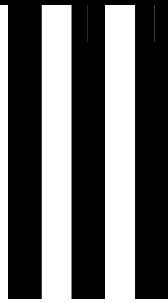


Fifteenth
in a Series of
Technical
Reports



Obesity Reduction & Prevention Strategies for Individuals with Serious Mental Illness

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Executive Summary

Within the general population, obesity is a public health crisis. Approximately 65% of adults in the United State are either overweight or obese and projections are that this percentage could increase to 75% by 2015. If nothing is done to impact this rate of growth, obesity will likely become the leading preventable cause of death. In the U.S., health care expenditures related to obesity and associated medical conditions amount to \$100 billion annually and in 2000, obesity was estimated to contribute to approximately 400,000 deaths. Obesity is an epidemic for the general U.S. population.

Individuals with serious mental illness (SMI) constitute 6 to 8% of the U.S. population and during their lifetime these individuals not only face the challenge of their mental illness but are also affected by a higher prevalence of physical health problems, prominently including overweight and obesity. Overweight and obesity are more prevalent in persons with SMI than in the general population. A combination of factors associated with the mental disorder itself (e.g., poverty, reduced access to medical care and reduced utilization of appropriate care) as well as other environmental factors (e.g., ready access to calorie dense foods and adverse effects on some medications can all contribute to the increased body weight and adiposity in persons with SMI. This is an epidemic within an epidemic. Related in part to the increased prevalence of overweight and obesity as well as other health-related risk factors, persons with SMI have higher rates of morbidity and premature mortality, and have been estimated to lose between 13 and 30 mean years of potential life expectancy in comparison to the general population. With proper prevention and intervention strategies, persons with SMI and their healthcare providers can aim to minimize the impact of the various contributing factors on body weight and on related medical complications that can otherwise reduce life expectancy.

The National Association of State Mental Health Program Directors' (NASMHPD) Medical Director's Council developed this report through an information review, expert analyses, and extensive discussions at a technical report team meeting held in August 2007. Primary sources of data and information used within this report were gathered from presentations and commentary from content experts and from the published literature on obesity prevalence, incidence, and prevention literature.

This report addresses the following topics:

- 1) Obesity within the population of persons with serious mental illness is an epidemic within an epidemic which requires a public health perspective, including prevention and early intervention across the lifespan;
- 2) Obesity increases the burden of stigma on persons with serious mental illness;
- 3) Persons with serious mental illness are motivated to lose weight and can successfully lose weight;
- 4) Interventions to prevent obesity include behavior modification to reduce calorie intake and increase physical activity and avoiding medications with high weight gain risk where possible;
- 5) Behavioral programs for the treatment of obesity can reduce weight by 15%;

-
- 6) Switching from a high weight gain psychiatric medication to a low weight gain psychiatric medication can result in significant weight loss;
 - 7) Antipsychotic and other psychotropic choices should be carefully considered, and switching medications for each individualized patient should be used judiciously because of the potential risks of losing the effectiveness of the antipsychotic medication and increasing troublesome side effects;
 - 8) Adjunctive medications for weight loss can reduce weight by 10% but carries some risk;
 - 9) Surgery for weight loss usually results in substantial reductions in weight but only should be resorted to when there is clear danger to health and other interventions have failed;
 - 10) Use of practical assessment and monitoring guidelines by behavioral health facilities, mental health clinics, psychiatrists, prescribers and other members of the treatment team with surveillance data required to be collected, analyzed, and interpreted as appropriate, and reported;
 - 11) Persons with serious mental illness may be excluded or not informed of obesity interventions; and the
 - 12) Obesity in the following subpopulations:
 - a) Children and Adolescents;
 - b) New consumers with serious mental illness;
 - c) Established Consumers; and the
 - d) Elderly.

This report makes specific recommendations that, when implemented, should substantially reduce the weight and improve the overall health of a population with SMI. These recommendations are made at the National, State, and local levels. They should improve the systems that provide care and treatment to this population. The recommendations are:

1. Encourage research on obesity in people with serious mental illness;
2. Implement national obesity surveillance/monitoring system for persons with serious mental illnesses;
3. Create federal tax incentives, through the use of employer-sponsored pre-tax medical expense accounts, to encourage physical activity;
4. Include weight management interventions and appropriate laboratory tests as a reimbursable service in existing federal healthcare programs;
5. Create a memorandum of understanding (MOU) with NASMHPD and Substance Abuse and Mental Health Systems Administration (SAMHSA) on U.S. Department of Agriculture (USDA) nutritional counseling;
6. Collaborate with federal healthcare agencies on the development of a provider toolkit of best practices for the prevention and reduction of obesity in persons with severe mental illnesses and actively support dissemination of this report in the toolkit through national meetings, Web seminars, continuing education and other available venues;
7. Educate national mental health stakeholder organizations regarding the impact of obesity in the populations they serve and also about available interventions;

-
8. Educate mental health professionals on the importance of weight monitoring and weight reduction in people with serious mental illness;
 9. Develop standards of care for mental health providers and work with State Medicaid agencies and other health insurers to ensure that persons with severe mental illness and obesity have access to educational/behavioral, medication switching, medical, and surgical treatment interventions;
 10. Promote opportunities for health care providers, including peer specialists, to teach health lifestyles to families, individuals, and older adults;
 11. Adopt American Diabetes Association (ADA) and American Psychiatric Association (APA) Second Generation Antipsychotic (SGA) monitoring as a standard of care practice for the population with SMI;
 12. Collaborate between the SMHA and the State Health Authority (SHA) to address physical health assessment, health monitoring, and improvement options for the population with SMI;
 13. Bridge the collaboration gap between physical and mental health care;
 14. Monitor mental health consumers with diabetes and related metabolic risk conditions in mental health clinics;
 15. Establish linkages with public health programs and community-based programs in diabetes prevention and control, cardiovascular disease prevention, and healthy weight management;
 16. Offer all consumers preventative intervention strategies targeting weight loss and management;
 17. Implement weight control programs that incorporate nutrition, exercise, and behavioral therapy/interventions for persons with serious mental illness.
 18. Utilize medications with lower risk of weight gain when possible;
 19. Utilize weight loss medication to control weight when medically appropriate, and when other interventions are not feasible or effective;
 20. Consult with the patient, and when medically appropriate, recommend bariatric surgery when all other methods of weight loss have been tried and failed; and
 21. Encourage the development of novel approaches to educate and support weight control through community programs.

The epidemic of obesity in persons with mental illness is a major cause of morbidity and early death and a significant obstacle to wellness and recovery that requires immediate action by policy makers, administrators, healthcare providers, and consumers. Effective interventions are available.

Introduction

The National Association of State Mental Health Program Directors (NASMHPD) is a 501(c) (3) organization, operating under a cooperative agreement with the National Governors' Association (NGA), which represents the \$29.5 billion public mental health service delivery system serving 6.1 million people annually in all 50 states, 4 territories, and the District of Columbia.

The Commissioners/Directors of state mental health agencies make up the membership of NASMHPD and are those individuals, many of whom are appointed by the Governors of their respective states, responsible for the provision of mental health services to citizens utilizing the public system of care. There are 220 state operated psychiatric hospitals nationwide and they serve approximately 50,000 patients at any given point in time. Within the structure of NASMHPD are 5 divisions made up of directors of special populations/services (Children/Youth/Families, Older Persons, Forensic, Legal, and Financing/Medicaid) as well as a Medical Directors Council and formal collaborative relationship with National Association of Consumer/Survivor Mental Health Administrators and State Hospital Superintendents. The purpose of these entities is to provide technical assistance and expert consultation to the Commissioners/Directors related to issues specific to those populations/services.

NASMHPD is uniquely suited to identify, assess, and recommend Mental Health policies and best practices. It is the only organization representing the state-level public mental health authorities in every state and territory. NASMHPD's members are unique in that they simultaneously represent a broad array of viewpoints - as funders of health care, regulators of health care, and direct providers of health care – and, must balance the interests of all three viewpoints. NASMHPD and its membership have a proven track record of a bringing together a wide and diverse array of stakeholders to address the complicated issues involved in behavioral health, primary health care and public health programming. A number of stakeholders are consistently included in such policy development and implementation endeavors including: primary consumers, family members, advocates, providers, professional organizations, accreditation bodies, federal partners, and sister organizations that represent substance abuse, behavioral health, and health. NASMHPD has built coalitions that have succeeded in addressing and moving the field forward on many new programs including co-occurring disorders; the reduction/elimination of seclusion and restraint; trauma; smoking cessation; promotion of evidence based practices; mortality related to serious mental illness (SMI); and the integration of mental health with primary care.

The NASMHPD Medical Directors Council, which conducts its work under the auspices of the National Association of State Mental Health Program Directors (NASMHPD), was authorized by the Board of Directors in 1995 and its membership includes medical directors of state mental health authorities from across the country. The NASMHPD Medical Directors Council has developed over 13 technical papers (8 over the past 4 years) addressing key areas of clinical policy for the public mental health system including Polypharmacy, Pharmacy Utilization Management, Seclusion and Restraint,

Prevention and Integrating Primary Care and Behavioral Health Systems and Reducing Excess Mortality in Persons with Severe Mental Illness. These technical papers have guided recent policy changes and practices in the public mental health system.

The NASMHPD Medical Directors Council developed this fifteenth technical report through a review of materials and extensive discussions at a work group meeting held August 9-10, 2007 in Kansas City, Missouri. Primary sources of data and information used within this report were gathered from presentations and commentary from work group meeting participants, published literature on obesity prevalence, incidence, and prevention literature distributed prior to the meeting, and materials distributed at the meeting.

Participants included State Mental Health Authority (SMHA) medical directors and commissioners as well as leadership from the Centers for Disease Control and Prevention, the Substance Abuse and Mental Health Services Administration (SAMHSA), the University of Pittsburgh School of Medicine, Washington University School of Medicine, Yale University and Connecticut Mental Health Center, the University of Medicine and Dentistry of New Jersey/University Behavioral HealthCare, and other technical experts. A complete list of participants is included as Attachment A.

The work group reviewed statistics on obesity in both the general population and the population with SMI, current literature on obesity and obesity prevention, and consulted with experts in mental health and obesity prevention activities.

Definitions

The Fourth edition of the American Heritage Dictionary of the English Language defines **Obesity**, as “the condition of being obese or increased body weight caused by excessive accumulation of fat.” While vivid, these definitions are not helpful in actually measuring the accumulation of excess weight. Several methods are available to assess overweight and obesity. The two methods below are practical and easy-to-use and are recommended in the National Heart, Lung, and Blood Institute’s (NHLBI) expert guidelines on identification, evaluation, and treatment of overweight and obesity in adults:

1. **Body Mass Index (BMI)** is a practical indicator of the severity of obesity. BMI is a direct calculation based on height and weight, regardless of gender and it can be calculated from existing tables (see attachment B). The resulting number is considered a largely reliable indicator of whether a person’s weight and adiposity is within a healthy range. The BMI is considered an indirect measure of body fat or adiposity. BMI does have limitations; for example, BMI can overestimate adiposity in a person who is very muscular and can underestimate body fat in person who have lost muscle mass (i.e., older adults).

In adults, BMI’s are categorized based on an absolute number according to the classification below:

- BMI < 18.5 kg/m² underweight;
- BMI 18.5-24.9 kg/m² normal weight;
- BMI 25.0-29.9 kg/m² overweight;
- BMI 30.0-34.9 kg/m² mild obesity;
- BMI 35.0-39.9 kg/m² moderate obesity; and
- BMI > 40.0 kg/m² extreme obesity.

The predictive value of specific BMI numbers for morbidity and mortality risk can vary by ethnicity. For example, BMI criteria for overweight and obesity in Asian populations, including Indian Asians, has been modified by the National Heart, Lung, and Blood Institute (NHLBI) and World Health Organization (WHO), based on evidence for higher morbidity and mortality risk at lower BMIs in Asian populations, compared to Caucasians for example. Most commonly, the threshold for the definition of overweight in Asian populations is modified to 23 and the threshold for obesity to 25 (compared to 25 and 30, respectively, described above).

In children, BMI is routinely interpreted by graphing height and weight on age and gender-specific growth charts. Children’s BMI percentiles are thereby calculated describing an individual child’s BMI relative to children of the same age and gender.

Using BMI as a public health standard for measuring obesity, the NHLBI has issued guidelines on the identification, evaluation, and treatment of overweight and obese adults. These standards offer solid evidence that the risk for cardiovascular disease, type 2 diabetes, and other diseases tends to increase progressively as BMI increase

progressively from values less than to greater than 25. Risk of mortality tends to increase progressively as BMI increases from at least 30.

2. **Waist circumference** is emerging as a potentially more valid and reliable indicator of central or truncal adiposity and medical risk compared to BMI, with BMI offering no accounting of the true distribution of adiposity across body regions (e.g., truncal versus peripheral adiposity). Findings from some studies (Palamara, 2006) have suggested that waist circumference is a better predictor of risk for cardiovascular disease, type 2 diabetes, and other metabolic risk-related conditions, compared with BMI.

While a lack of uniformity about appropriate abdominal landmarks for the measurement of the “waistline” have permeated the research and could undermine the reliability of measurements in clinical practice; the National Heart, Lung, and Blood Institute (NHLBI) of the National Institutes of Health has issued new guidelines standardizing the measurement of both the waist and hip. To measure waist circumference, locate the upper hip bone and the top of the right iliac crest. Place a measuring tape in a horizontal plane around the abdomen at the level of the iliac crest. Before reading the tape measure, ensure that the tape is snug, but does not compress the skin, and is parallel to the floor. The measurement is made at the end of a normal expiration. Waist measurement should be done at the iliac crest defined as the narrowest circumference between the ribs and the umbilicus.

Current guidelines suggest that a waist measurement of greater than 40 inches in men and greater than 35 inches in women is associated with increased cardiometabolic risk.

For additional information on waist circumference refer to attachment C.

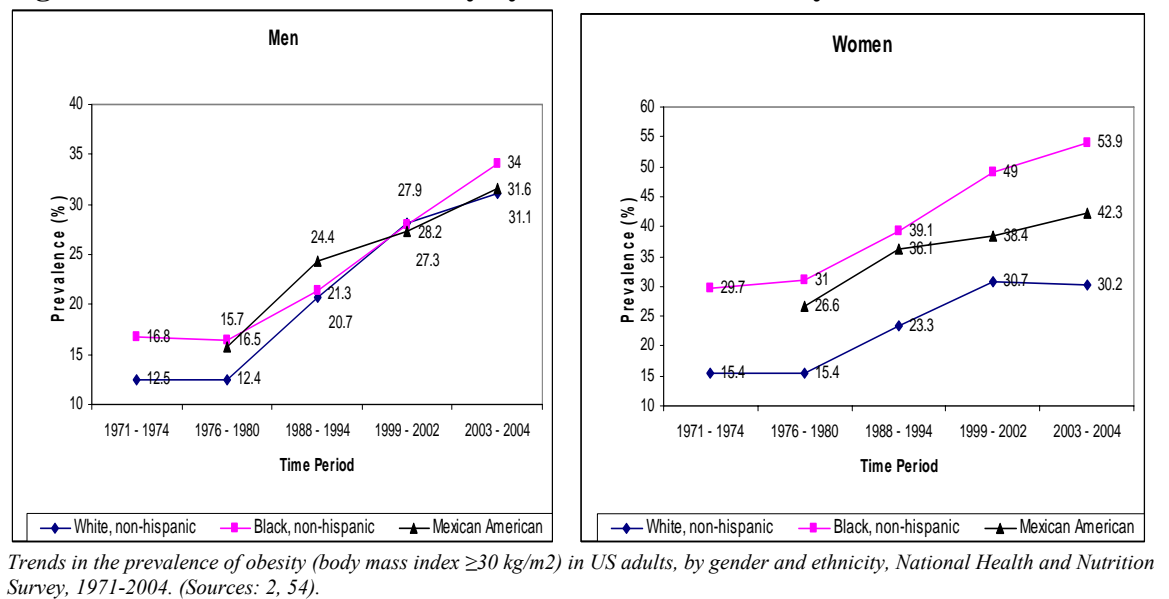
Background

Trends:

“Obesity is a public health crisis” (Wang, 2007). It is a chronic disease that has serious health consequences. In the general population rates of obesity worldwide and within the United States continue to grow at epidemic rates. Worldwide, it is estimated that more than 300 million people are obese (DeMaria, M.D.). Approximately 65% of adults in the United States are either overweight or obese (National Health and Nutrition Survey [NHANES] 1999-2002). This percentage has steadily increased by approximately 40% over the past three decades compared to previously published NHANES data. If the rates of obesity and overweight continue at this pace, by 2015, 75% of adults and nearly 24% of U.S. children and adolescents will be overweight or obese (Youfa Wang, 2007).

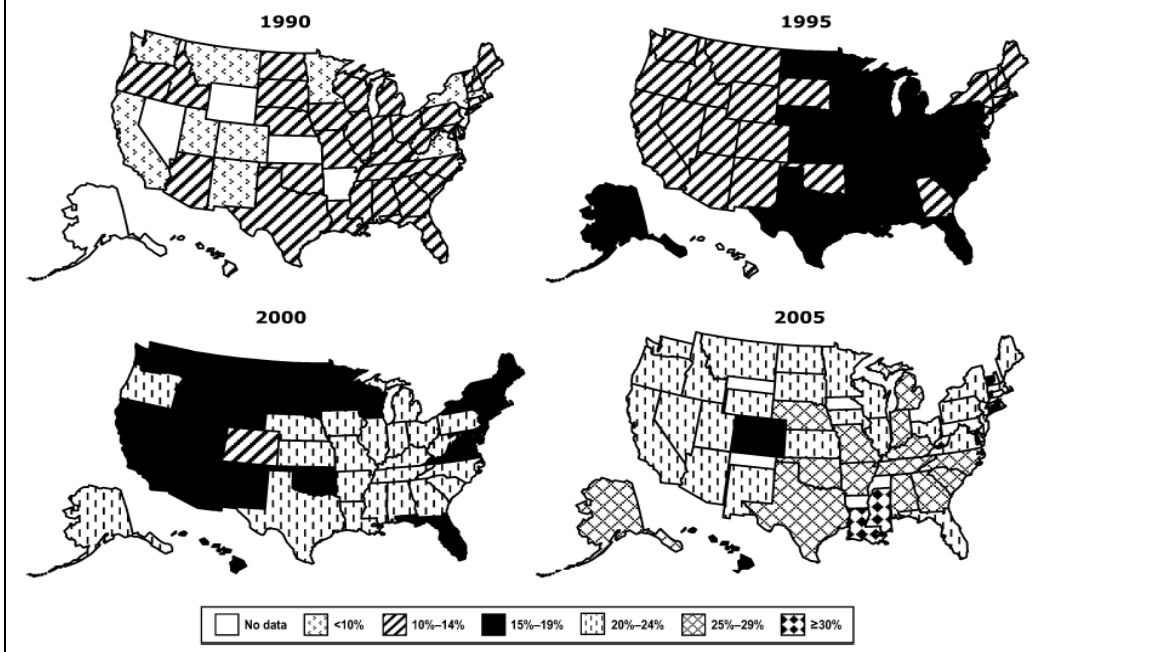
Figure 1.1 below displays the historic trends in the prevalence of obesity by gender and ethnicity from 1971 to 2004.

Figure 1.1: U.S. Trends in Obesity by Gender and Ethnicity.



Within the United States, plotted over time, regional differences become apparent. Figure 1.2 below from the Centers for Disease Control and Prevention, displays the regional differences from 1990 to 2005.

Figure 1.2: U.S. Regional Differences in Obesity Prevalence.

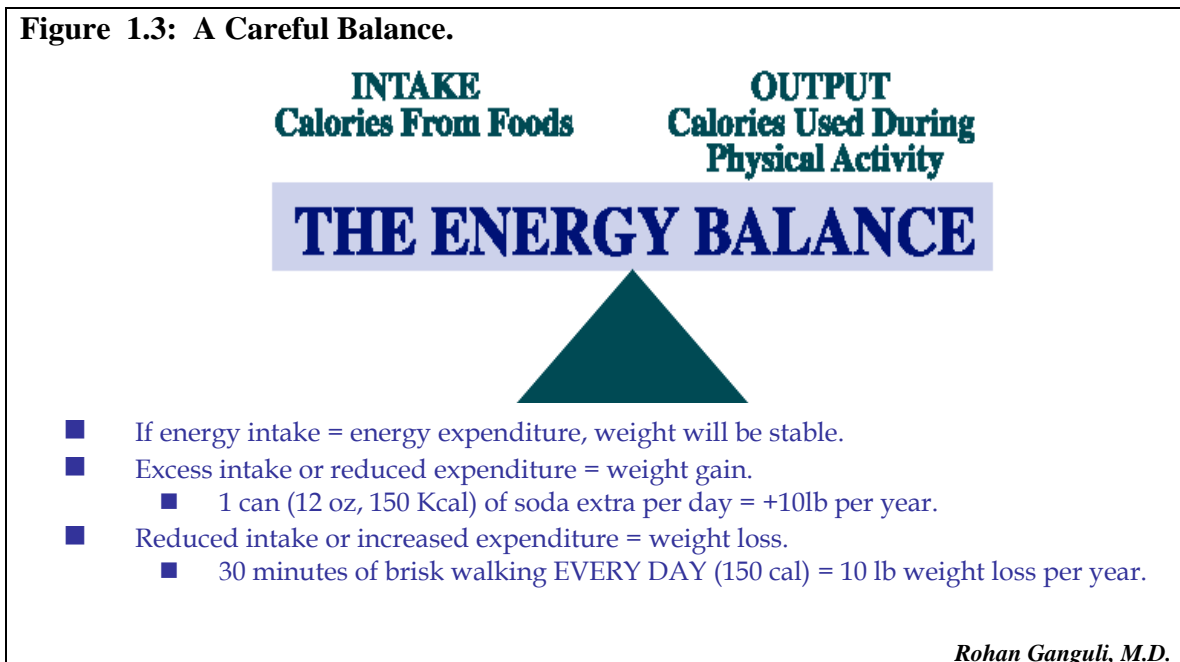


Cause:

Obesity is a complex, multifactorial, and chronic disease that develops from an interaction of genotype and the environment. According to NHLBI expert consensus, the understanding of how and why obesity develops is incomplete, but involves the integration of social, behavioral, cultural, physiologic, metabolic and genetic factors. And some risk factors are more strongly linked to specific ethnic groups.

There are generally two hallmark behaviors that account for obesity: too much calorie consumption and too little calorie expenditure. Figure 1.3 is a simplified visual representation of the careful balance between caloric intake and output (physical activity) to maintain a consistent weight. A shift in either of these can cause an individual to gain or lose weight.

Figure 1.3: A Careful Balance.



In addition to behaviors there are a variety of other risk factors, such as environmental conditions that affect physical activities (such as, elevators & escalators), genetics, diseases (for example, Cushing’s disease or polycystic ovary syndrome), or drugs (such as steroids that can cause weight gain).

Some obesity experts state that we live in an “obesigenic environment,” and that declining physical activity and increases in the consumption of energy dense foods (Foods containing more than 225-275 kcal per 100g) is contributing to the rise in weight problems. Side effects of psychotropic medications can add to this problem.

Health Consequences:

Researchers indicate that if nothing is done to impact its growth rate, obesity will likely become the leading preventable cause of death. Within the United States, “obesity has become an epidemic condition” (DeMaria, M.D.).

The U.S. Surgeon General’s Call to Action notes that the “primary concern of overweight and obesity is one of health and not appearance.” This increasing overweight and obese population is troubling because of the well-established health risks that are associated with these conditions. According to the “Surgeon General’s Call to Action to Prevent and Decrease Overweight and Obesity,” obesity is connected to an increase in the following health risks:

- Premature death;
- Type 2 diabetes;
- Heart disease;
- Stroke;
- Hypertension;

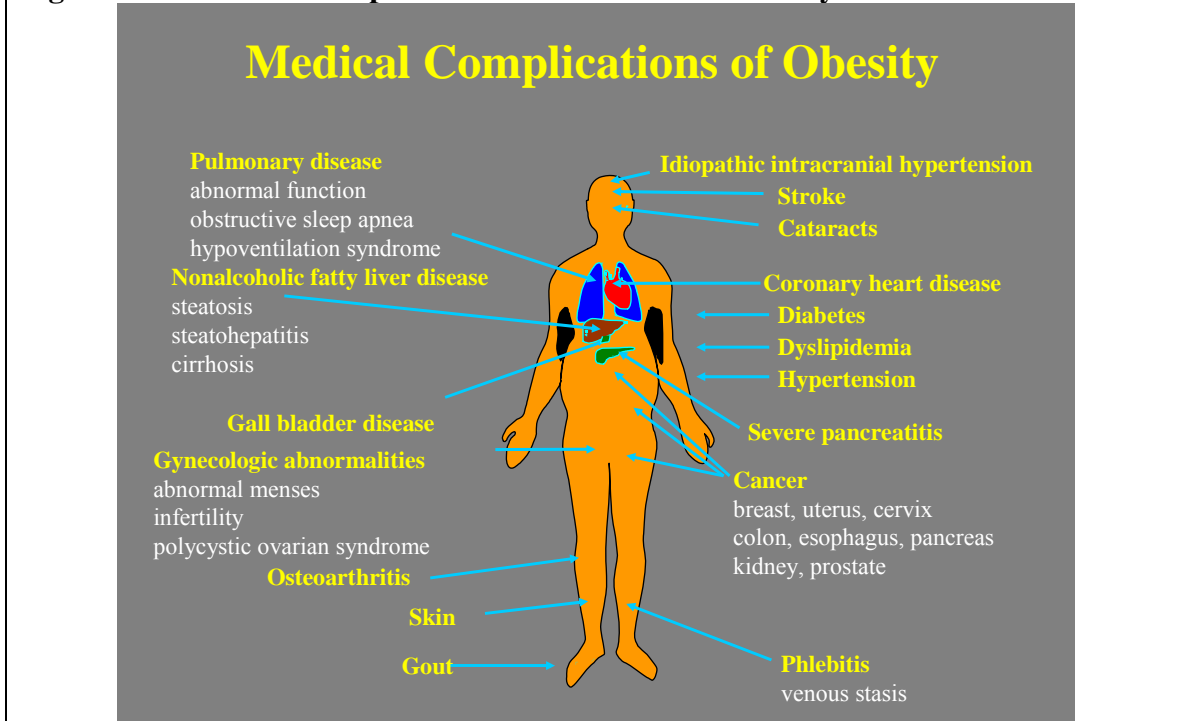
-
- Gallbladder disease;
 - Osteoarthritis (degeneration of cartilage and bone in joints);
 - Sleep apnea;
 - Asthma;
 - Cancer (endometrial, colon, kidney, gallbladder, and postmenopausal breast cancer);
 - High blood cholesterol;
 - Complications of pregnancy;
 - Menstrual irregularities;
 - Hirsutism (presence of excess body and facial hair);
 - Stress incontinence (urine leakage cause by weak pelvic-floor muscles);
 - Increased surgical risk;
 - Psychological disorders such as depression; and
 - Psychological difficulties due to social stigmatization.

The National Heart, Lung, and Blood Institute (NHLBI)¹ recognize being overweight and obesity as chronic diseases, and have published guidelines for the identification and treatment of these conditions.

As depicted in Figure 1.4, patients who are overweight or obese are at an increased risk of acquiring other serious, possibly chronic conditions. These include, but are not limited to hypertension, Type 2 diabetes, hyperlipidemia, sleep apnea, mellitus, coronary heart disease, asthma, hypothyroidism, Cushing’s syndrome, obstructive pulmonary disease, emphasema, stroke, as well as multiple forms of cancer and orthopedic problems” (DeMaria, M.D.; Schnee, 2006).

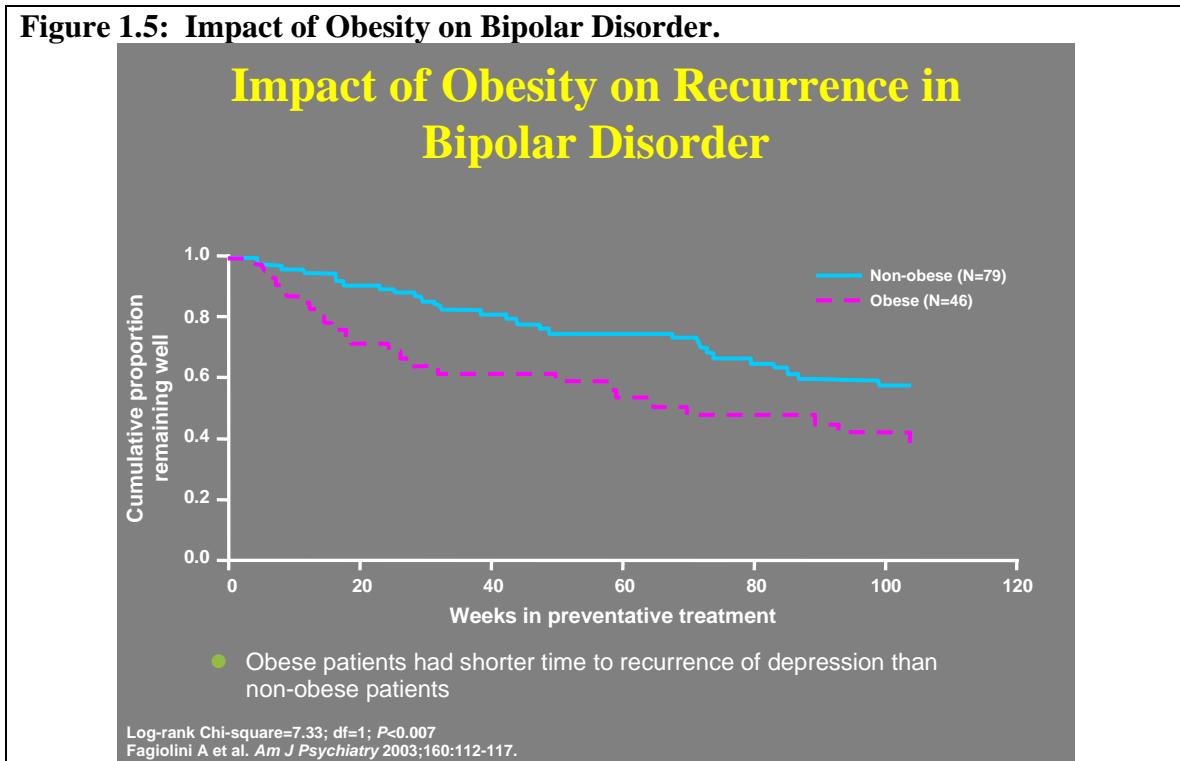
¹ Similar information is available from the National Institute of Health (NIH).

Figure 1.4: Medical Complications Associated with Obesity.



Persons with obesity have been found to experience depression more often than non-obese persons (Fagiolini, 2003). Illustrated in figure 1.5 below, individuals with bipolar disorder have been observed to have a shorter time to recurrence of depression than people with bipolar disorder who were not obese.

Figure 1.5: Impact of Obesity on Bipolar Disorder.



Obesity also has additional consequences, including limitations in activities of daily living (ADL's) and stigmatization.

Stigmatization:

In addition to poorer health and decreased physical functional capacity, obese individuals are also limited by social stigma in our society. There is a commonly held belief of our society that overweight and obese people are lazy and weak-willed. Under this misperception, if overweight persons just had willpower, they would push themselves away from the table and not be overweight. This view is unfortunately shared both by some members of the public and even by some health professionals charged with caring for these individuals. When persons with obesity who believe that their health care providers look down upon them, they may not seek necessary medical care (Carr, 2005). People with co-occurring mental illness and obesity may face a “double whammy:” stigma associated with the mental illness and stigma related to body weight.

While most public health interventions that target persons with obesity focus on their lifestyles and health behaviors, Carr found that interventions should also focus on the practices of “those who do the discriminating.” Public education about the distinctive challenges facing obese persons and about the pervasiveness of prejudicial attitudes toward them may help to reduce unfair treatment of severely overweight Americans.

Societal Costs:

When assessing the economic consequences of obesity, both direct and indirect costs of illness need to be considered. “Direct costs are the value of resources (personal health care, hospital care, physicians’ services, nursing home care, other professional services, and drugs) that could be allocated to other uses in the absence of disease. Indirect costs are the value of the lost output because of cessation or reduction of productivity caused by morbidity and mortality” (Colditz, 1992). Cost-of-illness studies have suggested variable estimates of the percentage of total health care costs attributable to obesity.

Prevalence-based cost of illness studies of obesity show that “aggregate economic costs associated with specific obesity related diseases have demonstrated that the annual burden to society totals in the billions of dollars, representing 5.5% to 7.8% of the total health care expenditure in the United States” (Kortt et al, 1998 citing work completed by Colditz, 1992).

“In the United States, health care expenditures related to obesity and associated medical conditions amount to \$100 billion annually and in 2000, obesity was estimated to contribute to approximately 400,000 deaths. It has been suggested that in the 21st century, increasing rates of obesity may lead to a decline in overall life expectancy in the United States” (DeMaria, M.D.).

Commenting on the impact of obesity in the workplace, Schmier and colleagues have noted that obese employees use more sick leave, have higher health care costs and have more workplace injuries (Schmier, et al, 2006).

In their report, the *Economic Burden of Obesity in Youths Ages 6-17 Years; 1979-1999* published in the May 2002 issue of *Pediatrics*, Wang, Guijing and Dietz reported that obesity-associated annual hospital costs increased from \$35 million from the 1979 - 1981 reporting period to \$127 million during the 1997 - 1999 reporting period. Compared to overall costs for discharges, this represents an increase from 0.43% in 1979-1981 to 1.7% in 1997-1999. In another study of overweight children, Hampl and associates found that health care expenditures were significantly higher for obese children when compared to normal weight children (Hampl et al, 2007).

Special Populations

Children and Adolescents:

The U.S. Department of Health and Human Services reports that 9 million children, 16% of the population, within the United States are overweight. According to Youfa Wang, MD, PhD, lead author of a study by researchers at the Johns Hopkins Bloomberg School of Public Health, 34% are at risk of becoming overweight in 2003-2004. White children and adolescents had the lowest prevalence of overweight and being at risk of overweight compared with their black and Mexican counterparts (Wang, 2007). The Institute of Medicine reports that 24% of African American and Hispanic children are obese.

The incidence of overweight children in the United States has steadily increased in the same manner as the adult population over the past decades. Since the 1980's, the estimated percentage of overweight children and adolescents has more than doubled (Schnee, 2006).

Excess weight in childhood and adolescence can predict overweight in adults. According to the U.S. Surgeon General's Call to Action, overweight adolescents have a 70% chance of becoming overweight or obese adults. Furthermore, this problem is intensified by demographic disparities. Low-income 2 to 5 year olds represent 18% of the statewide average number of overweight children (Pennsylvania, 2006).

The Institute of Medicine reports that obesity in children places them at risk for serious health complications. Approximately 60% of obese children in the U.S. had at least one risk factor for cardiovascular disease; 25% had two or more risk factors. In the past, physicians considered Type 2 diabetes an adult affliction that was rare in children. Now, girls born in the United States in the year 2000 have a 30% lifetime risk of developing Type 2 diabetes. The risk increases to 40% for boys born in the same year. The risk is even higher for minorities. Some experts have determined that childhood obesity also quickly increases the severity and prevalence of asthma (Pennsylvania, 2006).

Obesity in youth has a variety of mental health consequences. The University of Medicine and Dentistry of New Jersey reports that obese girls ages 13 to 14 are four times more likely to experience low self-esteem than non-obese girls. An article from the January 2000 publication *Pediatrics*, entitled "Childhood Obesity and Self-Esteem" reports that obese boys and girls with low self-esteem had higher rates of loneliness, sadness, and nervousness. According to the article these children were more likely to smoke and drink alcohol compared with obese children with normal self-esteem. Depression, often an outcome of low self-esteem, affects as many as 750,000 teens in the U.S. Finally, according to an August 2003 article entitled, "Associations of Weight-Based Teasing and Emotional Well-being Among Adolescents," from the *Archives of Pediatrics and Adolescent Medicine* children who were teased about being overweight were more likely to have a poor body image, low self-esteem, and symptoms of depression. Twenty-six percent of teens who were teased at school at home reported they had considered suicide, and 9% had attempted suicide. In the youth population, a higher BMI correlates with victimization in younger children and perpetration in older youth

(Janssen, 2004). There is a higher prevalence of disruptive behavior, including Oppositional Defiant Disorder (ODD) and chemical dependency. In addition, anxiety disorders, combined with poor social skills have been found to be prevalent (Villa, 2004).

Older and Disabled Adults:

The percentage of older adults who were obese increased from 16.4% in 1997 to 21.4% in 2002 (Doshi, 2007). Doshi's study of the Medicare population also indicated that this percentage also increased from 32.5% in 1997 to 39.3% in 2002 for the disabled population. Analysis of the data between 1997 and 2002 indicated that the prevalence of obesity among all beneficiaries increased by 31%.

Doshi's study indicated that the health consequences of obesity were numerous. In both the aged and disabled groups, obese beneficiaries were significantly more likely than normal weight beneficiaries to have one of the five examined medical comorbidities. The prevalence of Type 2 diabetes was almost three times higher in obese aged beneficiaries and two times higher in obese disabled beneficiaries than in their normal weight counterparts.

Ninety-three percent obese aged and 84.5% of disabled beneficiaries had at least one comorbidity (Doshi, 2007). The prevalence of at least one comorbidity among beneficiaries with a BMI ≥ 35 was similarly high. In both groups, more than two of five obese beneficiaries and more than half of those with a BMI ≥ 35 had three or more of these comorbidities. In addition, almost one-third of obese aged and two thirds of obese disabled beneficiaries reported fair to poor health. Obese beneficiaries were significantly more likely to report an ADL limitation than normal-weight beneficiaries in both the aged and disabled groups.

Women:

Globally, women generally have higher rates of obesity than men do, although men may have higher rates of being overweight. According to the American Obesity Association, 62% of women between 20 and 76 years are overweight, and 34% are obese.² Additionally, women are more likely to become obese as they age. Obesity among women ages 35 to 64 has increased in prevalence 2% per year from 1960 to 2000. Low-income women in minority populations are most likely to be overweight; black (non-Hispanic) women have the highest prevalence of overweight (78%) and obesity (50.8%). Forty to Sixty-Five percent of women report having sedentary lifestyles, an obvious contributor to obesity.

As demonstrated by Figure 1.6 below, women, in this large study involving people with schizophrenia, had higher rates of obesity than men and have higher rates of the complications brought by obesity.

² http://obesity1.tempdomainname.com/subs/fastfacts/obesity_women.shtml

Figure 1.6: Obesity Rates in Men & Women.

Comparison of Metabolic Syndrome and Individual Criterion Prevalence in Fasting CATIE Subjects and Matched NHANES III Subjects

	Males			Females		
	CATIE	NHANES	P	CATIE	NHANES	P
	N = 509	N = 509		N = 180	N = 180	
Metabolic Syndrome Prevalence	36.0%	19.7%	.0001	51.6%	25.1%	.0001
Waist Circumference Criterion	35.5%	24.8%	.0001	76.3%	57.0%	.0001
Triglyceride Criterion	50.7%	32.1%	.0001	42.3%	19.6%	.0001
HDL Criterion	48.9%	31.9%	.0001	63.3%	36.3%	.0001
BP Criterion	47.2%	31.1%	.0001	49.6%	26.8%	.0001
Glucose Criterion	14.1%	14.2%	.9635	21.7%	11.2%	.0075

McEvoy JP, et al. *Schizophr Res.* 2005;80:19-32.

Health consequences for obese women are particularly serious.³ Obese women have four times the risk of osteoarthritis as other women. Obese women also have a higher risk for developing breast cancer after menopause. Women who gain more than 45 pounds after reaching adulthood are twice as likely to develop breast cancer as women who do not gain weight. Similarly, obese women have a significantly higher risk of getting endometrial cancer than non-obese women. For both genders, but particularly for women, higher BMI is correlated with cardiovascular disease. Obesity is also the best predictor of gallbladder disease for women, where obese women have double the risk of women of normal weight. Obesity can impact a woman's ability to have children, and can affect ovulation, fertility treatment success, and pregnancy rates. Some studies have found that neural tube defects are more frequent among women with higher weight before pregnancy; obesity also carries a higher risk of pregnancy hypertension, gestational diabetes, urinary infection, and Cesarean section delivery. Obese women thought to be infertile actually have higher rates of successful pregnancy terms, longer labors, and induced labor.

While all obese people experience stigma and discrimination, obese women experience this significantly more than obese men; for those women who reduce obesity through surgery, unemployment rates fall from 84 to 64%.⁴ The societal importance placed on thinness as a measure of beauty can make establishing and maintaining relationships more difficult for obese women.

³ http://obesity1.tempdomainname.com/subs/fastfacts/obesity_women.shtml

⁴ http://obesity1.tempdomainname.com/subs/fastfacts/obesity_women.shtml

Racial/Ethnic Groups:

The American Obesity Association states that in comparison to white Americans, minority populations such as African Americans and Hispanic Americans have higher rates of obesity, whereas Asian Americans show relatively low levels of obesity.⁵ African Americans cultural dynamics associated with food choices, physical activity, and cultural norms around excess weight can play a role in failed weight loss. Generally, African Americans get less exercise than white populations, particularly among women.

American Indian and Alaska Native populations show particularly high rates of being overweight or obese; over 30% are obese, and among those ages 45 to 77 years, that number increase to over 39% for men and 43% for women.⁶ The American Obesity Association reports that, “44 to 60 percent of Native American men report having sedentary lifestyles, an obvious contributor to obesity.”

With regard to gender, black women (51%) and Mexican American men (30%) have the highest rates of obesity.⁷ Overall, lower socioeconomic status populations have a much higher likelihood of being obese. Specifically, women and minorities of lower socioeconomic status are affected by obesity at higher rates.

⁵ http://obesity1.tempdomainname.com/subs/fastfacts/Obesity_Minority_Pop.shtml

⁶ <http://www.americanheart.org/downloadable/heart/1014745957045FS02AM02WEB.pdf>

⁷ http://obesity1.tempdomainname.com/subs/fastfacts/Obesity_Minority_Pop.shtml

Persons with Serious Mental Illness

Adult persons with a serious mental illness (SMI) are the core focus of this report and can be defined as those aged 18 years or older with a diagnosable mental disorder that is so long lasting and severe that it seriously interferes with their ability to take part in major life activities. According to the 2004 U.S. Census, about 1 in 17 adults suffer from a serious mental illness. Illnesses such as schizophrenia and bipolar disorder affect an estimated 8.1 million American adults yearly (NIMH, 2006). During their lifetime these individuals not only face the challenge of their mental illness but are also affected by a higher prevalence of physical health problems, such as obesity.

Obesity is more prevalent in persons with SMI than in the general population (Hoffman, 2005). A study by Strassnig, Brar, and Ganguli, published in 2003 in the *Schizophrenia Bulletin* reviewed 276 patients with schizophrenia in Pittsburgh and found that:

- 19% were of normal weight with a BMI within the range of 19 to 25;
- 22% were overweight with a BMI within the range of 25 to 30; and
- 59% were obese with a BMI greater than 30.

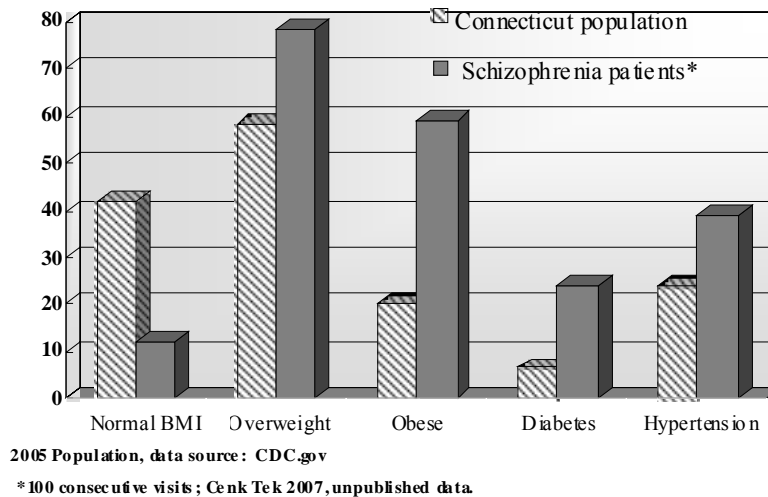
Several other studies have addressed the prevalence of obesity in the population of patients with severe mental illness such as schizophrenia or bipolar disorder. Allison et al (1999) found that 42% of a group of individuals with schizophrenia had a BMI of 27 or greater, compared to 27% of the general population. In that study, the difference was mostly due to the high proportion of women with schizophrenia who are obese. In another study (Homel, 2002), women with schizophrenia had higher mean BMI's compared with non-psychiatric controls whereas men with schizophrenia were similar to controls.

In the Northern Finland 1966 cohort study, rates of abdominal obesity and metabolic syndrome in patients with schizophrenia were 42% and 19.4%, respectively, as compared to health members of the cohort, which were 13% and 6%, respectively (Saari et al., 2006). In the same study, the probability of changing from underweight or normal during adolescence to overweight or obese in adulthood was 3.01 in females, and 2.24 in males as compared to the healthy members of the cohort. Physical inactivity and high alcohol consumption were the common risk factors for both sexes (Hakko et al, 2007). Another recent study found that the prevalence of overweight, obesity, and diabetes mellitus were significantly higher in patients with severe mental illness (schizophrenia, schizoaffective disorder, bipolar disorder and major depressive disorder) as compared to those in the Kentucky adult general population (Susce et al., 2005). The odds ratio for overweight was 1.7 and the odds ratio for obesity was 2.6. The results were particularly worrisome since Kentucky is one of the states with the highest prevalence of overweight people. Keck et al (2004) reviewed 45 studies of patients with bipolar disorder and found that the results of these studies indicated that the overall prevalence of overweight and obesity was higher in these patients than in control populations. Several risk factors for weight gain and obesity in patients with bipolar disorder were identified: excessive carbohydrate consumption, low rate of exercise, and treatment with medications associated with weight gain. In the 1460 patient CATIE study, the prevalence of metabolic syndrome among

patients with chronic schizophrenia was 36% for males and 52% for females as opposed to the rates in general population, which were 20% and 25% respectively. In the same study mean BMI for females was 33 and for males was 29 kg/m²; the rates for abdominal obesity were 73% for males 37% for females as compared to 57% and 25% respectively in the US population (McEvoy et al. 2005). In the CATIE study, obesity was associated with significantly increased outpatient medical costs (25% more), even after controlling for demographic characteristics and medical comorbidity (Chwastiak et al, 2006). A recent study of schizophrenia patients conducted in the state of Connecticut revealed an overweight rate of 78% vs. 58.2% in the population, and an obesity rate of 59% vs. 20.1 % in the population (See figure 2.0 below).

Figure 2.0: Compounding Affects of Risk Factors.

Weight Status, Diabetes, and Hypertension Rates of Yale - CMHC Schizophrenia Patients



Additional studies indicate that the risk of obesity in persons with SMI vary by diagnosis. Those with:

- Depression have a 1.2 to 1.8 increased likelihood of being obese;⁸
- Bipolar disorder have a 1.5 to 2.3 increased likelihood of being obese;⁹ and
- Schizophrenia have a 3.5 increased likelihood of being obese.¹⁰

A combination of the mental disorder itself and some of the medications used to treat it, a sedentary lifestyle, poor nutrition, overeating, smoking and substance abuse, irregular and inadequate sleep, lack of access to adequate medical care, including poor coordination of

⁸ Simon GE et al. (July 2006). Arch Gen Psychiatry. Vol. 63, No. 7, pp. 824-30 and Petry et al. (April 2008) Psychosom Med. Vol. 70 No. 3, pp.288-97.

⁹ Simon GE et al. (July 2006). Arch Gen Psychiatry. Vol. 63, No. 7, pp. 824-30 and Petry et al. (April 2008) Psychosom Med. Vol. 70 No. 3, pp.288-97.

¹⁰ Coodin et al. (2001). Can J Psychiatry. Vol. 46, pp. 549-55.

care between multiple providers, and lack of access to nutrition and exercise programs have contributed to increased weight gain in persons with SMI (Hoffman, 2005). Studies suggest that persons with SMI tend to have a diet consisting of an increased quantity and caloric intake, diet composition – consuming foods low in fiber, high in fat, with fewer fruits and vegetables primarily because of elevated rates of poverty in this population.¹¹ In addition, inactivity among persons with SMI tend to contribute to rates of obesity. Studies indicate that the odds of inactivity in persons with SMI vary by diagnosis. Those with:

- Severe mental illness have a 1.5 increased likelihood of being inactive;¹²
- Bipolar disorder have a 3.2 increased likelihood of being inactive;¹³ and
- Depression have a 2.0 increased likelihood of being inactive.¹⁴

Persons with SMI have higher rates of morbidity and premature mortality compared with the general population. As stated earlier, obesity risk factors can contribute to the increased morbidity and mortality. Research suggest that “this population loses...13 to over 30 years of life compared with their nonpsychiatric cohorts” (Vreeland, 2007).

The National Alliance on Mental Illness (NAMI) has identified that persons with SMI are at a greater risk of developing adult onset, or Type 2 diabetes (Duckworth, 2007). This type of diabetes can sometimes be prevented by exercise and healthy eating habits, and maintaining normal body weight, but takes awareness and motivation on behalf of the individual. Usually, many risk factors combine, leading to a slowly developing problem. These risk factors include:

Biological/Genetic:

- There is some evidence that individuals with some psychiatric conditions may have a higher genetic risk of developing diabetes.
- Antipsychotic medications, including some second generation antipsychotics, carry a risk of weight gain, a major contributor of diabetes. Not all antipsychotics, however, confer the same relative risk. Antipsychotics commonly cause sedation, predictably leading to reduced caloric expenditure, and some medications may also reduce satiety or increase hunger, causing some people to lose the feeling of fullness they used to get at the end of an ordinarily sufficient meal. The magnitude of these effects varies across individual medications, for example with medications that have more histamine type 1 receptor antagonism having larger adverse effects on body weight. In addition, some psychotropic medications may directly alter insulin sensitivity or lipid metabolism, contributing to insulin resistance or dyslipidemia, risk factors for hyperglycemia, type 2 diabetes mellitus, and cardiovascular disease.

¹¹ Strassnig, Brar and Ganguli. (2003). *Schizophr Res*. Vol. 62, pp. 73–6, McCreadie et al. (2003). *Br J Psychiatry*. Vol. 183, pp. 534–9, Brown et al. (1999). *Psychol Med*. Vol. 29, pp. 697–701, Lin, B. (February 2005). USDA, Economic Research Service, Kant. (Feb. 2007). *AKPublic Health Nutr*. Vol. 2, pp. 158-67.

¹² Daumit et al. (Oct. 2005). *J Nerv Ment Dis*. Vol. 193, No. 10, pp. 641-6.

¹³ Elmslie et al. (June 2001). *J Clin Psych*. Vol. 62, No. 6, pp. 486-91.

¹⁴ Farmer et al. (Dec. 1988). *Am J Epidemiol*. Vol. 128, No. 6, pp. 1340-51.

-
- Negative symptoms and co-occurring depression may reduce people’s motivation to eat well or be physically active, thereby further increasing for obesity and conditions related to obesity.
 - A family history of type 2 diabetes, dyslipidemia, and cardiovascular disease appears to further add to the risk.

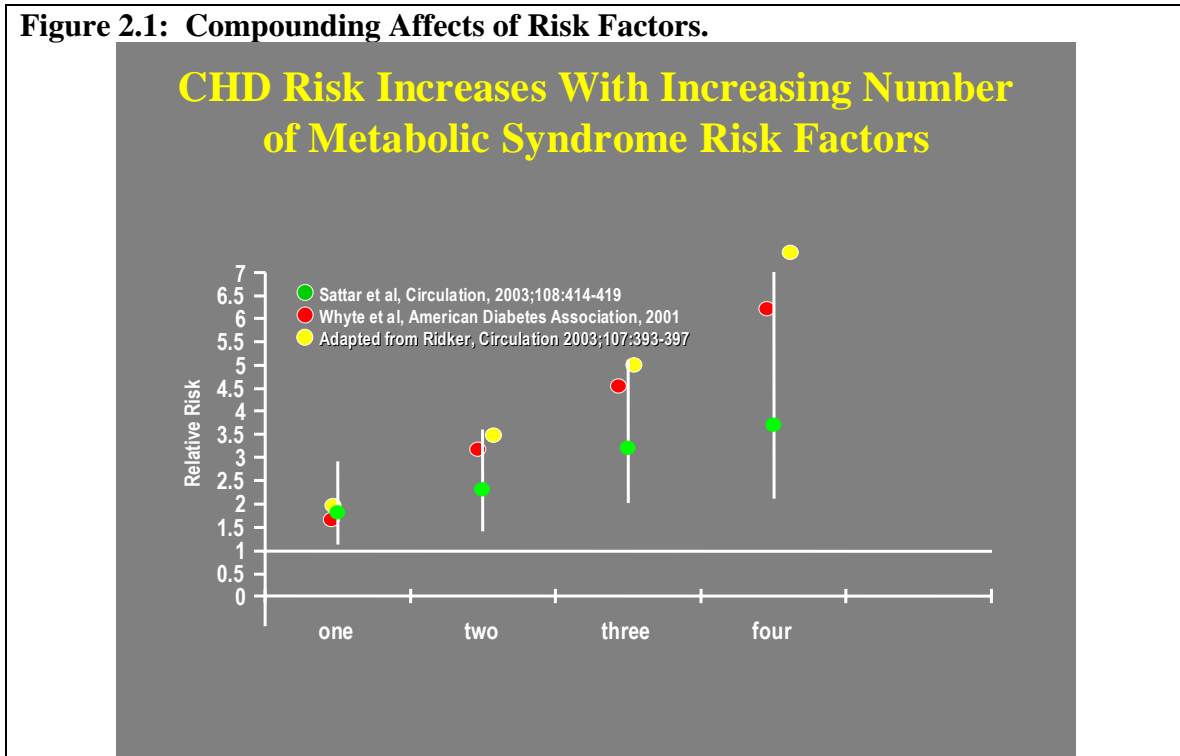
Cultural/Societal:

- The culture surrounding mental health has historically and traditionally encouraged passivity. Providers have reinforced the idea that mental health consumers should take their meds, get a ride or take a bus to their program, and sit in groups. Diabetes prevention, however, is about action: walking to an appointment, participating in community recreational activities, playing a sport, dancing, incorporating some form of physical activity into your daily schedule along with careful monitoring of food choices.
- Psychiatrists and other professionals may be reluctant to address weight and ways to possibly prevent weight gain for fear that the individual will refuse to take the medications that may have weight gain as a potential side effect.
- Clinicians often have insufficient training and may feel too pressed for time to focus on lifestyle choices and thus often focus on more traditional psychiatric goals such as reducing symptoms, leaving lifestyle choices to the individual. However, dialogue between the provider and the consumer about healthy lifestyle choices may help to inspire and motivate a person to make healthy choices (such as being more physically active and making healthier food and beverage choices. This may prevent or minimize weight gain and its secondary medical complications.)
- Psychiatrists and other clinicians have limited time available to spend with a person during an office visit. Concerns about the liability of the doctors managing medical problems can arise, which may result in an individual not getting timely treatment for a potential medical problem. New concerns may arise around liability related to prescribing psychotropic medications with large weight gain profiles.
- People with SMI often receive fragmented or poor medical care, which increase the time and effort to identify a problem and manage it. Furthermore, barriers to receiving prompt and appropriate physical health care include the difficulties faced by all consumers in accessing and negotiating the complexities of our present health care system.
- Mental health worker attitudes may contribute to the risk. These attitudes include the belief that one of the few pleasures a person receives is from eating.
- Low socio-economic status can cause financial barriers. Little money can limit choices. For example, high calorie foods, such as fast food are normally less expensive than healthier alternatives such as fresh fruits and vegetables. In addition, items like sugar-containing soft drinks are usually cheaper than healthier alternatives such as low-fat milk. Packaged foods, high in sodium and sugar, are also less expensive than fruits and vegetables, have a longer shelf life, and are easier to prepare for individuals with limited food preparation experience and for those living alone where the social activity of healthy dining with others is not routine. Group home and congregate care housing providers, often conscious of costs and ease of preparation may also opt for less nutritious foods. Nutritional counseling is rarely

covered by Medicaid. Health club fees can be expensive, and some people find going to gyms intimidating.

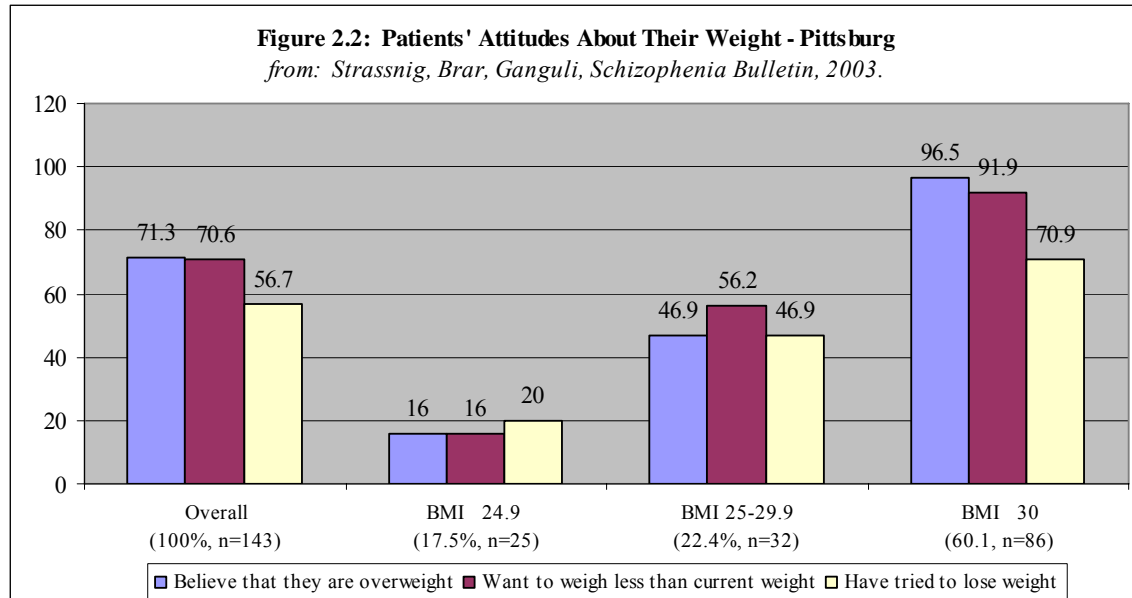
As risk factors accumulate, the relative risk of cardiovascular disease increases significantly. As illustrated by Figure 2.1, risk factors such as abdominal obesity, dyslipidemia, hyperglycemia, and hypertension can have at least additive effects on risk.

Figure 2.1: Compounding Affects of Risk Factors.



Motivation and Ability to Lose Weight:

There is a commonly held belief that persons with mental illness cannot make changes that improve their lives including achieving weight loss and better health. Contrary to this common belief, persons with SMI are self-conscious about their weight and interested in reducing their weight. A study of 143 patients with SMI in Pittsburgh indicates that over 71% believe that they are overweight and over 50% have tried to lose weight (Figure 2.2). In addition, the study found that there was a correlation between the more a patient weighed and the desire to lose weight.



A survey of 2,222 patients in the United Kingdom conducted by the British National Schizophrenia Fellowship (MIND) and the National Association for Mental Health & Manic Depression found that the top five “bad things” about taking psychotropic medications to manage ones mental illness were:

- Weight gain, eat a lot, etc. identified by approximately 20% of responders;
- Sedating side effects, tiredness, and drowsiness, identified by approximately 15% of responders;
- Lethargic, demotivated, less active, and apathetic, identified by more than 5% of responders;
- Imprecise negative comments, identified by more than 5% of responders; and
- Tremors and shaking identified by slightly more than 5% of responders.

These concerns can contribute to medication non-adherence unless mitigated.

“While the body of evidence is not as vast as that in the general population, studies have shown that people with SMI can adopt healthy lifestyle behaviors. Despite the known health risks intrinsically associated with mental illness, research indicates that, like those without mental illness, people with schizophrenia, bipolar disorder, and other types of mental illness can adopt healthier choices (Vreeland, 2007).”

Interventions

The impact on one's overall health even with modest weight loss, are considerable. According to a study by Gregg and Williamson published in 2004, which analyzed data from 7 randomized controlled trials of approximately 7,000 subjects over 1 to 6 years lost 2 to 6% of body weight lost through lifestyle intervention. This modest amount of weight loss results was associated with:

- Decreased the hypertension incidence by 20 to 40%;
- Decreased diabetes incidence by 30 to 60%; and
- Decreased cardiac events by 30 to 40%.

Additional studies have reported that moderate weight loss of:

- 4 to 5% loss can lower or eliminate the need for antihypertensive medication in adults & the elderly (Stamler, 1987; Langford, 1985; Whelton, 1998);
- 5 to 7% loss is associated with 58% reduced risk for type 2 diabetes in adults (Knowler, 2002);
- 6 to 7% loss can improve the metabolic syndrome by decreasing low-density lipoprotein cholesterol, LDL concentration, and fasting insulin (Brook, 2004); and
- 10% loss can reduce lifetime risk for heart disease up to 4% and increase life expectancy for up to 7 months (Oster, 1999).

Figure 3.1:

Goals: Lower Risk for CVD

- Blood cholesterol
 - 10% ↓ = 30% ↓ in CHD (200-180)
- High blood pressure (> 140 SBP or 90 DBP)
 - 4-6 mm Hg ↓ = 16% ↓ in CHD; 42% ↓ in stroke
- Cigarette smoking cessation
 - 50%-70% ↓ in CHD
- Maintenance of ideal body weight (BMI = 25)
 - 35%-55% ↓ in CHD
- Maintenance of active lifestyle (20-min walk daily)
 - 35%-55% ↓ in CHD

Hennekens CH. *Circulation*. 1998;97:1095-1102.

Reducing Calories Is Much More Effective at Losing Weight Than Increasing Physical Activity.

However, increase in exercise without reducing calories may not contribute to weight loss.

Increasing Physical Activity Is Effective for Improving Physical Health Independent of Any Change in Weight.

Exercise independent of improvements in diet, can lead to additional metabolic improvements.

It is important to note that psycho-education, lifestyle interventions must be based on consumer choice. Behavioral treatment professionals need to help individuals with psychiatric disabilities understand health consequences of lifestyle choices and build a clinical alliance supporting any patient chosen therapeutic interventions. Shared decision making in clinical settings becomes critical to reinforcing the ability of individuals with psychiatric disabilities to make healthy choices.

Prevention of obesity in non-obese individuals is a key primary prevention goal and various combinations of diet, exercise, and behavioral treatment can also help to prevent continued weight gain and foster weight loss when weight gain has already occurred. These interventions also have promising indications of reducing weight in overweight and obese individuals with SMI.

Public Health Interventions:

In response to the obesity epidemic, in 2005, the United States Department of Agriculture (USDA) updated their Dietary Guidelines for Americans and now promote a new food guidance system for Americans. MyPyramid replaces the old Food Pyramid as represented in Figure 3.3.

Figure 3.3: Old and New Food Pyramid.



As depicted in MyPyramid, the USDA incorporated, for the first time, regular physical activity (a minimum of 30 minutes a day). By doing so, the USDA has acknowledged

that physical activity is an essential element when combined with a healthy diet in maintaining a healthy weight. The eating plan emphasized is one that will give the body the balanced nutrition it needs for eating a variety of nutrient packed foods everyday. These eating patterns are not “fad diets,” but rather a lifestyle of health eating that promotes well-being and reduces the risk of many chronic illnesses linked to obesity. MyPyramid has 12 different versions: caloric intake and recommended servings for different food groups will differ depending upon age, gender, and physical activity level (Dietary Guidelines and MyPyramid Mini-Poster).

In addition, the National Weight Control Registry, which is a registry of over 6,000 individuals who have been successful in losing a minimum of 30 pounds and keeping the weight off for at least a year, suggests six key strategies when helping people lose weight and keeping it off:

1. Engage in high levels of physical activity;¹⁵
2. Eat a diet low in calories and fat;¹⁶
3. Eat breakfast;¹⁷
4. Self-monitor weight regularly;¹⁸
5. Maintain a consistent eating pattern;¹⁹
6. Catch slips before they turn into larger regains;²⁰
7. Watch a limited amount of television;²¹
8. Initiate weight loss after a medical event;²² and
9. Eat a diet with limited variety in all food groups.²³

Behavioral Treatment:

“According to the guidelines of the National Heart, Lung, and Blood Institute (NHLBI), treatment of overweight or obese adults is a two-step process involving assessment and treatment management. Assessment includes assessing BMI, diet, waist circumference, risk status, and level of motivation (NHLBI, 1998).” Lifestyle modification programs are typically heavily influenced by learning theory and, principles of classical and operant conditioning. To remain atheoretical and pragmatic, these programs often incorporate strategies like cognitive restructuring to induce behavior change from cognitive-behavioral therapy. The key elements to behavioral approaches are giving participants a set of structured, gradual lifestyle change principals and methods in order to modify diet and physical activity, cognitive techniques for attitude change, and strategies for increasing social support. Thus the interventions both attempt to provide self-knowledge of where the problem behaviors originate, and teach skills for changing them.

¹⁵ Klem, M.L. et al. (2003). *Am J Clin Nutr.* Vol. 66, pp. 239-246.

¹⁶ Klem, M.L. et al. (2003). *Am J Clin Nutr.* Vol. 66, pp. 239-246.

¹⁷ Wyatt H.R. et al. (2002). *Obesity Research.* Vol. 10, pp. 78-82.

¹⁸ Klem, M.L. et al. (2003). *Am J Clin Nutr.* Vol. 66, pp. 239-246.

¹⁹ Gorin, A.A. et al. (2004). *Intl J Obesity.* Vol. 28, pp. 278-282.

²⁰ Phelan, S. et al. (2003). *Am J Clin Nutr.* Vol. 78, pp. 1079-1084.

²¹ Nutrition Action Healthletter Jan/Feb 2008, p.8.

²² Gorin, A.A. et al. (2004). *Prev Med.* Vol. 39, pp. 612-616.

²³ Raynor, H.A. et al. (2005). *Obesity Research.* Vol. 13, pp. 883-90.

Behavioral strategies include:

- Self monitoring, including record keeping;
- Nutrition education;
- Goal setting;
- Stimulus control;
- Behavioral Substitution;
- Problem Solving;
- Cognitive Restructuring;
- Relapse Management; and
- Other behavior change like slowing eating, portion control, and lifestyle activity.

Therapies that combine modifications to diet, behavior management, and physical activity are the most successful at obtaining weight loss. Results of such non-pharmacological treatment methods to reduce obesity appear in Table 3.4 below.

Table 3.4: Results of Non-pharmacological treatment of Obesity and Diets.

Non-Pharmacological Treatment of Obesity - Diets			
Success rate for reported study groups, subdivided according to initial treatment, energy level of initial diet and intensity of follow-up.			
	No. of patients	No. of study groups	Median success rate (range)
Overall success rate	2131	21	15% (0-49%)
Influence of initial treatment:			
Diet * alone **	1337	10	15% (6-28%)
Diet * plus group therapy	487	4	27% (14-31%)
Diet * plus behaviour modification	307	7	14% (0-49%)
Influence of energy level of initial diet:			
Very-low-calorie diet (300-600 kcal/24 h)**	304	8	14% (6-49%)
Conventional diet (800 - 1800 kcal/24 h)	1827	13	18% (0-31%)
Influence of intensity of follow-up:			
Passive follow-up **	597	10	10% (0-31%)
Active follow-up	1534	11	19% (13-49%)
* Conventional diet or very-low-calorie diet. ** Fasting was initially used in one study group. Ayyad and Andersen, 2000.			

There is emerging evidence that behavioral treatments that were shown to be effective in non-mentally ill individuals appear to be effective for individuals with severe mental illness as well. O'Keefe et al. (2003) performed a retrospective chart review of 35

patients who had initially gained at least 20 lbs. and then lost at least 10 lbs. while taking antipsychotics over a 5 year period. The most frequent weight loss interventions were regular dietician visits (42.9%), self-directed diet (28.6%), and weight loss as a treatment goal (25.7%). There are no less than fifteen published clinical intervention trials that confirmed the effectiveness of a wide range of behavioral interventions from lifestyle change to commercial Weight Watchers program. A summary of these interventions are presented in the Table 3.5.

Table 3.5. Summary of Prospective Behavioral Weight Management Studies for Psychotic Outpatients*

	Intervention N	Intervention BMI (weighted average)	Control N	Control BMI (weighted average)	Intervention weight change (weighted average, lbs)	Control weight change (weighted average, lbs)
Randomized Studies Prevention of weight gain	79	27.9	76	23.4	+4.64	+15.56
Randomized Studies Weight loss	141	30.2	121	30.5	-5.7	+0.9
All Published Studies	544	30.1	217	28.7	- 4.3	+ 5.9

* Adapted and updated from Jean-Baptiste et al, 2007

As reported in the study, “Wellness Intervention for Patients with Serious and Persistent Mental Illness,” the Solutions for Wellness Personalized Program is one example of an ongoing 6-month program targeted towards combining diet, exercise and behavioral therapy. Psychiatrists and primary care physicians throughout the United States caring for patients with mental illness living in the community were provided with enrollment forms and asked to distribute them to the target population. Patients were not required to meet any enrollment criteria, including diagnosis, treatment, weight, or risk for weight gain. Selection of participants was at the sole discretion of the clinician, and the decision to enroll belonged entirely to the patient.

Participants completed an enrollment survey that queried the self-perceived need to improve overall health and well-being; eat healthier; improve fitness, stress management, and sleep habits; and increase self-esteem. Participants’ readiness to change eating habits and to start being more physically active was also assessed. Information on diet and exercise preferences from the enrollment survey was used to generate a personalized menu planner that included a weekly menu with dinner recipes and shopping list, which was developed with the assistance of mental health clinicians and registered dietitians. A

public health clinician and a certified health fitness instructor developed a personalized exercise plan. Participants also received regular educational mailings, such as newsletters that were developed by health care professionals, monthly motivational progress updates, motivational progress updates, and motivational gifts, like exercise videos.

The results of the study of this program found that the participants who were motivated to make a change were able to make healthy lifestyle changes, which helped them to lose weight and gain self-confidence. The success of these individuals was significantly associated with their readiness to make lifestyle changes. And the results are consistent with those of a prospective naturalistic study in patients with schizophrenia or schizoaffective disorder who were motivated to change their behavior in order to lose weight and benefited from a weight control program that focused on nutrition, exercise and motivation.

There is also a Solutions for Wellness manualized program (Vreeland B., Toto A.M., and Sakowitz M., 2008). It is a free, easy-to-use psychoeducational wellness program designed to inspire and assist persons with mental illness to make healthier eating, physical activity, and other lifestyle factor choices. Research findings suggest that the program is significantly associated with weight control in people with schizophrenia (Littrell et al., 2003) and also in people with other serious mental illnesses (Vreeland et al., 2008). Additionally, other similar programs such as the Healthy Living program assist with weight reduction. The Healthy Living program was designed to assist individuals who had gained weight as a result of their medications to make long-lasting lifestyle and behavioral changes that would have a positive effect on weight loss, overall health, and well-being.

Healthy Living consisted of nutritional counseling, exercise, and behavioral interventions designed to help adults with schizophrenia implement healthy life style changes. Behavioral strategies included self-monitoring of eating and physical activity, stress management, stimulus control, problem solving, and social support. Stage-based motivational counseling strategies (see table 3.6 below) were utilized and the participants were encouraged to make healthier choices around food and physical activity. Select materials from the Solutions for Wellness program (mentioned above) were utilized. “Small steps” that could fit into the individual’s every day lifestyle (taking into account the challenges that people with serious mental illness may encounter) were encouraged.

Table 3.6: Transtheoretical Stage of Change Model.

Stages of Change Model

Stage	Definition	Intervention
Precontemplation	Unaware of need to change behavior	Increase awareness
Contemplation	Thinking about change	Motivate, tip the balance
Preparation	Making a plan	Concrete action plan
Action	Implementing plan	Assist with feedback, support
Maintenance	Continuation of desirable actions	Reminders, avoiding slips

Prochaska J, DiClemente C, Norcross, J (1992). *Amer Psychologist*, 47: 1102-1114

Results from the Healthy Living study not only suggest that people diagnosed with schizophrenia can lose more weight than those who receive usual psychiatric care, but that they also may be able to lose more weight than their non-psychiatric cohorts who participate in weight loss programs such as Adkins and Weight Watchers (Vreeland, 2007).

Potential benefits to the patient from weight loss include:

- Reduction in risk of diabetes, cardiovascular disease, and other obesity related illnesses;
- Reduction of serum triglycerides and total and low-density lipoprotein (LDL)-cholesterol concentrations;
- Increase in high-density lipoprotein (HDL)-cholesterol concentrations; and
- Reduction in blood glucose concentrations and in hemoglobin A1C among patients with type 2 diabetes.

The Small Changes (Small Steps) Approach to Weight Management:

Some experts recommend using a “small changes approach” to preventing and reversing weight gain (Hill J.O. & Wyatt H.R., 2006; Vreeland, 2007). A combination of reduced energy intake (food) and increased physical activity that equals 100 kcal/day should prevent weight gain in most adults. A small changes approach can be applied to individuals or a population. Several examples of “small steps” people could choose to achieve this appear below.

Reducing consumption of any foods can result in substantial weight loss within a year. For instance:

- Elimination one 12-ounce can of soda per day can result in reduction of between 10 and 16lbs;
- Switching from whole milk to 2% (served three times per day) can result in a reduction of 5.6lbs;
- Refusing larger sizes can reduce about 500 calories;
- Watching TV two hours less per day can result in a 23% decrease in obesity; and
- Walking 2,000 steps (or about 1 mile) every day may reduce an additional 10 lbs. (Consider pedometers as a safe and easy way to increase awareness about physical activity and add more steps to each day).

Diabetes Prevention Program:

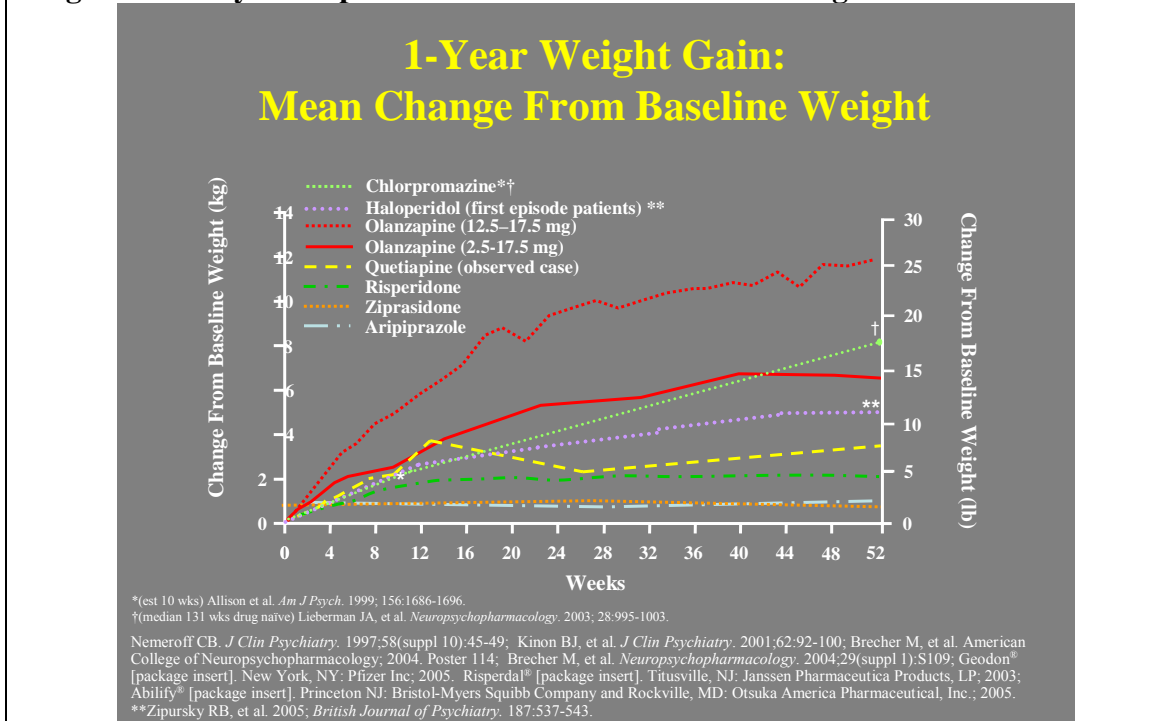
Diabetes Prevention Program (DPP) is a very large NIH sponsored trial that have shown a behavioral lifestyle intervention is very effective in decreasing rates of diabetes and other obesity related morbidity in non-mentally ill individuals (Knowler et al., 2002, Hamman et al., 2006). DPP has been shown to be effective for mentally ill individuals as well (McKibbin et al., 2006). All the manuals and materials of the DPP are freely available on the internet from the NIH, and can be adapted by mental health professionals for use in severe mentally ill population²⁴.

Psychiatric Medications:

Psychotropic medications are known to contribute to overweight and obesity. Figure 3.7 demonstrates the differential weight gain across several antipsychotic medications by monitoring weight gain in an individual with mental illness.

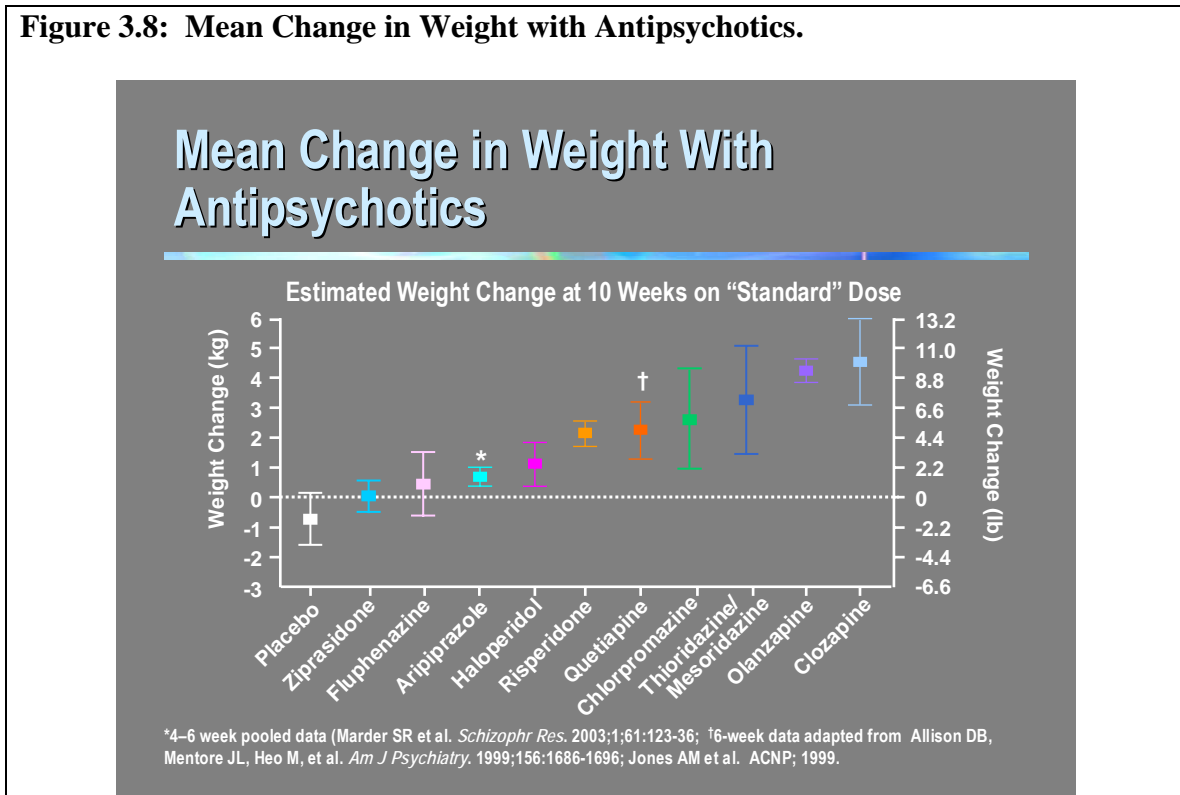
²⁴ Visit <http://diabetes.niddk.nih.gov/dm/pubs/preventionprogram/> for more information.

Figure 3.7: Psychotropic Medications and Associated Weight Gain within Year 1.



As outlined in figure 3.8, antipsychotic medications vary considerably in causing weight gain.

Figure 3.8: Mean Change in Weight with Antipsychotics.



In addition, many of these medications contribute to the following health complications:

- Insulin resistance;
- Diabetes/hyperglycemia; and
- Dyslipidemia.

Both the American Diabetes Association (ADA) and the American Psychiatric Association (APA) have indicated that when beginning Second Generation Antipsychotics (SGA), the prescriber should consider metabolic risk. For patients starting antipsychotics, a prescriber should consider the patients baseline BMI when choosing medications and choose medications with lowered risk of exacerbating obesity in overweight individuals or those at risk for obesity. In addition, for patients with high or borderline values or in patients with family history of obesity, high blood pressure, diabetes, or heart disease or stroke, drugs with lower risk of metabolic side effects should be chosen.

The figure 3.9 below provides a useful reference when prescribing psychotropic medications.

Figure 3.9: Affects of Antipsychotic Drugs on Weight and Diabetes.

ADA/APA Consensus Statement* on Second Generation Antipsychotics

Drug	Weight Gain	Risk for Diabetes	Worsening Lipid Profile
Olanzapine	+++	+	+
Clozapine	+++	+	+
Risperidone	++	D	D
Quetiapine	++	D	D
Aripiprazole	+/-	-	-
Ziprasidone	+/-	-	-

+ Increase effect - No effect D, Discrepant results

- Consideration of metabolic risk when starting SGA
- If a patient gains $\geq 5\%$ of initial weight during therapy, consider therapeutic options including switching SGA
- If a patient develops worsening glycemia or dyslipidemia while on antipsychotic therapy, consider switching to an SGA reduced risk

*Adapted from *Diabetes Care*. 2004;27:596-601 and *J Clin Psychiatry*. 2004;65:267-272.

Practice standards have been developed for monitoring the metabolic consequences of anti-psychotic medication including weight gain. These practice standards are outlined within figure 3.10 below. The regular monitoring of fasting lipid profiles is now recommended as a result of an increased understanding of the relationship between the level of certain lipid fractions and risk for cardiovascular disease and diabetes. While the ADA Consensus statement suggested that fasting lipid profiles might only need to be monitored every 5 years after an initial year of treatment, this recommendation is in fact derived from U.S. Public Health Service (USPHS) guidelines for individuals at low risk for cardiovascular disease, with wide agreement since that time that this is not a low risk population. In addition, lipid fractions like plasma triglyceride can serve as an indicator of insulin resistance, and can be elevated long before changes in plasma glucose, giving providers and patients a chance to intervene before disease progression and tissue damage occurs. The value of screening and monitoring can not be overemphasized, since intervention efforts require knowledge of the level of risk for an individual. Recent evidence indicates very low levels of screening and monitoring of plasma glucose and even lower levels for plasma lipids in patients taking antipsychotic medications (Morrato et al., 2008).

Figure 3.10: Monitoring Protocols.

ADA Consensus on Antipsychotic Drugs and Obesity and Diabetes: Monitoring Protocol*

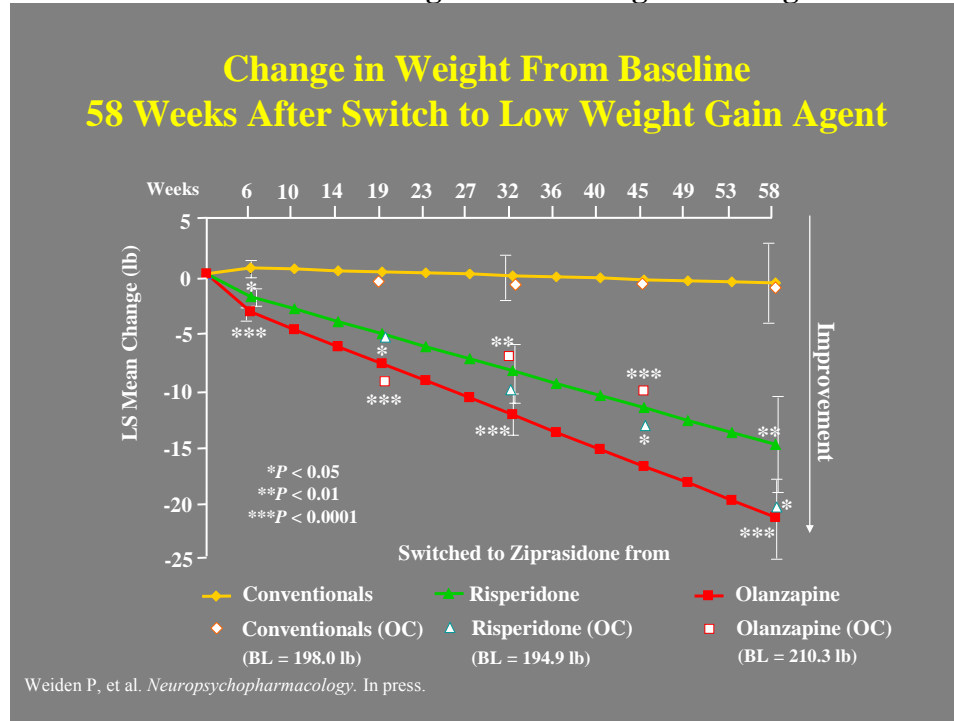
	Start	4 wks	8 wks	12 wks	3 mos.	12 mos.	5 yrs.
Personal/family Hx	X					X	
Weight (BMI)	X	X	X	X	X		
Waist circumference	X					X	
Blood pressure	X			X		X	
Fasting glucose	X			X		X	
Fasting lipid profile	X			X		X	X

**More frequent assessments may be warranted based on clinical status
Diabetes Care. 27:596-601, 2004*

Standard monitoring worksheets such as the one in attachment D have been developed and should be used for patients on SGA.

Switching antipsychotics when possible can result in a decrease in weight as depicted in figure 3.11.

Figure 3.11: 58 Weeks after Switching to a Low Weight Gain Agent.



If a patient gains more than 5% of his/her initial weight and/or develops worsening glycemia or dyslipidemia during therapy, the prescriber should consider therapeutic options, including changing the medication regimen to utilize agents with lower risk. However, since not all patients benefit or are harmed equally during treatment with individual antipsychotic medications, it is necessary to carefully consider trade-offs involving individual drug response and individual patient risk factors and preferences. This should optimally occur as an ongoing, shared, decision-making process between individual patients and their prescribers, re-evaluated on an ongoing basis as risks and benefits emerge. If a patient is taking multiple psychotropics, further attention may be necessary to determine risks, benefits and alternatives especially if the patient is gaining weight. Monitoring protocols for all individuals taking antipsychotic medications should include the following:

- Personal/family history;
- Weight (BMI);
- Waist circumference;
- Blood pressure;
- Fasting glucose; and
- Fasting lipid profile.

Weight Loss Medications:

While some individuals with SMI are able to maintain normal weight through diet and exercise, many are not able to avoid obesity. An important principle for this population is expressed in the USPHS guidelines targeting prevention of cardiovascular disease, the

National Cholesterol Education Program and the Adult Treatment Panel (now ATP III) guidelines from the National Heart Lung and Blood Institute (NHLBI). Adjunctive pharmacotherapy to lower risk, using drugs of proven benefit (e.g., lipid lowering agents), can be an important approach to lower risk when therapeutic lifestyle change (TLC) has failed, or when risk levels are sufficiently elevated to warrant pharmacological intervention without waiting for the results of TLC. However, when secondary causes of risk (e.g., adverse effects of antipsychotics, protease inhibitors or glucocorticoids on lipid levels) are identified, efforts to address these secondary causes should first be made whenever clinically possible. If secondary causes of risk can be removed, risks and costs associated with adjunctive pharmacotherapy can be minimized. When determining if drug therapy is appropriate for the treatment of obesity, the clinician should understand that drug therapy is not indicated until after all non-pharmacological attempts of weight loss have failed, excluding bariatric surgery. Pharmacotherapy is not indicated and should never be used as first line therapy for the treatment of obesity. The National Heart, Blood, and Lung Institute (NHLBI)²⁵ has indicated that medication treatment for obesity should be reserved as adjunct therapy to diet and physical activity for overweight and obese patients. Additionally, drug therapy may have more risks for people with serious mental illness, related in part to mechanisms of action for specific agents, with almost no currently available long term safety data for any agent in the SMI population. Therefore any adjunctive drug therapy for the treatment of obesity should be administered under the close supervision of a medical professional. Medical professionals should monitor adherence to the plan, side effects and potential effects when combined with the drugs used to treat the person's mental illness.

According to Bray, to use pharmacological treatment properly for the treatment of obesity, it is important to start with the following framework in mind:

- Obesity is due to an imbalance between energy intake and energy expenditure;
- Drugs can either reduce food intake or increase energy expenditure;
- Drug treatment does not cure the overweight patient;
- The therapeutic range of medications for practitioners is limited to only a few drugs;
- The use of drugs labors under the negative halo of treatment mishaps;
- Drugs do not work when they are not taken; when the drugs are stopped weight gain is the expected outcome;
- Weight loss plateaus during continued treatment when compensatory mechanisms come into play to counterbalance the effect of the drug;
- Monotherapy usually produces weight loss in the range of 10%;
- Frustration with the failure to continue to lose weight often leads to discontinuation of therapy and then to weight regain with labeling of the drug as a failure.

The NHLBI²⁶ recommends pharmacological treatment in patients with a BMI ≥ 30 or a BMI ≥ 27 with at least two risk factors. According to Schnee, with any of the current medications available for long-term treatment and maintenance, a patient can achieve at best a 10% reduction in weight from baseline with strict adherence to the medication and

²⁵ As well as the National Institute for Health.

²⁶ As well as the National Institute for Health.

an appropriate diet with most data informing such predications coming from non-SMI samples.

Presently, three classes of prescription medications have FDA approval for weight loss in the United States are:

- Noradrenergic agents (phentermine);
- Adrenergic and serotonergic agents (sibutrimine); and
- Lipase inhibitors (xenical).

Both the noradrenergic agents and the adrenergic and serotonergic agents exert their effects by decreasing appetite while increasing satiety. Lipase inhibitors exert their effects by decreasing nutrient absorption in the gastrointestinal tract, resulting in weight loss.

Medications without FDA approval that have been used for weight loss include:

- Metformin – an oral insulin sensitizing agent indicated for diabetes;
- Exenatide – an injected glucagon-like agent indicated for diabetes;
- Topiramate and zonisimide – oral anticonvulsants; and
- Bupropion – an oral antidepressant.

(See attachment E for more information.)

Adjunctive Medications to Reduce Weight for persons with Schizophrenia:

Weight loss and other types of adjunctive medications have been utilized to try to reduce weight in people with schizophrenia. Figure 3.12 below indicates, rather small and non-definitive studies that have utilized adjunctive medication to reduce weight in persons with schizophrenia. A recent Cochrane review of adjunctive pharmacological interventions to lower weight or prevent weight gain in patients with SMI suggested that currently published results do not identify any well-characterized agents with consistent beneficial and well-tolerated effects. For example, it remains unclear whether reported favorable effects of metformin on weight in this population are related to insulin sensitization or simply adverse gastrointestinal (GI) drug effects that make patients want to eat less. (The induction of unpleasant adverse GI effects is probably not a preferred approach to weight reduction in any population). Furthermore, the safety of weight loss medications in the population with SMI has not been established.

Figure 3.12: Adjunctive Medication to Reduce Weight in Schizophrenia Patients.

From: Strassnig & Ganguli (2007). *Clinical Schizophrenia and related Psychoses*.

Authors	Sample Characteristics	Agent	Behavioural Augmentation	N	Duration weeks	Results
Correa et al, 1987 (56)	Inpatients; cross-over design	200–300 mg amantadine	NO	10	7	–1.82 kg; all lost weight
Floris et al, 2001 (57)	Outpatients receiving olanzapine; pre-post design	100–300 mg amantadine	NO	12	21	–3.5±2 kg weight loss
Breier et al, 2001 (62)	Schizophrenia and schizoaffective patients treated with olanzapine	Nizatadine 300 mg po twice daily	NO	132	16	H2 blocker –2.8 kg vs. placebo –5.5 kg
Cavazzoni et al, 2003 (63)	In- and outpatients on olanzapine	Nizatadine 150 mg bid vs. 300 mg bid vs. placebo	NO	175	16	No in-between group differences (+3.56±4.95 vs. 3.29±5.33 vs. 4.18 ±4.33 kg)
Poyurovsky et al, 2002 (51)	Inpatients receiving olanzapine	Fluoxetine 20 mg/d vs. placebo	NO	30	8	No difference (+5.9±4.6 kg for intervention vs. 6.1 ±5.5 kg placebo)
Poyurovsky et al, 2003 (59)	First episode schizophrenics on olanzapine 10 mg/day	Reboxetine 4 mg/day vs. placebo	NO	26	6	Significantly lower wt. gain in reboxetine group (+2.5±2.7 kg vs. placebo 5.5 ±3.1 kg)
Poyurovsky et al, 2003 (59)	First episode schizophrenics on olanzapine 10 mg/day	Reboxetine 4 mg/day vs. placebo	NO	26	6	Significantly lower wt. gain in reboxetine group (+2.5±2.7 kg vs. placebo 5.5 ±3.1 kg)
Ko et al, 2005 (54)	Inpatients with schizophrenia; atypical antipsychotics	Topiramate 200 mg vs. 100 mg vs. placebo	NO	66	12	–5.35, –1.68, –0.35 kg with 200 mg, 100 mg, and placebo, respectively. Significant only in 200 mg group
Kim et al, 2006 (55)	Outpatients with schizophrenia; newly treated with olanzapine	Topiramate 50 mg bid vs. placebo	NO	48	12	Less weight gain with concomitant topiramate vs. placebo (2.66±1.79 vs. 4.02±2.52 kg)
Baptista et al, 2006 (66)	Inpatients with schizophrenia or schizoaffective disorder; switched to olanzapine	Metformin 850–1700 mg daily vs. placebo	NO	40	14	5.5 kg vs. 6.3 kg weight gain with metformin vs. placebo, not significant
Henderson et al, 2005 (47)	Patients with schizophrenia or schizoaffective disorder on olanzapine; BMI ≥30	Sibutramine (up to 15 mg/day) vs. placebo	YES	37	12	Significantly lower weight gain in sibutramine group (–8.3±2.4 lbs vs. +1.8 ±1.6 lbs for placebo)
Henderson et al, 2007 (48)	Patients with schizophrenia or schizoaffective disorder on clozapine	Sibutramine (up to 15 mg/day) vs. placebo	YES	21	12	No significant difference in weight loss between sibutramine and placebo groups

Risk factors associated with this method of weight loss include, but are not limited to additional side effects and an increased cost to one's health. Furthermore, while utilizing a combination of the various medications is possible, more study is needed in this area to determine the multiplicative affects of taking two or more medications. Limited research

in this area suggests that behavioral interventions are just as, if not more effective, in people with schizophrenia, and are also safer. Importantly, the removal of secondary causes of increased weight (e.g., therapeutic substitution of antipsychotics with lower risk for weight gain for agents with higher risk) can produce even larger weight lowering effects than behavioral interventions or adjunctive medication (see, for example, figure 3.11). However, adjunctive medication could be considered if a combination of diet, exercise, and behavioral interventions fail, and when psychotropic medication switching opportunities are limited due to patients already being on lower risk drugs or switching medications is psychiatrically unfeasible. These risks and potential benefits of any of these courses should be weighed with the consumer in determining an appropriate course of action.

“Evidence-based medicine dictates that effective obesity management must incorporate an integrated program of caloric and fat restriction in combination with exercise and behavior modification in addition to pharmacotherapy (Palamara, 2006).”

Surgery:

For morbid obesity, bariatric surgery is a highly effective therapy, although efficacy and tolerability have received limited formal testing in the SMI population. Bariatric surgical procedures reduce caloric intake by modifying the anatomy of the gastrointestinal tract. These operations are classified as either restrictive or malabsorptive. Restrictive procedures limit intake by creating a small gastric reservoir with a narrow outlet to delay emptying. Examples of restrictive procedures include:

- Gastric stapling (gastroplasty);
- Adjustable gastric banding (wrapping a synthetic, inflatable band around the stomach to create a small pouch with a narrow outlet); or
- A combination of these two approaches.

Malabsorptive procedures bypass varying portions of the small intestine where nutrient absorption occurs. Examples of malabsorptive procedures include:

- Biliopancreatic diversion; and
- Proximal Roux-en-Y, a combination restriction-malabsorption procedure.

While there may be complications in post-operative individuals, which may include death, the evidence suggests that Bariatric surgery is an effective method to reduce weight, and weight related medical co-morbidities in individuals. In general, weight loss with malabsorptive procedures tends to be greater than weight loss with solely restrictive procedures. According to DeMaria, improvements in the conditions that are often associated with obesity have been consistently reported after Bariatric surgery. These include the following results:

- 77% of patients with preoperative diabetes no longer require medication after surgery;
- 83% of patients saw improvements in hyperlipidemia;
- 66% of patients saw improvements in hypertension; and
- 88% of patients saw improvements with sleep apnea.

DeMaria writes that “it has not been clearly established whether bariatric surgery results in reduced mortality as compared with medical management of obesity, although such a benefit is suggested in the results of several studies.”

Estimates of the median hospital costs for bariatric surgery range from approximately \$10,000 to \$14,000. The Medicare physician fees for 2007 range between \$800 to \$2,000 depending upon the method used (DeMaria, 2007).

The National Institutes of Health ²⁷ recommends the following criteria for bariatric surgery in the general population:

- A BMI of 40 or higher; or
- A BMI of 35 or higher in a patient with a high-risk condition such as severe sleep apnea, obesity-related cardiomyopathy, or severe diabetes mellitus; and
- Failure of medical weight control; and
- An absence of medical or psychological contraindications; and
- The patient’s understanding of the procedure and its risks; and
- Strong motivation on the patient’s behalf to comply with the post-surgical regimen.

Evaluation of the surgical candidate should include:

- A comprehensive nutritional and weight history, covering trends, previous weight loss efforts, and perceived obstacles to success management;
- Current weight, height, and BMI;
- Measuring waist circumference (for additional information regarding health risks);
- A complete medication history, including evaluation of antidepressants, oral contraceptives, oral hypoglycemic agents, and other drugs associated with weight gain;
- A complete physical examination, assessing common conditions that accompany obesity, such as diabetes, hypertension, hyperlipidemia, coronary artery disease, sleep apnea, pulmonary hypertension, musculoskeletal disease and others;
- A complete and recent psychological evaluation of the candidate (a mental health diagnosis in and/or itself should not rule out this option).

Preoperative education is important in improving the patient’s understanding of the anticipated consequences of the procedure and to assist with managing unreasonable expectations.

The NIH Consensus panel emphasizes the necessity of multidisciplinary care of the bariatric surgical patient, by an expert team of physicians and therapists to manage associated co-morbidities, nutrition, physical activity, behavior and psychological needs. The surgical procedure is best regarded as a tool which enables the patient to alter lifestyle and eating habits.

Contraindications rendering the risks to bariatric surgery unacceptably high include:

- Mental or cognitive impairment that limits the patient’s ability to understand the procedure and thus precludes informed consent; and

²⁷ As well as the NIH Consensus Panel.

-
- Very severe coexisting medical conditions, such as unstable coronary artery disease or advanced liver disease with portal hypertension.

On February 21, 2006, the Center for Medicare and Medicaid Services expanded national coverage for certain bariatric surgeries to Medicare beneficiaries with a BMI of 35 or greater, and no success with medical treatment for obesity. About 22% of all obese disabled beneficiaries were entitled to Medicare because of a mental disability.

Bariatric Surgery and Persons with SMI:

While having a history of mental health problems should not prevent people from getting obesity surgery, evaluation of patient's preoperative psychiatric status may play an important role in maximizing successful postoperative outcomes (Sarwer D.B. et al., 2004). Additionally, symptoms of mental illness including depression, psychosis, and cognitive impairment could add to the challenges that people without mental illness experience when trying to adhere to postoperative regimens.

“Mental status is a difficult area in which to define standards for patient selection. Selected screening for severe depression, untreated or undertreated mental illness associated with psychosis, active substance abuse, bulimia nervosa, and socially disruptive personality disorders may help avoid adverse postoperative outcomes. History of compliance with nonoperative therapy may be beneficial in assessing the risk-to-benefit ratio of bariatric surgery” (Buchwald, 2004).

Research is lacking about bariatric surgical procedures in persons with serious mental illness. A small study of 5 patients with schizophrenia with morbid obesity suggests that bariatric surgery in this group was comparable to those of non-psychotic morbidly obese patients. In morbidly obese persons with SMI, who have failed other attempts to address their disease, a careful individualized risk-to-benefit ration for bariatric surgery should be considered.

Recommendations

Based on the review of the obesity research and prevention literature, weight management and mental illness literature, materials, presentations and commentary from work group participants at the meeting held on August 9-10, 2007 in Kansas City, MO, meeting participants drew the following conclusions and recommendations for NASMHPD. This list is recognized to be limited in its scope as it does not include every conclusion and recommendation made within the body of this report; however, it does represent those priorities determined at the meeting for obesity prevention efforts for individuals with SMI focused specifically on the following three levels:

- National – through NASMHPD;
- State – through the State Mental Health Authority; and
- Community Mental Health Center and other providers.

Furthermore, it is recognized that for the greatest success coordination must occur between all of these levels.

Recommendations at the **National Level** include:

1.1: Encourage research on obesity in people with serious mental illness.

Better data is needed on the prevalence of obesity in people with serious mental illnesses, in order to identify high-risk groups, including women, children, the elderly and ethnic/racial minorities. There have been few randomized and controlled clinical trials studying obesity and its management in people with serious mental illness; more study of this population is necessary.

1.2: Implement national obesity surveillance/monitoring system for persons with serious mental illnesses. Develop and implement community programs for weight monitoring in all people with SMI, weight maintenance among those persons with SMI who are in the normal weight category and weight loss for those who are overweight or obese.

Surveillance of the overall health status of persons with serious mental illnesses should include continued monitoring of weight, BMI, waist circumference, fasting blood sugar (FBS), lipids, and the affects of pharmaceuticals on the weight of the individuals in the SMI population. NASMHPD should partner with SAMHSA and other federal agencies to develop and disseminate specialized programs tailored at weight reduction for persons with SMI who are overweight or obese. Education and counseling should be tailored for persons with SMI to ensure that persons with normal weight do not become overweight or obese.

1.3: Create federal tax incentives, through the use of employer-sponsored pre-tax medical expense accounts, to encourage physical activity.

Federal tax policy can be used to promote health and healthy activities. For individuals who are employed and able to participate in pre-tax spending accounts

for medical expenses, dues and fees for membership to a local gym or local Park and Recreation Center could be included as a valid expense for reimbursement. Such expense reimbursement can create financial incentives for pursuing and adopting physical activity into one's lifestyle.

For those individuals who do not have the ability to participate in pre-tax spending accounts for medical expenses; a memorandum of understanding (MOU) with the local Park and Recreation Department is a strong possibility. The MOU could delineate the criteria necessary to be eligible for reduced membership fees.

1.4: The Centers for Medicaid and Medicare Services should include weight management interventions and appropriate laboratory tests as a reimbursable service in existing federal healthcare programs.

NASMHPD should encourage the Centers for Medicaid and Medicare Services (CMS) to cover weight management interventions and corresponding lab tests to establish a comprehensive weight loss program for individuals with serious mental illnesses. Such interventions should include psychoeducational and behavioral interventions, pedometers, scales, medications for weight loss, and surgery. Furthermore, as weight loss medications are studied for release, the FDA should study the effects these medications have on persons with SMI.

1.5: Create a MOU with NASMHPD and SAMHSA on USDA nutritional counseling.

Dietary consultations are an effective intervention to prevent and reduce obesity. Dietary consultations are an available resource for primary care and psychiatric professionals to utilize for persons with SMI. Accessing USDA nutritional counseling will benefit persons with SMI while conserving public mental health system resources.

1.6: Federal Healthcare agencies should collaborate on the development of a provider toolkit of best practices for the prevention and reduction of obesity in persons with severe mental illnesses and actively support dissemination of this report in the toolkit through national meetings, Web seminars, continuing education and other available venues.

NASMHPD, SAMHSA, NIH and other federal agencies should assess the efficacy and utility of available strategies for the prevention and reduction of obesity in people with serious mental illness and create a 'toolkit' of best practices for providers. Once developed, this toolkit should be widely disseminated, using a variety of strategies.

1.7: Educate national mental health stakeholder organizations regarding the impact of obesity in the populations they serve and also about available

interventions.

Reducing this epidemic of obesity and subsequent mortality will require support of and actions by the broader community of public mental health stakeholders. Provider groups such as the National Council of Community Behavioral Health (NCCBH) and the American Psychiatric Association and advocacy groups such as Mental Health America and the National Alliance for the Mentally Ill need to be informed of this reports findings and involved in implementing it's recommendations.

Recommendations at the **State Level, to be implemented through the State Mental Health Authority** include:

2.1: Educate mental health professionals on the importance of weight monitoring and weight reduction in people with serious mental illness.

Behavioral health care professionals are often not trained to assess and address physical health care issues and some clinicians may still believe that persons with SMI are not able to live healthy lifestyles, due to a variety of factors, including:

- The belief that obesity is related to the person's mental illness;
- The belief that people with SMI lack the motivation to improve their health and well-being;
- The socioeconomic challenges of living with a SMI;
- Discrimination and stigma;
- The difficulty in accessing good-quality medical care for people with SMI; and
- The high prevalence of weight gain as a side effect in mental health medications.

Education about weight management and reduction can help to overcome these factors. Providers need to be encouraged to treat the whole person and to address both the physical health and the mental health of the person. This typically means coordinating care between primary care providers and mental health professionals. State authorities should foster this coordination of care by educating both groups of health providers on the issue of obesity in SMI.

2.1.1: Develop standards of care for mental health providers and work with State Medicaid agencies and other health insurers to ensure that persons with severe mental illness and obesity have access to the following interventions:

- Educational/behavioral interventions for weight management;
- Switch to low weight gain antipsychotics when weight increases;
- Medical treatment of obesity; and
- Surgical treatment of obesity

2.2: Promote opportunities for health care providers, including peer

specialists, to teach healthy lifestyles to families, individuals, and older adults.

The incorporation of health lifestyle choices in any behavioral program should become a standard. Simple practice assignments in traditional psycho-social programs can increase learning and efficacy. Having participants in a program develop a plan to hold a progressive dinner²⁸ builds multiple psycho-social skills, increases natural support networks, provides opportunities to learn or improve shopping and food preparation skills and creates economies of scale where healthy food choices are more available. The focus of lifestyle changes should include at least informational support for the individual's extended support network.

Family and peer support groups should provide materials and information to support healthy lifestyle choices. These groups can provide training to address the stereotypical beliefs that overweight individuals are lazy. They can also provide training and support to better prepare individuals, their families and providers in shared decision making approaches.

Peer specialists can aid in the training process by working with recipients of programs developing goals and interventions based on individual choice. Examples could be a recipient lead health fair, educational symposium, menu planning, or demonstration of how to monitor one owns' weight and abdominal circumference.

2.3: Adopt American Diabetes Association (ADA) and American Psychiatric Association (APA) Second Generation Antipsychotic (SGA) monitoring as a standard of care practice for the population with serious mental illness. Monitoring should include family history, BMI, waist circumference, FBS, lipids, and screening for the additional cardiometabolic risk factors of smoking and physical inactivity.

Monitoring of people with SMI should include family history, BMI, waist circumference, FBS, lipids, and screening for the additional cardio metabolic risk factors of smoking and physical inactivity. Patients maintained on antipsychotics should:

- Be weighed on every visit;
- Receive testing of glucose and lipids every year;
- Receive blood pressure checks at 12 weeks and then annually; and
- Have waist circumference measured at baseline and annually.

²⁸ From Wikipedia, the free encyclopedia , a progressive dinner is a dinner party in which each successive course is prepared and eaten at the residence of a different host. Alternatively, each course may be eaten at a different dining area within a single large establishment.

If weight gain, glucose abnormalities, or hyperlipidemia occur, considerations should include lifestyle modifications and changing to medication with lower risk of weight gain. Consumers should be educated about the need for routine monitoring and may be able to self-monitor data such as weight and waist circumference. Referrals to primary care should also occur for treatment of medical conditions when appropriate.

2.4: State Mental Health Authorities (SMHA) should collaborate with State Health Authorities (SHA) to address physical health assessment, health monitoring, and improvement options for the population with serious mental illness.

The issue of obesity in people with SMI provides a unique opportunity to merge physical and behavioral healthcare. State Mental Health and Health Authorities can jointly support educational and policy efforts related to obesity, and should consider conjoined mental health and physical health clinics, like the federally qualified integrated clinics, by encouraging mental health care provider agencies to assume greater responsibility for the overall care of the person with SMI.

Linkages with public health programs and community-based programs in diabetes prevention and control, cardiovascular disease, and healthy weight management can be established. Many community-based programs for the general population exist which can support, aid, and augment mental health services. Cooperative extension services often provide nutritional counseling, food preparation, shopping, and other training for communities at no or minimal costs. Utilizing these natural community resources conserves SMHA resources and advances community inclusion of persons in the public mental health system.

2.5: Bridge the collaboration gap between physical and mental health care.

Behavioral health care systems, including State Mental Health Authorities (SMHA) should assume responsibility for assuring that individuals under their care receive the recommended routine screening, monitoring, and management of medical conditions including obesity. Behavioral health care systems and SMHAs have a specific responsibility since certain conditions (such as weight gain and its complications) may create an adverse effect on the prescribed pharmacological treatment regimens. Additionally, behavioral health care professionals may come into contact with mental health consumers on a more frequent basis. Treating persons with SMI in holistic ways should allow for a free flow of information between the physical and mental health sides.

2.6: Monitor mental health consumers with diabetes and metabolic syndromes in mental health clinics.

SMHAs should mandate and support implementation of care management protocols directed at simultaneous management of both mental health and

diabetes designed to build on and support the individual's self-management skills. A quality improvement process can be developed in mental health settings that measures access, quality of care and outcomes for diabetes, and add health outcomes for physical health to mental health treatment plans.

2.7: Establish linkages with public health programs and community-based programs in diabetes prevention and control, cardiovascular disease, and healthy weight management.

Recommendations at the **Community Mental Health Center and other Provider Level** include:

3.1: All people with SMI should have access to weight monitoring and weight management programs.

Clinicians and mental health consumers are partners in the decision to address and treat weight problems. Clinicians should emphasize that even moderate weight loss can improve a persons' health, well-being, and extend the life of that individual.

Consumers and their families need to be educated on key weight management strategies:

- Energy expenditure must exceed energy intake to achieve weight loss (physical activity);
- Dietary interventions that increase knowledge about healthy eating such as reading Nutrition Facts labels, being aware of total calorie content, serving size, and nutrient values of different food products;
- Physical activity interventions: How to reduce sedentary behaviors (such as watching TV) and safely and slowly add more physical activity to ones' daily routine (such as walking);
- Utilize a "small steps approach" a combination of reduced energy intake (food) and increased physical activity that equal 100 kcal/day to prevent weight gain in most adults (for example, giving up one can of regular soda per day or adding 2,000 steps to ones' day);
- Increase awareness to engage and motivate mental health consumers to adopt a healthy lifestyle and make healthier choices;
- Utilizing an illness management, recovery, and wellness model, consumers should be educated on their different illness (i.e., schizophrenia and obesity), self regulation, and management;
- Inspire and encourage a healthy environment by offering healthy foods and beverages in all treatment settings and waiting areas. Provide and make available wellness fliers, posters, and other materials in visible areas such as waiting rooms and group room bulletin boards. Consider hosting wellness fairs;

-
- Act as “healthy role” models by eating healthy snacks, lunches, and participating in regular physical activity; and
 - Highlight mental health consumer’s wellness achievements by sharing and recognizing successes.

3.2: Weight control programs for people with SMI should incorporate nutrition, exercise, and behavioral strategies.

Consumers and their families need to be educated on key weight management strategies:

- Energy expenditure must exceed energy intake to achieve weight loss (physical activity);
- Dietary interventions that increase knowledge about healthy eating such as reading Nutrition Facts labels, being aware of total calorie content, serving size, and nutrient values of different food products;
- Physical activity interventions: How to reduce sedentary behaviors (such as watching TV) and safely and slowly add more physical activity to ones’ daily routine (such as walking);
- Utilize a “small steps approach” a combination of reduced energy intake (food) and increased physical activity that equal 100 kcal/day to prevent weight gain in most adults (for example, giving up one can of regular soda per day or adding 2,000 steps to ones’ day);
- Increase awareness to engage and motivate mental health consumers to adopt a healthy lifestyle and make healthier choices;
- Utilizing an illness management, recovery, and wellness model, consumers should be educated on their different illness (i.e., schizophrenia and obesity), self regulation, and management;
- Inspire and encourage a healthy environment by offering healthy foods and beverages in all treatment settings and waiting areas. Provide and make available wellness fliers, posters, and other materials in visible areas such as waiting rooms and group room bulletin boards. Consider hosting wellness fairs;
- Act as “healthy role” models by eating healthy snacks, lunches, and participating in regular physical activity; and
- Highlight mental health consumer’s wellness achievements by sharing and recognizing successes.

Therapies that combine modifications on diet, behavior, and physical activity have been proven to be successful at obtaining weight loss. While the Solutions for Wellness Personalized and Manualized Programs are just two examples of this type of behavioral therapy program designed to achieve weight management and weight loss, other similar programs exist and should be implemented with patients with serious mental illness. Interventions should not be applied without regard to individual choice. Treatment alliance should be primary consideration with interventions other than education and encouragement only applied when the individual identifies weight control as their objective.

3.3: Prescribing clinicians should use medications with lower risk of weight gain when possible.

Clinicians should include weight gain as a major factor to consider when recommending mental health medications. In general, medications that have a lower risk of weight gain should be preferred. Include the consumer when considering trade-offs between symptom control and risk of weight gain.

3.4: Utilize weight loss medication with care when appropriate.

Follow the NIH recommendation for consideration of pharmacological treatment of obesity with weight loss drugs in patients with a BMI \geq 30 or a BMI \geq 27 with at least two risk factors. Psychiatric side effects of these medications should be monitored more closely in this special population.

3.5: In consultation with the patient, recommend bariatric surgery when all other methods of weight loss have been tried and failed.

Follow the National Institutes of Health recommendation for considering and referring for bariatric surgery in persons with a BMI of 40 or higher; or a BMI of 35 or higher in a patient with a high-risk condition such as severe sleep apnea, obesity-related cardiomyopathy, or severe diabetes mellitus; and failure of medical weight control.

Use of bariatric surgery should be a treatment of last resort and offered after consulting with the patient assuring ability to give informed consent and carefully weighing the risks and benefits. People with SMI may benefit from additional pre and post operative supports. More research is needed.

3.6: Encourage the development of novel approaches to educate and support weight control through community programs.

Programs have developed a number of novel approaches to encourage staff and individuals with mental illness to make healthier lifestyle changes. These include holding “biggest loser” contests, walking clubs, and point of decision support. Simple things like reminders to consider using stairs instead of elevators can aid everyone to make healthier choices. Encouraging staff and recipients with mental illness to partner with an individual for support and motivation will also increase efficacy. Practice assignments which build on healthy decision-making, such as planning and holding a progressive dinner, increase the effectiveness of psycho-social interventions.

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Attachment A
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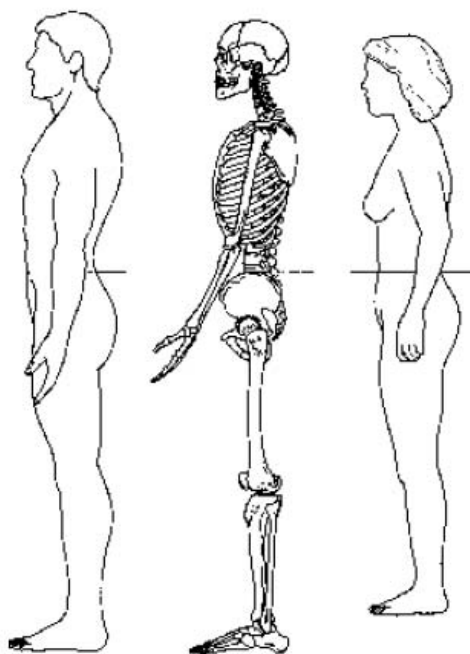
Attachment B

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

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

Attachment C

Measuring Tape Position for Waist (Abdominal) Circumference



The waist circumference at which there is an increased relative risk is defined as follows. Waist circumference cutpoints lose their incremental predictive power in patients with a BMI ≥ 35 kg/m² because these patients will exceed the cutpoints noted below.

HIGH RISK
Men: >102 cm (>40 in.)
Women: >88 cm (>35 in.)

Evidence Statement: *Sex-specific cutoffs for waist circumference can be used to identify increased risk associated with abdominal fat in adults with a BMI in the range of 25 to 34.9 kg/m². An increase in waist circumference may also be associated with increased risk in persons of normal weight. Evidence Category C.*

Waist circumference cutpoints can generally be applied to all adult ethnic or racial groups. On the other hand, if a patient is very short (under 5 feet) or has a BMI above the 25 to 34.9 kg/m² range, waist cutpoints used for the general population may not be applicable. Evidence Category D.

NHLBI. *The Clinical Guidelines on the Identification, Evaluation, and Treatment of Overweight and Obesity in Adults.* Available at http://www.nhlbi.nih.gov/guidelines/obesity/e_txtbk/txgd/4142.htm.

Rationale: A high waist circumference is associated with an increased risk for type 2 diabetes, dyslipidemia, hypertension, and CVD in patients with a BMI in a range between 25 and 34.9 kg/m² (Chan 1994). Monitoring changes in waist circumference over time may be helpful, in addition to measuring BMI, since it can provide an estimate of increased abdominal fat even in the absence of a change in BMI. Furthermore, in obese patients with metabolic complications, changes in waist circumference are useful predictors of changes in CVD risk factors (Lemieux 1996).

There are ethnic and age-related differences in body fat distribution that modify the predictive validity of waist circumference as a surrogate for abdominal fat (Gallagher 1996). These variations may partly explain differences between ethnic or age groups in the power of waist circumference or waist-to-hip (WHR) ratio to predict disease risks (Dowling 1993, Conway 1995).

In some populations, waist circumference is a better indicator of relative disease risk than is BMI: examples include Asian Americans or persons of Asian descent living elsewhere (Klatsy 1991, Fujimoto 1991, Potts 1994). Waist circumference also assumes greater value for estimating risk for obesity-related disease at older ages. The table below incorporates both BMI and waist circumference in the classification of overweight and obesity, and provides an indication of disease risk.

Classification of Overweight and Obesity by BMI, Waist Circumference, and Associated Disease Risk*

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

* Disease risk for type 2 diabetes, hypertension, and CVD.

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

Recommendation: For adult patients with a BMI of 25 to 34.9 kg/m², sex-specific waist circumference cutoffs should be used in conjunction with BMI to identify increased disease risk. Evidence Category C.

References

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Dowling HU, Pi-Sunyer FX. Race-dependent health risks of upper body obesity. *Diabetes*. 1993;42:537-543.

Fujimoto WY, Newell-Morris LL, Grote M, Bergstrom RW, Shuman WP. Visceral fat obesity and morbidity: NIDDM and atherogenic risk in Japanese-American men and women. *Int J Obes*. 1991;15 (Suppl2):41-44.

Gallagher D, Visser M, Sepulveda D, Pierson RN, Harris T, Heymsfield SB. How useful is body mass index for comparison of body fatness across age, sex, and ethnic groups? *Am J Epidemiol*. 1996;143:228-239.

Klatsky AL, Armstrong MA. Cardiovascular risk factors among Asian Americans living in northern California. *Am J Public Health*. 1991;81:1423-1428.

Lemieux S, Prud'homme D, Bouchard C, Tremblay A, Despres J. A single threshold value of waist girth identifies normal-weight and overweight subjects with excess visceral adipose tissue. *Am J Clin Nutr*. 1996;64:685-693.

Potts J, Simmons D. Sex and ethnic group differences in fat distribution in young United Kingdom South Asians and Europeans. *J Clin Epidemiol*. 1994;47:837-841.

NHLBI. *The Clinical Guidelines on the Identification, Evaluation, and Treatment of Overweight and Obesity in Adults*. Available at http://www.nhlbi.nih.gov/guidelines/obesity/e_txtbk/txgd/4142.htm.

Attachment D

METABOLIC SCREENING AND MONITORING FORM

PATIENT NAME: _____

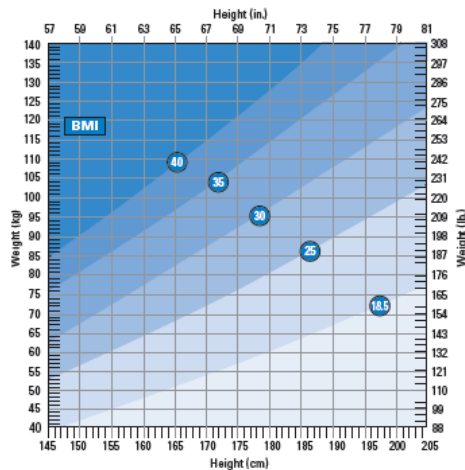
Physician: Screen for the following parameters annually. Increase the frequency of screening according to the level of risk (determined by the presence of one or more risk factors listed below and on the back of this form).

► Cardiometabolic Risk Monitoring Guidelines

SCREENING	RISK CRITERIA	BASELINE	NEXT VISIT	NEXT VISIT
		Date ___/___/___	___/___/___	___/___/___
OBESITY¹	Consider BMI (weight/height in kg/m ²) at each visit: Normal (18.5–24.9); Overweight (25–29.9); Obese (≥ 30)	Height _____	_____	_____
	Consider Waist Circumference (Abdominal Obesity) at each visit: Men ≥ 40 inches; Women ≥ 35 inches	Weight _____	_____	_____
DYSLIPIDEMIA² <i>Use Tables 3 and 4 on the back of this form to determine target treatment levels (based on 10-year risk category).</i>	Total Cholesterol	BMI _____	_____	_____
	LDL	Waist Circum. _____	_____	_____
	HDL and Triglycerides (see below)	_____	_____	_____
METABOLIC SYNDROME (MS)² <i>(≥ 3 criteria = Metabolic Syndrome)</i>	HDL (Men < 40 mg/dL; Women < 50 mg/dL, or drug Rx)	_____	_____	_____
	Triglycerides (≥ 150 mg/dL, or drug Rx)	___ <input type="checkbox"/> At Risk	___ <input type="checkbox"/>	___ <input type="checkbox"/>
	Abdominal Obesity (Waist Circumference: Men ≥ 40 inches, Women ≥ 35 inches)	___ <input type="checkbox"/> At Risk	___ <input type="checkbox"/>	___ <input type="checkbox"/>
	Blood Pressure (≥ 130/≥ 85 mmHg, or drug Rx)	___ <input type="checkbox"/> At Risk	___ <input type="checkbox"/>	___ <input type="checkbox"/>
	Fasting Plasma Glucose (≥ 100 mg/dL, or drug Rx)	___ <input type="checkbox"/> At Risk	___ <input type="checkbox"/>	___ <input type="checkbox"/>
PREDIABETES/ DIABETES MELLITUS¹ <i>Fasting Plasma Glucose Normal < 100 mg/dL Prediabetes 100–125 mg/dL Diabetes ≥ 126 mg/dL</i>	Fasting Plasma Glucose	_____	_____	_____
	Optional 2h PG	_____	_____	_____

Table 1: Body Mass Index Adapted from NHLBI Clinical Guidelines.²

Note: This table does not take into account age, sex, or ethnicity.



BACK-OF-FORM CONTENTS

- Diabetes Risk Factors
- Diabetes Classification and Intervention Chart
- Cardiovascular Disease (CVD) Risk Factors
- 10-Year Risk Calculation for Coronary Heart Disease
- Target Lipid Levels Chart

Form by John W. Newcomer, MD and Dan W. Haupt, MD.
Compiled primarily from ATP III and ADA guidelines.^{1,2,3}

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Diabetes Risk Factors^{1,4} (check all that apply)

- Overweight or obese state (BMI ≥25 kg/m²)^{*}
- Sedentary lifestyle
- Hypertension (> 140/90 mmHg in adults)
- History of vascular disease
- Family history of diabetes
- Race/ethnicity†
- History of IFG or IGT
- Psychiatric illness
- HDL ≤ 35 mg/dL and/or triglyceride ≥ 250 mg/dL
- Female:
 - History of GDM or delivery of macrosomic infant
 - Polycystic ovary syndrome

^{*}May not be correct for all ethnic groups; †High-risk ethnic groups include Latino/Hispanic, Non-Hispanic black, Asian American, Native American, or Pacific Islander ethnicity
 IFG = Impaired Fasting Glucose; IGT = Impaired Glucose Tolerance; FPG = Fasting Plasma Glucose; GDM = Gestational Diabetes Mellitus

Table 2: Diabetes Risk: Classification and Intervention Chart

Screen with FPG every 3 years for persons aged 45 and older. Test persons earlier than age 45 and more frequently who are overweight (BMI ≥ 25) or have the presence of more than one risk factor.^{1,4}

CLASSIFICATION	FPG (mg/dL)	and	2hPG (mg/dL)	INTERVENTION
Normal	< 100		< 140	Rescreen as clinically indicated.
Prediabetes	100–125		< 140–199	Implement strategies (i.e., diet, therapeutic lifestyle changes, and medication) to prevent diabetes and modify CVD risk factors. Rescreen for diabetes at appropriate intervals.
Diabetes	≥ 126		≥ 200	Initiate pharmacotherapeutic intervention immediately.

FPG = Fasting Plasma Glucose; 2hPG = Two-hour Postload Glucose

Cardiovascular Disease (CVD) Risk Factors (check all that apply)

- Cigarette smoking
- Low HDL cholesterol (< 40 mg/dL)
- Age (men > 45 years; women > 55 years)
- Hypertension (BP > 140/90 mmHg or on antihypertensive medication)
- Family history of premature CHD (CHD in male first degree relative < 55 years; CHD in female first degree relative < 65 years)

Table 3: Ten-Year Risk Model of Calculating Risk Category for Coronary Heart Disease (CHD)²

Use the following risk factor charts to assess the percentage of risk of CHD in a patient without diabetes mellitus or clinically evident cardiovascular disease. Circle the risk points for each factor. Add together all of the risk points and then determine the gender appropriate 10-year risk using the charts below.

AGE RISK FACTOR			CHOLESTEROL RISK FACTOR										HDL-C RISK FACTOR			SYSTOLIC BLOOD PRESSURE RISK FACTOR						
Age (years)	Risk Points for MEN	Risk Points for WOMEN	Total Cholesterol (mmol/L)	Risk Points for MEN age:					Risk Points for WOMEN age:					(mmol/L)	Risk Points for MEN	Risk Points for WOMEN	(mm Hg)	Risk Points for MEN:		Risk Points for WOMEN:		
				< 39	40–49	50–59	60–69	70–79	< 39	40–49	50–59	60–69	70–79					Untreated	Treated	Untreated	Treated	
20–34	-9	-7	< 4.14	0	0	0	0	0	0	0	0	0	0	0	0	0	0	< 120	0	0	0	0
35–39	-4	-3	4.15–5.19	4	3	2	1	0	4	3	2	1	0	1.3–1.54	0	0	120–129	0	1	1	3	
40–44	0	0	5.2–6.19	7	5	3	1	0	8	6	4	2	1	1.04–1.29	1	1	130–139	1	2	2	4	
45–49	3	3	6.2–7.2	9	6	4	2	1	11	8	5	3	2	< 1.04	2	2	140–159	1	2	3	5	
50–54	6	6	≥ 7.21	11	8	5	3	1	13	10	7	4	2				≥ 160	2	3	4	6	
55–59	8	8																				
60–64	10	10																				
65–69	11	12																				
70–74	12	14																				
75–79	13	16																				

CORONARY HEART DISEASE 10-YEAR RISK — MEN

Total Risk Points	< 0	0–4	5–6	7	8	9	10	11	12	13	14	15	16	≥ 17
10-YEAR RISK	< 1%	1%	2%	3%	4%	5%	6%	8%	10%	12%	16%	20%	25%	≥ 30%

CORONARY HEART DISEASE 10-YEAR RISK — WOMEN

Total Risk Points	< 9	9–12	13–14	15	16	17	18	19	20	21	22	23	24	≥ 25
10-YEAR RISK	< 1%	1%	2%	3%	4%	5%	6%	8%	11%	14%	17%	22%	27%	≥ 30%

Table adapted from the Framingham Heart Study. Recent recommendations suggest that mental disease and treatment can increase metabolic risks.² Consider therapeutic lifestyle change recommendations and psychotropic treatment choices that mitigate future risk.

Table 4: Risk Categories and Target Lipid Levels³

Calculate the 10-year risk of CHD using Table 3 above, then identify target treatment lipid levels below.

RISK CATEGORY	TARGET LEVEL		
	LDL-C Level (mg/dL)	and	Optional LDL-C Target Level
High^a (10-year risk from Table 3 ≥ 20% or history of diabetes mellitus or any atherosclerotic disease)	< 100	and	< 70
Moderate (10-year risk 11%–19%)	< 130	and	< 100
Low (10-year risk < 10%)	< 160	and	NA

^aApolipoprotein B can be used as an alternative measurement, particularly for follow-up of patients treated with statins. Optimal levels of apolipoprotein B in a patient at high risk is < 0.9 g/L, moderate risk < 1.05 g/L, low risk < 1.2 g/L.

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Metabolic Screening and Monitoring Form

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- Grundy SM, Cleeman JI, Daniels SR, et al. Diagnosis and management of the metabolic syndrome: an American Heart Association/National Heart, Lung, and Blood Institute scientific statement. *Curr Opin Cardiol*. Jan 2006;21(1):1–6.
- National Heart, Lung, and Blood Institute. The practical guide identification, evaluation, and treatment of overweight and obesity in adults. NIH publication no. 00-4084, October, 2000 (pg. 46).
- American Association of Clinical Endocrinologists (AAACE). Medical guidelines for clinical practice for the management of diabetes mellitus. *AAACE Diabetes Mellitus Clinical Practice Guidelines Task Force, Endocrine Practice*. Vol 13 (Suppl 1) May/June 2007.

Produced by **Compact** Clinicals Kansas City, MO

Attachment E

TABLE 1. Medications Approved for the Long- and Short-Term Treatment of Obesity

Generic	Brand Name	Dose	Mechanism of Action	Precautions	Side Effects	Drug-Drug Interaction	Drug-Food Interaction
Long-term treatment							
Orlistat	Xenical	120 mg orally with each meal	Peripheral lipase inhibitor (30% of consumed fats passed unabsorbed/undigested)	Maintain dose of $\leq 30\%$ fat, not safe in pregnancy	Fatty/oily stools, loose stools, flatulence (temporary), reduced absorption of fat-soluble nutrients, eg, vitamins E, K, beta carotene May complicate gallbladder problems or history of kidney stones Body ache/chills Less common: chest tightness or trouble breathing	Cyclosporine Statins (additive antilipemic effects with statins) Warfarin (reduced vitamin K absorption)	None
Sibutramine	Meridia	5–15 mg orally once a day	Central; inhibits reuptake of serotonin and norepinephrine	May be habit-forming; use with caution in patients with hypertension, stroke, heart disease, history of gallstones, liver or kidney disease; not safe in pregnancy	Dry mouth, constipation, drowsiness, insomnia, headache, increased blood pressure, tachycardia	Decongestants, eg, pseudoephedrine, phenylephrine Cough suppressants, eg, dextromethorphan Antidepressants Lithium Monoamine oxidase inhibitors Migraine drugs, eg, ergots triptans Select opioids Ketoconazole Erythromycin Antihypertensives Certain antihistamines Antiepileptic drugs Sedatives Serotonergic agents Tryptophan	None
Short-term treatment							
Phentermine	Ionamin, Fastin, Adipex	15–37.5 mg, single or split dose	Stimulates central release of norepinephrine	Contraindicated sympathomimetics/monoamine oxidase inhibitors; furazolidone	Central nervous system stimulation, palpitations, dry mouth, insomnia	Selective serotonin reuptake inhibitors Tricyclics Guanethidine Any sympathomimetic	None

Taken from Palamara, K.L., Mogul, H.R., Peterson, S.J., Frishman, W.H. (September/October 2006). Obesity: New Perspectives and Pharmacotherapies; *Cardiology in Review*. Vol. 14, No. 5, pp. 238-258.

TABLE 4. U.S. Food and Drug Administration-Approved Medications Used Off Label in the Treatment of Obesity

Generic	Brand Name	Dose	Mechanism of Action	Precautions	Side Effects	Drug-Drug Interaction	Drug-Food Interaction
Metformin	Glucophage	Initiate with 500 mg/d and increase weekly to 1000–2000 mg/day in divided doses	Reduces food intake; also lowers insulin and free fatty acids; exact primary mechanism in weight reduction not identified	Contraindicated in patients with renal impairment (creatinine >1.5), hepatic disease, congestive heart failure, chronic pulmonary disorders, or alcohol abuse; discontinue 48 h before and after general anesthesia or use of iodinated contrast materials; discontinue with severe fever or dehydration secondary to vomiting or diarrhea	Diarrhea, nausea, vomiting, abdominal bloating, flatulence, and anorexia (generally transient); pregnancy can occur as a result of increased fertility	Iodinated contrast materials Sulfonylurea and/or insulin—hypoglycemia Furosemide—increases plasma concentrations of both drugs Nifedipine—increases plasma concentrations of metformin with minimal change in pharmacokinetics Cimetidine—increases plasma concentration of metformin Adrenergic-blocking agents—beta blockers increase the frequency and severity of hypoglycemia Alcohol—increased risk of hypoglycemia and acidosis Clomiphene—increased ovulatory response None listed	None
Topiramate	Topamax	25–100 mg	GABAergic	Drowsiness, blood dyscrasias, liver function test abnormalities	Confusion, dizziness, nervousness, paresthesias, breast pain, nausea, tremors, memory and cognitive impairment	None listed	None listed
Zonisamide	Zonegran	100–600 mg/day	Serotonergic and dopaminergic	Contraindicated in patients with hypersensitivity to sulfonamides; discontinue if skin rash develops; caution in patients with renal and hepatic impairment; may cause kidney stones; discontinue if patient develops acute renal failure or sustained elevated blood urea nitrogen/creatinine; teratogenic	Somnolence, dizziness, headache, nausea, agitation/irritability, fatigue	None listed	None listed
Bupropion	Wellbutrin	100 mg twice a day or 75 mg once daily	Precise mechanism not known	Do not use in patients with renal and hepatic impairment; avoid alcohol; monitor for seizures	Agitation, anxiety, abdominal pain, anorexia, constipation, dizziness, dry mouth, increased sweating, insomnia, nausea, tremors, vomiting, weight loss	Monoamine oxidase inhibitors—contraindicated Ritonavir—moderate	None

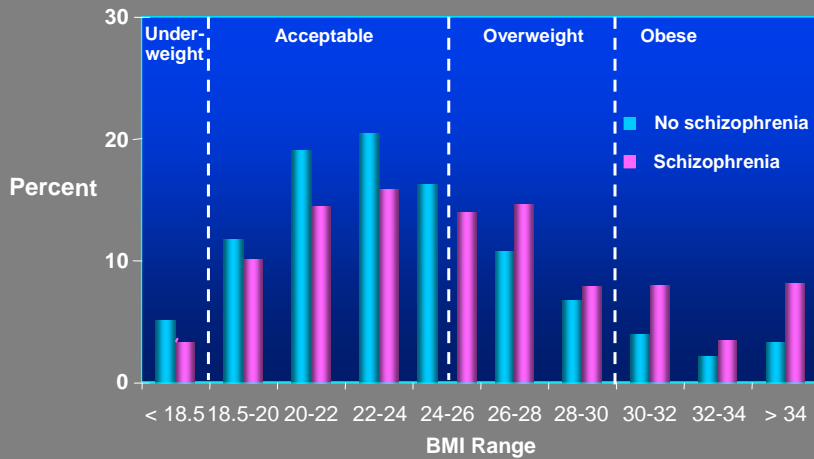
GABA indicates γ -aminobutyric acid

Taken from Palamara, K.L., Mogul, H.R., Peterson, S.J., Frishman, W.H. (September/October 2006). *Obesity: New Perspectives and Pharmacotherapies; Cardiology in Review*. Vol. 14, No. 5, pp. 238-258.

Attachment F

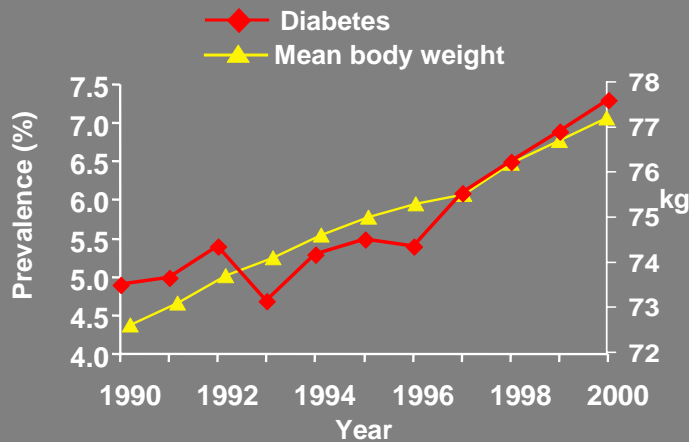
The following selections of slides were presented at the work group meeting by John W. Newcomer, MD. They provide additional information related to adiposity, medical risk, and switching medications in persons with mental illness.

BMI Distributions for General Population and Those With Schizophrenia (1989)



Allison DB et al. *J Clin Psychiatry*. 1999;60:215-220.

Diabetes and obesity in the US

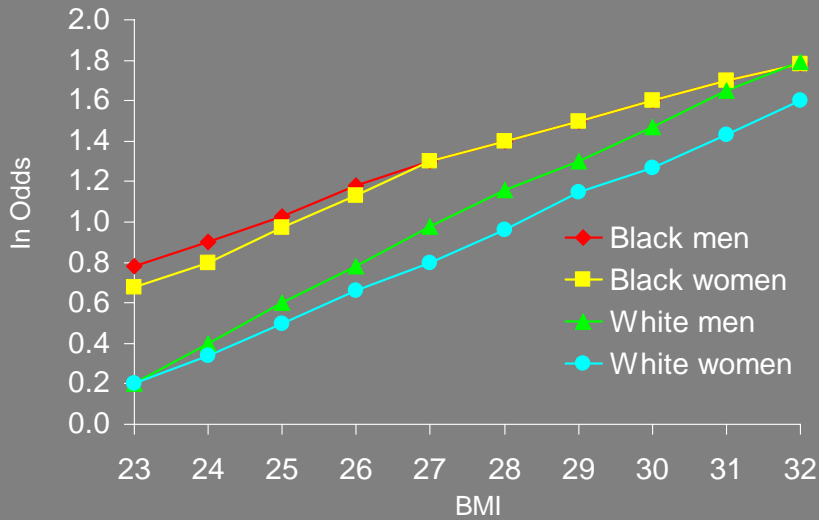


Mokdad et al. *Diabetes Care*. 2000;23:1278.
 Mokdad et al. *JAMA*. 1999;282:1519.
 Mokdad et al. *JAMA*. 2001;286:1195.

CHD Risk Increases With Increasing Number of Metabolic Syndrome Risk Factors

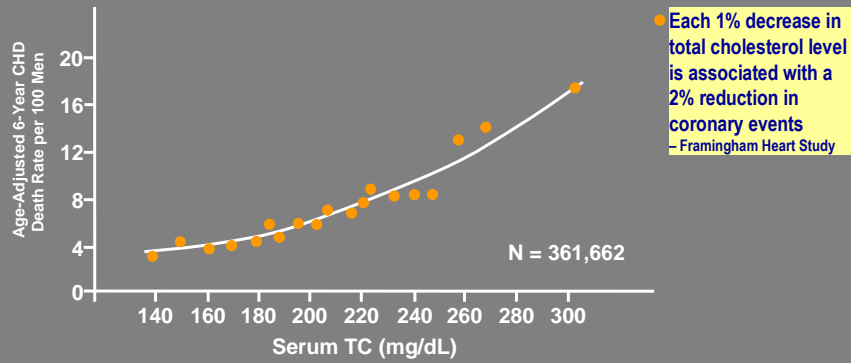


Adjusted Log-Odds of Diabetes in Relation to Baseline BMI by Sex and Race



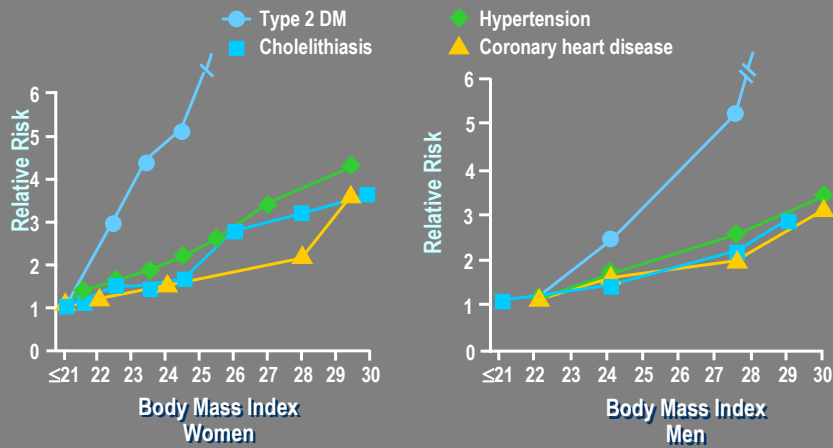
Relationship Between Cholesterol and CHD Risk

Screenees for Multiple Risk Factor Intervention Trial (MRFIT)



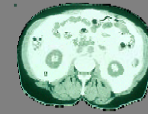
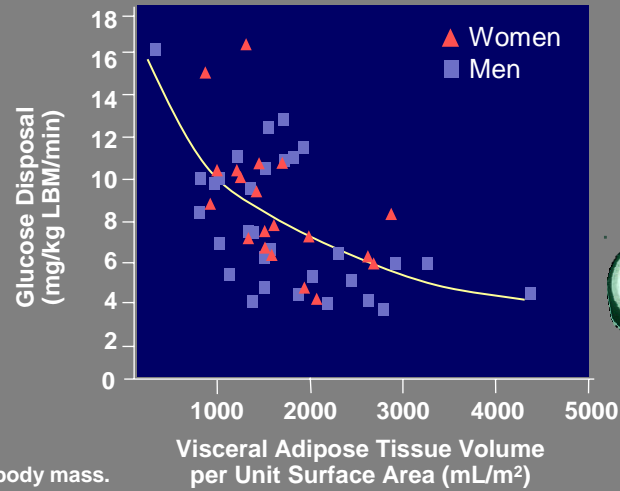
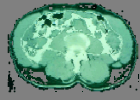
LaRosa JC, et al. *Circulation* 1990;81:1721-1733.
Data from: MRFIT. *JAMA* 1982;248:1465-1477.

Adiposity and Medical Diseases



Willett WC, Dietz WH, Golditz GA. *N Engl J Med* 1999 Aug 5;341(6):427-434

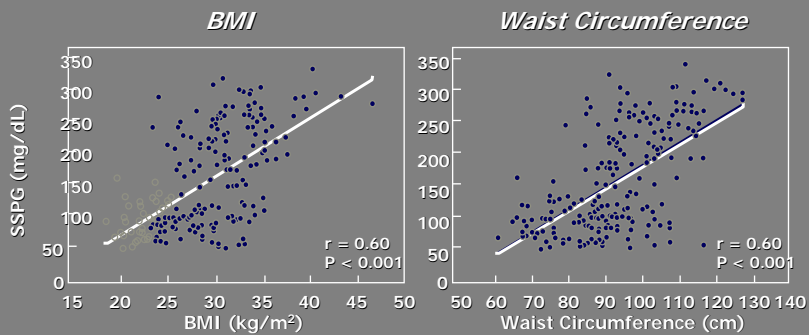
Relationship Between Visceral Adipose Tissue and Insulin Action



LBM = lean body mass.

Banerji et al. *Am J Physiol.* 1997;273(2 pt 1):E425-E432.

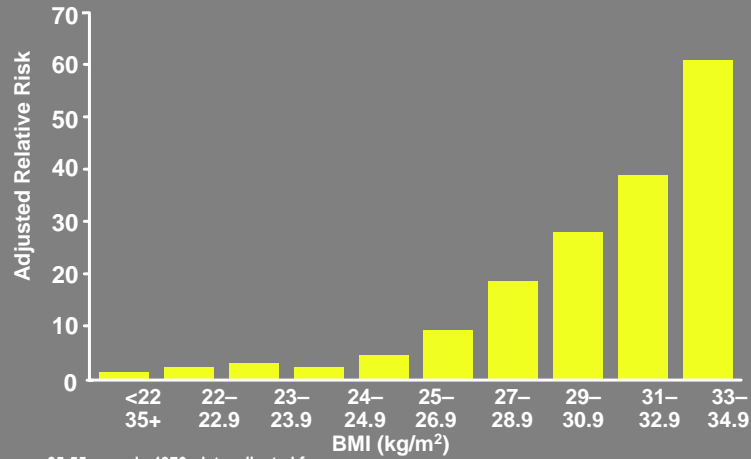
Relationship Between Insulin Resistance and either BMI or Waist Circumference



Insulin resistance measured using gold-standard steady state plasma glucose (SSPG) concentration during fixed-dose glucose and insulin infusions

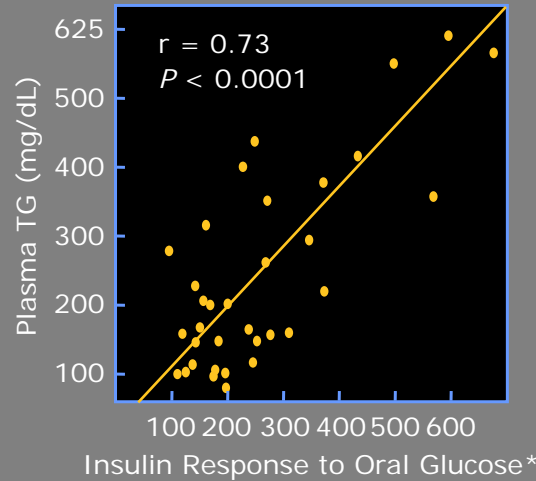
Farin H, et al. *Metabolism* 2005;54:1323.

Body Mass Index (BMI) And Relative Risk Of Type 2 Diabetes



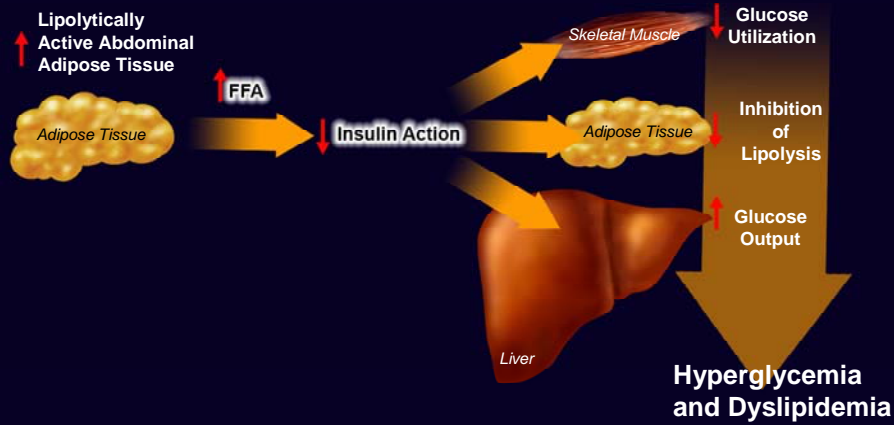
In women age 35-55 years in 1976; data adjusted for age.
Adapted from Colditz et al. *Am J Epidemiol.* 1990;132:501-513.

Relation Between Insulin Resistance and Hypertriglyceridemia



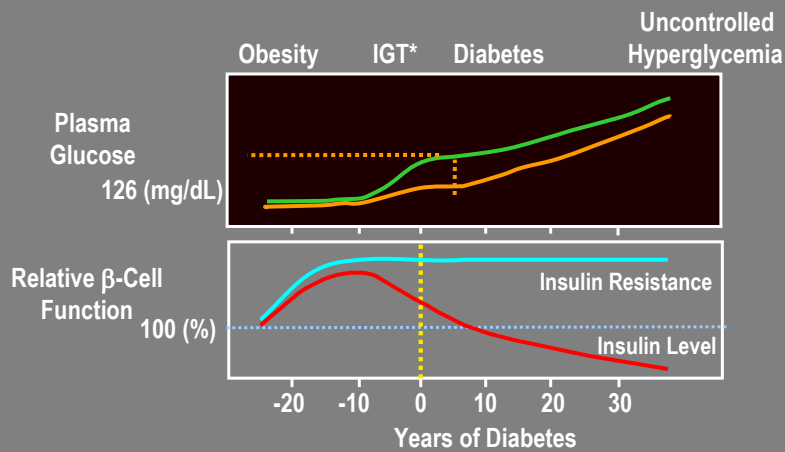
* Total area under 3-hour response curve (mean of 2 tests).
Olefsky JM et al. *Am J Med.* 1974;57:551-560.

Adiposity and Insulin Resistance



Steinberg HO, Baron AD. *Diabetologia*. 2002;45:623-633
 Caballero AE. *Obesity Res*. 2003;11:1278-1288
 Reaven GM. *Diabetes*. 1988;37:1595-1607

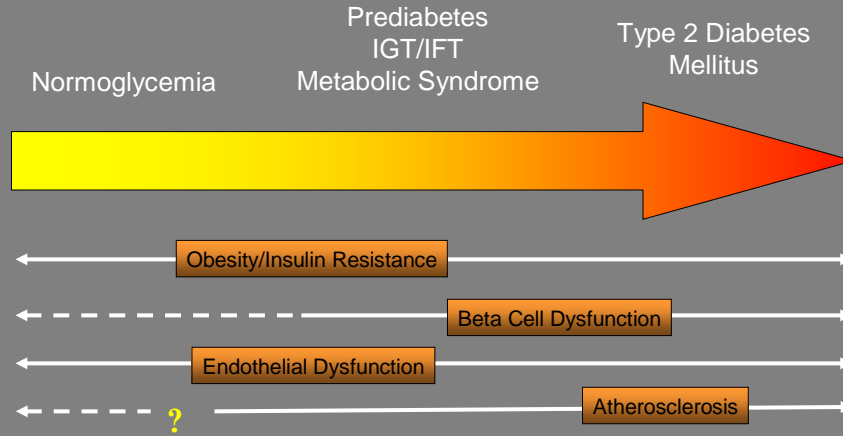
Natural History of Type 2 Diabetes



*IGT = impaired glucose tolerance

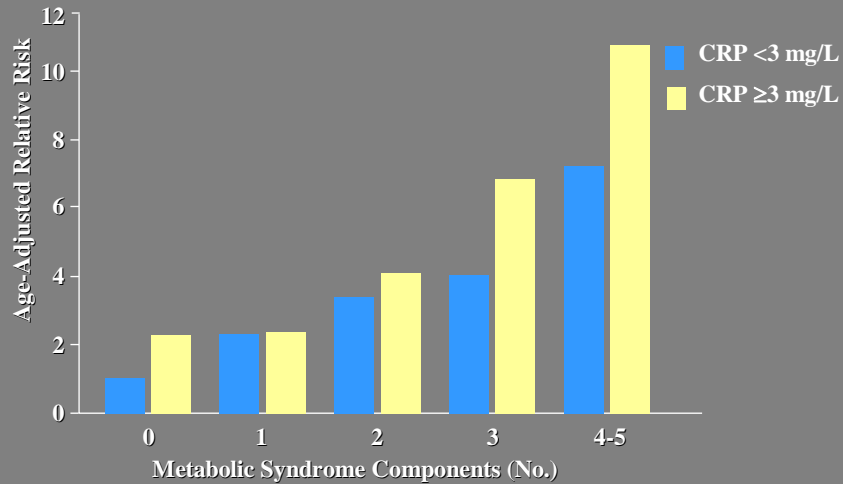
Adapted from: International Diabetes Center (IDC), Minneapolis, Minnesota.

Obesity, Insulin Resistance, Endothelial Dysfunction, and Atherosclerosis



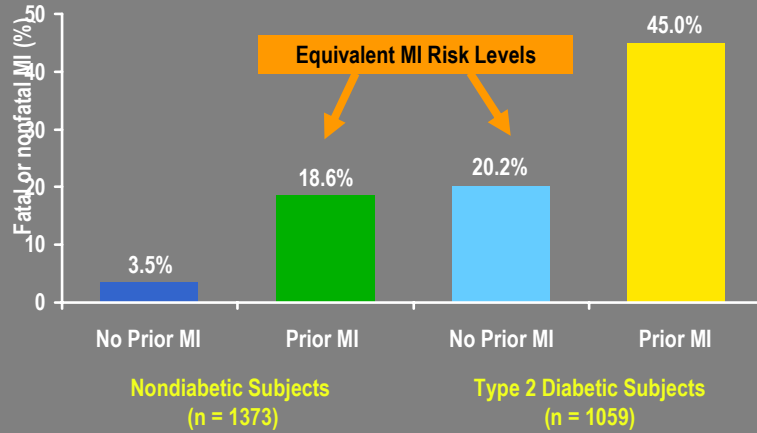
Steinberg HO, Baron AD. *Diabetologia*. 2002;45:623-634.
Caballero AE. *Obesity Res*. 2003;11:1278-1289.

Risk of Future CV Events: CRP and the Metabolic Syndrome



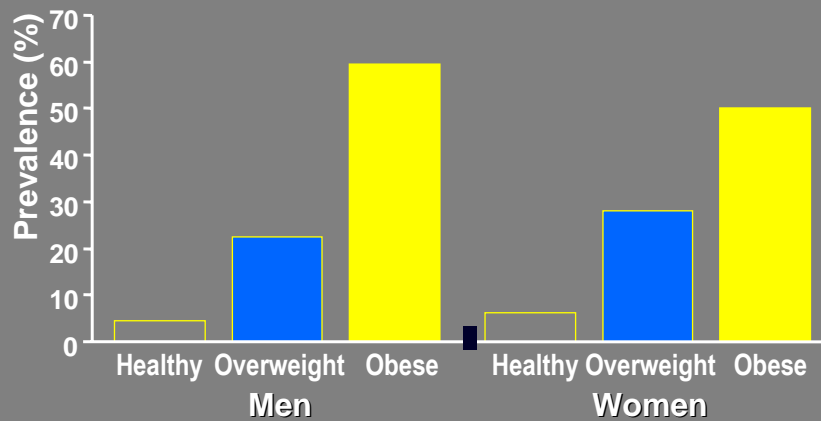
N = 14,719.
Ridker et al. *Circulation*. 2003;107:391-397.

Incidence of MI During 7-Year Follow-Up



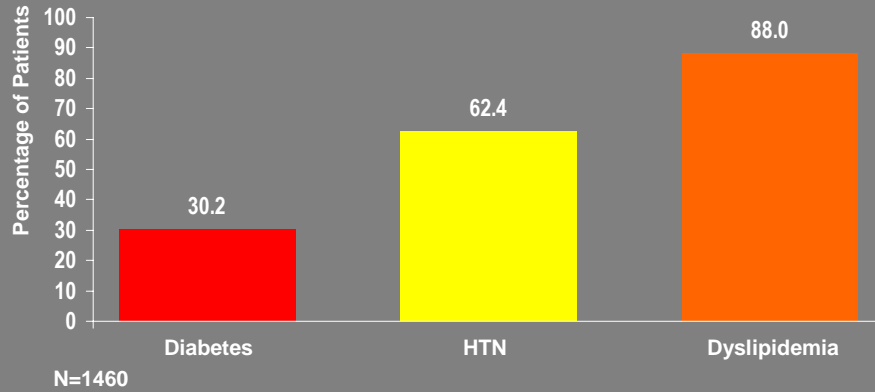
Haffner SM et al. *N Engl J Med.* 1998;339:229-234.

Prevalence of Metabolic Syndrome According to BMI



"Overweight" = BMI 25-29.9; "obese" = BMI \geq 30 (National Heart, Lung and Blood Institute, Obesity Guidelines); N=12,363; Park YW, Zhu S, Palaniappan L, et al. *Arch Intern Med.* 2003(Feb 24);163:427-436

Prevention Opportunities Missed: Low Rates of Treatment for Metabolic Disorders In Schizophrenia in CATIE



Nasrallah H et al. *Schizophrenia Research* 2006; 86:15–22

Psychotropic-Associated Weight Gain

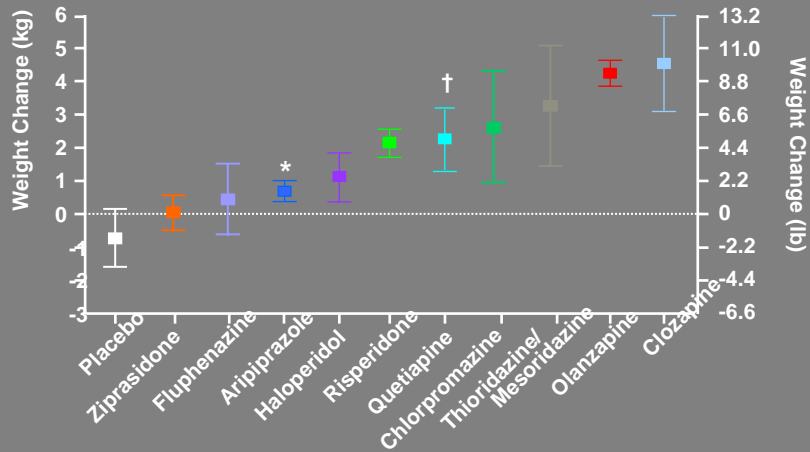
Data from Pivotal Trials

Agents	5% Weight Gain	Length	Mean Change
Lithium ¹	62%	1 year	4.0 kg
Valproate ²	21%	1 year	Not reported
Agents	7% Weight Gain	Length	Mean Change
Olanzapine ³	29%	6 weeks	+2.8 kg
Quetiapine ³	21%	6 weeks	+2.6 kg
Risperidone ³	18%	6 weeks	+1.6 kg

FDA = US Food and Drug Administration; N/R = not reported. *Weight gain was stratified according to BMI.
 1. Peselow ED, et al. *J Affect Disord.* 1980;2:303-310. 2. Bowden CL, et al. *Arch Gen Psychiatry.* 2000;57:481-489.
 3. Adapted from: Prescribing Information. *Physicians' Desk Reference.* 59th ed. Montvale, NJ: Medical Economics Co; 2005.

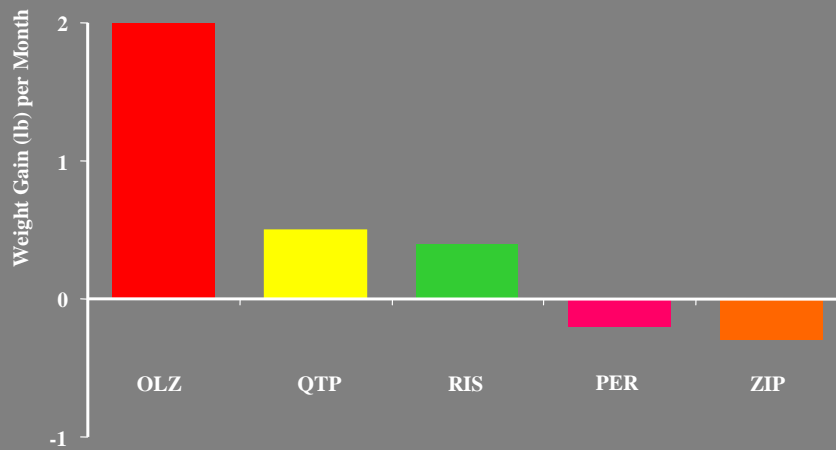
Mean Change in Weight With Antipsychotics

Estimated Weight Change at 10 Weeks on "Standard" Dose



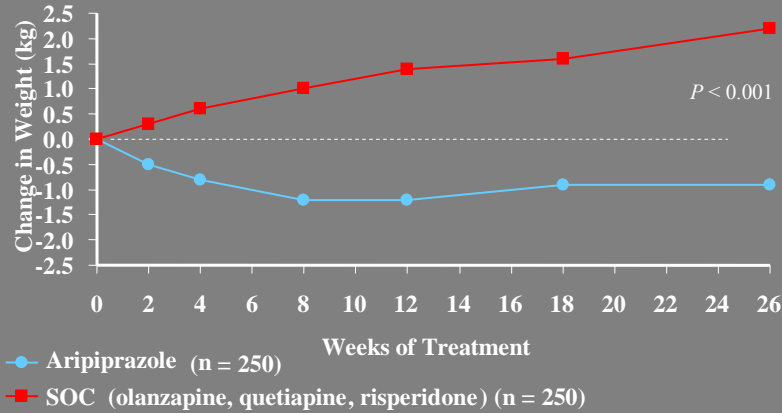
*4-6 week pooled data (Marder SR et al. *Schizophr Res.* 2003;1;61:123-36; †6-week data adapted from Allison DB, Mentore JL, Heo M, et al. *Am J Psychiatry.* 1999;156:1686-1696; Jones AM et al. *ACNP*; 1999.

CATIE Phase 1 Trial Results: Weight Gain per Month of Treatment



Lieberman JA, et al. *N Eng J Med.* 2005;353:1209-1223.

STAR Trial: Weight Change Over 26 Weeks



Kerwin R, et al. A Multicentre, Randomized, Naturalistic, Open-Label Study Between Aripiprazole and Standard of Care In the Management of Community-Treated Schizophrenic Patients—Schizophrenia Trial of Aripiprazole (STAR) Study. *European Psychiatry*. In Press.

ADA Consensus on Antipsychotic Drugs and Obesity and Diabetes: Monitoring Protocol*

	Start	4 wks	8 wks	12 wks	3 mos.	12 mos.	5 yrs.
Personal/family Hx	X					X	
Weight (BMI)	X	X	X	X	X		
Waist circumference	X					X	
Blood pressure	X			X		X	
Fasting glucose	X			X		X	
Fasting lipid profile	X			X		X	X

*More frequent assessments may be warranted based on clinical status
Diabetes Care. 27:596-601, 2004

Attachment G

The following selection of slides were presented at the work group meeting by Rohan Ganguli, M.D. They provide additional information related to medications for weight loss in persons with mental illness.

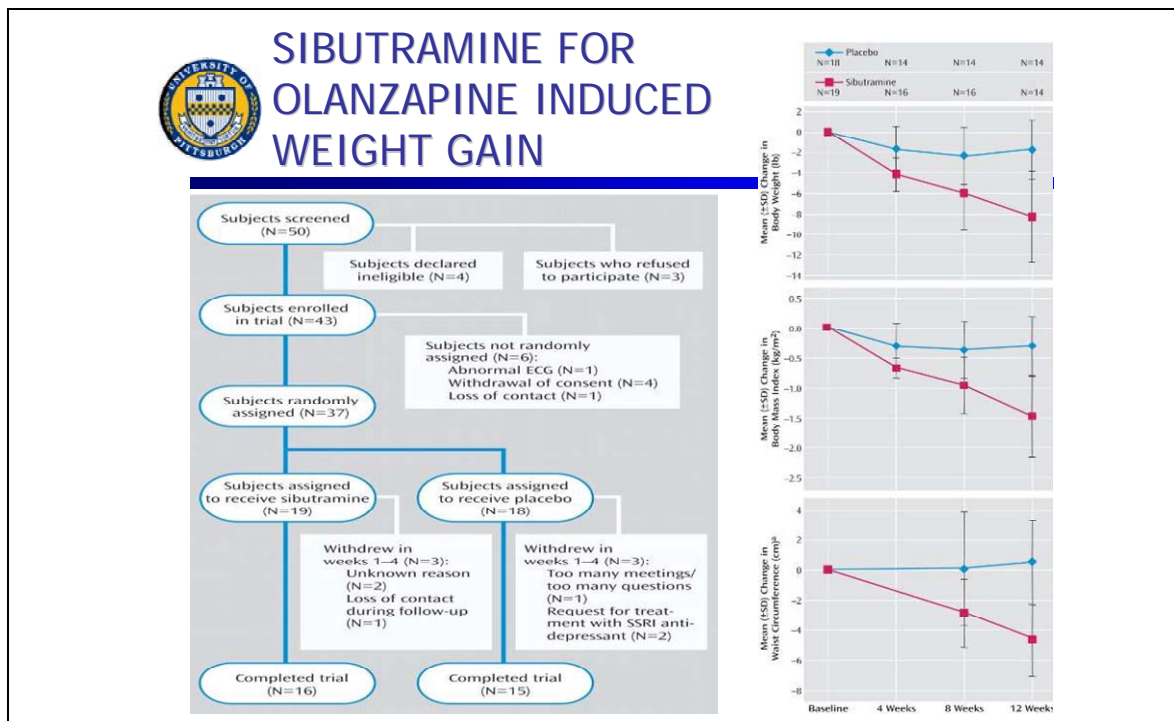


TABLE 6. Patients Who Reported Adverse Events in a 12-Week Placebo-Controlled Trial of Sibutramine for Olanzapine-Associated Weight Gain

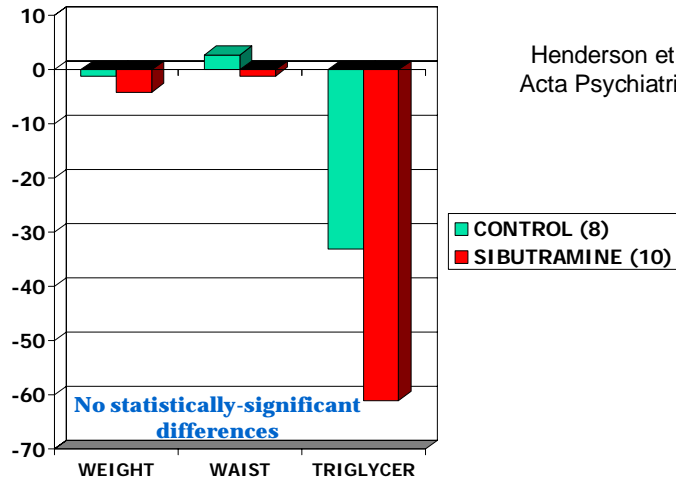
Adverse Event	Patients Reporting Adverse Event, Controlled for Baseline Level			
	Placebo (N=17)		Sibutramine (N=19)	
	N	%	N	%
Rapid heart rate	1	6	2	11
Headaches	5	29	4	21
Difficulty falling asleep	5	29	7	37
Interrupted sleep ^a	1	6	5	26
Shortened sleep ^a	2	12	5	26
Early waking	3	18	3	16
Decreased appetite	11	65	12	63
Excessive appetite	6	35	3	16
Excessive thirst ^a	2	12	5	26
Dry mouth ^a	2	12	8	42
Nausea	6	35	4	21
Constipation ^a	2	12	5	26
Rhinitis	4	24	4	21
Dizziness	3	18	1	5
Blurred vision ^a	1	6	3	16

^a Occurred in more than 5% of the patients taking sibutramine and was at least twice as common as in the placebo group.

Rohan Ganguli, M.D.



SIBUTRAMINE FOR CLOZAPINE-INDUCED WEIGHT GAIN



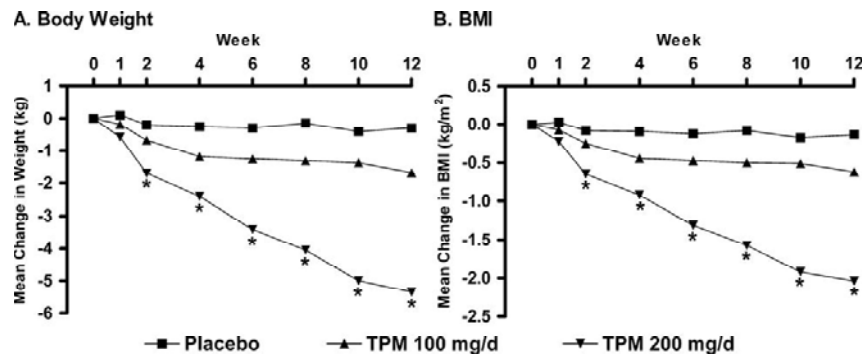
Henderson et al., 2007
Acta Psychiatrica Scand.

Rohan Ganguli, M.D.



TOPIRAMATE FOR WEIGHT LOSS

* Not FDA-approved for weight loss

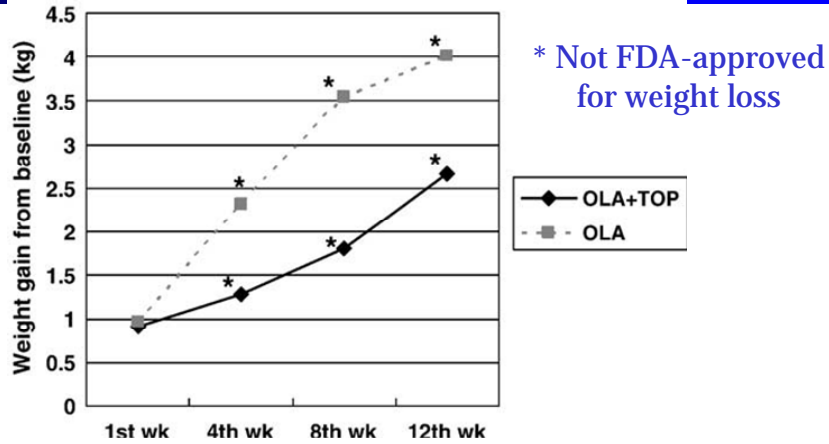


Ko YH, Joe SH, Jung IK, Kim SH. (2005) Topiramate as an adjuvant treatment with atypical antipsychotics in schizophrenic patients experiencing weight gain. Clin Neuropharmacol 28(4):169-75

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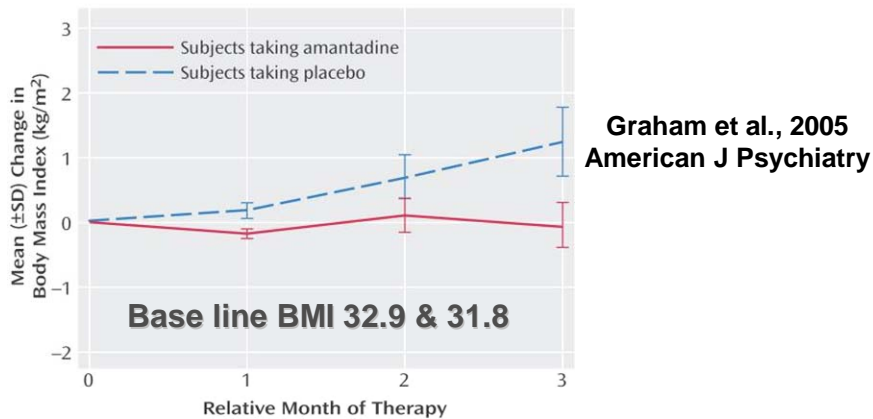
TOPIRAMATE TO PREVENT WEIGHT GAIN



Kim JH, Yim SJ, Nam JH. A 12-week, randomized, open-label, parallel group trial of topiramate in limiting weight gain during olanzapine treatment in patients with schizophrenia. *Schizophr Res* 2006;82:115-7 Rohan Ganguli, M.D.



AMANTADINE* IN OBESE SUBJECTS TAKING OLANZAPINE

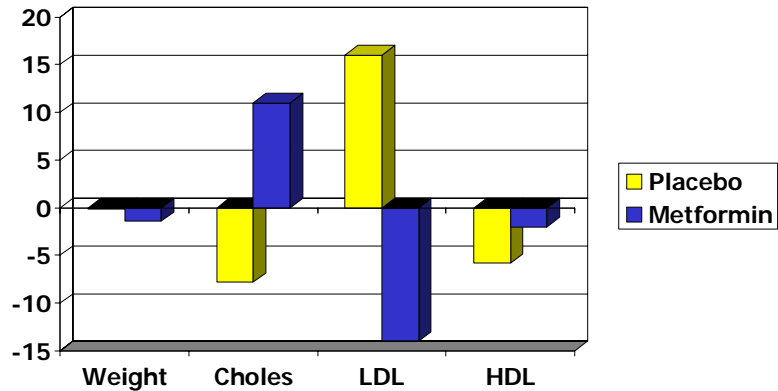


* Not FDA-approved for weight loss

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METFORMIN IN PATIENTS ON OLANZAPINE WHO HAVE ALREADY GAINED WEIGHT

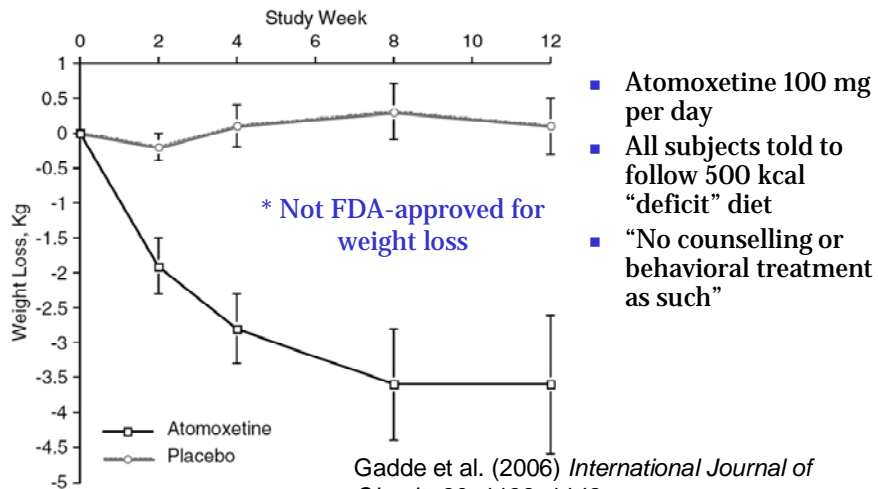


T. Baptista et al. (2007) *Schizophrenia Research* 93: 99–108

Rohan Ganguli, M.D.



ATOMOXETINE FOR WEIGHT LOSS



Gadde et al. (2006) *International Journal of Obesity* 30, 1138–1142

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