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Chapter I

Review of the Literature

Overweight and obesity in both adults and adolescents has been steadily increasing throughout the past three decades. Along with the weight gain come several other consequences of this condition. Being overweight leads to other physical/medical consequences, individual economic consequences as well as health care costs to the country as a whole, and finally a variety of psychological consequences. With the knowledge that overweight and obesity is a problem, the next step is to find the best way to treat it. Various behavioral, psychopharmacologic, and medical procedures have been tried to reduce weight, though many of the tried procedures have failed to produce significant and permanent weight loss. However, bariatric weight loss surgery is one method that appears to be effective in both adults and adolescents. There are a variety of ways the weight loss surgery can be performed, with each having its strengths and weaknesses. Despite the fact that the surgery has actually been around for years, adult literature concerning the surgery’s long-term effectiveness as well as the resulting improvement in other areas of an obese individual’s life is lacking. There is even less literature available on these constructs in adolescents. While the initial literature on weight loss surgery in adolescents seems promising, there is a lot of room for investigation.

What is Obesity?

Obesity is defined as the condition of being obese, or having increased body weight caused by excessive accumulation of fat (The American Heritage Stedman’s Medical Dictionary,
In adulthood, overweight is talked about in terms of specific values assigned to a body mass index (BMI). This BMI is a measure of body fat based on height and weight, applying to both adult men and women (www.cdc.gov). In adults, obesity is classified as a BMI $\geq 30$. The definition of pediatric overweight is also talked about in terms of a BMI, but for youth the value is adjusted for height. A child or adolescent is considered overweight if he or she has a BMI greater than the 95th percentile when adjusted for age and gender (Inge et al., 2004c). This will be the description of obesity used throughout this paper, unless otherwise specified. A child or adolescent is considered to be at risk for overweight if the BMI falls in the range of the 85th to the 94th percentile. While these descriptors of body mass index are common throughout the literature and often referred to in practice, they are essentially arbitrary numbers being used by default. This is because youth with a BMI $\geq 40$ are very poorly represented in the norms used to create height and weight information for pediatric growth charts (Kuczmarski, Ogden, Guo, Grummer-Strawn, Flegal, Mei, et al., 2000), thus little is known about individuals with this physical condition. Without epidemiologically accurate information guiding the definition of severe obesity in each year during adolescence, a BMI $\geq 40$ has been decided as a conservative criterion to consider surgical intervention (Inge, Garcia, Daniels, Langfor, Kirk, Roehrig, et al., 2004a).

Why does Obesity Matter?

This description of obesity and how it is measured is important because excessive weight gain has been steadily increasing over the past several years. Unhealthy and inactive lifestyles are contributing to an increasingly overweight and obese population in America, with children and adolescents as no exception. In the past 30 years, the number of overweight individuals in the pediatric age range has almost tripled in the United States (Inge et al., 2004b). Strauss &
Pollack (2001) reported that pediatric obesity rates in the United States have increased 50% in the last decade alone. These increases in youth obesity are resulting in rates of obese youth ranging anywhere from 15.5% to 37% of youth across the country (Inge et al., 2004a). Van Hout, van Oudheusden, & van Heck (2004) reported that while obesity is an international disease that is spreading worldwide, at the turn of the 21st century obesity is the epidemic with the greatest incidence and prevalence in the United States. Lowry, Galuska, Fulton, Wechsler, & Kann (2002) cited obesity as the most prevalent nutritional disease of children and adolescents in the United States. Serdula, Ivery, Coates et al. (1993) reviewed literature indicating that children who are obese as adolescents have a 50 – 77% risk of becoming obese as adults, and this risk increases to 80% if at least one parent is also obese. Capella, & Capella (2003) indicated that though obesity research specific to adolescents is limited, it is theorized that adolescent obesity will persist into adulthood in nearly 100% of extremely obese individuals.

Medical Consequences

As childhood obesity is determined to be a problem in the United States, it is important to consider what this means to the country’s youth. The growing epidemic of obesity, especially in childhood and adolescence, is a concern for many reasons. To begin with, morbid obesity is often associated with a variety of medical conditions. Inge et al. (2004b) reviewed some of the conditions frequently associated with morbid obesity. Among them are premature death, heart disease, obstructive sleep apnea, hypertension, and type II diabetes mellitus. The diabetes alone creates significant cardiac, renal, and ophthalmic complications for young adults (Dean, 2002). Also implicated are medical difficulties such as hypertrophic cardiomyopathy, a disorder where the heart muscle is so strong that it does not relax enough to fill the heart with blood and creates a reduced pumping ability; pulmonary insufficiency, a disorder in which there is a problem with
the heart valve, allowing blood to flow backwards and creating a murmur; degenerative arthritis, gallbladder disease, and increased prevalence for selected types of cancer (Hsu et al., 1998).

Capella & Capella (2003) also discuss obesity related problems that are rarely mentioned such as hormonal imbalances and dermatological problems.

Financial Consequences

It is apparent throughout the literature that obesity is a problem in America for both the adult and pediatric population. In addition to the individual medical consequences of obesity, obesity has an economic impact on the country as well. Roszac (2004) reports that health care spending on obese Americans accounted for 27 percent of the growth in overall health care spending between 1987 and 2001. Health care costs of overweight individuals are 37% higher than those incurred by normal weight individuals. This percentage is 22% higher than it was 15 years ago. An editorial in the Lancet (2004) indicates that in 2003 alone, treating obesity cost America 75 billion dollars, totaling 175 dollars per United States tax payer. Epperson (2003) reports that obese people spend 700 dollars more a year on health care than non-overweight individuals. This equals 93 billion dollars in medical expenses for treating overweight individuals. These expenses are passed on to all Americans in the form of higher premiums and greater co-payments for those with health insurance. An article in the Pennsylvania Nurse (2002) reported even higher costs. This article reported that the increase in obese Americans has resulted in total health care costs for obesity at 117 billion dollars annually, including 61 billion dollars in direct costs and 56 billion dollars in indirect costs. These indirect costs include lost productivity due to mortality, morbidity, and disability. In addition, the article reports that Americans spend 33 billion dollars each year on “quick-fix” weight loss solutions. While these “quick fix” solutions as a whole have essentially created an economic niche where jobs have
been created, buying them is a cost to the individual using them. Finally, the article indicates that being overweight increases an individual's healthcare costs by 36 percent and his or her medication costs by 77 percent, compared to the general population. After a review of the literature, including 18 studies looking at the impact of obesity on healthcare, employment, and future disease risks, Thompson and Wolf (2001) concluded that obesity exacts and immense economic toll on America, as well as other countries around the world.

Psychological Consequences

In addition to negative physical effects of severe obesity and the economic expenses, there are also psychosocial effects associated with the chronic condition. While the various conditions have been documented throughout the adult obesity literature, less is known about emotional conditions associated with adolescent obesity. Also absent throughout the child and adult literature are studies focusing specifically on body-esteeem and/ or body-efficacy. For this reason, related constructs in the adult literature will be considered first, followed by related constructs in the pediatric literature.

Adults.

Friedman, Reichmann, Costanzo, & Musante (2002) found evidence indicating that while non-clinical samples of obese individuals do not differ from non-obese counterparts in psychological symptoms, the sub-set of obese individuals seeking treatment does differ. Renman, Engstrom, Silfverdal, & Aman (1999) also stated that clinical hospital-based studies more often indicate negative associations between obesity and self-esteem in comparison with findings from population based studies. While obesity cannot be named as a direct cause of negative associations it should be seen as related. Cash (1993) compared 102 adults enrolled in a low-calorie weight loss program to 258 matched controls and found that the overweight
individuals were more invested in their appearance, but were less pleased with how they looked.

In addition, the author found that compared to the control group, those seeking treatment felt less healthy, but their evaluation of and investment in their physical fitness were more positive.

Regardless of the construct being measured in an adult obese population, there seems to be some psychological distress associated with the condition, at least in those seeking treatment.

However, the exact distress tends to vary across the population and specific subsets of obese individuals.

Youth.

When considering younger individuals, Boutelle, Neumark-Sztainer, Story, & Resnick (2002) suggested that psychosocial consequences of being overweight do exist and begin early in life, are hard to manage and can have long-term psychological consequences. These consequences do not necessarily begin in adulthood, as the limited research literature shows that children are emotionally affected by their overweight status, as well. A study conducted by Kimm, Sweeney, Janosky, & MacMillan (1991) showed similar findings. This study investigated 130 obese children ages eight to 17 years old seeking treatment for obesity in an out-patient clinic. The children were administered the Piers-Harris Children’s Self-Concept Scale. Total self-esteem scores of the obese kids did not differ from population norms, though the obese children did show more dissatisfaction in some areas.

In addition to treatment-seeking youth, non-treatment-seeking individuals seem also to be affected by their weight. Vander Wal & Thelen (2000) studied a group of 526 school children from the Midwest. The children in the study were in either the second, third, fifth, or sixth grade. The Body Image and Eating Questionnaire for Children and the Body Image Scale were administered. This study of non-clinical children revealed that obese youth exhibit body image
dissatisfaction. These findings suggest that in addition to being large in size these children are also experiencing psychological distress related to their physical state.

A Dutch study published in 1999 by Stradmeijer, Bosch, Koops, and Seidell found differences in body and self-esteem in overweight early to middle adolescents. The authors compared 73 overweight (as defined by the Dutch concept of weight-for-height >90P) to 70 normal weight youth ages 10 to 16. The group was then further divided into boys versus girls and younger (ages 10-13) versus older (ages 14 -16). The participants were administered Dutch versions of the Self-Perceived Competence Scale and the Body-Esteem Scale. The results indicated lower body-esteem was found in the older overweight girls, while in older overweight boys higher body-esteem was found. These results suggested that age and gender may play a role in how an overweight adolescent is affected by his or her weight.

French et al. (1995) conducted a review of the literature and concluded that there is a negative association between relative weight and body esteem between the ages of seven and twelve years, though the correlation of weight with self-esteem was inconsistent. They also determined that adolescents between the ages of 13 and 18 years showed an inverse relationship between relative weight and both body and self-esteem. French, Perry, Leon, & Fulkerson (1996) studied a group of 1,278 white males and females in grades seven through nine at baseline, and followed them for three years. Harter's Self-Perception scale was administered and resulting analysis showed an inverse relationship between BMI and physical appearance self-esteem. In addition, the obese females were found to exhibit an inverse relationship between their BMI and global self-esteem, close friendship self-esteem, and behavioral conduct self-esteem. An inverse relationship between BMI and athletic self-esteem as well as romantic self-esteem was found in boys. This study does not apply to the specific category of obese youth, but
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does speak to the relationship between increased weight and how one views his or her own body and the things that the body can do.

