

Effectiveness of Interventions for Overweight and Obesity in Adults

**Prepared for:
Department of Health and Hospitals
In Response to Senate Concurrent Resolution 153**

**Prepared by:
Pamela Davis Martin, Ph.D.
Valerie H. Myers, Ph.D.
Phillip J. Brantley, Ph.D.**

**Pennington Biomedical Research Center
6400 Perkins Road
Baton Rouge, LA 70808**

March 2004

ACKNOWLEDGMENTS

This study was supported by a contract from the Department of Health and Hospitals. We acknowledge at DHH the continuing support of C. Virginia Moore, R.N., C.S., N.P., Coordinator of the Louisiana Council on Obesity Prevention and Management. Obesity Council; Jimmy Guidry, MD, Chief Medical Director of the Department of Health and Hospitals and the Vice Chairman of the Obesity Council; and Liz Sumrall, the Public Health Executive Director. We would also like to acknowledge assistance and support of David Hood and Dr. Fred Cerise. We also owe our thanks to Dori Whitehead for her assistance with the extensive references.

INDEX

Executive Summary	7
Introduction	23
Statement of Problem of Overweight and Obesity	
Louisiana statistics	
Health Consequences	
Economic Burden	
Causes	
Guidelines for Treatment of Obesity	31
Weight Management Goals	32
Weight Management Strategies	32
Dietary Modification	33
Types of diets	
Effectiveness of Dietary Modification	
Use with other treatments	
Compliance with and Barriers to use of Dietary Modification	
Costs	
Future Directions	
Physical Activity	38
Types of Physical Activity	
Effectiveness of Physical Activity	
Use with other treatments	
Compliance with and Barriers to use of Physical Activity	
Costs	
Future Directions	
Behavior Therapy	43
Components of Behavior Therapy	
Effectiveness of Behavior Therapy	
Use with other treatments	
Compliance with and Barriers to use of Behavior Therapy	
Costs	
Future Directions	
Pharmacotherapy	48
Types of Medications	
Orlistat	
Sibutramine	
Over the Counter	
Costs	

Surgery	55
Types of Procedures	
Effectiveness of Procedures	
Contraindications, Compliance with or Barriers to Procedures	
Costs	
Future Directions	
Other Weight Loss Programs and Techniques (Alternative Treatments)	63
Commercial	
Fad/Popular Diets	
Self-Help	
Settings for Adult Weight Management	74
Medical	
Work Site	
Church/Religious Organizations	
Community Organizations	
Other	
At Risk Population Targets for Weight Management	80
Ethnicity/Racial Minorities	
Menopause	
Medication	
Smoking Cessation	
Cost Associated with Obesity and Treatment	83
Results of Weight Management on Comorbid Conditions	85
Blood Pressure	
Lipids	
Blood Glucose	
Public Health Approaches	88
Recommendations	89
Scientific literature	
Louisiana Programs	
Pennington	
PCOMO	
DPP	
SHOP	
Rolling Store	
LSU Ag Center	
Portions	
Louisiana Obesity Council	
1999 Louisiana Obesity Council Recommendations	
National Organization Recommendations	
Office Of Surgeon General	

American Medical Association
American Heart Association
American Obesity Association
Centers for Disease Control

National and Legislative Actions related to Obesity	117
Summary/Conclusions	120
Appendices	124
References	125

Literature Search Strategy and Synthesis

We examined the scientific literature over the past ten years. We searched the MEDLINE, PUBMED, EBSCO, PSYCINFO databases available through the Pennington Biomedical Research Center and Drexel University for reviews and relevant human population studies published in the English language between 1995 and 2003, using search terms consistent with the areas of interest.

The contents of this report are dictated by Senate Concurrent Resolution No.153, sponsored by Senator Bajoie. This report completed a search of the scientific literature as it relates to the following areas:

- 1) The effectiveness of existing methods for treating or preventing obesity;
- 2) The effectiveness of alternate methods for treating or preventing obesity;
- 3) The fiscal impact of treating or preventing obesity;
- 4) The compliance and cooperation of patients with various methods of treating or preventing obesity; and
- 5) The reduction in serious medical problems associated with diabetes that results from treating and preventing obesity.

While all of the areas requested have been incorporated into the report, additional information has been included in order to give a comprehensive overview of obesity as a chronic illness, the effectiveness of available treatments, the available data on cost effectiveness, the effects of treatment on all available comorbid conditions, the future directions of obesity research and treatment and finally, the recommendations from national organizations and obesity experts on the methods for treating or preventing obesity.

PREPARATION OF THIS LITERATURE REVIEW

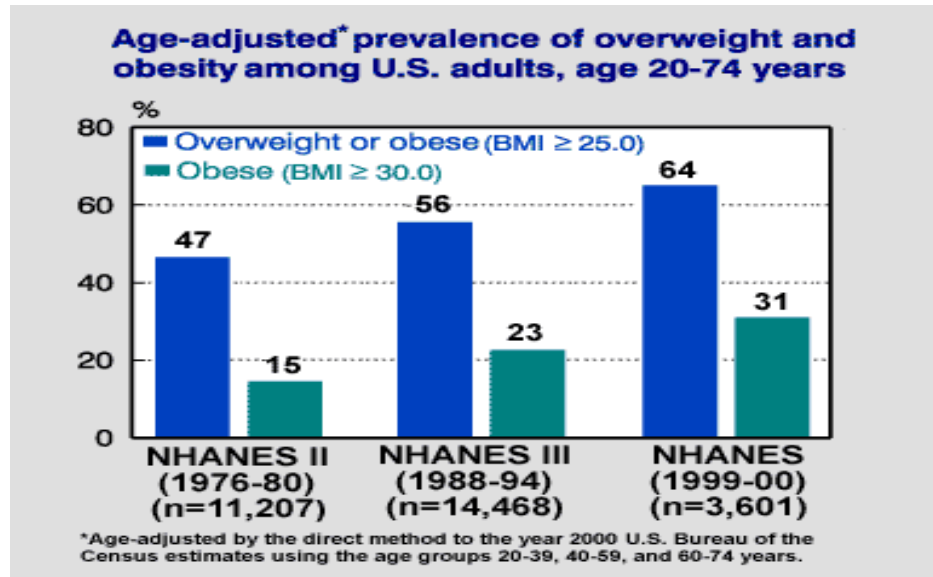
The authors worked with three members of DHH throughout the review (see Acknowledgments) and during October 2003 presented a working outline. After feedback, the literature search and interim report were completed between October 15, 2003 and January 7, 2004. The preliminary report was distributed for broad-based review to the previously mentioned DHH staff on January 7th. Following initial presentation of the report to Senator Bajoie, and the DHH staff on January 20th, we revised the report and prepared it for DHH to use in presentation to the Louisiana Obesity Task Force on March 10th for final recommendations to the legislature and the Senate and House committees, and a final presentation to the Secretary of DHH, Fred Cerise, M.D., and the Medical Director of OPH, Jimmy Guidry, M.D., on March 12th for recommendations and feedback for the March 31, 2004 meeting to the joint Health and Welfare Committees to aid in possible legislation regarding the prevention and treatment of obesity in the state.

We identified 3 major forms of treatment for obesity that can be offered through various health care settings: counseling and behavioral interventions aimed at lifestyle intervention (Behavior therapy, Diet and Physical Activity), pharmacotherapy, and surgery. We present results broken down by types of interventions with information pertaining to available outcomes such as weight loss and maintenance of weight loss, glucose tolerance, blood pressure, lipid status, and other various health outcomes.

EXECUTIVE SUMMARY

Overview of the Problem of Obesity

Obesity is a chronic medical condition characterized by excess weight and body fat. Obesity has reached epidemic proportions and poses a major public health threat. The costs of chronic obesity are substantial. Thus, obesity is a health hazard, which is increasing in prevalence, is difficult to treat, and is costly when it becomes a chronic medical condition. Currently, more than 64% of US adults are either overweight or obese, which represents a 14% increase from 1994 and a 36% increase from 1980.



- In women, overweight and obesity are higher among racial/ethnic minority populations.
- In men, the prevalence of overweight and obesity in Caucasians is greater than African Americans.
- 69% of African American women are overweight/obese compared to 58% of African American men.
- 62% of Caucasian men are overweight/obese compared to 47% of Caucasian women. However, when looking at obesity alone more Caucasian women are obese compared to Caucasian men (23% and 21%, respectively).
- Women of lower socioeconomic status (income < 130% of poverty threshold) are approximately 50% more likely to be obese.
- 400,000 deaths each year in the U.S. are associated with obesity, second only to smoking-related deaths.

State of Obesity in Louisiana

- Louisiana ranked as the 8th highest state in obesity.
- 23.3% of the population is obese compared to 20.9% in United States.

Louisiana Demographic Make-up Associated with Overweight/Obesity

- Louisiana's population is 32.5% African American compared to 12% of the United States
- Louisiana has 19% of the population in poverty compared to 9% in the United States
- 62% of low SES, African American females were obese in a 1995 Louisiana Medicaid study
- Louisiana was the 7th highest state for diabetes at 8.5% of the population.
- 52% of Medicaid recipients reported no leisure activity in 1995
- 61% of Medicaid recipients reported dietary fat intake greater than 30% in 1995
- Medicaid participants reported eating one or fewer servings of fruits and vegetables daily in 1995

Health Consequences of Obesity

Obesity is a major public health threat contributing significantly to increased morbidity and mortality. Obesity is associated with significantly increased risk of diabetes mellitus, hypertension, dyslipidemia, certain forms of cancer, sleep apnea, and osteoarthritis.

- 30% - 78% of cases of hypertension may be attributable to obesity
- High blood pressure is twice as common in adults who are obese
- Obesity is associated with elevated triglycerides (blood fat) and decreased HDL cholesterol ("good cholesterol").
- Diabetes prevalence increases with BMI and was 2%, 8% and 13% in those with BMI 25-29.9 kg/m² (overweight), 30-34.9 kg/m² (class 1 obesity), and >35 kg/m² (class 2 and 3 obesity), respectively.
- A weight gain of 11 to 18 pounds increases a person's risk of developing Type 2 diabetes to twice that of individuals who have not gained weight.
- Over 80% of people with Type 2 diabetes are overweight or obese.

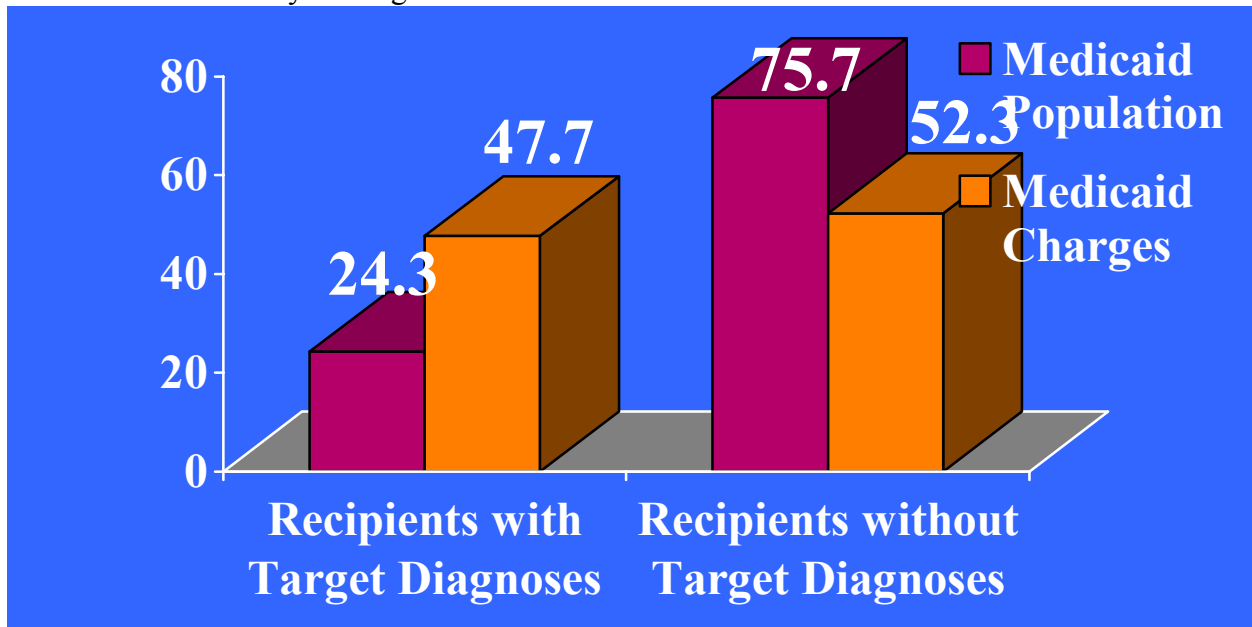
The Economic Burden of Obesity

- Costs attributable to obesity totaled \$99.2 billion in 1995 (5.7% of National Health Costs)
- \$51.6 billion in direct medical costs,
- \$3.9 billion (39.2 million days) in lost work,
- 239 million restricted-activity days,
- 89.5 million bed-days, and
- 62.6 million physician visits.
- The economic cost of obesity in the United States was about \$117 billion in 2000.
- \$ 77 million per month is paid by Social Security for individuals with obesity disability claims.

Louisiana Economic Burden:

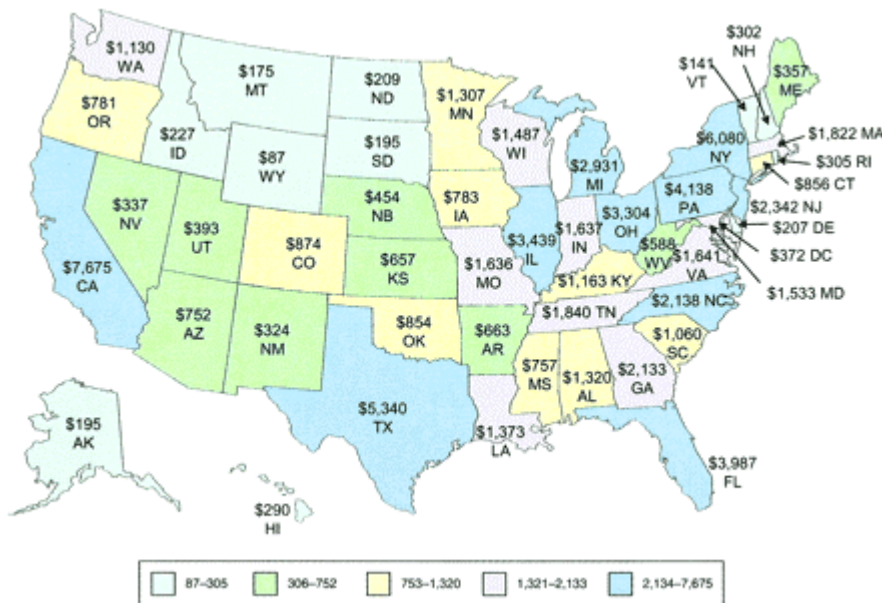
- In a 1995 study of Louisiana Medicaid patients 62% of the patients were classified as obese.
- 25% had a chronic disease and accounted for 48% of total annual Medicaid expenditures.
- 16% of all Medicaid patients had diseases associated with high fat diet and 36% of total Medicaid charges were spent on these patients.

Economic Burden of “Preventable” Chronic Diseases within the Medicaid Population
associated with obesity and high fat diet



- Louisiana is in the top 6 states in total obesity related expenditures
- Louisiana is in the top 6 states in Medicaid obesity related expenditures

In an examination of estimates of annual medical expenditures attributable to obesity study published in January 2004, it was estimated that Louisiana spends \$1.4 billion annually on obesity.



STATE	TOTAL POPULATION		MEDICARE		MEDICAID	
	%	MILLIONS \$	%	MILLIONS \$	%	MILLIONS \$
Louisiana	6.4	\$1373	7.4		12.9	\$525
US	5.7		6.8	\$402	10.6	

Risk Factors Associated with the development of Obesity

The following factors are a summary of risk or predisposing factors for obesity.

- Parental Overweight
- Lower Socioeconomic Status*
- Smoking Cessation
- Low Level of Physical Activity
- High Carbohydrate Oxidation
- Childhood Overweight
- High Birth/infancy Weight
- Lack of Maternal Knowledge of child's sweet eating habits
- Recent Marriage
- Multiple Births
- Medication
- Menopause
- Ethnicity*
- Female

*Those of particular interest to Louisiana based upon demographics

Concurrent Resolution 153

In Senate Concurrent Resolution No. 153, Senator Bajoie requested information to assist the Louisiana Obesity Task Force in making final recommendations to the legislature and the Senate and House committees regarding possible legislation to aid in the prevention and treatment of obesity, and ways to decrease the number of cases of obesity in the state. The following key areas were explored to aid in these recommendations.

I. What is the effectiveness of existing methods for treating or preventing obesity?

There is strong evidence that combined lifestyle interventions of a Low Calorie Diet (LCD), increased physical activity, and behavior therapy are appropriate for all populations, have minimal if any risks or side effects and are successful in producing weight loss. Medications approved by the FDA (e.g., sibutramine, orlistat) may be used as part of a lifestyle intervention program for patients with a BMI of ≥ 30 (without risk factors or diseases), and for patients with a BMI of ≥ 27 with concomitant obesity-related risk factors or diseases. Continual assessment of drug therapy for efficacy and safety is necessary. Weight loss surgery is an option for carefully selected patients with clinically severe obesity (BMI ≥ 40 or ≥ 35 with comorbid conditions) when less invasive methods of weight loss have failed and the patient is at high risk for obesity-associated morbidity or mortality. On average, behavioral and pharmacological treatments can result in a weight loss of up to 10% of initial weight while surgery results in more substantial weight loss of up to 50-75%. General estimates of effectiveness and costs are summarized below.

<u>Treatment</u>	<u>Effectiveness</u>	<u>Annual Cost Estimates</u>
<u>Commercial</u>		
Weight Watchers	6% at 6 months	\$12/week \$624/year
<u>Behavioral Programs</u>		
	8-10% at 6 months	\$800/yr group \$1700/yr individual
<u>Meal Replacement</u>		
(Slimfast)	8% at 3 months	\$12/week \$624/year
<u>Medically Supervised Liquid Diet</u>		
	15-25% at 4 months	\$3,000/6 months \$6,000/year
<u>Pharmacotherapy</u>		
Sibutramine/Orlistat	7-10% at 6 months	\$1100-\$1350/year
<u>Combined Behavior/Medication</u>		
	16% at 6 months	\$1900 – \$3000/year
<u>Gastric Surgery</u>		
	25-30% at 6 –12 months	\$ 25,000 surgery +\$1,200/ yr for next 6 yrs

After successful weight loss, the likelihood of weight loss maintenance is enhanced by a lifestyle program consisting of dietary therapy, physical activity, and behavior therapy which should be continued indefinitely. Drug therapy can also be used. However, while studies are ongoing, drug safety and efficacy beyond 1 year of total treatment have not been well established. A weight maintenance program should be a priority after the initial 6 months of weight loss therapy. Treatments which have more frequent contact with individuals tend to be more successful than minimal contact interventions. There are few studies on weight maintenance and further research is needed.

The National Weight Control Registry (NWCR) is a database of people who have self-reported a weight loss of 30 pounds or more and kept it off for at least a year. The average NWCR participant has lost about 60 pounds and kept it off for about five years. However, research from the National Weight Loss Registry found the following commonalities among successful individuals.

- 89% changed their diets and increased physical activity (10% diet only; 1% activity only).
- 55% used a formal program (Weight Watchers) or professional (dietitian, psychologist)
- 87.6% limited some type or class of food (high-fat/high-calorie foods).
- 44.2% limited the quantities of food they ate.
- 43.7% counted calories.
- 92% exercised at home, 40.3% with a friend, and 31.3% with a group.

- Walking was the most common activity reported.
- 77% said a medical or emotional event triggered weight loss.
- 42.7% described losing weight as hard, 31.4% as moderately hard, and 25.7% as easy.
- Two-thirds were overweight as children (about 46% by age 11 and 25.3% after).
- 46% had one overweight biological parent, and 26.8% both biological parents overweight.
- 91% had tried to lose weight before.
- They consumed an average of 1400 calories per day, of which 24% of calories was from fat, 19% protein, and 56% carbohydrates.
- They ate five times a day, on average.
- They burned an average of 2,800 calories a week through exercise (an equivalent of about 400 calories day).
- 75% weighed themselves regularly - at least once a week.

The recommended treatments for various BMIs are summarized as follows:

BMI	Description	Health Risk	Weight Goal	Strategy
19-25	Acceptable Weight	Very Low	Maintain Weight	Healthy Diet and Regular Physical Activity
25-29	Over weight	Low	Maintain Weight or Lose 5% of Weight	Health Diet (Low-Fat, Low Energy Density), Portion Control, Exercise, Behavior Therapy
30-34	Obese	Moderate	Lose 10% of weight or BMI <30	Healthy Diet (Low-Fat, Low Energy Density Diet, Portion Control, Exercise, Behavior Therapy and Medication
>35	Morbidly Obese	High	Lose >15% weight or BMI reduction of >3 units	Exercise and Health Diet, Medication, Surgery

The summary of findings of treatment modalities are presented below:

Dietary Therapy

Dietary modification (dieting) can generally achieve modest, short-term weight reduction. An average weight loss of 8% can be obtained over 3 to 12 months with an LCD and this weight loss affects a decrease in abdominal fat. Average weight loss on a low-calorie diet (1200 kcal/day) is 8.5 kg in 20 weeks, and 20 kg over 16 weeks on a very low-calorie diet (VLCD [800 kcal/day]). Lower-fat diets with targeted caloric reduction promote greater weight loss than lower-fat diets alone. VLCDs (e.g., commercial weight-loss programs or use of formula diets or drinks) have demonstrated primarily short-term benefits. While VLCDs produce greater initial weight losses at one year, both LCD and VLCD are equivalent in their effectiveness at one year. Most of the weight lost in the early phase (16–20 weeks) is regained within 2–5 years unless the initial strict

regimen is maintained. Although dieting alone is associated with significant weight loss in the short term, the chance of long-term maintenance of weight loss is significantly increased when diet is combined with exercise.

- Dietary therapy involves instruction on how to adjust a diet to reduce the number of calories eaten.
- Reducing calories moderately is essential to achieve a slow but steady weight loss, which is also important for maintenance of weight loss.
- Strategies of dietary therapy include teaching about calorie content of different foods, food composition (fats, carbohydrates, and proteins), reading nutrition labels, types of foods to buy, and how to prepare foods.
- Some diets for weight loss include low-calorie, very-low calorie, and low-fat.

Example of Simplified Standard Dietary Recommendations for Weight Loss

Weight	Daily Caloric Intake	Daily Fat Intake
<200 lbs	1200-1500	27-33 grams
>200 lbs.	1500-1800	33-40 grams

The general consensus of the scientific and healthcare community related to Dietary Therapy suggests that a diet that creates a deficit of 500 to 1,000 kcal/day is a necessary part of any weight loss program. While any diet that produces an energy deficit will result in weight loss, some diets are nutritionally inadequate and may require supplementation. Low Calorie Diet Plans that are well researched are recommended such as those proposed by the NCEP's Step I or Step II Diet or following the USDA recommendations of the food guide pyramid. Decreasing total fat intake to 30% or less of total calories and emphasizing the reduction of saturated fats to enhance lowering of LDL-cholesterol levels is recommended. Awareness needs to be raised that reducing the percentage of dietary fat alone will not produce weight loss unless total calories are also reduced. Frequent contacts with the healthcare professional help to promote weight loss and weight maintenance.

Physical Activity

While increasing physical activity is integral for weight management, it will not likely lead to substantially greater weight loss over 6 months since most weight loss occurs because of decreased caloric intake. Most controlled studies of an exercise alone treatment component have found modest weight loss (e.g., 2-3 kg). The benefit of sustained physical activity is related to the prevention of weight regain. It has the additional benefit of reducing cardiovascular and diabetes risks over and above the benefits produced by weight loss alone. Since most individuals are sedentary, exercise should be initiated slowly, with gradual increases in intensity. Simple walking programs can be effective and adults should set a long-term goal to accumulate at least 30 minutes or more of moderate-intensity physical activity on most days of the week. For the purpose of calorie expenditure, the exercise can be done all at one time or intermittently over the day. This type of regimen, can produce a calorie expenditure of approximately 100 to 200 calories per day. Modifying lifestyle physical activity is also recommended and individuals should be encouraged to increase "every day" activities such as taking the stairs instead of the elevator. With time, depending on progress and functional capacity, engaging in more strenuous activities such as

sports which provide an enjoyable form of exercise may be considered. Reducing sedentary time is another strategy to increase activity by undertaking frequent, less strenuous activities.

- Physical activity contributes to weight loss, especially when it is combined with calorie reduction.
- Regular physical activity is extremely helpful for the prevention of overweight and obesity.
- Regular physical activity is very important in maintaining weight loss.
- In addition to weight control, physical activity helps prevent heart disease, helps control cholesterol levels and diabetes, slows bone loss associated with advancing age, lowers the risk of certain cancers, and helps reduce anxiety and depression.
- It is recommended that Americans accumulate at least 30 minutes (adults) of moderate physical activity most days of the week. More may be needed to prevent weight gain, to lose weight, or to maintain weight loss.
- Less than 1/3 of adults engage in the recommended amounts of physical activity.
- Many people live sedentary lives; in fact, 40% of adults in the United States do not participate in any leisure time physical activity.

Behavior Therapy

Behaviorally based strategies that are founded on learning principles such as reinforcement and provide tools for overcoming barriers to compliance with lifestyle modification are helpful in achieving weight loss and weight maintenance. Specific strategies include self-monitoring of both eating habits and physical activity, stress management, stimulus control, problem solving, contingency management, cognitive restructuring, and social support. The average duration of behavioral treatment ranges from 18-24 weeks and results in an approximately 1 lb weight loss per week. Attrition is usually below 20% and it appears that group programs are more effective than individual programs.

Combined Therapy

A combined intervention of behavior therapy, a Low Calorie Diet, and increased physical activity provides the successful therapy for weight loss and weight maintenance. The National Heart Lung and Blood Institute recommends that these lifestyle interventions be maintained for at least 6 months before considering pharmacotherapy.

Pharmacotherapy

Medications can augment lifestyle modification programs. Weight loss drugs that have been approved by the FDA for long-term use can be useful adjuncts to dietary therapy and physical activity for some patients with a BMI of ≥ 30 with no concomitant risk factors or diseases, and for patients with a BMI of ≥ 27 with concomitant risk factors or diseases. The risk factors and diseases considered important enough to warrant pharmacotherapy at a BMI of 27 to 29.9 are hypertension, dyslipidemia, CHD, Type 2 diabetes, and sleep apnea. Continual assessment by the physician of drug therapy for efficacy and safety is necessary.

At the present time, sibutramine and orlistat are available for long-term use and can result in weight losses of up to approximately 10% and facilitate weight loss maintenance. The side effects must be considered and patients need to be medically evaluated for their appropriateness for initiation of pharmacotherapy treatments, as well as carefully monitored for adverse side effects. Sibutramine is associated with increases in blood pressure and heart rate and should not be used in patients with a history of hypertension, CHD, congestive heart failure, arrhythmias, or history of stroke. Orlistat requires replacement of fat soluble vitamins because of partial malabsorption.

Weight Loss Surgery

It is recommended that the use of weight loss surgery be limited to individuals with severe obesity (i.e., BMIs ≥ 40 or ≥ 35) with comorbid conditions in whom efforts at medical therapy have failed. Gastrointestinal surgery (gastric restriction [vertical gastric banding] or gastric bypass [Roux-en Y]) is an intervention weight loss option for motivated subjects with acceptable operative risks. Surgical interventions can result in dramatic weight losses of up to 50-75%. An integrated program must be in place to provide guidance on diet, physical activity, and behavioral and social support both prior to and after the surgery. Additionally, many programs require a psychological evaluation to screen for issues of mental health, motivation and expectations that may interfere with compliance with the extreme lifestyle modification necessary after surgery.

In summary, there is strong evidence that combined interventions of a low calorie diet (LCD), increased physical activity, and behavior therapy are successful and appropriate treatments with minimal if any risks for all individuals to obtain and maintain a healthy weight. Weight loss medications produce results similar to lifestyle modification and have a few treatment side effects that need to be considered. Surgery can produce dramatic changes in weight (up to 50-75% loss) but involve the types of risks expected with surgical interventions. Studies over the last 40 years have established that obesity is difficult to treat and that lasting changes in body weight are very difficult to achieve. Therefore, there is considerable need for continuing efforts to improve upon the effectiveness of available methods to treat and prevent obesity.

II. What is the effectiveness of alternate methods for treating or preventing obesity?

Various alternative approaches for the treatment of obesity have begun to emerge. The data on the efficacy of these treatments is limited based on the paucity of controlled clinical studies. For the purpose of this report alternative treatments are defined as weight loss treatments that are typically marketed by commercial programs or are new innovations that have not been subject to the rigors of scientific evaluation.

Most alternative treatments for obesity have not been proven to be safe or effective. In 2001, a review of the literature found that the following types of treatments were not found to produce consistent scientifically validated significant effects on weight or were associated with significant health side effects, and therefore were not recommended as a weight loss treatment: Acupuncture/Acupressure, Aromatherapy, Chitosan, Conjugated Linoleic Acid, Dehydroepiandrosterone (DHEA), Garcinia Cambogia, Germander, Hypnosis, Plantain (Psyllium, Plantago) Pyruvate, St. John's Wort, Subliminal Suggestions, and Sunflowers.

Alternative psychotherapy treatments include the size acceptance nondiet movement, the "addiction model" as a conceptualization for the poor maintenance outcomes for weight loss, and virtual reality based therapy. The data on these models are limited and inconclusive.

Commercial weight loss programs are a 2 billion dollar a year industry in the United States. The most common commercial weight loss programs are Weight Watchers International, Jenny Craig, L.A. Weight Loss, Nutrisystem, Slim-Fast, and Deal-a-Meal Plan. Commercial weight loss programs do not commonly publish data on their efficacy, but a few positive treatment studies do exist for Slim-Fast and Weight Watchers. Previous survey data suggest that none of the top commercial weight loss programs are superior to one another in weight loss success, and only a fourth of people maintain two-thirds of the lost weight after two years. Data suggests also that the structured weight loss programs provide modest weight loss, but are superior to self-help programs. In addition to limited efficacy studies, commercial weight loss programs have also reported high dropout rates. The average dropout rate from a commercial weight loss program was approximately 80% at 20- 25 weeks. Costs for these programs vary depending on whether packaged foods must be bought separately, sign-up fees, weekly meeting charges, and fees “per-pound” lost.

Medically-based and residential weight loss programs include combined use of very low-calorie diets (VLCD), behavioral modification, and are usually administered by a multidisciplinary team with a focus on nutrition, medical management, exercise, and lifestyle modification. Several trials have shown that patients lose 15-20% of their initial weight during a 2-3 month treatment phase on these very low-calorie diets, however, weight regain has been estimated to be 35-50% of lost weight. The cost of these programs are very expensive with weekly expenses ranging from \$2,730-\$3,095/week excluding housing costs, and limited efficacy data have been published.

Self-help programs are popular, and usually free or of little cost. The most popular programs are Overeaters Anonymous (OA), Take Off Pounds Sensibly (TOPS), and the Trevoise Behavior Modification Program. There is no published data available on the efficacy of the programs.

Over-the-counter medications (OTC) marketed as weight loss agents have increased in popularity over the last few decades. Two of the most commonly marketed and used OTC drugs are phenylpropanolamine (PPA) and ephedrine. However, these drugs have been associated with significant health effects and have been removed from retail sale.

A variety of diets are being touted in the popular press. Total Fasting or starvation are associated with significant health risks and are not recommended as a viable treatment for obesity. Balanced deficit diets are usually the most recommended diets by health professionals. They are low in calories and “balanced” in their macronutrient content. These dietary recommendations are close to those recommended for health in nondieting individuals. They are low in fat <30%, high in complex carbohydrates (>55%) moderate in protein (10-15%), high in fiber (25-30g) and encourage limiting alcohol. These diets are promoted commercially by Weight Watchers, Diet Center, Physician’s Weight Loss Centers, Take Off Pound Sensibly (TOPS), Overeaters Anonymous (OA), The Calloway Diet, The T-factor Diet and the Fat Attack Plan.

High protein diets are usually associated with low carbohydrate intake. Popular diets that tout these types of plans include Sugar Busters, Carbohydrate Addict Diet, The Zone, and Dr. Atkin’s New Diet Revolution. These diets are not usually recommended due to false assumptions regarding metabolism, deficiencies in carbohydrates and micronutrients and potentially harmful intake levels of protein and fat. Several national organization have issues warnings against the use of high protein diets: The American College of Sports Medicine, The American Dietetic Association, The Women’s Sports Foundation. Some of the most recent research has concluded that Low Carbohydrate Diet: appear to have insufficient evidence to make recommendations for or against these dietary programs. From the studies evaluated it appears that weight loss was primarily obtained through restriction of calories not the decrease in carbohydrates. High Carbohydrate Diets are usually well balanced and safe since they tend to promote fruits,

vegetables and whole-grains. Popular diets which are consistent with this regimen include Dr. Ornish: Eat More, Weigh Less, Volumetrics, The Pritikin Diet and the T-Factor Diet. However, some dietary experts indicate that extreme restriction of calories or fat should be viewed with caution since this can lead to endocrine problems and nutrient deficiencies. Popular diets that are based on faulty science or exclude necessary food groups include: Eat Right 4 Your Type, The Beverly Hills Diet, The 5-day Miracle Diet, Fit for Life, The Hilton Head Over 35 Diet and The Rotation Diet.

In summary, there is currently insufficient scientific evidence on a variety of alternate methods for treating or preventing obesity. Those that are most credible and effective are usually marketing scientifically validated recommendations consistent with lifestyle modification of diet and physical activity. Consumers need to be educated on the principals of energy balance, realistic weight loss expectations, and how to evaluate weight loss products claims.

III. What is the fiscal impact of treating or preventing obesity?

It has been estimated that obesity costs the American healthcare system over \$117 billion each year. Louisiana is the 8th highest state in obesity and in the top 6 states in regard to obesity related costs. The personal costs to the population that are not calculated in this fiscal impact include decreased years of life, increased years of disability and increased risk of developing comorbid conditions. The psychological and social costs are also noted with discrimination and depression.

Despite the economic burden of obesity, limited data are available on the cost effectiveness of various methods for treating obesity. Accurately estimating the cost of treating obesity must also be offset by the decrease in additional medical care costs which is very complicated. More data on pharmacotherapy and surgical weight loss have been published which is likely due to their ability to be reimbursed by insurance in some instances.

Obesity drugs vary in costs, and therefore, these must be considered in relation to their respective weight losses and the incidence of side effects associated with their use. A comparative cost effectiveness study found that the cost per month for phentermine is \$60 compared to \$116 and \$119 for sibutramine and orlistat, respectively. Additionally, the cost for 1 kg of weight loss is \$91, \$323, and \$433 for phentermine, sibutramine, and orlistat, respectively. Cost of medications also should be evaluated in relation to the overall reduction in cost for non anti-obesity medications. One study reported that weight loss of 6-10% reduced pharmacy cost \$122.64 per month for insulin-treated diabetes, \$42.92 per month for sulfonylurea-treated diabetes, \$61.07 per month for hyperlipidemia, and \$0.20 per month for hypertension. In many studies it is unclear if the costs of physician visits for medical monitoring are also included in these estimates.

Data is also scarce on the cost-effectiveness of bariatric surgery in the long-term. Preliminary data on the cost-effectiveness of medication costs and use for various obesity-related disease after bariatric surgery have been published. Findings suggest that among those patients medication-free at the time of bariatric surgery, those not receiving the surgery were five times more likely to use diabetes medication at 6 year follow-up. Cost analyses indicated that a weight loss of greater than 10% was required to reduce costs of cardiovascular disease and diabetes medication for those that were on medication prior to receiving surgery or a structured diet. A weight loss greater than 15% was needed to reduce the risk of initiation of medication for those not on medication initially. The average annual cost of medication increased by 96% for those that lost less than 5% of their weight, whereas a decrease of 8% in costs was associated with weight loss greater than 15 %. Data on the cost of in-patient care for those treated surgically and

by traditional methods found that the cumulated number of hospital day stays for the surgical group over a six year period was 23.4 days compared to 6.9 days for the diet group. After hospitalizations for the surgery and conditions common after bariatric surgery were excluded from the analyses, there were no significant differences between the surgical and conventional group with regards to hospitalization costs. The data suggest that weight loss of less than 15% was not sufficient to reduce hospitalization costs over a six year period, and that the cost benefits of bariatric surgery may be limited to the improvements associated cardiovascular and diabetes risks. The initial findings from the extensive SOS study however, does not appear to find clear cut savings in medication use post surgery compared to conventional treatments. Additionally, it appears that the increased cost of hospital care associated with surgical patients complications and secondary plastic surgery may be as much as \$1200 annually for the 6 years following surgery. Therefore more long-term data are necessary to determine cost effectiveness.

A review of the literature found limited studies on the cost of adopting a healthy diet. It appears that most consumers perceive that eating healthy will be unappetizing and more expensive. A few European studies suggested that cost for eating healthy were more costly than those for a traditional diet due to the expense of fruits and vegetables. However, one study found that food costs consistent with traditional weight loss treatment (reduced energy intake >30% fat) did not increase during the initial 6 months of family based treatment which is consistent with other findings. More importantly they noted that food costs actually decreased at one year which was not merely attributable to reduction in food intake. Future research on the costs of healthy diets has been recommended in the time for preparing, shopping and healthcare costs. To date, most of the studies completed have been with children. Future studies should evaluate costs related to adult programs.

However, few studies of cost-effectiveness of physical activity on obesity exist. A study from England examined the cost of promoting physical activity among individuals over the age of 65. The goal of the study was to examine the financial costs and health benefits of a publicly funded program of regular exercise. Twice weekly exercise classes were provided to 10,000 participants over the age of 65 years. The total estimated cost was approximately \$483,500. However, 76 deaths and 230 hospital inpatients stays would be avoided resulting in a savings of approximately \$340,000. The authors assumed that the mean life expectation after the age of 65 years would be 10 years. The program would cost approximately \$186.00 per year life-year saved. The authors concluded that important health benefits could be achieved at a relatively low cost.

In summary there is a paucity of data regarding the cost of treating obesity. While lifestyle modification is the most frequent recommendation for all individuals to obtain or maintain a healthy weight, this is the area with the least amount of cost effectiveness data. However, the data on the financial and personal cost of not treating obesity are staggering. Further research is needed to adequately address the question of which treatments are most cost effective as well as the cost incurred to achieve a healthful effect. However, it appears that the question of how much does it cost not to treat obesity is more relevant since effective treatments are available. Actions to make the lifestyle modification and medical treatments of obesity an available and reimbursable health care expense appears warranted.

IV. What is the compliance and cooperation of patients with various methods of treating or preventing obesity?

There are several factors that impact compliance to obesity prevention methods. Primary factors contributing to noncompliance are understanding the diets, time commitment for

food planning and preparation, and the restrictions. One common problem is the lack of use of scientifically proven methods. One study suggests that only 21.5% of men and 19.4% of women reported using the recommended combination of eating fewer calories and engaging in at least 150 minutes of leisure-time physical activity per week in order to lose weight. However, the use of self-help educational materials and intensive counseling have been found to be helpful. It has been also suggested that physicians often lack the resources and time to conduct specialized dietary programs. Another factor is weight loss expectations of the individual. Studies have found that obese women wish to lose >30% of their weight in order to be satisfied, and would be disappointed with a loss of weight less than 35 lbs in one year. This demonstrates the dramatic disparity between the current efficacy of available treatments and expectations. This expectation has been found to be resistant to verbal and written information about the realistic weight loss expectations. However, it is estimated that approximately 80-85 % of participants complete behavioral treatment programs. Medication adherence is a longstanding problem for the treatment of most chronic health conditions and in general it is estimated that as many as 50% may not be compliant.

There are limitations of extended treatment/maintenance programs. Long-term therapy can be expensive and labor-intensive. However, the benefits of preventing weight regain should be considered when examining the costs of long-term behavioral management of obesity. The motivation of individuals fluctuates over time, and as duration of treatment reaches one year, session attendance decreases, and weight plateaus occur. Patients hold onto unrealistic expectations of “an ideal weight” or changing appearance drastically, which can negatively impact adherence to behavioral programs. After weight loss treatment, fewer reinforcements are available to maintain adherence to the intervention goals. For example, many patients are motivated to lose weight by a desire to look better, and therefore have unrealistic expectations about the amount of weight that can be lost. After patients stop losing weight, motivation to maintain newly learned dietary and physical activity regimens can wane resulting in a regain of weight. Due to the problems with relapse, recent studies have focused on long-term maintenance strategies. Studies on relapse prevention of weight gain have demonstrated that individuals who possess skills to cope with challenges are less likely to relapse.

The adherence after bariatric surgery is also compromised. Surgical “success” is determined by maintenance of at least 50% weight loss. The majority of patients regain a percentage of excess body weight lost, and 14-16% of patients fail to maintain satisfactory weight loss. Often weight regain is associated with staple failure, or maladaptive eating patterns that promote ingestion of excessive calories. Approximately, 20% of patients who receive bariatric surgery develop maladaptive eating patterns leading to ingestion of high calorie, high fat carbohydrates. Commonly, noncompliance with taking required nutritional supplements is demonstrated. One study suggests that 89% of adolescent patients within two years of surgery took vitamin supplements compared to only 56% who had surgery more than two years earlier. Another study found that only 13% reported taking nutritional supplements as prescribed, and adherence to exercise and dietary recommendations was poor.

Obesity is a very significant problem in African Americans, and is especially common in African American women. Research has shown that African American men and women have greater difficulty losing weight in clinical trials for obesity. Low SES and minority individuals are at increased risk for obesity, because they lack many of the resources needed to pursue weight loss strategies. It has been noted that African American women are less likely than Caucasian women to comply with primary prevention behaviors such as exercise and healthy weight maintenance. The cost of food associated with recommended healthy diets is often cited as a barrier for African

Americans. In the 1995 study of Louisiana Medicaid patients, only a small percentage expressed a desire to change their dietary and physical activity patterns. Additionally, cultural factors have been implicated in dietary preferences and acceptance or preference of excessive weight in African Americans. Additionally, financial and neighborhood safety concerns have been cited as prominent barriers preventing minority and low income individuals from taking steps to achieve a healthy weight.

In summary, the factors for poor compliance in obesity prevention and treatment are multifactorial and are similar to treatments for other chronic illnesses such as hypertension. Rates of nonadherence may range from 20-50% depending on the type of treatment or definition used. Despite the many reasons for poor adherence, several behavioral relapse prevention techniques have been systematically studied, and have shown promise with reducing weight regain. However, future research must focus on methods to increase individual motivation to make the consistent lifestyle changes necessary to achieve a healthy weight. Awareness of appropriate weight loss expectations and understanding of realistic claims are necessary to make individuals more adherent and therefore more successful with weight loss.

V. What is the reduction in serious medical problems associated with diabetes that results from treating and preventing obesity.

Obesity is related to a variety of medical conditions including cardiovascular disease, diabetes, cancer, osteoarthritis, sleep apnea, and premature death. Weight loss is associated with short-term improvements in glucose tolerance, hyperlipidemia, and high blood pressure. Diabetics who lose 5-10% of their body weight may have decreases of glycosylated hemoglobin of 1-2.5%. Weight loss may also improve symptoms of sleep apnea, osteoarthritis mobility, and pulmonary functioning. While weight losses of 5-10% are usually associated with health benefits, maintaining modest losses of <5% have been associated with a variety of health benefits in the areas of cardiovascular disease and diabetes, both leading causes of death in the U.S.

Blood Pressure

- weight losses between 2-4% have been associated with 20 -30% decrease in HTN;
- weight losses of 4-8% were associated with decreases in blood pressure of 3-8 mm HG at six to 12 months.
- weight loss producing lifestyle trials in both overweight hypertensive and nonhypertensive patients reduces blood pressure levels.
- increased aerobic activity to increase cardiorespiratory fitness reduces blood pressure (independent of weight loss).
- weight loss produced by most weight loss medications, except for sibutramine, in combination with adjuvant lifestyle modifications will be accompanied by reductions in blood pressure.

Lipids

- reductions of 5-10% in total and LDL cholesterol have been noted with weight loss that is associated with changes in fat intake and physical activity
- weight loss is accompanied by reductions in serum triglycerides and by increases in HDL-cholesterol.
- weight loss generally produces some reductions in serum total cholesterol and LDL-cholesterol. aerobic activity to increase cardiorespiratory fitness favorably affects blood lipids, particularly if accompanied by weight loss.

Blood Glucose

- Diabetics who lose 5-10% of their body weight may have decreases of glycosylated hemoglobin of 1-2.5%
- weight loss between 2-4% have been associated 30%-50% decrease in diabetes incidence.
- lifestyle therapy trials that weight loss produced reduces blood glucose levels in overweight and obese persons without diabetes
- weight loss reduces blood glucose levels and HbA1c in some patients with Type 2 diabetes.
- decreases in abdominal fat will improve glucose tolerance in overweight individuals with impaired glucose tolerance,
- there is limited evidence that increased cardiorespiratory fitness improves glucose tolerance in overweight individuals with impaired glucose tolerance or diabetes, although not independent of weight loss.
- weight loss induced by weight loss medications does not appear to improve blood glucose levels any better than weight loss through lifestyle therapy in overweight persons both with and without type 2 diabetes.

In summary based upon the findings of health improvements associated with weight loss: weight loss as a treatment for the following medical conditions has been recommended for obese/overweight persons with the following:

- **High Blood Pressure**
- **Dyslipidemia.**
- **Type 2 Diabetes**
- **Metabolic Syndrome**

Recommendations:

Immediately implementing effective methods to target the epidemic of obesity in the adult population of Louisiana is warranted. Use of lifestyle modification methods consisting of dietary and physical activity counseling and behavior therapy is effective, safe, and recommended for persons across all weight classifications. Use of medications and surgery is effective and recommended for individuals with BMIs of 30 and greater. The side effects of these treatments must be weighed against the benefits for each individual.

This report provides a variety of detailed recommendations from the literature and from national organizations which should provide the guidance needed to assist the Department of Health and Hospitals, the Louisiana Obesity Council and Task Force, and the Louisiana State Legislature in identifying and implementing the most effective and appropriate interventions to positively impact the residents of Louisiana.

The suggested areas of focus to target obesity in adults include: 1) Increasing the public awareness of the problems with being overweight or obese, how to determine if they are overweight or obese, realistic weight loss expectations as well as how to identify effective and appropriate weight loss methods. 2) Improving the provision of weight loss interventions in the primary care setting by training community care providers on how to incorporate obesity interventions into their practice and providing appropriate educational materials to supplement individual counseling. 3) Consider providing scientifically proven educational and counseling programs as well as environmental changes in worksites, community organizations and churches to broaden the reach of obesity programs.

INTRODUCTION

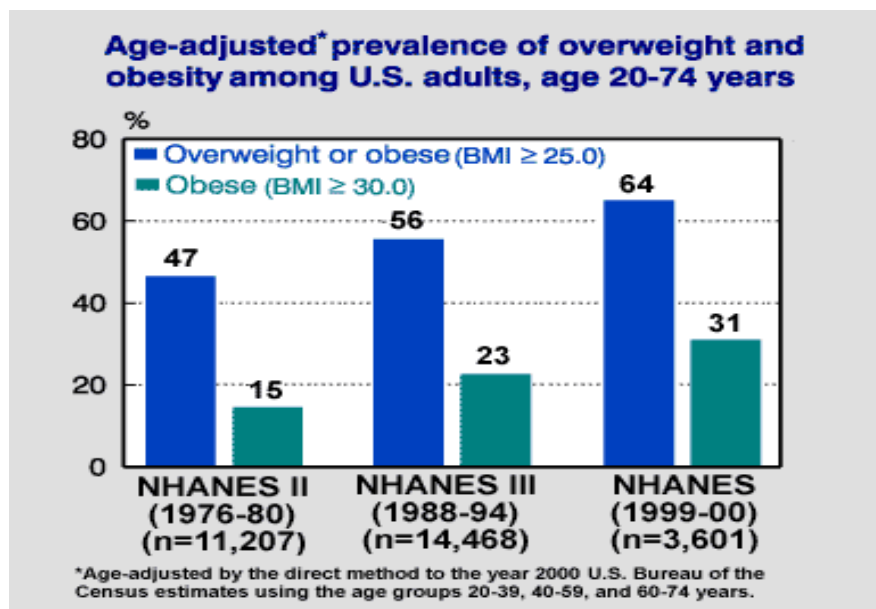
Statement of Problem of Overweight and Obesity Nationally

Obesity is a chronic medical condition characterized by excess weight and body fat. Obesity has reached epidemic proportions and poses a major public health threat¹. Obesity is usually defined by body mass index (BMI, calculated by dividing kilograms of weight by meters of height squared), which is a measure of weight adjusted for height closely correlated with body fat. Adults with a BMI of 25 to 29.9 are identified as overweight and those with a BMI ≥ 30 as obese. These cutoffs are linked to increases in mortality². Access to BMI calculators or tables are readily available from the National Institutes of Health, <http://www.nhlbisupport.com/bmi/>

It is estimated that approximately 300,000 people die each year as a result of obesity. These figures are similar to those of deaths attributable to smoking (440,000)³. However, obesity has yet to receive the same coordinated effort of focus as a public health threat. If the current patterns of obesity continue recent data from the CDC anticipate that about 40% of Americans, or 68 million people, will be obese by 2010. Despite these staggering statistics and availability of effective weight loss treatments most individuals do not receive treatment for obesity. This is in part due to the minimal if any coverage provided for the scientifically proven methods (lifestyle management, pharmacotherapy and surgery) as well as the lack of knowledge by physicians and consumers on how to lose weight. The surgeon general's recent call to action has highlighted the epidemic of obesity which will likely require the same wide reaching multilevel, multidisciplinary treatment approaches that were successful with smoking rates.

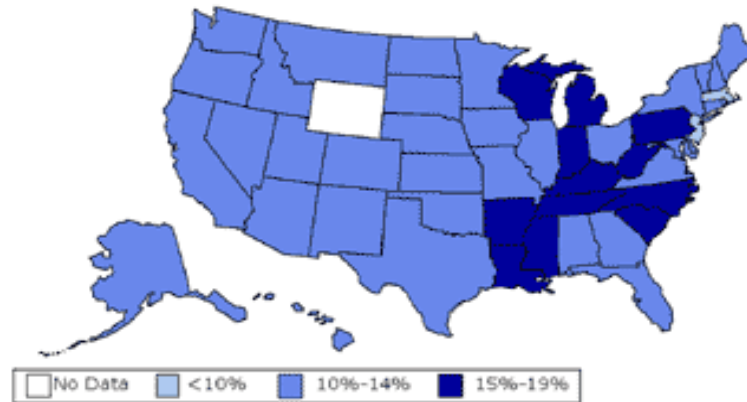
U.S. Obesity Trends

Over the past 40 years in the United States, adult obesity prevalence increased from 13% to 27% while adults classified as overweight increased from 31% to 34%. These trends are also noted in child and adolescent populations. Currently, more than 64% of US adults are either overweight or obese, according to the 1999-2000 National Health and Nutrition Examination Survey (NHANES)⁴. This represents a 14% increase from NHANES III (1988-94) and a 36% increase from NHANES II (1976-80)⁴.



Obesity Trends* Among U.S. Adults BRFSS, 1993

(*BMI ≥ 30 , or ~ 30 lbs overweight for 5'4" woman)

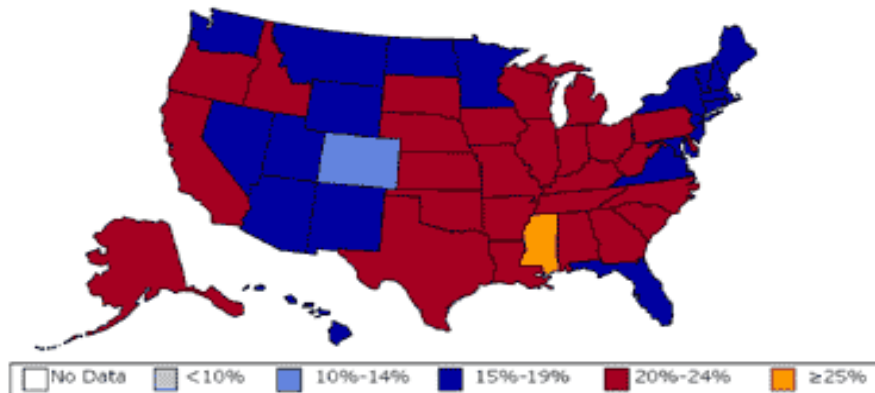


Source: Mokdad A H, et al. *J Am Med Assoc* 1999;282:16, 2001;286:10.



Obesity Trends* Among U.S. Adults BRFSS, 2001

(*BMI ≥ 30 , or ~ 30 lbs overweight for 5'4" woman)



Source: Mokdad A H, et al. *J Am Med Assoc* 1999;282:16, 2001;286:10.



These weight increases are seen across all ages, racial/ethnic groups, and both genders. There are groups that are disproportionately affected. In particular, women are more likely to be obese while men are more likely to be overweight. Additionally, minorities and those from lower socioeconomic backgrounds are at high risk for the development of obesity. With each of these categories representing a distinct category of risk, low-income minority females represent individuals with a triple threat of obesity.

- In women, overweight and obesity are higher among members of racial and ethnic minority populations.
- In men, Mexican Americans have a higher prevalence of overweight and obesity. The prevalence of overweight and obesity in Caucasian men is greater than in African American men.
- 69% of African American women are overweight or obese compared to 58% of African American men.
- 62% of Caucasian men are overweight or obese compared to 47% of Caucasian women. However, when looking at obesity alone (BMI>30), slightly more Caucasian women are obese compared to Caucasian men (23% and 21%, respectively).
- For all racial and ethnic groups combined, women of lower socioeconomic status (income < 130% of poverty threshold) are approximately 50% more likely to be obese.

