideration of the concept of the periodic medical checkup as an effective platform for prevention, early detection, and treatment
- Prevention of morbidity and premature mortality from overweight and obesity with associated diseases
- Prevention of human and economic costs of overweight and obesity with associated diseases

- Prevention of individual and collective risk of overweight and obesity with associated diseases

Weight loss is difficult to achieve and maintaining the weight loss is an even greater challenge. In several experimental studies, participants of a structured weight loss program regained all of their weight loss within five years. Dietary and physical activity modifications need to be integrated and accepted as a way of life (Anderson et al., 2001).

The identification of factors associated with weight loss maintenance can enhance our understanding of the behaviors and prerequisites that are crucial in sustaining a lowered body weight. The limited knowledge of behaviors that contribute to successful weight maintenance comes from reports of individuals who have lost significant weight and sustained the loss for several years. The diet and intake of selected nutrients of subjects, who had maintained a weight loss of at least 13.6 kg for at least 1 year, were compared with that of similarly aged men and women in the NHANES III cohort. Those original enrollees in the on-going National Weight Control Registry, who were able to maintain their weight reported consuming less energy and a lower percentage of energy from fat, increased levels of physical activity, and frequent weighing. Women in the registry reported eating an average of 1,306 kcal/day (24.3 percent of energy from fat); men reported consuming 1,685 kcal/day (23.5 percent of energy from fat) (Schick et al., 1998; Wing & Hill, 2001). These changes in lifestyle produced long-term weight loss maintenance; however, the minimally necessary behaviors have not been established in clinical trials. Weight loss maintenance may get easier over time. Once the weight loss is maintained for 2 to 5 years, the chances for longer term success greatly increase (Wing & Hill, 2001).

A review of the literature of factors associated with weight loss maintenance and weight regain suggests that successful weight maintenance is associated with more initial weight loss, reaching a self-determined goal weight, having a physically active lifestyle, and a regular meal rhythm including breakfast and healthier eating. In addition, these individuals exhibit control of over-eating and self-monitoring of behaviors. Weight maintenance is further associated with an internal motivation to lose weight, social support, better coping strategies and ability to handle life stress, self-efficacy, autonomy, assuming responsibility in life, and overall more psychological strength and stability. Factors that may pose a risk for weight regain include a history of weight cycling, disinhibited eating, binge eating, more hunger, eating in response to negative emotions and stress, and more passive reactions to problems (Elfhag et al., 2005).

G. Repeat Screening Annually

OBJECTIVE

Follow up patients with normal weight.

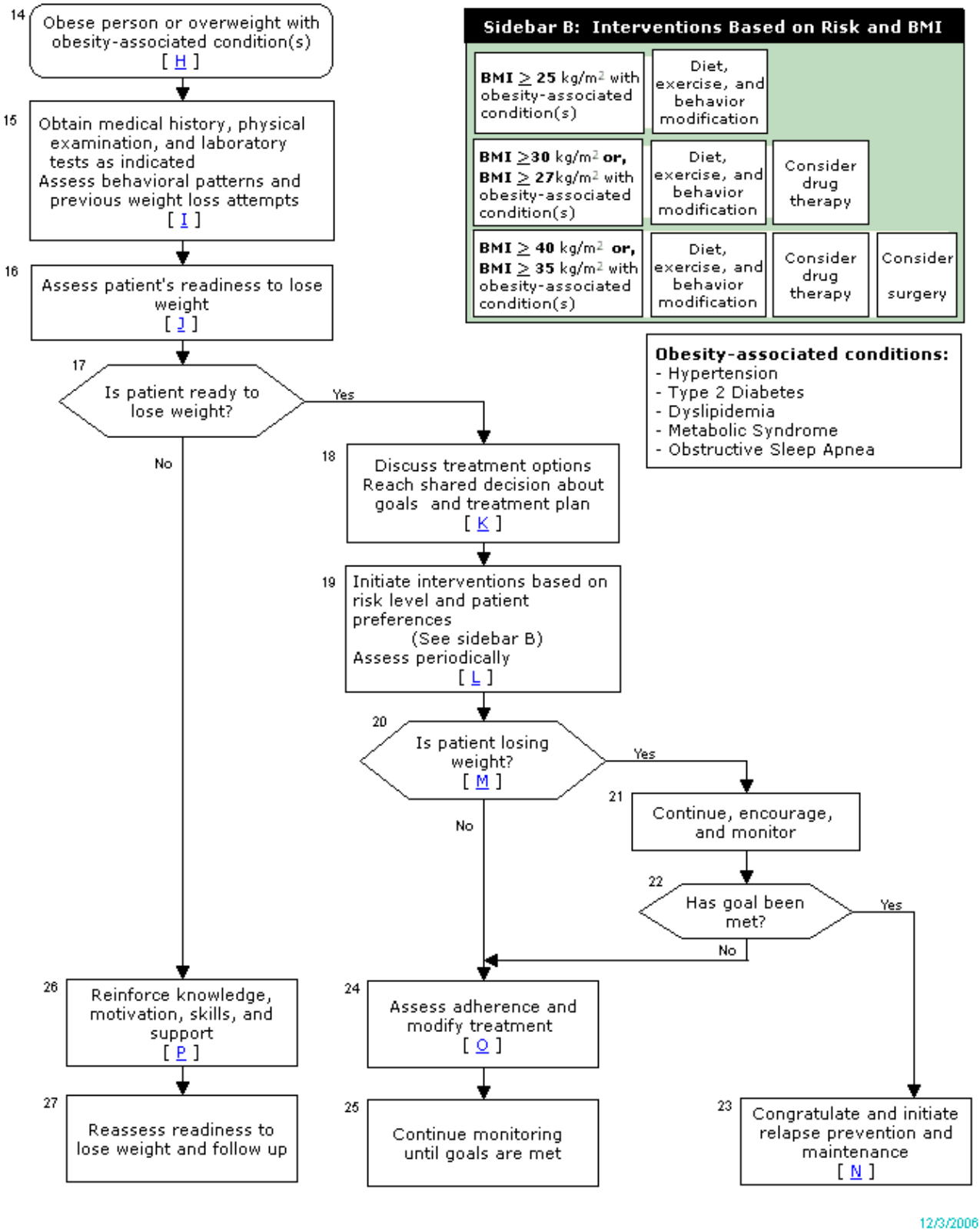
BACKGROUND

The optimal frequency for measuring height and weight in the clinical setting has not been evaluated and is a matter of clinical discretion.

RECOMMENDATION

1. Screening for overweight and obesity should be performed at least annually. [Expert Opinion]

Module B: Treatment for Weight Loss and Weight Maintenance



MODULE B

TREATMENT FOR WEIGHT LOSS AND WEIGHT MAINTENANCE

TABLE OF CONTENTS

ANNOTATIONS

ASSESSMENT

H. Obese Person or Overweight with Obesity-Associated Condition(s)

DEFINITION

Patients who are obese, and patients who are overweight or have an elevated waist circumference with one or more obesity-associated conditions should be offered treatment for the reduction of body weight.

DISCUSSION

The U.S. Preventive Services Task Force (USPSTF, 2003) concluded that "the most effective interventions combine nutrition education and diet and exercise counseling with behavioral strategies to help patients acquire the skills and supports needed to change eating patterns and to become physically active. The 5-A framework (Assess, Advise, Agree, Assist, and Arrange) has been used in behavioral counseling interventions such as tobacco use cessation and may be a useful tool to help providers guide interventions for weight loss. Initial weight loss interventions paired with maintenance interventions help ensure that weight loss will be sustained over time."

I. Obtain Medical History, Physical Examination, and Laboratory Tests as Indicated

OBJECTIVE

Identify medical disorders that may cause or complicate obesity.

BACKGROUND

A thorough clinical assessment is essential for making appropriate recommendations for intervention. Obesity is usually caused by energy intake (eating) that is greater than the amount of energy expended. Obesity can also be induced by health conditions or certain medications and therefore, it is important to identify all causes of obesity when evaluating the patient. Obesity itself may be complicated by various health conditions that result in early mortality. The initial assessment of weight-related risk provides an opportunity to raise the discussion with the patient regarding the benefits of weight loss and assess the patient's readiness to engage in treatment. Weight-related conditions should also be identified and treated based on the evaluation.

RECOMMENDATIONS

1. The clinical assessment of the overweight or obese patient should be done by the primary care provider. The assessment should include a basic medical history, a relevant physical examination, and laboratory tests as clinically indicated. The history should include age of onset or periods of rapid increase in body weight, precipitating factors, and maximum lifetime weight. [Expert Opinion]
2. The clinical assessment should rule out organic and drug related causes and identify health risks and/or the presence of weight-related conditions. [Expert Opinion]
3. In addition to a medical assessment, a social and psychological assessment may be indicated to identify barriers to participating in dietary or physical activity programs. The assessment may also include screening for behavioral health conditions that may hinder successful weight loss (i.e., depression, post-traumatic stress disorder, anxiety, bipolar disorder, addictions, binge eating disorder, bulimia, and alcoholism). [Expert Opinion]
4. A nutritional evaluation should include an assessment of current intake as well as the use of supplements, herbs, and over-the-counter weight loss aides. In addition, meal and snack

patterns and problem eating behaviors need to be assessed. The weight and dieting history should include the age of onset of weight gain, number and types of diets and attempts, possible triggers of weight gains and losses, and range of weight change. [Expert Opinion]

5. Current levels of physical activity and sedentary lifestyle should be assessed, including exercise frequency, duration, and intensity as well as the patient's motivation to increase physical activity. [Expert Opinion]

DISCUSSION

MEDICAL HISTORY

The health history identifies the patient's medical, social, and lifestyle factors. The information obtained may be useful in counseling the patient on healthy practices. Identification of specific lifestyle problems such as sedentary lifestyle and tobacco or alcohol use will facilitate a focused risk and health education intervention by the provider. Evaluation of social support systems allows insight into which therapies may be most appropriate for a given patient. Identification of an underlying psychiatric illness is important for recognition and treatment in the overall care of obese patients.

The assessment of the obese patient should also include a complete medication history to identify medications that may induce weight gain or interfere with weight loss. Weight gain does occur with most medications used in the treatment of diabetes. Weight gain is commonly associated with thiazolidinediones; however; they also improve insulin sensitivity and promote favorable redistribution of fat. Several drugs commonly used in treatment of psychosis, depression, and epilepsy can induce significant weight gain. This weight gain can negatively impact patient adherence to therapy and increase the risk of adverse health outcomes. (See Table 3)

The medical history should cover the following areas:

a. Detailed history of overweight/obesity and previous weight loss attempts to include age of onset or periods of rapid increase, precipitating factors, and maximum lifetime weight
b. Current motivation for, and barriers to, weight loss
c. Current and past medical history and psychiatric history
d. Current and past medical therapy including over-the-counter and prescribed medications
e. Alternative therapies including any herbs, vitamins, and nutritional supplements
f. Details on dietary habits, tobacco and alcohol use, sedentary lifestyle, and exercise
g. Family history of medical disease and obesity
h. Social history including support systems
i. Symptoms of sleep apnea
j. Pain history relevant to arthritis
k. Physical functioning
l. Dyspnea, chest pain, other signs/symptoms of CVD, and hypoventilation syndrome

PHYSICAL EXAMINATION

The evaluation of the overweight or obese patient should also include a complete physical examination to obtain baseline measurements and identify any medical conditions which may induce weight gain and require specific therapy. The following information should be obtained:

a. Height and weight
b. Calculated BMI
c. Measurement of waist circumference
d. Blood pressure
e. Focused examination for obesity related conditions (acanthosis, excess skin folds, stria, bruits, lower extremity edema, skin breakdown, skinfold infections, buffalo hump)

LABORATORY TESTS

Laboratory tests (if not already completed) should be obtained as clinically appropriate based on medical history and physical examination. These include, but not limited to:

a. Fasting lipid profile
b. Liver function tests (LFTs)
c. Fasting blood glucose

Table 3: Effect of Medications on Body Weight

Medication Classes	Marked Weight Gain	Moderate Weight Gain	Slight Weight Gain	No Weight Change
Antidepressants	Amitriptyline Clomipramine Doxepin Imipramine Maprotiline Nortriptyline Trimipramine	Desipramine Isocarboxazid Mirtazapine Paroxetin	Phenelzine	Citalopram Fluoxetine Fluvoxamine Nefazodone Protriptyline Sertraline Tranylcypromine Venlafaxine
Mood stabilizers/ anticonvulsants	Lithium Valproate	Carbamazepine	–	Gabapentine Lamotrigine
Antipsychotics	Chlorpromazine Clozapine Olanzapine Perphenazine Thioridazine Trifluoperazine	Aripiprazole Risperidone	Flupentixol Fluphenazine Haloperidol Molindone Pimozide	Quetiapine Ziprasidone
Antihistamines	Cyproheptadine	–	–	Inhalers, decongestants
Antihypertensives	Propranolol Terazosin	–	–	ACE Inhibitors Calcium channel blockers
Anti-diabetics	Insulin Sulfonylureas Thiazolidinediones	–	–	Acarbose Exesatide Metformin Pramlintide
Contraceptives	–	Depomedroxy progesterone acetate (DMPA)	–	Other contraceptives
Corticosteroids	Betamethasone Cortisone Dexamethasone Hydrocortisone Prednisone Prednisolone Triamcinolone	–	–	–

J. Assess Patient's Readiness to Lose Weight

OBJECTIVE

Identify the patient who is ready and willing to attempt weight loss.

BACKGROUND

Many patients do not feel ready to make a serious attempt to lose weight even though they have been told by their healthcare provider to do so for health reasons. In most cases, patients are unsuccessful if they are undecided about attempting weight loss. Many healthcare providers wrongly assume that patients will comply with their instructions regardless of the patient's readiness; many patients "agree" to attempt weight loss just to please the provider. Medical care providers often become frustrated when patients repeatedly fail to comply with weight loss programs and damage to the patient-provider relationship often results.

A patient-centered approach is preferable. This approach allows the healthcare providers to inquire about their patients' readiness to attempt weight loss in a non-judgmental fashion that implies a partnership. In this fashion, patients who do not feel ready may feel less threatened and may be more honest about their readiness. In such cases, motivational techniques may be utilized to move the behavior change process forward (See Annotation P – Reinforce Knowledge, Motivation, Skills, and Support and Appendix E: Behavioral Modification Strategies). For patients who do indicate readiness, providers should proceed with appropriate assistance.

RECOMMENDATIONS

1. Readiness to lose weight should be assessed by direct inquiry. Those indicating an adequate readiness to lose weight (preparation or action stage) should proceed to treatment. Those not yet ready to lose weight (precontemplation or contemplation stage) should receive motivational counseling. [Expert Opinion]

DISCUSSION

THEORETICAL APPROACH

A review of the patient's desire to lose weight, as well as an assessment of strengths and vulnerabilities, can lead to more effective strategies to address the identified barriers and serve to engender hope. The "Transtheoretical Model" of behavioral change is a useful approach to determine patients' readiness to change their health behavior (Prochaska & DiClemente, 1983; Prochaska et al., 1994). The model describes five stages of change, and a possible sixth, as follows:

1. Precontemplation – no intention to change
2. Contemplation – considering a change
3. Preparation – preparatory actions following the decision to change
4. Action – currently engaged in behavioral change activities
5. Maintenance – the continuation of a changed behavior beyond six months
6. Relapse – in cases where the individual in question reverts to the baseline behavioral pattern

TOOLS TO ASSESS READINESS

Specific assessment scales have been utilized to study the success of weight control programs and incorporate stages of the transtheoretical model and processes of change, decisional balance (the pros and cons of change), and self-efficacy (confidence in ability to change) (Rossi et al., 1995). The Stages

of Change Questionnaire (SCQ) was used in a 1992 study to link readiness to attendance at therapy sessions and weight loss. Patients who moved into the action stage by the fifth week of the program were more likely to attend therapy sessions and achieve greater weight loss (Prochaska et al., 1992). However, a 1999 study found no correlation between the initial scores on the SCQ and amount of weight lost. In addition, the initial stages of change score did not differentiate those patients who would and those who would not attend the second of two planned visits (4 to 6 weeks after the first appointment).

In 2002, Macqueen and colleagues studied patients who were referred for weight loss counseling. Patients who were sent a SCQ were more likely to attend their first appointment (Macqueen, 2002). Sutton and colleagues developed and tested a Multi-item SCQ that studied specific behaviors (e.g., readiness to drink skim milk vs. readiness to eat a low-fat diet) and linked them to readiness to change (Sutton et al., 2003).

Readiness may be assessed by providers through a simple series of questions about the patient's recent attempts to lose weight, the importance the patient places on losing weight, and their confidence in losing weight. Examples include:

> *"Are you currently working to lose weight? If so, for how long?"*
>
> *"On a scale from 1-10, with 10 being the most important, how important would you say losing weight is to you?"*
>
> *"On a scale from 1-10, with 10 being the most confident, how confident are you that you can actually lose weight?"*
>
> *"Tell me about what helped you be successful with weight loss in the past, and what led you to relapse back to your former habits and regain the weight".*

The answer to these questions can be categorized in terms of the various stages of change and subsequent actions. A low rating for the personal importance of losing weight may suggest a lack of genuine readiness. Similarly, a low rating on confidence may suggest either a lack of readiness, or if other data indicates genuine readiness, a need for an intensive treatment intervention inclusive of supportive action to build confidence. An inquiry about former successes and relapses may also contribute to the stage of change assessment and assist with treatment planning.

K. Reach Shared Decisions about Goals and Treatment Plan

OBJECTIVE

Incorporate patient preferences in the treatment goals and plan to optimize the patient's success in achieving and maintaining sustained weight loss.

BACKGROUND

The approach that will best serve a particular patient often depends critically on the patient's own preferences and values. Effective obesity treatment is reliant on good communication and mutual understanding between healthcare providers and patients. Providers can offer advice regarding medication use, diet, and exercise programs. Patients can communicate what they believe is possible for them to implement based on their past experiences. For weight loss to be achieved, patients need to demonstrate some willingness to modify their diet and implement an exercise plan, however, providers must make available a regimen that is individualized and realistic for any given patient. Thus, more so than for most disease processes, weight loss management plans must incorporate shared decision process between the patients and the providers caring for them.

RECOMMENDATIONS

1. The clinical team, together with the patient, should reach shared decisions regarding the treatment program. [Expert Opinion]
   - The clinical team should convey to the patient that obesity is a chronic disease that will require lifelong treatment
   - The clinical team should suggest the personalized preferred treatment options based on disease risk and patient characteristics (e.g., describe to the patient/caregiver the treatment options, including behavioral modification, diet and activity patterns, prognosis, estimated length and frequency of therapy, and expectations)
   - The patient should describe his or her needs, preferences, and resources and assist the team in determining the optimal environment for therapy and preferred interventions
   - The patient and the clinical team together should reach conclusions on the goals of therapy and preferred treatment plan
2. The patient's family/caregiver may participate in the treatment process and should be involved in assisting the patient with changing lifestyle, diet and physical activity patterns. [Expert Opinion]
3. Patient education should be provided in an interactive and written format. The patient should be given an information packet that includes printed material on subjects such as preferred foods to eat or foods to avoid, healthy lifestyle tips, support group information, and available audio/visual programs on weight loss. [Expert Opinion]
4. A detailed treatment plan needs to be documented in the medical record to provide integrated care. [Expert Opinion]

DISCUSSION

SHARED DECISION-MAKING

Shared decision-making between providers and patients is based on sound ethical principles. Some data are accruing about the effects of such approaches on health or other patient-based outcomes. These effects often vary substantially between studies (Edwards et al., 2004b). Enhancing patient involvement in decision-making will depend on developing both skills and attitudes of professionals.

GOALS OF THERAPY

Efffective long term weight loss involves behavioral change and the setting of goals is central to the process. The use of patient goals that transcend treating disciplines is a common method of creating consistency in the delivery of care. Joint participation in the setting of goals is a mechanism for active patient involvement and an effective approach for achieving patient “buy-in” to the weight loss program. Goal setting should use both short-term and long-term perspectives. Both short-term and longer term goals need to be realistic in terms of current levels and the potential for weight loss. Setting patient goals has multiple utilities. Goals should be realistic targets for use by the patient, family, and staff and can serve in the capacity of a "self-fulfilling prophecy." Well thought out goals can create an environment of treatment consistency among treating disciplines, serve as benchmarks for response, and provide a basis for follow-up.

TREATMENT PLAN

The clinical team presents the patient with information regarding the treatment and the alternatives available to achieve weight loss goals. Patients tend to respond better to treatments that are directed toward their personal needs. In determining these needs, it is essential to involve the patient as a partner to utilize a process that considers his or her values and goals, readiness for change, and personal and environmental resources. The treatment plan is determined on an individual basis for each patient,

taking into account the patient's goals and needs. The patient ultimately determines their treatment plan and establishes short-term and long-term goals.

TREATMENT FOR WEIGHT LOSS

L. Initiate Interventions Based on Risk Level and Patient Preferences

OBJECTIVE

Stratify patients according to risk and provide weight loss treatment accordingly.

BACKGROUND

There are several options to consider when selecting a weight loss treatment including diet, exercise, behavioral modification, potential drug therapy, and possible bariatric surgery. In general, the intervention should be tailored to the patient's risk level based on calculated BMI and the presence of obesity-associated health conditions (see Table 4). Regardless of the intervention identified, all patients should be advised about the potential risks and benefits of treatment, and their personal preferences should guide the choice of therapy.

All overweight and obese patients identified as needing weight loss should be enrolled in a program to improve their diet, exercise, and related behaviors to promote weight loss. A detailed discussion of the evidence for dietary, exercise, and behavioral interventions is included in Module C. Briefly, the evidence indicates that multimodal interventions that combine dietary therapy, increased physical activity, and behavioral modification strategies are more effective than those that include only one of these interventions. Diet and exercise should be designed to produce a negative energy balance such that daily caloric expenditure exceeds caloric intake. Once weight loss goals have been achieved, a dietary intake for weight maintenance should be prescribed in combination with physical activity and aimed at avoiding weight regain. Diet, exercise, and behavioral modification should also be part of every long-term weight maintenance plan.

Individuals with higher levels of BMI and those with obesity-associated health conditions can be considered candidates for more aggressive weight loss interventions, such as drugs and surgery, to reduce their body weight and improve their health outcomes. The NIH recommends including drug and surgical options in the treatment of obesity (NIH, 1998; NIH, 1992). The NIH recommends that drug therapy be considered for obese patients with a BMI $\geq$ 30 kg/m^2 and for overweight patients with a BMI $\geq$ 27 kg/m^2 who have obesity related health conditions. Similarly, the NIH recommended that surgical treatment be considered for severely obese patients with a BMI $\geq$ 40 kg/m^2 and those with a BMI $\geq$ 35 kg/m^2 who have obesity-associated health conditions. These treatment recommendations have been widely accepted by the clinical and research community, and most randomized trials of drug and surgical therapy have used these thresholds as participant inclusion and exclusion criteria (WHO, 2000). However, the definition of "obesity-associated health condition" has not yet been clearly and universally determined in the medical literature. Regarding drug and surgical treatment in this clinical practice guideline, "obesity-associated health condition" is defined as a chronic health condition for which there is at least grade B evidence that treatment will improve health outcomes. For example, among patients with type 2 diabetes and/or dyslipidemia, at least fair evidence suggests that drug and surgical therapy improved glycemic control and lipid levels, and that the benefits of treatment outweigh the harms. The list of obesity-associated chronic health conditions that warrant the use of drug and surgical treatment appears in Table 4. A detailed discussion of the evidence behind these recommendations can be found in the Discussion section.

RECOMMENDATIONS

1. Weight loss therapy should be tailored to risk level based on calculated BMI and based upon the balance of benefits and risks and patient preferences. [C]
2. Patients who may benefit from weight loss should be offered interventions to improve their diet, increase exercise, and change related behaviors to promote weight loss. [A]
3. Weight loss interventions should combine dietary therapy, increased physical activity, and behavioral modification strategies rather than utilizing one intervention alone. [A]
4. A reasonable initial goal of weight loss therapy (intervention) is a 10 percent reduction in body weight. [B]
5. Drug therapy in combination with a reduced-calorie diet and exercise interventions should be considered for obese patients (BMI $\geq$ 30 kg/m^2) or overweight patients (BMI $\geq$ 27 kg/m^2) with an obesity-associated chronic health condition (i.e., hypertension, type 2 diabetes, dyslipidemia, metabolic syndrome, and sleep apnea). [B]
6. Bariatric surgery to reduce body weight, improve obesity-associated comorbidities, and improve quality of life may be considered in adult patients with a BMI $\geq$ 40 kg/m^2 and those with a BMI $\geq$ 35 kg/m^2 with at least one obesity-associated chronic health condition (i.e., hypertension, type 2 diabetes, dyslipidemia, metabolic syndrome, and sleep apnea). [B]
7. There is insufficient evidence to recommend drug or surgical interventions specifically for patients who have documented coronary artery disease (CAD). [I]
   However, there is good evidence that drug and surgical weight loss interventions may improve cardiovascular risk factors, such as hypertension, dyslipidemia, and diabetes mellitus. [A]
8. There is insufficient evidence to recommend drug or surgical interventions specifically for patients who have degenerative joint disease (DJD). However, physical activity and diet may improve physical function and chronic pain in patients with DJD. [I]

Table 4: Indications for More Intensive Weight Loss Therapy

The presence of the following conditions, directly influenced by weight loss, warrants consideration of more intensive therapy with drugs or surgery:

Hypertension
Type 2 Diabetes
Dyslipidemia
Metabolic Syndrome
Obstructive Sleep Apnea

DISCUSSION

BASELINE DIETARY INTAKE

To determine estimated baseline caloric intake, it is recommended that providers evaluate current dietary practices using a food frequency questionnaire or food recall to include common food choices, portion sizes, and cooking techniques. This information identifies dietary practices needing focus and improvement. After reviewing the patient's usual food intakes, the provider and patient can determine which excesses should be reduced or eliminated to create the recommended caloric deficit. In order to provide patients with the necessary knowledge and strategies to lose weight through dietary modification, providers should educate patients regarding the energy values of foods, evaluation of food

labels, healthy food preparation techniques, and portion control. Providers may consider using Food Exchange Lists for calorie and nutrient composition of common foods (see Appendix C for handouts).

