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MANAGED CARE MEDICINE

GBI Reports

Supplement

**Rethinking Pharmacy Benefit
Design to Reduce the Burden
of the Healthcare System**

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RETHINKING PHARMACY BENEFIT DESIGN TO REDUCE THE BURDEN OF THE HEALTHCARE SYSTEM

This special edition of the *Journal of Managed Care Medicine* was developed from the proceedings of the symposium, "Rethinking Pharmacy Benefit Design to Reduce the Burden of the Healthcare System: The Role of Pharmaceuticals in Reducing Cardiometabolic Risk Factors," held Oct. 14, 2005, in Phoenix, Ariz.

Target Audience

This is intended for corporate medical directors, employee benefit managers, health plan medical directors, benefit design experts, occupational health nurses, and other managed care health professionals.

Needs Assessment

Cardiovascular disease, the number one killer of people in the United States, is associated with more than \$400 billion in direct and indirect costs. As costs escalate, employers and health plans must reevaluate their approach to health benefit design. Innovative health benefit design strategies must be developed and applied to therapeutic areas responsible for the greatest impact on healthcare expenditures and employee productivity.

Learning Objectives

After reading this monograph, participants will be able to:

- Discuss the benefits of improving cardiometabolic health and preventing metabolic syndrome
- Describe strategies to reduce cardiovascular risk through the identification and mitigation of cardiometabolic risk factors
- Review data regarding the beneficial effects of early intervention on cardiometabolic risk
- Explain the value of pharmaceutical interventions in optimizing clinical and economic outcomes associated with improved cardiometabolic health
- Describe how current structures of benefit design plans impede appropriate management of cardiometabolic disorders
- Discuss innovative approaches to benefit design and human capital management that enhance quality of care, improve metabolic health, reduce healthcare expenditures, and increase employee productivity.

Accreditation

This activity has been planned and implemented in accordance with the Essential Areas and Policies of the Accreditation Council for Continuing Medical Education (ACCME) through the joint sponsorship of the National Association of Managed Care Physicians (NAMCP) and Managed Market Resources (MMR). The NAMCP is accredited by the ACCME to provide continuing medical education to physicians.

Rethinking Pharmacy Benefit Design to Reduce the Burden of the Healthcare System: The Role of Pharmaceuticals in Reducing Cardiometabolic Risk Factors

ABOUT \$1.8 TRILLION IS spent yearly on the healthcare system, which is approximately 15.3 percent of the gross domestic product (GDP).¹ By 2013, healthcare spending is projected to double to \$3.6 trillion and increase to about 18.7 percent of the GDP.¹ This is in comparison to other countries around the world that are spending 7 to 11 percent of GDP.

The traditional model for providing healthcare in the United States is to focus on disease status rather than health status, treatment rather than prevention, an individual medical model rather than a population-based health model, and single rather than multiple risk interventions, with segregated rather than integrated management systems.² Currently, the system is oriented to a curative model. Little money is being spent on prevention, yet 75 percent of spending is diverted toward treatment of chronic illnesses, many of which are preventable.

There are 125 million Americans who have one or more chronic illnesses. Two major cost drivers in chronic illness are type 2 diabetes and excess weight (obesity). More

than 20 million Americans have type 2 diabetes.³ Total costs of treating type 2 diabetes are estimated at \$135 billion annually. Forty-one million Americans are pre-diabetic and at significant risk for developing type 2 diabetes.³ A change must be made to prevent these 41 million Americans from progressing to type 2 diabetes and overloading the healthcare system. Overweight and obesity, which has a direct impact on the development of pre-diabetes, type 2 diabetes, and metabolic syndrome, are other significant drivers of chronic illness and healthcare costs.

Seven out of 10 deaths in 2004 could have been prevented by lifestyle changes. The National Institutes of Health (NIH) Diabetes Prevention Program study showed that walking 30 minutes a day and losing 5 to 10 percent of starting body weight reduced the incidence of type 2 diabetes by 60 percent.⁴

The healthcare system needs to be reoriented to prevention and wellness in order to improve Americans' health status.⁵ According to the World Health Organization's definition of health, a healthy workforce is characterized by four key attributes to achieve optimal performance. Individuals and organizations must be

- 1. Healthy:** demonstrating optimal health status as defined by positive health behaviors, minimal modifiable risk factors, and minimal illnesses, diseases, and injuries
- 2. Productive:** functioning to produce the maximum contribution to achievement of personal goals and the organizational mission
- 3. Ready:** possessing an ability to respond to changing demands given the increasing pace and unpredictable nature of work
- 4. Resilient:** adjusting to setbacks, increased demands, or unusual challenges, and returning to optimal "well-being" and performance without severe functional decrement.⁶

Cardiovascular Disease: Progress, Opportunities, and Challenges

More than 21 million Americans have coronary heart disease or a history of stroke.⁷ That number does not include the full range of cardiovascular disease cases such as peripheral vascular disease. Every year, almost 1 million Americans will have a first heart attack; another 700,000 will suffer strokes.

Cardiovascular disease is the leading cause of death in the U.S. (see Exhibit 1).⁸ More than 700,000 people die from coronary heart disease each year. The age-adjusted mortality rate among men has declined over the last decade but the rate among women has remained relatively stable.

The estimated total medical costs of cardiovascular disease exceed \$257 billion annually and is rising quickly.⁸ If disability insurance, life insurance, work absenteeism, and decreased productivity are included, this estimate is more than \$400 billion.

Atherosclerosis is the underlying culprit behind heart disease, strokes, peripheral vascular disease, and dementia. Risk factors for developing cardiovascular disease and the other long-term consequences of atherosclerosis include those that cannot be changed (age, gender, and family history) and those that can be ameliorated. Modifiable risk factors—dyslipidemias, hypertension, diabetes, and pre-diabetes—are treatable with lifestyle changes and medical therapy. Behavioral or lifestyle risk factors (smoking, lack of physical activity, and excess weight) are also treatable.

Interaction occurs between many of the cardiovascular risk factors. For example, if a patient has both hypertension and dyslipidemia, heart disease mortality increases dramatically more than when only one disease is present. There is also interplay when the risk factors are treated. For example, a 50-year-old

Designation Statement

The National Association of Managed Care Physicians (NAMCP) is accredited by the Accreditation Council for Continuing Medical Education to sponsor continuing medical education for physicians. NAMCP designates this activity for a maximum of 1 *AMA PRA Category 1 Credit™*. Physicians should only claim credit commensurate with

the extent of their participation in the activity.

To receive CME credits, read the entire monograph and answer the post-test questions. An answer sheet is available online at www.namcp.org/cmeonline.htm.

The release date of this activity is March 15, 2006. This activity is valid through Dec. 31, 2006.

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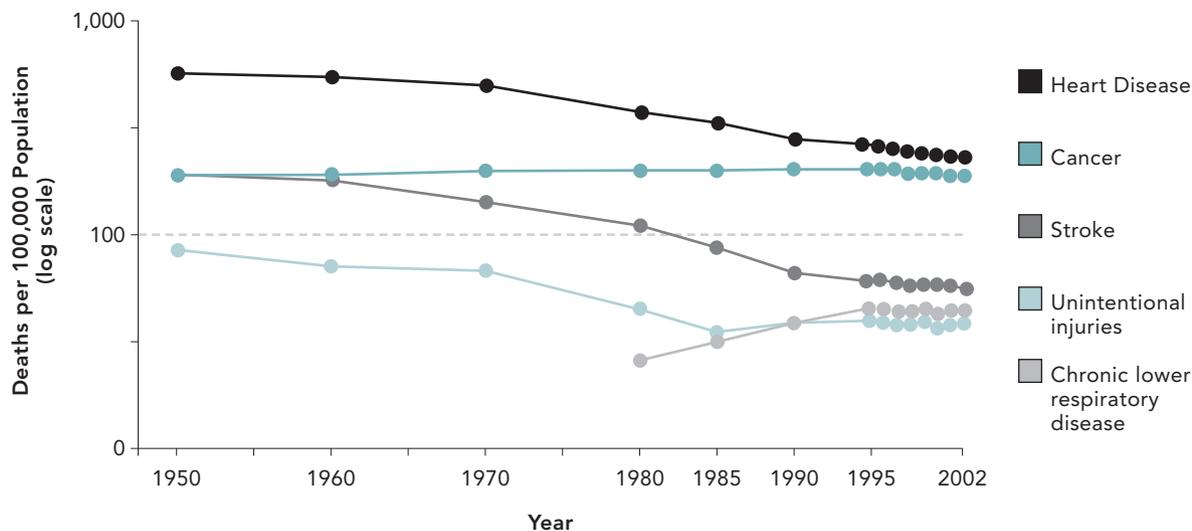
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Exhibit 1: CVD Remains Leading Cause of Death in the U.S.⁸

Death Rates for Leading Causes of Death for All Ages (U.S., 1950-2002)



man with elevated blood pressure and high cholesterol has a 40 percent reduction in cardiovascular events by lowering blood pressure. If his cholesterol is reduced, his chance of a coronary event is reduced by 32 percent.