Statement of Problem in Louisiana

According to the BRFSS data for 2001, Louisiana ranked as the 8th highest state in obesity with 23.3% of the population categorized as obese ⁵. This is higher than the national average of 20.9%. Louisiana was also the 7th highest state for diabetes at 8.5% of the population.. The national rise in obesity of 19.8% to 20.9% from 2000 to 2001 also coincided with increases in diabetes of 7.3% to 7.9%.

Louisiana is in the upper ranking of states with regard to percent of overweight adults as well as deaths from preventable chronic illnesses related to obesity such as cardiovascular disease, cancer, and diabetes ³. In a study of Louisiana primary care patients consisting mainly of uninsured, African-American females, a high prevalence of modifiable high risk behaviors associated with obesity was shown to be present and only a small percentage of patients reported a desire to change their eating or activity patterns⁶.

1995 Louisiana Medicaid participants:

- Specifically, 62% of the sample met criteria for obesity BMI \geq 30
- 52% of participants engaged in no leisure-time physical activity
- 61% of participants consumed greater than 30% of their calories from fat.
- average consumption of less than 1 serving of fruits and only 1 serving of vegetables per day.
- Over 40% reported that they did not consistently avoid high fat foods.

Health Consequences of Obesity

Obesity is a major public health threat contributing significantly to increased morbidity and mortality. Obesity is a leading cause of death among Americans, second only to tobacco-related

deaths⁷. Obesity is associated with significantly increased risk of diabetes mellitus, hypertension, dyslipidemia, certain forms of cancer, sleep apnea, and osteoarthritis. In addition, the increasing prevalence of obesity and its associated complications places a tremendous burden on healthcare utilization and costs. This epidemic of obesity warrant immediate attention from the state and national policy makers, health care and preventive health services in order to minimize the rise in the incidence of new cases of comorbid conditions of diabetes, heart disease and other obesity-related complications.

Metabolic Syndrome

The recently defined "Metabolic Syndrome" is a cluster of metabolic abnormalities associated with high cardiovascular and diabetes risk. In 2001, the National Cholesterol Education Program at the National Institutes of Health (NIH) formulated a working definition of Metabolic Syndrome that requires three or more of the following criteria⁸: 1) Abdominal obesity (waist circumference >102 cm in men and >88 cm in women); 2) Triglycerides > 150 mg/dl; 3) HDL-cholesterol <40 mg/dl in men and <50 mg/dl in women; 4) High blood pressure (>130/85 mm Hg); 5) High fasting glucose (>110 mg/dl). The prevalence of the metabolic syndrome in the U.S. adult population is about 24%. The prevalence increases with age (7% adults in their 20s), to over 40% (adults >60 years). As with obesity, ethnic minority groups appear to be at higher risk. It is widely recognized that obesity is a major factor in the development of the metabolic syndrome and weight management is a primary component of treatment.

Premature Death

On average, adults overweight at age 40 lived about 3 years less while those obese at age 40 lived 13 to 14 years less⁹. The Surgeon General Report found the following:

- 400,000 deaths each year in the United States are associated with obesity.
- The risk of death rises with increasing weight.
- Even moderate weight excess (e.g., 10 to 20 lbs) increases the risk of death, especially adults aged 30 to 64 years.
- Individuals who are obese have a 50% to 100% increased risk of premature death from all causes, compared to normal weight individuals.

Cardiovascular Disease

Roughly 30-78% of cases of hypertension may be attributable to obesity, with the figures being higher for males¹⁰. Obesity increases the risk of developing hypertension. Each 1kg increase in weight after age 18 was associated with a 5% increase in risk for hypertension^{11, 12}. The incidence of heart disease (heart attack, congestive heart failure, sudden cardiac death, angina or chest pain, and abnormal heart rhythm) is increased in persons who are overweight or obese. The Surgeon General reached the following conclusions:

- High blood pressure is twice as common in adults who are obese than in those who are at a healthy weight.
- Obesity is associated with elevated triglycerides (blood fat) and decreased HDL cholesterol ("good cholesterol").

Diabetes

It is likely that the 25% increase in the prevalence of diabetes in the last 20 years in the United States is due to the marked increase in obesity ¹³. Body mass index, abdominal fat distribution, and weight gain are important risk factors for Type 2 diabetes mellitus. The National Task Force on the Prevention and Treatment of Obesity ¹⁴ noted that data from NHANES III indicated that two-thirds of adult men and women in the United States diagnosed with Type 2 diabetes have a BMI of 27 kg/m² or greater. Diabetes prevalence increases with BMI and was 2%, 8% and 13% in those with BMI 25-29.9kg/m² (overweight), 30-34.9 kg/m² (class 1 obesity), and >35 kg/m² (class 2 and 3 obesity), respectively. Weight gain during adulthood also increases the risk of diabetes. Women who gained only 11-17.6 lbs were nearly twice as likely to develop diabetes while those who gained 24 to 44 lbs were more than 5 times as likely to develop diabetes ¹⁵. The Surgeon General reported that:

- A weight gain of 11 to 18 lbs increases a person's risk of developing Type 2 diabetes to twice that of individuals who have not gained weight.
- Over 80% of people with Type 2 diabetes are overweight or obese.

Cancer

- Overweight and obesity are associated with an increased risk for some types of cancer including endometrial, colon, gall bladder, prostate, kidney, and postmenopausal breast cancer.
- Women gaining more than 20 lbs from age 18 to midlife double their risk of postmenopausal breast cancer.

Respiratory Impairment

- Sleep apnea is more common in obese persons.
- Obesity is associated with a higher prevalence of asthma.

Arthritis

- For every 2 lb increase in weight, the risk of developing arthritis is increased by 9% to 13%.
- Symptoms of arthritis can improve with weight loss.

Pregnancy

- Obesity during pregnancy is associated with increased risk of death in both the baby and the mother and increases the risk of maternal high blood pressure by 10 times.
- In addition to many other complications, women who are obese during pregnancy are more likely to have gestational diabetes and problems with labor and delivery.

- Infants born to women who are obese during pregnancy are more likely to be high birth weight and, therefore, may face a higher rate of Cesarean section delivery and low blood sugar (which can be associated with brain damage and seizures).
- Obesity during pregnancy is associated with an increased risk of birth defects, particularly neural tube defects, such as spina bifida.
- Obesity in premenopausal women is associated with irregular menstrual cycles and infertility.

Miscellaneous Health Related Consequences

- Overweight and obesity are associated with increased risks of gall bladder disease, incontinence, increased surgical risk, and depression.
- Obesity can affect the quality of life through limited mobility and decreased physical endurance as well as through social, academic, and job discrimination.

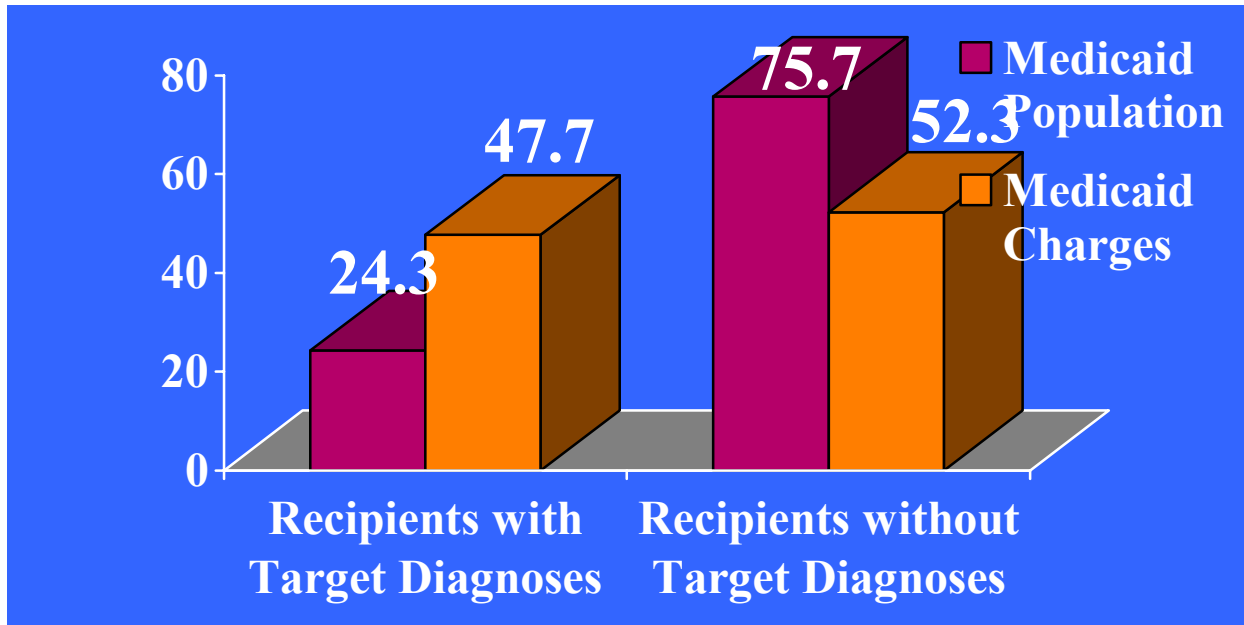
The Economic Burden of Obesity

Costs attributable to obesity totaled \$99.2 billion in 1995 (5.7% of the National Health Expenditure), with \$51.64 billion in direct medical costs, \$3.9 billion (39.2 million days) in lost work, 239 million restricted-activity days, 89.5 million bed-days, and 62.6 million physician visits¹⁶. The economic cost of obesity in the United States was about \$117 billion in 2000¹. A U.S.-based study looking at the impact of obesity on the cost of expected lifetime medical care on 5 diseases (hypertension, hypercholesterolemia, diabetes mellitus, coronary heart disease, and stroke) found that costs increased by 20% with mild obesity, by 50% with moderate obesity, and nearly 200% with severe obesity¹⁷. Not surprisingly, physician visits associated with obesity was estimated to increase 88% between 1988 and 1994. Additionally, a study designed to estimate the clinical and economic burden of obesity in a managed care setting suggested that in a hypothetical plan of 1 million members, the healthcare costs attributable to obesity would be greater than 300 million dollars annually¹⁸. According to the American Obesity Association, the Social Security Administration has standards which establishes obesity as a disease which can compromise the ability to perform some occupational duties. In 2000, it was estimated that approximately \$77 million is paid monthly to the 137,000 individuals qualified for benefits¹⁹. It appears that the substantial costs associated with formal disability are yet to be included in cost estimates related to obesity.

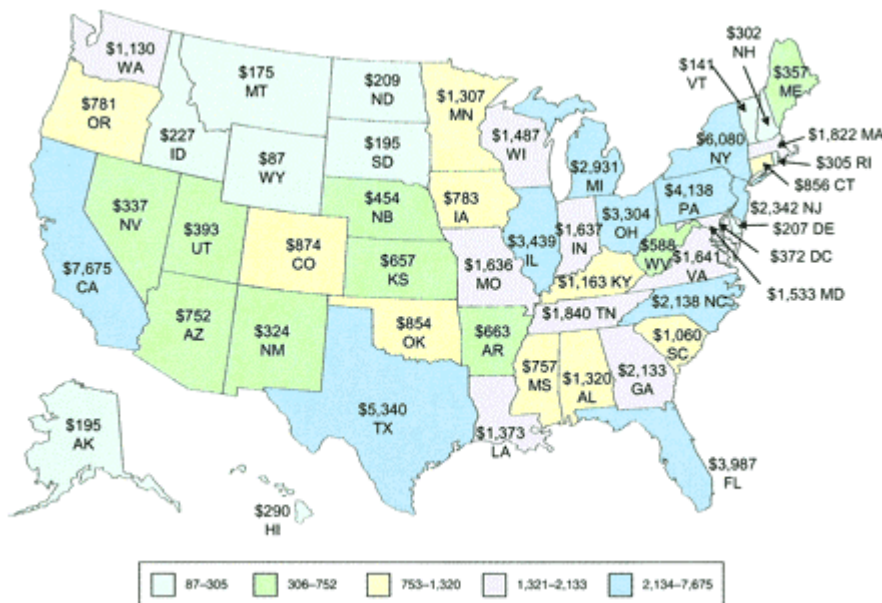
The Economic Burden in Louisiana

In a study of Louisiana Medicaid patients in 1995, 62% of the patients were classified as obese²⁰. Approximately 25% of the population had a chronic disease and accounted for 48% of total annual Medicaid expenditures²⁰. Further analysis found that 16% of all Medicaid patients had diseases associated with high fat diet and 36% of total Medicaid charges were spent on these patients²⁰. Additionally, chronic diseases were higher in African Americans and most prominent in older, African American females. The results of these studies clearly show a patient population in Louisiana characterized by poor health outcomes and the need for programs to adequately address the modification of dietary and activity patterns associated with the development and maintenance of obesity.

Economic Burden of “Preventable” Chronic Diseases within the Medicaid Population associated with obesity and high fat diet ²⁰.



In an examination of estimates of annual medical expenditures attributable to obesity study published in January 2004 ²¹, it was estimated that Louisiana spends \$1.4 billion annually on obesity.



STATE	TOTAL POPULATION		MEDICARE		MEDICAID	
	%	MILLIONS \$	%	MILLIONS \$	%	MILLIONS
Louisiana	6.4	\$1373	7.4	\$402	12.9	\$525
US	5.7		6.8		10.6	

Table 1 in the appendix- shows the state by state obesity related expenditure. As shown above, Louisiana's percentages are higher than the US average in all categories. Louisiana is in the top 6 states with total percentage costs, as well as Medicaid related costs. These estimates of obesity-attributable medical expenditures present the best available information concerning the economic impact of obesity at the state level. Policy makers should consider these estimates, along with other factors, in determining how best to allocate scarce public health resources.

Causes of Obesity

Body weight is the combined result of genes, metabolism, behavior, environment, culture and socioeconomic status. The more than 200% increase in obesity prevalence in the past 20 years clearly reflects behavioral and environmental influences since the genetic component of the population does not change rapidly²². There is ample evidence to conclude that there are strong genetic determinants of obesity²³, but it is also believed that the person's environment, (eating and activity habits, and other lifestyle variables) interact with one's genetic predisposition to determine adiposity^{24, 25}. Since behavior and environment have such a large role in the development of expression of obesity these are the current areas of focus for the treatment and prevention of obesity.

No single physiological disorder accounts for the imbalances which contribute to obesity, however the following biological factors are believed to impact the composition of the human body: genetic differences, disorders of the neurotransmitters, hormonal abnormalities, resting metabolic rates, body weight set points and energy expenditure rates during physical activity and digestion. Genetic research during the past decade has found that the molecular basis of obesity is complex, and rich with possible avenues for reversing the epidemic of obesity²⁶. However, research has suggested that in most individuals, variation in body composition is not associated with genetic predisposition. These individuals may be positively impacted by appropriate clinical and educational interventions.

Despite strong genetic determinants, overweight and obesity result from an imbalance involving excessive calorie consumption and/or inadequate physical activity. Therefore, there is strong consensus that weight loss or the prevention of weight gain is ultimately tied to energy balance²⁷⁻³⁰. In order to gain weight, a person's energy intake must exceed energy expenditure. In order to prevent weight gain, a person must either consume less energy or increase energy expenditure.

Calorie Intake

The United States has experienced significant changes in eating habits that coincide with the rise in obesity. Most fast or convenient foods are calorically dense and commonly contain high amounts of fat and sugar. Portion sizes have increased for both grocery store items as well as

restaurant servings which results in increased calorie consumption. Food labeling remains somewhat confusing, and consumers who are not well informed may attempt to improve their food choices by purchasing foods marketed as healthy, low or fat free only to find that these foods may contain more calories than the original foods. Additionally, many packages are deceptive in the number of serving sizes which lead to over consumption since consumers often assume that packages or bottles contain only one serving.

Sedentary Behavior

The goals of the year 2000 were to reduce the rate of sedentary lifestyle to 15% of adults over 18 years and 17% of low-income individuals³¹. The rate of adults engaging in no leisure activity in the United States ranged from 16.6% (Montana) to 42.6% (Mississippi). In Louisiana, this rate for low-income individuals was 36.8%³¹. In the 1995 Medicaid study,³² they found significantly higher rates of sedentary behaviors in a group of low income individuals (52%) which was substantially higher than national (28%) and Louisiana (32.6%) averages. These rates are also higher than national rates for females (32%), low income individuals (40%) and those with less than a high school education (48%)³³. According to the Surgeon General:

- Less than 1/3 of adults engage in the recommended amounts of physical activity.
- Many people live sedentary lives; in fact, 40% of adults in the United States do not participate in any leisure time physical activity.
- 43% of adolescents watch more than 2 hours of television each day.

Additional Risk Factors

There is a significant body of literature that has been devoted to identifying risk factors for the development or expression of overweight or obesity. Bray³⁴ summarized the following factors as being risk or predisposing factors for obesity.

- Parental Overweight
- Lower Socioeconomic Status
- Smoking Cessation
- Low Level of Physical Activity
- High Carbohydrate Oxidation
- Childhood Overweight
- High Birth/Infancy Weight
- Lack of Maternal Knowledge of child's sweet eating habits
- Recent Marriage
- Multiple Births
- Medication
- Menopause

Guidelines for Treatment of Obesity

The NHLBI developed a comprehensive model to be used in the assessment and treatment of obesity (Appendix A)

The types of treatments that are recommended vary based upon the amount of weight loss necessary to obtain a healthy weight, as well as the presence of comorbid conditions. The following table represents the generally recommended treatments based upon the research and experience of the scientific and health care communities. The recommendations that are consistent

across all weight categories (healthy through morbid obesity) involve lifestyle modification through counseling and education, yet these are services that are not reimbursed as a health expense.

BMI	Description	Health Risk	Weight Goal	Strategy
< 25	Acceptable Weight	Very Low	Maintain Weight	Healthy Diet (Low-Fat, Low Energy Density Diet), Portion Control and Regular Physical Activity
25-29	Over weight	Low	Maintain Weight or Lose 5% of Weight	Health Diet (Low-Fat, Low Energy Density Diet), Portion Control, Exercise, Behavior Therapy
30-34	Obese	Moderate	Lose 10% weight or BMI <30	Healthy Diet (Low-Fat, Low Energy Density Diet), Portion Control, Exercise, Behavior Therapy and Medication
>35	Morbidly Obese	High	Lose >15% weight or BMI reduction of >3 units	Exercise and Healthy Diet, Behavior therapy, Medication, Surgery

The Practical Guide to the Identification, Evaluation, and Treatment of Overweight and Obesity in Adults³⁵ has been endorsed by more than 40 organizations with concerns about obesity, including the Agency for Healthcare Research and Quality, the American Academy of Family Physicians, the American Medical Association, the American College of Obstetricians and Gynecologists, the American Diabetes Association, the American Dietetic Association, the American Heart Association, the Centers for Disease Control, and the North American Association for Study of Obesity and NIDDK National Task Force on the Prevention and Treatment of Obesity.

Weight Management Goals

The general goals of weight loss and management are to reduce body weight, and prevent further weight gain. Attaining and maintaining a moderate weight loss usually requires continued use of some form of therapy. There is strong and consistent evidence from randomized trials that overweight and obese patients in well-designed programs can achieve a weight loss of as much as 10% which would be considered a reasonable individualized goal. Weight loss should be about 1 to 2 lbs/week for a period of 6 months, with the subsequent strategy based on the amount of weight lost.

Treatment Strategies

There is strong consensus that weight loss or the prevention of weight gain is tied to energy balance. In order to gain weight, a person's energy intake must exceed energy expenditure. In order to prevent weight gain, a person must either consume less energy or increase energy expenditure. Interventions with proven success focus on the behavioral targets that represent healthy lifestyle behaviors that would lead to negative energy balance and also improve health and fitness. Overall the scientific and health care community emphasize the potential effectiveness of weight management using multiple interventions and strategies, including dietary therapy,

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

Dietary Modification

National and Louisiana Data on Dietary Fat Intake

Louisiana has been in the upper ranking of states with deaths from preventable chronic illnesses related to obesity such as cardiovascular disease, cancer, and diabetes for the past 10 years³⁶. In addition to obesity, approximately one-fifth of heart disease cases and one-third of cancer cases are attributed to a high fat diet³⁷. Direct cost savings related to reducing dietary fat intake and CHD have been estimated to be between \$754 million and \$2.3 billion³⁸. The average American adult diet is comprised of 34% of calories from total fat and 12% of calories from saturated fat³⁹. However, only 22% of the population met the Healthy People 2000 goals for total fat intake (30% or less), and only 21% of the population met the goal for saturated fat intakes (10% or less)³⁹. Increasing fruit and vegetable intake has been used in conjunction with reducing dietary fat intake for health promotion and disease prevention. However, less than one-third of the population eats 5 or more servings of fruits and vegetables a day³⁹. People with an education level less than 12 years have been found to be twice as likely to eat less than 2 servings of vegetables a day as those who had a higher education level⁴⁰. Low fruit and vegetable consumption was observed in younger adults and the unemployed. Therefore, special efforts will be necessary to increase fruit and vegetable consumption in these populations⁴¹. The data from the Louisiana Medicaid study found that most patients reported eating one or fewer servings of fruits and vegetables daily³².

Standard Dietary Recommendations for Weight Loss

Weight	Daily Caloric Intake	Daily Fat Intake³⁰
<200 lbs	1200-1500	27-33 grams
>200 lbs.	1500-1800	33-40 grams

Dietary Therapy

Dietary modification (dieting) can generally achieve modest, short-term weight reduction. Average weight loss on a low-calorie diet (1200 kcal/day) of 8.5 kg in 20 weeks has been reported, as has 20 kg over 16 weeks on a very low-calorie diet (VLCD [800 kcal/day])⁴². However, a variety of VLCDs often used with commercial weight-loss programs have shown only short-term benefits⁴³. For most individuals who use dieting as a means to lose weight, it has been reported that most of the weight lost in the early phase (16–20 weeks) is regained within 2–5 years⁴⁴. One meta-analysis suggests that, although dieting alone is associated with significant weight loss in the short term, the chance of long-term maintenance of weight loss is significantly increased when diet is combined with exercise⁴⁵.

With regard to diet modification, the behavioral targets are: 1) increased consumption of fruits, vegetables, and grains, 2) decreased intake of dietary fat and sugars, and 3) overall reduction of calories. While there is some controversy about the role of dietary fat in obesity, there is consistent evidence that a diet with less than 30% fat is desirable for a number of health reasons⁴⁶ and continues to be a primary goal of prevention programs for obesity-related problems⁴⁷⁻⁴⁹.

- Dietary therapy involves instruction on how to adjust a diet to reduce the number of calories eaten.
- Reducing calories moderately is essential to achieve a slow but steady weight loss, which is also important for maintenance of weight loss.
- Strategies of dietary therapy include teaching about calorie content of different foods, food composition (fats, carbohydrates, and proteins), reading nutrition labels, types of foods to buy, and how to prepare foods.

The NHLBI panel reviewed Randomly Controlled Trials (RCT) to determine the effectiveness of diets on weight loss⁵⁰. The diets evaluated included low calorie diets (LCDs), very low-calorie diets (VLCDs), vegetarian diets, American Heart Association dietary guidelines, the NCEP's Step I diet with caloric restriction, and other low-fat regimens with varying combinations of macronutrients. They found that an average weight loss of 8% can be obtained over 3 to 12 months with an LCD and that this weight loss effects a decrease in abdominal fat. They also noted that lower-fat diets with targeted caloric reduction promote greater weight loss than lower-fat diets alone. While VLCDs produce greater initial weight losses at one year, both LCD and VLCD are equivalent in their effectiveness at one year.

Conclusions of the NHLBI:

- LCDs are recommended for weight loss in overweight and obese persons.
- Reducing dietary fat alone without reducing calories is not sufficient for weight loss. Reducing dietary fat, along with carbohydrates, can facilitate caloric reduction.
- An individually planned diet to help create a deficit of 500 to 1,000 kcal/day should be an integral part of any program aimed at achieving a weight loss of 1 to 2 lbs/week.

Ayyad and Anderson⁵¹ completed a systematic review of 898 papers to determine the long-term efficacy of dietary treatment of obesity between 1931 and 1999. They found that success was maintained for approximately 14 years, and that diet combined with group therapy had better long-term success. Conventional diets were more efficacious when combined with group therapy, while VLCD were more efficacious if combined with behavior therapy. The authors reported that they found a success rate of 15% and concluded that dietary therapy is helpful as an adjunct treatment to group and behavioral therapy.

A consistent body of evidence links dietary fat intake to body fat, which likely because of the energy density of fat⁵². There is no evidence (once controlling for fat intake) linking carbohydrate intake to obesity risk⁵³. Similarly, to date there is no evidence in support of claims that carbohydrate-restricted diets, such as the popular Atkins' diet, are effective in promoting sustainable weight loss. Satiety relates to appetite control and consequently to weight regulation. Available evidence suggests that protein is more satiating than carbohydrate or fat, but high-fiber carbohydrate satiety is comparable to protein⁵⁴.

Diet Classification

Diets related to weight loss can be classified as starvation (< 200kcal per day), very low calorie diet (VLCD 200-800 kcal per day) or low calorie diet (LCD >800 kcal per day). Despite claims and testimonials of numerous individuals with regard to weight loss, the compositions of diets do not have a differential impact as long as it results in an energy deficit. As with all dietary treatments, long-term success is poor due to cessation of the regimen.

Starvation (<200 kcal/d): Use of these diets can produce weight loss of 1kg/day but slows to .05 kg/day after three to four weeks. Problems with deficiencies in sodium, potassium, protein, and thiamine are common with resulting hypotension, syncope, and uric acid kidney stones. Usually starvation is discouraged as a weight loss method and very low calorie diets need to be closely medically supervised. Total Fasting or starvation is associated with significant health risks and is not recommended as a viable treatment for obesity.

Very Low Calorie Diets (200-800 kcal/day): VLCD provide less than 800 kcal per day that is below the resting metabolic rate (RMR) of most adults. They can provide rapid weight loss but require nutritional supplementation and medical supervision. However, research suggests that overtime, the VLCD is no more effective than the less dramatic LCD. According to Bray³⁴, use of these diets can be perilous and medical supervision is suggested if used for more than two months or if more than 18kg of weight loss is obtained. Long-term success is difficult and after 3 years maintenance may only be 3.3 kg⁵⁵.

Low Calorie Diets (800-1200 kcal/day): LCD are also usually below the energy requirements of most adults. A variety of calorie and portion controlled products are now available that are designed to be used in conjunction with a LCD. Examples of these products include, Slim-fast, Healthy Choice, Smart Ones, Lean Cuisine, and Budget Gourmet Light. These products provide low calorie servings (200-500 kcal per serving) and usually are low in fat. Commercial weight loss programs such as Jenny Craig also provide similar products. Dietitians and commercial programs also teach individuals how to use conventional foods in their daily life to achieve a reduced level of intake.

Balanced Deficit Diets: Balanced deficit diets are usually the most recommended diets by health professionals. They are low in calories and balanced in their macronutrient content. These dietary recommendations are close to those recommended for health in nondieting individuals. They are low in fat <30%, high in complex carbohydrates (>55%) moderate in protein (10-15%), high in fiber (25-30g) and encourage limiting alcohol. These diets are promoted commercially by Weight Watchers, Diet Center, Physician's Weight Loss Centers, Take Off Pound Sensibly (TOPS), Overeaters Anonymous (OA), The Calloway Diet, The T-factor Diet and the Fat Attack Plan. Adherence with these diets is compromised by the participant's perception of slow progress.

Glycemic Index Diets: Diets based upon Glycemic Index have been proposed as treatments for obesity⁵⁶. The premise is that some foods trigger rapid peaks in blood glucose and a subsequent surge in insulin secretion resulting in hunger and increased energy consumption. Melanson and Dwyer⁴⁶ noted that the satiety of these diets is still being researched and while some find positive findings other do not support the claims. In a review of the literature, Melanson & Dwyer⁴⁶ also state that the practicality of learning the GI index of all foods would be at least as complicated as learning calories counts in regard to patient education and participant burden. Conflicting research exists regarding the use of the glycemic index diet. While there are those who endorse this as a promising area⁵⁷, there are those who do not endorse the use of this diet⁵⁸.

High protein diets: These are usually associated with low carbohydrate intake. Popular diets that tout these types of plans include Sugar Busters, Carbohydrate Addict Diet, The Zone, and Dr. Atkin's New Diet Revolution. In a review of the literature, Melanson and Dwyer⁴⁶ note that these diets are not recommended due to false assumptions regarding metabolism, deficiencies

in carbohydrates and micronutrients and potentially harmful intake levels of protein and fat. These diets produce weight loss because they lead to energy deficits and lead to ketosis and dehydration. The initially large weight losses are due to water loss and prolonged adherence could lead to calculia, kidney stones and high blood urea nitrogen in vulnerable individuals. These diets usually have the following macronutrient make-up: High-fat (55% to 65%), low-CHO (<100 g of CHO per day), high-protein diets (e.g., *Dr. Atkins' New Diet Revolution*, *Protein Power*, *Life Without Bread*). Several national organization have issues warnings against the use of high protein diets: The American College of Sports Medicine, The American Dietetic Association, and The Women's Sports Foundation⁴⁶.

Low Carbohydrate Diets: In an extensive review of the literature, Bravata and colleagues⁵⁹ noted that there was insufficient evidence to make recommendations for or against these dietary programs. From the studies evaluated it appears that weight loss was primarily obtained through restriction of calories not the decrease in carbohydrates.

High Carbohydrate Diets: These diets are usually well balanced and safe since they tend to promote fruits, vegetables and whole-grains. Low-fat (11% to 19%), and very-low-fat (VLF) (<10%), very-high-carbohydrate, moderate-protein diets (e.g., *Dr. Dean Ornish's Program for Reversing Heart Disease*, *Eat More, Weigh Less*, *The New Pritikin Program*). Popular diets which are consistent with this regimen include Dr. Ornish: Eat More, Weigh Less, Volumetrics, The Pritikin Diet, and the T-Factor Diet. However, Melanson & Dwyer⁴⁶ note that extreme restriction of calories or fat should be viewed with caution since this can lead to endocrine problems and nutrient deficiencies.

Unfounded Popular Diets: Eat Right 4 Your Type purports to develop a program based upon blood type and is scientifically unfounded. The Beverly Hills Diet restricts various foods at certain times of day which is not based upon scientific principals of metabolism. The 5-day Miracle Diet, according to Melanson and Dwyer⁴⁶, recommends a potentially dangerous VLCD without medical supervision. Diets that exclude necessary food groups include Fit for Life, The Hilton Head Over 35 Diet, and The Rotation Diet.

Meal Replacements

Meal Replacements are calorie and portion controlled foods in the form of drinks or bars used to replace a meal. Meal replacements have become increasingly popular with the public and have been found appetizing and effective in a number of studies. They are attractive since they simplify food choices, and are easy to obtain, prepare and transport. In a review of the literature, Heber (2002)⁶⁰ found weight losses of approximately 17 lbs at 12-24 weeks (males and females respectively) that was maintained for up to 2 years. Heber reported one study that at 12 weeks meal replacement participants lost 16 lbs while those prescribed a calorie restricted diet lost 3 lbs which was attributed primarily to compliance. In a community intervention in Pounds, WI a five-year study found a 10 lb weight loss and 90% compliance rate.

Meal replacements have been proposed as a means to teach individuals stimulus control and techniques for relapse prevention. Use of replacements is a viable alternative to skipping meals since individuals tend to consume more calories in the next meal than those saved by skipping. Most meal replacements are nutritionally balanced and seem promising for future treatment and prevention efforts.

Prepackaged foods can also be considered meal replacements. These include a variety of frozen dinners and shelf items. They require more preparation time but some individuals find them

appealing since they are more “food” like in their presentation. They offer many of the benefits of the meal replacement drinks and bars such as convenience and ease of preparation and are calorie and portion controlled. It is likely that the combination of meal replacement and prepackaged foods will provide answers to many individual’s need to lose weight in the midst of their busy lives.

Compliance with Diets

Compliance with most low fat diets is often problematic even with intensive counseling⁶¹. Primary factors contributing to noncompliance are understanding the diets, time commitment for food planning and preparation, and the restrictions⁶². In a study of Louisiana Medicaid participants, responses to the nutrition module of the Behavioral Risk Factor Surveillance Survey⁶³ suggested average consumption of less than 1 serving of fruits and only 1 serving of vegetables per day for this sample. Over 40% of the sample reported that they did not consistently avoid high fat foods.

Dietary fat reduction recommendations have been linked to weight loss control without significantly impacting the palatability of the diet⁶⁴. Simplified meal plans that utilize meal replacement or food provision have improved patient compliance possibly because they decrease meal planning, reduce delays in preparing unfamiliar food, and do not rely on restriction or elimination of foods⁶⁵. Additionally, using structured meal plans and grocery lists can improve weight loss outcomes.

Some foods are more effective in producing satiation and controlling appetite, whereas others are associated with hyperphagia (overeating), thereby producing positive energy balance and excess weight gain⁶⁶⁻⁶⁸. The characteristics of dietary fat associated with promotion of obesity include: 1) low ability to produce satiation, 2) high energy density, 3) ability to increase total caloric intake, 4) inability to acutely increase its own oxidation upon intake, 5) high storage capacity, and 6) low thermic effect^{52, 69}. Teaching individuals how to make dietary choices that are nutrient dense and provide satiety may improve compliance since hunger is a common complaint.

Meal replacements are offering a method to attain caloric deficits while being nutritionally balanced. Initial studies of meal replacements suggest that individuals are more compliant with these methods presumably due to the ease and simple nature of the diet. Additionally, it appears that many of the barriers noted by individuals such as problems with taste and taste fatigue are being addressed with increase variety of choices of flavors and products.

Cost Effectiveness

In a review of the literature, Raynor and colleagues⁷⁰ found limited studies on the cost of adopting a healthy diet. It appears that most consumers perceive that eating healthy will be unappetizing and more expensive. A few European studies suggested that cost for eating healthy was more costly than those for a traditional diet due to the expense of fruits and vegetables^{71, 72}. However, other US studies found that food costs consistent with traditional weight loss treatment (reduced energy intake >30% fat) did not increase during the initial 6 months of family based treatment which is consistent with other findings^{70, 73}. They noted that food costs actually decreased at one year which was not merely attributable to reduction in food intake. Future research on the costs of healthy diets has been recommended in the time for preparing, shopping and healthcare costs. To date, most of the studies completed have been with children. Future

studies should evaluate costs related to adult programs. Very low calorie diets usually require medical supervision and can be costly for example \$3000 for a 6 month program ⁷⁴.

Future Research on Dietary Therapy:

A recent research announcement by DHHS noted that there is an important gap in knowledge regarding the role of diet composition in energy balance ⁷⁵. Low carbohydrates diets have been reported to enhance weight loss, while high carbohydrates diets may contribute to weight gain. Studies (up to six months) have reported greater weight loss with a low-carbohydrate diet; however, weight loss as a result of reduced caloric consumption has not been adequately studied. Factors such as glycemic index, nutrient density, fiber content, and dietary variety, have also been proposed to affect energy intake, with potential relevance for enhancing weight loss and prevent weight gain. Further research is needed to elucidate the role of other macronutrients in energy balance (including fats, proteins and ethanol). The mechanisms by which diet composition affects energy balance may include alternations in appetite, nutrient absorption, neuroendocrine and gastrointestinal factors, energy partitioning, physical activity and other components of energy expenditure, but this needs further research to determine. The impact of diet composition on body composition, risk factors for comorbid conditions are not well documented. The research announcement concluded that “ In addition to long-term studies of weight gain in response to standardized diets, short-terms studies with well-characterized diets varying in macro- and micronutrient composition would help to define the effect of diet composition on endocrine and neuronal axes involved in regulation of both food intake and energy partitioning.”

Summary of Dietary Treatments

Any dietary modification that reduces caloric intake will result in weight loss. In regard to body composition, all low calorie diets result in loss of body weight and fat. However, the low carbohydrate (CHO) diets cause a greater weight loss initially due to body water loss. The diet must be maintained long term to produce loss of body fat. It is generally recognized that diets classified as moderate-fat ensure for adequate nutritional intake due to the focus on balanced macronutrient consumption. Diets classified as high-fat, low CHO will require supplementation due to being deficient in vitamins E, A, thiamine, B6, folate, calcium, magnesium, iron, potassium, and fiber. Very low fat diets will be low in vitamins E, B12 and zinc. As noted by the ADA in their publication on weight management “ Of greatest importance is stressing “healthy eating” advised for all Americans according to the Food Pyramid Guide and the US Dietary Guidelines. Dietary planning and employing caloric dilution to keep the volume of food up while reducing total calories, may decrease feelings of deprivation and restriction”. Dietary energy density continues to be the most commonly endorsed dietary focus for weight loss. In a review of the literature Yao and Roberts ⁷⁶ found that diets that are low in fat and high in fiber appear to be the most effective in promoting weight loss.

Physical Activity

There is strong evidence that exercise is associated with long-term weight loss and prevention of weight gain ^{77, 78}. In a 25 year review of the literature, Miller ⁴⁵ noted that exercise alone is not associated with significant weight loss when compared to diet alone or the combination of diet and exercise.

- Physical activity contributes to weight loss, especially when it is combined with caloric reduction.
- Regular physical activity is extremely helpful for the prevention of overweight and obesity.

- Regular physical activity is very important in maintaining weight loss.
- In addition to weight control, physical activity helps prevent heart disease, helps control cholesterol levels and diabetes, slows bone loss associated with advancing age, lowers the risk of certain cancers, and helps reduce anxiety and depression.

Multiple cohort and cross-sectional studies have shown an association between obesity and inactivity. Weight loss with regular exercise alone is modest and generally less than that achieved with caloric restriction. Exercise in combination with caloric restriction leads to relatively greater fat loss, preserves lean body mass, and has been shown to maintain initial weight loss. Even in the absence of significant weight loss, regular exercise provides additional health benefits of, improved cardiovascular fitness, enhanced psychological well-being, and reduced risk of mortality.

The behavioral targets for physical activity are: 1) reduction of sedentary behavior, and 2) increased lifestyle physical activity. There is a growing consensus that the current obesity epidemic may stem, in part, from increased sedentary behaviors (e.g., watching television, playing video games, use of computers, etc.)⁷⁹⁻⁸².

- It is recommended that Americans accumulate at least 30 minutes (adults) of moderate physical activity most days of the week. More may be needed to prevent weight gain, to lose weight, or to maintain weight loss.
- Less than 1/3 of adults engage in the recommended amounts of physical activity.
- Many people live sedentary lives; in fact, 40% of adults in the United States do not participate in any leisure time physical activity.
- Physical activity is important in preventing and treating overweight and obesity and is extremely helpful in maintaining weight loss, especially when combined with healthy eating.

Types of Physical Activity

Decreasing sedentary lifestyle is also an important goal for weight management and obesity prevention. Regular physical activity (PA) is defined as 30 minutes of moderate physical activity at least 5 days a week⁸³. More than 60% of adult and adolescent Americans are physically under-active, and 25% of the US population report no leisure time physical activity⁸⁴. Chronic health conditions are commonly seen in primary care settings, and currently affect more than 100 million people and account for 76% of all direct medical costs⁸⁵. Physical activity is a first line therapy against many chronic health conditions⁸⁶ since it is associated with weight loss/maintenance, cardiovascular health, hypertension control, lipid profile improvements, diabetes control, osteoporosis prevention, sleep regulation, reductions in anxiety and depression, colon cancer prevention, and improved longevity⁸⁷. In the United States, it has been estimated that approximately 250,000 deaths per year are attributable to physical inactivity³⁹. One out of 10 Americans die prematurely of disorders related to physical inactivity, and data suggest that minimal PA can have important reductions in chronic disease⁸⁸. Data suggest that moderate PA provides at least a 30% reduction in CHD, colon cancer, and Type 2 diabetes among previously sedentary individuals^{89,90}.

Effectiveness of Physical Activity

Comprehensive reviews of the relationship between obesity and physical activity have yielded three common conclusions: 1) physical activity in combination with energy restriction is more effective for weight reduction than caloric restriction alone, 2) during weight loss, physical activity preserves lean muscle mass while promoting fat loss, and 3) there is a dose-response relationship (i.e., frequency, duration) of physical activity that affects the rate of weight loss⁹¹⁻⁹³. Furthermore, the benefits of physical activity on quality of life and reduction of disease risk have been well established^{91, 94-96}. Most studies examining physical activity on weight loss and maintenance have utilized calorie restrictive diets. However, data do exist on the effectiveness of exercise alone on weight reduction. Most controlled studies of an exercise alone treatment component have found modest weight loss (e.g., 2-3 kg)^{91, 97}. Large amounts of exercise are required to achieve weight loss, and too often overconsumption of calories can negate weight loss. In a comprehensive meta-analysis of 25 years of research, Miller and colleagues evaluated the effectiveness of diet, exercise, and diet plus exercise in weight loss⁴⁵. The authors concluded exercise only studies were of longer duration and utilized younger participants who had lower BMIs than diet alone and diet plus exercise studies. Exercise only studies reported statistically lower weight loss and reduction in BMI (2.9 kg and 0.8, respectively) compared to diet only (10.7 kg and 4.0, respectively) and diet plus exercise (11.0 and 4.2, respectively) studies⁴⁵. Another meta-analysis revealed that exercise increased weight loss effects of caloric restriction as well as promoted beneficial effects on the nature of the weight loss (i.e., lean muscle mass lost) compared to diet alone⁹⁸.

Subject demographics and program lengths.			
Variable	Diet ^a	Exercise ^a	Diet + exercise ^a
Age	40.0 ± 0.5 (171)	36.5 ± 1.4* (63)	39.5 ± 0.7 (90)
Initial weight (kg)	96.4 ± 1.1 (196)	82.9 ± 2.4* (75)	96.3 ± 1.9 (114)
Initial BMI	34.9 ± 0.6 (87)	26.4 ± 1.5* (27)	34.8 ± 1.0 (56)
Initial percentage body fat	38.5 ± 0.9 (56)	28.5 ± 1.2* (55)	36.6 ± 1.0 (42)
Program length (weeks)	15.1 ± 0.8 (224)	20.9 ± 1.8* (76)	13.4 ± 0.7 (119)

BMI = Body mass index. Data are means ± s.e.m. *Significantly different from other program types (ANOVA). ^aNumber in parenthesis represents the number of studies reporting data for that particular variable.

Table adapted from Miller and colleagues⁴⁵

The Coronary Artery Risk Development in Young Adults (CARDIA) was a prospective investigation of the impact that multifactorial influences have on the development of coronary heart disease risk factors. Over 5,000 African American and Caucasian men and women between the ages 18-30 years were recruited and followed for ten years. The researchers found that physical activity was significantly inversely related with weight gain for both genders and ethnicities⁹⁹. Also, the researchers found that an increase in physical activity during the 2-3 year follow-up was associated with a reduction in weight gain, and this reduction was maintained through the fifth year follow-up regardless of whether the physical activity increase was maintained.

The NHLBI found 13 of 23 RCT articles appropriate to determine the effect of physical activity on weight loss, abdominal fat, and changes in cardiorespiratory fitness. They found strong evidence that physical activity alone results in modest weight loss and increases cardiorespiratory fitness, independent of weight loss. Physical activity in overweight and obese adults reduces abdominal fat only modestly if at all, but regular physical activity independently reduces the risk for cardiovascular disease. They concluded that: Physical activity should be an integral part of weight loss therapy and weight maintenance.

- Initially, moderate levels of physical activity for 30 to 45 minutes, 3 to 5 days a week, should be encouraged.
- All adults should set a long-term goal to accumulate at least 30 minutes or more of moderate-intensity physical activity on most, and preferably all, days of the week.

Prevention of Weight Gain /Weight Maintenance

Physical activity has been significantly correlated with weight loss maintenance^{91, 100}. Findings suggest that either alone or in combination with other treatment modalities, physical activity that expends 1,500-2,000 kcal/week is necessary to maintain weight loss⁹¹. In the seminal study by Pavlou and colleagues, 160 overweight male police officers were randomly assigned to one of four diet conditions¹⁰¹. Half of the participants in each weight loss condition were given 90 minutes of supervised exercise, three times a week. There were nonsignificant differences between participants receiving diet alone or in combination with exercise at the end of the 8 week trial period. However, follow-up at 8 and 18 months demonstrated that those who continued to exercise were significantly less likely to have regained weight. A more recent study examining 5 year follow-up of patients losing 12 kg at the end of a weight loss period found that 89% of patients maintained their weight loss through increased exercise and dietary attention¹⁰². A review article of obesity treatments found 50-60% success rates for maintenance of weight loss over a two year period when caloric restriction and increased physical activity were utilized¹⁰³. The meta-analysis by Miller and colleagues⁴⁵ replicated that at one year follow-up, diet in combination with exercise tended to be the superior approach to weight maintenance compared to diet or exercise alone (8.6 kg, 6.6 kg, 6.1 kg, respectively)⁴⁵. Additionally, a small review paper of six studies that investigated long-term maintenance effects of dietary restriction and exercise revealed that all studies found a consistent maintenance of weight loss in conditions that promoted physical activity¹⁰⁴.

Use with Other Treatments

Multiple studies have replicated the finding that exercise in combination with proper nutrition is the most effective intervention for weight loss and prevention of weight gain^{91, 105}. In a review of randomized clinical trials with at least one year follow-up data, the authors concluded that exercise in combination with diet was more effective for weight loss than diet alone¹⁰⁶. The authors concluded also that light exercise (e.g., calisthenics, stretching) may be as effective as moderate exercise, however, without the cardiorespiratory benefits of moderate exercise. A recent randomized trial of overweight, sedentary women concluded that significant weight loss and cardiorespiratory fitness could be produced through a combination of exercise and diet¹⁰⁷. A notable finding of the research was that no differences in weight loss were noted between groups of women assigned to different exercise durations and intensities. However, another study

examining the effects of intermittent versus continuous exercise found that the continuous exercise group lost significantly more weight from baseline compared to the intermittent exercise group¹⁰⁸. However, both groups yielded improvements in cholesterol and insulin levels. Another meta-analysis that examined studies combining diet and exercise reported that the average weight lost was 8.5 kg for the combined group compared to 6.7 kg in diet only conditions¹⁰⁹. A recent randomized controlled trial compared weight loss in men across 4 groups (e.g., diet-induced weight loss, exercise-induced weight loss, exercise without weight loss, and control)¹¹⁰. The authors found that body weight decreased by 7.5 kg in both weight loss conditions, and no significant changes were observed in the exercise without weight loss and control groups. Both exercise conditions showed significant improvements in cardiorespiratory fitness compared to the control condition. Total fat loss was greater among the exercise-induced weight loss group compared to the diet-induced group. In summary, available studies suggest that exercise in combination with caloric restriction is more effective in weight loss than exercise or diet alone. However, finding regarding the duration, intensity, and regularity of exercise need further replication.

Compliance with and Barriers to use of Physical Activity

It is estimated that when exercise is used as a treatment for a variety of chronic illnesses, approximately half of participants will discontinue within 6 months and the number of participants will continue to decline over time. Home based programs, having access to exercise equipment in the home, have been found to improve adherence and treatment effectiveness^{111, 112}.

Brisk walking has been identified as an effective means to exercise for those who are overweight or obese¹¹³. However, overweight and obese individuals may initially have difficulty with walking because of exhaustion and pain which may have a negative influence on adherence for exercise¹¹⁴. A recent Australian study found that 4.4% of all participants reported “being too fat” as a barrier to exercising, of which 6.2% of these respondents were female, and 22.6% reported being obese¹¹⁵. Frequently identified barriers to exercise include comorbid conditions that make it difficult to exercise, lack of time, lack of exercise equipment, poor familial support, and lack of child care. Another barrier to starting a physical activity program is the belief that small amounts of low intensity activity are not beneficial. Several strategies have been identified to improve adherence for physical activity programs¹¹⁴. Developing good rapport which includes discussions of barriers to treatment and providing patient education are helpful. Patient education can include ensuring that patients understand the dietary and activity prescriptions provided to them, discussing patients’ beliefs about their obesity, discussing how diet and exercise are beneficial to them, and assessing patients’ expectations. Additionally, modifying treatment regimens to be more compatible with the patient lifestyle (i.e., emphasis of moderate lifestyle activities), as well as including patients in the development and management of treatment goals. Providing feedback on patient progress and assisting the patient with self-monitoring has also been found to be an effective tool¹¹⁴. Finally, involving the patient’s family and social supports can improve long-term adherence.

Costs

Few studies of cost-effectiveness of physical activity on obesity exist. A study from England examined the cost of promoting physical activity among individuals over the age of 65 years¹¹⁶. The goal of the study was to examine the financial costs and health benefits of a publicly funded program of regular exercise. Twice weekly exercise classes were provided to

10,000 participants over the age of 65 years. The total estimated cost was approximately \$483,500 (based on current British pounds to American dollars conversions). However, 76 deaths and 230 hospital inpatients stays would be avoided resulting in a savings of approximately \$340,000. The authors assumed that the mean life expectation after the age of 65 years would be 10 years. The program would cost approximately \$186.00 per year life-year saved. The authors concluded that important health benefits could be achieved at a relatively low cost.

Behavioral Treatments of Obesity

Behavior therapy or behavior modification is one of the most widely used strategies for the treatment of obesity. These techniques are an extension of learning theory, and were first applied to obesity treatment in the 1960s¹¹⁷. Behavioral treatments are based on the energy balance model of obesity, and focus on maladaptive eating and exercise patterns that lead to a positive energy balance and eventually to weight gain. The components of behavior therapy offer a unique emphasis on modification of environmental factors related to eating and exercise behaviors and a system through which any behavior (i.e., eating) can be altered¹¹⁸. Cognitive-behavioral strategies have also been used in the treatment of obesity and offer an emphasis on traditional behavioral components as well as thought processes, emotions, and attitudes related to eating and exercise behaviors.

Components of Behavioral Therapy

Environmental antecedents and the consequences of eating behavior are the focus of behavioral weight programs. Antecedents are viewed as modifiable cues for responding. Positive behavioral consequences are likely to increase specific eating or activity patterns while negative consequences are likely to decrease the frequency of these behaviors. The basic treatment methods for obesity include stimulus control, modification of eating behaviors, modification of activity patterns, and self-monitoring. These treatment approaches are designed to increase awareness of eating and activity patterns, to normalize eating patterns, to reduce exposure to cues for maladaptive eating or activity patterns, and to alter the response to problem situations. Behavioral treatment sessions for obesity are usually conducted in a group format and last for 10 - 20 weeks. The following is a brief review of the common behavioral techniques¹¹⁹⁻¹²³.

Goal Setting: This is an important technique in the initiation of a treatment program. Patients set goals for calories, fat, physical activity, and other modifiable behaviors. Short-term goals of 1-2 lbs of weight loss a week, and daily caloric intake are discussed. Realistic short-term and long-term goals are discussed to facilitate behavior change.

Self-Monitoring: This technique is considered the “cornerstone” of behavioral treatment. Monitoring of all eating and exercise behaviors is used to raise awareness of behavior patterns and to identify faulty eating and activity patterns. In the most basic form, individuals record time, stimuli, place, and quantity of eating and activity behaviors. Monitoring strategies are used throughout the treatment to regulate behavior change (e.g., reducing calorie intake). Record-keeping can also be expanded to include information on feelings associated with eating.

Stimulus Control: Stimulus control techniques are used to modify environmental antecedents that influence eating or activity patterns. The goal is to restrict environmental circumstances that serve as discriminative stimuli for maladaptive eating or sedentary behavior.

Techniques include: eating 3 meals, eating at same time and place, changing serving and food storage techniques. These procedures are used to decrease the number of conditioned stimuli or situations that may trigger eating behavior.

Modification of Eating and Activity Patterns/Nutrition: The goal of these techniques is to modify faulty eating behaviors that may interfere with satiety or lead to excessive calorie intake. Techniques used include slowing pace of eating, reducing portion sizes, measuring food intake, leaving food on plate, improving food choices, and eliminating second servings. Additionally, the patient is educated on the Food Guide Pyramid, and encouraged to follow a diet of reduced fat. Sedentary behaviors are also targeted and efforts are made to incorporate increased activity into daily routine (i.e., taking stairs). Exercise can be categorized as either programmed (regularly scheduled times of physical activity for a determined amount of time and intensity) and lifestyle (increasing energy expenditure throughout the day). Lifestyle activity has been associated with weight loss in several studies, and provides a viable alternative to the patient who “hates to exercise”.

Contingency Management: Positive reinforcement is used to stabilize and increase the maintenance of new eating and activity patterns rather than weight loss. Punishment or loss of reinforcement may also be used to change eating and activity behaviors. Patients are encouraged to eliminate all food rewards. Monetary incentives or penalties have been used in many treatment programs to improve motivation. Behavioral contracting with a therapist or support group may also be used to gain social reinforcements. Behavioral contracting is helpful because 1) it makes the patient involved and invested in his/her treatment, 2) provides a written outline of expected behaviors which reduces forgetfulness and disagreement on goals, and 3) provides incentives to change based on reward of goal.

Cognitive Behavioral Strategies: Cognitive behavioral strategies combine the traditional behavioral treatment components with emphasis on thinking patterns that may affect eating behaviors. These interventions may focus on perfectionistic standards, negative self-statements, unrealistic weight loss goals, justifications for eating, and limited self-control. The goal is to alter mood, irrational beliefs, unrealistic standards, and negative evaluations that affect eating patterns. These techniques may also include stress management and assertiveness training to improve resistance to high risk situations. Most patients present for treatment desiring a weight loss of 20-30% of their initial weight. Therefore, a focus on reasonable weight loss goals (i.e., significant health benefits with 5-10% weight loss) is emphasized rather than attaining a specific weight.

Stress Management: Stress is a primary predictor of overeating and relapse. Stress management skills include progressive muscle relaxation, diaphragmatic breathing, and meditation. The goal of stress management is to reduce arousal and provide distraction from stressful events.

Effectiveness of Behavioral Treatment of Obesity

In more than 100 controlled studies, behavioral weight loss treatments have demonstrated efficacy over placebo, traditional diet, insight therapy, nutritional information, and control groups^{124, 125}. In a review of the literature, Foreyt & Goodrick¹²⁶ found that weight loss was positively correlated with a number of behavioral therapy components including self monitoring, incentives, goal setting, eating rate, positive coping, social support, and therapist contact.

The effectiveness of behavioral weight loss programs has improved over the past three decades years. Ferster and colleagues¹¹⁷ and Stuart¹²⁷ pioneered the application of behavioral principles to weight loss. Stuart¹²⁷ found promising results with greater than 9 kg weight loss and 20% attrition rate. In the 1970s, treatment lasted 8-10 weeks and resulted in 8-9 lbs losses. In the 1980s, there was an increased focus on improving weight loss and treatment was lengthened to 13-16 sessions and resulted in 15-22 lb losses¹²⁸. More recently, the focus of behavior therapy in weight loss has been on long-term maintenance and improving the effects of other weight loss strategies such as low calorie diets (LCD) and pharmacotherapy. Foreyt and Goodrick¹²⁹ found that the average duration of behavioral treatment was 18 weeks with weight losses of 9.9 kg (.5 kg per week), and an attrition rate of less than 15%. In a review of 3 articles from 1991-1995, treatment length increased to 20 weeks and follow-up to 43 weeks, but weight loss remained fairly stable at 19 lbs¹³⁰. In another review, behavioral treatments were typically delivered in a group format for 15 to 24 weeks with an average weight loss of 8.5 kg¹³¹. Comparisons of weight loss between individual and group formats suggest that group therapy produces greater weight loss than individual therapy¹³². While the weight losses obtained with behavior therapy are modest, a few studies have noted weight losses over 20 lbs^{42, 133, 134}. Therefore, behavior therapy appears to be an effective weight loss strategy for mildly to moderately obese individuals, and the modest weight losses obtained appear to have important health benefits^{135, 136}.

Improvements in the weight loss noted with behavior therapy are likely due to a number of factors. Firstly, patients in more recent studies represent heavier clinical populations. In 1974, the mean weight of patients was 74.1 kg; while in 1986, the mean initial weight was 95.7 kg¹³⁷. Secondly, attrition rates have increased from 11% in 1974 to 21% in 1986. It is possible that those patients doing poorly are more likely to drop out; therefore, selective attrition may overestimate outcome¹³⁷. Thirdly, the length of treatment and follow-up appear to be major determinants of improved treatment outcome. In 1974, average treatment time was 8.4 weeks with average follow-up of 15.5 weeks¹²⁸. However, in a more recent review of the literature the average treatment was 18 weeks with 52 weeks of follow-up¹²⁹. Finally, improvements in the weight loss of behavioral treatments may be attributed to the intensive and multifaceted nature of the current treatment programs.

Since the initial behavioral treatments began, the average weight loss has almost doubled, and attrition has remained relatively low (10-17%) with follow-up increases up to 1 year^{135, 138}. The average weight loss per week has remained stable at approximately .5 kg, but treatment times have doubled from 9 weeks to 18 weeks. At one year follow-up, 60-80% of the weight loss is likely to be maintained with gradual increases over the next 5 years^{42, 135}. Additional follow-up studies conducted 2 to 5 years after behavioral treatment have shown a gradual regain of weight to baseline^{131, 139}. Therefore, behavioral techniques appear to be effective with short-term behavioral change; however, additional research is needed in the area of long-term maintenance¹³⁹.

Maintenance Strategies

While most behavioral programs demonstrate short-term weight loss, studies with follow-up periods of greater than 1 year found that most patients regained the weight lost during treatment. Average follow-up for early programs in 1974 was 15.5 weeks, and patients maintained 4.0 kg. In the 1980s, follow-up increased to between 44 to 58.4 weeks with average weight of 6.6 kg¹²⁸. A review of available long term treatments indicated that there is a gradual return to baseline with a gain of 47% of weight lost at 5 years¹²⁸. The mean weight loss was 16 lbs after treatment, 12.7 lbs at one year, 11.1 lbs at 2 years, 7.95 lbs at 3 years, 5.3 lbs at 4 years and 7.5 lbs at 5 years. However, in an intensive 20 week program, patients lost 8.8 kg and

maintained a loss of 6.41 kg at 18 months, while individuals in a 40 week behavior therapy program lost 13.64 kg and maintained a loss of 9.85 kg at 18 months ¹⁴⁰.

After weight loss treatment, fewer reinforcements are available to maintain adherence to the intervention goals. For example, many patients are motivated to lose weight by a desire to look better, and therefore have unrealistic expectations about the amount of weight that can be lost. After patients stop losing weight, motivation to maintain newly learned dietary and physical activity regimens can wane resulting in a regain of weight ¹³¹. Because of the problems with relapse, recent studies have focused on long term maintenance strategies. A variety of strategies to improve maintenance have been studied and include relapse prevention (problem solving, coping, identification high risk situations), therapist contact (mail in progress with phone contact), food provisions/monetary incentives, peer groups (meeting for problem solving and social support), social support (inclusion of family members), aerobic exercise, home based exercise, personal trainers, and social influence (contingency management, peer counseling) ¹⁴¹. Additional strategies to improve long term weight loss include longer treatment and follow-up, treatment matching based on patients' needs and characteristics, skills training, increased emphasis on lifestyle modification (exercise/low fat diet), problem solving training, long term incentive systems, and body image and binge eating assessment ^{131, 135}. It has been suggested that approaching obesity as a chronic illness may be more effective in long term management ^{128, 142}. Foreyt and Goodrick ¹²⁹ completed a review of 6 controlled studies of maintenance strategies utilized after behavioral treatment for obesity. They found average weight losses of 10.08 kg with follow-up maintenance of 8.37 kg during an average 17.5 month follow-up. Therefore, it appears that instruction in relapse prevention strategies may improve long term maintenance. Additionally, the use of multicomponent maintenance programs has shown success in long-term adherence of weight loss ¹³¹. Specifically, studies have shown superior maintenance effects of multicomponent programs compared to single comparison conditions ^{131, 133, 143, 144}. Multicomponent maintenance programs can include any combination of the strategies described above. A few examples in the literature include peer group meetings combined with telephone/mail contacts with the therapist, inclusion of a group based exercise program, and inclusion of a social influence program ¹³¹.

There are limitations of extended treatment/maintenance programs. Specifically, continued therapy can be expensive and is labor-intensive. However, the benefits of preventing weight regain should be considered when examining the costs of long-term behavioral management of obesity ¹³¹. Additionally, the motivation of patients fluctuates over time. As duration of treatment reaches one year, session attendance decreases, and weight plateaus occur. Frequently, patients hold onto unrealistic expectations of "an ideal weight" or changing appearance drastically which can negatively impact adherence to behavioral programs. In order to combat these limitations, clinical directions during maintenance programs should focus on maintenance of behavior change (e.g., focusing on behaviors that are under the control of the patient such as food quality and quantity, rather than how much weight is lost), comprehensive assessments including physical and emotional health, redefining success (e.g., focusing on beneficial changes in health risk factors and improvements in quality of life), and continuous care model (e.g., physicians and patients viewing obesity as a chronic condition) ^{119, 131}. Studies on relapse prevention of weight gain have demonstrated that individuals who possess skills to cope with challenges are less likely to relapse ¹⁴⁵. For healthy eating patterns to be maintained, adequate coping skills to avoid lapses and enhanced self-efficacy are needed to promote long-term weight control ¹⁴⁵.

Use of Behavior Therapy with Other Treatments

While the ability to lose or maintain weight is limited by physiological mechanisms, behavioral aspects such as eating and exercise patterns can exert some influence. Therefore, behavior therapy has been most recently applied to enhancement of other weight loss methods since it offers strategies to improve motivation or compliance with treatment recommendations.

Behavioral therapy combined with VLCD (very low calorie diet) demonstrated a 32% maintenance at one year compared with 5% maintenance with VLCD alone⁴² and 25%- 30% at 15 months and 2 years with commercial programs^{146, 147}. However, no differences were noted between any conditions at 5 year follow-up. Wadden and Stunkard¹⁴⁸ found behavior therapy and VLCD to be superior to either treatment alone for weight loss and to be comparable to the behavior therapy only group at 1 year follow-up. Intensive 4 year behavior therapy following VLCD inpatient treatment resulted in a 12.6 kg weight loss after treatment with 10.6 kg maintenance at 10 years¹⁴⁹. Studies of behavior therapy with food provision have also demonstrated more positive long term outcomes¹¹⁸.

Behavior therapy has also been studied as a possible enhancement strategy for pharmacotherapy for obesity. One of the earliest studies on the use of behavior therapy with pharmacotherapy in an open label study found that the drug groups lost more weight initially; however, at one year follow-up the behavior therapy only group gained significantly less weight after termination of treatment¹⁵⁰. In a review of behavioral and pharmacotherapy treatment studies, Craighead and Agras¹⁵¹ concluded that medication was most effective when added during the middle of a behavioral program, but at one year follow-up combination treatment was not superior to behavior therapy alone. In another study, the feasibility of combining medication and lifestyle counseling at brief individual primary care visits was investigated¹⁵². Results showed that those patients treated using the brief individual physician sessions and medication lost as much as those patients treated with medication and weekly group sessions. This suggests that protocol-driven lifestyle counseling by physicians in combination with pharmacotherapy may be an effective treatment option. In a long term maintenance study of pharmacotherapy and behavior therapy, behavior therapy did not prevent weight gain after drug withdrawal, but the authors concluded that long term maintenance of weight loss is possible if medications are used in conjunction with other interventions and periodic reinforcement¹⁵³.

Future Directions

Over the past 20 years there has been significant improvement in the application of behavior therapy to weight loss programs. There also has been a growing consensus that the treatment of obesity is best approached as a chronic disorder which requires long-term treatment and follow-up^{128, 142}. While the weight losses associated with behavioral treatment alone are modest, future weight loss approaches should attempt to incorporate the components of self-monitoring, realistic goal setting, exercise, nutrition education, cognitive restructuring, stress management, and social support in order to achieve maximum treatment effect. Additionally, the definition of treatment success will have to be broadened to focus on factors other than weight loss. Specifically, success and improvement will have to be measured by other outcomes such as improvements in metabolic profiles, self-esteem, self-efficacy, quality of life, physical activity, and functional capacity¹²¹.

Finally, future behavioral weight loss research should continue to focus on improving weight loss maintenance. Some proposed techniques include: a) realistic weight loss goals with emphasis on health benefits and success of modest weight loss, b) emphasis on relapse prevention instruction, c) use of behavior therapy to enhance effectiveness of other treatments such as VLCD

and pharmacotherapy strategies, d) use of stages of change model and self-efficacy training, e) emphasis on improved exercise maintenance, f) use of social support, g) screening and treatment of binge eating patterns, h) matching treatments to clients, and i) examining schedules of follow-up care^{129, 135, 141}.

Pharmacotherapy

Introduction and Rationale

Anorectic drugs have been prescribed for over 40 years, nonetheless few overweight patients were prescribed weight loss medications prior to the mid 1990s¹⁵⁴. The publication and media marketing of “fen-phen”, a combination of fenfluramine and phentermine, fueled an explosion in prescribing of weight loss medications. Over 10 million prescriptions for fen-phen had been written by 1997 compared to 60,000 prescriptions of fenfluramine in 1992¹⁵⁴. Of notable interest, pharmaceutical companies had not marketed any new weight loss drugs for 23 years. Subsequently, three new drugs were released within a two year period starting in 1996¹⁵⁴. The increased use of these medications has coincided with a paradigm shift with regards to the use of medication in the treatment of obesity. Specifically, scientific evidence is dispelling the myths once associated with obesity. The medical model is now understanding that obesity is a true disease with genetic determinants, is a major public health concern, and that the regaining of weight after ceasing medication suggests that obesity is a typical chronic disease, not that drug treatment is a failure¹⁵⁴.

Types of Medications

The majority of weight loss drugs work by suppressing the appetite through central mechanisms. One exception is orlistat (Xenical), which blocks absorption of fat rather than suppressing appetite. Anorectic medications are classified as either noradrenergic or serotonergic based on their mechanism of action. Phentermine, orlistat, and sibutramine are the only drugs presently indicated for the long-term treatment of obesity. FDA approval is based upon studies of up to 2 years duration. There are other drugs approved for the short-term treatment of obesity. Drugs approved for the short-term treatment of obesity include benzphetamine, phendimetrazine, diethylpropion, mazindol, and phenylpropanolamine. Single drugs, in general, give approximately 10% loss of initial weight over the first six months of treatment which is maintained with continued medication for the remainder of the year long studies.

Noradrenergic Mechanisms

Noradrenergic weight loss drugs can be classified into several sub-categories. The sympathomimetic drugs, (i.e., diethylpropion, mazindol, and phentermine) all have very low addictive potential. The mechanism of action is through the release of norepinephrine or by blocking its reuptake. In turn, the norepinephrine acts upon hypothalamic beta adrenergic receptors to reduce food intake. These drugs have equal efficacy with respect to weight loss and the most common side effects of this group of medications is nervousness, insomnia, dry mouth, and constipation.

Diethylpropion

Diethylpropion was introduced in 1960 under the name Tenuate. This drug is usually taken three times a day, 25 mg per dose. This drug is also available in an extended release

formula under the name Tenuate Dospan¹⁵⁴. There have been a few long-term double-blind, placebo-controlled studies examining weight loss at six months^{155, 156, 157}. Interestingly, Silverstone and Solomon¹⁵⁷ found that weight loss at six months (7.0 kg versus 8.7 kg) and one year (8.9 kg versus 10.5 kg) was less in the drug treated condition than placebo condition. In two shorter trials, McKay¹⁵⁶ and DeRamos¹⁵⁵ reported significantly higher weight loss about the drug treated patients compared to placebo at six months (11.7 kg versus 2.5 kg and 7.8 kg versus 1.9 kg, respectively). Overall, data on diethylpropion are scant, and interpretations are limited by the small sample sizes of the studies. A relatively rapid tolerance to the anorectic effects¹⁵⁸ and a higher addiction potential in animal models than the other drugs of this group has been noted¹⁵⁹, and is therefore probably the least desirable drug in this subgroup.

Mazindol

Mazindol is a norepinephrine reuptake inhibitor. It is structurally related to the tricyclic antidepressants and lacks the phenylethylamine structure of the other noradrenergic drugs¹⁵⁴. Mazindol has been studied in two long-term studies of six months or longer^{160, 161}. In an open-label study, mazindol demonstrated superior weight loss to a diet alone condition over a 12.5 month period (14 kg versus 10 kg)¹⁶⁰. An uncontrolled observation of weight loss over a 60 week period showed 12 kg weight reduction with mazindol¹⁶¹. Mazindol was associated with cardiac events (i.e., atrial fibrillation, syncope) in stable cardiac patients in one study¹⁶² and significant withdrawal effects^{160, 161}. Overall, the long-term efficacy of mazindol in randomized, double-blinded, placebo-controlled trials has not been studied and its safety among cardiac patients is unclear¹⁵⁴.

Phentermine

Phentermine, also known as the “phen” of the “fen-phen” phenomenon has had one long-term, double-blind, placebo-controlled study¹⁶³. Obese women either received 36 weeks of continuous phentermine or 4 weeks on/ 4 weeks off of phentermine for 36 weeks. Both treatment conditions resulted in significantly greater weight loss than placebo (continuous = 12.2 kg; intermittent = 13.0 kg; placebo = 4.8 kg). Adverse effects were minor. Most of the weight loss occurred in the first 6 months of treatment, however continued weight loss at a slower rate occurred between 6 and 9 months. Several shorter double-blind, placebo-controlled and comparative studies replicate the efficacy of phentermine¹⁶⁴⁻¹⁶⁶. Overall, data on phentermine suggest that it is well tolerated and efficacious in weight loss. Its efficacy is greater than monotherapy with fenfluramines^{165, 166}, and is comparable to the combination therapy of fen-phen¹⁶⁵.

Sibutramine

Sibutramine, marketed as the drug Meridia, has received an approvable rating by the FDA for the long-term treatment of obesity. This medication is a reuptake inhibitor of both serotonin and norepinephrine. Long-term data on the benefits of sibutramine are available^{167, 168}. A year long study examining initial weight loss of 10 mg/d and 15 mg/d to placebo indicated that the treatment conditions were superior to placebo (10 mg/d = 4.8 kg; 15 mg/d = 6.1 kg; placebo = 1.8 kg)¹⁶⁷. Similar results have been found in trials lasting six months or longer. Specifically, weight is lost over the first six months and then maintained while the medication is continued over the first year^{167, 169-172}. However, in a review by Arterburn and Noel, the authors concluded that limited evidence demonstrates sibutramine as more effective than placebo in promoting modest weight loss¹⁷³. The authors found that in 7 randomized clinical trials, weight loss was between 2.8-4.2 kg over 0.5-24 months duration. However, the majority of patients regained weight after

terminating treatment¹⁷⁴. In a recent review by McTigue et al¹⁷⁴, the authors reported there have been six RCTs for sibutramine since 1996. Five of the studies lasted 6 to 12 months, and participants lost an average of 2.8 kg to 4.8 kg more than placebo patients. Differences by dose of drug revealed that dosage did not materially affect outcomes.

Sibutramine has also been studied in combination with very low-calorie diets with positive findings. Apfelbaum treated 159 obese patients with a very-low-calorie diet to induce a 7.2% weight loss over four weeks and then randomized them to receive placebo or sibutramine 10 mg/d. After treatment for one year, patients on sibutramine lost a total of 13.5% of their weight compared to 6.7% for the placebo group. The mean reduction in weight from baseline in sibutramine-treated patients is impressive, but the percentage of patients who received significant benefit is even more so. At least 5% reduction from baseline was achieved and maintained at one year by 86% in the sibutramine group (55% in placebo). Similarly, at month 12, 75% of patients in the sibutramine group maintained at least 100% of the weight loss achieved with very-low-calorie diet, compared with 42% in the placebo group.

Overall, the data on sibutramine suggest that weight loss appears similar to that seen with the other single medications, and it is relatively well tolerated. The most frequent side effects include dry mouth, insomnia, nervousness, tachycardia, and a rise in blood pressure^{154, 175}. Recently, the risks versus benefits of sibutramine have been under debate¹⁷⁶. Since the release of sibutramine in 1998, there have been 397 adverse events reported including 29 deaths. Nineteen of these deaths were related to cardiovascular events, and three of the deaths were women under the age of 30 years¹⁷⁷. In March of 2002, Italy banned the use of sibutramine due to two cardiovascular deaths¹⁷⁸. Sibutramine should not be used in patients with poorly controlled hypertension, symptomatic heart disease, severe hepatic or renal dysfunction, or with those with a history of stroke, seizures, and glaucoma¹⁷⁶. Additionally, the medication should not be taken with monoamine oxidase inhibitors, SSRIs, or any other drug that affects serotonin uptake or release due to the risk of serotonin syndrome¹⁷⁶.

Orlistat

Orlistat, marketed as the drug Xenical, is an inhibitor of pancreatic lipase that causes a dose-related loss of the fat in the stool. The result is a blocking of approximately 30% of ingested fat calories¹⁵⁴. On a typical American diet this would theoretically amount to about 30g/d (250 calories) a day or about one half pound of weight loss per week. It is given at a dose of 120 mg before meals three times daily. Data from clinical trials support that about 70% of patients will achieve >5% weight loss and at two years, 70% of them will have maintained that loss. There are clinical trials documenting orlistat use for up to four years. Two long-term multi-center, randomized, double-blind placebo-controlled trials have been conducted, and yielded similar results^{179, 180}. In the American study, one year weight loss for orlistat treated patients was 8.8 kg compared to 5.8 kg in the placebo treated¹⁸⁰. During the second year of the study, weight regain occurred in all treatment conditions. However, weight regain was less among those patients receiving 120 mg/d of orlistat compared to those receiving 60 mg/d or placebo (3.2 kg, 4.3 kg, 5.6 kg regain, respectively). In the European study, one year weight loss for those treated with orlistat was 10.3 kg compared to 6.1 kg in the placebo-treated condition. During the second year of the study, patients switched from placebo to orlistat lost an additional 0.9 kg, whereas those patients maintained on orlistat regained 25% of their lost weight¹⁷⁹. Similar findings have been replicated in studies of shorter duration¹⁸¹, varying orlistat dose¹⁶⁹⁻¹⁷¹, and in individuals with Type 2 diabetes¹⁸². There are no published trials where orlistat was given following a VLCD. Overall, orlistat has had the most well-designed studies to date, and data from ten randomized clinical trials suggest that the drug promotes a 3-4 kg weight loss of over one year¹⁷⁴. Of the six orlistat trials

since 1996, overall findings suggested participants treated in the normal dosing range lost significantly more weight than controls (i.e., 2.8 kg to 4.5 kg) ¹⁷⁴.

Orlistat is not systemically absorbed, does not affect the metabolism of other drugs with which it has been tested, and does not cause changes in any of the hormonal systems tested. Since orlistat works through a different mechanism than the appetite suppressants, it is logical to assume that its weight loss will be additive when combined with these medications. Orlistat reduces total and LDL cholesterol by 10%, and it can cause a loss of fat soluble vitamins into the stool which should be supplemented with an oral multivitamin. The side effects of orlistat are like that of mineral oil due to the undigested oil in the stool. Anal leakage, flatulence with discharge, and loose oily stools have been reported, but are rarely severe enough to require withdrawal of the medication.

Serotonergic Mechanisms

Selective Serotonin Reuptake Inhibitors (SSRIs)

Sertaline (Zoloft) and fluoxetine (Prozac) have been studied for long-term weight loss. Neither drug has received FDA approval as a weight loss medication ¹⁵⁴. A dose ranging study of fluoxetine demonstrated that 60 mg/d was optimal for a 4.0 kg versus 0.6 kg weight reduction compared to placebo ¹⁸³. Despite these promising results, long-term data from multicenter trials indicate that maximal weight loss occurs in the first 20 weeks, and subsequent weight regain is significantly faster among those treated with the drug ¹⁸⁴. Similar data on sertaline suggest that weight regain is significantly faster compared to placebo control after the maximal weight loss period expires ¹⁸⁵. Overall, the data on SSRIs suggest that the humble weight loss findings are temporary, and long-term weight loss is not evident.

Nonselective Serotonin Reuptake Inhibitors (withdrawn September 1997)

This class of drugs blocks synaptic reuptake of serotonin, and stimulates the release of serotonin in the central nervous system and peripheral storage pool ¹⁵⁴. Fenfluramine is the combination of 50% levo-fenfluramine and 50% dexfenfluramine. Dexfenfluramine contains similar weight loss properties which is what led to the development of dexfenfluramine as a separate new drug. One long-term open label study was conducted using fenfluramine ¹⁸⁶. Results showed that fenfluramine treated patients lost 8.2 kg versus 4.5 kg among those treated with diet alone. Additional fenfluramine studies of various lengths have demonstrated similar results ¹⁸⁶⁻¹⁸⁹. Long-term data on dexfenfluramine come from a double-blind, placebo-controlled trial ^{190, 191}. Findings demonstrated a 9.8 kg weight loss among those treated with dexfenfluramine compared to 7.2 kg in the placebo condition. Similar weight loss results have been found in other studies of varying lengths ^{190, 192-198}. The most common side effects associated with fenfluramine or dexfenfluramine are dry mouth, drowsiness, and diarrhea. Two special concerns with dexfenfluramine deserve comment: neurological changes and primary pulmonary hypertension. Concerns have been raised regarding neurological changes based on studies in squirrel monkeys given 5-20 times the human dose ¹⁹⁹. The brains of these monkeys were depleted in serotonin and there were pathologic changes in serotonergic axons. Monkeys metabolize dexfenfluramine differently than humans and the significance of these findings to humans is unclear. Dexfenfluramine has a ten year experience in Europe treating an estimated ten million obese people and these concerns of neurological changes have not borne out even when formal memory testing was performed. However, all appetite suppressants including fenfluramine and dexfenfluramine have been associated with an increased incidence of primary pulmonary hypertension. The incidence of primary pulmonary hypertension in patients taking these drugs for more than 3 months is 23-46 cases per million ²⁰⁰. It has been estimated that if given to

individuals with a BMI ≥ 30 kg/m² or to individuals with a BMI ≥ 27 kg/m² with hypertension, diabetes, or hyperlipidemia, fenfluramine or dexfenfluramine will save 280 lives per million people. Therefore, the risk to benefit ratio is 20:1 in favor of this drug when given to people whose obesity represents a significant medical risk²⁰¹. Despite these findings, on September 15, 1997 the fenfluramines were voluntarily withdrawn from the market in response to a FDA survey suggesting asymptomatic heart valve abnormalities among those patients taking “fen-phen”.

Drug combination therapy: “Fen-Phen” (withdrawn September 1997)

Both norepinephrine and serotonin affect eating behavior²⁰². In order to improve weight loss efficacy and reduce the side effects of anorectic drugs, a combination of fenfluramine and phentermine, “fen-phen” became popular in the U.S. and Europe. Initially, studies demonstrated efficacy and safety of this drug combination^{153, 165, 203}. However, a survey study suggested that there was a severe risk of valvular cardiac abnormalities with the use of this drug combination²⁰⁴. Specifically, Connolly et al.²⁰⁴ reported that 32% of fen-phen patients showed signs of asymptomatic valve abnormalities. After reports of these findings were published, the drug manufacturer voluntarily withdrew fenfluramines from the world market. Since the original FDA survey study, four uncontrolled studies examining the prevalence of electrocardiographic findings associated with anorectic drugs have been conducted¹⁵⁴. These studies noted lower prevalence of mild aortic regurgitation (ranging from 6.6% -12%) in fen-phen treated patients^{205, 206} than in the original FDA survey study. Additionally, a small study of Mayo Clinic patients also suggested a smaller prevalence of valvulopathy compared to the FDA survey study²⁰⁷. Several additional incidence, case-controlled, and clinical case studies on cardiac conditions that may be attributable to the use of fen-phen have been published. The reader is referred to Glazer¹⁵⁴ for a comprehensive review.

Over-the Counter Medications

Phenylpropanolamine (withdrawn November 2000)

Phenylpropanolamine (PPA) has no addictive potential and is sold without a prescription as a short-term treatment for obesity as well as a component of cough and cold preparations due to its decongestant actions. Phenylpropanolamine has its mechanism of action at the hypothalamic alpha-1 adrenergic receptors, and therefore differs from the prescription appetite suppressant medications discussed previously. Phenylpropanolamine was examined over 20 weeks in one study which demonstrated a 6.5% loss of initial weight²⁰⁸. Meta-analysis of studies of phenylpropanolamine concluded that longer-term treatment with phenylpropanolamine gave approximately half the weight loss of prescription medication²⁰⁹. Specifically, a meta-analysis of phenylpropanolamine studies suggests that this medication may be less effective than the prescription appetite suppressants in trials lasting for more than a month. The most common side effects of this medication include tachycardia, blood pressure elevation, palpitations, restlessness, insomnia, and dry mouth. Recently, a case-controlled study demonstrated a link between PPA and an increase in hemorrhagic stroke in women²¹⁰. The Hemorrhagic Stroke Project demonstrated an adjusted odds ratio of 16.58 for the association between the use of PPA appetite suppressants and the risk of hemorrhagic stroke in women. This study spurred a voluntary recall of all PPA products in November 2000¹⁷⁶.

Ephedrine/caffeine (Ephedra withdrawn December 2003; FDA ban in progress)

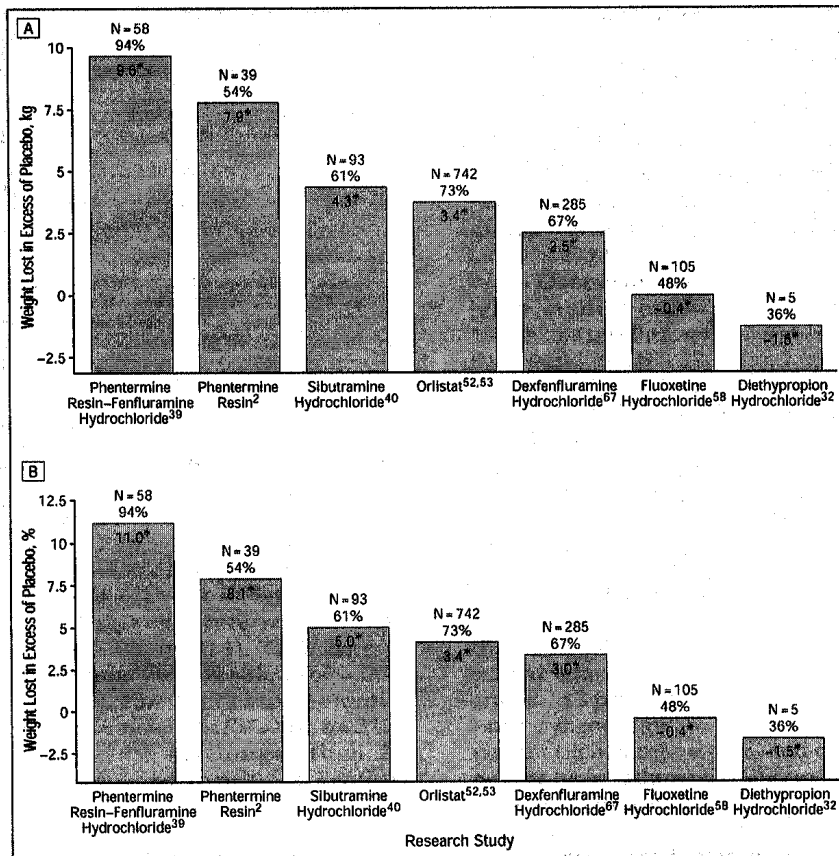
Ephedrine and xanthine derivatives, such as caffeine, increase metabolic rate²¹¹. For example, the amount of caffeine in two cups of coffee will increase the metabolic rate by 4%,

however, this effect is short-lived²¹¹. Chemically, ephedrine belongs to the phenylpropanolamine group, and is a synthetic adrenergic drug which stimulates norepinephrine secretion^{202, 212}. High dose ephedrine has demonstrated arterial pressure increases, poorer glycemic control, and tremor²⁰². Therefore, caffeine is often added to lower doses of ephedrine which delays the degradation of norepinephrine. Clinical trials have demonstrated that these drugs either alone or in combination promote weight loss in obese patients²¹³⁻²¹⁵. However, the magnitude of the difference between ephedrine/caffeine and placebo is generally no more than 4 kg by 24 weeks^{213, 216}, and long-term data are lacking²¹⁷. One study suggested that although there was no increase in blood pressure with the medication, there was no decrease in blood pressure with weight lost²¹³. Recently, concerns have arisen regarding the safety of ephedrine. Side effects can include insomnia, nausea, dizziness, fatigue, heart palpitations, high blood pressure, chest pain, stroke, heart attack, seizure, and death²¹⁷. Fatalities have been reported in healthy individuals²¹⁷. In February 2003, the RAND study, commissioned by the National Institutes of Health, released their review of evidence on the risks and benefits of ephedra/ephedrine²¹⁸. This study found limited evidence of effects of ephedra in short-term weight loss, and minimal evidence of improved athletic performance. Additionally, the study concluded that ephedra is associated with a higher risk of mild-to-moderate side effects including heart palpitations, autonomic hyperactivity, psychiatric, and gastrointestinal effects. The study reviewed over 16,000 adverse events reported after the use of ephedra. The authors concluded that 20 “sentinel” events occurred (e.g., heart attack, stroke, and death) in the absence of other contributing factors. Specifically, two deaths, three myocardial infarctions (MI), nine cerebrovascular accidents (CVAs), three seizures, and five psychiatric cases were associated with ephedra consumption. Three deaths, two myocardial infarctions (MI), two cerebrovascular accidents (CVAs), one seizure, and three psychiatric cases were associated with ephedrine consumption. The authors further identified 50 “possible sentinel events”. Notably, half of the sentinel events reported occurred in individuals under the age of 30 years. Ephedra/ephedrine continues to receive media and scientific attention regarding its safety issues. On February 28, 2003, the Department of Health and Human Services and the FDA disseminated a press release indicating that their organizations were going to seek rapid public comment on 1) health risks associated with ephedra, 2) whether available evidence and medical literature present a “significant or unreasonable risk of illness or injury”, 3) a stronger warning label on current ephedra products, and 4) execute a series of actions against ephedra products making unsubstantiated claims regarding sports performance enhancement²¹⁹. On Dec. 30, 2003, the FDA issued a consumer alert on the safety of dietary supplements containing ephedra. The FDA advised consumers to immediately stop the use and purchase of ephedra products. Furthermore, the FDA notified manufacturers that a final rule will be disseminated stating that dietary supplements containing ephedrine alkaloids present an unreasonable risk of illness or injury. Upon the publishing of this final rule, all sales of ephedra products will be banned within 60 days²²⁰.

Cost-effectiveness

Since obesity disproportionately afflicts the poor, women, and minorities, it is of particular importance that treatments be cost effective²²¹. If obesity continues to be considered non-reimbursable by third party payers, only a cost effective treatment has a chance of reaching those most burdened by the disease. Even if obesity is recognized as a chronic disease like hypertension, many of those afflicted depend upon the government for medical care. The costs of governmentally sponsored health care is already a subject about which much energy is spent devising safe ways to reduce costs without compromising the quality of medical care.

Unpublished data from the obesity research clinic at the Pennington Center has shown no difference in side effects or efficacy between mazindol and phentermine. Therefore, the choice between the two would appear to hinge upon their expense. Mazindol costs approximately ten times as much as equivalent doses of generic phentermine hydrochloride. Obesity drugs vary in their costs, and therefore, these must be considered in relation to their respective weight losses and the incidence of side effects associated with their use. A month's supply of mazindol 1 mg/d is \$30. The equivalent dose of phentermine HCl 15 mg/d in generic form is approximately 1/10 of the cost of mazindol. Glazer (2001)¹⁵⁴ provided a comparative cost efficacy of available weight loss drugs (*please see Table below*). The author reports that cost per month for phentermine is \$60 compared to \$116 and \$119 for sibutramine and orlistat, respectively. Additionally, the cost for 1 kg of weight loss is \$91, \$323, and \$433 for phentermine, sibutramine, and orlistat, respectively. Cost of medications also should be evaluated in relation to the overall reduction in cost for non anti-obesity medications. Specifically, one study examined the cost of medications for patients taking prescriptions for diabetes, hyperlipidemia, or hypertension²²². Patients received either fenfluramine/mazindol, fenfluramine/phentermine, caffeine/ephedra, or mazindol. Pharmaceutical costs were calculated for those patients receiving fenfluramine with either mazindol or phentermine. Weight loss of 6-10% reduced pharmacy cost \$122.64 per month for insulin-treated diabetes, \$42.92 per month for sulfonylurea-treated diabetes, \$61.07 per month for hyperlipidemia, and \$0.20 per month for hypertension.



Graphs show weight loss using diet drugs (A) and the percentage of weight loss using diet drugs (B). N indicates the total number of patients completing drug treatment for the referenced trials; percentage, the completion rate for patients assigned to drug treatment in the referenced trials; and the asterisk, $P < .001$ vs placebo. See "References" section for research study source.

Table adapted from Glazer¹⁵⁴

Surgery

Overview and Patient Selection

As previously mentioned, the severely obese population is at risk for a number of medical complications. Please see table below by Cowan et al.²²³ for a list of common comorbidities of massive obesity. Medical conditions among the obese result in significant financial costs to the health care system. Recent scientific and media attention has been given to the role of bariatric surgery as a method for weight loss in severely obese individuals. The general scientific consensus is that surgical procedures for weight loss should be a last resort option that is reserved only for those individuals with refractory obesity. Annually, nearly 40,000 clinically severely obese individuals opt for weight loss surgery²²⁴. In 1991, the National Institutes of Health Consensus Development Conference Panel²²⁵ formulated a consensus statement that concluded the recommended criteria for considering a patient for bariatric surgery were; a body mass index (BMI) of 35 kg/m² or higher with at least one obesity-related comorbidity, or a BMI of 40 kg/m² or higher without obesity-related comorbidity. Additionally, the panel established that the patient should be well informed of lifestyle and behavior changes that are required post-surgery. In 1997, the International Federation for the Surgery of Obesity (IFSO)²²⁶ established four accepted definitions to further clarify the role of obesity surgery: 1) Bariatric surgeon is a physician who has demonstrated specialized skill and knowledge in the areas of diagnosis, preoperative, perioperative, and postoperative clinical management of patients with clinically severe obesity. The reader is referred to²²⁷ for a more comprehensive list of surgeon qualifications, 2) Ideal Body Weight (IBW) is defined as the weight associated with the lowest mortality-rate in insured persons based on the 1983 Metropolitan Life Insurance tables for height, body frame, and gender, 3) "Morbidly Obese" patients are those individuals whose weight exceeds 45 kg of their ideal body weight which approximates to a BMI of 40 kg/m², and 4) "Medically Necessary" is what is necessary and appropriate for the symptoms, diagnosis, or treatment of a medical condition. The IFSO established a statement on patient selection for bariatric surgery based on these definitions. Recommendations included that clinically severe obesity merits operative intervention if it is requested by the patient and is acceptable to the bariatric surgeon. Additionally, the patient should have a documented present or previous BMI of 40 kg/m² or above or be 45 kg or more above ideal body weight (IBW). If the patient has a BMI between 35-40 kg/m² or less than 45 kg above IBW, there should be a significant medical, psychological, or other comorbidity which requires weight loss and outweighs the risks of surgery. The IFSO also recommended that the patient must be able to demonstrate self-care or adequate support to care by others to insure their return for follow-up. Other patient selection criteria are based on the policies of third-party insurers²²³. For example, many health care insurers require a "letter of necessity" by the primary care physician explaining the need and benefits of surgery²²⁴, and 3 to 5 years of documented, failed physician-supervised weight loss attempts²²³. Additionally, the patient is required to complete several preoperative consultations with various specialists (e.g., dietician, psychologist, cardiologist, anesthesiologist)²²⁴. The cost of bariatric surgery varies, however, general estimates price the surgery between \$20,000 and \$25,000²²⁴. Denial of service for bariatric surgery is common. Data suggest that severe obesity and poverty are highly correlated since many individuals are unable to be avidly employed given their health status. Thus, the out-of-pocket expense of the surgery is beyond the financial means for the majority of the severely obese.

Co-morbidities of massive obesity		
Obstructive sleep apnoea	Cervical disk disease	Hepatomegaly
Obesity hypoventilation syndrome	Lumbar disk disease	Hepatic steatosis
Restless leg syndrome	Chronic lower extremity oedema	Cirrhosis
Dyspnoea on exertion	Varicose veins	Weakness, tires easily
Sleep orthopnoea	Venous stasis ulcers	Depression
Chronic wheezing	Deep venous thrombosis	Anxiety disorder
Chronic bronchitis	Pulmonary embolus	Accident proneness
Calculous cholecystitis	Difficulty ambulating	Diastasis recti
Other gall bladder/biliary disease	Urinary stress incontinence (female)	Pseudotumour cerebri
Sliding hiatus hernia	Renal disease	Hyperlipidaemia
Reflux oesophagitis	Menometrorrhagia	Diabetes mellitus
Chronic gastritis	Dysmenorrhoea	Glucose intolerance
Ventral hernia	Amenorrhoea	Gout
Umbilical hernia	Infertility (female)	Hirsutes (female)
Retrosternal pain	Endometrial hyperplasia	Acanthosis nigricans
Difficulty reaching perineum to cleanse	Endometrial carcinoma	Intertriginous dermatitis
Severe body odour	Ovarian carcinoma	Panniculitis
Chronic back pain	Breast carcinoma	Chronic skin abscesses
Chronic neck pain	Prostate carcinoma	Social problems
Chronic foot pain	Colon carcinoma (male)	Economic problems
Chronic ankle pain	Chest pain	Physical problems
Chronic leg pain	Angina pectoris	Increased operative risk
Chronic knee pain	Coronary insufficiency	Difficult intubation
Chronic hip pain	Cardiomyopathy	Sudden death
Painful heel spurs	Hypertension	
Osteoarthritis	Cardiomegaly	

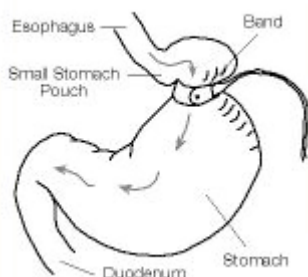
Table adapted from Cowan et al.²²³

Types of Surgical Procedures

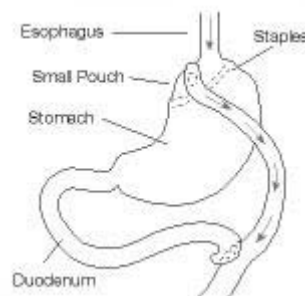
A comprehensive history on the development of the various surgical techniques is beyond the scope of this report. However, the reader is referred to²²⁸ for a more in depth review of the history and empirical research of ten different surgical techniques developed since the 1960s. There are two broad classifications of weight loss surgeries, restrictive procedures and restrictive procedures with malabsorption²²⁴. Restrictive procedures reduce the size of the stomach pouch to hold approximately one ounce of food. The result of the smaller stomach volume allows the individual to eat less and feel full with smaller portions. In turn, this restriction of food intake results in weight loss by decreasing the daily caloric intake of the individual. Over time, the stomach size will expand to accommodate approximately a half of cup of food at a time. There are several types of restrictive procedures that are commonly performed. Vertical banded gastroplasty (VBG), also known as “stomach stapling”, is the most common restrictive surgical procedure²²⁹ and was developed in 1980. In this procedure, the upper stomach near the esophagus is partitioned from the rest of the stomach using a row(s) of vertical staples. A 5mm band is placed around the lumen at the outlet of the upper stomach to the lower stomach^{224, 230}. Specifically, the anterior and posterior walls of the stomach are pressed together, and a hole is punched through the walls. The walls are then stapled together which creates a channel in the stomach. A band is then placed through the hole and is sutured into place²³¹. Waitman & Aronne²³⁰ suggest that the Laparoscopic Adjustable Silicone Gastric Band (LASGB) is rapidly replacing the VBG as the restrictive procedure of choice. In this procedure, an inflatable band which encircles the stomach is laparoscopically placed and creates a small pouch near the upper stomach. The device is then inflated with saline to restrict the gastric pouch. This procedure requires no partitioning or stapling of the stomach. This gastric banding can be performed laparoscopically or through traditional “open” procedures.

Restrictive-malabsorptive procedures combine a restrictive procedure with a partial bypass of the small intestine²²⁴. This bypass causes a decrease in the absorption of nutrients thus the term ‘malabsorptive’. The most known and commonly performed restrictive-malabsorptive procedure is the Roux-en-Y (RYGB). The stomach is partitioned or stapled to create a small

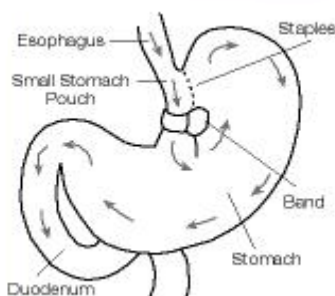
gastric pouch, similar to the restrictive methods. Then, a Y-shaped section of the small intestine is attached to the gastric pouch. This allows food to bypass the lower part of the stomach, and the upper and middle parts of the small intestine (duodenum and jejunum) ²³². By bypassing the stomach, duodenum, and jejunum there is less absorption of proteins, fats, and carbohydrates resulting in more weight loss ²²⁴. With this procedure, weight loss occurs through two mechanisms: 1) the small gastric pouch prevents consumption of large quantities of food and creates a feeling of satiety, and 2) the bypass (gastrojejunostomy) produces a phenomenon known as the “dumping syndrome” ²³⁰. “Dumping” occurs when the lower end of the intestine fills to quickly with undigested food. Symptoms include vomiting, nausea, diarrhea, bloating, sweating, and dizziness ²³³. Patients will often adjust their eating patterns to avoid the “dumping” experiences, which in turn promotes weight loss. The RYGB can be performed laparoscopically or through traditional open methods. Another restrictive-malabsorptive technique is a biliopancreatic diversion which can be performed with (BPDS) or without a duodenal switch (BPD). The biliopancreatic diversion procedures are more complex and complicated than other restrictive-malabsorptive techniques ²³⁰. Portions of the stomach are removed, and only a small gastric pouch remains attached to the final segment of the small intestine. Therefore, food completely bypasses the duodenum and jejunum ²³². The BPD with duodenal switch keeps a larger portion of the stomach intact, and maintains a small portion of the duodenum in the digestive pathway ²³².



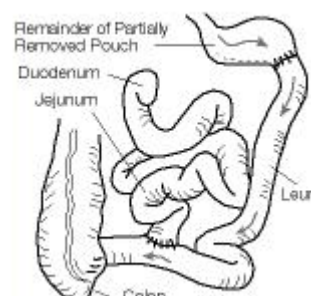
Adjustable Gastric Banding



Roux-en-Y Gastric Bypass



Vertical Banded Gastroplasty



Biliopancreatic Diversion

Diagrams adapted from NIDDK ²³²

Effectiveness and Contraindications of Procedures

Overall, data on restrictive and restrictive-malabsorptive procedures have documented successful weight loss of excess body weight. Surgical procedures for weight reduction have demonstrated superiority over “conservative” treatments (e.g., low calorie diet, exercise, behavioral modification programs, and pharmacotherapy) for maintenance of weight loss among

the clinically severely obese²²⁹. The Canadian Task Force on Preventive Health Care reviewed four randomized trials and one cohort study and found that mean weight loss post surgery was 17 kg to 46 kg after 2 to 5 years²³⁴. Another review of six clinical trials showed weight loss of 9.7 kg to 57.9 kg²³⁵, whereas the NIH National Heart, Lung and Blood Institute review of five randomized trials revealed weight loss of 10 kg to 159 kg over 1 to 4 years²³⁶.

Data suggest that long-term weight loss for conservative weight loss regimens is poor²²⁹. Specifically, a 10% weight loss in the short-term for these treatments is typical. However, two-thirds of the lost weight is regained within the first year, and almost all of the weight is regained five years after initial weight loss²³⁷. Weight loss by surgical means is effective and long lasting. The average patient loses two-thirds of his/her body weight within the first year, and maintains 60% and 50% of the lost weight at 5 and 10 years, respectively^{238 239 240}.

The restrictive procedures have demonstrated substantial loss of excess weight. Data from the United Kingdom suggest that vertical banded gastroplasty procedures (VBG) results in a mean weight loss of 53% with operative mortality of 0.17%²⁴¹. VBG was popular in 1980s and early 1990s, and is preferred by many surgeons because it is technically simpler. This procedure is associated with less operative death, shorter operation time, ease of endoscopic examination, and a reduction in nutritional deficiencies²³¹. However, staple line failures are common. One study found staple-line failure may occur in up to 20% of patients annually²⁴².

Gastric banding is also more common in Europe. Weight loss and complication rates are slightly better with the inflatable bands compared to the noninflatable²³¹. This procedure can be performed laparoscopically or through open methods. Laparoscopic compared to open surgery in adjustable gastric banding is associated with a three times shorter hospital stay²⁴³. However, revisional surgery is common with this procedure due to needing to in/decrease the tension of the band²²⁹. One study found that 13% of patients that have LASGB will require a revisional surgery within the first postoperative year²⁴⁴. Another study reported that 50% of bands were removed due to failure to lose weight, esophageal dilation, and band leakage²⁴⁵. In a study comparing the open to laparoscopic adjustable silicone gastric banding, both groups showed similar weight loss over the first year (i.e., 35 kg in the laparoscopic, 34 kg in the open)²⁴⁶. No randomized studies comparing VBG to gastric banding have been conducted. However, the SOS intervention study suggests that similar weight loss occurs at follow-up for both procedures, but banding has more reoperations²²⁸.

Among the restrictive-malabsorptive surgeries, the Roux-en-Y (RYGB) is the most commonly performed. This procedure is typically performed more frequently in the United States. Weight reduction is significant and this procedure has demonstrated better weight loss than the purely restrictive procedures. Data suggest that 70% of patients are “successful” and lose 50% of their excess body weight, and up to 85-90% of this weight loss will be maintained after 5 years²⁴⁷. Additional data suggest that weight loss of 50-75% at 5 years is common with RYGB²³¹. Additional follow-up data on maintenance is promising. In one study, 600 patients 14 years post-operatively showed weight loss exceeding 50%²⁴⁸. The RYGB is technically more challenging, but is best proven for significant and sustained weight loss²³¹.

Roux-en-Y gastric bypass and VBG procedures have been compared in several randomized short-term and long-term studies and several nonrandomized studies²²⁸. All of the studies demonstrated superiority of the RYGB over the VBG for weight loss. Several comprehensive long-term studies have revealed that the percentage of weight loss was 24% versus 16% at eight years²⁴⁹, 34% versus 28% at three years²⁵⁰, 32% versus 22% at two years²⁵¹. Additionally, the RYGB has shown greater weight loss than VBG for those patients who are addicted to sweets due to the development of the “dumping” syndrome following the ingestion of sugary foods²⁵². Also of interest, RYGB has been shown to have better weight loss outcomes for

African American patients than the VBG procedure²⁵². There are no differences in data when the procedures are done laparoscopically compared to open. However, laparoscopic procedure patients report less postoperative pain, improved respiratory status, shorter hospital stay, and faster mobilization²²⁸. Finally, no randomized studies comparing RYGB to gastric banding exist. However, the SOS intervention study suggested that RYGB was superior to banding at 2 and 8 year follow-up²²⁸.

Data on biliopancreatic diversion (BPD) suggest excellent weight loss. Studies have reported a loss of up to 75% of excess weight²⁵³, and significant reductions in BMI²²⁸. Data on BPD with duodenal switch (BPDS) have also demonstrated significant weight loss findings (i.e., 80% weight loss at two years), however severe medical complications were found in 9% of the cases²⁵⁴. This procedure has higher complication risks and is technically more complicated to perform. Therefore, it is reserved typically for the “super” obese (i.e., BMI > 50 kg/m²)²⁵². Biliopancreatic diversion with and without duodenal switch have resulted extreme micronutrient deficiencies, secondary hyperparathyroidism, and profound gastrointestinal upset²²⁸.

Operative complications for gastric bypass (RYGB) include death (0.3-1.2%), anastomotic leak (0.5-1%), wound dehiscence (0.5%), wound infection (1.5-6%), deep venous thrombosis (0.3-0.7%), pulmonary embolism (0.3-0.7%), and pneumonia (0.5-4%)²⁴⁷. Long-term metabolic effects are relatively minor. Nutritional deficiencies of micronutrients (e.g., iron, vitamin B₁₂, folate) are common^{247, 252}. Patients are routinely given nutritional supplements to prevent these deficiencies²⁵². The most extreme side effect of nutritional deficiencies can result in Wernicke-Korsakoff syndrome. This syndrome is associated with thiamin deficiency, and can cause irreversible neurological damage if not caught early²²⁹. Additionally, folic acid deficiencies in childbearing aged women can result in neural tube defects (i.e., spina bifida) during pregnancy. Typically, women are prescribed oral contraceptives for the first year postoperatively to reduce the risk of pregnancy during the highest nutritional deficit period of weight loss. Regardless of surgical procedure used, rapid weight loss is associated with a 32% risk of gallstone formation, but the risk can be decreased with prophylactic medication²⁵².

Benefits of Surgery

Besides the benefits of significant weight loss, there are several medical complications secondary to obesity that are ameliorated with profound weight reduction. The benefits of gastric bypass on Type 2 diabetes has been documented^{255, 248}. Following gastric bypass patients have demonstrated decreases in blood glucose and required exogenous insulin. Pories et al.²⁴⁸ found that 14 years post-operation, 91% of patients who had preoperative non-insulin dependent diabetes had normal blood glucose and glycosylated hemoglobin values. Furthermore, of the 58.1% that exhibited hypertension prior to surgery, only 14% continued to have high blood pressure after surgery. Other studies have demonstrated significant improvements in cholesterol values (e.g., up to 25% reduction in triglycerides, 10% reduction in blood pressure, 5% reduction in total cholesterol)²⁵⁶ (e.g., 20% reduction in total cholesterol, 50% reduction in triglycerides)²⁵⁷, gastroesophageal reflux disease (GERD)^{258 259}, sleep apnea²⁶⁰, and asthma²⁶¹. Additionally, significant improvements in psychosocial functioning have been demonstrated²⁶².

Surgery in Adolescents

There is a dearth of data on the impact of adolescent bariatric treatments, and the majority of studies on this topic are retrospective in nature. Bariatric surgery for adolescents has not been formerly recommended due to the lack of sufficient data on the topic²²⁵. Nonetheless, adolescents with clinically severe obesity have been provided surgery as a viable treatment option. In 1994,

Rand and Macgregor interviewed 34 adolescents aged 11 to 19 years who were 6 years post-surgery²⁶³. Preoperative BMI for these patients was 47 kg/m², and was 32 kg/m² at the time of follow-up. Seventy-three percent of the patients had 50% weight loss. The average weight regain was 9 kg. The majority of patients had RYGB (34) and four had VBG. The mean age at time of surgery was 17 years. Growth rate appeared unaffected, and health and psychosocial improvements were reported by most. Only 13% reported taking nutritional supplements as prescribed, and adherence to exercise and dietary recommendations was poor. Overall, 85% of the sample reported that they would “definitely” have the surgery again if they had an opportunity to go back and remake their initial decision. In another study, follow-up data on gastric bypass outcome was evaluated among ten adolescents²⁶⁴. The average weight for the sample preoperatively was 148 kg and the mean weight loss was 53.6 kg. Postoperative recovery was uneventful in all adolescents, and micronutrient deficiency was the most commonly reported late complication. All of the three women who became pregnant after surgery had weight regain, however, the pregnancies were uncomplicated. Overall, the authors concluded that bariatric surgery is well tolerated in adolescence and produces similar results as in adulthood. Dolan and colleagues prospectively collected data since 1996 on adolescents who received laparoscopic adjustable gastric banding (LAGB)²⁶⁵. Seventeen patients with a mean age of 17 years received the surgery. Two of the patients experienced complications (i.e., a leaking port and slipped band). Preoperative BMI was 44.7 kg/m², and at 24 months BMI was 30.2 kg/m². Over 75% of patients lost a minimum of 50% of their excess weight. The authors reported that LAGB is a safe and effective treatment for severely obese adolescents, and may be a preferred method in this population given that the procedure is reversible. In another study, the authors reviewed a 20 year old database on bariatric surgery in adolescents²⁶⁶. Of the 33 adolescents in the registry from 1981 to 2001, one received horizontal gastropasty, two received VBG, 17 received standard gastric bypass (two of which were laparoscopic), ten received long-limb gastric bypass, and three received distal gastric bypass. Mean preoperative BMI was 52 kg/m², and the mean age at time of surgery was 16 years. Follow-up at 14 years found that 61% of excess weight lost was maintained. No operative deaths were reported, however, two patients died two years and six years postoperatively to conditions unrelated to the surgery. Early and late complications, as well as revisional surgeries approximated the prevalence found in the adult literature. Five of the patients had regained all weight by 10 years post-operation, however, significant weight loss was maintained in the majority up to 14 years post-surgery. None of the patients displayed impaired sexual or physical maturation, and remission of comorbid conditions and improved psychosocial functioning were reported. The authors concluded that bariatric surgery in adolescence was safe, promoted significant weight loss, and improved comorbidities, socialization, and self-image. In a recent article Garcia, Langford, and Inge reviewed the application of laparoscopic surgery in adolescents²⁶⁷. They report that no prospective, randomized studies comparing the efficacy of bariatric surgery to other conventional methods have been conducted. Despite the scarcity of research, outcome reports are promising. The authors encourage the use of behavioral management programs, and meeting the psychosocial and emotional needs of adolescents undergoing bariatric surgery. Additionally, the authors address the need for systematic data to evaluate the uses of RYGB versus adjustable gastric band in this population. Specifically, adjustable gastric bands require no partitioning of the stomach thus reducing nutritional deficits, are reversible, and bands can be adjusted for times of pregnancy. However, the short and long-term weight loss with the gastric banding is not as promising, and the deterrent to developing maladaptive eating patterns is not as present as with the gastric bypass procedure.

Compliance

The risk of failed weight loss or weight regain exists among the surgical procedures. The majority of patients regain a percentage of excess body weight lost, and 14-16% of patients fail to maintain satisfactory weight loss^{250, 268}. Surgical “success” is determined by maintenance of at least 50% weight loss. Often weight regain is associated with staple failure, or maladaptive eating patterns that promote ingestion of excessive calories. Sugerman et al.²⁶⁹ found that 20% of patients who received VBG developed maladaptive eating patterns. Specifically, they would ingest high calorie, high fat carbohydrates. Those who received RYGB can also develop maladaptive eating patterns by ingesting foods that crumble easily and avoid the problems associated with “dumping” (e.g., potato chips, milkshakes, peanut butter). In another study, patients demonstrated noncompliance with taking required nutritional supplements. Specifically, 89% of adolescent patients within two years of surgery took vitamin supplements compared to 56% who had surgery more than two years before the interview²⁶³. Additionally, adherence to exercise and dietary recommendations was poor.

Cost-effectiveness

Data is scarce on the cost-effectiveness of bariatric surgery in the long-term. The Swedish Obesity Study (SOS) is the only empirical investigation that has examined the financial sequelae associated with weight loss surgery. The SOS intervention project is an ongoing nationwide intervention study in Sweden that is examining the morbidity and mortality of obese patients who reduce their weight via surgical means or conventional methods. The study began in 1987 and will compare over 2000 surgically treated obese patients with a matched control group receiving traditional treatment methods over the course of twenty years²⁷⁰. Preliminary data on the cost-effectiveness of the SOS study have been published^{271 272}. In one study, the association between weight loss and medication for diabetes and cardiovascular disease was examined²⁷². Over 500 surgically treated and 455 conventionally treated patients followed for 6 years were evaluated on the uses and cost of medication. Results found that 91.2% of controls compared to 61.7% of surgical patients were on CVD medication at 2 year follow-up, and 86.4% of controls and 64.7% were on medication at 6 year follow-up. All of the control patients were on diabetes medication at 2 year and 6 year follow-up compared to 56.2% and 68.8% of surgical patients, respectively. Among patients not initially on medication, surgery reduced the frequency of patients starting pharmacotherapy. Specifically, among those patients medication-free at the time of surgery, controls were five times more likely to use diabetes medication at 6 year follow-up. Cost analyses indicated that a weight loss of greater than 10% was required to reduce costs of CVD and diabetes medication for those that were on medication at baseline. A weight loss greater than 15% was needed to reduce the risk of initiation of medication for those not on medication at baseline. Overall, for the six year period, the average annual cost of medication increased by 96% for those that lost less than 5% of their weight, whereas a decrease of 8% in costs was associated with weight loss greater than 15%. Additional data from the SOS intervention study was published providing data on the cost of in-patient care over a seven year period for those treated surgically and by traditional methods²⁷¹. This study compared the hospitalization cost of a total of 962 surgically and conventionally treated patients. Results found that after six years, the surgical group averaged a weight loss of 16.7% and the traditional group gained 0.9%. The cumulated number of hospital day stays for the surgical group over six years was 23.4 days compared to 6.9 days for the conventional group. After hospitalizations for the surgery and conditions common after bariatric surgery were excluded from the analyses, there were no significant differences between the surgical and conventional group with regards to hospitalization costs. The authors

concluded that weight loss of 16% was not sufficient to reduce hospitalization costs over a six year period, and that the cost benefits of bariatric surgery may be limited to the improvements associated cardiovascular and diabetes risks.

Conclusions and Future Directions

Systematic studies of the balance of risk and efficacy for surgical procedures and more conservative treatment methods is needed²²⁵. Additionally, head-to-head comparisons of various surgical procedures and more traditional forms of treatment are lacking. The majority of data on surgical procedures are limited by the use of convenience samples, and no standardized protocols to compare study findings with one another. Standards of comparison for studies (i.e., operationalizing what is “weight loss”) is needed to better understanding treatment findings among current studies. A clearer definition of the natural history of severe obesity is needed to serve as a baseline for evaluation of the long-term effects of any type of treatment²²⁵. Cost-effectiveness studies and program evaluation for primary and secondary obesity-related conditions are lacking, and could further elucidate what types of treatments should be reimbursable. Further investigation of the mechanisms by which surgical procedures work, and a better understanding of surgical results stratified by patient-centered demographics (e.g., gender, age, ethnicity) would clarify which treatments work best for which patients²²⁵. Finally, a systematic evaluation of the impact of surgical treatments in pregnancy is needed given the increase in childbearing aged women seeking bariatric treatment²²⁵. While most of these recommendations were made in a 1991 panel, a research funding announcement released by the bariatric surgery clinical research consortium and the National Institute of Diabetes and Digestive and Kidney Disease in 2002 still indicated that most of these same issues needed to be addressed²⁷³.

Weight Maintenance

Maintenance of Weight Loss

Most weight loss occurs in the initial 6 months of treatment³⁰. While treatments can obtain successes of up to 10% of weight, maintaining weight loss remains a challenge. In review of the treatment literature, Wing³⁰ found that weight regain is as much as 35-40% of initial loss. However, it appears that exercise appears to be important during the maintenance period¹⁰². Individuals successful with long-term weight loss engage in significant changes in dietary intake primarily related to dietary fat and enough physical activity to expend >2500 calories per day²⁷⁴. Jackicic and colleagues¹¹² found that individuals who engaged in an average of 280 minutes of exercise per week had more weight maintenance.

National Weight Control Registry (NWCR)

NWCR is a database of people who have self-reported a weight loss of 30 pounds or more and kept it off for at least a year. The average NWCR participant has lost about 60 pounds and kept it off for about five years. Participants were asked questions about how they achieved their weight loss:

- 89% changed their diets and increased physical activity (10% used diet modification only and one percent used activity only).
- 55% used a formal program (like Weight Watchers) or professional assistance (dietitian, psychologist, etc.).
- 87.6% limited some type or class of food (especially high-fat and high-calorie foods).

- 44.2% limited the quantities of food they ate.
- 43.7% counted calories.
- 92% exercised at home, 40.3% exercised regularly with a friend, and 31.3% exercised regularly with a group.
- Walking was the most common activity reported.
- 77% said a medical or emotional event triggered weight loss.
- 42.7% described losing weight as hard, 31.4% as moderately hard, and 25.7% as easy.
- Two-thirds were overweight as children (about 46% indicated that they became overweight at age 11 years or younger and 25.3% at 12 to 18 years).
- 46% had one biological parent who was overweight, and 26.8% indicated that both biological parents overweight.
- 91% had tried to lose weight before.

When participants were asked questions about how they **maintained** their weight loss, the NWCR researchers found that:

- 92% limited their intake of certain foods (one example: eating at fast food restaurants less than once a week).
- They consumed an average of 1400 calories per day, of which 24% of calories was from fat, 19% protein, and 56% carbohydrates.
- They ate five times a day, on average.
- They burned an average of 2,800 calories a week through exercise (an equivalent of about 400 calories day).
- 75% weighed themselves regularly - at least once a week.
- About one-third described weight maintenance as hard, one-third as moderately easy, and one-third as easy.
- 42% reported that maintaining their weight loss was less difficult than initially losing the weight.

Other Weight Loss Programs and Techniques

Alternative Treatments

Most alternative treatments for obesity have not been proven to be safe or effective²⁴. In review of the literature theses authors noted the following information on a variety of products making weight loss claims.

Acupuncture/Acupressure is purported to suppress appetite through stimulation of the auricular branch of the vagal nerve. According to Allison and colleagues review of the literature, most of the studies finding benefits were uncontrolled case series studies and the two studies that provided some type of control and direct outcome on weight showed no significant effects²⁷⁵.

Aromatherapy attempts to produce weight loss through olfactory stimuli was also not found to have any scientific basis.

Bladderwrack (focus vesiculosus) preparations do not have any evidence or support or plausible mechanism of action. Additionally, the iodine content could produce health risks associated with hyperthyroidism.

Chitosan (a polymer of Chitin from shellfish) is touted to block the absorption of fat. There have been limited studies that showed some minimal effectiveness, but these studies noted that these claims needed to be more rigorously tested and safety needed to be addressed.

Chromium is believed to effect weight and body composition through possible increase of insulin sensitivity and decrease in insulin. The results are equivocal and those that demonstrated positive benefits were not published in peer-reviewed journals or used poor methodology.

Conjugated Linoleic Acid a trans-fatty acid in meat and dairy products has shown to have some adiposity reducing effects. No studies on humans have been conducted related to weight loss.

Dehydroepiandrosterone (DHEA) has claimed to have possible rejuvenating effects that may be related to reducing adiposity. Only one study on normal weight participants found benefits in body composition. There have been numerous safety warnings regarding this product.

Garcinia Cambogia, a product in a variety of commercial weight loss products is believed to suppress food intake and decrease weight. The most rigorous study of this product does not support its use as a weight loss treatment. However, some studies have shown some effect but the lack of standardization of methods across studies does not allow for conclusions about efficacy.

Germander a mint like herb has been associated with serious side effects (hepatitis, jaundice) which resulted in withdrawal or banning in European countries.

Hypnosis used alone as a treatment for obesity has not been found to have an effect on weight loss or maintenance. Studies that have examined its use in combination with cognitive-behavioral treatment programs have found some enhancement of weight loss. However, significant psychological side effects (anxiety, dissociation) were noted in a study of adolescents.

Ma Huang (ephedra) has been recently withdrawn as a treatment agent due to safety concerns.

B-hydroxy B-methylbutyrate monohydrate (HMB) has been purported to increase the body's ability to burn fat and build lean muscle mass. There is evidence to support that this product can improved body composition when combined with strength training. The safety parameters have not been fully evaluated.

Plantain (Psyllium, Plantago) has been associated with some reduction in short-term food intake but there has been no evidence of effect on body weight. Gastrointestinal distress and possible malabsorption of medications are side effects.

Pyruvate is purported to produce weight loss through thermogenesis. Minimal weight loss has been found in poorly controlled studies. Safety has not been well documented.

St. John's Wort has no evidence of producing weight changes.

Subliminal Suggestions has no evidence of producing weight changes above placebo tapes or no treatment.

Sunflower has no evidence of producing weight changes.

Thigh Cream can produce some minor cosmetic changes in skin "smoothness".

Alternative Psychotherapy Treatments

Various alternative psychotherapy approaches for the treatment of obesity have begun to emerge. There is a paucity of research in these areas, however a brief review is merited. The most publicized alternative psychotherapy treatment is the size acceptance nondiet movement²⁷⁶. This movement endorses many similar techniques found in more traditional behavioral and cognitive-

behavioral therapies. The foundation of this approach is to target individuals with BMI > 30 kg/m², and decrease thoughts associated with body image. The basic tenets of this approach are 1) good health is a state of physical, social, and mental well-being. All people regardless of size should adopt healthy lifestyles and eating patterns, 2) people come in a variety of shapes and sizes which should be considered positively, 3) there is no ideal body size, shape, or BMI, 4) self-esteem and body image are linked, 5) individuals are responsible for taking care of their own bodies, and 6) appearance stereotyping is wrong. No clinical trials have compared the efficacy of the size-acceptance nondiet approach to other modalities. However, small demonstration projects have shown that this approach may be effective²⁷⁷. A few clinical trials have examined components of the size-acceptance nondiet approach, and these studies resulted in improved behavioral outcomes²⁷⁸⁻²⁸⁰. However, these studies have not reported significant improvements in biological indices such as body weight, blood pressure, or cholesterol. In 2000, “nondiet approaches” received the U.S. government’s tacit imprimatur when it was added to the Department of Agriculture’s Food and Nutrition Information Center website²⁸¹. Additional clinical trials to demonstrate efficacy to established obesity treatments are lacking.

Obesity within the scope of the Addiction Model has been hypothesized as an explanation for poor maintenance outcomes²⁸². Specifically, in this model, obesity is a result of dependence on particular food substances. Obese patients are powerless to control their dependence on these foods. Effective management includes admission that the individual is powerless over food, and complete abstinence over “offending” foods is needed. The data are lacking for this model and no clinical studies have systematically evaluated this hypothesized approach.

Virtual reality-based multidimensional therapy has also been studied in the treatment of body image disturbances in the obese²⁸³. In a study comparing virtual-reality to psychonutritional groups based on cognitive-behavioral techniques, 28 obese females received adjunctive low-calorie diets and physical training and either virtual reality (VR) or a psychonutritional group. Virtual Reality for Eating Disorders Modification (VREDIM) is a virtual reality based treatment used for body image therapy in obesity. In this study, the virtual reality condition consisted of the VREDIM and various “3D Healing Experiences” that were displayed via a 3D virtual reality helmet worn by the participant. The Healing Experiences were stimuli that could elicit abnormal eating behavior (e.g., vision of a physical fit and attractive female dressed in a bikini). The reader is referred to Thompson et al. (1999) for a more detailed description of the VR techniques used²⁸⁴. In the short-term, VR was better than the psychonutritional groups in improving body satisfaction, self-efficacy, and motivation for change. However, one should caution about overinterpreting these findings. The study lasted only 6.5 weeks, no follow-up data are available, and has not been replicated.

Commercial Weight Loss Programs

Commercial weight loss programs are a 2 billion dollar a year industry in the United States. The Sandoz Nutrition Study⁵⁵ found that participants in a commercial weight loss study lost on average 22 kg during the program and 57% maintained at least 5% of their weight loss during a three year follow-up. While the commercial weight loss programs do not consistently publish data on efficacy, they were evaluated initially in a reader survey in 1993 by Consumer Reports^{146, 285}. Over 19,000 readers had enrolled in a professionally managed program in the preceding 3 years. Consumer Reports concluded that none of the top 5 programs were better at helping people lose weight or keep it off. “About a quarter” had kept off more than “two-thirds” after 2 years. Weight Watchers was given the highest rating, with 75% in overall satisfaction compared to Jenny Craig (62%), Physician Weight Loss (57%), Diet Center (52%), and Nutri System (50%)²⁸⁵. In addition to limited efficacy studies, commercial weight loss programs have

also reported high attrition rates²⁸⁶. In a review of the literature, Volkmar and colleagues²⁸⁶ found that the average attrition of commercial weight loss programs was approximately 80% at 20- 25 weeks. Nonprofit weight reduction organizations had lower attrition rates that ranged from 14 - 25% at 3 months and 47-67% at one year. The authors hypothesized that the fee involved in the commercial weight loss programs may account for the higher attrition.

Commercial weight loss programs can be categorized into 1) nonmedical commercial weight loss programs, 2) medically based proprietary programs, 3) residential programs, and 4) self-help programs²⁸⁷. The nonmedical weight loss programs are nutrient-balanced deficit diets (BDD) which offer behavior modification training. The most popular of these programs is Weight Watchers International. Weight Watchers International is the largest commercial weight loss program and was established in 1963²⁸⁷. Weight Watchers reports that it has assisted over 25 million people worldwide²⁸⁸, and there are almost 600,000 active members in North America alone²⁸⁹. According to Spielman and colleagues²⁹⁰, the Weight Watchers program is a nutritionally sound program that uses an exchange list of food choices that can be bought at the grocery store. The current "Success Plan" assigns a point value to all foods, and members are instructed to stay within a certain point-value based on age and weight. Total caloric intake is approximately 1,200-1,500 kcal/day yielding a 1-2 lbs weight loss per week, and the focused goal is a 10% weight reduction. Members are encouraged to attend weekly group meetings led by laypersons who have successfully reach personal weight loss goals and maintained the weight loss for at least 6 weeks. The weekly meetings include weight checks and instruction in behavior modification and exercise. Behavior modification has been a part of the Weight Watchers treatment program since 1974¹⁴⁷. Cost for the program includes a sign-up fee which ranges from \$15-\$40 depending on area of the country that membership is obtained, and a \$9.95 to \$15 weekly meeting charge depending on which plan is chosen²⁹¹. "Lifetime members" are individuals who have met and maintained their weight loss goals for at least 6 weeks.

There are limited published data on the Weight Watchers program. In a national survey by Stuart and Guire¹⁴⁷ among over 700 women enrolled in the Weight Watchers program, those who reached their goal weight indicated a 19% loss of body weight in 31 weeks. Additionally, over 85% reported reaching their goal weight the first time they joined. However, as with other weight loss methods, these members also reported regaining 21% of the weight lost within 12 -15 months. More recent published studies on the efficacy of the Weight Watchers program exist²⁸⁷. Successful "Lifetime members" have been studied, and results from one study suggest that 37% of these individuals have maintained their goal weight for 5 years²⁹². An additional study demonstrated that 19.4% of "Lifetime members" were within 5 lbs of their goal weight 5 years posttreatment²⁹³. A two-year multicenter randomized clinical trial compared a structured Weight Watchers program to a self-help group condition consisting of two brief nutritional counseling sessions and self-help materials²⁹⁴. After one year, participants in the Weight Watchers condition had lost significantly more weight than the self-help group, 4.3 kg and 1.3 kg, respectively. At two year follow-up, the commercial weight loss participants' weight loss was significantly greater than the self-help group, 2.9 kg and 0.2 kg, respectively²⁹⁴. The authors concluded that the structured weight loss program provided modest weight loss, but was superior to self-help. One should caution at overinterpreting the findings since for half of these studies, only successful members (i.e., Lifetime members), were evaluated. Additionally, one study suggests that 50% of participants in Weight Watchers attended less than seven group sessions, and lost only about 1 kg²⁹⁵.

Three other popular commercial weight loss programs include Jenny Craig, Inc., L.A. Weight Loss, and Nutrisystem, Inc. Jenny Craig, Inc. was founded in 1983 and is the second largest commercial weight loss program²⁸⁷. This company offers various weight loss packages of

varying length and price. A lifetime membership costs \$369, however, clients are reimbursed \$185 if they reach and maintain their goal weight for one year. Jenny Craig also offers “per-pound” programs, where the individual pay only \$10 for the first 10 lbs lost, and then gradually higher amounts for additional weight lost²⁸⁷. All meals must be purchased through Jenny Craig regardless of which weight loss package is chosen. A day’s meals average cost is between \$12 –15²⁹⁶. Jenny Craig also provides the option of “in-center” service, or “Jenny Direct”, an at home program which includes delivery of foods directly to the home. No published data are available on the efficacy of this program.

L.A. Weight Loss was established in 1987. The company promotes a 2-3 lbs weekly weight loss through individual counseling, and 1,100-1,900 kcal/day diet²⁸⁷. The meal plan is developed by a registered dietician of the company. Given the rapid weight loss that is encouraged, individuals are screened for potential medical contraindications. Clients with a preexisting condition must obtain physician approval prior to starting the plan²⁸⁷. The cost of the program is \$6/week for membership, and \$28/week for food. No published data are available on efficacy of this program.

Nutrisystem, Inc. was founded in 1972, and included comprehensive weight loss packages including very-low-calorie diets (VLCD), prepackaged foods, and medication²⁸⁷. In 1993, the company filed for bankruptcy, but returned in 1999 as nutrisystem.com. The company is now entirely web-based, and over 150,000 people have already joined²⁸⁷. Food is the only cost, at \$49.95, which is delivered directly to the home. These meal packages consist of 1,200-1,500 kcal/day over three meals. Free on-line counseling is available, and a registered dietician is on-call during counseling visits. One study has examined the use of Nutrisystem foods in weight loss²⁹⁷. Forty-nine women were either assigned an exercise or no-exercise condition, and all followed a 1,000 kcal/day diet using foods from Nutrisystem. At 8 weeks, those women who exercised lost 10.9% on their initial body weight compared to 7.9% of those in the non-exercise condition. There were no significant differences among groups.

Other diet plans are constantly emerging. One recent program is the Deal-a-Meal program developed by Richard Simmons. This program focuses on nutrition, exercise, and motivation. Cards representing daily food exchanges provide between 1,000-2,000 calories a day which is also determined by gender and starting weight. Deal-a-Meal is based on the ADA exchange list and is consistent with the Food Guide Pyramid²⁹⁸. Cost of the program varies. The Deal-a-Meal Food Plan is approximately \$10.00. Exercise videos, audiotape walking programs, and motivational tapes are available for approximately \$20.00-25.00 each. Multicomponent packages are also available at higher rates²⁹⁸.

The Diet Workshop is a program that consists of diet, exercise, and behavior modification. Diets range from 1,200 to 2,600 kcal/day and 27-40 grams of fat per day, and follow the Food Guide Pyramid. Special foods are available for purchase. Prior to its removal from the market, drug therapy with the fenfluramine/phentermine combination or dexfenfluramine was available²⁹⁹. The cost of the program ranges from \$12 to \$34 per week. The three-month behavior modification program costs \$169. There is no charge for a maintenance program. Once a client reaches his/her goal weight, attendance at Diet Workshop is free.

Popular or “Fad Diets”

Information regarding many popular diets has been previously reviewed in the diet section. Additional information regarding organizational recommendations are provided as supplemental information.

The American Heart Association recommends adopting healthy eating habits permanently, rather than impatiently pursuing crash diets in hopes of losing unwanted pounds in a few days³⁰⁰.

- **We want to inform the public about misleading weight-loss claims.** Many of these diets -- like the infamous **Cabbage Soup Diet** -- can undermine your health, cause physical discomfort (abdominal discomfort and flatulence [gas]) and lead to disappointment when you regain weight soon after you lose it.

Quick-weight-loss diets usually overemphasize one particular food or type of food. They violate the first principle of good nutrition: Eat a balanced diet that includes a variety of foods. If you are able to stay on such a diet for more than a few weeks, you may develop nutritional deficiencies, because no one type of food has all the nutrients you need for good health. The Cabbage Soup Diet mentioned above is an example. This so-called fat-burning soup is eaten mostly with fruits and vegetables. The diet supposedly helps heart patients lose 10-17 pounds in seven days before surgery.

- There are no "superfoods." That's why you should eat moderate amounts from all food groups, not large amounts of a few special foods.
 - These diets also violate a second important principle of good nutrition: Eating should be enjoyable. These diets are so monotonous and boring that it's almost impossible to stay on them for long periods.
 - A special problem was seen with a liquid protein diet that became popular several years ago. It used digested collagen with little or no essential substances added. In 1977 this diet was blamed for at least 60 deaths.
- Many of these diets falsely say they are endorsed by or authored by our association. **The public should know that the real American Heart Association eating plan gives recommended servings per day of various food categories, not of specific foods.** Our eating plan for those who want to maintain their weight emphasizes reducing saturated fats and trans fats and advises adequate amounts of total fat to reach a caloric level balanced with energy output or activity. For weight management or weight loss, we recommend no more than 30 percent of calories from fat. Our eating plan recommends a variety of foods, including five or more servings of fruits and vegetables every day. It also recommends moderation in sodium intake and adequate amounts of whole grains and low-fat dairy products.

Any diet that gives specific menus or suggests that it be followed for a set time period isn't from our organization. Our eating plan has been carefully researched and is intended for a lifetime of use. **Most important, the real American Heart Association eating plan accommodates people with diverse needs and food preferences.**

Unlike an incomplete liquid protein diet or other fad diets, a good diet can be eaten for years to maintain desirable body weight and good health. Fad diets fail to provide ways to keep weight off.

- **Some major medical centers prescribe extremely low-calorie, high-protein diets for selected patients carefully monitored by physicians.**

In what other ways are quick-weight-loss diets flawed?

- Many don't encourage physical activity -- for example, walking 30 minutes most or all days of the week. This helps you maintain weight loss over a long time. Physical inactivity is a major risk factor for heart disease. It increases the risk of stroke, too.
- Because because quick-weight-loss diets require drastic changes in eating patterns, you can't stay on them for long. People on such diets don't learn anything about permanently changing their eating patterns.
- In addition, many fad diets are based on "food folklore," some dating back to the early 19th century. Diets high in protein, for example, are also usually higher in fat. They have not been documented to be safe in the long term. Ideas about "fat-burning foods" and "food combining" are also classified by the American Heart Association as unsubstantiated myths.

Despite what quick-weight-loss diet books may say, the only sensible way to lose weight and maintain a healthy weight permanently is to eat less and balance food intake with physical activity.

What is the best way to lose weight?

A healthy diet rich in fresh fruits and vegetables, whole grains and low-fat dairy products, along with regular physical activity, can help most people manage and maintain weight loss for both cardiovascular health and appearance. The American Heart Association urges people to take a safe and proven route to losing and maintaining weight -- by following our guidelines for healthy, nutritionally balanced weight loss for a lifetime of good health.

AHA Recommendation

The American Heart Association doesn't recommend high-protein diets for weight loss. Some of these diets restrict healthful foods that provide essential nutrients and don't provide the variety of foods needed to adequately meet nutritional needs. People who stay on these diets very long may not get enough vitamins and minerals and face other potential health risks.

USDA Findings: Popular Diets: a Scientific Review,³⁰¹

The proliferation of diet books is nothing short of phenomenal. A search of books on Amazon.com using the key words "weight loss" revealed 1214 matches. Of the top 50 best-selling diet books, 58% were published in 1999 or 2000 and 88% were published since 1997. Many of the top 20 best sellers at Amazon.com promote some form of carbohydrate (CHO) restriction (e.g., *Dr. Atkins' New Diet Revolution*, *The Carbohydrate Addict's Diet*, *Protein Power*, *Lauri's Low-Carb Cookbook*). This dietary advice is counter to that promulgated by governmental agencies (US Department of Agriculture [USDA]/Department of Health and Human Services, National Institutes of Health) and nongovernmental organizations (American Dietetic Association, American Heart Association, American Diabetes Association, American Cancer Society, and Shape Up America!).

Weight Loss

Diets that reduce caloric intake result in weight loss. In the absence of physical activity, a diet that contains ~1400 to 1500 kcal/d, regardless of macronutrient composition, results in weight loss. Individuals consuming high-fat, low-CHO diets may lose weight because the intake of protein and fat is self-limiting and overall caloric intake is decreased. Low-fat and VLF diets contain a high proportion of complex CHOs, 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, CHO, 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, as well as diets recommended by governmental and nongovernmental organizations, result in weight loss. However, it is important to note that weight loss is not the same as weight maintenance.

Body Composition

As body weight decreases, so does body fat and lean body mass. The optimal diet for weight loss is one that maximizes loss of body fat and minimizes loss of lean body mass. All low-calorie diets result in loss of body weight and body fat. Macronutrient composition does not seem to play a major role. In the short-term, however, high-fat, low-CHO ketogenic diets cause a greater loss of body water than body fat). When these diets end, water weight is regained. Eventually, however, all reduced calorie diets result in loss of body fat if sustained long term.

Physical activity, an important factor with respect to lean body mass, should be promoted to enhance the effects of diet on body composition.

Nutritional Adequacy

Proper food choices are always important when considering the nutritional quality of a diet. When individuals consume foods from all food groups, it is more likely that their diet will be nutritionally adequate. The moderate-fat, balanced nutrient reduction diet is optimal for ensuring adequate nutritional intake. However, poor food choices may result in inadequate levels of nutrients (e.g., calcium, iron, zinc), regardless of overall macronutrient composition. High-fat, low-CHO diets are nutritionally inadequate. They are low in vitamins E, A, thiamin, B₆, folate, calcium, magnesium, iron, potassium, and dietary fiber, and require supplementation. These diets are high in saturated fat and cholesterol. VLF diets are low in vitamins E, B₁₂, and zinc because meat and fat intake is low.

Metabolic Parameters

Low-CHO diets result in ketosis, and may cause a significant increase in blood uric acid concentrations.

Blood lipid levels (e.g., total cholesterol [TC], low-density lipoprotein [LDL], high-density lipoprotein [HDL] and triglycerides [TGs]) decrease as body weight decreases. However, the macronutrient and fatty acid composition of energy-restricted diets can exert substantial effects on blood lipids. There are significantly greater decreases in LDL cholesterol during active weight loss when diets are low in saturated fatty acids. Changes in HDL cholesterol depend on dietary fat content and duration of energy restriction. Moderate-fat, balanced nutrient reduction diets reduce LDL-cholesterol and normalize the ratio of HDL/TC.

Plasma TG levels also decrease with weight loss. Although they increase in response to short-term consumption of a VLF, high-CHO diet, the type of CHO consumed must be considered. High-fiber foods, including vegetables and legumes, do not lead to hypertriglyceridemia, and may easily be incorporated into moderate-fat, balanced nutrient reduction diets to help normalize plasma TG levels.

Energy restriction, independent of diet composition, improves glycemic control. As body weight decreases, so does blood insulin and plasma leptin levels.

Blood pressure decreases with weight loss, independent of diet composition. However, the DASH diet, high in fruits, vegetables, and low-fat dairy products effectively lowers blood pressure.

Hunger and Compliance

Many factors influence hunger, appetite, and subsequent food intake. Macronutrient content of the diet is one, and it may not be the most important. Neurochemical factors (e.g., serotonin, endorphins, dopamine, hypothalamic neuropeptide transmitters), gastric signals (e.g., peptides, stomach distention), hedonistic qualities of food (e.g., taste, texture, smell), genetic, environmental (e.g., food availability, cost, cultural norms) and emotional factors (e.g., eating when bored, depressed, stressed, happy) must be considered. These parameters influence appetite primarily on a meal-to-meal basis. However, long-term body weight regulation seems to be controlled by hormonal signals from the endocrine pancreas and adipose tissue, i.e., insulin and leptin. Because insulin secretion and leptin production are influenced by the macronutrient content of the diet, effects of different diets on these long-term regulators of energy balance also need to be considered when investigating hunger and appetite.

All fat-restricted diets provide a high degree of satiety. Subjects who consume fat-restricted diets do not complain of hunger, but of having "too much food". These diets, high in fiber and water content are low in caloric density. Subjects who consume these diets develop a distaste for fat, which may be useful in long-term adherence to reduced fat, low-calorie diets. However, it is not clear that restricting fat provides any advantage over restricting CHOs. Ogden reports weight loss maintainers used healthy eating habits and adhered to calorie-controlled diets.

Long-term compliance to any diet means that short-term weight-loss has a chance to become long-term weight maintenance. Dietary compliance is likely a function of psychological issues (e.g., frequency of dietary counseling, coping with emotional eating, group support) rather than macronutrient composition, per se. Being conscious of one's behaviors, using social support, confronting problems directly, and using personally developed strategies may enhance long-term success. Ogden notes that successful weight loss and maintenance may be predicted by an individuals' belief system (e.g., that obesity is perceived as a problem that can be modified and if modifications bring changes in the short-term that are valued by the individual concerned).

USDA Summary and Recommendations regarding Popular Diets

Caloric balance (calories in vs. calories out), rather than macronutrient composition is the major determinant of weight loss. However, what is not clear is the effect of macronutrient content on long-term weight maintenance and adherence. Furthermore, it is not known whether maintenance of weight loss and dietary adherence is related to psychological issues (and brain neurochemistry), physiological parameters (e.g., hormones involved in body weight regulation such as insulin and leptin), physical activity, energy density, or some other factor(s).

Controlled clinical trials of high-fat, low-CHO, and low-fat and VLF diets are needed to answer questions regarding long-term effectiveness (e.g., weight maintenance rather than weight loss) and potential long-term health benefits and/or detriments.

Prevention of weight gain and weight maintenance are important goals. Scientifically validated, yet understandable information is clearly needed by millions of overweight and obese Americans who often find weight loss attainable, but maintaining weight loss nearly impossible.

Medically based and Residential Diets

Medically based weight loss programs include combined use of very low-calorie diets (VLCD) and behavioral modification²⁸⁷. Typically, VLCDs offer medically supervised dietary restriction. Several trials have shown that patients lose 15-20% of their initial weight during a 2-3 month treatment phase²⁸⁷. However, weight regain has been estimated to be 35-50% of lost weight. The OPTIFAST program was introduced in 1970, and has been used by over 700,000 individuals²⁸⁷. Initial treatment is 8-16 weeks, and the patient is prescribed an 800 kcal/day diet along with lifestyle modification classes. During the second phase of treatment, patients are gradually reintroduced to conventional foods. The third phase is a maintenance phase. Cost for this program averages \$1,500-\$3,000²⁸⁷. The efficacy and safety of OPTIFAST has been extensively researched. Results suggest significant initial weight loss (e.g., 22-32 kg) with a weight regain approaching 50%.

Health Management Resources (HMR) is a medically supervised weight loss program that was introduced in 1983 and reports helping over 800,000 people³⁰². Patients can choose from one of three programs: VLCD (520 kcal/day), a low-calorie diet (800 kcal/day), and a Healthy Solutions diet (1,000-1,600 kcal/day)²⁸⁷. All the diets use shakes and nutrition bars, and the Healthy Solutions diet incorporates five servings of fruits and vegetables. Patients attend lifestyle modification groups and are expected to exercise regularly (expending 2,000 kcal/week)²⁸⁷. Level of medical supervision required is contingent on which plan is chosen. The cost of the program can range from \$150-\$250 per week²⁸⁷. The maintenance program costs \$95/month²⁸⁷. Several studies have demonstrated the safety and efficacy of this program²⁸⁷. Average weight lost is approximately 29 kg, and approximately 26% maintain weight loss at 3 years posttreatment²⁸⁷.

Residential programs for weight loss are usually administered by a multidisciplinary team with a focus on nutrition, medical management, exercise, and lifestyle modification²⁸⁷. Two well-known programs are Duke Diet and Fitness Center, and the Pritikin Program. Both of these programs are very expensive with weekly expenses ranging from \$2,730-\$3,095/week excluding housing costs²⁸⁷. No published data are available for the Duke Center, however research is being conducted currently. Data on the Pritikin Program showed that a three week program resulted in 5.5% and 4.4% body weight reduction, in men and women respectively, and improvements in lipid profiles³⁰³.

Self Help Programs

Self-help programs have also been growing in popularity²⁸⁷. These programs are usually free or of little cost, and are organized and conducted by laypersons who have struggled with their own weight²⁸⁷. The most popular program is Overeaters Anonymous (OA). OA was established in 1960 and is modeled after the Twelve-Step Approach of Alcoholics Anonymous which requires the individual to admit that they are powerless over their ability to control overeating³⁰⁴. OA focuses on spiritual and psychological issues of compulsive eating²⁸⁷. Nutritional and biological reasons are not explored. Empirical data on OA is lacking. One noncontrolled study reviewed improvements in binge eating among bulimic women³⁰⁵. The authors report that roughly 50% of their participants stopped bingeing within the first month of joining OA. However, 62.5% of their sample was concurrently receiving psychotherapy for bulimia.

Take Off Pounds Sensibly (TOPS) was established in 1948. TOPS endorses the American Dietetic Association exchange program, and members are encouraged to contact their personal physician for specific diet recommendations²⁸⁷. TOPS consists of informative group sessions that also focus on motivation and camaraderie. Cost of the program is a \$20 membership fee per

year²⁸⁷. There is no treatment outcome data on the efficacy of TOPS. However, a few descriptive studies exist for various health populations²⁸⁷. Additionally, the TOPS foundation has contributed several million dollars to fund obesity and metabolic research²⁸⁷.

The Trevoze Behavior Modification Program was started in 1970 by David Zeitlich who lost 100 lbs and wanted to maintain his weight loss²⁸⁷. Membership is free and groups are led by laypeople. Group sessions include behavioral instruction on weight loss. Members must choose an “ultimate weight loss goal”, and must achieve 15% of this weight loss goal within the first 5 weeks²⁸⁷. If goals are not met, the individual is not granted Full Membership privileges. Members have specific attendance and weight loss/maintenance requirements, and failure to meet the requirements will result in expulsion from the program²⁸⁷. One study of this program which evaluated 171 Full Members from 1992-1993 showed that 47.4% of members remained in the program after two years³⁰⁶. Membership at five years was 21.6%. Average weight lost at two years was 17.9 kg, and 15.7 kg at five years³⁰⁶. Overinterpretation of the findings is cautioned. Participants in this study were the “successes” since they obtained Full Membership status²⁸⁷.

Self-help programs also come in the form of books. The LEARN (Lifestyle, Exercise, Attitudes, Relationships, Nutrition) program is a manualized, 16 week weight loss program developed by leading researchers in the field³⁰⁷. The program is based on a 1,200-1,500 kcal/day diet. Participants are encouraged to eat what they want in moderation, maintain food records, and to exercise²⁸⁷. Studies of the LEARN program in conjunction with behavioral modification classes have demonstrated a 7-10 kg of initial weight loss²⁸⁷.

Slim-Fast is another popular self-help program for dieters. Slim-Fast is a meal replacement program that highlights 1-2 shakes a day, and a sensible, well-balanced dinner²⁹⁸. Total daily caloric intake is recommended at 1,200-1,400 kcal. Expected weight loss is 3-4 lbs the first week and 1-2 thereafter. Maintenance of weight lost is encouraged by drinking one meal replacement shake a day. A multicenter study of participants who consumed two Slim-Fast meal replacement shakes a day for 12 weeks showed that women lost 6.3 kg, and men lost 8.3 kg³⁰⁸. The study included a two year maintenance phase which encouraged one meal replacement shake daily. At one year, 41% maintained full weight loss, and 36% maintained greater than 80% of their original weight lost. At two years, 22.8% maintained all of their initial weight lost, and 39% were within 80% of their initial weight loss. Findings are limited since only 44.2% of the original sample remained in the study at 2 years.

New web technologies have also entered the domain of commercial weight loss. In 1996, eDiets.com was launched²⁸⁷. This site provides a virtual visit with a dietician. Members are also provided a recommended grocery list based on member’s likes and dislikes, caloric recommendations based on the member’s weight, online chat rooms, and newsletters²⁸⁷. Furthermore, the member can take a “diet analysis” to see which diet works best for them, and then choose a plan based either on eDiets, Shape Up! Plan, Atkins diet, or The Zone, all popular fad diets³⁰⁹. Cost of the program is \$35 for 3 months, and \$10 for each additional month²⁸⁷. No published data on the efficacy of this program is available.

The cost of commercial weight loss programs vary dramatically. A 1992 review of the cost of these programs found that a 12 week outpatient program can range from \$176 /wk for a very low calorie diet program to \$9/wk for a nutrient-balanced diet program (e.g., Weight Watchers). In this survey, Weight Watchers was the most economical program with an average cost of \$2.30/kg for a 91kg person to achieve a 1% loss per week in a 12 week program²⁹⁰. A more recent article noted that Weight Watchers International was the most cost effective weight loss program³¹⁰. Specifically, it costs approximately \$12 a pound to use Weight Watchers compared to \$45 for Nutrisystem, and \$50 for Jenny Craig³¹⁰.

Barriers to Weight loss

Lack of Use of Scientifically Proven methods

Serdula and colleagues found that the prevalence of attempting to lose weight was 28.8% among men and 43.6% among women³¹¹. A common strategy to lose weight was to consume less fat but not fewer calories (34.9% of men and 40.0% of women); only 21.5% of men and 19.4% of women reported using the recommended combination of eating fewer calories and engaging in at least 150 minutes of leisure-time physical activity per week.³¹¹

Unrealistic Weight Loss Expectations

Wadden and colleagues found that obese women reported that they expected to lose approximately 28% of their body weight during 1 year of treatment with sibutramine³¹². This expectation was resistant to verbal and written information about the realistic weight loss expectations of 5% to 15% of loss initial weight³¹². Studies have found that obese women wish to lose >30% of their weight in order to be satisfied and would be disappointed with a loss of weight less than 35 lbs in one year. This demonstrates the dramatic disparity between the current efficacy of available treatments and expectations¹²³.

Benefits of Weight Loss

The National Institutes of Health found that behaviorally mediated weight losses of approximately 5-10 kg are associated with immediate and at least short-term improvements in health indicators such as blood pressure, lipids and glycemic indices². Substantial improvements in these same health outcomes have been noted after surgical treatments²⁵¹. Pharmacological treatments also are associated with similar improvements. McTigue and colleagues in an exhaustive review found that Orlistat has been associated frequently with improvements in glucose indicators as well as total cholesterol and LDL^{313, 314}. However, their findings for sibutramine were more equivocal. They concluded that neither orlistat or sibutramine impacted HDL or triglycerides.

There is limited data regarding the long-term health outcomes of weight loss. Based on observational data there is some suggestion of reduced mortality. Studies have suggested that behavioral treatments have been associated with a 58% reduction in the development of diabetes while pharmacological treatment with metformin can result in a 31% reduction³¹⁵. In a studies of surgical outcomes it appears that while 50% had impaired glycemic indices at baseline more than 90% had normal glycemic control after surgery^{251, 316}. The long term effects on blood pressure are now questionable since hypertension has been found to recur in patients who are able to maintain a 20kg loss³¹⁷.

Settings for Weight Management

Medical

Primary care clinics offer an excellent setting to assess primary and secondary obesity prevention interventions since most adults in the U.S. visit a physician more than twice per year^{318, 319}. The primary care physician is the most important and expected source of health risk advice³²⁰⁻³²³. Additionally, obesity-related physician visits have increased >80% in the past few years³²⁴, and obesity-related health expenditures are approximately 7% of total health care in the U.S.³²⁵. Therefore, the medical community is a logical and naturalistic setting to provide weight management programs and as a result, there have been increasing calls for physician-delivered weight loss interventions^{326, 327}.

Physician Intervention Programs The importance of utilizing health care providers to achieve changes in diet, exercise, and weight have been highlighted in the Surgeon General's Call to Action to Prevent and Decrease Overweight and Obesity as well as the goals and objectives of Healthy People 2010. Advice from a health care provider is a powerful predictor of patient behavior change^{328, 329}. While physicians acknowledge the importance of weight management, many lack the training, knowledge, and confidence to provide proper dietary^{330, 331}, activity³³² and behavioral interventions to enhance weight loss³³³⁻³³⁵. Therefore, less than half of obese adults reported that their physician advised them to lose weight^{336, 337}, and most physicians do not counsel on diet or exercise³³⁸⁻³⁴⁰. There has been a focus on using primary care physicians to primarily monitor weight, give educational materials or referrals, and manage weight related comorbidities³⁴¹. However, weight management interventions delivered by the physician alone^{342, 343} or in combination with specific dietary interventions^{344, 345} can produce weight losses ranging from 2.0 kg to 4.7 kg, while participants in controlled conditions gained or maintained weight. Additionally, research has suggested that brief physician directed weight loss programs are comparable to intensive group treatments in the pharmacological treatment of obesity¹⁵².

Training physicians in behavior change techniques has a variety of positive effects. Physicians have reported improved confidence and patient response, as well as improved quality and frequency of weight management recommendations^{326, 346-349}. Non-didactic instructional methods (e.g. modeling, role-playing) and concise, simplistic educational materials have been most effective in teaching physician counseling skills³⁵⁰⁻³⁵². Finally, Field and colleagues noted that "the doctor should counsel their patients on the importance of maintaining healthy weight and help overweight patients lose weight and maintain the loss"³²⁵. (pg.13).

Dietary change in the form of low fat diet and increased fruit and vegetable consumption are often recommended in the treatment and prevention of obesity. Traditional education-based dietary interventions have been relatively ineffective for long term maintenance of dietary change³⁵³. It has been estimated that physicians provide nutrition assessment/counseling for approximately 40% to 50% of their patients³³⁸. Results from our survey of primary care clinics indicated that although most patients are encouraged to make dietary changes, more than 30% reported that they were not given specific dietary instruction and only 30% of physician recommendations included increasing intake of fruits and vegetables³⁴⁰. Using self-help educational materials in primary care has been effective in improving dietary fat intake³⁵⁴. It has been suggested that physicians often lack the resources and time to conduct specialized dietary programs, but should implement clear messages and customize treatments toward the individual patient³⁵⁵. Recently, attempts have been made to tailor medically recommended diets to the food preferences of African Americans³⁵⁶. Improving physician counseling skills in behavioral modification would appear to be beneficial since more physician are reporting that they are counseling for weight loss and diet rather than referring for these services³⁵⁷.

Physicians do not frequently counsel about exercise^{333, 358-361} and are not well informed on the proper activity recommendations³⁶². Physician interventions that have focused on giving advice and calling attention to sedentary behavior have produced some improvement in sedentary behavior³²¹. It has been demonstrated that sedentary lifestyle can have an adverse impact on health status and result in significant health care expenditures. The results of our data indicate that approximately half of the patients report that specific information regarding the amount and frequency of exercise was not addressed in the discussion of weight loss³⁴⁰.

Louisiana Medical Programs:

Because Louisiana's rates of obesity are in excess of the national average^{363, 364}, two separate follow-up studies were designed to assess the current obesity management practices of primary care physicians from both the physician and patient perspective³⁴⁰. The results of the physician survey indicated that the physicians spend a fair amount of time counseling their patients on obesity and feel prepared to offer information in the areas of exercise, weight loss, and diet modification. However, they report feeling ineffective in their efforts due to time constraints and patient motivation. With regard to reported treatment provisions, most physicians did not recommend counseling on caloric balance, and increasing fruit and vegetable intake in case vignettes of obese patients. The patient survey validated the physician report by confirming that the physicians did counsel in weight loss and diet and exercise modification. However, the survey highlighted the need for the physicians to be more specific in their recommendations to explain the risks associated with obesity and the benefits of weight loss, and to follow-up more consistently with patients on weight loss progress. These studies highlight a health care system attempting to address the significant needs of their obese patients.

Work Site

The increasing problem of obesity has lead to innovative treatment approaches to improve outreach. One recent area of interest is worksite interventions³⁶⁵. Some of the benefits associated with workplace interventions are 1) it can reach large numbers of people, at little cost, who may not otherwise seek treatment on their own, 2) it has an established concentration of workers with a preexisting communication system, 3) it facilitates access by interested workers because of proximity, 4) social support from employers and fellow coworkers, and 5) cost recovery by the company since a reduction in obesity related conditions results in a reduction in direct care costs. In 1996, Hennrikus and Jeffery published a review paper of worksite interventions for health behavior change³⁶⁵. Their review revealed 43 worksite weight-loss programs. However, of those studies only 10 were properly conducted studies with a randomized comparison or control group. The first effectiveness study in this area compared various treatment conditions (e.g., site, layperson versus experienced therapist, frequency of treatment) among 40 female union members³⁶⁶. Attrition was high (e.g., only 17 completed the program). Results found that attrition was lower among those groups led by laypersons, and those conditions with more frequent contact. There were no significant differences in weight loss among groups. Average weight lost after the 16 week program was 3.6 kg, and at 6 month follow-up, 1.2 kg.

The WHO European Collaborative Trial in the Multifactorial Prevention of Coronary Heart Disease conducted by Rose and colleagues evaluated the effectiveness of advice about cardiovascular disease risk delivered through factory medical departments³⁶⁷. This was one of the first large scale worksite intervention programs. Twenty-four factories were matched by various demographic information, and over 18,000 men were recruited. Treatment included advice on cholesterol-lowering diet, tobacco use, weight control, exercise, and high blood pressure. The study lasted 5-6 years and showed moderate reduction in cigarette use, however other cardiovascular risk factors were minimally reduced and not well sustained. Notably, there was a 36% reduction in the rate of intervention participants reporting illness with CHD, however, it is unclear whether this represents a bias in reporting symptoms or actual clinical effect. A few more recent randomized studies of a larger scale have been conducted. The Health Worker Project evaluated the effectiveness of reducing obesity and cigarette use¹¹⁸. Thirty-two work sites were randomly assigned to treatment or no treatment over a two-year period. Treatment included health education classes and a payroll incentive program. Only 2,041 (obesity program) and 270 (smoking cessation program) participated in the study out of 10,000 available employees. Average weight loss was 4.8 lbs and 43% quit tobacco use. No significant differences were found

for weight loss, but reduction in smoking were effective. Take Heart was a study that evaluated the short-term effects of a low intensity cardiovascular risk reduction program using a matched pair design³⁶⁸. Twenty-six worksites with a range of 125-750 employees per company were matched on various demographics and then randomly assigned to receive either an early or delayed intervention. The intervention was an 18 month multifactorial program consisting of a steering committee and key topics tailored to each individual site. The authors revealed no significant differences within and between the early and delayed conditions with regards to smoking cessation, dietary intake, and cholesterol levels. In 2001, a multicomponent study in Japan evaluated the effectiveness of a health program for a group of male building maintenance employees³⁶⁹. The intervention and control group consisted of men having abnormal findings in one or more of the following areas: BMI, systolic or diastolic blood pressure, total cholesterol, HDL cholesterol, triglycerides, and fasting blood glucose. Overall, BMI, systolic blood pressure (SBP), total cholesterol, and triglycerides improved significantly in the intervention group compared to the controls.

Other clinical studies have examined methods to improve adherence to weight-loss program (e.g., incentive programs)^{370, 371}, as well as various populations including hospital employees³⁷⁰, department store workers³⁷², university employees^{371, 373}, technological firms³⁷⁴, chemical plants and oil refineries employees³⁷⁵, ambulance station employees³⁷⁶, and other diverse populations¹¹⁸. Additionally, several dozen other studies of less empirical vigor exist on many diverse populations³⁶⁵. The review by Hennrikus and Jeffery³⁶⁵ concludes that as a whole the research methodology for worksite prevention varies considerably and is weak. The majority of empirical and nonempirical studies utilized many of the following: behavior modification techniques, educational topics, incentives, and competitions. Results of the studies suggest modest weight loss over the short-term (e.g., 1-2 lbs/week), however no longer term data (i.e., 6 months or longer posttreatment) are available.

Church Based Programs

Churches and religious organizations are an influential source of information for many individuals. The church serves a central role in the communication, social, and support networks for many African Americans³⁷⁷. This is combination with the fact that minorities are at increased risk for high blood pressure and overweight/obesity, the advent of church-based interventions have become important in the domain of preventative medicine³⁷⁷. The Baltimore Church High Blood Pressure Program (CHBPP) was established in 1979 to organize African American churches as high blood pressure control centers with the hopes of teaching lay volunteers to perform blood pressure screenings, referrals, and monitoring services³⁷⁷. This program was offered to all African American churches in the greater Baltimore area. In 1984, the Lose Weight and Win Program in combination with CHBPP was established. This 8 week program offered screening, nutritional education, behavioral counseling, and referral for high blood pressure, diabetes, hyperlipidemia, and overweight. The Lose Weight and Win Program was held in group formats with weekly meeting lasting 1.5 to 2 hours. Participants were routinely weighed, had blood pressure checked, and then received nutritional education from a dietician, and behavioral counseling³⁷⁷. In this study, African American women were weighed and had blood pressure readings pre- and post-program. Results comparing women who took antihypertensive medication to those who did not showed that mean weight loss for both groups was 6 lbs. Systolic/diastolic blood pressure decreases were significantly higher in the medication group (10/6 mmHg) compared to the non-medication group (5/3 mmHg). Prior to the program, 52% of the participants had systolic blood pressure values < 140 mmHg. After completing the church-based program, 74% of the participants had systolic blood pressure < 140 mmHg.

In 1997, McNabb and colleagues developed a weight loss program (PATHWAYS) designed specifically for urban African Americans to be administered in urban churches by trained laypersons³⁷⁸. PATHWAYS was a 14 week program administered in a group format on a weekly basis. Content included guided learning activities on weight loss and health improvement facilitated by trained laypersons. The reader is referred to Quinn and McNabb (2001) for a detailed description of training lay health educators³⁷⁹. The program was designed specifically to address sociocultural weight loss issues that may be unique to urban African American women (e.g., use of ethnic foods in discussions, inner city lifestyle issues, etc.). Women who completed the program were compared to women waiting to start the groups (e.g., waitlist control group). Results showed that women who received the program lost an average of 10 lbs compared to a 1.9 lbs gain for those in the control condition. Additionally, the waist circumference decreased 2.5 inches for those in the PATHWAYS program while waist circumference for those in the control condition remained the same³⁷⁸.