GOALS OF WEIGHT LOSS

A single best strategy for weight loss or maintenance has yet to be defined. Available evidence favors a combination of prudent diet and physical activity, with the application of supportive behavioral modification methods. Treatment goals should focus on long-term outcomes rather than short-term weight loss. As is true of most chronic conditions, obesity appears to require long-term therapy and management.

Modifications in diet are essential to create a negative energy balance to treat and manage overweight and obesity. Any weight loss plan should initially include discussion and agreement between patient and provider as to the appropriate amount of weight loss needed, as well as the time frame in which it should be achieved. NHLBI guidelines recommend diet therapy to promote weight loss of 1 to 2 pounds per week (NHLBI, 1998). Weight loss of 5 to 10 percent body weight in obese patients can significantly reduce the risk and severity of weight-related comorbid conditions (NHLBI, 1998; Pi-Sunyer, 1996). Providers should individualize overweight/obesity treatment goals giving careful consideration to the needs and values of each patient, baseline weight and risk, and the presence and/or severity of weight-related disease. Once the initial weight loss is achieved, further weight loss can be attempted, if indicated, through further assessment.

There are limitations to relying on weight loss alone as an outcome, especially in patients who are extremely obese. First, short-term weight loss may be misleading as an outcome because of the tendency to regain weight over longer periods of time. Second, the potential benefits of weight loss depend on the initial weight and the degree of pre-existing weight-related morbidity. As the amount of excess weight increases, the amount of weight loss required to achieve a health benefit will also likely increase. Extremely obese patients, who have greater amounts of excess weight to begin with, may lose a large amount of weight in absolute terms yet still remain obese or overweight and in a very high-risk category.

For a discussion of weight loss intervention therapies, see Module C: Interventions for Weight Loss.

OBESITY-ASSOCIATED CHRONIC CONDITIONS - INDICATIONS FOR MORE INTENSIVE WEIGHT LOSS THERAPY

There is at least grade B evidence that the obesity-associated chronic health conditions described in Table 4 are improved by weight loss, and individuals with these conditions may warrant more intensive therapy including the use of drugs or surgery. While there are other conditions that could theoretically benefit from weight loss (i.e., degenerative joint disease), there is not currently enough evidence to make a recommendation for weight loss drugs and surgery in patients with these conditions. The following discussion provides evidence to consider when advising patients about the drug and surgical weight loss options; however, even within these conditions, there is a large degree of variability in the quality of the evidence.

HYPERTENSION

Weight loss improves blood pressure in overweight and obese patients with hypertension (Appel et al., 2003; NIH, 1998). A systematic review that evaluated the long-term effects of weight loss on hypertension outcome measures in adults, included RCT studies performed on participants with a BMI ≥ 28 kg/m^2 with a follow-up of >2 years (Aucott et al., 2005). Previous reviews on shorter term studies indicate a drop in blood pressure of 1 mmHg for every 1 kg of weight loss. (Neter et al., 2003) The findings of the review suggested that for 10 kg of weight loss, decreases of 4.6 mmHg in diastolic, and 6 mmHg in systolic blood pressure may be expected. The model excluded studies with surgical interventions that exhibited huge weight losses with dramatic blood pressure changes.

Sufficient evidence exists to recommend treatment with orlistat and bariatric surgery to achieve improvement in blood pressure (Buchwald et al.,2004; Sharma & Golay, 2002; Sjostrom et al., 2004). However, weight loss with sibutramine has been associated with increases in blood pressure in many patients (Arterburn et al., 2004a).

Weight loss induced by orlistat is effective in treating hypertension in overweight and obese patients. A meta-analysis of 5 RCTs revealed that after one year of treatment, average systolic and diastolic blood pressure reductions were significantly greater with orlistat than placebo (-9.4 versus –4.6 mmHg systolic and -7.7 versus –5.6 mmHg diastolic) (Sharma & Golay, 2002).

The effect of sibutramine on the blood pressure of overweight and obese patients with and without hypertension is highly varied (Arterburn et al., 2004a). Many patients do experience significant increases in their systolic and diastolic blood pressure readings (up to 5 mmHg higher on sibutramine 10-15 mg daily). Sibutramine is contraindicated in patients with uncontrolled hypertension, and close monitoring of blood pressure is required among patients with controlled hypertension.

Bariatric surgery in obese patients has the most dramatic effect on blood pressure reduction after weight loss. In a meta-analysis of mostly non-RCTs or uncontrolled case series, hypertension resolved in 61.7 percent and resolved or improved in 78.5 percent of study subjects (Buchwald et al., 2004). In the Swedish Obese Subjects (SOS) study, patients experienced a 4 to 5 mmHg reduction in blood pressure at two years post surgery. At 10 years, the impact of bariatric surgery on blood pressure differed according to the type of procedure performed; gastric bypass patients had the largest reductions in blood pressure of 5 to 10 mmHg, while gastric banding patients experienced a 2 mmHg increase in systolic blood pressure and only a 1 mmHg reduction in diastolic blood pressure (Sjostrom et al., 2004).

EVIDENCE

	Recommendation	Sources of Evidence	QE	Overall Quality	SR
1.	Weight loss with diet, exercise, and behavioral modification is recommended for patients with a BMI ≥25 kg/m^2 and hypertension.	NHLBI, 1998 PREMIER, 2003	I	Good	A
2.	Orlistat is associated with lowering blood pressure as a secondary effect of weight loss in patients with a BMI ≥ 27 kg/m^2 and hypertension.	Sharma & Golay, 2002	I	Good	B
3.	Bariatric surgery is effective in lowering blood pressure in patients with a BMI ≥ 35 kg/m^2 and hypertension.	Buchwald et al., 2004 Sjostrom et al., 2004	I	Fair	B
4.	Sibutramine has been shown to raise blood pressure in patients with a BMI ≥ 27 kg/m^2.	Arterburn, 2004	I	Good	D

QE = Quality of Evidence; SR = Strength of Recommendation (see Appendix A)

TYPE 2 DIABETES AND IMPAIRED GLUCOSE TOLERANCE

Weight loss, whether by diet, exercise, behavioral modification, pharmacotherapy, or bariatric surgery, has been well documented to improve glycemic control in type 2 diabetes. During the Finnish Diabetes Prevention Study, the risk of diabetes was reduced by 58 percent (P<0.001) in subjects of the

intervention group who received individualized counseling aimed at reducing weight, total intake of fat, and intake of saturated fat and increasing intake of fiber and physical activity. The reduction in the incidence of diabetes was directly associated with changes in lifestyle. The cumulative incidence of diabetes after four years was 11 percent (95% CI: 6 to 15 percent) in the intervention group and 23 percent (95 % CI:17 to 29 percent) in the control group. (Tuomilehto et al., 2001)

Use of Pharmacotherapy for Weight Control and Type 2 Diabetes

The effect of weight loss on glycemic control in subjects with type 2 diabetes has been extensively evaluated in RCTs of sibutramine and orlistat; however, neither of these drugs is specifically approved for the treatment of hyperglycemia.

A number of RCTs have evaluated the effect of orlistat on glycemic control in patients with type 2 diabetes (Didangelos et al., 2004; Hanefeld & Sachse, 2002; Kelley et al., 2002; Miles et al., 2002). In the largest and longest duration orlistat study to date, 3,305 non-diabetic obese adults with normal or impaired glucose tolerance received orlistat 120 mg TID plus lifestyle changes or lifestyle changes alone for four years (Torgerson et al., 2004). At the end of the study, the cumulative incidence of diabetes was 9 percent with lifestyle changes alone and 6.2 percent with orlistat plus lifestyle changes, corresponding to a 37.3 percent relative risk (RR) reduction and a number needed to treat of 35 ($P = 0.003$). Differences in diabetes incidence was detectable in the impaired glucose tolerance subgroup. The mean weight loss after 4 years was significantly greater with orlistat (5.8 vs. 3 kg with placebo; $P < 0.001$) (Torgerson et al., 2004). Furthermore, weight loss with orlistat 120 mg TID improved fasting glucose and HbA1c in adults with type 2 diabetes and other components of the metabolic syndrome (Didangelos et al., 2004; Hanefeld & Sachse, 2002; Kelley et al., 2002; Miles et al., 2002).

Sibutramine 10 to 15 mg taken daily has also been shown to improve fasting glucose and HbA1c (McNulty et al., 2003; Redmon et al., 2003; Sanchez-Reyes et al., 2004).

Use of Bariatric Surgery and Type 2 Diabetes

A main limitation in evaluating the impact of bariatric surgery on type 2 diabetes is the lack of RCTs. However, numerous retrospective reviews and studies have demonstrated both short- and long-term improvement in glycemic control in subjects with type 2 diabetes who undergo bariatric surgery for weight loss. The largest prospective study evaluating the long-term impact of bariatric surgery on type 2 diabetes is the Swedish Obese Subjects (SOS) study (Sjostrom et al., 2004). In this prospective controlled trial, obese subjects who underwent gastric surgery for weight loss were matched with conventionally treated obese control subjects. The 4,047 subjects were followed for at least 2 years and 1,703 subjects were followed for 10 years. The subjects in the surgical intervention group had a BMI of 34 or more (men) or 38 or more (women) and were between ages 37 to 60 years. At both the two and 10-year follow-up, the surgical intervention group had a significantly greater weight loss. In addition, the incidence rate of diabetes was markedly lower in the surgically treated group compared to the control group after 2 and 10 years (Sjostrom et al., 2004).

Another systematic review and meta-analysis was performed on bariatric surgery and its impact on health outcomes (Buchwald et al., 2004). From the 708 studies included for evaluation, the mean age was 38.97 years (16.20 – 63.60) with a mean BMI of 46.85 kg/m^2 (range 32.30 –68.80 kg/m^2). In this meta-analysis, bariatric surgery resulted in the ability to discontinue all diabetes related medications and maintenance of normal blood glucose levels in 76.8 percent of all patients. Additionally, 86 percent of patients were found to have resolution or improvement of their diabetes. While a meta-analysis is limited by variable lengths of follow-up in the different studies and by different study designs, it is generally accepted that patients with type 2 diabetes have improvement in glycemic control following bariatric surgery for weight loss. This improvement in glycemic control is usually maintained long-term and is more likely in patients who are not insulin requiring at the time of surgery and in patients who have had diabetes for a fewer number of years.

EVIDENCE

	Recommendation	Sources of Evidence	QE	Overall Quality	SR
1.	Weight loss with diet, exercise, and behavioral modification is recommended in patients with a BMI $\geq$ 25 kg/m^2 and diabetes.	Tuomilehto et al., 2001 The Diabetes Prevention Program, 2002	I	Good	A
2.	Orlistat and sibutramine modestly improve glycemic control in patients with a BMI $\geq$ 27 kg/m^2 and type 2 diabetes.	Didangelos et al., 2004 Hanefeld & Sachse, 2002 Kelley et al., 2002 Miles et al., 2002 Torgerson et al., 2004	I	Fair	B
3.	Bariatric surgery improves glycemic control or resolves diabetes in patients with a BMI $\geq$ 35 kg/m^2.	Buchwald et al., 2004	I	Good	B

QE = Quality of Evidence; SR = Strength of Recommendation (see Appendix A)

DYSLIPIDEMIA

There is ample evidence that weight loss should be recommended for overweight and obese patients whose lipids are not at goal levels (NCEP ATP-III, 2002). Current evidence is mostly based on short-term studies. A systematic review of the long-term lipid outcomes of weight loss in studies published between 1966 and 2001 was conducted by Poobalan and colleagues (2004). Thirteen long-term studies on participants with a BMI of greater than or equal to 28 kg/m^2 with a follow-up of more than 2 years were included. Cholesterol had a significant positive linear relationship with weight change (r = 0.89) where change in weight explained about 80 percent of the cholesterol difference variation. For every 10 kg weight loss, a drop of 0.23 mmol L(-1) in cholesterol may be expected for a person who is obese or overweight.

In overweight and obese patients, orlistat and sibutramine have been shown to have a positive effect on dyslipidemia. Micic and colleagues (1999) did a placebo-controlled, multicenter trial with 119 patients with a BMI greater than 30 kg/m^2 who received orlistat or placebo. All lipid parameters were improved in the orlistat group. Lucas and colleagues (2003) showed that plasma cholesterol and low-density lipoprotein cholesterol (LDL-C) were significantly reduced in obese patients treated with orlistat. Dujovne et al.,(2001) studied the effects of sibutramine on body weight and serum lipids in a randomized trial of 322 patients with a BMI greater than or equal to 27 kg/m^2. The study showed a statistically significant decrease in triglycerides in those who lost weight while taking sibutramine.

Seventeen studies including 10,041 patients compared use of orlistat (3 x 120 mg/day) with placebo or an inactive control along with a hypocaloric diet over a one-year period. Relative risks (RRs) associated with clinically significant weight losses of 5 percent and 10 percent were 1.74 (95% CI: 1.57, 1.91) and 1.96 (1.74, 2.21), both favoring orlistat. Improvement in total cholesterol, LDL-C, high density lipoprotein cholesterol (HDL-C), and LDL:HDL were also greater with orlistat. Hutton & Fergusson (2004) concluded that orlistat is effective for improving both weight loss and serum lipid profiles in obese patients at low and high CVD risk and in obese patients with type 2 diabetes.

Orlistat has a beneficial effect on serum cholesterol concentration that is independent of weight loss alone. The decrease in serum LDL-C concentrations after weight loss with orlistat therapy is greater than after placebo therapy, even after adjusting for percentage of weight loss. The mechanism

responsible for this additional lipid lowering effect may be related to orlistat's effect in blocking both dietary cholesterol and triglyceride absorption (Davidson, 1999; Klein, 2004; Sjostrom, 1998).

Hypertriglyceridemia is improved with bariatric surgery (Buchwald et al., 2004; Sjostrom et al., 2004). In the SOS study the incidence of hypercholesterolemia did not differ between the control and surgery groups, but the incidence of hypertriglyceridemia was significantly decreased at 2 and 10 years in the surgery group (Sjostrom et al., 2004).

EVIDENCE

	Recommendation	Sources of Evidence	QE	Overall Quality	SR
1.	Weight loss is recommended in all patients with a BMI ≥ 25 kg/m^2 with dyslipidemia.	NCEP ATP-III, 2002 NHLBI, 1998	I	Good	A
2.	Orlistat and sibutramine improve lipid levels in patients with a BMI ≥ 27 kg/m^2 with dyslipidemia.	Dujovan et al., 2001 Hutton & Fergusson, 2004 Klein, 2004 Lucas et al., 2003 Micic et al., 1999	I	Good	B
3.	Bariatric surgery improves triglycerides in patients with a BMI ≥ 35 and dyslipidemia.	Buchwald et al., 2004 Sjostrom et al., 2004	I	Good	B

QE = Quality of Evidence; SR = Strength of Recommendation (see Appendix A)

METABOLIC SYNDROME

Metabolic syndrome is characterized by the presence of multiple interrelated risk factors for CHD. Most patients with metabolic syndrome are overweight or obese. The metabolic syndrome is identified by the presence of three or more of the components listed in Table 5.

Table 5: Diagnosis of Metabolic Syndrome ***[NCEP ATP-III, 2002]***

Three or more of the following risk factors indicate metabolic syndrome:	Defining Level
Abdominal Obesity:	Waist Circumference (WC):
Men†	Greater than 102 cm (>40 in)
Women	Greater than 88 cm (>35 in)
Triglycerides	Greater than or equal to 150 mg/dL
HDL cholesterol:	
Men	Less than 40 mg/dL
Women	Less than 50 mg/dL
Blood pressure	Greater than or equal to 130/85 mmHg
Fasting glucose	Greater than or equal to 110 mg/dL

† Some men can develop multiple metabolic risk factors when the WC is only marginally increased, e.g., 37–39 inches (94–102 cm). Such persons may have a strong genetic contribution to insulin resistance. They should benefit from changes in life habits, similarly to men with categorical increases in WC.

Clinical trials show that modifying three major components of the metabolic syndrome—atherogenic dyslipidemia, hypertension, and the prothrombotic state — will reduce the risk for CHD (NCEP ATP-III, 2002).

To achieve maximal benefit from the modification of multiple metabolic risk factors, the underlying insulin resistant state must become a target of therapy. The safest, most effective, and preferred means to reduce insulin resistance is weight reduction in overweight and obese persons and increased physical activity.

One RCT evaluated the effect of orlistat on the metabolic syndrome in overweight and obese patients. In this study, orlistat plus a hypocaloric diet was more effective than a hypocaloric diet alone in reducing body weight, WC, fasting glucose, HbA1c, and blood pressure (Didangelos et al., 2004).

No RCTs were identified that specifically examined the impact of sibutramine or bariatric surgery on the metabolic syndrome; however, there is evidence that bariatric surgery improves glycemic control, hypertension and triglycerides – three components of the metabolic syndrome. Sibutramine improves glycemic control and triglycerides (Buchwald et al., 2004; McNulty et al., 2000).

EVIDENCE

	Recommendation	Sources of Evidence	QE	Overall Quality	SR
1.	Weight loss is recommended in all patients with a BMI $\geq$ 25 kg/m^2 with metabolic syndrome.	NCEP ATP-III, 2002 NHLBI, 1998	I	Good	A
2.	Orlistat improves the components of the metabolic syndrome in patients with a BMI $\geq$ 27 kg/m^2.	Didangelos et al., 2004 Lindgarde, 2000	I	Fair	B

QE = Quality of Evidence; SR = Strength of Recommendation (see Appendix A)

SLEEP APNEA

There is sufficient evidence to recommend weight loss to improve sleep apnea among overweight and obese patients. In epidemiological studies, excess weight is strongly associated with the presence of sleep apnea (Carmelli et al., 2000). Several small, generally non-randomized studies show a benefit from lifestyle alteration for weight loss, even among mild to moderately obese patients, as a means of improving sleep apnea (Kansanen et al., 1998; Smith et al.,1985; Suratt et al., 1992). Sustainability of improvement is not universally seen after weight loss associated with dietary change, and the explanation for that observation is not known (Sampol et al., 1998).

There are no trials of weight loss aided by sibutramine or orlistat specifically for the management of sleep apnea associated with excess weight.

Larger weight loss achieved through bariatric surgery among patients whose BMI is greater than 35 kg/m^2 (Dixon et al., 2001; O'Brien et al., 2002), and particularly for those with BMI greater than 40 kg/m^2 (Brolin et al., 2001; Papasavas et al., 2004; Rasheid et al., 2003), has stronger data supporting effectiveness. These studies are small controlled trials or observational in design, but two meta-analyses have concluded that the available evidence supports improvement in sleep apnea by bariatric surgery (Buchwald et al., 2004; Maggard et al., 2005). The available evidence typically does not allow for separate analysis of patient response for those with BMI between 35 and 40 kg/m^2. The Swedish Obese Subjects (SOS) study showed a benefit of apnea status, after two years follow-up, when patients with a BMI greater than 34 kg/m^2 who lost weight through bariatric surgery were compared to a matched control group (Karason et al., 2000).

EVIDENCE

	Recommendation	Sources of Evidence	QE	Overall Quality	SR
1.	Weight loss is recommended in patients with a BMI $\geq$ 25 kg/m^2 with sleep apnea.	Carmelli et al., 2000 Kansanen et al., 1998 Smith et al., 1985 Suratt et al., 1992	II-3	Fair	B
2.	The use of orlistat and sibutramine has not been adequately studied in obese or overweight patients with sleep apnea.	N/A	N/A	N/A	I
3.	Bariatric surgery is recommended in morbidly obese patients with sleep apnea.	Buchwald et al., 2004 Brolin et al., 1992 Dixon et al., 2001 Karason et al., 2000 Maggard et al., 2005 O'Brien et al.,2002	II – 2	Good	B

QE = Quality of Evidence; SR = Strength of Recommendation (see Appendix A);
N/A = Not Applicable

DEGENERATIVE JOINT DISEASE (DJD)

Overweight and obese patients suffering from degenerative joint disease (DJD) of the back or lower extremities, especially the knees, may benefit from weight loss, but clinical evidence supporting this

view is insufficient to support a recommendation. The Working Group did not find sufficient eveidence to include DJD as a condition that warrants a more intensive weight loss intervention.

Very strong epidemiological associations are found between excess weight and the presence of lower body DJD. In the Framingham observational study, patients who lost weight had a better DJD outcome than those who did not (Felson et al., 1992). Two randomized trials comparing weight loss, fitness training, and the combination of the two to usual care found that combined weight loss and training program provided the best outcome (Messier et al., 2004; Rejeski et al., 2002). In a third, small RCT, Christensen and colleagues found that self-reported symptoms in women with knee osteoarthritis had significantly improved as a result of a decrease in body weight. Improvement was best predicted by the percentage of body fat loss. (Christensen et al., 2005).

There are no specific trials of weight loss for the treatment of lower body DJD that have employed sibutramine, orlistat, or bariatric surgery. There is no reason to suppose that expected clinical improvement would be different than that seen with lifestyle changes alone.

EVIDENCE

	Recommendation	Sources of Evidence	QE	Overall Quality	SR
1.	Weight loss is recommended in all obese or overweight patients with lower extremity DJD.	Christensen et al., 2005 Felson et al., 1992 Messier et al., 2004 Rejeski et al., 2002	I	Poor	C

QE = Quality of Evidence; SR = Strength of Recommendation (see Appendix A)

WEIGHT MAINTENANCE AND FOLLOW-UP

M. Is Patient Losing Weight?

OBJECTIVE

Assess response to therapy and progress toward weight loss goals.

BACKGROUND

Initial non-pharmacologic interventions include diet, behavioral interventions, and increased physical activity. A reasonable weight loss as a percentage of a patient's initial body weight (e.g., 5 to 10 percent) may have health benefits that may be reasonably achieved with a consistent weight loss of 1 to 2 pounds per week. The average patient achieves most of their weight loss within 6 months. The amount of weight loss will depend on the extent daily calorie intake was reduced and physical activity increased. Weight loss greater than 2 pounds per week is typically not sustainable and likely to result in weight regain in the long run. Patients should have their treatment plan and adherence reviewed regularly.

RECOMMENDATIONS

1. Patients on diet, exercise, and behavioral therapy who have lost on average 1 to 2 pounds per week should continue with their current treatment until their weight loss goal is achieved. [B]
2. Patients who have lost on average less than 1 pound per week should have their adherence to therapy assessed and treatment plan reevaluated. [I]

3. Obese patients with a BMI ≥ 30 kg/m^2 , and overweight patients with a BMI ≥ 27 kg/m^2 and obesity-associated chronic health conditions who fail to achieve adequate weight loss through non-pharmacologic interventions may be candidates for pharmacotherapy with orlistat or sibutramine. [B] (See Module C, Section C-4 Pharmacotherapy.)

DISCUSSION

Patients who fail to achieve adequate weight loss through non-pharmacologic interventions may be candidates for pharmacotherapy with orlistat or sibutramine. Not every patient responds to drug therapy. An initial trial period of several weeks with a given drug may help determine the efficacy of the intervention in a given patient. Orlistat should be considered before sibutramine, given the potentially serious adverse effects associated with sibutramine. If a patient does not respond to a drug with reasonable weight loss, adherence to the medication regimen and adjunctive therapies should be reevaluated or an adjustment of dosage may be considered. If the patient continues to be unresponsive to the medication, or serious adverse effects occur, the use of medication should be discontinued.

Note: In research protocols, pharmacotherapy is added to the treatment early to demonstrate weight loss compared to a placebo. Introduction of drugs this early in treatment is not suggested in clinical practice. Hence, the initial weight loss experienced after starting pharmacotherapy may be less than expected.

EVIDENCE

	Recommendation	Sources of Evidence	QE	Overall Quality	SR
1.	An energy deficit of 500 – 1,000 calories can lead to weight loss of 1 to 2 pounds per week.	Institute for Clinical Systems Improvement (ICSI), 2004 NHLBI, 1998	I	Good	B
2.	A reasonable time to achieve a 10% reduction in body weight is 6 months of therapy.	NHLBI, 1998	I	Good	B
3.	Patients who have lost on average 1 pound or more per week should continue with their current treatment.	NHLBI, 1998	II	Fair	B
4.	Use of medications for maintenance.	See Module C, Section C-4: Pharmacotherapy			

QE = Quality of Evidence; SR = Strength of Recommendation (see Appendix A)

N. Congratulate and Initiate Relapse Prevention/Maintenance

OBJECTIVE

Continue the necessary interventions to maintain the weight loss and prevent weight gain.

BACKGROUND

Successful weight maintenance is defined as a weight regain of less than 3 kg (6.6 lb) in 2 years and a sustained reduction in WC of at least 4 cm (NHLBI, 1998). The ideal weight loss maintenance program has not been identified. Some studies suggest that focus on active problem solving efforts by the provider to help the obese patients make maintenance lifestyle changes is more effective than either no follow-up or a standard relapse prevention program.

RECOMMENDATIONS

1. Patients who have met their weight loss goals or have stopped losing weight and are ready to sustain current weight loss should be offered a maintenance program consisting of diet, physical activity, and behavioral support. Weight status should be reevaluated and diet and physical activity should be adjusted so that energy balance is maintained (energy intake is equal to energy expenditure). [B]
2. Providers should continue to maintain contact with patients providing on-going support, encouragement, and close monitoring during the maintenance phase of weight loss to prevent weight regain. [B]
3. Patients who achieve their weight loss goal with a combination of medication, diet, and exercise may be considered candidates to include their medication as a component of their weight maintenance program with continued monitoring of effectiveness and adverse effects. [B] (See Module C, Section C-4 Pharmacotherapy recommendations.)
4. Lifelong follow-up after bariatric surgery is necessary to monitor adherence to treatment, adverse effects and complications, dietary restrictions, and behavioral health. [I]
5. There is no established optimum visit length or duration between maintenance visits, but it seems reasonable to establish a minimum of quarterly follow-up (every three months) for the sustainment of weight loss and more frequently if the patient requests it. [I]

DISCUSSION

Patients who achieve their initial weight loss goals may benefit from additional weight loss to further reduce their risk/severity of weight-related disease. In a comprehensive review of the non-surgical treatments of obesity, the Institute of Medicine (IOM) concluded however, that the majority of those who have successfully attained their initial weight loss goals have been unable to maintain their reduced body weight, regaining nearly two-thirds of it within 5 years (Thomas, 1995). This may be multifactorial and due to decreases in metabolic rate and/or a return to negative lifestyle habits. Weight regain, however, may make it unlikely that the benefits of that initial weight loss will have a lasting impact on weight-related comorbidities (Dekker, 2004).

