COGNITIVE INTERVIEWING TO ASSESS A NEW MEASURE OF ATTITUDES AND BELIEFS HELD BY CANDIDATES FOR BARIATRIC SURGERY

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Thank you Mom, Dad, sisters Namrata and Angel, and colleagues, for your invaluable and indispensible moral support.

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COGNITIVE INTERVIEWING TO ASSESS A NEW MEASURE OF ATTITUDES AND BELIEFS HELD BY CANDIDATES FOR BARIATRIC SURGERY

By

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The University of Texas Southwestern Medical Center at Dallas, 2010

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Abstract: Increases in the obese population of the United States have subsequently led to increases in the numbers of bariatric surgeries pursued. However, despite increases in the number of surgeries performed, the success rate of the surgeries still remains acutely tied in with adherence to lifestyle modifications post-surgery, which are products of individuated attitudes and beliefs. Identification of these variables pre-surgery may enable health-care professionals to brainstorm preemptive intervention techniques aimed at providing support to bariatric patients post-surgery. However, no measures to identify such attitudes and beliefs exist. This qualitative study utilized Cognitive Interviewing to assess sources of response error in two new measures designed to identify attitudes and beliefs of candidates for bariatric surgery. Our hypothesis was that the newly created measures would be easy to understand and answer. METHODS: Twenty patients attending a bariatric clinic were offered $20 gift cards to answer questions on The Eating Behaviors Self-Efficacy Measure and The Perceived Barriers to Exercise Measure. A standardized instruction script asking participants to "think-aloud" while answering questions was read before each interview. Interviews were audio recorded and transcribed to assess similarities in sources of

response error. RESULTS: The majority of participants (90%) struggled with understanding/executing instructions of the measures. In addition, several specific items were identified as sources of confusion. Recommendations to reduce sources of response error were made to the test-makers. CONCLUSION: Although the hypothesis was not supported, future adaptation of recommendations could decrease most sources of response error. Additional Cognitive Interviewing after instrument refinement was recommended. After revision, The Eating Behavior Efficacy Measure and The Perceived Barriers to Exercise Measure should receive pilot testing in a longitudinal investigation of the scales' validity and reliability for clinical use.

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Cognitive Interviewing to Assess a New Measure of Attitudes and Beliefs Held by Candidates for Bariatric Surgery

Chapter One.

Introduction. One of the growing health concerns of today's society is the increase in the obese and clinically obese population. The Current International Obesity Task Force (CIOTF) reported estimates of 1.1 billion overweight people in the world, with 312 million individuals of this group meeting criteria for obesity. These numbers reflect a direct concern in the United States (U. S.) that unhealthy weight is becoming epidemic (Modkad, Serdula, & Dietz, 2000). Based on data from the 2003 - 2004 U. S. National Health and Nutrition Examination Survey (NHANES), approximately 66 million American adults (30 million men and 36 million women) are obese and an additional 74 million (42 million men and 32 million women) are overweight.

The most convenient and common way of quantifying and defining the degree of obesity is by the body mass index (BMI), which is a ratio of a person's weight in kilograms to height in meters squared (Horton, 1994; Kral & Heymsfield, 1987; Najar & Roland, 1987). The BMI required for a clinical definition of obesity is BMI $\geq$ 30 kg/m^2. When BMI is between 35kg/m^2 and 40kg/m^2 , particularly when accompanied by other illnesses, the term morbid obesity, or more appropriately termed, Clinically Severe Obesity, (National Institute of Health Consensus Statement, [NIOHCS], 1992) is used. Table 1 portrays the current classification system based on BMI.

Weight Category	Body Mass Index Range
Normal Weight	18.5 - 24.9
Overweight	25.0 - 29.9
Class I Obesity	30.0 - 34.9
Class II Obesity	35.0 - 39.9
Class III Obesity	≥ 40.0

Table 1: Body Mass Index Classifications. BMI= wt (kg)/ ht $(m)^2$

Prevalence. Worldwide, obesity is more prevalent in women (James, Leach, Kalamara, & Shayeghi, 2001). One hypothesis for this disparity is the difference between the biological body fat content of women and men: the body of an average woman is composed of approximately 25% fat, whereas the body of an average man is about 15% (Gelber et al., 2008). In addition, female hormones such as estrogen facilitate the storage of fat in the body (Gelber et al.).

Although obesity is a global concern, prevalence rates vary across regions, with Central and Eastern Europe, North America, and the Middle East having higher prevalence rates. Figure 1 shows a comparison of the percentages of obese and overweight men and women in 191 countries (Philip, Leach, Kalamara, & Shayeghi, 2001). A hypothesized rationale for this differentiation is that the growing urbanization of lifestyles brings about decreases in physical activity, which subsequently increases time spent in sedentary activities (Population Reference Bureau, [PRB], 2008). The move towards more urban societies coupled with changes in globalization of food production around the world has also brought decreases in the cost of food and increases in the cost of physical

exercise (PRB, 2008). In addition, the incorporation of energy-saving technological devices has further economized physical energy (PRB).

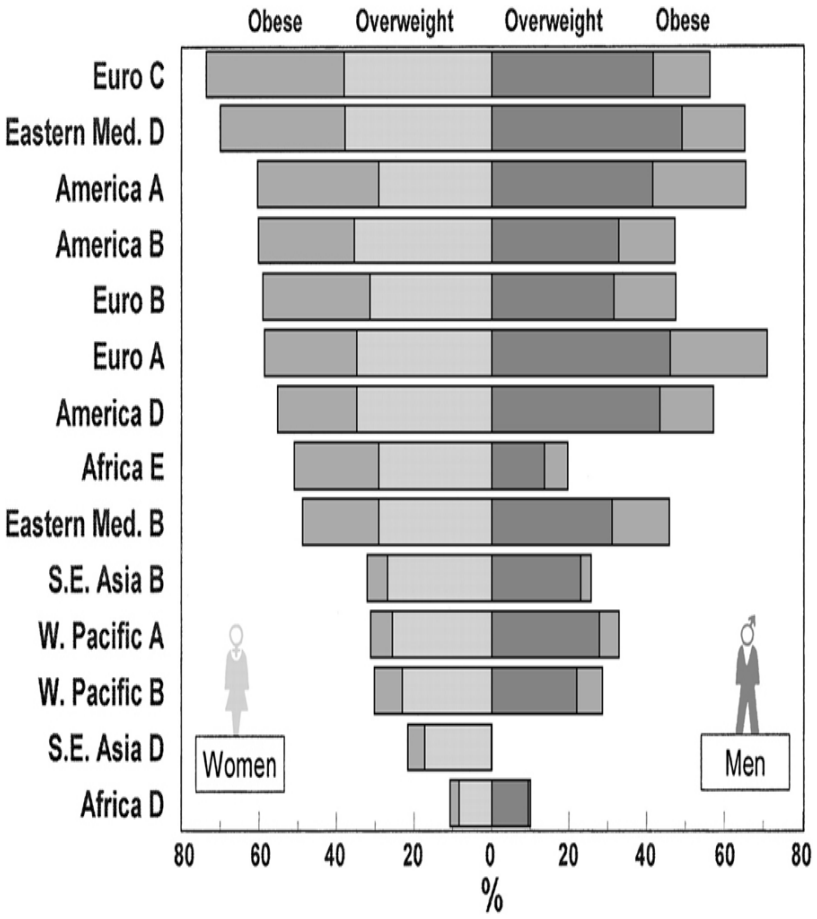
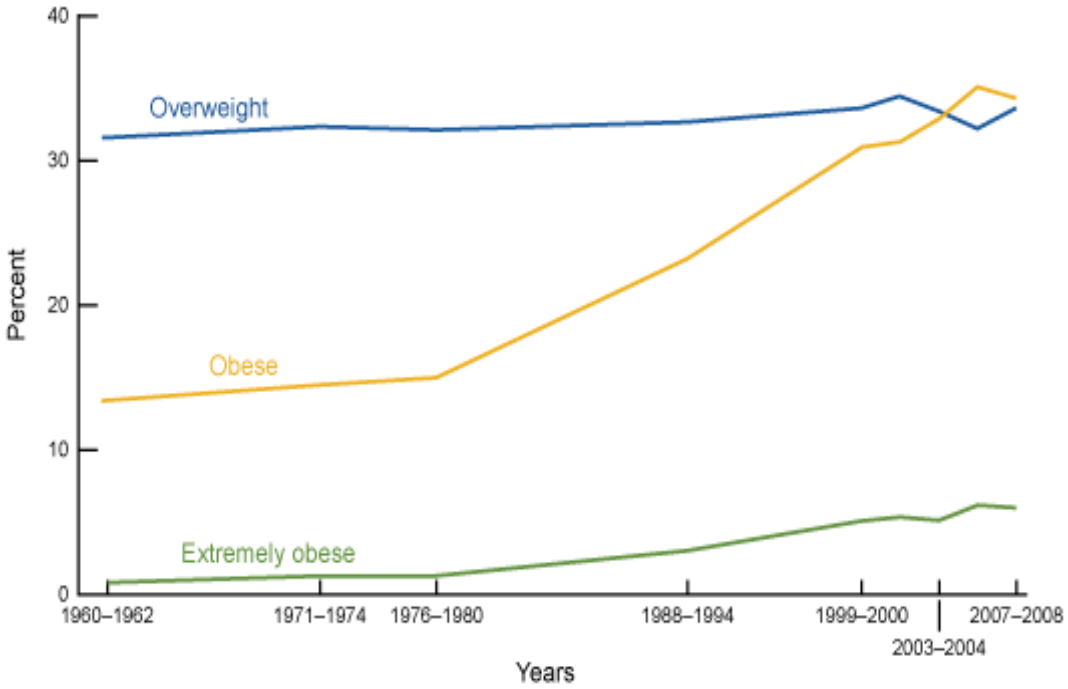


Figure 1: Estimates of the prevalence of overweight and obesity in 45- to 59-year-olds in different parts of the world. Source: Philip, T. J., Leach, R, Kalamara, E., Shayeghi, M. (2001). The Worldwide Obesity Epidemic. Obesity Research, 9, S228-S233. doi:10.1038/oby.2001.123 Used with permission.

According to the 2003 - 2004 survey by NHANES, the prevalence of overweight people in the U. S. includes approximately 66.3 % of all adults. Between 23.0 % - 35.0 % of the U.S. population is obese (Hedley et al., 2004). The prevalence of morbid obesity is 4.7% according to the last published figures from the Centers for Disease Control and Prevention (CDC, 2010). Assuming that

the same trends continue, by 2015, two in every five adults, and one in every four children in the U. S. will be obese (Kucsmarski, Flegal, & Campbell, 1994; Kumanyika et al., 2008). The prevalence of obesity in 18 - 29 year-olds has increased from 12.0 % to 19.0 % between 1991 and 1999 (Mokdad, Serdula, & Dietz, 1999). The results of the 2003 - 2004 NHANES survey extrapolated to the year 2048 predicted that most individuals in the U. S. will be overweight or obese by that time (Wang et al., 2008). Figure 2 presents a summation of the growing trends in overweight, obese and clinically obese adult populations over the course of 48 years (Ogden & Carroll, 2010).

In the U. S., the prevalence of adult obesity has doubled since 1980, and presently ranks as one of the top ten major cause of preventable death (Danaei, Ding, Mozaffarian, Taylor, & Rehm et al., 2009; Hedley et al., 2004). Mortality rates in the clinically obese are 12 times higher in men aged 25 - 34 years and six times higher in men aged 35 - 44 years, compared with non-obese men of the same age (Drenick, Bale, & Seltzer, 1980). Manson et al. (1995), found a positive correlation between increased weight and mortality rates in women. In people aged 50 - 71 years, obesity was strongly associated with the risk of death in both men and women in all racial and ethnic groups (Adams et al., 2006). Figure 3, from the Center for Disease Control, shows the dispersion of the obese and overweight population by states in the United States. The BMI of individuals in almost all states falls into either the overweight or the obese category, thereby indicating the expansive nature of the current weight-related health epidemic.



NOTE: Age-adjusted by the direct method to the year 2000 U.S. Census Bureau estimates, using the age groups 20–39, 40–59, and 60–74 years. Pregnant females were excluded. Overweight is defined as a body mass index (BMI) of 25 or greater but less than 30; obesity is a BMI greater than or equal to 30; extreme obesity is a BMI greater than or equal to 40.
SOURCE: CDC/NCHS, National Health Examination Survey cycle I (1960–1962); National Health and Nutrition Examination Survey I (1971–1974), II (1976–1980), and III (1988–1994), 1999–2000, 2001–2002, 2003–2004, 2005–2006, and 2007–2008.

Figure 2: Growing trends of overweight and obesity among adults aged 20-74 in the United States between the years 1960-2008.
Source: Ogden, C. L., Carroll, M. D. (2010). Prevalence of Overweight, Obesity, and Extreme Obesity Among Adults: United States, Trends 1976–1980 Through 2007–2008. The National Center for Health Statistics. Retrieved from http://www.cdc.gov. Copyright permission obtained from CDC.gov

The increased prevalence of obesity worldwide today appears to be an ongoing disturbing trend. Researchers Wang, Beydoun, Liang, Caballero, and Kumanyika (2008) suggested that by the year 2030, 86.3% adults will be overweight, with 51.1% of this group meeting the criteria for obesity. In addition, these researchers predicted that by the year 2048, there is potential for all American adults to become overweight or obese if current trends in obesity continue (Wang et al.).

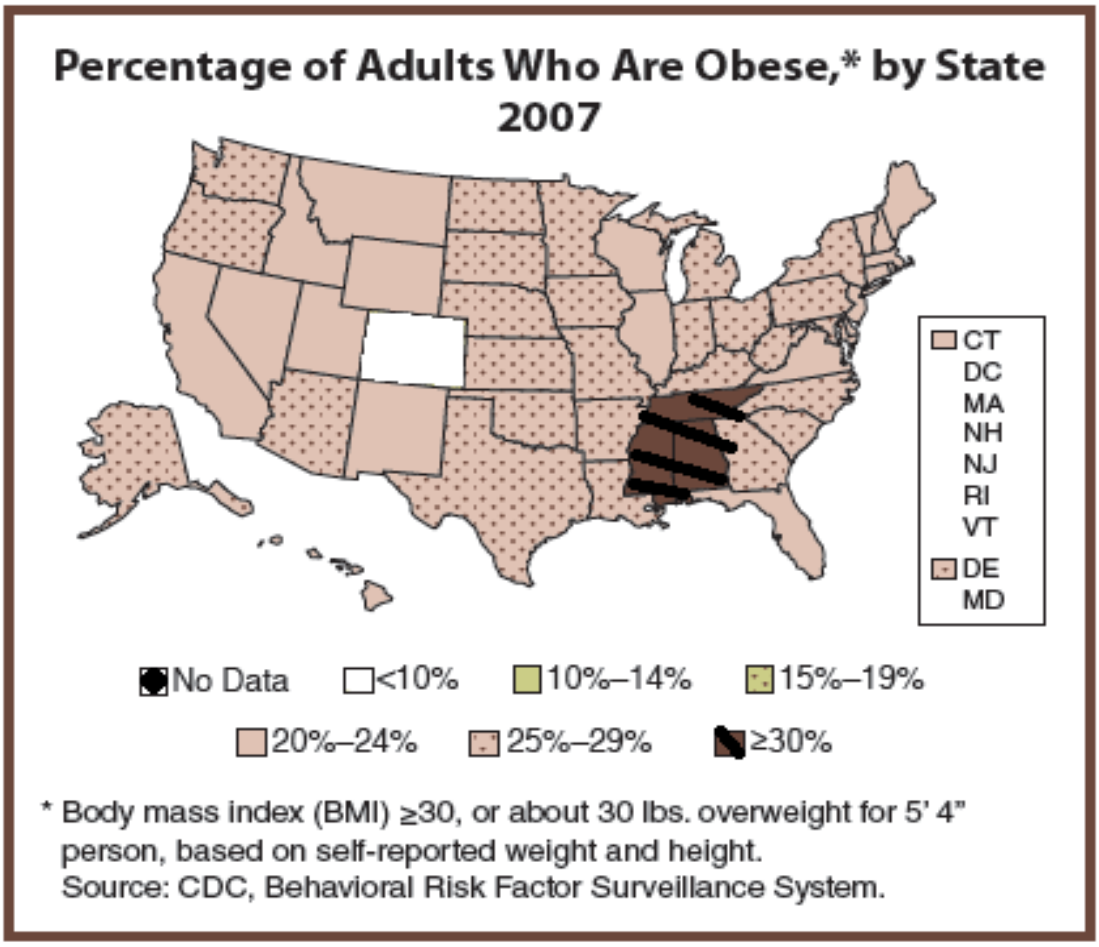


Figure 3: 2007 Percentage of Adults Who Are Obese, by State.
Source: Centers for Disease Control and Prevention. Copyright permission obtained from CDC.gov

Public Health Concerns. Obesity restricts individuals from participating in many typical activities, which in turn, makes it more difficult to lose excess weight. Strum, Ringel, and Andreyeva (2004) analyzed trends of obesity with time series estimates of obesity based on the 1985 – 2002 Behavioral Risk Factor Surveillance Survey (BRFSS) and extrapolated them to the year 2020. Their research found that for men, moderate obesity was associated with a 50% increase in the probability of limitations of Activities of Daily Living (ADLs), and severe obesity was associated with a 300% increase**.** In women, the probability of ADLs

limitations increased by 200% with moderate obesity and by 400% with severe obesity. Researchers continue to seek to identify the causes of differences in ADL limitations between men and women.

Because clinically obese individuals have higher mortality rates than overweight individuals, public health concerns expand beyond those related to the compromised quality of life (Flegal, Graubard, & Williamson, 2007). Total mortality rates due to obesity in the U. S. have been estimated between 280,000 and 325,000 in 1999 (Allison, Fontaine, & Manson, 1999), although a subsequent study found the annual rate of mortality due to obesity to be 111,909 deaths (Flegal et al.). Specifically, obesity is associated with more than 112,000 deaths attributed to cardiovascular disease, over 15,000 deaths due to cancer; and over 35,000 deaths due to non-cancer, non-cardiovascular diseases per year in the U. S. population, relative to healthy-weight individuals (Flegal et al.). Improvements in public health and medical care might be positive determinants of reduced mortality (Flegal et al.). However, despite these improvements, the impact of obesity on human health is comparable to that of several other leading causes of health impairment.

Interestingly, these morbidity rates of obesity are comparable to the morbidity rates of poverty, smoking, and problem drinking (Sturm & Wells, 2001). In addition, clinical obesity has been associated with 90% of individuals suffering from Type II diabetes, 70% from cardiovascular disease, 42% from breast and colon cancer, 30% from gall bladder disease and 26% of those struggling with high blood pressure (World Health Organization, [WHO], 2010).

Not only is obesity associated with a high personal cost to physical health, but also with a high cost to the nation's health related financial resources.

The national estimated cost of obesity in the U. S. reflects the changes in the prevalence of the overweight and obese. Estimated aggregate adult medical expenditures attributable to being overweight and obese in 1988 were $51.5 billion using Medical Expenditure Panel Survey (MEPS) data, and $78.5 billion using 1998 National Health Accounts (NHA) data (Wolf & Colditz, 1998). For obesity alone, the estimated costs were $26.8 billion and $47.5 billion respectively, with NHA rates also reporting costs associated with institutionalized populations, including psychiatric inpatients (Wolf & Colditz). Medical spending on conditions associated with obesity has doubled in the past decade and was estimated to have reached an annual rate of $147 billion in 2008 (Finkelstein, Trogdon, Cohen, & Dietz, 2009). Obesity now accounts for 9.1% of all medical spending, up from 6.5 % in 1998 (Finkelstein et al.). A research study conducted by Wang and colleagues (2008), predicted that the total healthcare costs attributable to obesity/being overweight will double every decade to vary anywhere from $860.7 to $956.9 billion by the year 2030. Secondary to the enormous costs associated with the obese/overweight, treatment is imperative to prevent further physical and health related comorbidities. Identification of such characteristics will enable professionals in this field to consider potential areas of struggle and devise customized post-surgical treatment plans to help patients reach their weight loss goals.

Consensus is that mortality rates are higher for obese individuals than for overweight individuals (Flegal et al.). Strong evidence exists indicating that weight loss in overweight and obese individuals reduces risk factors for diabetes and cardiovascular disease (Peterson, Dufor, Befrpy, Lehrke, Hendler, & Shulman, 2005). In addition, weight loss reduces blood pressure, cholesterol, and blood glucose levels in both overweight hypertensive and non-hypertensive individuals (Clinical Guidelines on the Identification, Evaluation, and Treatment of Overweight and Obesity in Adults: Executive Summary, [CGIETOOA], 1998).

Yet, given all the knowledge regarding the increasing rates of obesity and the adverse individual and socioeconomic consequences, we know less about successful intervention and healthy weight maintenance than is needed to contain the current trends toward obesity. The following discussion will: 1) Summarize the etiology of excessive weight gain; 2) discuss the psychosocial implications of obesity; 3) identify current interventions for obesity; 4) describe the most effective intervention for clinically severe obesity and the behavioral challenges to success; 5) outline three specific theories of behavior that are widely utilized in the psychological world for measuring and implementing change; and 6) report the results of a qualitative project utilizing Cognitive Interviewing to test a new measure of attitudes and beliefs of candidates for bariatric surgery.

Chapter Two

Literature Review.

Etiology. The etiology of being overweight/obese is complex. Energy imbalance, that is, greater caloric intake than caloric expenditure, is probably the chief cause of weight gain (Webber, 2003). Perhaps as a result of our automated and automobile-oriented environment (Epstein & Saelens, 2000), low levels of physical activity are common in the U.S. and clearly associated with obesity and weight gain (DiPietro, 1995). Deficient expenditures of energy are also associated with the physiological changes that naturally occur during the aging process (Taylor et al., 2004).

Today's food and beverage choices certainly facilitate high caloric intakes. Widely available and inexpensive sugar-sweetened beverages (e.g., soda sweetened with sugar, corn syrup, or other caloric sweeteners and other carbonated and noncarbonated drinks, such as sports and energy drinks) may be the single largest driver of the obesity epidemic (Brownell & Frieden, 2009). A recent meta-analysis by Vartanian, Schwartz, & Brownell (2007), found that the intake of sugared beverages was associated with increased body weight, poor nutrition, and displacement of more healthful beverages. Additionally, increasing consumption of such liquids is associated with increased risk for obesity and diabetes (Hill & Peters, 1998). Conversely, interventional studies have demonstrated improved health following reduced intake of soft drinks (Vartanian, Schwartz, & Brownell, 2007). Another dietary villain, high-fat foods, in excess

also lead to increased body weight, whereas incorporation of low-fat foods leads to maintenance or decreased body weight (Hill & Peters, 1998).

Geographical and sociological factors, particularly urban sprawl, also occupy a role in the epidemic of obesity. While disagreements exist about the exact definition of a "sprawl," most agree that sprawl results in large areas of low-population density, facilitating a sedentary lifestyle. City dwellers are more prone to use cars and other motorized vehicles instead of walking to areas of interest such as grocery stores, community centers, and parks, thereby reducing levels of energy expenditure (Kumanyika et al., 2001).

Multiple researchers have contributed towards our understanding of the urban sprawl. Ewing et al. (2003) constructed a Country Sprawl Index (CSI) that included population density measures and block size. Large scores indicated less sprawl. Results indicated that residents of counties characterized by greater sprawl walked less, weighed more, were more likely to be obese, and were more likely to have hypertension (Ewing et al.). A similar study by Lopez (2004), offered more evidence for a significant relation between sprawl index and the risk for being overweight and obese. The sprawl effect produces new location patterns considerably displaced from a town center. Design considerations likely increase the magnitude of the problem. City and regional planners argue that modern suburbs limit travel choice by physically designing out all options except travel by car (Beinborn et al., 1991; Cervero, 1991). In addition, certain "obesogenic" environmental factors, such as sedentary professions, urban designs, and labor saving devices may promote obesity in individuals and communities via the cross-

interaction of environment, opportunities, and life-conditions (Lake & Townshend, 2006). In addition to environmental factors, heredity is implicated in weight management and obesity. Chromosomal sites of genes responsible for rare familial obesity syndromes have been identified, and more than 20 genes are suspected to be linked to body fat in humans (Krauss, Winston, & Fletcher, 1998). However, the exact mechanisms by which these genes exert their pathophysiologic effects and their interaction with other environmental factors are unknown (Sharon et al., 2006). Although Wang & Brownell identified genetic vulnerabilities for weight gain and for determining body size in 2005, no consistent causal link was identified. Nevertheless, the relative risk of obesity is higher between monozygotic twins than between dizygotic twins, and adoptees weight was often closer to their biological parents than that of their adoptive parents (Allison et al., 1996; Maes et al., 1986; Sturnkard et al., 1986).

In 2006 researchers found a common genetic variant that was associated with obesity in adults and children (Herbert et al., 2006). This determinant was present in 10% of the individuals across four different populations of people: African American, Western European, children, and cardiac patients (Herbert et al.). Researchers believe that while this deviation may have been present in the human genome since before some populations started migrating out of Africa and into the rest of the world about 50,000 years ago, its activation began only recently. Although the human genome has not changed much in the past few centuries, the initiation may be in part because of the genome's interaction with environmental changes, presumably calorie-dense foods (Wade, 2006).

Regardless of the etiology of this epidemic, medical issues are clearly present in these conditions.

Medical implications. Concurrent with increasing rates of obesity, obesity-related disorders such as cardiovascular disease, including essential hypertension, pulmonary hypertension, left ventricular hypertrophy, congestive heart failure, and ischemic heart disease are also on the rise (Kannel, D'Agnostino, & Cobb, 1996). Obese adults are at a significantly increased risk for comorbid conditions such as dyslipidemia, coronary heart disease, diabetes mellitus type II, gallbladder disease, respiratory disease, gout, arthritis, sleep apnea, and many types of cancer (Health Implications of Obesity, 1985; Melissas, Christodoulakis, & Spyridakis et al., 1998). In addition to the above mentioned health consequences, obese individuals are at an increased risk of certain surgical and medical complications in the early and late post-operative periods, such as respiratory insufficiency, deep vein thrombosis, pulmonary embolism, pneumonia, skin breakdown, inadequate wound healing, and wound infection (Malnick & Knobler, 2006; Oria & Moorehead, 1998). Malnick and Knobler found that weight reduction has beneficial effects and is therefore, an integral part of treating these morbidities. In addition to medical consequences, a myriad of psychological consequences also exist.

Psychological implications. Psychological implications of a rising clinically obese population include reduced overall quality of life, depression, higher rates of anxiety, and low self-esteem (Black, Goldstein, and Mason, 1992; Dixon, Dixon, and O'Brien, 2003; Wadden & Phelan, 2002). Subtypes of

psychological disorders associated with obesity include Major Depressive Disorder with childhood or adolescent onset, with atypical features, and with hypercortisolemia, a disorder in which high levels of cortisol in the blood are associated with depression and visceral fat deposition; Wyatt, Winters, & Dubbert, 2006).

After examining studies of the prevalence of mood disorders in overweight populations, researchers concluded that mood disorders are two to three times more prevalent in persons seeking treatment, especially those with clinical obesity, compared with community control subjects (Black et al.; Wyatt et al.). More recently, in 2007, Kinzl et al., found that 32.0 % of morbidly obese persons had one, and 7.0 % had two or more mental disorders. Findings by Marcus, Kalarchian and Courcoulas (2009), indicated that a lifetime history of mood or anxiety disorders was associated with poorer short-term weight loss. However, researchers suggest that the mental illnesses of obese individuals may be reversed post weight loss because their mental illnesses stem from the sequelae of their physical appearance instead of from chronic personality characteristics (Kinzl et al.; Vallis et al., 2001).

Social implications. The social consequences of being overweight can trigger social sequelae such as stigma, teasing, and discrimination in employment, education, and healthcare (Carr & Friedman, 2005; Link & Phelan, 2001; Puhl & Brownell, 2001). Stigma often results from associations between being overweight and being lazy, less intelligent, unmotivated, and unhygienic (Wyatt et al.).

Wyatt et al., (2006), hypothesized that the relationships between obesity and psychosocial factors, in accordance with the current environment, are leading to increases in the prevalence of obesity and depression. They identified plausible reciprocal mechanisms by which depression contributes to weight gain and obesity, and obesity contributes to depressed mood (Wyatt et al.). In addition, Wyatt et al. also identified lower levels of education, poverty, food insecurity, and certain cultural beliefs as appearing to be consistently associated with obesity. These factors may also serve as moderators of eating and physical activity behaviors, such as overeating, eating high-calorie foods, and not engaging in physical activity. In turn, these factors can contribute to both depression and weight gain. These researchers outlined the need for additional studies to explore the causes, implications, and potential interventions for obesity (Wyatt et al.). Because the implications are so pervasive, the cost of being overweight/obese is enormous, consequently warranting the need for prevention methods.

Vocational Implications. In addition to the above-mentioned implications of obesity, the effects of obesity also extend to the work place. Obesity is related to interpersonal problems with coworkers in addition to higher absenteeism (Pronk, Martinson, Kessler, Beck, Simon, & Wang, 2004). Burton and Conti (1999) reported that obese workers tend to incur greater productivity losses than non-obese workers. Obese individuals also account for greater healthcare costs (Burton & Conti, 1999). Highly educated obese individuals are more likely to

report workplace discrimination than normal weight counterparts (Hansson, Naslund & Rasmussen, 2010).

Prevention. In the U. S. alone, the added annual healthcare cost due to obesity in 2009 was $174 billion (CDC, 2009). Preventing or reducing obesity in adulthood may be cost effective, based on the potential immediate benefits of avoiding the otherwise high prevalence of obesity-related comorbidities that develop during adulthood (Hill, Wyatt, Reed, & Peters, 2003). Strategies across the spectrum designed to promote changes in food intake, physical activity, and the needs for interventions have been adapted in the U. S. and globally (The Osaka Declaration, [OSD], 2001). Achievement and maintenance of permanent lifestyle changes is essential to prevent obesity and weight gain (OSD). Intensification of these changes in response to environmental influences that continue to create the conditions for positive energy imbalance is needed (Kumanyika et al., 2001). Since prevention is integral to this epidemic, several treatment methods exist.

Current Obesity Interventions. Several treatment options are available for overweight and obese individuals, beginning with lifestyle interventions such as low calorie diets and regular exercise (U.S. Department of Health and Human Services, [USDOHAHS], 2008). Particularly, individuals with Class I obesity (no life threatening co-morbidities) are highly encouraged to make lifestyle modifications, and are usually offered the support of medications designed to help with weight loss. Current weight loss medications approved by the Food and Drug

Administration (FDA) for individuals in this category include Xenecal, Meridia, and Ritalin (Mayo Clinic, 2010).

Many programs exist for facilitating weight loss in individuals. Most of the programs for facilitating weight loss operate using a very low calorie diet (VLCD). A Very Low Calorie Diet is a doctor-supervised diet that typically uses commercially prepared formulas to promote rapid weight loss in patients who are obese (Weight Control Information Network, [WCIN], 2008). Clinically significant weight and fat loss is achievable in adults who are motivated to follow the diets for a substantial period (Truby et al., 2006). Achievement of optimal weight loss is possible in combination with comprehensive behavioral therapy, nutrition counseling, physical exercise and possible weight loss drugs (CGIETOO, 1998).

Despite success with minor weight loss, weight loss programs, diets, and drug therapy have not shown long-term effectiveness in treating clinical obesity (Fisher & Schauer, 2002). Clinical and commercial weight loss programs can produce short-term weight loss, but the majority of adults regain about 40% of the lost weight within the first year (CGIETOO, 1998). Simple dietary restriction has not been associated with successful weight control (Wilson, 1994). Fields, Haines, Rosner, and Willett (2010), found that none of the customary dietary approaches to weight control, including eliminating between-meal snacking, following low-calorie or low-fat diets, or limiting portion sizes, predicted weight change. The most successful strategy for weight loss among women participants was to limit portion sizes combined with frequent exercise, with the women who exercised at

least five times a week gaining significantly less weight than did their peers who did not exercise (Fields et al.). Additionally, self-monitoring behaviors, such as controlling portion-size and engaging in physical activity, emerged as critical skills for obesity management, as those who reported monitoring their weight on a daily or weekly basis had greater success in achieving overall weight loss (Qi & Dennis, 2000; Wing & Hill, 2001). Outside of the limited research reporting the small success of such programs, current science has focused primarily on surgical options.

Once a state of clinical obesity has been reached, the ability to lose weight successfully through diet, exercise, or medical management becomes extremely difficult, if not impossible (Garza, 2003).Those individuals who fall in Class II and Class III obesity categories (with life threatening co-morbidities), are encouraged to initiate the above interventions but are also eligible for surgical interventions to facilitate weight loss (American Society for Metabolic and Bariatric Surgery, [ASMBS], 2005). A 1992 statement from the NIHCDC affirmed the superiority of surgical over non-surgical interventions to this epidemic, and bariatric surgery is increasingly becoming a feasible treatment option for obese individuals (ASMBS, 2010). The number of bariatric procedures increased from about 16,000 in the early 1990s to more than 103,000 in 2003 (ASMBS, 2010), with the ASMBS estimating that 220,000 people in the U. S. had bariatric surgery in 2008.

Three of the most common surgical interventions for weight loss are gastric banding, gastric bypass, and the sleeve gastrectomy (Julio, Coelho, &

Campos, 2001; Mognol, Chosidow, & Marmuse, 2005). Functionally, weight loss occurs through the reduction of the size of the stomach by either an implanted medical device, as the gastric band or the sleeve gastrectomy, or through removal of a portion of the stomach (gastric bypass) (Robinson, 2009). Buchwald and Williams (2004) found that gastric banding comprised approximately 24.4% of bariatric surgeries, while gastric bypass comprised approximately 65.1%. Although the sleeve gastrectomy, a newer method, is still being studied, researchers have identified the superiority of the sleeve gastrectomy over gastric banding in terms of increased weight loss, and decrease in feelings of hunger one and three years post-surgery (Frezza, 2006; Himpens, Dapre, & Cadière, 2006).

For the clinically obese patient, bariatric surgery offers an opportunity for effective, long-term weight loss after conventional methods have failed (Rusch, Andris, & Wallace, 2009). Surgery leads to significant long-term weight loss for a majority of patients and is associated with decreases in long-term mortality, morbidity, and usage of healthcare (Adams et al., 2007; Christou et al., 2004; Sjöström, 2005). Bariatric surgery has also been associated with decreased depressive symptomatology and improved quality of life in obese individuals (Legenbauer, Burgmer, Senf, & Herpertz, 2007). Certain negative psychosocial post-operative changes have been reported, such as changes in close relationship dynamics, struggles accepting body changes, and difficulty integrating the "old" obese identity with a "new" thinner one, but these changes are usually surmountable and outweigh the positive changes (Stuerz, Piza, Niermann, and Kinzl, 2007). Positive post-operative changes reported include increases in self-

esteem and positive emotions, decreases in body disparagement, improved eating behaviors, reductions of symptoms of anxiety and depression, and increases in health-related quality-of-life scores (Dixon & O'Brien, 2002; Kinzl et al.).

Measuring surgical weight-loss success. Two of the most common ways of defining successful weight loss are either by percentage of excess weight lost, or absolute weight lost (Fisher & Schauer, 2002). Surgeries are considered successful if the individual is able to lose 50% of his/her excess body weight and maintain the loss, or if the individual is able to maintain his/her normal weight range five and a half years post-surgery (Mayo Clinic, 2010).

Patients typically lose about 10% of their total body weight by post-operative day 30 (CDC, 2008). The average post-surgical weight loss at two years can represent a loss of up to 70% of pre-surgical excess body weight (Rusch et al.), but varies depending on the specific type of surgery. Excess weight loss following gastric bypass is approximately one-half to two-thirds, or 50 - 80% of excess body weight (Mayo Clinic). Weight loss of more than 50% of excess body weight, can occur 10 or more years post surgery (Mayo Clinic). Weight loss after gastric banding may be slower in the initial period, but eventually matches the weight loss of gastric bypass patients (Mayo Clinic). A systematic evidence review concluded that the effectiveness of sleeve gastrectomy for clinical obesity is currently unknown (DeLaet & Schauer, 2009).

However, despite the increase in the number of surgeries performed, the success rate of the surgeries still remains acutely tied in with adherence to post-surgical lifestyle modifications. Approximately 20% of patients either fail to lose

a significant amount of weight or experience significant weight regain (Sugarman, Londrey, and Kellum, 1989; Qi & Dennis, 2000; Wing & Hill, 2001). Specifically, food preferences, eating habits, general nutritional knowledge, motivation, and self-efficacy beliefs are important determinants of successful surgery that need consideration (Garza, 2003).

While most individuals achieve a certain level of weight loss after these procedures, maximal loss of weight is highly dependent upon post-surgical lifestyle modifications made by the individual (ASMBS). Currently, little evidence exists to identify who will or will not achieve satisfactory weight loss after bariatric surgery, or whether additional post-surgical support might increase long-term success of this intervention (Kalarchian & Marcus, 2003). Post-operative success of bariatric procedures depends almost entirely on the behavioral changes implemented by the patients, and unfortunately, subgroups of patients fail to benefit, largely due to post-surgical behavioral factors (Rusch et al., 2009). Excessive calorie consumption usually leads to variance in weight loss and usually occurs in patients who evade the post-operative diet with liquid calories including shakes, long-term use of pureed or soft foods, or snacking (Rusch et al.). The most common causes of such self-destructive post-surgical behaviors are emotional eating and stress (Rand & Kuldau, 2006; Sarwar, Wadden, and Fabricatore, 2005).

Thus, there is a need to identify individuals who may benefit from additional support to ensure post-surgical success (Bauchowitz et al., 2005). Given the risks inherent in surgical interventions, it is reasonable for clinical

research to pursue methods and treatments that maximize the success of this approach.

Requirements for Surgical Success. Key to successful patient outcomes in bariatric weight loss surgery is education (Garza, 2003). An understanding gained by the evaluation that takes place before surgery and the psychological changes that occur after surgery of the prevalence of psychological disorders in bariatric surgery candidates is necessary (Psych Considerations, 2005). Mounting evidence suggests a significant increase in the prevalence of psychopathology in the clinically obese population (Glinski, Wetzler, & Goodman, 2001). This increase seems particularly relevant in individuals seeking weight loss surgery (Glinski, Wetzler, & Goodman). The prevalence of depression in post-operative patients is especially important to gauge since depression can bring about an inability for self-care, along with feelings of worthlessness and hopelessness, poor sleep patterns, and fluctuations in food intake. All of these impact the post-operative care the patient needs to ensure surgical success (American Psychiatric Association [DSM-IV-TR], 2000), Psychological Considerations of the Massive Weight loss Patient, [PCMWLP], 2006). Lack of motivation and non-adherence to post-operative guidelines are important determinants of lack of surgical success (Leahey, Bond, Irwin, Crowther, & Wing, 2008). Attendance at follow-up and intervention sessions helped measure these important traits (Leahey et al.). Comprehensive bariatric surgery programs are best when considering a balance of the needs of the pre-operative patient presenting with maladaptive eating behavior with the likelihood of participation in behavioral intervention before surgery

(Leahey et al.). As the importance of attitudes and beliefs is evident, specific models explaining the process of behavioral change require examination.

Models of Behavioral Change. Despite the above-mentioned ways available for weight loss, success can be hard to achieve. Three primary theories explain these inconsistencies in achieved weight loss: The Transtheoretical Model [TTM] (Prochaska & Velicer, 1977), also known as the Stages of Change Model [SOCM], The Theory of Planned Behavior [TPB] (Ajzen, 1985), and The Health Belief Model [HBM] (Rosentock, 1966).

The TTM defines change as a progressive process of six stages, involving Precontemplation, Contemplation, Preparation, Action, Maintenance, and Relapse (Prochaska & Velicer). In the Precontemplation stage, an individual is unaware of any problems and has no desire to make any changes in the next six months. In the Contemplation stage, individuals consider the pros and cons of the action they may take within the next six months. The Preparation stage involves actual intent to make changes in a behavior. The Action stage involves implementation of the behaviors necessary to make the change. The Maintenance change involves continuation of the behaviors. Figure 4 contains a summation of these various stages. All stages of the TTM involve the role of conscious thoughts in governing future beneficial behavior. Thus, the core belief of this model is that peoples' attitudes and beliefs influence their long-term goals (Prochaska & Velicer, 1977).

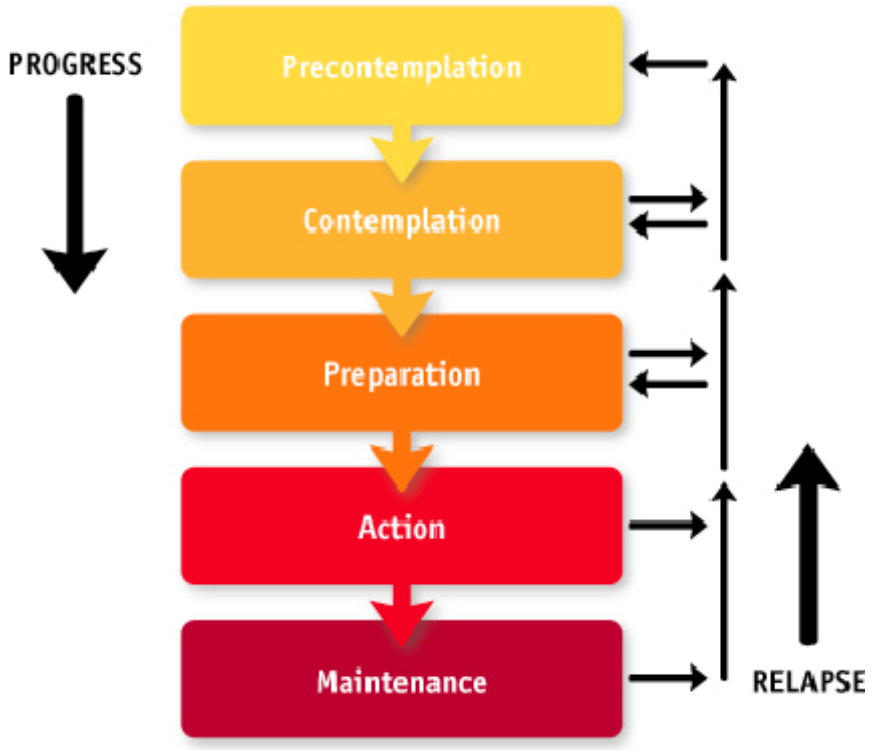


Figure 4: The stages of the Transtheoretical Model of Change (TTM).

A similar hypothesis forms the basis for Theory of Planned Behavior, which explains the relationship among Behavioral Beliefs, Behavioral Attitudes, Intention, and Behavior (Ajzen, 1985). Developed by Icek Ajzen in 1985, the theory helps study the relationships among beliefs, attitudes, behavioral intentions, and actual behaviors themselves in various fields, including healthcare. In addition, The TPB also includes the concept of perceived behavioral control. This concept emerges from the Self-Efficacy Theory proposed by Albert Bandura in 1977. According to Bandura, expectations such as motivation, performance, and feelings of frustration associated with repeated failures determine affect and behavioral reactions (Bandura, 1994). The motivation includes a person's belief in

the potential successful execution of the behavior along with his/her belief that such a behavioral change will lead to positive outcomes.

According to TPB, the presence of an individual's beliefs leads to a change in attitude and, ultimately, new cognitions are transformed into actual behaviors (Ajzen). These behaviors are guided by three kinds of beliefs: Behavioral Beliefs, Normative Beliefs, and Control Beliefs. Behavioral Beliefs pertain to the outcome of the behavior and the evaluation of this behavior. In general, the more favorable the attitude and subjective norm, and the greater the perceived control, the stronger a person's intent is to perform the behavior. Figure 5 below outlines the interplay of the various beliefs and attitudes required to produce the intent required for behavioral change.

Recently, researchers found that TPB helped predict health-related behavioral intention in women's decisions to lose weight (Conner, Kirk, Cade, & Barrett, 2003). Utilized in a study designed to measure a woman's likelihood to take vitamins, researchers found that in line with The TBP, a belief in the positive outcome of making the change was the most important indicator of the occurrence of the change itself (Pawlak et al., 2009).

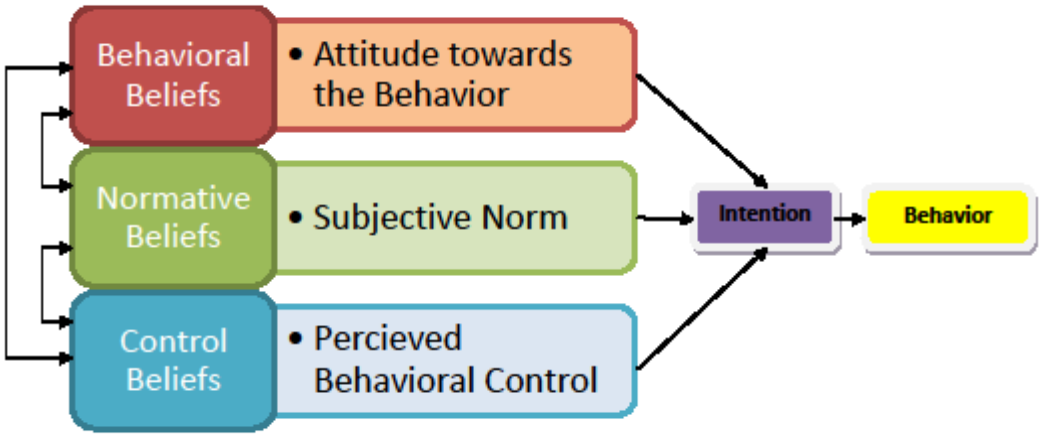


Figure 5: Diagram explaining the interaction of beliefs and attitudes required to produce intent towards behavioral change according to the Theory of Planned Behavior (TBP).

The Health Belief Model is a psychological model that attempts to explain and predict health behaviors by focusing on the attitudes and beliefs of individuals regarding Perceived Threat/Susceptibility, Perceived Severity, Perceived Benefits, Perceived Barriers, Cues to Action, and Self-Efficacy of their current negative health behaviors (Rosenstock, Strecher, & Becker, 1994). Perceived Susceptibility is an individual's perception of his/her chances of contracting a condition. Perceived Severity is an individual's opinion of how serious a condition and its consequences will likely be. Perceived Benefits include the individual's belief in the efficacy of the advised action to reduce risk, or seriousness of impact. Perceived Barriers involve an individual's opinion of the tangible and psychological costs of the advised action. Cues to Action are strategies to activate readiness towards the change. Finally, Self-Efficacy is the confidence an individual has in his/her ability to take action. Thus, belief in higher Self-Efficacy will likely lead to increased confidence in being able to commit to a desired

behavioral change. Figure 6 presents a summary of the interactions of these factors.

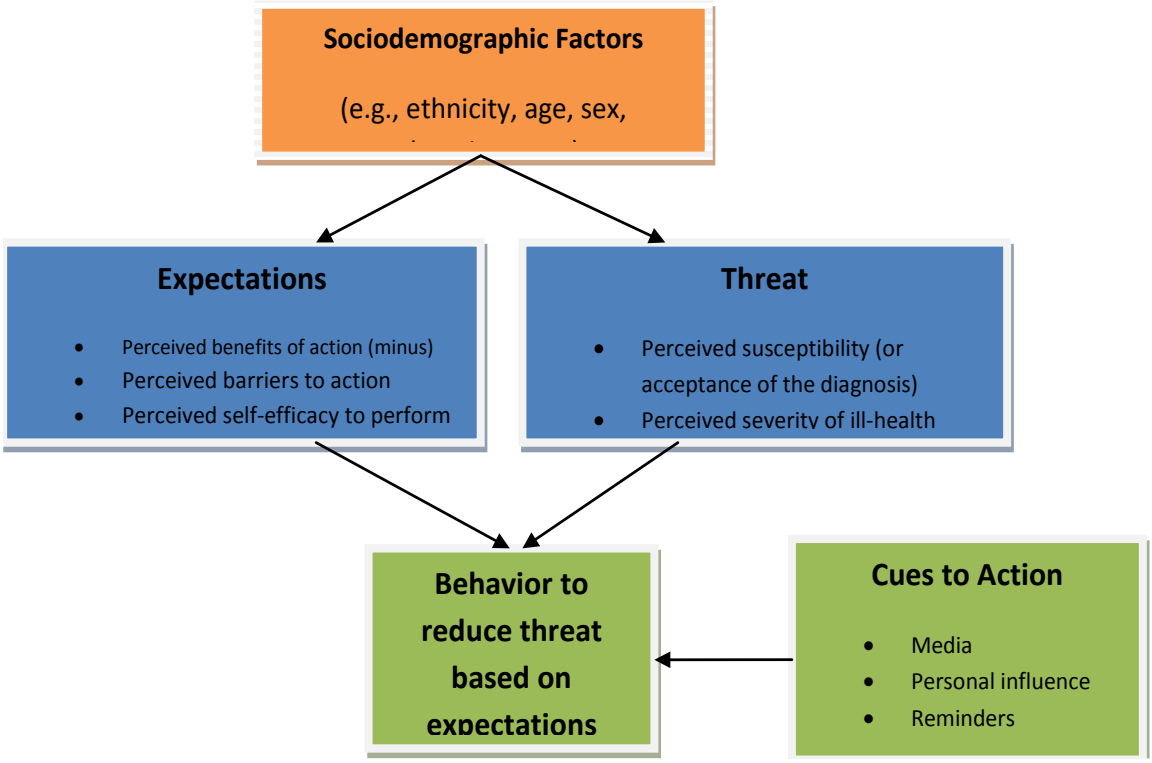


Figure 6: **A flowchart depicting the interplay of perception and action required for successful behavioral change according to The Health Belief Model.**

Application of Models of Behavioral Change to weight loss strategies.

The Transtheoretical Model [TTM] enables an understanding of the motivational mechanisms for change that could implement successful post-surgical bariatric lifestyle interventions. Applying the six stages of Precontemplation, Contemplation, Preparation, Action, Maintenance, and Relapse (Prochaska & Velicer) to obesity, one could say that an obese individual in the Precontemplation stage will not be inclined to make any behavioral changes associated with weight loss. An obese individual in the Contemplation stage may

consider the advantages and disadvantages of attempting to lose weight, or of having bariatric surgery. During the Preparation stage, an obese individual may sign up for gym membership or start self-education on healthier eating habits. In the Action stage, an obese individual begins going to the gym or practicing healthier eating habits. The Maintenance change involves continuation of beneficial behaviors such as exercising at the gym or incorporating healthier eating habits in the individual's lifestyle.

The process of weight loss can also be explained by using The Theory of Planned Behavior (TPB), which explains the relationships between Behavioral Beliefs, Behavioral Attitudes, Intention, and Behavior (Ajzen, 1985). In the context of obesity, the model suggests that Behavioral Beliefs in an obese individual considering increasing physical activity may be those of wanting successful weight loss. Normative Beliefs in an obese individual produce internal and external motivation, and may come from repeated suggestions by his/her doctor and family members to lose weight. Control Beliefs may be present in the form of chronic joint-pain which could prove to be a barrier to increasing physical activity in an obese individual; one over which he/she feels no control. Consequently, this Control Belief may inhibit the individual from making the desired behavioral change. Whether an individual chooses to initiate weight loss, or comply with the required modifications, interplay of his/her attitudes and beliefs predicts the eventual outcome.

The Health Belief Model (HBM) helps predict compliance with preventive health recommendations (Glanz et al., 2002). This theory states that when a

person's perception of the value of an outcome associated with a lifestyle change exceeds the implications of implementing the change, then change will occur (Glanz et al.). The cognitive stages contained in HBM consist of Perceived Susceptibility, Perceived Severity, Perceived Benefits, Perceived Barriers, Perceived Self-Efficacy and Cues to Action (Rosenstock, Strecher, & Becker, 1994. An obese individual considering weight loss options will journey through an analysis of the above-mentioned perceived factors before arriving through a final decision. An obese individual's Perceived Susceptibility to the medical, psychological, social or vocational implications of obesity, determines initiation of the thought processes associated with consideration of weight loss. This individual's Perceived Severity may promote contemplation of the effects of contracting an obesity-related disease, such as diabetes, on his/her lifestyle. Perceived Benefits include the individual's belief in the efficacy of the advised action to reduce risk, or seriousness of impact. Consequently, an obese individual may explore his/her belief in the success of weight loss measures suggested by his/her physician. The monetary costs of committing to a gym or to a low-calorie diet, may prove to be Perceived Barriers associated with the behavioral change. Psychological costs of the action, such as reduced family time, or diminished food choices may also prove to be Perceived Barriers. Cues to Action might come in the form of asking friends for motivation or sticking reminder post-it notes around the refrigerator to encourage healthier eating habits. Finally, belief in higher Self-Efficacy will likely lead to increased confidence in being able to commit to a weight loss regimen.

For obese individuals committed to losing weight, bariatric surgery continues to be the treatment of choice secondary to the associated benefits. Implementation of the above-mentioned ideologies into suggested post-surgery lifestyle modifications could help enhance the compliance of the modifications. Comprehensive discussion of necessary post-surgical behavioral change, paired with individualized identification of specific attitudes and beliefs held by the patient that could challenge such change, would enable health care providers maximize the benefits of surgery by customizing post-surgical interventions. This approach to the unacceptable failure rates of surgical interventions fills an urgent need to treatment for obesity but, to date, is not accommodated in current screening protocols for bariatric surgery candidates.

Psychological Screening Measures. Studies assessing the value of pre-operative psychological evaluation to screen for factors that can predict post-operative success or failure have not yielded consistent findings (PCMWLP, 2005). A survey of current practices in psychosocial evaluation of bariatric surgery candidates by Bauchowitz et al. in 2005 indicated the need for research to identify psychological, behavioral, cognitive, and social characteristics that predict outcomes of surgery. Personal and social history, eating habits, history of psychiatric disorders, and treatment are essential aspects of the psychological evaluation (PCMWLP). Also included are measures of personality profiling, presence or absence of a support system, and expected level of compliance (PCMWLP).

Psychological tests most commonly used for screening clients for bariatric surgery are the Minnesota Multiphasic Personality Inventory- 2nd edition TM (MMPI-2), the Eating Disorder Inventory (EDI), the Beck Depression Inventory-2nd edition (BDI-II), and the Social Support Appraisal Scale (Beck, 1993; Garner, Olmstead, & Polivy, 1983; Graham, 1992; Vaux et al., 2005). The MMPI-2 is helpful in assessing general coping styles and the presence of symptoms indicative of acute psychiatric disturbances, and the EDI is a measure of psychological features commonly associated with anorexia nervosa and bulimia nervosa (Garner, Olmstead, & Polivy; Graham). The BDI is one of the most popular measures of depressive symptoms and suicidal ideation, while the Social Support Appraisal Scale measures the amount of perceived support from family and friends (Psych Considerations, 2005; Vaux et al.). However, empirical evidence regarding the adaptability of the above-mentioned tests to the bariatric population remains unknown. Consequently, professionals make decisions about bariatric candidates without empirical support (Coehlo & Campos, 2001). In addition, no tools designed to identify potential struggles post surgery exist. Identification of these struggles can help professionals brainstorm possible intervention strategies.

Challenges to Assessment. In addition to the dilemma surrounding reliable measurement, many candidates for bariatric surgery circumvent answers to pre-operative questions about their coping strategies and self-restraint, thus, providing an inadequate assessment of their attitudes during the pre-surgical period (Rusch et al.). Although many pre-surgical psychological assessment

methods are clearly inadequate, a paucity of research exists in this area. Since little data exists on how best to evaluate these individuals, and no uniform guidelines for the psychological assessment of surgery candidates exist, Bauchowitz et al., in 2005, outlined the need for establishing such uniform guidelines for bariatric pre-surgical screening. These researchers also concluded that very few studies have systematically investigated psychosocial and behavioral variables as negative or positive prognostic indicators for surgery outcome.

As outlined above, the measure of success of the surgery depends on the behavioral changes implemented by the patients. Creation and validation of an ideal survey will provide a way to measure the presence of these attitudes and beliefs surrounding necessary behavioral changes in candidates for bariatric surgery, in order to identify potential struggles a patient may have post surgery. In addition to measuring internal factors affecting success, the survey may also help identify potential post-operative external barriers (*e.g.* financial and temporal resources) to compliance of the required regimen so that clinician and patient may brainstorm strategies for increasing adherence. This study aimed to test sources of response error of two new instruments designed to increase the success of bariatric surgery.

Chapter Three

Purpose and Hypothesis

Successful weight loss post-surgery depends on the implementation of multiple lifestyle changes, such as controlled eating, physical activity, medication management, medical follow up, wound care, and participation in support groups. According to the previously described Theory of Planned Behavior, intentions to perform behaviors of different kinds can be predicted with high accuracy from attitudes toward the behavior (Ajzen, 1985). In addition, subjective norms and perceived behavioral control contribute towards the required intent, and an interplay of these three variables accounts for variance in actual behavior (Ajzen). Attitudes, subjective norms, and perceived behavioral control correlate with appropriate sets of salient behavioral, normative, and control beliefs about the behavior (Ajzen).

The aim of this study was to test for sources of response error in two new diagnostic tools designed to measure the attitudes and beliefs of bariatric candidates. The primary study task was the use of Cognitive Interviewing to investigate the cognitive responses to items in two self-report questionnaires measuring beliefs and attitudes associated with recommended post-surgical behaviors (Appendix A). Cognitive Interviewing seeks to identify what, if any, were the problems that participants encountered when completing the questionnaire.

The two new questionnaires under investigation are the "Eating Behavior Efficacy Measure" and the "Perceived Barriers to Exercise Measure" (Puzziferri

& Brandon, 2009). The Eating Behavior Efficacy Measure is based upon clinical data and assesses the likelihood of an individual adhering to the necessary dietary changes post surgery, and the Perceived Barriers to Exercise Measure assesses the likelihood of an individual adhering to the recommended exercise changes post-surgery (Puzziferri & Brandon). Individual items on each scale were developed after comparison of required post-surgical dietary, and exercise-related behavioral changes with patients' self-reported reasons for lack of adherence to the recommendations (Puzziferri & Brandon). In combination, the instruments seek to measure attitudes and beliefs related to weight loss, depression and anxiety symptoms, eating behaviors and activity levels.

Qualitative research provides a scientific model for gaining understanding of a given research problem from the perspectives of the population it involves (Ulin, Robinson, & Tolley, 2005). As opposed to the goal of quantitative research, that is, to provide statistical information that describes a sample of individuals that can be generalized to populations of similar individuals, qualitative research gives precedence to the goal of understanding complex social phenomena by acquiring narrative information regarding the behaviors, beliefs, values, and opinions of people. Data are gathered by one or more of three widely-accepted methods: participant observation, in-depth interviews, and focus groups. The types of data produced are field notes, audio or video recordings, and transcripts.

In harmony with the aims of qualitative research, our aims were to:

1. Answer the questions: “Are these two questionnaires easily understood and do participant responses reflect comprehension?
2. Use the predefined set of procedures outlined in Cognitive Interviewing to answer the above questions.
3. Collect evidence from a small group of individuals completing the questionnaires.
4. Highlight problematic areas of the questionnaires.
5. Produce recommended changes to items based on participant feedback to iteratively refine the scale for use in a subsequent pilot study.

Chapter Four

Methods

Current research is the first phase of a larger study aiming to describe the pre- and post-surgical attitudes and beliefs of bariatric surgery patients using the Theory of Planned Behavior principles. This intermediate phase of instrument development specifically assesses sources of response error in each item of the instrument. Individual responses to the items are irrelevant to this study. Instead, the outcome measures are ease of completion, comprehension, and uniformity of responses on the instrument.

After expedited approval from the University of Texas Southwestern Medical Center at Dallas Institutional Review Board, twenty voluntary participants undergoing post-operative care at the university affiliated Aston Bariatric Clinic were invited to provide response data for the ensuing qualitative analysis. Each participant received a $20 gift card at the end of his/her participation. Since population statistics suggest more than 80% of patients choosing bariatric surgery are women, the sample recruited was similarly representative, with 75% female participants (n = 15), and 25% male participants (n = 5) (Santry, Gillen, and Lauderdale, 2005). Demographic data was not collected to maintain anonymity of participants.

A guide to Cognitive Interviewing developed by Gordon Willis of the Research Triangle Institute (1999) served as the technical manual for conducting and interpreting cognitive interviews. Trained study staff administered individual in-depth interviews; each interview was audio-recorded and transcribed. All

researchers involved in this study received a written protocol of the method and study procedures as well as training in Cognitive Interviewing methodology and conduct. Both interviewers collecting data observed the execution of a cognitive interview in a practice interview before administering the questionnaire to study participants.

Cognitive Interviewing is an approach for evaluating sources of response error in survey questionnaires (Willis, 1999), and was utilized in this study to evaluate the comprehension of the questions of the survey. Such a style focuses mainly on the cognitive processes that respondents use to answer the survey questions, making covert and overt observations of thought processes (Willis). The researchers assessed four main thought processes during the interview: comprehension of the question (question intent and wording), retrieval from memory of relevant information (recall ability of information and recall strategy), decision processes (motivation of response and sensitivity/social desirability to content of item), and response processes (mapping of the internally generated response to response categories provided; Willis).

Utilized in this study were two major subtypes of Cognitive Interviewing methods, "think-aloud interviewing" and verbal probing techniques. The think-aloud interview process was derived from psychological procedures described by Ericsson and Simon (1980), and consists of participants being explicitly instructed to think-aloud as they respond to a survey item. All participants listened to a standardized Instruction Script read aloud by the interviewer (Appendix A). Using the think-aloud technique, the participants read the questions aloud and verbalized

their thoughts processes. Recordings of the sessions allowed the interviewer to record thought processes utilized by the participant via transcription of session recordings after all sessions were done. Verbal Probing techniques, utilized during the course of the interview, included further probes into the basis for arriving at the responses (Willis, 1999). At completion of the interview process, participants were invited to make suggestions to the creators of the instruments for either restructuring or eliminating questions posing structural or cognitive deficits. This process included open-ended verbal probes such as, "Were any questions harder to answer than the rest?" and "Were you able to read and understand the instructions easily?"

To measure proper understanding of the demands of the questions, respondents thought-aloud through the answers, offering the researchers a glimpse into the process of cognitive understanding of the individual items on the survey. Thus, only feedback concerning the clarity of the individual items was considered, and not the actual responses to the questionnaire. Support for the hypothesis, that this instrument will have ease of understanding when responding to the individual items after the removal, or rephrasing of any confusing statements, was expected. The results indicated several sources of response error that contributed to lowered confidence in answering the questionnaire adequately. Items deemed unreliable measures of the survey's purpose due to inconsistencies in cognitive understanding of the actual semantics, or decreased level of confidence in recalling answers to the items required restructuring.

Recommendations were made to the creators of the test. Following these

recommendations will help create an instrument with low response error. Subsequent research can then test the criterion validity of this instrument.

Chapter Five

Results

Only two participants (10%) were able to complete both measures without indicating any sources of response error. The majority of the participants (90%) had some manner of difficulty in understanding the instructions of the questionnaire and efficiently executing them. Five primary areas of difficulty were identified: (1) Overlooking one of the two parts of each question on page 5 and 6 (55%), (2) failing to provide a reason for every option on page 5 and 6 (65%), (3) not providing a reason when required (5%), (4) answering all questions on page 5 and 6 in a Yes/No format (45%), and (5) inconsistent responding to Likert Scale options for responses on page 7 (20%).

A closer inspection of individual items revealed that questions containing the word "avoid" (e.g., "I avoid high-fat foods," "I avoid skipping meals," "I avoid eating between meals,") were misunderstood by 40% of participants. The question, "I would exercise if it was easier" brought inconsistent responses from participants, with 50% either believing that exercise is meant to be strenuous, or verbalizing that they would exercise regardless of the difficulty level. In addition, questions starting with negatives (e.g., "I don't have time for exercise," "I can't afford to belong to a gym," "I can't exercise because of severe joint pain," etc.) were confusing to 65% of the participants. The item, "Eating helps me sleep better" was reported to be confusing by 30% of participants with difficulty determining whether the inquiry regarded physical or psychological effects of eating. The statements, "I can exercise in hot weather" and "I can exercise in cold

weather" were confusing to some participants (20%) who asked if the question referred to exercising indoors or outdoors. Lastly, almost half of the participants (40%) verbalized the need for True/False answer choices instead of the provided Likert Scale for questions on The Perceived Barriers to Exercise Measure. Table 2 summarizes these results.

Sources of response error in following instructions:	**Raw Data (N = 20)**	**Percentage**
• Difficulty comprehending/executing instructions	18	90%
• Answering only one part of two-part questions	11	55%
• Providing reasoning when not required	13	65%
• Not providing reasoning when required	1	5%
• Answering questions on pages 5-6 using Yes/No format	9	45%
• Confusion following likert scale options on page 7	4	20%
• Confusion interpreting the word "avoid" in questions	8	40%
• Confusion interpreting questions starting with negatives	13	65%
Specific sources of error in comprehension:		
• "I would exercise if it was easier"	10	50%
• "Eating helps me sleep better"	6	30%
• "I can exercise in hot(or cold) weather"	4	20%
Sources of response error identified by participants		
• Unavailability of appropriate (True/False) answer choices for questions on page 7	8	40%

Table 2: Summary of findings. Total number of participants = 20.

Discussion. Cognitive Interviewing is designed to reduce misinterpretations and confusion brought about by the wording of items in self-report measures. The two main techniques of Cognitive Interviewing namely, think-aloud and verbal probing, allow interviewers to observe the clarity of cognitive understanding of the questions as the participant is answering the

question. The current study used Cognitive Interviewing to identify sources of confusion on two newly created surveys designed to measure the attitudes and beliefs of bariatric surgery patients. Suggestions to reduce sources of confusion, as well as recommendations to facilitate smooth administration of this survey follow below.

Professionals who use this survey are encouraged to verbalize detailed instructions to patients prior to completion of the instrument, rather than rely upon written instructions of the surveys. Patients should be encouraged to verbalize their comprehension of survey instructions, and invited to ask questions to clarify their understanding. In addition, instructions on each page should be highlighted in a larger font. Instructions for pages 5 and 6 (The Eating Behaviors Efficacy Measure) should be restructured to reflect the two different demands of the questions; While one part of the question asks respondents to identify the presence or absence of the specific behavior, the other part requires them to answer the question, "Is this important to your weight loss?" using provided Yes/No responses. To solve the issue of patients not providing reasons for every numerical choice, or not providing reasons at all, a sentence structure similar to most multiple-choice tests is suggested. An example of such restructuring is:

I usually complete a meal in 20-30 minutes:

(1) I do now

(2) I could begin doing

(3) I will never be able to do because _____.

To further facilitate a smooth transition the following recommendations are made:

- Questions 7 and 9, which provide four answer choices, should be grouped together, preferably at the end of all questions that utilize only three answer choices.
- In addition to correcting a typo asking patients to score themselves from 1 to 5 on the ensuing *16* statements instead of the presented *22* statements, instructions for page 7 should also follow the guidelines listed above for those on pages 5 and 6.
- It might be worth considering providing the options of *True* and *False* in parenthesis adjacent to *Always* and *Never* to allow patients to choose from these options when responding to questions whose responses do not necessarily follow the provided Likert Scale.

The last set of recommendations made pertain to specific questions contained in the questionnaire.

- Questions containing the word "avoid" ("I avoid high fat foods", "I avoid drinking 30 minutes before, during, and after meals", "I avoid skipping meals" etc. should contain a description of the word from the test-makers' perspective. For example, "avoid" could refer to "Less than twice a month" or "Less than once a week."
- The suggestion to remove question 13 on page 7, "I would exercise if it was easier," is presented to the test developers, as this question assumes that the patient does not currently exercise because of its strenuous nature.

In addition, the question contains the oxymoron of exercise being easy, which by definition exercise is not or else it risks losing the resulting beneficial nature towards human health.

- Confusion about answering question 14, "Eating helps me sleep better," can be minimized by including the type of eating being questioned, to distinguish normal eating habits from Binge eating or compulsive/habitual eating. Thus, this statement could be reworded to state "Eating appropriate meals and snacks through the day help me sleep better."
- Lastly, rewording of questions containing double negatives will likely facilitate the ease of answering these questions by reducing the complexity of cognitive functions required to pick an appropriate answer choice. Alternative structures for these statements are provided in Table 3.

Table 3: Recommended restructuring of confusing statements in The Perceived Barriers to Exercise Measure

Existing Statement	**Recommended Restructured Statement**
Q5: I can't afford to belong to a gym or take exercise classes.	I have affordable access to workout equipment either at home, or at a gym.
Q7: I can't cook so I have to eat out, limiting my food choices.	Cooking at home allows me to avoid eating out and provides me with healthier food choices.
Q10: I don't have time to control what I eat by packing my lunch or cooking at home.	I have time to control what I eat by packing my lunch, or cooking at home.
Q12: I can't exercise because of severe joint pain.	Severe joint pain restricts my exercise regimen.
Q19: I don't have the right clothing for exercise.	Alternate: I have appropriate clothing for exercise.
Q21: I don't have time to eat breakfast.	Alternate: I have time to eat breakfast.

Table 3: Recommended restructured statements

Clinical Implications. In conclusion, there is great need for measures to screen for attitudes and behaviors indicative of post-operative success in the

bariatric population, but few such measures exist. The current instrument could fill an important gap in the field. Responses to this measure could add individualization to the surgical treatment by suggesting what supportive interventions post-surgically may be necessary for the individual. Such an indicator can likely become a strong tool for professionals who routinely work with this population, and can possibly increase the number of successful surgeries by identifying problematic post-surgical lifestyle modifications and educating patients about them.

After iterative revision, including additional cognitive interviewing where necessary, The Eating Behavior Efficacy Measure and The Perceived Barriers to Exercise Measure should receive pilot testing in a longitudinal investigation of the scales' feasibility and efficacy for clinical use.

Limitations: No demographic data were collected in order to maintain anonymity of the participants. Such data, including assessment of the reading level of participants, should be collected in subsequent study to further augment the clinical data, since response error can likely be affected by reading levels. In addition, elapsed time since surgery was not an exclusionary criteria for participations; consequently, participants in various stages of post-operative care were interviewed. Since health-care professionals impress lifestyle modifications upon patients during the course of post-operative care, it is likely that some participants were more familiar with the modifications contained in the survey questions. This familiarity with the terminology may have facilitated ease of comprehension for some participants. In addition, interviewing was conducted at

only one location, where social desirability was likely present due to the presence of health-care professionals in the clinic. Inclusion of other sites for data collection could likely add variability to the sample population. Finally, two of the participants in this study were wheelchair bound. This variation in current physical health, may have accounted for variability in responding to statements on The Perceived Barriers to Exercise Measure since a physical disability can limit an individual's choice of exercises.

Future Directions. It is expected that the population of individuals seeking bariatric surgery will increase based on the predictions surrounding the prevalence of obesity. However, despite an increase in the number of surgeries performed, the success rate of the surgeries still remains acutely tied in with adherence to lifestyle modifications post surgery. Recent studies have focused on identifying attitudes and beliefs indicative of struggles complying with suggested lifestyle changes, generally with the aim of qualifying/disqualifying individuals for surgery. Unfortunately, existing measures have poor predictive value for identifying candidates unable, or unwilling to comply with post-surgical behavioral changes. Therefore, the two instruments assessed in this study are designed to *anticipate* struggles individuals may have making the necessary adaptations in lifestyle for surgical success, in the effort to provide individuated support to them. Despite the rises in bariatric surgery, no such instruments currently exist. Creation and validation of this instrument can help achieve customized understanding of the individual's potential struggles due to inherent attitudes and beliefs about weight loss changes. Such an instrument can help

professionals provide preemptive support to individuals post surgery, thereby enhancing the benefits of bariatric surgery.

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Appendix A

IRB Approval with Instruction Script for Participant Feedback and Measures used attached

THE UNIVERSITY OF TEXAS
SOUTHWESTERN MEDICAL CENTER
AT DALLAS

Institutional Review Board

TO: Nancy Puzziferri, MD
c/o Taylor Tran
Surgery - 8871

FROM: Ahamed Idris, MD
Institutional Review Board 4 Chairperson
IRB - 8843

DATE: September 25, 2009

RE: Expedited Approval of NR1-Exp, Protocol/Project Summary, Instruction Script, Participant Surveys and HIPAA Waiver
IRB Number: 082009-048
Title: Attitudes & Beliefs; Improving Outcomes of Bariatric Surgery

The Institutional Review Board reviewed this research activity via an expedited review procedure in accordance with 45 CFR 46.110(a)-(b)(1), 63 FR 60364, and 63 FR 60353. Having met the conditions as set forth by the IRB Chairman on September 18, 2009 your research protocol is now approved for a period of 12 months. This approval period will begin September 25, 2009 and last until September 17, 2010. If the research continues beyond approval period, the study will require continuing review from the IRB and a reminder will be mailed to you 60 days prior to the expiration date stated above.

The use of consent form is waived in accordance with 45 CFR 46.116(d). Your approved subject sample size is 20 subjects.

Federal regulatory law requires that you report to the Institutional Review Board any unexpected and/or serious adverse events/unanticipated problems, as defined on the IRB website at http://www.utsouthwestern.edu/irb , that occur to research subjects or others during the course of your study.

In the future, should you require a change or need to modify the research, including the informed consent document(s) and HIPAA Authorization, per federal regulation you must obtain prospective review and approval of the Institutional Review Board. For any change to the research, prior review and approval before implementing such changes is mandatory except when prompt implementation is necessary to eliminate apparent immediate hazard to a subject.

Enc: NR1-Exp, Protocol/Project Summary, Instruction Script, Participant Surveys and HIPAA Waiver

AI/ca

The University of Texas Southwestern Medical Center at Dallas
Institutional Review Board[1]

IRB Form NR1- EXP: Application for Review of Expedited Research
(Revised April 2005)

Title of Research[2]

Attitudes & Beliefs; Improving Outcomes of Bariatric Surgery

08-19-09 P03:53

Sponsor and Grant Number[3]

Sponsored by the Department of Clinical Sciences

082009-048

Assurances of the Principal Investigator and Sub-investigators

- To safeguard human subjects involved in this research, I agree to use procedures that conform to the policies of the University of Texas Southwestern Medical Center at Dallas and the regulations of the Department of Health and Human Services and the Food and Drug Administration.
- Unless it is necessary to eliminate apparent immediate hazard to a human subject, I shall seek prior approval from the Institutional Review Board (IRB) for substantive changes in the investigative procedures involving human subjects that may be called for during the research covered by this application.
- I shall agree to follow the advice of the IRB.
- I agree to report immediately to the IRB any unanticipated, life-threatening, or fatal complications with respect to human subjects.
- My signature certifies that I assure compliance with the ethical principles and institutional policies regarding the protection of human subjects in research as stated in Title 45 Code of Federal Regulations Part 46 (revised June 18, 1991; reprinted April 2, 1996) and the Federal Wide Assurance.[4]

Assurances of Department and Collaborating Chairmen

- I understand that responsibility for assessing the quality of research must be shared by both the department and the IRB.
- My signature certifies that I assure compliance with the ethical principles and institutional policies regarding the protection of human subjects in research as stated in Title 45 Code of Federal Regulations Part 46 (revised June 18, 1991; reprinted April 2, 1996) and the Federal Wide Assurance, and that I have reviewed the proposed research for the proper use of human subjects.
- This review encompassed experimental design, scientific merit, and accuracy of the proposed research.

Date of Application:

[1]The IRB reviews all research involving human subjects for Children's Medical Center, Parkland Health & Hospital System, Texas Scottish Rite Hospital for Children, and the University of Texas Southwestern Medical Center at Dallas. The Board also reviews all research conducted at the Presbyterian Hospital of Dallas, The Retina Foundation of the Southwest and the Veteran's Affairs Medical Center of Dallas for which a member of the faculty at UT Southwestern serves as principal investigator.

[2]Title printed on the cover of the protocol, including the sponsor's protocol number, version, and date

[3]Complete name of the organization(s) funding the research

[4]Available as an electronic file at http://www8.utsouthwestern.edu/utsw/cda/dept31018/files/41623.html

Study Signatures

Nancy Puzziferri, MD Principal Investigator (PI)	Surgery MD Asst. Prof. 214-645-8424 9156 Nancy.puzziferri@utsouthwestern.edu
Anna Brandon, MD Co-Investigator	Psychiatry PhD Asst. Prof. 214-648-0103 9086 Anna.brandon@utsouthwestern.edu
Robert Rege, MD Department Chairperson	Surgery MD Professor 214-648-3050 9031 Robert.rege@utsouthwestern.edu
Rosemary Son, RD Research Coordinator	Surgery RD 214-645-2906 8871 Rosemary.son@utsouthwestern.edu
Taylor Tran, RD Research Coordinator	Surgery RD Dietician 214-645-2930 8871 Taylor.tran@utsouthwestern.edu
Rachita Sharma, BA,BS Research Fellow	Rehabilitation Counseling BA,BS Graduate Student Fellow 214-648-1740 9088 Rachita.Sharma@utsouthwestern.edu
Ryan Gallagher, BA Research Assistant	Surgery BA Research Assistant 214-648-3484 9156 Ryan.gallagher@utsouthwestern.edu
Victoria Warren, RN Research Nurse	Surgery RN Research Nurse 214-648-9491 9031 Victoria.warren@utsouthwestern.edu

Make additional rows or copies of this page to add other study collaborators.

Investigators' and Chairmen's Signatures

Name (printed)	Dept	Degree	Rank	Phone	Mail	E-mail	Signature
Nancy Puzziferri, MD Principal Investigator (PI)[5]	Surgery	MD	Asst. Prof.	214-648-0268	9156	Nancy.puzziferri@utsouthwestern.edu	
Anna Brandon, PhD Co-Investigator	Psychiatry	PhD	Asst. Prof.	214-648-0103	9086	Anna.brandon@utsouthwestern.edu	
Victoria Warren, RN Research Nurse[6]	Surgery	RN		214-648-9491	9031	Victoria.warren@utsouthwestern.edu	
Rosemary Son, RD Research Assistant	Surgery	RD		214-645-2906	8871	Rosemary.son@utsouthwestern.edu	
Ryan Gallagher, BA Research Assistant	Surgery	Research Asst.		214-648-3484	9156	Ryan.Gallagher@utsouthwestern.edu	
Rachita Sharma, BA, BS Research Fellow	Surgery	Research Fellow		214-648-1740	9088	Rachita.Sharma@utsouthwestern.edu	
Taylor Tran, RD Research Coordinator	Surgery	RD		214-645-2930	8871	Taylor.tran@utsouthwestern.edu	
Robert Rege, MD Department Chairperson[7]	Surgery	MD	Prof.	214-648-3050	9031	Robert.rege@utsouthwestern.edu	

Please note that to qualify for expedited review, the research must present no more than minimal risk to human subjects and cannot explore sensitive topics. Designate below the category that qualifies this proposal for expedited review, and justify this designation by responding to the statements below each category. (Click on, http://www8.utsouthwestern.edu/vgn/images/portal/cit_56417/13/61/69669expcategories.pdf for a list of "Expedited Categories.) The IRB will review your justification and decide if this study can be approved on an expedited basis. If it is decided that it doesn't meet expedited criteria completely, then you will be informed and submission of an NR1 form will be necessary.

Category #: 7

Information Required for Justification (specific information in attachments):

1. **This research is on individual behaviors before and after bariatric surgery**
2. **We will use a new survey tool to collect the data, the survey is attached to this IRB submission**

1. PROBLEM UNDER INVESTIGATION:

Medical condition or scientific problem to be studied: Weight loss behaviors before and after Bariatric Surgery

[5]Investigator responsible for the global aspects of the research. The IRB acknowledges one PI for a study.

[6]Person designated by the PI to report information about the research to the IRB and the person to whom all correspondence from the IRB will be sent.

[7]Chairman of the PI's or faculty sponsor's department (or center director).

Describe the research in simple language **by attaching a project summary** (template available on the IRB website). If this is a retrospective chart review (Category 5) (health records research) all of the following must be addressed: a) describe specifically what data (variables) will be extracted from each medical record, whether or not subject identifiers (name, medical record number, social security number, etc.) will be present, and at what point in time identifiers (if used) will be destroyed. Clarify how subject confidentiality will be protected. b) State why the research could not practicably be carried out without access to and use of the protected health information.

2. SUBJECTS:

a) General Inclusion:

Approximate number of subjects: **20 Patients**

Age range (indicate whether months or years): **18-70 years of age**

Gender: Male (**X**) Female (**X**)

Explain below if either gender is excluded:

Will all racial/ethnic groups be included? Yes ( ) No (**X**) (If no, explain in project summary)
Please note that a consent document in the subject's own language will need to be provided.

Expected time to completion of enrollment or conclusion of study: **1 year**

b) Protocol inclusion criteria: **Patients will be considered eligible if they are age 18-70 and have an upcoming appointment in the UTSW bariatric clinic**

c) Protocol exclusion criteria: **Individuals younger than age 18 will be excluded, as bariatric surgery is not yet considered standard care in children. Patients who do not speak or read English will not be eligible for participation; at this time, the measures under development have not been translated. Patients who are cognitively impaired will be excluded.**

Specify all classes of subjects included in the research:

Healthy volunteers: Medical students ( ), Center employees ( ), Minors (<18 yrs) ( ), Men ( ), Women ( )

Patients: Outpatients (**X**), Inpatients ( )

Vulnerable Subjects: Pregnant women ( ), Minors (<18 yrs) ( ), Men ( ), Women ( )
Cognitively impaired ( ), Terminally ill ( ), etc.

Other: Other class ( ) please explain below

3. RECRUITMENT:

Specify procedures for recruiting subjects:

Patients will be recruited from the investigators patients and the other bariatric patients within the bariatric clinic

4. CONSENT OF SUBJECTS: Describe the method used to obtain informed consent. Prospective research ordinarily requires written informed consent. If any special subject classes are eligible to participate, discuss how the consent process will differ. Inclusion of children in minimal risk research requires permission of at least one parent and the assent of the child.

An administrator, who is employed by the UT Health System and is <u>not</u> a member of the research team, will ask potentially eligible patients as they present for scheduled bariatric appointments if they may be interested in participating. For those patients who agree, a member of the research team will then explain the study, including the study's purpose, potential risks and benefits, procedure, and protection of confidentiality. We are requesting that when a patient agrees to participate, and gives feedback on instrument questions, implied verbal consent has been given.

f requesting a waiver or alteration of informed consent, justify such in accordance with the following four criteria established under 45CFR46.116(d)(1-4):

1) The research involves no more than minimal risk* to the subjects? Yes (**X**) No ( ) **AND**

2) The waiver or alteration will not adversely affect the rights and welfare of the subjects? Yes (**X**) No ( ) **AND**

3) The research could not practicably be carried out without the waiver or alteration? Yes (**X**) No ( ) **AND**

4) Whenever appropriate, the subjects will be provided with additional pertinent information after participation? Yes (**X**) No ( )

*"***Minimal risk** means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests" (45 CFR 46).

Please note that the IRB will make the final determination if waiver of consent is appropriate.

5. RISKS AND BENEFITS:

Specify the risks and benefits to the subjects and/or society:

Risks of participation in this research are minimal for subjects. The proposed study's potential contribution to future intervention research and clinical practice with bariatric surgery candidates fully justifies the minimal risks to patients. We do not anticipate any real harm to patients, but adverse events will be monitored. Potential adverse events (AE) for this project are all non-medical in nature

6. RESEARCH PERSONNEL:

Is there a conflict of interest between any investigator and the sponsor?

Yes ( ) explain below and notify the Conflict of Interest Office
No (**X**)

Have all research personnel completed the required human subject protection training?	(**X**) yes ( ) no	(name(s) and completion date(s) under Comments) (enclosed with current submission)
Have all research personnel completed the required HIPAA training?	(**X**) yes ( ) no	(name(s) and completion date(s) under Comments) (enclosed with current submission)
Is this study industry sponsored?	( ) yes (**X**) no	**(please skip the next question)**
Have all research personnel completed the required Good Clinical Practice training?	( ) yes ( ) no	(name(s) and completion date(s) under Comments) (enclosed with current submission)

7. PERFORMANCE SITES:

Specify the sites where (1) study procedures will be conducted, (2) patients will be seen, and (3) resources (equipment, supplies, personnel, etc.) will be utilized. Indicate whether Form NR3 has been sent to the appropriate authority at the performance site.

Performance Site	Recruitment	Resources	Form NR3 sent
Aston Ambulatory Care Center	XX	XX	XX
Children's Medical Center			
Dallas County Mental Health			
Dallas Veteran's Affairs Medical Center			
General Clinical Research Center			
Parkland Health & Hospital System			
Presbyterian Hospital of Dallas			
Sprague Clinical Sciences Center			
Texas Scottish Rite Hospital for Children			
UT Southwestern Medical Center			
UT Southwestern Moncrief Cancer Center			
UT Southwestern University Hospital-St. Paul			
UT Southwestern University Hospital-Zale Lipshy			
Other (specify below)			

Other approvals needed:

	Environmental Health & Safety Committee
	Radiation Safety Committee
	IRB at the Veteran's Affairs Medical Center
	IRB at Presbyterian Hospital of Dallas
	Grants Management (UT Southwestern)
	General Clinical Research Center
X	Form NR3
	Other (specify below)

Have all approvals been requested?

X	Yes
	no (explain below)

8. OTHER PAPERWORK REQUIRED:

a) Project summary including any questionnaires, surveys, telephone scripts, etc.

Also, when applicable:

b) Complete grant application, with budget (when project is federally funded). Block out confidential salary information and total dollar amount.

c) Consent form, information sheet, brochure, and/or letter, script for verbal consent.

d) Recruitment materials (e.g., posted notices, advertisements, telephone script, letters, etc.)

COMMENTS:

	Belmont	HIPAA
Nancy Puzziferri, MD	**8/20/2003**	**2/22/2006**
Anna Brandon, MD	**6/5/2003**	**9/19/2005**
Robert Rege, MD	**9/19/2000**	**4/1/2003**
Rosemary Son, RD	**03/16/2009**	
Taylor Tran, RD	**12/09/2005**	**07/10/2007**
Victoria Warren, RN	**03/24/2006**	**03/28/2006**
Ryan Gallagher, BA	**05/21/2008**	**05/22/2008**
Rachita Sharma, BA, BS		

For IRB office use only:

Expedited Review:

☐ **Approved As Submitted**

Reviewer: _____
IRB Chair or Designee

Date: _____

☐ **Approved - Minor Changes (may be verified by designee)**

Reviewer: _____
IRB Chair or Designee

Date: 9/17/09

☐ **Deferred – Substantive Issues (needs IRB Chair approval)**

Reviewer: _____
IRB Chair or Designee

Date: _____

☐ **Refer for Full Board Review**

Reviewer: _____
IRB Chair or Designee

Date: _____

Project Summary

Title: Attitudes and Beliefs: Seeking to Improve Weight-loss Outcomes after Bariatric Surgery

PURPOSE: The primary aim of this project is to identify attitudes and beliefs associated with successful weight-loss behaviors in bariatric surgical patients. This knowledge will provide a foundation for the development of specific interventions to improve weight-loss outcomes.

BACKGROUND: Obesity is an urgent public health problem affecting a third of the U.S. population. Greater than 400,000 U.S. deaths per year are attributed to obesity related illnesses. Bariatric surgery is the most effective treatment for sustained weight-loss, leading to improved mortality and morbidity. Weight-loss after bariatric surgery, however, varies greatly among individuals. Though it is well established that diet and exercise lead to weight-loss in general, there has been little research on these weight-loss behaviors specifically after bariatric surgery. In particular, there is little information regarding attitudes, beliefs that support behaviors associated with successful or unsuccessful surgical weight-loss. Post-surgery eating behavior change is radical and necessary for maintained weight loss. There is a need to increase our knowledge of behavioral weight-loss constructs in bariatric surgery so that individually based interventions can be developed and tested for efficacy. Currently, no such customized postoperative bariatric treatments exist. Especially critical is physician evaluation of the barriers to necessary eating behavior change after surgery, in order to identify areas of risk for patient non-compliance.

In an effort to develop treatment recommendations based on patients' individual risks for dietary non-compliance, attitudes and beliefs, particularly in regard to self-efficacy for necessary eating behavior changes, must be ascertained and evaluated. Attitude and belief factors that determine patients' readiness to change their eating behaviors are currently not evaluated in surgery candidates. Absence of preoperative readiness evaluation is, in part, due to the lack of available relevant validated instruments for the bariatric population. This study will utilize two new instruments to evaluate patient attitudes and beliefs toward needed behavioral changes after bariatric surgery. Such knowledge will enable physician recommendations for patient-tailored behavioral interventions across the course of surgical treatment. Ultimately, this process will be initiated at the patient's first office visit and incorporated in all visits before and after surgery, as a helpful and non-obstructive adjunct to patient assessment for surgery candidacy in addition to an augmentation of existing medical postsurgical care.

CONCISE SUMMARY OF PROJECT: This is the cognitive refinement of two new instruments to be used in a prospective descriptive study of beliefs and attitudes associated with bariatric surgical outcomes including weight loss, symptoms of anxiety and depression, eating behaviors, and level of activity. Cognitive testing seeks to identify what, if any, are the problems that people encounter when they complete

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questionnaires. Cognitive testing of the new instruments will be conducted on 20 bariatric patients over two months for refinement of end user clarity.

STUDY PROCEDURES:

SPECIFIC AIM and Hypothesis:

Aim 1. Cognitively test and refine two new instruments measuring attitudes and beliefs toward dietary and exercise weight loss regimens recommended to postoperative bariatric patients in 20 individuals undergoing care at the UTSW bariatric clinic.

Hypothesis 1. The new instruments measuring attitudes and beliefs toward dietary and exercise weight loss regimens recommended to postoperative bariatric patients will have content that is unclear and in need of refinement as interpreted by individuals undergoing care at the UTSW bariatric clinic.

After refinement, the new instrument will be used clinically and/or used in a future research protocol to prospectively characterize and correlate attitudes, beliefs, and weight-loss behaviors with weight-loss outcomes after surgery.

METHODS:

Upon presentation for their scheduled appointment, study staff will explain the project to each patient and carry out the process of implied verbal consent. Those who agree to participate will be given the new questionnaires to complete. The cognitive testing session will be conducted in an interview room. Questionnaires will have no identifying data; they will only reflect participant number. We will not collect questionnaire responses. We will only collect feedback on the clarity and meaning of each question.

MEASURES:

1. Eating Behavior Efficacy Measure This new measure developed by the investigators will ultimately be included in a battery consisting of other validated measures. This Eating Behavior Efficacy Measure is based upon clinical data and assesses the likelihood of an individual adhering to the necessary dietary changes post-surgery. Data collected from this project will contribute to the validation of this instrument in a population of individuals being assessed for bariatric surgery suitability.

2. Perceived Barriers to Exercise Measure

This new measure was also developed by the investigators based upon clinical data. This Perceived Barriers to Exercise Measure assesses the likelihood of an individual adhering to the recommended exercise changes post-surgery. Data collected from this project will contribute to the validation of this instrument in a population of individuals being assessed for bariatric surgery suitability.

DATA COLLECTION:

Subsequent to IRB approval, all individuals presenting for care to the Aston Bariatric Clinic at UTSW will be invited to participate in a cognitive feedback session regarding the new instruments. Those who consent to participate will receive the assessment

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instrument at the current clinic appointment and feedback collected in aggregate for use in refining. Individual feedback will be recorded, transcribed and coded for similarities. The study questionnaires have 36 items total.

COGNITIVE INTERVIEWING PROCEDURE: Cognitive testing seeks to identify what, if any, are the problems that people encounter when they complete questionnaires. Cognitive interviewing is employed where participants are asked to 'think aloud' as they complete a questionnaire, verbalizing all thoughts that would normally be silent. (Ericsson and Simon, 1993; Gilhooly and Green, 1996) Participants are not asked to explain the reasons for their thoughts, or provide any commentary, but just report the information that they are currently thinking about. (Ericsson and Simon, 1993, 1998) Generally information currently held in short-term memory can be accurately reported without interfering with the task at hand. Participants' verbal reports are recorded, transcribed and subsequently coded; in the present case, for evidence of misunderstandings of the questions that they are answering. The four most common areas of difficulty are: comprehension, retrieval, judgement and response. (Tourangeau, Rips and Rasinski, 2000)

FEEDBACK ELICITATION PROCEDURE: Individuals will be recorded while 'thinking aloud' and completing the study questionnaire. Before beginning, they will be read the following instructions adapted from French et. al. (2007), and Green and Gilhooly (1996):

We will shortly be beginning a study to understand the attitudes and beliefs of people who have bariatric surgery. We want to understand the thoughts people have toward the diet and exercise changes recommended after weight loss surgery. We think that by identifying difficulties people have in changing their eating and exercise habits, that we may be better able to help them make the needed changes.
For this study, we have developed a questionnaire based on what patients who have had bariatric surgery have told us. We want to check that people understand the questions in the way we meant them. To do this, I am going to ask you to think aloud as you complete the questionnaire. What I mean by 'think aloud' is that I want you to tell me everything you are thinking as you read each question and decide how to answer it. I would like you to talk aloud constantly. I don't want you to plan out what you say or try to explain to me what you are saying. Just act as if you are alone in the room speaking to yourself. If you are silent for any long period of time, I will ask you to talk. Please try to speak as clearly as possible, as I shall be recording you as you speak. Do you understand what I want you to do?

After answering any questions, the researcher will then sit out of the line of sight of individuals to minimize influence. Once individuals begin completing the questionnaire, they will not be interrupted, unless they fall silent for approximately 10 seconds, at which time they will be prompted to 'keep talking'.

CRITERIA FOR INCLUSION OF SUBJECTS: Patients will be considered eligible if they are age 18-70 and have an upcoming appointment in the UTSW bariatric clinic.

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CRITERIA FOR EXCLUSION OF SUBJECTS: Individuals younger than age 18 will be excluded, as bariatric surgery is not yet considered standard care in children. Patients who do not speak or read English will not be eligible for participation; at this time, the measures under development have not been translated. Patients who are cognitively impaired will be excluded.

SOURCES OF RESEARCH MATERIAL: The only source of patient feedback will be verbal patient input in an interview over the 36-question instrument. The questionnaire takes approximately 5-10 minutes to complete. All recorded feedback will bear only study participant number and no personal identifiers. Implied verbal consent will be gained. A web-based Microsoft Access database will be used to store transcribed comments regarding each instrument question.

RECRUITMENT OF SUBJECTS: An administrator, who is employed by the UT Health System and is not a member of the research team, will ask potentially eligible patients as they present for scheduled bariatric appointments if they may be interested in participating. For those patients who agree, a member of the research team will then explain the study, including the study's purpose, potential risks and benefits, procedure, and protection of confidentiality. We are requesting that when a patient agrees to participate, and gives feedback on instrument questions, implied verbal consent has been given.

POTENTIAL RISKS: Risks associated with the proposed study are minimal. The only identified risks are that patient confidentiality could be breached or that participants might experience psychological stress if questions asked as part of their reaction to instrument questions makes them uncomfortable. Methods for protecting against these risks are described below. Patients who choose not to participate will continue to receive their usual care from their bariatric surgery provider. No study personnel are applying for Certificates of Confidentiality.

SPECIAL PRECAUTIONS: Because there is a chance that some of the questions asked as part of this study may make a participant feel uncomfortable, the consent process will clarify that they can refuse to answer any of the questions, take a break, or stop participation in the study at any time. Additionally, if the participant feels psychological stress, they should report it to the researchers (who will be trained to address concerns and, if appropriate, refer to a qualified mental health professional).

PROCEDURES TO MAINTAIN CONFIDENTIALITY: Personally identifying data will *not* be saved with the questionnaires. Data saved or transferred will be limited to non-identifying data. Feedback data collected will be stored in the clinic in a locked file cabinet in the locked office of the Research Coordinator until entered on a web-based database.

Patient privacy will be protected, as no link to patient identification data will be created. All study staff will participate complete training and certification in protection of human subjects, confidentiality and HIPAA regulations.

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Once data collection begins, we will have biweekly research team meetings that will include the investigators, project manager, and Data Technicians to discuss project implementation, address questions or concerns that might arise, and monitor the safety of the intervention. Data Technicians, the project manager and the PI will record, review and discuss any unusual events, such as deviations from protocol or adverse events that have occurred since the last meeting. Decisions will be recorded in meeting minutes.

POTENTIAL BENEFITS: There is no direct benefit to the participants except potential insight into rational, understandable and sensitive querying of eating and exercise behaviors as a result of being interviewed regarding the questionnaire. However, there could be significant benefits to others who may be recipients of future interventions developed on the basis of this knowledge.

RISK/BENEFIT ASSESSMENT: Risks of participation in this research are minimal for subjects. The proposed study's potential contribution to future intervention research and clinical practice with bariatric surgery candidates fully justifies the minimal risks to patients. All adverse events (serious or not, related or unrelated, anticipated or unanticipated) will be reported in the annual report to the IRB.

Biostatisics: No formal statistical analysis will be conducted on this short-term qualitative study whose purpose is only to refine the understandability of 36 questions.

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Instruction Script for Participant Feedback

We will shortly be beginning a study to understand the attitudes and beliefs of people who have bariatric surgery. We want to understand the thoughts people have toward the diet and exercise changes recommended after weight loss surgery. We think that by identifying difficulties people have in changing their eating and exercise habits, that we may be better able to help them make the needed changes.

Your participation today is voluntary. Responding to our questions implies that you are consenting to participate. You can stop participating at any time during this research.

For this study, we have developed a questionnaire based on what patients who have had bariatric surgery have told us. We want to check that people understand the questions in the way we meant them. To do this, I am going to ask you to think aloud as you complete the questionnaire. What I mean by 'think aloud' is that I want you to tell me everything you are thinking as you read each question and decide how to answer it. I would like you to talk aloud constantly. I don't want you to plan out what you say or try to explain to me what you are saying. Just act as if you are alone in the room speaking to yourself. If you are silent for any long period of time, I will ask you to talk. Please try to speak as clearly as possible, as I shall be recording you as you speak. Do you understand what I want you to do?

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Expiration Date:
SEP 1 7 2010

THE UNIVERSITY OF TEXAS SOUTHWESTERN MEDICAL CENTER AT DALLAS

CHILDREN'S MEDICAL CENTER OF DALLAS, PARKLAND HEALTH & HOSPITAL SYSTEM
RETINA FOUNDATION OF THE SOUTHWEST, TEXAS SCOTTISH RITE HOSPITAL FOR CHILDREN
ZALE LIPSHY UNIVERSITY HOSPITAL, ST. PAUL UNIVERSITY HOSPITAL
THE UNIVERSITY OF TEXAS SOUTHWESTERN MONCRIEF CANCER CENTER

REQUEST FOR WAIVER OF HIPAA PRIVACY AUTHORIZATION FOR RESEARCH

IRB Number: 082009-048

Study Title: Attitudes & Beliefs; Improving Outcomes of Bariatric Surgery

Principal Investigator: Nancy Puzziferri, MD

Principal Investigator Mail Code: 214-645-8424

Research Coordinator: Victoria Warren, RN

Research Coordinator Phone #: 214-648-9491

Research Coordinator Mail Code/Address (if applicable): 9031

SEE INSTRUCTION PAGE FOR GUIDANCE AND EXAMPLES

1. I am requesting this waiver of authorization for the following purpose:
   <Please select only one>

   ☒ The collection of initial screening data to recruit potential research subjects, or to determine study eligibility only. (Authorization is required for the remainder of the research study.)

   ☐ Retrospective reviews, research database or repository, or other research study where obtaining a signed authorization is not practical.

2. The following protected health information will be created, collected, used and/or disclosed for the purpose of conducting this research: *(Please list the specific protected health information)*
   Demographics, Diagnoses, Medical History, type of surgery scheduled, date of surgery, previous treatments

3. I certify that the use or disclosure of protected health information involves no more than minimal risk to the privacy of individuals based on at least the following elements:
   a. An adequate plan is in place to protect the identifiers from improper use and disclosure. The plan is as follows;
      <Select all that apply. Include additional information when applicable.>
      ☒ All electronic study data will be password protected.
      ☒ Passwords will be changed on a regular basis.
      ☒ Access to study data will be restricted to the following authorized study personnel only.
      Nancy Puzziferri, MD
      ☒ All paper study records will be kept in locked file cabinets and access limited to authorized study personnel only.
      ☐ Other: ____

b. An adequate plan is in place to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law.

The plan is as follows;
Participants will be screened prior to coming into the bariatric clincic for an appointment. Researchers will keep no patient identifiers or medical record information. Researchers will only keep a recording of the participants voice with no identifiers.

c. The protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of protected health information would be permitted by HIPAA regulations.

4. I certify that the research could not practicably be conducted without this requested waiver.
5. I certify that this research could not practicably be conducted without access to and use of the protected health information.
6. I certify that I will only access the minimum amount of PHI necessary to accomplish the purpose(s) of the research described under this waiver.

I attest that the above statements are correct and complete to the best of my knowledge.

Nancy Puzziferri MD
Signature of Principal Investigator

8-14-09
Date

Nancy Puzziferri
Printed name of Principal Investigator

For IRB Office Use Only

This waiver was approved under: Full Review _____ Expedited Review ✓

Signature of IRB Administrative Representative or Board Member

9/17/09
Approval Date

UT SOUTHWESTERN MEDICAL CENTER
Department of Surgery, University of Texas

UTSW Weight Loss Program

Form C

Patient No.	Visit ID			Date of contact	
⌊⌊⌊	⌊⌊⌊			month ☐ day ☐ year ☐	

Please score yourself from 1 to 5 on the following 16 statements. A rating of 1 means the statement does not describe you at all, and 5 means it describes you perfectly.

①-Never ②-Sometimes ③-Not Sure ④-Most times ⑤-Always

1. I am comfortable exercising in public (gym, walking trail, park, etc).	①	②	③	④	⑤
2. I don't have the time to exercise.	①	②	③	④	⑤
3. I believe I deserve to eat what I want whenever I want.	①	②	③	④	⑤
4. There are places nearby where I can walk safely.	①	②	③	④	⑤
5. I can't afford to belong to a gym or take exercise classes.	①	②	③	④	⑤
6. I can exercise in cold weather.	①	②	③	④	⑤
7. I can't cook so I have to eat out, limiting my food choices.	①	②	③	④	⑤
8. I can exercise in hot weather.	①	②	③	④	⑤
9. I belong to a gym or have gym equipment at home.	①	②	③	④	⑤
10. I don't have time to control what I eat by packing my lunch or cooking at home.	①	②	③	④	⑤
11. I take exercise classes at a community center (YMCA, etc).	①	②	③	④	⑤
12. I can't exercise because of severe joint pain.	①	②	③	④	⑤
13. I would exercise if it was easier.	①	②	③	④	⑤
14. Eating helps me sleep better.	①	②	③	④	⑤
15. I know I should exercise, but I can't seem to make myself.	①	②	③	④	⑤
16. I like to exercise.	①	②	③	④	⑤
17. I prefer to snack often rather than eating at mealtimes.	①	②	③	④	⑤
18. I have transportation for getting to a place where I can exercise.	①	②	③	④	⑤
19. I don't have the right clothing for exercise.	①	②	③	④	⑤
20. I think I'm just lazy.	①	②	③	④	⑤
21. I don't have time to eat breakfast.	①	②	③	④	⑤
22. I believe exercise is important for my weight loss success.	①	②	③	④	⑤

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UT SOUTHWESTERN MEDICAL CENTER
Department of Surgery, University of Texas

UTSW Weight Loss Program

Form B

Patient No.	Visit ID			Date of contact	
⌊⌊⌊⌋	⌊⌊⌊⌋			month day year	

This questionnaire about how and what you eat asks if you have these habits now, if you could start making this action a habit, or if you could never do it. If you think you could never do one of these things, please tell us in one sentence why you think it would be a problem. Also, on the right, tell us if you think this is important (yes) or not important (no) in order for you to lose weight.

① -I do now ② -I could begin doing ③ -I will never be able to do (give reason)

Is this important for your weight loss? Yes/ No

1. I usually complete a meal in 20-30 minutes.
   ① ② ③ Reason: _____ (Y) (N)

2. I take small (pea-sized) bites and chew around 8 to 10 times before swallowing.
   ① ② ③ Reason: _____ (Y) (N)

3. I usually eat breakfast.
   ① ② ③ Reason: _____ (Y) (N)

4. I avoid drinking 30 minutes before, during, or for 30 minutes after my meals.
   ① ② ③ Reason: _____ (Y) (N)

5. I keep a food diary.
   ① ② ③ Reason: _____ (Y) (N)

6. I start my meal by eating protein (meat, eggs, fish) first.
   ① ② ③ Reason: _____ (Y) (N)

① -I do now ② -I could begin doing ③ -I will never be able to do (give reason) ④ - I never feel full

7. I stop eating when I am full.
   ① ② ③ ④ Reason: _____ (Y) (N)

8. I avoid high-fat foods (fried foods, oily foods, butter, etc).
   ① ② ③ Reason: _____ (Y) (N)

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UT SOUTHWESTERN MEDICAL CENTER
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UTSW Weight Loss Program

Form B

Patient No.	Visit ID			Date of contact	
⌊_⌊_⌊_⌊	⌊_⌊_⌊_⌊			month day year	

① -I do now ② -I could begin doing ③ -I will never be able to do (give reason) ④ - I am never hungry

Is this important for your weight loss? Yes/ No

9. I eat only when I am hungry. ① ② ③ ④ Reason: _____ (Y) (N)

① -I do now ② -I could begin doing ③ -I will never be able to do (give reason)

10. I avoid skipping meals. ① ② ③ Reason: _____ (Y) (N)

11. I avoid eating between meals. ① ② ③ Reason: _____ (Y) (N)

12. I drink at least three 8-oz glasses (24 ozs) of water a day. ① ② ③ Reason: _____ (Y) (N)

13. I avoid soft foods (ice cream, pudding, hot cereal, etc). ① ② ③ Reason: _____ (Y) (N)

14. I can tell the difference between feeling hungry and just wanting to eat. ① ② ③ Reason: _____ (Y) (N)

15. I avoid salty snacks (chips, peanuts, etc). ① ② ③ Reason: _____ (Y) (N)

16. I avoid foods high in sugar content (cakes, pies, cookies, etc). ① ② ③ Reason: _____ (Y) (N)

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