Project Joy was a study designed to evaluate three strategies (i.e., standard group behavioral meetings, standard group behavioral meeting supplemented with a spiritual/church cultural component, and self-help group) within the context of inner city churches to reduce weight and cardiovascular risk factors³⁸⁰. Churches were randomized to receive one of the three conditions. Churches in the standard behavioral group condition received weekly sessions of nutrition and physical activity education by trained female African American health educators. Churches in the standard behavioral group condition supplemented with spiritual support received the same sessions as the standard intervention with the addition of spiritual components (e.g., group prayer, use of scripture, physical activity done to gospel music, church bulletins, and reminders by the pastor of the church). Churches in the self-help condition received materials from the American Heart Association on healthy eating and physical activity. Each participant in this condition received personal feedback regarding their health screen, and the educational materials from Project Joy, NIH, and the YMCA. Lay leaders in the self-help churches received the same educational materials as the leaders in the other conditions, but were not instructed on using the materials. Results indicated that there were no significant differences between the standard and spiritual conditions on risk factors and anthropometric data. Therefore, the standard and spiritual conditions were combined to form the 'active intervention' condition which was compared to the self-help condition. Participants in the active intervention showed significant improvements compared to the self-help condition in body weight (-1.1 lb versus +0.83, respectively), BMI (-0.017 versus +0.14, respectively) waist circumference (-0.66 versus -0.007, respectively), and energy intake (-177 versus -7, respectively).

Community Organizations/National:

Traditional approaches to the treatment of obesity have been less than optimal in accessing the public. Therefore, there has been a rise in the number of community-based and national organizations targeting weight loss. There have been a handful of large-scale community wide programs that have attempted to change health behaviors³⁸¹. Two of the earliest studies were the Stanford Three Community Study^{382,383} and the North Karelia Project³⁸⁴. In the Stanford Three Community Study, a field experiment on cardiovascular risk was conducted with three northern California towns. Two of the towns received extensive mass media campaigns over a two year period, and within one of these towns a subset of high risk individuals received face-to-face counseling. The third town served as a control. At two year follow-up, in the control town the risk for cardiovascular disease increased. In the experimental towns there was a significant decrease in self-reported cardiovascular risk factors (e.g., cigarette use, decrease in calories, salt, sugar, saturated fat, and cholesterol). The subset of individuals within a single community that received

counseling initially demonstrated greater improvement in reducing smoking, however, by two years this group had similar risk levels as the other treatment participants.

The North Karelia Project was a Finnish study that attempted to reduce cardiovascular risk factors. Mass media campaigns were used to educate the public, and the food and dairy industries collaborated with the researchers to make changes in milk, butterfat, and high fat meats. Results demonstrated a 21% decrease in myocardial infarctions and 31% decrease in strokes.

Other health campaigns have emerged since that time. In 1981, the Office of Health Information and Health Promotions launched a national health promotion campaign entitled, the Health Style Campaign. The goals of this campaign were to increase public awareness of lifestyle on health, assist the public in assessing individually relative lifestyle changes, increase information seeking behavior, and develop health promotion campaigns and community organizations at the local level³⁸⁵. Mass media and community organization were utilized to accomplish the goals of the campaign. Media campaigns varied locally, and included television newspaper, and radio advertisements, and bus transit cards. Individuals were encouraged to obtain a self-scoring booklet that allowed them to test their health behaviors in the areas of smoking, alcohol use, drug use, nutrition, exercise, stress, and safety. Individuals were encouraged to obtain further information on any of the topics by returning an enclosed return card. The campaign was implemented by local agencies. The nine test communities that were chosen for the campaign were Baltimore, Columbia, SC, Denver, Kansas City, Milwaukee, Pittsburgh, Salt Lake City, San Francisco, and Washington, D.C. Detailed information and data are available elsewhere³⁸⁶. Published data for the Denver site found that 83% of respondents who received the booklet reported that they had read the booklet. When asked what information they learned from the booklet, 28% reported 'smoking', 25% 'nutrition', and 17% 'exercise' information. One-third of the respondents reported that they had changed something in their lives after reading the booklet. The self-reported behavior changes most commonly mentioned were in the areas of nutrition (60%) and exercise (52%).

In 1982, the Multiple Risk Factor Intervention Trial (MRFIT) was a primary prevention trial that examined the effects that a multifactor intervention program would have on coronary heart disease³⁸⁷. Over 12,000 men were randomly assigned to receive either a special intervention (SI) consisting of stepped-care treatment for high blood pressure, cigarette use, and dietary advice for lowering blood cholesterol levels, or to their usual care (UC) condition. Seven year follow-up showed that risk factor levels decreased in both groups, but to a greater extent in the SI condition. Mortality from CHD for the SI group was 17.9 deaths per 1000 compared to 19.3 deaths per 1000 in the UC group. Differences were not statistically significant. Total mortality for the SI group was 41.2 deaths per 1000 compared to 40.4 per 1000 in the US which was also not significantly different.

In 1991, the Pawtucket "Weigh-In" study, residents were encouraged to participate in a city-wide "weigh-in"³⁸⁸. This study was implemented by volunteers and residents were encouraged to set a weight loss goal (e.g., typically 10-20 lbs), and pledge a monetary incentive toward the goal (e.g., typically \$1.00 or 1 hour of volunteer work). The 10 week program consisted of 1) a self-help weight loss kit which included education material, tips, guides, and reading lists, 2) an overview of weight loss theory, 3) an educational movie, 4) an optional support group, and 5) monthly weigh-ins. Mean weight loss for the participants was 8.2 lbs, and large decreases in total serum cholesterol levels were observed (decrease of 29 mg/dL).

The Minnesota Heart Health Program was a ten year community trial of cardiovascular risk prevention across three communities with matched control communities for comparison³⁸⁹. Intervention communities received mass media campaigning, risk factor screening and education, environmental changes to encourage healthy behavior, and education of the young, adults, and

health professionals. The intervention communities demonstrated 2394 cases of CHD and 818 cases of stroke compared to 2526 case of CHD and 739 cases of stroke in the comparison communities. Differences were not statistically significant. However, a significant decline in CHD was revealed among the intervention communities for both men (1.8% decrease) and women (3.6% decrease), but not for stroke.

Environmental Approaches

Environmental factors believed to play a role in the development of obesity include those that increase energy intake, such as advertisements for and low price of high-energy density foods, marketing of larger portion sizes, and changes in the number of working women, leading to greater frequency of restaurant meals and the use of more fast-foods and convenience foods³⁹⁰. Numerous environmental factors also lead to decreased energy expenditure. Work is more likely to be sedentary than in the past, with near universal use of automated equipment and electronic communications. At home, wireless phones, remote controls, and various labor saving devices for household chores also decrease physical activity. Suburban communities often lack sidewalks, and lack of neighborhood resources make it difficult to walk even short distances to stores and recreation. Many individuals report difficulties going out to exercise because their neighborhoods are perceived as unsafe³⁹¹.

Prevention of obesity is frequently attempted through educational approaches aimed at improving knowledge and motivation, with consequent presumed impact on individual lifestyle choices yet this has been largely ineffective at preventing weight gain^{392, 393}. In contrast, environmental and policy approaches that attempt to modify the environment to promote healthful eating, increase physical activity, and decrease sedentary behaviors offer the potential for safe and effective programs for obesity prevention that could be widely disseminated.

Behavioral genetic studies have shown that variations in adiposity, is probably determined by an “obesogenic” environment that promotes sedentary lifestyles and unhealthy diets²⁷⁵. In recent years, there is a strong consensus that it is the environment (e.g., availability of foods in vending machines and fast food restaurants, technical advances that promote sedentary activity, watching television or playing video games) that determines considerable variance in food selections, food intake, and levels of physical activity^{81, 82}. Over the past few years, there have been several demonstrations of the potential power of environmental approaches for the prevention of obesity³⁹³.

Changes in food pricing have been proposed as an environmental approach to preventing obesity. Many individuals perceive that eating healthy is more expensive. Using public policy to reduce the cost nutrient dense foods while increasing the costs of calorically dense but nutrient poor foods has been proposed as possibly strategies⁷⁰.

At Risk Population Targets for Weight Management

Vulnerable periods for the development of future obesity include: prenatal periods, ages 5-7 years, adolescence, early adulthood, pregnancy and menopause.

Ethnicity/Racial Minorities

Barriers to Weight Loss in Indigent or Minority Populations

Obesity is a very significant problem in African Americans, and is especially common in African American women³²⁵. Flegal et al.³⁹⁴ reported that in the NHANES III survey, 62.5% of non-Hispanic African American adults were overweight or obese. The increased prevalence of obesity in adult African American women extends to African American children and adolescents³⁹⁵. Obesity is a very significant problem in African Americans, and is especially common in

African American women³⁹⁶. Furthermore, research has shown that African American men and women have greater difficulty losing weight in clinical trials for obesity³⁹⁷. African American women have a higher mortality rate from cardiovascular diseases and have a higher prevalence of diabetes and hypertension in comparison to women from most other racial and ethnic groups. African American women are known to have difficulty with weight loss³⁹⁸. It has been estimated that on average, African American women may lose between 2.5 kg-4.8 kg less than Caucasians^{397, 399}. Behavioral weight loss studies with African American populations have involved weekly weight loss sessions with weight losses ranging from 0.18 to 4.45 kg with 10-16 hours of patient contact^{353, 398, 400-403}. Kumanyika³⁹⁸ concluded that African Americans tend to lose less weight and lose at a slower rate. Participants in a previous physician directed program did not find the dietary information helpful or appetizing and noted childcare and transportation were barriers. Additionally, research has suggested that African American women are likely to be sedentary, have higher caloric intake, prefer foods that are sweet, high in fat, and fried and be more accepting or have preference for excessive weight⁴⁰⁴⁻⁴¹⁰. Studies have indicated that African American women are more likely to respond to recommendations for weight loss based on health improvements, instruction on meal patterns, and exercise^{407, 411}.

Low SES and minority individuals are at increased risk for obesity, because they lack many of the resources needed to pursue weight loss strategies. It has been noted that African American women are less likely than Caucasian women to comply with primary prevention behaviors such as exercise and healthy weight maintenance^{404, 405}. The cost of food associated with recommended healthy diets is often cited as a barrier for African Americans⁴¹². Additionally, cultural factors have been implicated in dietary preferences and acceptance or preference of excessive weight in African Americans^{221, 407, 408}. A 1995 Chicago survey commissioned by Dr. Koop for Shape Up America found that financial and neighborhood safety concerns were the most prominent barriers preventing minority and low income individuals from taking steps to achieve a healthy weight. Therefore, the primary documented barriers to weight loss for minority women include cost, dietary preferences, acceptance/preference of excessive weight, and safety.

Menopause:

Greater attention has been given to the impact that menopause has on weight gain and obesity in recent years⁴¹³. A recent survey of women in their early menopausal years, indicated that obesity increased 47% between 1991 and 1998⁴¹⁴. Additional studies have highlighted the relationship between menopause and obesity. The Health Women Study was a longitudinal study of cardiovascular risk in middle-aged women. The average weight gain for perimenopausal women was 2.25 kg, and 20% of the population gained over 4.5 kg⁴¹⁵. Other studies suggest that menopause is associated with weight gain regardless of age. One study showed that BMI was significantly higher among perimenopausal and menopausal women compared to premenopausal women after adjusting for age, diet, smoking, and physical activity habits⁴¹⁶. Another study comparing pre- and postmenopausal women of similar age found that postmenopausal women had 6% higher body weight and 17% higher body fat⁴¹⁷. The Study of Women's Health Across the Nation (SWAN study) surveyed approximately 13,000 women. BMI was significantly higher among those women who were perimenopausal and in women who had surgical menopause compared to premenopausal women. However, there was not a significant difference in BMI among women who had undergone "natural" menopause versus premenopausal women⁴¹⁸.

Health risks are associated with gained weight at menopause. Women who gain weight during menopause reportedly have significant increases in total cholesterol, LDL, and insulin⁴¹⁵. Changes in fat distribution have also been reported. Studies have conflicting results. One study

found higher waist-to-hip ratio in postmenopausal women compared to premenopausal women⁴¹⁹. However, other studies have reported that postmenopausal women did not have increased waist-to-hip ratio compared to premenopausal women after statistically adjusting for BMI and age^{416, 420}. Other studies suggest that there may be a shift in abdominal fat distribution. Specifically, increased upper body and trunk fat in postmenopausal women, and increased abdominal fat with menopause have been reported⁴²¹⁻⁴²³.

Most studies suggest that hormone replacement therapy (HRT) is associated with lower body weight despite most women thinking otherwise. The Postmenopausal Estrogen/Progestin Intervention Trial was a randomized, placebo-controlled clinical trial that examined the effects of HRT on body weight. Results found that women who were taking estrogen replacement had a significantly lower weight gain at the end of a three year period compared to women given placebo⁴²⁴. Similar findings in another study found that women who used HRT over a 15 year period had significantly lower BMIs compared to women who never used HRT⁴²⁵. Overall, the literature suggests that exogenous HRT impacts abdominal fat accumulation⁴¹³.

Overall, an increased risk of obesity tends to be associated with menopause. Additionally, a redistribution of abdominal fat appears to be associated with increased health risk⁴¹³. Changes in body composition may be related to decreases in endogenous estrogen given the positive impact that HRT has on body weight in menopausal women.

Medication

Drug induced weight gain can occur during the treatment of other medical conditions. While the weight gain is usually considered small there are patients who may be particularly vulnerable to the weight altering effects. Greenway⁴²⁶ noted that glucocorticoids are the most likely to produce weight gain and can unintentionally produce Cushing's syndrome. Several classes of psychotropic medications are associated weight gain including antipsychotics, antidepressants, mood stabilizers, and to a lesser degree anxiolytics⁴²⁷. Medications that block receptors for histamine H1, Serotonin 5-HT, and dopamine, could be associated with weight gain. Patients being treated for psychotic and depressive disorders may also be at risk for weight gain. Phenothiazines, Tricyclic antidepressants, Antiepileptic medications in particular place individuals being treated for mental health disorders are at risk for weight gain. Individuals being treated for obesity are also at risk for weight gain. Antidiabetic drugs such as insulin, sulfonylureas, thiazolidinediones are associated with weight gain.

Drugs Associated with Weight Gain:

Glucocorticoids

Megace

Cyproheptadine

Phenothiazines

Antipsychotics

Tricyclic Antidepressants (not protryptiline)

Antiepileptic Medications (not topiramate)

Beta-adrenergic blocking

Insulin

Drugs stimulating insulin release

Smoking Cessation

Froom et al.⁴²⁸ showed that post cessation weight gain consisted of an average of 5-6 kg. Smokers do have a lower average body weight than nonsmokers and a metabolic rate that is approximately 10% higher than that of nonsmokers⁴²⁹. However the literature suggests that the weight gained post cessation

would be equivalent to the amount of weight that the smokers would have gained had they never initiated smoking⁴³⁰.

Weight gain following smoking cessation has been shown to be greater in women than in men⁴³⁰. Women also express greater concern about post cessation weight gain than men⁴³¹⁻⁴³⁴. A reason that many young women begin and continue to smoke is to control appetite and reduce body weight⁴³⁵⁻⁴³⁸, and women are more likely than men to report using smoking as a weight control strategy⁴³⁹. Fear of weight gain has increasingly become a primary deterrent that prevents many women from quitting smoking and may be a major trigger for relapse⁴⁴⁰. Women get more weight-control benefits from smoking, suffer more postcessation weight gain, and are more concerned about postcessation weight gain than men^{441, 442}. Moreover, one of the primary withdrawal symptoms differentiating men and women is increased appetite in women^{416, 438}. Also, high dietary restraint occurs much more frequently in women than men^{443, 444}, and this may identify a subset of women who are particularly vulnerable to smoking to control appetite and weight⁴⁴⁴. Smoking is especially effective in suppressing food intake in these women⁴⁴⁵, and they are more likely than low-restraint women to increase their caloric intake and report weight gain postcessation^{394, 445-448}. Many studies have, however, suggested that the increase in total caloric intake observed postcessation is primarily due to selective increase in high-sugar and other high-carbohydrate foods that typically also have a high-fat content⁴⁴⁹⁻⁴⁵¹, and are most likely to be associated with weight gain⁴⁵². Furthermore, this effect has been reported to be significantly greater in women than in men^{453, 454}.

While there has been a vast amount of research in the area of smoking cessation, only a few studies have assessed weight concerns⁴⁵⁵ and even fewer empirically validated studies have attempted to formally combine weight control and smoking cessation programs^{438, 456}. Smoking cessation programs that included weight management components reported more recruiting success, indicating that these programs were highly desired by patients⁴³⁸. Recently, an intensive program aimed at limiting high fat foods and increasing physical activity was effective in attenuating weight gain after smoking cessation⁴⁴⁰.

Nicotine replacement therapy has been found to prevent weight gain post cessation due to its effects of increasing metabolism and/or ability to lessen withdrawal symptoms such as increased hunger^{432, 434}. The literature suggests that a successful smoking cessation/weight maintenance treatment would include using nicotine replacement therapy until abstinence is controlled, then address weight issues as the nicotine dosage is tapered^{434, 457}. Research also suggests that cognitive behavioral treatments might improve smoking cessation outcomes for female smokers who express weight concern^{433, 458}. Using cognitive-behavioral techniques to reinforce the fact that weight gain does not negate the positive effects of smoking cessation could function to “normalize” post cessation weight gain⁴³⁰. It is likely that future efforts in regard to weight control should focus on the cognitions regarding the perceived significance of weight gain associated with weight gain rather than only basic skills acquisition to control^{459, 460}.

Researchers have noted that both smoking cessation interventions and weight loss interventions that are individualized often have a higher success rates than generalized interventions^{461, 462}. Kreuter et al.⁴⁶² suggests that tailoring is most effective when it is customized specifically to the needs and concerns of the individual and excludes any information about issues that the individual has not identified as a concern. Pinto et al.⁴⁶³ suggests using tailored interventions specifically for weight concerned female smokers.

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

Costs of Treating Obesity

While the association between obesity and health care costs has been well established there is limited data regarding the economic benefits of treating obesity. Models have been developed

to attempt to address the potential cost offset that could be associated with weight loss. Oster and colleagues⁴⁶⁴ estimated that a 10% weight loss could be associated with decrease of 1-3 years with comorbid illnesses (e.g., hypertension, diabetes), an increase of up to 7 months of life expectancy and would decrease lifetime medical costs by 2,000-5,000 per person. While this appears insignificant, Wolf et al.⁴⁶⁵ noted that cost savings in treating chronic illness is uncommon since life saving interventions are often costly.

Examining the reduction in comorbid medication use following weight loss is a common way to evaluate cost effectiveness. Collins and Anderson⁴⁶⁶ found that a 12 week weight program for diabetics resulted in 75% of the patients were able to discontinue insulin and the other were able to decrease their dose by >70%. At one year the cost of insulin had dropped >90% and resulted in a \$443 annual savings per patient. In a study of a variety of chronic health conditions, Greenway et al.,²²² found that weight losses of 6-10% resulted in a cost savings on medication of \$123 per month for insulin users, \$43 per month for sulfonylurea users, \$61 per month for individual treated for hyperlipidemia and \$0.20 per month for individuals treated with hypertensive agents. Similar findings with sulfonylurea use was also noted with a trial of Orlistat¹⁸². In a group of morbidly obese individuals, Malone and colleagues⁴⁶⁷ found that patients daily medication cost was \$391 daily prior to surgery and was reduced to \$230 by 3 months with continuing reductions of cost of >50% through 12 months. However, there is some indication that these short-term findings may need to be viewed with caution since more recent data have suggested that a 10% weight loss for 6 years post-surgery is necessary for reduction in medication for diabetes and hypertension. The initial findings from the extensive SOS study however, does not appear to find clear cut savings in medication use post surgery compared to conventional treatments. Additionally, it appears that the increased cost of hospital care associated with surgical patients complications and secondary plastic surgery may be as much as \$1200 annually for the 6 years following surgery²⁷¹. In comparison of surgery and VLCD combined with behavior therapy, surgery was found to be cost effective but the post surgery costs associated with complications and secondary surgery were not included^{271, 468}.

Prevalence data has been used to estimate cost effectiveness of obesity treatment. Some authors have criticized the use of this methodology (e.g., Agren et al.²⁷²). Allison and colleagues⁴⁶⁹ found that the lifetime health care costs in the US could be reduced by up to 4.3% by curing obesity. However, the costs associated with the treatments utilized to treat obesity were not included in this estimate.

<u>Treatment</u>	<u>Effectiveness</u>	<u>Annual Cost Estimates</u>
<u>Commercial</u>		
Weight Watchers	6% at 6 months	\$12/week \$624/year
<u>Behavioral Programs</u>	8-10% at 6 months	\$800/year group \$1700/year individual
<u>Meal Replacement</u> (Slimfast)	8% at 3 months	\$12/week \$624/year
<u>Medically Supervised Liquid Diet</u>	15-25% at 4 months	\$3,000/6 months \$6,000/year
<u>Pharmacotherapy</u>		
Sibutramine/Orlistat	7-10% at 6 months	\$1100-\$1350/year

<u>Combined Behavior/Medication</u>	16% at 6 months	\$1900 – \$3000/year
<u>Gastric Surgery</u>	25-30% at 6 –12 months	\$ 25,000 surgery +\$1,200/ yr for next 6 yrs

Based on Data by Wolf et al. ⁴⁶⁵, Agren ²⁷², NHLBI 2000⁵⁰, Wadden & Osei, 2002⁷⁴

Results of Weight Management on Comorbid Conditions

Obesity is related to a variety of medical conditions including cardiovascular disease, diabetes, cancer, osteoarthritis, sleep apnea, and premature death. Weight loss is associated with short-term improvements in glucose tolerance, hyperlipidemia, and high blood pressure ⁴⁷⁰. Diabetics who lose 5-10% of their body weight may have decreases of glycosylated hemoglobin of 1-2.5% (e.g., ⁴⁷¹). Weight loss may also improve symptoms of sleep apnea, osteoarthritis mobility, and pulmonary functioning ⁴⁷². While weight losses of 5-10% are usually associated with health benefits, maintaining modest losses of <5% have been associated with a variety of health benefits in the areas of cardiovascular disease and diabetes, both leading causes of death in the U.S.

Blood Pressure

While weight losses of 5-10% are usually associated with health benefits, even weight losses between 2-4% have been associated with 20% -30% decrease in HTN⁴⁷³⁻⁴⁷⁵. In a review of the literature, Gregg and Williamson ⁴⁷⁶ noted that weight losses of 4-8% were associated with decreases in blood pressure of 3-8 mm HG at six to 12 months. The NHLBI found 45 (35 lifestyle and 10 medication) of 76 articles acceptable to evaluate the effect of weight loss on blood pressure and hypertension. They found strong and consistent evidence that weight loss producing lifestyle trials in both overweight hypertensive and nonhypertensive patients reduces blood pressure levels. There is considerable evidence that increased aerobic activity to increase cardiorespiratory fitness reduces blood pressure (independent of weight loss). There is also suggestive evidence from randomized trials that weight loss produced by most weight loss medications, except for sibutramine, in combination with adjuvant lifestyle modifications will be accompanied by reductions in blood pressure.

Lipids

Reductions of 5-10% in total and LDL cholesterol have been noted with weight loss that is associated with changes in fat intake and physical activity ⁴⁷⁶. The NHLBI found 22 (14 lifestyle and 8 medication) of sixty-five RCT articles appropriate to determine the effect of weight loss on serum/plasma concentrations of total cholesterol, LDL-cholesterol, very low-density lipoprotein (VLDL)-cholesterol, triglycerides, and HDL-cholesterol. They found strong evidence from the 14 lifestyle trials that weight loss is accompanied by reductions in serum triglycerides and by increases in HDL-cholesterol. Weight loss generally produces some reductions in serum total cholesterol and LDL-cholesterol. There is strong evidence that increased aerobic activity to increase cardiorespiratory fitness favorably affects blood lipids, particularly if accompanied by weight loss. There is suggestive evidence from the eight randomized pharmacotherapy trials that weight loss produced by weight loss medications and adjuvant lifestyle modifications, including caloric restriction and physical activity, does not result in consistent effects on blood lipids.

Blood Glucose

Diabetics who lose 5-10% of their body weight may have decreases of glycosylated hemoglobin of 1-2.5%⁴⁷¹. However, weight loss between 2-4% have been associated 30%-50% decrease in diabetes incidence^{315, 477}.

The NHLBI found 17 (9 lifestyle and 8 medication) of 49 RCT appropriate to evaluate the effect of weight loss on fasting blood glucose and fasting insulin levels. They found strong evidence that lifestyle therapy trials that weight loss produced reduces blood glucose levels in overweight and obese persons without diabetes, and weight loss reduces blood glucose levels and HbA1c in some patients with Type 2 diabetes. There is suggestive evidence that decreases in abdominal fat will improve glucose tolerance in overweight individuals with impaired glucose tolerance, and there is limited evidence that increased cardiorespiratory fitness improves glucose tolerance in overweight individuals with impaired glucose tolerance or diabetes, although not independent of weight loss. In addition, there is suggestive evidence from randomized trials that weight loss induced by weight loss medications does not appear to improve blood glucose levels any better than weight loss through lifestyle therapy in overweight persons both with and without type 2 diabetes.

Based upon the findings of health improvements associated with weight loss the NHLBI has recommended weight loss as a treatment for the following medical conditions:

- to lower elevated blood pressure in overweight and obese persons with high blood pressure.
- to lower elevated levels of total cholesterol, LDL-cholesterol, and triglycerides, and to raise low levels of HDL-cholesterol in overweight and obese persons with dyslipidemia.
- to lower elevated blood glucose levels in overweight and obese persons with type 2 diabetes.

Potential Risks of Weight Loss

The risk of gallstone formation has been found to increase with weight losses in excess of 1.5 kg per week⁴⁷⁸. Weight loss medications have been associated with cardiac problems including valvulopathy and pulmonary hypertension⁴⁷⁹. Long-term use of VLCD have also been associated with cardiac arrest, arrhythmias, electrolyte imbalance and protein deficiency⁴⁷². There is also evidence to suggest that lean muscle mass and bones may be adversely affected in some individuals⁴⁸⁰. Lifestyle modification has few if any risks.

New Innovations

Internet

Consumer Searches

The Internet provides the public with access to a wide variety of health information resources. The Web has become an international common ground not only for researchers wanting to share information and data, but for health professionals, corporations, and information specialists to display and promote their services, opinions and products⁴⁸¹. Recent estimates suggest that approximately 63.2 million Americans use Internet health resources^{482, 483}.

While the Web is one of the most highly utilized resources of the 21st century, its information may be beneficial or harmful since the information is disorganized and unregulated^{484, 485}. This lack of standardization has resulted in fraudulent health care claims and practices which have been difficult to legislate due to the international nature of the Internet. Results from the Pew Internet Health survey indicate that eighty-six percent of Internet health seekers are concerned about getting health information from an unreliable source, yet only fifty-eight percent report checking

the source of the information they obtain⁴⁸⁶. Interestingly, approximately thirty percent of individuals report trusting information on websites selling products, while thirty three percent do not trust this information⁴⁸⁷.

Weight management is an area that is a prime target for fraudulent claims and services. In 2000 it was estimated that 70 million Americans were trying to lose weight and spent approximately \$35 billion on products to assist in their efforts⁴⁸⁸. It has long been noted that individuals desperate to lose weight may fall victim to unrealistic programs. Additionally, most individuals seeking weight loss tend to rely on non-medical sources. The Federal Trade Commission estimated that as many as 55% of weight loss advertising made at least one claim that was suspect and lacked substantiation⁴⁸⁸. Additionally, the quality of dietary information on the Internet has been assessed with findings suggesting that 30%-60% of the information was inconsistent with the standard nutrition recommendations⁴⁸⁹. The most inconsistent results were noted for the private vendors (57%) rather than the health organizations (1%). To date, only one study has systematically studied the content of the Internet in regard to weight loss searches. Miles and colleagues⁴⁹⁰ reviewed the top 50 websites related to "weight loss diets". They noted that only 3 of the 50 sites reviewed provided sound dietary advice and most of the sites reviewed promoted dietary supplements. Additionally, in December 2000, a "surf day" was initiated as a part of the Federal Trade Commission's evaluation of weight loss advertising. They used students to collect data from various search engines and keyword searches. The FTC then randomly evaluated 44 of the identified sites but a break down of the quality of these sites was not included in the report.

A recently completed study at Pennington Biomedical Research Center found that there is a vast amount of health information specific to weight management available through the Internet³⁴⁰. The two most significant problems with use of the Internet to access weight management information is the lack of regulation of websites and the intensely commercial nature of the Web. These weaknesses combine to make suspect or fraudulent information easily accessible, especially in regard to such a widely sought quick fix for weight loss. The results indicate that the use of the standard search engines is acceptable, but as expected, these searches did identify a significant number of commercial sites produced by terms that would be associated with typical weight loss searches (e.g., "weight loss"). This highlights the need for effective search strategies. It was found that when using the standard search engines, use of clinical or academic terms such as "weight management", were more likely to yield noncommercial sites. Use of "filtering sites" or "portals" specifically designed for health information may also assist in identifying the most credible noncommercial sites. Filtering processes such as "upstream" filtering may be useful since it provides independent panel review⁴⁹⁰. For example, Medline Plus, maintained by the National Library of Medicine, regularly evaluates websites on hundreds of medical conditions. The use of health-related filtering sites may assist individuals in finding focused information, and the use of typical terms such as "weight loss", which is a mesh heading, will yield reliable and credible information. Use of government sponsored, nonprofit organizations, and sites maintained by universities with specific areas of expertise are also very helpful. Their missions are usually consistent with providing the most up-to-date and research based information. Additionally, since these types of sites are usually supported by government or state tax dollars, they are not likely to have the same product sales agenda as for-profit organizations.

In an attempt to provide some quality control or information regulation, there are increasing attempts to set up "seals of approval" for web sites. For example, the Health on the Net Foundation (HON) has set up a monitoring system for web sites. A website may display the HON icon if it has met and maintains the HON standards in the areas of authority, confidentiality, and

honesty in advertising etc. However, given the plethora of sites and continued rapid expansion of marketing on the Internet, it will take some time before reliance on these types of approvals are a stand-alone means of determining credibility.

Results obtained using only one search strategy must be viewed cautiously due to the “invisible web”⁴⁹¹. This means that some information may not be accessed when using more focused or less comprehensive search engines. The differing number of sites yielded with the various search engines and the terms used found in the results confirms this recommendation. Therefore, as demonstrated in this document, the best strategy may be to use a combination of general and focused search terms and search engines to yield both comprehensive and credible information.

Professional Use:

The internet provides unique opportunities for the delivery of health services. The internet allows the opportunity to provide services in a cost effective fashion. Further, the nature of the communication allows individuals to receive services in their homes. Being able to log on at any time and work at their own pace, could allow more regular contact with health care professionals, and could facilitate the completion of assignments necessary to learn lifestyle management. Most importantly, individuals who are unable to meet personally with counselors due to geographic or physical constraints would be able to use their computer to gain this information. A few studies have tested computerized treatment programs for obesity⁴⁹². These studies found that the computerized treatments were effective in producing small weigh losses.

Public Health Approaches:

Public Health approaches to obesity focus on environmental factors. According to a review of the literature by Jeffery⁴⁹³ these interventions have focused on primarily mass distribution on individual change information. The author concluded that while public health approaches have been somewhat successful with other health problems have yet to be applied to obesity. The World Health Organization has indicated that obesity is a global epidemic that is a greatly neglected public health problem that may have an impact comparable to smoking. Although genetic factors contribute to obesity, lifestyle factors such as unhealthy dietary habits and physical inactivity are responsible for the rapid increase and are amenable to public health measures. It appears that individual motivation are insufficient to manage body weight and public health measures are needed to moderate the environmental pressures that are contributing to positive energy balance.

Eating Out: It is estimated that many American spend up to 50% of their food money on meals prepared outside the home. The frequency of eating out has been associated with intake of excessive calories and fat since these meals are often double size portions, high fat, energy dense and easily accessible. It is estimated that 45% of daily intake of food is classified as energy dense but nutrient poor⁴⁹⁴.

Food Advertising: It is estimated that McDonalds spends a billion dollars annually while the health promoting “5 a day” budget is a million dollars⁴⁶.

Physical Inactivity: Time saving devices and technological advances have resulted in decreased energy expenditure. The increased use of computers, motorized transportation, elevators, and leisure time organized around television and video games continue to contribute to the rise in

obesity. Environmental factors contributing to this trend are school districts that have reduced or eliminated physical education or sports programs and neighborhoods which individuals perceive as unsafe or where access to stores or recreational facilities require automobiles.

Public Policy:

The government must play a role if the obesity epidemic is to be properly addressed. In a review of the literature on public policy, Brownell ⁴⁹⁵ concluded that “intervention with public policy offer the most immediate and perhaps most powerful means to have an impact”. The following areas for public policy recommendations were suggested: 1) Enhance opportunities for physical activity 2) regulate food advertising aimed at children, 3) prohibit fast foods and soft drinks from schools, 4) restructure school lunch programs, 5) subsidize sale of health foods, 6) tax foods with poor nutritional value.

Summary Of Obesity Treatments

Over the past thirty years, many studies of pharmacological, surgical, behavioral, dietary, and exercise interventions for obesity in adults have been conducted ⁷⁴. Approaches that combine behavioral, dietary, and exercise components have become recognized as “lifestyle behavior modification for obesity”. This approach is regarded as a standard component of more complex interventions that include anti-obesity medications ⁴⁹⁶, surgery ⁴⁹⁷ and low calorie diets or meal replacements ⁴⁶. This lifestyle behavior modification approach has been successful for weight loss induction, but has been plagued with a failure to yield long-term weight loss as have most other weight loss treatments. The phenomenon of regaining weight is not unique to lifestyle modification approaches. Instead, it is a significant problem for most anti-obesity interventions, with the exception of surgery, which is reserved for the most severe cases of obesity ⁴⁹⁷. In summary, most treatment approaches for obesity in adults have yielded only short-term weight losses for most people. When long-term changes in weight are accomplished, the intervention often requires intensive and costly long-term care ^{498, 499}. An alternative to tertiary treatment of this intractable condition is needed from the public health perspective ²⁷.

Summary of Scientific Literature Recommendations

Recommendations for Improving the Management and Prevention of Obesity¹⁴¹

Recommendations for matching treatment approaches to patients based on the severity of obesity and response to previous weight loss attempts.

Managing Obesity

1. *Comprehensive Assessment:* A comprehensive assessment on the impact of obesity on the patient’s physical and emotional health is needed. An evaluation should include calculating the BMI and waist circumference (WC), an evaluation of the impact of obesity on current and future health. Patients should receive a complete physical examination with careful consideration of risk for diabetes, hypertension, and dyslipidemia. Behavioral risk factors such as sedentary lifestyle, high fat diet, and possible binge eating should be assessed. Patient’s quality of life should be discussed including level of social adjustment, satisfaction with body image, and presence of mood/anxiety disorders and other psychopathology. Behavioral and psychological targets for intervention should be identified and addressed along with the weight loss goals.

2. *Discuss Treatment Expectations:* The majority of patients have unrealistic expectations about the amount of weight that they can lose. Faulty expectations can result in dismissing or diminishing the positive impact that modest weight loss (i.e., 5-10%) can have on overall health and well-being. Identifying and treating these unrealistic expectations can improve the patient's satisfaction with modest weight loss, and improve maintenance efforts. Patient education on social pressures for the "ideal body" should be addressed, along with separating body weight ideals and self-esteem.

3. *Focus on Behavior Change:* Treatment goals should be controllable behaviors of the individual (i.e., quantity and quality of food, amount of physical activity, portions). Modest weight loss, maintenance of stable weight, and prevention of weight gain should be emphasized as legitimate treatment goals.

4. *Include multiple indicators of "success":* Success should not solely be measured based on the amount of weight lost. Positive improvements in disease risk factors and quality of life should be emphasized as success. Beneficial changes in diet quality and physical activity levels, and self-acceptance should be independent successes regardless of whether weight loss occurs.

5. *Adopt a lifelong perspective:* Obesity should be reviewed as a chronic condition, which requires lifelong care. Successful management of weight requires constant vigilance and effort at managing eating and exercise patterns. Providers must communicate to the patient the chronicity of the problem while remaining empathetic and optimistic.

Prevention of Obesity

1. *Develop a national plan to prevent/treat obesity:* The obesity epidemic requires serious attention from policymakers and the general public. Plans should include identifying and implementing educational, behavioral, and environmental approaches to control, manage, and prevent obesity. A national plan would require efforts of both the public and private sectors including agricultural and food industry leaders, researchers, educators, physicians, public health officials, and politicians.

2. *Intervene in schools:* Interventions in school environments have demonstrated improvements in both diet and exercise. Physical activity programs should emphasize enjoyable regular exercise for all students. Schools should promote healthy eating behaviors by providing health food choices, and low-cost nutritional vending machines. Furthermore, schools should prohibit the establishment of fast-food chains in the schools, and consider reducing the number of high caloric soda machines available. The goal is to increase the number of healthy choices while simultaneously decreasing less desirable food and beverage options. School-based interventions should have multiple components including parental involvement, changes in school food programs, support from the food industry, and behavioral curriculum.

3. *Regulate advertising of junk foods:* Companies spend over \$400 billion a year to advertise their food, beverage, and candy products, and the average child views more than 9,500 television

commercials for these products annually. Conversely, little money or time is spent advertising healthy dietary practices. More stringent regulation of the number and frequency of unhealthy food advertising should be considered particularly during children's television shows.

4. *Impose a "fat tax"*: This is a controversial approach is aimed at modifying the environmental factors that promote weight gain. The premise is to tax unhealthy foods, and use these tax funds to create public health initiatives that promote healthy eating and physical activity patterns. Heavy taxation is unlikely to gain popular acceptance, therefore, others have suggested modest taxes (i.e., one cent per 12 oz soda, etc.) that could go toward subsidizing healthier food choices. Recent studies have demonstrated that consumption of healthier foods can be increase with such a tax⁵⁰⁰, and that 45% of adults would support such a tax if funds were used to benefit health education programs⁵⁰¹.

What Can Be Done? :⁴⁶

Public Health Messages focused on balanced energy intake and expenditure. Governmental policies can offer methods to change the environmental factors that encourage or promote increase dietary intake and limit energy expenditure. Policies need to be developed to make schools, worksites, medical centers more health promoting environments. Regulations could also be enacted on education, mass media, food labeling, advertising, food assistance, health care and training, transportation and urban development.

Consumers: education:

- 1) BMI and health implication
- 2) How to obtain energy balance
- 3) How to read food labels and make health choices when purchasing foods for the home or in restaurants
- 4) Educate about ways to and benefits of increased physical activity
- 5) Educate about association of childhood obesity and hours of television viewing
- 6) Develop educational materials that target specific groups based on risk (e.g., gender, ethnicity, age, comorbid conditions, level of obesity)

Medical Community

Education for multidisciplinary providers How to assess weight and health risks

- 1) Provide CEs related to obesity treatment in mass and in office practices
- 2) Education for providers What treatment recommendations to make
- 3) Education for providers How to use effective treatments in office and where to make referrals
- 4) Provide patient educational handouts
- 5) Consider provision of samples of healthy products to patients related to behavioral change rather than focus on only pharmacology samples
- 6) Provide payment for treatment of the chronic medical condition of obesity
- 7) Provide incentives for provides who provide obesity treatment

Media

- 1) Education on providing scientifically sound information to public
- 2) Involve media in promoting energy balance, through healthy eating and activity

- 3) Provide messages about healthy body image and realistic weight goals

Food Industry

- 1) Increasing the availability, of healthy products that are convenient, palatable, affordable, adequately labeled and “normal” portion sizes.
- 2) Restaurants provide nutrition information for consumers
- 3) Participate in educational campaigns on their advertising

Vending

- 1) Make healthy choices available and less costly
- 2) Make choices with poorer nutrition more costly

City

- 1) Increasing access to areas that promote physical activity
 - a. Walking, biking, parks, gyms, pools, skating rinks,
- 2) Promote and organize more clubs and organization activity programs
- 3) Community planning that fosters ability to use walking for errands rather than automobiles.

Worksite

- 1) Provide wellness programs that target weight
- 2) Provide healthy food options in the work environment limit unhealthy vending
- 3) Provide opportunity for physical activity at the work site
- 4) Provide reading materials that would give ideas on how to incorporate healthy lifestyle principals at their worksite

State Government

- 1) Statewide advertising campaigns to increase awareness of health hazards of excess weight
- 2) Healthy Diet Promoting and Physical activity promoting policies in public places
- 3) Taxes on unhealthy food items or sedentary leisure equipment
- 5) Provide culturally sensitive education materials to providers to use in social service agencies. Educational materials must also be developed for age, gender, socioeconomic groups
- 6) Encourage state associations with multidisciplinary medical professionals to require education on weight management (e.g., nutrition, physical activity)
- 7) Encourage food industry to use marketing to promote more nutritious less energy dense foods
- 8) Expand the public health department collaboration with schools, service providers, and employers in development and implementation of public education programs
- 9) Promote community environments that encourage physical activity and healthy food choices
- 10) Incentives for food stamp recipients to purchase more nutritious and less energy dense foods
- 11) Remove taxes or provide incentives on purchase of exercise equipment
- 12) Develop state campaign to reduce television viewing
- 13) Develop state mass media campaign
- 14) Regulate advertising to increase health promotion of nutritious foods.

- 15) Taxing unhealthy products and use money to fund healthy initiatives, public exercise trails, education programs, healthy food subsidies

Louisiana Programs

Louisiana Obesity Council:

The Louisiana Council on Obesity Prevention and Management (Council) is a legislated mandated Council to address obesity in the state of Louisiana.

Purpose/Goal The severity of the obesity in Louisiana was recognized in 1998 when the Louisiana Legislature created the Council. The Council was mandated and the Department of Health and Hospitals was charged with studying the issues relative to obesity in Louisiana, collecting data on the subject, and developing recommendations for improving society's awareness regarding the health risks associated with obesity and suggesting modalities for treatment. Its diverse and committed membership includes professionals in the fields of health and education, including staff from the Louisiana Department of Health and Hospitals, the Louisiana Department of Council presented to the Louisiana Legislature recommendations for the future role of the Obesity Council as well as a plan to address this critical problem in Louisiana. However, the Obesity Council was created by law without the necessary provisions for staffing or funding to support activities. The Department of Health and Hospitals Office of Public Health in 2001 made a commitment to address the problem of obesity by supporting the Obesity Council and hiring a coordinator with Preventative Block Grant funding.

What services are provided?

Articulating standards of obesity prevention and management through the dissemination of material, identification of expert opinion, identification of alternate means of developing effective population-based programs, and development of policy in identified health risk.

Awareness of health risks due to overweight and obesity conditions among payers, providers, and patients.

Enhance reporting mechanisms of outcomes and health trends in the area of overweight and obesity concerns.

Conducting evaluations of program effectiveness.

The encouragement of research and the identification of resources which seek ways to promote cost-effectiveness methods of treating overweight and obesity concerns.

The policy direction on obesity issues is integrated with Healthy People 2010.

Advising and assisting participating agencies with the development and implementation of obesity programs.

Who are the recipients of these services?

All the citizens of Louisiana who are at risk of overweight or obesity and their friends and families.

Funding is through the Federal Preventative Block Grant program only. No state funding has been appropriated for the Council.

Program Accomplishments

The Council is developing a website to disseminate information on obesity to health insurance companies and other third party payers, employers, health care providers, government agencies, and the general public. The website will also provide links to other agencies and organizations who are combating obesity and the health problems resulting from obesity.

The Council presented a full report to the legislature on the problem of obesity in the state and a plan to address this issue in 2001. A report on the progress on this plan was given to the Governor and the Health and Welfare Committees of the House and Senate in 2003.

The Council in coordination with the Environment and Health Council of Louisiana has presented two Conferences on Obesity. The first conference in 2002 was targeted at the general public. The second conference in 2003 was targeted at those who have an influence on childhood obesity: teachers, school and health officials, food service personnel, and parents. Many press stories on childhood obesity resulted from these conferences.

The Council, the Environment and Health Council, Pennington Biomedical Research Center, and the Louisiana Department of Labor is planning a Wellness Conference in April 2004 which will feature Louisiana Worksite Wellness Programs, who will demonstrate to other organizations how to implement programs to address obesity and other health issues in the workplace.

The Council conducted a survey of school principals in conjunction with the Department of Education to determine what practices and policies in nutrition and physical activity are presently implemented in Louisiana public schools. An evaluation of these policies and practices will be used to determine what changes in the school environment will assist in decreasing childhood obesity.

The Council assisted in writing and supported the passage of legislation to require a minimum of 30 minutes of physical activity daily in grades kindergarten through 6 in Louisiana schools.

The Council integrated the policy direction of the Council with the goals of Healthy People 2010. The Council coordinator is a member of the Healthy People 2010 Committee.

The Council has participated in applying for Center for Disease Control and Prevention grants for obesity, nutrition, and physical activity through the Louisiana Office of Public Health.

The Council is publishing a supplement on obesity to the Louisiana Medical Society Journal. The editors are Dr. John Udall, Chairman of the Council, Dr. Bouchard, Director of the Pennington Biomedical Research Center, and C. Virginia Moore, RN, FNP, Coordinator of the Council.

The Council has advised Louisiana agencies with the development and implementation of obesity programs. These agencies include: the Adolescent School Health School Based Health Center Initiative, the Medicaid Insurance Program, the LSU Ag Center Extension Offices, the Louisiana Department of Education, the Louisiana Office of Public Health Chronic Disease Programs of Cardiovascular Disease and Diabetes, the Environment and Health Council of Louisiana, the Action for Healthy Kids State Team, and others.

Recommendations of Louisiana Obesity Council 1999 report

The following summaries relevant to recommendations for methods to treat or manage obesity in Louisiana are from the 1999 report of findings on House Concurrent Resolution #11, Louisiana Legislature, 1998.

George A. Bray, M.D., Pennington Biomedical Research Center Recommendations for a Statewide Approach, February 5, 1999

Prevention efforts should address environmental and societal influences, and must be targeted to populations under the age of twenty. Management strategies should be aimed at populations over the age of twenty. Prevention efforts targeted at those high-risk families should include educational, dietary, and physical activity components.

The three levels of obesity prevention measures include: universal prevention, directed at everyone in a community; selective prevention, aimed at high-risk individuals and groups; and targeted prevention, directed at those with existing weight problems. Obesity management encompasses strategies directed at four areas: the prevention of weight gain; weight maintenance; the management of obesity-related health complications; and weight loss. Both prevention and management efforts should include consumer education and public awareness elements, for example the institution of a public education campaign to “Know Your BMI”.

BMI can be used as a useful guide for risk of obesity-related health complications. For example, the plotting of BMI distribution curves over time can give useful information on weight change in specific populations, and BMI and risk factors can be adjusted for age or ethnic variables. These types of plots have identified, for example, that BMIs have increased significantly in the upper ranges for child populations, but have remained unchanged in the lower ranges. This information indicates that prevention and management strategies for both adults and children need to target populations in the upper BMI ranges.

Therapeutic strategies for the treatment of obesity should be based on level of overweight (preoverweight at risk, preclinical overweight, or clinical overweight) and age of patient. Strategies for children aged 1-10 include: family counseling and programs to reduce inactivity (preoverweight at risk); family behavioral therapy, exercise programs and low-fat, low energy-dense diets (preclinical overweight); and treatment of comorbidities, exercise programs and low-fat, low energy-dense diets (clinical overweight). Inclusion of children and their parents in behavioral therapy for overweight and obesity has been more successful over the long-term than behavioral therapy for the child alone.

Strategies for patients aged 11-50 include: programs to reduce sedentary lifestyle, low-fat, low energy-dense diets and portion control (preoverweight at risk); behavior therapy, programs to reduce sedentary lifestyle and low-fat, low energy-dense diets (preclinical overweight); and treatment of comorbidities, programs to reduce sedentary lifestyle, low-fat, low energy-dense diets, drug treatment, behavior therapy and surgery (clinical overweight).

Strategies for patients over age 51 include: behavior therapy, programs to reduce sedentary lifestyle and low-fat, low energy-dense diets (preclinical overweight); and treatment of comorbidities, programs to reduce sedentary lifestyle, low-fat, low energy-dense diets, drug treatment, behavior therapy and surgery (clinical overweight).

Basic principles for effective weight management should include the following components: recruitment and referral, comprehensive health assessment, goal-setting, selection and implementation of an appropriate management scheme and monitoring and evaluation.

Management of obesity programs can be broken down by targeted population:

<u>Target:</u>	<u>Strategy:</u>
Children	Prevention: more activity, lower fat Management: identify rapid weight gain, family behavioral therapy
Adults	Selected and targeted prevention Management based on risk assessment Education of healthcare providers
Schools	Increased activity; reduce sedentary time; teach good nutrition
Private Sector	Increase access to stairs; improve exercise facilities
University	Provide good nutrition in dining halls and opportunities to exercise

Recommendations for a Statewide Approach in the Prevention of Obesity:

1. Public education campaign to “Know Your BMI”
2. Health care education campaign to increase provider awareness and competence
3. Policy initiative to target USDA commodity programs
4. Commitment to obesity research to identify strategies to prevent childhood and adult obesity; target WIC clinics

William Dietz, M.D., Ph.D., Centers for Disease Control Obesity – National Perspective, January 15, 1999

Food consumed outside the home now accounts for 35% of the American family’s food expenditures, and 12,000 new food products are introduced to the U.S. marketplace annually. In addition, the U.S. population is very inactive, with 30% of the population getting no regular physical activity, and another 30% getting only intermittent physical activity. Research on this trend concludes that there is a direct relationship between television viewing and the prevalence of obesity in children, an effect which is accounted for by both the increase in sedentary activity and the change in child eating habits while they are sedentary. Reductions in sedentary activity therefore appear to be the most effective short and long-term interventions on the reduction of childhood obesity.

One study has suggested that childhood onset obesity may be associated with more severe adult obesity and a significant increase in morbidity, and it is well documented that adolescent obesity is significantly associated with an increase in adult morbidity.

There have traditionally been four sites for obesity intervention: medical settings, school, work sites, and community-based interventions. Three current problems with medical site interventions include: a lack of physician knowledge about obesity and nutrition, the lack of training and time constraints physicians have in counseling patients on behavioral change

strategies, and the lack of reimbursement for the provision of both obesity prevention and obesity management services.

One under-utilized intervention site is work-based programs. Fifty to sixty percent of a corporation's pre-tax profits are spent on employee medical plans, and obesity and obesity-related diseases have produced a concomitant increase in medical utilization rates, physician utilization rates, laboratory usage and pharmaceutical usage. As a result, the interests of both managed care and corporate businesses would be served by the implementation effective work-site interventions. The promotion of physical activity programs can be implemented in both schools and work sites; increased physical activity, or decreased sedentary behaviors, positively impact obesity and obesity-related diseases, as well as improve overall health.

Successful school-based programs have thus far focused on decreasing child sedentary behaviors, but a more comprehensive approach could also include a dietary component, such as targeting school lunches and outside vendors. An additional target for schools would be P.E. classes, which have reduced daily physical activity from 35% to 25% over the past 10 years, and reduced actual minutes spent engaged in physical activity to less than 25% of class time.

Environmental change models are the prevailing community-based disease interventions, and two of the most successful nutrition interventions have been the iodine enrichment of salt to reduce thyroid disease and fluoridated water to reduce dental disease. Targets for community-based interventions can include the reduction of sedentary behavior; however, obstacles to reducing sedentary behavior must be addressed, such as community-structure variables (i.e. - as the availability of safe sidewalks, parks and bike trails).

Overall, it must be emphasized that reducing obesity and obesity-related illnesses requires a long-term environmental approach, and making and sustaining lifestyle changes must focus on broad cultural issues rather than targeting only the narrower medical or school-based strategies.

Kate Galatas, M.P.H., Office of Public Health: Social Marketing, November 20, 1998

Social marketing is a strategy for changing behavior that combines the best elements of the traditional approaches to social change in an integrated planning and action framework, and utilizes the advances in communication technology and marketing skills. Social marketing strategies need to be comprehensive, to target audience orientation, be based on market research, be adequately evaluated and grounded in theories of behavior change. Comprehensive social marketing plans need to include components of price, product, place and promotion, and utilize multiple channels of reaching the target audience. Utilizing the mass media can be very expensive, and should be part of an on-going investment in a larger community focused program.

An example of a social marketing program is Project: LEAN, a national campaign sponsored by the Henry Kaiser Foundation to reduce dietary fat consumption to 30% of calories, by using public service announcements, publicity and point-of-purchase campaigns. Project: LEAN was not considered a successful social marketing campaign for several reasons, including lack of use of formative research, expensive production costs, failure to buy placement time and a discontinuation of the public service announcements after one year. However, successful components of the Project: LEAN campaign included a dense publicity effort, an extensively cultivated network of community partnerships, creative use of messengers and good fundraising

and collaboration with the private sector. It is estimated that a good social marketing campaign directed at preventing and treating obesity in Louisiana will cost approximately \$2 million.

Rebecca A. Meriwether, M.D., M.P.H., Office of Public Health

Louisiana Statewide Obesity Prevention Plan Budget, November 20, 1998

To develop a long-range statewide obesity prevention plan for the state several components are required. Step one is the development of community programs to promote healthy lifestyles, including improved physical activity and dietary patterns. Physical activity recommendations should reflect those of the U.S. Surgeon General for moderate physical activity, and dietary adjustments should focus on five-a-day servings of fruits and vegetables and lowering dietary fat intake. These steps are identical to those recommended by the Centers for Disease Control, and can be incorporated into community, school and work site programs. It will be necessary to have at least one person in each of the state's public health regions who has the responsibility for initiating, coordinating and developing partnerships around physical activity and dietary plans. A second component includes the measuring and monitoring of health behaviors, such as keeping track of BMIs, height, weight, and amount of physical activity, as well as evaluating those programs which are instituted. The third component encompasses community programs to reduce the burden of obesity related diseases, such as diabetes, hypertension, and cardiovascular disease. This includes, for example, building partnerships between public health professionals and rural regions which do not have adequate services. The fourth component is partnership grants, which would make funds available to organizations that have the capacity to integrate prevention aspects into their programs. Fifth, social marketing will be necessary to get the information out to the public, and sixth, coordinated school programs are necessary in order to develop a comprehensive school curriculum for K-12. Finally, administration and management costs are also included. The proposed cost of each of these components is outlined as follows:

Community programs to promote healthy lifestyles:	\$540,000
Measuring, monitoring and evaluation:	\$80,000
Community programs to reduce obesity related diseases:	\$1,000,000
Partnership grants:	\$1,000,000
Social marketing:	\$2,000,000
Coordinated school health programs:	\$2,000,000
Administration and management:	\$100,000
TOTAL:	\$6,720,000

Rick Streiffer, M.D., Tulane Medical Center: Recommendations September 18, 1998

1. Fund research to answer key, Louisiana-specific questions, to set specific goals for the state, and to address best projected strategies for the state.
2. Explore the development of a public awareness campaign that includes alternatives to feeling helpless and hopeless about obesity. As a subset of this, consider the initiation of a public debate on a regulatory approach to the "Toxic Food Environment" in Louisiana.
3. Set the stage with the Legislature and the public that this is a long-term undertaking that must include concentrating on obesity prevention in future generations and recognizing that societal norms shift slowly.