The effort required to adhere to restrictive diet and increased physical activity over an extensive time period makes it difficult for most patients to continue to lose weight after an initial period of 6 months (NHLBI, 1998). Weight loss often plateaus after 6 months, despite great efforts, causing frustration and limiting patient motivation to continue practicing positive lifestyle behaviors (NHLBI, 1998). If this occurs, the health impact of maintaining the initial weight loss should be positively reinforced. Patients who plateau at this point may be focused on maintaining their initial weight loss for up to 6 months before attempting further weight loss (NHLBI, 1998). Other patients who are continuing to lose weight and who need to lose more weight to achieve a normal BMI should be encouraged to continue successful strategies.

Maintaining an energy balance is required to maintain a lower body weight. To prevent weight regain, patients should be encouraged to maintain their positive lifestyle changes. In 1999, a study and analysis by Tremblay et al. found that, in adults, a combination of diet and physical activity in conjunction with behavioral counseling is probably more effective in sustaining weight loss than diet and exercise alone. The type of activity does not seem important. Maintenance strategies should include continued support, for example self-help peer groups, relapse prevention strategies, and continued therapist contact (by either face-to-face individual or group sessions, phone, mail, and/or Internet).

Physical activity is probably the most important predictor of long-term maintenance and the amount of physical activity needed is likely to be higher after weight loss than for preventing obesity. (see Module C, Section C-2: Physical Activity).

Baum et al. (1991) compared the relative effectiveness of a therapist supported maintenance with a minimal contact maintenance in preventing relapse following an obesity treatment program. Thirty-two

subjects who completed an initial 12-week cognitive/behavioral plus aerobic exercise treatment program were matched on absolute weight loss and randomly assigned to one of two maintenance groups. Subjects were assessed at pretreatment, post-treatment, and 3-, 6-, and 12-months following post-treatment using measures of weight, blood pressure, and depression. Three- and six-months follow-up results indicated that subjects who participated in the therapist supported maintenance group continued to lose weight and/or maintained therapy induced weight loss to a greater degree than control subjects. At the 12-month follow-up assessment, therapist supported subjects maintained therapy induced weight loss better than the control subjects. These findings suggest that maintenance programs that provide continued contact emphasizing relapse prevention training might be an important adjunct in the maintenance of therapy induced weight loss.

A study by Perri and colleagues found improved long-term management of obesity by using problem solving therapy (PST) as compared to relapse prevention training (RPT). The authors attribute the success of PST to the assumption that few obese individuals are able to sustain changes for weight loss on their own and that active problem solving efforts by providers can help the obese person "negotiate the myriad of problems that impede successful weight management" (Perri et al., 2001a). However, this study did not capture the reasons that PST was more successful than RPT. Other study limitations included: small sample size, 31percent of the participants did not complete the program, and men were not included in the study.

Another study by Perri and colleagues (2001b) indicated that one-on-one programs may be less effective than group programs, possibly because patients benefit from the lessons and successes of others in their peer group. A 2004 study by Harvey-Berino et al. followed participants of a 6-month weight loss program with a 12-month weight maintenance program and compared the efficacy of frequent in-person support, minimal in-person support, and Internet support. Participants assigned to an Internet-based weight maintenance program sustained comparable weight loss over 18 months compared with individuals who continued to meet face-to-face. The authors concluded that the Internet appears to be a viable medium for promoting long-term weight maintenance.

The National Weight Control Registry provides information about the strategies used by successful weight loss maintainers to achieve and maintain long-term weight loss. To maintain their weight loss for more than 5 years, members report engaging in high levels of physical activity (more than 30 minutes per day); eating a low-calorie, low-fat diet; eating breakfast regularly; self-monitoring weight, and maintaining a consistent eating pattern across weekdays and weekends. Weight loss maintenance appears to get easier over time; the chance of longer term success greatly increases after maintaining the weight loss for 2 to 5 years (Wing & Phelan, 2005).

More research is needed in this area, particularly for ethnic groups other than women of Northern European extraction and the efficacy of commercial weight loss programs (Fernandez et al., 2003).

EVIDENCE

	Recommendation	Sources of Evidence	QE	Overall Quality	SR
1.	Continued contact with patients providing on-going support, encouragement, and monitoring to prevent weight regain.	NHLBI, 1998	II	Fair	B
3.	A maintenance program of diet, physical activity, and behavioral support should be offered beginning at 6 months.	NHLBI, 1998 Tremblay et al., 1999	II-2	Fair	B
4.	Emphasize working with patients to solve problems that impede weight management.	NHLBI, 1998 Perri et al., 2001a & b Tremblay et al., 1999 Wing & Phelan, 2005	II-2	Fair	B

QE = Quality of Evidence; SR = Strength of Recommendation (see Appendix A)

O. Assess Adherence and Modify Treatment

OBJECTIVE

Assess the patient's progress toward treatment goals and determine adjustments as needed.

BACKGROUND

A patient may not be successful in meeting their weight loss goals for many reasons. At this point in the process, it is important to assess progress from several standpoints such as physical findings, change in medical condition, understanding of instructions, and behavioral/environmental aspects. Providers can motivate patients by offering concrete results of physical progress (or the lack of it) and objective feedback in a structured format.

RECOMMENDATIONS

1. Adherence to weight loss programs should be assessed by periodically measuring the patient's BMI and waist circumference and providing feedback. [Expert Opinion]
2. Patients should be encouraged to record activities by using food logs, exercise logs, and personal diaries to provide structure and allow the provider to identify compliance or relapse issues. [B]

DISCUSSION

Experts in the prevention of relapse have developed models to explain the environmental, emotional, and behavioral variables that impact successful goal attainment or relapse. Patients' success in weight loss is contingent on many complex variables. Relapse to previous behaviors or lifestyles that prevent goal attainment and maintenance can be detected by physical findings (increased BMI, WC, and perhaps elevated lab results or blood pressure). Measures of positive changes in BMI, WC, cholesterol, triglycerides, and blood pressure are helpful to strengthen motivation.

Food logs, exercise logs, or personal diaries, if done honestly, can alert the provider when motivation is waning or additional education is needed. Providers may then make additional referrals to the dietitian or behavioral specialist to support the patient and get them back on track.

EVIDENCE

	Recommendation	Sources of Evidence	QE	Overall Quality	SR
1.	Provide patient with objective evidence of goal attainment.	Marlatt et al., 2000 Wadden, 1999	II-2	Fair	B
2.	Analysis/reinforcement of food logs, exercise records, and personal diaries confirms compliance.	DiLillo et al., 2003 NHLBI, 1998	II	Poor	B

QE = Quality of Evidence; SR = Strength of Recommendation (see Appendix A)

P. Reinforce Knowledge, Motivation, Skills, and Support

OBJECTIVE

Motivate overweight or obese patients who are presently not ready to undertake weight loss to do so in the future.

BACKGROUND

Many individuals are unwilling or unmotivated to lose weight for health purposes. Even those motivated to begin weight loss efforts often fail to continue their weight control behaviors over a long period. Although evidence that motivational interventions can influence the adoption of weight control behaviors is limited, extrapolation from the substance abuse and tobacco cessation literature suggests that the following techniques are readily applicable to weight control:

- Behavioral change using the transtheoretical model
- Motivational intervention strategies/techniques
- Counseling using the "five R's" of relevance, risks, rewards, repetition and roadblocks

RECOMMENDATIONS

1. Motivational interviewing techniques should be utilized to motivate patients to improve their dietary habits. [B]
2. Motivational interviewing techniques should be considered to motivate patients to increase their physical activity. [Expert Opinion]
3. Patients who may benefit from weight loss but are not willing to attempt to lose weight at this time should receive brief, non-judgmental motivational counseling designed to increase their motivation to lose weight. This counseling should include discussion about: [Expert Opinion]
   - Relevance: connection between overweight and current symptoms, disease, and medical history
   - Risks: risks of continued overweight status, tailored to individual risk/relevance of cardiovascular disease or exacerbation of pre-existing disease

- Rewards: potential benefits for losing excess weight to patients' medical, financial, and psychosocial well-being
- Roadblocks: barriers to losing weight, with options and strategies to address patient's barriers
- Repetition: reassess willingness to lose weight at subsequent visits; repeat intervention for unmotivated patients at every visit

DISCUSSION

TRANSTHEORETICAL MODEL OF BEHAVIORAL CHANGE

Like other health behaviors, weight control may follow the transtheoretical model of change described in Annotation J. Healthcare providers may assess the patient's stage of readiness and employ motivational strategies to help move the unmotivated overweight patient through this cycle. As applied to weight loss, the model describes the following stages:

1. Refusing to consider losing weight
2. Considering a weight loss attempt
3. Preparing to lose weight
4. Actively engaging in weight control behaviors
5. Maintaining the change or relapsing

MOTIVATIONAL INTERVENTION STRATEGIES

Motivational intervention is any clinical strategy designed to enhance a patient's motivation to change (see Appendix E: Behavioral Modification Strategies). Counseling that is delivered in a non-judgmental and non-argumentative manner is considered to be most effective. Motivational strategies utilized in counseling include, but are not limited, to the following:

1. Reinforce any movement towards change in the desirable direction
2. Avoid confrontation
3. Remain non-judgmental
4. Empathize with the patient's situation
5. Acknowledge the patient's ambivalence about attempting weight loss
6. Elicit the overweight person's view of the pros and cons of making a weight loss attempt and how it may relieve symptoms
7. Correct any misperceptions about health risks of excess weight and the process of weight loss
8. Have an agenda – make it explicit (e.g., "I want to help you come to a decision you are comfortable with.")
9. Avoid conflict of agendas (e.g., "You insist that I change, but I don't want to.")
10. Negotiate
11. Summarize

Motivational interviewing, developed by Miller and Rollnick in 2002, considers motivational enhancement to be an interpersonal process. This approach encourages individual responsibility and increases patients' dissonance between their ideal goal and their present behavior. A combination of discrepancy and self-efficacy is utilized to better motivate people for change. In Motivational Interviewing, the counselor's behavior directly affects the patient's motivation for change.

Motivational interventions have been demonstrated to influence patients' readiness to change health behaviors. Researchers have found positive outcomes in using Motivational Interviewing with patients who abuse alcohol and other substances (Burke, et al., 2003) and tobacco users. Level B evidence demonstrating the effectiveness for motivating smokers to quit by using Motivational Interviewing techniques is described in the VA/DoD Clinical Practice Guideline for the Management of Tobacco Use in Primary Care (2004). A complete bibliography for studies evaluating the use of Motivational Interviewing for motivating substance users to quit can be found in www.motivationalinterview.org.

In research related to, but not directly addressing weight loss, one high-quality RCT (Resnicow et al., 2001) study conducted in African American churches with a total of 1,011 subjects compared fruit and vegetable intake among groups that received: (1) standard self-help nutrition education; (2) standard self-help nutrition education plus one reminder call; and 3) standard self-help nutrition education plus one reminder call and three motivational interviewing calls. The group that included the three Motivational Interviewing calls significantly increased both fruit and vegetable intake by approximately 1.1 serving relative to the other groups. Low-fat vegetable preparation practices also improved, as did use of a healthy eating cookbook.

A separate analysis from the same study (Resnicow et al., 2003) found that subjects who were not intending to change their fruit and vegetable consumption ("precontemplators") actually moved forward to the "contemplation" stage after receiving Motivational Interviewing and in fact significantly increased their fruit and vegetable consumption as well.

Bowen et al. (2002) studied changes in the percent of dietary calories from fat in 175 females enrolled in the Women's Health Initiative trial. Participants who received three Motivational Interviewing interventions from dietitians, in addition to the usual dietary modification treatment, significantly reduced their percent of calories from fat.

Treatment techniques such as motivational interventions proven useful in tobacco use and substance abuse treatment may be applicable to the treatment of overweight and obesity as well.

COUNSELING WITH THE FIVE R'S

Utilizing the "five R's" in counseling has been recommended for tobacco users and could be applied with overweight individuals. The "5 R's" include *Relevance, Risks, Rewards, Repetition, and Roadblocks.* Overweight individuals who express an unwillingness to attempt weight loss at any time may benefit more from an emphasis upon Relevance, Risks, Rewards, and Repetition. Overweight individuals who express a willingness to consider making a weight loss attempt at some future time may respond most favorably to a discussion of Roadblocks (barriers) and potential solutions. All discussions should be followed by an offer to help when the person is "ready" to attempt weight loss.

MODULE C

INTERVENTIONS FOR WEIGHT LOSS

TABLE OF CONTENTS

C-1. Diet Therapy

BACKGROUND

The critical component for weight loss is a negative energy balance, that is, calories taken in must be less than those expended. Caloric restriction, combined with increased physical activity, is the most commonly prescribed treatment for obesity. The most effective weight loss plan will be the combination of a modified diet, increased physical activity, and behavioral modification.

Any nutritionally sound diet can be recommended, as long as it addresses the patient's preferences, lifestyle patterns, and medical profile. A current dietary intake must be established before a diet is advised. When proposing a caloric deficit, certain foods will need to be substituted, eliminated, and/or reduced, without compromising the nutritional quality of the diet. Studies demonstrate that obese adults who consume 500 to 1,000 kcal/day less than the caloric intake required for the maintenance of their current weight can lose about 1 to 2 pounds per week and achieve a 5 to 10 percent weight loss. Weight loss is achieved by varying the proportion of the major nutrients (fat, carbohydrate, and protein) as the source of necessary energy, while establishing the desired energy deficit. This can be best accomplished by reducing portion sizes, minimizing snacks and desserts, and replacing high-fat and high-calorie foods with lower fat and lower calorie choices. The use of self-help commercial programs with good track records may be considered as an option for some patients.

Despite continued efforts, a patient's weight often plateaus in 3 to 6 months. Therefore, the initial phase of a weight loss program should be scheduled within this 3 to 6 months time frame. At that point, an interim evaluation should be completed and next step goals established. Once the new goals have been achieved, a maintenance program to sustain weight loss and prevent regain should be established with the patient.

Patients should be counseled regarding weight maintenance diets to prevent weight gain. A low-fat diet is preferred, because the patient will benefit from improved cardiac risk as a result of weight loss and a restricted saturated fat content is healthier. Other diets and approaches are acceptable if they are hypocaloric and do not negatively impact the patient's health (e.g., some high-protein, high-fat diets can increase lipid levels; high-carbohydrate diets can increase triglycerides in patients that have type 2 diabetes).

RECOMMENDATIONS

WEIGHT LOSS

1. Dietary interventions should be individually planned, in conjunction with physical activity, to create a caloric deficit of 500 to 1,000 kcal/day. Such negative energy balance may lead to a weight loss of 1 to 2 pounds per week. [B]

SELECTION OF SPECIFIC DIETS

2. Dietary programs should at a minimum reduce the usual caloric intake by 500 to 1,000 kcal/day to achieve modest weight loss. [B]
3. Low-calorie diets (LCDs) should generally include 1,000 to 1,200 kcal/day for women and 1,200 to 1,600 kcal/day for men and should include the major nutrients in appropriate proportions (see Appendix C, Table C-1). [B]
4. Very-low-calorie diets (VLCDs) that restrict calories to less than 800 kcal/day [15 kcal/kg ideal body weight] are not recommended for weight loss, but may be used short term (12 to 16 weeks) under medical supervision. [B]

5. Low-fat intake (20 to 30 percent of total calories/day), as part of low-calorie diets (LCDs), can be recommended to induce weight loss and should be recommended for patients with cardiovascular disease or lipid abnormalities. [B]
6. Low-carbohydrate diets (less than 20 percent of total calories) may be used for short-term weight loss, but are not recommended for long-term dieting or weight maintenance. [B]
7. Low-carbohydrate diets can be recommended to reduce serum triglyceride levels for overweight patients with mixed dyslipidemia. [B]
8. Low-carbohydrate diets are not recommended for patients with hepatic or renal disease or for patients with diabetes who are unable to monitor blood glucose. [C]
9. Low-calorie diets (LCDs) or very low-calorie diets (VLCDs) may include meal replacements (e.g., bars and shakes). [A]
10. There is insufficient evidence to recommend for or against a diet limited to foods with a glycemic index less than 55 as a means of producing weight loss. [C]

COMMERCIAL DIET

11. Patients should be encouraged to adhere to a specific diet, as adherence to any diet plan from a variety of programs (e.g., Atkins, Ornish, Weight Watchers, and Zone) has been shown to be the most important factor in achieving weight reduction. [B]

DISCUSSION

SELECTION OF DIETS

A variety of diets, containing varying proportions of the major macronutrients (i.e., carbohydrate, protein, and fat), are effective and may be safely used to produce a caloric reduction leading to weight loss. Most diets plans modify the combination of the major macronutrients. In general, these plans claim that the balance of food groups and a certain fat/carbohydrate content play a greater role in weight control than does energy balance.

As noted in the Guideline Introduction, the body of literature specific to dieting for overweight and obesity contains certain inherent limitations which make it difficult to generalize findings to the target population for this guideline (VA and DoD health care systems).

Many of the studies did not report the setting, and only a few studies were based in primary care. In most reported studies the participants were recruited as volunteers or through selection (that is, some element of referral from screening programs). The drop-out rates and the duration of intervention varied considerably (range 8 weeks to 36 months).

A wide variety of personnel delivered the different components of the interventions; this included physicians, researchers, health educators, exercise coaches, trained interventionists, dietitians, commercial services (physical activity), and psychologists. One assumption could be that when applying the intervention in day-to-day practice with a less motivated, non-volunteer population and less intensive follow-up, delivered by generalist, the effect size will be smaller than achieved in the research studies.

Virtually all of the articles use common terms to describe types of diets. Examples include low-calorie diets (LCD), low- or moderate- fat diets, low- or high- carbohydrate diets, and very-low-calorie diets (VLCD). However, variability throughout the studies is noted in the definitions of macronutrient content and kcals. For example; McManus et al. (2001) identifies a moderate fat diet as one in which 35 percent of total kcals consist of fat and a low-fat diet as containing 20 percent. Freedman (2001) states that a moderate-fat diet is one in which 20 to 30 percent of total kcals consumed are fat and a

low-fat diet has <10 to 19 percent of total calories. Similarly, Avenell (2004) defined a very-low-calorie diet (VLCD) as one in which <1000 kcal/day were ingested. However, others have stated that VLCDs consist of less than 800 kcal/day and Foster and colleagues (1992) and Rossner (1997) used 400 to 600 kcals/day in their VLCD research. It is beyond the scope of this guideline to determine standardized macronutrient measures and calories to be applied as definitions for each diet.

The reality of a lack of standardization of commonly used terms notwithstanding; a discussion of approaches to dieting requires that some descriptors be applied to guide the reader's comprehension. Therefore, for the purposes of this guideline, the Working Group has adopted the following definitions spelled out by Freedman et al. (2001) (see also Table 6):

- High-fat (55 to 65 percent), low-carbohydrates (100 grams of carbohydrates per day), high-protein diets
- Moderate-fat (20 to 30 percent), balanced nutrient reduction diets, high in carbohydrates and moderate in protein
- Low-fat (11 percent - 19 percent), and very-low-fat (VLF) (10 percent), very high-carbohydrates, moderate-protein diets

A systematic review by Freedman et al. (2001) stated:

> *"Diets that reduce caloric intake result in weight loss. In the absence of physical activity, a diet that contains 1400 – 1500 kcal/day, regardless of macronutrient composition, results in weight loss. Individuals consuming high-fat, low-carbohydrate diets may lose weight because the intake of protein and fat is self-limiting and overall caloric intake is decreased. Low-fat and very-low-fat (VLF) diets contain a high proportion of complex carbohydrates, fruits, and vegetables. They are naturally high in fiber and low in caloric density. Individuals consuming these types of diets consume fewer calories and lose weight. Balanced nutrient reduction diets contain moderate amounts of fat, carbohydrates, and protein. When overall caloric intake is reduced, these diets result in loss of body weight and body fat. Importantly, moderate-fat, balanced nutrient reduction diets produce weight loss even when they are consumed ad libitum. In sum, all popular diets result in weight loss. However, it is important to note that weight loss is not the same as weight maintenance."*

Table 6: Definitions of Common Diets

Diet approach	Content (% of total calories)		
	Fat	Carbohydrates	Protein
Very-low carbohydrates (High-fat)	55-65	<20 (<100g)	25-30
Low carbohydrates (Moderate-fat)	20-30	30 – 40	25 – 30
Moderate-fat, balanced nutrient reduction (Low-calorie)	20-30	55-60	15-20
Low-fat	11-19	>65	10-20

(Adapted from Freedman et al., 2001)

A meta-analysis by Avenell et al. (2004) systematically reviewed diet related RCTs lasting 1 year or more, in any language. The analysis has shown that low-fat diets produced significant weight losses up to 36 months (-3.55 kg; 95% CI: -4.54 to -2.55 kg). Blood pressure, lipids, and fasting plasma glucose improved with these diets after 12 months. Four studies found that low-fat diets may prevent type 2 diabetes and reduce antihypertensive medication for up to 3 years. A VLCD (< 1,000 kcal/day) was associated with the most weight loss after 12 months (-13.40 kg; 95% CI: -18.43 to -8.37 kg) in one small study with beneficial effects on asthma. There was no evidence that low carbohydrate protein-sparing modified fasts (PSMFs) were associated with greater long-term weight loss than low-calorie diets (4.2 to 6.7 mega joul/day) or VLCDs. PSMFs were, however, associated with a greater lowering of fasting plasma glucose and HbA1c than LCDs. Avenell concluded that there is little evidence to support the use of diets other than low-fat diets for weight reduction.

Low-Calorie Diets (LCDs)

Low-calorie diets recommend a minimum calorie intake (1,000 to 1,200 kcal per day for women; 1,200 to 1,600 kcal per day for men) combined with physical activity to produce a negative energy balance, typically an energy deficit of 500 to 1,000 kcal/day. This type of program offers a range of food choices which may improve compliance and enhance nutritional balance (Finer, 2001; Freedman et al., 2001).

Thirty-four randomized controlled trials (RCTs) reviewed by NHLBI cited a mean weight loss of 8 percent over 3 to 12 months (NHLBI, 1998). All of the studies showed LCDs can achieve weight loss.

Five studies published between 1988 and 1990 involving moderate caloric restriction were reviewed by Wadden (1993) over a treatment period of 21 weeks, resulted in a weight loss of 8.5 kg. Follow-up at 53 weeks showed a mean weight loss of 5.6 kg.

Leslie et al. (2002) compared an energy deficit diet of 800 to 1,800 kcal/day with a generalized low-calorie (GLC) diet of 1,500 kcal/day. The study included a 12-week weight loss period and a 12-week maintenance period. For participants who completed the 12-week period, the energy deficit group lost 4.3 kg and the GLC group lost 5 kg. Between 12 and 24 weeks, the overall weight gain was 0.9 kg for the energy deficit group and 1.4 kg for the GLC group. Following the maintenance phase, triglyceride levels remained significantly reduced and HDL levels were increased.

McManus et al. (2001) compared a moderate-fat diet (35 percent of total calories) to a low-fat diet (20 percent of total calories), where energy intake was limited to 1,200 kcal/day for women and 1,500 kcal/day for men, combined with behavioral modification and physical activity. At 18 months, the moderate-fat diet group had a weight loss of 4.1 kg (and 3.5 kg at 30 months) and the low-fat diet group had a weight gain of 2.9 kg. When only those adhering to the program were included in the analyses, the moderate-fat group had lost 4.8 kg at 12 and 18 months; the low-fat group had lost 5 kg at 12 months and 2.9 kg at 18 months.

Four RCTs have also shown that the use of LCDs alone can lead to significant reductions in abdominal fat, as measured by WC. In reducing WC, LCDs may therefore lead to reductions in risk/severity of weight-related morbidity (NHLBI, 1998).

Very-Low-Calorie Diets (VLCD)

VLCDs became popular in the 1970s. VLCDs include, but are not limited to, the use of liquid formulas or protein-sparing modified fasts (PSMF) and may limit dietary intake to as little as 400 – 500 kcal/day. However, the programs at that time, often labeled “liquid protein diets,” contained inadequate sources of protein and amounts of vitamins, minerals, and electrolytes and were reported to be linked to fatal dysrhythmias. Newer products are nutritionally complete and typically offer daily caloric intake levels of between 400 and 800 kcal/day.

A VLCD, less than 800 kcal per day (or 6 – 10 kcal/kg of ideal body weight [IBW] per day), will result in substantial weight loss within 12 – 16 weeks. When put on such extreme restrictions of diet and combined with physical activities, the energy deficit is increased significantly and weight loss will occur. However, continuing this diet for a long period of time may not be safe. The NHLBI guidelines recommend VLCDs for a short period (12 – 16 weeks) with close medical supervision.

Intake of a high biologic value protein of 1 g/kg of body weight will help preserve lean muscle mass (Deeshka, 1993). The recommendations of the NIH National Task Force (Deeshka, 1993) on the prevention and treatment of obesity were validated by two randomized trials by Foster and colleagues (1992) and Rossner et al. (1997) showing that VLCDs between 400 – 600 kcal/day are no more effective than those allowing 800 – 1,000 kcal/day. In addition, the NIH National Task Force has deemed VLCD generally safe only when used under close medical supervision (NHLBI, 1998).