The following studies can be used to help inform the literature on obese youth, but need to be viewed with caution, as they were conducted in a time when pediatric obesity was not as prevalent and therefore the effects may have been more severe. Banis et al. (1988) examined a group of hospitalized in-patients in a general pediatric clinic. The sample consisted of 30 obese children, defined as at least 20% overweight for the height, age, and sex. The 15 boys and 15 girls were ages seven to twelve years old, and free of any known medical complication that could potentially confound assessment or subsequent treatment of their obesity. The children were administered the Self-Perception Profile for Children and the mothers completed the Child Behavior Checklist and the Family Environment Scale. The children’s self-report showed lower self-esteem, self-worth, physical appearance, athletic competence, and social competence. When interpreting this study, other factors, in addition to the obesity, need to be taken into consideration, including the hospital stay and factors related to it. In a study by Strauss, Smith, Frame, & Forehand (1985) 18 obese children were compared to 18 non-obese children in the second through fifth grade. After completing the Piers-Harris Children’s Self-Concept Scale it was determined that the overweight children exhibited a lower self-concept than their average weight peers. Sallade (1973) administered the Piers-Harris self-report measure to 120 obese and 120 non-obese children, equally divided among sexes in grades 3, 5, 8, and 11 and found significantly lower self-esteem in the obese group compared to the non-obese.
How is Obesity Treated?

Adults.

There are many methods individuals try in an attempt to lose weight. Some of these ways are considered healthy, such as changing diets through eating healthier foods and smaller portions as well as exercising on a regular basis. There are also less healthy means of losing weight including purging, skipping meals, and use of laxatives. While these may or may not be ideal methods of weight loss, for many morbidly obese patients they prove ineffective regardless. Kinzl, Trefalt, Fiala, & Biebl (2002) argued that while the need for dietary management, physical activity, and behavior modification is undisputed, in morbidly obese patients, the success of these conservative treatments alone is limited. The authors further indicated that surgical treatment is the first choice for long-lasting and satisfactory weight loss.

Dymek, le Grange, Neven, et al. (2001) viewed weight loss surgery as a forced behavior modification and report that it leads not only to weight reduction, but improvement or cure of comorbidities and improvement in quality of life, as well. Rand, MacGregor, & Alex (1994) confirmed this belief by indicating that conservative treatments for morbid obesity are rarely effective, while surgery typically results in significant permanent weight loss. Dymek, le Grange, Neven, & Alverdy (2001) reported that morbidly obese patients typically respond poorly to traditional weight-loss regimens, and though initial response does sometimes occur, it is typically poorly maintained. However, effects on health and weight loss seem to be more consistent after surgery. Information on the long-term outcome of individuals after surgery is scarce in the literature, though a few investigators have looked into it. Solomon & Dluhy (2004) conducted a study consisting of 3505 subjects evaluated two years post surgery and 1268 evaluated 10 years after surgery. The mean weight loss at two years was 23% and 16% at 10
In addition, many of the comorbid health conditions were reduced or resolved at two years. While these improvements were less dramatic at the 10 year follow-up, the group which underwent surgery was still doing better than the control group. Waadegaard, Clemmesen, & Jess (2002) followed an initial group of 56 patients, aged 20-55 years old, six, twelve, 24, and 36 months after surgery and a median of 15 years after the operation. The median reduction in BMI 15 years after operation was 22%. The authors concluded that the weight loss surgery is an effective operation for morbidly obese individuals. Waters, Pories, Swanson, Meelheim, Flickinger, & May (1991) reported that 462 patients undergoing gastric bypass surgery effectively maintained satisfactory weight loss after nine years. Through the limited available data, it would appear that bariatric surgery benefits morbidly obese individuals, immediately after surgery and perhaps to a lesser degree at long term follow-up. While many individuals who receive surgery are still not skinny, and in fact remain overweight, the weight that has been lost is typically enough to improve comorbidities and the patient’s overall feeling of physical well-being.

*Adolescents.*

In outlining treatment of adolescent obesity, current guidelines contend interventions should begin early, involve the family, and institute permanent changes through gradual targeted increases in physical activity and targeted decreases in high-fat, high calorie foods (Lowry, Galuska, Fulton, Weschsler, & Kann, 2002). However, after review of various treatments for adolescent obesity, including dietary treatments, exercise, drug treatments, and behavior change Epstein, Myers, Raynor, & Saelens (1998) contended that though progress has been made, most interventions only effect small changes in weight and are followed by substantial relapse. They go on to suggest that it is too early to assume that there are standardized treatments that are
efficacious, and there is a need for further research to improve treatment outcome and sustain
treatment effects. Capella & Capella (2003) reiterated these findings in their report that
overwhelming evidence suggests that non-surgical treatments aimed at weight control fall short
in adolescents.

In agreement with Capella & Capella (2003), Hsu et al. (1998) argued for surgical
treatment of obesity. They suggest that while behavior therapy and various diets may work for
mild to moderate obesity, they are usually ineffective for severe obesity. In addition, the long-
term use of pharmacological agents such as “phen-fen” often results in fairly small weight loss
that is typically not sustained. As in all cases, the benefits of this method of weight loss also
need to be measured against the potential risks, such as pulmonary hypertension and valvular
heart disease. Inge et al. (2004b) suggested for those adolescents who are severely overweight
and have failed at organized attempts to lose weight and/ or maintain weight loss through non-
operative measures and also have serious co-morbid conditions, bariatric surgery may be the
only option for achieving a healthy weight and avoiding the potentially harmful physical and
psychological effects of being overweight. In summary, the literature reported overwhelming
belief that more conventional weight loss treatments such as dieting, exercising, and behavior
modification plans have produced minor results, most of which are difficult to maintain. In light
of this, bariatric surgery, proven effective for adults, is now becoming a viable option for
adolescents.

History of Bariatric Surgery

Though only recently becoming more publicized, bariatric surgery has been around for
many years, for the treatment of morbidly obese individuals. The idea was initially conceived
when doctors noticed weight loss in patients after receiving surgery resectioning parts of the
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stomach and intestines for other medical reasons (O’Connell, 2004). The first surgery for morbid obesity was described in 1954 when Kremen published a report of an end-to-end jejunoileostomy done specifically for weight loss. The first clinical program for intestinal bypass was established in 1956 and treatment of severe obesity by gastric bypass was first described 11 years later by Mason and Ito (O’Connell, 2004). This early surgery was performed by creating a loop gastrojejunostomy and a stapled pouch consisting of only 10% of the gastric volume.

While the early surgeries were effective for weight loss they often came with unpleasant complications. Diarrhea, malabsorption of nutrients, electrolytic disturbances, liver failure, vitamin deficiencies and in some cases death are among the complications that occurred. Due to these complications and the resulting negative attitudes, the following years were marked by revisions of early procedures creating a better weight loss surgery. There are currently three major forms of gastric restrictive weight loss surgery being performed. Each works by decreasing gastric volume, slowing gastric emptying, and creating an early sensation of being full (O’Connell, 2004).

Since weight loss surgery began, the number and types of techniques have expanded, as well as the number of surgeries being performed. Jones (2004) quoted the American Society of Bariatric Surgery on the number of operations being done. The numbers have increased dramatically from around 16,000 procedures in the early 1990’s to 103,000 in 2003, and were predicted to exceed 140,000 in 2004. There are now several forms of bariatric surgery being performed including adjustable gastric banding, vertical banded gastroplasty, and the Roux-en-Y procedure. There are also procedures that prohibit the stomach from absorbing what is entering; among these are the biliopancreatic diversion and the duodenal switch. These procedures combine gastric restriction with reduced calorie and nutrient absorption. However, these
procedures are used less often due to the possibility and high incidence of nutritional deficiencies (O'Connell, 2004).

The most common form of weight loss surgery is currently the Roux-en-Y procedure, or RNYGB. This surgery is performed by creating a 30-ml restrictive stomach pouch by placing staples across the stomach and dividing it. An 11-mm stoma can also be added (Dymek, le Grange, Neven, & Alverdy, 2001). This surgery can be performed either by open incision or with a laparoscope. The laparoscopic method involves using a slender tubular endoscope and inserting it through an incision in the abdominal wall to perform the procedure. This method is advantageous for obese individuals. Due to the high incidence of comorbidities in the severely obese, patients undergoing surgery have increased risk for postoperative cardiopulmonary and wound related complications with open incision. The potential for these complications declines when the surgery is performed with the laparoscope.

Hall, Watts, O'Brien et al. (1990) determined RNYGB was the most effective surgery in comparison with gastrogastostomy and vertical gastroplasty. They studied a group of 310 morbidly obese patients undergoing weight loss surgery. Success was defined as loss of 50% or more of excess weight and the percentages of success were 17%, 48%, and 67%, respectively. While losing 50% of excess weight still leaves 50% of excess weight on these individuals, such substantial loss is enough to effect significant improvement in medical comorbidities and physical well-being. Schauer et al. (2000) investigated the outcomes of a series of 275 laparoscopic RNYGBs and compared the short and long-term outcomes to outcomes of published open procedures. The follow-up period ranged from one to 31 months. The laparoscopic group began an oral diet sooner (mean 1.58 days), had a shorter hospital stay (two days), and returned to work sooner (21 days). Incidence of early major and minor complications
was 3.3% for laparoscopic patients and 27% for those having the open surgery. One person died. Overall, the authors determined that laparoscopic RNYGB is an effective means of weight loss while shortening recovery time and postoperative complications.

Though the Roux-en-Y procedure has been deemed the “gold-standard” in surgical treatment of weight loss, it is not without its risks and complications. Schnieder et al. (2003) reported some of these outcomes and complications. The first complication discussed is gastrointestinal leakage. This is the leading cause of death in bariatric patients, though it is relatively rare and the risk decreases as the surgeons become more practiced. After surgeons have performed 75 to 100 operations the risk is typically no greater than 1.6%. Hemorrhaging, or excessive blood loss, is an uncommon risk associated with RNYGB and when it does occur it is usually at the closure site. Inge et al. (2004b) also reported on complications associated with the surgery. Accidental perforation of the bowel, esophagus, stomach, small intestine, or colon, as well as anesthetic impediments associated with management of a difficult airway, are all common minor complications of surgery. In a laparoscopic procedure, this might lead to a conversion to an open procedure to manage the problem.

In addition to complications during the surgery, postoperative complications are also possible. These include respiratory insufficiency, pneumonia and wound infection. Inge et al. (2004b) reported a 5% mortality risk associated with these complications and go on to discuss late complications, those occurring further out after surgery, including dehydration, nutritional deficiencies, dumping syndrome and internal hernia. All of these risks and consequences need to be taken into consideration and dealt with carefully when considering Roux-en-Y treatment for morbid obesity.
Outcomes of Bariatric Surgery

Adults.

Aside from the medical and weight loss aspects of obesity surgery there are other psychological and quality of life indications involved. While related topics are being studied currently, there is very little data available on psychosocial functioning after bariatric surgery. Further, of the literature that is available, it is mostly focused on adults. Dymek, le Grange, Neven, & Alverdy (2001) completed a study investigating several of these areas. Their sample consisted of 32 morbidly obese patients who underwent RNYGB surgery at the University of Chicago Hospitals between November 1998 and March 1999. Eighty one percent of the participants were female and the mean age was 39.1 years old. Individuals received a packet of questionnaires prior to surgery, one to three weeks post-surgery, and approximately six months post-surgery. Among the scales included in the packets were the SF-36 Health Survey and the Rosenberg Self-Esteem Scale. First, the sample showed substantial weight loss after surgery. The authors report significant improvement in most areas of health related quality of life right after surgery, including general health, vitality, and mental health subscales. By six months post-surgery the participants showed significant improvement on physical functioning, role-physical, bodily pain, vitality, social functioning and mental health. The data collected on this group of subjects indicates significant improvement in self-esteem following the surgery. All of the findings from this study are positive indicators for weight loss surgery.