4. Address the training, skills and attitudes of all health professionals, with an emphasis on targeting primary care providers.
5. Address “systems” issues in the delivery of obesity treatment, including the redirection of resources within the health systems, both public and private.

Nutrition Education in Medical Training, December 18, 1998

Nutrition education in medical schools is not currently emphasized, due primarily to the historical trend of placing nutrition into the province of other professionals, such as biochemists and dietitians. In 1976, 19% of U.S. medical schools had a required course in nutrition; that number peaked in the early 1980’s at 37%, but was down to 26% by 1991. In 1985 a national research council recommended that all U.S. medical schools include a required course in nutrition, however, currently only two-thirds of U.S. medical schools have electives in nutrition, and less than 10% of medical students elect to take these courses. Currently, Tulane Medical School has approximately 9 required predoctoral hours on Nutrition and Behavior Change, as well as a few additional elective courses.

Accreditation standards are not particularly helpful in emphasizing nutrition education, as National Board examinations do not cover nutrition-related screening and preventive counseling areas. Residency education requirements are also of limited utility in emphasizing nutrition education, and currently only the family medicine and pediatric subspecialties specifically include training regarding nutrition, prevention, counseling, patient education and eating disorders.

McGinnis and Forge, in a 1993 Journal of the American Medical Association article identified diet and activity patterns as their 2nd leading “Actual” cause of death, contributing significantly to five of the top ten causes of death in the United States (heart disease, cancer, stroke, diabetes and arteriosclerosis).

Barriers to making nutrition education standard within medical education include: the interdisciplinary nature of nutrition education; the lack of importance placed on nutrition by physicians; the increasing amount of information currently included in medical school curricula; the hospital-based, short-term learning structure of medical school education; and inadequate accreditation standards and examination methods. Numerous resources exist for addressing these barriers, including: the National Consensus on Essentials of Nutrition Education in Medical Schools; the Report on the National Conference on Nutrition Education in Family Medicine; the Nutrition Screening Initiative; the Physician’s Curriculum in Clinical Nutrition; and numerous medical textbooks.

Recommendations to improving nutrition education in the medical schools include:

1. A required nutrition curriculum in Louisiana medical schools and primary care residencies, which is interdisciplinary, ambulatory and longitudinal, which includes a skill-building component, and which emphasizes problems in Louisiana.
2. Development of an in-state grant program to fund curriculum development and implementation, faculty development programs, and loan repayment for physicians demonstrating nutritional expertise and leadership.
3. Develop programs to encourage medical trainees to participate in community-based nutrition education.

**Larry Weber, Ph.D., Tulane School of Public Health
Epidemiology of Obesity in Louisiana Children, November 20, 1998**

The Child and Adolescent Trial for Cardiovascular Health (CATCH) has found that school systems are eliminating physical education classes from their curricula, and that alternatives opportunities for physical activity are not being provided. In addition, Louisiana schoolchildren are participating in physical activity fewer minutes per day and sedentary activity more minutes per day than the other states studied (California, Minnesota and Texas). The Bogalusa Heart Study has found that the minutes per day of moderate and vigorous physical activity in Louisiana 5th to 8th graders declines as age of the child increases.

The CATCH PE program is designed, therefore, to promote children's enjoyment and participation of moderate to vigorous physical activity (MVPA) during PE classes, at other times in school, and away from school with family and friends. The CATCH PE intervention strategy includes curriculum and materials (activity boxes, guidebooks, videotapes and athletic equipment), teacher training materials and on-site assistance at two week intervals.

The key objectives of CATCH PE include:

1. MVPA for 50% of PE class time.
2. Provide multiple opportunities to participate and practice skills.
3. Foster student enjoyment of physical activity.
4. Encourage students to participate in physical activity outside of the school setting.

Results of the CATCH PE study indicate that children attending schools implementing the CATCH intervention participated in significantly more minutes of moderate to vigorous physical activity than children attending control schools for all grade levels. In addition, after two semesters the CATCH PE schools were meeting the US Department of Health and Human Services "Healthy People 2000" Objective 1.9, which is the increase of physical activity to at least 50% of allotted physical education class time.

It is concluded that interventions must provide education for children and create environments which support healthful behavior. It is critical that public health policy address not only how school health programs can be more effective, but also how effective programs can be more widely implemented to reach the entire population of children.

Melinda S. Sothorn, Ph.D., LSU Medical Center: Childhood Obesity, September 18, 1998

Environmental factors may contribute as much as 80% to the causes of childhood obesity. These factors include increased calorie and fat intake, especially snacking and dining out, emotional disorders, and sedentary behaviors, such as television viewing. The prevention of adult obesity by targeting children and their parents may provide the best solution to the increasing prevalence of obesity. Research indicates that obese children are better able to maintain weight loss over a long-term period than adults. Programs to treat childhood obesity are not commonly available, and when available, are usually unsuccessful in maintaining weight loss. This may be due to the fact that lifestyle factors contributing to the development of obesity are not effectively altered. Successful treatment of mild to moderate levels of childhood obesity have included multi-disciplinary approaches containing family based, group educational interventions with diet and nutrition education, structured exercise programs, and behavior modification. Exercise treatment

recommendations for childhood obesity include reductions in sedentary behaviors, participation in activities with a high caloric cost, and walking programs.

Research indicates that school based programs have been successful at treating and preventing childhood obesity, and programs incorporating behavior therapy and physical activity into dietary interventions appear to improve weight loss maintenance.

Successful prevention and treatment of childhood obesity is not only dependent on safe and effective nutritional therapies, but also on increasing the physical activity levels of obese youth. However, motivating the obese child to participate in physical activity is difficult. Obese children have a decreased exercise tolerance. Movement may be uncomfortable or painful, due to factors such as increased joint discomfort and distressed breathing. Once activity is reduced, body fat will continue to increase, leading to even more aversion to exercise, thus creating a vicious cycle of inactivity and further weight gain. Prior failure to motivate and maintain increased physical activity in obese children may be attributed to inappropriate exercise prescription. Appropriate exercise interventions for obese children should include realistic methods for increasing energy expenditure through motivational/incentive sessions and educational techniques to increase body awareness. Structured exercise prescriptions should be specific to the needs of each range of obesity, defined as follows: mild (24-26 BMI); moderate (27-29 BMI); and severe (> 29 BMI). Initially, mildly obese children should be prescribed more frequent and longer exercise sessions than moderately or severely obese children. The volume (duration x frequency) of exercise should gradually increase over time, allowing for a steady improvement in exercise tolerance. Initially the intensity of exercise should be moderate, to allow for sustained durations of exercise adequate to promote a significant caloric deficit and a moderate improvement in physical fitness. All exercises should follow the guidelines of the American College of Sports Medicine (ACSM).

The Committed to Kids Pediatric Weight Management Program was developed by the Department of Pediatrics, Louisiana State University, and Children's Hospital of New Orleans. It is a one year, four phase program structured to the specific needs of children of varying levels of obesity. A medical treatment team consisting of a pediatrician, registered dietitian, exercise physiologist and psychologist meet once a week with obese children and their families to discuss topics of nutrition, exercise and overall health. The children are placed on a structured diet and exercise plan and provided with nutritional education, fitness education and behavior modification during each weekly session. The program has a short-term success rate of 95% and a one year success rate of 70-75%. Preliminary data indicate that after five years, 85% of the children treated maintained an average weight loss of 31%. This program has been successfully reproduced in other clinical settings throughout the state of Louisiana.

A summary list of recommended initiatives follows:

Informational brochures containing general and referral information on childhood obesity should be provided to pediatricians, hospitals, schools and community centers.

A pediatric statewide health care network should be established to standardize assessment, treatment and medical recommendations.

A school based pediatric obesity prevention curriculum should be developed, to be implemented by classroom teachers with assistance from school personnel, community and state professionals.

Development of after school, family based obesity treatment programs, to be supervised by medical professionals and conducted in key centers throughout the state.

Development of preschool obesity prevention and treatment programs, designed to the needs of children 2-5 years, and implemented in preschool daycare centers, schools and early intervention programs.

Development of family obesity treatment programs, targeting families with several overweight members, to be implemented in community centers, recreation centers, churches and schools.

Portions Healthy Weight Program: LSU AgCenter

The Portions Healthy Weight Program emphasizing healthy lifestyles was developed to address Louisiana's growing obesity problem by a team of five LSU AgCenter FCS nutrition specialization agents and a nutrition specialist. Portions was launched in spring 2001. Currently, Portions workshops have been conducted in approximately one-third of Louisiana's parishes for more than 1000 people. Portions provides current, research-based information and recommendations to help Louisiana citizens achieve and maintain a healthy weight by setting realistic goals for better health and learning to balance the food they eat with appropriate physical activity.

Ninety-seven percent of Portions Program participants said they had made at least one recommended lifestyle change including:

- increasing physical activity (some groups formed walking clubs or enrolled in fitness classes)
- increasing consumption of vegetables and fruit
- decreasing consumption of saturated fat.
- using nutrition information on food labels to select foods.
- choosing a diet moderate in sugar.
- choosing foods lower in salt and sodium.
- breaking habits that led to overeating and physical inactivity

Although participants were not required to weigh, and the number of pounds lost was not emphasized, a healthy weight loss of 4-8 pounds was experienced by participants who chose to report their weights during the program.

Ninety-one percent of the participants (where beginning and ending health assessments were taken) improved their cholesterol, blood pressure or blood glucose levels. Participants reported that the program helped them break habits that had led to overeating and not being physically active. The discussion on fad diets revealed that participants had tried numerous fad diets. Observations by FCS Agents showed knowledge gained by participants and a resolve not to go on unhealthy fad diets again.

Pennington Biomedical Research Center: Recent or Current Treatment Studies

Diabetes Prevention Program (DPP). NIH sponsored DPP trial ⁴⁹⁸ was one of the most important studies of lifestyle interventions for obesity. It found that modest weight losses of about 7% of body weight, that were sustained for 2.8 years, reduced the conversion rate to Type 2 diabetes by 58%. The intensive lifestyle intervention was significantly more effective than a diabetes medication (metformin). Pennington Biomedical Research Center was one of 27 centers across the United States that participated in this trial. Lifestyle was successful with all participants

across age, ethnicity and gender. The key components of this study included goal based intervention, focus on diet and physical activity, behavioral strategies, intensive on-going contact, individualized treatment.

Primary Care Office Management of Obesity (PCOMO) The NIH sponsored PCOMO trial was designed to assess the feasibility and efficacy of the primary care physician in delivery weight loss interventions to a population of low income African American Females.

The participants in the patient centered intervention group demonstrated significantly greater weight loss after six months of treatment. At 9 –18 months, the intervention group continued to demonstrate significantly greater weight loss. The proportions of participants who lost or gained weight and percentage weight loss in each group are below:

	<u>Intervention</u>			<u>Standard Care</u>		
	6	9	12	6	9	12
Lost Weight	78.8%	71%	71.4%	46.8%	42%	51.7%
Lost 5%	14.3%	19%	19%	3.6%	7.4%	15%
Lost 10%	2.4%	4.8%	7%	0	0	1.7%

LookAHEAD :The LookAHEAD (Action for Health in Diabetes) trial is a multi-site clinical trial sponsored by the National Institutes of Health. Pennington Biomedical Research Center is one of 16 sites across the United States. The primary aims of the LookAHEAD trial are to answer two questions: 1) Do interventions designed to produce sustained weight loss in obese individuals with type 2 diabetes mellitus improve health?, and 2) How do the benefits and risks of interventions designed to produce weight loss compare with the benefits and risks related to treatment of obesity-related comorbid conditions (heart attacks and strokes) and death in the absence of weight-loss interventions? The research design calls for four years of intervention and up to seven years of follow-up. To achieve this aim, 5000 people will be enrolled and randomized to two arms: 1) Diabetes Support and Education and 2) Weight Management combined with Diabetes Support and Education. The goals of the intervention are to yield a weight loss of at least 7% of initial (baseline) body weight during the first six months of the program and weight maintenance of this weight loss over subsequent years. During the first six months of the intervention, participants will attend 3 group therapy sessions per month and 1 individual therapy session per month. During the second six months, participants are asked to attend at least one group therapy session and one individual therapy session per month. The program includes standard behavioral components such as self-monitoring, stimulus control, diet and exercise modification, and relapse prevention. It also includes a meal replacement program and an option for using a weight loss medication.

Shiloh's Healthy Obedience Program (SHOP) Pilot Study. SHOP was a six-month pilot study designed to test the effectiveness of a church-based program to improve diet and health in African Americans through nutrition education, self-monitoring, and self-assessment of diet and physical activity. Forty participants were randomized into two groups and both groups received intervention. Two trained Health Educators from within the church managed the program and each worked with 20 participants. The specific objective was to determine whether the combined nutrition education, self monitoring, and self-assessment was effective in improving diet and physical activity in study participants who received individual intervention compared to those who received group intervention with nutrition education only. The primary measurable health outcome was body weight. The results of SHOP overall was successful with a participation rate of

90 % (36/40). Of the 36 participants completing the study, 28 participants lost weight (average loss 3.8 kg.), with 10 participants losing more than 5 kg. There was no difference between the group delivery and individual delivery in terms of efficacy of weight loss intervention and therefore it was concluded that a combination of group and individual intervention strategies may be more effective than either strategy alone.

The “Rolling Store” Pilot Study. The “Rolling Store” was a six-month pilot study designed to test the feasibility of the “Rolling Store,” an innovative food delivery medium, providing healthy food choices (such as fruits and vegetables) to prevent weight gain in African American women. The study was based on the hypothesis that increased utilization of the “Rolling Store” with ready access to healthy foods which are economically within reach may lead to a direct improvement of diet quality and an adoption of healthy eating habits thus resulting in the prevention of weight gain and/or initiation of weight loss. Forty African American women (20 per group) were randomly assigned to 1) the Control Group – an intervention with nutrition education on healthy eating and physical activity information only, or 2) the Treatment Group – six monthly group classes taught by the Health Study (H/S) coordinator on healthy eating, physical activity, and weekly shopping on the “Rolling Store.” Although the primary purpose of the program was to prevent weight gain, participants in the treatment group who received monthly group meetings taught by the H/S coordinator on healthy eating and exercise, plus weekly shopping on the “Rolling Store,” lost an average of 1.9 kilograms (4.2 pounds) by the end of the six month study, while the control group gained 1.1 kilograms (2.4 pounds) at the end of the study. The “Rolling Store” was feasible, accessible, and an economical approach in producing satisfactory health outcomes.

Other State Programs:

CDC's State-based Nutrition and Physical Activity Program to Prevent Chronic Diseases, Including Obesity

In October 2000, the Division of Nutrition and Physical Activity initiated a program to support state health departments and their partners in developing and implementing targeted nutrition and physical activity interventions in an effort to prevent chronic diseases, especially obesity. States were encouraged to use a social marketing approach in designing their population-based strategies, particularly policy-level and environmental interventions.

States Funded in FY 2000 and 2001

During the first year of CDC funding, six states won cooperative agreements with proposals to prevent chronic diseases including obesity:

California

Connecticut

North Carolina

Massachusetts

Rhode Island

Texas

In Fiscal Year 2001, six additional states received funding including:

Colorado

Florida

Michigan

Montana

Pennsylvania

Washington

National Recommendations

The need for an obesity prevention initiative has been recognized by a number of NIH advisory groups. In 1994, the National Task Force on Prevention and Treatment of Obesity developed a long range plan focused on prevention of Obesity⁵⁰² and reaffirmed obesity prevention as a priority area for clinical research. The NHLBI/NIDDK Clinical Guidelines on the Identification, Evaluation, and Treatment of Overweight and Obesity in Adults include a discussion of the importance of preventing obesity and suggestions for strategies to be attempted⁵⁰³. The February 1998 NHLBI Report of the Task Force on Behavioral Research in Cardiovascular Lung and Blood Health and Disease also has recommended development of obesity prevention research efforts⁵⁰³. Nestle and Jacobson note that there is an urgent need for research to determine effective obesity prevention strategies on which to base public health policies³⁹².

In December 2000, the Surgeon General held a listening session in an effort to develop a national action plan to combat overweight and obesity¹. The session identified obesity prevention as a critical target, and suggested that efforts focus on environmental factors targeting the family and community, schools, work sites, the health care delivery system, and the media.

Office Of The Surgeon General Call To Action

The Surgeon General identifies the following 15 activities as national priorities for immediate action. Individuals, families, communities, schools, worksites, health care, media, industry, organizations, and government must determine their role and take action to prevent and decrease overweight and obesity¹.

Communication:

The Nation must take an informed, sensitive approach to communicate with and educate the American people about health issues related to overweight and obesity. Everyone must work together to:

- Change the perception of overweight and obesity at all ages. The primary concern should be one of health and not appearance.
- Educate all expectant parents about the many benefits of breastfeeding.
 - Breastfed infants may be less likely to become overweight as they grow older.
 - Mothers who breastfeed may return to pre-pregnancy weight more quickly.
- Educate health care providers and health profession students in the prevention and treatment of overweight and obesity across the lifespan.
- Provide culturally appropriate education in schools and communities about healthy eating habits and regular physical activity, based on the Dietary Guidelines for Americans, for people of all ages. Emphasize the consumer's role in making wise food and physical activity choices.

Action:

The Nation must take action to assist Americans in balancing healthful eating with regular physical activity. Individuals and groups across all settings must work in concert to:

- Ensure daily, quality physical education in all school grades. Such education can develop the knowledge, attitudes, skills, behaviors, and confidence needed to be physically active for life.
- Reduce time spent watching television and in other similar sedentary behaviors.
- Build physical activity into regular routines and playtime for children and their families. Ensure that adults get at least 30 minutes of moderate physical activity on most days of the week. Children should aim for at least 60 minutes.
- Create more opportunities for physical activity at worksites. Encourage all employers to make facilities and opportunities available for physical activity for all employees.
- Make community facilities available and accessible for physical activity for all people, including the elderly.
- Promote healthier food choices, including at least 5 servings of fruits and vegetables each day, and reasonable portion sizes at home, in schools, at worksites, and in communities.
- Ensure that schools provide healthful foods and beverages on school campuses and at school events by:
 - Enforcing existing U.S. Department of Agriculture regulations that prohibit serving foods of minimal nutritional value during mealtimes in school food service areas, including in vending machines.
 - Adopting policies specifying that all foods and beverages available at school contribute toward eating patterns that are consistent with the Dietary Guidelines for Americans.
 - Providing more food options that are low in fat, calories, and added sugars such as fruits, vegetables, whole grains, and low-fat or nonfat dairy foods.
 - Reducing access to foods high in fat, calories, and added sugars and to excessive portion sizes.
- Create mechanisms for appropriate reimbursement for the prevention and treatment of overweight and obesity.

Research

The Nation must invest in research that improves our understanding of the causes, prevention, and treatment of overweight and obesity. A concerted effort should be made to:

- Increase research on behavioral and environmental causes of overweight and obesity.

- Increase research and evaluation on prevention and treatment interventions for overweight and obesity and develop and disseminate best practice guidelines.
- Increase research on disparities in the prevalence of overweight and obesity among racial and ethnic, gender, socioeconomic, and age groups and use this research to identify effective and culturally appropriate interventions.

American Medical Association:

H-150.953 Obesity as a Major Public Health Program⁵⁰⁴

Recognizing the public health importance of reducing overweight and obesity in children and adults and further recognizing the public's interest and investment in lifestyle changes aimed at achieving a healthy body weight, the following statements, recommended by the Council on Scientific Affairs, were adopted by the AMA House of Delegates as AMA policy at the 1999 AMA Annual Meeting.

1. The AMA urges physicians as well as managed care organizations and other third-party payers to recognize obesity as a complex disorder involving appetite regulation and energy metabolism that is associated with a variety of comorbid conditions.
2. The AMA will work with appropriate federal agencies, medical specialty societies, and public health organizations to educate physicians about the prevention and management of overweight and obesity in children and adults, including education in basic principles and practices of physical activity and nutrition counseling; such training should be included in undergraduate and graduate medical education and through accredited continuing medical education programs.
3. The AMA urges federal support of research to determine (a) the causes and mechanisms of overweight and obesity, including biological, social, and epidemiological influences on weight gain, weight loss, and weight maintenance; (b) the long-term safety and efficacy of voluntary weight maintenance and weight loss practices and therapies, including surgery; (c) effective interventions to prevent obesity in children and adults; and (d) the effectiveness of weight loss counseling by physicians.
4. The AMA encourages national efforts to educate the public about the health risks of being overweight and obese and provide information about how to achieve and maintain a preferred healthy weight.
5. The AMA urges physicians to assess their patients for overweight and obesity during routine medical examinations and discuss with at-risk patients the health consequences of further weight gain; if treatment is indicated, physicians should encourage and facilitate weight maintenance or reduction efforts in their patients or refer them to a physician with special interest and expertise in the clinical management of obesity.
6. The AMA urges all physicians and patients to maintain a desired weight and prevent inappropriate weight gain.
7. The AMA encourages physicians to become knowledgeable of community resources and referral services that can assist with the management of overweight and obese patients.

8. The AMA urges the appropriate federal agencies to work with organized medicine and the health insurance industry to develop coding and payment mechanisms for the evaluation and management of obesity.

D-440.980 Recognizing and Taking Action in Response to the Obesity Crisis ⁵⁰⁵

Our AMA will: (1) collaborate with appropriate agencies and organizations to commission a multidisciplinary task force to review the public health impact of obesity and recommend measures to better recognize and treat obesity as a chronic disease; (2) actively pursue, in collaboration and coordination with programs and activities of appropriate agencies and organizations, the creation of a "National Obesity Awareness Month"; (3) strongly encourage through a media campaign the re-establishment of meaningful physical education programs in primary and secondary education as well as family-oriented education programs on obesity prevention; (4) promote the inclusion of education on obesity prevention and the medical complications of obesity in medical school and appropriate residency curricula; and (5) provide a progress report on the above efforts to the House of Delegates by the 2004 Annual Meeting (Res. 405, A-03)

Assessment and Management of Adult Obesity: A Primer for Physicians ⁵⁰⁶

The American Medical Association (AMA) released in December 2003, a new comprehensive guide to help physicians identify and treat obesity in their adult patients. *Assessment and Management of Adult Obesity: A Primer for Physicians* is now available. This primer, authored by Robert Kushner, M.D., Professor of Medicine, Northwestern University Feinberg School of Medicine, and Medical Director of the Wellness Institute at Northwestern Memorial Hospital was funded by a grant from The Robert Wood Johnson Foundation, was developed in partnership with the U.S. Department of Health and Human Services in conjunction with its *Healthy People 2010 and Steps to a Healthier US* initiatives to improve the health of all Americans. *Assessment and Management of Adult Obesity* consists of 10 booklets that offer practical recommendations for addressing adult obesity in the primary care setting. The primer offers practical advice on:

- evaluating patients for current and potential health risks related to weight - beginning with a measure of the body mass index (BMI);
- understanding medication and surgical options;
- improving communication and counseling; and
- making office environments more accommodating to obese patients.

Summary of Recommendations (United States Preventive Services Task Force) ⁵⁰⁷

- **The USPSTF recommends that clinicians screen all adult patients for obesity and offer intensive counseling and behavioral interventions to promote sustained weight loss for obese adults.**
- **The USPSTF concludes that the evidence is insufficient to recommend for or against the use of moderate- or low-intensity counseling together with behavioral interventions to promote sustained weight loss in obese adults.**

- **The USPSTF concludes that the evidence is insufficient to recommend for or against the use of counseling of any intensity and behavioral interventions to promote sustained weight loss in overweight adults.**

The USPSTF found that behavioral interventions showed small to moderate degrees of weight loss sustained over at least 1 year. Counseling interventions led to weight changes in the range of 1 kg to -6 kg or from -4 to -8 percent of body weight. Although several trials were of good quality, most were judged only fair, with limitations such as small sample size, potential selection bias (trials often enrolled volunteers), and high drop-out rates. Studies tended to report mean group weight change and not frequency of response to the interventions. Trials of higher-intensity interventions (defined by the USPSTF as person-to-person meetings more than once a month for at least the first 3 months), and combinations of interventions appeared to promote greater weight loss than trials of lower-intensity interventions.

The USPSTF found the evidence supporting pharmacotherapy of mostly fair quality. Data for sibutramine and orlistat suggest that these drugs have modest but potentially sustained effects. Although average weight loss was consistently modest (weight reduction of 3-5 kg), the percentage of patients achieving clinically significant weight loss (5-10 percent of body weight) was sometimes substantial. Weight maintenance trials suggested that prolonged pharmacotherapy confers some benefit but that its discontinuation may lead to rapid weight regain. There are limited data on combined behavioral and pharmacological interventions. One fair-quality trial showed that a combination of intensive behavioral therapy and sibutramine led to greater weight loss (mean of 7.3 kg over 1 year) compared with sibutramine alone, and that a combination of intensive behavioral therapy and diet control with sibutramine led to even greater weight loss (mean of 12.8 kg over 1 year) compared with sibutramine alone.

Obesity surgery has been performed for only a select group of patients; the NHLBI clinical guide for identification, evaluation, and treatment of overweight and obesity in adults recommends surgical intervention only for those people with a BMI > 40 or a BMI of 35 to 40 with at least 1 obesity-related comorbidity. National data indicate that 5 to 6 percent of the general population has a BMI in this range. Surgical data are typically limited by the lack of placebo-controlled RCTs; the internal validity of the controlled trials is of only "fair" quality. Nonetheless, the degree of weight reduction obtained with surgical intervention is consistently dramatic (typically 20 kg or more). Based on a large literature of controlled and uncontrolled cohort studies, the weight loss may be prolonged and can be achieved in patients who have multiple comorbidities.

American Heart Association ³⁰⁰:

The American Heart Association strongly advocates more research on the prevention and treatment of obesity, and continues to recommend an overall healthy dietary pattern that is rich in fruits, vegetables, whole grains, low-fat dairy products, lean meats, poultry and fish. To lose weight using this approach, individuals should eat fewer calories than they burn. Diets rich in fruits, vegetables, whole grains, and fish have been associated, in many studies, with a lower risk of cardiovascular disease and stroke.

American Obesity Association (AOA) ⁵⁰⁸: Morgan Downey, Executive Director

"Obesity is the most neglected public health crisis of the 21st Century. It is neglected not because many health leaders in both the public and private sector do not understand the

importance of obesity, but because it receives a miniscule amount of attention and policy development at the federal, state or local level.

Obesity is second only to tobacco as the leading cause of preventable death in the United States. The costs of treating adults with obesity are over \$238 billion a year, making it one of the most expensive diseases in the country. It is increasing among all ages, gender, racial and ethnic groups, and it is increasing across the entire world. The United States Government, the leader in the world's public health efforts, has a minimal research program for obesity, and spends no money for prevention and virtually none for treatment. There is no trend to indicate a reversal in the increasing prevalence of obesity. Yet, obesity is not more intractable than cancer, heart disease, violence, HIV/AIDs or smoking. Effective public health measures can be established and implemented."

Healthy Weight 2010

Healthy People 2010 Goals related to Obesity

Increase the proportion of adults who are at a healthy weight to 60% (Baseline: 42%)

Reduce the proportion of adults who are obesity to 15% (Baseline: 23%)

Reduce the proportion of children and adolescents who are overweight or obese to 5% (Baseline 10%).

This publication was developed by the American Obesity Association (AOA) as a resource to complement *Healthy People 2010*. However, *Healthy People 2010* lacks a separate focus area (chapter) on obesity. This publication is intended for health professionals, public health officials, managed care organizations, and policy makers to improve public health by making the prevention and treatment of obesity a priority.

The public must be thoroughly informed about obesity. They should know that obesity is difficult, but possible, to manage. Obesity does not occur overnight. It has a long duration and can frequently recur if not managed properly. It has a definite morbid process and affects the entire body. Understanding the causes and health risks of obesity, its assessment, prevention and treatment strategies, and the benefits of losing excess weight should become common public knowledge.

Objectives for Increasing Public Understanding of Obesity

1.1. Increase the proportion of adults, adolescents, and children who understand the health risks of being overweight or obese.

1.2. Increase the proportion of adults, adolescents, and children who understand BMI and its use to measure and monitor overweight and obesity.

1.3. Increase the proportion of adults, adolescents, and children who understand that excess weight is caused by an interaction of genetic (inherited) and environmental (social and cultural) factors, which include metabolic (chemical reactions of biological molecules) and behavioral (psychological and emotional) components.

1.4. Increase the proportion of overweight or obese adults, adolescents, and children who understand that even a modest amount of weight loss can reduce the severity of illness associated with excessive body fat.

1.5. Increase the proportion of adults, adolescents, and children who understand that pharmacological and surgical interventions are medical treatment options for individuals with obesity, and that these interventions be discussed with appropriate medical professionals.

1.6. Increase the proportion of adults and adolescents who understand how to set reasonable weight goals.

1.7. Increase the proportion of mothers who understand that maternal obesity is associated with risk of birth defects to infants.

Objectives for Improving Weight Status

2.1. Increase the proportion of adults who stabilize their body weight or BMI by adopting or maintaining sound principles of weight maintenance.

2.2. Increase the proportion of adults, adolescents, and children who implement sound principles of achieving or maintaining a healthy weight, which includes healthful eating, regular physical activity, and behavioral strategies.

2.3. Increase to at least 60 percent the prevalence of healthy weight, BMI equal to or greater than 19.0 and less than 25.0, among all people aged 20 and older.

2.4. Reduce to less than 15 percent the obesity prevalence, BMI of 30.0 or above, among people aged 20 and older.

2.5. Reduce the overweight prevalence, BMI equal to or greater than 25.1 and less than 29.9, among people aged 20 and older.*

2.6. Reduce to 5 percent or less the prevalence of obesity (at or above the sex- and age-specific 95th percentile of BMI from the revised NCHS/CDC growth charts) in children (aged 6-11) and adolescents (aged 12-19).

2.7. Increase the proportion of people aged 18 and older who follow sensible guidelines for the amount and type of physical activity that enhances weight loss or prevents weight gain.

2.8. Increase the proportion of children (aged 6-11) and adolescents (aged 12-17) who engage in regular physical activity to promote lifestyle behavior that enhances weight management.

2.9. Increase the proportion of people aged 18 and older who follow sensible dietary guidelines that enhances weight loss or prevents weight gain.

2.10. Increase the proportion of children (aged 6-11) and adolescents (aged 12-17) who follow sensible dietary guidelines that enhances weight management.

2.11. Increase the proportion of mothers who achieve a weight gain consistent with the Institute of Medicine (IOM) guidelines during their pregnancies.

2.12. Increase the proportion of overweight and obese people with diseases, disorders, conditions, and complications associated with excessive weight who have adopted appropriate forms of weight management strategies to attain an appropriate body weight.

2.13. Reduce the number of employee work days missed due to obesity related medical conditions.

Objectives for Implementing Obesity Education Programs

- 3.1. Increase the proportion of elementary, secondary, and undergraduate students who receive age appropriate educational information on the importance of a healthy weight.
- 3.2. Increase the proportion of parents of school-aged children who receive educational materials regarding healthy weight for children through social, cultural, and educational organizations and associations.
- 3.3. Increase to at least 50 percent the proportion of worksites with 50 or more employees that offer weight management programs for employees.
- 3.4. Increase the proportion of all employees who participate in employer-sponsored weight management programs.
- 3.5. Increase the proportion of patients who are routinely screened for obesity risk factors and counseled on weight management strategies by managed care organizations, health care organizations, and clinicians.
- 3.6. Increase the proportion of managed care organizations with health care plans that provide patients and family's access to education on the importance of a healthy weight, access to weight management programs, and comprehensive coverage of obesity education, prevention, and intervention including surgical and pharmacological treatment.
- 3.7. Increase the proportion of local and state health agencies that provide community education on the importance of a healthy weight, and access to weight management programs.
- 3.8. Increase the proportion of social organizations and faith-based groups that provide community education on the importance of a healthy weight and access to weight management programs with the specific objective of reaching women, racial and ethnic groups, and low income populations who are at increased risk of developing obesity.
- 3.9. Increase the proportion of primary care providers who receive obesity education training for the purpose of routinely counseling patients.
- 3.10. Increase the proportion of smoking cessation programs that provide concurrent weight management counseling.
- 3.11. Increase the proportion of worksite back injury programs that provide concurrent weight management counseling.
- 3.12. Reduce the proportion of children and adolescents who engage in improper weight loss practices that may lead to eating disorder behaviors.

Objectives for Integrating Obesity Management into the Public Health Infrastructure

- 4.1. Increase the number of communities that require zoning and city planning that includes parks and recreation areas to provide individuals with resources to achieve or maintain a healthy weight.

4.2. Increase the proportion of patients who have coverage for clinical preventive services and treatment of obesity as part of their health insurance.

4.3. Establish a standard measurement for data collection of obesity and its related variables for local, state, national and managed care health data systems.

4.4. Increase health communication and partnerships regarding obesity between primary care physicians, clinics, hospitals, government health departments, health organizations, and businesses.

American Obesity Association (Community) ⁵⁰⁹

Promoting healthy lifestyles to prevent obesity in a community involves the creation of a healthy environment. The first step is to become aware of the environmental causes of obesity, some of which are listed in the table below.

Location or Type of Activity	Effect of Modernization	Impact on Obesity
Transportation	<input type="checkbox"/> Rise in car ownership. <input type="checkbox"/> Increase in driving shorter distances	<input type="checkbox"/> Decrease in walking or cycling
At Home	<input type="checkbox"/> Increase in the use of modern appliances (e.g. microwaves, dishwashers, washing machines, vacuum cleaners). <input type="checkbox"/> Increase in ready-made foods and ingredients for cooking. <input type="checkbox"/> Increase in television viewing, and computer and video game use.	<input type="checkbox"/> Decrease in manual labor. <input type="checkbox"/> Increase in consumption of convenience foods that contribute to obesity. <input type="checkbox"/> Decrease in time spent on more active recreational pursuits.
In the Work Place	<input type="checkbox"/> Increase in sedentary occupational lifestyles due to technology - increase in computerization	<input type="checkbox"/> Decrease in physically demanding manual labor.
Public Places	<input type="checkbox"/> Increase in the use of elevators, escalators and automatic doors.	<input type="checkbox"/> Decrease in daily physical activity patterns such as climbing stairs.
Urban Residency	<input type="checkbox"/> Fear of crime in urban areas.	<input type="checkbox"/> Deters outdoor exercise and leisure activities

Strategies for Integrating Obesity Management into Communities⁵⁰⁹

Here are some strategies for integrating an obesity action program into your community:

1. Form a community coalition or neighborhood association. Look for volunteers that can share their skills and resources.
 - Learn how to build and run a healthy community coalition from the U.S.Department of Health's *Healthy People in Healthy Communities*.
 - Find out how a coalition was formed in a Florida community from the Healthy Community Initiative of Greater Orlando.
 - Learn how to start a neighborhood association from The Council of Albany Neighborhood Associations.
 - Read the Centers for Disease Control's *Planned Approach to Community Health*.
2. Evaluate the infrastructure of your community. Find out where improvements can be made to reduce the prevalence of obesity and make it healthier.

Suburban sprawl has created communities with fewer sidewalks, and where schools, shopping, and recreational areas are no longer in walking distance. People rely more on driving cars than walking.

- Read an article on how *Suburban Sprawl is Inducing a Sedentary Lifestyle* from Smart Growth Online.
- Read Healthy Places, Healthy People: *Promoting Public Health & Physical Activity through Community Design* from the Robert Wood Johnson Foundation.
- Learn about the Northwest Obesity Prevention Project's The Interface of Urban Design, Public Health and Physical Activity in Preventing Obesity.

In some parts of the country, neighborhoods, parks and recreational areas are considered unsafe. In low-income areas, the lack of neighborhood safety is a significant barrier to physical activity, as is the lack of recreational opportunities.

Learn about the Rebuilding Communities Initiative, that has helped to turn troubled, low-income neighborhoods into safe, supportive and productive environments.

Transportation - Re-designing the layout of a community can promote physical activity by reducing dependence on driving cars.

- Learn about SMARTRAQ, a transportation and land use research project being conducted by Georgia Tech for the Atlanta metropolitan area.
- America Walks

- The Pedestrian and Bicycle Information Center
- Walkable Communities Inc.

Parks, Recreation Areas and Sidewalks - Re-zoning or planning cities with parks, recreation areas, and sidewalks can provide opportunities for physical activity.

- Active Community Environments (ACEs) is a CDC-sponsored initiative to promote walking, bicycling, and the development of accessible recreation facilities.
3. Determine the important issues, and back them up with facts to give to a policy maker that supports your case.
 - Find helpful abstracts from research studies on various health-related topics at the National Library's PubMed.
 - Search a database of articles on various topics at FindArticles.com.
 4. Partnerships - Developing partnerships with local businesses can create important resources to minimize cost and open lines of communication to the community. Hospitals, media (newspaper, TV and radio stations), and various government agencies are some examples of potential partners.
 - Sustainable Communities Network "Linking citizens to resources and to one another to create healthy, vital, sustainable communities."
 - Read the Healthy People 2010 State Toolkit, *A Free Guide to Health Planning: Identifying and Engaging Community Partners*.
 5. Bring your case to the city council. Find out of what is happening in city council committees (such as land use committees) that are important to helping your community to prevent and manage obesity.
 - Read about how a youngster made a case for building a skate park in his Michigan community.
 - Publicize your activities and information in the newspaper, on TV, and radio. Learn about public service announcements and how the Ad Council may be able to help you promote your campaign.
 7. Create a website for your coalition to keep the community informed about your activities and to solicit volunteers and partners.

American College of Preventive Medicine⁵¹⁰

Independent of weight or BMI, all adult patients should consistently receive counseling about healthful dietary and physical activity patterns in the context of primary care. Such counseling should be reinforced in the context of specialty care (e.g., cardiology) as dictated by clinical judgment and discretion. Periodic measurement of BMI (weight in kilograms/height in meters²) is

recommended for all adults. Although an emphasis on health-promoting behaviors may be preferred to an emphasis on weight per se, weight monitoring is considered useful to both clinician and patient in gauging the adequacy of behavioral interventions. The American College of Preventive Medicine (ACPM) endorses the practical guidelines of the NIH in advising obese and overweight patients. Moderate physical activity for 30–45 minutes, at least 3–5 days per week, should be encouraged for all patients unless specifically contraindicated. Overweight or obese patients should be counseled regarding an energy-reduced, or low-calorie diet (800–1500 kcal/day). Surgery should be reserved for severely obese subjects (generally, BMI>40). Evidence available to date is insufficient to support any specific behavioral therapy, short-term use of pharmacotherapy, or chronic pharmacotherapy; such interventions should be individualized in accord with clinical judgment. Clinicians are encouraged to apply prevailing models of behavior modification, such as the Stages of Change, in support of counseling by clinicians for weight control. Physicians should be attentive to the stigmatizing effects of obesity and should strive to address weight-control counseling of patients in a manner that supports, rather than erodes, patients' self-esteem. As a large proportion of obese patients will have engaged in multiple unsuccessful weight-control efforts, the ACPM encourages an approach to counseling that distinguishes between blame for weight gain and responsibility for weight control, in an effort to prevent exacerbation of the well-documented psychological sequelae of obesity. Specifically, those patients with multiple failed attempts at weight control should receive counseling directed at the impediments to weight control and strategies for circumventing them. ACPM encourages further research into the pathogenesis and treatment of obesity, as well as initiatives to enhance physician–patient interaction regarding weight management and to minimize barriers to such counseling. Ultimately, for obesity control at the population level, environmental modification to support healthful eating and levels of physical activity is likely to be necessary. The lack of clearly effective treatment for obesity once established requires that obesity prevention be addressed consistently in clinical practice. Counseling by clinicians to encourage health-promoting dietary patterns and levels of physical activity in all patients is therefore warranted, both as a means to control weight and to confer health benefits by other means.

Summary of CDC Community Guide Branch ⁵¹¹

According to the Guide to Community Preventive Services systematic review of the effectiveness of population based interventions there are a number of programs with strong evidence of effectiveness. The findings of the interventions designed to increase physical activity are presented below:

Informational Approaches to increase physical activity:

Community-wide campaigns	Recommended strong evidence
“Point of Decision” Prompts	Recommended sufficient evidence
School-based physical education	Recommended strong evidence
Non-family social support	Recommended strong evidence
Mass media	Insufficient evidence to determine
Classroom based health education/information provision	Insufficient evidence to determine

Behavioral/Social approaches to increase physical activity

Individually adapted health behavior change	Recommended strong evidence
Health education with TV/Video game turnoff component	Insufficient evidence to determine
College age physical/health education	Insufficient evidence to determine

Family-based social support

Insufficient evidence to determine

Environmental and policy approaches

Creation and/or enhanced access to places for physical

Activity combined with informational outreach

Recommended strong evidence

Transportation policy and infrastructure change to promote

Non-motorized transit

In progress

Urban planning approaches – zoning and land use

In progress

The following reviews on nutrition relevant areas are expected to be available as follows:

Review	Expected Completion
School-based nutrition programs	Spring 2004
Food and beverage advertising to children	Summer 2004
Community approaches to increase fruit & vegetable intake	Fall 2004
Food & beverage availability, price, portion size, and labeling in restaurants	Winter 2004

Recent National Organizational and Legislative Actions related to Obesity⁵¹²

Internal Revenue Service

On April 2, 2002, the IRS announced a new policy (IRS Ruling 2002-19) stating that "Obesity is medically accepted to be a disease in its own right." For taxpayers, this means that treatment specifically for obesity can now be claimed as a medical deduction. According to the IRS:

"Uncompensated amounts paid by individuals for participation in a weight-loss program as treatment for a specific disease or diseases (including obesity) diagnosed by a physician are expenses for medical care that are deductible under § 213, subject to the limitations of that section."

Food and Drug Administration⁵¹³

In August 2003, the FDA established the FDA Obesity Working Group to address the obesity epidemic in the U.S. and to develop new and innovative ways to help consumers to lead healthier lives through better nutrition. This Working Group sponsored a public meeting on October 23, 2003 to in an attempt to gain information and guidance on future directions to assist in the management of obesity.

The meeting focused on the following six questions related to obesity:

- 1 What is the available evidence on the effectiveness of various education campaigns to reduce obesity?
- 2 What are the top priorities for nutrition research to reduce obesity in children?
- 3 What is the available evidence that FDA can look to in order to guide rational, effective public efforts to prevent and treat obesity by behavioral or medical interventions, or combinations of both?

4 Are there changes needed to food labeling that could result in the development of healthier, lower calorie foods by industry and the selection of healthier, lower calorie foods by consumers?

5 What opportunities exist for the development of healthier foods/diets and what research might best support the development of healthier foods?

6 Based on the scientific evidence available today, what are the most important things that FDA could do that would make a significant difference in efforts to address the problem of overweight and obesity?

On November 20, 2003, The Food and Drug Administration (FDA) and Office of the Assistant Secretary of Planning and Evaluation of the Department of Health and Human Services, are sponsoring “Exploring the Link Between Weight Management and Food Labels and Packaging” on Thursday, November 20, 2003, a scientific workshop to collect data relevant to FDA efforts to help consumers make better-informed weight management decisions. This workshop was established to enable FDA’s Obesity Working Group to build on the information presented at the October 23, 2003 public meeting. Experts were asked to provide new scientific and economic data on how to communicate more effectively important messages to consumers about managing weight and achieving better nutrition through dietary choices. The following key questions were addressed:

1) What are the messages, suggested by the available data, that are likely to affect weight gain, weight management, or weight loss?

2) How might those messages be communicated through labeling?

3) What are the pros and cons of communicating, through labeling, the messages that the data suggest?

Currently there are no summary statements from the meeting but individual comments can be viewed on the FDA website.

Federal Trade Commission ⁵¹⁴

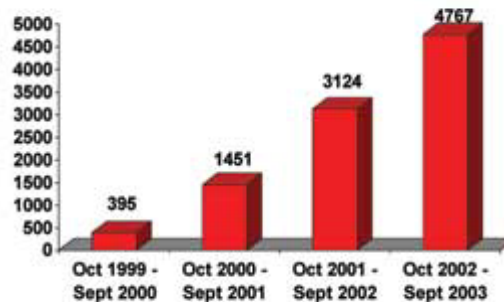
In December 2003, the FTC issued a statement encouraging the FDA to improve the guidelines for food labeling in an effort to combat the rise in obesity. They proposed 3 changes to labeling practices that they suggest make it easier for consumers to take advantage of products with fewer calories, more closely approximate the portions that consumers eat and drink, and provide methods to allow comparisons between products.

Media Based Initiatives ⁵¹⁵

Media Coverage:

Since 1999, the International Food Information Council (IFIC) Foundation has tracked the growing media coverage of the obesity issue. The number of stories has escalated from just 395 for the 12-month period ending September 30, 2000, to 4,767 for the 12 months ending September 30, 2003. This increase reflects both an expansion in the volume of coverage as well as in the number of media outlets reporting about obesity. The data come from a sampling of U.S. and English-language international Web-based media outlets and wire reports, and may not constitute the total coverage of overweight and obesity.

Trends in Obesity-Related Media Coverage



Note: Figures represent International Food Information Council Foundation (IFIC) tracking of U.S. and International (English-speaking) wire reports and print articles on the issue and do not necessarily reflect the true number of stories.

Discovery Challenge: National Body Challenge ⁵¹⁶

The Discovery Health Channel is challenging people from across the country to participate in a 12-week nationwide event to lose weight, get fit for free and have the chance to be on TV. It's the Discovery Health National Body Challenge. Participants who weigh in *at Discovery Channel stores* will receive:

- A "Get Fit Kit," which includes a three-month FREE guest membership to Bally Total Fitness®, a diet and fitness journal, special savings to Discovery Channel stores and more!
- A chance to be on TV when the television program, National Body Challenge, premieres on the Discovery Health Channel on April 5, 2004.
- A FREE personal review from a registered dietitian, who will provide participants with a read of their weight and body fat.

- FREE use of a diet and fitness program on the National Body Challenge Web site, along with access to food and activity journals, community boards, nutrition and fitness tips and strategies, and expert advice from nationally recognized weight-loss expert.

Authors note: Web site should be used with caution due to the inaccuracies noted in the recommended goal weights. Some recommendationa produced by this program do not correspond to standard recommended weight loss goals or BMI categories therefore safety checks do not appear to be in place.

Legislative Actions

According to the state legislative action information provided by the CDC, there have been thirty bills proposed that were related to obesity between 2001 and 2003. The status of these bills as of October 2003 were 20 dead, 3 pending and 15 enacted.

A Library of Congress literature review of the 108th Congress found 50 bills that were relevant to the area of obesity. Twenty-seven were classified as introduced in House, seventeen were introduced or reported in Senate, three were engrossed as agreed to or passed by House or Senate, two were placed on calendar in Senate and one was public print.

"Improved Nutrition and Physical Activity Act," or IMPACT Act; a comprehensive bill aimed at reducing obesity, particularly among children and adolescents was passed by the Senate on December 3, 2003. One provision of the legislation is to instruct the Secretary of Health and Human Services to report on what research has been conducted on obesity treatment and prevention, what has been learned from this research, and what future research should be conducted. Corresponding legislation was introduced in the House of Representatives earlier this year. The bill still awaits House debate.

Conclusion of Findings:

Based upon the review of the literature, a concentrated widespread state effort to treat those who are overweight or obese as well as prevent other individuals from gaining excessive weight is a clear and immediate need for Louisiana. Use of lifestyle modification methods consisting of dietary and physical activity counseling and behavior therapy is effective, safe, and recommended for persons across all weight classifications. Use of medications and surgery is effective and recommended for individuals with BMIs of 30 and 35 or greater, respectively. The side effects of these treatments must be weighed against the benefits for each individual. This report provides a variety of detailed recommendations from the literature and from national organizations which should provide the guidance needed to assist the Department of Health and Hospitals, the Louisiana Obesity Council and Task Force, and the Louisiana State Legislature in identifying and implementing the most effective and appropriate interventions to positively impact the residents of Louisiana.

The suggested areas of focus to target obesity in adults include:

- 1) Increasing the public awareness
 1. of the problems with being overweight or obese,
 2. how to determine if they are overweight or obese,
 3. realistic weight loss expectations as well as

4. how to identify effective and appropriate weight loss methods through statewide media campaigns and state funding of educational and treatment programs,
- 2) Improving the provision of weight loss interventions in the primary care setting by
 1. training community care providers on how to incorporate obesity interventions into their practice and
 2. providing appropriate educational materials to supplement individual counseling,
- 3) Consider steps to make obesity treatment, including lifestyle management, a reimbursable medical expense,
- 4) Consider providing educational and counseling programs
 1. in worksites,
 2. community organizations and
 3. churches to broaden the reach of obesity programs.

For adults concentrating on providing better treatments in the medical setting as well as targeting worksites, community organizations and churches would appear to provide the most logical and wide reaching scope. Programs to better train physicians to treat obesity are necessary and new tools have been recently developed. In Louisiana, a study funded by the NIH (the primary care office management of obesity) was successfully completed and demonstrated that obesity treatment could be incorporated in the primary care setting and could be successful in producing weight loss in high risk populations (Low-income, African American females)⁵¹⁷. Use of a proven program such as this as a template to develop more tools for Community Care Providers could be of benefit to the Louisiana Department of Health and Hospitals. Using churches and other community organizations to provide weight management programs also appears to be another method to increase the reach of an obesity management effort. There are still few studies available on effective worksite programs, but having a stronger focus on weight in wellness programs may provide a vehicle to begin to promote effective weight management in the work force. There are a few programs that have been used with churches and a proven program Louisiana program such as those highlighted by the LSU AG Center Portions or Pennington Biomedical Research Center Shop studies may be a useful template to use in worksite, church or organizational programs.