Several randomized trials (Foster et al., 1992; Wadden & Stunkard, 1986; Wadden et al., 1994; Williams et al., 1998; Wing et al., 1994) have shown that VLCDs can achieve clinically significant weight loss of 14 – 19 kg within 6 months when combined with behavioral therapy. In these trials, initial weight loss at 6 months was more statistically significant with VLCD compared with traditional LCD; however, one RCT (Wadden et al., 1994) showed that after 1 year there was no long-term advantage of VLCD over LCD due to the considerable amount of weight regain on VLCD between 6 – 12 months. Two RCTs (Williams et al., 1998; Wing et al., 1994) involving intermittent use of a VLCD showed that after 6 months and 1 year, patients on a VLCD achieved more weight loss as compared with LCD. Although the data achieved statistical significance, the clinical significance was questionable after the 1 year trial. The end result was that weight loss at 12 months using LCDs was as effective as VLCD.

The PSMF is the quickest, most aggressive means of losing weight. A PSMF is one approach of instituting VLCDs in which no carbohydrates are eaten at all, and calories are provided by high-protein foods, such as chicken, meat and fish (Deeshka, 1993). In the 1970's, methods were developed to concentrate the amino acids found in these foods into a liquid form.

PSMF may improve glucose control and blood pressure. In a non-randomized study of 150 patients, Hamdy (1999) showed that a short-term PSMF lasting 8 weeks produced statistically significant improvements in glucose control and blood pressure. Improved glycemic control through the use of PSMF was also demonstrated by Bistran et al. (1977).

It is a common belief that weight loss achieved at a slow rate is better preserved than if the weight is lost more rapidly. However, Astrup et al. (2000) suggests that the literature shows that initial weight loss is positively, not negatively, related to long-term weight maintenance. Analyzing 19 controlled trials of low-fat diets versus moderate-fat diets lasting 2 to 12 months, Astrup found evidence to support that a greater initial weight loss induced without changes in lifestyle (e.g., liquid formula diets or anorectic drugs) improves long-term weight maintenance when it is followed by a one- to two-year integrated weight maintenance program consisting of lifestyle interventions involving dietary change, behavioral therapy, and increased physical activity. According to this study, there is evidence to suggest that a greater initial weight loss as the first step of a weight management program may result in improved sustained weight maintenance.

Most research maintains that participants of a structured weight loss program regain all of their weight loss within 5 year after the initial weight loss. A meta-analysis by Anderson et al. (2001) examined the long-term weight loss maintenance of individuals completing a structured weight loss program. Twenty nine studies, all conducted in the United States, included participants in a structured weight loss program and provided follow-up data for 2 years or more following the program. The data shows that successful VLCDs were associated with significantly greater weight loss maintenance than were successful LCDs at all years of follow-up. The percentage of individuals at 4 or 5 years of follow-up for VLCDs and LCDs were 55.4 percent and 79.7 percent, respectively. Weight loss maintenance in the VLCD was 7.1 kg (95 CI: 6.1, 8.1 kg) and only 2 (1.5, 2.5) kg for LCD; weight loss maintenance did not differ significantly between women and men. Six studies reported that groups who exercised

more had significantly greater weight loss maintenance than did those who exercised less. The authors concluded that five years after completing a structured weight loss program, the average individual maintained a weight loss of >3 kg and a reduced weight of >3 percent of initial body weight. After VLCDs or weight loss of 20 kg or more, individuals maintained significantly more weight loss than after LCDs or weight losses of <10 kg.

In conclusion, VLCDs may be useful to induce rapid weight loss and motivate obsese patients in the early stages of a weight loss program. They should, however, be followed up with a maintenance program if the weight loss is to be sustained.

Low-Fat Diets

During the 1980s and 90s, low-fat diets were promoted by some as the key to weight loss producing plethora of low-fat foods were put on the market. Many of these low-fat foods replaced the fat with carbohydrates. The focus of these diets is on the type of calories consumed. Individuals are encouraged to eat complex carbohydrate and high fiber foods (low-calorie density) (Freedman et al., 2001).

The Cochrane review (Pirozzo et al., 2002) looked at 12 RCTs, which varied in length from 6 – 18 months, and found that fat restricted diets (providing up to 30 percent of total calories from fat) are no better than calorie restricted diets in achieving long-term weight loss in people who are overweight or obese. There was also no significant difference in BMI, percent body fat, or waist-to-hip ratio between the groups at 6, 12 and 18 months of follow-up. The review indicated that participants lost more weight on the control diets, but this difference was not statistically significant.

In comparison, the NHLBI report (1998) based on nine studies states that restricting fat alone (20 - 30 percent of total calories from fat) helps promote weight loss by producing a reduced-calorie intake. Furthermore, restricting fat and energy together produces a greater weight loss. The authors concluded that there is little evidence that low-fat diets (per se) cause weight loss independent of energy reduction. Therefore, reducing dietary fat along with total calories is needed to promote weight loss.

In the meta-analysis by Astrup et al. (2000), a reduction in dietary energy from fat was significantly associated with a spontaneous weight loss of 3.2 kg more in the intervention group compared with the control group of overweight participants. Weight loss was dependent on the pretreatment bodyweight – the heavier the participant, the more weight was lost. However, no trials involving groups of subjects with a BMI greater than 30 fulfilled the inclusion criteria, so the authors did not draw any conclusions for obese subjects.

There is good evidence that adherence to a low-fat diet will positively impact lipid abnormalities.

The National Cholesterol Education Program Adult Treatment Panel III (NCEP ATP-III, 2002) recommends the Therapeutic Lifestyle Changes (TLC) diet to reduce low-density lipoprotein cholesterol (LDL-C). NCEP ATP-III defines a low-fat diet as a daily fat intake of 25 – 35 percent of total calories. Short-term controlled feeding studies have shown that the TLC–diet, which consists of less than 20 percent up to 30 percent of daily calories from fat, typically decreases total cholesterol and LDL-C by 7 – 9 percent and 10 – 20 percent, respectively. As a low-fat diet is typically higher in carbohydrates, the effect on triglycerides and HDL-C is not as favorable. Details of the NCEP TLC diets may be found in Appendix C. Medical history should be considered when choosing a suitable low-fat diet. See the VA/DoD Dyslipidemia Guideline for a complete review of low-fat diet therapies.

Foster et al. (2003) compared a conventional, low-fat diet (1,200 – 1,500 kcal/day for women; 1,500 – 1,800 kcal/day for men; with 60 percent calories from carbohydrate, 25 percent from fat, and 15 percent from protein) to a low-carbohydrate diet (20 gram carbohydrates/day for the first two weeks with a gradual increase in carbohydrates as the patient attains goal weight). The conventional, low-fat diet

showed significant reductions in LDL-C at 3 months and total cholesterol at 3 and 6 months when compared to the low-carbohydrate diet.

Participants with diabetes on a calorie restricted, low-fat diet had a significantly greater weight loss and reduction in BMI at 52 weeks compared with a calorie restricted alone group (Pascale et al., 1995). The calorie restricted, low-fat diet group had a statistically significant improvement in high density lipoprotein cholesterol (HDL-C). Those with a family history of diabetes on a calorie restricted, low-fat diet had a statistically significant reduction in their total cholesterol.

Krauss (2001a; 2001b) found that a low-fat, high-carbohydrate diet may worsen triglycerides and HDL and increase LDL in many people.

Low-Carbohydrate Diets

Low-carbohydrate diets have been regarded as fad diets in the last decade, claiming to be effective in producing weight loss despite ad-libitum consumption of fatty meat, butter, and other high-fat dairy products. The low-carbohydrate, high-protein diet, promoted extensively by Atkins and others, is one of the most popular weight loss approaches (Freedman et al., 2001).

The high-protein, low-carbohydrate diets promise to induce weight loss with approximately 60 percent of energy from fat and no restrictions on the type of fat (from saturated and unsaturated sources) or cholesterol. These diets have little credible scientific evidence of their efficacy or safety. Even the literature lacks consensus as to what level of carbohydrates per day constitutes a low-carbohydrate diet. A review of English language studies of high-protein, low-carbohydrate ketogenic diets published since 1966 showed wide variations in design, carbohydrate content (0 – 901 grams/day), total caloric content (525 – 4629 kcal/day), diet duration (4 – 365 days), and participant characteristics (e.g., baseline weight range, 57 – 217 kg). Only 5 studies lasted longer than 90 days.

An earlier systematic review of carbohydrate diets reported that the weight loss is associated with only the duration of the diet and the restriction of energy intake, not the carbohydrate restriction itself. There were no evaluations of diets with 60 grams/day or less of carbohydrates in participants with a mean age older than 53.1 years (Freedman et al., 2001).

There is fair evidence to suggest that short-term, low-carbohydrate diets (6 months or less) result in greater weight loss than conventional, reduced-calorie or low-fat diets. Low-carbohydrate diets, with carbohydrate intake between 20 and 40 grams of carbohydrates/day, will result in weight loss over a three to six month period.

One study by Yancy et al. reported that a low-carbohydrate ketogenic diet program had better participant retention and greater weight loss compared with a low-fat diet, among 120 veterans that were overweight and hyperlipidemic. At 24 weeks, weight loss was greater in the low-carbohydrate diet group than in the low-fat diet group (mean change -12.9 percent vs. -6.7 percent; $P < 0.001$) (Yancy et al., 2004).

However, three RCTs of longer terms that compared low-carbohydrate diets with low-fat, calorie restricted diets have shown no difference in weight loss outcome after 12 months (Brehm et al., 2003; Foster, 2003; Samaha et al., 2003). Long-term studies are needed to measure the changes in body composition and nutritional status during use of low-carbohydrate diets and to assess the cardiovascular risk factors and adverse effects. Without that information, low carbohydrate diets can not be recommended. The three studies are important, but do not provide conclusive evidence that low-carbohydrate diets in the long-term are superior to low-calorie/low-fat diet. The three RCTs had important limitations. Adherence to the diet was low (Foster, 59 percent completed the study; Samaha, 60 percent; and Brehm 79 percent). Furthermore, the low-fat diet used by Samaha provided higher ratio of total calorie intake from fat than usually indicated by low-fat diets. All the studies and the summary by Bravata (2003) demonstrated difficulties in explaining the results. According to the Atkin's book,

weight is lost on the ad libitum diet because of increased energy expenditure (Atkins, 1998). Low-carbohydrate diets are theoretically designed to promote ketosis, lipid oxidation, satiety, and increased energy expenditure with negative energy balance and weight loss as a result (Bravata et al., 2003; Brehm et al., 2003; Freedman et al., 2001; Halton, 2004; Westman et al., 2003). Opponents contend that there may be serious medical consequences of a low-carbohydrate diet with greatest risk in patients with cardiovascular disease, type 2 diabetes, dyslipidemia, or hypertension. The accumulation of ketones may affect insulin metabolism and liver and kidney function. Salt and water depletion may cause postural hypotension, fatigue, constipation, and nephrolithiasis. Too much animal protein and fat may promote hyperlipidemia, and renal function may be impaired (Bravata et al., 2003; Westman et al., 2003).

All of the above studies concluded, at the time of publication, that the weight loss observed in those following a low-carbohydrate diet was likely not due to the macronutrient composition of meals, but instead to a reduction in total calorie intakes. Bravata further suggests that low-carbohydrate diets are safe, but concluded that no weight loss beyond that which would be expected by the amount of caloric reduction is provided, irrespective of how those calories were delivered.

A later study by Brehm et al. (2005) attempted to answer some of these hypotheses. The study demonstrated that women consuming a low-carbohydrate diet lose more weight than women consuming a low-fat diet over several months. The more pronounced weight loss in the low-carbohydrate dieters is not explained by increased resting energy expenditure, thermic effect of food, or physical activity and cannot be accounted for by their reported energy intakes. The difference between the low-fat and low-carbohydrate diets could not be explained by different energy intake. The authors stated at their conclusion "the major point is that the principal means of voluntarily shifting energy balance to promote weight loss is restriction of intake and increase in expenditure. At present, the best methods for accomplishing these lifestyle changes for prolonged periods of time remain elusive."

Other studies during 2004 have concluded that long-term use of a low-carbohydrate diet is not recommended for healthful control of body weight. The use of a low-carbohydrate diet may be beneficial for the initiation of weight loss and may improve compliance associated with limited carbohydrate choices and food specific satiety (Raynor et al., 2004). However, patients should be encouraged to resume a more balanced diet after 6 months, as habitual carbohydrate restriction has a limiting effect on vitamin, mineral, fiber, and phytochemical intake (Kappagoda et al., 2004).

Improvement of cardiovascular risk factors: There is fair evidence that a low-carbohydrate diet positively impact triglycerides. Foster et al. showed that low-carbohydrate dieters had greater improvements in triglycerides at 12 months compared with low-fat dieters. Samaha showed similar results after six months. No sustained benefit on triglycerides has been found, however, with the use of this diet after 12 months (Foster et al., 2003; Samaha et al., 2003; Stern et al., 2004).

During active weight loss in the Yancy et al. (2004) study, serum triglyceride levels decreased more and high-density lipoprotein cholesterol levels increased more with the low-carbohydrate diet than with the low-fat diet. Changes in low-density lipoprotein cholesterol level did not differ statistically.

Blood pressure improvement was the same for both diets (Foster et al., 2003; Samaha et al., 2003). Low-carbohydrate diets have been shown to improve glucose metabolism in studies up to 6 months (Brehm et al., 2003; Samaha et al., 2003).

Despite the positive effects of a low-carbohydrate diet on triglyceride levels (in up to 6 months), data has not yet shown beneficial effects on LDL cholesterol levels. Foster et al. (2003) found that at 3 months, LDL-C actually increased with a low-carbohydrate diet and decreased with the conventional weight loss diet. After 12 months, however there were no significant differences between either diet groups. Foster did observe improvements in HDL-C after 3-, 6- and 12-months compared to the conventional diet group. Because even minor weight loss markedly improves lipid profile and glucose tolerance, these improvements can be attributed to the greater weight loss on the low-carbohydrate diets. No studies have lasted long enough to evaluate the impact on cardiovascular risk when the

weight loss declines. The restriction on intake of vegetables and fruit and the ketosis induced in some of the diets may pose other increased risks for cardiovascular diseases.

An RCT (Stern, 2004) reported one-year outcomes on weight loss and metabolic changes in severely obese people assigned to either a low-carbohydrate diet or a conventional weight loss diet. At one year, weight loss was similar for both groups (mean of 2 – 5 kg). There was a favorable effect on triglyceride levels and glycemic control in the low-carbohydrate diet group.

Low-Glycemic Index (GI) Diets

Evidence associated with weight loss: There is limited evidence that a diet based upon glycemic index (GI) will result in weight loss, when followed over a six-month period.

The concept of glycemic index was first proposed in 1981 (Jenkins et al., 1985). The glycemic index of a dietary carbohydrate is an assessment of its post-prandial effect on blood glucose. The GI is defined as the incremental area under the blood glucose response curve after consumption of 50 grams of available carbohydrate from a test food, divided by the area under the curve after consumption of 50 grams of carbohydrates from a reference food (Wolever et al., 1991).

Weight loss associated with the glycemic index has been a studied component of some of the trials. Short-term intervention studies have found the low GI diet to be no more beneficial than other caloric restricted diets in terms of weight loss (Ebbeling et al., 2005; Raben et al., 2003). Randomized trials have been short in duration; less than 12 weeks, and of small sample size, primarily of overweight adults without diabetes, and adults who were diabetic and overweight and obese. The effect of a low GI diet upon HbA1c has been weak (Kelly et al., 2005).

Evidence associated with impact on comorbidities: There is fair evidence that a diet based upon GI has positive impact on glycemic control and lipid profile.

There is increasing evidence that a diet based upon GI is important in terms of disease prevention and control. While not universally accepted, several health organizations now recommend the consumption of low GI foods in the management of type 2 diabetes (Buchhorn, 1997) and as part of a healthy diet (FAO/WHO Report, 1998). Risk of cardiovascular disease has been inversely associated with dietary GI in some small, randomized, epidemiological studies. The intervention studies have described the beneficial effects of a low GI diet on blood lipids in overweight adults, short-term (Rizkalla et al., 2004; Sloth et al., 2004). The long-term efficacy of a low GI diet in reducing cardiovascular risk disease has not been evaluated.

Because no deleterious effects of a low GI diet have been documented, the diet may be considered in the management of some diseases (Colombani, 2004). However, there is insufficient evidence to promote the use of low GI diets alone.

Low-Energy Density Diets

Energy density is defined as the amount of energy (calories) in a given weight of food (grams). The aim of this diet is to meet or stay below an energy intake goal per day. Foods low in energy density contain less calories and allow the participant to consume a greater amount of food (in grams); foods high in energy density contain more calories and require the consumption of less food (McCrory et al., 2000; Rolls & Bell, 2000). Carbohydrates and proteins contain 4 kcal/gram; fat contains 9 kcal/gram. Fat content is directly related to energy density; water content is inversely related although neither relationship is perfect in that all foods with the same energy density do not have the same fat and water content. Fiber content is also a factor (Rolls & Bell, 2000). Foods that are higher in energy density are also likely to be more palatable (McCrory et al., 2000). There is limited, short-term, evidence of the effectiveness of low-energy density diets (Rolls & Bell, 2000). Low-energy-density diets can be

successfully applied, since they help lower calorie intake without reducing food volume and help individuals avoid feeling hungry and deprived.

Meal Replacement (MR)

Commercial meal replacements (MR) have become increasingly popular as a strategy among people trying to lose weight and have emerged as one of the most cost-effective self-help tools for weight loss and maintenance (Anderson et al., 2004; Blackburn & Rothacker, 2003; Rothacker, 2000). Fifteen percent of women and thirteen percent of men reportedly use MRs as their weight loss strategy, suggesting that they can easily be incorporated into the lifestyle of the participant (Noakes et al., 2004).

Heymsfield and colleagues (2003) conducted the first systematic evaluation of RCTs using MR plans for long-term weight management and found that MRs safely and effectively produce significant sustainable weight loss and improve weight-related risk factors of disease.

Flechtner-Mors et al. (2000) showed that structured meal plans, which provide good nutrition and portion control for 1 or 2 meals a day, improve risk factors for metabolic syndrome and help patients make healthy food choices, including increased consumption of fruits and vegetables. MRs are also safe and effective for weight management in patients with type 2 diabetes.

Intake of two meal replacements per day (e.g., pre-packaged energy bars, drinks or shakes) and a sensible third meal (e.g., steamed vegetables, grilled chicken, and fresh fruit) produce weight loss; one MR per day, combined with sensible eating, enables weight maintenance. Improved outcomes were seen among those who satisfied between-meal hunger with snacks that included fruits, vegetables, or a meal-replacement bar. In general, those who added frequent water intake and exercise to their daily regimens had greater short- and long-term success (Heymsfield et al., 2003).

In one study, two-thirds of 252 patients chose to use MRs at least once daily (Bowerman, 2001). After 6 months, weight loss was 8.62 ± 1.81 kg for women and 7.03 ± 3.72 kg for men. Participants of another study found the MR strategy convenient to use and provided manageable dining out options (Noakes et al., 2004). Management of and compliance on the diet, therefore, was good, supporting the notion that MRs offer an effective alternate strategy for long-term dieting.

COMMERCIAL DIET PROGRAMS

The incidence of obesity in the United States has escalated along with its physiological and psychological comorbidities (Flegal et al., 2002). The imperative for effective weight loss methods has stimulated the promotion of numerous alternative diet plans, most of which are based on some modification of macronutrient content (i.e., low-carbohydrate and high-carbohydrate diets).

Dansinger et al., (2005) compared the relative merits of four of the most popular weight loss diets. These included the Atkins (carbohydrate restriction), Ornish (fat restriction), Weight Watchers (calorie and portion size restriction), and Zone (high-glycemic-load carbohydrate restriction and increased protein) diets. In the year-long study, 160 people that were overweight and obese were randomly assigned to one of these four regimens. All participants were generally healthy but had at least one additional major risk factor for heart disease, such as high blood pressure, elevated blood cholesterol, increased blood sugar levels, or diabetes. Findings after one year were that weight loss among participants averaged 4.7 to 7 pounds. On average, participants on the Atkins plan lost 4.6 pounds; participants on the Weight Watchers plan lost 6.6 pounds; participants on the Zone plan lost 7.1 pounds; and participants on the Ornish plan lost 7.3 pounds. Adherence to the diets was a problem in all groups. Fifty-three percent of participants stuck with the Atkins plan for one year; 65 percent stuck with the Weight Watchers plan for one year; 65 percent stuck with the Zone plan for one year; and 50 percent stuck with the Ornish plan for one year. Approximately half of the patients on Atkins and Ornish and 35 percent of those on Zone and Weight Watchers dropped out before the one year mark. The researchers concluded that the strongest predictor of weight loss was not the type of diet, but compliance with the diet plan that subjects were given. Dietary adherence, as opposed to diet

composition, appears to be the most important factor in short-term weight loss for obese individuals subscribing to a diet program for weight reduction.

Table 7: Popular Commercial Diet Programs*

Type of diet	Examples
High-fat Low carbohydrate	Atkins Diet ™ South Beach ™ Sugar Busters ® The Carbohydrate Addict's Diet ® Protein Power
High-protein Moderate carbohydrate	Zone Diet ®
Moderate-fat Balanced Nutrient LCD	Jenny Craig Nutri-Systems ® Weight-Watchers ® LA Weight Loss ® Mediterranean Diet
VLCD	Medifast ® Optifast ®
Meal Replacements	SlimFast ™
Low-Fat Very-Low-Fat	Dean Ornish Program Pritikin Program ™

*This is a partial list and is not an endorsement of the diets mentioned.

Tsai et al. (2005) reviewed 1,500 weight loss studies of adults in an effort to describe the components, costs, and efficacy of the major commercial and organized self-help weight loss programs in the United States. Using those studies, plus additional data supplied by the programs themselves, this systematic review examined nine plans: Weight Watchers, Jenny Craig, L.A. Weight Loss and eDiets.com; the self-help groups Take Off Pounds Sensibly (TOPS) and Overeaters Anonymous (OA); and three medically supervised commercial programs, Optifast, Health Management Resources, and Medifast/Take Shape for Life.

With the exception of one trial of Weight Watchers, the evidence to support the use of the major commercial and self-help weight loss programs is modest or nonexistent. Weight Watchers is the only commercial weight loss program whose efficacy has been demonstrated in a large, multi-site, RCT. Weight Watchers participants lost on average 5 percent of their weight in six months. After two years, the average weight loss was about three pounds. Commercial interventions available over the Internet and organized self-help programs produced minimal weight loss. The authors' conclusion was that additional controlled trials are needed to assess the efficacy and cost-effectiveness of these interventions. However, "practitioners can support patients' participation in commercial or organized self-help programs by reviewing changes in weight and health complications at office visits and by monitoring patients' efforts to improve their eating and activity habits."

EVIDENCE

	Recommendation	Sources of Evidence	QE	Overall Quality	SR
1.	An energy deficit of 500 – 1,000 kcal/day will lead to weight loss of 1 to 2 pounds per week.	ICSI, 2004 (TA#83) NHLBI, 1998	I	Fair	B
2.	Energy deficit (calories in vs. calories out), rather than macronutrient composition is the major determinant of weight loss.	Avenell et al., 2004 Freedman, 2001 ICSI, 2004 (TA#83) McTigue et al., 2003	I	Fair	B
3.	No single type of diet has been shown to be more effective than the others.	Avenell et al., 2004 Dansinger et al., 2005 ICSI, 2004 (TA #83) McTigue et al., 2003	I	Fair	B
4.	**LCDs** may result in moderate weight loss for patients that adhere to the diet program (3 to 18 months).	Avenell et al., 2004 ICSI, 2004 McTigue et al., 2003 NHLBI, 1998	I	Good	A
5.	**VLCDs** (less than 800 kcal/day) produce greater initial weight loss than other form of calorie restriction at 12 to 16 weeks.	Wadden et al., 1986 & 1994 Williams et al., 1998 Wing et al., 1994	I	Good	B
6.	**VLCDs** should be monitored under medical supervision.	Deeshka, 1993	III	Poor	C
7.	Greater initial weight loss induced without changes in lifestyle (e.g., **VLCD**) may improve long-term weight maintenance.	Anderson et al., 2001 Astrup & Rossner, 2000	I	Fair	I
8.	**Low-fat** diets produce a caloric deficit and lead to modest weight loss at 3 to 6 months. Greater weight loss is observed in patients with greater baseline weights.	NHLBI, 1998	I	Good	A
9.	**Low-fat**, calorie restricted diets may lead to weight loss and reduction in LDL-cholesterol for patient with dyslipidemia.	NCEP, 2002 NHLBI, 1998	I	Fair	B
10.	**Low-carbohydrate** diets result in more rapid short-term (6 months) weight loss than low-fat LCDs. **Low-carbohydrate** diets may	Bravata et al., 2003 Brehm et al., 2003 Foster et al., 2003	I	Fair	B

	reduce serum triglyceride levels and improve HDL-C in patients with mixed dyslipidemia.	Samaha et al., 2003			
11.	**Low-carbohydrate** diets are contraindicated in patients with renal or hepatic disease and patients with diabetes that cannot monitor their blood sugars.	Working Group Consensus	III	Poor	I
12.	**Meal replacements** are safe to promote weight loss in conjunction with LCDs and VLCDs.	Bowerman et al., 2001 Flechtner-Mors et al., 2000 Heymsfield et al., 2003 Noakes et al., 2004	I	Good	A
13.	The evidence is insufficient to substantiate the recommendation of a diet based on the **glycemic index**, without caloric reduction.	Kelly et al., 2005	III	Poor	I
14.	Low-**energy**-dense diets can help lower calorie intake without reducing food volume and lead to weight loss.	McCrory et al., 2000 Rolls & Bell, 2000	I	Fair	B

QE = Quality of Evidence; SR = Strength of Recommendation (see Appendix A)

C-2. Physical Activity

BACKGROUND

The centerpiece of any weight loss program is the creation of an energy deficit which, regardless of any co-existing metabolic condition, will result in weight loss. Exercise is a valid tool if utilized properly and can benefit primary and secondary health outcomes as well as mental health. Exercise is most effective for achieving weight loss goals when combined with dietary therapy and behavioral modification. Another benefit to exercise is in the increase in resting or basal metabolic rate that follows exercise and is also a function of increased muscle mass.

In 1996, the U.S. Surgeon General recommended that all adults expend at least 150 kcal per day or 1000 kcal per week in moderate and vigorous physical activity. Many organizations have translated this recommendation into one that prescribes 30 – 45 minutes of exercise four or five days per week. Exercise should be initiated after the patient and provider have developed a plan that includes exercise type, intensity, duration, and frequency. A detailed exercise prescription is more likely to increases intensity, duration, and frequency for a type of exercise depending upon factors such as patient preference, progress, target weight loss, and physical abilities.

RECOMMENDATIONS

1. Weight loss interventions should include exercise to promote weight loss [A], maintain weight loss [A], decrease abdominal obesity [B], improve cardiovascular fitness [A], improve cardiovascular outcomes [A], and decrease all-cause and cardiovascular mortality [B].
2. Home fitness/lifestyle activities or structured supervised programs may be effectively used to produce a caloric expenditure leading to weight loss. [A]
3. Moderate levels of physical activity should be performed at least 30 minutes most days of the week. [B]
4. Physical activity may include short intermittent bursts (10 minutes or longer) as well as longer continuous exercise. [A]

DISCUSSION

Physical activity in overweight and obese adults results in modest weight loss independent of the effect of caloric reduction through diet. When combined with a reduced-calorie diet it can create a net caloric deficit that leads to increased weight loss. Ross and colleagues (2000) performed a detailed study demonstrating the principle that one pound of weight loss is always achieved when an energy deficit of 3,500 kcal is attained. Obese sedentary men with an average BMI of 31 kg/m^2 and stable weight for 6 months prior to intervention were randomized to one of 4 groups for 12 weeks: control, diet-induced weight loss, exercise-induced weight loss, and exercise plus an increase in ingested calories. Through very careful monitoring, the control group maintained their same baseline diet and sedentary lifestyle, the diet group consumed a 700 kcal deficit diet daily while maintaining the same level of sedentary lifestyle, the exercise-induced weight loss group maintained their same diet while expending 700 kcal per day in exercise, and the final group expended 700 kcal per day via exercise but ingested 700 kcal above their baseline dietary intake. As expected, the control group and the group that exercised but consumed more kcal (resulting in a neutral energy balance) had no change in their weights. More importantly, the men in the two groups using diet alone and exercise alone lost an average of 16.5 pounds. This result confirms the predicted weight loss of 16.8 pounds per person that is based on a calculation using known energy balance principles. Thus, when compliance is assured, exercise is an as effective weight loss means as dietary caloric reduction.

The benefits of exercise extend beyond weight loss. Secondary outcomes of cardiovascular risk are improved with exercise (Halbert et al., 1999; Sigal et al., 2004; Whelton et al., 2002). Studies conducted in the last 15 years in both male and female populations have concluded that physically

active individuals are less likely to develop cardiovascular heart disease than those who are sedentary (Bassuk & Manson, 2004). Cross-sectional and prospective data provide an emerging picture of associations of both physical activity habits and cardiorespiratory fitness in individuals with metabolic syndrome. Regular exercise lowers blood pressure, reduces the risk of developing type 2 diabetes, and increases levels of high density lipoprotein cholesterol in the blood (Carroll & Dudfield, 2004). For example, for three years the U.S. Diabetes Prevention Program followed 3,234 men and women aged 25 to 85 years with impaired glucose tolerance and a BMI of 24 kg/m² or more. Members of the intervention group, who exercised at moderate intensity for 30 minutes per day, realized a 58 percent reduction in diabetes risk as compared to the sedentary control group (Knowler et al., 2002). Therefore, regular exercise is an important part of a weight loss and maintenance program for overweight patients with a BMI between 25 and 30 kg/m² in order to decrease cardiovascular risk factors.

Furthermore, epidemiological studies have clearly shown the benefits of exercise on primary outcomes. The Harvard College alumni study longitudinally tracked 10,269 men over a period of 11 to 15 years (Paffenbarger et al., 1993). The initiation of moderately vigorous sports activity at an intensity of 4.5 or more metabolic equivalents was associated with a 23 percent lower risk of death than those not taking up exercising. Lee and co-workers (1999) followed 21,925 men aged 30-83 years for an average of 8 years and determined level of fitness by treadmill testing. Unfit lean men had a higher risk of all-cause mortality and cardiovascular mortality than did fit men who were obese. Blair and colleagues (1995) followed 9,777 men for an average of 4.9 years and found that men who improved from unfit to fit at subsequent examinations had a 44 percent reduction in mortality risk; for each minute increase in maximal treadmill time, there was a 7.9 percent decrease in mortality.

TYPE OF EXERCISE

Simply increasing activity by 30 minutes per day above baseline by walking or taking stairs instead of elevators may be all that it takes to achieve some weight loss (Anderson et al., 1999). A similar regimen can be helpful in maintaining weight loss (Fogelholm et al., 2000). Such home-based lifestyle interventions can be just as effective as formal structured and supervised exercise and may actually result in greater adherence the longer the physical activity continues (Anderson et al., 1999; Dunn et al., 1999). Walking is the most common leisure activity in the U.S. and can be very effective in weight control. The Women's Health Study, a 7-year follow-up of 39,000 healthy middle-aged female health professionals, found that walking at least 1 hour per week was associated with a 50 percent reduction in CHD risk in women reporting no vigorous physical activity (Lee et al., 2001). In a 30-year study of over 1,500 middle-aged University of Pennsylvania alumnae, walking 10 or more blocks per day as compared to walking less than 4 blocks per day was associated with a one third reduction in cardiovascular disease incidence (Sesso et al., 1999).

Older individuals also benefit from moderate intensity, home-based physical activity. Men aged 71 to 93 years who walked 1½ miles per day as part of the Honolulu Heart Program experienced half the risk of cardiovascular heart disease of those who walked less than ¼ mile per day (Hakim et al., 1999). In the Zutphen Elderly Study, men aged 64 to 84 years who walked or cycled at least 3 times per week for 20 minutes were 31 percent less likely to die from CHD over a 10-year follow-up period, compared with their counterparts who did not meet this activity criterion (Bijmem et al., 1998).

INTENSITY OF EXERCISE

The intensity of an activity is quantified by a metabolic equivalent (MET) (Ainsworth, 2003). MET is defined as 3.5ml O^2/kg/min. A 1.0 MET represents the energy cost of sitting quietly at rest. A 2.0 MET activity, such as driving a car, requires twice the energy required to sit quietly. Walking slowly requires 3.0 METs. Walking briskly consumes 3.8 METs. Swimming vigorously is a 10 MET activity. Three to six MET activities are considered moderate and are characterized by an increase in heart rate and depth of breathing without restricting the ability to talk. Activities that are worth more than 6 METS are considered vigorous. Vigorous activity increases heart rate and breathing to near maximal levels generally making conversation difficult. The kcal energy expenditure associated with any physical activity can be calculated as follows:

Kcal per week = METs x Number of sessions per week x Hours per session x Body weight in kg

The Compendium of Physical Activities was developed to provide consistency in scoring physical activity questionnaires and provides METs associated with common physical activities in 21 general categories. The 2000 version of the Compendium of Physical Activities can be found at (http://prevention.sph.sc.edu/tools/docs/documents_compendium.pdf) (Ainsworth, 2002). A brief MET table for a sample of physical activities can be found in Appendix D: Physical Acitivity/Exercise (Ainsworth, 2002).

DURATION OF EXERCISE

Short intermittent bursts of exercise are just as effective as longer duration exercise when the total estimated calorie expenditure is the same (Frick et al., 2001; Jakicic et al., 1999). Due to noncompliance, longer duration exercise is typically not any more effective or may be less effective than shorter duration exercise for the maintenance of weight loss (Fogelholm et al., 2000; Jakicic et al., 2003). Several organizations have made recommendations on the amount of physical activity to engage in and there is general agreement that the intensity of exercise should be moderate and carried out at least 30 minutes per day to achieve improved health outcomes (Jakicic et al., 2001; NLHBI, 1998; Saris et al., 2003).

In 2002, the Institute of Medicine (IOM) recommended 60 minutes of exercise per day, concluding that 30 minutes per day is not sufficient to maintain a healthy weight or to achieve maximal health benefits in the absence of curtailing caloric intake. This recommendation was questioned for its unrealistic expectations. A national survey conducted in 1997 and 1998 by the U.S. Department of Health and Human Services found that 73 percent of women and 66 percent of men fail to meet the 30-minute guideline, and 41 percent of women and 35 percent of men engage in no leisure-time physical activity at all (Lee et al., 2001).

However, as demonstrated by the previously stated data on walking, lesser amounts of physical activity can also have a beneficial effect on weight control. Moderately intense exercise for 30 minutes per day confers significant and measurable cardiovascular health benefits. Yet, a dose-response relationship between physical activity and cardiovascular outcomes exists such that *another* 30 minutes of exercise would, on average, be expected to confer additional protection against the development of cardiovascular disease (Bassuk & Manson, 2004).

EXERCISE FOR WEIGHT MAINTENANCE

Exercise is an equally important component of a weight maintenance program, once the weight loss goal has been reached. Descriptive studies of formerly obese individuals suggest that 80 minutes per day of moderately intense activity or 35 minutes per day of vigorous activity is required for long-term maintenance of weight loss. A sample of 629 women and 155 men (the mean age was 38.97 years) who were part of the National Weight Control Registry initially lost an average of 30 kg. These individuals maintained a minimum weight loss of 13.6 kg for 5 years by expending, on average, approximately 2,800 kcal per week, or about 1.5 hours of brisk walking per day for a 65-kg woman (Klem et al., 1997).

LIMITATIONS OF PHYSICAL EXERCISE

Energy expenditure using exercise as a means to achieve weight loss is a matter of physical principle. In the Ross study, men had to exercise one hour per day at approximately 75 percent of maximum predicted heart rate in order to expend nearly 700 kcal per exercise session (Ross et al., 2000). However, reaching this level of energy deficit may be difficult for some to achieve due to limitations such as musculoskeletal conditions or risk of harm. Others, because of cardiovascular risk factors, may require a screening treadmill test and a detailed exercise prescription based on test findings. Women may have to exercise relatively more then men to attain the same caloric deficit given the same relative

intake. Some evidence suggests that the reason for this is that women experience lower resting and exertional energy expenditure. For those who can exercise, adherence is the key and it appears that this is difficult to achieve without active external intervention (Perri et al., 1988).

EVIDENCE

	Recommendation	Sources of Evidence	QE	Overall Quality	SR
1.	***Physical Activity / Exercise should occur to:***				
	a. Promote weight loss	NHLBI, 1998 Ross et al., 2000	I	Good	A
	b. Maintain weight loss	Miller et al., 1998	I	Good	A
	c. Decrease abdominal obesity	NHLBI, 1998	I	Fair	B
	d. Improve cardiovascular fitness	NHLBI, 1998	I	Good	A
	e. Reduce cardiovascular risk factors	Bassuk & Manson, 2004 NHLBI, 1998	I	Good	A
	f. Decrease all-cause and cardiovascular mortality	Blair et al., 1995 Lee et al., 1999 Paffenbarger et al., 1993	II-2	Fair	B
2.	Lifestyle physical activities (home fitness programs) are just as effective in promoting weight loss as structured supervised exercise programs.	Anderson et al., 1999 Fogelholm et al., 2000	I	Good	A
3.	Moderate levels of physical activity should be performed at least 30 minutes most days of the week.	IOM, 2002 Jakicic et al., 2001 NHLBI, 1998 Saris et al., 2003	I	Fair	B
4.	Short intermittent bursts of physical activity are just as effective as longer continuous exercise.	Frick et al., 2001 Jakicic et al., 1999	I	Good	A

QE = Quality of Evidence; SR = Strength of Recommendation (see Appendix A)

C-3. Behavioral Modification Strategies

BACKGROUND

There is good evidence that behavioral modification interventions provide additional benefit to diet or exercise therapy alone in helping patients lose weight and prevent weight regain. Behavioral modification strategies provide education and encouragement to facilitate the adoption and maintenance of improved dietary and exercise patterns. Behavioral modification can be self-administered, a component of counseling, or part of a commercial/peer weight loss program. Common behavioral modification strategies include self-monitoring, stimulus control, positive reinforcement, stress management, problem solving or other skill training, social support, and cognitive restructuring activities. An explanation of specific behavioral modification strategies is found in the Appendix E: Behavioral Modification Strategies. *Evidence suggests that no single type of behavioral strategy is superior to the others and that multimodal strategies appear to work better than one strategy alone.*

RECOMMENDATIONS

1. Behavioral modification interventions to improve adherence to diet and physical activity should be given to overweight or obese individuals. [B]
2. Behavioral modification interventions should be provided at a higher intensity when possible for greater effectiveness. Higher intensity is defined as more than one personal contact per month for the first three months (individual or group setting). Less frequent intervention may be an ineffective and inefficient use of manpower. [B]
3. Multiple behavioral modification strategies should be used in combination for greater effectiveness. [A]
4. Behavioral modification intervention should be delivered in a group format when possible rather than individually. [B]
5. For individuals unable or unwilling to participate in weight loss treatment in person, telephone or internet-based behavioral modification intervention may be considered. [B]
6. Behavioral modification intervention should be continued on a long-term basis to promote maintenance of weight loss. [B]

DISCUSSION

Evidence for the efficacy of behavioral modification in promoting weight loss and maintenance has been described in the NHLBI Guidelines (1998), the United States Preventive Services Task Force (USPSTF, 2003) review, Wadden & Butryn (2003), the Health Technology Assessment review by NHS (Avenell et al., 2004), and the Institute for Clinical Systems Improvement (ICSI, 2005). Numerous RCTs have demonstrated additional benefit when behavioral modification was used with diet and exercise therapy. Behavioral modification is also often labeled "behavior therapy", "behavioral treatment" or "behavioral counseling." These terms refer to a variety of strategies which, in most studies reported in the literature, are not described in detail. Accordingly, clarity is compromised regarding the type of behavioral strategies utilized.

A meta-analysis of 4 RCTs described in the Health Technology Assessment (Avenell et al., 2004) demonstrated that adding behavioral modification to diet alone resulted in additional weight loss of 7.67 kg at 12 months and 4.1 kg at 18 months. At 36 and 60 months the addition of behavioral modification to diet still resulted in weight loss, but the outcomes were not statistically significant However, the number of participants contributing to the comparison decreased over time, limiting the accuracy of the comparisons over the longer time frame.

One cluster RCT assessed the added effects of 2 forms of behavioral modification to diet and exercise and measured change in weight at 12 months, where participants were randomized by appointment time. The added effect of "overt behavior therapy" (defined as self-monitoring, stimulus control and

cue reduction, slower eating, coping skills, and problem solving) to diet was associated with a mean weight change at 12 months of -3.26 kg compared with -4.82 kg in the diet only group and was not statistically significant. The added effect of "cognitive therapy" (defined as modifying eating behavior, cognitive restructuring, and relapse prevention) to diet was associated with a statistically significant difference in mean weight change at 12 months of -6.68 kg compared with -4.82 kg in the diet only group. Another study assessed the added effect of behavioral modification to diet, exercise, and sibutramine. Although results must be interpreted with caution due to a very low number of participants in the study, behavioral modification was reported to be associated with a mean weight change at 12 months of 10.69 kg. In comparing all treatments added to diet ("behavior therapy", exercise, sibutramine, and orlistat), the Health Technology Assessment review concluded that behavioral therapy was associated with the greatest weight change (-7.67 kg) (Avenell et al., 2004).

INTENSITY OF BEHAVIORAL INTERVENTION

The USPSTF (2003) defined behavioral modification interventions as:

High-intensity – if more than one person-to-person session occurred per month for the first three months

Moderate-intensity – if one session occurred per month for three months

Low-intensity – if anything less frequent

The USPSTF review documented evidence that high intensity interventions had greater effectiveness than moderate and low intensity interventions. That review concluded that evidence was insufficient to recommend either moderate or low intensity interventions.

COMBINATIONS OF BEHAVIORAL MODIFICATION STRATEGIES

Evidence related to behavioral strategies is summarized in the NHLBI Guideline (1998). Although no single behavioral modification strategy is more effective than another, combinations of several strategies have been shown to be more effective than relying on a single strategy. The vast majority of treatment programs and studies in the literature utilize multiple behavioral modification strategies.

GROUP VERSUS INDIVIDUAL BEHAVIORAL MODIFICATION

Intensive behavioral modification treatment is delivered in group settings in most cases, although treatment utilizing either group or individual formats is effective. Literature comparing the efficacy of group to individual interventions is sparse. One well controlled study by Renjilian and colleagues (2001) compared group versus individual behavioral modification treatment, as well as participant preference for group or individual format. For participants who completed the program, weight loss was greater for those in the group format compared to those who received treatment individually (11 kg vs. 9.1 kg, respectively). There was no difference in whether or not the group format was preferred by the participants.

TELEPHONE OR INTERNET-BASED TREATMENT

Treatment by telephone may be an alternative for those who cannot participate in face-to-face treatment. Although one study (Hellerstedt & Jeffery, 1997) found no difference among groups followed by telephone compared to groups without any follow-up, other studies have reported better results. Taken together, the studies suggest that telephone behavioral modification treatment may be an effective method for promoting weight loss. Jeffery et al. (2003) compared mail and telephone interventions with usual care in a managed care organization. At the 6 month follow-up, all groups had lost weight, but the telephone group had lost significantly more than the usual care group (2.38 kg vs. 1.47 kg, respectively). However, the differences between groups disappeared by 12 months. The phone group completed significantly more of the lessons than the mail group.

The internet provides another alternative to person-to-person treatment. Studies indicate that although intensive in-person treatment may be superior in effectiveness in many cases, internet adaptations are

also effective. Tate and colleagues (2003) compared a group which was given a basic internet behavioral weight loss program to a group given the basic internet program supplemented by individualized behavioral modification counseling by e-mail from an assigned weight loss counselor. Although both groups lost weight, an intention to treat analysis demonstrated significantly greater weight loss at 12 months (4.4 kg vs. 2 kg.) as well as reduction in BMI and WC for the group given additional e-mail behavioral modification counseling. The group given additional e-mail counseling logged in more often than the basic internet program group. Among both groups, those who logged in more often lost more weight. Tate et al. (2001) compared basic internet education on weight loss with internet education plus weekly behavioral lessons via email. An analysis of program completers showed a significantly higher weight loss in the education plus behavioral e-mail group compared to the education only group (4.1 kg vs. 1.6 kg). An intention to treat analysis of these groups had similar results. Harvey-Barino and colleagues (2004) compared groups who participated in a 6 month interactive television weight loss program. A 12 month maintenance program following the interactive television component offered one of two levels of on-going in-person support versus internet support. Results indicated no differences in weight loss among these groups at the end of 18 months of treatment, suggesting that internet follow-up was as effective as in-person follow-up contact.

MAINTENANCE

Evidence consistently demonstrates that the majority of people who lose weight regain most of that weight (over a period of one to five years) in the absence of continued intervention. This emphasizes the importance of continuing a maintenance behavioral program on a long-term basis. Reviews by Wadden and Butryn (2003), Jeffery et al. (2000), McTigue et al. (2003) and the ICSI review (2003) describe studies indicating that continued contact related to behavioral modification counseling facilitates weight maintenance.

Jeffery and colleagues (2000) reviewed studies that attempted to improve long-term maintenance of weight loss through a variety of means. The review concluded that extending the length of treatment and increasing the emphasis on exercise were beneficial in delaying the regain of weight formerly lost.

Perri et al. (1988) compared groups that underwent a 20 week behavioral treatment with no follow-up to four forms of follow-up contact, each with a different emphasis. The participants in the four continued contact groups maintained 82.7 percent of the mean post-treatment weight loss compared with 33.3 percent in the no-contact group.

Perri et al. (2001) compared two extended follow-up groups to a no contact group following a 20 week treatment program. Both the completer only and the intention-to-treat analysis found that those groups who were given extended contact maintained a significantly greater percentage of their initial weight loss at the 12 month post-treatment point.

Latner and colleagues (2002) followed participants in satellite clinic behavioral modification groups over 5 years. Participants remaining in the program at 1, 2, and 5 years achieved mean weight losses of 18 percent, 19 percent, and 18.4 percent, respectively. Ninety percent or more of the participants who continued the program maintained weight loss between 5 percent and 10 percent of their initial body weight. The average length of treatment was 2.3 years.

EVIDENCE

	Recommendation	Sources of Evidence	QE	Overall Quality	SR
1.	Behavioral modification interventions add effectiveness to diet and exercise interventions in promoting weight loss.	Avenell et al., 2004 ICSI, 2005 (TA #87) McTigue et al., 2003 NHLBI, 1998 Wadden & Butryn, 2003	I	Fair	B
2.	Behavioral modification interventions with greater intensity are more effective than those with less intensity in promoting weight loss.	NHLBI, 1998 McTigue et al., 2003	I	Fair	B
3.	Combined behavioral modification strategies are more effective than a single behavioral modification strategy in promoting weight loss.	NHLBI, 1998	I	Good	A
4.	Group-based behavioral modification counseling is more effective than individual counseling in promoting weight loss.	Renjilian et al., 2001	I	Fair	B
5.	Telephone and internet behavioral treatment is effective in promoting weight loss.	Boucher et al., 1999 Harvey-Barino et al., 2004 Jeffery et al., 2003 Tate et al., 2003	I	Fair	B
6.	Continued behavioral modification interventions are effective in sustaining weight loss.	Jeffery et al., 2000 Latner et al., 2002 McTigue et al., 2003 NHLBI, 1998 Perri et al., 1988 Perri et al., 2001 Wadden & Butryn, 2003	I	Fair	B

QE = Quality of Evidence; SR = Strength of Recommendation (see Appendix A)

C-4. Pharmacotherapy

BACKGROUND

Although lifestyle changes can result in weight loss for some, many overweight and obese patients need more efficacious interventions for weight reduction. The use of pharmacologic treatment has increased in response to the increasing prevalence of obesity. A number of medications have been approved for short-term use; diethylpropion, phentermine, as well as other medications have been used in research studies and shown to reduce weight (Li et al., 2005). The evidence of long-term efficacy is limited to orlistat and sibutramine.

Orlistat creates a caloric deficit by reducing the systemic absorption of dietary fat and the accompanying calories. Sibutramine is thought to induce weight loss by enhancing the feeling of satiety and by stimulating thermogenesis. Both orlistat and sibutramine are approved by the FDA for people with BMI greater than 30 kg/m^2 or BMI greater than 27 kg/m^2 with other obesity-associated conditions (e.g., diabetes, dyslipidemia or sleep apnea). However, side effects are possible with both medications and continual assessment by the provider for efficacy and safety is necessary.

A combined intervention of reduced-calorie diet, increased physical activity, and behavioral modification provides the most successful therapy for weight loss and weight maintenance. This type of intervention should be initiated or continued when pharmacotherapy is initiated.

Controversy exists around the *timing* of introducing pharmacotherapy into a weight loss program. Some providers favor prescribing these agents only after diet, exercise, and behavioral interventions have failed to provide weight loss consistent with weight loss goals. Others offer these agents earlier in treatment to assist in the initiation of weight loss, boost patient self-confidence, and expedite the reduction in risk for obesity related complications. Regardless of when pharmacotherapy is introduced, it should always be in combination with a lower calorie diet and other lifestyle changes.

For drug information please see Appendix F: Pharmacotherapy.

RECOMMENDATIONS

1. Adult patients with a BMI greater than 30 kg/m^2 or a BMI greater than 27 kg/m^2 with obesity-associated conditions may be considered for pharmacotherapy in combination with a reduced-calorie diet, increased physical activity and behavioral therapy. [B]
2. Patients who do not respond to medication with a reasonable weight loss should be evaluated for adherence to the medication regimen and adjunctive therapies or considered for an adjustment of dosage. [I]
3. If the patient continues to be unresponsive to the medication, or serious adverse effects occur, the use of medication should be discontinued. [I]

ORLISTAT

4. Orlistat may be considered to reduce body weight [B] and improve obesity-associated cardiovascular risk factors [C].
5. Patients who have lost 5 percent or more of their body weight after 12 weeks of treatment or lost an average of 1 pound or more per week with orlistat should continue their current treatment, as they are more likely to experience sustained weight loss. [B]
6. Orlistat may be considered as a component of weight maintenance programs for up to 4 years. [B]
7. Patients prescribed orlistat should take a multiple vitamin that includes fat soluble vitamins. [Expert Opinion]

SIBUTRAMINE

8. Sibutramine may be considered to reduce body weight [B] and improve glycemic and lipid parameters [C].
9. Patients who have lost an average of 1 pound or more per week during the first 4 weeks of therapy with sibutramine should continue treatment, barring any intolerable side effects. [Expert Opinion]
10. Patients who fail to lose 4 pounds after 4 weeks treated with sibutramine should have their adherence assessed and, if appropriate, an increase in the dose for an additional 4-week trial. [I]
11. Sibutramine may be considered as a component of weight maintenance programs for up to 2 years. [B]
12. Sibutramine should be discontinued if it is not efficacious in helping the patient to lose or maintain weight loss. [B]
13. Sibutramine should be used with caution as it can elevate blood pressure and heart rate. [A]
14. Adult patients with uncontrolled hypertension, cardiovascular disease, or a history of myocardial infarction (MI) or stroke should not include sibutramine as a part of their weight loss program due to the increased risk of harm. [D]
15. Sibutramine should be avoided in patients taking selective serotonin reuptake inhibitors (SSRIs), monoamine oxidase inhibitors (MAOIs), triptans, pseudoephedrine, and other agents that affect serotonin. [D]

DISCUSSION

COMBINED THERAPY

Systematic reviews, meta-analyses and subsequent RCTs provide good evidence that the use of medications (orlistat or sibutramine) combined with diet, exercise, and behavioral interventions result in weight loss in obese adults when used for 6 months to 1 year and can lessen weight regain as a part of a weight maintenance program (Apfelbaum et al., 1999; Arterburn et al., 2004a, Arterburn et al., 2004b; James et al., 2000; Li et al., 2005; O'Mera et al., 2002; Padwal et al., 2004; Shekelle et al., 2004; Torgerson et al., 2004, Wadden et al., 2005).

