



The Economics of Obesity:

A Compelling Case for Augmenting Traditional Workplace Wellness Programs with a Disease Management Program Targeting Obesity

White Paper

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updated September 2022

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SUMMARY:

Over the last several decades, an epidemic of “lifestyle diseases” has developed in the United States. Unhealthy lifestyles, such as poor nutrition, inactivity, tobacco use and frequent alcohol consumption are driving up the prevalence of chronic diseases such as obesity, diabetes, heart disease and a multitude of other health conditions. These chronic conditions have become a major economic burden, as they lead to increased health care costs, decreased quality of life, and premature death and disability. In 2014, the direct and indirect costs of obesity and obesity-related comorbidities alone totaled \$1.42 trillion, equivalent to 8.2 percent of the U.S. gross domestic product.

Although chronic disease was once a problem of older age groups, there has been a shift toward onset during Americans’ working age that adds to the economic burden. In addition to the increase in direct healthcare costs, working Americans with chronic disease also suffer from increased rates of illness-related loss of productivity due to absence from work (absenteeism) and reduced performance while at work (presenteeism).

Out of concern about the impact of chronic disease on employee health and well-being as well as the cost of health care coverage, employers are adopting health promotion and disease prevention strategies, commonly referred to as workplace wellness programs and disease prevention programs. These programs aim either to prevent the onset of disease (primary prevention) or to diagnose and treat disease at an early stage before complications occur (secondary prevention). Primary prevention addresses health-related behaviors and risk factors – for example, by encouraging a healthy diet to improve diabetes control. Secondary prevention attempts to improve disease control – for example, by promoting medication adherence.

Most adults don’t want to suffer from chronic lifestyle diseases. In fact, Americans spend billions of dollars of their own money every year trying to improve their health and weight. Despite these heroic efforts, rates of excess weight and chronic lifestyle diseases in the US population continue to increase each year. This suggests that our methods, rather than our intentions, are the problem.

Misconceptions about health and obesity abound in today’s world. A poor diet has been recognized as the leading cause of preventable death in the U.S. Despite this evidence, efforts at improving lifestyle diseases have remained laser focused on treating obesity. Individual and commercial programs aimed at improving health and weight typically promote the treatment of excess weight using calorie restriction and aim to improve personal responsibility or willpower. Obesity has been defined as a chronic, progressive, multifactorial, neurobehavioral disease influenced by a multitude of genetic, epigenetic and extragenetic factors. Despite the common sense theories that weight is a simple process of balancing calorie-in and calories-out, there is little data to support this idea and even less data that changing those variables works to improve excess weight. Nor do improvements in excess weight always result in improving other chronic lifestyle diseases.

In fact, a large body of evidence is emerging that obesity itself is not the primary driver of poor health. More often than not, obesity itself is a consequence of metabolic dysfunction. Metabolic dysfunction, or metabolic syndrome, is emerging as the primary driver of excess weight gain and other chronic lifestyle diseases. And we know for certain that metabolic syndrome is absolutely related to diet quality. Metabolic dysfunction is a complex problem, one rooted in biochemistry and medicine, not calories and personal responsibility.

In order to make progress improving the economic burden of lifestyle diseases, we have to make a global shift in the way we understand and treat these problems. Corporate disease management programs offer an ideal platform for the dissemination of evidence-based weight management opportunities, as corporations have vested financial interest in improving employee health. This is due, in part, to the fact that American adults are spending increasingly larger portions of their waking hours at work and because poor employee health comes at a cost to employers. A robust disease management program aimed at targeting metabolic syndrome, obesity and other related chronic lifestyle diseases is radically different from traditional wellness programs offered today that have their basis in outdated, unscientific information and rhetoric. Although some of these traditional wellness programs have been shown to provide a small ROI after being implemented for several years, they have not done enough to offset the financial burden shouldered by employers. A robust, evidence-based disease management program aimed at preventing and improving obesity and metabolic disease is needed to make an impact on the economics in the workplace.

DEFINITIONS AND EPIDEMIOLOGY:

The terms **overweight** and **obesity** refer to body weight that is greater than what is considered healthy for a certain height. The international standard for measuring obesity is the body mass index (BMI). BMI is calculated as a person's weight, measured in kilograms, divided by the square of his or her height, measured in meters. A BMI of 18.5-24.9 is considered normal, a BMI of 25-29.9 is considered overweight, and a BMI ≥ 30 is considered obesity. Obesity is then subcategorized into obesity grade I (BMI 30-34.9), obesity grade II (BMI 35-39.9) and obesity grade III (BMI ≥ 40), sometimes referred to as severe obesity.

In some circumstances (those individuals with a great deal of muscle mass or those with very little), BMI can be misleading. Since the definition of obesity is excess body fat, accurately determining body fat percentage is the best way to make this diagnosis. Women with a body fat percentage greater than 35% and men with a body fat percentage $>30\%$ are considered to have obesity. Although this is a more accurate classification system than BMI, measuring body fat percentage is expensive and is not easily obtainable. Waist circumference is also well-correlated with excess adiposity. Women with a waist circumference greater than 35" and men with a waist circumference greater than 40" are considered to have obesity.

According to the Centers for Disease Control and Prevention, the prevalence of obesity was 42.4% among US adults in 2017-2018. That equates to over 139 million U.S. adults suffering from obesity. Another 99 million (approximately 30% of the US adult population) suffers from overweight. (National Center for Health Statistics, 2020). To put it another way, a total of 70% of the population age 2 and above is defined as having either overweight or obesity. The highest prevalence of obesity is currently highest among adults aged 40-59 (44.8%). The prevalence among older adults (aged 60 and over) is 42.8%. The prevalence among younger adults (aged 20-39) is 40.0%. Obesity rates in the U.S. have increased steadily for the past several decades. Projections suggest that approximately half of U.S. residents will have obesity by 2030 (Ward 2019).

In addition to the increase in the prevalence of obesity, there is also a worsening of the severity of the disease. In 2009-2010, it was estimated that 6.4% of the U.S. adult population had severe obesity (BMI ≥ 40). By 2017-2018, this had increased to 9.2% (National Center for Health Statistics 2019). It is expected that the prevalence of severe obesity will increase to over 25% by 2030 (Ward 2019).

Although metabolic syndrome is the primary driver of poor health, obesity is arguably the most important **measurable** risk factor for overall chronic disease burden and increased health care spending. Preliminary results presented by Cleveland Clinic at the 2017 Society of General Internal Medicine Annual Meeting analyzed the contribution of modifiable behavioral risk factors to causes-of-death in the U.S. population and found the greatest number of preventable life-years lost were due to (in order from greatest to least) obesity, diabetes, tobacco use, high blood pressure and high cholesterol.

OBESITY-RELATED COMORBIDITIES:

Metabolic syndrome:

Metabolic disease - or metabolic syndrome is a cluster of risk factors that dramatically increases a person's risk for developing heart disease, stroke and type 2 diabetes. There is a strong correlation between metabolic syndrome and excess weight. Although once thought to be a consequence of excess weight, new evidence is emerging that metabolic syndrome may be the primary driver of excess weight gain rather than a consequence of it. In addition to excess weight, metabolic syndrome is associated with many other chronic diseases, most notably type II diabetes and cardiovascular disease, but also:

High blood pressure (hypertension)

Arthritis

Gallstones / Gallbladder surgery

Asthma

Stroke

Certain cancers (breast, endometrial, colon, thyroid, esophageal)

Pregnancy complications and birth defects

Dementia

Depression

Surgical complications

Incontinence

Decreased immune function

Gastroesophageal reflux disease (GERD)

Poor wound healing

Obstructive sleep apnea

Premature death

Type II Diabetes, Prediabetes and Cardiovascular Disease:

Type II diabetes is one of the most prevalent and expensive diseases confronting the nation. Type II diabetes is a chronic, progressive disease characterized by the body's inability to regulate glucose levels in the bloodstream. As of 2018, 34.2 million people (just over 1 in 10 adults) have diabetes (National Center for Health Statistics 2019). 61% of people with diabetes are currently in the workforce. A report by The Milken Institute estimated that the direct costs of diabetes attributable to obesity and overweight in the United States increased from less than \$1 billion in 1962 to \$111.9 billion in 2014 (Waters, 2017).

Prediabetes is a condition in which individuals have high blood glucose or hemoglobin A1C levels but these values are not high enough to be classified as diabetes. The Centers for Disease Control and Prevention estimate that 88 million adults in the US (approximately one in three) have prediabetes (National Center for Health Statistics 2019). Without intervention, approximately 11% of people with prediabetes will develop type II diabetes within 5 years and almost all will develop it within 10 years (CDC, 2014, NIDDK, 2014).

Often thought to be a result of obesity, excess weight is not the only cause. Although there is a genetic predisposition, diabetes is more closely related with dietary patterns and diet quality. Rates of diabetes are rising almost twice as fast as rates of obesity and currently affects millions of people without obesity. However, the more adiposity a person has, the more likely they are to also suffer from prediabetes or diabetes. Approximately 18.5% of people with obesity also have type II diabetes compared to 8.2% of those with overweight and 5.4% of people of normal weight. The associated relative risk for people with obesity to develop type II diabetes is 3.43, meaning that obese individuals are 3.43 times more vulnerable to contracting diabetes than a person of normal weight. The relative risk of type 2 diabetes related to being overweight is 1.52 (Waters, 2017)

As part of the disease process, type II diabetes doubles to triples the risk for cardiovascular disease. Hyperglycemia (elevated blood sugar) affects the structure of blood vessels, making them prone to atherosclerosis (Mayer, 2016). The cardiovascular death rate is 1.7 times higher in patients with type II diabetes, hospitalization for heart attacks is 1.8 times higher, and hospitalizations for stroke is 1.5 times higher among adults with type II diabetes. The risk of premature death is 50% higher for adults with diabetes. (NIDDK, 2014).

Even in the absence of diabetes, excess weight increases a person's risk of developing cardiovascular disease. On average, a 1-point increase in an individual's BMI leads to a 10-percent increase in the risk of coronary heart disease (Waters, 2017). A 20-year follow-up analysis of the Nurses' Health Study cohort found that women with overweight have a 1.43 relative risk of developing CHD compared to women of normal weight; the relative risk for women with obesity was found to be 2.44 (Waters, 2017). A larger meta-analysis of 31 studies—encompassing 389,239 individuals and 20,652 coronary heart disease events—found an relative risk of developing cardiovascular disease of 1.33 for people with overweight and 1.69 for people with obesity - after adjusting for age, gender, and smoking status (Waters, 2017).

2009-2012 data demonstrated that of adults aged 18 or older with diagnosed diabetes, 71% have hypertension or use medications to lower their blood pressure. 65% have hyperlipidemia or use cholesterol-lowering medication (CDC, 2014). Diabetes is also the primary cause of kidney failure requiring dialysis. End stage renal disease (ESRD) parallels type 2 diabetes in its association with obesity. A recent meta-analysis showed that individuals with overweight have a relative risk of developing end-stage renal disease of 1.87, and those with obesity have a relative risk of 3.57 (Waters, 2017).

Diabetes is the leading cause of limb amputation and new-onset blindness in American adults. Patients with poor control of their disease have much higher rates of complications than those with good control.

Unfortunately, glycemic control is maintained in only 40% of diabetic patients. Patients with intensive medication regimens and polypharmacy (especially those requiring insulin) often face multiple side effects, which decreases adherence and, thus, disease management (Mayer, 2016) In 2012, 3 million US adults (14.4%) were not treating their disease with any type of medication.

In an analysis of more than 600 studies involving over 135,000 patients, 78% of patients with type II diabetes had complete resolution of their disease after surgery, and 87% had improved blood glucose levels (Mayer, 2016) Clearly, studies have shown that significant weight loss (in these cases, caused by surgical intervention) results in resolution of diabetes for most patients. These results typically persist for the rest of a person's life, as long as weight loss is maintained. This argues that the weight loss (not the surgery itself) is primarily responsible for the resolution of diabetes. Furthermore, weight-loss following gastric bypass in patients without diabetes decreases their likelihood of developing diabetes by 60 percent over four years. A key finding of all studies is that the less time one suffers from diabetes, the more likely he or she will have complete remission of diabetes following surgery (Mayer, 2016)

Because of this data, both the International Diabetes Federation and the American Diabetes Association have endorsed bariatric surgery as a treatment for patients with type II diabetes and severe obesity, especially those who have a shorter duration of diabetes and those with cardiovascular risk factors. However, bariatric surgery is not a magical cure-all. Many people have significant weight regain following their initial loss. Furthermore, bariatric surgery is not without risk. Gastric bypass surgery (Roux-en-Y) has a 30-day mortality rate of 0.5% and a 1-year mortality rate of 1%. Sleeve gastrectomy rates are only slightly better. The risk of postoperative

complications and reoperation rates are high with all types of bariatric surgery. Behavioral adjustments and changes are still needed postoperatively. Adherence to lifestyle change is vital to sustain weight loss, prevent dietary deficiencies and reduce the risk of complications and/or diabetes recurrence.

Cancer:

Multiple studies have found a strong association between obesity and cancers of the breast, colon, endometrium, gallbladder, liver, pancreas, and ovaries. There is a linear relationship between breast, ovarian and endometrial cancer risk and BMI. Obesity has a double impact on women's risk for breast cancer, increasing the prevalence by up to 50 percent. In addition, among women who have breast cancer, those with overweight or obesity have shorter survival times and worse prognoses. Women with excess weight have a higher risk of ovarian cancer compared to women of normal weight— the relative risk of developing ovarian cancer is 1.53 for women with overweight and 3.22 for women with obesity. For endometrial cancer, the statistics are even more concerning; the relative risk is 2.0 for women with overweight and 3.5 for those with obesity. Obesity is a significant risk factor for liver cancer; the relative risk for those with obesity is between 1.5 and 4.0 (Waters, 2017).

Gallbladder Disease:

Gallbladder disease is one of the most common surgical conditions seen in our society, with more than a half million cholecystectomy operations performed each year. Although there are many risk factors which would increase the likelihood of developing gallbladder disease, two of the major causes are obesity and rapid weight-loss; therefore, gallbladder disease is an important issue for patients with obesity

Asthma and other diseases of the Respiratory System:

Obesity can lead to inflammation of the airways in the lungs, increasing the risk of asthma and potentially the severity of asthma cases. The emergence of the COVID-19 pandemic has demonstrated the significant risk of respiratory complications in patients with obesity, including difficulty with hypoventilation syndrome and respiratory failure.

Chronic Back Pain:

Individuals who have obesity also have a 2.81 relative risk of chronic back pain, compared to those of normal weight. People with overweight have a relative risk of 1.59. Osteoarthritis is strongly linked to overweight and obesity as well,

Dementia / Stroke:

In the past decade, several studies have demonstrated a strong causal relationship between obesity and Alzheimer's and vascular dementia. A meta-analysis of 15 prospective studies published in 2011 found that the relative risk of Alzheimer's disease or vascular dementia was 1.35 and 2.04 for individuals with overweight and obesity, respectively. Obesity is also a significant risk factor for stroke; a systematic review covering more than 2 million participants in prospective studies found that the relative risk of stroke associated with obesity is 1.64 (Waters, 2017).

Despite the prevalence of the disease, very few people with obesity are happy with their disease state. Reviews of the literature have consistently demonstrated that obesity is linked with decreased physical and psychosocial aspects of quality of life. As the degree of obesity increases, so does the level of impairment in health-related quality of life, with the greatest impairment observed in physical domains. Most Americans (63%) have seriously

attempted to lose weight at some point in their lives, and 29% report currently trying to lose weight (Gudzune, 2015). Despite this, NHANES data shows that Americans gain an average of approximately 1-2 pounds per year from early adulthood through middle age. Adults with overweight and obesity typically gain 2.2 – 3.3 pounds per year, thereby gradually worsening the underlying problem (Van Dorsten, 2008).

DIRECT MEDICAL COSTS ATTRIBUTABLE TO OBESITY:

There is an undeniable link between rising rates of obesity and rising medical spending. In a report by the Milken Institute published in 2014, researchers found that the direct costs in the US for medical treatment for health conditions causally related to overweight and obesity totaled \$427.8 billion. Among those conditions, type II diabetes had the highest treatment costs at \$111.9 billion, accounting for 26.1 percent. Alzheimer’s disease and vascular dementia were next, with \$56.0 billion in direct treatment costs. Gallbladder disease was third with \$43.9 billion followed by osteoarthritis at \$42.1 billion. In total, the direct medical expenses associated with treating diseases caused by obesity accounted for 14.3 percent of U.S. health-care spending in 2014 (Waters, 2017).

Although pharmaceutical, medical and surgical interventions to treat obesity are available; these treatments remain rare and account for only a minute portion of the medical costs of obesity. The costs attributable to obesity are almost entirely a result of costs generated from treating the diseases that obesity promotes or exacerbates.

The burden associated with excess weight is borne, in large part, by employers, who pay a large percentage of employee healthcare costs. Overall, 63% of covered employees are enrolled in a plan that is either partially or completely self-funded by their employers (Kaiser, 2015). Even within those plans that are not self-funded, excess medical costs are indirectly borne by the employers by way of increasing premium costs in subsequent years. It should also be noted that although much of increased health care costs are initially covered by employers, they are ultimately passed along to employees in the form of higher premiums, copayments, and deductibles for medical services (Finkelstein, 2010).

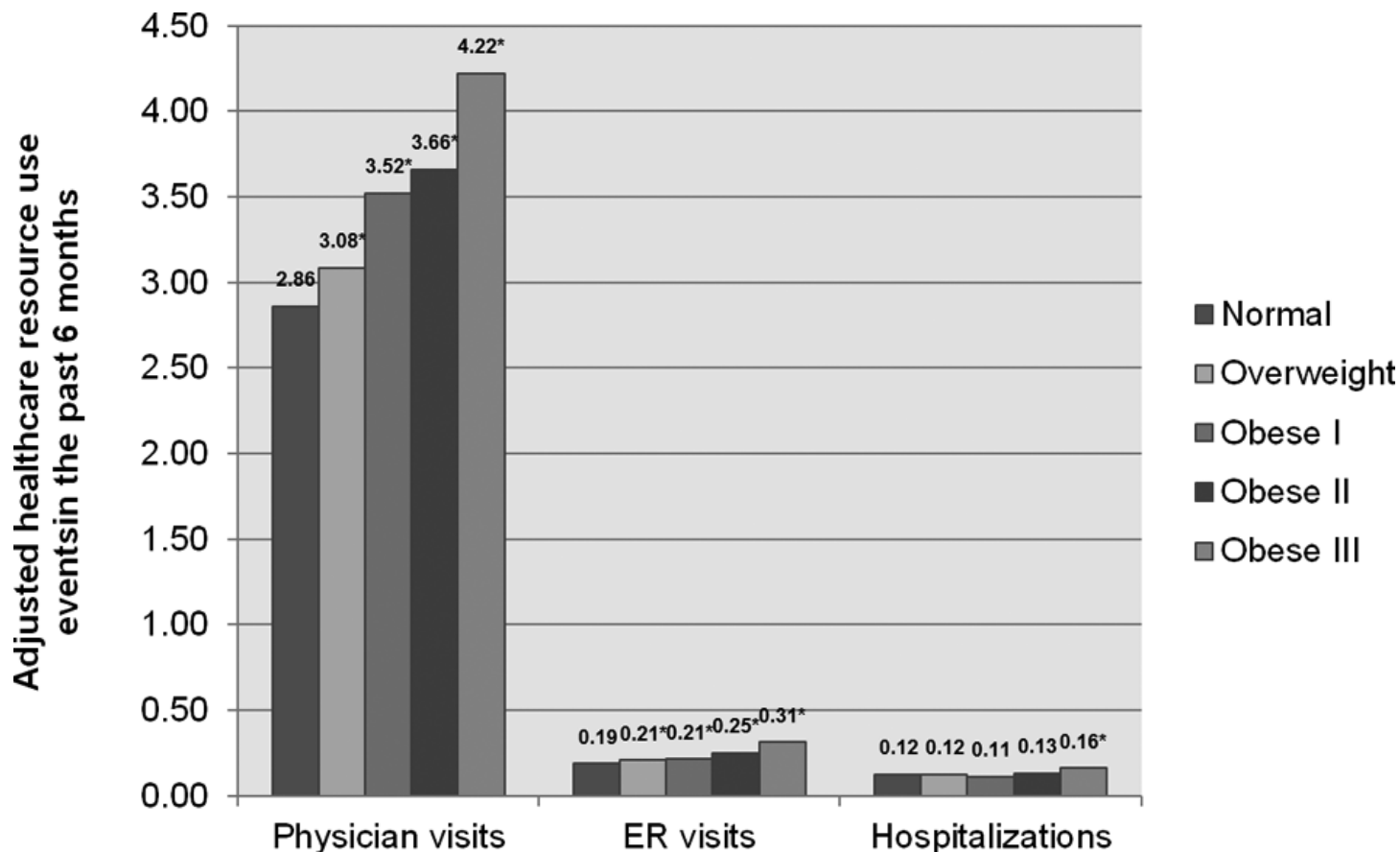
Estimations of the burden of obesity vary from one study to the next depending upon criteria used to quantify the costs, but every one of the studies shows a significant increase in direct medical costs for individuals with obesity.

We had the opportunity to examine healthcare claims data from several large employers in the Kansas City area. Between 2017-2019, evaluating a total of 13,500 covered lives, we found that the average annual healthcare cost for a full-time employee without a diagnosis of obesity was \$4,734 compared to an average annual cost of \$12,612 for employees with obesity. The variance was \$7878. In other words, between 2017-2019 in the greater Kansas City area, several large companies spent 166% more money per person per year insuring employees with obesity.

Among patients with type II diabetes, the cost differential between annual medical expenditures for individuals of normal weight (\$24,573) and individuals with grade III obesity (\$29,451) is less pronounced but still statistically significant – and notably higher than patients without type II diabetes (DiBonaventura, 2015). Patients with prediabetes also incur a substantially higher cost with normal weight individuals, incurring an average yearly cost between \$17,087 and \$22,914 (DiBonaventura, 2015). Approximately 34.4% of the costs of diabetes in the U.S. are paid for by private insurance (with Medicare, Medicaid, and the military bearing approximately 62.4% of the

cost and 3.2% of the uninsured bearing the financial burden) (DiBonaventura, 2015).

Data relying on MEPS (Medical Expenditure Panel Surveys) confirms that across all payers, obesity increases costs by approximately 37%. This comes from a 90% increase in the cost of inpatient services, a 37.9% increase in cost for non-inpatient services and 81.8% increase in cost for prescription drugs. In percentage terms, these increases represent 82% higher prescription drug cost and 90% higher inpatient services compared with people of normal weight. DiBonaventura et al showed that increasing BMI is associated with an increasing number of physician visits and emergency department visits.



(Image courtesy of DiBonaventura, 2015)

In a 1998 benchmark study of health risks, Goetzel et al used the Health Enhancement Research Organization (HERO) database and found significant associations between increased health care costs and blood glucose, blood pressure, body weight, depression, physical activity, tobacco use, and stress (Goetzel, 2014). A 2012 update of this study using data from seven large employers reconfirmed the risk and cost relationships demonstrated in the earlier study. In this analysis, White et al used a study sample of 174,019 employees and spouses from small, medium and large-sized employers. Despite excluding the top 2.5 percentiles as outliers, relative to low risk individuals, annual health care costs were significantly higher for those individuals in the at-risk categories for medication/drug use for relaxation, extremely high stress, high cholesterol, inadequate physical activity, blood pressure and obesity (White, 2013).

Paralleling the studies using the Health Enhancement Research Organization data (which found weight and blood

glucose to be the strongest predictors of medical costs), another large study found overweight/obesity, high blood pressure, high blood glucose, high triglycerides and inadequate physical activity to be strong predictors of high medical costs (Kowlessar, 2011). O'Donnell et al performed a cross-sectional multivariate analysis of 223,461 employees from seven industries and found that modifiable risk factors elevated healthcare costs even when overt disease was not present and high BMI was the most prevalent and most expensive risk factor in terms of total excess costs for those with and without a medical condition. (O'Donnell, 2015).

The presence of type II diabetes, which is strongly correlated with excess weight, dramatically increases an individual's direct medical costs in every analysis performed. In 2012, the estimated annual cost of treating people with diabetes was \$245 billion. Of this, \$176 billion was direct medical costs, which is 2.3 times higher than for people without diabetes. The largest components of medical expenditures are:

- Hospital inpatient care (43%)
- Prescription medications to treat complications of diabetes (18%)
- Anti-diabetic medications and diabetes supplies (12%)
- Physician office visits (9%)
- Nursing / residential facility stays (8%)

In addition to direct medical costs, approximately \$69 billion of the \$245 billion spent each year treating diabetes is indirect costs such as disability, work loss, and premature death. People with diabetes have increased absenteeism (\$5 billion in costs), reduced productivity while at work (\$20.8 billion), inability to work as a result of a disease-related disability (\$21.6 billion) and lost productive capacity due to early mortality (\$18.5 billion) (CDC, 2014).

INDIRECT COSTS ATTRIBUTABLE TO OBESITY:

While direct medical expenditures are the most manifest costs of illnesses caused by obesity, they are by no means the only costs. Obesity-related illnesses take their tolls in lost productivity. Higher rates of emotional exhaustion, psychological complaints and lower quality of life are correlated with obesity (Kleinman, 2014). Measurable indirect costs include absenteeism, presenteeism, short- and long-term disability claims, worker's compensation claims, life insurance premiums, and premature death. Levels of work productivity loss rises as BMI increases with the most pronounced effects in overall work impairment observed among employees with class III obesity (DiBonaventura, 2015). According to a recent report by The Milken Institute, total indirect costs related to lost work time or lower productivity caused by diseases attributable to excess weight amounted to \$988.8 billion in 2014. Because it is too difficult to quantify, this data does not include the time costs for informal caregivers—which for some conditions, such as Alzheimer's disease, can be considerable. Nor does the estimate include the full costs of the effects of chronic disease on employee performance and output. For this reason, all estimates of indirect costs should be considered conservative.

Again, it is important to note that not all of the indirect costs of obesity are shouldered by employees themselves. Obesity costs employers up to \$73.1 billion dollars per year in medical costs and absenteeism.

Studies have repeatedly found that employees with obesity are 25% to 100% more likely to be absent from work compared with employees of normal weight (Kleinman, 2014). Among full-time employees in 2008, annual work days missed because of health issues ranged from an additional 0.5 days for overweight men to 9.4 days for women with severe obesity. The annual cost of such preventable losses can exceed \$1000 per employee in the highest BMI range. Some industries are more affected than others, as obesity-related absenteeism is shown to vary with occupation (Andreyeva, 2014).

Presenteeism is defined as getting ill or feeling uncomfortable but still going to work, which therein causes loss of productivity. The most measurable way of defining presenteeism is the average amount of time between arriving at work and starting work on days when an employee is not feeling well and the average frequency of engaging in five specific behaviors: losing concentration, repeating a job, working more slowly than usual, feeling fatigued at work and doing nothing at work. In 2005 Ricci and Chee estimated that workers with obesity cost U.S. employers an additional \$11.7 billion per year compared with workers of normal weight as a result of increased absenteeism and presenteeism, with presenteeism accounting for roughly two-thirds of this total (Finkelstein, 2009).

DiBonaventura et al also demonstrated that the greatest contribution to work impairment in individuals with obesity is observed in increased presenteeism. For employees with type II diabetes, indirect costs were higher, from \$4854 (normal weight) to \$9689 (obesity class III). The data was equally discrepant in individuals with prediabetes as well (DiBonaventura, 2015).

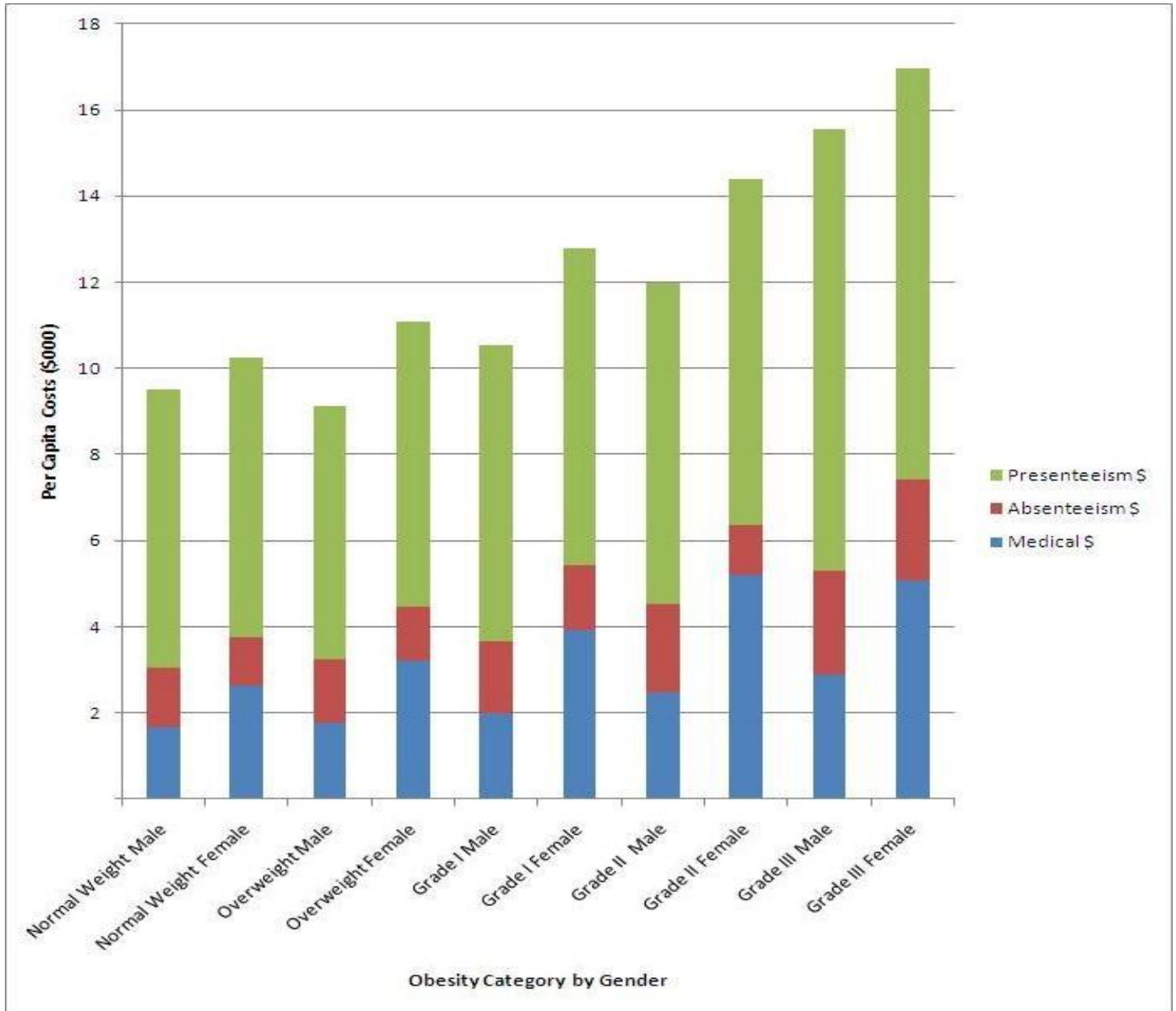
Multiple studies have shown that presenteeism is the single largest driver of the costs of poor health among full-time employees, regardless of BMI. Moreover, with the exception of overweight men, medical expenditures, absenteeism, and presenteeism increase with increasing BMI (Edington, 2007).

Incorporating NHWS data, Finkelstein et al studied the association between BMI and loss of work productivity. They found incremental increases of approximately \$1000, \$1600, and \$4500 for individuals with obesity class I, II, and III, respectively, relative to individuals of normal weight (Finkelstein, 2010). Several years later, DiBonaventura studied similar data, which suggested increases closer to \$1200, \$2100, and \$4000 (DiBonaventura, 2015). Variability could be due to different populations studied or they could suggest that these

costs are on the rise.

Using 2006-2008 data from MEPS, Finkelstein et al determined that across the three categories (medical expenditures, absenteeism and presenteeism), average per capita costs ranged from \$9507 for men with normal weight to \$15,561 for men with grade III obesity. Annual missed workdays ranged from 0.5 to 5.9 days more for men with overweight and obesity, increasing predictably with the severity of the obesity. Presenteeism was also significantly greater for men with obesity, ranging from 2.3 - 21.9 days compared to men of normal weight. The value of presenteeism ranged from \$391 for grade I obesity to \$3792 for grade III obesity, with the latter equating to more than 1 month per year of lost work time while at work for men with grade III obesity (Finkelstein, 2010).

For women, the estimated average per capita costs (medical expenditures, absenteeism and presenteeism) ranged from \$10,241 for women of normal weight to \$16,969 for women with grade III obesity. Medical expenditures and absenteeism were found to be greater among those women with increasing levels of excess weight. Days and dollars lost to presenteeism for female employees were significantly higher with each successive weight category; the incremental number of days lost approximately doubled for each obesity grade (6.3 to 11 to 22.7 days respectively). Across the three categories, the combined costs of medical expenditures and lost productivity due to absenteeism and presenteeism attributable to obesity ranged from \$797 for women with overweight to \$6694 for women with grade III obesity (Finkelstein, 2010).



Employees with obesity have higher costs in the areas of disability, workers compensation, sick leave and other health related absences (Kleinman, 2014). Employees suffering from obesity having significantly more self-reported presenteeism, work impairment or limitations as well as increased difficulty getting along with coworkers (Kleinman, 2014).

A review of 11 US studies by Neovius et al found that workers with obesity had 1-3 additional absence days per-person year than employees with normal weight. Greater differences were found when looking specifically at short-term disability and workers' compensation. This study found a 70% difference in short-term disability days between BMI >30 and BMI <27 cohorts, while two prior studies found employees with obesity had approximately twice as many disability days as employees with normal weight. The previous studies showed that depending on the level of obesity, employees with obesity had 239%-700% more workers compensation days and 143%-550%

more costs than employees with normal weights (Kleinman, 2014).

In 2014, Van Nuys et al looked at a panel database of 26,699 individuals observed over 3 years. Total and out-of-pocket health care spending, including medical and prescription spending, increased with BMI, as did the number of sick days, short-term disability claims, and workman's compensation claims. The probability of both types of claims was lowest among normal weight employees and rose as BMI increased. Compared with an employee with a BMI of 25, an employee with a BMI of 35 had nearly double the risk of a short-term disability claim (3.2% vs 6.0%) or a worker's compensation claim (1.8% vs 3.2%) (Van Nuys, 2014).

The number of days missed for illness also rises as BMI rises. Compared to an employee with a BMI of 25, a worker with a BMI of 40 misses about 77% more days of work from sick leave, short-term disability and workman's compensation (Van Nuys, 2014). Furthermore, the effect of BMI on these costs increases with age (Van Nuys, 2014).

Studies that have evaluated the impact of health risks on workplace productivity, including absenteeism and presenteeism, have shown that employees with other risk factors in addition to obesity have a higher magnitude of productivity losses. Although biometric risks such as high blood glucose and excess weight are significant predictors of higher absenteeism costs, other risk factors associated with obesity (such as depression and stress) have been shown to predict greater absenteeism and presenteeism (Kowlessar, 2011).

Certain comorbidities are particularly influential in the relationship between BMI and employer costs. Individuals with a comorbid condition demonstrate a significantly steeper relationship between BMI and the probability of a short-term disability claim. An employee with BMI of 35 plus either diabetes, hypertension, or hyperlipidemia has a higher risk of short-term disability (6.7%) and higher average claims than does someone with a BMI 5 points higher but with none of these comorbidities). Milken estimated that the indirect productivity costs of diabetes alone attributable to obesity and overweight totaled \$207.6 billion in 2014 (Waters, 2017).

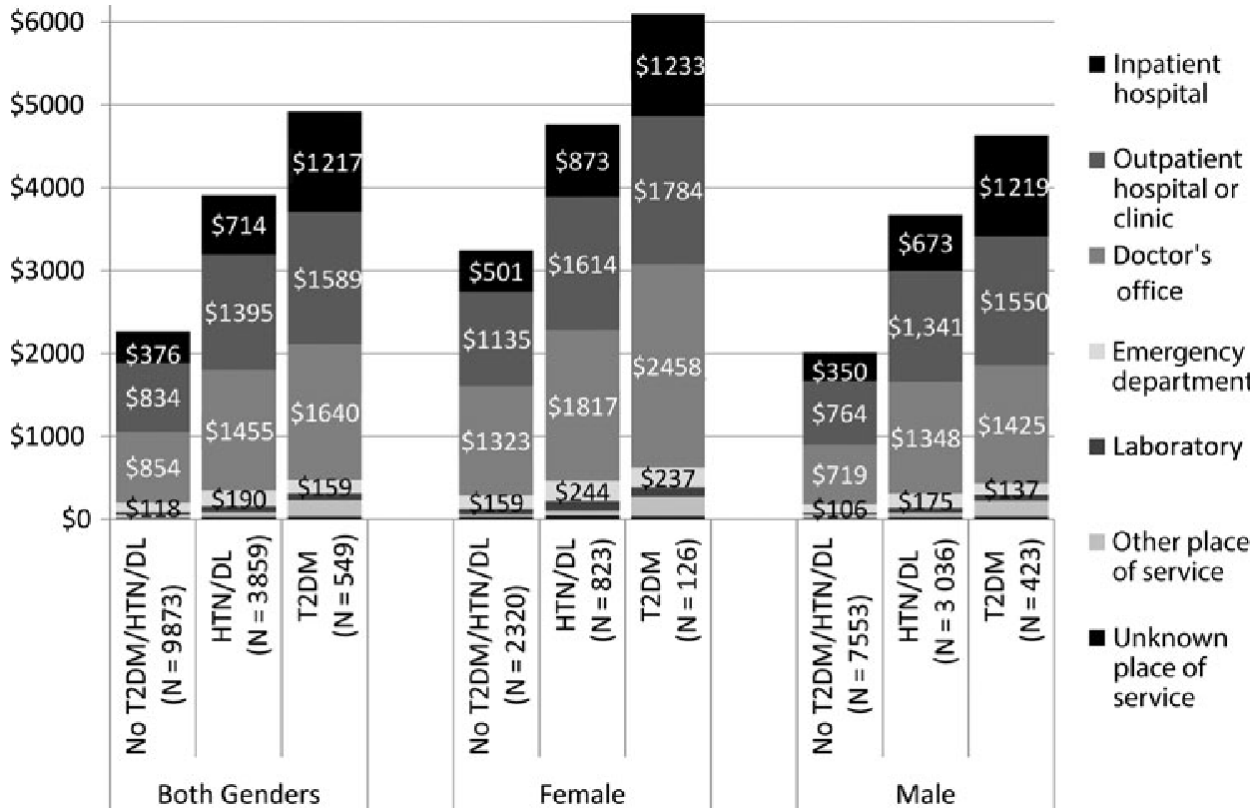
In 2014, using data from 1,700,000 employees representing various industries, Kleinman et al found that adjusted outcomes comparisons between study cohorts revealed that medical costs, drug costs, sick leave, short-term disability, and workers' compensation costs were higher in cohorts with higher BMI and were all statistically significant for those over a BMI of 30 (Kleinman, 2014). Those patients with type II diabetes mellitus generally had the highest costs and most absence days (Kleinman, 2014). Total costs and days absent based upon BMI were:

Women:		
BMI	Medical Costs	Days Absent
< 27	\$5302	5.58

27-30	\$5946	6.91
> 30	\$7932	8.66

Men:		
BMI	Medical Costs	Days Absent
< 27	\$3648	3.58
27-30	\$4248	4.61
> 30	\$4471	6.95

In 2016, Tao et al evaluated workers' compensation claims relative to body mass index. For open claims with an initial reserve of at least \$15,000, the average incurred cost was \$181,413 for individuals of normal weight versus \$270,332 and \$472,713 for individuals with overweight and obesity, respectively (Tao, 2016). Interestingly, there was no statistically significant difference observed between BMI groups for an initial reserve of less than \$15,000. Unlike claim costs, claim duration did not change for claimants with overweight and obesity, indicating that higher claim costs associated with higher BMI occurred independent of claim duration and were probably related to increased medical costs (Tao, 2016).



Kleinman et al looked at the relationship between obesity and other coexisting chronic diseases. They compared obese employees with type II diabetes (T2DM), hypertension and/or hyperlipidemia (HTN/DL) with a comparison group that did not suffer from these lifestyle diseases. Not surprisingly, their data showed that the subcohort with type II diabetes had significantly higher inpatient, outpatient, laboratory and other medical costs than the HTN/DL subcohort and that both groups incurred higher costs than the comparison group that did not suffer from one or more of these chronic diseases (Kleinman, 2014).

The disproportionately high per capita and total cost of grade II and grade III obesity is particularly concerning, given that this BMI range is the fastest growing subset of our population. Individuals with severe obesity (BMI >35) represent 37% of the population with obesity, yet they are responsible for 61% of the costs resulting from excess weight (Finkelstein, 2010).

On the flip side, among workers with health insurance, employees with obesity earn significantly lower wages than their counterparts with normal weight (Van Nuys, 2014). Annual salary is significantly lower when BMI is highest, averaging \$87,604, \$83,178, and \$65,843 in the BMI <27, 27-30, and >30 cohorts. This may offset some of the increased medical costs to the employers (Kleinman, 2014). Interestingly, baseline BMI is also inversely related to job satisfaction, with employees with the highest BMI reporting the least satisfaction with their jobs (Barham, 2011).

WORKPLACE WELLNESS PROGRAMS:

A 2013 industry survey of large US employers reported that employers' number one strategic focus was developing a healthy workplace culture where employees are accountable for their health behavior but supported by workplace health and well-being initiatives (Nyce, 2012). According to the CDC, a workplace health program is defined as "a coordinated and comprehensive set of health promotion and protection strategies implemented at the worksite that includes programs, policies, benefits, environmental supports, and links to the surrounding community designed to encourage the health and safety of all employees (Dement, 2015). In other words, workplace health promotion (wellness) programs are employer initiatives directed at improving the health and well-being of workers, and, in some cases, dependents. They include initiatives designed to avert the occurrence of disease or the progression of disease from its early unrecognized state to a more severe one.

As of 2013, lifestyle management programs were offered by 77 percent of employers with a wellness program (Soeren, 2013). Lifestyle programs target a broad range of risk factors and focus on prevention, and almost all offer nutrition and weight activities. Disease management programs, which are offered by 56 percent of employers with wellness programs, are designed to help employees and dependents improve specific disease states, such as diabetes, heart disease, depression and cancer (Soeren, 2013).

Elevated health risks often precede health care cost increases, so prevention of future health risks is imperative to decrease healthcare costs. Longitudinal studies have demonstrated that health care cost increases associated with health risk increases are typically greater than the health care cost decreases associated with health risk decreases. Furthermore, the impact of risk change on health care costs often takes a year or more to emerge (White, 2013). Not surprisingly, cost changes associated with both decreases and increases in health risks are much larger among individuals with chronic conditions. Prevention of obesity in a population that does not already suffer from it and prevention of progression from mild to severe obesity has significant long-term

cost-savings.

As employers develop, evaluate and justify their budgets for population health management initiatives, they routinely seek to quantify the financial value or return that such initiatives will produce for the organization. The ROI is difficult to assess and measure, not only because of the duration of time required to see the results of the intervention but also because healthcare costs continue to rise despite improvements. Evidence demonstrating the financial value of these programs are mixed, with only some demonstrating a positive ROI for employer-based weight management programs. Average annual per-capita costs of workplace obesity prevention programs ranged from \$11 to \$1,384, with a median of \$155 (Kubendran, 2017).

As part of a meta-analysis of obesity interventions, The Milken Institute reported that only four quality reviews presented information on workplace wellness programs and only one review examined worksite interventions under the lens of profitability. In this study, they found returns in terms of averted medical costs and/or productivity loss ranging from \$1.40 to \$4.60 per dollar spent (Kubendran, 2017).

The RAND corporation estimated that the wellness program effects on health care costs were lower than most results reported in the literature. They found statistically significant and clinically meaningful improvements in exercise frequency and weight control in wellness program participants and those improvements were found to be sustainable over an observed four years. Furthermore, there were cumulative effects with ongoing program participation. Although these differences were statistically significant, they were not large. The one year participation in a weight control program was associated with a reduction of BMI of 0.15, which corresponds to a weight loss of about 1 pound (Soler, 2010). Although they did not detect statistically significant decreases in cost and use of emergency department and hospital care, the trends in health care cost and use of high-cost care for program participants and nonparticipants diverged over time. Therefore, they stated that there is reason to believe that a reduction in direct medical costs would materialize if employees continued to participate in a wellness program and they would likely be cost-neutral after five program years (Soeren, 2013).

A widely cited meta-analysis of the literature on costs and savings association with worksite health promotion programs conducted by Harvard economists Baicker et al reported that medical and absenteeism ROIs amounting to \$3.27 and \$2.70, respectively, saved for every \$1.00 invested over a 3-year time (Goetzel, 2014). In another analysis, Dement et al found that on average, total mean monthly healthcare costs were approximately \$35.1 less for health promotion participants compared with controls and participants experienced significant reductions in emergency department visit rates, rates of hospital admissions and days in the hospital compared with controls and estimated a health care cost savings of \$2.53 for each dollar invested (Dement, 2015). In a meta-study of employee wellness initiatives at large employers, Baicker and Cutler found that every dollar invested in such initiatives resulted in a reduction in medical costs of \$3.27 and absenteeism costs of \$2.73. (Baicker, 2010). Similarly, Soler et al reported economic summary measures in terms of a ROI ratio, which ranged from 1.4:1 to 4.6:1 (median 3.2:1) meaning that an annual gain of \$1.40 to \$4.60 for every dollar invested into the program would be realized. Large-scale analyses have shown that most positive ROI results are reported only after a program has been in place for 3 or more years (Goetzel, 2014).

A January 2014 article made headlines introducing doubt about the effectiveness of workplace health promotion – in this case, a study of PepsiCo employees. The focus of this study was only on the ROI from PepsiCo's program.

The study authors estimated the cost savings from the PepsiCo program and concluded that although the lifestyle management program component did save the company money, it was not enough to offset the cost of the program and therefore did not produce a positive ROI. However, what was almost ignored was that the authors did find net program savings for the company's disease management program. For individuals who were in both the lifestyle and disease management programs, substantial savings were realized totaling \$360 per employee per year. The paper also reported absenteeism reductions among workers engaged in one or both programs (Goetzel, 2014).

Although difficult to measure, workplace wellness programs may have more of an impact on indirect health costs. Pelletier et al used a small single-employer sample (n=500) and conducted repeated measures regression analysis. The results suggested that people who reduced the number of health risks by one were observed to have a 9% improvement in presenteeism and a 2% reduction in absenteeism. Lenneman et al used a larger sample consisting of 77,088 employees and confirmed that for those whose health improved, productivity impairment level also decreased.

Conducting a rigorous and credible ROI analysis is time-consuming, expensive and requires a high level of expertise in statistical analysis, health services research, econometrics, and benefit plan design. Well-designed ROI studies of workplace health promotion programs are rare, and even the best of these studies contain methodological flaws, simply because they are conducted in real-world settings with limited ability to control for confounding factors. Fees paid to vendors that administer the program are a program expense. But, less straightforward is the salaries of staff that manage the program internally, compensation to employees for their time to participate during work hours, facilities cost, and incentives payouts to workers.

Data examining costs and cost-effectiveness of obesity interventions is rarely reported. However, several trends surrounding costs have emerged. Most behavioral interventions tended to be cost-effective. Programs that are not cost-effective are often hindered by expenses associated with program operation, such as large administrative costs and/or high levels of patient time and transportation, both of which reduce cost-effectiveness. Highly intensive interventions, with greater frequency of contact, more components, and/or increased duration, typically cost more but also generally improve health outcomes. They tend to be more cost-effective for at-risk populations and thus may be more appropriate for secondary prevention of disease rather than primary prevention (Kubendran, 2017).

Interestingly enough, few employer-provided benefits are expected to produce a positive ROI. A typical US employer today spends large sums on health insurance and there is little evidence that these expenditures produce a positive ROI (Kubendran, 2017). Despite this, workplace health promotion programs are often held to a much higher standard of producing a financial gain or profit.

Employers overwhelmingly express confidence that workplace wellness programs reduce medical costs, absenteeism, and health-related productivity losses. However, only about half formally evaluate program impacts and only 2 percent have reported actual savings estimates. Furthermore, uptake of these programs remains limited. Employers who use incentives for screening activities report significantly higher participation rates than those who do not. Despite incentives, fewer than half of employees actually complete a health risk assessment (HRA) each year. What is even more discouraging is that of those identified for an intervention based on screening results, less than a fifth choose to participate in the recommended intervention (Soeren, 2013).

To further complicate the issue, previous research has shown that individuals completing an HRA may have different characteristics than those not completing an HRA. It may be difficult to extrapolate data about HRA completers to all employees across an organization.. Individuals actively participating in wellness programs and/or lifestyle intervention programs may have a differential motivation to change behavior and that intrinsic motivation may affect statistics.

We cannot ignore the role that the overall workplace culture plays in employee wellness. Social factors are instrumental in the development of health problems and their resolution. For example, the incidence of obesity has been shown to occur in clusters, with the development of obesity in one person increasing the odds that obesity will develop in their close friends. These social processes have been harnessed as a means to improve outcomes in several approaches to behavioral weight loss. For example, Wing and colleagues recruited participants with several of their friends and/or family members and treated these participants as a team, with group activities utilized to stress intra-group cohesion and inter-group competition. This social intervention improved overall weight loss outcomes. Moreover, there was a clustering in the weight loss outcomes among the team members; weight losses of one member of the team were found to be strongly related to that of the other members. Even better, such social contagion appeared to extend even outside the program; the untreated spouses of patients in a behavioral weight loss program were shown to achieve weight losses similar to the patients actually participating in the program.

Weight losses achieved in group programs appear to surpass those seen with individual contact. Using Look AHEAD data, it appears that the composition of the group and the size of the group have little effect on the outcome (Wing, 2014). Findings suggest that in addition to using existing relationships and social influence, programs also need to provide focused strategies, such as developing within-group activities or between-group competitions.

Improving population health requires more than simply convincing people to take better care of themselves. It requires that the organization where individuals spend a good portion of their waking hours creates an environment where leading a healthy lifestyle is the “default” option (Goetzel, 2014). Broad-based changes in an organization’s culture are essential for effective treatment of obesity. A culture of health and well-being has to be woven into the fabric of the organization – defined as one in which individuals and their organizations are able to make healthy life choices within a larger social environment that values, provides, and promotes options that are capable of producing health and wellbeing for everyone. Comprehensive health promotion programs are built on a culture of health that supports individuals’ efforts at changing lifelong health habits by putting in place policies, programs, benefits, management, and environmental practices that intentionally motivate and sustain health improvement.

As an example, a supportive company culture is exemplified by company cafeterias, where healthy food is abundant, affordable, clearly labeled, tastefully prepared and situated at eye level at the checkout counter. When possible, these foods are also priced lower than less healthy items. In addition, healthy and appealing food is served at meetings and available in vending machines. When possible, stairwells are open and accessible and prompts are in place to encourage people to take the stairs at decision points. An employee garden can be created and employees can teach other employees how to grow healthy food. Allowing employees to get deliveries of fresh produce at their worksites at their own expense is also beneficial.

BARRIERS TO SUCCESSFUL OBESITY TREATMENT:

Expert panels sponsored by both the World Health Organization and the National Institutes of Health have recommended that adults with obesity as well as those with overweight and comorbid conditions, lose 10% of their initial weight (Wadden, 2012). The definition of successful weight loss is loss of 5-10% of baseline body weight for at least a year. This standard has been recommended by the 2013 AHA/ACC/TOS Guideline for the Management of Overweight and Obesity in Adults as well as the NIH and CDC (Montesi, 2016).

Although the perception persists that there are no effective long-term treatments for obesity, decades of research has provided convincing evidence that individuals with obesity can lose and maintain significant weight. In doing so, they significantly reduce their risk for long-term health complications. Although a 10% weight loss may not return an individual with obesity to achieve a normal BMI, the health impact of a 10% weight loss is well-documented. From a clinical point of view, 5-10% weight loss significantly reduces the risk of developing type II diabetes in susceptible people, and eliminates many of the other risks associated with obesity. Moreover, this modest amount improves psychological functioning, in particular mood, body image and binge eating (Montesi, 2016).

Based upon current population data, the Obesity Treatment Foundation estimates that a reduction in the average BMI by 2020 by 5% would result in:

- 3.5 million cases of hypertension avoided
- 0.3 million cases of cancer avoided
- 2.9 million cases of heart disease and stroke avoided
- 3.6 million cases of diabetes avoided
- 1.9 million cases of arthritis avoided

The belief that obesity is purely a behavioral issue remains widespread, despite a plethora of published evidence indicating otherwise. Underlying most recommendations for weight loss is an assumption that people suffering from obesity simply need to “eat less and move more” and that failure to follow such simple instructions is a result of poor self-discipline or laziness. Successful treatment of obesity requires an approach that combines environmental and behavioral modification as well as understanding of the chronic metabolic aspects of the disease.

Commonly available commercial weight loss programs are far from satisfactory – primarily because they focus only on calories and simple behavioral modification. Physician advice to lose weight combined with common diet and exercise information is also insufficient to produce clinically significant sustained weight loss. These interventions typically fail because they are not grounded in science, nor do they take into account the biological adaptations that occur when patients with obesity lose weight, which predisposes them to weight regain. These biological adaptations provide a strong rationale for using medications, surgery, and/or intense medical intervention to treat obesity, particularly severe obesity. In humans, many other cues such as reward and emotional factors play a role in food intake aside from hunger, and multiple pathways are responsible for reward-associated feeding behavior. Increased hunger and decreased satiety after weight loss are associated with significant changes in various appetite-related hormones. These changes appear to persist for at least a year after weight reduction and may remain altered indefinitely in a manner that promotes increased energy intake and

ultimately weight regain (Apovian, 2015).

Despite their lack of efficacy, branded weight loss programs represent a multibillion dollar industry. Americans spend billions of dollars every year on commercial or proprietary weight loss services, with Weight Watchers (WW) dominating the market share. There is a paucity of unbiased data demonstrating the effectiveness of these programs and available data only addresses short-term weight loss with no statistics about long-term weight loss and weight-loss maintenance. Using different methods to analyze data, the American Heart Association, the American College of Cardiology, and the Obesity Society have all come to similar conclusions and have issued joint guidelines concluding that popular diets are roughly equally effective and that evidence is inadequate to recommend any particular diet (Johnston, 2014).

Because of the lack of long-term data regarding the efficacy of commercial weight loss programs, it shouldn't come as a surprise that healthcare organizations rarely consider them covered services for obesity treatment. In 2007, after extensive study, CMS determined that they needed to focus on long-term weight loss because short-term weight loss is not a cure for obesity. Wisely, they determined that population-level changes in obesity (and presumably its concomitant health problems) will only occur if losses are maintained. They acknowledged that direct indicators of health, such as blood pressure, cholesterol levels, disease incidence, and even mortality, are important outcomes of obesity treatments and should be considered when determining effectiveness of an obesity treatment program. CMS stated that they believed that low follow-up rates biased the results of commercial weight loss studies, making the programs appear to be more effective than they were. Because of these findings, they determined that they would not reimburse commercial weight loss programs as part of their coverage (Mann, 2007).

SUCCESSFUL OBESITY TREATMENT PROGRAMS:

In contrast to commercial weight-loss programs that are poorly studied, most of what the scientific community knows about the treatment of obesity comes from well-designed, randomized controlled trials conducted at academic medical centers. Despite having numerous studies, meta-analyses report high levels of heterogeneity among individual studies, which makes it difficult to compare effectiveness of various programs. (Kubendran, 2017). Furthermore, it is difficult to translate these study findings to the general population since throughout most of these programs, experienced therapists treat highly motivated patients, and the cost of treatment is not a factor. It is typically unrealistic to apply the programs and results to non-academic populations (Wadden, 2004).

However, due to the rigorous scrutiny required by academic programs, we can learn a lot from the data generated by their results. Currently, intensive lifestyle interventions yield an average weight loss of up to 10% at 1 year. These academic-based lifestyle modification programs include 3 primary components: diet, exercise and behavior therapy. They typically include a weight loss phase, consisting of 16-24 weekly sessions over the course of 6 months, followed by a weight maintenance phase, which typically lasts at least 1 year with monthly or more frequent contacts. Lifestyle modification programs are traditionally delivered by trained health professionals such as dietitians, or subjects having masters' degree training in exercise physiology, behavioral psychology or health education and are typically provided to groups of 10-20 participants at a time.

Data from large-scale lifestyle programs has demonstrated that weight loss typically reaches its peak within 6

months of the start of treatment and in the absence of a weight maintenance program; the trend begins to reverse thereafter (Montesi, 2016). Therefore, traditional lifestyle modification programs typically require a greater focus on long-term maintenance. A recent systematic review on the outcome of weight loss lifestyle modification programs found that at 1 year, approximately thirty percent of participants had a weight loss $\geq 10\%$ of their starting weight, twenty-five percent lost between 5% - 9.9% of their starting weight and forty percent lost $\leq 4.9\%$ of their starting weight. Weight regain typically slows after the first year, but by 5 years, approximately 50% of patients are likely to have returned to their baseline weight. On a positive note, 50% have not. However, regardless of the degree of weight change, the incidence of type II diabetes in these participants is still significantly lower than in controls, showing that modest weight loss, even when followed by slow regain, can be beneficial to long-term health. Furthermore, patients in these programs have typically avoided many years of weight gain that would have occurred in the absence of treatment, making the net loss even more significant.

In a lifestyle intervention, assessing and working on the factors affecting motivation to change seem to be fundamental in order to facilitate behavioral change. Subjects need at least 3-6 months to start to change and a longer time (1 year and more) to stabilize this new acquisition (Livia, 2016). The Milken Institute performed a meta-analysis of weight-loss interventions and came to a conclusion that certain behavioral or psychological techniques significantly improve weight loss (Kubendran, 2017). Among the factors they deemed important for success are:

- Having weight as a primary outcome
- Having a clearly defined goal
- Using an attention control
- Measuring treatment fidelity
- Using a behavioral component as part of a multi-component trial
- Using a trans-theoretical model (instead of social cognitive theory)
- Using behavior-change techniques that compare participant behaviors with those of others

There are several well-studied lifestyle intervention programs that can be modified to apply to non-academic populations. In the U.S., the ongoing **Diabetes Prevention Program (DPP)** provides the most long-term, comprehensive, successful treatment for obesity and is considered by most to be the gold standard by which to measure other programs. CMS has acknowledged that the DPP has the most promising results, with three-year lifestyle participants losing an average 8.8 lbs. This is in contrast to placebo participants, who gain an average of 1.1 lbs during over the same amount of time. Approximately half the lifestyle group reaches a 7% weight loss goal and 37% remain at their weight goal after 3.2 years. Although the DPP has demonstrated statistically significant weight loss sustained over three years, what is more important is that, during this time, the lifestyle group has consistently reduced their incidence of type II diabetes by 58% compared with the placebo group (Mann, 2007).

The 10-year follow up analysis of the original DPP group showed that the cumulative incidence of diabetes among adults remained lower in the lifestyle group. This outcome occurred even if the original lifestyle group partly regained weight – which underlies that the effect of lifestyle modification programs may produce significant health benefits even if the weight lost is partly regained (Montesi, 2016). The Centers for Disease Control (CDC) National Diabetes Prevention Program (NDPP) and others have focused on training a competent workforce to implement DPP-adapted interventions and build infrastructure to sustain group based diabetes prevention programs (Vendetti, 2014). These DPP programs are commonly delivered at medical and community sites.

However, they are limited, as they are labor-intensive and expensive to administer. Modifications have been made to the DPP to decrease costs and improve access. Telephonic and web-based approaches are increasingly being utilized as a cost-effective means, however, face-to-face interaction has consistently been shown to be most effective for weight loss and maintenance (Vendetti, 2014).

The **Look AHEAD** (Action for Health in Diabetes) trial studied the long-term health consequences of intentional weight loss in individuals with type II diabetes and overweight or obesity. The Look AHEAD trial enrolled 5,145 overweight and obese adults with type II diabetes and randomly assigned half to an intensive lifestyle intervention and half to diabetes support and education. The intensive lifestyle intervention group showed an average weight loss of 8.5%, which was significantly greater than the 0.6% seen with the diabetes support and education group. More importantly, by year 8, the lifestyle intervention group had maintained an average weight loss of 4.7% compared to 2.1% of the diabetes support group. Nearly 25% of the lifestyle participants were able to maintain a loss of $\geq 10\%$ of initial weight at year 4 and fully 46% maintained a loss of $\geq 5\%$, an amount widely agreed to produce clinically significant improvements in cardiovascular disease risk factors. Furthermore, the lifestyle group demonstrated significantly greater improvements, including improved hemoglobin A1C levels, fitness, systolic blood pressure, HDL cholesterol levels, as well as other markers of cardiovascular health (Melchart, 2015, Wadden, 2012).

Weight loss in the Look AHEAD trial is among the largest reported at this length of follow-up for individuals in a randomized controlled trial who were treated by lifestyle intervention. Just like the DPP, the Look AHEAD trial was also an intense, multidisciplinary lifestyle intervention. During the first year, participants were provided a comprehensive intervention adapted from the DPP and was delivered to groups of 10-20 persons by experienced lifestyle counselors. During the first 6 months, participants had weekly in-person sessions either as a group or individually with an interventionist, consisting of a registered dietician, psychologist or exercise specialist all who followed detailed protocols. Interventionists were trained to tailor the behavioral intervention to the participants' cultural differences. They used elements of problem solving, motivational interviewing, self-regulation theory and relapse prevention.

This study used intensive meal replacements and structured meal plans and in addition to dietary interventions, they also focused on physical activity, usually consisting of brisk walking. After the initial six months, the focus of treatment shifted to maintaining the weight losses and high levels of physical activity. During months 7-12, participants continued to have monthly individual meetings with their interventionist but the number of group sessions was reduced slightly. After 12 months, participants had one on-site visit with their interventionist and one additional phone call or email between these visits. Several forms of group intervention were offered but not required.

During each of the first 4 years of the Look AHEAD trial, participants in the diabetes support group (placebo group) were invited to attend three one-hour group meetings that discussed diet, physical activity, and social support. Participants who desired more help in losing weight were told to speak with their own primary care providers, who were permitted to recommend whatever treatments they thought were appropriate. It is important to note that participants in the DSE (placebo) group received substantially more intervention than patients not enrolled in a structured program, so program results would be even more impressive if they could be compared to patients without any intervention at all.

Importantly, in the Look AHEAD trial, Unick et al demonstrated that weight loss in the first few weeks of an

intervention was predictive of longer-term weight loss success. Findings from their analysis showed that weight losses in the first two months of treatment were strongly correlated with weight loss following the first year of an intensive lifestyle intervention. Even more interestingly, the amount of weight lost during the second month of the program was a stronger predictor of long-term success than month one. In addition to initial weight loss, weight loss in the first year of treatment was strongly related to weight change at year 4. Very few individuals who lost less than 3% at months 1 and 2 went on to achieve clinically significant weight loss at year 1 (Unick, 2014).

Retrospective analysis of the Look AHEAD participants demonstrated that those patients that were able to maintain 10% weight loss had significantly more treatment contacts during years 2-4 than did participants who maintained a loss of less than 5% or who gained weight. At year 4, successful maintainers in the Look AHEAD trial appeared to have taken greater advantage of the treatment sessions provided in addition to displaying improved eating and activity behaviors. Data from other studies has shown that group sessions delivered twice a month for 1 year after the weight loss phase, keeping patients in active treatment, helps patients maintain weight loss. An extended care model of treatment provides patients with the support and motivation needed to continue to practice weight control behaviors.

A program at Harvard called “**Why WAIT**” helped 450 people with type 2 diabetes to lose an average of 24 pounds and to keep most of it off three years later. Participants improved their disease profile enough that 70% were able to reduce their medicine, and 21% of those taking insulin were able to stop. Annual total health care savings were calculated at \$1,619 per patient, with \$996 saved on diabetes-only care. “Why WAIT” takes a comprehensive approach, providing nutritional counseling, an exercise program, and counseling to help patients modify behavior. Why WAIT also adjusted medications to emphasize drugs that either don’t encourage weight gain or that promote weight loss (Hamdy, 2008).

Bischoff et al studied a large group of patients in Germany that underwent a defined multidisciplinary non-surgical weight loss program. In addition to an intense 6-month program, the program also included additional weight loss maintenance training for 6 months. This maintenance phase focused primarily on weight regain prevention and improvement of long-term success rates. The program was based upon four modules (psychology, medicine, dietetics and exercise), imparted by a team of trained qualified health professionals such as psychologists, medical doctors, dieticians / nutritionists and physical therapists. During the program, closed groups of 8-15 people met weekly for about 3.5 hours per session. Although data from the study demonstrated statistically significant weight loss, it suffered from a high attrition rate similar to commercial weight loss programs. Of the 8296 recruited participants, 3446 (42%) terminated the program before 52 weeks. The high dropout rate was likely due to a very low calorie diet that was not considered sustainable. However, of the participants that stayed on the program, 82.1% of the completers successfully reduced their initial body weight by 10% or more. The reduction in waist circumference was also highly significant. In a subgroup of 301 of the subjects, data on body weight beyond the intervention period of 1 year could be obtained and analyzed for up to 3 years. The baseline parameters of these patients matched the overall study population during the 1-year intervention program, suggesting that this data could be reasonably well extrapolated to the remainder of the participants. The data showed that even 3 years after the start of intervention, the extent of weight loss remained statistically significant, despite a relative weight gain of 15.1%. The mean weight loss after 3 years was 13 lbs; a relative weight loss of 4.2% of initial body weight (Bischoff, 2011).

All of these programs provide statistically significant data demonstrating that an effective long-term weight

reduction and maintenance program is possible. A common theme throughout is that success relies on an integrated, multidisciplinary approach that combines changes in nutrition, increased physical activity, and individual behavior modification. Success also heavily depends upon an intensive, long-term weight management program.

Few studies have examined the long-term effects of behavioral weight loss programs in people with severe (grade III) obesity, but of those that have differentiated this very high-risk group, the results are promising. The Louisiana Obese Subjects Study (LOSS) was a 2-year, randomized clinical trial that assessed whether primary care physicians could effectively implement a lifestyle weight loss program in patients with severe obesity. Individuals who completed this intensive program achieved a 13.1% weight loss at 1 year and regained approximately ¼ of the lost weight by year 2, despite continued monthly group meetings and the use of prescription weight loss medications. Unick et al set out to examine the effects of an intensive lifestyle intervention on body weight and cardiovascular disease risk factors in individuals with severe obesity over a 4-year period. Although weight regain occurred between year 1 and 4 in each BMI group, participants with severe obesity regained a smaller percentage of their lost weight (40.7%) than those with overweight, grade I, or grade II obesity (56.5%, 46.7%, and 47.5%, respectively) (Unick, 2013).

Multiple analyses have concluded that an extended care approach, with monthly or more frequent contacts, in person or via telephone or internet, improves successful weight loss. It also reduces the risk of weight regain during the maintenance phase. The 2013 obesity treatment guidelines published by the American Heart Association / American College of Cardiology / The Obesity Society sets a standard of at least 14 visits over a period of 6 months, using individual or group counseling. Patients typically must use a combination of programming (group classes, one-on-one office or telephone visits with providers, and online programs) to meet high-intensity standards. To be successful, these are all to be offered without copays. Kaiser Permanente has a high-intensity lifestyle intervention that meets these standards. An additional Kaiser goal is that all physicians with a specialty weight management practice are certified by the American Board of Obesity Medicine (Kaiser, 2015).

However, as mentioned earlier, intensive lifestyle interventions that extend for a year or more are time-consuming and expensive to administer. In order to make programs more cost-effective, multiple attempts have been made to create technology-based interventions using the Internet, mobile phones, computer programs, telemedicine, and/or SMS messaging in various functions and frequencies. Unfortunately, these types of programs have had limited efficacy, with 7 of 15 studies showing no significant changes in body weight. The **STOP Regain** trial demonstrated that a face-to-face program improved weight loss maintenance over a period of 18 months when compared to an internet-based program (Wing, 2006)

In a report released by the Milken Institute, researchers concluded that a technology-based intervention combined with an in-person intervention results in larger weight reductions compared with in-person interventions alone (Kubendran, 2017). Other recent research has supported the idea that integrating additional treatment components (such as interactive multimedia lessons, small financial incentives, and automated tailored feedback) demonstrates promise for improving the efficacy of behavioral weight management programs (Ross, 2016). Current evidence does not support the potential for technology to completely replace in-person interventions, however, it has the potential to improve results and lower costs when used in addition to typical lifestyle interventions, if the population has easy access to the technology platform (Kubendran, 2017)

MAINTENANCE OF WEIGHT LOSS:

Obesity is a chronic, relapsing disease and cannot be cured by 6 months of therapy, any more than type 2 diabetes or hypertension can be cured by such a brief intervention. Weight gain and regain is complex and involves a number of factors, including compensatory metabolic responses to weight loss that include reductions in resting energy expenditure and alterations in hormones regulating appetite and satiety. These factors explain why weight-loss interventions that focus on the traditional model of calorie restriction are rarely successful long-term. Adaptive responses to both energy restriction and weight loss are thought to be in place in order to protect humans against the adverse effects of starvation. However, they also create the biological pressure to return the body to its original weight (MacLean, 2015). Without taking into account the physiological reasons for weight gain and the metabolic consequences of excess weight, maintaining weight loss is a never ending, exhaustive process for most people. In order to counteract these biological responses to weight loss, multiple therapeutic interventions must be applied for an extended period of time, if not indefinitely.

In the absence of follow-up care, individuals typically regain an average of 1/3 of their lost weight in the year following treatment with return to baseline weight frequently observed in 5 years (Van Dorsten, 2008). However, it has also been demonstrated that maintenance of weight loss gets easier over time; after individuals have successfully maintained their weight loss for 2-5 years, the chance of long-term success greatly increases (Wing, 2005).

Participation in lifestyle based, weight-maintenance sessions following acute weight loss is the most reliable method of facilitating long-term weight control. Continued patient-provider contact is associated with improved maintenance of lost weight. In one study, it was shown that Individuals who attend group maintenance sessions every 2 weeks during the first year after weight reduction maintained almost all of their original weight loss, whereas study participants assigned to a control group regained almost half by the end of the year (Wadden, 2011). In a separate study, Wing et al showed that monthly patient-provider contact, whether in person or via the Internet, similarly improved the maintenance of a previous loss (Wing, 2014). Van Dorsten concluded that long-term contact with treatment providers has widely been identified as an important factor in facilitating weight maintenance (Van Dorsten, 2008). Maintenance sessions seem to provide many patients with the support they need to continue to practice weight control behaviors.

Strategies for weight loss maintenance differ from strategies for initial weight loss. Several psychological variables are related to weight regain during maintenance including depressive symptoms, dietary hunger, and disinhibition (Wing, 2014). Several psychosocial factors have been associated with successful weight loss maintenance in long term observational and randomized studies. A few pertain to the behavioral area, a few to the cognitive component and a few to personality traits and patient-therapist interaction. People that are successful at weight maintenance have higher physical health-related quality of life, lower eating disinhibition and perceived hunger, and higher exercise enjoyment and perceived competence. Older adults whose primary motivation for weight loss is improving health are more compliant in continuous care (Montesi, 2016).

Behavioral fatigue plays a big part in weight regain for many people. Patients eventually tire of attending treatment sessions and drop out. Reasons for attrition are not fully understood but are likely to be associated with several factors. The first is that patients perceive the cost of adherence gradually exceeds the perceived benefits. Initially, the positive consequences of weight loss (e.g., sense of accomplishment; better fit of clothes) outweigh the cognitive and physical effort needed to lose weight. Later, when the goal is to maintain lost weight,

the positive feedback is less compared to the effort required to keep adhering to the same regimen. Thus, the benefits no longer seem to justify the costs (MacLean, 2015).

Individuals who set out to lose weight often have unrealistic expectations. Most patients who receive lifestyle modification or pharmacotherapy cannot lose more than 15 - 20% of their initial weight, even if treated continuously for more than 2 years. However, most people set a weight loss goal of more than 25% of their initial weight, despite efforts to convince them otherwise. Expected weight loss plateaus are frustrating to patients, many of whom continue to have excess weight despite substantial weight loss.

Another factor associated with attrition from therapy is complaints that treatment is monotonous and sometimes demoralizing. Patients often feel that they do not acquire new information or skills after the first 6-12 months of therapy. In addition, weight maintenance sessions give greater attention to individuals that suffer lapses and regain weight than to people that are successful (Wadden, 2004).

Ultimately, we must tackle what can be referred to as a “toxic environment” that explicitly encourages the consumption of super-sized servings of highly processed foods that are positively associated with metabolic syndrome and weight gain. People are confronted daily by an environment that explicitly encourages them to consume a poor diet. This same environment discourages physical activity as a result of sedentary work and leisure habits. For many, weight regain appears to be a nearly inevitable response to this environment. Changing this environment is going to take widespread changes both at the individual level as well as the community level.

The **National Weight Control Registry (NWCR)** was established in 1993 to identify and study people that are successful at weight loss and maintenance. Data from this registry is used to gather strategies successful at achieving and maintaining weight loss. Eligibility criteria for the NWCR includes ≥ 30 lbs weight loss maintained for ≥ 1 year. The NWCR continues to accrue individuals and currently has over 10,000 members. Analysis of the 3284 individuals who enrolled between 1993-2000 (available for 10 year follow-up) and using a 10% weight loss as the criterion of success, 88% were estimated to be still successful at year 5 and 87% at year 10. Not surprisingly, data from the NWCR clearly demonstrates that those individuals with larger initial weight losses maintained larger weight losses throughout the entire follow-up period. The study also provides important data on the trajectory of weight change. Regain was shown to be fastest in the early years of follow-up with decreasing rates over each of the first 5 years, followed by relatively stable maintenance over the subsequent 5 years, confirming that weight-loss maintenance becomes less effortful over time (Thomas, 2014).

Over the past 15 years, researchers have identified common behaviors and strategies used by these successful NWCR individuals. These include: consuming a healthy diet, engaging in high levels of physical activity (about an hour per day), consistent self-monitoring of body weight, eating breakfast regularly, and maintaining a consistent eating pattern across weekdays and weekends. Continued adherence to each of these behaviors seems to improve long-term outcomes in these participants (Thomas, 2014). With the exception of high dietary restraint and low levels of disinhibition, participants in the NWCR do not show higher levels of psychological symptoms (depression, emotional distress, binge eating and self-induced vomiting) than observed in the general population. Interestingly, successful NWCR individuals have a high rate of medical triggers that they report to have sparked their motivation to lose weight (i.e., a physician promoting weight loss for medical reasons and/or having a family member with a heart attack) (Monesi, 2016).

Ogden et al has attempted to identify unique clusters of individuals within the NWCR that have distinct

experiences, strategies and attitudes with respect to weight loss and weight loss maintenance. Cluster 1 is identified as the “typical” NWCR participant and encompasses 50.5% of the participants. These members can be described as weight-stable, healthy, exercise-conscious individuals. On average, these individuals have been maintaining a weight loss of at least 30 lbs below lifetime maximum weight for an average of 5.8 years. At entry into this registry, this group had a BMI average of 23.4, reduced from a maximum lifetime BMI of 33.5. The majority (56.1%) report losing weight on their own without the help of any specific program or contact with a healthcare professional and 94.5% report having modified their physical activity to accomplish their successful weight loss. Following an exercise routine is rated extremely important by this cluster for maintaining weight loss. In addition to exercise, the most commonly reported strategies for maintaining or losing weight during the year before registry entry include keeping many healthy foods in the house (96.6%), and weighing on a regular basis (85.5%). These individuals are the most satisfied with their current weight and report low levels of depression and stress (Ogden, 2012).

Cluster 2 is identified as the “struggling” NWCR participants and consists of 26.9% of participants. These individuals struggle the most with their weight, are more likely to weight cycle, require more effort to lose and maintain weight, and have poorer overall health compared to other NWCR members. This group has the highest maximum lifetime BMI (44.7) as well as the highest BMI (28.6) at entry into the registry. This cluster is also trying to maintain the greatest weight loss, an average of 100.5 lbs. below maximum weight. The members of this cluster are much more likely to have been overweight during childhood and adolescence compared to other clusters. Despite being the youngest group, this cluster was the least healthy of the four clusters before successful weight loss. The members of this cluster are least likely to report losing weight on their own (38%) and they utilize all professional resources more than the other clusters, such as commercial weight loss programs (30.6%), physicians (21.8%), and self-help groups (19.4%). This group is also most likely to report using prescription weight loss medications and diet pills, surgical procedures, diet programs from books or magazines and hypnosis for their successful weight loss. Compared to other clusters, this cluster is least satisfied with their weight loss, is most depressed, and least able to cope with stress (Ogden, 2012).

Cluster 3 participants are those with “immediate and long-term success” and comprise approximately 12.7% of NWCR participants. The distinguishing characteristic of the third cluster is that 94.8% of them had no previous weight loss attempts before their successful attempt. At entry into the registry, this group had an average BMI of 25.3 but also had the lowest maximum lifetime BMI of 32. This is the most weight-stable group (79%) and members of this cluster are least likely to have been overweight as children or adolescents. This group has the highest proportion of males (41.6%) and an average age of 51 years. The individuals belonging to this cluster have the highest education and are most likely to be married. This group is by far the most likely to report losing weight on their own and participants are less likely to report using other tools (consultation with a psychologist, counselor, join commercial weight loss programs, use self-help groups, prescription weight-loss medications) or strategies during loss or maintenance. Similar to cluster 1, the members of this cluster are satisfied with their current weight and have low levels of depression and stress (Ogden, 2012).

Cluster 4 participants are the “less physically active” individuals and compromise 9.9% of participants. This group is the oldest group with a mean age of 53.3 years and with a lower proportion of females (71.7%). The average BMI at registry entry was 26.1 and participants have a maximum lifetime BMI of 37.3. Except for cluster 2, this group is the least healthy. This group is more likely to utilize self-help groups, and more likely to consult with physicians, psychologists or counselors. Only 45.8% report modifying physical activity for weight loss and the importance of currently following an exercise routine was rated extremely low by this cluster of individuals. This

group reports eating fewer meals per day than the other clusters, but consumes a higher proportion of calories from fat and lower proportion of calories from carbohydrates (Ogden, 2012).

The diversity among NWCR participants as well as the variability among non-participants demonstrates that weight loss maintenance is not a “one size fits all” strategy.

THE IMPORTANCE OF A PROGRAM LED BY PHYSICIANS:

Lifestyle modifications, including nutritional interventions, physical activity interventions and behavioral therapy form the basis of most successful large-scale obesity treatment programs to date. However, as scientists have uncovered more about the physiologic and biochemical factors contributing to and worsening the disease of obesity, there has been an increasing emphasis upon understanding and modifying the underlying processes contributing to weight gain. Thankfully, treatment is shifting away from blaming patients for lack of discipline and willpower. The medical field has begun creating interventions based upon these biochemical processes. Despite these changes, there is still a huge discrepancy between the number of patients needing treatment for their excess weight and available therapeutic options and medical professionals comfortable with treating obesity.

To address this treatment gap, several major medical centers have established weight management centers. Sadly, although most patients do not have access to these programs and participation is limited, we can learn from these programs. A majority of these programs are led by physicians with advanced training in the disease of obesity. Montesi et al aggregated data and highlighted the benefits of a lifestyle modification-based approach for the management of obesity, featuring an obesity medicine physician as a pivotal member of the team – whose primary role is in engaging patients, team coordination and supervision, managing the complications associated with obesity and making decisions about drug treatment or bariatric surgery (Montesi, 2016).

The physician is often seen as the best source of health information for a patient and advice from such a healthcare provider can significantly increase patient motivation. The US Preventive Services Task Force recommended in 2003 that clinicians should screen all adult patients for obesity and offer intensive counseling and behavioral interventions to promote sustained weight loss for obese adults (USPSTF, 2003). However, too often during routine medical visits (not visits specifically for weight management), the subjects of weight, nutrition, and physical activity are overlooked by the physician or brought up only as an afterthought, which can negatively affect the level of perceived importance the patient assigns to these topics (Blackburn, 2008). Many physicians are unaware of how to approach the subject of weight or they fear offending their patients through direct discussion about the topic.

Most physicians have very little training in weight management techniques and are often inadequately informed regarding appropriate therapeutic options for obesity; therefore, the advice most often given is to “eat less and move more” - advice that can often be detrimental to weight loss. It is unrealistic to expect primary care physicians to provide effective weight management for all of their patients who require it, unless greater resources are provided in their practices.

Obesity Medicine is defined as the field of medicine dedicated to the comprehensive care of patients with obesity. Obesity Medicine physicians are physicians with advanced training and certification by the American

Board of Obesity Medicine (ABOM). The American Board of Obesity Medicine was created by the Obesity Medicine Association and The Obesity Society in 2011 and as of 2020, has over 4,000 diplomats in the U.S. and Canada. The growth of this group is faster than any other sub-specialty in medicine. Board-certification distinguishes a physician as having achieved a higher level of understanding in obesity care by completing specialized education. After completing rigorous education requirements, physicians must then prepare for and pass a National Certification Board Examination. This requires competency in and a thorough understanding of the treatment of obesity as well as the genetic, biological, environmental, social, and behavioral factors that contribute to obesity. An ABOM physician is trained to employ evidence-based therapeutic interventions for patients affected by excess weight and recognize the need for a comprehensive approach that considers the multiple factors that contribute to obesity; including lifestyle, medical, pharmacological and surgical treatment options.

The field of Obesity Medicine is relatively new in terms of physician specialization, but it is growing rapidly as physicians recognize the need for and seek out advanced training in the field. In fact, prior to 2012, it was considered fraud by most payers to bill for services rendered primarily to treat obesity. Since then, ABOM members have advocated for and achieved recognition of obesity as a disease, and payers are starting to provide coverage for obesity medicine services.

Many Obesity Medicine physicians are practicing in academic institutions where they combine clinical practice with medical research. Because this type of practice is funded by grant money, reimbursement by third-party payors is typically not sought. In the past several years, a growing number of ABOM diplomates have begun practicing Obesity Medicine outside of academia. Community-based Obesity Medicine clinics have expanded access to treatment to a larger, more diverse population and have the potential to have a large impact on the health of local communities. However, insurance reimbursement for specialized obesity treatment remains scarce, so most of these clinics are operating as cash businesses, which inevitably limits access for those individuals without the disposable income to pay for it. As we transition health care from a fee-for-service model to a value-based care model, the role of Obesity Medicine physicians will inevitably change and these clinics will likely exist under the umbrella of larger Accountable Care Organizations. In fact, Kaiser has multiple clinics devoted to obesity medicine and has a goal that all physicians with a specialty weight management practice within their organization become certified by the American Board of Obesity Medicine.

Obesity Medicine physicians practicing independently and those supervising multidisciplinary lifestyle modification teams are tasked with managing the medical and psychosocial complications associated with obesity as well as referring the patients to other physicians and health professionals according to specific comorbidities. Obesity medicine physicians are responsible for monitoring the effects of treatment, both on lifestyle and on weight outcomes, and potentially adding adjunctive treatment with obesity drugs, residential rehabilitative treatment and any recommendations for bariatric surgery.

Prior to formation of the American Board of Obesity Medicine (ABOM) and recognition of Obesity Medicine as a medical specialty, treatment of obesity was traditionally performed by primary care physicians and was rarely founded upon evidence-based medicine. Medications were occasionally used to treat obesity, but since few of the medications had any long-term data about effectiveness or risk, they were used sporadically and/or used as a primary treatment for obesity rather than adjunctive to dietary counseling and lifestyle modification. Inevitably, most of these medications failed to achieve substantial weight loss and their use declined. Several were removed

from the market due to unfavorable risk/benefit ratios. During that time, obesity was attributed to a lack of willpower or personal responsibility. Taking medications to treat something that was essentially viewed as poor self-control was stigmatized. Weight-loss medications essentially fell out of favor for many years.

However, with the organization of a large number of physicians practicing evidence-based medicine for the treatment of obesity, combined with a plethora of new data regarding the biochemical pathways that contribute to obesity, interest in weight-loss medications has been renewed. In fact, weight-loss medications are recommended as an adjunct to lifestyle modification in patients unable to lose sufficient weight (approximately 10% of initial body weight) with diet and exercise alone. In fact, it is the position of the Obesity Medicine Association (OMA) that pharmacotherapy may be used for patients affected by obesity, but only in a comprehensive obesity management program that includes a thorough medical evaluation and support for lifestyle change (Vetter, 2010) The addition of weight-loss medications to lifestyle modification has been shown to increase weight loss over a year. Adding weight loss medications to lifestyle modification programs not only improves long-term weight loss, but also reduces the incidence of diabetes in the future (Montesi, 2016).

Since obesity is a chronic disease with a high risk of relapse when treatment is discontinued, treatments that are offered must be appropriate for chronic use. This applies for support visits, nutritional interventions, behavioral programs, exercise programs, medical care, anti-obesity medications, and even surgery. However, it is important to note that pharmacotherapy for the treatment of obesity should be prescribed only by licensed health care professionals qualified by training and experience to treat obesity as when these medications are prescribed alone, without a comprehensive treatment program, they rarely result in sustained weight loss. In those cases, the risks of treatment often outweigh the benefits.

Because most of the pharmacologic interventions are relatively new, there is very little data available regarding long-term weight loss maintenance with pharmacotherapy. To improve maintenance, in addition to permanent lifestyle changes, long-term drug treatment should be considered for those patients who have been unsuccessful with diet and exercise alone.

In February 2015, the Endocrine Society released clinical practice guidelines for the pharmacological management of obesity. The Endocrine Society voiced agreement with the opinions of prominent medical societies that current scientific evidence supports the view of obesity as a disease. They acknowledged that weight loss produces many benefits including risk factor improvement, prevention of disease, and improvements in feeling and function. They stated that modest weight loss (5-10% loss), such that produced by lifestyle modifications and medications, has been shown to produce significant improvements in many conditions. The Endocrine Society outlined many steps that clinicians should take in the clinical encounter with the patient suffering from overweight or obesity. These include:

- Annual and symptom-based screening for major chronic conditions associated with obesity in all adult patients with a BMI >30
- Timely adherence to national cancer screening guidelines with the understanding that individuals with obesity are at increased risk for many malignancies
- Identification of factors contributing to obesity
- Identification and appropriate screening for secondary causes of obesity
- Adherence to AHA/ACC/OTS guidelines for the management of overweight and obesity in adults
- Identification of medications that may contribute to weight gain

- Formulation of a treatment plan based on diet, exercise and behavior modification.

The Endocrine Society position statement was that drugs may amplify adherence to behavior change and may improve physical functioning such that increased physical activity is easier on those that cannot exercise initially. Patients who have a history of being unable to successfully lose and maintain weight and who meet label indications are considered candidates for weight loss medications. They make a powerful statement that *“if permanent weight loss could be achieved exclusively with behavioral reductions in food intake and increases in energy expenditure, medications for obesity would not be needed. Weight loss is difficult for most patients and the patients’ desire to restrict food and energy intake is counteracted by adaptive biological responses to weight loss. The fall in energy expenditure (out of proportion to reduction in body mass) and increase in appetite that are observed after weight loss are associated with changes in a range of hormones. Some of them represent adaptive responses to weight loss and result in altered physiology that promotes weight regain”* (Apovian, 2015).

Although the use of anti-obesity medications is helpful in achieving and sustaining clinically-significant weight loss, pharmacotherapy does not form the basis of successful obesity treatment. Regular follow-up by physicians and other members of the care team has been demonstrated to be strongly associated with patient compliance and long-term success. The more accountable patients are to weight loss programs, the better the outcomes that are expected. The AHA/ACC/TOS Guideline for the Management of Overweight and Obesity in Adults reviewed randomized clinical trials on weight loss interventions and determined that the best weight loss outcomes occur with frequent face-to-face visits; an average of 16 visits per year (Apovian, 2015). Studies have consistently shown that continued contact is important for maintaining weight loss (Teixeira, 2015). Maintenance of weight after the initial 6 months is crucial to long-term success and benefits. After weight stabilization following the first 6 months of treatment and after a careful evaluation, a physician may recommend that some individuals attempt additional weight loss to achieve desired health goals, but this is a complex decision requiring a close evaluation of the patient as a whole.

The importance of active physician involvement in the patients’ efforts to initiate and maintain a healthy body weight and healthy lifestyle practices cannot be overemphasized. However, engaged patients should also be managed by trained lifestyle counselors (dietitians, psychologists, physical activity supervisors) to implement both the weight loss phase and the long-term maintenance phase of the lifestyle modification. This multidisciplinary approach based on lifestyle modification has the potential to address several obstacles to reach the optimum long-term management of obesity (Montesi, 2016).

THE BENEFITS OF A MULTIDISCIPLINARY TEAM:

Trained Health Coaches: The primary role of the health coach is to provide regular, structured patient visits designed to provide the mental preparation and structure to help patients manage obstacles and identify and achieve their goals (Blackburn, 2008). Health coaches are often used to supplement treatment between medical visits. Coaches provide ongoing support, accountability, and information by providing behavior therapy. Behavior therapy teaches patients how to achieve their eating and exercise goals by methods such as keeping records of their physical activity and food intake or modifying cues that elicit unwanted eating (e.g., the sight of food on the counter). In a traditional behavior therapy model, patients receive treatment sessions weekly for an initial 16-26 weeks. Interventionists often introduce a new topic at each session, but the majority of time is devoted to

discussing methods to help participants adhere to their eating and activity regimens (Wadden, 2004). However, educational instruction alone has not been sufficient to induce clinically significant weight loss (Wadden, 2004). Trained health coaches often have a background in nursing or dietetics, although this is not required. Physicians that are board-certified in obesity medicine have extensive training in the field of nutrition as it relates to weight loss and type II diabetes. An obesity medicine physician can often oversee or administer nutrition education for most patients. However, having access to registered dietitians can be beneficial for patients that have more complex nutritional issues.

Effective health coaching can occur in person, via the internet or over the phone. In a randomized controlled study, Leahey and Wing studied the efficacy of three types of health coaches. Participants with a professional coach lost an average of 9.6% of their weight compared with 9.1% for peer coaches and 5.7% for mentor coaches (Leahey, 2013).

Psychologists/Therapists: Many people participating in weight loss programs are nervous and afraid and have been unsuccessful with weight loss in the past, despite having expended tremendous efforts. This can create significant obstacles to success and promote resistance to change. Commercial weight loss programs, based mainly on the principles of behavioral therapy, typically neglect cognitive therapies. Cognitive behavioral therapy (CBT) for obesity is founded upon the premise that the manner in which a person thinks about themselves or a given event impacts how they will emotionally and behaviorally respond to the event. Cognitive approaches to weight loss focus on identifying thought patterns that affect eating and then modifying thoughts or self-perceptions (Van Dorsten, 2008). CBT incorporates skills of self-monitoring, stimulus control and cognitive restructuring. Self-monitoring helps participants become aware of any patterns to their intake. Stimulus control techniques help patients manage cues or triggers associated with eating. Cognitive restructuring teaches participants how to identify and challenge problem thinking patterns (Vetter, 2010). Shaw et al reported collective results for two studies testing psychological interventions for weight treatment and concluded that CBT, when added to diet and exercise interventions, produced superior weight losses than diet and exercise treatment alone. (Shaw, 2005). Since that time, multiple other studies have shown similar results. To be effective, CBT should be provided by a practitioner with extensive training in the field of clinical psychology.

In addition to addressing crucial cognitive behavioral issues such as motivation, self-efficacy and self-monitoring, it is increasingly being recognized that patients that suffer from obesity often struggle with food addictions and binge eating disorder (BED) (Gearhardt, 2011). Binge eating disorder is a severe, treatable eating disorder and is the most common eating disorder in the United States. About 3.5 percent of adult women and 2 percent of adult men have binge eating disorder (NIDDK/NIH, 2017). Cognitive Behavioral Therapy is the best-established treatment for binge eating disorder and to be effective, should only be administered by someone with advanced training in the field of CBT.

For most people, effective weight loss and maintenance of weight loss requires significant shifts in thinking, reasoning and motivation. Repeatedly addressing these issues throughout the process is crucial to success, as is individualized treatment for those patients with more complex issues.

Physical Therapists: To maintain weight loss, individuals must adhere to behaviors that counteract physiological adaptations favoring weight regain. Physical activity has very little effects on weight during the initial loss period, but becomes essential once patients transition to maintenance of weight loss. Both volitional and regimented exercise attenuate weight regain after weight loss and counter the biological factors that promote weight regain

(MacLean, 2015). Data from case studies, correlational investigations, and randomized trials all have concluded that high levels of physical activity facilitate long-term weight loss maintenance. According to the National Weight Control Registry (NWCR), 90% of its participants use regular physical activity as a strategy to maintain their weight loss (Ogden, 2012, Thomas, 2014).

There are two ways that patients can increase their energy expenditure – structured exercise or non-exercise activity thermogenesis (NEAT). Structured exercise (walking, hiking, biking, etc.) is typically planned and completed in a discrete period of time at a moderate or high-intensity level. NEAT, by contrast, involves increasing energy expenditure while completing everyday tasks. There is a trend (especially among children) for NEAT to be associated with less weight regain than structured exercise after treatment, which suggests that NEAT should be practiced by all patients that struggle with excess weight (Venditti, 2014).

Regardless of its effects on active weight loss, physical activity is critical for improving cardiovascular disease risk factors in individuals with obesity (Vetter, 2010) and an effective treatment plan for people with obesity and other comorbidities should include a physical activity component. Multiple studies have shown that cardiorespiratory fitness helps counteract the increased mortality associated with obesity. In addition to addressing daily lifestyle activities (NEAT), a treatment plan should address cardiovascular fitness and strength (resistance) training. For the majority of adults with overweight and obese, walking is recommended as the safest, most convenient, and most effective aerobic activity. When osteoarthritis or other joint conditions are a factor, other comparable low-impact choices can be considered. However, when dealing with patients with obesity, who are often at high risk of injury, a provider trained in physical fitness and injury prevention must consider the safety and accessibility of the activity. Physical therapists are highly qualified to provide instruction in physical activity with a focus on safety and injury prevention.

CONCLUSION:

There is no doubt that obesity and obesity-related complications take a huge toll on population health and well-being. Without a strong and sustained reduction in obesity prevalence, the disease of obesity will continue to impose major costs on the health system. Although health reform is necessary to address health inequities and rein in rising health spending, real savings are likely to be achieved through reforms that reduce the prevalence of obesity and related risk factors. There is no magic bullet or no single tactic to address the obesity epidemic. Multiple factors are responsible for its rise; consequently, effective treatment will require a comprehensive assessment aimed at developing a multidimensional and individualized treatment which is best managed by a multidisciplinary team led by a physician with advanced training in obesity.

Employers, medical providers, insurers, biopharmaceutical firms, the food and beverage industry, governments, and communities need to begin to work together—and the individuals affected by excess weight need the most current, evidence-based treatment to manage their disease. By its nature, obesity is not a permanent affliction, and therein lies an opportunity to improve public health and economic conditions. On an individual scale, weight loss even as small reductions is associated with multiple health benefits, and on a population scale, these incremental changes could result in significant economic improvements.

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