If both blood pressure and cholesterol are reduced, risk is reduced by 59 percent (see Exhibit 2).⁹

A significant public health issue related to the development of cardiovascular disease is the prevalence

of overweight and obesity in the United States. Obesity is an independent risk factor for the development of hypertension, coronary heart disease, and type 2 diabetes (see Exhibit 3).¹⁰ Overweight and

Exhibit 2: Cholesterol and Blood Pressure Lowering—Population Impact, Alone and in Combination

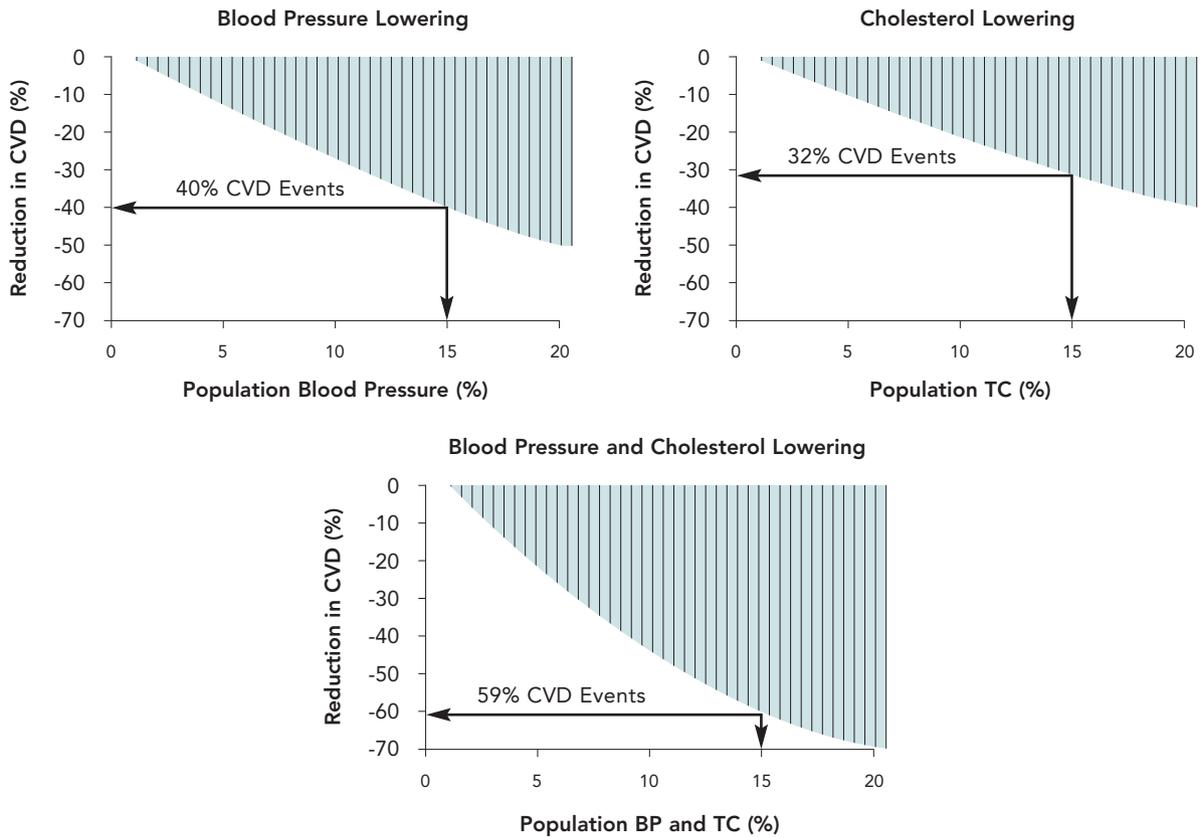
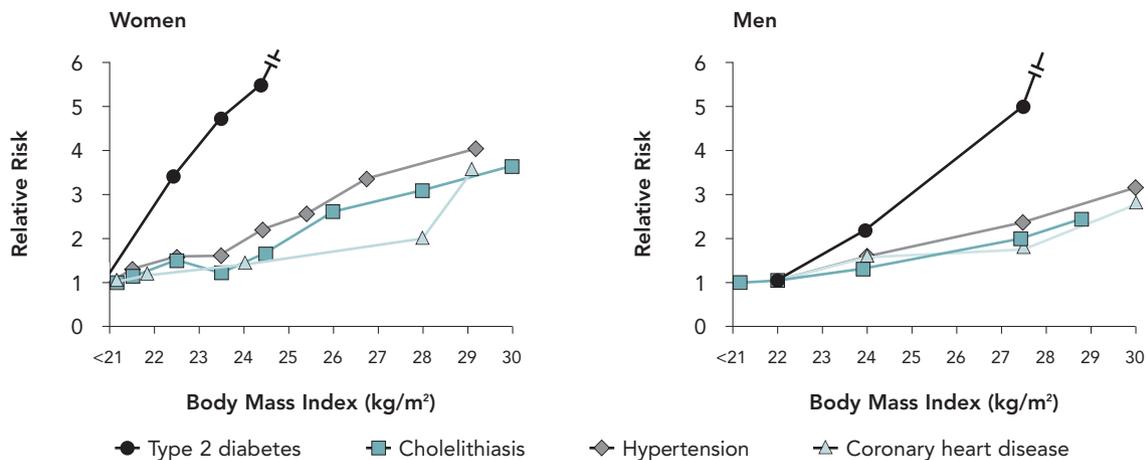


Exhibit 3: BMI and Comorbidities¹⁰



obesity are defined by one's body mass index (BMI, weight in kg divided by height in meters squared). The National Heart Lung Blood Institute (NHLBI) defines overweight as a BMI between 25 and 29.9 kg/m².¹¹ Obesity is present when BMI is greater than 30 kg/m².

In 1960, only 13 percent of adult Americans were considered obese. In 2000, more than 30 percent of U.S. adults were obese and more than 60 percent were overweight.¹² Of greater concern is the prevalence of weight issues among U.S. children and adolescents. During the past 40 years, the rate of overweight children and adolescents (age 6 to 19) has increased fourfold.¹³ The youth of today are getting a head start on

developing cardiovascular disease.

The location of fat accumulation in the body is critical to evaluating the risk of developing diseases related to weight. Accumulation of fat around the abdomen, as assessed by an increased waist circumference, is a risk factor for developing cardiovascular events (see Exhibit 4) and type 2 diabetes (see Exhibit 5).^{14,15} The most critical fat to monitor is visceral fat, which is defined as intra-abdominal fat bound by the parietal peritoneum or transversalis fascia. Visceral fat is more metabolically active than subcutaneous fat, has greater endocrine activity, and has a greater adverse effect on metabolism and cardiovascular risk.¹⁶ Excess visceral fat can lead to the

development of insulin resistance, type 2 diabetes, and metabolic syndrome. Subcutaneous fat is located superficial to the abdominal and back muscles. Subcutaneous fat does not affect metabolic and cardiac risk to the same degree as visceral fat.

Cardiometabolic risk is a cluster of modifiable risk factors predisposing individuals to cardiovascular and metabolic disease (type 2 diabetes). These risk factors include elevated blood pressure, smoking, elevated triglycerides, low high-density lipoprotein cholesterol (HDL-C), elevated low-density lipoprotein cholesterol (LDL-C), abdominal obesity (increased waist circumference), inflammation, insulin resistance, and elevated blood

Exhibit 4: Waist Circumference and CV Events¹⁵

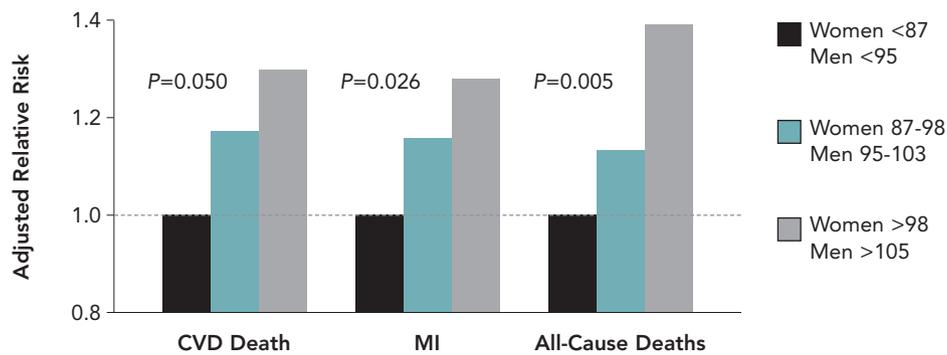
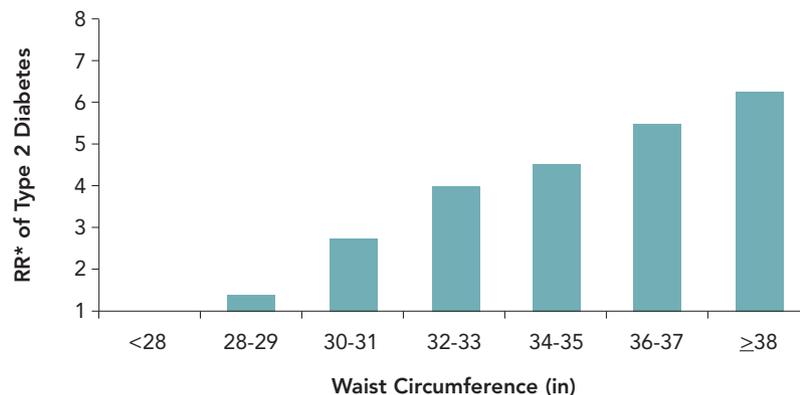