ORLISTAT

Biological Effects

Orlistat is an irreversible inhibitor of pancreatic and gastric lipases. Inhibition of these enzymes prevents the hydrolysis of dietary fat (in the form of triglycerides) into absorbable free fatty acids. As a result, undigested triglycerides are eliminated in the feces.

Efficacy for Acute Weight Loss

At least fair evidence was found that orlistat modestly increased weight loss compared with placebo in healthy obese adults and obese adults with diabetes, dyslipidemia, and hypertension. Mean difference in weight loss for orlistat-treated patients compared to placebo-treated patients was -2.51 kg at 6 months and -2.75 kg at 12 months. Mean absolute weight loss after 12 months of treatment ranged from -10.6 kg to -3.20 kg with orlistat and -6.2 kg to -1.3 kg with placebo (Padwal et al., 2004; Shekelle et al., 2004).

Efficacy in Weight Maintenance

Four orlistat weight loss trials included a continuation phase to assess weight maintenance. A total of 1,159 patients entered these continuation phases. All four studies included an orlistat 120 mg three times a day treatment arm (3 of the 4 studies included 60 mg three times a day treatment arms). In two studies patients were re-randomized to placebo or orlistat, patients in the other 2 studies continued on their previously assigned treatment. Diets either remained unaltered or were increased by 200-300 kcal/day for those continuing to lose weight.

In all four studies, weight regain during the maintenance phase was similar for the orlistat and placebo groups and the weight differential observed after the weight loss phase was preserved. Patients taking orlistat regained from 0.5 percent less to 0.5 percent more weight than those taking placebo. The absolute amount of weight lost during the year was greater in all orlistat treatment arms, thus when weight regain is expressed as a percentage of weight lost during year one, orlistat-treated patients regained 7 - 22 percent less weight than placebo-treated arms. Patients taking orlistat regained between 0.5 percent less to 0.5 percent more weight compared to those taking placebo (Padwal et al., 2004; Shekelle et al., 2004).

Effect on Secondary Outcome Measures

There is no direct evidence that orlistat reduces cardiovascular morbidity or mortality. Orlistat has been shown to improve cardiovascular risk factors in some clinical trials, although the clinical significance of these changes is likely to vary for each patient (Padwal et al., 2004; Shekelle et al., 2004).

Table 8 describes the differences between secondary outcomes (e.g., lipids, blood pressure, and glycemic control) measured in patients taking orlistat and those taking a placebo as reported by the Cochrane group (Padwal et al., 2004).

Table 8: Secondary Outcome Measures of Orlistat

Secondary Outcome Reduction	Number of Studies	Differences between Orlistat & Placebo (95% CI)	Test for Heterogeneity (p – value)
Total cholesterol, mg/dL	10	-12.9 (-14.7, -10.8)	0.88
LDL, mg/dL	10	-10.4 (-12.0, -8.5)	0.70
HDL, mg/dL	8	-0.8 (-7.5, -0.4)	0.33
TG, mg/dL	7	-4.4 (-15.1, 6.2)	0.02, I2=61%
SBP, mm Hg	9	-1.8 (-2.6, -0.9)	0.52
DBP, mm Hg	8	-1.6 (-2.4, -0.7)	0.04, I2=52%
Change in HbA1c	4	-0.2 (-0.3, 0.2)	0.4

[LDL – low-density lipoprotein, HDL – high density lipoprotein, TG – triglycerides, SBP – systolic blood pressure, DBP – diastolic blood pressure, HbA1c – glycosylated hemoglobin, I2 = amount of variation explained by heterogeneity, values greater than 65% indicates substantial heterogeneity.]

Change in WC was reported in five studies, with the reduction greater in patients taking orlistat compared to placebo; the effect size ranged from 0.7 to 3.4 cm (p less than 0.05) in four of the five studies. Due to heterogeneity, the nine trials reporting fasting plasma glucose results could not be pooled. Patients treated with orlistat, compared to placebo, showed greater reductions in fasting blood plasma glucose concentrations ranging from 1.8 to 23.4 mg/dL. The results were statistically significant in five of these studies. Four studies reported changes in glycosylated hemoglobin

concentrations; pooled results found a 0.2 percent (95%CI: 0.2 - 0.3 percent; test for heterogeneity 0.4) greater reduction in patients treated with orlistat compared to placebo.

Another systematic review of the clinical effectiveness and cost effectiveness of orlistat was completed in 2001. The methodology was similar to that of other systematic reviews and evaluated 14 clinical trials. Orlistat was shown to reduce a person's weight between 2 to 5 kilograms greater than placebo over a period of a year. This was accompanied by small but significant reductions in total cholesterol, the ratio of total cholesterol to high-density lipids, and both diastolic and systolic blood pressure (O'Mera et al., 2002).

Orlistat produced statistically significant improvements in glycemic control, cholesterol, and blood pressure; however, the clinical significance of these changes in cardiovascular risk factors may be small. One RCT with a high rate of attrition found that orlistat treatment for four years increased weight loss and significantly reduced the incidence of type 2 diabetes in patients with impaired glucose tolerance at baseline (Torgerson et al., 2004).

Adverse Effects

Orlistat treatment is associated with an increase in diarrhea, flatulence, and bloating/abdominal pain/dyspepsia in orlistat-treated patients, compared to placebo, with relative risks for these adverse events of 3.4, 3.1, and 1.5, respectively (Shekelle et al., 2004).

Patients prescribed orlistat are not to consume more than 30 percent of their daily calories from fat and their dietary fat intake is to be divided equally between their three meals in order to minimize their risk for gastrointestinal adverse events.

Drug Interactions

The absorption of fat soluble vitamins has been shown to be reduced with orlistat. A pharmacokinetic interaction study found that beta-carotene supplement absorption was reduced by 30 percent when taken simultaneously with orlistat. Orlistat inhibited the absorption of a vitamin E supplement by approximately 60 percent (Xenical Package Insert, 2000).

SIBUTRAMINE

Biological Effects

Sibutramine, through two active metabolites (M_1 and M_2), inhibits the reuptake of norepinephrine and serotonin within the hypothalamic areas involved in the regulation of eating behavior. Sibutramine does not directly affect the neuronal release of serotonin, norepinephrine, or dopamine, thus differentiating it from anorectic agents such as fenfluramine and amphetamines.

Efficacy for Acute Weight Loss

Fair evidence was found that sibutramine modestly increased weight loss compared with placebo in healthy obese adults and obese adults with diabetes, dyslipidemia, and hypertension. Mean weight loss differences for sibutramine-treated patients, compared to placebo-treated patients, were -4.45 kg (95% CI: −3.62 to −5.29 kg) and −2.78 kg (95% CI: -2.26 to -3.29 kg), respectively. In clinical trials of 12 months duration, mean absolute weight loss ranged from -6.4 to -4.4 kg with sibutramine and -1.6 to +0.5 kg for placebo (Arterburn et al., 2004b). In a study requiring patients to lose at least 6 kg in four weeks on a LCD prior to randomization to sibutramine or placebo, patients taking sibutramine lost an absolute average of ~14 kg in 12 months, while those taking placebo lost an absolute average of ~7.2 kg (Apfelbaum et al., 1999). Another trial randomized patients to sibutramine or placebo after 6 months of sibutramine and a reduced-calorie diet. At the end of the study, patients who took sibutramine the entire 24 months lost an absolute average of 10.2 kg compared to 4.7 kg for those randomized to

placebo for the final 18 months of the trial. Sibutramine in combination with lifestyle modification (weekly group meetings for 18 weeks followed by 10 weeks at every other week) resulted in significant greater mean weight loss (12.1 kg) than sibutramine-alone (5 kg), lifestyle modification alone (6.7 kg) or sibutramine plus brief therapy (7.5 kg) after 18, 40 and 52 weeks ($p<0.001$ for all comparisons) (Wadden et al.,2005). There was no direct evidence that sibutramine reduces incident obesity-associated disease or mortality (James et al., 2000).

Efficacy in Weight Maintenance

At the end of a two year study, mean weight loss with sibutramine was 4 kg greater than with placebo.

Effect on Secondary Outcome Measures

There is no direct evidence that sibutramine reduces cardiovascular morbidity or mortality. The effect of sibutramine on cardiovascular risk factors has been studied in some clinical trials and found to be small and of no clinical benefit. Of greater concern is the potential for sibutramine to significantly increase blood pressure and heart rate in susceptible patients increasing their risk for cardiovascular events.

Table 9 describes the differences between secondary outcomes (e.g., lipids, blood pressure and glycemic control) measured in patients taking sibutramine and those taking a placebo as reported by the Cochrane group (Padwal et al., 2004).

Table 9: Secondary Outcome Measures of Sibutramine

Outcomes	Difference: Sibutramine to Placebo (95% CI)	Test for Heterogeneity (p – value0
Change in BMI	1.5 kg/m^2 reduction (1.2 – 1.8 kg/m^2)	0.79
Waist circumference	4 to 5 cm reduction	<0.05
Waist:Hip	0.1 reduction	>0.05
HDL	1.3 – 3.5 mg/dL increase	<0.05
Triglycerides	15.9 – 20.4 mg/dL decrease	<0.05
Total cholesterol and LDL	No difference	–
Fasting blood glucose (FBG)	1.4 and 1.6 mg/dL decrease	–

I2 = amount of variation explained by heterogeneity; values >65% indicates substantial heterogeneity.

Table 10 describes the effects on the mean difference between sibutramine and placebo from another systematic review and meta-analysis of secondary outcome measures according to study duration (Arterburn et al., 2004a & 2004b).

Table 10: Secondary Outcome Measures of Sibutramine According to Study Duration

Outcomes	8 to 12 Weeks	16 to 24 Weeks	44 to 55 Weeks
Blood Pressure, mmHg			
Systolic	-0.2	-1.6 to +5.6	+4.6
Diastolic	+1.6	-0.8 to +1.7	+2.8
Heart Rate, BPM	+1.3	+0.75 to +5.9	+5.9
Glycemic Control			
Fasting glucose, mg/dL	-19.8	-9.0 to -4.0	-3.6
HbA1c, %	-0.4	-0.1	-0.3
Lipids, mg/dL			
Total cholesterol		-1.9 to +1.8	0
LDL	N/A	+0.6 to +2.6	0
HDL		+1.5 to +5.5	1.8
Triglycerides		-16.8 to 0	-3.6

At the end of a two year study, WC decreased by a mean of 3.7 cm more with sibutramine (95% CI: 2 - 5.4) and waist:hip ratio was reduced by 1.3 with sibutramine (95% CI: 0.2 – 2.4). High density lipids increased by 0.13 mmol/L with sibutramine, $p<0.05$ (James et al., 2000).

Adverse Effects

There is fair evidence that sibutramine treatment is associated with a modest increase in heart rate and blood pressure. A systematic review found no deaths were reported in 44 published clinical trials (Arterburn et al., 2004a). However, Italy suspended use of sibutramine because of reported deaths. This suspension was lifted after a review by Europe's Committee for Proprietary Medicinal Products released a report in June of 2002 that sibutramine's benefit/risk ratio was favorable (Petition to the FDA, 2002). Health Canada reviewed the 28 adverse reactions reported in Canada between December 2000 and February 2002, and another 53 reported between March 2002 and November 2002. It was concluded that the reactions reported were consistent with those known to occur with sibutramine including increased blood pressure, chest pain, stroke, and eye pain and hemorrhage. No deaths were reported. Health Canada concluded that sibutramine continued to meet the requirements for sale in Canada (Health Canada Online 2002, 2003).

In the U.S., Public Citizen, a nationwide consumer organization, petitioned to have the FDA withdraw sibutramine from the market. Public Citizen based its petition on the concerns raised during the initial FDA approval, Italy's recent suspension of sibutramine marketing, and its own review of 397 serious adverse reactions reported to the FDA between February 1991 and September 2001. Of the 397 patients, 152 were hospitalized and 29 died, 19 from cardiovascular causes. Another 143 patients were reported to have an arrhythmia (Petition to the FDA, 2002). The FDA rejected Public Citizen's petition on August 17, 2005 stating that "sibutramine's overall risk-benefit profile supports it remaining available as a prescription drug for the treatment of appropriately selected obese patients."

Drug Interactions

The use of sibutramine with a monoamine oxidase inhibitor is contraindicated. The use of sibutramine in combination with other central nervous system (CNS) agents that affect serotonin concentrations (e.g., selective serotonin reuptake inhibitors [SSRI] antidepressants and the triptans) may increase the

risk of serotonin syndrome and patients requiring these combinations should be monitored. Sibutramine is not to be taken with other agents that may increase blood pressure and heart rate such as pseudoephedrine (Merida Package Insert, 2003).

EVIDENCE

	Recommendation	Sources of Evidence	QE	Overall Quality	SR		
					↓ Weight	↓ CV Risk	↓ Morbidity Mortality
1.	Pharmacotherapy may be considered for BMI greater than 30 kg/m^2 or a BMI greater than 27 kg/m^2 with one or more obesity related risk factors.	Apfelbaum et al., 1999 Arterburn, 2004 James et al., 2000 Li et al., 2005 McTigue et al., 2003 O'Meara et al., 2002 Shekelle et al., 2004 Torgerson et al., 2004	I	Fair	B	C	I
2.	Orlistat may be considered to reduce body weight and improve obesity-associated cardiovascular risk factors.	Lindegarde et al., 2000 Padwal et al., 2004 Shekelle et al., 2004	I	Fair	B	C	I
3.	Patients who have lost greater than or equal to 5% of their body weight after 12 weeks of treatment with orlistat are more likely to experience sustained improvement.	Rissanen et al., 2003	II-2	Fair	B	C	I

	Recommendation	Sources of Evidence	QE	Overall Quality	SR		
					↓ Weight	↓ CV Risk	↓ Morbidity Mortality
4.	Orlistat may be considered as a component of weight maintenance programs for up to 4 years.	Padwal et al., 2004 Shekelle et al., 2004 Torgerson et al., 2004	I	Fair	B	C	B (new onset diabetes)
5.	Sibutramine may be considered to reduce body weight and improve glycemic and lipid parameters.	Arterburn, 2004 Arterburn, 2004 McTigue et al., 2003 Padwal et al., 2004 Shekelle et al., 2004	I	Fair	B	C	I
6.	Sibutramine may be considered as a component of weight maintenance program for up to 2 years.	Arterburn, 2004a Arterburn, 2004b Padwal et al., 2004 Shekelle et al., 2004	I	Fair	B	C	I
7.	Sibutramine should be used with caution as it can elevate blood pressure and heart rate.	Arterburn et al., 2004a Arterburn et al., 2004b Padwal et al., 2004	I	Good	A		
8.	Avoid sibutramine in adult patients with uncontrolled hypertension, cardiovascular disease, and history of MI or stroke due the increased risk of harm.	Arterburn et al., 2004a Arterburn et al., 2004b Padwal et al., 2004	II-3	Fair	D		

QE = Quality of Evidence; R = Recommendation (see Appendix A); N/A = Not Applicable

C-5. Bariatric Surgery

BACKGROUND

Because surgery has significant technical issues, complications, and cost, and requires extensive pre- and peri-operative preparation, it is usually considered in those with more severe obesity who have failed to control weight by other means and who remain at high-risk of medical comorbidities. Postoperative lifestyle modifications, as well as monitoring for complications of surgery, require life-long follow-up.

Morbidly obese patients (i.e., those with BMI greater than 40) do not usually achieve substantial weight loss as a result of lifestyle modifications and drug therapy. Only bariatric surgery has been demonstrated to consistently result in profound and long-term weight loss for the morbidly obese. There are several types of surgical options for qualified patients. Bariatric operations can be broadly categorized into two types: restrictive and malabsorptive. Currently there two accepted surgical

approches to bariatric surgery. Restrictive procedures include gastric banding (GB), adjustable gastric banding (AGB), and horizontal- and vertical-banded gastroplasty. Malabsorptive procedures include biliopancreatic diversion (BPD) and biliopancreatic diversion with duodenal switch (BPD/DS). The Roux-en-y gastric bypass (RYGB) combines both restrictive and malabsorptive techniques. (See Appendix G: Bariatric Surgery)

The RYGB procedure is most commonly performed in the United States. Laparoscopic approaches are available for most bariatric procedures, and have lower mortality and morbidity than open approaches, although specialized skills and equipment are required. Bariatric procedures have been shown to result in substantial weight loss, and they may also improve or resolve several comorbid conditions including diabetes, hypertension, and dyslipidemia.

These operations are associated with some degree of morbidity and mortality and also require good adherence to medical follow-up. Thus, any patient being considered for bariatric surgery should be carefully evaluated. Patients who are older than age 65, weigh more than 400 pounds, or who have severe comorbidity may be at greater risk for morbidity and mortality. The decision regarding surgery should be individualized, weighing both the benefits and risks.

RECOMMENDATIONS

1. Adult patients with extreme obesity (BMI 40 kg/m^2 or more) or severe obesity (BMI 35 kg/m^2 or more with one or more obesity-associated chronic health condition) may be considered for bariatric surgery to reduce body weight [A], improve obesity-associated comorbidities [B], and improve quality of life [B].
2. Roux-en-y Gastric Bypass (RYGB) is recommended as the bariatric procedure with the most robust evidence for inducing sustained weight loss [B] for patients with BMI greater than 40 kg/m^2.
3. There is insufficient evidence to recommend for or against the routine use of bariatric surgery in those over 65 years of age and patients with a substantial surgical risk. [I]
4. Providers should engage all patients who are candidates for bariatric surgery in a detailed discussion of the benefits and potential risks of bariatric procedures. [I]
5. Relative contraindications to bariatric surgery that are supported only by expert consensus include:
    - Unstable coronary artery disease, severe pulmonary disease, portal hypertension or other conditions that can compromise anesthesia or wound healing
    - Patients who are unable to comprehend basic principles of surgery or follow-up postoperative instructions
    - Patients having had multiple abdominal operations, complicated incisional hernias
    - Patients who have illnesses that greatly reduce life expectancy and/or are unlikely to be improved in their medical condition by surgically-induced weight reduction (e.g.,., cancer).
6. Lifelong medical follow-up after surgery is necessary to monitor adherence to treatment, adverse effects and complications, dietary restrictions, and behavioral health. [I]

PREOPERATIVE REQUIREMENTS

Nearly all issued candidacy guidelines for bariatric surgery have emulated the 1991 NIH consensus conference (NIH, 1991). By their own admission, the NIH panel derived guidelines based on what little evidence existed at the time and called for more research to refine the criteria. Since that time, little has been added to the literature to change these recommendations. Surgery may be considered for patients with a body mass index of 40 kg/m^2 or higher, or for those with a body mass index exceeding 35 kg/m^2, if their obesity is complicated by significant comorbid disease.

There is no consensus regarding what is required for patients before considering bariatric surgery. Numerous insurance companies require enrollment in a structured weight loss program for a prescribed period of time before patients can be considered for these procedures. There is no evidence supporting this practice, either as a legitimate preoperative criterion or as an effective means to prepare patients for surgery. Similarly, although often required preoperatively, no evidence supports routine preoperative assessment by mental health providers. As with all general surgical procedures, a complete history and physical is required. A history of diabetes and hypertension control, the presence of sleep apnea, and asthma should be investigated. Nearly all obese patients have shortness of breath. If shortness of breath is severe, cardiac evaluation looking for pulmonary hypertension is warranted. Smokers should be encouraged to quit and must abstain from smoking

An integrated program should be in place, both prior to and after the surgical procedure, that will provide guidance and support. The support includes necessary dietary regimen, appropriate physical activity, patient education, behavioral therapy and social support. Adherence to restricted diet, physical activity and lifestyle changes is essential to long-term maintenance of weight loss after surgery. Patients should receive preoperative nutritional counseling to ensure they understand postoperative dietary requirements and the need for lifestyle alteration. Many patients suffer from clinical depression pre-operatively. Occasionally, these depressions persist post-operatively or patients who were not previously depressed become depressed post-operatively and require treatment. In addition, lifelong medical surveillance after bariatric surgery should include monitoring for inadequate nutrition, changes in the status of chronic health conditions and procedure-specific complications such as anemia.

- While evidence to support absolute contraindications for bariatric surgery is lacking, expert consensus states that women who are pregnant or who are considering pregnancy in the next two years should not be considered candidates for bariatric surgery. Other relative contraindications to bariatric surgery that are supported only by expert consensus (Saltzman, 2005) include conditions that compromise anesthesia or wound healing, lack of patients' ability to follow pre- and postoperative instructions, general high risk surgical conditions (multiple operations or complicated incisional hernias), and reduce life expectancy..

DISCUSSION

WEIGHT LOSS

For adults with a BMI greater than or equal to 40 kg/m^2 there is good evidence from numerous high quality systematic reviews that bariatric surgery is the only effective therapy for promoting clinically significant weight loss (ECRI, 2005; Maggard et al., 2005; Shekelle et al., 2004). The Emergency Care Research Institute (ECRI) technology assessment reported that weight loss was maintained for at least 3 years for all types of bariatric procedures examined (ECRI, 2005) even though the typical patient remained obese (BMI $\geq 30kg/m^2$) following surgery. The studies included in the assessment typically excluded patients with uncontrolled psychiatric disorders, substance abuse, oxygen dependence, severe cardiovascular disease, or status post MI, or who were wheelchair bound. Therefore, the safety and efficacy of weight loss surgery in these populations remains unknown.

BMI Less than 40 kg/m^2

Patients with a BMI between 35 and 40 kg/m^2 who have obesity-associated comorbidity should also be considered for weight loss surgery. Available data strongly supports bariatric surgery to promote weight loss and also supports improvement of a number of obesity-associated comorbidities in this patient group; however, the evidence for this group is not as robust as for patients with a BMI above 40 kg/m^2 (Shekelle, 2004). Notably, the NIH has consistently recommended consideration of bariatric surgery for this group of patients if other weight loss attempts have failed (NHLBI 1998; NIH, 1991). More data are needed to confirm or refute the relative efficacy of surgery for less severely obese persons.

COMORBIDITY

There is fair evidence that surgery induced weight loss improves obesity-associated comorbidities (Maggard et al., 2005; Shekelle et al., 2004). Evidence from numerous studies suggests that several obesity related conditions including diabetes (Pories et al., 1995; Sugerman et al., 2003), hypertension (Sugerman et al., 2003), dyslipidemia (Gleysteen, 1992: Gleysteen et al., 1990; Gleysteen & Barboriak, 1983; Karason et al., 2000), and sleep apnea (Karason et al., 2000) were improved or resolved following bariatric surgery. However, the evidence was graded as fair, because relatively few studies reported these outcomes and most studies were not designed to prove that surgery caused the morbidity resolution. Additionally, all but one study has incomplete follow-up for the cohorts examined.

QUALITY OF LIFE

Fair evidence exists for substantial improvement in quality of life (QOL) (Livingston & Fink, 2003) for patients following bariatric surgery (Karlsson J, 1998).

TYPE OF SURGERY

There is fair evidence from RCTs and observational studies demonstrating that Roux-en-y gastric bypass (RYGB) results in greater weight loss than vertical banded gastroplasty and adjustable gastric banding (ECRI, 2005; Shekelle et al., 2004; Sugerman et al., 1989 & 1987) and that vertical banded gastroplasty results in greater weight loss than adjustable gastric banding procedures (ECRI, 2005). Data regarding the efficacy of adjustable gastric banding procedures includes only a minority of studies reporting long-term (longer than 3 year) weight loss outcomes.

Evidence is rated as fair to support the application of long-limb gastric bypass (LL-RYGB) to effect substantial weight loss, but the evidence supporting comorbidity control is weaker (Brolin et al., 2001; Inabnet, 2005). Only a small number of studies of Biliopancreatic Diversion (BPD) and Biliopancreatic Diversion with Duodenal Switch (BPD/DS) meet criteria for inclusion in an evidence-based review. All had a small number of patients. In general, there is weak evidence supporting their efficacy for weight loss and comorbidity control.

There is consistent evidence from several RCTs that laparoscopic procedures result in equivalent weight loss and fewer wound complications than open procedures. Less consistent evidence from the same RCTs suggests that laparoscopic procedures result in reduced duration of hospital stay when compared with open procedures. There is insufficient evidence to compare laparoscopic and open procedures in regards to other major complications and long-term survival (Colquitt et al., 2004; Lee et al., 2004; Lujan et al., 2004; Olbers et al., 2005; Shekelle et al., 2004).

ADVERSE EFFECTS OF SURGERY

Bariatric procedures have complications and adverse effects and there is a risk for mortality from these procedures. Adverse events occur in about 10 to 20 percent of cases (Flum & Dellinger, 2004; Livingston, 2004). The rates of mortality and adverse events vary according to the type of procedure performed.

A series of systematic reviews of randomized controlled trials, cohort studies, and case-series have found the 30-day risk of death from surgery varies with the type of bariatric procedure performed and ranges from 0 to 1.9 percent (Maggard et al., 2005; Shekelle et al., 2004). Advanced age, male gender, and super obesity have consistently been associated with higher mortality risk from these operations (Livingston et al., 2002; Livingston, 2004; Livingston & Ko, 2002; Melinek et al., 2002; Zingmond et al., 2005). The rates of mortality and adverse events vary according to the type of procedure performed.

One retrospective cohort study of people who underwent bariatric surgery (16,155 Medicare beneficiaries) found that 30-day, 90-day, and 1-year mortality rates were 2 percent, 2.8 percent, and 4.6 percent, respectively (Flum, 2005). Mortality rates were greater for those aged 65 years or older compared with younger people (4.8 percent vs 1.7 percent at 30 days; 6.9 percent vs 2.3 percent at 90 days; and 11.1 percent vs 3.9 percent at 1 year; $P<0.001$) (Flum, 2005).

Operative and postoperative complications are common and vary with the type of bariatric procedure performed. Major complications, such as pulmonary emboli, anastomotic leaks, peritonitis, and abscesses can occur resulting in significant morbidity. In general, these major complications are uncommon, each having an approximately 1 percent incidence. Other less severe complications of weight loss procedures include incisional and internal hernias, wound infections, and anastomotic strictures. When they occur, these complications typically can be resolved with appropriate therapy. Re-operations are required in 1.3 percent to 11.3 percent of cases, and this rate varies according to the type of procedure performed (Shekelle et al., 2004).

Gastrointestinal symptoms are common after bariatric procedures, occurring in 7.7 to 37.7 percent of cases (Shekelle et al., 2004). These can usually be managed with careful patient follow-up and compliance with postoperative dietary guidelines. Patients that have had a gastric bypass operation may experience dumping syndrome when they ingest sugars and fats. Dumping Syndrome is manifested by abdominal cramps, diarrhea, heart palpitations, or dizziness.

Bariatric patients, especially those who undergo procedures with malabsorptive components, are prone to developing nutritional deficiencies, including reduced levels of iron, calcium, folate, and vitamins A, D, E, K, and B12. Multivitamin/mineral pills can usually provide enough of these substances to avoid deficiencies. One exception is Vitamin B12, which is poorly absorbed following gastric bypass procedures and may need to be supplemented by periodic injections.

In pregnancy all bariatric procedures can lead to deficiencies in iron, vitamin B12, folate, and calcium. These deficiencies can result in maternal complications, such as severe anemia, and in fetal complications including neural tube defect, intrauterine growth restriction, and failure to thrive. Nutrient supplementation following bariatric surgery and close supervision before, during, and after pregnancy can help prevent nutrition-related complications and improve maternal and fetal health.. Therefore, women who have undergone weight loss surgery and subsequently become pregnant need to receive intensive nutritional follow-up by providers with expertise in clinical nutrition.

EVIDENCE

	Recommendation	Sources of Evidence	QE	Overall Quality	SR
1.	Bariatric surgery (RYGB, AGB, & vertical banded gastroplasty [VBG]) to promote substantial long-term (3 years) weight loss in patient with BMI ≥40 or BMI ≥35 with comorbid conditions.	ECRI, 2005 Maggard et al., 2005 Shekelle et al., 2004	I	Good	B
2.	Bariatric surgery (RYGB, AGB, & VBG) to improve or resolve comorbid conditions.	Buchwald et al., 2004 ECRI, 2005 Sjostrom et al., 2004	I	Fair*	B
3.	Bariatric surgery (RYGB, AGB, & VBG) to improve quality of life.	ECRI, 2005 Karlsson J, 1998 Shekelle et al., 2004	I	Fair*	B
4.	Bariatric surgery to improve long-term (greater than 5 years) survival.	Christou et al., 2004 Flum & Dellinger, 2004	II-2	Poor	I
5.	RYGB to promote greater weight loss than VBG or ABG.	Buchwald et al., 2004 ECRI, 2005 Maggard et al., 2005 Shekelle et al., 2004	I	Fair	B
6.	Bariatric surgery in those over 65 years of age has higher risk of mortality	ECRI, 2005 Flum, 2005 Shekelle et al., 2004	II-3	Fair	I
7.	Preoperative requirements or effective means to prepare patients for surgery.	Expert Opinion Saltzman E., 2005	III	Poor	I
8.	Contraindication for bariatric surgery.	Expert Opinion	III	Poor	I

***** *Evidence quality was rated as fair, because few studies reported these outcomes consistently, and few studies were designed to examine the impact of surgery on these outcomes.*

QE = Quality of Evidence; SR = Strength of Recommendation (see Appendix A)

APPENDICES

APPENDIX A
Guideline Development Process

The development of the Screening and Management of Overweight and Obesity Guideline was initiated in January 2005 and continued through August 2005. The development process followed the steps described in "Guideline for Guidelines," an internal working document of VHA's National Clinical Practice Guideline Council, which requires an on-going review of the work in progress. The Working Group of the VHA/DoD was charged to provide evidence-based action recommendations whenever possible; hence, major clinical randomized controlled trials (RCTs) and observational studies published from 1995 through December 2004 in the areas of diagnosis and treatment of overweight and obesity were used.

Guideline Development Process

The Offices of Quality and Performance and Patient Care Services, in collaboration with the network Clinical Managers, the Deputy Assistant Under Secretary for Health, and the Medical Center Command of the DoD identified clinical leaders to champion the guideline development process. During a preplanning conference call, the clinical leaders defined the scope of the guideline and identified a group of clinical experts from the VA and DoD that formed the Guideline Development Working Group. Working Group members included representatives of the following specialties: internal medicine, cardiology, surgery, endocrinology, medical nutrition therapy, social work, family practice, nursing, pharmacy, and healthcare systems management and policy.

As a first step, the guideline development groups defined a set of clinical questions within the area of the guideline. This ensured that the guideline development work outside the meeting focused on issues that practitioners considered important and produced criteria for the search and the protocol for systematic review and, where appropriate, meta-analysis.

The Working Group participated in an initial face-to-face meeting to reach consensus about the guideline algorithm and recommendations and to prepare a draft document. The draft continued to be revised by the Working Group at-large through numerous conference calls and individual contributions to the document. Following the initial effort, an editorial panel of the Working Group convened to further edit the draft document. Recommendations for the performance or exclusion of specific procedures or services were derived through a rigorous methodological approach that included the following:

- Determining appropriate criteria, such as effectiveness, efficacy, population benefit, or patient satisfaction
- Reviewing literature to determine the strength of the evidence in relation to these criteria
- Formulating the recommendations and grading the level of evidence supporting the recommendation

Experts from the VA and DoD internal medicine, cardiology and primary care reviewed the final draft and their feedback was integrated into the final draft document. This document will be updated every three years, or when significant new evidence is published to ensure that Department of Veterans Affairs (VA) and Department of Defense (DoD) healthcare delivery remains on the cutting edge of the latest medical research.

This 2005 Guideline is the product of many months of diligent effort and consensus building among knowledgeable individuals from the VA, DoD, academia, as well as guideline development consultants from the private sector. An experienced moderator facilitated the multidisciplinary Working Group. The list of participants is included in Appendix I.

Formulating of Questions

The Working Group developed researchable questions and associated key terms after orientation to the scope of the guideline and to goals that had been identified by the Working Group. The questions specified (adapted from the Evidence-Based Medicine (EBM) toolbox, Center for Evidence-Based Medicine, (http://www.cebm.net):

- **P**opulation – Characteristics of the target patient population
- **I**ntervention – Exposure, diagnostic, or prognosis
- **C**omparison – Intervention, exposure, or control used for comparison
- **O**utcome – Outcomes of interest

These specifications served as the preliminary criteria for selecting studies. Research questions focused on the following areas of inquiry: screening; risk assessment; and treatment strategies for weight loss including diet, exercise and behavioral modification, drug therapy, and bariatric surgery.

Selection of Evidence

Published, peer-reviewed RCTs were considered to constitute the strongest level of evidence in support of guideline recommendations. This decision was based on the judgment that RCTs provide the clearest, scientifically sound basis for judging comparative efficacy. The Working Group made this decision recognizing the limitations of RCTs, particularly considerations of generalizability with respect to patient selection and treatment quality. Evidence-based systematic reviews were considered to be the strongest level of evidence as well as meta-analyses that included randomized controlled studies. The evidence selection was designed to identify the best available evidence to address each key question and ensured maximum coverage of studies at the top of the hierarchy of study types: evidence-based guidelines, meta-analyses, and systematic reviews. When available, the search sought out critical appraisals already performed by others that described explicit criteria for deciding what evidence was selected and how it was determined to be valid. The sources that have already undergone rigorous critical appraisal include Cochrane Reviews, Best Evidence, Technology Assessment, and EPC reports.

The search was performed using the National Library of Medicine's (NLM) Medline database. The terms "obesity", "weight gain", "body mass index" and "overweight" were used together with the following Boolean expressions and terms:

- Screening
- Lifestyle
- Caloric restriction, diet
- Behavioral therapy
- Anti-obesity agents
- Gastric bypass
- Patient education
- Human, adults

In addition to Medline/PubMed, the following databases were searched: Database of Abstracts of Reviews of Effectiveness (DARE) and Cochrane Central Register of Controlled Trials (CCTR). For Medline/PubMed searches, limits were set for language (English), date of publication (1995 through 2004) and type of research (RCT, systematic reviews and meta-analysis).

Once definitive reviews or clinical studies that provided valid relevant answers to the question were identified, the search ended. The search was extended to studies/reports of lower quality (observational studies) only if there were no high-quality studies.

Exclusion criteria included reviews that omitted clinical course or treatment. Some retrieved studies were rejected on the basis of published abstracts, and a few were rejected after the researchers scanned the retrieved citation for inclusion criteria. Typical exclusions included studies with physiological endpoints or studies of populations that were not comparable to the population of interest (e.g., studies of obesity in children). The bibliographies of the retrieved articles were hand-searched for articles that may have been missed by the computer search. Working Group members also contributed articles as part of the evidence gathering process.

The results of the search were organized and evidence reports as well as copies of the original studies were provided to the Working Group for further analysis. Each reference was appraised for scientific merit, clinical relevance, and applicability to the populations served by the Federal healthcare system. Recommendations were based on consensus of expert opinions and clinical experience only when scientific evidence was unavailable.

Literature Review and Inclusion Criteria

As a result of the original and updated literature reviews, articles were identified for possible inclusion. These articles formed the basis for formulating the guideline recommendations. The following inclusion criteria were used for selecting randomized controlled trial studies:

- Articles published between 1995 and 2004, with some exceptions
- English language only
- Full articles only
- Age limited to adults greater than 18 years
- Randomized controlled trials only; no cross-over trials
- Minimum 6 months of follow-up
- Baseline BMI or body weight levels reported
- Key outcomes cited (decrease in body weight, BMI)

For some questions, special inclusion criteria (mostly related to minimum clinical trial size) were developed based upon research question content and available literature.

The literature search for the guideline update was validated by: (1) comparing the results to a search conducted by the independent research and appraisal team, (2) a review of the database by the expert panel, and (3) requesting articles pertaining to special topics from the experts in the Working Group.

Preparation of Evidence Tables (Reports) and Evidence Rating

A group of research analysts with experience in evidence-based appraisal independently read and coded each article that met inclusion criteria. The articles have been assessed for methodological rigor and clinical importance using the following criteria:

- Appropriateness of inclusion and exclusion criteria
- Concealment of allocation
- Blinding of patients, interventions and providers
- Objective method of data collection
- Valid method of data analysis
- Completeness and length of follow-up
- Appropriateness of outcome measures
- Statistical power of results

The information was synthesized and reported in a brief summary of the critical appraisal of each article that included the following components:

- Description of patient population
- Interventions
- Comparisons
- Outcomes
- Summary of results
- Analysis of findings
- Evidence appraisal
- Clinical significance

Quality of evidence ratings were assigned for each source of evidence using the grading scale presented in Table A-1 [USPSTF, 2001).

Recommendation and Overall Quality Rating

Evidence-based practice involves integrating clinical expertise with the best available clinical evidence derived from systematic research. The Working Group received an orientation and tutorial on the evidence USPSTF 2001 rating process, reviewed the evidence and independently formulated Quality of Evidence ratings (see Table A-1), a rating of Overall Quality (see Table A-2), and a Strength of Recommendation (see Table A-4).

Evidence Rating System

Table A-1: Quality of Evidence (QE)

I	At least one properly done RCT
II-1	Well-designed controlled trial without randomization
II-2	Well-designed cohort or case-control analytic study, preferably from more than one source
II-3	Multiple time series evidence with/without intervention, dramatic results of uncontrolled experiment
III	Opinion of respected authorities, descriptive studies, case reports, and expert committees

Table A-2: Overall Quality

Good	High grade evidence (I or II-1) directly linked to health outcome
Fair	High grade evidence (I or II-1) linked to intermediate outcome; *or* Moderate grade evidence (II-2 or II-3) directly linked to health outcome
Poor	Level III evidence or no linkage of evidence to health outcome

Table A-3: Net Effect of the Intervention

Substantial	More than a small relative impact on a frequent condition with a substantial burden of suffering; *or* A large impact on an infrequent condition with a significant impact on the individual patient level.
Moderate	A small relative impact on a frequent condition with a substantial burden of suffering; *or* A moderate impact on an infrequent condition with a significant impact on the individual patient level.
Small	A negligible relative impact on a frequent condition with a substantial burden of suffering; *or* A small impact on an infrequent condition with a significant impact on the individual patient level.
Zero or Negative	Negative impact on patients; *or* No relative impact on either a frequent condition with a substantial burden of suffering; or an infrequent condition with a significant impact on the individual patient level.

Table A-4: Strength of Recommendation

	The net benefit of the intervention			
Quality of Evidence	**Substantial**	**Moderate**	**Small**	**Zero or Negative**
Good	A	B	C	D
Fair	B	B	C	D
Poor	I	I	I	I

A	A strong recommendation that the clinicians provide the intervention to eligible patients. *Good evidence was found that the intervention improves important health outcomes and concludes that benefits substantially outweigh harm.*
B	A recommendation that clinicians provide (the service) to eligible patients. *At least fair evidence was found that the intervention improves health outcomes and concludes that benefits outweigh harm.*
C	No recommendation for or against the routine provision of the intervention is made. *At least fair evidence was found that the intervention can improve health outcomes, but concludes that the balance of benefits and harms is too close to justify a general recommendation.*
D	Recommendation is made against routinely providing the intervention to asymptomatic patients. *At least fair evidence was found that the intervention is ineffective or that harms outweigh benefits.*
I	The conclusion is that the evidence is insufficient to recommend for or against routinely providing the intervention. *Evidence that the intervention is effective is lacking, or poor quality, or conflicting and the balance of benefits and harms cannot be determined.*

Lack of Evidence – Consensus of Experts

The majority of the literature supporting the science for these guidelines is referenced throughout the document and is based upon systematic reviews and technology assessment that serve as the basis for other evidence-based guidelines for overweight and obesity, and key RCTs and longitudinal studies published from 1995 through 2004. Following the independent review of the evidence, a consensus meeting was held to discuss discrepancies in ratings and formulate recommendations. Where existing literature was ambiguous or conflicting, or where scientific data was lacking on an issue, recommendations were based on the clinical experience of the Working Group. These recommendations are indicated in the evidence tables as based on "Working Group Consensus."

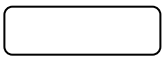
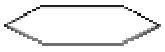
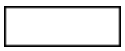
Algorithm Format

The goal in developing the guideline for overweight and obesity was to incorporate the information from several existing, national consensus, and evidence-based guidelines into a format which would maximally facilitate clinical decision-making. The use of the algorithm format was chosen because of the evidence that such a format improves data collection, diagnostic and therapeutic decision-making and changes patterns of resource use. However, few guidelines are published in such a format. To enhance continuity of care, the guideline was designed to encompass a broad spectrum of outpatient care to detect and treat obese or overweight persons. This required incorporating multiple published guidelines into a single, unified document.

The algorithmic format allows the provider to follow a linear approach to critical information needed at the major decision points in the clinical process, and includes:

- An ordered sequence of steps of care
- Recommended observations
- Decisions to be considered
- Actions to be taken

A clinical algorithm diagrams a guideline into a step-by-step decision tree. Standardized symbols are used to display each step in the algorithm (Society for Medical Decision-Making Committee [SMDMC], 1992). Arrows connect the numbered boxes indicating the order in which the steps should be followed.

	Rounded rectangles represent a clinical state or condition.
	Hexagons represent a decision point in the guideline, formulated as a question that can be answered Yes or No. A horizontal arrow points to the next step if the answer is YES. A vertical arrow continues to the next step for a negative answer.
	Rectangles represent an action in the process of care.
	Ovals represent a link to another section within the guideline.

A letter within a box of an algorithm refers the reader to the corresponding annotation. The annotations elaborate on the recommendations and statements that are found within each box of the algorithm. Included in the annotations are brief discussions that provide the underlying rationale and specific evidence tables. Annotations indicate whether each recommendation is based on scientific data or expert opinion. A complete bibliography is included in the guideline.

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APPENDIX B
Body Mass Index (BMI) Calculation Chart

For additional BMI calculators and tables see: http://www.cdc.gov/nccdphp/dnpa/bmi/

Body Mass Index Table

	Normal						Overweight					Obese										Extreme Obesity														
BMI	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38	39	40	41	42	43	44	45	46	47	48	49	50	51	52	53	54
Height (inches)																Body Weight (pounds)																				
58	91	96	100	105	110	115	119	124	129	134	138	143	148	153	158	162	167	172	177	181	186	191	196	201	205	210	215	220	224	229	234	239	244	248	253	258
59	94	99	104	109	114	119	124	128	133	138	143	148	153	158	163	168	173	178	183	188	193	198	203	208	212	217	222	227	232	237	242	247	252	257	262	267
60	97	102	107	112	118	123	128	133	138	143	148	153	158	163	168	174	179	184	189	194	199	204	209	215	220	225	230	235	240	245	250	255	261	266	271	276
61	100	106	111	116	122	127	132	137	143	148	153	158	164	169	174	180	185	190	195	201	206	211	217	222	227	232	238	243	248	254	259	264	269	275	280	285
62	104	109	115	120	126	131	136	142	147	153	158	164	169	175	180	186	191	196	202	207	213	218	224	229	235	240	246	251	256	262	267	273	278	284	289	295
63	107	113	118	124	130	135	141	146	152	158	163	169	175	180	186	191	197	203	208	214	220	225	231	237	242	248	254	259	265	270	278	282	287	293	299	304
64	110	116	122	128	134	140	145	151	157	163	169	174	180	186	192	197	204	209	215	221	227	232	238	244	250	256	262	267	273	279	285	291	296	302	308	314
65	114	120	126	132	138	144	150	156	162	168	174	180	186	192	198	204	210	216	222	228	234	240	246	252	258	264	270	276	282	288	294	300	306	312	318	324
66	118	124	130	136	142	148	155	161	167	173	179	186	192	198	204	210	216	223	229	235	241	247	253	260	266	272	278	284	291	297	303	309	315	322	328	334
67	121	127	134	140	146	153	159	166	172	178	185	191	198	204	211	217	223	230	236	242	249	255	261	268	274	280	287	293	299	306	312	319	325	331	338	344
68	125	131	138	144	151	158	164	171	177	184	190	197	203	210	216	223	230	236	243	249	256	262	269	276	282	289	295	302	308	315	322	328	335	341	348	354
69	128	135	142	149	155	162	169	176	182	189	196	203	209	216	223	230	236	243	250	257	263	270	277	284	291	297	304	311	318	324	331	338	345	351	358	365
70	132	139	146	153	160	167	174	181	188	195	202	209	216	222	229	236	243	250	257	264	271	278	285	292	299	306	313	320	327	334	341	348	355	362	369	376
71	136	143	150	157	165	172	179	186	193	200	208	215	222	229	236	243	250	257	265	272	279	286	293	301	308	315	322	329	338	343	351	358	365	372	379	386
72	140	147	154	162	169	177	184	191	199	206	213	221	228	235	242	250	258	265	272	279	287	294	302	309	316	324	331	338	346	353	361	368	375	383	390	397
73	144	151	159	166	174	182	189	197	204	212	219	227	235	242	250	257	265	272	280	288	295	302	310	318	325	333	340	348	355	363	371	378	386	393	401	408
74	148	155	163	171	179	186	194	202	210	218	225	233	241	249	256	264	272	280	287	295	303	311	319	326	334	342	350	358	365	373	381	389	396	404	412	420
75	152	160	168	176	184	192	200	208	216	224	232	240	248	256	264	272	279	287	295	303	311	319	327	335	343	351	359	367	375	383	391	399	407	415	423	431
76	156	164	172	180	189	197	205	213	221	230	238	246	254	263	271	279	287	295	304	312	320	328	336	344	353	361	369	377	385	394	402	410	418	426	435	443

Source: Adapted from *Clinical Guidelines on the Identification, Evaluation, and Treatment of Overweight and Obesity in Adults: The Evidence Report.*

APPENDIX C
Diet Therapy

Table C-1: Low-Calorie Diet – General GuideLine

Nutrient	Recommended Intake
Calories	To achieve and maintain desired weight
Total Fat	30% or less of total calories
Saturated Fat	7 – 10% of total calories
Polyunsaturated Fat	Up to 10% of total calories
Monounsaturated Fat	Up to 15% of total calories
Cholesterol	Less than 300 mg/day
Protein	Approximately 15% of total calories
Carbohydrate	55% or more of total calories
Sodium Chloride	No more than 100 mmol/day (approximately 2.4 grams of sodium or 6 grams of sodium chloride)
Calcium	1,000 – 1,500 mg/day
Fiber	20 – 30 grams/day

NHLBI, 1998

Table C-2: Nutrient Composition of the Therapeutic Lifestyle Changes (TLC) diet

Nutrient	Recommended Intake
Saturated Fat*	Less than 7% of total calories
Polyunsaturated Fat	Up to 10% of total calories
Monounsaturated Fat	Up to 20% of total calories
Total Fat	25 – 35% of total calories
Carbohydrate**	50 – 60% of total calories
Fiber	20 – 30 grams/day
Protein	Approximately 15% of total calories
Cholesterol	Less than 200 mg/day
Total calories (energy)***	Balance energy intake and expenditure to maintain desirable body weight/prevent weight gain

NHLBI, 1998

* Trans fatty acids are another LDL-raising fat that should be kept as a low intake.

** Carbohydrate should be derived predominantly from foods rich in complex carbohydrates including grains, especially whole grains, fruits, and vegetables.

*** Daily calorie expenditure should include at least moderate physical activity (contributing approximately 200 kcal per day).

Exchange Lists For Meal Planning

Table C-3: STARCH LIST

1 Starch exchange = 80 calories, 15 grams carbohydrate, 0-1 grams fat

Breads	**Serving Size**
Bread: White, Whole wheat, Pumpernickel, Rye	1
Bread, reduced-calorie	2
White, Whole Wheat Pita, reduced-calorie	½
Tortilla, corn or flour (6 inch across)	1
Bagel, 4 oz	¼
English Muffin	½
Hamburger or hot dog bun	½
Cereals and Grains	
Bran cereals (concentrated)	⅓ cup
Bran cereals (flaked)	½ cup
Cereal, unsweetened, ready to eat	¾ cup
Cereal, sugar frosted, ready to eat	½ cup
Cereal (cooked)	½ cup
Rice, white or brown (cooked)	⅓ cup
Grits	½ cup
Pasta, white, whole wheat (cooked)	½ cup
Noodles, egg (cooked)	½ cup
Couscous (cooked)	3 cups
Starchy Vegetables	
Corn	½ cup
Corn on cob (6 inch)	½
Dried beans and peas, cooked	½ cup
Miso	3 Tbsp
Potato, baked, boiled (medium)	½ or ½ cup
Potato, mashed	½ cup
Sweet potato, yam	½ cup
Squash, winter	½ cup
Crackers and Snacks	
Popcorn (plain)	3 cups
Animal crackers	8
Pretzels, thin	12
Saltines	6
Whole wheat crackers, no fat added	2-5 (¾ oz)
Graham crackers, squares	8

* Choose high fiber starchy foods whenever possible.

Table C-4: vegetable (non-starchy) list
1 Vegetable exchange = 25 calories, 5 grams carbohydrate, 0 grams fat
1 cup cooked vegetables or vegetable juice
1 cup raw vegetables

Artichoke	Mixed vegetables (without corn, peas, pasta)
Artichoke hearts	Mushrooms
Asparagus	Okra
Beans (green, waxed, Italian)	Onions
Bean sprouts	Pea pods
Beets	Peppers (all types)
Broccoli	Radishes
Brussels Sprouts	Rutabaga
Cabbage	Salad greens
Carrots	Spinach
Cauliflower	Summer squash
Celery	Tomato
Cucumber	Tomato or vegetable juice
Eggplant	Turnips
Green onions or scallions	Water chestnuts
Greens (collard, kale, mustard, turnip)	Watercress
Kohlrabi	Zucchini
Leeks	

Table C-5: FAT LIST
1 Fat exchange = 45 calories, 5 grams fat

***Monounsaturated Fats**	**Serving Size**
Avocado	2 Tbsp
Oil (canola, olive, peanut)	1 tsp
Nuts (almonds, cashews)	6 nuts
Peanut Butter	½ Tbsp
Olives, black	8 large
Polyunsaturated Fats	
Mayonnaise, reduced fat	1 Tbsp
Nuts, walnuts	4 halves
Salad dressing, regular	1 Tbsp
Salad dressing, reduced fat	2 Tbsp
****Saturated Fats**	
Butter, stick	1 tsp
Coconut, shredded	2 Tbsp
Cream cheese, regular	1 Tbsp
Cream cheese, reduced fat	1½ Tbsp
Sour cream, regular	2 Tbsp
Sour cream, reduced fat	3 Tbsp

*Beneficial, heart healthy fats, however, use in moderation.
**Limit as often as possible.

Table C-6: FRUIT LIST

1 Fruit exchange = 60 calories, 15 grams carbohydrate, 0 grams fat

Fresh, frozen, no sugar added fruit	**Serving Size**
Apple	1
Applesauce	½ cup
Apricots	4
Banana (9 inch)	½
Blackberries, raw	¾ cup
Blueberries, raw	¾ cup
Cherries, raw	12
Cantaloupe (5 inch diameter)	⅓ melon
Fruit cocktail	½ cup
Grapefruit, medium	½
Grapes	15
Honeydew melon	⅛ melon
Kiwi	1
Mandarin Oranges, canned	¾ cup
Mango, small	½
Nectarine, small	1
Orange, small	½
Papaya	1 cup
Peach, medium, fresh	¾-1 cup
Pear, large, fresh	½
Pears, canned	½ cup
Pineapple, canned	⅓ cup
Pineapple, fresh	¾ cup
Plum (2 inch diameter)	2
Raspberries, raw	1 cup
Strawberries, raw	1 cup
Tangerine, small	2
Watermelon	1¼ cup
Dried fruit	
Apples	4 rings
Apricots	7 halves
Dates	2½
Figs	1½
Prunes	3 medium
Raisins	1 Tbsp
Fruit Juice	
Apple, grapefruit, orange, pineapple	½ cup (4 oz)
Cranberry, grape, prune	⅓ cup

Avoid canned fruits packed in heavy syrup.

Table C-7: MILK(DAIRY) LIST

1 Milk exchange = 12 grams carbohydrate, 8 grams protein

Fat free/Low-fat Milk: 90 calories, 0-3 grams fat/serving	**Serving Size**
Milk (skim, or 1%)	1 cup
Evaporated milk, canned	½ cup
Buttermilk (skim or low-fat)	1 cup
Soy milk, (fat free or low-fat)	1 cup
Yogurt (fat free plain, low-fat flavored with nonnutritive sweetener and fructose)	1 cup
Non-dairy creamer	(varies)
Frozen yogurt (fat free or skim)	½ cup
Reduced Fat Milk: 120 calories, 5 grams fat/serving	
2 % milk	1 cup
Soy milk	1 cup
Yogurt, low-fat	1 cup

Table C-8: MEAT AND PROTEIN LIST

1 Meat/Protein exchange = 0 grams carbohydrate, 7 grams protein; 1 oz unless otherwise stated

Very Lean Meats: 35 calories, 0-1 grams fat/serving
Chicken, turkey, white meat, no skin
Fish – fresh or frozen
Shellfish – clams, oysters, shrimp, squid, scallops, octopus, lobster
Tuna – canned in water (rinse to remove sodium)
Cheese, fat free
Cottage cheese, low-fat
Egg substitutes (¼ cup)
Beans, peas, lentils (cooked) - (count as 1 starch exchange and 1 very lean meat exchange) (½ cup)
Lean Meats: 55 calories, 3 grams fat/serving
Chicken, turkey – dark meat, no skin
Lean beef – round, sirloin, flank steak
Lean pork – tenderloin, ham
Low-fat luncheon meats with < 3 grams fat/serving)
Salmon, tuna canned in oil
Cheese with < 3 grams fat per ounce
Cottage cheese, 4.5% (¼ cup)
Medium Fat Meats: 75 calories, 5 grams fat/serving
Beef, most cuts, prime cuts, short ribs
Pork, chop, top loin
Chicken, turkey (dark meat, with skin)
Fried fish
Cheese with < 5 grams fat/serving
Egg
Tempeh (¼ cup)
Tofu (4 oz or ½ cup)

Choose very lean and lean meats more often than medium fat meats.

American Diabetes Association and American Dietetic Association. Exchange Lists for Weight Management, 2003.

APPENDIX D
Physical Activity/Exercise

Table D-1: Examples of Moderate* Amounts of Activity (NHLBI, 1998)

- Washing and waxing a car for 45-60 minutes
- Washing windows or floors for 45-60 minutes
- Playing volleyball for 45 minutes
- Playing touch football for 30-45 minutes
- Gardening for 30-45 minutes
- Wheeling self in wheel-chair for 30-40 minutes
- Walking 1¾ miles in 35 minutes (20 min/mile)
- Basketball (shooting baskets) for 30 minutes
- Bicycling 5 miles in 30 minutes
- Dancing fast (social) for 30 minutes
- Pushing a stroller 1½ miles in 30 minutes
- Raking leaves for 30 minutes
- Walking 2 miles in 30 minutes (15 min/mile)
- Water aerobics for 30 minutes
- Swimming laps for 20 minutes
- Wheelchair basketball for 20 minutes
- Basketball (playing a game) for 15-20 minutes
- Bicycling 4 miles in 15 minutes
- Jumping rope for 15 minutes
- Running 1½ miles in 15 minutes (10 min/mile)
- Shoveling snow for 15 minutes
- Stairwalking for 15 minutes

*A moderate amount of physical activity is roughly equivalent to physical activity that uses approximately 150 calories of energy per day or 1,000 calories per week.
**Some activities can be performed at various intensities; the suggested durations correspond to expected intensity of effort.

Table D-2: Duration of Various Activities to Expend 150 Kilocalories for an Average 70 kg (154 lb) Adult

Intensity	Activity	Approximate Duration in Minutes
Moderate	Volleyball, noncompetitive	43
Moderate	Walking, moderate pace (3 mph, 20 min/mile)	37
Moderate	Walking, brisk pace (4 mph, 15 min/mile)	32
Moderate	Table tennis	32
Moderate	Raking leaves	32
Moderate	Social dancing	29
Moderate	Lawn mowing (powered push mower)	29
Hard	Jogging (5 mph, 12 min/mile)	18
Hard	Field hockey	16
Very Hard	Running (6 mph, 10 min/mile)	13

Source: Surgeon General's Report on Physical Activity and Health

APPENDIX E

Behavioral Modification Strategies

"Behavioral modification" includes a wide variety of techniques designed to alter unhealthy behavior and may be effectively utilized in weight control. Behavioral modification can be self-administered, a component of counseling (behavioral counseling), or a part of a commercial/peer weight loss program. The purpose is to facilitate the adoption and maintenance of weight control behaviors such as altered dietary intake, eating behaviors, and exercise. Several of the more commonly utilized techniques are described below.

Self-monitoring is perhaps the most often employed strategy. This involves recording all instances of the behavior in question. In weight control, patients record their food intake in detail on either an intermittent or continuous basis. Time of day, and associated thoughts, feelings, and/or events are often recorded as well. Recording food intake and associated events allows the identification of eating patterns, eating cues, and measurement of actual food intake. Awareness of these factors promotes the development of methods to change.

Stimulus control or **cue reduction** strategies refer to efforts to change the environmental signals or cues for any specific behavior, in this case, eating and/or sedentary behaviors. Examples include removing fattening food from sight, eating only at the table rather than when watching TV, avoiding fast food restaurants, having healthy snacks immediately available, having walking shoes placed in a convenient spot where they will be noticed, and so on. The overall idea is to eliminate signals for inappropriate eating, and substitute cues for helpful weight control behaviors in their place.

Positive reinforcement refers to the provision of rewards for desirable behavior. **Contingency management** is establishing a defined schedule for the delivery of either rewards or punishments. Accordingly, a reward is delivered "contingent upon" completion of a specified behavior or performance of a desired behavior (e.g., staying within a certain caloric intake for a day or performing 30 minutes of exercise). Positive reinforcement is generally preferred over punishment to alter weight control behaviors, because people develop a positive association between desirable behaviors and receipt of reward. In this fashion, the desirable behavior eventually becomes self-rewarding.

Stress management is utilized in treatment of numerous conditions to reduce felt stress, because excess stress often stimulates inappropriate or self-defeating behavior. In weight control, excessive stress frequently leads to over-eating and/or failure to exercise. Stress management includes a wide variety of techniques such as relaxation training, biofeedback training, stimulus control, cognitive restructuring, social support, assertiveness training, problem solving, and skill training. Taken together, the patient becomes more resistant to becoming overly stressed and more capable of coping with and reducing felt stress when it is noticed.

Problem solving involves training the patient to more effectively analyze problems which might otherwise lead to inappropriate or self-defeating behavior such as over-eating. Once contributing factors are accurately analyzed, possible solutions are considered and evaluated for the pros, cons, and probable outcome of each solution and a workable solution is agreed upon.

Skill training refers to training a patient in those skills that are likely to enhance success. For example, weight control patients are taught skills in evaluating the caloric content of various foods and in planning ahead to avoid overly tempting eating situations. Patients might also be taught skills in eating more slowly, cooking more healthfully, or refusing offers for second helpings or dessert from relatives or friends who might be pressuring them to overindulge.

Social support is widely acknowledged to facilitate almost every difficult behavior and to improve coping in troublesome situations. People receive encouragement, positive reinforcement, emotional empathy and support, and guidance from others. A comforting (and stress reducing) feeling of "not

being alone" comes from being in the presence of others who are in the same difficult situation, as occurs in weight control groups, Alcoholics Anonymous, cancer support groups, and many others.

Cognitive therapy or "cognitive restructuring" is a process whereby patients are taught to become fully aware of their negative or self-defeating thoughts, to counteract those thoughts, and to then replace them with more realistic, adaptive, and positive thoughts. Those thoughts then stimulate more desirable behaviors. Negatively oriented, discouraging, self-defeating, over-reactive, and unrealistic thoughts mediate much inappropriate and/or maladaptive behavior. People are frequently not fully aware of thoughts such as "I MUST clean my plate!", "I'll just DIE if I can't have that piece of cake!", "Taking a walk is really going to HURT!" These thoughts often lead to engaging in undesirable behavior.

APPENDIX F

Pharmacotherapy

Table F-1: Recommended Dosage For Selected Obesity Drug Therapy

Drug	Usual Dosage Range	Comments
Gastrointestinal Lipase Inhibitor		
Orlistat	120 mg three times daily	Taken with or within 1 hour of each meal containing fat. Omit dose if a meal is skipped or a meal contains no fat. Must take once daily multivitamin at least 2 hours prior to orlistat. (containing fat soluble vitamins A,D,E and K) *Cautions:* Increased gastrointestinal events (adverse effects) when orlistat is taken with diet high in fat (greater than 30% total daily calories from fat). Orlistat is FDA Category B and is not recommended for use during pregnancy. It is not known if orlistat is secreted in human breast milk. Orlistat should not be taken by mothers who are nursing.
Dopamine, Serotonin, Norepinephrine Reuptake Inhibitor		
Sibutramine	10 mg daily 15 mg daily (if after 4 weeks weight loss not adequate)*	Taken with or without food. *Contraindications:* Contraindicated in patients receiving monoamine oxidase inhibitors (MAOIs). Contraindicated in patients who have a major eating disorder (anorexia nervosa or bulimia nervosa). *Cautions:* Sibutramine substantially increases blood pressure and/or pulse rate in some patients. Regular monitoring of blood pressure and pulse rate is required when prescribing. Sibutramine should not be used in patients with a history of coronary artery disease, congestive heart failure, arrhythmias, or stroke. Sibutramine can cause mydriasis; it should be used with caution in patients with narrow angle glaucoma. Organic causes of obesity (e.g., untreated hypothyroidism) should be excluded before prescribing. Certain centrally-acting weight loss agents that cause release of serotonin from nerve terminals have been associated with pulmonary hypertension, a rare but lethal disease. It is not known if sibutramine can cause this disease. Use cautiously in patients with a history of seizures. Discontinue in patients who develops seizures. There have been reports of bleeding in patients taking sibutramine. While a causal relationship is unclear, caution is advised in patients predisposed to bleeding events and those taking concomitant medications known to affect hemostasis or platelet function. Weight loss can precipitate or exacerbate gallstone formation. Patients with severe renal impairment or severe hepatic dysfunction have not been systematically studied; therefore it is not be used in such patients. Sibutramine did not affect psychomotor or cognitive performance in healthy volunteers; however, any central nervous system active drug has the potential to impair judgment, thinking, or motor skills. Sibutramine is FDA Category C and its use during pregnancy is not recommended. It is not known if sibutramine or its metabolites are secreted in human breast milk. Sibutramine should not be taken by mothers who are nursing.

For complete drug information, review the manufacture's prescribing information: *Roche, Inc. package literature for Xenical, 1999, revised September 2, 2005; Abbott, Inc. package literature for Meridia, Sep 2004. Check for updated monographs at www.pbm.va.gov*

* Sibutramine dosage:

- Patients who have lost less than 4 pounds after 4 weeks of treatment with sibutramine 10 mg per day can have their dose increased to 15 mg per day.

- Patients who have lost greater than or equal to 4 pounds after 4 weeks of treatment with sibutramine 10 mg or 15 mg per day should continue sibutramine. Those who do not should be reevaluated.

Table F-2: Cost for Obesity Drug Therapy

Drug	Usual Dose	DoD cost/day/patient	VA cost/day/patient	DoD cost/year	VA cost/year	Cost-effective analysis/Year
Orlistat	120 mg three times daily	$1.76	$1.76	$643	$643	$3421 5 patients need to be treated for 1 patient to loose 5% of body weight
Sibutramine	5 mg daily	$1.88	$1.88	N/A	N/A	$1835 to $2372
	10 mg daily	$1.87	$1.87	$683	$683	3 patients need to be treated for 1 patient to loose 5% of body weight
	15 mg daily	$2.42	$2.42	$883	$883	

*This table reflects usual doses and does not reflect equivalent doses.

N/A = not applicable since 5 mg is only used in dose titration

1. DoD does not cover obesity drugs as part of the TRICARE Pharmacy Benefit
2. DoD Pricing: updated prices may be obtained from the Defense Supply Center Philadelphia (DSCP)
3. VHA Federal Supply Schedule (FSS) Pricing: updated prices may be obtained from the Pharmacy Benefits Management (PBM) Bulletin Board at 708-531-7947.
4. No products at this time are National Formulary item (VA/DoD)

Table F-3: Drug or Nutrient Interactions with Anti-Obesity Agents

Interactive Agent(s)		Clinical Manifestations
Orlistat	Cyclosporine	May decrease CYCLOSPORINE whole blood concentrations (possibly resulting in a decrease in the immunosuppressive action of CYCLOSPORINE; monitor and adjust as necessary). Take cyclosporine 2 hours before or after orlistat. More frequent monitoring of cyclosporine levels should be considered.
	Fat Soluble Vitamins (A, D, E)	May decrease absorption of some fat soluble vitamins (A, D, E, and K). Levels of vitamin D and beta-carotene may be low in obese patients compared with non-obese subjects. The supplement should be taken 2 hours before or after orlistat.
	Warfarin	Patients taking warfarin should be monitored closely and warfarin dose adjusted accordingly.
Sibutramine	Dextromethorphan Ergot Alkaloids Dihydroergotamine Ergotamine Methysergide Lithium MAO Inhibitors Isocarboxazid, Phenelzine, Tranylcypromine Meperidine Selective 5-HT1 Receptor Agonists Naratriptan, Rizatriptan, Sumatriptan, Zolmitriptan Serotonin Reuptake Inhibitors Fluoxetine, Fluvoxamine, Nefazodone, Paroxetin, Sertraline, Venlafaxine Tryptophan Pseudoephedrine	May increase the risk of serotonin syndrome. Typical symptoms of serotonine syndrome include tachycardia and hypertension. In severe cases hyperthermia and dramatic swings in pulse and blood pressure may develop. Physical examination findings include: hyperthermia; agitation; slow, continuous, horizontal, eye movements (referred to as ocular clonus); tremor; akathisia; deep tendon hyperreflexia; inducible or spontaneous clonus; muscle rigidity; bilateral Babinski signs; dilated pupils; dry mucus membranes; increased bowel sounds; flushed skin; and diaphoresis. Neuromuscular findings are typically more pronounced in the lower extremities. Concomitant administration of these agents is not recommended by the manufacturer. If concurrent use cannot be avoided, carefully monitor the patient for adverse effects. The serotonin syndrome requires immediate medical attention.

*This table includes significant drug interactions (to date) and may not encompass all possible agents.

For complete drug information, review the manufacture's prescribing information:

1. Roche, Inc package literature for Xenical, 1999.

2. Abbott, Inc. package literature for Meridia, Sep 2004.

3. Drug Facts & Comparisons. Drug Interaction Facts. J.B. Lippincott Co., St. Louis, Missouri, 2004.

APPENDIX G
Bariatric Surgery

The performance of bariatric surgery has increased over the last decade, corresponding with a number of factors, not the least of which is the growing epidemic problem of morbid obesity in the United States. The other major factor that has led to its growing acceptance is the advent of minimally invasive techniques to perform bariatric operations. In 2005, the most common procedure performed is the Roux-en-y gastric bypass in which an as-small-as-possible gastric pouch is stapled and a roux limb of jejunum is anastomosed. The next most common bariatric procedure, which is increasing in numbers, is adjustable gastric banding (*LapBand* [BioEnterics/Inamed Corp.; Santa Barbara, California]). In this procedure, a silastic inflatable band is placed around the cardia of the stomach; a reservoir port placed under the skin can expand or desufflate the band to create more or less restriction to food. There are a number of issues surrounding these operations with which clinicians must be familiar.

1. Stricture of gastrojejunostomy: Gastrojejunostomy stricture occurs in 1 to 10 percent of patients after Roux-en-y gastric bypass. The complication occurs more frequently following the laparoscopic than the open gastric bypass. Anastomotic stricture presents with dysphagia, vomiting, and/or food intolerance. This problem is generally easily addressed by endoscopic balloon dilation. Follow-up dilations may be required, but surgical revision is rarely required. Most surgeons are comfortable performing this procedure approximately 2-3 weeks after surgery and this complication rarely develops before that time.

2. Gastrointestinal bleeding: Gastrointestinal bleeding occurs in approximately 1 to 2 percent of patients after Roux-en-y gastric bypass, and usually occurs from one of the various staple lines. The gastric pouch and anastomotic staple lines are easily identified with upper endoscopy. The jejunojejunostomy may be as far as 150 cm distal to the gastrojejunostomy making this anastomosis less accessible by endoscopy unless a very long enteroscope is used. As with most gastrointestinal bleeding, endoscopic therapy is the preferred method of management and should be performed with the knowledge of the operating surgeon. Bleeding can also occur from the gastric remnant staple line, which is usually not accessible through normal endoscopy. If this occurs in the acute setting, surgical intervention is often required. If this complication occurs remote from the original operation, it can be managed by angiography and potentially by creating a gastrostomy to the gastric remnant, performing endoscopy through this access. Under these circumstances, the patient should be referred to a center with experienced bariatric surgeons.

3. Marginal ulcer: Ulcers may occur, usually on the gastric side of the gastrojejunostomy. These ulcers are usually thought to be ischemic in nature; however, in most cases, the gastric pouch looks otherwise well perfused. Almost all of these patients will heal with a course of proton-pump inhibition. Follow-up endoscopy should be performed to document resolution. When refractory to medical treatment, the anastomosis might require revision. Marginal ulcer bleeding can be severe but usually responds to endoscopic intervention. Patients with perforated marginal ulcers can occasionally be managed nonoperatively if they are not septic.

4. Bowel obstruction: As with any operation, adhesive bowel obstructions may occur as a result of gastric bypass. Laparoscopic gastric bypasses have a relatively high rate of internal hernias resulting in bowel obstructions. As with any obstruction, the presenting symptoms are vomiting, abdominal distension and pain. Internal hernias can present more insidiously with intermittent symptoms such as cramping and abdominal pain that resolves spontaneously. A high index of suspicion is needed to make the diagnosis. Contrast X-rays or CT scan may suggest the diagnosis of internal hernia but often surgical exploration based on a high index of suspicion confirms the diagnosis of internal hernia. Fortunately, most partial bowl obstructions resulting from adhesions resolve with bowel rest alone. Complete bowel obstructions require emergent surgery.

5. Complications of the *LapBand* : Although this procedure is associated with fewer acute peri-operative complications, it has its own set of potential problems. As with any prosthesis, there can be migration of the band caudal or cephalad, as well as *into* the esophagus or stomach. Patients may also present with severe food intolerance. A certain degree of such intolerance is necessary, however, in order for the action of the band to allow for weight loss. There have been reports of significant esophageal dilation and promotion of gastroesophageal reflux but these are seen less frequently than was the case for banded gastroplasties. In most cases, deflating the band will correct these problems if the patient has not lost the desired weight; conversion to a Roux-en-y gastric bypass may be required.

TYPE OF SURGERY

Figure G-1. Roux-en-y gastric bypass. The stomach is either divided or stapled closed. A limb of jejunum is brought to the resultant pouch. The length of this limb is usually about 75 cm, however, in the long-limb variation of this procedure the limb may be as long as 150 cm.

Figure G-2. Biliopancreatic diversion or duodenal switch. These operations add significant nutrient malabsorption to the gastric restrictive component typical of the gastric bypass. The biliopancreatic diversion operation is similar to the gastric bypass but the intestinal limb is very long. Approximately 100 to 150 cm of small bowel is in contact with both the biliopancreatic secretions as well as food. Consequently, these operations can cause substantial nutrient malabsorption. Vitamin deficiencies are common. The most problematic is profound hypocalcemia caused by diminished small bowel absorption of calcium as well as vitamin D deficiency. Deficiencies of fat soluble vitamins (A, D, E, and K) are relatively common. The major advantage of these operations is that weight loss results irrespective of a patient's eating habits. A common side effect of the operation is malodorous flatus. The duodenal switch procedure is similar to the biliopancreatic diversion except that the duodenum is capped and is bypassed along with the small bowel. Rather than create a pouch, the gastric remnant is a sleeve along the lesser curve and about four times the size of the gastric bypass pouch. This operation has the advantage of retaining the pylorus, minimizing problems related to dumping syndrome and marginal ulcer.

Figure G-3. Adjustable gastric banding procedure. An inflatable band is placed around the proximal stomach by a laparoscopic approach. A reservoir is placed in a subcutaneous location that enables the band to be inflated or deflated depending on what the patient's requirements are. This operation has few complications and almost no mortality. Although safe, the weight loss effect is more gradual than from gastric bypass procedures. Ultimately, however, patients will lose the same amount of weight as from a gastric bypass.

Figure G-4. Vertical band gastroplasty. This operation was very commonly performed in the 1970's and 1980's. Because weight loss is transient most surgeons now perform gastric bypass procedures as their primary operation. Limitations from of the banded gastroplasty operations are not seen with the laparoscopic adjustable banding procedure. This appears to result from the adjustable nature of the band in contrast to the fixed obstruction that exists with a banded gastroplasty.

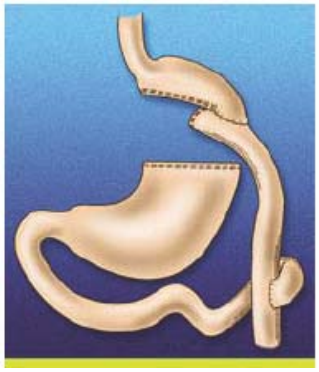

Figure G-1. Roux-en-y gastric bypass

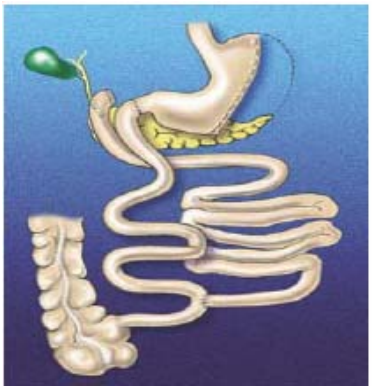

Figure G-2. Biliopancreatic diversion or duodenal switch

Figure G-3. Adjustable gastric banding procedure

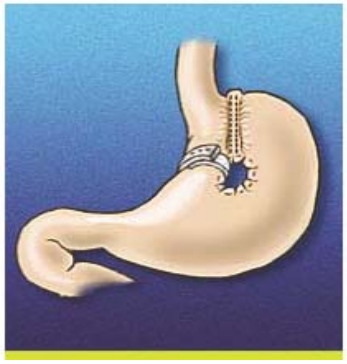

Figure G-4. Vertical band gastroplasty

Source: Adopted from the Bariatric Surgery Association

APPENDIX H
Acronym List

AGB	Adjustable Gastric Band
AHCPR	Agency for Health Care Policy and Research
BMI	Body Mass Index
BPD	Biliopancreatic Diversion
BPD/DS	Biliopancreatic Diversion with Duodenal Switch
CAD	Coronary Artery Disease
CCTR	Cochrane Central Register of Controlled Trials
CDC	Centers for Disease Control and Prevention
CHD	Coronary Heart Disease
CNS	Central Nervous System
CPG	Clinical Practice Guideline
CVD	Cardiovascular Disease
DARE	Database of Abstracts of Reviews of Effectiveness
DJD	Degenerative Joint Disease
DM	Diabetes Mellitus
DMPA	Depot Medroxy Progesterone Acetate
EBM	Evidence-Based Medicine
ECRI	Emergency Care Research Institute
FBG	Fasting Blood Glucose
GB	Gastric Banding
GI	Glycemic Index
GLC	Generalized Low-Calorie
HDL-C	High Density Lipoprotein Cholesterol
HTN	Hypertension
IBW	Ideal Body Weight
ICSI	Institute of Clinical Systems Improvement
IOM	Institute of Medicine
LCD	Low-Calorie Diet
LDL-C	Low-Density Lipoprotein Cholesterol
LFT	Liver Function Tests
LL-RYGB	Long-Limb Gastric Bypass
MAOI	Monoamine Oxidase Inhibitors
MET	Metabolic Equivalent
MI	Myocardial Infarction
MR	Meal Replacement
MTF	Medical Treatment Facility
NHANES	National Center for Health Statistics National Health And Nutrition Examination Survey
NHLBI	National Heart, Lung, and Blood Institute
NIH	National Institutes of Health
NLM	National Library of Medicine
NQMP	National Quality Management Program
OA	Overeaters Anonymous
PBM	Pharmacy Benefits Management
PSMF	Protein-Sparing Modified Fasts
PST	Problem-Solving Therapy
QOL	Quality of Life
RCT	Randomized Controlled Trial
RPT	Relapse Prevention Training
RR	Relative Risk
RYGB	Roux-en-y Gastric Bypass
SCQ	The Stages of Change Questionnaire
SOS	Swedish Obese Subjects
SSRI	Selective Serotonin Reuptake Inhibitor

TLC	Therapeutic Lifestyle Changes
TSH	Thyroid Function Tests
USPSTF	U.S. Preventive Services Task Force
VBG	Vertical Banded Gastroplasty
VISN	Veterans Integrated Services Network
VLCD	Very-Low-Calorie Diet
VLF	Very-Low-Fat
WC	Waist Circumference
WHO	World Health Organization

APPENDIX I
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APPENDIX J
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