Adami, Meneghelli, Bressani, & Scopinaro (1999) assessed body image in obese adults both prior to surgery, and three years post when their weight had stabilized. They studied a group of 21 women and nine men, ranging in age from 21 to 56 years old undergoing biliopancreatic diversion. Prior to surgery the patients completed the Eating Disorders Inventory...
(EDI), the Body Shape Questionnaire (BSQ), and the Body Attitude Questionnaire (BAQ). The patients normalized, or nearly normalized (the authors do not offer a definition of “normalized”) their weight within the first year after surgery and maintained their reduced body weight until the time of the study, three years after surgery. A group of never obese individuals matched for age and gender served as controls. At follow up the authors found several things. First, prior to surgery the EDI body dissatisfaction, the BSQ, and the BAQ were significantly different from the scores of the control group. All patients’ experienced highly agreeable weight loss within the first year after surgery and at three years post surgery, when weight had been stable for two years, other significant changes had occurred, as well. Significant decreases in the EDI body dissatisfaction score and BAQ feeling fat and lower body fatness score were recorded. The values on those scales became very similar to the values of the controls. The BAQ attractiveness score increased to a level similar to the controls’. Finally, the BAQ strength and fitness score stayed the same postoperatively, at a level nearly identical to the control groups’. Bocchieri, Meana, & Fisher (2002) reviewed the literature on psychosocial outcomes of surgery for morbid obesity and found a variety of results. In all, they believe the findings to be inconsistent, with a deficit in controlled comparisons and standardized measures designed specifically to measure the hypothesized psychosocial effects.

Adolescents.

All of the research above, discussing the effectiveness and the risks of bariatric surgery is based on surgeries performed on adult obese individuals. This type of surgery on adolescents is a newer procedure and much less researched. Therefore, much less is known about its benefits and consequences on this population. Inge et al. (2004c) reported that the surgery results in weight loss and improvement of comorbidities in adults, and early, limited reports suggest this is
true for adolescents as well. However, the authors acknowledged that a gap exists between current knowledge and the long-term effectiveness of the surgery and any potentially aversive effects. The medical concerns lie in the surgery induced decreased absorption and limited intake of nutrients, which could be detrimental to patients at a young age. In addition, it is unknown how these dramatic changes in weight will affect other areas of life such as self-esteem, body image and relationships. It is recognized that while bariatric surgery has been shown effective for adults, even with the highly selective patient criteria, the specific guidelines cannot simply be transferred down to adolescents (Inge et al., 2004b). Adolescents have unique psychological, metabolic and developmental needs that warrant careful selection and multidisciplinary treatment. Only continued study of this population will provide the experience and knowledge necessary to best treat obese adolescents.

Capella & Capella (2003) reported on a group of 19 adolescents, ages 13 to 17, which underwent a form of gastric bypass combining the vertical banded gastroplasty with a Roux-en-Y gastric bypass between May 1990 and August 2001. They received a written or oral questionnaire at least three years after surgery. The results of the questionnaire from all patients contacted were “overwhelmingly positive” (pg 829). This sample included no mortality or serious morbidity following surgery. Dolan (2004) was interested in comparing laparoscopic adjustable gastric banding in adults and adolescents. She studied data collected prospectively on weight loss surgery patients since 1996. Seventeen adolescent patients less than 20 years old at the time of surgery were compared with patients ranging in age from 23 to 70 years old matched for sex and BMI. The author found no significant differences in weight loss or in complications. The author concluded that the laparoscopic adjustable gastric banding is as effective in adolescents as it is in adults.
Soper (1975) reviewed reports of 25 patients, under the age of 20 years old who had undergone gastric bypass or gastroplasty. Eighteen of the patients considered genetically normally obese averaged 15% weight loss six months after surgery and a 25% weight loss 36 months after surgery. Seven of the patients were younger and had Prader-Willi syndrome and six of those children lost weight post-operatively. The author reports that the procedures were performed with acceptable morbidity and no mortality. There was no interruption in growth in height and no metabolic problems were encountered after surgery. Soper concluded that gastric bypass is a safe and effective method of controlling body weight in morbidly obese children and adolescents.

Rand & MacGregor (1994) investigated a group of 34 adolescents (27 women, 7 men) ranging in age from 11 to 19 years at the time of surgery. Patients received either the Roux-en-Y procedure (n = 30) or the vertical banded gastroplasty (n = 4) between January 1979 and December 1990. The study measure was administered, on average, six years post surgery and consisted of a 30 minute phone interview including questions about current weight, appearance, medical compliance, eating behavior, food choices, dieting, exercise, occupation, social and emotional adjustment, psychosocial changes post surgery and evaluation of surgery. In the area of appearance and well-being 82% of patients considered themselves attractive post-surgery compared to 94% feeling unattractive before surgery. Only 12% continued to feel unattractive. Seventy four percent of patients reported feeling less embarrassed than before surgery, while 12% reported feeling more embarrassed. Eighty five percent of patients reported themselves to be in good spirits daily and that they were in better spirits now than before the surgery. Another 85% of patients said they would definitely have the procedure done again, 9% said probably, and 6% said they would not. In response to an open-ended question concerning the best things that
had happened since surgery, as a group responses indicated that surgery had improved their feelings about themselves, increased their self-confidence, made them feel more attractive, and facilitated their social relationship (e.g., dating and marriage). Responses to questions about the worst part of surgery were more idiosyncratic. Most frequently mentioned were the loose skin resulting from the weight loss and the surgical scar. Some patients regained their weight and had subsequent health problems. Some problems reported by only one or two patients included: embarrassment because the surgery was necessary, being ridiculed for having the surgery, throwing up, being too young at the time of surgery, and losing a boyfriend who preferred heavy women. The findings of this study were more qualitative and gave a more individualized view of outcomes of the surgery, specifically on adolescents.

Obesity across America has been an increasing problem over the past several decades. Not only does the extra weight create a problem for the individual, but there are other obesity related consequences including various medical comorbidities, individual medical expenses as well as costs to the country as a whole, and related psychological distress. In order to reduce and or eliminate the extra pounds several weight loss treatments have been created and tried. Bariatric surgery seems to be the method that results in the most significant and permanent weight loss. While surgery has been performed for many years now, there is limited documented evidence on its effectiveness in adults, and even less available for adolescents. In addition to the medical effectiveness, it is important to consider how the surgery affects other domains of an individual’s life, including his or her psychological well-being. While this aspect is important to be aware of, there is little information available on the many psychological domains and there is a lot of room for research.
Chapter II
Rationale and Hypotheses

Though bariatric surgery, specifically on adolescents, has been performed occasionally for nearly 30 years, it is now becoming more popular and occurring on a more regular basis. Cincinnati Children's Hospital Medical Center is one of the first strictly children's facilities in the country with surgeons performing the procedure specifically on adolescents. With input from an ethicist, a gastroenterologist, a pulminologist, an endocrinologist, a nurse, a psychologist and an adolescent medicine physician, guidelines for patient selection, evaluation, and bariatric surgical management were created and applied. The first surgery was performed in April of 2004 and the program has been running steadily, operating on an average of two to three patients a month. With such a novel procedure there is lot that is unknown about the effects of the surgery on weight loss, general health, and psychological well-being. The psychology department at Children's Hospital is working closely with the families involved in the bariatric program and studying many facets of the mental health of these adolescents. There is a study currently in place through the psychology department that is investigating the psychosocial health and quality of life in adolescents who are pursing bariatric surgery. The research is being conducted to identify and describe psychosocial health and quality of life experienced by those adolescents who are overweight and pursuing surgical weight loss, and looking at the changes in those particular factors associated with the weight reduction.

The proposed study is intended to investigate two related areas of psychosocial functioning that are currently lacking in the literature, especially in the adolescent bariatric surgery literature. Specifically, the adolescents' body efficacy, or their beliefs about what their
bodies are and are not able to do, and their body esteem or body image, the way their beliefs about how they look make them feel about them are of interest.

Lewis, Marcus, Pate, & Dunn (2002) defined self-efficacy for physical activity as one’s confidence regarding participating in specific types of physical activity, or specific amounts of physical activity, or both. They also stated that there have been many correlations found between physical activity and physical self-efficacy. However, there is essentially no available research on physical self-efficacy in obese individuals, especially obese adolescents. Given the limited available literature, it is assumed that physical self-efficacy is lower in obese adolescents. This may be due to a history of criticisms during physical activity leading to decreased confidence in one’s actual ability to perform and/or a physical inability to participate because of shape and size leading to a decreased confidence in ability.

Body image, or body esteem, is an individual’s psychological experience of the appearance and function of his or her body and is one aspect of an individual’s mental representation of him or her self. While there are conflicting outcomes in the research on self-esteem and obesity, the research on body image of obese individuals has proven clearer. In regards to the adult obese population, Friedman, Reichmann, Costanzo, & Musante (2002) reported that obese individuals overestimate or distort the size of their body more, are more dissatisfied or preoccupied with their appearance, and tend to avoid more social interactions because of their appearance than do non-overweight individuals. A more specific study by Adami, Gandolfo, Campostano, Meneghelli, Ravera, & Scopinaro (1998) investigated body image in severely obese patients and patients who used to be obese, but had achieved normal weight after weight loss surgery. They found that in the obese patients, affective and cognitive aspects of body image are considerably impaired. Further, the stable normalization of body
weight and shape sharply improves the obese patient’s body image. In the limited adolescent literature, Barton et al. (2004) studied adolescents at the start of a weight loss camp with subsequent weight loss during camp and found that the campers showed improvement on measures of perceived self-competence and body shape satisfaction. These findings appear to be positive indicators for individuals, including adolescents, receiving bariatric surgery, in that it would be expected that they would have lower body image to begin with but improvements in their body image would result as they lose weight post-surgery.

Though this procedure has been around for awhile operations are being performed in larger volumes now than in the past. While facilities do a fine job ensuring patients receiving surgery are appropriate, very little is known about the outcomes of the surgery, both mental and physical. Every aspect of these adolescents’ subsequent development needs to be closely monitored and evaluated to ensure that the patients are remaining healthy and to determine if they perceive an improved quality of life, and why they are feeling the way they are. The limited literature talks in terms of obese and normal sized individuals. However, many individuals undergoing bariatric surgery, while losing significant amounts of weight, will never reach the normal weight range or ever be thin. This issue has yet to be addressed in the literature and is very important in the population being studied. It is assumed that significant changes will occur in these adolescents having surgery, but what do these changes mean? This research area is so vast and yet unexplored that it provides a great opportunity for study and learning.

Regardless of anything else, these adolescents’ bodies are undergoing dramatic change and it is of interest to find out how the patients view their new bodies and what their bodies can or cannot now do. This particular area of study proves to be a gap in the current literature. While the medical comorbidities of obesity are important and necessary to address, so are the
psychological consequences. However, in the recent move towards bariatric surgery as a
treatment for morbidly obese individuals the psychological outcomes have remained somewhat
neglected. While there are countless psychological constructs that could be measured, the
present study is focusing only how adolescents think and feel about their bodies after a presumed
dramatic weight change. The resulting weight loss, BMIs, and attitudes towards their bodies
may mediate or moderate other psychological variables the adolescents are experiencing and are
an important starting point in the massive amount of research that can be conducted with this
population.

The proposed study is designed to test three null hypotheses.

• There are no changes in how these adolescents view their bodies and how they feel about
  their bodies from the time before surgery until six months following surgery.

• There are no changes in what these adolescents believe their bodies can do, when
  comparing their abilities before surgery to those abilities six months after surgery.

• There are no correlations between the amount of weight loss and subsequent BMI and the
  resulting body-esteem and body-efficacy scores.
Chapter III

Method

Participants  The participants in this study will include 24 adolescent between the ages of 13 and 17 receiving laparoscopic or open Roux-en-Y bariatric surgery at Cincinnati Children’s Hospital Medical Center. To be considered for this surgery and adolescent must be obese and have a Body Mass Index ≥ 40. Body Mass Index is measured using the adolescent’s height in meters and weight, measured to the nearest 100 grams (BMI: kg/m²). These values will be determined using age- (to the nearest month) and sex-specific median, standard deviation, and power of the Box-Cox transformation based on national norms from the Centers for Disease Control.

The individuals will have already been met by a multidisciplinary team and approved for the surgery. Individuals can be of either sex and can potentially come from any area of the country. The adolescents must have the ability to understand the questionnaires, though they do not necessarily have to read them themselves.

Measures  In order to measure each adolescent’s body-esteem and body efficacy the following measures have been chosen. Each adolescent will fill out a portion of the Impact of Weight on Quality of Life for Kids [(IWQL-Kids), Kolotkin, Zeller, Modi, Sams, Poanichka, Yanovski, Bell, Maahs, Gonzales de Serna, & Roehrig, in press], a portion of the Children’s Physical Self-Perception Profile [(C-PSPP) Whitehead, 1995], and each adolescent will be shown the Stunkard (1983) Figure Rating Scale and asked questions about self-perception.

The Impact of Weight on Quality of Life- Kids version (IWQL-Kids) is a new measure that assesses the impact of an adolescents’ weight on his or her quality of life (See Appendix D). The measure consists of 73 items that were developed, pilot tested and administered to 642
adolescents, aged 11 to 19, who were recruited from weight loss studies and community samples. From the initial items, 27 items were taken to comprise four factors; Physical Comfort, Body Esteem, Social Life and Family Relations. These four factors account for 71% of the variance. The measure exhibited excellent psychometric properties. Internal consistency ranged from .88 to .96. Convergent validity (r = .76, p < .0001) was shown, with strong correlations between the IWQL-Kids total score and the Pediatric Quality of Life scale. The measure is sensitive, with significant differences appearing across BMI groups and between the clinical and community samples. For this study, only the Body Esteem, consisting of nine items, scale will be analyzed. The Body-Esteem scale reflects an adolescent’s preoccupation with weight and appearance in addition to how he or she feels about his or her self and body. This scale has an eigenvalue of 13.7 and accounts for 51% of variance. Internal consistency coefficients were reported as strong and factor intercorrelations were positive and ranged from .32 to .65.

The Physical Self Perception Profile, Children’s edition (C-PSPP) is a 32-item measure created to assess physical self-worth and four subdomains (See Appendix E). These include sports competence, condition/stamina, body attractiveness, and physical strength. Whitehead (1995) tested this measure on 505 students and the results supported the reliability of the construct and its concurrent validity. Analysis showed that the scales were moderately correlated with each other, with rs ranging from .33 to .66. The only exception was a .77 correlation between the Physical Condition Adequacy and Sport/Athletic Competence for a specific grade of girls. Reliability coefficients for the scales ranged from .80 to .88 for males, and .86 to .90 for females. Scores on the four subscales clearly discriminated between the extreme groups identified by corroborating individuals.
The final assessment of body image will be conducted using Stunkard’s Figure Rating Scale. This measure consists of nine silhouettes ranging in size from very underweight to very overweight (See Appendix F). Typically, respondents are asked to choose which one looks most like them now and which one they would prefer to look like. The difference between the two, if there is one, is interpreted as a measure of body dissatisfaction. At the six month follow-up, participants will again be asked to choose 1) which figure looks most like him or her, 2) which one he or she would most like to look like, and for the first time 3) which figure used to look most like him or her, prior to surgery. This measure was developed by Albert Stunkard in 1983. The measure was developed to determine the weight status of parents of adoptees who were involved in a study being conducted at the time. The measure was novel at the time and no investigation of psychometric properties was performed, though the measure has continued to be widely used and accepted. In 2001 Bulik, Wade, Heath, Martin, Stunkard, and Eaves conducted a study with the intention of establishing BMI norms for the scale and to determine the effectiveness of the figural stimuli to identify individuals as obese or thin. The subjects of this study were 16,728 Caucasian females and 11,366 Caucasian males, ages 18 to 100. The authors report that the scale appears to be significantly and highly correlated with measured percentage overweight (r= 0.79) and a reliable predictor of obesity. In this sample the polyserial correlations between the log of BMI and the figural stimuli were 0.81 for women and 0.73 for men. The measure also appears to be valuable in correctly identifying individuals as obese (0.93 for women and 0.88 for men) or thin (0.87 for women and 0.88 for men). One limitation of this study is the entirely Caucasian sample.

In an attempt to develop a culturally relevant body image instrument Pulvers, Lee, Kaur, Mayo, Fitzgibbon, Jeffries, Butler, Hou, & Ahluwalia (2004) had 35 African Americans
complete body image measures and evaluate their cultural relevance. The study showed that 40% of the women believed the Stunkard scale resembled African Americans while the men 40% believed the figures to be no particular race. The findings from this study imply that the African Americans sampled were able to identify as well with the Stunkard figures as other measures and some believed the figures to be African American. This suggests that the measure is adequate for use in this population being studied.

**Procedure** Participants will be recruited for the study by the Principle Investigator (PI) at the time of the family’s first visit to the hospital. The PI will explain the procedure and the value of the study and be available to answer any questions. Participants will be met at their baseline data collection visit by a member of the PI’s research team and the consent form will be reviewed (see Appendices A & B). As all participants are minors, consent will be obtained from the parent and assent will be given from the patient. The initial data collection session will be conducted in a private room in the Behavioral Medicine Division. All procedures will be explained to the adolescent and his or her caregiver(s) and the research assistant will be available throughout to answer any questions. One or two research assistants will administer the packet of measures to the adolescent and his or her caregiver(s), reading the directions of each individual measure to the participants (see Appendix C). All measures are self-report and will be completed by the appropriate individual. However, if a participant cannot read the information but is capable of understanding the questions, the questionnaires will be read to the participant (the research team will be keeping track of whether or not questionnaires are read to a participant). After the questionnaires have been completed the participants will sign a receipt and receive compensations for their time. Participation in the baseline data collection pays the adolescent $45 and $30 to the caregiver(s).
Prior to the patients' scheduled six month follow-up in the clinic the family will be contacted by a member of the research team and the second data collection session will be scheduled. In this session another packet of questionnaires will be administered to both the patient and his or her caregiver(s). This data collection is also held in a private treatment room in the Behavioral Medicine Division at CCHMC. The research assistants will again be present administering the questionnaires and available to answer any questions. At the completion of the second visit the patient and caregiver(s) will sign another receipt, acknowledging receiving the $60 offered to the adolescent and the $40 offered to the parent for their time and participation. Should a patient and/or family not return to the hospital for a six month follow-up, a member of the research team will contact the family and make arrangements to send the measures via Federal Express to the family. A member of the research team will then call the family, review the measures, and answer any questions. The family will then return the measures in the pre-paid self-addressed Federal Express envelope and be compensated upon completion.
Chapter IV

Proposed Analyses

Change in adolescent’s view of their bodies and how they feel about their bodies six months after surgery will be measured the Stunkard Figural Stimuli scale, the body-esteem scale of the Impact of Weight on Quality of Life-Kids (IWQL-Kids) version, and the body attractiveness scale of the Physical Self-Perception Profile, Children’s edition (C-PSPP). Change in what the adolescents believe their bodies can do six months after surgery will be measured using the sports competence, condition/stamina, and physical strength scales of the C-PSPP. The correlation between individual BMIs and the scores obtained on the measures above will be investigated using each adolescent’s height and weight and his or her scores on the measures.

Repeated measures t-tests will be used to compare the mean scores on the above mentioned measures prior to surgery to the sample means six months after surgery. Given the small sample size in this study, Cohen’s (1992) power tables suggest a large effect size as power to detect effects approaches .80.

Each hypothesis will be tested individually. The first hypothesis states there will be no change in how these adolescents view their bodies and how they feel about their bodies from the time before surgery until six months following the surgery. This belief will be tested using the body-esteem scale from the IWQOL-Kids and the body attractiveness scale from the C-PSPP. Sample means from each of these measures will be collected at baseline and through a repeated measures t-test will be compared to the means of these scales at the six month follow-up. The hypothesis will be tested against an alpha level of .01. The Stunkard Figure Rating Scale will also be measured to test this hypothesis. For this measure, each figure is assigned a numerical
value and the difference between how the patients look and how they would like to look is calculated as a discrepancy score. The means of these scores will be calculated and used in a repeated measures t-test, as well. Also, at the six month follow-up, in addition to being asked the first two questions, the patients will be asked a third question about how they looked before surgery. This is more of an investigative and qualitative question and will not be analyzed.

The second hypothesis states that there will be no change in what these adolescents believe their bodies can do, when comparing their abilities before surgery to those abilities six months after surgery. This hypothesis will be tested using the condition/stamina scale, sports competence scale, and physical strength scale from the C-PSPP. Means on each of these scales will be collected pre-surgery and with a repeated measures t-test compared to means collected at six month follow-up. The hypothesis will be tested against an alpha level of .01.

The third hypothesis states there will be no correlation between the amount of weight loss and subsequent BMI and the resulting body-esteem and body-efficacy scores. This belief will be tested by running a simple bivariate correlation between the amount of weight lost from pre-surgery to six month follow-up and the change in scores from baseline to six month follow-up.

In addition, there will be a post-hoc comparison of gender and its effects on these adolescent’s feelings about how their bodies look and the things it can and cannot do. First, an overall F-ration will be calculated to determine if there are any significant differences between the males and the females. If it is found that there is, it will be investigated to determine on which constructs the groups differ.
References


Friedman, K. E., Reichmann, S. K., Costanzo, P. R., Musante, G. J. (2002). Body image partially mediates the relationship between obesity and psychological distress, *Obesity Research*, 10 (1), 33-41.


Appendix A

Outlook Consent form

CINCINNATI CHILDREN'S HOSPITAL MEDICAL CENTER
CONSENT TO PARTICIPATE IN A RESEARCH STUDY

STUDY TITLE: Observing Unique Teens Living With Obesity: Outcomes and Knowledge (The OUTLOOK Study)

SPONSOR NAME: National Institutes of Health

CCHMC IRB # 05-04-34

IRB APPROVAL STAMP:

INVESTIGATOR INFORMATION:
Meg Zeller, Ph.D.
(513) 636-2712 (phone)
(513) 636-4200 (On-call service)

Subject Name: __________________________ Date of Birth: ______/_____/______

Throughout this document, references to “You” may stand for either the research study subject or for the parents or legal guardians of the research study subject if the subject is under 18 years of age or otherwise unable to legally give informed consent to participate in the research study. The signature(s) at the end will clarify whether the research study subject is signing this consent form on their own behalf or via a legal guardian or legal personal representative.

INTRODUCTION:
You have been asked to participate in a research study. Before agreeing to participate in this study, it is important that you read and understand the following explanation. It describes, in words that can be understood by a lay person, the purpose, procedures, benefits, risks and discomforts of the study and the precautions that will be taken. It also describes the alternatives available and the right to withdraw from the study at any time. No guarantee or assurance can be made as to the results of the study. Also, participation in the research study is completely voluntary. Refusal to participate will involve no penalty or loss of benefits to which you are otherwise entitled. You may withdraw from the study at any time without penalty.

Version 2 - June 2006
WHY IS THIS RESEARCH BEING DONE?
The main purposes of this study are to describe: 1) psychosocial health and quality of life experienced by adolescents who are overweight and their families, 2) the changes in these factors over time associated with weight change. The researchers are interested in your viewpoint and have called this the "Outlook Study".

WHY HAVE YOU BEEN ASKED TO TAKE PART IN THIS RESEARCH STUDY?
You are being asked to take part in this research study because you were referred to the Comprehensive Weight Management Center (CWMC) or the HealthWorksI program of Cincinnati Children's Hospital Medical Center.

WHO SHOULD NOT BE IN THE RESEARCH STUDY?
Only adolescents and families referred to the CWMC or HealthWorksI program with a Body Mass Index ≥ 40 kg/m² (a weight to height ratio) are eligible to participate. Adolescents under age 13 and adolescents older than 17 who were referred to these programs are not eligible to participate in this research study.

HOW LONG WILL YOU BE IN THE RESEARCH STUDY?
Adolescents and their primary caregivers will be in the research study for approximately 1 year. This consent, unless you choose to withdraw it, shall remain in effect until the end of the research study. The researcher may decide to take you off this research study at any time.

WHO IS CONDUCTING THE RESEARCH STUDY?
The study is directed by Dr. Meg Zeller, a clinical psychologist and researcher at Cincinnati Children's Hospital Medical Center. This study is sponsored by the National Institutes of Health.

HOW MANY PEOPLE WILL TAKE PART IN THE RESEARCH STUDY?
Approximately 48 adolescents and their families will take part in this study at Cincinnati Children's Hospital Medical Center

WHAT IS INVOLVED IN THE RESEARCH STUDY?
If you agree that you will participate in this study you will be asked to complete questionnaires and height/weight measurements will be obtained from all participants. At the first or baseline visit, the adolescent will complete 11 questionnaires. Each parent will complete 8 questionnaires. Height/weight measurements will be completed. It is understood that these assessments will require approximately 2½ hours for the adolescent and 2 hours for a parent or caregiver. Parents and adolescents will complete questionnaires in separate testing areas.

Follow-up visits will be scheduled at 6- and 12-months following the baseline visit. At these follow-up visits, each parent and the adolescent will complete all the same questionnaires and again height/weight measurements will be completed. Therefore, it is understood that the 6- and 12-month assessments will require approximately 2½ hours for the adolescent and 2 hours for a parent or caregiver. All assessments will be conducted in the Division of Psychology at Cincinnati Children's Hospital Medical Center and will be scheduled at a time convenient for your family.

In addition, it is understood that the adolescent's medical record will be reviewed for medical information related to his/her obesity-related health status, including the presence/absence of Type II diabetes, insulin resistance, sleep apnea, hypertension, and dyslipidemia, all which are routinely assessed as part of the medical care of the CWMC or HealthworksI programs.

Version 2 - June 2006
WHAT ARE THE RISKS AND DISCOMFORTS OF THE RESEARCH STUDY?
There are minimal risks to adolescent or adult participants in this study. All questionnaires and interviews have been used in research without any reported negative effects. If problems should occur, you will be encouraged to discontinue any of the procedures that cause you to feel uncomfortable in any way. Dr. Zeller will meet with you to discuss your concerns, and if appropriate, assist in making appropriate clinical referrals. In addition, given the length of time needed to complete questionnaires (i.e., $21/4$ hours at each visit) participants may become fatigued. Participants will be allowed brief rest breaks at the end of each hour. Another risk may be loss of confidentiality. Please see the section of this consent form entitled How Will Information About You Be Kept Private And Confidential to learn steps that will be taken to reduce the risk of loss of confidentiality. Finally, there may be unknown or unforeseen risks associated with study participation.

ARE THERE DIRECT BENEFITS TO TAKING PART IN THE RESEARCH STUDY?
If you agree to take part in this research study, there are no direct benefits to you. However, the information that the researchers acquire from this study will allow professionals to have a better understanding of the psychosocial health issues that face adolescents who are overweight and their families. Through your efforts and honest participation, researchers hope to influence the manner in which health professionals work with families to provide more optimal care.

WHAT OTHER CHOICES FOR CARE ARE THERE?
You may choose not to participate in the study and this will not affect your adolescent’s care at Cincinnati Children’s Hospital Medical Center.

HOW WILL INFORMATION ABOUT YOU BE KEPT PRIVATE AND CONFIDENTIAL?
Every effort will be made to maintain the confidentiality of your medical and research information (“Protected Health Information” or “PHI”), consisting of your responses to questionnaires, your and height and weight measurements, and medical information related to your adolescent’s treatment at the CWMC or Healthworks! program.

Protected Health Information is defined as health information, whether verbal or recorded in any form (such as on a piece of paper or entered in a computer), that identifies you as an individual or offers a reasonable basis to believe that the information could be used to identify you.

By signing this consent form you are giving permission for representatives of the Cincinnati Children’s Hospital Medical Center (“CCHMC”), the Investigator and CCHMC employees involved with the research study including the Institutional Review Board and the Office for Research Compliance, and any sponsoring company or their appointed agent as well as the National Institutes of Health to be allowed to inspect sections of your medical and research records related to this study. The information from the research study may be published; however, you will not be identified in such publication. The publication will not contain information about you that would enable someone to determine your identity as a research participant without your authorization.

Cincinnati Children’s Hospital Medical Center and/or the Investigator will take the following precautionary measures to protect your privacy and confidentiality of your research and/or medical records. All questionnaires and the results of the study will be treated in strict confidence. Participants will remain anonymous as all information is coded to a number, not to you or your adolescent’s name. The information will be kept in locked cabinets in the Principal Investigators’ offices at Children’s Hospital Medical Center. The names associated with the identifying numbers will be kept in a locked cabinet separate from the questionnaires.
A copy of this consent form will be included in your medical record. You will be registered in the Children's Hospital Medical Center's computer system as a research subject which may be beneficial for future clinical care.

USE AND DISCLOSURE OF YOUR PROTECTED HEALTH INFORMATION
The Protected Health Information described in the section above will be used / disclosed for the purpose of research by CHMCC to the other persons or entities identified above. "Use" of an individual's health information is defined as the sharing, examination or analysis (break down) of the information that is collected and maintained for the length of the research study. "Disclosure" of an individual's health information is defined as the release, transfer, providing access to, or to reveal in any other manner, the information outside the persons or entity holding the information as described in the section "How Will Information About You Be Kept Private And Confidential" in this consent form. Once your Protected Health Information is disclosed, the information may be subject to re-disclosure and may no longer be protected by the federal privacy regulations.

AVAILABILITY OF INFORMATION? If you have questions or would like more information about the study you may contact Dr. Meg Zeller (513-636-2712).

WHAT ARE YOUR COSTS TO BE IN THIS STUDY?
There are no costs for participating in this research study. You will be responsible for the usual costs your adolescent's medical care, but you will not be charged any additional costs for participation in this study.

WILL YOU BE PAID TO PARTICIPATE IN THIS RESEARCH STUDY?
Participating adolescents will be compensated with a cash payment of $45, and parents $30 (for a total of $75) upon completion of the first study visit. Participating adolescents will be compensated with a cash payment of $60, and parents $40 (for a total of $100) upon completion of the 6-month follow-up study visit. Participating adolescents will be compensated with a cash payment of $75, and parents $50 (for a total of $125) upon completion of the 12-month follow-up visit. The total combined compensation is $300 for adolescents and parents who complete all three study visits.

WHAT ARE YOUR RIGHTS AS A PARTICIPANT?
Your participation in this study is completely voluntary. You may choose either to take part or not to take part in this research study. Your decision whether or not to participate will not result in any penalty or loss of benefits to you and the standard medical care for your condition will remain available to you. If you decide to take part in this research study, you are free to withdraw your consent and discontinue participation in this research study at any time. Leaving the study will not result in any penalty or loss of benefits to you.

You may revoke (choose to withdraw) this Authorization as provided under the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") at any time after you have signed it by providing Dr. Meg Zeller (Cincinnati Children's Hospital Medical Center, Mail Location D-3015) with a written statement that you wish to withdraw this Authorization. Your withdrawal of this Authorization will be effective immediately and your Protected Health Information can no longer be used/disclosed for research purposes by CCHMC and the other persons or entities that are identified in the "Use or Disclosure of Your Protected Health Information" section of this consent, except to the extent that CCHMC and/or the other persons or entities identified above have already taken action in reliance upon your consent. In addition, your Protected Health Information may continue to be used/disclosed to preserve the integrity of this research study. The investigators will tell you about significant new findings developed during the course of the research and new information that may affect your health, welfare, or willingness to stay in this study.
study. If you are an employee at Cincinnati Children's Hospital Medical Center, refusal to participate or withdrawal from the study will not jeopardize any of your employee rights, benefits, or opportunities.

If you have questions about the study, you will have a chance to talk to one of the study staff or your regular doctor. Do not sign this form unless you have had the chance to ask questions and have received satisfactory answers. Nothing in this consent form waives any legal rights you may have nor does it release the investigator, the sponsor, the Institution, or its agents from liability for negligence. For further information about your rights, please see CCHMC Notice of Privacy Practices.

ABILITY TO CONDITION TREATMENT ON PARTICIPATION IN THIS STUDY
You have a right to refuse to sign this consent to use/disclose your Protected Health Information for research purposes. If you refuse to sign this consent, your rights concerning treatment, payment for services, enrollment in a health plan or eligibility for benefits will not be affected.

WHO DO YOU CALL IF YOU HAVE QUESTIONS OR PROBLEMS?
For questions about this research study or to report a research-related injury, you can contact the researcher, Dr. Meg Zeller at 513-636-2712. (Researchers are available to answer any questions you may have about the research at any time.) If you have general questions about your rights as a research participant in this research study, you can call the Cincinnati Children's Hospital Medical Center Institutional Review Board at 513-636-8039.

WITNESSING AND SIGNATURES
I have read the information given above. The investigator or his/her designee have personally discussed with me the research study and have answered my questions. I am aware that, like in any research, the investigators cannot always predict what may happen or possibly go wrong. I have been given sufficient time to consider if I (or my adolescent) should participate in this study. I hereby consent for myself (or my adolescent) to take part in this study as a research study subject.

________________ Date: ____________
Adolescent's signature indicating assent

________________ Date: ____________
Parent/Legal Guardian (Signature)

________________ Date: ____________
Parent/Legal Guardian (Signature)

I have witnessed the voluntary signing of this document by the research subject, or the legally authorized representative of the research subject.

________________ Date: ____________
Investigator or specific Individual who has been designated to obtain consent (Signature)

________________ Date: ____________
Investigator (Signature)

This research study and consent form have been reviewed and approved by the Cincinnati Children's Hospital Medical Center Institutional Review Board (telephone number 513-636-8039).

Version 2 - June 2006
Appendix B

CReff Consent Form

CINCINNATI CHILDREN'S HOSPITAL MEDICAL CENTER
CONSENT TO PARTICIPATE IN A RESEARCH STUDY

STUDY TITLE: Psychosocial Health and Quality of Life in Adolescents Pursuing Bariatric Surgery

CCHMC IRB # 04-1-53 IRB Approval Date: 03/04/04

Principal Investigator:
Meg Zeller, Ph.D.
(513) 736-4995 (24-hour pager)
(513) 636-2712 (phone)

Subject Name: Date of Birth: __________

Throughout this document, references to "You" may stand for either the research study subject or for the parents or legal guardians of the research study subject if the subject is under 18 years of age or otherwise unable to legally give informed consent to participate in the research study. The signature(s) at the end will clarify whether the research study subject is signing this consent form on their own behalf or via a legal guardian or legal personal representative.

INTRODUCTION:
You have been asked to participate in a research study. Before agreeing to participate in this study, it is important that you read and understand the following explanation. It describes, in words that can be understood by a lay person, the purpose, procedures, benefits, risks and discomforts of the study and the precautions that will be taken. It also describes the alternatives available and the right to withdraw from the study at any time. No guarantee or assurance can be made as to the results of the study. Also, participation in the research study is completely voluntary. Refusal to participate will involve no penalty or loss of benefits to which you are otherwise entitled. You may withdraw from the study at any time without penalty.

WHY IS THIS RESEARCH BEING DONE?
The aims of the present study are to describe: 1) psychosocial health and quality of life experienced by adolescents who are overweight and pursuing surgical weight loss, 2) the changes in these factors associated with weight reduction.

WHY HAVE YOU BEEN ASKED TO TAKE PART IN THIS RESEARCH STUDY?
You are being asked to take part in this research study because your adolescent has been referred to the Comprehensive Weight Management Program at Cincinnati Children's Hospital Medical Center.

WHO SHOULD NOT BE IN THE RESEARCH STUDY?
Only adolescents with who are referred to the Comprehensive Weight Management Program are eligible to participate. Children under age 13 and adolescents older than 18 who are referred to the Comprehensive Weight Management Program are not eligible to participate in this research study.
HOW LONG WILL YOU BE IN THE RESEARCH STUDY?
Surgery patients and their primary caregivers will be in the research study for approximately twenty-four months after their surgery. This consent, unless you choose to withdraw it, shall remain in effect until the end of the research study. The researcher may decide to take you off this research study at any time.

WHO IS CONDUCTING THE RESEARCH STUDY?
The study is directed by Dr. Meg Zeller, a researcher at Cincinnati Children's Hospital Medical Center. Medical supervision for the study is provided by Dr. Stephen Daniels and Dr. Thomas Inge. This study being sponsored in part by the General Clinical Research Centers Program, National Center for Research Resources of the National Institutes of Health.

HOW MANY PEOPLE WILL TAKE PART IN THE RESEARCH STUDY?
Approximately 30 adolescents will take part in this study at Cincinnati Children’s Hospital Medical Center.

WHAT IS INVOLVED IN THE RESEARCH STUDY?
If I agree that I, or my adolescent, will participate in this study we will be asked to complete questionnaires and height/weight measurements will be obtained from myself and my adolescent. At the first visit, I understand that my adolescent will complete 9 questionnaires and I will complete 4 questionnaires. Height/weight measurements will be completed for my adolescent and parent(s). We understand that these assessments will require approximately 25 minutes for adults and 1 hour for our adolescent. We also agree that our responses to the psychological questionnaires administered as part of my adolescent’s initial evaluation in the CWMP will be included in the present study.

For those who undergo surgery, follow-up visits will be scheduled at 3-, 6-, 12-, 18-, and 24-months post surgery. At these follow-up visits, my adolescent will complete 10 questionnaires and I will complete 4 questionnaires. Height/weight measurements will be completed for my adolescent and parent(s). We understand that these assessments will require approximately 40 minutes for adults and 1½ hours for my adolescent.

All assessments will be conducted In the Division of Psychology at Cincinnati Children’s Hospital Medical Center and will be scheduled at a time convenient for my family. In addition, I understand that my adolescent's medical record will be reviewed for medical information related to my adolescent's treatment at the Comprehensive Weight Management Program.

WHAT ARE THE RISKS AND DISCOMFORTS OF THE RESEARCH STUDY?
There are minimal risks to adolescent or adult participants in this study. All questionnaires and interviews used in this study are standardized and have been used in research without any reported negative effects as asking adolescents and adults about their quality of life and psychological adjustment typically does not result in distress. If problems should occur, you or your adolescent will be encouraged to discontinue any of the procedures that cause you to feel uncomfortable in any way. Dr. Zeller will meet with you to discuss your concerns, and if appropriate, assist in making appropriate clinical referrals. In addition, given the length of time needed to complete questionnaires (i.e., 1½ hours at each visit) participants may become fatigued. Another risk may be loss of confidentiality. Please see the section of this consent form entitled How Will Information About You Be Kept Private And Confidential to learn steps that will be taken to reduce the risk of loss of confidentiality. Finally, there may be unknown or unforeseen risks associated with study participation.
ARE THERE DIRECT BENEFITS TO TAKING PART IN THE RESEARCH STUDY?
If you agree to take part in this research study, there are no direct benefits to you or your adolescent. However, the information that the researchers acquire from this study will allow professionals and parents to have a better understanding of the psychological health issues that are faced by adolescents who are overweight. Through our efforts and honest participation, researchers hope to influence the manner in which health professionals work with families to provide more optimal care.

WHAT OTHER CHOICES FOR CARE ARE THERE?
We may choose not to participate in the study and this will not affect my adolescent's care at Cincinnati Children's Hospital Medical Center.

HOW WILL INFORMATION ABOUT YOU BE KEPT PRIVATE AND CONFIDENTIAL?
Every effort will be made to maintain the confidentiality of your medical and research information ("Protected Health Information" or "PHI"), consisting of you and your adolescent's responses to questionnaires, you and your adolescent's height and weight measurements, and medical information related to your adolescent's treatment at the Comprehensive Weight Management Program.

Protected Health Information is defined as health Information, whether verbal or recorded in any form (such as on a piece of paper or entered in a computer), that identifies you as an individual or offers a reasonable basis to believe that the information could be used to identify you.

By signing this consent form you are giving permission for representatives of the Cincinnati Children's Hospital Medical Center ("CCHMC"), the Investigator and CCHMC employees involved with the research study including the Institutional Review Board and the Office for Research Compliance, and any sponsoring company or their appointed agent to be allowed to inspect sections of your medical and research records related to this study.

The information from the research study may be published; however, you will not be identified in such publication. The publication will not contain information about you that would enable someone to determine your identity as a research participant without your authorization.

Cincinnati Children's Hospital Medical Center and/or the Investigator will take the following precautionary measures to protect your privacy and confidentiality of your research and/or medical records. All questionnaires and the results of the study will be treated in strict confidence. Participants will remain anonymous as all information is coded to a number, not to you or your child's name. The information will be kept in locked cabinets in the Principal Investigators' offices at Children's Hospital Medical Center. The names associated with the identifying numbers will be kept in a locked cabinet separate from the questionnaires. A copy of this consent form will be included in your medical record. You will be registered in the Children's Hospital Medical Center's computer system as a research subject which may be beneficial for future clinical care.

USE AND DISCLOSURE OF YOUR PROTECTED HEALTH INFORMATION
The Protected Health Information described in the section above will be used/disclosed for the purpose of research by CCHMC to the other persons or entities identified above.

"Use" of an individual's health information is defined as the sharing, examination or analysis (break down) of the information that is collected and maintained for the length of the research study.
"Disclosure" of an individual's health information is defined as the release, transfer, providing access to, or to reveal in any other manner, the information outside the persons or entity holding the information as described in the section "How Will Information About You Be Kept Private And Confidential" in this consent form.

Once your Protected Health Information is disclosed, the information may be subject to re-disclosure and may no longer be protected by the federal privacy regulations.

**AVAILABILITY OF INFORMATION?**
If we have questions or would like more information about the study we may contact Dr. Meg Zeller (513-636-2712).

**WHAT ARE YOUR COSTS TO BE IN THIS STUDY?**
There are no costs for participating in this research study. You will be responsible for the usual costs of you or your adolescent's medical care, but you will not be charged any additional costs for participation in this study.

**WILL YOU BE PAID TO PARTICIPATE IN THIS RESEARCH STUDY?**
Participating adolescents will be compensated with a payment of $25 upon completion of each visit. Participating parent(s) will be compensated with a payment of $10 upon completion of each visit.

**WHAT ARE YOUR RIGHTS AS A PARTICIPANT?**
Your participation in this study is completely voluntary. You may choose either to take part or not to take part in this research study. Your decision whether or not to participate will not result in any penalty or loss of benefits to you and the standard medical care for your condition will remain available to you. If you decide to take part in the research study, you are free to withdraw your consent and discontinue participation in this research study at any time. Leaving the study will not result in any penalty or loss of benefits to you.

You may revoke (choose to withdraw) this Authorization as provided under the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") at any time after you have signed it by providing Dr. Meg Zeller (Cincinnati Children's Hospital Medical Center, Mail Location D-3015) with a written statement that you wish to withdraw this Authorization. Your withdrawal of this Authorization will be effective immediately and your Protected Health Information can no longer be used/disclosed for research purposes by CCHMC and the other persons or entities that are identified in the "Use or Disclosure of Your Protected Health Information" section of this consent, except to the extent that CCHMC and/or the other persons or entities identified above have already taken action in reliance upon your consent. In addition, your Protected Health Information may continue to be used/disclosed to preserve the integrity of this research study.

The investigators will tell you about significant new findings developed during the course of the research and new information that may affect your health, welfare, or willingness to stay in this study. If you have questions about the study, you will have a chance to talk to one of the study staff or your regular doctor. Do not sign this form unless you have had the chance to ask questions and have received satisfactory answers. Nothing in this consent form waives any legal rights you may have nor does it release the investigator, the sponsor, the institution, or its agents from liability for negligence. For further information about your rights, please see CCHMC Notice of Privacy Practices.
ABILITY TO CONDITION TREATMENT ON PARTICIPATION IN THIS STUDY

You have a right to refuse to sign this consent to use/disclose your Protected Health Information for research purposes. If you refuse to sign this consent, your rights concerning treatment, payment for services, enrollment in a health plan or eligibility for benefits will not be affected.

WHO DO YOU CALL IF YOU HAVE QUESTIONS OR PROBLEMS?

For questions about this research study or to report a research-related injury, you can contact the researcher, Dr. Meg Zeller at 513-636-2712. Researchers are available to answer any questions you may have about the research at any time. If you have general questions about your rights as a research participant in this research study, you can call the Cincinnati Children's Hospital Medical Center Institutional Review Board at 513-636-8039.

WITNESSING AND SIGNATURES

I have read the information given above. The investigator or his/her designee have personally discussed with me the research study and have answered my questions. I am aware that, like in any research, the investigators cannot always predict what may happen or possibly go wrong. I have been given sufficient time to consider if I (or my child) should participate in this study. I hereby consent for myself (or my child) to take part in this study as a research study subject.

Check box if verbal assent is obtained from the child who is the research subject □

Subject's signature indicating consent or assent

Parent/Legal Guardian (Signature)

Date: 3-24-05

Date: 3/24/05

Date:

I have witnessed the voluntary signing of this document by the research subject, or the legally authorized representative of the research subject.

Witness as to the voluntary nature of the signatures noted above (Signature)

Date: 3/24/05

Date: 4-9-05

This research study and consent form have been reviewed and approved by the Cincinnati Children's Hospital Medical Center Institutional Review Board (telephone number 513-636-8039).
Appendix C
Directions for Administration

**IWQOL-Kids**

This measure assesses the impact of weight on quality of life for kids. It asks how weight affects their day-to-day life across a number of domains, including their ability to be physically active, their self-esteem, their social relations and family relationships, school, and whether it causes them distress. This measure is always administered *LAST*. The directions should be read directly from the questionnaire.

"Please answer the following statements by circling the number that best applies to you in the past seven days. Be as open as possible. There are no right or wrong answers."

When the child has completed this measure and you are checking it over for completeness, casually check their response to item #10/DISTRESS/PG 4.

If the participant endorsed "BECAUSE OF MY WEIGHT I HAVE THOUGHTS OF HARMING MYSELF OR DYING" *A 5 OR 4* ("Always true" or "Usually true"), please refer to the CDI and IWQOL-Kids Lethality procedures in the back of this manual and follow those procedures.
What I Am Like – CPSPP / PIP

This measure looks just like the Harter but is the Children’s Physical Self-Perception Profile, and the Children’s Perceptions of Importance Profile. The directions are the same for but should be reviewed.

Fill out this questionnaire just like you did the first. So first decide whether you are more like the teen on the left side who would rather go to a sports event, or whether you are more like the teen on the right who would rather go to the movies. Which one is more like you?

Now the second thing I want you to decide is whether that is “really true” for you or only “sort of true” for you. If it’s only “sort of true”, put an X or a check under “sort of true”. It it’s “really true”, put a mark in that box.

For each sentence only check one box. Sometimes it will be on one side of the page, and other times on the other side. You don’t ever check both sides.

Do you have any questions?
Stunkard

- Make sure you take a male protocol when seeing male patients and a female protocol when seeing females.
- At the baseline visit ONLY the first page, with questions 1 & 2 will be needed. At 6 month and 12 month follow-up, the first and second pages, questions 1, 2 & 3 will be needed. They are attached because the copyright information is on the second page.
- Read "Below are some drawings of (fe)male figures of the same height, but different weight or shape. Please circle the letter below the figure in response to the following questions." Hand the protocol to the patient. Make sure they have circled a letter for each question (1 & 2 at baseline; 1, 2 & 3 at follow up).

- For scoring, the letters (A-I) will correspond to numbers (1-9).

<table>
<thead>
<tr>
<th>Letter</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>1</td>
</tr>
<tr>
<td>B</td>
<td>2</td>
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<tr>
<td>C</td>
<td>3</td>
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<td>H</td>
<td>8</td>
</tr>
<tr>
<td>I</td>
<td>9</td>
</tr>
</tbody>
</table>

- At baseline you will record three numerical scores
  - 1. The answer to number 1
  - 2. The answer to number 2
  - 3. The discrepancy score (the difference between 1 & 2).

- At 6 month and 12 month follow up you will record four numerical scores
  - 1. The answer to number 1
  - 2. The answer to number 2
  - 3. The discrepancy score (the difference between 1 & 2).
  - 4. The answer to number 3
Weight/Height - Adolescent

1. Obtain height and weight from clinic charts.

2. Patient charts are located across from Dr. Inge’s office (Sabin 3rd floor).

3. When obtaining height and weight from patient charts it is important that you copy this information from the Nutritional Report. When obtaining data from the Nutritional Report make sure that you are getting the current height and weight and not the surgery height and weight. Also, it is important to make sure that date of which the visit occurred matches the date on the Medical Label.
**Weight/Height - Adolescent**

1. Obtain height and weight from clinic charts.

2. Patient charts are located across from Dr. Inge’s office (Sabin 3rd floor).

3. When obtaining height and weight from patient charts it is important that you copy this information from the Nutritional Report. When obtaining data from the Nutritional Report make sure that you are getting the current height and weight and not the surgery height and weight. Also, it is important to make sure that date of which the visit occurred matches the date on the Medical Label.
Appendix D

Impact of Weight on Quality of Life-Kids (IWQOL-Kids)

This measure is protected by copyright and unavailable for publication in this document.
Appendix E

Children's Physical Self-Perception Profile (C-PSPP)

This measure is protected by copyright and unavailable for publication in this document.
Appendix F

Stunkard Figure Rating Scale

This measure is protected by copyright and unavailable for publication in this document.
Chapter V

Dissertation

Abstract

The current study investigated the effects of weight loss achieved through bariatric surgery on adolescents’ body-esteeem and physical self-efficacy. Data were collected from 24 consecutive patients (ages 13 to 17) undergoing bariatric surgery at a Midwestern Children’s Hospital. The participants completed measures in the week prior to surgery and at a six-month follow-up visit. Improvements were seen in each area assessed, with significant improvements found on the following scales: body-esteem, condition competence, attractive adequacy, physical self-worth scale, and the dissatisfaction score on the Stunkard Figure Rating Scale. No significant correlations were observed between the amount of weight lost and the degree of improvement seen in the adolescents’ rating of their body-esteem and physical self-efficacy. Finally, post-hoc examination of the effects of gender on each measure found only a significant interaction for gender on strength competence, and a significant main effect for gender on sports competence, with males scoring higher than females. The findings of the current study suggest that adolescents undergoing bariatric weight loss surgery experience significant improvements in their perceptions of their physical appearance and abilities, generally independent of the amount of weight lost or the gender of the adolescent. The findings of the study are limited by the small sample size, as well as the brief follow-up period, and future research should address these limitations.
Adolescents’ Body Perceptions:

Pre- and Post- Bariatric Surgery

Obesity in both adults and adolescents has been steadily increasing throughout the past three decades (Ogden, Flegal, Carrol, & Johnson, 2002; Strauss & Pollack, 2001). This condition leads to physical/medical consequences (Dean, 2002; Freedman, Khan, Dietz, Srinivasan, & Berenson, 2001; Must, Jacques, Dallal, Bajema, & Dietz, 1992; Pinhas-Hamiel et al., 1996); individual and national economic consequences (Epperson, 2003; Roszac, 2004; Thompson and Wolf, 2001); and finally, a variety of psychological sequelae (Boutelle, Neumark-Sztainer, Story, & Resnick, 2002). Various behavioral, psychopharmacologic, and medical procedures have been used in an attempt to reduce weight, though many of these have failed to produce significant and permanent weight loss (Capella & Capella, 2003; Epstein, Myers, Raynor, & Saelens, 1998). Bariatric weight loss surgery is one method that is increasingly utilized and appears to be effective in reducing weight in both adults and adolescents (Hsu, Benotti, Dwyer, Roberts, Saltzman, Shikora, Rolls, & Rand, 1998; Inge et al., 2004b). This surgery has been performed in adults for years; however, the literature regarding the surgery’s long-term effectiveness in helping adults keep the weight off, or any subsequent improvements associated with the weight loss, is lacking. There is even less literature available on these constructs in adolescents, though the initial literature on weight loss surgery in adolescents seems promising.

Obesity is defined as having increased body weight caused by excessive accumulation of fat (The American Heritage Stedman’s Medical Dictionary, 2002). In adults, obesity is classified as a Body Mass Index (BMI) ≥ 30. In the pediatric population, the condition is also described in terms of a BMI, though for youth, the value is adjusted for height. A child or adolescent is
Adolescents’ Body Perceptions

considered obese if he or she has a BMI greater than the 95th percentile when adjusted for age and gender. A child or adolescent is considered to be at risk of becoming obese if the BMI falls in the range of the 85th to the 94th percentile. While these descriptors of body mass index are common throughout the literature, and often referred to in practice, they are essentially arbitrary numbers, as youth with a BMI ≥ 40 are very poorly represented in the norms used to create height and weight information for pediatric growth charts (Kuczmarski et al., 2000). Without accurate epidemiological information guiding the definition of severe obesity in each year during adolescence, a BMI ≥ 40 has been selected as a conservative criterion for consideration of surgical intervention (Inge et al., 2004a).

The prevalence of overweight individuals has been steadily increasing over the past several years, and there are many associated risks and consequences. Unhealthy and inactive lifestyles are contributing to an increasingly overweight and obese population in America, affecting children and adolescents, and adults. In the past 30 years, the number of overweight individuals in the pediatric age range has almost tripled in the United States, reflecting an increase in rates ranging anywhere from 15.5% to 37% of youth across the country (Ogden, Flegal, Carrol, & Johnson, 2002). Strauss & Pollack (2001) reported that pediatric obesity rates in the United States have increased 50% in white youth and 120% in black and Hispanic youth in the last decade alone. While this is an international problem, it appears to be most significant in the United States, as van Hout, van Oudheusden, & van Heck (2004) reported that, while obesity is an international disease that is spreading worldwide, at the turn of the 21st century, it has had the most profound impact in this country. Lowry, Galuska, Fulton, Wechsler, & Kann (2002) reported obesity to be the most prevalent nutritional disease of children and adolescents in the United States, and Freedman, Mei, Srinivasan, Berenson, & Dietz (2007) have reported that

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extreme obesity affects more children than childhood cancer, cystic fibrosis, HIV, and juvenile diabetes combined.

Once an individual becomes obese, it tends to be a life-long condition, and the implications of obesity tend to affect whole families, rather than just individuals. In a review of the literature, Serdula et al. (1993) indicated that children who are obese as adolescents have a 50 to 77% risk of becoming obese as adults, and this risk increases to 80% if at least one parent is also obese. Capella & Capella (2003) supported this argument, indicating that, although adolescent obesity prevalence and prognosis research is limited, researchers theorize that youth obesity will persist into adulthood in nearly 100% of extremely obese individuals.

The growing prevalence of obesity is problematic, as research has documented an array of consequences of this chronic condition. There are medical consequences associated with severe obesity including heart disease, obstructive sleep apnea, type II diabetes, and premature death (Freedman, Khan, Dietz, Srinivasan, & Berenson, 2001; Must, Jacques, Dallal, Bajema, & Dietz, 1992; Pinhas-Hamiel et al., 1996). Diabetes alone creates significant cardiac, renal, and ophthalmic complications for young adults (Dean, 2002). Capella & Capella (2003) also discussed obesity-related problems that are considered less often, such as hormonal imbalances and dermatological problems, which can also have devastating and lasting effects on an individual.

Along with the physiological consequences of obesity, there are economic impacts, as well. Roszac (2004) reported that health care spending on obese Americans accounted for 27% of the growth in overall health care spending between 1987 and 2001. Health care costs of overweight individuals are 37% higher than those incurred by normal weight individuals. Epperson (2003) reported that obese people spend $700 more per year on health care than non-
overweight individuals, equaling $93 billion in medical expenses for treating overweight individuals. These expenses are passed on to all Americans in the form of higher premiums and greater co-payments for those with health insurance. After a review of the literature, including 18 studies looking at the impact of obesity on healthcare, employment, and future disease risks, Thompson and Wolf (2001) concluded that obesity exacts an immense economic toll on America, as well as other countries around the world.

The physical and economic consequences of obesity are well-reviewed and documented throughout the literature. However, there are also potential psychosocial effects associated with this chronic condition, which have received less attention. While various comorbid psychiatric diagnoses including depression, binge eating disorder, poor body-image, general psychiatric symptoms, and low self-esteem have been discussed throughout the adult literature, less is known about the emotional conditions associated with adolescent obesity, and the research available has produced inconsistent findings. Moreover, harder to find throughout the child and adult literature is research focusing specifically on how obese individuals view their bodies and feel about their physical appearance, as well as what they believe their bodies are physically able to do. Given this gap in the literature, constructs related to body-esteem and physical self-efficacy are discussed.

Boutelle, Neumark-Sztainer, Story, & Resnick (2002) suggested that psychosocial consequences of being overweight do exist and begin early in life, are hard to manage, and can have long-term psychological consequences. These consequences do not necessarily begin in adulthood, as the research shows that children are emotionally affected by their overweight status, as well. Kimm, Sweeney, Janosky, & MacMillan (1991) and Vander Wal & Thelen (2000) studied both treatment and non-treatment seeking adolescents and found dissatisfaction in
areas assessed by body image and eating questionnaires and self-concept scales, suggesting that, in addition to being large in size, these children are also experiencing psychological distress related to their physical state. Stradmeijer, Bosch, Koops, and Seidell (1999) investigated not only the age at which obesity may affect an individual, but they also assessed the role of gender and found differences in body and self-esteem in overweight early to middle adolescents. The results indicated lower body-esteem in older overweight girls, while in contrast, older overweight boys showed higher body-esteem. These findings suggest that age and gender may interact to play a role in how an overweight adolescent is affected by his or her weight.

The following studies can be helpful in informing the literature on obese youth, however, they should be viewed with caution, as they were conducted during a time when pediatric obesity was not as prevalent, and therefore the effects may have been more distressing. Banis et al. (1988) studied a group of 30 obese, but otherwise healthy, boys and girls recruited from a general pediatric clinic. They found lower self-esteem, self-worth, physical appearance, athletic competence, and social competence in the sample when compared with published normative data. Strauss, Smith, Frame, & Forehand (1985) found that the overweight children in their study exhibited a poorer self-concept than their average weight peers, and Sallade (1973) found significantly lower self-esteem in an obese group of children and adolescents studied compared to the non-obese.

French et al. (1995) conducted a review of the literature and concluded that there is a negative association between relative weight and body-esteem between the ages of seven and 12 years, though the correlation of weight with self-esteem was inconsistent. They also determined that adolescents between the ages of 13 and 18 years showed an inverse relationship between relative weight and both body- and self-esteem. Similarly, French, Perry, Leon, & Fulkerson
(1996) found an inverse relationship between BMI and physical appearance self-esteem in a large group of males and females in grades seven through nine. Also, the obese girls were found to exhibit an inverse relationship between their BMI and global self-esteem, close friendship self-esteem, and behavioral conduct self-esteem. In boys, inverse relationships between BMI and athletic self-esteem, as well as romantic self-esteem, were found. This study did not apply only to obese youth, but it addressed the relationship between increased weight and how one views his or her own body and what the body is able to do.

Such findings have remained consistent across time, as Coldfield et al. (2007) described a strong inverse relationship between BMI and self-esteem related to physical self-perceptions and physical quality of life. The authors further suggested that body dissatisfaction, or physical appearance esteem, is one of the most reliable psychological correlates relating to physical perceptions in obese children. Thompson et al. (2007) had similar findings in their study of a group of 325 adolescent girls (ages 14 to 17), finding that those who were overweight or at risk for becoming overweight (≥95th percentile & 85th to 94th percentile, respectively) scored higher on an assessment of body dissatisfaction.

Marsh, Hau, Sung, & Yu (2007) found that both subjective and objective indices of body fat were negatively related to many components of physical self-concept in a group of 763 Chinese children ages 8 to 15. William, Wake, Hesketh, Maher, & Waters (2005) sampled children from a longitudinal, population-base cohort study and compared children classified as not overweight, overweight, and obese on measures of health-related quality of life. The authors found decreases in physical and social functioning in obese children compared with those that were not overweight. O’Dea (2006) investigated self-concept in 80 girls (mean age 12.8), finding that all nine self-concept domains assessed were lower in the highest BMI than in the
other groups. These findings remained stable over a three-year period, with the exception of physical appearance and close friendships, which actually decreased over the given time period. Further, the highest BMI group obtained scores substantially lower than population norms on all scales.

_Treatment_

As obesity is a problem in this country, with significant associated consequences, identifying the most effective treatment producing significant and sustained results has been an ongoing struggle. In outlining treatment of adolescent obesity, current guidelines contend interventions should begin early, involve the family, and institute permanent changes through gradual targeted increases in physical activity paired with targeted decreases in high-fat, high calorie foods (Lowry, Galuska, Fulton, Weschsler, & Kann, 2002). However, after review of various treatments for adolescent obesity, including dietary treatments, exercise, pharmacological aids, and behavior change, Epstein, Myers, Raynor, & Saelens (1998) contended that, though progress has been made, most interventions affect only small changes in weight and are followed by substantial relapse. Capella & Capella (2003) reiterated these findings, reporting overwhelming evidence suggests that non-surgical treatments aimed at weight control fall short in adolescents.

In agreement, Hsu et al. (1998) argued for surgical treatment of obesity. They suggested that, while behavior therapy and various diets may work for mild to moderate obesity, they are usually ineffective for severe obesity. Long-term use of pharmacological agents such as “phen-fen” often results in fairly small weight loss that is typically not sustained, and the benefits of such a method need to be measured against the potential risks. Inge et al. (2004b) suggested that for a select population of obese adolescents, bariatric surgery may be the only option for
achieving a healthy weight and avoiding the potentially harmful physical and psychological effects of being overweight. In summary, the literature reported overwhelming results indicating that more conventional weight loss treatments have produced minor results, most of which are difficult to maintain. In light of this conclusion, bariatric surgery, proven effective for adults, is now becoming a viable option for adolescents.

While the effectiveness and risks of bariatric surgery have been reported in adults, this type of surgery in adolescents is a newer, less researched procedure. Thus, less is known about its benefits and consequences for this population. Inge et al. (2004c) reported that surgery results in weight loss and improvement of comorbidities in adults, and early, limited reports suggest this to be true for adolescents as well. Dolan (2004) was interested in comparing laparoscopic adjustable gastric banding in adults and adolescents. She studied data collected prospectively on weight loss surgery patients since 1996. Seventeen adolescent patients less than 20 years old at the time of surgery were compared with patients ranging in age from 23 to 70 years old, matched for sex and BMI. The author found no significant differences in weight loss or in complications. The author concluded that the laparoscopic adjustable gastric banding produces equally positive results in adolescents and adults.

Strauss, Bradley, & Brolin (2001) retrospectively reviewed data on 10 adolescents (17 years of age, or less) who underwent gastric bypass surgery and concluded it was an effective treatment for weight loss in morbidly obese adolescents. Abu-Abeid, Gavert, Klausner, & Szold (2003) studied a group of 11 adolescents (ages 11 to 17) who also underwent laparoscopic adjustable gastric banding and observed a drop in mean BMI from 46.6 to 23.1 kg/m². Lawson et al. (2006) obtained one-year outcomes on 39 adolescents (ages 13 to 21) undergoing Roux-en-Y gastric bypass surgery across three medical centers and found significant weight loss.
compared to controls (37% decrease in BMI versus 3% decrease), as well as significant improvements in important lab values (i.e., triglycerides, total cholesterol, fasting blood glucose, and fasting insulin) which are central in the common medical conditions found in morbidly obese individuals.

Despite the positive finding thus far, researchers have acknowledged that a gap exists between current knowledge and evidence of long-term effectiveness of the surgery and/or any potentially adverse effects. It is recognized that while bariatric surgery has been shown effective for adults, the specific guidelines cannot simply be transferred to adolescents (Inge et al., 2004b). Adolescents have unique psychological, metabolic, and developmental needs that warrant careful selection and multidisciplinary treatment. Only continued study of this population will provide the experience and knowledge necessary to best treat obesity in adolescents.

Given that early research on bariatric surgery indicates significant and durable weight loss, it can be expected that surgical weight loss results in psychological benefits, as well. Stunkard (1983) reviewed the psychological outcomes associated with bariatric surgery from three studies and reported uniformly positive treatment effects, when compared to controls, including increased mood, body satisfaction, and self-esteem. Dymek, le Grange, Neven, et al. (2001) reported that surgery leads not only to weight reduction, but improvement or cure of comorbidities and improvement in quality of life, as well. Capella & Capella (2003) reported on a group of 19 adolescents, ages 13 to 17, which underwent a form of gastric bypass combining the vertical banded gastroplasty with a Roux-en-Y gastric bypass between May, 1990 and August, 2001. Participants completed a written or oral questionnaire at least three years after surgery. The results of the questionnaire from all patients contacted were “overwhelmingly positive” (pg 829). This sample included no mortality or serious morbidity following surgery.
Rand & MacGregor (1994) investigated a group of 34 adolescents (79% female, 21% male) ranging in age from 11 to 19 years at the time of surgery. Patients underwent surgery between January, 1979 and December, 1990. Prior to surgery, participants weighed an average of 131 kg, and had a BMI of 47, and at follow-up, participants’ average weight was 89 kg, with a BMI of 32. Despite the amount of weight lost, participants remained overweight after surgery, averaging 25 kg over the ideal weight. For the study, data were collected an average of six years post surgery and found that, in the area of appearance and well-being, 82% of patients considered themselves attractive post-surgery compared to 94% feeling unattractive before surgery. Only 12% continued to feel unattractive. Seventy-four percent of patients reported feeling less embarrassed than before surgery, while 12% reported feeling more embarrassed. Eighty-five percent of patients reported themselves to be in good spirits daily and that they were in better spirits now than before the surgery. Another 85% of patients said they would definitely have the procedure done again, 9% said probably, and 6% said they would not. In response to an open-ended question concerning the best things that had happened since surgery, as a group, responses indicated that surgery had improved their feelings about themselves, increased their self-confidence, made them feel more attractive, and facilitated their social relationships (e.g. dating and marriage). