



Managing Obesity to Improve Population Health: A Toolkit



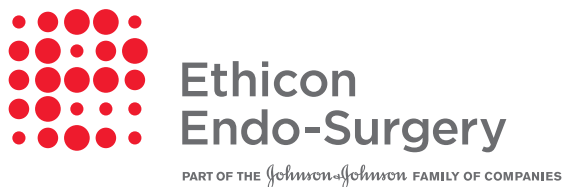
Care Continuum Alliance

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Nicole Kashine—
Contributor

Care Continuum Alliance
701 Pennsylvania Ave. N.W., Suite 700, Washington, D.C. 20004-2694
(202) 737-5980
info@carecontinuumalliance.org
www.carecontinuumalliance.org

Introduction

Obesity in the United States has become a recognized epidemic, one that is associated with high risk of chronic health conditions and is a major contributor to accelerating healthcare costs. According to the Centers for Disease Control and Prevention, more than one-third or approximately 72.5 million adults in the United States are obese.¹ A recent report from Trust for America's Health forecasts an increase so dramatic that, by 2030, all states could have rates above 44 percent if current trends persist.² Obesity often increases the risk for many serious health conditions, including coronary heart disease, hypertension, stroke, type 2 diabetes, certain types of cancer, and premature death. Recent estimates of the annual medical costs of obesity are as high as \$147 billion.¹ On average, persons who are obese have medical costs that are \$1,429 more annually than persons of normal weight.¹

The Care Continuum Alliance (CCA) represents the population health management industry. The population health management industry has a history of addressing weight management in many of the programs developed and delivered to a variety of populations. This expertise has continued to evolve as the industry incorporates health information technology and other innovations into new models of care and has been incorporated into the toolkit through case studies and evidence.

The original CCA Obesity toolkit, released in 2008, was accessed by over 500 organizations and individuals as a reference for benefit design development and program implementation. In a recent survey of current toolkit users, the majority of respondents indicated a current need for tools to enable conversations between primary care providers and their patients. *Managing Obesity to Improve Population Health: A Toolkit* was developed to address the management of obesity by all stakeholders including medical providers, employers, and payers. The toolkit includes updates to work previously released in the 2008 version as well as new information that expands the scope of the document and its applicability to program design. Toolkit sections include:

- **LITERATURE REVIEW OF THE CURRENT EVIDENCE**

An evaluative review of peer-reviewed and grey literature that supports the replication and adaptation of promising

approaches to population-based obesity interventions. The literature suggests that weight loss interventions have demonstrated efficacy in lowering and controlling diabetes and other chronic conditions. Also, this section offers an analysis of gaps in the evidence for program effectiveness in addressing overweight and obese populations and is organized in categories similar to those reflected in the value-based benefit design.

- **CASE STUDIES**

Insights from interviews with employers, payers, and population health management providers offer insight into programs that successfully address obesity and weight management through a variety of interventions.

- **OBESITY BENEFIT DESIGN**

The Value-Based Benefit Design for Obesity and Associated Comorbidities is an approach presented in the original Obesity Toolkit, now updated with current information since its 2008 release. This section helps determine the program framework that works best within a specific payer environment and is supported by scientific evidence and national practice guidelines.

- **OBESITY TREATMENT GUIDE**

The decision guide is designed to help all stakeholders understand program and intervention specific options for each level of the obesity benefit design and the evidence behind these options.

- **GUIDELINES INDEX**

The guidelines for lifestyle modifications have been updated from the original toolkit. This index is a compilation of obesity and weight management guidelines developed and released by a variety of organizations.

- **RESOURCES**

The amount of resources available on the topic of weight management and obesity can be overwhelming. This section offers links to several resources from credible sources that can enhance the work presented in this toolkit.

Obesity with Co-Morbid Conditions Definition

DEF: OBESITY

The most widely used and accepted metric for identifying obesity is having a BMI greater than 30. Waist circumference is also being recognized as an important factor in assessing obesity³. Men with a waist circumference of 40 inches or greater, and women with a waist circumference of 35 inches or greater, are considered obese⁴.

DEF: OBESITY AND ASSOCIATED CO-MORBIDITIES

Higher body weights are associated with an increase in mortality from all causes. Obese individuals with comorbidities are those who are at the highest risk because they tend to have multiple risk factors. Being overweight or obese substantially increases the risk of chronic conditions and illnesses such as hypertension, dyslipidemia, type 2 diabetes, coronary artery disease, stroke, gallbladder disease, osteoarthritis, and sleep apnea and respiratory problems, as well as cancers of the endometrium, breast, prostate, and colon⁵.

DETAILED INFORMATION

New thinking suggests the need to focus chronic condition management on those who are at highest risk, are already obese and have a cluster of risk factors or co-morbid conditions.

The following table from the National Heart, Lung and Blood Institute, and the National Institutes of Health presents categories for overweight and obesity. These are presented as both BMI and waist circumference measurements. Associated risk factors are also shown.

Cut-off points are used to identify increased relative risk for the development of obesity associated risk factors. While imperfect, these cut-off points indicate the need for management of the clinical issues relating to overweight and obesity to reduce risk factors, improve health overall, and reduce resource consumption.

Table 1 – Classification of Overweight and Obesity by BMI, Waist Circumference and Associated Disease Risks

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

* Disease risk for type 2 diabetes, hypertension, and cardiovascular disease.

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

METRICS FOR IDENTIFYING OBESE POPULATIONS

Most often body mass index (BMI) is used to determine overweight and obesity. Waist circumference is another key measure for identifying obese individuals in chronically ill populations. Both BMI and waist circumference have limitations in assessing obesity and risk. Other methods, which are expensive and not generally feasible in the clinic or home settings include calipers (skin-fold measurement), underwater weighing, and computerized topography.

BODY MASS INDEX (BMI)

Obesity is commonly assessed by using body mass index (BMI), defined as the weight in kilograms divided by the square of the height in meters (kg/m²). A BMI of over 25 kg/m² is defined as overweight, and a BMI of over 30 kg/m² as obese. These markers provide common benchmarks for assessment, but the risks of disease in all populations can increase progressively from lower BMI levels⁶.

LIMITATIONS OF BMI

Simple BMI calculations may be misleading. According to the existing definition and calculation of BMI, anyone with a BMI over 25 would be classified as overweight whether their body is composed of fat or muscle. Athletes, for example, may be considered to be overweight even though they may have very little visceral fat. BMI is an imperfect indicator of risk of disease. People with the same BMI but different amounts of visceral fat face different risks of disease. Furthermore, weight is only one among many risk factors.

BMI is calculated the same for adults and children but is interpreted differently for children. The CDC notes that “for children ages 2 – 20 years, BMI is plotted on a growth chart specific for age and gender.”⁷

Although some authors use categories such as “moderately overweight” for those with BMI of 25-30, the National Heart, Lung and Blood Institute (NHLBI) does not designate overweight with such qualifiers. The extreme obesity classification (BMI >40) is a commonly used cut-off for determining qualification for bariatric surgery. However, BMI cut-off points for obesity vary around the world⁶.

WAIST CIRCUMFERENCE

The National Heart, Lung and Blood Institute, part of the National Institutes of Health, (NIH), has the following definition of waist circumference:

[The] presence of excess fat in the abdomen out of proportion to total body fat is an independent predictor of risk factors and morbidity. Waist circumference is positively correlated with abdominal fat content. It provides a clinically acceptable measurement for assessing a patient's abdominal fat content before and during weight loss treatment.⁵

LIMITATIONS OF WAIST CIRCUMFERENCE

Waist circumference is valuable in assessing risk in the BMI <35 range and is particularly useful in ethnically diverse groups,⁴ where waist to hip ratio may be an even better predictor. Waist circumference in individuals with a BMI >35 generally exceeds the cut-off points noted above. The relative risk faced by individuals within a BMI or waist circumference range can be estimated compared to the risk that individual would face at a normal weight or waist size. These relative risk calculations do not reflect the individual's absolute risk, which is determined by adding all of his/her risk factors.

RISK PREDICTION

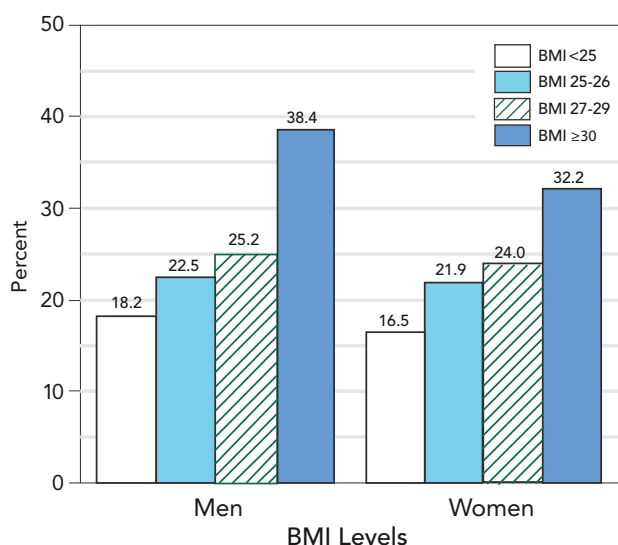
Predicting risk is essential to chronic condition management. The World Health Organization states:

The prevalence of overweight and obesity is commonly assessed by using body mass index (BMI), defined as the weight in kilograms divided by the square of the height in meters (kg/m²). A BMI over 25 kg/m² is defined as overweight, and a BMI of over 30 kg/m² as obese. These markers provide common benchmarks for assessment, but the risks of disease in all populations can increase progressively from lower BMI levels⁶.

According to The Obesity Society, "obesity is associated with more than 30 medical conditions, and scientific evidence has established a strong relationship with at least 15 of those conditions."⁸ The American Heart Association also now recognizes obesity as a risk factor for heart attack⁹.

The prevalence of various medical conditions increases with overweight and obesity for men and women, as shown in the Table 2 below in correlation to BMI.

TABLE 2 – NHANES III AGE-ADJUSTED PREVALENCE OF HYPERTENSION* ACCORDING TO BODY MASS INDEX



*Defined as mean systolic blood pressure ≥140 mm Hg, mean diastolic as ≥90 mm Hg, or currently taking antihypertensive medication.
Source: Brown C. et al. Body Mass Index and the Prevalence of Risk factors for Cardiovascular Disease (submitted for publication).

BARIATRIC SURGERY

What is Bariatric Surgery?

- The word bariatric comes from the Greek root baros meaning “weight” or “heavy” and the New Latin *iatria* meaning “to treat.”
- This obesity treatment is designed to confine stomach size, which in turn leads to decreased absorption of nutrients.
- Three different procedures:
 - o gastric bypass (malabsorptive and restrictive)
 - o adjustable gastric band (restrictive)
 - o sleeve gastrectomy (restrictive)
- 90 percent of procedures are performed laparoscopically.
- These procedures have the ability to positively impact a wide range of chronic conditions.
- Patients lose an average of 55 percent of excess weight after their surgical procedure.

Indications for bariatric surgery

According to the guidelines established by the National Institutes of Health, bariatric surgery may be right for you if:

- Your body mass index (BMI) is greater than 40 or greater than 35 with comorbidities such as diabetes, high blood pressure, etc.;
- You are 18 years of age or older;
- You have a comorbid condition caused by obesity;
- Traditional methods of weight loss such as diet and exercise have been unsuccessful;
- You’re ready to commit to a healthy and active lifestyle;
- You don’t have any medical conditions that could present complications during surgery; and
- You fully understand the benefits, risks and complications of bariatric surgery.¹⁰

Pre- operative evaluation

- The evaluation must include a comprehensive medical history, physical examination, and laboratory testing.
- Patients should be well informed about the different procedure options as well as the risks and benefits of each.
- Nutrition and meal planning management should be supplied before the patient undergoes bariatric surgery.
- Patients should understand the operation and lifestyle changes required as well as long-term follow up.
- Best practice programs that ensure long-term commitment, multidisciplinary care, and access to centers of excellence are recommended for patients who plan to undergo bariatric surgery.

Table 3 – ADVERSE OUTCOMES WITHIN 30 DAYS AFTER SURGERY, ACCORDING TO SURGICAL PROCEDURE

Outcome	Total (N = 4610) ^a	Laparoscopic Adjustable Gastric Banding (N = 1138)	Laparoscopic Roux-en-Y Gastric Bypass (N = 2975)	Open Roux-en-Y Gastric Bypass (N = 437)	P Value ^b
		number (percent)			
Death	15 (0.3)	0	6 (0.2)	9 (2.1)	<0.001
Deep-vein thrombosis or venous thromboembolism	20 (0.4)	3 (0.3)	12 (0.4)	5 (1.1)	0.05
Tracheal reintubation	20 (0.4)	2 (0.2)	12 (0.4)	6 (1.4)	0.004
Endoscopy	51 (1.1)	1 (0.1)	45 (1.5)	5 (1.1)	<0.001
Operation					
Tracheostomy	11 (0.2)	0	6 (0.2)	5 (1.1)	0.001
Placement of percutaneous drain	16 (0.3)	0	13 (0.4)	3 (0.7)	0.48
Abdominal operation	118 (2.6)	9 (0.8)	94 (3.2)	15 (3.4)	<0.001
Failure to be discharged by day 30	17 (0.4)	0	13 (0.4)	4 (0.9)	0.02
Composite end point ^c	189 (4.1)	12 (1.0)	143 (4.8)	34 (7.8)	<0.0001

^a The total excludes 166 procedures, including 117 sleeve gastrectomies, 47 biliopancreatic diversions with or without a duodenal switch, 1 vertical banded gastroplasty, and 1 open adjustable gastric banding.

^b P values are for the comparison between treatment groups. Values were calculated with the use of the chi-square test.

^c This end point is a composite of death, deep-vein thrombosis or venous thromboembolism; reintervention with the use of a percutaneous, endoscopic, or operative technique; or failure to be discharged from the hospital within 30 days after surgery.

Source: The Longitudinal Assessment of Bariatric Surgery (LABS) Consortium. Perioperative safety in the longitudinal assessment of bariatric surgery. *N Engl J Med* 2009; 361:445-54.

- The safety of these procedures has demonstrated significant improvements in recent years.
- One study reported major adverse outcomes in a cohort of obese patients who underwent common bariatric surgical procedures.¹¹
- Results show that the overall 30-day mortality and the rate of major adverse outcomes were low.

Post-operative dietary changes

Weight loss and lifestyle tips

- A weight loss lifestyle includes planning and commitment.
- Meals should be high in protein and should be eaten in small volumes.
- Listen to your body's signals that you are full. Meals should be eaten at a slow pace of 20 minutes or more to allow the feeling of satiety to occur. Doing so will help you get used to having a smaller stomach.
- Food should be eaten in small volumes.
- 64 ounces of fluid should be consumed throughout the day.
- Follow doctors' recommendations regarding vitamins and minerals. Individuals who undergo a malabsorptive procedure (gastric bypass) need to take vitamin and mineral supplements in order to prevent vitamin deficiencies. Restrictive procedures (gastric banding and sleeve gastrectomy) allow the body to absorb nutrients, but some doctors will advise one to take supplements.

Exercise recommendations

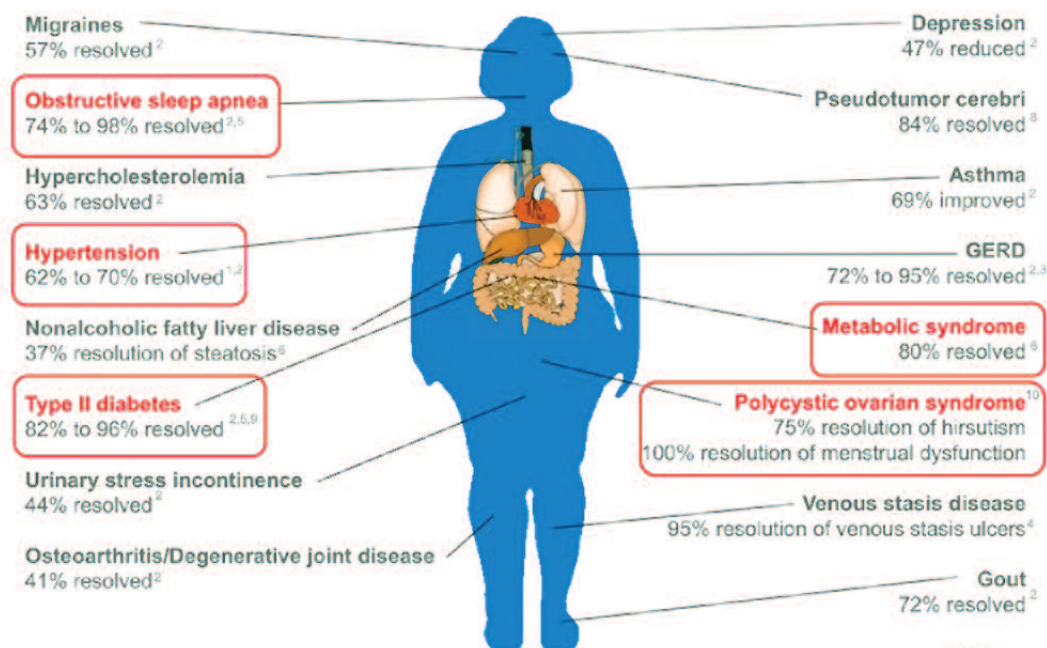
- At least 30 minutes of exercise can elicit health benefits and reduce the risks associated with diabetes, premature death, heart disease, high blood pressure, and colon cancer, improve muscle and bone structure, and improve mental health.
- Regular exercise will exploit the amount of weight lost.

Benefits of bariatric surgery

"Bariatric surgery can result in improvement or complete resolution of obesity comorbidities."¹²

Weight loss is not the only potential benefit...

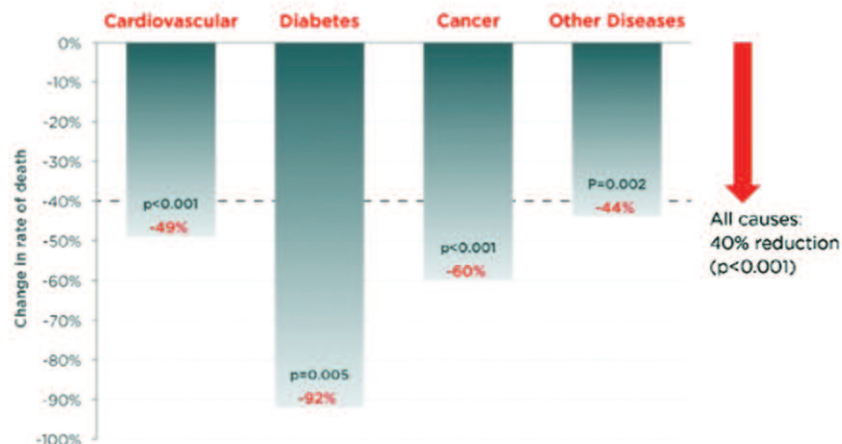
Comorbidity reduction as found in various studies



Resolution observed in the confines of studies. EES has no independent data to suggest permanent resolution. See end of presentation for references.



Long-term mortality reduction by comorbid disease type



Patients followed up on average for 7.1 years.

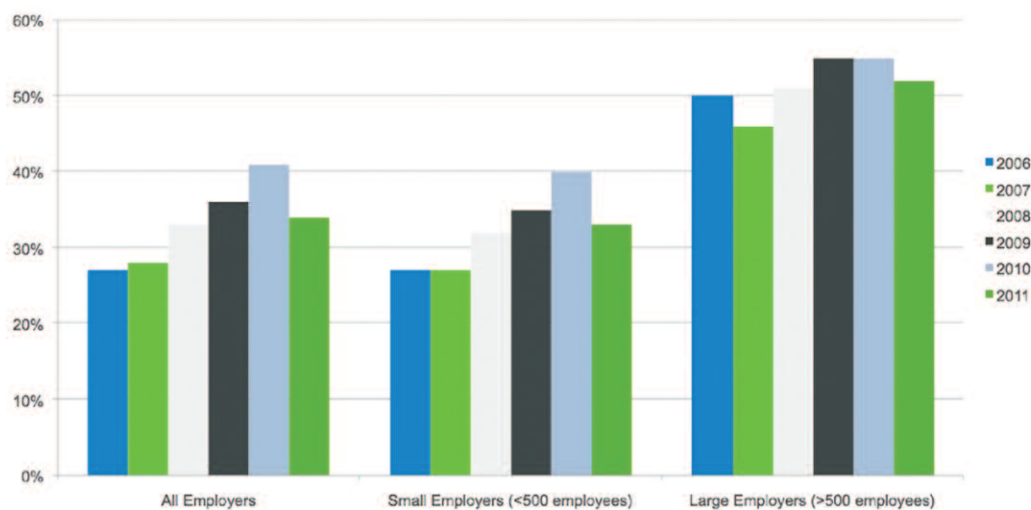
Note: in the Adams, et al. study, the rates of death not caused by disease, such as accidents and suicide, were 58% higher in the surgery group ($P = 0.004$, 63 versus 36 deaths for 15,850 matched patients in the study).

Adams TD, Gress RE, Smith SC et al. Long-term mortality after gastric bypass surgery. *N Engl J Med* 2007; 357(8):763-61.



- Bariatric surgery is a viable and effective treatment for morbid obesity that generates stable weight loss and reduces chronic conditions.
- Evidence supports that bariatric surgery is linked to decreased overall mortality, specifically deaths associated with diabetes, heart disease, and cancer.
- The results of bariatric surgery positively impact a wide range of chronic conditions, including those listed on the charts above.

BARIATRIC SURGERY COVERAGE ALL EMPLOYERS



Source: Mercer National Survey of Employer-Sponsored Health Plans



- Employer coverage of bariatric surgery dropped 7 percent among small employers and 3 percent among large employers between 2010 and 2011 after increasing year to year since 2006.¹³
- If the individual bariatric surgery procedure is not covered in the employer's Medical Benefits Summary Plan Description, you may be able to negotiate coverage with or through the employer.

TYPE 2 DIABETES AND BARIATRIC SURGERY

"The beneficial effect of surgery on reversal of existing diabetes mellitus and prevention of its development has been confirmed in a number of studies"

– American Association of Clinical Endocrinologists¹⁴

According to the World Health Organization, 90 percent of individuals with type 2 diabetes worldwide are obese or overweight.⁶ Recent data elicits strong evidence showing that bariatric surgery can lead to improvements and resolutions of type 2 diabetes and other comorbidities. New findings also suggest that bariatric surgery may prevent type 2 diabetes. Professional associations are currently taking action by updating their recommendations to propose that bariatric surgery procedures be taken into account for the treatment of diabetes, not solely obesity.

Summary of the evidence

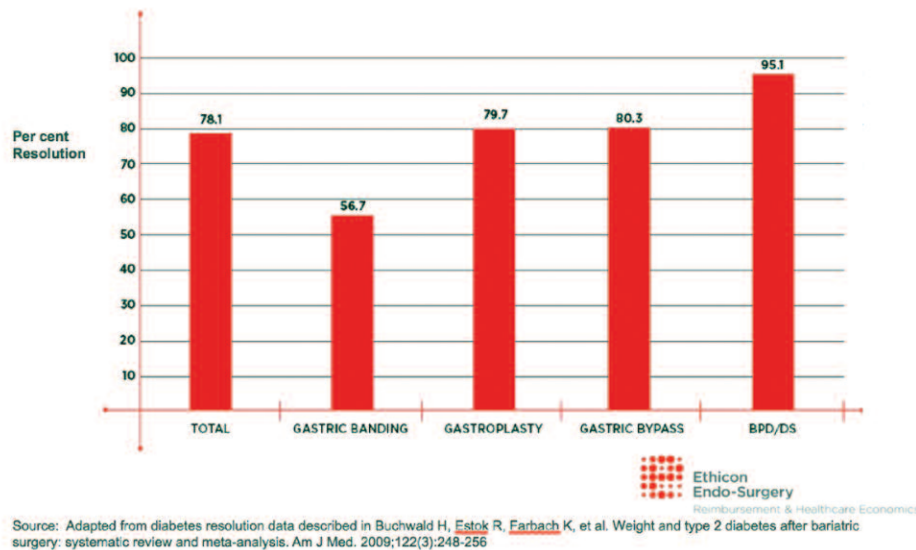
- Helped type 2 diabetic patients achieve glycemic control more effectively than intensive medical therapy within 1 year.^{15, 16}
- Resolved or improved type 2 diabetes and other obesity-related cardiovascular comorbidities for up to five years.^{15, 17, 18, 19}
- Reduced medication use for type 2 diabetes and other cardiovascular comorbidities for up to three years.^{15, 20, 18}
- Reduced the risk of cardiovascular death (myocardial infarction or stroke) compared to customary intervention at 15 years.²¹
- Resulted in morbidity/mortality rates similar to well-established general surgery procedures such as gallbladder surgery and hysterectomy.²²
- Bariatric surgery, as compared with usual care, reduces the long-term incidence of type 2 diabetes by 78 percent in obese patients.¹²
- Bariatric surgery has a preventive effect on incident type 2 diabetes, particularly in participants with impaired fasting glucose.¹²
- Bariatric surgery is associated with reductions in overall health care costs in patients with type 2 diabetes.²³

Implications for referring physicians

- The Endocrine Society recommends that practitioners consider the patient's BMI and age, the number of years of diabetes, and an assessment of the ability to comply with the long-term lifestyle changes that are required to maximize success of surgery and minimize complications.²⁴
- Focus on those patients who are highest at risk for a cardiovascular event:
 - Younger than 60 years old
 - Treated less than 10 years
 - Difficulty maintaining glycemic control with pharmacological agents
 - Has at least one other cardiovascular risk factor in addition to type 2 diabetes
 - Has difficulty controlling weight

Diabetes resolution per bariatric procedure

Bariatric Surgery Resolves/Improves Clinical Manifestations of Diabetes (Buchwald)



Medication use reduced for diabetes and other comorbidities¹⁹

In a cohort study including more than 6,000 bariatric surgery patients, using Blue Cross/Blue Shield administrative data from 2002-2005, investigators found:

- At 12 months, use of diabetes medication had declined by 75 percent¹⁹
- Use of medications for hypertension and hyperlipidemia also declined significantly in diabetic patients—down 45 percent and 55 percent at 12 months, respectively¹⁹

More cost effective than standard therapy for diabetes²⁰

Using an administrative claims database of privately insured patients from 1999-2007, comparing 808 diabetes patients who had bariatric surgery with a matched cohort who did not have surgery, investigators found:

- After 6 months, 28 percent of surgery patients had a diabetes diagnosis vs. 74 percent of control patients²⁰
- Surgery costs were fully recovered after 26 months (95 percent CI, 20-32) for patients who had laparoscopic surgery²⁰

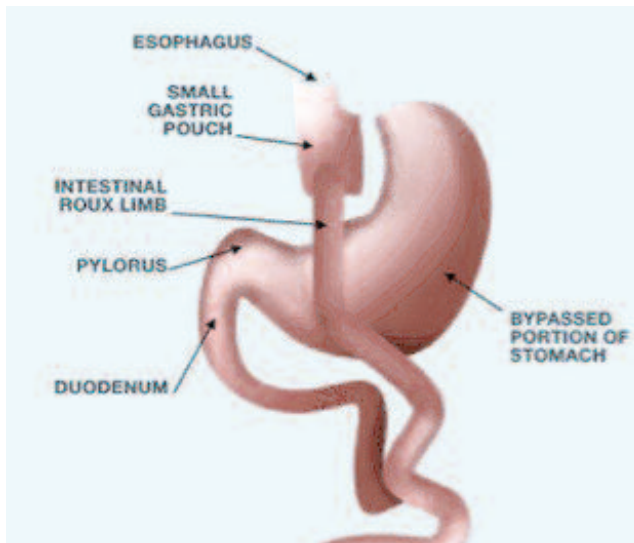
CONCLUSIONS

- Resolves or improves diabetes (78.1 percent resolved, 86.6 percent improved or resolved) and other obesity-related comorbidities.
- Reduces medication use for diabetes (down 75 percent after 12 months) and other comorbidities.
- Offers a more cost-effective option than standard therapy for diabetes—with laparoscopic surgery costs fully recovered after 26 months.
- Offers a safety profile that has improved significantly in recent years, with increased safety associated with increased procedure adoption.
- Demonstrates morbidity and mortality rates that are similar to well-accepted procedures such as elective gallbladder or gallstone surgery.¹⁵

BARIATRIC PROCEDURE OPTIONS

The most common bariatric procedures are gastric bypass, sleeve gastrectomy, and gastric banding. Each of these surgical procedures has different benefits and risks that should be considered. The surgical options should be discussed between the patient and the provider to ensure appropriate selection. Body mass index, obesity-related health conditions, the patient's eating habits, and their commitment to a healthier lifestyle should be considered before pursuing bariatric surgery.

GASTRIC BYPASS

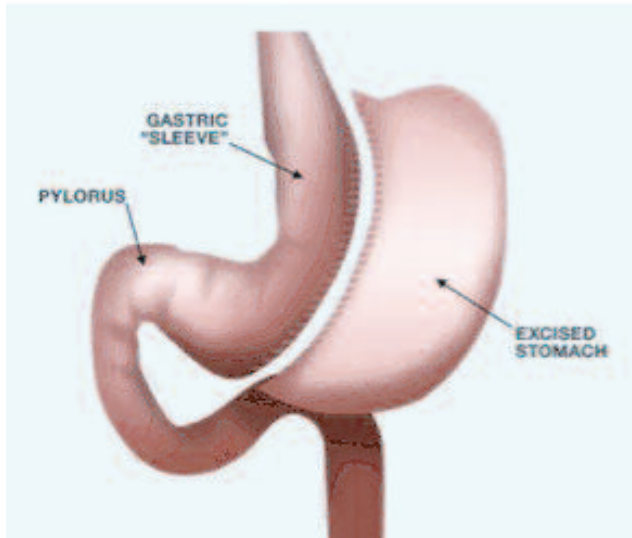


A gastric bypass restricts food intake and the amount of calories and nutrients the body absorbs. The surgeon creates a small stomach pouch and attaches a section of the small intestine directly to the pouch, which limits food intake. This procedure lets food bypass a portion of the small intestine and affects how the digestive tract absorbs food. Having a smaller stomach pouch causes you to feel full sooner and absorb fewer calories.

GASTRIC BYPASS LEADS TO SIGNIFICANT WEIGHT LOSS AND IMPROVED HEALTH

Studies conducted on gastric bypass surgery show that after one year, weight loss can average 77 percent of excess body weight. A comprehensive clinical review of bariatric surgery data showed that patients who had a bariatric surgical procedure experienced complete resolution or improvement of some of their obesity-related health problems (known as comorbid conditions), including type 2 diabetes, hyperlipidemia (high lipid [fat] levels in the bloodstream), high blood pressure, and obstructive sleep apnea. One gastric bypass information study found that gastric bypass surgery reduced the total number of serious health problems of participating patients by 96 percent.²⁵

SLEEVE GASTRECTOMY



Sleeve gastrectomy can lead to significant weight loss and improved health

Sleeve gastrectomy patients have been shown to experience significant weight loss and improvements in their health. Patients have been shown to lose an average of 55 percent²⁶ of their excess weight.

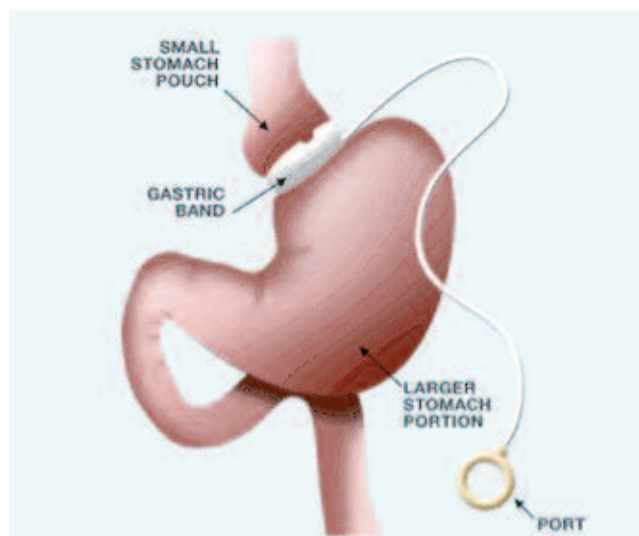
TABLE 4: HEALTH IMPROVEMENTS AFTER SLEEVE GASTRECTOMY

A clinical study on sleeve gastrectomy showed the following health benefits.

Health Problem (Comorbidity)	Result After Sleeve Gastrectomy	
	Resolved	Improved
Type 2 Diabetes	56%	37%
High Blood Pressure	37%	37%
High Cholesterol	37%	37%
Obstructive Sleep Apnea	37%	37%

Source: Gastric sleeve surgery. (2007). Retrieved from <http://www.realize.com>

GASTRIC BANDING



Gastric banding is a restrictive procedure. Food intake is reduced by a gastric band that is placed on the top part of the stomach, forming a small pouch that holds approximately a half of a cup of food. Additionally, this restricts the size of the opening from the throat to the stomach, which controls and limits the amount of food consumed at one time.

In a 3-year clinical trial:

- Patients lost a mean of 40 percent of their excess weight at one year and 43 percent at three years.
- The REALIZE Band helped resolve 48.7 percent of type 2 diabetes, 78.3 percent of high cholesterol, and 94.6 percent of obstructive sleep apnea problems.
- Patients experienced a 22 percent increase in good cholesterol (HDL) 36 months after surgery. They also experienced a decrease in bad cholesterol (LDL), total cholesterol, and triglycerides.²⁷

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Literature Review of the Current Evidence

INTRODUCTION

Over time, Americans have adopted a lifestyle that results in both health and economic consequences. Since 1980, the percentage of obese adult Americans has grown from 15 percent to 34 percent of the population. For employers, the cost of obesity results in higher medical claims expenses for obesity and its associated chronic health conditions, including but not limited to, diabetes, heart disease, and cancer.¹ In addition to the direct medical costs, obesity affects the financial health of the workplace, particularly through increased absenteeism and presenteeism.²

Evidence from peer-reviewed literature around weight loss and management programs points to several types of interventions that have shown promise. Goetzel et al³ found that obese employees had 20 percent more doctor visits and 26 percent more emergency room visits compared to normal weight employees. In addition, they found that the amount of obesity-related spending for absenteeism and presenteeism was approximately \$2596.00 per employee per year in 2006 dollars.

Evidence has demonstrated that comprehensive, multi-component worksite health promotion programs can improve employees' health, reduce absenteeism, and lower health spending for employers.⁴ Petersen et al⁵ evaluated the effectiveness of an interactive online weight management tool offered to a large employee population. The online tools available to employees included food and weight tracking, community support, e-mail communications, an information library, and periodic progress reports. The authors found a 20 percent decrease in junk food intake, a 12 percent decrease in the frequency of fast foods, and a 3 percent increase in eating breakfast. The percentage of obese participants decreased from 35.9 percent to 34.2 percent, and the average weight decreased from 182.6 to 180.2 between enrollment and 6-month follow-up. An additional study that evaluated the impact of a weight management program was conducted by Hughes et al.⁶ The authors examined a variety of short-term health outcomes, as well as the pharmaceutical use and long-term weight maintenance results from an employer-sponsored weight management program implemented in three different companies. The intervention consisted of a 26

or 52-week program, incorporating exercise, behavioral counseling, registered dietitians, certified diabetic educators, and physicians. It was found that employees' body weight decreased 5.4 percent, average waist circumference decreased 7.2 percent, and minutes of exercise per week increased from 58 minutes to 236 minutes.

Behavioral/lifestyle interventions have contributed to the success of weight loss as well. The Healthy Incentives study assessed by Scoggins et al⁷, successfully provided employees with effective tools and resources that led to better weight management. These programs and tools highlighted healthy eating, stress management, and weight management which generated wellness by encouraging an improved healthy lifestyle. Archer et al⁸ evaluated studies that illustrated potential for promoting employee weight loss. Given the criteria and the extent in weight-related outcomes, it was concluded that these methods are promising practices in the worksite setting for the prevention and control of obesity. Cost effectiveness of traditional and technology-based approaches to weight loss was evaluated by Archer et al.⁹ Although both methods were proven cost-effective, the technology-based approaches were more cost-effective than the traditional interventions.

Additionally, bariatric surgery is considered a viable solution for obese patients who have been unsuccessful with other weight loss methods. Kleinman et al¹⁰ concludes that bariatric surgery is effective in decreasing the rates of many comorbidities. Schauer et al¹¹ focuses on type 2 diabetes, a common condition in obese patients. The findings of this study suggest that in obese patients with uncontrolled type 2 diabetes, 12 months of medical therapy plus bariatric surgery attained glycemic control in considerably more patients than medical therapy alone.

Employers are making efforts to identify and contain the costs associated with obesity and improve the health and quality of life of their workers. Many large employers are integrating population health management (PHM) programs into the workplace in order to address problems of obesity.

Several significant developments have led to the emergence of the population health management model that address health all along the health continuum.¹² The core characteristics of a PHM program include, but are not limited to:

- covers the full continuum of care;
- provides a seamless and coordinated experience; and
- integrates multiple disciplines and programs.¹²

This literature review introduces strong evidence from published data on the best practices of population-based obesity interventions. The review is organized into the following categories:

- employer-based studies,
- behavioral/lifestyle studies,
- pharmacotherapy studies,
- surgical studies, and
- the role of chronic conditions in the treatment of obesity.

METHODS

This literature review employed a standard methodology designed to identify studies published in peer-reviewed journals relevant to population-based obesity interventions. Studies were extracted from the Medline database of peer-reviewed, medical and public health literature from the preceding nine years. The references in the published literature were also reviewed to identify earlier-published relevant articles identified as highly significant.

Our search produced more than 400 studies that were relevant to the study objective. Each manuscript was evaluated on the basis of study design, study methods and study population. Search terms employed in our database queries are included in the table below:

SEARCH TERMS
"obesity" AND "intervention" AND "population health"
"obesity" AND "employer" AND "population health"
"obesity" AND "population health"
"population health" AND "weight loss"
"population health" AND "weight management"
"population health management"
"population health intervention"
"population-based disease management"
"disease management" AND "obesity"
"employer" and "weight loss"
"employer" and "obesity"
"employer" and "weight control"
"worksite" and "weight loss"
"worksite" and "obesity"
"worksite" and "BMI"
"worksite" and "weight control"
"disease management" and "weight loss"
"disease management" and "obesity"
"disease management" and "BMI"
"disease management" and "weight control"
"population health management"
"populations based" and "intervention" and "obesity"
"primary care" and "intervention" and "obesity"
"health" and "weight loss"
"health" and "obesity" and "intervention"
"health" and "weight control" and "intervention"

Results of the literature review are found below. Each article is summarized and key findings and conclusions are discussed. In addition, each summary is followed by a discussion of the study's significance in the ever-growing field of population-based obesity management and its implications for healthcare professionals.

EMPLOYER-BASED STUDIES

IMPACT OF THE CORONARY HEALTH IMPROVEMENT PROJECT (CHIP) ON SEVERAL EMPLOYEE POPULATIONS

The authors assessed whether participation in a facilitator-based video version of the Coronary Health Improvement Project (CHIP) would improve health behaviors and significantly reduce employee risks.¹³ The CHIP program was originally developed as a 30-day, 40-hour live-lecture educational course highlighting the importance of making better lifestyle choices for preventing and reducing coronary heart disease. The program also taught participants how to implement these choices through a change in diet and physical activity.

Six companies in Rockford, IL, participated in the study. The cost of providing the video program was shared between the employer and the employee; however, most companies reimbursed participating employees a portion of the cost. At baseline, participants completed a self-reported questionnaire, which included a patient's medical history. Participants then participated in an 8-week educational video lecture. At the end of the eight weeks, the same medical history questionnaire was administered again. Participants were encouraged to set diet and exercise goals, including exercising for at least 30 minutes a day. Outcome variables that were measured included LDL, BMI and smoking status.

The authors found that overall healthy lifestyles knowledge had significantly improved. All worksites were able to demonstrate significant improvements in weight, BMI, total cholesterol, and LDL. Men showed significantly greater improvements in reductions in weight, BMI, total cholesterol and triglycerides. The most significant improvements in health risks were experienced by participants who had the highest risk at baseline.

Implications for Healthcare Professionals and Researchers

The CHIP video program is an effective method of decreasing employee health risks. It was found to teach participants the behavioral skills necessary to make healthy lifestyle changes.

Long-term studies of behavior change have demonstrated that it is difficult to sustain lifestyle modification. With the passage of time, most newly adopted behaviors tend to revert to previous behaviors. Future research is needed to determine how long these reductions may persist.

THE LONG-TERM IMPACT OF JOHNSON & JOHNSON'S HEALTH & WELLNESS PROGRAM ON EMPLOYEE HEALTH RISKS

Johnson & Johnson's Health & Wellness Program, which began in 1995 and consisted of two health screening programs, was aimed at reducing the health risks of employees.¹⁴ The program placed emphasis on health promotion and disease prevention. Components of the program included health risk assessments (HRA), referral to high-risk intervention programs known as Pathways to Change (PTC), preventive health services and screening programs, and health education. Financial incentives in the form of a \$500 medical benefit plan credit were offered to employees who completed an initial HRA, and enrolled in a high-risk intervention program, if appropriate.

Significant risk reductions were seen in high cholesterol, poor exercise habits, and high blood pressure, whereas four risk categories worsened over time, including high body weight and risk of diabetes. For employees in the Pathways to Change program, risks decreased for those with poor exercise habits, high total cholesterol and high blood pressure. The percentage of employees with high fat intake, however, increased significantly. Pathways to Change participants outperformed non-participants with regard to improvements in high fat intake, high body weight, poor exercise habits, diabetes risk, high cholesterol, and high blood pressure.

Implications for Healthcare Professionals and Researchers

This study underscores the ability of large-scale, corporate health programs to positively impact the health and well-being of workers. It also demonstrates a large corporation's ability to successfully implement a comprehensive population health management program that achieves high participation rates.

A LIFESTYLE-BASED WEIGHT MANAGEMENT PROGRAM DELIVERED TO EMPLOYEES: EXAMINATION OF HEALTH AND ECONOMIC OUTCOMES

The objective of this study was to examine the health and economic outcomes associated with a comprehensive weight management program directed to employees.¹⁵

This study is unique in that it reports not only a variety of short-term health outcomes, but also the pharmaceutical use and long-term weight maintenance results from an employer-sponsored weight management program implemented in three Fortune 500 companies. The inclusion criteria was employees with a BMI >30 or a BMI >27 with two or more risk factors. The employer subsidized approximately 70 percent of the program costs. The intervention, consisting of a 26- or 52-week program, incorporated exercise, behavioral counseling, registered dietitians, certified diabetic educators, counselors and physicians.

Data one-year post intervention was collected from 46 participants. Average body weight decreased 5.4 percent and average waist circumference decreased 7.2 percent. Minutes of exercise per week increased throughout the intervention from an average of 58 min/week at baseline to 236 min/week. At one-year post-intervention, weight loss and BMI were maintained.

The study concluded that an employer-sponsored, comprehensive weight management program may decrease weight, improve obesity-related outcomes and decrease costs.

Implications for Healthcare Professionals and Researchers

The results of the study suggest that an employer-sponsored, lifestyle-based weight management program delivered to a large population may be an integral component to decreasing weight and the prevalence of chronic diseases.

EFFECTS OF A TAILORED HEALTH PROMOTION PROGRAM FOR FEMALE BLUE-COLLAR WORKERS: HEALTH WORKS FOR WOMEN

This randomized trial assessed the effects of the Health Works for Women (HWW) intervention on improving nutrition, physical activity, smoking, and cancer screening among female blue-collar workers, compared to a more minimal intervention.¹⁶ The two-tiered intervention included individualized, computer-tailored “women’s magazines” that provided personalized feedback, strategies for change, and community resource information. A natural helper intervention that trained women to disseminate information and provide support for healthy behavior changes was an additional program component.

During the first six months of the study, the minimal intervention included health education sessions on a variety of topics. Participation was approximately 73 percent. Measures that were collected from each participant included demographic information, BMI, diet and physical activity, smoking and cancer screening. At the 6-month follow-up, the mean dietary fat score decreased by 3g among intervention women compared to no change in the minimal intervention group. Intervention women increased their average frequency of both aerobic and strengthening and flexibility exercise over time, whereas the minimal intervention group decreased both types of exercise. At the 18-month follow-up, the intervention group had increased fruit and vegetable consumption by 0.7 daily servings compared to no change in the other group.

The HWW program was the first that developed and tested a combined intervention approach using individualized tailored messages and a natural helper/social support program in workplaces. The study results suggest that the combination of two tailored magazines plus the natural helper program over 18 months resulted in the observed behavior changes, whereas giving one tailored magazine alone had no measurable effect.

Implications for Healthcare Professionals and Researchers

Women working in blue-collar occupations tend to have elevated health risks due to a high prevalence of unhealthy behaviors and increased stress due to jobs with high demand. They also face unique barriers to participation, including lack of time due to balancing multiple roles.

The study findings suggest that this intervention model may be feasible and effective for changing lifestyle behaviors among blue-collar women.

PROMOTING WEIGHT LOSS AND BLOOD PRESSURE CONTROL AT WORK: IMPACT OF AN EDUCATION AND INTERVENTION PROGRAM

A tailored intervention on BMI and blood pressure among hypertensive employees as part of an employer-based screening program was implemented at Merrill Lynch.¹⁷ Eligible employees had to have a systolic BP >140mm Hg and/or a diastolic BP >90mm Hg. Worksites were divided into experimental and control groups. All sites shared the following components: a hypertension screening program,

blood pressure reading, weight measurement, a Health Information card containing suggested lifestyle modifications to improve blood pressure, and educational brochures promoting physical activity. The control group had blood pressure and weight measurements plus education whereas the experimental groups also received a pedometer, body fat measurement, and education encouraging physical activity.

Change in BMI and blood pressure in both groups was compared after one year. The reduction in blood pressure was significantly greater in the experimental group compared to the control group. In addition, a 100 percent increase in those undertaking vigorous physical activity (>3x/week) in the experimental group and a 23.8 percent increase in the control group was seen. Significantly more employees in the experimental group reported that they tried to improve their diet. Participants were asked the primary reasons behind what motivated them to exercise. Responses included blood pressure reading, BMI measurement, and educational brochures. The motivation reported was significantly higher in the experimental group versus the control group.

Implications for Healthcare Professionals and Researchers

A targeted worksite intervention program may be an effective way to lower blood pressure and promote exercise and weight loss. The results indicated statistically significant improvements in BMI and blood pressure using this targeted intervention approach. Overall, this intervention provided a feasible, practical, and adaptable approach that can be incorporated into other worksites' programs.

WORKSITE INTERVENTION EFFECTS ON PHYSICAL HEALTH: A RANDOMIZED CONTROLLED TRIAL

This randomized controlled trial was conducted at an Australian casino and assessed the impact of a comprehensive exercise and lifestyle intervention on physical fitness.¹⁸ The authors hypothesized that combined aerobic and weight-training exercise (~150 min/week) plus dietary and health education counseling would improve waist circumference and BMI.

Employees were randomized to a treatment group or wait-list control group for 24 weeks. Each employee received a written health risk assessment (HRA) that included asterisks used to mark values that indicated an increased risk of disease. Components of the intervention included supervised moderate-to-high intensity exercise and diet and health

education. The behavioral component of the program, conducted at the worksite, aimed to provide general health education, and was delivered via group seminars, one-on-one counseling and through the dissemination of a worksite manual. Program incentives included massage gift certificates, a polo shirt and two bottles of wine. The wait-list control group was not offered the intervention, nor were they given any education or exercise counseling.

Improved waist circumference and physical fitness were observed. Higher intervention compliance predicted greater improvements in physical fitness. No significant effects on BMI were found. Compared to general population studies, the effects seen here on waist circumference are comparable to those reported in two of the largest randomized controlled trials that used similar interventions.

Implications for Healthcare Professionals and Researchers

The findings emphasize the enormous opportunities available to healthcare specialists and employers who aim to combat the increasing burden of overweight and obesity, and encourage physical activity.

THE IMPACT OF AN INTEGRATED POPULATION HEALTH ENHANCEMENT AND DISEASE MANAGEMENT PROGRAM ON EMPLOYEE HEALTH RISK, HEALTH CONDITIONS, AND PRODUCTIVITY

This study evaluated the impact of an integrated population health enhancement program on health risks, health conditions, and productivity of employees at DIRECTV.¹⁹ All employees enrolled in a self-insured health plan were asked to complete a health risk assessment (HRA). Employees were provided with a \$15 gift certificate for completing the HRA. Eligibility for the program included employees who were defined as high-risk based on HRA responses.

Program components included coaching in person or on-line from a personal coach; an individual action plan that specified 6- and 12-month risk reduction goals; and a minimum of six educational mailings and six phone sessions with the personal health coach. One year after implementation, all DIRECTV employees were again offered financial incentives to take the HRA and participate in the programs for which they were identified as suitable candidates. The follow-up initiative included two additional program enhancements – demand management and disease management.

The demand management program offered a 24 hour/7 day a week nurse help line that allowed employees to call with questions or to seek advice. Additionally, employees who had complex medical conditions were eligible for telephonic, nurse-based disease management. The disease management program covered multiple chronic conditions and consisted of coaching, care management, health education, lifestyle management, and consultation with the employee's physician. Employees in the disease management program were assigned to a primary nurse who would build an ongoing relationship with them and help them manage their symptoms and comply with their medications. This program was offered to all eligible DIRECTV employees over a 3-year period.

Results were examined among a cohort of 543 employees who completed two HRAs. Results were compared to two different sets of employees who were not offered the intervention. The most noticeable changes included a reduction in the proportion of employees with high cholesterol, improvement in diet, management of high blood pressure, increased exercise, and a decrease in obesity rates. Moreover, the majority of employees who improved their risk levels maintained their improvements. Employees who improved their risk levels also demonstrated relative improvement in absenteeism.

Implications for Healthcare Professionals and Researchers

The DIRECTV population health enhancement program yielded sustained health behavior change and health risk reduction. Employers can use this study to support the business case for investing in the health of their workforce as it will translate into improved productivity.

LIFESTYLE INTERVENTION AT THE WORKSITE— REDUCTION OF CARDIOVASCULAR RISK FACTORS IN A RANDOMIZED STUDY

The authors sought to test a feasible method of screening for cardiovascular risk patients at the worksite and to test the effects of a comprehensive program of lifestyle intervention to prevent cardiovascular disease (CVD).²⁰ The setting was in the public sector in Sweden. The study included a self-administered questionnaire with questions about family history of CVD, lifestyle, medical history, current treatment, psychosocial factors, social network characteristics, and work-related stressors. Individuals with a risk score sum greater than 9 were randomized to a lifestyle intervention for 18

months and then invited for an individual health check including a physical examination.

The intervention included 16 educational group sessions a year, and individual counseling by a nurse. All activities took place outside the workplace, at a health center, but were scheduled during work hours to improve attendance. Components of the program included weight reduction among the obese, diet improvement, and physical activity, as well as stress management and smoking cessation. The employees who were randomized into the control group received standard written and oral advice about CVD risk factors at the beginning of the intervention but they did not participate in any other activities.

Significant differences between the intervention and control groups were seen for BMI, diastolic blood pressure, and HDL cholesterol, all in favor of the intervention group. The smoking prevalence decreased in the intervention group, but no change was recorded in the control group. The mean number of sick days decreased in the intervention group and increased in the control group.

Implications for Healthcare Professionals and Researchers

This study demonstrated that several CVD risk factors can be improved during a long-term lifestyle intervention program with a randomized design using a worksite population of middle-aged subjects. Moreover, the use of a 2-step screening program, with an initial questionnaire followed by a health check of subjects with elevated risk, is feasible for worksite settings.

EFFECTIVENESS OF EMPLOYEE INTERNET-BASED WEIGHT MANAGEMENT PROGRAM

The objective of the study was to evaluate an employee internet-based weight management program offered to a large employee population at International Business Machines (IBM).²¹ The intervention, the Virtual Food Pro, (VFP), was added to IBM's portfolio of web-based wellness offerings for the U.S. and was accessible to all active employees. There was limited promotion of the program and no incentive offered for participation.

The VFP was an interactive online weight management tool. The goal of the program was to create lifelong habits that enable weight management. Program registration and evaluation included assessment of current weight, physical

activity level, weight management goals, stage of change, and dietary habits. Online tools available to employees included food and weight tracking, interactive tools, community support, expert assistance, e-mail communications, information library, and progress reports.

HRA data were used to compare baseline characteristics of VFP participants and non-participants. Forty-nine percent of IBM employees completed the HRA on a voluntary basis. Participation levels and the volume of interaction with the VFP website were categorized based on the number of days that a participant had logged into the website. Twelve-month weight and BMI changes were compared among VFP non-participants and VFP participants who had completed both the 2005 and the 2006 HRAs. Among the enrollees, 1,639 completed both the enrollment and 6-month survey. A 20 percent decrease in junk foods, a 12 percent decrease in the frequency of fast foods, a 12 percent decrease in pre-packaged foods, and a 3 percent increase in eating breakfast was seen. The percentage of participants in normal weight categories increased from 27 to 29.8 percent, the percentage of obese participants decreased from 35.9 to 34.2 percent, and the average weight decreased from 182.6 to 180.2 lbs. between enrollment and six-month follow-up.

HRA data were used to compare 12-month weight changes between a subset of VFP participants and a matched comparison group of non-participants. No significant changes were found between the two groups over the 12-month time period. The percentage of normal weight individuals increased in the participant group from 29.6 to 29.2 percent.

Implications for Healthcare Professionals and Researchers

The VFP program demonstrates success in changing employees' eating habits, improving stage of change regarding weight management and healthy eating, and in movement into normal weight categories.

EFFECT OF INDIVIDUAL COUNSELING ON PHYSICAL ACTIVITY FITNESS AND HEALTH: A RANDOMIZED CONTROLLED TRIAL IN A WORKPLACE SETTING

The effectiveness of the Patient-centered Assessment and Counseling for Exercise and Nutrition (PACE) materials on physical activity, health-related fitness, and health were evaluated using a randomized, controlled, single blind trial.²²

Inclusion criteria were employment as a civil servant; work in office environment; work > 24 hours a week at the local service; and a signed informed consent form.

The intervention took place over nine months. All subjects randomized into the intervention group were offered seven individual counseling sessions, which were each 20 minutes long and conducted by a physiotherapist. Counseling focused on increasing the employee's level of physical activity and the promotion of healthy nutrition habits. Using PACE protocols, the counseling included pre-contemplators, contemplators, and maintenance/action stage. Subjects in the control group received written information about lifestyle factors only. Physical fitness tests, a questionnaire, and a structured interview were used to gather data on the outcome measures. Primary outcome measures included physical activity, cardio-respiratory fitness, and prevalence of musculoskeletal symptoms.

Results showed a significant positive effect of the intervention on the percentage of body fat and cholesterol. No effects were found for changes in moderate-intensity physical activity, physical activity leisure-time index, and BMI. Both groups significantly decreased their diastolic and systolic blood pressure, but no significant difference between the two groups was found. In the intervention group, a significant improvement of cardio-respiratory fitness, percentage of body fat, blood pressure, and blood cholesterol was observed without a substantial change in physical activity.

Implications for Healthcare Professionals and Researchers

This study provides evidence that physical activity counseling has a positive effect on health-related fitness, including cardio-respiratory fitness and percentage of body fat. Moreover, participation in physical activity counseling offered to employees with a less-favorable health profile is recommended.

COMBINED DIET AND EXERCISE INTERVENTION IN THE WORKPLACE: EFFECT ON CARDIOVASCULAR DISEASE RISK FACTORS

The objective of the study was to assess the effectiveness of a 12-week pilot, employee wellness program in reducing risk factors for coronary heart disease.²³ Employees with at least one cardiovascular disease were eligible to participate. Participants were recruited via a university e-mail advertising

the program. All participants attended a one-hour program orientation session. The intervention included dietary changes, exercise regimens, and participation in a minimum of four one-hour workshops in three months. In addition, employees were asked to keep and submit a log of daily food servings and minutes of exercise.

Participants received a notebook containing a meal plan, a week of sample menus, recipes, an individualized exercise program, a log to record food intake and physical activity, and literature about resources related to physical activity on campus. In addition, they received discounts for aerobics classes offered on campus. The one-hour workshops were held at varying times throughout the day to accommodate employees' schedules. Workshop topics included, but were not limited to, quick and healthy meals; stress and eating; yoga, stretching, and Pilates; diabetes management; healthy snack foods; and surviving special occasions.

Pre- and post-intervention measurements including weight, body composition, blood pressure, total cholesterol, low-density lipoprotein (LDL) cholesterol, high-density lipoprotein (HDL) cholesterol, total cholesterol/HDL ratio, triglycerides, and blood sugar were recorded. A post-intervention survey was administered 13 weeks after the pre-intervention measurements were taken to assess adherence to different components of the intervention.

Significant differences were observed between pre- and post-intervention measurements of total cholesterol, LDL cholesterol, total cholesterol/HDL cholesterol ratio, triglycerides, and weight. The most noticeable improvements included a decrease in total cholesterol levels, which correlated with a significant reduction in CVD risk. A correlation existed between participation in the diet aspect of the program and changes in LDL cholesterol levels.

Implications for Healthcare Professionals and Researchers

The authors found that this multi-component, 12-week pilot, employee wellness program was effective in reducing cardiovascular disease risk. Results demonstrate that adherence to a healthy diet is linked to reduced LDL cholesterol.

WORKSITE STUDY PROMOTING ACTIVITY AND CHANGES IN EATING (PACE): DESIGN AND BASELINE RESULTS

This study reports the baseline results from the first two cycles of worksites taking part in the Promoting Activity and

Changes in Eating (PACE) project, a randomized controlled trial of worksites.²⁴ The PACE program is divided into five phases. Each phase has a number of strategies that build a particular behavior change focus. Each worksite is required to complete a defined minimum number of components in each phase before moving to the next phase.

Phase 1 of the PACE intervention is to increase awareness of physical activity and healthy eating among employees. Phase 2 focuses on providing motivation and support for increasing physical activity behavior and encompasses the development of an indoor/outdoor walking trail or path at the worksite. Participants are also given the PACE Self-Help manual. The goal of Phase 3 is to provide motivation and support to improve dietary habits among employees. Participants are encouraged to use the tracking tools in the PACE manual and additional self-assessment tools to evaluate current dietary habits and identify strategies to improve the quality of their diet. Phase 4 focuses on the establishment of a support system to encourage increased physical activity and healthy eating. Worksites are encouraged to offer discounts to health clubs for their employees and to provide healthy food choices at company meetings and in worksite vending machines. Phase 5 aims to provide support to maintain the physical activity and dietary changes that were made in the earlier phases by providing the resources and social support necessary to maintain these behavior changes.

The intervention lasted 18 months, with follow-up at two years from baseline. The main outcome measure was BMI, calculated from self-reported weight and height. Employees' dietary behavior and physical activity was assessed.

The authors found that the measures of physical activity and eating behaviors were associated with baseline BMI. Strong associations were found with frequency of soft drink consumption and fast food restaurant use. In men, consumption of fruits and vegetables were also strongly associated with BMI. In women, on the other hand, physical activity was strongly associated with BMI, as well as frequency of eating while doing another activity.

Implications for Healthcare Professionals and Researchers

This multi-level intervention demonstrates potential for success in combating obesity through the use of behavior change. Many of the skills introduced in the intervention, including fruit and vegetable consumption, healthy food

choices and increased physical activity, are associated with BMI in both men and women.

A WORKSITE DIABETES PREVENTION PROGRAM: TWO-YEAR IMPACT ON EMPLOYEE HEALTH

The impact of a two-year worksite version of the Diabetes Prevention Program implemented at BD Medical was examined.²⁵ The program incorporated physical activity, dietary changes, and emotional and group support in an effort to improve employee health and productivity. All adult employees were invited to participate in the study. Recruitment involved e-mail, posted flyers, and word of mouth.

Phase 1 of the program involved fasting finger-stick glucose testing, height and weight measurement, and waist girth measurement to identify those suspected of having impaired glucose tolerance or diabetes. Employees were also asked to complete a brief diabetes and demographics survey. Phase 2 consisted of 2-hour oral glucose tolerance testing of those employees. Phase 3 involved participation of those employees in a worksite diabetes prevention program lasting 12 months. All employees within the range of pre-diabetes as well as those newly diagnosed with diabetes were invited to participate in the intervention.

Physical activity, dietary education, and behavior change activities were offered in both group and individual settings. Employees were encouraged to participate in the program for one full year. At six months, participants received a \$10 gift certificate for continued participation in the program. Program participants received a pedometer, diabetes risk assessment, and diabetes education at no cost. Participants received free membership to the employee fitness center and were encouraged to participate in the exercise classes offered daily. Participants were also encouraged to reduce dietary fat intake to less than 25 percent of their daily calories. After one year, participating employees were mainstreamed back into the regular health and wellness program offered at BD Medical.

Weight, BMI, waist circumference, 2-hour oral glucose tolerance testing, very low-density lipoproteins (VLDLs), triglycerides, and aerobic fitness were significantly improved at six and 12 months. Fasting blood insulin, total cholesterol-low density lipoproteins (LDLs), and total cholesterol-high density lipoproteins (HDLs) ratio were significantly improved at six months, but not at 12 months.

Across the entire period, baseline to 24 months, a significant decline in glucose was found. After two years, employees

were found to have transitioned from the category of impaired glucose tolerance into the normal glucose tolerance or provisionally diabetic category. At baseline, 22 participants could be classified as having impaired glucose tolerance or diabetes. After two years, only 12 participants could still be classified, by current blood glucose, as having glucose intolerance or diabetes – a 55 percent reduction.

Implications for Healthcare Professionals and Researchers

Several of the clinical measures in the current study were no longer significantly improved after two years. These results demonstrate that after initial health risk improvement, the tendency is to revert back to pre-intervention habits. The motivation and inspiration provided by the program faded with time and most employees were on their own to continue adhering to a healthy lifestyle. Unless individuals can bolster significant internal personal, family, and peer support and overcome policy and environmental forces directly opposed to healthy living, healthy lifestyle decay is likely to result.

PAUSA PARA TU SALUD: REDUCTION OF WEIGHT AND WAISTLINES BY INTEGRATING EXERCISE BREAKS INTO WORKPLACE ORGANIZATIONAL ROUTINE

This study describes the implementation and evaluation of *Pausa para tu Salud* (Pause for Your Health), an intervention incorporating physical activity into workplace breaks.²⁶ All employees were strongly encouraged to participate in the exercise breaks as a regular work activity. The breaks were conducted at a specific time each morning and gradually increased in intensity as participants' fitness levels improved. Additional intervention activities included posting of stair prompts, distribution of written materials, and encouragement of staff by their supervisors and leadership to engage in additional physical activity outside the workplace. Baseline and one-year follow-up data, including socio-demographic, waist circumference, weight, height, and blood pressure was collected.

Weight, BMI, and waist circumference had decreased significantly after one year; however, results were varied by sex. Weight and BMI were found to have decreased significantly for men but not for women. Waist circumference, on the other hand, decreased significantly for both men and women. The decrease in diastolic blood pressure, however, was significant only for women.

Implications for Healthcare Professionals and Researchers

The intervention was associated with significant improvements in both measures of body composition. Significant benefits for both the employee and employer may result from incorporating short periods of physical activity into the workday if the findings in this study are replicated in randomized controlled trials in other worksites.

BEHAVIORAL/LIFESTYLE STUDIES

THE ACTIVATE STUDY: RESULTS FROM A GROUP-RANDOMIZED CONTROLLED TRIAL COMPARING A TRADITIONAL WORKSITE HEALTH PROMOTION PROGRAM WITH AN ACTIVATED CONSUMER PROGRAM

The purpose of the ACTIVATE study was to compare a traditional worksite health promotion program with an activated consumer education program, using a personal development education program as a control group.²⁷ The ACTIVATE study, which consisted of 320 participants, compared two different interventions and a control group.

One intervention offered traditional worksite-based group health promotion programs which included seminars and interactive educational campaigns on topics such as physical activity, nutrition, injury prevention, and stress management. The activated consumer intervention included population-level campaigns for evaluating health information, choosing a health benefits plan, and understanding the risks of not taking medications as prescribed. The control group, which was also known as the personal development intervention, offered information on hobbies such as photography and quilting. Individual-level coaching was offered for high-risk individuals in both active intervention groups. Coaches were assigned to one of the two interventions and coached that intervention group throughout the duration of the study. Health risk status was determined from self-reported information and clinical measures. These self-reported measures were collected using the Personal Wellness Profile. In order to provide additional clinical information, study participants also attended an on-site health screening. Activation was measured using the 13-item Patient Activation Measure.

Although the traditional intervention had higher engagement rates and better health outcomes, both interventions resulted in positive effects on health practices. The improved health practices for the at-risk individuals who took part in the

individual-level coaching revealed the effectiveness of worksite education interventions and showed the importance of motivational interviewing.

Implications for Healthcare Professionals and Researchers

Program engagement at the population level was low, but worksite education was shown as an important program component. Supplemental strategies, such as the use of incentives can be implemented in upcoming studies. Further research is needed regarding recruitment and retention methods that will improve participation in future interventions.

EFFECTIVENESS OF A WORKPLACE WELLNESS PROGRAM FOR MAINTAINING HEALTH AND PROMOTING HEALTHY BEHAVIORS

The aim of this study was to evaluate the efficacy of a worksite wellness program designed to fiscally incentivize maintenance of good health practices and improved health behaviors.²⁸ This study was based on Syngenta employee data from 2007 through 2009. After assessing an internal program at one of the Syngenta plants and several other successful wellness programs, the Reaping Rewards Program was developed.

Good health behaviors such as physical examinations, educational nutrition programs, fitness, and related topics were encouraged. Employees who participated in the program earned points that could be exchanged for cash as a form of motivation. Other incentives included drawings and giveaways for those employees who accumulated the maximum number of points. Outcome measures were collected through the health risk appraisal (HRA). The HRA included information on the participant's height and weight which was used to calculate their body mass index. Other factors that were taken into account included physical pain, health limitations, physical activity, diet, stress, and biometric measures.

A total of 3,033 employees participated in the company wellness program, which amounts to an 80 percent participation rate. The high level of participation was most likely a result of the incentivized approach of the Reaping Rewards Program. Results of the study show that the program had a very positive effect among those with a poorer health status at baseline. Among obese participants in the study,

selected mental and dietary variables demonstrated significant improvements. Participants who were able to lower their BMI showed considerable decreases in fat intake as well as increased weekly physical activity.

Implications for Healthcare Professionals and Researchers

A financial incentive very likely contributed to the high participation rate for the program. Future research could include an analysis of effective incentives to increase participation among healthy or low-risk individuals.

SHORT-TERM AND LONG-TERM WEIGHT MANAGEMENT RESULTS OF A LARGE EMPLOYER-SPONSORED WELLNESS PROGRAM

Healthy Incentives is an employer-sponsored program that attempted to generate wellness by encouraging an improved healthy lifestyle.⁷ Programs and tools highlighting healthy eating, stress management, and weight management were put into practice. Weight management results of the Healthy Incentives employer-sponsored program were evaluated in this study.

Self-reported data were gathered from health risk assessments in three different samples. One sample was the first year of participation from each participant, regardless of which year they entered the program. The next sample included the participants who completed health risk assessments in 2006 and 2011 and participated in the five-year cohort. The last sample was a subset of the five-year cohort who completed health risk assessments in each year from 2006-2011. This last sample was used to exemplify the annual change in BMI. In order to create a comparison group, longitudinal data files from the Medical Expenditures Panel Survey were used. The measures gathered from the health risk assessments included height, weight, and demographic data. Body mass index values were calculated for each participant.

A total of 19,559 first-year participants lost weight on average, while the comparison sample gained weight. Successful weight loss was present in 10,432 five-year participants. Most of their weight loss occurred in the first year of the study. The affirmative first-year results led to long-term weight loss for several obese participants and less weight gain by many members in the normal weight range. Overall, the Healthy Incentives has provided employees with

effective tools and resources that lead to better weight management.

Implications for Healthcare Professionals and Researchers

In general, the program was exceptionally beneficial for women, members older than 60, African Americans, and members who did not graduate from college. Healthy Incentives is a practical educational program that might be particularly useful for individuals who are unaware of the adverse health risks of obesity and ways to combat this health condition.

RECENT EXPERIENCE IN HEALTH PROMOTION AT JOHNSON & JOHNSON: LOWER HEALTH SPENDING, STRONG RETURN ON INVESTMENT

The definitive goal of this article is to show the positive effects of the current study that can be applied to the vast majority of US adults in the workforce. In this study, the effect of Johnson & Johnson's health risks and medical care costs were compared to sixteen other large companies between 2002-2008.²⁹

The sample included U.S. employees from Johnson & Johnson and comparison companies who were active, employed full time, and were between the ages of 18 and 64. Johnson & Johnson selected the comparison companies at random based on their correspondence to Johnson & Johnson in terms of the industry and their size. A survey was used to measure the comprehensiveness of the wellness programs offered by the comparison companies. Five core program elements were considered and were rated on a four-point scale that ranged from "not in place" to "fully operational/mature." Medical care costs were calculated as total payments and included both the employer and employee shares of costs. Obesity, high blood pressure, high cholesterol, physical inactivity, poor nutrition, excessive alcohol consumption, tobacco use, depression, and high stress were the nine health risks that were considered.

The results showed that Johnson & Johnson experienced a 3.7 percent lower average annual growth in medical costs compared to the comparison group from 2002-2008. Results from the health risk analysis demonstrated that Johnson & Johnson employees had a lower average predicted likelihood of being at high risk for six of the nine health risks examined.

Implications for Healthcare Professionals and Researchers

This study supplements new evidence to the health promotion evaluation literature by documenting the experience of employees at an entire company in addition to that of employees at other like companies, rather than a study solely based on the effect of program participation within an organization.

PROMISING PRACTICES FOR THE PREVENTION AND CONTROL OF OBESITY IN THE WORKSITE

The objective of this review is to identify worksite practices that illustrate potential for promoting employee weight loss.⁸ A systematic review was conducted, adding to earlier reviews to determine promising weight loss practices of worksites by using the Community Guide method.

The Community Guide advocates worksite programs intended to improve diet or physical activity behaviors based on strong evidence of their effectiveness for reducing weight among employees. A conceptual model was used for this review which focused on environmental and policy strategies, informational and educational strategies, and behavioral strategies. English language articles were searched from peer-reviewed and grey literature. Studies were selected for the review if they were conducted in a worksite and reported a weight-related outcome for adult employees aged at least 18 years.

A total of 21,297 titles and abstracts were found. After reviewing these titles and abstracts, 1,556 studies were retrieved. Given the criteria and the extent in weight-related outcomes, it was concluded that these methods are promising practices in the worksite setting for the prevention and control of obesity.

Implications for Healthcare Professionals and Researchers

Implementing effective weight loss programs have the potential to decrease health care costs associated with obesity and its comorbidities. It has the added benefit to reduce absenteeism, increase productivity, and over time result in a positive return on investment. Because it was difficult to identify the strength of the evidence of effectiveness for one promising practice over another, these practices should be tested by worksites and call for further evaluation.

AN ECONOMIC ANALYSIS OF TRADITIONAL AND TECHNOLOGY-BASED APPROACHES TO WEIGHT LOSS

The current review introduced a cost-effective analysis of the Lifestyle Education for Activity and Nutrition (LEAN) study, which examined the efficiency of traditional and technology-based approaches to weight loss³⁰. The LEAN study was a nine-month randomized control trial of a technology-based intervention to promote weight loss through changes in lifestyle behaviors in 197 sedentary, overweight, and obese adult men and women.

The participants were randomized to one of four conditions. Standard care control and group weight loss education were the two traditional approaches used, while the SenseWear armband alone and the SenseWear in combination with group-based, weight loss education were the two novel approaches used. The intervention groups of the study were the weight loss education group, the SenseWear armband group, and the group weight loss education plus armband. At nine months, there were significant within-group weight reductions compared to baseline in the three intervention groups.

In each of the cost-effectiveness analyses, the technology-based approaches were more cost-effective than the interventions based on standard care/traditional approaches. The results of this study suggest that technology-based approaches to weight loss may be more cost-effective than traditional counseling/educational-type and pharmacologic interventions alone or in combination.

Implications for Healthcare Professionals and Researchers

Interventions that rely on advanced technology may provide a competent and cost-effective investment. Therefore, future research is needed to reproduce the present findings and expand on this research over a long period of time with more diverse populations and outcomes.

COMPARATIVE EFFECTIVENESS OF WEIGHT-LOSS INTERVENTIONS IN CLINICAL PRACTICE

In order to address the need for treatment models, a randomized control trial was conducted to examine the effects of two behavioral weight-loss interventions.³¹ One intervention provided patients with virtual weight loss support through the telephone, a study-specific web site, and e-mail. The other intervention offered in-person support during group and individual sessions. The three remote means of support were made available as well. In addition there was a control group in which weight-loss was self-directed.

This two-year study recruited 415 obese patients with at least one cardiovascular risk factor. Eligibility, baseline, and follow-up data were collected by telephone, through the web, and through in-person visits. In-person follow-up visits were requested at six, 12, and 24 months after randomization. Height was measured once at the beginning of the study, while weight and blood pressure were recorded at each of the three visits. Waist circumference and fasting levels of blood glucose lipids were measured at baseline and six and 24 months after randomization.

Significant improvements in body weight were demonstrated in both intervention groups. A large percentage of participants lost 5 percent or more of their initial body weight, an amount that had been linked to several health benefits. The results of this study emphasize the effectiveness of remote support due to the similarities between the two intervention groups. Remote support is a compliant method that accommodates both participants and coaches.

Implications for Healthcare Professionals and Researchers

The effectiveness of these programs suggests that similar interventions be put into action. Implementing programs similar to those used in the intervention groups in primary care could help relieve strain on obesity-related disease. This tactic would also demand changes in health care delivery systems and reimbursement policies.

EFFECTIVENESS OF A WORKSITE TELEPHONE-BASED WEIGHT MANAGEMENT PROGRAM

This study examined the long-term effect of a telephone-based coaching intervention on weight loss and related behaviors.³² The study sample was recruited from 10 different companies that offered health management programs between 2004 and 2006. In order to be considered for the study, individuals had to have a BMI of 30 or greater or a BMI of 25-29.9 with a waist circumference of over 40 inches if male or over 35 inches if female.

A total of 1,298 participants enrolled in this telephone-based weight management program. Weight, BMI, and lifestyle factors were self reported and assessed via health risk assessment at baseline and 1-year follow up.

Among those who participated in this study, program completers averaged 2.6 times more weight loss than non-completers. The findings of this research highlight the

potential of a modest intensity telephone-based intervention. Results show that this type of intervention can have a positive impact on the weight and health of obese or overweight worksite participants.

Implications for Healthcare Professionals and Researchers

Meaningful weight loss can be achieved by implementing a population-based approach at the workplace. Evidence shows that even a slight decline of obesity rates in the workplace can affect medical costs, absenteeism, and presenteeism. Additional phone calls were added to maintain the relative advantages of the protocol while pursuing greater average weight loss subsequent to this intervention. The present study adds to a growing literature suggesting that lifestyle changes supporting modest weight loss may be feasible.

PHARMACOTHERAPY STUDIES

PHARMACOTHERAPIES FOR OBESITY: PAST, CURRENT, AND FUTURE THERAPIES

The ultimate goal of this review was to assess the safety and effectiveness of long-term drug therapy for the treatment of obesity.³³ Recent randomized control trials (RCTs) of past and current pharmacotherapies were used for this evaluation of long-term therapy (orlistat), short-term therapy (amfepramone [diethylpropion], phentermine), recently withdrawn therapies (rimonabant, sibutamine) and drugs evaluated in Phase III studies (taranabant, pramlintide, lorcaserin and tesofensine and combination therapies of topiramate plus phentermine, bupropion plus naltrexone, and bupropion plus zonisamide).

There is some controversy in establishing the most essential outcome measures for evaluating drug therapies. Typically, absolute weight loss (in excess of placebo), percentage of weight loss, percentage of patients achieving 5-10 percent weight loss, BMI, or waist circumference are used. Secondary efficacy endpoints such as clinical measures (i.e., blood pressure, glycemic control, and cholesterol levels) are becoming more common in recent studies.

Past therapies and current approved drugs such as amphetamines, fenfluramines, antidepressants, orlistat, sibutamine, and rimonabant were assessed in this review. In addition, drug monotherapies such as pramlintide, glucagon-like peptide, taranabant, lorcaserin, tesofensine, naltrexone,

bupropion plus naltrexone, bupropion plus zonisamide, topiramate plus phentermine, and pramlintide combination therapies were evaluated as well.

Results of the study show that of the drugs evaluated, orlistat and sibutramine are currently approved and accessible for long-term treatment of obesity. Among the drugs in late phase trials, lorcaserin is a plausible possibility for long-term treatment in obesity because of its effectiveness and safety demonstrated in the review. Although topiramate and tarenabant have shown significant weight loss results in long-term studies, they are also associated with major adverse effects. Both combination therapies of bupropion with naltrexone and bupropion with zonisamide have exhibited successful weight loss, while safety of combination therapy using topiramate with phentermine remains doubtful.

Implications for Healthcare Professionals and Researchers

There are several drugs and combination drug therapies undergoing Phase III trials that may be approved in the next few years.

SURGICAL STUDIES

BARIATRIC SURGERY VERSUS INTENSIVE MEDICAL THERAPY IN OBESE PATIENTS WITH DIABETES

The ultimate goal of this randomized, nonblinded, single-center trial, was to evaluate the effectiveness of intensive medical therapy alone versus medical therapy plus Roux-en-Y gastric bypass or sleeve gastrectomy as a means of improving glycemic control in obese patients with type 2 diabetes.¹¹ All patients in the study were counseled by a diabetes educator, encouraged to participate in the Weight Watchers program, and received intensive medical therapy. In addition, all patients were treated with lipid-lowering and antihypertensive medications. Patients who were assigned to undergo bariatric surgery were evaluated by surgical, nutrition, and psychology services as required.

One hundred and fifty patients from the Cleveland Clinic were eligible and selected to participate in this study. Using a block-randomization method, the patients were split up equally to undergo intensive medical therapy alone or intensive medical therapy plus either Roux-en-Y gastric bypass or sleeve gastrectomy. At baseline, demographic information, coexisting illnesses, rates of diabetes complications, anthropometric values, use of medications and laboratory values were collected from each participant.

Additionally, body weight, waist and hip circumference, blood pressure, and levels of glycated hemoglobin and fasting plasma glucose were assessed at baseline and at months 3, 6, 9, and 12. The primary end point of this study was the proportion of patients with a glycated hemoglobin level of 6 percent or less, 12 months after randomization.

The findings of this study suggest that in obese patients with uncontrolled type 2 diabetes, 12 months of medical therapy plus bariatric surgery attained glycemic control in considerably more patients than medical therapy alone. The targeted glycated hemoglobin level of 6 percent or less at 12 months occurred in 12 percent of those in the medical therapy group, as compared with 42 percent in the gastric bypass group and 37 percent in the sleeve gastrectomy group.

Implications for Healthcare Professionals and Researchers

The results were generally similar in the two surgical groups although somewhat more favorable in the gastric bypass group. Other variables such as BMI, body weight, waist circumference and the HOMA-IR index also showed more beneficial results in the surgical groups than in the medical therapy group. Further research will be needed to assess the strength of these results.

THE IMPACT OF MORBID OBESITY AND BARIATRIC SURGERY ON COMORBID CONDITIONS: A COMPREHENSIVE EXAMINATION OF COMORBIDITIES IN AN EMPLOYED POPULATION

The ultimate goal of this study was to consider the effect of bariatric surgery on the prevalence of comorbid conditions after surgery.¹⁰ The data source of the retrospective analytic database supporting this research was produced from the Human Capital Management Services Research Reference Database.

In order to examine the effect of morbid obesity on comorbidities, two study cohorts were identified. The first cohort contained employees who were diagnosed with morbid obesity (DMO). The second cohort was in the control group in which employees had no such diagnosis. Successive portions of the study were centered around employees who had a morbid obesity diagnosis and had bariatric surgery.

This study observed many outcomes of interest. The first comparison was that of those diagnosed with morbid obesity compared with those of the control group. Seventeen major diagnostic categories (MDC) and the 261 specific Agency for

Health care Research and Quality's (AHRQ) categories were compared for each of the cohorts. The change in the prevalence of each AHRQ-specific diagnostic category was examined. The analysis included comparison of the prevalence of conditions during the period two to four months before bariatric surgery with the prevalence in the period two to four months after. Finally, the last analysis looked at trends in prevalence of conditions starting with the 90-day period before surgery and in subsequent 90-day increments beginning with the 30th day after surgery and ending 749 days after surgery.

This study reveals that employees DMO are at higher risk for a larger list of conditions than what has been discovered in past studies. A broad examination of all AHRQ diagnostic categories in this research suggests that bariatric surgery is a considerable solution for the obese population. Findings in the study show that those in the DMO cohort had higher diagnosis rates in most MDC categories and higher prevalence in most AHRQ-specific categories. The study also observed prevalence declines in 26 of 106 AHRQ-specific diagnostic categories within two to four months after surgery.

Implications for Healthcare Professionals and Researchers

Several additional conditions with higher prevalence among employees with a morbid obesity diagnosis were found in this study. Those conditions not identified in previous studies include intervertebral disc disorders, malaise and fatigue, anemia, other upper respiratory disease, other lower respiratory disease, abdominal pain, nonspecific chest pain, and symptoms categorized as residual codes/ill-defined symptoms. Further research will make future studies stronger. It is recommended that monitoring the long-term effects of bariatric surgery beyond the second year post-procedure would strengthen the study. Comparing other methods of weight loss to bariatric surgery is another way to strengthen future studies.

THE ROLE OF CHRONIC CONDITIONS IN THE TREATMENT OF OBESITY

Today's health setting is dominated by lifestyle chronic disease, including type 2 diabetes mellitus. The incidence of this chronic disease is extensively recognized as one of the most challenging contemporary threats to public health. Adults with type 2 diabetes mellitus often experience mobility limitations that worsen as they get older. These limitations

ultimately compromise quality of life.

Current evidence points to the positive impact that weight management interventions can have on type 2 diabetes. The study of a lifestyle intervention (below), as well as the two preceding studies on the effect of surgical interventions, demonstrates this impact.

LIFESTYLE CHANGE AND MOBILITY IN OBESE ADULTS WITH TYPE 2 DIABETES

A lifestyle intervention was implemented to slow down the decrease of mobility in these patients with type 2 diabetes.³² This intervention aimed to produce weight loss and improve fitness. An important byproduct of weight loss and improved fitness is the healthier mental outlook of/for the patient.

Overweight and obese patients with type 2 diabetes between the ages of 45 and 74 years were enrolled in the study. From 2001 through 2004, participants were randomly assigned to either an intensive lifestyle intervention or to a diabetes support and education program. The primary goals of the lifestyle intervention were to stimulate a mean weight loss from baseline of more than 7 percent and to increase the period of physical activity to more than 175 minutes a week. The diabetes support and education group involved three group meetings a year to discuss nutrition, physical activity, and support. Mobility was assessed on the Medical Outcomes Study 36-Item Short-Form Health Survey Physical Functioning subscale. The items in this study included vigorous activity and moderate activity. Limitations on mobility were self-reported with annual assessments for four years.

At year 4, 20.6 percent of participants in the lifestyle intervention group had severe disability while 38.5 percent had good mobility. In the support group, 26.2 percent of participants had severe disability, while 31.9 percent had good mobility. The findings of the study verify the clinical significance of declining mobility as adults with type 2 diabetes become older. It is evident that weight loss and improved fitness slowed the loss of mobility in overweight adults with type 2 diabetes.

Implications for Healthcare Professionals and Researchers

Among overweight and obese adults with type 2 diabetes, participants in the lifestyle intervention group were 48 percent less at-risk for loss of mobility compared to the support group. Insufficient mobility is a risk factor for the onset and development of most chronic conditions.

CONCLUSIONS

Nearly two-thirds of American adults are overweight or obese, and the percentage of adults classified as obese doubled from 1980 to 2000 to 31 percent of the population.¹ Obesity is a risk factor for several chronic illnesses, including type 2 diabetes and heart disease. Employers are becoming increasingly aware of the human and economic burden that poor health imposes on their employees. As a result, many employers are investing in health promotion and population health management programs aimed at reducing the prevalence of obesity in the workplace through the promotion of physical activity, healthy eating, and behavior change.

Studies in the published literature demonstrate that a population-based obesity management program can result in a significant improvement in employee health and a reduction in risk factors. Moreover, evidence shows that obesity management programs may be associated with lower levels of absenteeism and healthcare costs, and programs incorporating physical fitness are associated with reduced healthcare costs.

The literature identifies best practices for weight management programs which should be considered in developing interventions. Many of these employer-based best practices were incorporated and include securing senior management support, employee input, conducting HRAs and biometric screenings and educating employees about the value of health promotion, prevention, and chronic condition management. In addition, evidence from the literature suggests that other interventions to consider in a weight management program should be a variety of nutritional and physical

activity programs with educational components. Best practices also generally incorporate realistic, measurable goals, participant incentives and tracked outcomes. Components not seen in these studies, but highly recommended as key elements to a successful population-based obesity intervention, are community involvement, employee inputs about accessible health information and stress management initiatives.³⁵

OPPORTUNITIES FOR FUTURE RESEARCH

As health care continues to seek innovative and population-based methods to encourage weight management and improve, it is imperative that research efforts continue to evaluate current programs to determine what constitutes a successful program, how to successfully implement these programs, for what population, and how to measure program outcomes.

Many employers are integrating a variety of weight management programs, however most worksite obesity management studies have been conducted in large organizations with greater than 5,000 employees, yet more than 70 percent of adults in the U.S. workforce are employed in organizations with fewer than 5,000 employees.³⁵ Future research should include broader samples of small, mid-size and large employers in the public and private sectors. In addition, well-defined health measures should be tracked to evaluate long-term patient outcomes and their impact on healthcare costs for all weight management efforts regardless of the delivery setting.

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Case Studies

Programs that address the needs of overweight and obese individuals are varied and based on the specific needs of the population. The following case studies offer an overview of several strategies for development and deployment of these programs, as well as the clinical and financial outcomes that can be realized. The case studies vary by setting and include program delivery through the worksite, health plan, hospital and population health vendor.

The first case study summarizes findings from qualitative interviews with eight employers that were selected based on the duration of their programs and collection of measurable outcomes.

Population-Based Worksite Obesity Management Interventions: A Qualitative Case Study

ABSTRACT

Background

Due to the increased prevalence of obesity and associated direct and indirect costs to employers, weight-management programs have become an integral component of employer and insurer benefits plans. The programs vary in foci, scope, breadth, and implementation.

Aim

To explore promising employer-sponsored population-based obesity management programs.

Setting

Small and large organizations located in different regions of the United States were recruited to participate in a qualitative case study utilizing a telephonic semi-structured questionnaire.

Method

Eight employers and one healthcare advocacy coalition who met the inclusion criteria were interviewed about features of their weight management programs.

Results

The case study revealed a number of themes consistent with reports in the literature and reflecting many cited best practices. Key findings include confirmation that weight management is a significant component of the wellness strategy in all participating organizations because employers

are invested in population health programs and cost savings. Based upon their experience and knowledge, professionals responsible for designing, implementing, managing and evaluating employee health programs, employee health specialists are strategically planning organizational programs. Almost all employers are utilizing electronic media as a prominent component of wellness and chronic condition management initiatives. Experience has shown that incentives—both financial and non-monetary—are effective motivators for employee engagement and outcomes. However, while employers report success, favorable outcomes have been difficult to quantify.

INTRODUCTION

Since 1980, the percentage of obese adult Americans has grown from 15 percent to 34 percent of the population. For employers, the cost of obesity results in higher medical claims expenses for obesity and its associated chronic health conditions, including for example, diabetes, heart disease, and cancer.¹ In addition to the direct medical costs, obesity affects the financial health of the workplace, particularly through decreased productivity (absenteeism and presenteeism).² A study conducted by RTI International Health, Social and Economics Research and the Centers for Disease Control and Prevention found that the annual additional cost for an obese worker can reach \$2,500.³

Employers are making efforts to identify and contain the costs associated with obesity and improve the health and quality of life of their employees. Many employers are implementing

population-based obesity management programs in order to address the growing problem of obesity. A 1999 study found that 46 percent of employers offered some type of physical activity program, 38 percent provided weight management programs, and 25 percent offered disease management programs that address obesity.⁴ This has undoubtedly increased over the past 13 years. While many employers are integrating a variety of these types of programs into the workplace, limited evidence exists to demonstrate which programs and which program components are successful in reducing obesity.⁵ Moreover, most worksite obesity management studies⁶ have been conducted at large worksites with greater than 5,000 employees, yet more than 70 percent of adults in the U.S. workforce are employed in organizations with fewer than 5,000 employees.⁷ A review of seven studies⁵ found worksite programs that combined nutrition and physical activity were successful in encouraging initial weight loss, in the range of 4 to 26 pounds. Consequently, we performed a qualitative case study to identify and describe diverse population-based obesity management interventions in a variety of workplace settings.

METHODS

Sampling and recruitment

Organizations that accessed the Care Continuum Alliance Obesity Toolkit, or were recommended by Care Continuum Alliance, were invited to participate in the study. In addition, programs suggested by potential participants as well as attendees at two major population health conference sessions were also recruited. Potential participants were initially notified through e-mail, followed by telephone calls, about the study purpose, the inclusion criteria, the screening and survey processes. The three inclusion criteria were: (1) employer-sponsored programs in existence for at least one year; (2) collected measurable outcomes (e.g., pounds, BMI, participation, assessment of changes in health); (3) programs not yet published in the peer-reviewed or lay literature. The study plan and interview instruments were reviewed by Thomas Jefferson University's Institutional Review Board (IRB) and approved for exemption prior to initiation of the study.

Design

Screening interviews were conducted with 14 potential participants prior to enrollment in the study to ensure that their programs met the inclusion criteria. Reminder e-mails and telephone calls were made to all non-responders.

Variables included in the screener included:

- Size of the population,
- History of the program (start date),
- Key program components and activities,
- Enrollee participation,
- Availability of objective data on outcomes (weight loss or BMI change),
- Length of follow-up (at least a year, except for newer, innovative programs), and
- Willingness to participate in a case study.

Based on the initial screening, eight employers were selected to participate in a more comprehensive case study. In addition, an interview was conducted with the director of a healthcare coalition of large self-insured corporations that collaboratively addressed population health issues.

Comprehensive semi-structured telephonic interviews were conducted between July and December 2009. Two study team members participated in each telephone interview, one serving as the interviewer, and the other as the recorder. Each case study was documented in a standardized format, including program description, evidence of effectiveness, key lessons, and specific tools and techniques. In-depth information about program components which appear to be most successful, or for which data supporting success are available, were collected. Additionally, lessons learned in the implementation process, including facilitators and barriers, program costs and advice on sustainability were also captured. Objective data, subjective impressions regarding program success, and specific tools which interviewees are willing to share with a broader audience were requested from each site.

Nine interviews were conducted with individuals knowledgeable about their participating organizations' weight-management programs. The sample included organizations based across the United States including the east and west coasts and the southeast, southwest, and northeast regions and three organizations with an international presence. Seven of the eight businesses were for-profit organizations involved with manufacturing, retailing, insurance, banking and investments and healthcare. In one instance, interviews were conducted with two individuals at a large corporation with decentralized local business sites. Employee health services are developed, managed and

financed by each local site. Therefore, an interview was conducted with the corporate medical director about corporate programs and practices and a separate interview was conducted with a corporate site program manager about their specific programs and experiences. The two non-profit organizations included an academic medical center and a healthcare coalition. The number of employees per company ranged from 1,400 to 180,000. The individuals interviewed included employee health medical directors, a human resource benefit manager, wellness managers, strategic healthcare consultants and healthcare providers with direct responsibility for wellness program design, implementation and/or management. (Study participants are referred to as “employee health specialists” (EHSs) in this paper.) For smaller companies, only one individual was responsible for the organization’s wellness programs. Larger organizations have dedicated personnel (both staff and contractors) based in corporate headquarters and offices throughout the country including health and wellness specialists, health coaches, personal trainers, and nutritionists.

Data analysis

This qualitative study followed the case study format. Interview notes were transcribed and reviewed several times for relevant and unique information provided by each interviewee. These statements were highlighted and categorically outlined. The transcripts and outlines were read in the context of pre-determined areas of interest and themes were identified by both interviewers. Significant comments were highlighted in the outline and the themes that emerged formed the structure for the report of the findings. The main themes are listed according to a logical progression from overall program management and staffing to evaluation of the programs.

RESULTS

Program management and staffing

Each organization’s programs are managed by professionals with health care, management or education training and experience. These managers have knowledge, expertise and insight about employee health issues, interventions, and challenges as well as reflect commitment to implementing appropriate value-based programs for their populations.

Program staffing varies by employer size and location. Larger corporations have additional and diverse health professionals (e.g., nutritionists, coaches, fitness trainers) to support their employees. Smaller companies may have only one EHS at the corporate site who performs all occupational health responsibilities and utilize employees as volunteers to support health initiatives. For example, one corporation with several sites in one small regional area has a medical director for employee health and wellness, three health fitness managers, twelve staff employees and fifteen coaching contractors. Another company of 30,000 employees, conducting business in twelve states, employs eight “wellness consultants” situated around the country in addition to telephonic health coaches. Other companies staff on-site health clinics and/or fitness centers at different locations.

Senior management support

Senior executives from each company have demonstrated commitment to population health management for their employees, and in some cases, employee families, through financial support of programming and insurance benefits. Some of the enhancements supported by senior management include opening on-site clinics, fitness centers, walking trails, and adding stairwells to encourage walking. Another senior manager has advocated through the media about the benefits of wellness programs. Others are financially supporting new programs (e.g., bariatric surgery, subsidizing health club memberships and weight loss programs, and implementing a tobacco-free work environment).

Employee screening

All eight companies offer health risk assessments (HRAs) and health screenings for their employees. Health screenings include measurement of weight, body mass index (BMI), height, blood pressure, serum glucose, cholesterol and triglycerides. Mammograms and full blood panels were also offered. One company provides preventive care (e.g., dental cleanings and exams, vaccinations, flu shots, etc.), to insured employees and their families at no cost. Three companies offer incentives to employees who complete annual HRAs and/or health screenings. Incentives include cash, gift cards,

team-targeted incentives, and raffles. Results from HRAs are used by employee health managers to develop population-based and/or individual health programs.

Wellness committees

The literature reflects that wellness committees including employee participants are considered a best practice because of the diverse representation of ideas, recommendations, and feedback to guide development, implementation and evaluation of programs. One corporation utilizes an employee volunteer as a wellness contact for sites without occupational health services. Wellness contacts publicize and coordinate programs, recruit participants and provide input to the corporate health department. Other companies seek employees to participate on wellness committees for their input and evaluation of programs.

Program Design

Employers are utilizing a wide spectrum of programmatic design and support. Online tools are used by all but one company. These include company intranet sites, health and disease management webinars, online coaching, and online tracking of health behaviors. Challenges such as “The Biggest Loser at Work” and “Family Fit” have proven to be successful models for at least three organizations.

Nutrition Programs

All eight companies offer multiple nutrition-based programs for their employees. Weight-Watchers-at-Work is offered by five companies, with reimbursement for attendance and weight loss provided by two employers. One company discontinued the program due to reduced enrollment over time and has implemented other programs. Two companies have on-site cafeterias with healthy food options and accessible nutritional information. Negotiations are underway to reduce the costs of more nutritious food. Additionally, one employer is only reimbursing business catering costs for foods selected from the cafeteria’s new “healthy menu.” While some businesses have vending machines with traditional snacks, three companies have considered including healthy snacks in vending machines. In one organization where 35 percent of employees access the cafeteria and vending machines, vending machines with

“stop lights” adjacent to snack selections were installed. Green lights indicate low fat items; yellow lights indicate medium fat items; and red lights indicate high fat items. The vendor who operates both the cafeteria and machines is tracking food selections. One EHS reported discontinuing the inclusion of healthy food in vending machines because employees were not selecting those options and the food was spoiling.

Among these employers, nutrition programs are either unique programs specifically developed for employees (e.g., focused on calorie counts, pounds, or portion sizes) or components of general wellness programs (e.g., Blueprint for Wellness offered by 2 employers; the American Cancer Society’s “Choose to Change”).

Physical Activity Programs

All eight employers offer programmatic and financial support for walking and fitness programs. Five organizations have on-site fitness centers, while two other companies subsidize memberships at off-site facilities. Fitness trainers are hired by four companies to support individual regimens and organized programs, for example “Biggest Loser”, “Family Fit”, “Aim for a Healthy Weight” and other activities such as walking clubs. Three of the company-sponsored health challenges offer financial and non-financial incentives (see below) to employees for tracking steps in walking programs.

Behavioral Health Programs

While three EHSs mentioned providing psychological support (e.g., through EAP), one company specifically targets behavioral change as a precursor to initiating weight-loss programs. Rather than focusing on motivation as the driver of change, this model approaches behavior change as a game. The foundation of behavior change is “keeping your word” which underlies all employee health programs, including weight loss. Behavior change training is implemented prior to initiating the weight-loss intervention.

Communication

Companies are using many types of communication vehicles for employees, including newsletters, e-newsletters, posters, telephone reminders, and on-line webinars, coaches, trainers, and health professionals. For example, posters are placed in stairwells and alongside vending machines; program

announcements appear on company intranet sites and in e-newsletters; and instructional materials and webinars are accessible to employees both at work and off-site.

Incentives

Every employer is providing financial and/or non-monetary incentives. These range from small items (e.g., pedometers, water bottles), cash, commercial and company gift cards, raffles, subsidized gym memberships, reimbursement of program costs, reduced insurance premium, rewards for winning individual or team challenges (e.g., gift cards, trinkets) and company recognition.

Participation and Evaluation

Rates and percentage of employee participation vary from year to year and from program to program. For example, EHSs reported that 900 employees registered for a twelve-week behavioral nutrition program and ~ 45 percent completed the intervention. In another organization, one-third of the 10,000 employees completed HRAs and received \$25 gift cards. A company offering Weight-Watchers-at-Work; health coaching for stress-reduction, physical activity and nutrition; and no-cost or subsidized fitness club membership, reported an average of fifty to sixty percent employee participation annually. Experience indicates that incentives are a powerful motivator for engaging and sustaining participation, particularly financial rewards.

Formal and/or informal evaluations are being conducted by each employer. Two companies use surveys to solicit employee feedback on program success and their satisfaction. Several companies utilize electronic self-tracking tools for tabulating HRA results, vegetable and fruit consumption, time spent exercising and seatbelt use. Pedometers are distributed to employees in another company. Tracking includes participation, specific program measurements and outcomes (e.g., calories, portions, points, steps, health screening measurements).

INNOVATIVE INTERVENTIONS

While each participant organization has demonstrated success with their selected programs, three interventions deserve mention. What makes these initiatives innovative is their approach to addressing healthcare issues. The first example is a creative program which simply and effectively meets the weight-management needs of a manufacturing

company's employees. The second example reflects a non-traditional behavioral approach to addressing healthcare needs. The third example demonstrates the impact of collaborative efforts to effectively implement change.

A solo healthcare practitioner responsible for the occupational health needs of a manufacturing company with more than 1000 employees identified obesity as a critical health problem. While aware of the many effective weight-management programs, the EHS also knew the employee population well and the associated occupational health budget. The EHS implemented a nutrition and exercise program based upon portion control without the need for technology, complex food plans or calculations and regular exercise which involved walking. A 12-month team challenge was initiated for non-monetary rewards to incentivize employees. Twenty-eight employees lost over 400 pounds in 3 months.

Recognition of the critical need for understanding and preparing for behavioral change as a precursor to implementing programs to change health behaviors led one organization to redesign their approach to weight-loss health programs. The primary focus is thinking of behavior change as a game. The foundation of behavior change is posited as "keeping your word." The program involves ten face-to-face professionally-facilitated sessions to introduce the concept and strategy. For this weight loss program, exercise was the identified behavior with homework assignments centered on engaging in exercise. Weight loss was not discussed as part of the training sessions. After completing the training, participants evaluated different nutrition programs which they would self-manage utilizing new behavioral strategies. As part of the self-empowerment training, participants are encouraged to consider different nutrition and weight loss programs to determine which will work best for them. Results from this pilot study reflect weight loss of over ten pounds for individuals with BMIs of 25-29 and BMIs of 30-34.9 for 32 percent and 33 percent respectively. Forty-seven percent of participants maintained their weight loss longer than one year. The organization plans to expand the pilots, assess "enjoyment" of activities and study sustainability of behavior change.

A non-profit coalition, founded over twenty years ago as a forum for large self-insured employers, works to address health care issues. The coalition brings together employers and healthcare delivery stakeholders including healthcare

professionals, hospitals, pharmaceutical companies, health plans, unions, academic institutions, public health and governmental representatives to collaboratively address issues of health care quality, safety and costs. A “model wellness program” and “corporate health care action plan” were developed, pilot tested and evaluated. Evaluations including a cost-benefit analysis reflected the success and return on investment as early as sixth months.

DISCUSSION

Summary of main findings

The types of available interventions varied, but each company offers at least one physical activity and one nutrition-based intervention, either as individual programs or as part of a wellness initiative. All programs are voluntary but restricted to insured employees; some employers offer services to their covered family members. Every employer offers incentives including monetary benefits and/or non-monetary rewards tied to either completing an intervention (e.g., completing a HRA, health screenings, Weight Watchers at Work program), program participation, or achieving a specified outcome (e.g., maintaining a preset goal). Each employer tracks some aspect of the offered programs, most commonly, program participation, weight loss, “steps walked”, blood pressure and/or cholesterol. Two companies are reviewing medical claims data to assess whether healthcare costs are lower as a result of interventions. All programs are evaluated either formally or informally to determine outcomes based upon participation rates, employee feedback and/or pre-defined outcome measures, and implement modifications based upon the findings. Determining a financial return on investment was difficult to ascertain due to privacy constraints, access to health and financial records, and definitions and methods of tracking outcomes.

Successes

Each company is tracking the success of its programs but in different ways. Most companies are tracking success by participation rates but acknowledge that it is difficult to estimate return on investment to any one program. Other measures of success include weight loss and reduced BMI, steps walked, increased seatbelt use, improved nutrition, programs completed. Still other companies are tracking data, e.g. entry and exit HRA results, lowered cholesterol levels, blood pressure rates, and/or cessation of smoking. One EHS

has been tracking the costs of health benefits for nine years and opines that the costs are two-thirds of what they would be if the company had not integrated any programming. Two companies are analyzing medical claims to assess monthly costs of program participants versus non-program participants. They reported healthcare spending eight times higher for non-participating employees. This demonstrates the success of reduced healthcare costs.

Challenges

A universal challenge reported by all participants is sustaining motivation of employees. Maintaining interest and keeping employees energized and engaged are concerns for EHSs.

Funding for programs and staff, particularly for companies with many locations, providing services for employees at sites without occupational health services and identifying evidence-based programs pose additional challenges.

Strengths and limitations of the study

The study used a qualitative design with open-ended questions to encourage the wellness/health specialists to fully describe all of the aspects of their weight-management programs, including program components, incentives, rates of participation, measured outcomes and evaluation, strengths and challenges, sustainability and best practices. Such a design emphasizes the participants’ own perspectives and minimizes the impact of the researchers’ agenda. While participant companies were diverse, both geographically and by industry, the sample size was small. In addition, due to the selection process, not every business type participated in the study, including government employers, primary and secondary educational institutions, and non-profit health organizations, thereby limiting the generalizability of the results. Additionally, the recruitment of the sample primarily included organizations affirmatively seeking obesity management information from Care Continuum Alliance or companies recommended for their innovative population-based weight management programs. Therefore, the sample selection was not randomized and subject to selection bias.

Evaluations of employer-based programs have not been formalized and outcomes data may be difficult to retrieve or not accessible to program directors, therefore no uniform method was utilized by study participants for evaluating their interventions. Each program is tracking and reviewing data

but scientific return-on-investment assessments have not been consistently performed in every case. Therefore the case study findings are subject to participants' reports, perspectives and interpretations. Maintaining the privacy of the participating organizations prevented the disclosure of detailed information about the respective programs. A larger scale quantitative study with a randomized and broader spectrum of employers would provide a more representative sample and a richer data set.

Implications for clinical practice and future research

The literature identifies best practices for weight management programs which should be considered in developing interventions. Many of these best practices were incorporated by the study participants including securing senior management support and employee input, conducting HRAs and biometric screenings, and educating employees about results and the value of health promotion, prevention, and population health management. A variety of nutrition

and physical programs and educational interventions should be offered with realistic goals; incentives tracking and measured outcomes were implemented in the various interventions. Recommended components not included in the survey programs were community involvement, employee inputs about accessible health information and stress management initiatives.⁸

Future research should include larger samples of small, mid-size and large employers in the public and private sector. In addition, well defined economic and outcomes measures should be tracked and measured to assess the value of respective programs. The sustainability of current programs should be evaluated, including the participation and weight status of current study participants in their respective programs, and outcomes should continue to be tracked and measured to determine return on investment and the impact on healthcare costs.

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Employer: MGM Resorts International™

OVERVIEW

One of the world's leading hospitality companies, operating a portfolio of destination resort brands (Bellagio®, MGM Grand®, Mandalay Bay® and The Mirage®), wanted to create an innovative weight management program across the continuum of care that was inclusive of metabolic and bariatric surgery and a medically supervised weight management program. With senior management support from the start, MGM sought to improve employee quality of life and offer a "best in class" benefit for the Las Vegas area. Many other employers either did not offer a bariatric benefit or offered one that was more basic. Based on the success of the initial launch, the program has been implemented within other MGM facilities in Mississippi and development is under way for equivalent programs within MGM facilities in Michigan, and Reno, Nevada.

KEY SUCCESS STRATEGIES

- This program design addresses the issue of obesity and assists members to lose and maintain weight as well as provide metabolic and bariatric surgery for those members in need of an effective intervention for a higher BMI.
- Even though the clinical outcomes and ROI data were positive, the program was implemented because it was "the right thing to do."
- Senior MGM leadership pushed for more innovation, which was the impetus for adding the cosmetic surgery incentive to MGM's benefit.

POPULATION

Employees are eligible after 91 days of employment and must be at least 18 years old. The plans that are covering the procedure vary by location of the employee (NV, MS, MI), with MGM total covered lives at 40,000.

BARIATRIC BENEFIT COMPONENTS

The program is developed and managed internally by the MGM benefits team. Direct supervision is provided by a programs manager with oversight by the area director who has decision-making authority. As a self-administered benefit, MGM has sole responsibility for contracting, communication to employees, and ongoing business reviews from each of the surgical centers. These quarterly business reviews analyze weight loss achieved, first year goal achievement, number of therapy visits, resolution of comorbid conditions, and medication use; future use of a quality-of-life survey is currently under consideration. Internal reviews across all wellness programs monitor how well the bariatric benefit conforms to the overall corporate wellness strategy.

To qualify for surgery (or for the benefit), employees must meet minimum BMI requirements and agree to participate in a weight management program, psychological evaluation, and a pre-op/post-op program. To enroll, employees must be evaluated by a designated program physician and meet all requirements: BMI ≥ 40 ; or BMI = 35-39.9 with at least one clinically significant health issue, including but not limited to, cardiovascular disease, Type 2 diabetes, hypertension, coronary artery disease or pulmonary hypertension. The next step is the medically supervised nutritional counseling—a six-month educational process that includes 13 classes covering nutrition, exercise and weight management. Part of the engagement strategy is making the weight management program available to all employees regardless of the decision for/against surgery.

The bariatric benefit covers Gastric Bypass, Sleeve Gastrectomy, and Gastric Band at a designated Center of Excellence (COE)¹. Other elements of the benefit design include:

- \$5,000 reimbursement of the out-of-pocket surgical co-pay if employee reaches a predetermined annual weight-loss goal (40 percent targeted weight loss at year 1 post-surgery, with an additional loss of 10 percent/year at the 2-year, 3-year, and 4-year surgical anniversary);

- \$5,000 incentive toward cosmetic procedures to remove excess skin (minimum of two years post-surgery, or when participant has lost 70 percent excess weight);
- 20 percent coinsurance related to incidentals related to pre-operative clearance tests, prescription co-pays;
- \$20 co-pay for office visits associated with the medically supervised weight loss program;
- Stop-loss benefit to minimize plan exposure for expenses related to complications; and
- Expenses related to surgical revisions when deemed medically necessary.

MGM's communication strategy includes both employees and providers. A fact sheet is sent to all employees upon launch of the benefit. Ongoing communication is facilitated with the contracted surgical centers.

EVALUATION AND RESULTS

In the eight months since implementation, a total of 41 surgeries have been completed with average preoperative BMI of 47.5. In spite of the relative short time since the program started, several positive outcomes have been identified. Direct claims costs have been reduced; indirect

costs have been reduced; and employees are experiencing improved quality of life. Average weight loss during the pre-surgery, medically supervised weight-loss program was 18 lbs. Average weight loss post-surgery was 45 lbs., and up to 100 lbs. 6 months post-surgery. During the first six months of the program post-surgery, there was a 70.8 percent reduction in medications taken (pre-surgery: 113 total medications/month by 39 patients), and comorbidities were reduced 88.3 percent (pre-surgery: 128 comorbidities present in 39 patients). The non-surgical component is a significant piece of the overall program and demonstrates MGM's philosophy of supporting employees regardless of their decision for/against surgery. Of the 67 patients in the medical weight loss program, average weight loss is 31 lbs. For the 30 percent of participants with diabetes, results indicate 80 percent improvement, and the 30 percent with hypertension have seen 100 percent improvement.

LESSONS LEARNED

- Benefits of having an exclusive COE provider.
- Importance of the non surgical benefit.
- High touch and collaborative culture (key to have all elements working together—patient, provider and plan).

REFERENCES

¹Centers of Excellence are developed and maintained through the American College of Surgeons and the American Society for Metabolic and Bariatric Surgery. Most health insurance companies utilize this information and designate COEs also. For information, go to <http://www.acsbscn.org/Public/Centers.jsp>

Hospital: *Florida Hospital Celebration Health*

OVERVIEW

Since 2008, Florida Hospital Celebration Health (FHCH) has directed the Metabolic Medicine and Surgery Institute, a multidisciplinary program for the treatment of obesity through bariatric surgery. Through this program located in Celebration, FL—the community that Disney built—obese patients receive surgical treatment and important education and follow-up support. In addition, surgeons worldwide have access to virtual training in bariatric surgery and ongoing research.

Staffed by highly qualified health care professionals, this clinic-hospital partnership offers a comfortable environment for surgical patients, with attention given to the size of the rooms, beds, doorways and showers. The FHCH nurses are specially trained in bariatrics for six months. A director of bariatrics oversees a multidisciplinary team of experts, including a bariatric-specialized nutritionist, exercise physiologist, social work and psychologist. A bariatric-certified nurse coordinator provides patients education and is in charge of floor staff and patient activities.

Education and training are important and well-supported by senior leadership at FHCH. Funding is available for staff education, travel, and presentations. For example, FH provided travel funds this year for staff to attend national and international bariatric conferences. Research and international collaborations supplement the FHCH mission and accelerate the adoption of best practices. Collaborative research on mechanisms responsible for the remission of diabetes or different procedures for gastric cancer surgery with bariatric surgery helps to further the evidence-based science.

KEY SUCCESS STRATEGIES

1. **Hospital environment.** The hospital setting promotes collaboration for all providers to work together as a team.
2. **Financial support.** Administrators show their support of the program by providing funding for staff education and travel, as well as for marketing.

3. **Patient-centered focus.** The holistic approach coordinates all providers around the patient from patient education and support to life-long care and follow-up.
4. **Multidisciplinary approach.** In addition to the surgeon and surgical team, FHCH employs trained bariatric clinical nurses in both the clinic and the hospital, a bariatric nutritionist, an exercise physiologist, a social worker and a psychologist.
5. **International interaction.** As a large training center, the Nicholson Center teaches courses to surgeons worldwide, including Turkey, Chile, Venezuela, Korea, China, Brazil, Germany, India and Mexico.

POPULATION

Individuals may be referred by their physician or may self-refer. FHCH adheres to the NIH guidelines for identification of eligible bariatric patients, which include BMI > 35 and existing co-morbidities. Patients with cardiac issues require clearance for surgery.

PROGRAM COMPONENTS

FHCH's program focuses on patient education, support, life-long care and follow-up through these core components:

1. **Information sessions on obesity and surgery** — The FHCH team holds weekly information sessions for anyone who is interested in learning more about bariatric surgery. At that time, interested parties are weighed and provide their insurance information. Within a few days of the session, each individual receives a follow-up call notifying them of their available coverage and benefits, as well as information about additional funding available through health loan organizations. Medicare patients are accepted. Online information sessions are also available through the FHCH website. If the individual opts for surgery, the next step is satisfactory completion of the necessary clinical work-up and surgery clearance requirements, as well as an appointment with the surgeon. The type of surgery performed is an individual decision.

2. **Patient education classes** — Once accepted into the program, individuals are required to attend preoperative clinical education classes and pass a test to assure their understanding of the surgical procedure and benefits, the possible risks and complications, expectations for the hospital stay, and early postoperative nutrition and exercise requirements. The patient is expected to re-train if they do not pass the test. These classes are available both in-house and online.
3. **Nutrition classes** — Extensive nutrition education is developed by a bariatric nutritionist and offered in-house and online and includes recipes and regular cooking classes.
4. **Exercise classes** — Exercise education is provided by an in-house physiologist who provides education, metabolic rate analysis, a personal exercise program for both pre- and post-surgery. The patient also practices his exercises in the hospital room to help reduce the risk for pulmonary embolism. Patients have access to the on-site gymnasium and pool. Classes are provided both in-house and online.
5. **Support groups** — The psychologist and social work lead monthly support groups for individuals who are early postoperative as well as those needing long-term support. Patient issues addressed include causes for weight gain, sleep and surgical weight loss success, alcohol use post-surgery, relationship issues, nutrient needs, etc. The groups are offered in-house and through online chat rooms.
6. **Patient social events** — Post-surgery follow-up activities include social events and parties. Cooking classes support groups add to the social support for patients following surgery.
7. **Multidisciplinary follow-up care** — Bariatric nurses and clinic coordinators provide postoperative care coordination. Post-surgery follow-up visits at the clinic are required at 2 weeks, 1 month, 3 months, 6 months, 12 months and annually thereafter for follow-up care, including counseling by the nutritionist and exercise physiologist. Patients also have access to physical therapy and spa offerings. In addition, online follow-up education and support is offered.

FHCH supplements its in-house education and support through online information sessions, support groups, and nutrition and exercises classes. The website is an important tool for program communication to both patients and providers. Also, a quarterly newsletter discusses issues and new research for obesity and bariatric surgery.

EVALUATION AND RESULTS

Results show 80 percent remission of diabetes for individuals who have had bariatric surgery, as well as 80 percent reduction in the recurrence of gastric cancer.

LESSONS LEARNED

- It is important to understand that the disease of obesity is different from many other disease processes (e.g., gall bladder removal, cancer). Obesity is unique in that successful outcome in treatment depends more on the individual patient than on the surgery itself. Successful treatment with surgery will depend on patient compliance.
- Planning for success requires a multidisciplinary approach and appropriate resource application (e.g., physician extenders, appropriate staff). Successful outcomes require adequate follow-up. Appropriate patient support is critical to success.
- Track program outcomes and continually survey the published literature for benchmark data. Be an outcomes-based practitioner.

Health Plan: ODS Health

OVERVIEW

ODS Health, a health company based in Portland, OR, offers eight specialized ODS Health Coaching programs designed to give members one-on-one attention to help manage and improve individual health. Originally focused on disease and condition rather than patient behaviors, the ODS Health coaching program has shifted care toward a more holistic and behavior-based approach. ODS Health has integrated the Patient Activation Measure (PAM) and Motivational Interviewing (MI) into the health coaching program, leading to improved outcomes in member activation, satisfaction, and engagement.

In March 2009, ODS Health responded to the health and financial burden of obesity by initiating development of an obesity management program. The obesity management program workgroup—key ODS Health stakeholders and community partners, including an endocrinologist, a bariatric surgeon, a registered dietitian and a clinical psychologist—convened to create a comprehensive program that would specifically address the unique needs of this population. Program development was completed in July 2009, and is now governed by a Quality Council - comprised of community providers - that oversees all programs and materials as well as an internal Medical Quality Improvement Committee that ensures continuous quality improvement and adherence to evidence-based guidelines.

Around this same time, ODS Health formalized a corporate partnership with the National Institute of Health's (NIH) We Can!™ (Ways to Enhance Children's Activity & Nutrition) to help community members establish healthy behaviors early in life. The We Can!™ program is unique among existing youth obesity-prevention initiatives in its focus on reaching parents, families and caregivers as a primary group for influencing young people.

For more details and resources about the We Can!™ program, visit the National Heart Lung and Blood Institute.

KEY SUCCESS STRATEGIES

- **Leadership commitment.** The appropriate complement of resources and leadership commitment combine for a successful program. Leadership understood the value of the program and continues to ensure resources are available on an ongoing basis.
- **Comprehensive team.** A multi-disciplined team was responsible for program development and has ensured appropriate review and guidance to keep the program moving forward.
- **Patient-centered approach.** ODS integrated the PAM into its health coaching program to move to a total population approach, improving patient engagement and health outcomes.
- **Community-based support.** ODS recognized the need for community-based support and used guidelines from both the American Heart Association and the NHLBI identifying Weight Watchers® as a sound weight loss strategy.
- **Targeted communication strategy.** A multi-channel communication strategy targeted to specific groups informs both members and providers about the benefit, how to access the program, and how to discuss the program with their respective audience. One critical aspect is helping providers to understand the additional support available to members between office visits, encouraging doctor-patient conversations.

POPULATION

The adult population in Oregon is estimated to be 2,900,000, and 61 percent are either overweight or obese. The obesity prevalence rate jumped 140 percent from 1990 to 2007, and today one in four adults is obese. The ODS Health Weight Care program is available to select groups, and as of October 2011, 16,457 adults engaged in at least one of the program components.

PROGRAM COMPONENTS

The ODS Health Weight Care program benefit includes seven key components:

1. **Screening and assessment** – ODS encourages providers to assess members' weight as part of routine exams, at a minimum, and to use BMI as the primary weight measurement. Measuring waist circumference is also recommended.
- 2 **Follow-up to screening** – Providers counsel or refer eligible patients to resources/services including dietary, physical activity and behavioral therapy. Patients with BMI ≥ 30 are referred to the ODS Health Weight Care health coaching program.
3. **Health coaching** – The ODS Health Weight Care program assists members in developing and implementing weight loss strategies through individualized plans that address members' specific needs and challenges. The health coach initiates one to two contacts per month for 12 months, followed by monthly maintenance calls depending on the member's preferences. Bariatric surgery health coaching is available to members preparing for bariatric surgery and post-surgery. Health coaches coordinate care with ODS medical management teams as appropriate.
4. **Educational resources** – Members can access information (print and online) on weight management strategies, diet/nutrition, physical activity, behavior/lifestyle changes and skills necessary to maintain sustained weight loss. Online weight management tools include calculators for BMI, calories burned, healthy weight, meal planning and tracking, and calorie intake.
5. **Weight loss support program** – ODS provides access to Weight Watchers™. The incentive rate is based on employer specific requirements. Weight Watchers™ is a well-researched community support service that combines dietary therapy, exercise and behavioral skills, supporting participants in maintaining sustained weight loss goals.
6. **Pharmaceutical therapy** – For obese patients who have failed to achieve their weight loss goals through

diet and exercise, adjunctive drug therapy is available. Prior to initiating therapy, ODS recommends a doctor-patient discussion of the drugs' side effects, the lack of long-term safety data, and the temporary nature of the weight loss achieved with medications.

7. **Severe obesity surgery** – The surgical benefit is offered by select groups as part of their plan design. Program components may include intensive behavioral, dietary and physical activity counseling to determine the eligible member's appropriateness for bariatric surgery. To be eligible for surgery, the member must be 18 or older, have evidence of persistent obesity, have BMI ≥ 40 or BMI ≥ 35 with one or more comorbidities, and prior participation in a medical supervised weight reduction program.

Communications are tailored to the various audiences (e.g., members, providers), and are distributed via print and online. Providers and group administrators have access to online information describing ODS Health's programs and guidelines. Members are initially contacted by mail with a letter introducing the program along with an initial survey. With the integration of PAM into ODS health's coaching, the initial letter has changed from condition-focused to a whole person approach. Members then have the opportunity to enroll in any of the programs depending on interest rather than condition.

Among the ODS Health Care programs, a variety of incentives are used for engagement. Health coaches provide incentives as appropriate for the individual, with a focus especially on pre-contemplators. Examples of incentives include peak flow meters, portion control plates, and a self-guided relaxation CD. ODS Health is currently running a promotion where anyone who completes the first session with a health coach can receive a gift card as an incentive.

In addition to ODS Health's Weight Care program, there are seven other specialized Care programs offered to members: cardiac, diabetes, depression, respiratory, women's health, spine & joint, and lifestyle coaching. All eight programs utilize the PAM and MI, providing a system for tracking and reporting outcome and providing resources for the clinician/coach to tailor support for the member and customize communications, increasing engagement and retention in the program. With feedback from the initial

survey, the health coach is better equipped to tailor the approach for the first call to the member and continually reassesses activation throughout the program. The ODS Care programs were recently featured in the Quality Profiles: The Leadership Series. The Quality Profiles are a joint publication between NCQA and Pfizer.

EVALUATION AND RESULTS

ODS Health uses the PAM and MI as the foundation for all of its health coaching programs and assesses the patient before engagement, at specified intervals, and at program completion or “close out.” PAM data is analyzed quarterly and indicated a 9.8 percent score improvement most recently. Early results show that the PAM tool coupled with the coaching intervention has enabled ODS to migrate or shift approximately one-third of the population at the lowest activation levels to levels three or four. In addition, early trends of program participants show a significant increase in levels of medication adherence. Preliminary data also demonstrate a decrease in emergency and urgent care utilization and slight decreases in lengths of stay.

Member satisfaction is assessed at program completion. Results consistently show 88-94 percent of respondents marking “very good” or “excellent” satisfaction with education materials and the coaching experience.

Based on the NHLBI guidelines, ODS Health promotes frequent weight measurements in order to meet the expected result of 5 to 10 percent weight loss in 6 to 12 months. ODS also encourages members to self-report waist circumference.

Weight Watchers™ reports 127,098 pounds lost among the 16,457 patients enrolled in the program.

LESSONS LEARNED

- Due to limited guidelines, ODS initially was challenged with effectively communicating the program to the health care providers, specifically regarding the best way to approach certain populations.
- While weight loss support is provided to ODS Health’s general book of business, some groups have been slow to understand the importance of adding the service to the benefit.
- BMI screening is important to establish program eligibility and to drive outreach. However, not all providers screen for BMI, so ODS Health is working with providers to increase the rate of BMI screening.
- Adding Weight Watchers™ to the benefit required a substantial amount of front end work to match the program attendance data to the ODS Health claims system process. The success of the process demonstrates ODS Health’s commitment to the issue by allocating the resources and personnel to ensure the system worked seamlessly. Weight Watchers™ was also supportive.

With dramatic increases over the last 20 years in obesity and obesity related conditions, including heart disease, stroke, type 2 diabetes and certain types of cancer, ODS Health remains committed to providing services and support to providers and members. The programs are designed to complement the member provider relationship with ongoing support between - care office visits.

Population Health: *Healthways*

OVERVIEW

Johns Hopkins Medicine conducted a two-year randomized controlled clinical trial (the POWER trial) to stress the need for treatment models for achieving sustained, clinically significant weight loss in an obese population. The resulting paper, "Comparative Effectiveness of Weight Loss Interventions in Clinical Practice," published in *The New England Journal of Medicine*, reveals the effects of two behavioral weight-loss interventions. One intervention supplied patients with remote weight-loss support (Healthways provided the coaches for this intervention), while the other intervention provided in-person support during group and individual sessions along with remote means of support. There was also a control group in which weight loss was self-administered.

This study achieved clinically significant, sustained weight loss and its design provided an opportunity for research to become practice. Healthways has subsequently developed an application of the trial for the marketplace in collaboration with Johns Hopkins. Implementing programs similar to those used in the intervention groups in primary care could help slow the increase of obesity-related disease, but this would also require change in health care delivery systems and reimbursement policies.

KEY SUCCESS STRATEGIES

- For both interventions, primary care providers reinforced participation at routinely scheduled visits.
- Participants were encouraged by the coaches and through the web application to self monitor their progress routinely.
- Remote support is effective because of the flexibility it offers both participants and coaches.

POPULATION

The study population consisted of individuals who are most likely to be obese with at least one of the following conditions: diabetes, high cholesterol, or hypertension. In order to participate, individuals needed access to the Internet and basic computer skills, as well as a willingness to participate.

PROGRAM COMPONENTS

Coaches

The coaches presented the interventions in collaboration with the primary care providers to promote weight loss. They focused on key weight management behaviors such as reduced calorie intake, increased exercise, regular log-in to the study web site, and calorie tracking. Additionally, coaches used motivational interviewing techniques and followed re-engagement procedures when participants did not log into the study web site.

Web-based support

Participants in the study were given learning modules consisting of objectives, educational content, quizzes, and worksheets. Self-monitoring tools, feedback, and weight loss progress were provided for this group of participants.

Primary care providers

Primary care providers reviewed reports on patient's weight loss progress at each routine office visit. They encouraged participation in the intervention and sent letters to participants as part of the re-engagement strategy after prolonged periods with no participation contact. In addition, they reported events that might affect a patient's ability to participate in the intervention and provided assistance with self-monitoring of glucose levels and medication adjustment for patients with diabetes.

EVALUATION AND RESULTS

This two- study was one of the longest recorded trials of remote interventions. Significant improvements in body weight were exhibited in both intervention groups. Sustained weight loss was the main goal and a large percentage of participants were able to lose 5% or more of their initial body weight.

The findings of this study accentuate the effectiveness of remote support due to similar results for patients receiving both in-person and remote support. Remote support is an effective method to achieve sustained weight loss and could improve the management of other chronic conditions.

LESSONS LEARNED

- Two behavioral interventions achieved and sustained clinically significant weight loss over 24 months in obese medical patients.
- The remote and in-person interventions were similarly effective.
- The Remote intervention that consists of phone counseling, interactive website and physician support has the potential for widespread implementation and should be applicable to management of other chronic conditions, such as diabetes, hypertension, and dyslipidemia.

DISCLOSURE

Johns Hopkins faculty members and staff advise and collaborate with Healthways regarding the Innergy weight management program. Johns Hopkins receives financial compensation from Healthways in the form of royalties and fees for its contribution to the Innergy program.

Population Health: Optum

OVERVIEW

As a leader in population health and wellness services, Optum delivers its behavioral health solutions, clinical care management and financial services through employers, health care payers, and providers. This leadership is particularly evident in Optum's integrated approach to the management of obesity. From its wellness solution to bariatric surgery case management, these programs support the individual across the full spectrum of weight management.

KEY SUCCESS STRATEGIES

Healthy Weight

The Optum Wellness programs offer ongoing consultation and program evaluations. Optum builds a custom solution and helps ensure long-term success by functioning as an integral part of program planning, strategy, delivery, and execution. Achieving a successful and impactful program depends on a close partnership with the employer.

Factors that drive program success include:

1. Incentive design
2. Executive sponsorship
3. Strong employee communication plan
4. Creating a culture of health at the company

Bariatric Resource Services

Bariatric Resource Services identifies the best candidates for surgery through pre-operative case management and monitors for complications and offers participant support post-operatively, reducing the overall costs of surgery. The program also steers individuals to a network of qualified Centers of Excellence providers, delivering quality outcomes to patients, employers, and health care payers.

POPULATION

Healthy Weight

Participants are identified through health assessments, medical claims, onsite wellness or biometric screenings,

referral from other Optum programs, and self-referral. Once identified, an engagement specialist enrolls the participant and stratifies into Healthy Weight.

Bariatric Resource Services

If individuals meet the National Institutes of Health (NIH) definition of morbidly obese (BMI>40 or BMI>35 with at least one comorbid condition) and have the bariatric benefit through their health plan, they are eligible for Bariatric Resource Services. Eligible participants are identified by self-referral or referral from another Optum program. Individuals can request information and are classified as "enrolled" as soon as they agree to continue with the program and pursue surgery.

PROGRAM COMPONENTS

Healthy Weight

Healthy Weight is an intense, non-surgical weight management coaching solution. Together the individual and coach focus on adopting healthy behaviors that lead to a healthy lifestyle to produce long-lasting results. The program's goal is long-term weight loss through coaching and relapse prevention.

Optum's portfolio of clients includes clients of all sizes. The smaller clients usually rely on the program completely through telephonic interaction. Some larger clients may incorporate onsite coordination (e.g., wellness champions, biometric screenings) with the Healthy Weight program. Organizations also have the option of adding incentives to increase positive behavior changes.

Key components of the Healthy Weight program include:

- Program helps individuals who need more support; six-month design allows for up to 10 coaching calls.
- A dedicated wellness coach fosters a strong and effective coach/member relationship.
- Personalized techniques and tactics incorporate the whole-person approach.
- Multi-touch approach integrates on/offline tools and resources to create awareness and engagement to optimize experience.

- Dedicated wellness coach is matched to the member and helps develop individual goals and action plans. Matching incorporates individual preference for male/female, specific background, and language.
- Online tools, calculators, trackers, and articles complement coaching sessions to keep participant motivated and on-task.
- The transtheoretical stages of changes model helps stratify members and gauge their readiness to change.

The communications plan for Healthy Weight includes both the member and the provider. Reaching members at home is an important touchpoint and includes up to three standard campaigns annually. The full population receives direct mailings, and annual email campaigns are also available. In the workplace, wellness communications are an important way to build a culture of health. The Healthy Weight campaign includes worksite promotional templates for posters, flyers, table tents, etc., as well as a series of 30- to 60-minute podcasts on a variety of wellness topics.

Bariatric Resource Services

When a client purchases Bariatric Resource Services, Optum provides recommendations for the benefit requirements. For example, participant requirements may include psychological evaluation before surgery and a six-month physician supervised weight loss program (e.g., Healthy Weight). Generally, the member completes a number of steps over a four- to six-month period before surgery to learn about different procedures, satisfy surgical requirements outlined in the benefit, and choose a surgeon from the Centers of Excellence network.

Annually, Optum qualifies bariatric facilities around the country as Centers of Excellence. These Centers must satisfy tight criteria around outcomes and program structure, as well as a minimum threshold for volume, readmission rates, complication rates, reoperation rates, and mortality. Certain program criteria must be in place—a multidisciplinary team, for example.

After program enrollment, the member is assigned a bariatric nurse to assist with program management, both pre- and post-surgery. The nurse also has direct contact with the provider's office and can answer provider questions about benefit coverage. Care coordination is an important aspect of the bariatric nurse's role and includes a post-surgery phone

call (within 48 hours) to discuss immediate complications, what to look for, when to go to the emergency room, when to call the surgeon, etc. At 30 days post-discharge, the nurse calls to check on progress and focuses on adoption of diet, exercise, and other lifestyle changes, with the possibility of referring to the multidisciplinary team (e.g., nutritionist, dietitian) at the surgeon's office or into another Optum program (e.g., Healthy Weight). Finally, at six months post-surgery, the member completes a telephonic interview with report of weight loss, reduction in comorbid conditions, and change in pharmaceutical regimen, and can be referred for additional assistance with diet or exercise.

Initial communication of the program is provided through the member benefit document. Once enrolled, the participant receives a welcome kit in the mail, layered with telephonic nurse communication. Providers receive telephonic communication from the program.

EVALUATION AND RESULTS

Healthy Weight

Healthy Weight has shown improvements through reduced medical and pharmaceutical costs associated with comorbid conditions. It provides a return on investment (ROI) through direct costs, indirect costs, short-term disability, and productivity (including decreases in absenteeism and presenteeism). Return on investment for year two of the program has been calculated in excess of 2.0.

Participants report 94 percent "very satisfied" or "satisfied" overall with the program, and 86 percent "definitely" or "probably" would recommend the program to others. For Healthy Weight participants, 58 percent have lost weight, with mean weight loss of more than 7 pounds. Blood pressure improvement has been shown in 2 percent of participants. Twelve percent of participants report that they exercise at least three days/week, and 2 percent report stress reduction to a manageable level.

At the end of the program, the Optum client receives detailed tracking metrics and reports. Key metrics reported include utilization (i.e., members engaged, calls completed, inbound/outbound referrals, enrollment demographics), value metrics (i.e., program key outcomes, percent weight loss, blood pressure and cholesterol reduced, exercise improvement), and overall program satisfaction.

Bariatric Resource Services

If the benefit includes Centers of Excellence and the Optum bariatric surgery program, return on investment is 3.5 to 1. In 2011, overall program satisfaction was 94 percent. Two hundred clients have purchased the program, covering 4.5 million lives.

Client reporting occurs quarterly and shows the value of the program in the use of Centers of Excellence and surgery avoidance. Lower surgical costs and reduced costs associated with complication are two benefits of the Centers of Excellence network.

LESSONS LEARNED

The Optum programs of Healthy Weight and Bariatric Resource Services provide a comprehensive obesity management solution to address the variety of challenges faced by the obese population. Through the combination of structured wellness coaching and, when necessary, a bariatric surgery program with a Centers of Excellence network, Optum delivers sustained weight loss and the reduction or elimination of obesity-related comorbidities.

Value-Based Benefit Design for Obesity and Comorbidities: *A Practical Manual*

HOW TO USE THIS MANUAL

As it stands, much of the health and financial burden of the obesity epidemic is being borne by employers. Understandably, employers are asking:

- What combination of obesity-related services and products should health benefits cover?
- How well do the various interventions work?
- Are the benefits sustainable?
- How much would a comprehensive package cost?
- Is there a return on investment?

But answers to those questions are not readily available and experience creating such benefits is limited. We recognized that designing a comprehensive benefit for obesity and comorbidities presented a time-consuming and complex task due to the enormous volume and variable quality of information available and the requisite confluence of skills and knowledge needed to assemble it.

We also recognized that purchasers would favor benefit designs that conform to their unique needs, budgets, culture and values, and that our objective could not be to develop a single, universal “finished product.” Instead, we sought to gather and summarize high-quality information through the Obesity Factbook to describe an approach to benefit design, the Project Design Monograph, and to offer an actuarial format, the Obesity Rider Pricing Template, that could help benefit designers, consultants and other interested parties develop plans. As such, the hypothetical or prototypical model presented in this manual should be considered a well-thought-out illustration of how the myriad choices of benefit components could be assembled to support a comprehensive obesity and comorbidities program. Moreover, the illustrative prototype should not be construed as a recommended or endorsed benefit rider by the Care Continuum Alliance, Health & Technology Vector Inc. or sanofi-aventis, the project sponsor.

Our work led us to previously uncharted territory. It required that we make certain assumptions about members’ use of services, the interaction of existing benefits with new ones

and the effectiveness of interventions (under real-world conditions) known to be efficacious under experimental conditions. Our assumptions and reasoning are presented along the way with as much transparency as possible and most explicitly in the description of the actuarial model. Our style is purposefully telegraphic and concise.

By selecting, summarizing and modeling information pertinent to benefit designers, we hope not only to compress future benefit plan development time but also to steer attention toward interventions supported by scientific evidence and national practice guidelines, such as the National Institutes of Health Practical Guide for the Identification, Evaluation and Treatment of Overweight and Obesity in Adults. As new knowledge about obesity and comorbidities emerges, the information presented here will require appropriate updates.

Project participants and sponsors acknowledge that solutions to the obesity epidemic will require the confluence of enlightened public policy, private and public population-based initiatives, a massive public education campaign, additional training of health and allied health care professionals, and continued basic, clinical and translational research. The present work was not intended to be an all encompassing plan but a partial contribution to the larger agenda. For example, our work explicitly excluded the important topic of childhood obesity.

The Care Continuum Alliance produced the Value-Based Benefit Design for Obesity and Comorbidities as part of a broader research and education initiative focused on obesity with comorbidities. That initiative also has produced a first-ever definition of obesity with comorbid conditions; an annual Obesity Management Symposium; a 2007 literature review of assessment and management options published in the DMAA peer-reviewed journal, *Population Health Management*; partnerships with key obesity coalitions; and other print and online resources.

Project Design Monograph

PROJECT BACKGROUND AND RATIONALE

The project was undertaken to develop a prototypical, value-based benefit design for obesity with comorbidities that would:

- be based on the best available evidence;
- progress from a basic set of services to a comprehensive obesity program; and
- enable rapid adoption (with customization) by health care purchasers.

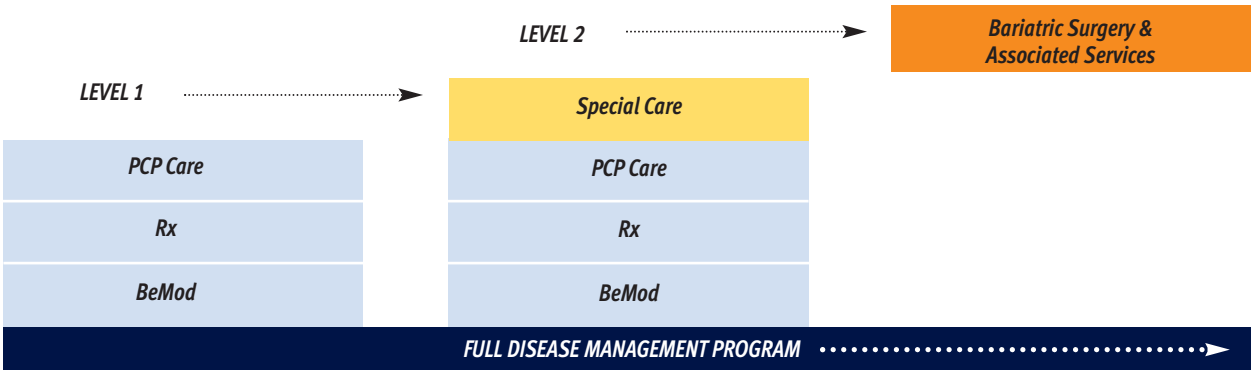
The primary audience for this product is employers and managed care organizations. The secondary audience includes organizations representing businesses, providers, academia and other stakeholders that can help shape and disseminate the adoption of obesity and cardiometabolic risk reduction initiatives.

The project focused on the well-known fact that obesity—and its attendant collection of cardiometabolic risks—is a leading cause of preventable and treatable health problems in America. Purchasers and payers are aware of this fact but are frustrated by the lack of effective and affordable, large-scale vehicles capable of managing obesity-related risks.

Despite the enormous health and financial burden of obesity, benefit coverage for obesity-related services and products before onset of one or more chronic diseases is inconsistent and insufficient to respond to the obesity epidemic. The problem is reflected in a survey of physicians, which found:

- 82 percent agree that treating overweight and obese patients with multiple cardiometabolic risk factors is complex.
- 75 percent believe health plans would deem as inappropriate efforts to gain reimbursement.
- 70 percent cited frequent restrictions by health plans on management of overweight and obese patients.
- Half felt they did not receive adequate reimbursement for treatment.
- Main barriers to treatment include inadequate access to education and counseling, weight management drugs and clinical laboratory testing.

PROTOTYPE PLAN—FINAL DESIGN



Model assumes eligibility criteria include overweight and obesity (BMI ≥ 25) with comorbidities.

HOW TO USE THE PROTOTYPE

Eligibility criteria varied among executive session participants. The prototype described in the previous section is only illustrative of one of many possible options. Users of this manual can vary input depending on the organization’s goals, budgetary considerations and other factors. An interactive template for modeling various inputs is provided, along with explanations of assumptions used to build the template.

CHALLENGES FOR THE DEPLOYMENT OF AN OBESITY WITH COMORBIDITIES BENEFIT

The prototype described herein represents a confluence of the best available evidence, where major gaps remain and a consensus of experts and stakeholders is likely to play a role in rendering the benefit operational. Our “reality check” highlighted significant challenges ahead. We highlight the most immediate.

Delivery System Considerations

Studies have described the effectiveness of commercial weight loss programs; however, there is a paucity of research describing particular organizations of care and their effectiveness in delivering effective weight loss and multiple risk reduction in clinical settings. For example, there are no clinical trials showing persuasively that primary care physicians armed with available knowledge can deliver an effective program under “real-world” conditions. Similar studies for smoking cessation have been published in the past.¹ These studies can serve as a template to test the

effectiveness of sustained weight loss interventions in primary care settings.

The existence of a network of specialized obesity clinics (other than bariatric surgery centers) is currently unrecognizable to managed care organizations for contracting purposes. We understand that The Obesity Society is developing an accreditation program for these clinics.² Moreover, outcomes research is demonstrating the ability of these clinics to obtain short-term results, such as averting the need to undergo more invasive bariatric surgery or demonstrating sustained multiple risk factor reduction and prevention of complications among multi-morbid patients.

Unrealistic Expectations

Executive session participants recognized that expectations of weight loss program participants may be determined by a cosmetic endpoint which often exceeds the 5 percent to 10 percent weight loss reductions necessary to reduce health risk. This mismatch of expectations is a setup for disappointment and discouragement that needs to be overcome through repeated messaging that 5 percent to 10 percent body weight loss represents a very significant reduction in health risks.

ACTUARIAL MODEL FOR OBESITY BENEFIT RIDER

Actuarial pricing models are used to develop expected costs and premium rates and for other financial management purposes, as well as to set targets for medical and network management. The purpose of the actuarial model in this

document is to present a template that payers can customize to estimate the cost impact of covering defined obesity treatments. We also provide illustrative assumptions, although we note that, for any particular program, many of these assumptions will need dramatic adjustments to reflect demographics, local prices and other factors.

Health benefits are always subject to limits and definitions. For example, even if a healthful diet is essential to health, health benefits programs do not pay for lunch. The starting point for any pricing is the definition of covered benefits, and we priced the definition shown in Appendix I (p. 59).

Benefit Riders and Adverse Selection

Insurers and health maintenance organizations (HMOs) commonly construct their product offerings as core medical and surgical benefits with optional riders available for purchase at an additional premium. Prescription drug benefits, vision care and out-of-network coverage are commonly offered on this basis. We have priced the obesity benefit as a rider. However, as described below, insurers and HMOs will cautiously offer this as an option and only for larger group buyers.

Choices in health benefit coverage can lead to adverse selection. Adverse selection of health benefits occurs when an insurance buyer uses knowledge of his own health status to “game” the system, and that can lead to financial problems for the insurer. This is an issue for all voluntary insurance systems (and even involuntary systems where choice exists) and is the basis for the old saw, “Insurers don’t sell fire insurance for a burning house.”

Small group purchasers bring higher risk of adverse selection than large group purchasers. Small employer groups are typically managed by the business owner, and the owner may well know the health needs of her employees and their dependents. The risk of adverse selection for an obesity benefit is that those who need the benefit will be concentrated among the purchasers, so the rider premium rate will be insufficient to cover the cost. A small employer with no overweight employees will not likely buy the rider. Large group purchasers are more likely to bring a typical mix of risks, although most insurers will still want to consider a variety of risk factors, including the presence of multiple carriers.

As an alternative to managing the risks of optional coverage, some insurers, especially those with local market dominant positions, may choose to add an obesity rider as a requirement for all purchasers, large and small. Insurers operating in very competitive markets will be less likely to take that approach, as some low-risk groups might switch to a competitor who offers a lower cost product without the obesity benefit.

BASIC STRUCTURE

Actuarial models used by payers generally have two core elements—utilization and unit price—along with numerous factors that reflect the program’s characteristics. Because the obesity benefit we priced is new, the elements of the pricing model could not be based on historical experience for this benefit. When feasible, we used elements of actual insurance programs that seemed analogous to our benefit designs.

To develop expected per capita costs for the obesity benefit, we follow pricing structures almost universally used by the managed care and insurance industry. We produce per member per month (PMPM) cost. The basic elements of the pricing are the following:

- **Utilization:** For each covered service, the annual utilization per 1,000 members.
- **Unit Price:** For each covered service, we applied a defined fee, 100% of the national average Medicare 2006 fee schedule (RBRVS for professional fees). For bariatric surgery, we applied a global case rate of \$30,000.
- **Cost sharing:** We deducted the member co-pays defined in Appendix I.
- **Loss ratio:** All benefit programs involve administrative costs, and insurers typically earn profit and risk charges. We divided the PMPM costs (net of cost sharing) by 0.75 for these costs. Although a 75 percent loss ratio is lower than most HMOs’ overall targets, low cost or new riders often contain margins for adverse fluctuation.

Although this benefit is provided to adults only, we followed industry convention in presenting all utilization and PMPM figures for the entire enrolled membership, including children.

MODEL ASSUMPTIONS

We assumed that a health plan will define adult members eligible for the obesity benefit by the member's BMI, perhaps in connection with his or her comorbidities (such as diabetes or metabolic syndrome). For the model, we used National Health and Nutrition Examination Survey (NHANES) 1999-2000 and 2001-2002 data adjusted to standard commercial large group demographics, to develop figures for the portion of members who are adults falling into BMI and comorbidity eligibility criteria.³ Because rider pricing is typically applied to all members, not just the members eligible for services, we show the eligible adults in various BMI/comorbidity categories as percentages of total membership. Of course, the actual distribution for a particular employer or health plan will likely vary from these.

Prevalence of Obesity Categories and Comorbidities for Working Age Adults from NHANES			
Adults as percent all members (including children)			
Obesity category	With or without comorbidities	With diabetes	With metabolic syndrome
Overweight	41.5%	3.6%	19.3%
Obese	19.0%	2.4%	11.9%
Morbidly obese	2.8%	0.7%	1.9%

As with opt-in chronic condition management programs or smoking cessation programs, we expect that only a fraction of those eligible will actually begin the program. We used the uptake percentages from those programs as a guide in choosing uptake assumptions, as credible data for the proposed programs are not readily available. This table shows how uptake would typically vary with the portion eligible:

Percent Eligible and Percent Uptake—Illustration		
Eligible population	Percent eligible	Annual percent uptake by eligibles
Obese w/ Diabetes	2.4%	20%
Obese w/ Metabolic Syndrome	11.9%	9%

The priced rider operates through three levels, which we envision as sequential:

- Level 1: Enhanced Primary Care Physician services plus pharmaceuticals to treat obesity.
- Level 2: Treatment by an obesity medical specialist plus obesity drugs.
- Level 3: Bariatric surgery and associated treatments. Due to the high number of patients who meet medical necessity criteria for bariatric surgery compared with current utilization, we de-linked bariatric surgery utilization from eligibility criteria for Levels 1 and 2.

A patient would start in Level 1 and may progress to Levels 2 and 3. The passage time for a patient means that an insurer offering the rider we describe will not see a “steady state” of claims for over a year, as it will take more than a year for a patient to reach Level 3. In practice, we expect insurers will expedite passage time for those needing bariatric surgery. Our illustrative pricing assumes a steady state of utilization.

Using the structures and assumptions described above and in the appendices, we developed the following PMPM pricing:

PMPM Rider Costs (using stated assumptions)		
	Eligible adults	
	Obese with diabetes	Obese with metabolic syndrome
Eligibles as percent of membership	2.4%	11.9%
Uptake (percent of eligible who begin program)	20%	9%
PMPM Rider Costs (after applying 75% loss ratio)		
Level 1	\$0.24	\$0.54
Level 2	\$0.64	\$1.44
Level 3	\$0.69	\$.69
Total without DM	\$1.57	\$2.67
Total with DM	\$2.07-\$3.00	\$3.42-\$4.67

The costs for Level 3, bariatric surgery, are the same for both populations of eligible adults because we delinked bariatric surgery utilization from eligibility for Levels 1 and 2, as described above.

Details of the pricing of each level are in Appendix II (p. 61). The calculation of the PMPM rate for the Obesity with Metabolic Syndrome eligibility is shown in summary in Appendix III (p. 62).

Appendix I:

Benefit Definition: Limits and Cost Sharing

These benefits are illustrative; a health plan would modify these to meet its needs.

Benefits Covered	Max Annual Visits Covered	Co-payment
Level 1		
<i>PCP Visits</i>		
Initial Comprehensive Evaluation	1 visit	\$20
Follow-up visit	2 visits	\$20
<i>Behavior Modification</i>		
Initial visit w/Registered Dietitian (RD)	1 visit	\$20
Follow-up visit w/RD	11 visits	\$20
<i>Drugs</i>		
Drug A	n/a	\$30
Drug B	n/a	\$30
Drug C	n/a	\$30
Other	n/a	\$30
Level 2		
<i>Registered Dietitian Visits</i>		
Initial visit	1 visit	\$0
Follow-up visit	11 visits	\$0
E-mail/phone contact	12 visits	\$0
<i>EKG</i>		
	1 visit	\$0
<i>Medical Doctor Visits</i>		
Initial visit	1 visit	\$0
Follow-up visit	4 visits	\$0
<i>Exercise Physiologist Visits</i>		
Initial visit	1 visit	\$0
Follow-up visit	3 visits	\$0
<i>Lab Panel</i>		
Initial	1 visit	\$0
Follow-up	1 visit	\$0
<i>Drugs</i>		
Drug A	n/a	\$30
Drug B	n/a	\$30
Drug C	n/a	\$30
Other	n/a	\$30

Benefits Covered	Max Annual Visits Covered	Co-payment
Level 2 (2nd Year, if needed)		
<i>Registered Dietitian Visits</i>		
Follow-up visit	6 visits	\$0
E-mail/phone contact	12 visits	\$0
<i>Medical doctor visits</i>		
Follow-up visit	3 visits	\$0
<i>Exercise physiologist visits</i>		
Follow-up visit	2 visits	\$0
<i>Lab panel</i>		
Follow-up	1 visit	\$0
<i>Drugs</i>		
Drug A	n/a	\$30
Drug B	n/a	\$30
Drug C	n/a	\$30
Other	n/a	\$30
Level 3		
<i>Bariatric surgery</i>		
Surgical procedure	n/a	\$250
Psychological evaluation	n/a	\$0
<i>Adjuvant services</i>		
Post-surgical reconstructive surgery	n/a	\$0
Travel-lodging allowance (\$1,000)	n/a	n/a

Appendix II: Pricing Assumptions

Level 1: The first option in the program will cover Primary Care Physician (PCP) visits or obesity and behavior modification visits, as well as prescription drugs for obesity. While only one or two obesity drugs are available today, we expect that several pharmaceuticals in development that treat obesity will become available in the United States over the next several years.

We assumed the CPT codes 99211 through 99215 would be used for office visits. These codes are for office visits for established patients ranging from 5 to 40 minutes. We used a normative distribution for these codes, and every eligible member who begins Level 1 will have a first visit. Subsequent visits will have lower frequency, as some members will fail to continue in the rider program. We used continuance tables we created from outpatient behavioral health claims to estimate follow-up visit utilization. The average allowed charge of these visits was set as 100 percent of the national Medicare RBRVS⁴ charge.

Behavior modification visits are covered as visits to a registered dietician or another qualified professional. These visits were priced similarly to the PCP visits with CPT codes 99203 and 99212.

Level 1 covers up to three weight loss drugs. We estimated utilization for these drugs based on historical supply for current weight loss drugs and used the average wholesale price from the RED BOOK⁵ less a 15 percent discount.

Level 2: After members complete Level 1, which may take about one year, they are eligible for Level 2. We estimated the transition to Level 2 from outpatient behavioral health continuance tables. Benefits covered under this option are visits with a registered dietitian (CPT codes 99203 and 99212), an EKG (CPT code 93000), visits with a medical doctor (CPT codes 99205, 99212, 99213, and 99215), e-mail and/or phone contact with a registered dietitian (CPT code 99371), visits with an exercise physiologist (CPT codes 99201 and 99212), lab panels (CPT codes 80053, 80061, 83036, 83525, 85025, and 86141) and drugs (same as option 1 drugs). The distribution of the CPT codes within a benefit was estimated using historical data. Utilization was calculated similar to PCP visits in Level 1, using outpatient behavioral health continuance tables. Average charges for all these services were set at 100 percent of the national Medicare RBRVS⁴ charge.

Drugs in Level 2 were priced as in Level 1 except that we assumed double the compliance.

The pricing includes the ability of a member to stay in Level 2 for an additional year, probably with medical approval.

Level 3: This option covers bariatric surgery. Benefits for this option include: the actual surgery (CPT codes 43645, 43659, 43770, 43846 and 43847), a psychological evaluation (CPT code 90806), post-surgical reconstructive surgery (CPT codes 15830, 15847 and 00802) and a travel-lodging allowance of \$1,000.

Utilization for this option was based on the number of patients ages 20 to 69 in 2004 and 2005 MedStat⁶, demographically adjusted by standard demographics of Milliman Health Cost Guidelines⁷ who had at least one claim with a CPT code for bariatric surgery. We assumed 50 percent of those having bariatric surgery will also have the post-surgical reconstructive surgery.

A \$30,000 global allowed charge was used for the surgery, assuming this is provided through a Center of Excellence. The outpatient facility code for post-surgical reconstructive surgery was set using Medicare's 2007 ASC Payment Rates⁸. The other prices were estimated as 100 percent of the national Medicare RBRVS⁴ charge.

Appendix III: Illustrative Pricing Summary

Illustrative Pricing Summary. Eligibility: Obesity with Metabolic Syndrome

Benefit	Utilization Per 1,000	Allowed Average Charge	PMPM* Claim Cost	Co-pay Utilization	Co-pay	PMPM Cost Sharing Value Net	PMPM Claim Cost
Level 1							
PCP Visits							
Initial Comprehensive Evaluation	10.9 visits	\$44.32	\$0.04	10.9	\$20	\$0.02	\$0.02
Follow-up visit	18.0 visits	\$44.32	\$0.07	18.0	\$20	\$0.03	\$0.04
Behavior Modification							
Initial visit w/Registered Dietitian	10.9 visits	\$67.08	\$0.06	10.9	\$20	\$0.02	\$0.04
Follow-up visit w/Registered Dietitian	65.1 visits	\$22.36	\$0.12	65.1	\$20	\$0.11	\$0.01
Drugs							
Drug A	28.1 scripts	\$85.00	\$0.20	28.1	\$30	\$0.07	\$0.13
Drug B	9.4 scripts	\$93.50	\$0.07	9.4	\$30	\$0.02	\$0.05
Drug C	9.4 scripts	\$178.50	\$0.14	9.4	\$30	\$0.02	\$0.12
Other			\$0.00		\$30	\$0.00	\$0.00
Total Level 1							\$0.41
Level 1 Premium (75% Loss Ratio)							\$0.54
Level 2							
Registered Dietitian Visits							
Initial visit	4.9 visits	\$67.08	\$0.03			\$0.00	\$0.03
Follow-up visit	29.4 visits	\$22.36	\$0.05			\$0.00	\$0.05
E-mail/phone contact	59.4 contacts	\$15.00	\$0.07			\$0.00	\$0.07
EKG							
	4.9 procedures	\$24.63	\$0.01			\$0.00	\$0.01
Medical Doctor Visits							
Initial visit	4.9 visits	\$144.01	\$0.06			\$0.00	\$0.06
Follow-up visit	14.5 visits	\$43.75	\$0.05			\$0.00	\$0.05
Exercise Physiologist Visits							
Initial visit	0.0 visits	\$21.98	\$0.00			\$0.00	\$0.00
Follow-up visit	0.0 visits	\$22.36	\$0.00			\$0.00	\$0.00
Lab Panel							
Initial	4.9 labs	\$99.01	\$0.04			\$0.00	\$0.04
Follow-up	4.3 labs	\$99.01	\$0.04			\$0.00	\$0.04
Drugs							
Drug A	25.9 scripts	\$85.00	\$0.18	25.9	\$30	\$0.06	\$0.12
Drug B	8.6 scripts	\$93.50	\$0.07	8.6	\$30	\$0.02	\$0.05
Drug C	8.6 scripts	\$178.50	\$0.13	8.6	\$30	\$0.02	\$0.11
Other			\$0.00		\$30	\$0.00	\$0.00

Benefit	Utilization Per 1,000	Allowed Average Charge	PMPM* Claim Cost	Co-pay Utilization	Co-pay	PMPM Cost Sharing Value Net	PMPM Claim Cost
Second Year, if needed (patient is losing weight at an acceptable rate)							
Level 2							
Registered Dietitian Visits							
Follow-up visit	18.0 visits	\$22.36	\$0.03			\$0.00	\$0.03
E-mail/phone contact	47.5 contacts	\$15.00	\$0.06			\$0.00	\$0.06
Medical Doctor Visits							
Follow-up visit	10.5 visits	\$43.75	\$0.04			\$0.00	\$0.04
Exercise Physiologist Visits							
Follow-up visit	7.4 visits	\$22.36	\$0.01			\$0.00	\$0.01
Lab Panel							
Follow-up	4.0 labs	\$99.01	\$0.03			\$0.00	\$0.03
Drugs							
Drug A	25.9 scripts	\$85.00	\$0.18	25.9	\$30	\$0.06	\$0.12
Drug B	8.6 scripts	\$93.50	\$0.07	8.6	\$30	\$0.02	\$0.05
Drug C	8.6 scripts	\$178.50	\$0.13	8.6	\$30	\$0.02	\$0.11
Other			\$0.00		\$30	\$0.00	\$0.00
Total Level 2							\$1.08
Level 2 Premium (75% Loss Ratio)							\$1.44
Level 3							
Bariatric Surgery							
Surgical Procedure	0.2 procedures	\$30,000.00	\$0.50	0.2	\$250	\$0.00	\$0.50
Psychological evaluation	0.2 evaluations	\$84.89	\$0.00			\$0.00	\$0.00
Adjuvant Services							
Post-surgical reconstructive surgery	0.1 procedures	\$1,981.74	\$0.02			\$0.00	\$0.02
Travel-lodging allowance (\$1,000)	0.0 allowances	\$1,000.00	\$0.00			\$0.00	\$0.00
Total Level 3							\$0.52
Level 3 Premium (75% Loss Ratio)							\$0.69
TOTAL ALL 3 LEVELS							\$2.00
TOTAL ALL 3 LEVELS Premium (75% Loss Ratio)							\$2.67

*PMPM = per member per month

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² NHANES 1999-2000 and 2001-2002 Data. These data are from the series of NHANES, a department within the Centers for Disease Control's National Center for Health Statistics. An intentionally designed sample of the non-institutionalized civilian population age 12 and older is selected with a stratified, multistage sampling design. The data items list contains well over 1,000 items of a person's clinical, demographic, and health status, as well as laboratory and physical examination data. We used NHANES data for people between ages 19 and 70 to estimate the prevalence of people with various degrees of obesity and comorbidities.

³ See NHANES methodology in Fitch, Pyenson, Iwasaki, "Metabolic Syndrome and Employer Sponsored Medical Benefits: An Actuarial Analysis," March 2006. Available at www.milliman.com

⁴ Centers for Medicare and Medicaid Services' (CMS) Medicare Physician Fee Schedule. For physician fees, CMS uses the Resource Based Relative Value Scale (RBRVS). This fee schedule develops work, practice and malpractice units for each CPT code. CMS applies area factors to these units and multiplies the sum by a dollar conversion factor. We used the 2007 RBRVS professional fees without area adjustment to reflect national average fees.

⁵ 2006 RED BOOK. A pharmacy reference book published by the Thompson Corporation that includes product information for nationally recognized average wholesale prices (AWPs), direct prices, and federal upper limit prices for prescription drugs, suggested retail prices for OTC products, complete package information including dosage form, route of administration, strength, and size and NDC numbers for all FDA-approved drugs.

⁶ MedStat MarketScan Claims Data 2004 and 2005. This annual dataset contains all paid claims generated by 4 million commercially insured lives. Member identification codes are consistent from year to year and allow multiyear longitudinal studies. Information includes diagnosis, procedure, and diagnostic-related group (DRG) codes; National Drug Codes (NDC), along with site-of-service information; and the amounts paid by commercial insurers. These data were used to estimate current utilization of bariatric surgery and the average duration of existing weight loss prescription drugs.

⁷ Milliman's 2006 Health Cost Guidelines. The Guidelines provide a flexible but consistent basis for determining health claim costs and premium rates for a wide variety of health plans, and are widely used by actuaries working for insurers and HMOs. The Guidelines are developed as a result of Milliman's continuing research on health care costs. First developed in 1954, the Guidelines have been updated and expanded annually. They are continually monitored, as they are used in measuring the experience or evaluating the rates of health plans, and as they are compared with other data sources. The Standard Demographics in the Guidelines were used to adjust the NHANES data to reflect the age and sex distribution of a typical large insured group.

⁸ Centers for Medicare and Medicaid Services' (CMS) Ambulatory Surgical Center (ASC) Approved HCPCS Codes and Payment Rates. These files contain the procedure codes which may be performed in an ASC under the Medicare program as well as the ASC payment group assigned to each of the procedure codes. The ASC payment group determines the amount that Medicare pays for facility services furnished in connection with a covered procedure. We used 2007 payment rates.

Obesity Treatment Guide

PROJECT BACKGROUND AND RATIONALE

The **Obesity Treatment Guide (Guide)** is a synopsis of the evidence related to the treatment of overweight and obesity that is intended to support employers and payers in the development of health insurance benefit designs and program interventions for their respective populations. This Guide includes a summary analysis of the latest guidelines, position statements, and algorithms produced by national and international organizations with authority and influence around obesity treatment. This section includes a Guideline Index through which guideline language produced by multiple organizations can be examined and contrasted by treatment approach. The guide includes a series of treatment algorithms for specific overweight and obese populations, organized by body mass index and branched by risk level. Each treatment algorithm leads to a collection of empirically tested interventions organized by treatment approach.

This section is intended to complement other tools contained in the Toolkit, offering users an additional resource to reference in their development of population health management approaches for overweight and obese populations.

When an employer or other purchasers and payers consider developing a benefit design for obesity to offer their employees or members, an inevitable balancing act ensues between limiting the size of the per-member, per-month (PMPM) costs, and building a completely evidence-based insurance benefit. Employers, specifically, may receive pressure from their employees to cover specific treatments for overweight and obesity. However, even the most socially responsible employers have to work within a budget. We know from previous research the insurance reimbursement for obesity does not consistently reflect the available evidence.¹ This is especially true for coverage of intense lifestyle modification therapy.¹ The inconsistency in insurance coverage likely reflects the costs of some obesity treatments, the public perception of obesity and the stigma associated with it, and an unfounded belief that anything short of bariatric surgery can cause enough weight loss to make any long-term difference in health or spending.

OBJECTIVES

The objectives for this section of the Toolkit include:

1. Create a guideline index for treatment of overweight and obesity that would align with the value-based benefit design.
2. Develop treatment algorithms for overweight and obese populations based upon existing guidelines and evidence from the literature.
3. Identify empirically tested interventions that correspond to branches of each of the treatment algorithms highlighted in the value-based benefit design.

METHODOLOGY

Overview of Methodology

The methodology for this project consisted of three parts:

- A) Review and synthesis of clinical practice guidelines and treatment algorithms for overweight and obesity,
- B) Development of treatment algorithms based upon the guidelines and evidence, and
- C) Identification and classification of interventions to complement the algorithm.

The emphasis for this project was to identify tangible, effective interventions for obesity that employers and payers could review when developing programs and benefits for the overweight and obese populations. Due to previous attention given to developing an obesity treatment algorithm by major institutions like the National Heart, Lung, and Blood Institute (NHLBI) and the Institute for Clinical Systems Improvement (ICSI), the algorithm to be developed through this project would be an adaptation of these consensus-based algorithms.

A. Review of Existing Guidelines, Position Statements, & Algorithms

This study required a detailed review of existing practice guidelines and treatment algorithms for obesity. This project did not aim to develop or update practice guidelines for obesity, nor did it aim to deviate from current consensus-based algorithms. However, the number of guideline sets and algorithms available and the variation between them required

the project team to identify the most common elements of each approach and develop a treatment algorithm based upon those common elements.

There are a number of organizations that have developed and published clinical practice guidelines for the identification, assessment, and/or treatment of overweight and obesity. Language that focused on broad recommendations such as treatment modalities to consider for specific populations based on body mass index (BMI) and risk level were considered for this section. Recommendations that were extremely specific, such as the macronutrient breakdown of a diet or how to perform a surgical procedure, were excluded. Exceptions were made to this exclusion for organizations focused on a specific treatment modality (e.g., diet). For instance, the American Dietician Association (ADA) developed guidelines for obesity that were heavily focused on dietary treatment. These recommendations, while more specific than most, were included given the expertise and narrow focus of the guideline developers.

The guidelines to be reviewed were identified through the development of the first components of the Toolkit, i.e., the Obesity Factbook, the Value-based Benefit Design Monograph, and the two systematic reviews conducted.^{2,3} Additional guidelines were identified by reviewing the websites of relevant professional societies and institutions, as well as the bibliographies of recent peer-reviewed publications.

Guidelines are often accompanied by treatment algorithms. Treatment algorithms are clinical support tools for bridging the divide between established practice guidelines and actual clinical practice. They are created to facilitate the practice of evidence-based medicine and are not meant to be substitutes for clinical judgment. Treatment algorithms are common in the peer-reviewed literature for many diseases and are often developed by professional societies to aid their members in adhering to evidence-based practice. The treatments for many obesity-related comorbidities are aided by treatment algorithms. There are treatment algorithms for hypertension⁴, high blood cholesterol⁵, and type 2 diabetes⁶. Publications containing algorithms for these obesity-related conditions were reviewed to assess how the algorithms were constructed and the approach used by the authors to incorporate the evidence. These algorithms were of particular interest because they consider similar patient characteristics as well as similar interventions. Furthermore, the guidelines

and algorithms developed for obesity have borrowed key methods from these obesity-related comorbidity guidelines, which are discussed in detail in the synopsis of the guidelines.

Obesity treatment algorithms were identified in the same method described above for the review of guidelines and position statements. This project was initiated with the acknowledgement that treatment algorithms for obesity already existed. The goal was not to reinvent an obesity treatment algorithm, rather, the goal was to identify commonalities within existing algorithms and produce a simplified version that reflects current guidelines identified through the guideline review. In addition, publications featuring *approaches or models* for obesity treatment, though not necessarily identified as “algorithms,” were included in this review.

B. Development of Treatment Algorithms

This project required treatment algorithms to serve as a framework or basis by which employers, program providers, and health plans could review interventions for obesity and determine which interventions might be most appropriate for their population. The treatment algorithms serve essentially as starting points for a review of obesity interventions. Given that consensus-based treatment algorithms for obesity exist, this project sought only to reconcile alternative algorithms through identification of commonly shared attributes. For instance, the algorithm developed in this study builds off of one section of the consensus-based NIH algorithm for the assessment and treatment of obesity. The structure of the original NIH algorithm is retained; this project attempts only to expand on one portion of the original algorithm.

The substance or evidence base for the algorithm was obtained through the review of existing guidelines and algorithms described previously. Key components of the algorithms and the reason for their adoption in this project are discussed in-depth in the preceding synopsis of the guidelines as well as the text surrounding each algorithm module. A total of six algorithm modules were developed.

C. Identification and Inclusion of Interventions

The third part of the methodology required the identification and aggregation of interventions to correspond to branches of each treatment algorithm. The algorithms serve as the framework from which employers, program providers, and

health plans can identify interventions shown effective in the literature at inducing clinically meaningful weight-loss. Interventions were organized into two tables: 1) Lifestyle Modification Therapy and 2) Lifestyle Modification Therapy with Pharmacotherapy. Separating these two treatment approaches was necessary because the addition of a pharmacologic agent can change the selection and role of health professionals in the intervention, which has implications for benefit design. Furthermore, perhaps the most common issue addressed across all of the clinical guidelines for obesity was when to consider pharmacotherapy. The algorithm does not include a surgical intervention. There is a wealth of evidence regarding efficacy of surgical procedures at reducing excess weight. However, there are guidelines for the preoperative and postoperative lifestyle components of surgical programs, which are discussed in lieu of an intervention table.

The criteria for including an intervention in one of the tables were as follows: randomized controlled trial, follow-up for at least 6 months, and interventions induced clinically meaningful weight loss (approximately 5% to 10% of initial weight). This level of weight loss has been found to improve obesity-related comorbidities and risk factors.⁷ Some studies did not report percent weight loss and instead reported reduction in kilograms (kg) of weight. In these cases, approximations were used.

There were exceptions made to the weight loss criterion. An exception was made for studies of physician-led lifestyle interventions. The reason for this exception is that the goal for this study was to provide interventions that could practically be covered in an insurance benefit. Some of the more successful interventions were delivered by academic medical centers and were perceived impractical for purchasers with limited resources or located in more rural regions. For this audience, a primary care physician (PCP) might be the most likely source of lifestyle counseling. Exceptions were also made for trials of short-term weight loss medications such as phentermine. There are no recent trials examining lifestyle programs with adjunct phentermine administration. The reason for this is that several of the short-term obesity medications were approved over 40 years ago and have received little study since. However, we know from recent survey research⁸, that phentermine is the most widely utilized medication by obesity specialists. Thus, to exclude mention of trials for the drug would be disingenuous to

benefit managers considering which medications to cover.

The tables contain only the “intervention arm” of the study. Furthermore, the tables contain only the core components of the intervention, i.e. individual vs. group therapy, type of health professional(s), number of contacts or visits, telephonic or face-to-face contact, duration of session, dietary component (e.g., use of specific meal replacement), physical activity component (e.g., pedometer included), and only for those interventions in the lifestyle with pharmacotherapy table, type and dose of medication. A reference list is included to provide the user with the information necessary to retrieve more specifics on the intervention if so desired.

SYNOPSIS OF GUIDELINES, POSITION STATEMENTS, AND ALGORITHMS

The results of the guideline review are presented in tables contained in **Appendix A** of this report and a summary of the guideline review is discussed below. We refer to these tables collectively as the obesity **Guideline Index** (Index). The Index is organized by treatment modality as follows: diet, physical activity, behavior, combined / lifestyle, pharmacy, and surgery. Guidelines produced by different institutions differ in their organization of recommendations. For instance, the section on “combined / lifestyle” contains recommendations that cross-cut diet, physical activity, and behavior therapy. An analysis and summary of guidelines for each treatment modality are discussed below. The use of each treatment approach in specific risk populations are described in the series of treatment algorithms that follow.

Guidelines from several organizations focused on one treatment area (e.g., weight loss surgery), while others developed guidelines for a comprehensive approach to obesity assessment and treatment. The organizations and research teams having developed guidelines, the year they were published, and the focus of the guidelines are shown in **Table 1**, in ascending order (beginning with the National Institutes of Health (NIH) Evidence Report in 1998). In terms of scope, organizations were careful to remain within their area of purview. For instance, though the ADA issued a set of very comprehensive guidelines, the bulk of their focus was on lifestyle modification, as opposed to pharmacologic or surgical treatments.

TABLE 1. ORGANIZATIONS AND RESEARCH TEAMS SUPPLYING OBESITY-RELATED TREATMENT GUIDELINES

TREATMENT FOCUS‡		
National Institutes of Health	1998	Comprehensive
National Institutes of Health	2000	Comprehensive
American Academy of Family Physicians	2001	Comprehensive
American Medical Association	2001	Comprehensive
American College of Preventive Medicine	2002	Dietary
U.S. Preventive Services Task Force	2003	Comprehensive
Brigham and Women's Hospital	2003	Comprehensive
American Medical Association	2003	Comprehensive
National Health & Medical Research Council (AUS)	2003	Comprehensive
American Diabetes Association	2004	Lifestyle
American Heart Association	2004	Comprehensive
American College of Physicians	2005	Comprehensive
Kelly J., Tarnoff M., et al.	2005	Surgery
American Dietetic Association	2006	Comprehensive
National Institute for Health and Clinical Excellence (UK)	2006	Comprehensive
Canadian Medical Association	2007	Comprehensive
American Association of Clinical Endocrinologists, The Obesity Society, and American Society for Metabolic & Bariatric Surgery	2008	Surgery
Society of American Gastrointestinal and Endoscopic Surgeons	2008	Surgery
European Association for the Study of Obesity	2008	Comprehensive
Institute for Clinical Systems Improvement	2009	Comprehensive
American College of Sports Medicine	2009	Physical Activity
Blackburn G., Hutter M. et al.	2009	Comprehensive

*A group of researchers published in a peer-reviewed general but not on behalf of a specific organization;

†The year in which the guidelines were published, in ascending order;

‡The form of treatment the guideline addressed. Comprehensive indicates the guideline addressed all forms of obesity treatment including lifestyle, pharmacologic, and surgical.

NIH Evidence Report

The most consistently referenced set of guidelines were developed by the NIH and published in 1998 and 2000.^{7,9} Subsequent guidelines most often reference or build on the guidelines contained in the *NIH Evidence Report*⁷ and subsequent Practical Guide.⁹ The *NIH Evidence Report* presents a comprehensive approach to the assessment and treatment of obesity. The guideline addresses components of the assessment such as the evaluation of BMI and risk status, as well as the patient's past attempts at weight loss and readiness to lose weight. The guidelines also provide

guidance on developing a treatment strategy based upon BMI and risk level.^{7,9}

Contained in the NIH Evidence Report is a "Guide to Selecting Treatment," which is presented in **Figure 1**.⁷ The "Guide to Selecting Treatment" has been republished or adapted in subsequent publications produced by the American Medical Association (AMA)¹⁰ and the American Heart Association (AHA).¹¹ Most other organizations publishing clinical guidelines on obesity treatment stay very close to the approach depicted in **Figure 1**.¹²⁻¹⁶ Health plans also pull from this approach in framing their benefit policies.^{17, 18}

FIGURE 1. "NIH GUIDE TO SELECTING TREATMENT"

BMI CATEGORY					
Treatment	25-26.9	27-29.9	30-34.9	35-39.9	≥40
Diet, physical activity and behavior therapy	with comorbidities	with comorbidities	+	+	
Pharmacotherapy		with comorbidities	+	+	+
Surgery				with comorbidities	

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The algorithms developed in this project adhere to this approach to treatment. However, attention is given to the interpretations of "with comorbidities" (as seen in **Figure 1**) and "risk status" and their use in the selection of treatment modality.

Often is the case, both in the guidelines and with insurance coverage, when the addition of medical or surgical therapy to lifestyle modification therapy is based heavily on the presence of comorbidities or risk factors.^{17, 18} The reason for this is that the presence of specific comorbidities or risk factors has implications for patient risk of morbidity and mortality.⁷

It is important to differentiate between the types of risk (relative vs. absolute) and to understand what the risk is referring to, i.e., risk of disease, which disease(s), or risk of mortality. The NIH is careful to point out the need for differentiating between types of risk and exactly how risk status should impact treatment for overweight and obesity.

Risk Stratification and Impact on Treatment Approach

BORROWING FROM HYPERTENSION AND HIGH BLOOD CHOLESTEROL

The *NIH Evidence Report* did not invent the philosophy of adjusting treatment for a primary condition based on the existence and combination of other risk factors. Rather, the philosophy was adopted from previous work on treatment guidelines developed for other cardiovascular-related conditions, primarily those drafted for hypertension¹⁹ and hypercholesterolemia²⁰. Guidelines for these conditions, also developed under the auspices of NIH, adjust treatment approaches based on the severity of the primary condition (e.g., LDL level in populations with high cholesterol) in combination with specific comorbidities and risk factors, i.e.,

treatments are based on a risk stratification methodology. It is the methodologies for risk stratification used in these non-obesity guidelines^{19, 20} that have been adopted for use in obesity treatment guidelines. Understanding this methodology is essential to understanding why obesity treatment guidelines, and some benefit policies, recommend for and against certain types of treatments for different overweight and obese patient populations.

In both hypertension and hypercholesterolemia, treatment strategy hinges on the severity of the primary condition (e.g., LDL level in populations with hypercholesterolemia) and, secondly, on the presence of select risk factors or diseases.^{19, 20} A similar approach is used for determining a treatment strategy for obesity. First, populations are assessed for the severity of obesity, measured through BMI and waist circumference (WC), and secondly, for presence of specific risk factors or diseases to determine *absolute* risk.

BMI AND RELATIVE RISK

The principle measures of overweight and obesity are BMI and WC.⁷ The severity of obesity, measured by BMI categories (e.g., BMI 30 to 34.9 kg/m² = Class I obesity), provides for the first step in risk stratification. The cutoffs in BMI for each category are based on evidence of the association between increased BMI and increased *relative* risk for morbidity and mortality.²¹⁻²⁸ That is, increases in BMI are directly associated with increased risk for diabetes, hypertension, and cardiovascular disease, *relative* to populations of normal weight.⁷ The use of WC in populations with a BMI 25 to 34.9 kg/m² provides more information on relative risk level for populations where BMI is not a reliable indicator or where the addition of the WC measurement to BMI classification actually increases the patient's relative risk

for disease.⁷ Relative risk is a good tool for determining whether or not to pursue treatment. However, relative risk does not indicate treatment intensity (e.g., whether or not to consider pharmacotherapy or surgical therapy).

ABSOLUTE RISK AND RISK FACTOR COUNTING

BMI and WC provide a foundation from which to begin assessing the patient's *absolute* risk level. Determining a patient's *absolute* risk aids in determining the required intensity of the intervention. The philosophy is that information regarding history of cardiovascular disease or associated risk factors can be used to assess whether the patient has reasons other than being overweight for being at high risk of a cardiovascular event or death.²⁰ This is exactly what they do in hypertensive populations and in populations with high cholesterol. For instance, in patients with only slightly elevated LDL cholesterol levels, lifestyle modification therapy might be the recommended treatment. However, if that same patient also had a family history of cardiovascular disease and was hypertensive, that patient would then be considered for statin drug therapy. In the treatment of obesity, the intensity of treatment could potentially mean the required frequency of behavioral counseling, the addition of medication therapy, or even the addition of surgical therapy. The methodology used for determining absolute risk in the *NIH Evidence Report* borrowed heavily from the methodology used in the Second Report of the Expert Panel on the Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel II / ATP II).⁷ The system was a "blending" of the concepts of relative and absolute risk, as discussed previously.⁵ The ATP II methodology used a simple system of risk assessment that relied upon *counting* of categorical risk factors.^{5, 20} For example, if a hypercholesterolemic patient that had 1 risk factor, say a family history of sudden cardiac death, that patient would be recommended for less intensive therapy than a patient with a family history, hypertension, and who smoked cigarettes, all other characteristics being equal. Presence of target organ damage or coronary heart disease (CHD) automatically inferred high absolute risk, without having to count risk factors. Counting of risk factors was more a concern for primary prevention as opposed to secondary prevention of cardiovascular disease.

This concept of risk factor counting or *summation* is now central to almost every version of clinical guidelines for

treatment of overweight and obesity. The mix of relevant diseases and countable risk factors for obesity, as defined by NIH, are presented in **Table 2**. An interesting departure from the ATP II methodology was the required number of risk factors to be considered at high absolute risk. The ATP guideline stated that populations with 2 or more risk factors should be considered as high risk.²⁰ However, the *NIH Evidence Report* stated that populations could be "classified as being at high absolute risk if they had *three or more risk factors*".⁷ Yet, in terms of when to consider therapy for overweight populations (BMI 25 to 29.9), the *NIH Evidence Report* recommends treatment only in populations with *two or more* risk factors.⁷

Our emphasis on the counting methodologies and the slight variation within them are meant to draw attention to this methodology, especially given its frequent use in clinical guidelines for obesity and, subsequently, obesity insurance coverage policies. It needs mentioning, however, that the most recent edition of the NIH guidelines for high blood cholesterol (ATP III / 2004) revisit the counting methodologies, discuss the limitations of the original methodology, and suggest other means of risk stratification e.g., Framingham risk scores.⁵ However, ATP III concludes that the alternative methods give similar results and physicians could begin with either approach.

RISK STRATIFICATION IN THE OBESITY TREATMENT GUIDE

For the purposes of this project, the counting methodology is used for assessing high absolute risk in populations without existing obesity-related diseases. The counting methodology used in this project is adapted from the ATP II approach²⁰ and *NIH Evidence Report* approach⁷ of assigning populations to one of three general risk categories: (1) those at highest risk for future cardiovascular events or mortality because of prior CHD, other atherosclerotic diseases, diabetes, or sleep apnea (Very High Absolute Risk); (2) populations without the aforementioned diseases, but who are at absolute high risk due to the presence of two or more risk factors (see Table 2, column 3); and (3) populations without the aforementioned diseases and have 0 to 1 risk factors. Practically speaking, for purposes of this project, the populations are either at "high absolute risk" or they are not. The first two categories equate to "high absolute risk" while the final category refers to "low risk".

The notion of gauging treatment intensity based on absolute risk deserves more attention. First, given the findings about the limitations of the counting methodology discussed in ATP III, more thought should be given to which methodology for risk stratification is used for obesity. Second, since the *NIH Evidence Report* adopted their risk stratification methodologies from guidelines for cardiovascular-related conditions, there is a bias toward assessment of risk factors for cardiovascular conditions as opposed to risk factors for

other conditions where obese populations are known to be at increased risk, including: various cancers (colon, breast, esophageal, uterine, kidney)²⁹, liver disease^{30, 31}, osteoarthritis³², and reproductive disorders³³⁻³⁵. Since we know that obese populations are at increased risk for other conditions, such as cancer, should risk factors for these conditions not be considered in determining absolute risk, and consequently, intensity of treatment strategy?

TABLE 2. DISEASES AND RISK FACTORS TO CONSIDER IN THE ASSESSMENT OF ABSOLUTE RISK, NATIONAL INSTITUTES OF HEALTH

VERY HIGH ABSOLUTE RISK OF MORTALITY	INCREASED RISK FOR OTHER MEDICAL CONDITIONS	IMPART HIGH ABSOLUTE RISK FOR OBESITY RELATED DISORDERS (PRIMARILY CVD) IF THEY HAVE THREE* OR MORE OF THE MULTIPLE RISK FACTORS LISTED BELOW:	OTHER RISK FACTORS (INCREMENTAL ABSOLUTE RISK)
<i>Established Coronary Heart Disease</i>	<i>Gynecologic disorders</i>	<i>Cigarette Smoking</i>	<i>Physical Inactivity</i>
<i>History of Myocardial Infarction</i>	<i>Osteoarthritis</i>	<i>Hypertension (systolic > 140, diastolic > 90), or taking hypertensives</i>	<i>High Triglycerides</i>
<i>History of angina pectoris</i>	<i>Gallstones</i>	<i>LDL > 160 mg / dL</i>	
<i>History of coronary artery surgery</i>	<i>Stress Incontinence</i>	<i>HDL < 35 mg / dL</i>	
<i>History of coronary artery procedures (angioplasty)</i>		<i>Impaired Fasting Glucose (110 - 125)</i>	
<i>Peripheral Arterial Disease</i>		<i>Family history of premature CHD</i>	
<i>Abdominal aortic aneurysm</i>		<i>Age (male > 45 years, females > 55 years)</i>	
<i>Symptomatic carotid artery disease</i>			
<i>Type 2 Diabetes</i>			
<i>Sleep Apnea</i>			

*The NIH suggests that three or more risk factors impart "high absolute risk". However, the guidelines from with the NIH adopted the counting methodology suggest that two or more risk factors impart high absolute risk.[ATP II] Furthermore, other organizations utilize two or more risk factors as an indicator to increase treatment intensity as opposed to three or more.[ICSI]

ALGORITHMS

As in the case of clinical guidelines for obesity, several organizations have developed algorithms for treating obesity. Fortunately, these algorithms look very similar, and again, largely stem from the clinical guidelines and algorithm developed by the NIH in 1998.² The organizations and research teams developing algorithms for obesity are shown in **Table 3**.

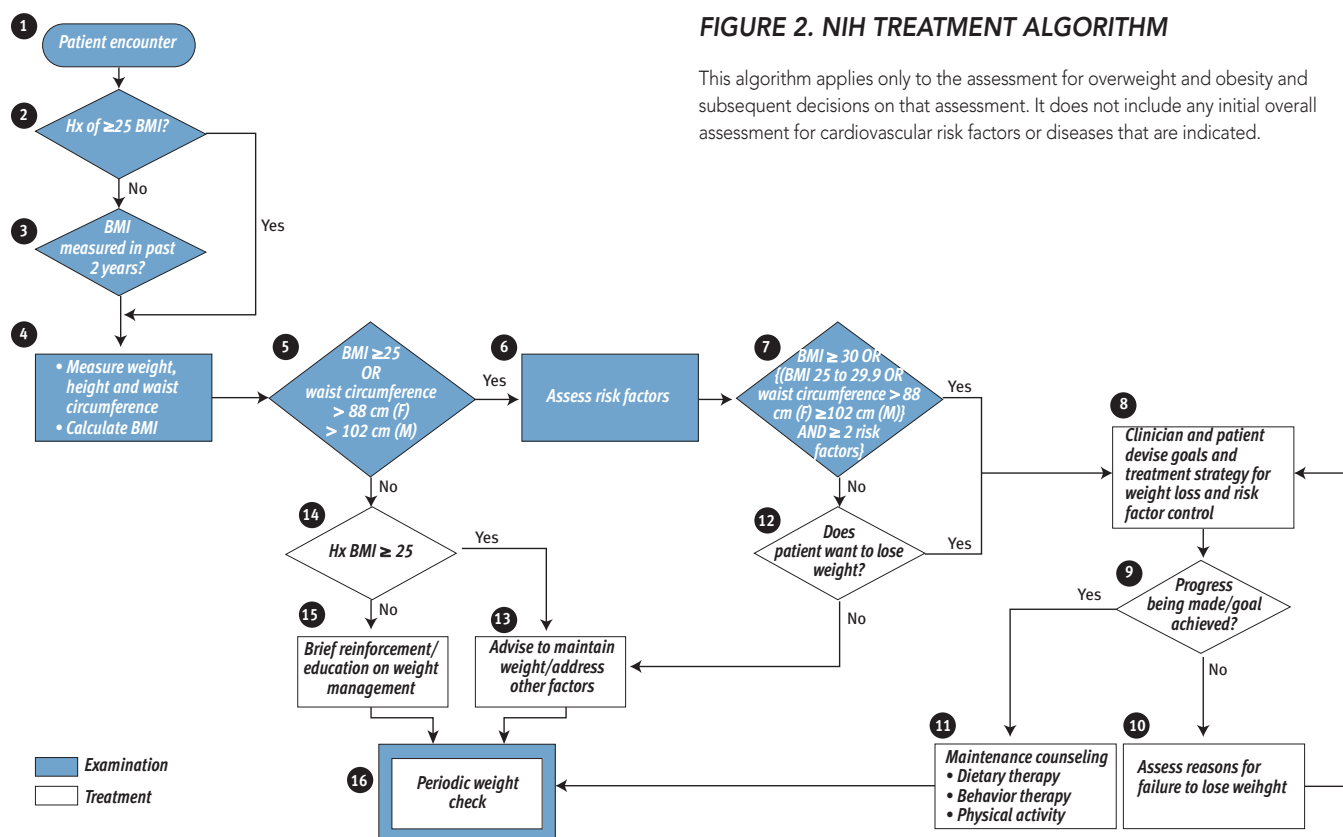
TABLE 3. PUBLISHED OBESITY ASSESSMENT AND/OR TREATMENT ALGORITHMS

ORGANIZATION OR RESEARCH TEAM	YEAR
National Institute of Health	1998
American Medical Association	2001
American College of Physicians	2005
Canadian Medical Association	2006
Sampsel S. May J. et al. (DMAA, NCQA)	2007
European Association for the Study of Obesity	2008
Institute for Clinical Systems Improvement	2009

Publications featuring algorithms for overweight and obesity generally present the algorithm in the form of a diagram (similar to a flowchart). These algorithms aim to define and summarize the assessment and treatment process for obesity and provide the audience with a representation and simplification of the process.

The NIH obesity treatment algorithm, like the NIH obesity guideline in general, is widely referenced and several organizations simply adapted the NIH algorithm making only minor revisions. The NIH treatment algorithm is presented in **Figure 2**.

The focus of the project can be described as honing in on one section of the NIH treatment algorithm.⁷: “Clinician and Patient Devise Goals and Treatment Strategy for Weight Loss and Risk Factor Control” (Box 8). The reason for this approach reflects our objective to take users to effective interventions for obesity. The approach assumes that populations have decided to lose weight and are at the appropriate readiness level.



HOW TO USE THE OBESITY TREATMENT GUIDE

The purpose of the Guide is to serve as a resource to employers, program providers, medical providers and payers in their development or continued modification of health insurance benefit designs and interventions for the treatment of obesity in their populations.

INDEX

The **Index** (Appendix A) provides a quick review of the guidelines from various organizations by treatment approach (e.g., diet, physical activity, behavioral therapy, pharmacotherapy, and surgical therapy). The Index also identifies where the completed guideline can be accessed for those who want more information from a specific organization.

USING THE ALGORITHMS AND INTERVENTION TABLES

The Guide can be conceptualized as follows: The synopsis of guidelines (described above) leads to the series of treatment algorithms (6 modules organized by BMI level), which in turn lead to interventions that employers can consider for populations falling into that module (e.g., populations with a BMI < 26 kg/m²). The algorithms are the framework by which employers can differentiate between which type of interventions are appropriate for various populations.

INFORMATION ON YOUR POPULATION

It would be helpful, though not required, for users of the Guide to have data on their own population, especially as it relates to the distribution of BMI, and the incidence of common obesity comorbidities (e.g., diabetes, cardiovascular disease, sleep apnea). Researchers acknowledge that this data is often hard to access. However, this Guide could be used to demonstrate to decision-makers the importance of having data when making critical decisions about an obesity benefit design. Health risk assessments (HRAs) are the best tools for accurate, up-to-date information on your population. HRAs usually collect information on BMI, WC, health history, and basic demographics.

TREATMENT ALGORITHMS

OVERVIEW

The purpose of the **Obesity Treatment Algorithm** is to aid users in identifying interventions that produce weight loss in

overweight and obese populations. The algorithm is broken down into sections or “modules” based on BMI category and risk level. Each module is based on the guidelines discussed above. There is discussion within each module regarding the population referenced and additional information to consider while reviewing the algorithm flowchart. These modules are focused only on the treatment end of the obesity assessment and treatment process. The modules assume that populations want to lose weight and are at the appropriate readiness level, per the NIH obesity treatment algorithm.⁷ The focus of these modules is on determining strategies for weight loss. These modules are decision support tools only and are not intended to be substitutes for clinical judgment.

Every algorithm module begins with a BMI category and ends with one of four treatment strategies: no treatment, lifestyle modification therapy, lifestyle modification therapy with adjunct pharmacologic therapy, or lifestyle modification therapy with surgical therapy. As mentioned in the methodology, two sets of intervention tables, one for lifestyle modification interventions (**Appendix B**) and one for lifestyle modification with pharmacologic therapy (**Appendix C**), are included in this report. These tools provide the core elements of programs that one might consider in developing an obesity benefit. The listings do not include every detail of the intervention but do provide the appropriate reference for further investigation.

Several of the algorithms feature a decision node that makes mention of “qualifying disease” and “two or more qualifying risk factors.” “**Qualifying Disease**” simply refers to the list of obesity-related diseases and risk factors utilized as determinants of absolute risk status in guideline sets. Refer to **Table 2** for the listing supported by the NIH guideline. Though there are diseases and risk factors not listed by the NIH that are associated with obesity and used by other organizations, the vetting of new criterion were not within the scope of this project.

TREATMENT ALGORITHMS

Body Mass Index 25.0 to 29.9 kg/m² (Overweight)

The relationship between weight and mortality begins at a BMI of 25 kg/m².⁷ This is the reason why populations are classified as “overweight” upon reaching this threshold. Populations with a BMI ranging from 25 to 29 kg/m² are

considered to be in this “overweight” category. Populations in this category are considered at increased risk (relative to normal weight populations) for type 2 diabetes, hypertension, and cardiovascular disease.⁷

Organizations differ somewhat in their approach to treating the overweight population. The American College of Physicians’ (ACP) practice guideline explicitly states that it does not apply to populations with a BMI under 30 kg/m² (i.e., it does not apply to overweight populations).¹² Furthermore, in their 2003 recommendations, the United States Preventive Services Task Force concluded that the “evidence was insufficient to recommend for or against the use of counseling of any intensity or behavioral interventions to promote sustained weight loss in overweight populations.”³⁶

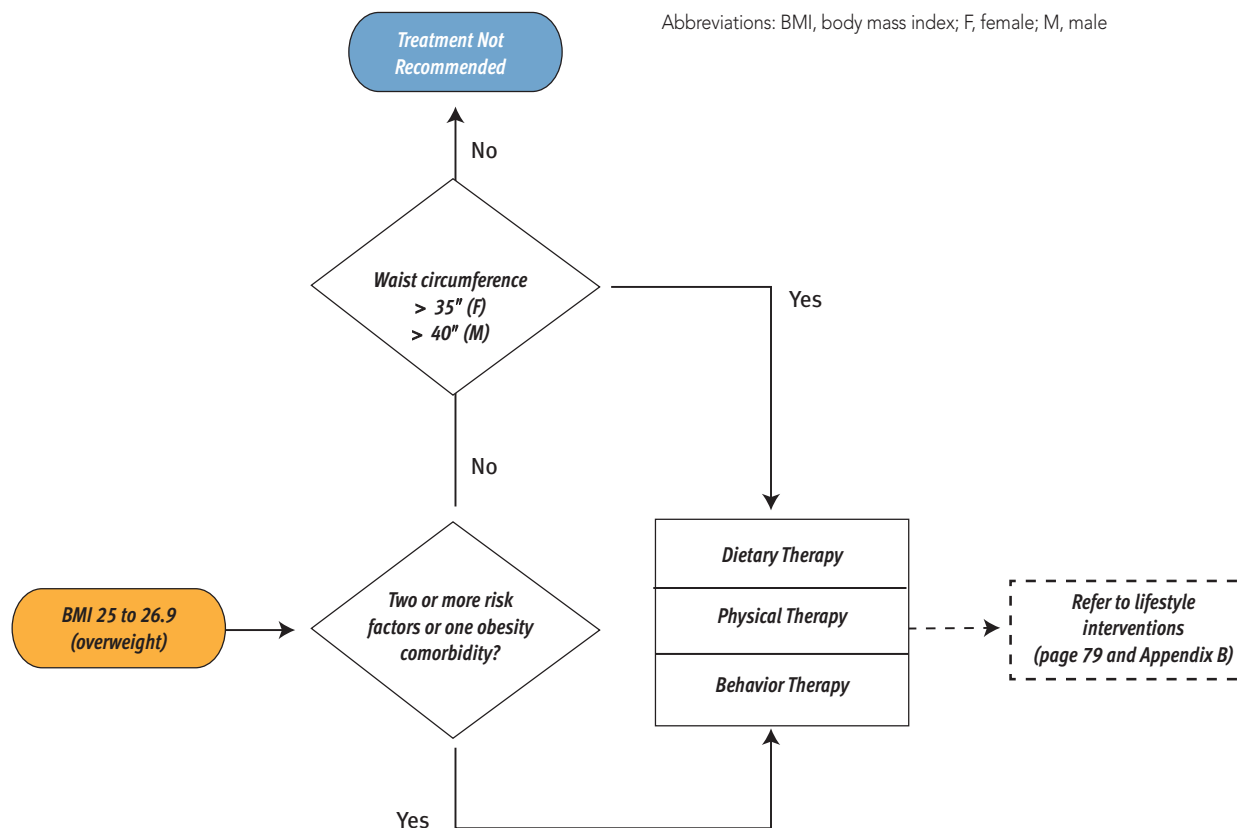
The NIH guideline states that treatment of overweight is recommended only when populations have two or more risk factors or a high WC.⁷ Experts recommend that populations between a BMI of 25 and 29 kg/m² who have one or no risk factors need only to maintain weight rather than begin a treatment program.⁷

In populations who do have multiple risk factors present or high WC, the type of treatment to be considered depends upon which half of the overweight category the patient falls into, thus the distinction between populations with a BMI of 25 to 26.9 kg/m² and a BMI of 27 to 29.9 kg/m². Populations in the latter half of the overweight category are considered to be at higher risk than populations only slightly overweight.

Module I: Therapeutic approaches to persons with BMI 25 to 26.9 kg/m²

FIGURE 3. TREATMENT ALGORITHM FOR POPULATIONS WITH A BMI 25 TO 26.1 KG/M²

Abbreviations: BMI, body mass index; F, female; M, male

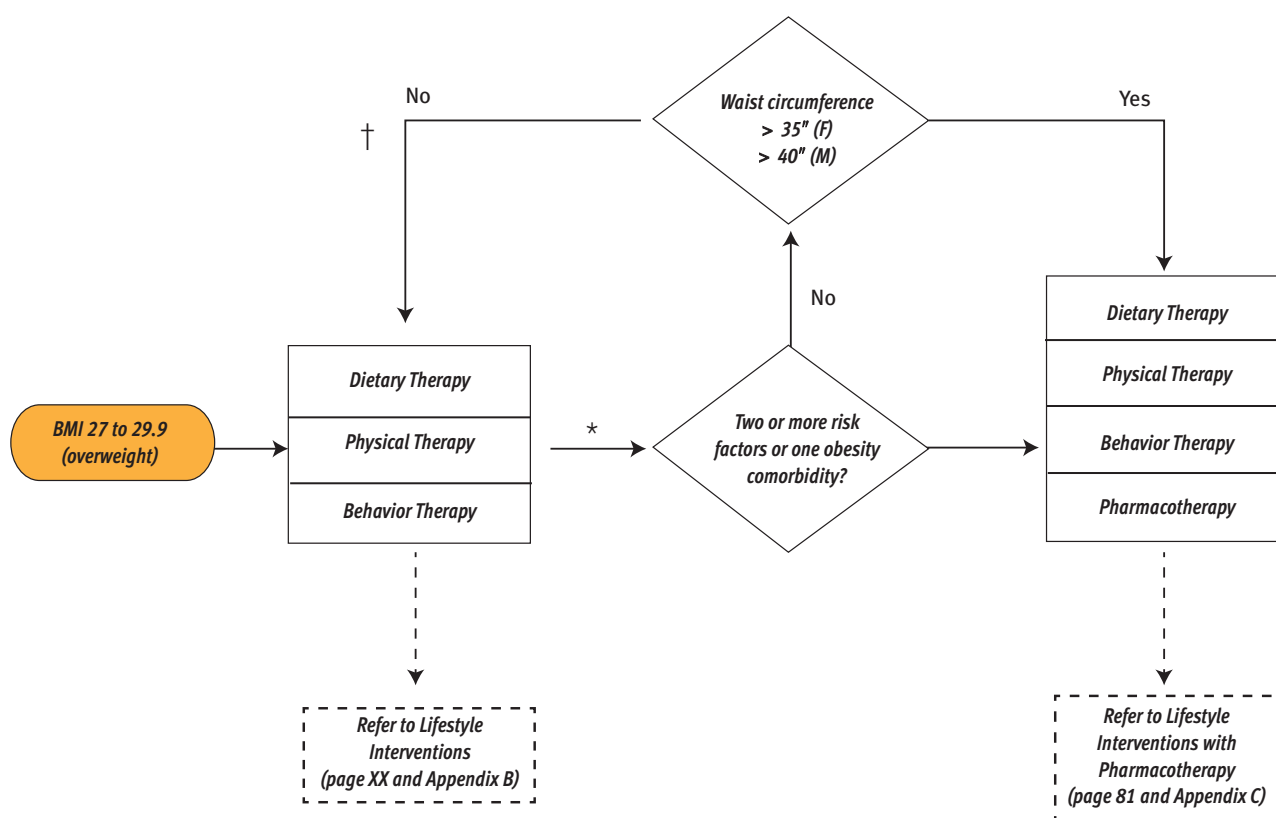


Populations with a BMI 25 to 26.9 kg/m² with two or more risk factors or who have a WC over 35 inches for females and 40 inches for males (refer to this WC threshold throughout modules), should be prescribed a lifestyle modification program (presented in Figure 3).^{7,10,11,37,38}

No guideline could be found that recommends medication therapy for this proportion of the overweight population. The goal of therapy for this population is to prevent development of obesity and to produce modest weight loss.⁷

Module II: Therapeutic approaches to persons with BMI 27 to 29.9 kg/m²

FIGURE 4: TREATMENT ALGORITHM FOR POPULATIONS WITH A BMI 27 TO 29.9 KG/M²



Abbreviations: BMI, body mass index; F, Female; M, Male;

*If after 6 months of intensive lifestyle modification therapy the patient has not lost the recommended 1 lb. per week, pharmacotherapy may be considered for patients at high risk (two or more risk factors, 1 obesity comorbidity, or high WC);

† If after 6 months the patient has not lost the recommended 1 lb. per week, consideration should be given to augmenting the lifestyle modification approach. For instance, switching from one-on-one therapy to group therapy.

§, ||, #, **, ††

Populations with a BMI in the range of 27 to 29.9 kg/m² are in one of the two BMI categories where the presence of disease or risk factors can significantly alter the treatment modalities considered (the other being a BMI of 35.9 to 40.0 kg/m², discussed later).

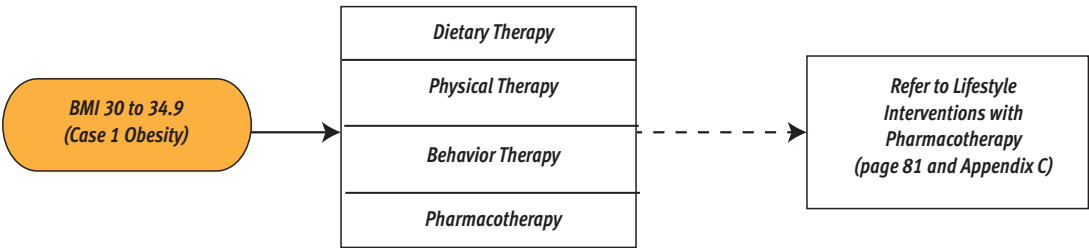
There is wide agreement across the guideline sets that a BMI of 27.0 kg/m² is the first threshold where treatment with pharmacologic agents may be considered.^{7,11,13,37} However, even for patients at high risk, some organizations recommend considering pharmacotherapy only if and when the patient is unsuccessful with six months of intense lifestyle modification therapy.^{7,12,39} Other organizations recommend consideration of pharmacotherapy in this BMI population for patients at high risk (one obesity comorbidity, two or more risk factors, or a high WC) without mention of the six-month period in the recommendation.^{13,14,16,37,40,41}

Populations with a BMI of 27.0 to 29.9 kg/m² are recommended to receive lifestyle modification therapy for a period of at least six months. If, after six months, patients do not lose the recommended 1 lb. per week, modification of the lifestyle modification program should be considered. For instance, the lifestyle modification approach could be modified to include group therapy as opposed to one-on-one therapy, or the dietary approach could be modified to include meal replacement therapy. For patients still at high risk (patients with 1 obesity comorbidity, two or more risk factors, or a high WC) after six months of lifestyle modification therapy, consideration of pharmacotherapy is recommended (see **Figure 4**).^{7,12,39}

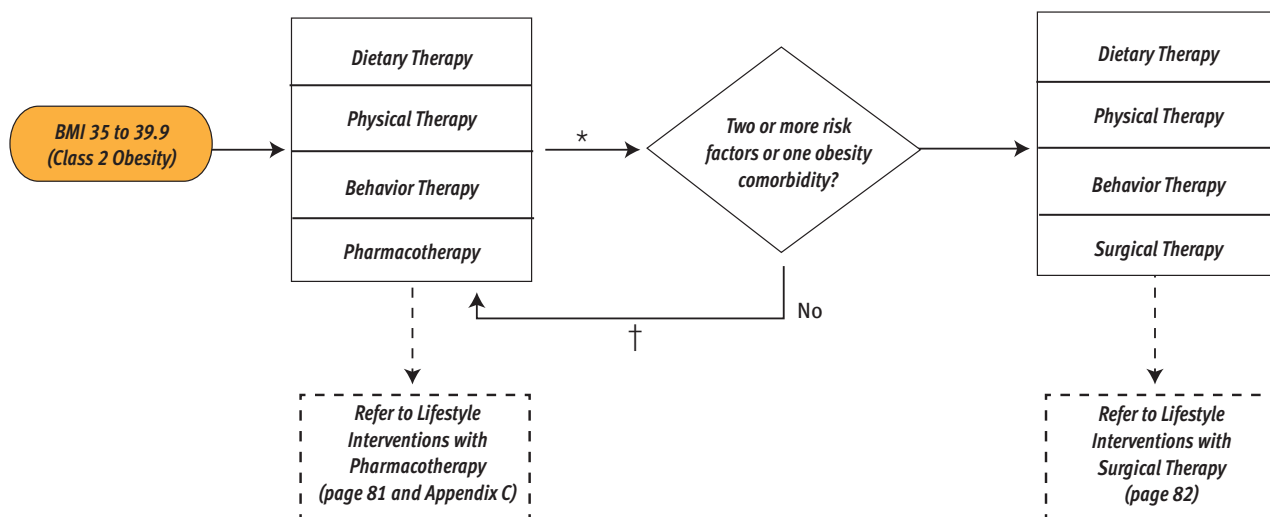
Module III: Therapeutic approaches to persons with BMI 30 to 34.9 kg/m²

FIGURE 5: TREATMENT ALGORITHM FOR POPULATIONS WITH A BMI 30 TO 34.9 KG/M²

Abbreviations: BMI, body mass index



Populations with a BMI of 30 to 34 kg/m² are at high risk (relative to normal weight populations) for developing type 2 diabetes, hypertension, and cardiovascular disease.⁷ There is little variation or ambiguity in the guidelines regarding recommended treatment for this BMI population. The broad approach to treatment for patients in this population is lifestyle modification therapy with pharmacotherapy (see **Figure 5**).⁷ Unlike populations in BMI categories 27 to 29 kg/m² and 35 to 49 kg/m², the treatment strategy recommended for this population is broadly the same regardless of the presence of obesity comorbidity, risk factors, or WC.

Module IV: Therapeutic approaches to persons with BMI 35 to 39.9 kg/m²FIGURE 6: TREATMENT ALGORITHM FOR POPULATIONS WITH A BMI 35 TO 39.9 KG/M²

Abbreviations: BMI, body mass index.

* Treatment with surgical therapy, in addition to lifestyle modification therapy, should be considered for populations in this BMI range who have one major comorbidity or two or more risk factors and have failed previous non-surgical attempts at weight loss;

† If after 6 months the patient has not lost the recommended 1 lb. per week, consideration should be given to augmenting the lifestyle modification and pharmacotherapy approaches. For instance, switching from one-on-one therapy to group therapy or considering an alternative medication.

Populations with a BMI of 35 to 40 kg/m² are in the second of two BMI categories (the first being BMI 27 to 29.9 kg/m²) where the presence of disease or multiple risk factors can significantly alter the treatment modalities considered. However, unlike the decision process in the 27 to 29 kg/m² population, the use of WC as a predictor of increased risk is no longer appropriate as populations in this BMI category most likely exceed the cutoffs noted for determining relative high risk.⁷

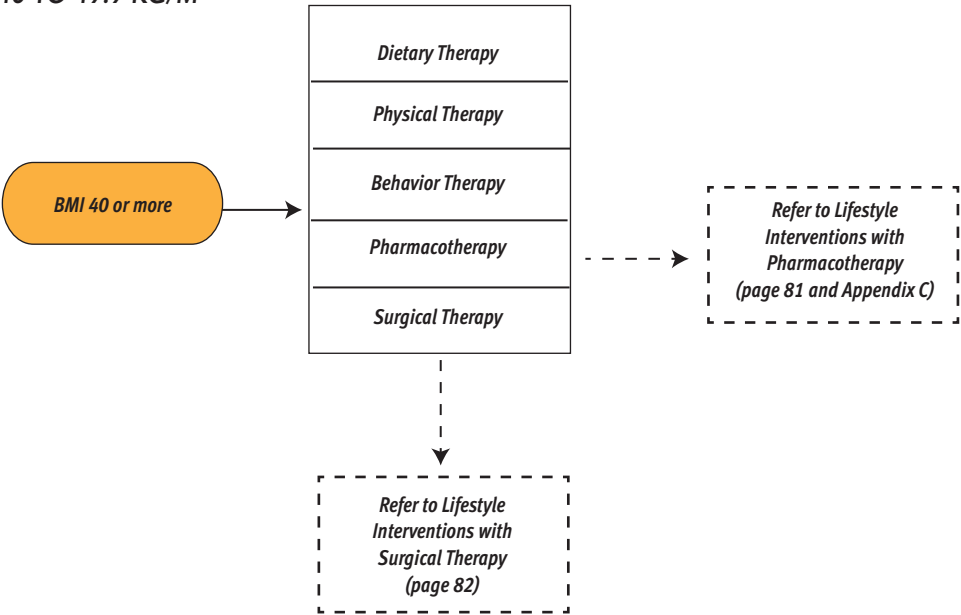
Similar to the issues that arise in the consideration of pharmacotherapy in specific overweight patients (BMI > 27 kg/m²), the criteria for surgical therapy in populations with a BMI of 35 to 40 kg/m² varies slightly between guidelines developed by different organizations. Almost all organizations recommend surgical therapy in this BMI range when an obesity-related comorbidity is present.^{7,11,14-16,37,39,42} Only the ACP reserved surgical therapy strictly for populations with a BMI > 40 kg/m.¹² However, the NIH and NICE add that surgery be considered in this population only when less invasive methods have failed.^{7, 39} The European Association for the Study of Obesity (EASO) adds that surgical therapy is only an option for patients in age groups from 18 to 60.¹⁶ Age-related criteria were not addressed in this Guide.

Populations in this BMI range should initially receive comprehensive lifestyle modification therapy with pharmacotherapy.^{7,11,14-16,37-39,42} Treatment with surgical therapy, in addition to lifestyle modification therapy, should be considered for populations in this BMI category who have one major comorbidity or two or more risk factors and have failed previous non-surgical attempts at weight loss (see **Figure 6**).^{7, 39}

Module V: Therapeutic approaches to persons with BMI 40 to 49.9 kg/m²

FIGURE 7: TREATMENT ALGORITHM FOR POPULATIONS WITH A BMI 40 TO 49.9 KG/M²

Abbreviations: BMI, body mass index.



There is almost universal agreement across clinical practice guidelines that populations with a BMI of 40 kg/m² or more should be considered candidates for weight loss surgery.^{7,11,14,37,38} Some guideline sets suggest that even populations with a BMI > 40 kg/m² should have failed previous non-surgical attempts at weight loss before surgery is considered.¹² Patients with a BMI > 40 kg/m² should be considered for any and all treatment options with consideration given to the patients' risk status, surgical risk profile, and past attempts at weight loss (see **Figure 7**).

BEST PRACTICES BY TREATMENT APPROACH:

Lifestyle Modification Therapy

Lifestyle modification therapy is the cornerstone treatment for overweight and obesity.⁴³ As illustrated in the algorithms included in this report, lifestyle modification therapy is recommended for overweight and obese populations, regardless of BMI class or risk level (exception being BMI 25 to 26.9 kg/m² with no risk factors). The introduction of

pharmacotherapy and surgical therapy do not replace the need for lifestyle modification therapy, rather, they build on its foundation.

Lifestyle modification therapy refers to a comprehensive weight loss intervention that incorporates (1) diet, (2) physical activity, and (3) behavioral therapy. The central notion is that diet alone, or physical activity alone, or behavior therapy alone, are less effective than the three modalities pursued simultaneously. One component complements and enhances the other. The **Guideline Index (Appendix A)** includes a section on guideline language for lifestyle modification in general, in addition to language specific to each component (e.g., diet, physical activity, behavior therapy).

The scientific literature around lifestyle modification therapy is robust enough to provide insight into what works and what doesn't work in the prevention and treatment of obesity. The literature is composed of a mixture of studies focused on either comparing one component of lifestyle modification therapy to an alternative (i.e., diet 1 vs. diet 2)⁴⁴⁻⁴⁶ and studies testing one variation of a comprehensive lifestyle intervention

against an alternative variation (i.e., program 1 vs. program 2).^{47, 48} Over the past several years, major randomized controlled trials have evaluated comprehensive lifestyle modification programs to hone in on the right combination of strategies for achieving clinically meaningful, sustainable weight loss.⁴⁹⁻⁵³ While the majority of these programs are conducted through academic medical centers, there are trials examining lifestyle modification programs delivered through traditional primary care practices.⁵⁴

In general, for lifestyle modification therapy to be effective, it needs to be intense.⁴³ Lifestyle modification should include weekly sessions with a health practitioner for an initial period of 16 to 26 weeks.^{43, 55} The core intervention could be delivered one-on-one or in groups of 10 to 20 individuals.⁴³ The duration of each session is generally 60 to 90 minutes.⁴³ The content or curriculum followed by a lifestyle modification program should be of less concern to the employer, as that is the job of the selected practitioner.

The main consideration for the employer is the selection of health professional(s) for inclusion in the lifestyle modification intervention. Medical providers, whether a primary care physician (PCP) or specialist, need to be included. However, the role of the physician will depend on the inclusion of other non-physician health professionals. Non-physician health professionals are essential to intensive lifestyle modification therapy. Appropriate health professionals for lifestyle modification therapy include registered dietitians, behavioral psychologists, and/or exercise physiologists.³⁷ Registered dietitians (RD) are probably the most common professionals selected for first-time intervention. The decision regarding which type of professional to include for obesity will largely depend on the goals for the intervention and the resources available.

Resources available, i.e., the supply and location of RDs, behavioral psychologists, or exercise physiologists, will also need to be assessed. Another consideration is which populations should have access to each type of professional. For instance, the prototype benefit design² included in the Toolkit allows for 12 visits with an RD in the first year at level one and then four visits with an exercise physiologist in the second year, or level two.

As previously mentioned, visits with a primary care provider should be included to monitor the patient's health and manage any comorbid conditions or risk factors; the required

intensity, duration, and skill set necessary for effective weight management counseling may exceed a PCP's capabilities.⁵³ For instance, the prototype benefit design included in this Toolkit includes three visits with a PCP in the first benefit level followed by five visits with a physician (not necessarily a PCP) in the second benefit level.²

Unfortunately, the guidelines do not provide this kind of employer-focused guidance for dietary therapy, other than that an RD is probably the most appropriate professional to deliver the dietary intervention and that the RD should coordinate efforts with a physician. Also, the greater frequency of contacts between the patient and the RD, the more likely the patient will be successful at achieving goals.¹⁵ To provide some guidance on how to approach the lifestyle component of lifestyle modification, the interventions included in the algorithm highlight the number of visits with a specified health professional, the type of visit (in person, telephonic, group or individual), and the duration of the visit. Toolkit users should review the approaches used in these interventions (**Appendices B and C**) and observe how those programs incorporate RD services.

Diet

The **Guideline Index (Appendix A)** includes guideline language on dietary therapy from 13 organizations. Fortunately, there are basic principles shared by each set reviewed. The level of detail offered by each guideline varied. For instance, one would expect the ADA to give comparatively more attention and detail to dietary best practice, given the nature of their membership and mission. This is in contrast to organizations like the NIH or ICSI that spread their attention across treatment approaches.

In reviewing the guidelines for dietary therapy, the scope and detail of the guidelines is probably more information than a program developer needs to know. A user should think about how an RD should be incorporated, i.e., whether or not to use an RD at a multispecialty primary care practice or utilize an independent RD. Perhaps the patient should be given that choice. Other considerations would include how many visits with an RD should be covered and how long those visits should be. For instance, the ADA recommends medical nutrition therapy for weight loss should last for at least six months or until weight loss goals are achieved, followed by a weight maintenance program after that time.¹⁵

Physical Activity

The **Guideline Index (Appendix A)** includes guideline language on physical activity for overweight and obese patients from 12 organizations. Again, like dietary guidelines, there is tremendous consistency between the guideline sets for physical activity. The guidelines are clear that physical activity alone is likely not effective at reducing weight.¹¹ However, physical activity when combined with energy restriction will increase weight loss^{40,56} and may have beneficial effects on fitness and obesity-related complications such as coronary heart disease and diabetes.¹¹ Physical activity is also necessary for successful weight maintenance.³⁷

Since most guideline sets recommend some level of physical activity per week (varies between organizations in terms of intensity and duration, but usually between 30 and 60 minutes on most days of the week), it will be beneficial to encourage and/or facilitate this activity. Financial incentives outside of traditional benefit designs could be considered here as well, such as subsidized gym membership, and may aid overweight and obesity patients at achieving physical activity goals. Finally, for some high-risk populations, medically supervised physical activity may be required, and should be incorporated into a benefit design.

Behavior Therapy

The **Guideline Index (Appendix A)** includes guideline language on behavioral therapy for overweight and obese patients from 11 organizations. The United States Preventive Services Task Force concluded that the benefits of behavioral interventions outweigh the harms and recommended that only *high intensity* counseling (frequent contacts), as opposed to moderate- or low-intensity counseling, is effective at promoting weight loss.³⁶

Behavior therapy strategies to promote diet and physical activity should be used routinely.⁷ It should be recognized that dietary counseling, by itself, is different than behavioral counseling, though the two will complement each other. A comprehensive weight management program should make maximum use of multiple strategies for behavior therapy (e.g., self monitoring, stress management, stimulus control, problem solving, contingency management, cognitive restructuring, and social support).¹⁵ Formal behavior therapy can be provided through group sessions or individual meetings with a healthcare professional who is skilled in the

delivery of behavioral techniques.¹¹ RDs and behavioral psychologists are the most commonly used professionals to deliver this type of therapy. However, identification of psychological and psychiatric issues that interfere with successful obesity management (e.g., anxiety, stress, depressions) necessitates inclusion of a physician in behavioral counseling.¹⁶

Lifestyle Modification with Pharmacotherapy

The **Guideline Index (Appendix A)** includes a section on guideline language for lifestyle modification therapy with adjunct pharmacotherapy. Several of the algorithms presented below take the user to interventions where lifestyle modification therapy is delivered simultaneously with pharmacotherapy. One of the most important questions regarding pharmacotherapy for obesity is for whom are they appropriate, when are they appropriate, and which of the several available medications should be covered, if any?

The guidelines are very consistent and specific as to for whom and when pharmacotherapy should be considered in the treatment of overweight and obesity. Most, if not all, of the guideline sets build off of the NIH guideline for pharmacologic treatment of obesity, which reads:

"Weight loss drugs approved by the FDA may be used as part of a comprehensive weight loss program, including dietary therapy and physical activity for patients with a BMI > 30 kg/m² with no concomitant obesity-related risk factors or diseases, and for patients with a BMI > 27 kg/m² with concomitant obesity-related risk factors or diseases. Weight loss drugs should never be used without concomitant lifestyle modifications. Continual assessment of drug therapy for efficacy and safety is necessary. If the drug is efficacious in helping the patient to lose and/or maintain weight loss and there are no serious side effects, it can be continued. If not, it should be discontinued." – NHLBI, NIH⁷

Weight loss medications are only to be used by populations who are at increased medical risk due to their weight and not for cosmetic use.⁷ Many organizations suggest that pharmacologic therapy only be offered to overweight and obese patients who have failed to achieve their weight loss goals through diet and exercise alone.^{12,37,39} The AHA states that effective pharmacotherapy for obesity is likely to require

long-term, if not life-long, treatment because patients who respond to drug therapy usually regain weight when the therapy is stopped.¹¹ The AMA echoes this sentiment in stating that pharmacotherapy cannot be expected to continue to be effective in weight loss or weight management after cessation of drug therapy.³⁷ Further, the ICSI states that short-term use of drugs has not been found effective.¹³

Some organizations provide specific time intervals for evaluating the efficacy of pharmacotherapy, such as EASO. The EASO suggests that the efficacy of pharmacotherapy should be evaluated after 3 months and continued only if successful over that time interval.¹⁶ Regular review is recommended to monitor the effect of drug treatment and to reinforce lifestyle advice and adherence.³⁹ This required monitoring necessitates the need for continued follow-up with a physician.

Selection of a medication is ultimately something a physician and patient will decide after discussing the potential benefits and limitations of the medication, including mode of action, adverse effects and monitoring requirements.³⁹ However, as in the case with medication therapy for most ailments, employers, pharmacy benefit managers, and health plans decide which medications will be covered. Coverage decisions will influence the prescribing habits of physicians.

Lifestyle Modification with Surgical Therapy

Weight loss surgery (WLS), often referred to as bariatric surgery, is an increasingly utilized treatment for clinically severe obesity. In reading this section, the user will recognize that WLS is not a silver bullet for obesity and populations receiving surgery will require additional health care services other than those related to the procedure. This is why WLS is presented as “lifestyle modification therapy with surgical therapy.” The preoperative and postoperative lifestyle modification therapy will require employers to think about other health care services that must be covered under a WLS benefit.

There are four procedures most commonly used in bariatric surgery: Roux-en-Y gastric bypass (RYGB), vertical sleeve gastrectomy (VSG), laparoscopic adjustable gastric band (LAGB), and the biliopancreatic diversion with duodenal switch (BPD-DS). Although risks and benefits are associated with both open and laparoscopic approaches to WLS,

guidelines suggest the laparoscopic approach is preferred if sufficient surgical expertise is available. Regardless of surgery type, the mechanisms of action of these procedures are similar: surgically restricting the stomach’s capacity and reducing nutrient absorption.

An estimated 220,000 people with morbid obesity in the United States had bariatric surgery in 2008.⁵⁸ The American Society for Metabolic and Bariatric Surgery (ASMBS) estimates that about 15 million people in the United States have morbid obesity, yet 1 percent of the clinically eligible population is treated with surgery.⁵⁸ The results of surgery are impressive. Patients lose significant amounts of excess weight and often experience improvement or complete resolution of obesity-related diseases.⁵⁸ For more details users should refer to the bariatric surgery section of this Guide that starts on page 7.

The guideline sets are fairly consistent with regard to populations that should be considered for bariatric surgery. As was the case with guidelines for pharmacotherapy, most guideline sets reflect the NIH guideline for surgical therapy for obesity, which reads:

“Weight loss surgery is an option for carefully selected patients with clinically severe obesity (BMI > 40 kg/m² or > 35 kg/m² with comorbid conditions) when less invasive methods of weight loss have failed and the patient is at high risk for obesity-associated morbidity and mortality.”
– NHLBI, NIH⁷

Several organizations and research teams have focused on practice guidelines specific to WLS. The **Guideline Index (Appendix A)** includes guidelines related to surgery for obesity from 12 organizations. The most in-depth set of guidelines was produced by a collaboration between the American Association of Clinical Endocrinologists (AACE), the Obesity Society, and the American Society for Metabolic and Bariatric Surgery.⁵⁷

There is widespread agreement around which populations should be considered for WLS, and most organizations follow the guidance provided by the NIH, described above. Small differences exist between the guideline sets. For extremely obese populations, WLS may be the only effective therapy available.¹¹

The guidelines suggest that the best choice for any procedure (type of procedure or type or approach) depends on the available local and regional expertise (surgeon and institution), as well as patient preference and patient-specific risks.⁵⁵ Thus, payers and employers choosing to cover WLS will likely need to cover the variety of options.

In selecting a provider(s) for bariatric surgery, there are several things employers and health plans need to consider. Employers should look for high-volume centers with surgeons experienced in bariatric surgery.¹² Accrediting bodies have done a good job of identifying high performing centers as "Centers of Excellence".⁵⁸ Multidisciplinary care is generally considered essential in the management of clinically complex and high-risk WLS patients.⁶⁰ The provider institution should have adequately trained and credentialed medical staff, including a physician director, a weight-loss program supervisor, a multidisciplinary team including medical subspecialties, nutritionists with experience with bariatric surgical patients, and critical care coverage 24 hours a day, 7 days per week.⁶⁰ For more information on recommendations related to WLS provider personnel and equipment, users should refer to publications by Lautz et al.⁶⁰, Apovian et al.⁶¹, and Mechanick et al.⁵⁷

The inclusion of WLS in a health insurance benefit design requires more than coverage for the procedure itself. This is a very important point. There are two areas that need to be considered in developing an obesity benefit: preoperative management and postoperative management.

Preoperatively, eligible populations should undergo an evaluation that includes a comprehensive medical history, physical examination, and appropriate laboratory testing.⁵⁷

These preoperative activities will need to be included in the benefit design. If preoperative weight loss is recommended, patients will need to be covered for whatever lifestyle modification therapy is recommended. Furthermore, WLS patients should undergo psychological evaluation by a credentialed expert in psychology and behavior change.⁶² Evaluations should be carried out by a social worker, psychologist, or psychiatrist with experience in obesity and WLS.⁶² These visits will need to be covered in the obesity benefit. Upon evaluation, it may be recommended that some severely obese patients lose 5 to 10 percent of their initial body weight to decrease operative time and reduce surgical risk.⁶² In these cases, patients will need to pursue lifestyle modification therapy, which will have costs.

Postoperatively, regular, specialist dietetic monitoring should be included in any WLS surgery program.³⁹ The frequency of follow-up depends on the bariatric procedure performed and the severity of comorbidities.⁵⁷ Specifically, patients undergoing laparoscopic RYGB (LRYGB) should have follow-up visits with the WLS surgery team every three to six months in the first year, and annually thereafter.⁵⁷ For LAGB, the follow-up visits should be monthly in the first six months (six visits) and once or twice every six months thereafter depending on nutritional or metabolic comorbidities.⁵⁵ These follow-up visits will also have costs. Finally, body-contouring surgery may be performed after bariatric surgery to manage excess tissue that impairs hygiene, causes discomfort, and is disfiguring.⁵⁷ This too could be reflected in a benefit design for obesity.

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Appendix A: Guideline Index

Developer	Guideline Language: Diet
ACPM (2002)	A diet rich in complex carbohydrate from unrefined cereal grains, vegetables, and fruits; moderate in total fat and restricted in saturated and trans fat; and moderate in protein is advisable for weight control, diabetes prevention, and health promotion. The College specifically recommends a macronutrient distribution within the newly released IOM ranges, with approximately 55% of calories from carbohydrate, approximately 25% of calories from fat, and approximately 20% of calories from monounsaturated and polyunsaturated fat. The College further recommends a fiber intake of at least 24 grams per day, with additional benefit likely from levels up to 50 grams per day in adults with diabetes. (p. 3) (Recommendation)
ACPM (2002)	The College advises against such diets, and all diets advocating restricted intake of grains, vegetables, or fruits, as they are incompatible with the aggregate evidence linking dietary pattern to human health. (p. 3) (Recommendation)
ACSM (2001)	It is recommended that overweight and obese individuals reduce their current level of energy intake by 500–1000 kcal·d ⁻¹ to achieve weight loss and that this be combined with a reduction in dietary fat to 30% of total energy intake. It is also recommended that an individualized level of energy intake be established that prevents weight regain after initial weight loss, while maintaining a low-fat diet (30% of total energy intake) (55). Additional research is needed with regard to changes in other macronutrients and long-term weight loss. (p. 2151) (Recommendation)
ADA (2004)	A moderate decrease in caloric intake (500-1,000 kcal/day) will result in a slow but progressive weight loss (1-2 pounds per week). For most patients, weight loss should supply at least 1,000-1,200 kcal/day for women and 1,600 kcal/day for men. (p. 2070) (Recommendation)
ADA (2008)	Individuals at high risk for type 2 diabetes should be encouraged to achieve the United States Department of Agriculture (USDA) recommendation for dietary fiber (14 g fiber/1,000 kcal) and foods containing whole grains (one-half of grain intake). (http://www.guideline.gov/content.aspx?id=12188) (Recommendation)
ADA (2004)	Overweight or obese patients with diabetes are encouraged to adopt the dietary recommendations known to reduce the risk of coronary heart disease. In conjunction with a moderate reduction in caloric intake (500-1,000 kcal/day), this diet is likely to result in moderate weight loss as well as improvement in cardiovascular risk factors. Dietary guidance should be tailored to each person, allowing for individual preferences and approaches to reduce caloric intake. (p. 2070) (Recommendation)
AHA (2004)	We suggest that patients who are overweight or obese and trying to lose weight consume a diet that induces an energy deficit of 500 to 1,000 kcal/day and has a macronutrient composition that is known to reduce the risk of CVD. This diet involves (1) consuming a variety of fruits, vegetables, grains, low-fat or nonfat dairy products, fish, legumes, poultry, and lean meats; (2) limiting intake of foods that are high in saturated fat, trans-fatty acids, and cholesterol; and (3) following current dietary guidelines of the American Heart Association and the NCEP ATP III (p.2956) (Scientific Statement)

Developer	Guideline Language: Diet
AHA (2004)	The key to successful weight management is to provide patients with a dietary regimen that results in long-term compliance. The available data suggest that it is unlikely that one approach is appropriate for all patients. (p. 2956) (Scientific Statement)
AMA (2001)*	An individually planned diet creating a deficit of 500 to 1,000 kcal per day should be an integral part of any program aimed at achieving a weight loss of 1 to 2 pounds per week. (Adapted from NIH 1998) (p. 2191). (Recommendation)
AMA (2001)*	Encourage low-calorie diets for overweight and obese adults. (p. 2191) (Recommendation)
AMA (2001)*	As part of a low-calorie diet, fat reduction is a practical way to reduce calories. (p. 2191) (Recommendation)
AMA (2001)*	Reducing dietary fat alone without reducing total calories is not sufficient for weight loss. (p. 2191) (Recommendation)
AMA (2001)*	Reducing dietary fat along with dietary carbohydrates facilitates caloric restriction. (p. 2191) (Recommendation)
American Dietetic Association (2006)	Medical nutrition therapy for weight loss should last at least 6 months or until weight loss goals are achieved, with implementation of a weight maintenance program after that time. A greater frequency of contacts between the patient and practitioner may lead to more successful weight loss and maintenance. (p.12) (Recommendation)
American Dietetic Association (2006)	Estimated energy needs should be based on resting metabolic rate (RMR). If possible, RMR should be measured (e.g., indirect calorimetry). If RMR cannot be measured, then the Mifflin-St. Jeor equation using actual weight is the most accurate for estimating RMR for overweight and obese individuals. (p. 12) (Recommendation)
American Dietetic Association (2006)	An individualized, reduced calorie diet is the basis of the dietary component of a comprehensive weight management program. Reducing dietary fat and/or carbohydrates is a practical way to create a caloric deficit of 500 to 1000 kcals below estimated energy needs and should result in a weight loss of 1 to 2 lbs per week. (p.12) (Recommendation)
American Dietetic Association (2006)	Total caloric intake should be distributed throughout the day, with the consumption of 4 to 5 meals / snacks per day including breakfast. Consumption of greater energy intake during the day may be preferable to evening consumption. (p. 13) (Recommendation)
American Dietetic Association (2006)	Portion control should be included as part of a comprehensive weight management program. Portion control at meals and snacks results in reduced energy intake and weight loss.
American Dietetic Association (2006)	For people who have difficulty with self selection and/or portion control, meal replacements (e.g. liquid meals, meal bars, calorie-controlled packaged meals) may be used as part of the diet component of a comprehensive weight management program. Substituting one or two daily meals or snacks with meal replacements is a successful weight loss and weight management strategy. (p. 13) (Recommendation)
American Dietetic Association (2006)	Nutrition education should be individualized and included as part of the diet component of a comprehensive weight management program. Short term studies show that nutrition education (e.g. reading nutrition labels, recipe modification, cooking classes) increases knowledge and may lead to improved food choices. (p. 14) (Recommendation)
American Dietetic Association (2006)	A low glycemic index diet is not recommended for weight loss or weight maintenance as part of a comprehensive weight management program, since it has not been shown to be effective in these areas. (p. 14) (Recommendation)

Developer	Guideline Language: Diet
American Dietetic Association (2006)	In order to meet current nutritional recommendations, incorporate 3 to 4 servings of low fat dairy food a day as part of the diet component of a comprehensive weight management program. Research suggests that calcium intake lower than recommended levels is associated with increased body weight. However, the effect of dairy and/or calcium at or above recommended levels on weight management is unclear. (p. 14) (Recommendation)
American Dietetic Association (2006)	Having patients focus on reducing carbohydrates rather than reducing calories and/or fat may be a short term strategy for some individuals. Research indicates that focusing on reducing carbohydrates intake (< 35% of kcals from carbohydrates) results in reduced energy intake. Consumption of a low-carbohydrate diet is associated with a greater weight and fat loss than traditional reduced calorie diets during the first 6 months, but these differences are not significant at 1 year. (p. 15) (Recommendation)
EASO (2008)	The use of self-recorded food diary allows a qualitative assessment of the diet. In addition, it can be used to help the patient identify perceptions and beliefs about emotional eating behavior (cognition) and eating habits (behavior). (p. 110) (Recommendation)
EASO (2008)	Dietary advice should encourage healthy eating and emphasize the need to increase consumption of grain, cereals and fiber as well as vegetables and fruit, and to substitute low-fat dairy products and meats for full- or high-fat alternatives. (p. 110) (Recommendation)
EASO (2008)	Energy (calorie) restriction should be individualized and take account of nutritional habits, physical activity, comorbidities and previous dieting attempts. (p. 110) (Recommendation)
EASO (2008)	An emphasis put on the macronutrient proportion in the various diets (low fat, low carbohydrate, or high protein) has not proved better than a classic hypocaloric diet, except for low glycemic load diets (carbohydrate content of the diet X glycaemic index) in the short term. Prescribing an energy-restricted diet may require the intervention of a nutritionist (dietician). (p. 110) (Recommendation)
ICSI (2009)	Encourage at least five servings of fruits and vegetables per day, whole grains with a fiber intake of 35 grams or more daily, less than or equal to 30% of calories from fat (7% to 10% of calories from saturated fat, less than or equal to 1% from trans fat). (p. 2) (Recommendation)
ICSI (2009)	For weight loss, encourage calorie reduction by evaluating portion sizes and number of servings recommended. (p. 2) (Recommendation)
ICSI (2009)	Provide tips for managing eating in social situations, dining out, take-out foods and food label reading. (p. 2) (Recommendation)
ICSI (2009)	Provide referral to a dietitian, nutritionist or structured medically supervised nutrition program if available. (p. 2) (Recommendation)
NHMRC (2003)	A reduction in total energy intake remains the basic mechanism whereby all dietary weight loss occurs. Evidence to date shows that low-fat ad libitum diets can results in long-term weight loss. Other strategies have shown short-term effectiveness but have not yet been assessed for long-term effect. (p. xx) (Recommendation)
NHMRC (2003)	Patients can benefit from being taught how to recognize and reduce fat in their diet in such ways as to maintain the micronutrient integrity of the diet. (p. xxi) (Recommendation)
NHMRC (2003)	Low-energy diets should not be considered for continuous long-term treatment of overweight and obesity. When they are used, close supervision is essential. (xxi) (Recommendation)

Developer	Guideline Language: Diet
NHMRC (2003)	Very low energy diets can result in quick, short-term weight losses, but they should be closely monitored and should not be used for extended periods. Behavioral or drug therapy as a follow-up increases likelihood of maintaining some of the weight loss. (p. xxi) (Recommendation)
NHMRC (2003)	Clinically significant weight loss can be achieved using meal-replacement programs. (p. xxi) (Recommendation)
NICE (2010)	Dietary interventions for weight loss should be calculated to produce a 600 kcal/day energy deficit. Programmes should be tailored to the dietary preferences of the individual patient. (http://guideline.gov/content.aspx?id=15597&search=obesity) (Recommendation)
NICE (2010)	Prevention of overweight and obesity in adults: should be advised to reduce: intake of energy-dense foods (including foods containing animal fats, other high fat foods, confectionery and sugary drinks) by selecting low energy-dense foods instead (for example whole grains, cereals, fruits, vegetables and salads), consumption of 'fast foods' (e.g., 'take-aways'), alcohol intake. (http://guideline.gov/content.aspx?id=15597&search=obesity) (Recommendation)
NICE (2006)	People should be encouraged to improve their diet even if they do not lose weight, because there can be other health benefits. (p. 48) (Recommendation)
NICE (2006)	The main requirement of a dietary approach to weight loss is that total energy intake should be less than energy expenditure.
NICE (2006)	Diets that have a 600 kcal/day deficit (that is, they contain 600 kcal less than the person needs to stay the same weight) or that reduce calories by lowering the fat content (low-fat diets), in combination with expert support and intensive follow-up, are recommended for sustainable weight loss. (p. 48) (Recommendation)
NICE (2006)	Low-calorie diets (1000–1600 kcal/day) may also be considered, but are less likely to be nutritionally complete. (p. 48) (Recommendation)
NICE (2006)	Very-low-calorie diets (less than 1000 kcal/day) may be used for a maximum of 12 weeks continuously, or intermittently with a low-calorie diet (for example for 2–4 days a week), by people who are obese and have reached a plateau in weight loss. (p. 49) (Recommendation)
NICE (2006)	Any diet of less than 600 kcal/day should be used only under clinical supervision. (p. 49) (Recommendation)
NICE (2006)	In the longer term, people should move towards eating a balanced diet, consistent with other healthy eating advice. (p. 49) (Recommendation)
NIH (1998)	Low calorie diets (LCDs) are recommended for weight loss in overweight and obese persons. Evidence Category A. Reducing fat at part of an LCD is a practical way to reduce calories. Evidence Category A. (p.xxv) (Recommendation)
NIH (1998)	Reducing dietary fat alone without reducing calories is not sufficient for weight loss. However, reducing dietary fat, along with reducing dietary carbohydrates, can facilitate caloric reduction. Evidence Category A. (p.xxv and p. 75) (Recommendation)

Developer	Guideline Language: Diet
NIH (1998)	A diet that is individually planned to help create a deficit of 500 to 1,000 kcal/day should be an integral part of any program aimed at achieving a weight loss of 1 to 2 pounds per week. Evidence Category A. (p.xxv and p.75) (Recommendation)
Obesity Canada (2006)	We suggest that the optimal dietary plan for achieving health body weight and dietary counseling for adults, adolescents, and children be developed with a qualified and experienced health professional (preferably a registered dietitian) together with the individual and family to meet their needs. (p. S8) (Recommendation)
Obesity Canada (2006)	We recommend a nutritionally balanced diet (designed to reduce energy intake) be combined with other supportive interventions to achieve a health body weight in overweight and obese people of all ages. (p. S8) (Recommendation)
Obesity Canada (2006)	We suggest a high-protein or a low-fat diet (within acceptable macronutrient distribution ranges indicated in the Dietary Reference Intakes) as a reasonable short-term (6-12 months) treatment option for obese adults as part of a weight-loss program. (p. S8) (Recommendation)
Obesity Canada (2006)	Meal replacements may be considered as a component of an energy-reduced diet for selected adults interested in commencing a dietary weight-loss program. (p. S8) (Recommendation)

Developer	Guideline Language: Physical Activity
ACSM (2001)	It is recommended that individuals with a body mass index ≥ 25 kg/m ² consider reducing their body weight, especially if this level of body weight is accompanied by an increase in abdominal adiposity. Individuals with a body mass index ≥ 30 kg/m ² are encouraged to seek weight loss treatment (see Table 1). Although it is recognized that body mass index may misclassify the health risk of very active and/or lean individuals, the use of body mass index provides a meaningful clinical assessment of health risk. Moreover, although it is also recognized that more sophisticated measures of body composition are available, there is no consensus on the absolute amount of body fatness at which health risk increases. (p. 2151) (Recommendation)
ACSM (2007)	Muscle-strengthening activities have now been incorporated into the physical activity recommendation, 5 days per week as the recommended minimum for physical activity, vigorous-intensity physical activity has been explicitly incorporated into the recommendation, and moderate- and vigorous-intensity activities are complementary in the production of health benefits and that a variety of activities can be combined to meet the recommendation. (http://www.guideline.gov/content.aspx?id=11688) (Recommendation)
ACSM (2007)	Recommended amount of aerobic activity is in addition to routine activities of daily living, physical activity above the recommended minimum amount provides even greater health benefits, minimum length of short bouts of physical activity is 10 minute bouts. (http://www.guideline.gov/content.aspx?id=11688) (Recommendation)
ACSM (2009)	Lifestyle physical activity is useful for weight management. (p. 463) (Evidence Statement)
ACSM (2009)	Physical activity combined with energy restriction will increase weight loss. (p. 464) (Evidence Statement)
ACSM (2009)	Resistance training will not promote clinically significant weight loss. (p. 464) (Evidence Statement)

Developer	Guideline Language: Physical Activity
ADA (2004)	Physical activity is an important component of a comprehensive weight management program. Regular, moderate intensity physical activity enhances long-term weight maintenance. Regular activity also improves insulin sensitivity, glycemic control, and selected risk factors for cardiovascular disease (i.e. hypertension and dyslipidemia), and increased aerobic fitness decreases the risk of coronary heart disease. (p. 2070) (Recommendation)
ADA (2004)	Initial physical activity recommendations should be modest, based on the patient's willingness and ability, gradually increasing the duration and frequency to 30-45 minutes of moderate aerobic activity, 3-5 days per week, when possible. Greater activity levels of at least 1 h per day of moderate (walking) or 30 minute per day of vigorous (jogging) activity may be needed to achieve successful long-term weight loss. (p. 2070) (Recommendation)
ADA (2004)	Physical activity is not an effective approach for achieving initial weight loss, but it does have beneficial effects on fitness and obesity-related complications such as CHD and diabetes. (p. 2957) (Scientific Statement)
ADA (2004)	A high level of regular physical activity is important for preventing and attenuating weight regain after diet-induced weight loss. Most data suggest that it is the total volume of physical activity that is important to weight management and that it does not matter whether the activity is of moderate or vigorous intensity, a lifestyle or structured program, or taken in a single bout each day or in several intermittent bouts. (p. 2957) (Scientific Statement)
AMA (2001)	Exercise contributes modestly to weight loss in overweight and obese adults (p. 2191) (Recommendation)
AMA (2001)	Physical activity may decrease abdominal fat (p. 2191) (Recommendation)
AMA (2001)	Physical activity increases cardiorespiratory fitness (p. 2191) (Recommendation)
AMA (2001)	Physical activity may help maintain weight loss (p. 2191) (Recommendation)
AMA (2001)	Physical activity should be an integral part of weight loss therapy and weight maintenance (p. 2191) (Recommendation)
AMA (2008)	The physical activity equivalent of 26 kilocalories per kilogram of body weight (1,560 MET-minutes) or more per week is needed for weight loss of 5% or greater. Smaller amounts of weight loss are seen with smaller amounts of physical activity. This relatively high volume of physical activity is equivalent to walking about 45 minutes per day at 4 miles per hour or about 70 minutes per day at 3 miles per hour, or jogging 22 minutes per day at 6 miles per hour. (http://www.health.gov/paguidelines/report/E_integration.aspx) (Recommendation)
AMA (2008)	Beneficial effects of 120 to 150 minutes per week of moderate- or vigorous-intensity activity, usually performed during 3 to 5 sessions per week, so we know that this frequency of activity is effective. (http://www.health.gov/paguidelines/report/E_integration.aspx) (Recommendation)
American Dietetic Association (2006)	Physical activity should be part of a comprehensive weight management program. Physical activity level should be assessed and individualized long-term goals established to accumulate at least 30 minutes or more of moderate intensity physical activity on most, and preferably, all days of the week, unless medically contraindicated. Physical activity contributes to weight loss, may decrease abdominal fat, and may help with maintenance of weight loss. (p. 15) (Recommendation)

Developer	Guideline Language: Physical Activity
Brigham and Women's Hospital (2012)	Experts agree that physical activity does not necessarily have to be vigorous, and they recommend at least 30 minutes of moderate continuous physical activity daily, or on most days of the week. (Recommendation)
Brigham and Women's Hospital (2003)	Depending on patient's age, symptoms, and risk factors, consider an exercise test for cardiopulmonary disease. (p. 14) (Recommendation)
Brigham and Women's Hospital (2003)	Simple exercise that can be gradually stepped up – such as slow walking or swimming – is best for most obese people. Stress consistency and frequency of duration and intensity. Example: 10 minutes of walking, three days a week. Extra time added in five-minute increments slowly builds the regimen to 30-45 minutes, three days a week. Eventually, expand to most or all days. (p. 14) (Recommendation)
Brigham and Women's Hospital (2003)	Lifestyle activities (stair climbing, gardening, housecleaning, and parking further away from destination) count toward goal. (p. 14) (Recommendation)
Brigham and Women's Hospital (2003)	Encourage more strenuous activities as patient progresses (e.g., faster walking, bicycling, rowing, aerobic dance, cross-country skiing, and weight lifting). (p. 14) (Recommendation)
Brigham and Women's Hospital (2012)	Experts now recommend participating in two types of physical activity each week to ensure aerobic health and muscle strengthening. Muscle strengthening activities include lifting weights, using resistance bands, and practicing yoga or Pilates. Such exercises should be performed twice a week and include the major muscle groups (legs, hips, back, chest, arms, shoulders, and abdomen). (Recommendation)
EASO (2008)	Patients should be advised and helped in undertaking (or increasing) physical activity. Exercise advice must be tailored to the patient's ability and health and focus on a gradual increase to levels that are safe. (p. 112) (Recommendation)
EASO (2008)	Current recommendations suggest that people of all ages should undertake 30-60 minutes of physical activity of moderate intensity (such as brisk walking) on most, if not all, days of the week. (p. 112) (Recommendation)
ICSI (2009)	Minimally, all patients should be encouraged to do at least 10 minutes of physical activity above what they are already doing each day and gradually increase the amount of time, followed by an increase in intensity. (p. 2) (Recommendation)
ICSI (2009)	Ideally, all patients should meet the current recommendations of 30 to 60 minutes of moderate – intensity activity on most days per week. (p. 2) (Recommendation)
ICSI (2009)	Patients with chronic activity limitations (e.g. arthritis, respiratory dysfunction, neuropathy, morbid obesity) should be evaluated and managed to establish or enhance patient mobility. (p. 2) (Recommendation)
ICSI (2009)	Provide tips for adding small bouts of physical activity to daily activities: for example, taking the stairs, parking farther away, exercising while watching TV. Activity breaks from screens (TV, computer, other media) are also important. (p. 2) (Recommendation)
NHMRC (2003)	Recommendations for physical activity for weight loss should be based on activity volume, where volume is defined by frequency, duration, and intensity. (p. xxii) (Recommendation)
NHMRC (2003)	When overweight or obesity is associated with low cardiovascular fitness, the volume of physical activity should be based on frequency and duration but not intensity.(p. xxii) (Recommendation)

Developer	Guideline Language: Physical Activity
NHMRC (2003)	When a person's cardiovascular fitness is high but overweight or obesity persists, more intense levels of activity may be considered. (p. xxii) (Recommendation)
NHMRC (2003)	Lifestyle-based changes that increase the physical activity volume significantly above the baseline level are likely to be the most successful for long-term weight loss. (p. xxiii) (Recommendation)
NHMRC (2003)	Patients should be encouraged to increase their physical activity level in order to gain associated health benefits, even in the absence of significant losses in body weight. (p. xxiii) (Recommendation)
NHMRC (2003)	Depending on initial fitness, health status, personal preferences, and lifestyle, any of several types of physical activity may be the right one for a particular individual. (p. xxiii) (Recommendation)
NHMRC (2003)	It is important to prescribe physical activity that a patient prefers and is therefore likely to maintain in the long term. (p. xxiii) (Recommendation)
NHMRC (2003)	For every immobile obese patients, a reduced weight-bearing form of activity (such as swimming, walking in water, or cycling) may be best in the early stages of a weight-loss program, until their fitness increases and weight-bearing activities (such as walking) can be more easily carried out. (p. xxiii) (Recommendation)
NHMRC (2003)	Physical activity should be a component of any weight-loss program, particularly for improve the effectiveness of weight maintenance. (p. xxiv) (Recommendation)
NICE (2010)	Overweight and obese individuals should be prescribed a volume of physical activity equal to approximately 1,800 to 2,500 kcal/week. This corresponds to approximately 225 to 300 min/week of moderate intensity physical activity (which may be achieved through five sessions of 45 to 60 minutes per week, or lesser amounts of vigorous physical activity). (http://guideline.gov/content.aspx?id=15597&search=obesity) (Recommendation)
NICE (2010)	Overweight and obese individuals should be prescribed approximately 225 to 300 min/week of moderate intensity physical activity (which may be achieved through five sessions of 45 to 60 minutes per week, or lesser amounts of vigorous physical activity). (http://guideline.gov/content.aspx?id=15597&search=obesity) (Recommendation)
NICE (2010)	Overweight or obese individuals should be supported to undertake increased physical activity as part of a multicomponent weight management programme. (http://guideline.gov/content.aspx?id=15597&search=obesity) (Recommendation)
NIH (1998)	Physical activity is recommended as part of a comprehensive weight loss therapy and weight control program because it: (1) modestly contributes to weight loss in overweight and obese adults (Evidence Category A), (2) may decrease abdominal fat (Evidence Category B), (3) increase cardiorespiratory fitness (Evidence Category A), and (4) may help with maintenance of weight loss (Evidence Category C) (p. xxvi) (Recommendation)
NIH (1998)	Physical activity should be an integral part of weight loss therapy and weight maintenance. Initially, moderate levels of physical activity for 30 to 45 minutes, 3 to 5 days a week, should be encouraged. All adults should set a long-term goal to accumulate at least 30 minutes or more of moderate-intensity physical activity on most, and preferably all, days of the week. Evidence Category B. (p. xxvi and p. 80) (Recommendation)

Developer	Guideline Language: Physical Activity
Obesity Canada (2006)	We suggest long-term, regular physical activity, which is associated with maintenance of body weight or a modest reduction in body weight for all overweight and obese people. (p. S8) (Recommendation)
Obesity Canada (2010)	Increase the time currently spent on physical activity, starting with 30 minutes/day more, and progress over approximately 5 months to 90 minutes/day more (Recommendation)
Obesity Canada (2010)	The 90-minute increase in physical activity should include at least 1 hour of moderate activity (e.g., brisk walking, skating, bicycle riding) and 30 minutes of vigorous activity (e.g., running, basketball, soccer). (Recommendation)
Obesity Canada (2006)	Endurance exercise training may reduce the risk of cardiovascular morbidity in healthy post-menopausal women, and we suggest its use for adults with an increased BMI. (p. S8) (Recommendation)

Developer	Guideline Language: Behavioral Therapy
ACSM (2001)	It is recommended that weight loss programs target changing both eating and exercise behaviors, as sustained changes in both behaviors have been shown to result in significant long-term weight loss. Moreover, it is important for programs targeting modifications in these behaviors to incorporate strong behavioral modification strategies to facilitate the adoption and maintenance of the desired changes in behavior. (p. 2151) (Recommendation)
AHA (2004)	The most important principles of behavioral treatment are that it (1) is goal-oriented, (2) is process-oriented and helps patients develop realistic goals and a reasonable plan for reaching those goals, and (3) involves making small rather than large changes to that incremental steps are taken to achieve larger and more distant goals. (p. 2957) (Scientific Statement)
AHA (2004)	Formal behavior therapy can be provided thorough group sessions or individual meetings with a healthcare professional who is skilled in the delivery of behavioral techniques used to modify lifestyle habits. If possible, contact should be regular, preferably once every 1 to 2 weeks, during the initial 6-month phase of a treatment program. (p. 2957) (Scientific Statement)
AMA (2001)	Behavior therapy is a useful adjunct to diet and physical activity. (p.2191) (Recommendation)
AMA (2001)	Assess patient motivation and readiness to implement the weight management plan and take steps to motivate patient for treatment. (p.2191) (Recommendation)
AMA (2001)	Behavior strategies to promote diet and exercise should be used routinely, as they are helpful in achieving weight loss and maintenance. (p.2191) (Recommendation)
American Dietetic Association (2006)	A comprehensive weight management program should make maximum use of multiple strategies for behavior therapy (e.g., self monitoring, stress management, stimulus control, problem solving, contingency management, cognitive restructuring, and social support). Behavior therapy in addition to diet and physical activity leads to additional weight loss. Continued behavioral interventions may be necessary to prevent a return to baseline weight. (p. 15) (Recommendation)
EASO (2008)	Cognitive Behavioral Therapy (CBT) elements should form part of the routine dietary management or, as a fuller, structured program, form the basis of specialist intervention. This care can be delivered in a group setting or through bibliotherapy using self-help manuals. CBT should be provided not only by registered psychologists but also by other trained health professionals such as physicians, dietitians, exercise physiologists, or psychiatrists. (p. 112) (Recommendation)

Developer	Guideline Language: Behavioral Therapy
EASO (2008)	Physicians should recognize where psychological or psychiatric issues interfere with successful obesity management, e.g. depression. Psychological support and/or treatment will then form an integral part of management, and in special cases (anxiety, depression, and stress) referral to a specialist may be indicated. Self-help lay groups and the support of the obesity treatment group may all be useful in this setting. (p. 112) (Recommendation)
ICSI (2009)	Identify behaviors that may lead to increased weight gain: for example, stress, emotional eating, boredom. (p. 2) (Recommendation)
ICSI (2009)	Help patients set specific, measureable, time-limited goals to decrease calorie intake and increase physical activity as appropriate.(p. 2) (Recommendation)
ICSI (2009)	Suggest patients weigh themselves weekly and record on a daily basis the amount and type of food/beverages consumed and physical activity required. (p. 2) (Recommendation)
ICSI (2009)	Provide support and encourage patients to also seek support from family, friends, support groups in order to assist them with their eating, activity, and weight goals. (p. 2) (Recommendation)
NHMRC (2003)	For optimal results, aspects of behavioral therapy should be combined with nutrition and physical activity. (p. xxiv) (Recommendation)
NHMRC (2003)	Consideration should be given to making aspects of behavioral therapy - for example, self-monitoring, social supports and stimulus control - a part of all weight-loss interventions. (p. xxv) (Recommendation)
NICE (2010)	Weight management programmes should include physical activity, dietary change and behavioural components. (http://guideline.gov/content.aspx?id=15597&search=obesity) (Recommendation)
NICE (2010)	Healthcare professionals should discuss willingness to change with patients and then target weight loss interventions according to patient willingness around each component of behaviour required for weight loss, e.g., specific dietary and/or activity changes. (http://guideline.gov/content.aspx?id=15597&search=obesity) (Recommendation)
NIH (1998)	Behavior therapy is a useful adjunct when incorporated into treatment for weight loss and weight maintenance. Evidence Category B. (p. xxvii) (Recommendation)
NIH (1998)	Practitioners need to assess the patient's motivation to enter weight loss therapy; assess the readiness of the patient to implement the plan and then take appropriate steps to motivate the patient for treatment. Evidence Category D. (p.xxvii) (Recommendation)
NIH (1998)	Behavior therapy strategies to promote diet and physical activity should be used routinely, as they are helpful in achieving weight loss and weight maintenance. Evidence Category B. (p.82) (Recommendation)
Obesity Canada (2006)	We suggest that individuals willing to participate in weight management programs be provided with education and support in behavior modification techniques as an adjunct to other interventions. (p. 2) (Recommendation)
USPSTF (2012)	Adequate evidence indicates that the harms of screening and behavioral interventions for obesity are small. Possible harms of behavioral weight loss interventions include decreased bone mineral density and increased fracture risk, serious injuries resulting from physical activity, and increased risk for eating disorders. (http://annals.org/article.aspx?articleid=1200996) (Recommendation)

Developer	Guideline Language: Behavioral Therapy
USPSTF (2012)	Adequate evidence indicates that intensive, multicomponent behavioral interventions for adults can lead to weight loss, as well as improved glucose tolerance and other physiologic risk factors for cardiovascular disease. (Recommendation)
USPSTF (2003)	Although the USPSTF did not find direct evidence that behavioral interventions lower mortality or morbidity from obesity, the USPSTF concluded that changes in intermediate outcomes, such as improved glucose metabolism, lipid levels, and blood pressure, from modest weight loss provide indirect evidence of health benefits. (p.1) (Recommendation)
USPSTF (2012)	The USPSTF recommends that clinicians screen all adult patients for obesity. Patients with a body mass index (BMI) of 30 kg/m ² or higher should be offered or referred to intensive, multicomponent behavioral interventions. (http://annals.org/article.aspx?articleid=1200996) (Recommendation)
USPSTF (2003)	The USPSTF found limited data that addresses the efficacy of counseling-based interventions in overweight adults (as defined by BMI from 25 to 29.9). As a results, the USPSTF could not determine the balance of benefits and potential harms of counseling to promote sustained weight loss in overweight adults. (p.2) (Recommendation)

Developer	Guideline Language: Lifestyle Modification
ACP (2005)	Clinicians should counsel all obese patients (defined as those with a BMI > 30) on lifestyle and behavioral modifications such as appropriate diet and exercise, and the patient's goals for weight loss should be individually determined (these goals may encompass not only weight loss but also other parameters, such as decreasing blood pressure or fasting blood glucose levels) (p. 526) (Recommendation)
ACSM (2001)	It is recommended that overweight and obese individuals target reducing their body weight by a minimum of 5–10% and maintain at least this magnitude of weight loss long-term. This amount of weight loss is consistent with what is attainable with standard weight loss programs that focus on modifying eating and exercise behaviors, and this amount of weight loss has been shown to be associated with improvements in risk factors and a reduced likelihood of chronic diseases including coronary heart disease, type 2 diabetes, hypertension, and hyperlipidemia. (p. 2151) (Recommendation)
AHA (2004)	Providing appropriate nutrition counseling and the behavior modification therapy needed to implement dietary changes within the setting of a busy outpatient practice is difficult if not impossible for most physicians because they do not have the time or expertise to provide this kind of care. Therefore, referral to a reputable weight loss program or experienced dietitian should be considered, if these resources are available. (p. 2962) (Scientific Statement)
AMA (2001)	(Adapted from NIH 1998). Weight loss and weight maintenance therapy should involve a combination of low-calorie diets, increased physical activity and behavior therapy. The combination of a reduced-calorie diet and increased physical activity has been shown to: produce weight loss, decrease abdominal fat; and increase cardiorespiratory fitness. (p. 2191) (Recommendation)
American Dietetic Association (2006)	Weight loss and weight maintenance therapy should be based on a comprehensive weight management program including diet, physical activity, and behavior therapy. The combination therapy is more successful than using any one intervention alone. (p. 11) (Recommendation)

American Dietetic Association (2006)	Individualized goals of weight loss therapy should be to reduce body weight at an optimal rate of 1 to 2 lbs per week for the first 6 months and to achieve an initial weight loss goal of up to 10% from baseline. The goals are realistic, achievable, and sustainable. (p. 12) (Recommendation)
NHMRC (2003)	Efforts should be made to moderate people's unrealistic expectations of weight-loss programs. (p. xix) (Recommendation)
NHMRC (2003)	People suffering from obesity should have long-term contact with, and support from, health professionals. (p. xix) (Recommendation)
NICE (2006)	Multicomponent interventions are the treatment of choice. Weight management programs should include behavior change strategies (see recommendations 1.2.4.15–17) to increase people's physical activity levels or decrease inactivity, improve eating behavior and the quality of the person's diet and reduce energy intake. (p. 42) (Recommendation)
NICE (2006)	When choosing treatments, the following factors should be considered: the person's individual preference and social circumstance and the experience and outcome of previous treatments (including whether there were any barriers); their level of risk, based on BMI and waist circumference (p. 42) (Recommendation)
NICE (2006)	The results of the discussion should be documented, and a copy of the agreed goals and actions should be kept by the person and the healthcare professional or put in the notes as appropriate. Healthcare professionals should tailor support to meet the person's needs over the long term. (p. 43) (Recommendation)
NICE (2006)	The level of support offered should be determined by the person's needs, and be responsive to changes over time.
NICE (2006)	Any healthcare professional involved in the delivery of interventions for weight management should have relevant competencies and have undergone specific training. (p. 43) (Recommendation)
NICE (2006)	To encourage the patient through the difficult process of changing established behavior, healthcare professionals should praise successes – however small – at every opportunity. (p. 43) (Recommendation)
NIH (1998)	Weight loss and weight maintenance therapy should employ the combination of LCDs, increased physical activity, and behavior therapy. Evidence Category A. (pp. xxvii, 83) (Recommendation)
NIH (1998)	The combination of a reduced calorie diet and increased physical activity is recommended since it produces weight loss that may also result in decreases in abdominal fat and increases in cardiorespiratory fitness. Evidence Category A. (p. xxvi) (Recommendation)
NIH (1998)	The literature suggests that weight loss and weight maintenance therapies that provide a greater frequency of contacts between the patient and practitioner and are provided over the long term should be put in place. This can lead to more successful weight loss and weight maintenance. Evidence Category C. (pp. xxix, 77) (Recommendation)
NIH (1998)	Weight loss should be about 1 to 2 lb/week for a period of 6 months with subsequent strategy based on the amount of weight lost. Evidence Category B. (p. 72) (Recommendation)
NIH (1998)	The initial goal of weight loss therapy should be to reduce body weight by approximately 10 percent from baseline. With success, further weight loss can be attempted, if indicated through further assessment. Evidence Category A. (p. 72) (Recommendation)

Obesity Canada (2006)	We recommend an energy-reduced diet and regular physical activity as the first treatment option for overweight and obese adults and children to achieve clinically important weight loss and reduce obesity-related symptoms. (p. S8) (Recommendation)
Obesity Canada (2006)	We recommend diet and exercise therapy for overweight and obese people with risk factors for type 2 diabetes and cardiovascular disease. (p. S8) (Recommendation)
Obesity Canada (2006)	We recommend comprehensive lifestyle interventions (combining behavior modification techniques, cognitive behavioral therapy, activity enhancement and dietary counseling) for all obese adults. (p. S8) (Recommendation)
USPSTF (2003)	There is fair to good evidence that high-intensity counseling (more than 1 person-to-person (individual or group) session per month for at least the first 3 months) - about diet, exercise, or both - together with behavioral interventions aimed at skill development, motivation, and support strategies produces modest, sustained weight loss (typically 3 -5 kg for 1 year or more) in adults who are obese (as defined by BMI > 30). (p.1) (Recommendation)
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Developer	Guideline Language: Pharmacotherapy
ACP (2005)	Pharmacologic therapy can be offered to obese patients who have failed to achieve their weight loss goals through diet and exercise alone. However, there needs to be a doctor-patient discussion of the drugs' side effects, the lack of long-term safety data, and the temporary nature of the weight loss achieved with medications before initiating therapy. (p. 256) (Recommendation)
ACP (2005)	For obese patients who choose to use adjunctive drug therapy, options include sibutramine, orlistat, phentermine, diethylpropion, fluoxetine, and bupropion. The choice of agent will depend on the side effects profile of each drug and the patient's tolerance of those side effects. (p. 256) (Recommendation)
ACSM (2001)	It is recommended that pharmacotherapy for weight loss only be used in individuals with a body mass index $\geq 30 \text{ kg}\cdot\text{m}^{-2}$, or with a body mass index $\geq 27 \text{ kg}\cdot\text{m}^{-2}$ in the presence of additional comorbidities. In addition, it is recommended that weight loss medications only be used in combination with a strong behavioral intervention that focuses on modifying eating and exercise behaviors, and be used under the supervision of a physician. (p. 2151) (Recommendation)
ADA (2004)	Pharmacotherapy can be a useful adjunct to lifestyle modification in the long-term management of obesity in selected patients. Weight loss medications may be considered for those with a BMI > 30 or those with a BMI > 27 plus obesity-related comorbid conditions. (p. 2067) (Statement)
AHA (2004)	The approved indications for drug therapy for obesity are a BMI > 30 or a BMI between 27 to 29.9 in conjunction with an obesity-related medical complication in patients with no contraindications for therapy. (p. 2958) (Scientific Statement)
AHA (2004)	Effective pharmacotherapy for obesity likely to require long-term, if not lifelong, treatment because patients who respond to drug therapy usually regain weight when the therapy is stopped. (p. 2958) (Scientific Statement)
AHA (2004)	Pharmacotherapy alone is not as effective as pharmacotherapy given in conjunction with a comprehensive weight-management program. (p. 2958) (Scientific Statement)
AMA (2001)	Lifestyle therapy should be considered before drug therapy. (p. 2191)

AMA (2001)	Weight loss drugs approved by the FDA may be used as part of a comprehensive weight loss program for patients with a BMI > 30 with no accompanying obesity-related risk factors or diseases, and for patients with a BMI > 27 with accompanying obesity-related risk factors or diseases. (p. 2191)
AMA (2001)	Avoid use of drugs without accompanying lifestyle modification. (p. 2191)
AMA (2001)	Assess drug efficacy and safety continually. (p. 2191)
AMA (2001)	Discontinue use if the drug is ineffective in weight loss or weight maintenance, or if there are serious adverse effects. (p. 2191)
AMA (2001)	Pharmacotherapy can not be expected to continue to be effective in weight loss or weight management after cessation of drug therapy. (p. 2191)
American Dietetic Association (2006)	FDA-approved weight loss medications may be part of a comprehensive weight management program. Dieticians should collaborate with other members of the health care team regarding the use of FDA-approved weight loss medications for people who meet the NHLBI criteria. Research indicates that pharmacotherapy may enhance weight loss in some overweight and obese adults.
EASO (2008)	Pharmacologic treatment should be considered as part of a comprehensive strategy of disease management. (p. 112) (Recommendation)
EASO (2008)	Current drug therapy is recommended for patients with a BMI > 30 kg/m ² or a BMI > 27 with an obesity-related disease (e.g. hypertension, type 2 diabetes). (p. 112) (Recommendation)
EASO (2008)	Drugs should be used according to their licensed indications and restrictions. (p. 112) (Recommendation)
EASO (2008)	The efficacy of pharmacotherapy should be evaluated after the first 3 months. If weight loss achieved is satisfactory (> 5% weight loss in non-diabetic and >3% in diabetic patients), treatment should be continued. Treatment should be discontinued in non-respondents. (p. 112) (Recommendation)
ICSI (2009)	The short-term use of drugs (less than three months) has not generally been found to be effective. (p. 2) (Recommendation)
ICSI (2009)	Pharmacotherapy should be included only in the context of a comprehensive treatment strategy. (p. 2) (Recommendation)
ICSI (2009)	Sibutramine and orlistat are safe for most patients when carefully monitored by a physician; they may be part of a program for weight management or maintenance, which should include nutrition and physical activity changes when indicated. (p. 2) (Recommendation)
NHMRC (2003)	Pharmacotherapy can be a useful adjunct to lifestyle change to induce weight loss in some patients with a BMI greater than 30 and in patients with a BMI greater than 27 with comorbidities. It is, however, clear that - like therapy for other chronic disorders such as hypertension, diabetes, and dyslipidemia - the medication is effective only while it is being taken. In the absence of long-term (more than two years) peer-reviewed data, the long-term risk benefit ratio of new drugs cannot be predicted. Drugs should be used only under careful medical supervision and into the context of a long-term treatment plan. (p.xxvi) (Recommendation)
NICE (2006)	Pharmacological treatment should be considered only after dietary, exercise and behavioral approaches have been started and evaluated. (p.49) (Recommendation)
NICE (2006)	Drug treatment should be considered for patients who have not reached their target weight loss or have reached a plateau on dietary, activity and behavioral changes alone. (p.50) (Recommendation)

NICE (2010)	Orlistat should be considered as an adjunct to lifestyle interventions in the management of weight loss. Patients with BMI ≥ 28 kg/m ² (with comorbidities) or BMI ≥ 30 kg/m ² should be considered on an individual case basis following assessment of risk and benefit. (http://guideline.gov/content.aspx?id=15597&search=obesity) (Recommendation)
NICE (2006)	Prescribing should be in accordance with the drug's summary of product characteristics. (p.50) (Recommendation)
NICE (2006)	Pharmacological treatment may be used to maintain weight loss, rather than continue to lose weight. (p.51) (Recommendation)
NICE (2006)	People whose drug treatment is being withdrawn should be offered support to help maintain weight loss, because their self-confidence and belief in their ability to make changes may be low if they did not reach their target weight. (p.52) (Recommendation)
NICE (2006)	Regular review is recommended to monitor the effect of drug treatment and to reinforce lifestyle advice and adherence.
NICE (2006)	Withdrawal of drug treatment should be considered in people who do not lose enough weight (see recommendations 1.2.5.19 and 1.2.5.24 for details). (p.52) (Recommendation)
NICE (2006)	Rates of weight loss may be slower in people with type 2 diabetes, so less strict goals than those for people without diabetes may be appropriate. These goals should be agreed with the person and reviewed regularly. (p.52) (Recommendation)
NIH (1998)	Weight loss drugs approved by the FDA may be used as part of a comprehensive weight loss program, including dietary therapy and physical activity for patients with a BMI of > 30 with no concomitant obesity-related risk factors or diseases, and for patients with a BMI of > 27 with concomitant obesity-related risk factors or diseases. Weight loss drugs should never be used without concomitant lifestyle modifications. Continual assessment of drug therapy for efficacy and safety is necessary. If the drug is efficacious in helping the patient to lose and/or maintain weight loss and there are no serious side effects, it can be continued. If not, it should be discontinued. Evidence Category B. (p. 86)
Obesity Canada (2006)	We suggest the addition of a selected pharmacologic agent for appropriate overweight and obese adults, who are not attaining or who are unable to maintain clinically important weight loss with dietary and exercise therapy, to assist in reducing obesity-related symptoms. (p. S8) (Recommendation)
Obesity Canada (2006)	We suggest the addition of a selected pharmacologic agent for overweight or obese adults with type 2 diabetes, impaired glucose tolerance or risk factors for type 2 diabetes, who are not attaining or who are unable to maintain clinically important weight loss with dietary and exercise therapy, to improve glycemic control and reduce their risk of type 2 diabetes. (p. S8) (Recommendation)

Developer	Guideline Language: Surgical
AACE, Obesity Society, ASMBS (2008)	[Eligible patients] Patients with a BMI > 35 and one or more comorbidities, including coronary artery disease (CAD), T2DM, obstructive sleep apnea, obesity-hypoventilation syndrome (OHS), pickwickian syndrome, NAFLD or nonalcoholic steatohepatitis, hypertension, dyslipidemia, pseudotumor cerebri, GERD, asthma, venous stasis disease, severe urinary incontinence, debilitating arthritis, or considerably impaired quality of life, may also be offered a bariatric procedure if the surgical risks are not excessive (Grade A; BEL 1)

AACE, Obesity Society, ASMBS (2008)	[Eligible patients] Currently, insufficient data are available to recommend bariatric surgery for patients with a BMI < 35 (Grade D)
AACE, Obesity Society, ASMBS (2008)	[Eligible patients] There is insufficient evidence for recommending bariatric surgery specifically for glycemic control independent of BMI criteria
AACE, Obesity Society, ASMBS (2008)	[Type of surgery] The best choice for any bariatric procedure (type of procedure and type of approach) depends on the available local-regional expertise (surgeon and institution), patient preferences, risk stratification, and other idiosyncratic factors, with which the referring physician (or physicians) must become familiar (Grade D). At this time, there is insufficient evidence to recommend specific bariatric surgical procedures for the general severely obese population (Grade D). Specialists in bariatric medicine, however, must also familiarize themselves with the outcome data among the various bariatric surgical procedures (Grade D). Physicians should exercise caution when recommending BPD, BPD/DS, or related procedures because of greater associated risks reported in the literature (Grade C; BEL 3)
AACE, Obesity Society, ASMBS (2008)	[Type of surgery] Although risks and benefits are associated with both approaches, laparoscopic bariatric procedures are preferred over open bariatric procedures if sufficient surgical expertise is available (Grade B; BEL 2)
AACE, Obesity Society, ASMBS (2008)	[Type of surgery] A first-stage sleeve gastrectomy may be performed in high-risk patients to induce an initial weight loss, with the possibility of then performing a second-stage RYGB or BPD/DS after the patient's operative risk has improved. This is currently an investigational procedure (Grade C; BEL 3)
AACE, Obesity Society, ASMBS (2008)	[Preoperative management] All patients should undergo evaluation for causes and complications of obesity, with special attention directed to those factors that could affect a recommendation for bariatric surgery (Grade A; BEL 1)
AACE, Obesity Society, ASMBS (2008)	[Preoperative management] The preoperative evaluation must include a comprehensive medical history, physical examination, and appropriate laboratory testing (Grade A; BEL 1)
AACE, Obesity Society, ASMBS (2008)	[Preoperative Management] The medical necessity for bariatric surgery should be documented (Grade D)
AACE, Obesity Society, ASMBS (2008)	[Preoperative Management] There should be a thorough discussion with the patient regarding the risks and benefits, procedural options, and choices for surgeon and medical institution (Grade D)
AACE, Obesity Society, ASMBS (2008)	[Preoperative Management] Patients should be provided with educational materials and access to preoperative educational sessions at prospective bariatric surgery centers (Grade D)
AACE, Obesity Society, ASMBS (2008)	[Preoperative Management] Financial counseling should be provided, and the physician should be able to provide all necessary clinical material for documentation so that third-party payer criteria for reimbursement are met (Grade D)
AACE, Obesity Society, ASMBS (2008)	[Preoperative Management] Preoperative weight loss should be considered in patients in whom reduction of liver volume can improve the technical aspects of surgery (Grade B; BEL 2 [nonrandomized])
AACE, Obesity Society, ASMBS (2008)	[Medical Clearance] Lipids: A fasting lipid panel should be obtained in all patients with obesity
AACE, Obesity Society, ASMBS (2008)	[Medical Clearance] Cardiology and Hypertension: Noninvasive testing beyond an electrocardiogram is determined on the basis of the individual risk factors and findings on history and physical examination (Grade D)
AACE, Obesity Society, ASMBS (2008)	[Medical Clearance] Cardiology and Hypertension: Patients with unknown cardiac disease should have a formal cardiology consultation before bariatric surgery (Grade D)

AACE, Obesity Society, ASMBS (2008)	[Medical Clearance] Pulmonary and Sleep Apnea: All patients considered for bariatric surgery should have a chest radiograph preoperatively (Grade D)
AACE, Obesity Society, ASMBS (2008)	[Early Post Operative Care] Nutrition: A consultation should be arranged with a registered dietitian who is a member of the bariatric surgery team (Grade D)
AACE, Obesity Society, ASMBS (2008)	[Late Post-Operative Management (> 5 days)] Follow-up: The frequency of follow-up depends on the bariatric procedure performed and the severity of comorbidities (Grade D)
AACE, Obesity Society, ASMBS (2008)	[Late Post-Operative Management (> 5 days)] Weight Loss: Inadequate weight loss should prompt evaluation for (1) surgical failure with loss of integrity of the gastric pouch in gastropasty or RYGB procedures, (2) a poorly adjusted gastric band, and (3) development of maladaptive eating behaviors or psychologic complications (Grade B; BEL 2)
AACE, Obesity Society, ASMBS (2008)	[Late Post-Operative Management (> 5 days)] Metabolic and Nutritional Management: In those patients without complete resolution of their T2DM, hyperlipidemia, or hypertension, continued surveillance and management should be guided by currently accepted practice guidelines for those conditions (Grade D)
AACE, Obesity Society, ASMBS (2008)	[Late Post-Operative Management (> 5 days)] Metabolic and Nutritional Management: In those patients in whom T2DM, hyperlipidemia, and hypertension have resolved, continued surveillance should be guided by recommended screening guidelines for the specific age-group (Grade D)
AACE, Obesity Society, ASMBS (2008)	[Late Post-Operative Management (> 5 days)] Metabolic and Nutritional Management: Routine metabolic and nutritional monitoring is recommended after all bariatric surgical procedures (Grade A; BEL 1)
AACE, Obesity Society, ASMBS (2008)	[Late Post-Operative Management (> 5 days)] Metabolic and Nutritional Management: Patients should be advised to increase their physical activity (aerobic and strength training) to a minimum of 30 minutes per day as well as increase physical activity throughout the day as tolerated (Grade D)
AACE, Obesity Society, ASMBS (2008)	[Late Post-Operative Management (> 5 days)] Metabolic and Nutritional Management: All patients should be encouraged to participate in ongoing support groups after discharge from the hospital (Grade D)
AACE, Obesity Society, ASMBS (2008)	[Late Post-Operative Management (> 5 days)] Recommended Biochemical Surveillance of Nutritional Status After Malabsorptive Bariatric Surgical Procedures; RYGBP - in the first year, every 3-6 months, and thereafter annually; BPD: every 3 months in first year, and every 3-6 months depending on symptoms
AACE, Obesity Society, ASMBS (2008)	[Late Post-Operative Management (> 5 days)] Body-Contouring surgery may be performed after bariatric surgery to manage excess tissue that impairs hygiene, causes discomfort, and is disfiguring (Grade C; BEL 3)
AACE, Obesity Society, ASMBS (2008)	[Eligible patients] Patients with a BMI > 40 for whom bariatric surgery would not be associated with excessive risk should be eligible for one of the procedures (Grade A; BEL 1)
ACP (2005)	Surgery should be considered as a treatment option for patients with a BMI of 40 or greater who instituted but failed an adequate exercise and diet program (with or without adjunctive drug therapy) and who present with obesity-related comorbid conditions, such as hypertension, impaired glucose tolerance, diabetes mellitus, hyperlipidemia, and obstructive sleep apnea. A doctor-patient discussion of surgical options should include the long-term side effects, such as possible need for reoperation, gall bladder disease, and malabsorption. (p. 527) (Recommendation)
ACP (2005)	Patients should be referred to high-volume centers with surgeons experienced in bariatric surgery. (p. 527) (Recommendation)

ADA (2007)	Bariatric surgery may be considered for some individuals with type 2 diabetes and body mass index (BMI) >35 kg/m ² and can result in marked improvements in glycemia. The long-term benefits and risks of bariatric surgery in individuals with pre-diabetes or diabetes continue to be studied. (http://www.guideline.gov/content.aspx?id=12188) (Statement)
AHA (2004)	Bariatric surgery is the most effective therapy available for people who are extremely obese (p. 2960) (Scientific Statement)
AHA (2004)	Current indications for obesity established at a consensus conference held at the NIH in 1991. The panel recommended that bariatric surgery be considered for obese persons who have a BMI of 35.0 to 39.9 plus > 1 severe obesity-related medical complication such as hypertension, type 2 diabetes, heart failure, or OSA and persons with a BMI > 40. (p. 2960) (Scientific Statement)
AMA (2001)	Weight loss surgery is an option in carefully selected patients with clinically severe obesity (i.e. persons with a BMI > 40 or with a BMI > 35 with comorbid conditions) when less invasive methods have failed and the patient is at high risk for obesity-related morbidity and mortality. (p. 2191) (Recommendation)
American Dietetic Association (2006)	Dietitians should collaborate with other members of the health care team regarding the appropriateness of bariatric surgery for people who have not achieved weight loss goals with less invasive weight loss methods and who meet the NHLBI criteria. Separate ADA evidence based guidelines are being developed on nutrition care in bariatric surgery.
EASO (2008)	Surgery should be considered for patients in age groups from 18-60 years with a BMI > 40 or with BMI between 35.0 and 39.9 kg/m ² and comorbidities in whom surgically induced is expected to improve the disorder (such as type 2 diabetes and other metabolic disorders, cardiorespiratory disease, severe joint disease and obesity-related severe psychological problems. (p. 113) (Recommendation)
EASO (2008)	Patients should be only be referred to units able to assess patients prior to surgery, able to offer a comprehensive approach to diagnosis and assessment and treatment, and able and willing to provide long-term follow-up. The referring physician and the inter-disciplinary team should collaborate closely to optimize the long-term post-operative care. (p. 113) (Recommendation)
EASO (2008)	A laparoscopic technique should be considered as the first treatment choice in bariatric surgery. (p. 113) (Recommendation)
ICSI (2009)	Bariatric surgery is indicated in carefully selected patients: evidence indicates that patients with preoperative BMI between 30 and 35 have comparable initial weight loss results and comorbidity interventions under both surgical and behavioral/pharmaco therapies, but one trial showed that only surgically treated patients continued to lose weight six months later with a BMI greater than or equal to 40 or with a BMI of 35 to 39.9 and who are at a very high absolute risk for increased morbidity or premature mortality. Patients are to be motivated, well-informed in disease management, psychologically stable and accepting of operative risks. (p. 2) (Recommendation)
NHMRC (2003)	Surgery is the most effective treatment for morbid obesity: for most procedures and most patients, good weight maintenance has been observed three to eight years after surgery. (p. xxvii) (Recommendation)
NHMRC (2003)	Assess both peri-operative risk and long-term complications is important; the risk-benefit ratio should be assess in each case.
NICE (2010)	Bariatric surgery should be offered to patients with a body mass index (BMI) of 35-40 who have other conditions caused by being overweight, such as diabetes and obstructive sleep apnea, those with a BMI of 40-50 with no other weight related conditions or those with a BMI of 50 and over, as a first-line treatment. (http://www.nice.org.uk/newsroom/news/NICEBariatricSurgeryRecommendations.jsp) (Recommendation)

NICE (2006)	Severely obese people who are considering surgery to aid weight reduction (and their families as appropriate) should discuss in detail with the clinician responsible for their treatment (that is, the hospital specialist and/or bariatric surgeon) the potential benefits and longer-term implications of surgery, as well as the associated risks, including complications and perioperative mortality. (p. 54) (Recommendation)
NICE (2010)	Bariatric surgery should be considered on an individual case basis following assessment of risk/benefit in patients who fulfil the following criteria: BMI ≥ 35 kg/m ² ; presence of one or more severe comorbidities which are expected to improve significantly with weight reduction (e.g., severe mobility problems, arthritis, type 2 diabetes). (http://guideline.gov/content.aspx?id=15597&search=obesity) (Recommendation)
NICE (2006)	Regular, specialist postoperative dietetic monitoring should be provided, and should include: information on the appropriate diet for the bariatric procedure; monitoring of the person's micronutrient status; information on patient support groups; individualized nutritional supplementation; support and guidance to achieve long-term weight loss and weight maintenance. (p. 55) (Recommendation)
NICE (2006)	Arrangements for prospective audit should be made, so that the outcomes and complications of different procedures, the impact on quality of life and nutritional status, and the effect on comorbidities can be monitored in both the short and the long term. (p. 55) (Recommendation)
NICE (2006)	In addition to the criteria listed in 1.2.6.1, bariatric surgery is also recommended as a first-line option (instead of lifestyle interventions or drug treatment) for adults with a BMI of more than 50 kg/m ² in whom surgical intervention is considered appropriate. (p. 55) (Recommendation)
NICE (2006)	In people for whom surgery is recommended as a first-line option, orlistat or sibutramine can be used to maintain or reduce weight before surgery if it is considered that the waiting time for surgery is excessive. (p. 56) (Recommendation)
NICE (2006)	Surgery for obesity should be undertaken only by a multidisciplinary team that can provide: preoperative assessment, including a risk-benefit analysis that includes preventing complications of obesity, and specialist assessment for eating disorder(s); information on the different procedures, including potential weight loss and associated risks; regular postoperative assessment, including specialist dietetic and surgical follow-up; management of comorbidities; psychological support before and after surgery; information on, or access to, plastic surgery (such as apronectomy) where appropriate; access to suitable equipment, including scales, theatre tables, Zimmer frames, commodes, hoists, bed frames, pressure-relieving mattresses and seating suitable for patients undergoing bariatric surgery, and staff trained to use them. (p. 56) (Recommendation)
NICE (2006)	Surgery should be undertaken only after a comprehensive preoperative assessment of any psychological or clinical factors that may affect adherence to postoperative care requirements, such as changes to diet. (p. 56) (Recommendation)
NICE (2006)	Revisional surgery (if the original operation has failed) should be undertaken only in specialist centres by surgeons with extensive experience because of the high rate of complications and increased mortality. (p. 56) (Recommendation)
NIH (1998)	Weight loss surgery is an option for carefully selected patients with clinically severe obesity (BMI > 40 or > 35 with comorbid conditions) when less invasive methods of weight loss have failed and the patient is at high risk for obesity-associated morbidity or mortality. (Evidence Category B). (p. 89) (Recommendation)
Obesity Canada (2006)	We suggest that adults with clinically severe obesity (BMI > 40 kg/m ² or > 35 kg/m ² with severe comorbid disease) may be considered for bariatric surgery when lifestyle intervention is inadequate to achieve healthy weight goals.
Obesity Canada (2006)	We suggest that a minimally invasive approach be considered for weight loss surgery when an appropriately trained surgical team and appropriate resources are available in the operating theater. (p. S9) (Recommendation)

Developer	Guideline Language: Weight Maintenance
NIH (1998)	A weight maintenance program should be a priority after the initial 6 months of weight loss therapy. Evidence Category B. (p. 73)
NIH (1998)	After successful weight loss, the likelihood of weight loss maintenance is enhanced by a program consisting of dietary therapy, physical activity, and behavior therapy, which should be continued indefinitely. Drug therapy can also be used. However, drug safety and efficacy beyond 1 year of total treatment have not been established. Category B. (p. 73)
ADA (2004)	Long-term maintenance of weight loss is more challenging than initial weight reduction. Some strategies that are associated with successful long-term weight loss include eating a diet low in calories (1,400 calories) and fat (24% of total energy intake), frequently monitoring body weight, and participating in regular physical activity (equivalent to 2,800 kcal/week or 60 minutes of moderate activity/day. Successful weight loss maintainers also reduced portion sizes and snacking, ate breakfast daily, ate meals away from home < 3 times / week, and watched television less than 3 hours per week on average.
Brigham and Women's Hospital (2012)	Support systems used effectively during weight loss can contribute to weight maintenance, physical activity, Once the desired weight has been reached, the gradual addition of about 200 calories of healthy, low-fat food to daily intake may be attempted for one week to see if weight loss continues. If weight loss does continue, additional calories of healthy foods may be added to the daily diet until the right balance of calories to maintain the desired weight has been determined. (2012) (http://healthlibrary.brighamandwomens.org/library/encyclopedia/85,P07862) (Recommendation)
EASO (2008)	The development of networks of care involving the general practitioner, obesity specialist, nutritionist (dietician), exercise physiologist (physiatrist), behavioral therapist (psychologist / psychiatrist) and often patient support groups is encouraged. (p. 114) (Recommendation)
EASO (2008)	No healthcare system can provide treatment for all those who are obese and overweight. Support groups, commercial and lay organizations, books and other media can provide useful help and support; the advice they give should conform to the principles of EASO guidelines. (p. 114) (Recommendation)
ACSM (2001)	It is recommended that individuals strive for long-term weight maintenance and the prevention of weight regain over the long-term, especially when weight loss is not desired, or when attainment of ideal body weight is not achievable. Prevention of weight gain or weight regain has been defined as maintaining a body weight that is within 2.3 kg (5 pounds) of one's current weight. (p. 2151) (Recommendation)

Appendix B: Lifestyle Modification Intervention

Author	Behavior	Physical Activity	Diet	BMI	WC	Age	Gender (%female)	Weight Loss (kg)	Weight Loss (% initial wt.)	Ethnicity
Pascale (1995)	Group Therapy Sessions (assumed RD, exercise physiologist, or behavioral psychologist); 16 Visits (weekly) over 16 weeks; Follow-up Group Meetings held 1, 2, 4, and 6 months after treatment	Instructed on benefits of exercise; Graded goals for programmed activity (i.e. structured walking) used throughout year; Tough self-management of caloric intake and expenditure.	Fat restrictive; Calorie restrictive; 1,000 - 1,500 kcal/day (individually calculated); Patients kept diaries, which were reviewed weekly by trained therapists; Recorded calories and number of grams of fat	36.2)	NM	49.6	100%	4.1	NM	
Diabetes Prevention Program (2002)	One-on-One Counseling with RD, exercise physiologist, or behavioral psychologist; 16 visits over first 6 months; One face-to-face meeting every 2 months following first 6 months; Contacted at least once via phone between visits.	Supervised exercise sessions offered at least two times per week; Approximate 700 kcal/week expenditure from physical activity; At least 150 minutes of moderate physical activity (brisk walking) per week.	Fat restrictive; Calorie restrictive; Individually calculated for 500-1,000 kcal deficit per/day	33.9 ± 6.8	105.1 ± 14.8	50.6 ± 11.3	68%	7	NM	53.8% White; 18.9% Black; 16.5% Hispanic
Look AHEAD Study; Pi-Sunyer (2007); University of Pittsburgh;	Group Therapy Sessions with RD, behavioral psychologists, or exercise specialists); 60-70 minutes in duration. 18 visits; 3 visits per month for 6 months; Twice monthly for months 7-12. (Total - 30 group visits) One-on-One Counseling with RD, behavioral psychologist, or exercise specialist) once per month; (Total - 12 visits) Attended weekly for first 3 weeks of each month for 6 months	Unsupervised exercise; PA initiated at 50 minutes/week of moderate activity with a goal of 175 minutes of moderate intensity physical activity by the end of month 6; Exercise episodes of ten minutes and longer are counted toward this goal. Encouraged to exercise 5 days per week.	1,200 to 1,800 kcal/day depending on weight; Two meal replacement products (either Slimfast, Glucerna, Optifast, HMR), and one portion-controlled snack.	35.8	114.6	58.6 ± 6.8	59.3%	NM	8.6%	
DIRECT Study; Shai (2008) NEJM	Group Therapy Sessions with RD (initially twice monthly for first 2 months, then every 6 weeks thereafter); 90 minutes each. (Total - 18 visits) 3 (10 to 15 minute) motivational telephone calls with patients experiencing difficulty; Spouses provided education to support. Curriculum based on Diabetes Prevention Program	NM	Low-carbohydrate Diet (based on ATKINS diet): Non-restricted-calorie diet aimed to provide 20 g of carbohydrates per day for 2-month induction phase, with gradual increase to 120 g per day for maintenance. Mediterranean Diet (based on Willet and Skerrett); Moderate-fat, restricted calorie, Mediterranean diet rich in vegetables, low in red meat, with poultry and fish replacing beef and lamb; 1,500 kcal limit for women, 1,800 kcal limit for men; no more than 35% of calories from fat.	30.8 ± 3.5*	106.3 ± 9.1*	52 ± 7*	99%*	4.7	NM	NM
Rengilian (2001)	Group Therapy Sessions with Clinical Psychologists Weekly for 6 Months; 90 minute sessions; Each therapist led group of 8 to 12 persons (Total - 26 visits)	Home based exercise program consisting of 30 minutes of brisk walking per day; 6 days/ week	Low calorie diet (i.e. 1,200 kcal/day for women, 1,500 kcal/day for men);	36.8	NM	45.8	88%	11		

Author	Behavior	Physical Activity	Diet	BMI	WC	Age	Gender (%female)	Weight Loss (kg)	Weight Loss (% initial wt.)	Ethnicity
Digenio (2009)	One-on-One, Face-to-Face Counseling with RD; Weekly for 3 months, every other week for months 4 through 6 (Total - 18 visits) [only 6 months duration]	Recommended walking as primary method of physical activity; All patients received a pedometer and recommended increasing number of steps per day by approximately 500 steps/week. Encouraged building toward goal of 10,000 steps/day.	750 kcal/day deficit diet; individually calculated using Harris-Benedict formula.	34.6 ± 3.0	41 ± 4.0	45 ± 9.0	88%	8.7	8.9%	
Digenio (2009)	One-on-One, Telephone Counseling with RD; Weekly for 3 months, every other week for months 4 through 6 (Total - 18 calls) [only 6 months duration]	Recommended walking as primary method of physical activity; All patients received a pedometer and recommended increasing number of steps per day by approximately 500 steps/week. Encouraged building toward goal of 10,000 steps/day.	750 kcal/day deficit diet; individually calculated using Harris-Benedict formula.	34.0 ± 3.0	41 ± 3.0	43 ± 10.0	91%	7.3	7.7%	
Wadden (2005)	One-on-One Physician (PCP) visits; Weeks 1, 3, 6, 10, 18, 26, a 40, and 52; (Total - 7 visits) Group Therapy Sessions with Trained Psychologist; 7-10 subjects per group, 90 minutes in duration; Weekly visits for weeks 1 through 18, every other week for weeks 20 through 40; (Total - 28 visits) [behavioral component of combined therapy that included sibutramine]	Encouraged to exercise 30 minutes/day most days of the week	1,200 to 1,500 kcal/day, adjusted individually for deficit;	37.9 ± 4.2	NM	44.2 ± 10.8	82%	12.1 ± 9.8kg	NM	
Wadden (2001)	One-on-One Physician (PCP) visits; Brief 5-10 minute visits; Weeks 2, 4, 8, 12, 16, 20, 24, 32, 40, and 52; (Total - 10 visits) Group Therapy Sessions with Trained Psychologist; Followed LEARN program; Weekly visits for first 20 weeks, monthly thereafter until week 52; (Total - 26 visits) [behavioral component of combined therapy that included sibutramine]	Encouraged to increase exercise (typically walking) to 4 to 5 sessions per week for 30 to 40 minutes per session.	Portion-controlled diet that consisted of 4 servings a day of a nutritional supplement (OPTIFAST, Novartis) combined with an evening meal of a frozen food entrée, serving of fruit, and a green salad. Beginning Week 17 they transitioned off OPTIFAST to conventional foods by Week 20)	37.2 ± 3.3	NM	40.1 ± 8.8	100%	16.6	16.5%	
TOHP (HTN) Trial; Stevens (2001)	One-on-One Counseling with RD; (Total - 1 visit) Group Therapy Sessions with RD or Health Educator; Weekly visits for 14 weeks, followed by 6 biweekly meetings, then monthly (Total - 26 visits) [6 mo. f/u used for results]	Gradually increase activity to 30 to 45 minutes/day, 4 to 5 days per week; primarily brisk walking.	Reduced caloric intake by decreasing fat, sugar, and alcohol consumption; daily food diaries used.	31	NM	43.4 ± 6.1	37%	4.4	NM	

Author	Behavior	Physical Activity	Diet	BMI	WC	Age	Gender (%female)	Weight Loss (kg)	Weight Loss (% initial wt.)	Ethnicity
Jenny Craig (JC); Rock (2007)	One-on-One Contacts with Counselor (JC Staff); Weekly visits up to 1 year. Visits at community-based JC facility;	Goal of 30 minutes of physical activity on 5 or more days of the week.	Low Calorie Diet (1,200 to 2000 kcal/day); Individualized based on energy requirements; Includes pre-packaged prepared food items provided at weekly interactions at a community-based facility;	34.2 ± 3.7	113.0 ± 10.6	42 ± 11	100%	6.6	7.1%	
Ashley (2001); PCP	One-on-One Physician (PCP) and RN Visits; Patients seen by same PCP for 2/3 or visits, same RN for 1/3 Biweekly visits for 1 year; 10-15 minutes; LEARN-based instruction manuals; (Total - 26 visits)	Counseled by PCP on physical activity; Patients given pedometer (Yamax Digi-Walker)	Meal replacements (Slim Fast) replaced 2 of 3 main meals/day. Patients reaching 10% weight loss switched to 1 meal replacement/day.	30.1 ± 3.7	92.8 ± 9.6	41.0 ± 5.7	100%	3.5	4.3%	
Ashley (2001);	Group Therapy Sessions with RD; Classes were weekly for first 12 weeks, biweekly for second 12 weeks, and monthly for final 6 months; 1 hour per class (Total - 26 visits)	Counseled by PCP on physical activity; Patients given pedometer (Yamax Digi-Walker)	1200 kcal/day using Dept. of Agriculture Food Pyramid	30.1 ± 2.9	93.7 ± 8.3	41.0 ± 4.3	100%	7.7	9.1%	
Christian (2008); PCP	One-on-One Physician (PCP) Brief Counseling; Patients seen by PCP every 3 months; (Total - 4 Visits) [Motivational Interviewing]	Tailored physical activity guidance provided by computer algorithm	Tailored dietary guidance provided by computer algorithm	35.4 ± 6.6	118.1 ± 15	53.0 ± 11	65%	0.18	NM	
Ely (2008); PCP	One-on-One Psychologist Counseling (Telephone-based); Bi-weekly during the first 3 months post-enrollment, followed by every month for final 3 months; (Total - 8 Calls) [Motivational Interviewing]	Pedometers; Physical Activity Diaries	Decreased fat and total caloric intake.	37 ± 8	NM	49 ± 14	71%	4.3	NM	
Martin (2007); PCP	One-on-One Physician (PCP) Counseling Visits; Monthly Visits for 6 months; 15 minutes per visit; (Total - 6 Visits)	150 minutes per week	Decreased consumption of energy-dense foods; increased fruits and vegetables; Dietary guidance tailored to individuals; Culturally-specific menus	38.3 ± 7.5	NM	40.8 ± 12.7	100%	1.4	NM	
Ockene (2009); PCP	One-on-One Physician (PCP) Counseling with Office Support; Intervention fit into already-scheduled visits; (Total - 3.6 visits)	NM	Nutrition Counseling	28.8	NM	49.3	56%	2.3	NM	

Appendix C: Lifestyle Modification with Pharmacotherapy Interventions

Intervention	Rx	Behavior	Physical Activity	Diet	BMI	WC(cm)	Weight	Age	Gender %Female	Ethnicity	Duration (Years)	% Initial Wt. Loss	Kg. Reduced	BMI Reduced	WC Reduced (cm)
Wadden (2001)	Sibutramine (15 mg)	Monthly Visits with MD; Weekly Group Lifestyle Modification Sessions with Psychologist (First 20 weeks); Based on LEARN	4 to 5 walking sessions/week (30 to 40 minutes)	OPTIFAST (Novartis); portion-controlled diet	37.2 ± 3.3	NM	102.1 ± 11.0	40.1 ± 8.8	100%	NM	1	16.5%	16.6		
Wadden (2005)	Sibutramine (15mg)	8 Visits with MD; Weekly Group Therapy Sessions (LEARN) in Weeks 1-18, Every Other Week in Weeks 20 - 40 (90 minutes)	30 minutes/day	1200 to 1500 kcal/day	37.9 ± 4.2	NM	108.5 ± 18.6	44.2 ± 10.8	82%	70% white, 30% black	1	73% lost 5% or more	12.1	NM	NM
Torgerson (2004)	Orlistat (120 mg TID)	Dietary Counseling Every 2 Weeks For 6 Months, the Monthly Thereafter	1 extra km per day in addition to usual activity	800 kcal deficit	37.3 ± 4.2	115.0 ± 10.4	110.4 ± 16.3	43.0 ± 8.0	55.2%	NM	1	41% > 10%; 72.8% > 5%	10.6	NM	6.4
Cuellar (2000)	Sibutramine (15 mg)	Monthly Counseling (MD) Visits for 6 Months	No Requirement	30 kcal/kg of ideal body weight	35.5 ± 4.2	NM	86.0 ± 11.8 kg	38.4 ± 10.1	94.3%	100% Hispanic	0.5	NM	10.3	4.17	12.51
Cercato (2009)	Diethylpropion (50 mg BID)	NM	Instructed to increased physical activity; 150 minutes /week	Hypocaloric Diet; 600 kcal /day diet	37 ± 3.6	108.0 ± 9.5	95.5 ± 15.1	38.0 ± 10.8	94.6%	(Brazil)	1	10.6%	10.1	NM	
Rossner (2000)	Orlistat (120 mg)	Dietary Advice From RD at Baseline (food diary); Food Intake Diaries Reviewed by RD at Visits with Advice and Counseling Provided Every 2 Weeks for First 2 months, Monthly up to Month 6, Every 2 months thereafter	NM	600 kcal/day deficit	34.7 ± 3.	96.7 ± 13.8	NM	43.6 ± 11.4	84%	NM	1	9.7%	9.4	NM	NM

Intervention	Rx	Behavior	Physical Activity	Diet	BMI	WC(cm)	Weight	Age	Gender %Female	Ethnicity	Duration (Years)	% Initial Wt. Loss	Kg. Reduced	BMI Reduced	WC Reduced (cm)
James (2000)	Sibutramine (10 mg to 20 mg)	RD Counseling Every 2 Weeks (then monthly), MD Monthly	30 minutes walk/day	600 kcal /day deficit	36.5 ± 4.1	107.6 (12.0)	102.3 ± 15	40.7 ± 10.2	83.5%	96% White	2*	NM	8.9	NM	4.9
Davidson (1999)	Orlistat (120 mg)	4 Behavior Modification Sessions (every 3 months)	Walking 20-30 minutes 3-5 times/week	No Change	36.2 ± 0.1	NM	100.7 ± 0.6	43.3 ± 0.6	83%	81% white, 13.4% black, 4.3% Hispanic	1*	8.8%	8.8		
Digenio (2009)	Sibutramine (10 mg)	Weekly Face-to-Face Individual Counseling for 6 Months	Pedometer, 500 to 10,000/day	750 kcal deficit	34.6 ± 3	104.1 ± 10.2	95.3 ± 14.5	45 ± 9	88%	84% White, 11% Black	0.5	8.9%	8.7	NM	8.6
Fanghanel (2000)	Sibutramine (10 mg)	Monthly Counseling (MD) Visits for 6 Months	Not Mentioned	30 kcal/kg of ideal body weight	36.1 ± 5.1	NM	87.5 ± 16	38.1 ± 10	92.7%	100% Hispanic	0.5	9.89%	8.6	3.59	8.09
Derosa (2003)	Orlistat (120 mg)	Food Diaries; Discussion During Visits to Ensure Compliance; Behavior-modification Provided by RD Every 3 Months; Discussions and Assessment of Diaries Used for Counseling Patients	Standardized Activity Program; Physical Aerobics >30 minutes, 4 days/week by Bicycle;	1500 kcal	32 ± 1.3	94.2 ± 9.8	100.8 ± 5.3	51.6 ± 8.3	51.9%	NM	1	9.1%	8.6	3	3
Derosa (2004)	Orlistat (120 mg)	Standard Diet Advice From RD and/or Specialist MD; One-on-One Behavior Modification Session on Weight-Loss Strategies with RD or Specialist MD at baseline, 6 months; Four Group Behavior Modification Seminars Every 3 months	Encouraged to Increase Physical Activity by Walking 20-30 minutes, 3-5 times/week, or by Bicycle	600 kcal/day deficit	33.1 ± 1.9	95.6 ± 5.9	104 ± 7	50 ± 4	51%	NM	1	8.9%	8.4	2.9	5

Intervention	Rx	Behavior	Physical Activity	Diet	BMI	WC(cm)	Weight	Age	Gender %Female	Ethnicity	Duration (Years)	% Initial Wt. Loss	Kg. Reduced	BMI Reduced	WC Reduced (cm)
Hauner (2004)	Sibutramine (15 mg)	3 Counseling Sessions Over 2 Years; 4 Education Sessions in First 4 Weeks; 16 Group Sessions	30 minutes /day	500 kcal deficit	35.1 ± 3.4	107.4 ± 11.9	8.1	43	78%	NM	2*	8.3%	8.1	NM	8.5
McNulty (2003)	Sibutramine (20 mg)	NM	NM	Dietary Advice	37.5 ± 1.0	113.0 ± 1.9	104.3 ± 2.9	48 ± 1.0	56%	NM	1	8%	8	2.9	6.6
Hauptman (2000)	Orlistat (120 mg)	Dietary Guidance at Lead-In Only from MD; Videos at 4 points in Study on Behavior Modification Techniques for Weight Control; 3 Dietary Records Completed	Encouraged to Increase Physical Activity by Walking 20-30 minutes, 3-5 times/week	Reduced Energy Diet; Dietary Guidance at Lead-in Only; 3 Dietary Records Completed During Study	36 ± 0.2	100.5 ± 0.9	NM	43.2 ± 0.7	79%	NM	1	7.9%	7.94		
Hadler (1968)	Phendimetrazine (105 mg)	NM	NM	NM	NM	NM	NM	NM	NM	NM	0.25	NM	7.4		
Krempf (2003)	Orlistat (120 mg)	5 Clinic Visits Over 1.5 Months	ND	Individually Tailored Diet Based on Food Diary by RD (20% energy reduction) Food diaries every 4 mo.	36.0 ± 0.3	105.6 ± 0.8	97.0 ± 0.9	40 ± 0.6	87.3%	NM	1*	7.4%	7.3	NM	6.5
Haddock (review) (2002)	Diethylpropion (75 mg)	Lifestyle Modification in 100%	NM	NM	NM				88.5%		6-52 weeks		6.5		
Smith (2001)	Sibutramine (15 mg)	NM	NM	Dietary Advice	32.7 ± 3.3	NM	87	42.7 ± 11.7	81.4%	99% White	1	7.3%	6.4	NM	NM
Haddock (review) (2002)	Phentermine (27.5)	Lifestyle Modification in 83.8%	NM	NM	NM				86.5%		2-24 weeks		6.3		

Intervention	Rx	Behavior	Physical Activity	Diet	BMI	WC(cm)	Weight	Age	Gender %Female	Ethnicity	Duration (Years)	% Initial Wt. Loss	Kg. Reduced	BMI Reduced	WC Reduced (cm)
Hollander (1998)	Orlistat (120 mg)	NM	NM	500 kcal deficit	34.5 ± 3.2	99.6 ± 14.5	NM	55.4 ± 8.8	51%	87% White, 8% Black, 2.5% Hispanic, 2.5% Other	1	6.2%	6.19	NM	4.8
Bakris (2002)	Orlistat (120 mg)	Lifestyle Intervention Literature Made Available; Meet with Dietician "Periodically"	Encourage Moderate Physical Activity	Nutritionally balanced, hypocaloric diet; 600 kcal deficit	35.8 ± 3.9	108.6 ± 12.2	101.2 ± 1.0	53.2 ± 0.5	63.2%	85% White, 11% Black, 4% Hispanic	1	46% > 5%	5.4	1.9	5.4
Apfelbaum (1999)	Sibutramine (10 mg)	Dietary Counseling	NM	Very-Low Calorie Diet	37.9 ± 5.9	NM	103.4 ± 17.5	36.3 ± 9.5	82%	NM	1	86% lost 5% or more	5.2	NM	NM
Miles (2002)	Orlistat (120 mg)	Dietary Counseling at Baseline and at Regular Intervals Throughout Study	Encouraged to Increase Physical Activity	600 kcal/day deficit; additional 200 kcal reduction after 6 months	35.6 ± 0.3	102.1 ± 1.1	NM	52.5 ± 0.4	48%	White 84%, Black 10%, Other 6%	1	4.6	4.7	NM	NM
McMahon (2000)	Sibutramine (20 mg)	Dietary Counseling at Initial Visit Only	NM	NM	34.5 ± 3.4	NM	97.0 ± 13.1	52.3 ± 10	61%	55% white, 39% black	1	4.7%	4.4	NM	NM
Kelley (2002)	Orlistat (120 mg)	Baseline Visit Dietary Instructions from RD; Additional Dietary Instruction Provided at Predetermined Intervals; Dietary Compliance Monitored by use of Dietary Intake Records	Encouraged to Participate in Moderate Physical Activity	Balanced Energy Deficit designed to induce weight loss of .25-.5 kg/week; further reduced by 200 kcal/day at week 24; minimum of 1,200 kcal/day	35.8 ± 0.2	102.0 ± 1.0	NM	57.8 ± 0.5	56%	71% White, 17% Black, 2% Asian, 10% Other	1	3.76%	3.89	NM	NM
Wirth (2001)	Sibutramine (15 mg)	No Formal Program Applied	NM	No Formal Program Applied	34.7 ± 3.4	106.6 (11.3)	98.6 ± 14.3	43.1 ± 11.2	74.6%	100% White	0.85	4%	3.8		7.8
Swinburn (2005)	Orlistat (120 mg)	Dietary Advice From RD (label reading); Patients Completed 5-7 Diet and Physical Activity Logs at Baseline, Week 12, and Week 52 visits.	Moderate Intensity Physical Activity of 30 min a day on most days	Individualized with RD	37.6 ± 5.1	103.3 ± 17.8	112.4 ± 12.8	52 ± 7.5	61%	NM	1	NM	3.7	NM	5

Intervention	Rx	Behavior	Physical Activity	Diet	BMI	WC(cm)	Weight	Age	Gender %Female	Ethnicity	Duration (Years)	% Initial Wt. Loss	Kg. Reduced	BMI Reduced	WC Reduced (cm)
Poston (2006)	Orlistat	Monthly Nurse Problem-Focused Counseling (15-20 min); LEARN manual; Individualized Dietary Instruction	Expend 200 calories/day in exercise	Dietary Counseling	36.0 ± 3.3	NM	94.8 ± 12.1	40.5 ± 9.2	89%	30% white, 36% black, 31% Hispanic	1	26.8% > 5%	1.7		
Sjostrom (1998)	Orlistat (120 mg)	NM	NM	600 kcal/day deficit; additional 300 kcal after month 6)	36	99.7	105.4	45.2	82.8%	NM	1	10.2%	NM	NM	NM
Finer (1999)	Orlistat (120 mg)	None	None	Low-Energy Diet; 1200 kcal/day; Individualized Calculations Done For 600 kcal/deficit; Further reduced by additional 300 kcal deficit (week 24)	36.8 ± 3.6	97.9 ± 112.9	NM	41.5 ± 10.5	89.1%	NM	1	8.5%	NM	NM	NM
McMahon (2000)	Sibutramine (20 mg)	Dietary Counseling at Initial Visit Only	NM	NM	34.5 ± 3.4	NM	97.0 ± 13.1	52.3 ± 10	61%	55% white, 39% black	1	4.7%	4.4	NM	NM
Harrison (2009)	Orlistat (120 mg)	Dietary Guidance from RN and MD; Xenicare (web-based nutrition program)	Instructed to Increase Physical Activity	1,400 kcal/day (Xenicare nutrition program)	37.3 ± 6.0	226 ± 37.0	NM	47.9 ± 7.5	69.6%	61% White, 30.3% Hispanic, 8.7% Black / Asian	0.7	8.3%	NM	NM	NM
Berne (2004)	Orlistat (120 mg)	RN/RD Dietary Counseling at Study Visits (every 3 months); All Dietary Advice Part of Self-Management Package Including Leaflets, Food Diary	Encourage Increase Physical Activity by a Daily 30 min. Walk	600 kcal/day deficit	32.6 ± 3.1	108.0 ± 9.0	95.3 ± 12.6	58.9 ± 9.1	45%	NM	1	5%	NM	NM	NM
Cass (1961)	Phendi-me-trazine	NM	NM	NM	NM	NM	NM	NM	NM	NM	0.25	NM	8.4 - 15.6	NM	NM
Harding (1962)	Phendi-me-trazine (35 mg 2-6 / day)	NM	NM	NM	NM	NM	NM	NM	NM	NM	0.25	NM	3.6 - 5.5		

Appendix D: Literature Review Bibliography

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Henke RM, Goetzel RZ, McHugh J, Isaac F. (2012). Recent Experience In Health Promotion At Johnson & Johnson: Lower Health Spending, Strong Return On Investment. *Health Affairs*, 31(7): 490-9.

Kowlessar NM, Goetzel RZ, Carls GS, Tabrizi MJ, Guindon A. (2011). The relationship between 11 risks and medical and productivity costs for a large employer. *Journal of Occupational and Environmental Medicine*, 53(5), 468-77.

Resources: *Publications and Resources for Community Groups and Organizations*

Centers for Disease Control and Prevention (CDC) – Strategies for early childhood education programs, hospitals, neighborhoods, schools, and worksites to help make the healthy choice the easy choice. Community Strategies are available for children, hospitals, neighborhoods, schools, and worksites.

<http://www.cdc.gov/obesity/strategies/communityStrategies.html>

CDC's LEAN Works! – A Workplace Obesity Prevention Program to help employers respond to the current obesity epidemic, the Centers for Disease Control and Prevention (CDC) conducted a systematic review of the literature on worksite health promotion programs and identified promising practices to prevent and control obesity.

<http://www.cdc.gov/leanworks/resources/communityguide.html>

State Programs Funded by CDC – CDC's Division of Nutrition, Physical Activity, and Obesity (DNPAO) currently funds 25 states to address the problems of obesity and other chronic diseases. The program's primary focus is to improve the health of Americans by changing environments where people live, work, learn, and play. The program will also work to build lasting and comprehensive efforts to address obesity and other chronic diseases through a variety of evidence-based nutrition and physical activity strategies.

<http://www.cdc.gov/obesity/stateprograms/fundedstates.html>

Communities Putting Prevention to Work (CPPW) – A locally driven initiative supporting 50 communities to tackle obesity and tobacco use. To help address these health issues, the U.S. Department of Health and Human Services (HHS) created CPPW, which is led by the Centers for Disease Control and Prevention (CDC).

<http://www.cdc.gov/CommunitiesPuttingPreventiontoWork/index.htm>

Obesity Education Initiative – The overall purpose of this National Heart Lung and Blood Institute (NHLBI) initiative is to help reduce the prevalence of overweight, obesity, and physical inactivity in order to lower the risk, and overall morbidity and mortality from coronary heart disease.

http://www.nhlbi.nih.gov/about/oei/oei_pd.htm

Weight-control Information Network (WIN) – An information service of the National Institute of Diabetes and Digestive Kidney Diseases (NIDDK). Publications and resources are available on nutrition, physical activity, and weight control for communities, groups, and organizations.

<http://win.niddk.nih.gov/publications/index.htm#groups>

Publications and Resources for Providers

Weight-control Information Network (WIN) – An information service of the National Institute of Diabetes and Digestive Kidney Diseases (NIDDK). Publications and resources on nutrition, physical activity, and weight control for providers.

<http://win.niddk.nih.gov/publications/index.htm#provider>

Prescription Medications for the Treatment of Obesity – As with other chronic conditions, such as diabetes or high blood pressure, the use of prescription medications may be appropriate for some people who are overweight or obese. The information in this fact sheet may help patients decide if and what kind of weight-loss medication may help to reach and stay at a healthy weight. It does not replace medical advice from a doctor.

http://win.niddk.nih.gov/publications/PDFs/Prescription_Medications.pdf

Bariatric Practice Guidelines – These guidelines provide suggestions for the work-up and follow-up of the bariatric patient. They are not intended to replace, and indeed cannot replace, the bariatrician's judgment regarding a particular patient's treatment. Neither are they intended to represent legal requirements for providing "good medical practice." The bariatrician is the one most capable of determining what is or is not appropriate for an individual patient.

http://www.asbp.org/resources/uploads/files/bariatric_practice_guidelines.pdf

Publications and Resources for Consumers

Alliance for a Healthier Generation – Founded in 2005 by the American Heart Association and William J. Clinton Foundation to reduce the prevalence of childhood obesity and empower children to make healthy lifestyle choices. Resources are provided for various settings and organizations: at school, at home, at the doctor, out-of-school time, and in business.

<http://www.healthiergeneration.org/>

Healthy Weight Tools - BMI calculator, menu planner, portion control.

http://www.nhlbi.nih.gov/health/public/heart/obesity/lose_wt/tools.htm

Medline Plus – Text summary for how to manage weight by eating healthy. The summary provides different healthy foods from each food group.

<http://www.nlm.nih.gov/medlineplus/ency/patientinstructions/000330.htm>

National Heart Lung and Blood Institute (NHLBI) – Successful weight-loss treatments include setting goals and making lifestyle changes, such as eating fewer calories and doing physical activity regularly. Medicines and weight-loss surgery also are options for some people if lifestyle changes aren't enough.

<http://www.nhlbi.nih.gov/health/health-topics/topics/obe/treatment.html>

Physical Activity for Everyone – Fitting regular exercise into your daily schedule may seem difficult at first, but the 2008 Physical Activity Guidelines for Americans are more flexible than ever, giving you the freedom to reach your physical activity goals through different types and amounts of activities each week. Guidelines are available for children, adults, and older adults.

<http://www.cdc.gov/physicalactivity/everyone/guidelines/>

The Weight of the Nation – A forum to highlight progress in the prevention and control of obesity through policy and environmental strategies. It is framed around five intervention settings: early care and education; states, tribes and communities; medical care; schools; and workplaces. This is a four-part documentary series, each featuring case studies, interviews with our nation's leading experts, and individuals and their families struggling for obesity.

<http://theweightofthenation.hbo.com/>

Weight-control Information Network (WIN) – An information service of the National Institute of Diabetes and Digestive Kidney Diseases (NIDDK). Publications and resources are available on nutrition, physical activity, and weight control for the public.

<http://win.niddk.nih.gov/publications/index.htm#public>

Weight Management – Includes an interactive multimedia tutorial, which includes questions, a self-running presentation, and a text summary.

<http://www.nlm.nih.gov/medlineplus/tutorials/weightmanagement/htm/index.htm>

Other Obesity Toolkits

Centers for Disease Control and Prevention. Road to Health Training Guide. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention; 2010. <http://ndep.nih.gov/media/road-to-health-training-guide.pdf>

CMA Foundation & CAHP. Adult Obesity Provider Toolkit. CMA Foundation and California Association of Health Plans; 2008.

http://www.thecmafoundation.org/projects/ObesityGeneralPDFs/AdultToolkit_Revised%20April%202008.pdf

Eat Smart, Move More NC.

<http://www.eatsmartmovemorenc.com/Worksites/Worksites.html>

National Institutes of Health. (2005). Energize our Community: toolkit for action. (NIH Publication No. 05-5272).

http://www.nhlbi.nih.gov/health/public/heart/obesity/wecan_mats/toolkit.pdf

National Obesity Forum. (2006). Care pathway & toolkit.

http://www.nationalobesityforum.org.uk/index.php/lifestyle/adults_/obesity-care-pathway/25-care-pathway-a-toolkit.html