Exhibit 5: Type 2 Diabetes and Waist Circumference—Nurses' Health Study¹⁴



*Controlled for age, family history of diabetes, exercise, smoking, saturated fat intake, calcium, potassium, magnesium, and glycemic index.

glucose (see Exhibit 6). A patient has metabolic syndrome if at least three of the risk factors in Exhibit 7 are present.^{17,18} Today, one of every four Americans meets the criteria for metabolic syndrome, which puts them at a significantly increased risk of having a coronary event (see Exhibit 8).¹⁹ Metabolic

syndrome increases the risk of heart attack by about fourfold, and stroke by two- to threefold.²⁰

Contemporary Strategies for Managing Cardiometabolic Risk Factors

Currently, each cardiovascular risk factor in a patient with metabolic

syndrome tends to be treated in isolation (see Exhibit 9). To effectively counter this syndrome, all risk factors need to be treated as a group, and the patient as a whole. This means seeking treatments that act on more than one of the risk factors. For example, a beneficial medication might be one that

Exhibit 6: Cardiovascular Dysmetabolic Syndrome

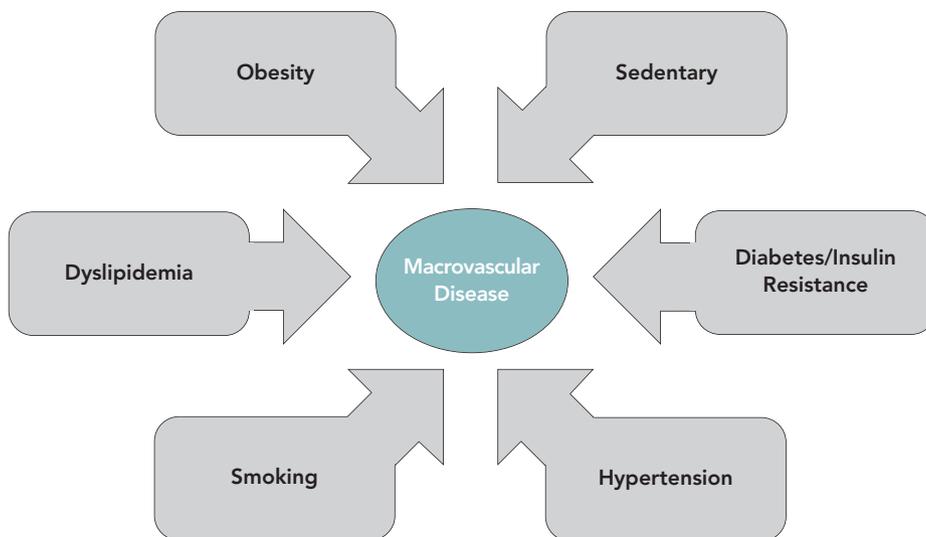


Exhibit 7: Diagnostic Criteria for Metabolic Syndrome^{17,18}

Measure	Categorical Cut Points
Elevated waist circumference*	<ul style="list-style-type: none"> • ≥ 40 inches (102 cm) in men • ≥ 35 inches (88 cm) in women
Elevated triglycerides	<ul style="list-style-type: none"> • ≥ 150 mg/dl or • drug treatment for elevated TG
Reduced HDL-C	<ul style="list-style-type: none"> • < 40 mg/dl in men • < 50 mg/dl in women or drug treatment for reduced HDL-C
Elevated BP	<ul style="list-style-type: none"> • ≥ 130 mm Hg systolic BP or • ≥ 85 mm Hg diastolic BP or drug treatment for hypertension
Elevated fasting glucose**	<ul style="list-style-type: none"> • ≥ 100 mg/dl or drug treatment for elevated glucose

*35 inches (88 cm) for Asian American men, and 31 inches (80 cm) for Asian American women.

**Previously ≥ 126 mg/dL. Revised following an update of ADA guidelines for diagnosis of prediabetes.

reduces blood pressure, insulin resistance, and lipids.

Overall management of cardiometabolic risk factors should focus on

- identifying at-risk patients
- recommending weight loss through an appropriate diet
- designing and recommending an exercise plan
- encouraging behavior modification
- exploring pharmacotherapy options.¹⁷

As shown by the Diabetes Prevention Program, weight loss of 7 to 10 percent of initial body weight can reduce cardiometabolic risk factors and reduce the risk of developing type 2 diabetes.⁴ In

addition to weight loss through dietary changes, physical activity is important for helping people lose weight and keep it off. The Institute of Medicine recommends that all Americans get at least one hour of physical activity at least five days per week.²¹ A person wanting to lose weight may need to exercise up to two hours per day. Pedometers are a great way to encourage people to add additional activity to their day. Achieving a goal of 10,000 steps per day will help maintain a steady weight.

Currently, there are no FDA-approved agents specifically indicated for reducing risk related to metabolic

syndrome. Approved medications such as angiotensin converting enzyme inhibitors (ACEI) and HMG-CoA reductase inhibitors (statins) can reduce risk of developing cardiovascular disease once the patient has been diagnosed with hypertension or dyslipidemia. In a person with multiple cardiometabolic risk factors, it is important that risk factors be identified and treated before the development of significant disease. The remainder of this discussion focuses on agents that can facilitate weight loss (orlistat and sibutramine), reduce insulin resistance (exenatide and pramlintide), and improve many aspects of

Exhibit 8: Metabolic Syndrome—U.S. Adults Prevalence¹³

47 Million, or 23%, of U.S. Adults Have Metabolic Syndrome

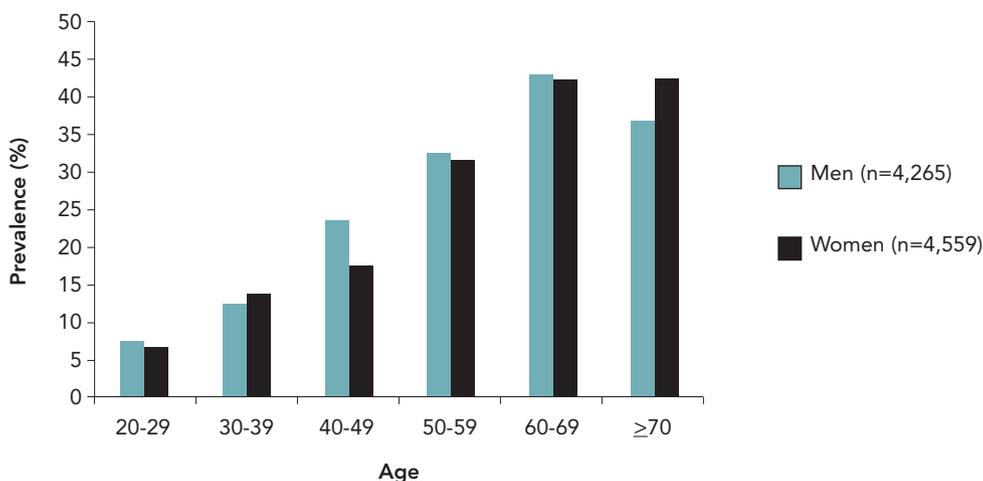


Exhibit 9: Current Therapies Often Address Individual Risk Factors



cardiometabolic risk (rimonabant).