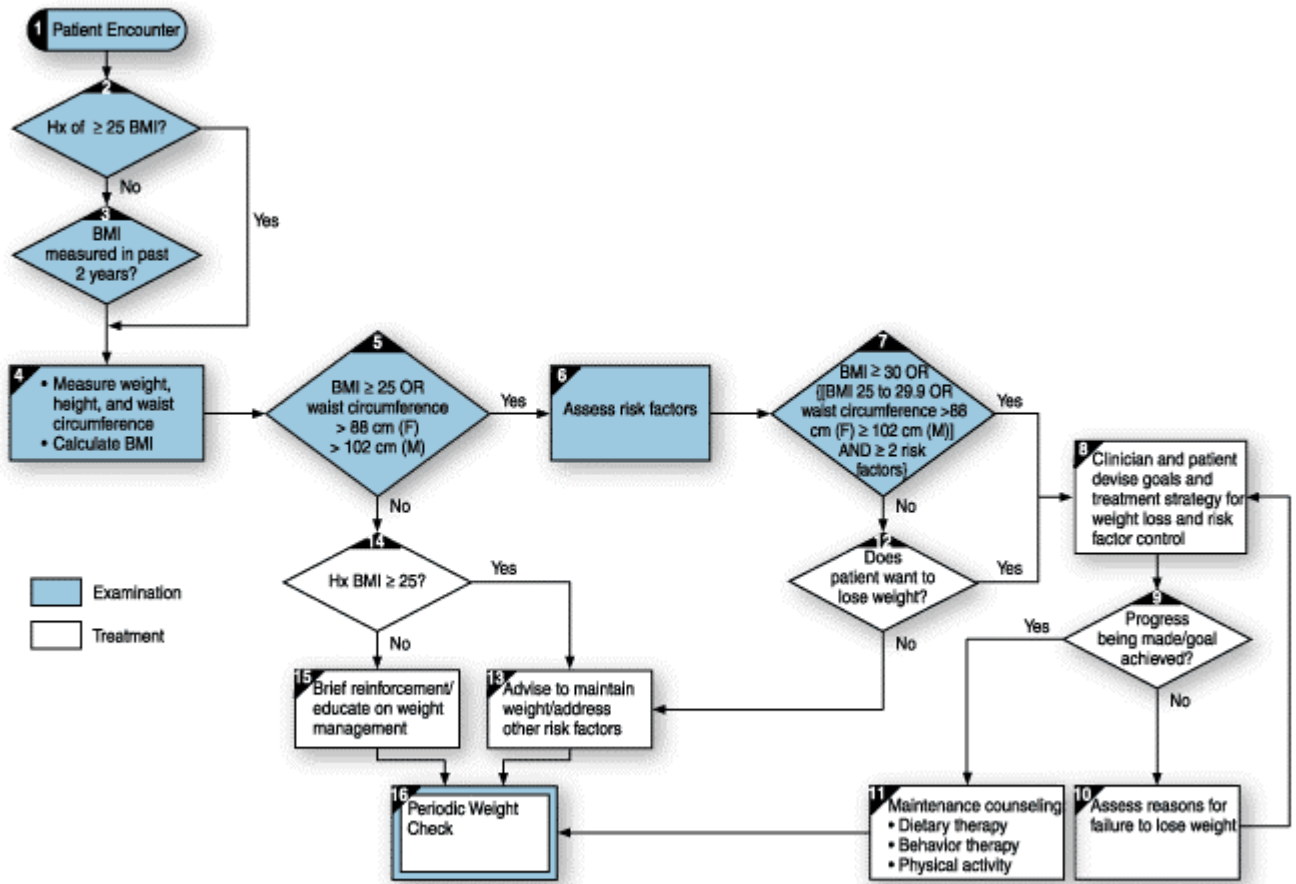
Table 1. Estimated adult obesity-attributable percentages and medical expenditures by state (BRFSS 1998 to 2000)

State	Total population		Medicare population		Medicaid population	
	(%)	(Millions \$)	(%)	(Millions \$)	(%)	(Millions \$)
Alabama	6.3	\$1320	7.7	\$341	9.9	\$269
Alaska	6.7	\$195	7.7	\$17	8.2	\$29
Arizona	4.0	\$752	3.9	\$154	13.5*	\$242
Arkansas	6.0	\$663	7.0	\$171	11.5	\$180
California	5.5	\$7675	6.1	\$1738	10.0	\$1713
Colorado	5.1	\$874	5.1	\$139	8.7	\$158
Connecticut	4.3	\$856	6.5	\$246	11.0	\$419
Delaware	5.1	\$207	9.8	\$57	13.8	\$66
District of Columbia	6.7	\$372	6.5	\$64	12.5	\$114
Florida	5.1	\$3987	6.1	\$1290	11.6	\$900
Georgia	6.0	\$2133	7.1	\$405	10.1	\$385
Hawaii	4.9	\$290	4.8	\$30	11.2	\$90
Idaho	5.3	\$227	5.6	\$40	12.0	\$69
Illinois	6.1	\$3439	7.8	\$805	12.3	\$1045
Indiana	6.0	\$1637	7.2	\$379	15.7	\$522
Iowa	6.0	\$783	7.5	\$165	9.4	\$198
Kansas	5.5	\$657	6.4	\$138	10.2*	\$143
Kentucky	6.2	\$1163	7.5	\$270	11.4	\$340
Louisiana	6.4	\$1373	7.4	\$402	12.9	\$525
Maine	5.6	\$357	5.7	\$66	10.7	\$137
Maryland	6.0	\$1533	7.7	\$368	12.9	\$391
Massachusetts	4.7	\$1822	5.6	\$446	7.8	\$618
Michigan	6.5	\$2931	7.8	\$748	13.2	\$882

Minnesota	5.0	\$1307	6.6	\$227	8.6	\$325
Mississippi	6.5	\$757	8.1	\$223	11.6	\$221
Missouri	6.1	\$1636	7.1	\$413	11.9	\$454
Montana	4.9	\$175	6.2	\$41	9.8	\$48
Nebraska	5.8	\$454	7.0	\$94	10.3	\$114
Nevada	4.8	\$337	5.0	\$74	10.1*	\$56
New Hampshire	5.0	\$302	5.4	\$46	8.6*	\$79
New Jersey	5.5	\$2342	7.1	\$591	9.8	\$630
New Mexico	4.8	\$324	4.6	\$51	8.5	\$84
New York	5.5	\$6080	6.7	\$1391	9.5	\$3539
North Carolina	6.0	\$2138	7.0	\$448	11.5	\$662
North Dakota	6.1	\$209	7.7	\$45	11.7	\$55
Oklahoma	6.0	\$854	7.0	\$227	9.9	\$163
Ohio	6.1	\$3304	7.7	\$839	10.3	\$914
Oregon	5.7	\$781	6.0	\$145	8.8	\$180
Pennsylvania	6.2	\$4138	7.4	\$1187	11.6	\$1219
Puerto Rico	7.4		8.1		10.1	
Rhode Island	5.2	\$305	6.5	\$83	7.7	\$89
South Carolina	6.2	\$1060	7.7	\$242	10.6	\$285
South Dakota	5.3	\$195	5.9	\$36	9.9	\$45
Tennessee	6.4	\$1840	7.6	\$433	10.5	\$488

Appendix A

NHLBI Treatment Algorithm



* This algorithm applies only to the assessment for overweight and obesity and subsequent decisions based on that assessment. It does not include any initial overall assessment for cardiovascular risk factors or diseases that are indicated.

1. U.S. Department of Health and Human Services. *The Surgeon General's Call to Action to Prevent and Decrease Overweight and Obesity*. Rockville, MD: U.S. Department of Health and Human Services, Public Health Services, Office of the Surgeon General; 2001.
2. National Heart Lung and Blood Institute. Clinical Guidelines on the Identification, Evaluation, and Treatment of Overweight and Obesity in Adults: The Evidence Report. *Obes Res*. Vol 6; 1998:51S-209S.
3. Centers for Disease Control and Prevention. The Burden of Chronic Diseases and Their Risk Factors: National and State Perspectives. *US Department of Health and Human Services*. 2002.
4. Flegal KM, Carroll MD, Ogden CL, Johnson CL. Prevalence and Trends in Obesity among Us Adults, 1999-2000. *Jama*. 2000;288(14):1723-1727.
5. National Center for Chronic Disease Prevention and Health Promotion. Behavioral Risk Factor Surveillance System. *National Center for Chronic Disease Prevention and Health Promotion*. Available at: http://www.cdc.gov/BRFSS/technical_infodata/surveydata/2001.htm.
6. Brantley PJ, Scarinci, I.C., Carmack, C.L., Boudreaux, E., Streiffer, R.H., Rees, A.C., et al. Prevalence of High Risk Behaviors and Obesity among Low-Income Patients Attending Primary Care Clinics in Louisiana. *J Louisiana State Med Soc*. 1999;121:126-135.
7. Mokdad AH, Marks JS, Stroup DF, Gerberding JL. Actual Causes of Death in the United States, 2000. *Jama*. 2004;291(10):1238-1244.
8. National Institutes of Health. *Third Report of the National Cholesterol Education Program Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel III)*. Bethesda, MD: National Institutes of Health; 2001. NIH publication 01-3670.
9. Peters JC. Combating Obesity: Challenges and Choices. *Obes Res*. Oct 2003;11 Suppl:7S-11S.
10. MacMahon SW, Blacket RB, Macdonald GJ, Hall W. Obesity, Alcohol Consumption and Blood Pressure in Australian Men and Women. The National Foundation of Australia Risk Factor Prevalence Study. *J Hypertens*. 1984;2:85-91.
11. Huang MH, Yang RC, Hu SH. Preliminary Results of Triple Therapy for Obesity. *Int J Obes*. 1996;20:830-836.
12. Brown R, Sothorn M, Suskind R, Udall J, Blecker U. Racial Differences in the Lipid Profiles of Obese Children and Adolescents before and after Significant Weight Loss. *Clin Pediatr*. 2000;39(7):427-431.
13. Harris MI, Flegal KM, Cowie CC, et al. Prevalence of Diabetes, Impaired Fasting Glucose, and Impaired Glucose Tolerance in U.S. Adults. The Third National Health and Nutrition Examination Survey, 1988-1994. *Diabetes Care*. 1998;21(4):518-524.
14. National Task Force on the Prevention and Treatment of Obesity. Overweight, Obesity, and Health Risk. *Arch Int Med*. 2000;160:898-904.
15. Colditz G, Willett, W.C., Ronitzky, A., Manson, J.E. Weight Gain as a Risk Factor for Clinical Diabetes Mellitus in Women. *Arch Int Med*. 1995;122:481-486.
16. Wolf AM, Colditz, G.A. Current Estimates of the Economic Cost of Obesity in the United States. *Obes Res*. 1998;6:97-106.
17. Thompson D, Edelberg J, Colditz GA, Bird AP, Oster G. Lifetime Health and Economic Consequences of Obesity. *Arch Int Med*. 1999;159(18):2177-2183.
18. Oster G, Edelsberg J, O'Sullivan AK, Thompson D. The Clinical and Economic Burden of Obesity in a Managed Care Setting. *Am J Manag Care*. Jun 2000;6(6):681-689.

19. American Obesity Association. Disability Due to Obesity. *American Obesity Association*. Available at: <http://www.obesity.org/subs/disability/>.
20. Brantley P, Kumar S, Ryan D, Martin PD. *Assessing and Evaluating the Economic Burden of Preventable Chronic Diseases within the Louisiana Medicaid System*. Baton Rouge, LA: Department of Health and Hospitals; 1996.
21. Finkelstein E, Fiebelkorn I, Wang G. State-Level Estimates of Annual Medical Expenditures Attributable to Obesity. *Obes Res*. 2004;12(1):18-24.
22. Louisiana Department of Health and Hospitals. *Report of Findings: LA DHH Ad Hoc Committee on Obesity*. 1999.
23. Chagnon P, & Bouchard. The Human Obesity Gene Map: The 1997 Update. *Obes Res*. 1998;6(1):76-92.
24. Allison DB, Fontaine KR, Heshka S, Mentore JL, Heymsfield SB. Alternative Treatments for Weight Loss: A Critical Review. *Crit Rev Food Sci Nutr*. Vol 41; 2001:1-28; discussion 39-40.
25. Battle EK, Brownell KD. Confronting a Rising Tide of Eating Disorders and Obesity: Treatment Vs. Prevention and Policy. *Addict Behav*. Vol 21; 1996:755-765.
26. Price A. Genetics of Human Obesity. *Ann Behav Med*. 1987;9(1):9-14.
27. Eggers G, Swinburn B. An "Ecological" Approach to the Obesity Pandemic. *BMJ*. 1997;315:477-480.
28. Goldfield GS, Raynor, H. A., & Epstein, L. H. Treatment of Pediatric Obesity. In: Wadden TA, Stunkard AJ, eds. *Handbook of Obesity Treatment*. New York: The Guilford Press; 2002.
29. Tataranni PA, & Rauvussin, E. Energy Metabolism and Obesity. In: Wadden TA, Stunkard AJ, eds. *Handbook of Obesity Treatment*. New York: The Guilford Press; 2002:42-72.
30. Wing R. Behavioral Weight Control. In: Wadden TA, Stunkard AJ, eds. *Handbook of Obesity Treatment*. New York: The Guilford Press; 2002:301-316.
31. Seigel PZ, Frazier EL, Mariolis P, Brackbill RM, Smith C. Behavioral Risk Factor Surveillance, 1991: Monitoring Progress toward the Nation's Year 2000 Health Objectives. *MMWR*. 1993;42(4):1-21.
32. Brantley PJ, Carmack CL, Boudreaux E, Scarcini I. *High Risk Behaviors in Low-Income Primary Care Patients in Louisiana. Report Presented to the Louisiana Legislature*. Baton Rouge, LA 1996.
33. U.S. Department of Health and Human Services. *Healthy People 2000: National Health Promotion and Disease Prevention Objectives*. Boston: Jones and Bartlett Publishers.; 1992.
34. Bray GA. *An Atlas of Obesity and Weight Control*. Boca Raton, FL: The Parthenon Publishing Group; 2003.
35. National Institutes of Health. *The Practical Guide to the Identification, Evaluation, and Treatment of Overweight and Obesity in Adults*. Bethesda, MD: National Institutes of Health; 2000. NIH Publication No. 00-4084.
36. National Center for Health Statistics. *Births, Marriages, Divorces and Deaths for June, 1993*. Hyattsville: Public Health Service.; 1993.
37. U.S. Department of Health and Human Services. Estimated National Spending on Prevention-- United States, 1988. *MMWR*. 1992;41(29):528-531.
38. Oster G, Thompson D. Estimated Effects of Reducing Dietary Saturated Fat Intake on the Incidence and Costs of Coronary Heart Disease in the United States. *J Am Diet Assoc*. 1996;96(2):127-131.

39. U.S. Department of Health and Human Services. Trends in Cancer Screening--United States, 1987 and 1992. *MMWR*. 1995;45(3):57-61.
40. Rogers MAM, Simon DG, Zucker LB, Mackessy JS, Newman-Palmer NB. Indicators of Poor Dietary Habits in a High Risk Population. *J Am Coll Nutr*. 1995;14(2):159-164.
41. Serdula MK, Coates RJ, Byers T, Simoes E, Mokdad AH, Subar AF. Fruit and Vegetable Intake among Adults in 16 States: Results of a Brief Telephone Survey. *Am J Public Health*. 1995;85(2):236-239.
42. Wadden TA, Sternberg JA, Letizia KA, Stunkard AJ, Foster GD. Treatment of Obesity by Very Low Calorie Diet, Behavior Therapy, and Their Combination: A Five-Year Perspective. *Int J Obes*. 1989;13(2 Suppl):39-46.
43. Atkinson R. Role of Nutrition Planning in the Treatment for Obesity. *Endocrinol Metab Clin North Am*. 1996;25:955-964.
44. Skender ML, Goodrick GK, Del Junco DJ, et al. Comparison of 2-Year Weight Loss Trends in Behavioral Treatments of Obesity: Diet, Exercise, and Combination Interventions. *J Am Diet Assoc*. 1996;96(4):342-346.
45. Miller WC, Koceja DM, Hamilton EJ. A Meta-Analysis of the Past 25 Years of Weight Loss Research Using Diet, Exercise or Diet Plus Exercise Intervention. *Int J Obes*. 1997;21:941-947.
46. Melanson K, Dwyer J. Popular Diets for Treatment of Overweight and Obesity. In: Wadden TA, Stunkard AJ, eds. *Handbook of Obesity Treatment*. New York: The Guilford Press; 2002:249-282.
47. Fitzgibbon ML, Stolley, M. R., & Kirschenbaum, D. S. An Obesity Prevention Pilot Program for African-American Mothers and Daughters. *J Nutr Educ*. 1995;27:93-99.
48. Luepker RV, Rastam L, Hannan PJ, et al. Community Education for Cardiovascular Disease Prevention: Morbidity and Mortality Results from the Minnesota Heart Health Program. *Am J Epidemiol*. Vol 144; 1996:351-362.
49. Perry CL, Luepker RV, Murray DM, et al. Parents' Involvement with Children's Health Promotion: A One-Year Follow-up of the Minnesota Home Team. *Health Educ Q*. Vol 16; 1989:171-180.
50. National Institutes of Health. *The Practical Guide to the Identification, Evaluation, and Treatment of Overweight and Obesity in Adults*. Bethesda, MD: National Institutes of Health; 2000. NIH Publication No. 00-4084.
51. Ayyad C, Andersen T. Long-Term Efficacy of Dietary Treatment of Obesity: A Systematic Review of Studies Published between 1931 and 1999. *Obes Rev*. 2000;1(2):113-119.
52. Bray GA, & Popkin, B.M. Dietary Fat Intake Does Affect Obesity. *Am J Clin Nutr*. 1998;68:1157-1173.
53. Bolton-Smith C. Intake of Sugars in Relation to Fatness and Micronutrient Adequacy. *Int J Obes Relat Metab Disord*. 1996;20(suppl2):s31-33.
54. Katz DA. *Nutrition in Clinical Practice*. Philadelphia, PA: Lippincott Williams & Wilkins; 2001.
55. Grodstein F, Levine R, Troy L, Spencer T, Colditz GA, Stampfer MJ. Three-Year Follow-up of Participants in a Commercial Weight Loss Program: Can You Keep It Off? *Arch Int Med*. 1996;156:1302-1306.
56. Ludwig DS, Majzoub, J., Al-Zahrani, A., et al. High Glycemic Index Foods, Overeating, and Obesity. *Pediatrics*. Vol 103; 1999:656.
57. Roberts SB. Glycemic Index and Satiety. *Nutr Clin Care*. 2003;6(1):20-26.
58. Raben A. Should Obese Patients Be Counseled to Follow a Low-Glycemic Diet? No. *Obes Rev*. 2002;3(4):245-256.

59. Bravata DM, Sanders L, Huang J, et al. Efficacy and Safety of Low-Carbohydrate Diets: A Systematic Review. *Jama*. 2003;289(14):1837-1850.
60. Heber D. Meal Replacements in the Treatment of Obesity. In: Fairburn CG, Brownell KD, eds. *Eating Disorders and Obesity: A Comprehensive Handbook*. 2nd ed. New York: The Guilford Press; 2002:529-533.
61. Henkin Y, Garber, D., Osterlund, L. & Darnell, B. Saturated Fats, Cholesterol and Dietary Compliance. *Arch Int Med*. 1992;152:1139.
62. Metz JA, Kris-Etherton PM, Morris CD, et al. Dietary Compliance and Cardiovascular Risk Reduction with a Prepared Meal Plan Compared with a Self-Selected Diet. *Am J Clin Nutr*. Vol 66; 1997:373-385.
63. Centers for Disease Control. *1994 Behavioral Risk Factor Questionnaire*. Atlanta: CDC; 1994.
64. Jeffery RW, Hellerstedt WL, French SA, Baxter JE. A Randomized Trial of Counseling for Fat Restriction Versus Calorie Restriction in the Treatment of Obesity. *Int J Obes*. 1995;19:132-137.
65. Barnard ND, Akhtar A, Nicholson A. Factors That Facilitate Compliance to Lower Fat Intake. *Arch Fam Med*. 1995;4:153-158.
66. Geiselman PJ, & Novin, D. The Role of Carbohydrates in Appetite, Hunger and Obesity. *Appetite*. 1982;3:203-223.
67. Kissileff HR. Satiating Efficiency and Strategy for Conducting Food Loading Experiments. *Neurosci Biobehav Rev*. 1984;8:129-135.
68. Geiselman PJ. Carbohydrates Do Not Always Produce Satiety: An Explanation of the Appetite- and Hunger-Stimulating Effects of Hexos. In: Epstein AN, Morrison A, eds. *Progress in Psychobiology and Physiological Psychology*. New York: Academic Press; 1987:1-46.
69. World Health Organization. Obesity: Preventing and Managing the Global Epidemic. *The WHO Consultation on Obesity, Geneva, Switzerland*. 1997.
70. Raynor H, Kilanowski, C., Esterlise, I., & Epstein, L. The Cost-Analysis of Adopting Healthful Diet in a Family Based Obesity Treatment Program. *J Am Diet Assoc*. 2002;102(5):645-655.
71. Cade J, Upmeier H, Clvert C, Greenwood D. Costs of a Healthful Diet: Analysis from the UK Women's Cohort Study. *Public Health Nutr*. 1999;2:505-512.
72. Stender S, Skovby F, Haraldsdottir J, Andresen G, Michaelson K, Nielson B, Ygil K. Cholesterol-Lowing Diets May Increase the Food Costs for Danish Children. A Cross-Sectional Study of Food Costs for Danish Children with and without Familial Hypercholesterolemia. *Eur J Clin Nutr*. 1993;47:776-786.
73. Mitchell D, Shannon, B., McKenzie, J., Smiciklas-Wright, H., Miller, B., Tershakovec, A. Lower Fat Diets for Children Did Not Increase Food Costs. *J Nutr Educ*. 2000;32:100-103.
74. Wadden TA, & Osei, S. Behavioral Assessment of the Obese Patient. In: Wadden TA, Stunkard AJ, eds. *Handbook of Obesity Treatment*. New York: The Guilford Press; 2002:242-248.
75. Department of Health and Human Services. *Diet Composition and Energy Balance*. Bethesda, MD: Department of Health and Human Services; 2003. PA-04-033.
76. Yao M, Roberts SB. Dietary Energy Density and Weight Regulation. *Nutr Rev*. 2001;59(8):247-259.
77. Anderson DA, Wadden TA. Treating the Obese Patient. Suggestions for Primary Care Practice. *Arch Fam Med*. Mar-Apr 1999;8(2):156-167.

78. DiPietro L, Kohl H, Barlow CE, Blair SN. Improvements in Cardiorespiratory Fitness Attenuate Age-Related Weight Gain in Healthy Men and Women: The Aerobics Center Longitudinal Study. *Int J Obes*. 1988;22:55-62.
79. Dietz WH. The Obesity Epidemic in Young Children. Reduce Television Viewing and Promote Playing. *BMJ*. 2001;322:313-314.
80. Dowda M, Ainsworth BE, Addy CL, Saunders R, Riner W. Environmental Influences, Physical Activity, and Weight Status in 8- to 16-Year-Olds. *Arch Pediatr Adolesc Med*. 2001;155(6):711-717.
81. French SA, Story M, Jeffery RW. Environmental Influences on Eating and Physical Activity. *Annu Rev Public Health*. 2001;22:309-335.
82. Hill J, Peters, J. Environmental Contributions to the Obesity Epidemic. *Science*. 1998;280:1371-1374.
83. U. S. Department of Health and Human Services. *Physical Activity and Health: A Report of the Surgeon General*. Atlanta, Georgia: Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, The President's Council on Physical Fitness and Sports; 1996.
84. West Virginia Bureau of Public Health. *Physical Activity and Health: A Report of the Surgeon General*.: Healthy People 2010: Physical Activity and Health Objectives; 1996.
85. Hoffman C, Rice D, Sung HY. Persons with Chronic Conditions: Their Prevalence and Costs. *Jama*. 1996;276:1473-1479.
86. Chakravarthy MU, Joyner MJ, Booth FW. An Obligation for Primary Care Physicians to Prescribe Physical Activity to Sedentary Patients to Reduce the Risk of Chronic Health Conditions. *Mayo Clin Proc*. 2002;77:165-173.
87. Fuscaldo JM. Prescribing Physical Activity in Primary Care. *WV Med Journal*. 2002;98:250-253.
88. Booth FW, Gordon SE, Carlson CJ, Hamilton MT. Waging War on Modern Chronic Diseases: Primary Prevention through Exercise Biology. *J Appl Physiol*. 2000;88:774-787.
89. Centers for Disease Control and Prevention. *Physical Activity and Health: A Report of the Surgeon General*. Atlanta, GA: U. S. Department of Health and Human Services; 1996.
90. U.S. Preventive Services Task Force (USPSTF). Guide to Clinical Preventive Services: Report of the U.S. Preventive Task Force, 2nd Edition. Baltimore, MD; 1996.
91. Rippe JM, Hess S. The Role of Physical Activity in the Prevention and Management of Obesity. *J Am Diet Assoc*. 1998;10(Supplement 2):S31-S38.
92. Stefanick ML. Exercise and Weight Control. *Exerc Sport Sci Rev*. 1993;21:363-396.
93. Wilmore JH. Body Composition in Sports and Exercise: Directions for Future Research. *Med Sci Sports Exerc*. 1983;15:21-31.
94. Rippe JM, Price J, Hess S, et al. Improved Psychological Well Being, Quality of Life and Health Practices in Moderately Overweight Women Participating in a 12 Week Structured Weight Loss Program. *Obes Res*. 1998;6:208-218.
95. Sullivan MB, Sullivan LG, Kral JG. Quality of Life Assessment in Obesity; Physical, Psychological and Social Function. *Gastroenterol Clin North Am*. 1987;16:433-442.
96. Blair SN, Kohl HW, Paffenbarger RS, Clark DG, Cooper KH, Gibbons LW. Physical Fitness and All-Cause Mortality. A Prospective Study of Healthy Men and Women. *Jama*. 1989;262:2395-2401.
97. Blix GG, Blix AG. The Role of Exercise in Weight Loss. *Behav Med*. 1995;21(1):31-40.
98. Garrow JS, Summerbell CD. Meta-Analysis: Effect of Exercise, with or without Dieting, on Body Composition of Overweight Subjects. *Eur J Clin Nutr*. 1995;49:1-10.

99. Schmitz KH, Jacobs Jr. DR, Leon AS, Schreiner PJ, Sternfeld B. Physical Activity and Body Weight: Associations over Ten Years in the Cardia Study. *Int J Obes.* 2000;24:1475-1487.
100. Thorogood M. Combining Diet with Physical Activity in the Treatment of Obesity. *J Hum Nutr Diet.* 1998;11:239-242.
101. Pavlou KN, Krey S, Steffee WP. Exercise as an Adjunct to Weight Loss and Maintenance in Moderately Obese Subjects. *Am J Clin Nutr.* 1989;49:1115-1123.
102. Klem ML, Wing RR, McGuire MT, Seagle HM, Hill J. A Descriptive Study of Individuals Successful at Long-Term Maintenance of Substantial Weight Loss. *Am J Clin Nutr.* 1997;66:239-246.
103. Safer DJ. Diet, Behavior Modification, and Exercise: A Review of Obesity Treatments from a Long-Term Perspective. *South Med J.* 1991;84:1470-1474.
104. Cowburn G, Hillsdon M, Hankey CR. Obesity Management by Lifestyle Strategies. *Br Med Bull.* 1997;53(2):389-408.
105. Blair SN. Evidence for Success of Exercise in Weight Loss and Control. *Ann Int Med.* 1993;199(7 (part 2)):702-706.
106. NHS Centre for Reviews and Dissemination. The Prevention and Treatment of Obesity. *Eff Health Care.* 1997;3(2):1-12.
107. Jakicic JM, Marcus BH, Gallagher KI, Napolitano M, Lang W. Effect of Exercise Duration and Intensity on Weight Loss in Overweight, Sedentary Women: A Randomized Trial. *Jama.* 2003;290(10):1323-1330.
108. Donnelly JE, Jacobsen DJ, Heelan KS, Seip R, Smith S. The Effects of 18 Months of Intermittent Vs Continuous Exercise on Aerobic Capacity, Body Weight and Composition, and Metabolic Fitness in Previously Sedentary, Moderately Obese Females. *Int J Obes.* 2000;24:566-572.
109. King AC, Tribble DL. The Role of Exercise in Weight Regulation in Nonathletes. *Sports Med.* 1991;11:331-349.
110. Ross R, Dagnone D, Jones PJH, et al. Reduction in Obesity and Related Comorbid Conditions after Diet-Induced Weight Loss or Exercise-Induced Weight Loss in Men. *Ann Int Med.* 2000;133(2):92-103.
111. Perri MG, Martin AD, Leermakers EA, Sears SF, Notelovitz M. Effects of Group- Versus Home-Based Exercise in the Treatment of Obesity. *J Consult Clin Psychol.* Vol 65; 1997:278-285.
112. Jakicic J, Wing, R. Butler BA, Jeffery RW. Relationship between Presence of Exercise Equipment in the Home and Physical Activity Level. *Am J Health Promot.* 1997;11(5):363-365.
113. Mattsson E, Larsson UE, Rossner S. Is Walking for Exercise Too Exhausting for Obese Women? *Int J Obes.* 1997;21:380-386.
114. Foreyt JP, Poston WSC. The Challenge of Diet, Exercise and Lifestyle Modification in the Management of the Obese Diabetic Patient. *Int J Obes.* 1999;23(Supplement 7):S5-S11.
115. Ball K, Crawford D, Owen N. Too Fat to Exercise? Obesity as a Barrier to Physical Activity. *Aust N Z J Public Health.* 2000;24(3):331-333.
116. Munro J, Brazier J, Davey R, Nicholl J. Physical Activity for the over-65s: Could It Be Cost-Effective Exercise for the NHS? *J Public Health Med.* 1997;19(4):397-402.
117. Ferster C, Nurberger, J, Levitt E. The Control of Eating. *J Mathematics.* 1962;1:87-109.
118. Jeffery RW, Forester JL, French SA, et al. The Healthy Worker Project: A Work-Site Intervention for Weight Control and Smoking Cessation. *Am J Public Health.* 1993;83:395-401.

119. Wadden TA, Sarwer DB, Berkowitz RI. Behavioural Treatment of the Overweight Patient. *Baillieres Best Pract Res Clin Endocrinol Metab.* 1999;13(1):93-107.
120. Poston WSC, Hyder ML, O'Byrne KK, Foreyt JP. Where Do Diets, Exercise, and Behavior Modification Fit in the Treatment of Obesity? *Endocrine.* 2000;13(2):187-192.
121. Foreyt JP, Poston WSC. The Role of the Behavioral Counselor in Obesity Treatment. *J Am Diet Assoc.* 1998;10(Supplement 2):S27-S30.
122. Foreyt JP, Poston WSC. What Is the Role of Cognitive-Behavior Therapy in Patient Management? *Obes Res.* 1998;6(Supplement 1):18S-22S.
123. Foster GD, Wadden TA, Vogt RA, Brewer G. What Is a Reasonable Weight Loss? Patients' Expectations and Evaluations of Obesity Treatment Outcomes. *J Consult Clin Psychol.* 1997;65:79-85.
124. Nutzinger DO, Cayiroglu S, Sachs G, Zapotoczky HG. Emotional Problems During Weight Reduction: Advantages of a Combined Behavior Therapy and Antidepressive Drug Therapy for Obesity. *J Behav Ther Exp Psychiatry.* 1985;16(3):217-221.
125. Brownell KD, Kramer FM. Behavioral Management of Obesity. *Med Clin North Am.* Vol 73; 1989:185-201.
126. Foreyt JP, Goodrick GK. Impact of Behavior Therapy on Weight Loss. *Am J Health Promot.* 1994;8(6):466-468.
127. Stuart RB. Behavioral Control of Overeating. *Behav Res & Therapy.* 1967;5(4):357-365.
128. Brownell KD, Jeffery RW. Improving Long-Term Weight Loss: Pushing the Limits of Treatment. *Behav Ther.* 1987;18:353-374.
129. Foreyt JP, Goodrick GK. Evidence for Success of Behavior Modification in Weight Loss and Control. *Ann Int Med.* 1993;119(7 Pt 2):698-701.
130. Williamson DA, Perrin LA. Behavioral Therapy for Obesity. *Endocrinol Metab Clin North Am.* 1996;25:943-954.
131. Perri MG. Obese Populations. In: Burke LE, Ockene IS, eds. *Compliance in Healthcare and Research.* Armonk, NY: Futura Publishing Company; 2001:219-233.
132. Renjilian DA, Perri MG, Nezu AM, McKelvey WF, Shermer RL, Anton SD. Individual Versus Group Therapy for Obesity: Effects of Matching Participants to Their Treatment Preferences. *J Consult Clin Psychol.* 2001;69(4):717-721.
133. Perri MG, McAllister DA, Gange JJ, Jordan RC, McAdoo WG, Nezu AM. Effects of Four Maintenance Programs on the Long-Term Management of Obesity. *J Consult Clin Psychol.* 1988;56:529-534.
134. Wing RR, Marcus MD, Salata R, Epstein LH, Miaskiewicz S, Blair EH. Effects of a Very-Low-Calorie Diet on Long-Term Glycemic Control in Obese Type 2 Diabetic Subjects. *Arch Int Med.* 1991;151:1334-1340.
135. Brownell KD, Wadden TA. Etiology and Treatment of Obesity: Understanding a Serious, Prevalent, and Refractory Disorder. *J Consult Clin Psychol.* 1992;60(4):505-517.
136. Wing RR. Behavioral Treatment of Severe Obesity. *Am J Clin Nutr.* 1992;55(2 Suppl):545S-551S.
137. Wing RR. Behavioral Treatment of Obesity: Its Application to Type II Diabetes. *Diabetes Care.* 1993;16(1):193-199.
138. Foster GD, Kendall PC. The Realistic Treatment of Obesity: Changing the Scales of Success. *Clin Psych Rev.* 1994;14(8):701-736.
139. Devlin MJ, Yanovski SZ, Wilson GT. Obesity: What Mental Health Professionals Need to Know. *Am J Psychiatry.* 2000;157(6):854-866.
140. Perri MJ, Nezu AM, Patti ET, McCann KL. Effect of Length of Treatment on Weight Loss. *J Consult Clin Psychol.* Vol 37; 1989:450-452.

141. Corsica JA, Perri MG. Obesity. In: Nezu AM, Nezu CM, eds. *Handbook of Psychology: Health Psychology*. Vol 9. New York: John Wiley & Sons, Inc.; 2003:121-145.
142. Wing RR, Greeno CG. Behavioural and Psychosocial Aspects of Obesity and Its Treatment. *Best Pract Res Clin Endocrinol Metab*. Vol 8; 1994:689-703.
143. Perri MG, McAdoo WG, Spevak PA, Newlin D. Effect of a Multicomponent Maintenance Program on Long-Term Weight Loss. *J Consult Clin Psychol*. 1984;52:480-481.
144. Perri MG, McAdoo WG, McAllister DA, Lauer JB, Yancey DZ. Enhancing the Efficacy of Behavior Therapy for Obesity: Effects of Aerobic Exercise and Multicomponent Maintenance Program. *J Consult Clin Psychol*. 1986;54:670-675.
145. Brownell KD. Diet, Exercise, and Behavioural Interventions: The Nonpharmacological Approach. *Eur J Clin Invest*. 1998;28(Supplement 2):19-22.
146. Consumer Reports. *Rating the Diets*. Consumer Reports; June 1993.
147. Stuart RB, Guire K. Some Correlates of the Maintenance of Weight Loss through Behavior Modification. *Int J Obes*. 1978;2:225-235.
148. Wadden TA, Stunkard AJ. Controlled Trial of Very Low Calorie Diet, Behavior Therapy, and Their Combination in the Treatment of Obesity. *J Consult Clin Psychol*. 1986;54(4):482-488.
149. Bjorvell H, Rossner S. Short Communication: A Ten-Year Follow-up of Weight Change in Severely Obese Subjects Treated in a Combined Behavioral Modification Programme. *Int J Obes*. 1992;16:623-625.
150. Craighead LW, Stunkard AJ, O'Brien RM. Behavior Therapy and Pharmacotherapy for Obesity. *Arch Gen Psychiatry*. 1981;38:763-768.
151. Craighead LW, Agras WS. Mechanisms of Action Cognitive-Behavioral and Pharmacological Interventions for Obesity and Bulimia Nervosa. *J Consult Clin Psychol*. 1991;59(1):115-125.
152. Wadden TA, Berkowitz RI, Vogt RA, Steen SN, Stunkard AJ, Foster GD. Lifestyle Modification in the Pharmacological Treatment of Obesity: A Pilot Investigation of a Potential Primary Care Approach. *Obes Res*. 1997;5:218-226.
153. Weintraub M. Long-Term Weight Control (Parts 1-7)-the National Heart Lung and Blood Institute Funded Multimodal Intervention Study. *Clin Pharm*. 1992;51:581-641.
154. Glazer G. Long-Term Pharmacotherapy of Obesity 2000: A Review of Efficacy and Safety. *Arch Int Med*. Aug 13-27 2001;161(15):1814-1824.
155. DeRamos EC. The Use of Diethylpropion in the Treatment of Obesity. *Br J Clin Pract*. 1964;18:210-211.
156. McKay RH. Long-Term Use of Diethylpropion in Obesity. *Curr Med Res Opin*. 1973;1:489-493.
157. Silverstone JT, Solomon T. The Long-Term Management of Obesity in General Practice. *Br J Clin Pract*. 1965;19:395-398.
158. Seaton DA, Duncan LJ, Rose K, Scott AM. Diethylpropion in the Treatment of "Refractory" Obesity. *BMJ*. 1961(April 8):1009-1111.
159. Griffiths RR, Brady JVS, Snell JD. Relationship between Anorectic and Reinforcing Properties of Appetite Suppressant Drugs: Implications for Assessment of Abuse Liability. *Biol Psychiatry*. 1978;13(2):283-290.
160. Enzi G, Baritussio A, Marchiori E, Crepaldi G. Short-Term and Long-Term Clinical Evaluation of a Non-Amphetaminic Anorexiant (Mazindol) in the Treatment of Obesity. *J Int Med Res*. 1976;4:305-318.
161. Inoue S. Clinical Studies with Mazindol. *Obes Res*. 1995;3(Suppl 4):549S-552S.

162. Bradley MH, Blum NJ, Scheib RJ. Mazindol in Obesity with Known Cardiac Disease: A Clinical Evaluation. *J Int Med Res.* 1974;2:347-349.
163. Munro JF, MacCuish AC, Wilson EM, Duncan LJ. Comparison of Continuous and Intermittent Anorectic Therapy in Obesity. *BMJ.* 1968;1:352-354.
164. Campbell CJ, Bhalla IP, Steel JM, Duncan LJP. A Controlled Trial of Phentermine in Obese Diabetic Patients. *Practitioner.* 1977;218:851-855.
165. Weintraub M, Hasday JD, Mushlin AI, Lockwood DH. A Double-Blind Clinical Trial in Weight Control: Use of Fenfluramine and Phentermine Alone and in Combination. *Arch Int Med.* 1984;144:1143-1148.
166. Steel J, Munro J. A Comparative Trial of Different Regimens of Phentermine and Fenfluramine in Obesity. *Practitioner.* 1973;211:232-234.
167. Jones SP, Smith IG, Kelly F, Gray JA. Long-Term Weight Loss with Sibutramine. *Int J Obes Relat Metab Disord.* 1995;19(Supplement 2):41.
168. Apfelbaum M, Vague P, Ziegler O, Hanotin C, Thomas F, Leutenegger E. Long-Term Maintenance of Weight Loss after a Very-Low Calorie Diet: A Randomized Blinded Trial of the Efficacy and Tolerability of Sibutramine. *Am J Med.* 1999;106:179-184.
169. Ryan DH, Kaiser P, Bray GA. Sibutramine: A Novel New Agent for Obesity Treatment. *Obes Res.* 1995;3(Suppl 3):553S-559S.
170. Bray GA, Blackburn GL, Ferguson JM, et al. Sibutramine Produces Dose-Related Weight Loss. *Obes Res.* Mar 1999;7(2):189-198.
171. Bray GA, Ryan DH, Gordon D, Heidingsfelder S, Cerise F, Wilson K. A Double-Blind Randomized Placebo-Controlled Trial of Sibutramine. *Obes Res.* 1996;4(3):263-270.
172. James WP, Astrup A, Finer N, et al. Effect of Sibutramine on Weight Maintenance after Weight Loss: A Randomised Trial. Sibutramine Trial of Obesity Reduction and Maintenance. *Lancet.* 2000;356(9248):2119-2125.
173. Arterburn D, Noel PH. Extracts from 'Clinical Evidence'. *BMJ.* 2001;322(7299):1406-1409.
174. McTigue K, Harris R, Hemphill MB, et al. *Systematic Evidence Review Number 21: Screening and Interventions for Overweight and Obesity in Adults*: U.S. Department of Health and Human Services Agency for Healthcare Research and Quality; December 2003. Contract No. 290-97-0011.
175. Lean ME. Sibutramine-a Review of Clinical Efficacy. *Int J Obes Relat Metab Disord.* 1997;21(Suppl):S30-S36.
176. Haller C, Schwartz JB. Pharmacologic Agents for Weight Reduction. *J Genet Specif Med.* 2002;5(5):16-21.
177. The Health Research Group. Petition to FDA to Ban the Diet Drug Sibutramine (Meridia). *HRG Publication # 1613*. Available at: <http://www.citizen.org/publications/release>. Accessed 11/11/2003, 2003.
178. Reuters Health. Abbott's Reductil [UK Name for Sibutramine] Linked to Two Deaths in Britain. *Reuters Health.* 2002(March 15, 2002).
179. Sjostrom L, Rissanen A, Andersen T, et al. Randomised Placebo-Controlled Trial of Orlistat for Weight Loss and Prevention of Weight Regain in Obese Patients. European Multicentre Orlistat Study Group. *Lancet.* 1998;352(9123):167-172.
180. Davidson MH, Hauptman J, DiGirolamo M, et al. Weight Control and Risk Factor Reduction in Obese Subjects Treated for 2 Years with Orlistat: A Randomized Controlled Trial. *Jama.* 1999;281(3):235-242.

181. Drent ML, Popp-Snijders C, Ader HJ, Jansen JB, van der Veen EA, (1995). Lipase Inhibition and Hormonal Status, Body Composition and Gastrointestinal Processing of a Liquid High-Fat Mixed Meal in Moderately Obese Subjects. *Obes Res.* 1995;3(6):573-581.
182. Hollander PA, Elbien SC, Hirsch IB, et al. Role of Orlistat in the Treatment of Obese Patients with Type 2 Diabetes. A 1-Year Randomized Double-Blind Study. *Diabetes Care.* 1998;21(8):1288-1294.
183. Levine LR, Enas GG, Thompson WL, et al. Use of Fluoxetine, a Selective Serotonin-Uptake Inhibitor, in the Treatment of Obesity: A Dose-Response Study (with a Commentary by Michael Weintraub). *Int J Obes.* 1989;13(5):635-645.
184. Goldstein DJ, Rampey AH, Jr., Roback PJ, et al. Efficacy and Safety of Long-Term Fluoxetine Treatment of Obesity--Maximizing Success. *Obes Res.* Nov 1995;3 Suppl 4:481S-490S.
185. Wadden TA, Bartlett SJ, Foster GD, et al. Sertraline and Relapse Prevention Training Following Treatment by Very- Low-Calorie Diet: A Controlled Clinical Trial. *Obes Res.* 1995;3(6):549-557.
186. Hudson KD. The Anorectic and Hypotensive Effect of Fenfluramine in Obesity. *J R Coll Gen Pract.* 1977;27(181):497-501.
187. Sensi S, Della Loggia F, DelPonte A, Guagnano MT. Long-Term Treatment with Fenfluramine in Obese Subjects. *Int J Clin Pharmacol Res.* 1985;5(4):247-253.
188. Douglas JG, Gough J, Preston PG, et al. Long-Term Efficacy of Fenfluramine in Treatment of Obesity. *Lancet.* 1983;1(8321):384-386.
189. Stunkard AJ, Craighead LW, O'Brien R. Controlled Trial of Behaviour Therapy, Pharmacotherapy, and Their Combination in the Treatment of Obesity. *Lancet.* 1980;2(8203):1045-1047.
190. Guy-Grand B, Apfelbaum M, Crepaldi G, Gries A, Lefebvre P, Turner P. International Study of the Effect of Dexfenfluramine in Obesity (ISIS): 6 Months' Results. *Rev Med Interne.* May-Jun 1989;10(3):271-277.
191. Guy-Grand B, Apfelbaum M, Crepaldi G, Gries A, Lefebvre P, Turner P. International Trial of Long-Term Dexfenfluramine in Obesity. *Lancet.* 1989;2:1142-1145.
192. O'Connor HT, Richman RM, Steinbeck KS, Caterson ID. Dexfenfluramine Treatment of Obesity: A Double Blind Trial with Post Trial Follow Up. *Int J Obes Relat Metab Disord.* Mar 1995;19(3):181-189.
193. Finer N. Body Weight Evolution During Dexfenfluramine Treatment after Initial Weight Control. *Int J Obes Relat Metab Disord.* 1992;16 Suppl 3:S25-29.
194. Mathus-Vliegen EM, van de Voorde K, Kok AM, Res AM. Dexfenfluramine in the Treatment of Severe Obesity: A Placebo-Controlled Investigation of the Effects on Weight Loss, Cardiovascular Risk Factors, Food Intake and Eating Behavior. *J Int Med.* 1992;232(2):119-127.
195. Andersen T, Astrup A, Quaade F. Dexfenfluramine as Adjuvant to a Low-Calorie Formula Diet in the Treatment of Obesity: A Randomized Clinical Trial. *Int J Obes Relat Metab Disord.* 1992;16(1):35-40.
196. Noble RE. A Six-Month Study of the Effects of Dexfenfluramine on Partially Successful Dieters. *Curr Ther Res.* 1990;47(4):612-619.
197. Breum L, Astrup A, Andersen T, et al. The Effect of Long-Term Dexfenfluramine Treatment on 24-Hour Energy Expenditure in a Man. A Double-Blind Placebo Controlled Study. *Int J Obes.* 1990;14(7):613-621.

198. Finer N, Craddock D, Lavielle R, Keen H. Effect of 6 Months Therapy with Dexfenfluramine in Obese Patients: Studies in the United Kingdom. *Clin Neuropharmacol.* 1988;11(Suppl 1):S179-S186.
199. Ricaurte GA, Molliver ME, Martello MB, Katz JL, Wilson MA, Martello AL. Dexfenfluramine Neurotoxicity in Brains of Non-Human Primates. *Lancet.* 1991;338(8781):1487-1488.
200. Abenhaim L, Moride Y, Brenot F, et al. Appetite-Suppressant Drugs and the Risk of Primary Pulmonary Hypertension. International Primary Pulmonary Hypertension Study Group. *N Engl J Med.* 1996;335(9):609-616.
201. Manson JE, Faich GA. Pharmacotherapy for Obesity: Do the Benefits Outweigh the Risks? *N Engl J Med.* 1996;335(9):659-660.
202. Scheen AJ, Lefebvre PJ. Pharmacological Treatment of Obesity: Present Status. *Int J Obes.* 1999;23(Suppl 1):47-53.
203. Atkinson RL, Blank RC, Loper LF, Schumacher D, Lutes RA. Combined Treatment of Obesity. *Obes Res.* 1995;3(Suppl 4):S497-S500.
204. Connolly HM, Crary JL, McGoon MD, et al. Valvular Heart Disease Associated with Fenfluramine-Phentermine. *N Engl J Med.* 1997;337:581-588.
205. Burger AJ, Sherman HB. Low Prevalence of Valvular Heart Disease in 226 Phentermine-Fenfluramine Protocol Subjects Prospectively Followed for 30 Months. *J Am Coll Cardiol.* 1999;34:1159-1162.
206. Kancherla MK, Salti JJ, Mulderink TA, Poike M, Mohlman DJ. Echocardiographic Prevalence of Mitral and/or Aortic Regurgitation in Patients Exposed to Either Fenfluramine-Phentermine Combination or Dexfenfluramine. *Am J Cardiol.* 1999;84:1335-1338.
207. Teramiae CY, Connolly HM, Grogan M, Miller FA. Diet Drug-Related Cardiac Valve Disease: The Mayo Clinic Echocardiographic Laboratory Experience. *Mayo Clin Proc.* 2000;75:456-461.
208. Schteingart DE. Effectiveness of Phenylpropanolamine in the Management of Moderate Obesity. *Int J Obes Relat Metab Disord.* 1992;16(7):487-493.
209. Greenway FL. Clinical Studies with Phenylpropanolamine: A Metaanalysis. *Am J Clin Nutr.* 1992;55(Suppl 1):203S-205S.
210. Kernan WN, Viscoli CM, Brass LM, et al. Phenylpropanolamine and the Risk of Hemorrhagic Stroke. *N Engl J Med.* 2000;343(25):1826-1832.
211. Finer N. Pharmacotherapy of Obesity. *Best Pract Res Clin Endocrin Metab.* 2002;16(4):717-742.
212. Halpern A, Mancini MC. Treatment of Obesity: An Update on Anti-Obesity Medications. *Obes Rev.* 2003;4:25-42.
213. Astrup A, Breum L, Toubro S, Hein P, Quaade F. The Effect and Safety of an Ephedrine/Caffeine Compound Compared to Ephedrine, Caffeine and Placebo in Obese Subjects on an Energy Restricted Diet. A Double Blind Trial. *Int J Obes Relat Metab Disord.* Vol 16; 1992:269-277.
214. Breum L, Pederson JK, Ahlstrom F, Frimodt-Moller J. Comparison of an Ephedrine/Caffeine Combination and Dexfenfluramine in the Treatment of Obesity. A Double-Blind Multi-Centre Trial in General Practice. *Int J Obes.* 1994;18:99-103.
215. Daly P, Krieger DT, Dulloo AG, Young JB, Landsberg L. Ephedrine, Caffeine and Aspirin: Safety and Efficacy for Treatment of Human Obesity. *Int J Obes.* 1993;17(Supplement 1):S73-S78.

216. Toubro S, Astrup AV, Breum L, Quaade F. Safety and Efficacy of Long-Term Treatment with Ephedrine, Caffeine and an Ephedrine/Caffeine Mixture. *Int J Obes Relat Metab Disord*. Feb 1993;17 Suppl 1:S69-72.
217. Poston WSC, Foreyt JP, Borrell L, Haddock CK. Challenges in Obesity Management. *South Med J*. 1998;91(8):710-720.
218. Shekelle P, Morton S, Maglione M, et al. *Ephedra and Ephedrine for Weight Loss and Athletic Performance Enhancement: Clinical Efficacy and Side Effects*. Rockville, MD: RAND: Southern California Evidence-based Practice Center; February 2003 2003. Evidence Report/Technology Assessment No. 76 AHRQ 03-E022.
219. U. S. Food and Drug Administration. *HHS Acts to Reduce Potential Risks of Dietary Supplements Containing Ephedra*: U. S. Food and Drug Administration Department of Health and Human Services; February 28, 2003 2003. PO3-13.
220. U. S. Food and Drug Administration. *Fda Announces Plans to Prohibit Sales of Dietary Supplements Containing Ephedra: Consumers Advised to Stop Using Ephedra Immediately*. Available at: <http://www.fda.gov/oc/initiatives/ephedra/december2003/>.
221. Kumanyika SK. Special Issues Regarding Obesity in Minority Populations. [Review]. *Ann Int Med*. 1993;119(7 Pt 2):650-654.
222. Greenway FL, Ryan DH, Bray GA, Rood JC, Tucker EW, Smith SR. Pharmaceutical Cost Savings of Treating Obesity with Weight Loss Medications. *Obes Res*. 1999;7(6):523-531.
223. Cowan GSM, Miler ML, Buffington C. Criteria for Selection of Patients for Bariatric Surgery. *Eur J Gastroenterol Hepatol*. 1999;11:69-75.
224. Craig J. Bariatric Surgery. An Option for Long-Term Weight Loss. *Diabetes Self Manag*. Sep-Oct 2002;19(5):14, 17-18, 20-11.
225. National Institutes of Health Consensus Development Conference Panel. Gastrointestinal Surgery for Severe Obesity. *Ann Int Med*. 1991;115(12):956-961.
226. International Federation for the Surgery of Obesity. Statement on Morbid Obesity and Its Treatment. *Obes Surg*. 1997;7:40-41.
227. International Federation for the Surgery of Obesity. IFSO Statement on Bariatric Surgeon Qualifications. *Obes Surg*. 1998;8:86.
228. Sjostrom L. Surgical Intervention as a Strategy for Treatment of Obesity. *Endocrine*. Oct 2000;13(2):213-230.
229. Thornley SJ, Windsor JA. The Role of Surgery in the Management of Obesity. *N Z Med J*. 1998;111:445-448.
230. Waitman JA, Aronne LJ. Obesity Surgery: Pros and Cons. *J Endocrinol Invest*. 2002;25:925-928.
231. Prystowsky JB. Surgical Management of Obesity. *Semin Gastrointest Dis*. Vol 13; 2002:133-142.
232. National Institute of Diabetes and Digestive and Kidney Diseases. Gastrointestinal Surgery for Severe Obesity. *National Institute of Diabetes and Digestive and Kidney Diseases*. Available at: www.niddk.nih/health/nutrit/pubs/gastric/gastricsurgery.htm. Accessed 10/24/2003, 2003.
233. National Digestive Disease Information Clearinghouse. Rapid Gastric Emptying. *National Institute of Diabetes and Digestive and Kidney Disease* [website]. Available at: <http://digestive.niddk.nih.gov/ddiseases>. Accessed 10/24/2003, January.
234. Douketis JD, Feightner JW, Attia J, Feldman WF. Periodic Health Examination, 1999 Update: 1. Detection, Prevention and Treatment of Obesity. Canadian Task Force on Preventive Health Care. *Can Med Assoc J*. 1999;160:513-525.

235. NHS Centre for Reviews and Dissemination University of York. The Prevention and Treatment of Obesity. *Eff Health Care*. Vol 3; 1997:1-12.
236. NHLBI Obesity Education Initiative. *Clinical Guidelines on the Identification, Evaluation, and Treatment of Overweight and Obesity in Adults: The Evidence Report*. Bethesda, MD: U.S. Department of Health and Human Services, Public Health Service, National Institutes of Health, National Heart, Lung, and Blood Institute; 1998. NIH Publication No. 98-4083.
237. National Institutes of Health Conference. Methods for Voluntary Weight Loss and Control: NIH Technology Assessment Conference Panel. *Ann Int Med*. 1992;116:942-949.
238. MacLean LD, Rhode BM, Nohr C. Late Outcome of Isolated Gastric Bypass. *Ann Surg*. 2000;231:524-528.
239. Pories WJ, MacDonald KG, Jr., Morgan EJ, et al. Surgical Treatment of Obesity and Its Effects on Diabetes: 10-Y Follow-Up. *Am J Clin Nutr*. 1992;55(2, supplement):582S-585S.
240. Sugerman HJ. The Epidemic of Severe Obesity: The Value of Surgical Treatment. *Mayo Clin Proc*. 2000;75(7):669-672.
241. Baxter J. Obesity Surgery-Another Unmet Need. *BMJ*. 2000;321:523-524.
242. Svenheden K, Akesson L, Holmdahl C, Naslund I. Staple Disruption in Vertical Banded Gastroplasty. *Obes Surg*. 1997;7:136-138.
243. Juvin P, Marmuse JP, Delorme S, et al. Post-Operative Course after Conventional or Laparoscopic Gastroplasty in Morbidly Obese Patients. *Eur J Anaesthesiol*. 1999;16(6):400-403.
244. Belachew M, Legrand M, Vincent V, Lismonde M, Le Docte N, Deschamps V. Laparoscopic Adjustable Gastric Banding. *World J Surg*. 1998;22(9):955-963.
245. Kothari SN, DeMaria EJ, Sugerman HJ, Kellum JM, Meador J, Wolfe L. Lap-Band Failures: Conversion to Gastric Bypass and Their Preliminary Outcomes. *Surgery*. Vol 131; 2002:625-629.
246. de Wit LT, Mathus-Vliegen L, Hey C, Rademaker B, Gouma DJ, Obertop H. Open Versus Laparoscopic Adjustable Silicone Gastric Banding: A Prospective Randomized Trial for Treatment of Morbid Obesity. *Ann Surg*. 1999;230:800-805.
247. Flancbaum L, Choban PS. Surgical Implications of Obesity. *Ann Rev Med*. 1998;49:215-234.
248. Pories WJ, Swanson MS, McDonald KG, et al. Who Would Have Thought It? An Operation Proved to Be the Most Effective Therapy for Adult Onset Diabetes Mellitus. *Ann Surg*. 1995;222(3):339-350.
249. Sjostrom CD, Peltonen M, Wedel H, Sjostrom L. Differentiated Long-Term Effects of Intentional Weight Loss on Diabetes and Hypertension. *Hypertens*. 2000;36:20-25.
250. Hall JC, Watts JM, O'Brien PE, et al. Gastric Surgery for Morbid Obesity. The Adelaide Study. *Ann Surg*. 1990;211(4):419-427.
251. Sjostrom CD, Lissner L, Wedel H, Sjostrom L. Reduction in Incidence of Diabetes, Hypertension and Lipid Disturbances after Intentional Weight Loss Induced by Bariatric Surgery: The SOS Intervention Study. *Obes Res*. 1999;7(5):477-484.
252. Sugerman HJ. Gastric Bypass Surgery for Severe Obesity. *Semin Laparosc Surg*. Jun 2002;9(2):79-85.
253. Scopinaro N, Adami GF, Marinari GM, et al. Biliopancreatic Diversion. *World J Surg*. 1998;22(9):936-946.
254. Hess DS, Hess DW. Biliopancreatic Diversion with a Duodenal Switch. *Obes Surg*. 1998;8(3):267-282.