The National Institute of Health/ National Heart Lung Blood Institute (NIH/NHLBI) obesity treatment guidelines include therapy recommendations (see Exhibit 10).¹¹ Weight loss through dietary changes, physical activity, and behavioral therapy are indicated for all patients, whether overweight or obese. Pharmacotherapy for weight loss is

indicated for overweight patients with a BMI between 27 and 29.9 kg/m², who have comorbidities such as hypertension, and for obese patients. Two FDA-approved antiobesity agents are sibutramine and orlistat. Sibutramine (Meridia®), a norepinephrine and serotonin-uptake inhibitor, causes moderate weight loss (10 to 15 pounds) over six months, but is also associated with

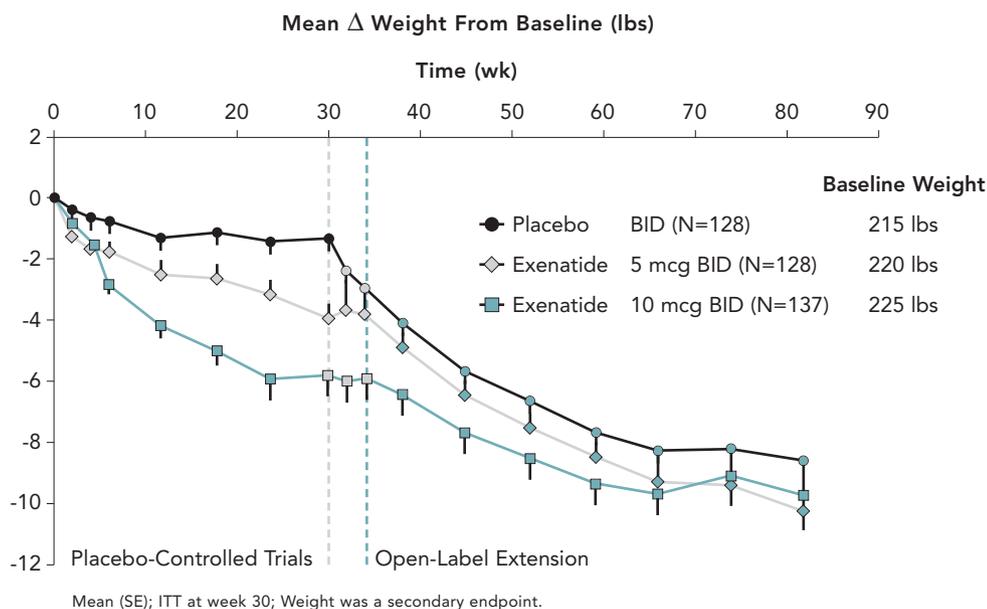
moderate increases in blood pressure and heart rate.²² Orlistat (Xenical®), which is a reversible lipase inhibitor, contributes to more weight loss (20 to 30 pounds over one year).²³ In the XENDOS study, orlistat combined with lifestyle changes reduced the risk of developing type 2 diabetes in overweight subjects with impaired glucose tolerance by 37 percent.²⁴ Because it is

Exhibit 10: A Guide to Selecting Treatment—NIH Guidelines¹¹

Treatment	BMI Category				
	25-26.9	27-29.9	30-34.9	35-39.9	≥40
Diet, physical activity, behavior therapy	Yes, with comorbidities	Yes, with comorbidities	Yes	Yes	Yes
Pharmacotherapy		Yes, with comorbidities	Yes	Yes	Yes
Weight-loss surgery				Yes, with comorbidities	Yes

*Yes alone indicates that the treatment is indicated regardless of the presence or absence of comorbidities. The solid arrow signifies the point at which therapy is initiated.

Exhibit 11: Open-Label Extension—Combined; Exenatide Continued to Reduce Weight²⁵



a fat-absorption blocker, orlistat treatment will reduce total cholesterol, triglycerides, and LDL-C.²³ Unfortunately, about 30 percent of patients will have fat malabsorption adverse effects. When therapy with either sibutramine or orlistat is discontinued, weight gain recurs.

Exenatide (Byetta[®]) is a new injectable antidiabetic agent approved for adjunct therapy for type 2 diabetes. It is an incretin mimetic agent that enhances glucose-dependent insulin secretion by the pancreatic beta-cell, suppresses inappropriately elevated glucagon secretion, and slows gastric emptying.²⁵ Most interestingly, weight loss over two years with this agent is significant at 8 to 12 pounds (see Exhibit 11). In humans and in animals, exenatide reduces food intake.²⁶

Pramlintide is another new injectable antidiabetic agent. It is a synthetic analogue of the pancreatic beta-cell hormone amylin, which has been shown to improve glycemic control and induce mild weight loss (see Exhibit 12).²⁷⁻²⁹ Like exenatide, pramlintide has been shown to reduce food intake, which may explain the weight loss seen in long-term trials with the agent.²⁹

There appear to be two major physiologic problems underlying obesity. One is excess food intake and the other is inefficient metabolism. Individuals with insulin resistance metabolize food differently than those without insulin resistance. The former is more likely to store excess energy in the form of fat.

Research has identified the endocannabinoid system as a novel regulator of both food intake and metabolism. Increased endocannabinoid system activity is associated with excessive food intake and subsequent accumulation of fat (see Exhibit 13).³¹ Cannabinoid receptors have two forms: CB₁, which are found throughout the brain, GI tract, liver, pancreas, and adipose tissues; and CB₂, which are found predominantly in immune cells. The CB₁ receptors are involved in food intake and metabolism.

Altering the activity of the endocannabinoid system, specifically via CB₁ receptor blockade, is a completely new paradigm of tackling obesity and treating cardiometabolic risk factors. The first agent to be studied to regulate the endocannabinoid system is rimonabant.

Four large multicenter, international trials involving more than 6,500 overweight or obese individuals have been conducted: RIO-Europe, RIO-North America (RIO-NA), RIO-Lipids, and RIO-Diabetes.³²⁻³⁶ These studies enrolled overweight or obese subjects who met the NIH/NHBLI criteria for pharmacologic treatment.¹¹ In each of these studies, subjects were placed on a moderate hypocaloric diet (600 calorie/day deficit) and orally received placebo, rimonabant 5 mg, or rimonabant 20 mg. The trials lasted for one to two years. Three trials have been published at this time, and results from the fourth trial has been presented at national medical meetings.³²⁻³⁶ Rimonabant is not yet FDA-approved.

Rimonabant appears to be an effective agent for promoting weight loss. In the RIO-Europe study, 20 mg/day study completers lost a mean of 18.9 pounds (8.6kg) and 3.4 inches (8.5cm) from their waist circumference over one year compared to a mean weight loss of 7.9 pounds (3.6kg) and a mean waist circumference reduction of 1.78 inches (4.5cm) in the placebo-treated group (see Exhibit 14).³² Also significant is the effect

Exhibit 12: Pramlintide Clinical Effects—Type 2 Diabetes Combined Pivots²⁷⁻²⁹

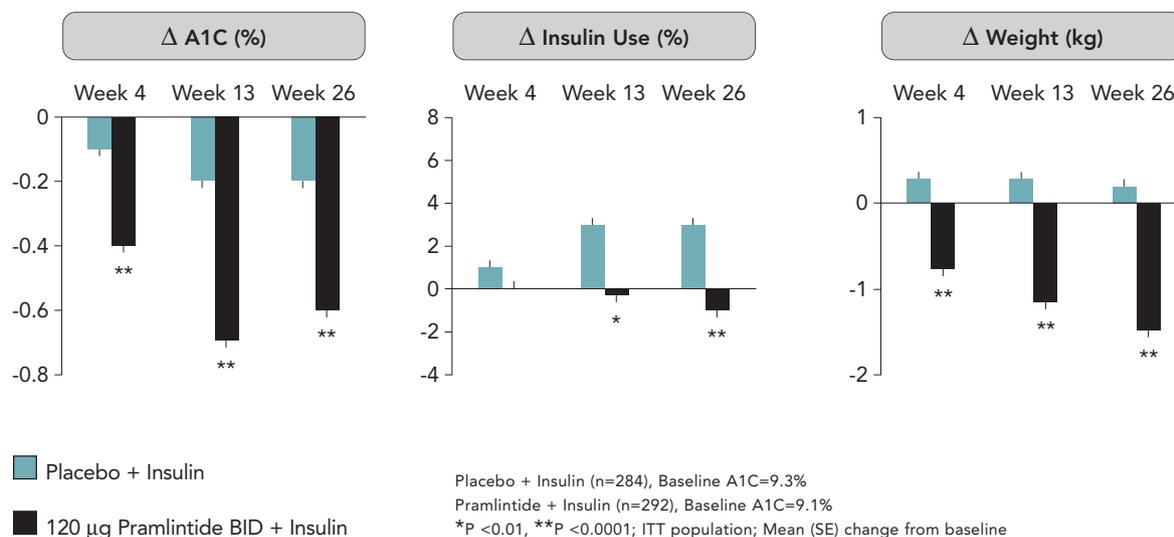


Exhibit 13: Effects of ECS Over-activity

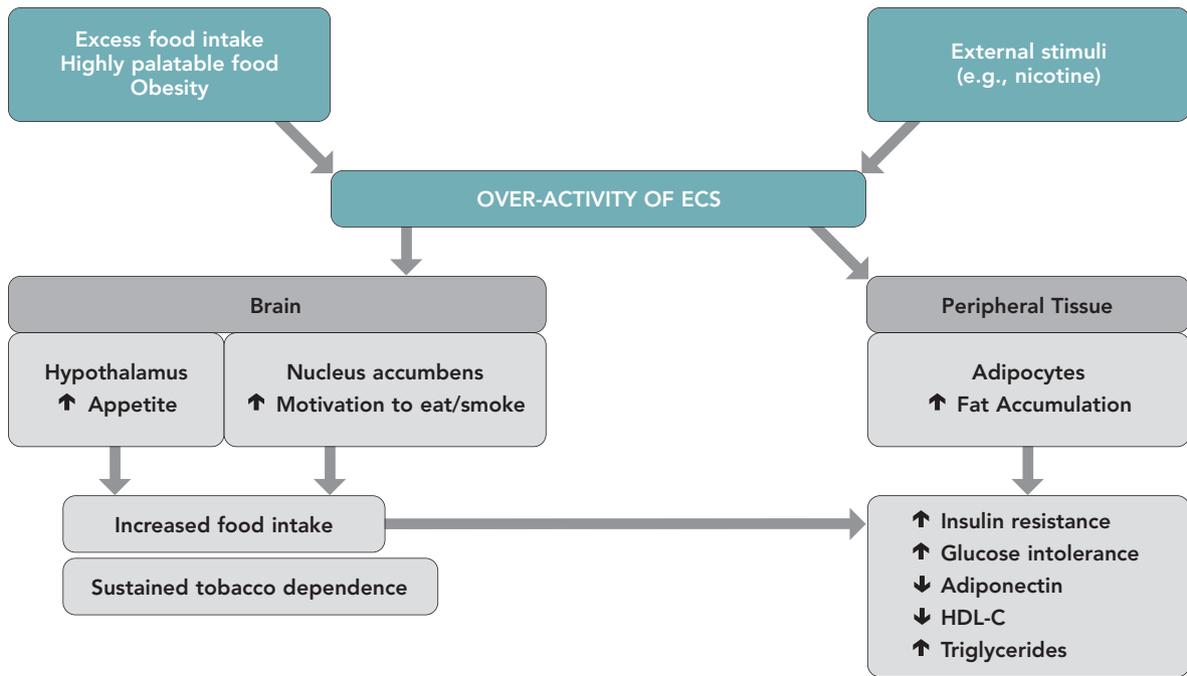


Exhibit 14: RIO-EUR—Changes in Weight and Waist Circumference at One Year³²

	Placebo	Rimonabant 5 mg	P vs. Placebo	Rimonabant 20 mg	P vs. Placebo
Weight					
Completers	-3.6	-4.8	0.042	-8.6	< 0.001
ITT LOCF	-1.8	-3.4	0.002	-6.6	< 0.001
Waist circumference (cm)					
Completers	-1.5	-5.3	NS	-8.5	< 0.001
ITT LOCF	-2.4	-3.9	0.002	-6.5	< 0.001

ITT = intent to treat analysis; LOCF = last observation carried forward;
2.2 lb = 1 kg.; 1 inch = 2.5 cm

of rimonabant on other components of metabolic syndrome. In RIO-NA, HDL-C increased a placebo-subtracted average of 7.2 percent in the ITT population, while triglycerides decreased a placebo-subtracted average of 13.2 percent in the ITT population (see Exhibit 15).³⁴ Similar effects on lipid values were seen in RIO-Lipids.³⁶

In RIO-NA, fasting insulin levels and insulin resistance (as estimated by HOMA-IR) decreased significantly compared to placebo (see Exhibit 16).³⁴ Both the lipid and the insulin changes appear to be partially a result of weight loss and partially a dose-dependent medication effect. It appears that rimonabant is working centrally to reduce food

intake and peripherally to improve glycemic and lipid metabolism. Leptin, which is tightly correlated with the amount of body fat, was decreased (suggesting improved leptin sensitivity) and adiponectin, an important modulator of insulin insensitivity, was increased by rimonabant.³²⁻³⁶ C-reactive protein, a marker of inflammation and

Exhibit 15: RIO-NA—Improvement in Lipids Adjusted for Weight Loss^{*34}

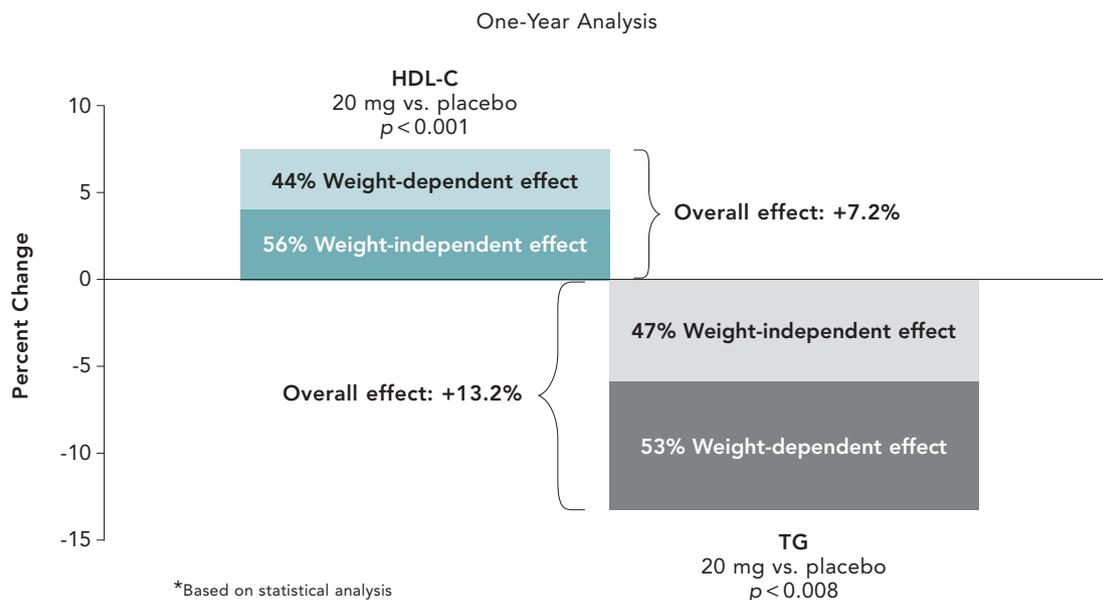
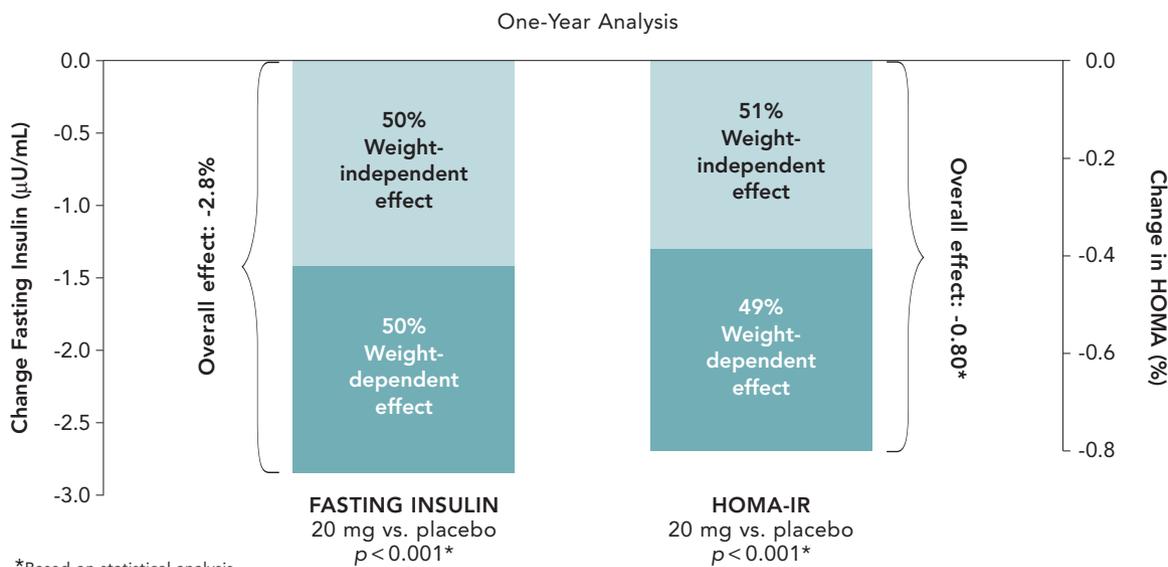


Exhibit 16: RIO-NA—Improvement in Fasting Insulin and Insulin Resistance Adjusted for Weight Loss^{*34}



atherosclerosis, decreased with rimonabant treatment.³²⁻³⁴

In RIO-NA, the prevalence of metabolic syndrome decreased by 35.3 percent compared to baseline following two years of rimonabant 20 mg treatment in the ITT population (see Exhibit 17).³⁴ This study included overweight patients who did not already have diabetes. In

RIO-Diabetes, there was a 18.9 percent reduction in the prevalence of metabolic syndrome at the end of one year.³⁵ Using rimonabant in combination with other diabetes medications (metformin or a sulfonylurea) improved glucose control. Sixty-eight (67.9) percent of the subjects receiving rimonabant 20 mg in RIO-Diabetes were able

to achieve American Diabetes Association (ADA) goals for hemoglobin A1C (<7 percent).³⁵

The adverse effects of rimonabant appear to be mild. Transient gastrointestinal adverse effects such as nausea, diarrhea, and vomiting appear to be the most frequent adverse effects. A concern with any agent that alters brain