255. Carson JL, Ruddy ME, Duff AE, Holmes NJ, Cody RP, Brolin RE. The Effect of Gastric Bypass Surgery on Hypertension in Morbidly Obese Patients. *Arch Int Med*. 1994;154:193-200.
256. Sjostrom L, Narbro K, Sjostrom D. Costs and Benefits When Treating Obesity. *Int J Obes*. 1995;19(Supple 6):S9-S12.
257. Brolin RE, Kenler HA, Wilson AC, Kuo PT, Cody RP. Serum Lipids after Gastric Bypass Surgery for Morbid Obesity. *Int J Obes*. 1990;14:939-950.
258. Smith SC, Edwards CB, Goodman GN. Symptomatic and Clinical Improvement in Morbidly Obese Patients with Gastroesophageal Reflux Disease Following Roux-En-Y Gastric Bypass. *Obes Surg*. Dec 1997;7(6):479-484.
259. Jones KB, Jr. Roux-En-Y Gastric Bypass: An Effective Anti-Reflux Procedure in the Less Than Morbidly Obese. *Obes Surg*. 1998;8:35-38.
260. Charuzi I, Lavie P, Peiser J. Bariatric Surgery in Morbidly Obese Sleep-Apnea Patients: Short and Long-Term Follow-Up. *Am J Clin Nutr*. 1992;55(Suppl):594S-596S.
261. Macgregor AMC, Greenberg RA. Effect of Surgically Induced Weight Loss on Asthma in the Morbidly Obese. *Obes Surg*. 1993;3:15-21.
262. Klem ML, Wing RR, Ho Chang C-C, et al. A Case-Control Study of Successful Maintenance of a Substantial Weight Loss: Individuals Who Lost Weight through Surgery Versus Those Who Lost Weight through Non-Surgical Means. *Int J Obes*. 2000;24:573-579.
263. Rand CSW, Macgregor AMC. Adolescents Having Obesity Surgery: A 6-Year Follow-Up. *South Med J*. 1994;87(12):1208-1213.
264. Strauss RS, Bradley LJ, Brolin RE. Gastric Bypass Surgery in Adolescents with Morbid Obesity. *J Pediatr*. Apr 2001;138(4):499-504.
265. Dolan K, Creighton L, Hopkins G, Fielding G. Laparoscopic Gastric Banding in Morbidly Obese Adolescents. *Obes Surg*. 2003;13:101-104.
266. Sugerman HJ, Sugerman EL, DeMaria EJ, et al. Bariatric Surgery for Severely Obese Adolescents. *J Gastrointest Surg*. Vol 7; 2003:102-107; discussion 107-108.
267. Garcia VF, Langford L, Inge TH. Application of Laparoscopy for Bariatric Surgery in Adolescents. *Curr Opin Pediatr*. Jun 2003;15(3):248-255.
268. Yale CE. Gastric Surgery for Morbid Obesity: Complications and Long-Term Weight Control. *Arch Surg*. 1989;124:941-946.
269. Sugerman HJ, Kellum JM, Engle KM, et al. Gastric Bypass for Treating Severe Obesity. *Am J Clin Nutr*. 1992;55:560S-566S.
270. Sjostrom L, Larsson B, Backman L, et al. Swedish Obese Subjects (SOS). Recruitment for an Intervention Study and a Selected Description of the Obese State. *Int J Obes Relat Metab Disord*. 1992;16:465-479.
271. Agren G, Narbro K, Jonsson E, Naslund I, Sjostrom L, Peltonen M. Cost of in-Patient Care over 7 Years among Surgically and Conventionally Treated Obese Patients. *Obes Res*. Vol 10; 2002:1276-1283.
272. Agren G, Narbro K, Naslund I, Sjostrom L, Peltonen M. Long-Term Effects of Weight Loss on Pharmaceutical Costs in Obese Subjects. A Report from the Sos Intervention Study. *Int J Obes*. 2002;26:184-192.
273. National Institutes of Diabetes and Digestive and Kidney Diseases. *Bariatric Surgery Clinical Research Consortium*. Bethesda, MD: National Institutes of Diabetes and Digestive and Kidney Diseases; November 1, 2002 2002. RFA DK-03-006.

274. Klem ML, Wing RR, McGuire MT, Seagle HM, Hill JO. Psychological Symptoms in Individuals Successful at Long-Term Maintenance of Weight Loss. *Health Psychol.* 1998;17(4):336-345.
275. Allison DB, Fontaine KR, Heshka S, Mentore JL, Heymsfield SB. Alternative Treatments for Weight Loss: A Critical Review. *Crit Rev Food Sci Nutr.* Jan 2001;41(1):1-28; discussion 39-40.
276. Spark A. Health at Any Size: The Size-Acceptance Nondiet Movement. *J Am Med Women's Assoc.* 2001;56:69-71.
277. Carrier KM, Steinhardt MA, Bowman S. Rethinking Traditional Weight Management Programs: A 3-Year Follow-up Evaluation of a New Approach. *J Psychol.* 1994;128:517-535.
278. Steinhardt MA, Bezner JR, Adams TB. Outcomes of a Traditional Weight Control Program and a Nondiet Alternative: A One-Year Comparison. *J Psychol.* 1999;133:495-513.
279. Dunn AL, Marcus BH, Kampert JB, Garcia ME, Kohl HW, Blair SN. Comparison of Lifestyle and Structured Interventions to Increase Physical Activity and Cardiorespiratory Fitness. *Jama.* 1999;281:327-334.
280. Sevick MA, Dunn AL, Morrow MS, Marcus BH, Chen GJ, Blair SN. Cost-Effectiveness of Lifestyle and Structured Exercise Interventions in Sedentary Adults. Results of Project Active. *Am J Prev Med.* 2000;19:1-8.
281. Department of Agriculture. Food and Nutrition Information Center. Available at: www.nal.usda.gov/fnic/etext/000060.html.
282. Stein RJ, O'Byrne KK, Suminski RR, Haddock CK. Etiology and Treatment of Obesity in Adults and Children: Implications for the Addiction Model. *Drugs & Soc.* 1999;15(1/2):103-121.
283. Riva G, Bacchetta M, Baruffi M, Molinari E. Virtual Reality-Based Multidimensional Therapy for the Treatment of Body Image Disturbances in Obesity: A Controlled Study. *Cyberpsychol & Behav.* 2001;4(4):511-526.
284. Thompson JK, Heinberg LJ, Altabe M, Tanleff-Dunn S, eds. *Exacting Beauty: Theory, Assessment, and Treatment of Body Image Disturbance*. Washington, D.C.: American Psychological Association; 1999.
285. Palmer J. Hey, Fatso! Despite a Glut of Diet Foods and Health Clubs, Americans Are Growing Plumper. *Barron's*; 1996:25-28.
286. Volkmar FR, Stunkard AJ, Woolston J, Bailey RA. High Attrition Rates in Commercial Weight Reduction Programs. *Arch Int Med.* 1981;141:426-428.
287. Wombie LG, Wang SS, Wadden TA. Commercial and Self-Help Weight Loss Programs. In: Wadden TA, Stunkard AJ, eds. *Handbook of Obesity Treatment*. New York: The Guilford Press; 2002:395-415.
288. Weight Watchers International. About Weight Watchers. Available at: www.weightwatchers.com.
289. Shape Up America. Guidance for the Treatment of Adult Obesity. *Shape Up America*. Available at: www.shapeup.org.
290. Spielman AB, Kanders B, Keinholz M, Blackburn GL. The Cost of Losing: An Analysis of Commercial Weight-Loss Programs in a Metropolitan Areas. *J Am Coll Nutr.* 1992;11(1):36-41.
291. Weight Watchers International. Personal Communication; 2003.
292. Christakis G, Miller-Kovach K. Maintenance of Weight Goal among Weight Watchers Lifetime Members. *Nutr Today.* 1996;31(1):29-31.

293. Lowe MR, Miller-Kovach K, Frye N, Phelan S. An Initial Evaluation of a Commercial Weight Loss Program: Short-Term Effects on Weight, Eating Behavior, and Mood. *Obes Res.* 1999;7(1):51-59.
294. Heshka S, Anderson JW, Atkinson RL, et al. Weight Loss with Self-Help Compared with a Structured Commercial Program. *Jama.* 2003;289(14):1792-1798.
295. Volkmar FR, Stunkard AJ, Woolston J, Bailey BA. High Attrition Rates in Commercial Weight Reduction Programs. *Arch Int Med.* 1981;141:426-428.
296. Kathryn Brumwell: Customer Care-Jenny Craig. 2003.
297. Pavlou KN, Whatley JE, Jannace PW, et al. Physical Activity as a Supplement to a Weight-Loss Dietary Regimen. *Am J Clin Nutr.* 1989;49:1110-1114.
298. Shape Up America. Available at: www.shapeup.org.
299. Diet Workshop. Available at: www.dietworkshop.com.
300. American Heart Association. Quick-Weight-Loss or Fad Diets. *American Heart Association.* Available at: <http://www.americanheart.org/presenter.jhtml?identifier=4584>.
301. Freedman MR, King J, Kennedy E. Popular Diets: A Scientific Review. *Obes Res.* 2001;9:1S-5S.
302. Health Management Resources. Available at: <http://www.hmrprogram.com>.
303. Barnard RJ. Effects on Life-Style Modification on Serum Lipids. *Arch Int Med.* 1991;151:1389-1394.
304. Overeaters Anonymous. Available at: www.overeatersanonymous.org.
305. Malenbaum R, Herzog D, Eisenthal S, Wyshak G. Overeaters Anonymous: Impact on Bulimia. *Int J Eat Disord.* 1988;7(1):139-143.
306. Latner JD, Stunkard AJ, Wilson T, Jackson ML, Zelitch DS, Labouvie E. Effective Long-Term Treatment of Obesity: A Continuing Care Model. *Int J Obes.* 2000;24:893-898.
307. LEARN. Learn-the Lifestyle Company; 2003. Available at: www.learneducation.com.
308. Heber D, Ashley JM, Wang HJ, Elashoff RM. Clinical Evaluation of a Minimal Intervention Meal Replacement Regimen for Weight Reduction. *J Am Coll Nutr.* 1994;6:608-614.
309. eDiets.com. Available at: www.ediets.com.
310. Florian E. When It Comes to Fat, They're Huge! *Fortune.* Vol 146; 2002:54.
311. Serdula MK, Mokdad AH, Williamson DF, Galuska DA, Mendlein JM, Heath GW. Prevalence of Attempting Weight Loss and Strategies for Controlling Weight. *Jama.* Oct 13 1999;282(14):1353-1358.
312. Wadden TA WL, Sarwer DB, Berkowitz RI, Clark VL, Foster GD. Great Expectations: "I'm Losing 25% of My Weight No Matter What You Say". *J Consult Clin Psychol.* 2003;71(6):1084-1089.
313. Hollander PA, Elbien SC, Hirsch IB, et al. Role of Orlistat in the Treatment of Obese Patients with Type 2 Diabetes. A 1-Year Randomized Double-Blind Study. *Diabetes Care.* Vol 21; 1998:1288-1294.
314. Sjostrom L, Rissanen A, Andersen T, et al. Randomised Placebo-Controlled Trial of Orlistat for Weight Loss and Prevention of Weight Regain in Obese Patients. European Multicentre Orlistat Study Group. *Lancet.* Vol 352; 1998:167-172.
315. Tuomilehto J, Lindstrom J, Eriksson J.G., Valle T.T., Hamalainen H., Ilanne-Parikka P., et al. Prevention of Type 2 Diabetes Mellitus by Changes in Lifestyle among Subjects with Impaired Glucose Tolerance. *N Engl J Med.* 2001;344:1343-1350.
316. Pories WJ, Swanson MS, McDonald KG, et al. Who Would Have Thought It? An Operation Proved to Be the Most Effective Therapy for Adult Onset Diabetes Mellitus. *Ann Surg.* Vol 222; 1995:339-350.

317. Sjostrom CD, Peltonen M, Sjostrom L. Blood Pressure and Pulse Pressure During Long-Term Weight Loss in the Obese: The Swedish Obese Subjects (SOS) Intervention Study. *Obes Res.* Vol 9; 2001:188-195.
318. U.S. Bureau of the Census. *Statistical Abstract of the United States: 1998.* 118 ed. Washington, DC; 1998.
319. Goldberg RJ, Ockene IS, Ockene JK, Merriam P, Kristeller J. Physicians' Attitudes and Reported Practices toward Smoking Intervention. *J Cancer Educ.* Vol 8; 1993:133-139.
320. Steptoe A, Doherty, S., Kerry, S., Rink, E., & Hilton, S. Sociodemographic and Psychological Predictors of Changes in Dietary Fat Consumption in Adults with High Blood Cholesterol Following Counseling in Primary Care. *Health Psychol.* 2000;19(5):411-419.
321. Lewis BS, Lynch WD. The Effect of Physician Advice on Exercise Behavior. *Prev Med.* 1993;22:110-121.
322. Ammerman AS, DeVellis RF, Carey TS, et al. Physician-Based Diet Counseling for Cholesterol Reduction: Current Practices, Determinants, and Strategies for Improvement. *Prev Med.* 1993;22:96-109.
323. Vogt TM, Hollis, J.F., Lichtenstein, E., Stevens, V.J., Glasgow, R., & Whitlock, E. The Medical Care System and Prevention: The Need for a New Paradigm. *HMO Practice.* 1998;12:5-13.
324. Horgen KB, & Brownell, K.D. Policy Change as a Means for Reducing the Prevalence and Impact of Alcoholism, Smoking, and Obesity. In: Miller WR, Heather N, eds. *Treating Addictive Behaviors.* 2 ed. New York: Plenum Press; 1998:105-118.
325. Field AE, Barnoya, J., & Colditz, G.A. Epidemiology and Health and Economic Consequences of Obesity. In: Wadden TA, Stunkard AJ, eds. *Handbook of Obesity Treatment.* New York: The Guilford Press; 2002:3-18.
326. Simkin-Silverman LR, Wing RR. Management of Obesity in Primary Care. *Obes Res.* 1997;5(6):603-612.
327. Rippe JM. The Case for Medical Management of Obesity: A Call for Increased Physician Involvement. *Obes Res.* 1998;6(supp 1):23S-33S.
328. Kottke TE, Battista, R.N., DeFries, G.H., & Brekke, M.L. Attributes of Successful Smoking Cessation Interventions in Medical Practice: A Meta-Analysis of 39 Controlled Trials. *Jama.* 1988;259:2883-2889.
329. Rimer BK, Orleans CT, Fleisher L, et al. Does Tailoring Matter? The Impact of a Tailored Guide on Ratings and Short-Term Smoking-Related Outcomes for Older Smokers. *Health Educ Res.* Vol 9; 1994:69-84.
330. Ammerman AS, DeVellis, R.F., Carey, T.S., Keyserling, T.C., Strogatz, D.S., Haines, P.S., et al. Physician Based Diet Counseling for Cholesterol Reduction: Current Practices, Determinants and Strategies for Improvement. *Prev Med.* 1993;22:96-109.
331. Hyman DJ, Maibach EW, Flora JA, Fortmann SP. Cholesterol Treatment Practices of Primary Care Physicians. *Public Health Rep.* Vol 107; 1992:441-448.
332. Patrick K, Sallis JF, Long B, et al. A New Tool for Encouraging Activity: Project Pace. *Phys Sportsmed.* Vol 22; 1994:45-55.
333. Friedman C, Brownson RC, Peterson DE, Wilkerson JC. Physician Advice to Reduce Chronic Disease Risk Factors. *Am J Prev Med.* 1994;10(6):367-371.
334. McArtor RE, Iverson, D.C., Benken, D., & Dennis, L.K. Family Practice Residents' Identification and Management of Obesity. *Int J Obes.* 1992;16:335-340.
335. Yanovski SZ. A Practical Approach to Treatment of the Obese Patient. *Arch Fam Med.* 1993;2:309-316.

336. Galuska DA, Will JC, Serdula MK, Ford ES. Are Health Care Professionals Advising Obese Patients to Lose Weight? *Jama*. 1999;282(16):1576-1578.
337. Wadden TA, Anderson, D.A., Foster, G.D., Bennett, A., Steinberg, C., & Sarwer, D.B. Obese Women's Perceptions of Their Physician's Weight Management Attitudes and Practices. *Arch Fam Med*. 2000;9:854-860.
338. Lewis CE. Disease Prevention and Health Promotion Practices of Primary Care Physicians in the United States. *Am J Prev Med*. 1988;4(4 Suppl):9-16.
339. Wee CC, McCarthy, E.P., Davis, R.B., & Phillips, R.S. Physician Counseling About Exercise. *Jama*. 1999;282:1583-1588.
340. Martin PD, Rhode, P.C., Howe, J.T. & Brantley, P.J. Primary Care Weight Management Counseling: Physician and Patient Perspectives. *J Louisiana State Med Soc*. 2003;155:49-53.
341. Aronne LJ. Treating Obesity: A New Target for Prevention of Coronary Heart Disease. *Prog Cardiovasc Nurs*. Summer 2001;16(3):98-106, 115.
342. Cohen MD, D'Amico FJ, Merenstein JH. Weight Reduction in Obese Hypertensive Hypertensive Patients. *Fam Med*. Vol 23; 1991:25-28.
343. Logsdon DN, Lazaro CM, Meier RV. The Feasibility of Behavioral Risk Reduction in Primary Medical Care. *Am J Prev Med*. 1989;5(5):249-256.
344. Bowerman S, Bellman M, Saltsman P, Garvey D., Pimstone K, Skootsky S, et al. Implementation of a Primary Care Physician Network Obesity Management Program. *Obes Res*. 2001;9(suppl 4):321S-325S.
345. Ashley J, St. Jeor S, Schrage J, Perumean-Chaney S, Gilbertson M, McCall N, et al. Weight Control in the Physician's Office. *Arch Intern Med*. 2001;161:1599-1604.
346. Evans A, Rogers L, Peden J, Seeling C, Layne R, Levine M, et al. Teaching Dietary Counseling Skills to Residents: Patient and Physician Outcomes: The Cadre Study Group. *Am J Prev Med*. 1996;12:259-265.
347. Lazarus K, Weinsier, R, & Boker, J. Nutrition Knowledge and Practice of Physicians in a Family-Practice Residency Program: The Effect of an Education Program Provided by a Physician Nutrition Specialist. *Am J Nutr*. 1993;58:319-325.
348. Lazarus K. Nutrition Practices of Family Physicians after Education by a Physician Nutrition Specialist. *Am J Clin Nutr*. 1997;65(Suppl 6):2007S-2009S.
349. Ockene JK, Ockene IS, Quirk ME, et al. Physician Training for Patient-Centered Nutrition Counseling in a Lipid Intervention Trial. *Prev Med*. Vol 24; 1995:563-570.
350. Davis D, O'Brien MA, Freemantle N, Wolf FM, Mazmanian P, Taylor-Vaisey A. Impact of Formal Continuing Medical Education: Do Conferences, Workshops, Rounds, and Other Traditional Continuing Education Activities Change Physician Behavior or Health Care Outcomes? *Jama*. Vol 282; 1999:867-874.
351. Roche AM, Eccleston P, Sanson-Fisher R. Teaching Smoking Cessation Skills to Senior Medical Students: A Block-Randomized Controlled Trial of Four Different Approaches. *Prev Med*. Vol 25; 1996:251-258.
352. Kenner MM, Taylor ML, Dunn PC, Gruchow HW, Kolasa K. Primary Care Providers Need a Variety of Nutrition and Wellness Patient Education Materials. *J Am Diet Assoc*. Vol 99; 1999:462-466.
353. Murphree D. Patient Attitudes toward Physician Treatment of Obesity. *J Fam Pract*. 1994;38(1):45-48.
354. Beresford SAA, Farmer EMZ, Feingold L, Graves KL, Sumner SK, Baker RM. Evaluation of a Self-Help Dietary Intervention in a Primary Care Setting. *Am J Public Health*. Vol 82; 1992:79-84.

355. Kushner RF. Long-Term Compliance with a Lipid-Lowering Diet. *Nutr Rev.* Vol 51; 1993:16-17.
356. Patel C, Nicol A. Adaptation of African-American Cultural and Food Preferences in End-Stage Renal Disease Diets. *Adv Ren Replace Ther.* Vol 4; 1997:30-39.
357. Mullen PD, Tabak ER. Patterns of Counseling Techniques Used by Family Practice Physicians for Smoking, Weight, Exercise, and Stress. *Med Care.* Vol 27; 1989:694-704.
358. Wells KB, Ware JE, Lewis CE. Physicians' Practices in Counseling Patients About Health Habits. *Med Care.* Vol 22; 1984:240-246.
359. Wells K, Lewis, C., Leake, B., Schleiter, M. & Brook, M. The Practices of General and Subspecialty Internists in Counseling About Smoking and Exercise. *Am J Public Health.* 1986;76:1009-1013.
360. Orleans T, George L, Hout J, Brodie K. Health Promotion in Primary Care: A Survey of U.S. Family Practitioners. *Prev Med.* 1985;14:636-647.
361. Calfas KJ, Long BJ, Sallis JF, Wooten WJ, Pratt M, Patrick K. A Controlled Trial of Physician Counseling to Promote the Adoption of Physical Activity. *Prev Med.* Vol 25; 1996:225-233.
362. Patrick K, Sallis JF, Long B, et al. A New Tool for Encouraging Activity: Project Pace. *Phys Sportsmed.* 1994;22(11):45-55.
363. Brantley PJ, Carmack CL, Boudreaux E, Scarcini I. High Risk Behaviors in Low-Income Primary Care Patients in Louisiana. Report Presented to the Louisiana Legislature; 1996.
364. Siegel PZ, Frazier EL, Mariolis P, Brackbill RM, Smith C. Behavioral Risk Factor Surveillance, 1991: Monitoring Progress toward the Nation's Year 2000 Health Objectives. *MMWR.* Vol 42; 1993:1-21.
365. Hennrikus DJ, Jeffery RW. Worksite Intervention for Weight Control: A Review of the Literature. *Am J Health Promot.* 1996;10(6):471-498.
366. Stunkard AJ, Brownell KD. Work-Site Treatment for Obesity. *Am J Psychiatry.* 1980;137:252-253.
367. Rose G, Tunstall-Pedoc HD, Heller RF. UK Heart Disease Prevention Project: Incidence and Mortality Results. *Lancet.* 1983;1(8333):1062-1066.
368. Glasgow RE, Terborg JR, Hollis JF, Severson HH, Boles SM. Take Heart: Results from the Initial Phase of a Work-Site Wellness Program. *Am J Public Health.* 1995;85(2):209-216.
369. Muto T, Yamauchi K. Evaluation of a Multicomponent Workplace Health Promotion Program Conducted in Japan for Improving Employees' Cardiovascular Disease Risk Factors. *Prev Med.* 2001;33:571-577.
370. Follick MJ, Fowler JL, Brown RA. Attrition in Worksite Weight-Loss Interventions: The Effects of an Incentive Procedure. *J Consult Clin Psychol.* 1984;52:139-140.
371. Forester JL, Jeffery RW, Sullivan S, Snell MK. A Work-Site Weight Control Program Using Financial Incentives Collected through Payroll Deduction. *J Occup Med.* 1985;27:804-808.
372. Brownell KD, Stunkard AJ, McKeon PE. Weight Reduction at the Work Site: A Promise Partially Fulfilled. *Am J Psychiatry.* 1985;142:47-52.
373. Jeffery RW, Forester JL, Snell MK. Promoting Weight Control at the Worksite: A Pilot Program of Self-Motivation Using Payroll Deduction. *Prev Med.* 1985;14:187-194.
374. Peterson G, Abrams DB, Elder JP, Beaudin PA. Professional Versus Self-Help Weight Loss at the Worksite: The Challenge of Making a Public Health Impact. *Behav Ther.* 1985;16:213-222.

375. Shannon B, Hendricks M, Rollins P, Schwartz RM. A Comprehensive Evaluation of a Worksite Nutrition and Weight Control Program. *J Nutr Educ.* 1987;19:109-116.
376. Gomel M, Oldenburg B, Simpson JM, Owen N. Work-Site Cardiovascular Risk Reduction: A Randomized Trial of Health Risk Assessment, Education, Counseling, and Incentives. *Am J Public Health.* 1993;83:1231-1238.
377. Kumanyika SK, Charleston JB. Lose Weight and Win: A Church-Based Weight Loss Program for Blood Pressure Control among Black Women. *Patient Educ Couns.* 1992;19:19-32.
378. McNabb W, Quinn M, Kerver J, Cook S, Karrison T. The Pathways Church-Based Weight Loss Program for Urban African-American Women at Risk for Diabetes. *Diabetes Care.* 1997;20(10):1518-1523.
379. Quinn MT, McNabb WL. Training Lay Health Educators to Conduct a Church-Based Weight-Loss Program for African American Women. *Diabetes Educ.* 2001;27(2):231-238.
380. Yanek LR, Beckler DM, Moy TF, Gittelsohn J, Koffman DM. Project Joy: Faith Based Cardiovascular Health Promotion for African American Women. *Public Health Rep.* 2001;116(Supplement 1):68-81.
381. Foreyt JP, Goodrick GK. Community-Based Programs for the Treatment of Obesity. In: Clark KL, Parr RB, eds. *Evaluation and Management of Eating Disorders: Anorexia, Bulimia, and Obesity.* Champaign, IL: Life Enhancement Publications; 1988:333-342.
382. Farquhar JW, Maccoby NM, Wood PD, et al. Community Education for Cardiovascular Health. *Lancet.* 1977;1(8023):1192-1195.
383. Maccoby N, Farquhar JW, Wood PD, Alexander JK. Reducing the Risk of Cardiovascular Disease: Effects of a Community-Based Campaign on Knowledge and Behavior. *J Community Health.* 1977;3(2):100-114.
384. Puska P, Virtamo J, Tuomilehto J, Mäki J, Neittaanmäki L. Cardiovascular Risk Factor Changes in a Three Year Follow-up of a Cohort in Connection with a Community Programme. *Acta Medica Scandinavica.* 1978;204(5):381-388.
385. Davis MF, Iverson DC. An Overview and Analysis of the Health Style Campaign. *Health Educ Q.* 1984;11(3):253-272.
386. Kappa Systems I. *Evaluation of a National Health Promotion Media Campaign (Volume 11): Community Campaigns and Case Studies:* Office of Health Information, Health Promotion, and Physical Fitness and Sports Medicine; 1984.
387. Multiple Risk Factor Intervention Trial Group (MRFIT). Multiple Risk Factor Research Trial: Risk Factor Changes and Mortality Results. *Jama.* Vol 248; 1982:1465-1477.
388. Lasater TM, Sennett LL, Lefebvre RC, DeHart KL, Peterson G, Carleton RA. Community-Based Approach to Weight Loss: The Pawtucket "Weigh-in". *Addict Behav.* 1991;16:175-181.
389. Luepker RV, Rastam L, Hannan PJ, et al. Community Education for Cardiovascular Disease Prevention: Morbidity and Mortality Results from the Minnesota Heart Health Program. *Am J Epidemiol.* 1996;144(4):351-362.
390. French SA, Story, M., & Jeffery, R. W. Environmental Influences on Eating and Physical Activity. *Annu Rev Public Health.* 2001;22:309-335.
391. Neighborhood Safety and the Prevalence of Physical Inactivity--Selected States, 1996. *MMWR.* 1999;48:143-146.
392. Nestle MJ, M. F. Halting the Obesity Epidemic: A Public Health Policy Approach. *Public Health Rep.* 2000;115:12-24.
393. Jeffery RW. Public Health Strategies for Obesity Treatment and Prevention. *Am J Health Behav.* 2001;25:252-259.

394. Flegal KM, Carroll MD, Kuczmarski RJ, Johnson CL. Overweight and Obesity in the United States: Prevalence and Trends, 1960-1994. *Int J Obes Relat Metab Disord*. 1998;22:39-47.
395. Sallis JF, Strikmiller PK, Harsha DW, et al. Validation of Interviewer- and Self-Administered Physical Activity Checklists for Fifth Grade Students. *Med Sci Sports Exerc*. 1996;28(7):840-851.
396. Kumanyika SK. Minisymposium on Obesity: Overview and Some Strategic Considerations. *Annu Rev Public Health*. 2001;22:293-308.
397. Kumanyika SK, Golden PM. Cross-Sectional Differences in Health Status in Us Racial/Ethnic Minority Groups: Potential Influence of Temporal Changes, Disease, and Life-Style Transitions. *Ethn Dis*. Vol 1; 1991:50-59.
398. Kumanyika S. Obesity Treatment in Minorities. In: Wadden TA, Stunkard AK, eds. *Handbook of Obesity Treatment*; New York: The Guilford Press; 2002:416-446.
399. Kumanyika SK, Dorosheko, L.H., Self, M.S., Bahnson, J., & Robertson, J. Nutritional Safety of Weight and Sodium Reduction in Hypertensive Older Adults. *Can J Cardio*. 1997;13(Suppl. B):51B.
400. Kanders BS, Ullmann-Joy P, Foreyt JP, et al. The Black American Lifestyle Intervention (Bali): The Design of a Weight Loss Program for Working-Class African-American Women. *J Am Diet Assoc*. Vol 94; 1994:310-312.
401. Kumanyika SK, Charleston JB. Lose Weight and Win: A Church-Based Weight Loss Program for Blood Pressure Control among Black Women. *Patient Educ Couns*. Vol 19; 1992:19-32.
402. Agurs-Collins T, Kumanyika S, Ten Have T, Adams-Campbell L. A Randomized Controlled Trial of Weight Reduction and Exercise for Diabetes Management in Older African-American Subjects. *Diabetes Care*. Vol 20; 1997:1503-1511.
403. Domel SB, Alford BA, Cattlett HN, Gench BE. Weight Control for Black Women. *J Am Diet Assoc*. Vol 92; 1992:346-348.
404. Ahijevych K, Bernhard L. Health Promoting Behaviors of African American Women. *Nurs Res*. 1994;43(2):86-89.
405. Duelberg SI. Preventive Health Behavior among Black and White Women in Urban and Rural Areas. *Soc Sci Med*. 1992;34(2):191-198.
406. Contunga N, Subar, A., Heimendinger, J, & Kahle, L. Nutrition and Cancer Prevention Knowledge, Beliefs, Attitudes and Practices: The 1987 National Health Interview Survey. *J Am Diet Assoc*. 1992;8:963-968.
407. Kumanyika S, Wilson JF, Guilford-Davenport M. Weight-Related Attitudes and Behaviors of Black Women. *J Am Diet Assoc*. 1993;93(4):416-422.
408. Meyers H, Kagawa-Singer M, Kumanyika S, Lex B, Markides K. Pane II: Behavioral Risk Factors Related to Chronic Diseases in Ethnic Minorities. *Health Psychol*. 1995;14:613-621.
409. Burke G, Savage P, Manolio T, Sprafka J, Wagenknecht L, Sidney S, et al. Correlates of Obesity in Young Black and White Women: The Cardia Study. *J Public Health*. 1992;82:1621-1625.
410. Swanson C, Gridley G, Greenberg R, Schoenberg J, Swanson G, Brown L, et al. A Comparison of Diets of Blacks and Whites in Three Areas of the United States. *Nutr and Cancer*. 1993;20:153-165.
411. Flynn K, & Fitzgibbon, M. Body Images and Obesity Risk among Black Females: A Review of the Literature. *Ann Behav Med*. 1998;20:31-24.

412. Cotunga N, Subar AF, Heimendinger J, Kahle L. Nutrition and Cancer Prevention Knowledge, Beliefs, Attitudes, and Practices: The 1987 National Health Interview Survey. *J Am Diet Assoc.* Vol 92; 1992:963-968.
413. Lovejoy JC. The Menopause and Obesity. In: Bray G, ed. *Primary Care: Clinics in Office Practice.* Vol 30. Philadelphia: W. B. Saunders Company; 2003:317-325.
414. Mokdad AH, Serdula MK, Dietz WH, Bowman BA, Marks JS, Koplan JP. The Spread of the Obesity Epidemic in the United States, 1991-1998. *Jama.* 1999;282(16):1519-1522.
415. Wing RR, Matthews KA, Kuller LH, Meilahn EN, Plantinga PL. Weight Gain at the Time of Menopause. *Arch Int Med.* 1991;151(1):97-102.
416. Pasquali R, Casimirri F, Labate AM, et al. Body Weight, Fat Distribution and the Menopausal Status in Women. *Int J Obes.* 1994;18(9):614-621.
417. Toth MJ, Tchernof A, Sites CK, Poehlman ET. Effect of Menopausal Status on Body Composition and Abdominal Fat Distribution. *Int J Obes Relat Metab Disord.* 2000;24(2):226-231.
418. Matthews KA, Abrams B, Crawford S, et al. Body Mass Index in Mid-Life Women: Relative Influence of Menopause, Hormone Use, and Ethnicity. *Int J Obes.* 2001;25(6):863-873.
419. Wing RR, Matthews KA, Kuller LH, Meilahn EN, Plantinga P. Waist to Hip Ratio in Middle-Aged Women: Associations with Behavioral and Psychosocial Factors and with Changes in Cardiovascular Risk Factors. *Arterio Thromb.* 1991;11(5):1250-1257.
420. Den Tonkelaar I, Seidell JC, van Noord PAH, Baanders-van Halewijn EA, Ouweland IJ. Fat Distribution in Relation to Age, Degree of Obesity, Smoking Habits, Parity and Estrogen Use: A Cross-Sectional Study in 11,825 Dutch Women Participating in the Dom-Project. *Int J Obes.* 1990;14(9):753-761.
421. Dawson-Hughes B, Harris S. Regional Changes in Body Composition by Time of Year in Healthy Postmenopausal Women. *Am J Clin Nutr.* 1992;56:307-313.
422. Ley CJ, Lees B, Stevenson JC. Sex- and Menopause-Associated Changes in Body Fat Distribution. *Am J Clin Nutr.* 1992;55:950-954.
423. Enzi G, Gasparo M, Biondetti PR, Fiore D, Semisa M, Zurlo F. Subcutaneous and Visceral Fat Distribution According to Sex, Age, and Overweight, Evaluated by Computed Tomography. *Am J Clin Nutr.* 1986;44(6):739-746.
424. Espeland MA, Stefanick ML, Kritz-Silverstein D, et al. Effect of Postmenopausal Hormone Therapy on Body Weight and Waist and Hip Girths. Postmenopausal Estrogen-Progestin Interventions Study Investigators. *J Clin Endocrinol Metab.* 1997;82(5):1549-1556.
425. Kritz-Silverstein D, Barrett-Connor E. Long-Term Postmenopausal Hormone Use, Obesity, and Fat Distribution in Older Women. *Jama.* 1996;275(1):46-49.
426. Greenway F. Clinical Evaluation of the Obese Patient. In: Bray G, ed. *Primary Care: Clinics in Office Practice.* Vol 30. Philadelphia: W. B. Saunders Company; 2003:341-356.
427. Devlin MJ. Obesity: What Mental Health Professionals Need to Know. *Am J Psychiatry.* Vol 157; 2000:854-866.
428. Froom P, Melamed S, Benbassat J. Smoking Cessation and Weight Gain. *J Fam Pract.* Jun 1998;46(6):460-464.
429. Jonsdottir D, Jonsdottir H. Does Physical Exercise in Addition to a Multicomponent Smoking Cessation Program Increase Abstinence Rate and Suppress Weight Gain? An Intervention Study. *Scand J Caring Sci.* 2001;15(4):275-282.

430. Williamson DF, Madans J, Anda RF, Kleinman JC, Giovino GA, Byers T. Smoking Cessation and Severity of Weight Gain in a National Cohort. *N Engl J Med*. Mar 14 1991;324(11):739-745.
431. Jeffery RW, Hennrikus DJ, Lando HA, Murray DM, Liu JW. Reconciling Conflicting Findings Regarding Postcessation Weight Concerns and Success in Smoking Cessation. *Health Psychol*. May 2000;19(3):242-246.
432. Rigotti NA. Treatment Options for the Weight-Conscious Smoker. *Arch Int Med*. Vol 159; 1999:1169-1171.
433. Borrelli B, Mermelstein R. The Role of Weight Concern and Self-Efficacy in Smoking Cessation and Weight Gain among Smokers in a Clinic-Based Cessation Program. *Addict Behav*. Sep-Oct 1998;23(5):609-622.
434. Dale LC, Schroeder DR, Wolter TD, Croghan IT, Hurt RD, Offord KP. Weight Change after Smoking Cessation Using Variable Doses of Transdermal Nicotine Replacement. *J Gen Int Med*. Vol 13; 1998:9-15.
435. McKinlay SM, Brambilla, D.J., Posner, J.G. The Normal Menopause Transition. *Maturitas*. 1992;14:102-112.
436. Timiras PS, Sentenac J. Aging of the Female Reproductive System. In: Timiras PS, Quay, W.D., and Vernadakis, A. (Eds.). ed. *Hormones and Aging*. Boca Raton, FL: CRC Press; 1995:123-134.
437. Cramer DW, Harlow BL, Xu H, Fraer C, Barbieri R. Cross-Sectional and Case-Controlled Analyses of the Association between Smoking and Early Menopause. *Maturitas*. 1995;22:79-87.
438. Cramer DW, Xu H. Predicting Age at Menopause. *Maturitas*. 1996;23(3):319-326.
439. DeBon M, Klesges RC. Smoking and Smoking Cessation. Current Conceptualizations and Directions for Future Research. In: Goreczny AJ, ed. *Handbook of Health and Rehabilitation Psychology*. New York: Plenum; 1995:135-136.
440. McKinlay SM. The Normal Menopause Transition: An Overview. *Maturitas*. 1996;23:137-145.
441. Chiechi LM, Ferreri R, Granieri M, Lobascio A, Bianco G, Berardesca C, Loizzi P. Smoking in Menopause. *Clin Exp Obstet Gynecol*. 1997;24(1):26-27.
442. Nilsson P, Moller L, Koster A, Hollnagel H. Social and Biological Predictors of Early Menopause: A Model for Premature Aging. *J Int Med*. 1997;242(4):299-305.
443. Manson J, Willett WC, Stampfer MJ, et al. Body Weight and Mortality among Women. *N Engl J Med*. 1995;333:677-685.
444. Heymsfield SB, Gallagher D, Poehlman ET, et al. Menopausal Changes in Body Composition and Energy Expenditure. *Exp Gerontol*. 1994;29:377.
445. Tchernof A, Poehlman ET. Effects of the Menopause Transition on Body Fatness and Body Fat Distribution. *Obes Res*. 1998;6:246.
446. Wang Q, Hassager C, Ravn P, Wang S, Christiansen C. Total and Regional Body-Composition Changes in Early Postmenopausal Women: Age-Related or Menopause-Related? *Am J Clin Nutr*. 1994;60:843-848.
447. Poehlman ET, Toth MJ, Gardner AW. Changes in Energy Balance and Body Composition at Menopause: A Controlled Longitudinal Study. *Ann Int Med*. 1995;126:673-675.
448. Aloia JF, Vaswani A, Russo L, Sheehan M, Flaster E. The Influence of Menopause and Hormonal Replacement Therapy on Body Cell Mass and Body Fat Mass. *Am J Obstet Gynecol*. Vol 172; 1995:896-900.
449. Colombel A, Charbonnel B. Weight Gain and Cardiovascular Risk Factors in the Post-Menopausal Women. *Hum Reprod*. Vol 12; 1997:134-135.

450. Bjorntorp P. Visceral Obesity: A "Civilization Syndrome." *Obes Res.* Vol 1; 1993: 206.
451. Dowling HJ, Pi-Sunyer FX. Race-Dependent Health Risks of Upper Body Obesity. *Diabetes.* Vol 42; 1993:537-543.
452. Fisler JS, Lupien JR, Wood RD, Bray GA, Schemmel RA Brown Fat Thermogenesis in a Rat Model of Dietary Obesity. *Am J Physiol.* Vol 253; 1987:R756-R762.
453. Blair D, Habicht J-P, Sims EAH, et al. Evidence for an Increased Risk for Hypertension with Centrally Located Body Fat and the Effect of Race and Sex on This Risk. *Am J Epidemiol.* Vol 119; 1984:526-540.
454. The writing group from the PEPI trial. Effects of Estrogen or Estrogen/Progestin Regimens on Heart Disease Risk Factors in Postmenopausal Women. The Postmenopausal Estrogen/Progestin Interventions (Pepi) Trial. *Jama.* Vol 273; 1995:199-208.
455. Carmody TP, Matarazzo, J.D., and Istvan, J.A. Promoting Adherence to Heart-Healthy Diets: A Review of the Literature. *J Compliance Health Care.* Vol 2; 1987:105-120.
456. Sclafani A. Diet-Induced Obesity in Rodents. In: Shimazu T, ed. *Progress in Obesity Research.* London: John Libbey and Company, Ltd.; 1990: 441-444.
457. Hudmon KS, Gritz ER, Clayton S, Nisenbaum R. Eating Orientation, Postcessation Weight Gain, and Continued Abstinence among Female Smokers Receiving an Unsolicited Smoking Cessation Intervention. *Health Psychol.* Jan 1999;18(1):29-36.
458. Perkins KA, Marcus MD, Levine MD, et al. Cognitive-Behavioral Therapy to Reduce Weight Concerns Improves Smoking Cessation Outcome in Weight-Concerned Women. *J Consult Clin Psychol.* Vol 69; 2001:604-613.
459. Mizes JS, Sloan DM, Segraves K, Spring B, Pingitore R, Kristeller J. The Influence of Weight-Related Variables on Smoking Cessation. *Behav Ther.* 1998;29:371-385.
460. Perkins KA, Levine MD, Marcus MD, Shiffman S. Addressing Women's Concerns About Weight Gain Due to Smoking Cessation. *J Subst Abuse Treat.* Mar-Apr 1997;14(2):173-182.
461. Strecher VJ. Computer-Tailored Smoking Cessation Materials: A Review and Discussion. *Patient Educ Couns.* Feb 1999;36(2):107-117.
462. Kreuter MW, Strecher VJ, Glassman B. One Size Does Not Fit All: The Case for Tailoring Print Materials. *Ann Behav Med.* Fall 1999;21(4):276-283.
463. Pinto BM, Borrelli B, King TK, et al. Weight Control Smoking among Sedentary Women. *Addict Behav.* Jan-Feb 1999;24(1):75-86.
464. Oster G, Thompson D, Edelsberg J, Bird AP, Colditz GA. Lifetime Health and Economic Benefits of Weight Loss among Obese Persons. *Am J Public Health.* Oct 1999;89(10):1536-1542.
465. Wolf AM, Manson JE, Colditz GA. The Economic Impact of Overweight, Obesity, and Weight Loss. In: Eckel RH, ed. *Obesity: Mechanisms and Clinical Management.* Philadelphia: Lippincott Williams & Wilkins; 2003:523-549.
466. Collins RW, Anderson JW. Medication Cost Savings Associated with Weight Loss for Obese Non-Insulin-Dependent Diabetic Men and Women. *Prev Med.* 1995;24(4):369-374.
467. Malone M, Alger S, Kispert P, Howard L. Changes in Medication Uses after Gastric Restrictive Surgery. Presentation at Naaso Annual Meeting, November 1999, Charleston, Sc. *Obes Res.* 1999;7(suppl):54S.
468. Martin TL, Selby JV, Zhang D. Physician and Patient Prevention Practices in Niddm in a Large Urban Managed-Care Organization. *Diabetes Care.* 1995;18(8):1124-1132.
469. Allison DB, Fontaine KR, Manson JE. Annal Deaths Attributable to Obesity in the United States. *Jama.* 1999;282:1530-1538.

470. Maggio C, Pi-Sunyer FX. The Prevention and Treatment of Obesity. Application to Type 2 Diabetes. *Diabetes Care*. Vol 20; 1997:1744-1766.
471. Agurs-Collins T, Kumanyika, S., Have, T. & Adams-Campbell, L. A Randomized Controlled Trial of Weight Reduction and Exercise for Diabetes Management in Older African American Subjects. *Diabetes Care*. Vol 20; 1997:1503-1511.
472. Pi-Sunyer FX. Short-Term Medical Benefits and Adverse Effects of Weight Loss. *Ann Int Med*. 1993;119(7 pt 2):722-726.
473. Trials of Hypertension Prevention (TOHP) Collaborative Research Group. Effects of Non-Pharmacologic Interventions on Blood Pressure of Persons with High Normal Levels. *Jama*. 1992;267:1213-1220.
474. Trials of Hypertension Prevention (TOHP) Collaborative Research Group. Effects of Weight Loss and Sodium Reduction Intervention on Blood Pressure and Hypertension Incidence in Overweight People with High-Normal Blood Pressure. *Arch Int Med*. 1997;157:657-667.
475. Whelton PK, Appel, LJ, Espeland, M, Applegate, WB, Ettinger WH, Kostis JB, et al. Sodium Reduction and Weight Loss in the Treatment of Hypertension in Older Persons. *Jama*. 1998;279:839-846.
476. Gregg EW, Williamson DF. The Relationship of Intentional Weight Loss to Disease Incidence and Mortality. In: Wadden TA, Stunkard AJ, eds. *Handbook of Obesity Treatment*. New York: The Guilford Press; 2002:125-143.
477. Pan X, Li G-W, Hu Y-H, Wang J-X, Yang W-Y, An Z-X, et al. Effects of Diet and Exercise in Preventing Niddm in People with Impaired Glucose Tolerance. *Diabetes Care*. 1997;20:537-544.
478. Weinsier R, Wilson L, Lee J. Medically Safe Rate of Weight Loss for the Treatment of Obesity: A Guideline Based on Risk of Gallstone Formation. *Am J Med*. Vol 98; 1995:115-117.
479. Centers for Disease Control and Prevention. Cardiac Valvulopathy Associated with Exposure to Fenfluramine or Dexfenfluramine: U.S. Department of Health and Human Services Interim Public Health Recommendation, November 1997. *MMWR*. 1997;46:1061-1065.
480. Salamone LM, Cauley JA, Black DM, et al. Effect of a Lifestyle Intervention on Bone Mineral Density in Premenopausal Women: A Randomized Trial. *Am J Clin Nutr*. 1999;70(1):97-103.
481. Littleton D. A Review of Strategies for Finding Health Information on the World-Wide Web. *Med Ref Serv Q*. 1998;17(2):51-55.
482. Block M. Consumer Health Information on the Net. *Library Journal*. 2001;126(8):21-24.
483. Manhattan Research. For 124.7 Million Americans, the Internet Is No Longer Considered "Alternative Medicine": Manhattan Research; 2002.
484. Jadad AR, Gagliardi A. Rating Health Information on the Internet: Navigating to Knowledge or to Babel? *Jama*. Feb 25 1998;279(8):611-614.
485. Silberg WM, Lundberg GD, Musacchio RA. Assessing, Controlling, and Assuring the Quality of Medical Information on the Internet: Caveant Lector Et Viewor--Let the Reader and Viewer Beware. *Jama*. 1997;277(15):1244-1245.
486. Fox SA, Rainie L, Horrigan J, Lenhart A, Spooner T, Burke M, Lewis O, Carter C. The Online Health Care Revolution: How the Web Helps Americans Take Better Care of Themselves. Available at: www.pewinternet.org/reports/pdfs/PIP_Health_Report.pdf.
487. Doldi SB, Micheletto G, Perrini MN, Librenti MC, Rella S. Treatment of Morbid Obesity with Intra-gastric Balloon in Association with Diet. *Obes Surg*. Vol 12; 2002:583-587.

488. Cleland G, Koss, Daynard, Muoio. Weight Loss Advertising: An Analysis of Current Trends. Available at: www.ftc.gov/opa/2002/09/weightlossrpt.htm.
489. Davison K. The Quality of Dietary Information on the World Wide Web. *Can Diet Assoc.* 1996;57(4):137-141.
490. Miles J, C. Petrie, and M. Steel. Slimming on the Internet. *J R Soc Med.* 2000;93(5):254-257.
491. Jacso P. Rating the Metasearch Engines. *Information Today.* 2001;18(11):28.
492. Tate DF, Wing RR, Winett RA. Using Internet Technology to Deliver a Behavioral Weight Loss Program. *Jama.* Mar 7 2001;285(9):1172-1177.
493. Jeffery RW. Public Health Approaches to the Management of Obesity. In: Fairburn CG, Brownell KD, eds. *Eating Disorders and Obesity: A Comprehensive Handbook*. 2nd ed. New York: The Guilford Press; 2002:613-618.
494. Kant A. Consumption of Energy Dense, Nutrient Poor Foods by Adult Americans: Nutritional and Health Implications: Third National Health and Nutrition Examination Survey, 1988-1994. *Am J Clin Nutr.* Vol 72; 2000:929-936.
495. Brownell KD. Public Policy and the Prevention of Obesity. In: Fairburn CG, Brownell KD, eds. *Eating Disorders and Obesity: A Comprehensive Handbook*. 2nd ed. New York: The Guilford Press; 2002:619-623.
496. Bray GA. Drug Treatment in Obesity. In: Wadden TA, Stunkard AJ, eds. *Handbook of Obesity Treatment*. New York: The Guilford Press; 2002:317-338.
497. Latifi R, Kellum JM, De Maria EJ, Sugerman HJ. Surgical Treatment of Obesity. In: Wadden TA, Stunkard AJ, eds. *Handbook of Obesity Treatment*. New York: The Guilford Press; 2002: 339-356.
498. Diabetes Prevention Program Research Group. Reduction in the Incidence of Type 2 Diabetes with Lifestyle Intervention or Metformin. *N Eng J Med.* Vol 346; 2002:393-403.
499. Perri MG, & Corsica, J. A. Improving the Maintenance of Weight Lost in Behavioral Treatment of Obesity. In: Wadden TA, Stunkard AJ, eds. *Handbook of Obesity Treatment*. New York: The Guilford Press; 2002:357-382.
500. French SA, Jeffery RW, Story M, Hannan P, Snyder P. A Pricing Strategy to Promote Low-Fat Snacks through Vending Machines. *Am J Public Health.* 1997;87:849-851.
501. Center for Science in the Public Interest. Bruskin-Goldring Research Telephone Survey. In: Author, ed. Washington, D.C.: Author; 1999.
502. National Task Force on the Prevention and Treatment of Obesity. Towards Prevention of Obesity: Research Directions. *Obes Res.* Vol 2; 1994:571-584.
503. NHLBI Obesity Education Initiative. Clinical Guidelines on the Identification, Evaluation, and Treatment of Overweight and Obesity in Adults: The Evidence Report. Bethesda, MD: U.S. Department of Health and Human Services, Public Health Service, National Institutes of Health, National Heart, Lung, and Blood Institute; 1998.
504. American Medical Association. Policy H-150.953 Obesity as a Major Public Health Program. *American Medical Association.* Available at: http://www.ama-assn.org/apps/pf_new/pf_online?f_n=browse&doc=policyfiles/HnE/H-150.953.HTM.
505. American Medical Association. D-440.980 Recognizing and Taking Action in Response to the Obesity Crisis. *American Medical Association.* Available at: http://www.ama-assn.org/apps/pf_new/pf_online?f_n=browse&doc=policyfiles/DIR/D-440.980.HTM.
506. American Medical Association. *Assessment and Management of Adult Obesity: A Primer for Physicians*. Atlanta, GA: American Medical Association; 2003.

507. U.S. Preventive Services Task Force. *Guide to Clinical Preventive Services, Second Edition*. Washington, D.C.: Department of Health and Human Services, Office of Public Health and Science, Office of Disease Prevention and Health Promotion; 2000.
508. American Obesity Association. Objectives for Achieving and Maintaining a Healthy Population, January, 2000. *American Obesity Association*. Available at: http://www.obesity.org/subs/advocacy/HealthyWeight_2010.shtml, 2003.
509. American Obesity Association. Creating a Healthy Environment: Strategies for Integrating Obesity Management into Communities. *American Obesity Association*. Available at: <http://www.obesity.org/subs/community/creating.shtml>, 2003.
510. American College of Preventive Medicine. Task Force Recommends That Clinicians Screen Adults for Obesity. Available at: <http://www.acpm.org/120403.htm>.
511. Centers for Disease Control and Prevention Community Guide Branch. Physical Activity. *Centers for Disease Control and Prevention*. Available at: <http://www.thecommunityguide.org/pa/>.
512. American Obesity Association. Internal Revenue Service Ruling 2002-19. *Internal Revenue Service*. Available at: <http://www.obesity.org/subs/tax/irsruling.shtml>.
513. The Food and Drug Administration. The Food and Drug Administration's (FDA) Obesity Working Group Report. Available at: <http://www.cfsan.fda.gov/~dms/owg-qa.html>.
514. Federal Trade Commission. FTC Staff Weighs in on Food Labels and Obesity: Recommended Label Changes May Help Consumers Choose Lower-Calorie Foods. *Federal Trade Commission*. Available at: <http://www.ftc.gov/opa/2003/12/fdaobesity.htm>.
515. International Food Information Council. Trends in Obesity-Related Media Coverage. Available at: <http://ific.org/research/obesitytrends.cfm>.
516. Discovery Health Channel. Discovery Health Channel: National Body Challenge. Available at: <http://bodychallenge.discovery.com/discovery/>.
517. Martin PD, Brantley P, Ryan D, Dutton G, Rhode PC, Redmann SM. Effectiveness of a Physician-Delivered Weight Management Intervention for Low-Income African-American Women. *manuscript underreview*.