Exhibit 17: Reduction in Metabolic Syndrome³⁴

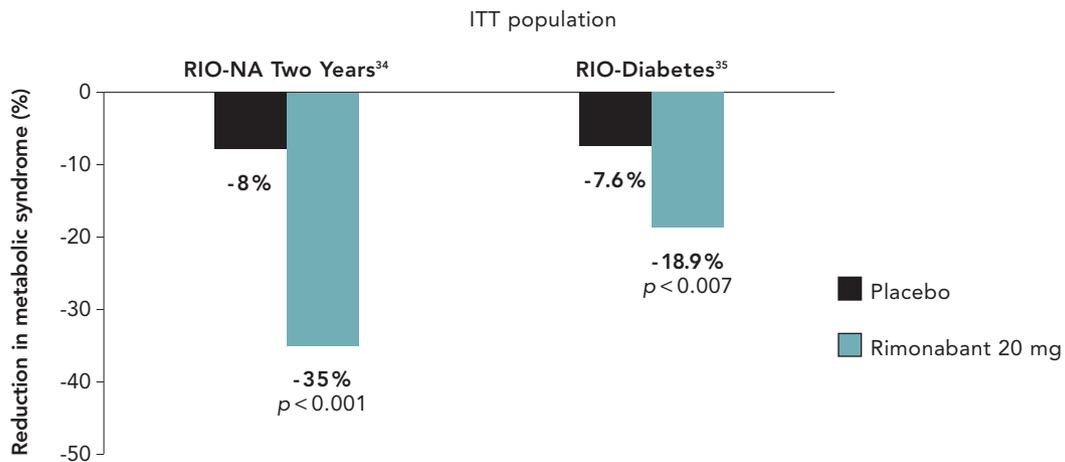
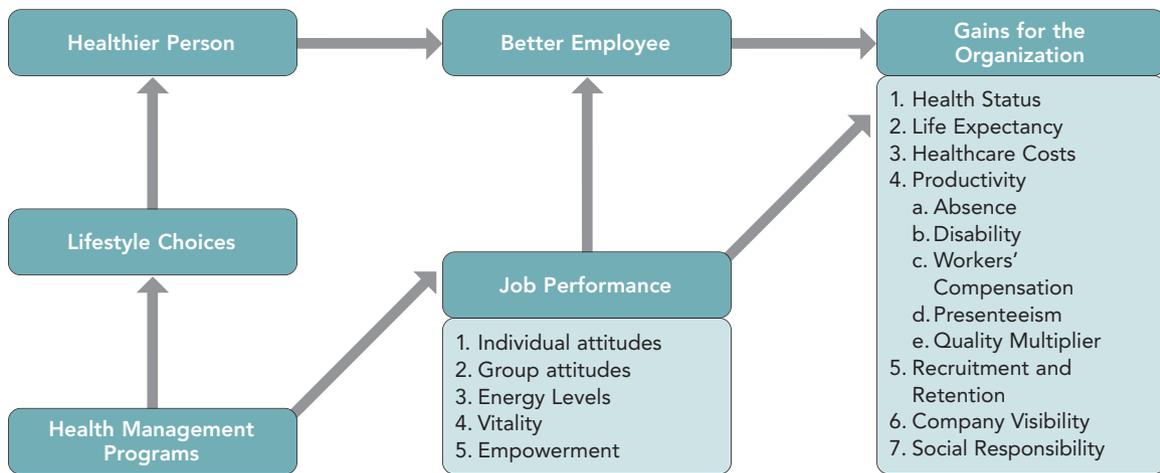


Exhibit 18: Health Management in the Workplace⁴²



neurotransmitters is the possibility of adverse effects on the central nervous system (CNS). The overall rate of CNS adverse effects does not appear to be significantly greater with rimonabant than with placebo, although discontinuations due to anxiety and depression were more frequently observed in patients on rimonabant 20 mg compared to placebo.³⁶

Current treatment paradigms treat only a single element of the constellation of cardiometabolic risk factors (i.e., dyslipidemia, glucose metabolism, abdominal obesity, or hypertension). New therapeutic

advances, including CB₁ receptor blockers, combined with a hypocaloric diet reduce cardiometabolic risk factors and offer sustained health benefits.

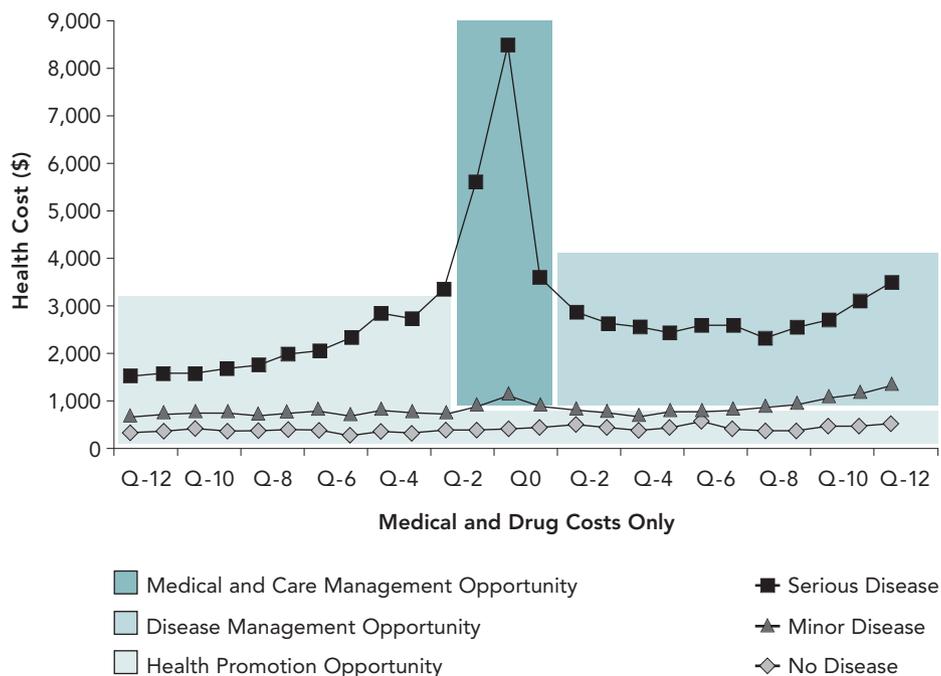
Cardiometabolic Risk Reduction: An Employer's Call to Action

To be competitive, employers require a workforce that is present, productive, in good health, reliable, and motivated (see Exhibit 18). It is estimated that 1.4 to 2.9 million people will leave the workforce early due to cardiometabolic risk-related chronic disease, and 508 mil-

lion work days will be lost annually as a consequence of an aging workforce that is chronically impaired. Many of those impairments trace their origins to obesity and associated cardiometabolic risk factors.

Significant direct costs to business are tied to metabolic syndrome in the workforce.³⁷⁻³⁹ Metabolic syndrome risk is estimated to contribute to 21 to 40 percent of the total U.S. healthcare budget.³⁸ Patients with metabolic syndrome and two or more other cardiovascular risk factors account for 40 percent of total pharmacy expenses,³⁹ and spend an average of four times more than the

Exhibit 19: Where Are the Opportunities for Population Health Management?⁴⁰



average for all other patients.³⁸

A number of indirect business costs are attributable to cardiometabolic risk factors. For example, one of the commonly reported effects of obesity is excessive daytime sleepiness, contributing to twice as many motor vehicle accidents involving employee drivers with a BMI over 35. Increased fuel consumption is also a significant indirect cost of obesity for companies that employ large numbers of overweight drivers. Since 1980, airlines reported spending \$275 million more each year in fuel costs carrying the increased average weight gained by passengers. Obesity also has a cost effect on furniture. While the average office chair is rated to support a worker weighing 270 pounds, 12 to 15 percent of the U.S. population now exceeds that rated capacity leading to an increase in workers' compensation claims related to seating failures. The capital expenditure required for U.S. corporations to upgrade the weight capacity of those workplace seats in a sin-

gle year would exceed \$4 billion.⁴⁰ The challenge for employers is to reduce the impact of obesity and cardiometabolic risk factors on business costs. Businesses can utilize human capital management to begin controlling costs: human capital management essentially treats employees as a business asset, making targeted investments to achieve a productive, healthy workforce.

In past decades, many employers and insurers focused significant cost-control efforts on cutting claims and managing acute care costs (see Exhibit 19).⁴¹ The next generation of solutions focused on disease management in certain costly chronic conditions and compliance with best evidence-based therapies. In short, disease management focused on applying good medicine to those people who consumed a disproportionate amount of total costs. There is an opportunity to apply the same idea behind disease management to the people who are not yet symptomatic or consuming healthcare resources, a classic health promo-

tion opportunity (see Exhibit 19).⁴¹

Since companies whose employee population have excess health risks incur excess costs related to these risks (see Exhibit 20),⁴² reducing health risks among such a population has been shown to decrease costs and increase productivity.⁴³ One opportunity for identifying and reducing risk is the sustained use of regular employee health risk appraisals. "what gets measured gets managed," and companies that encourage healthy behaviors for their employees through health risk appraisals have significantly lower percentage increases in annual healthcare costs (see Exhibit 21).

Achieving sustained maximal results from such risk-reduction programs in the workplace requires strong employee participation. However, a series of wellness and health promotion programs that only attract the worried, the well, or the fitness enthusiasts are not going to provide maximal risk reduction. The overall goal is to maintain a 70 percent low-risk population until retirement age.

Exhibit 20: Excess Risk = Excess Cost⁴¹

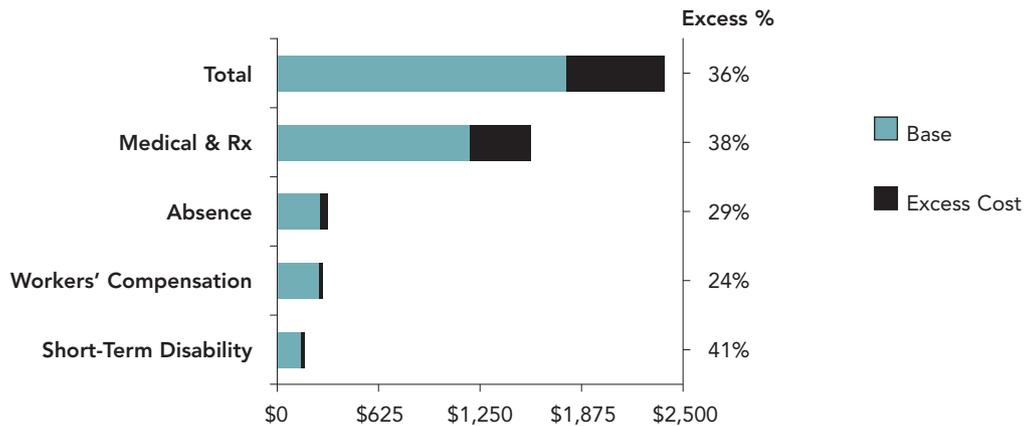
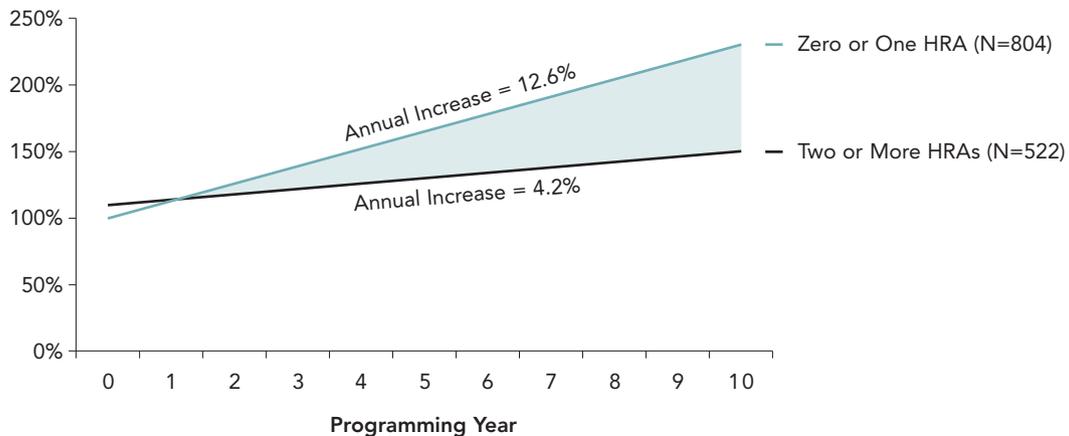


Exhibit 21: Cost Savings Associated With Program Involvement From 1985 to 1995⁴⁰



Thus it is essential to have at least 80 percent participation and a 70 percent low-risk population to achieve a durable actuarial effect over time. The two main reasons for these parameters are employee turnover and dependent coverage. Not every employee works for a particular company for an extended period; 70 to 80 percent participation in the program is needed to have the desired effect on the people who are actually employed with the company at a given time. In addition, for every employee, there are 2.5 dependents on average. Most companies currently cover healthcare for dependents, but they do not cover serious

health risk reductions programs for these dependents. So while it is possible to have an impact on employee health risk by implementing various programs, reducing health risks comes with a fairly high cost in terms of time, commitment, and consistency.

The best performing companies participating in risk-reduction programs, as studied by Watson Wyatt and the National Business Group on Health, experienced a 5 percent increase in overall cost for healthcare,⁴⁴ compared to moderate performers with 10 percent annual increases, and a 15 percent or greater annual growth rate for the worst performers. Best-performing

companies take an active role in managing not only healthcare benefits but also the health of their employees, utilizing many strategies to achieve these low growth rates in healthcare costs. Those strategies include

- lifestyle behavior change programs
- obesity reduction for employees
- specialty vendors for disease management
- integration of health-related benefits
- education of employees about healthcare cost challenges faced by the company
- health-related accountability and responsibility for employees
- communication to the employees.

Exhibit 22: Health Management as Serious Corporate Strategy

	Standard Health Promotion	Serious Prevention/Health Management
Risk Identification	Voluntary HRA, health screening	Hi-participation annual HRA Screening for metabolic risk factors (waist circumference, blood glucose, etc.)
Metrics	Multiple data sources; activity metrics	Integrated, predictive modeling Health outcomes metrics
Financial Incentives	Token participation rewards	\$1,500/family incentives Risk-based underwriting
Coverage:		
Medically supervised programs	Optional, limited/no coverage	Referral from HRA Ongoing worksite monitoring
Prescription drug therapies	Limited/no coverage	Higher coverage (Tier1, low co-pays) for prevention and chronic care medications
Bariatric procedures	Limited availability and coverage	Centers of Excellence for bariatric procedures
Health-contracting strategy	Multiple vendors, short-term agreements	Long-term agreements with strategic partners
Chronic condition management	Standard disease management	Integrated prevention and disease management
Work site design, operating practices	Fitness centers, health fairs	Work site activity thermogenesis On-site clinics, intelligent staffing/shift work, general manager MBOs

Traditionally, the various health programs such as pharmacy and medical benefits have been managed separately versus integrated. To be most effective, benefit design strategies must show integration of objectives, coverage, and processes among the various healthcare services. This allows a determination of the best outcome both economically and clinically for employees. Best-performing companies are more likely to integrate medical, pharmacy, short-term disability, long-term disability, and workers' compensation benefits across the spectrum. Such integration of benefits is increasingly necessary to sustain long-term reduction in overall human capital costs.

Effective health management for business requires a long-term focused commitment to programs that improve health risks in an employee population and reduce healthcare costs. A serious corporate health management strategy

includes risk identification, metrics, financial incentives, coverage for medically supervised lifestyle programs, prescription drug therapies, and bariatric procedures performed at clinical centers of excellence (see Exhibit 22). Additionally it includes performance-based health contracting strategies, chronic condition management, work site design changes, and defined operating practices. Companies that practice serious health management tend to hire a chief medical officer to manage corporate health programs and are accountable for their success.

Standard health promotion programs are often ineffective because participation is voluntary. A key component of serious health management is high participation in annual health risk appraisals, which, although voluntary, are often tied to direct, meaningful financial incentives. The former identifies risks so that the employee is better able to reduce or control them, and the

employer is better able to manage risks over time. Standardized health data collected about a given population over time can predict future costs with greater accuracy.

Best-performing companies must overcome a number of barriers to employee health management. Some of the major barriers include limited data for identifying the true impact of chronic disease within an individual workplace, lack of a line item on profit and loss statements for costs of chronic disease, the potential for discrimination and privacy violation legal claims, attitudes within a company about responsibility for employee health (i.e., aversion to social engineering), and the absence of an individual or group that is responsible for the health of employees (i.e., chief health officer).

Employees tend to respond positively to well-developed plan designs. Many employers offer incentives to employees who participate in health management

Exhibit 23: Sample Health Plan, Corporate Incentives⁴²

Corporation	Program Components	Incentive Programs	HRA Participation Rate
American Century	HRA + wellness programs	\$120/employee for HRA as insurance credit	90% - web
Australian Health Management Group		No incentive	15%
Bank One	HRA + education programs	Pedometer (2004)	30%
BCBSRI	Mandatory HRA + selected mandatory high-risk interventions and meet preventive service and immunization guidelines	15% discount on medical premium rates (value of about \$1,400 for a family plan)	2004
Crown Equipment	HRA + screening + counseling	\$260 annual health benefit credit for completing HRA and wellness screening	83%

programs (see Exhibit 23). To change behavior, financial incentives will range from \$200 to \$500 per employee.

In recent years, many employers and health plans have been trying to reduce healthcare costs by targeting pharmacy costs through increased co-pays, restrictive formularies, and aggressive purchasing programs to obtain the least costly medication, based on acquisition costs. Data suggest that these cost-cutting strategies are aiming at the wrong target.³⁸ A better approach is to make needed medications available in the most cost-effective manner. Using the appropriate medication and spending extra pharmacy money produces a direct benefit if the treated employees reduce their high blood pressure and cholesterol. Following the example of metabolic syndrome, businesses would benefit by getting employees to use medications at an earlier stage so that they lose weight, prevent diabetes, prevent stroke or heart attack, or avoid a disabling disease that will have a negative impact on them and the employer.

Pitney Bowes Corp. has successfully integrated pharmaceuticals into its long-term health management strategy. The company found that using a human capital investment strategy—instead of cost-containment strategy—was the key to bet-

ter return on investment (ROI).

In the past, the company sought lower costs from its vendors by focusing on the price of health services. Based on predictive modeling, the company found there was excessive spending on employees with certain chronic diseases (asthma, diabetes, cardiovascular disease, and depression) who were not taking their medications and not using prevention opportunities. A strong association between chronic condition progression and low medication possession rates was found primarily attributed to poor compliance and a lack of screening and prevention. To increase medication possession rates, the company eliminated prescription copays for certain chronic disease medications. Recognizing that the cost of the prescription medications is less than emergency room visits, hospitalization, and absenteeism, the company's goal was to ensure that employees had easy access to needed medications. Promoting prevention by enhanced coverage of chronic care medications appears to be a trend among leading-edge employers.

Health contracting strategies are another area in which employers can make changes to assist in human capital management. However, businesses need long-term contracts with their strategic health partners.

If the business uses short-term contracts, the health plan will not cover their population long enough to provide a meaningful return on population health programs, such as the above, and for employers to hold the health plan accountable and to see the full effect of health-promotion strategies. At least three years of health promotion is required to realize material improvements in employee health and productivity.⁴⁵

Pitney Bowes is also a good example of an employer that is confronting workforce aging, with a long-term workforce averaging more than 47 years. To minimize healthcare costs, the company integrated data, appropriate pharmaceutical use, and a continuous process of initiatives. Rather than focus on short-term initiatives, Pitney Bowes focuses on long-term programs.

Companies that have health plan persistency, acquire employees while they're young, and retain those employees for many years, will have a greater opportunity to benefit from adjustments in health management and realize a high ROI potential. Companies that change their health plans frequently or that have low benefits value will not have the same advantage. Companies with contract labor forces or high turnover also may not experience the benefits of health promotion.

The short-term benefits of managing employee health are improvements in employee absences and unscheduled short-term disability, reduced workers' compensation costs, and better employee retention and morale. Productivity benefits are usually obtained in the first three years of an investment in healthcare. The long-term benefits to employers are lower health costs and expanded workforce capacity.

Medically supervised programs for reducing cardiometabolic risks are the future of disease management. Long-term investment in health management involves applying disease management concepts before disease develops. Helping employees maintain low-risk health status is the best way to keep them healthy and reduce cost. Employers and health plans can use risk identification, prevention, and chronic condition management to develop a health management corporate strategy. Unless medications and other interventions such as lifestyle management programs are accessible and the focus of healthcare shifts to prevention, employers will have difficulty reducing healthcare expenditures.

Successful corporate healthcare strategy involves a shift from low-cost purchasing to seeking measurable value in healthcare. Employers recognize that real value comes from avoiding unnecessary healthcare costs and investing in population health. Prevention of cardiovascular disease and diabetes through reduction of cardiometabolic risk factors needs to be a priority for employers who want to achieve reduced healthcare costs and healthy, productive employees. To be successful in this endeavor, companies must commit to changing benefit design in order to make needed pharmacologic interventions and prevention programs available. **JMCM**

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INSTRUCTIONS

1. Read the monograph first.
2. Next, read the questions and mark your answers on the provided answer sheet (or make a copy). All questions and answers are based on the information in this monograph. Each question has only one correct answer.
3. After completing test and the activity evaluation, you may fax the answer sheet and evaluation to 804-747-5316, or mail to NAMCP CME Office, 4435 Waterfront Drive, Suite 101, Glen Allen, VA 23060.
4. You should receive your CME certificate within one month of completion. If you do not receive it, please call 804-527-1905 and ask for Ann Patrick or Katie Eads.

1. In the U.S., how many deaths occur each year as a result of cardiovascular disease?
 - a. 100,000
 - b. 350,000
 - c. 700,000
 - d. 1.2 million
2. The estimated yearly total cost of cardiovascular disease in the U.S. exceeds \$150 billion.
 - a. True
 - b. False
3. Non-changeable CHD risk factors include
 - a. Age, gender, and family history
 - b. Diabetes and hypertension
 - c. Dyslipidemia, obesity, and smoking
4. Which of the following best describes the relationship between waist circumference and cardiovascular disease?
 - a. As waist circumference increases, so does the relative risk of cardiovascular events.
 - b. Waist circumference is not a predictor of cardiovascular disease.
 - c. An elevated waist circumference predicts development of type 2 diabetes but not cardiovascular disease.
5. Based upon RIO-NA and RIO-Lipid studies, which of the following statements is FALSE regarding the effect of rimonabant on components of metabolic syndrome?
 - a. HDL-C increased while triglycerides decreased with rimonabant treatment
 - b. Fasting insulin and insulin resistance (as estimated by HOMA) decreased with rimonabant treatment
 - c. C-reactive protein, a marker of inflammation and atherosclerosis, was increased with rimonabant treatment
 - d. Changes in both lipid and insulin levels may be an effect of both weight loss and dose-dependent medication administration
6. The NCEP ATP III guidelines define metabolic syndrome as the presence of any three of five cardiometabolic abnormalities—elevated fasting glucose, abdominal obesity, elevated triglycerides, low HDL-C, and elevated blood pressure.
 - a. True
 - b. False
7. Metabolic syndrome increases a patient's risk of having a heart attack fourfold.
 - a. True
 - b. False
8. Providing coverage for chronic medications is likely to be
 - a. a better solution to rising healthcare costs than cost shifting through increasing prescription copays.
 - b. False
9. Management of cardiometabolic risk factors include
 - a. Identification of at-risk patients
 - b. Recommendations for diet
 - c. Exercise
 - d. Behavior modification
 - e. Pharmacotherapy options
 - f. All of the above
10. Decreased endocannabinoid system activity is associated with excessive food intake and subsequent accumulation of fat.
 - a. True
 - b. False
11. The National Institutes of Health Guidelines recommend treatment according to BMI category. At a 27 to 29.9 category, treatment should include
 - a. Diet, physical activity, behavior therapy, and pharmacotherapy (if comorbidities are present)
 - b. Diet, physical activity, and behavior therapy only if comorbidities are present
 - c. Pharmacotherapy only
 - d. Weight loss surgery
12. Excess food intake and external stimuli promote overactivity of ECS.
 - a. True
 - b. False
13. New therapeutic advances should be combined with a hypocaloric diet to reduce cardiometabolic risk factors.
 - a. True
 - b. False
14. Literature has demonstrated that metabolic syndrome consumes 21 to 40 percent of the U.S. healthcare budget.
 - a. True
 - b. False
15. With an increase in health risk factors, there is an increase of healthcare costs.
 - a. True
 - b. False
16. With an increase in health risk factors, there is a decrease in employee productivity.
 - a. True
 - b. False

17. Employers should use risk identification, prevention, and chronic condition management in developing a corporate health-management strategy.

- a. True
- b. False

18. Best employer performers showed a 15 percent increase in health plan costs versus a 5 percent increase for the worst performers.

- a. True
- b. False

19. Best-performing companies take an active role in managing not only healthcare benefits but also the health of their employees.

- a. True
- b. False

20. Best performers are more likely to integrate medical, short-term and long-term disability, and workers' compensation benefits across the spectrum.

- a. True
- b. False

21. A serious corporate health management strategy includes

- a. Risk identification, metrics, and financial incentives
- b. Risk identification, metrics, financial incentives, benefit coverage for medically supervised programs
- c. Risk identification, metrics, financial incentives, benefit coverage for medically supervised programs, prescription drug therapies, bariatric procedures, health contracting strategies, chronic condition management, and operating practices.
- d. Risk identification, metrics, and benefit coverage for medically supervised programs and chronic condition management

ANSWER SHEET

There is only one correct answer per question. Circle your answer clearly.

1. a b c d
2. a b
3. a b c
4. a b c
5. a b c d
6. a b
7. a b
8. a b
9. a b c d e f
10. a b
11. a b c d
12. a b
13. a b
14. a b
15. a b
16. a b
17. a b
18. a b
19. a b
20. a b
21. a b c d

ACTIVITY EVALUATION

Please rate this activity on the following scale:

4 Excellent 3 Good 2 Fair 1 Poor

Activity met my expectations 4 3 2 1

Activity was free of bias 4 3 2 1

Activity content was understandable 4 3 2 1

Method of learning was beneficial 4 3 2 1

I will change my practice patterns by (check all that apply)

- Reviewing methods of benefit design to become a best performer
- Establish policies and coverage for prevention of metabolic syndrome
- Work with partners to establish a best performer standards
- Start utilizing NCEP ATP III definition of metabolic syndrome to screen for at-risk patient
- Establish policies for prevention of metabolic syndrome
- Work with my plans to establish a standard of care for metabolic syndrome
- Review methods to reduce risk factors of metabolic syndrome
- Establish policies for prevention of metabolic syndrome
- Work with my plans to establish a standard of care for metabolic syndrome
- Patterns will not change

Name: _____

Mailing Address: _____

City: _____

State: _____ ZIP: _____

Phone: _____

Fax: _____

E-mail: _____

Send my certificate by:

- U.S. Mail
- E-mail

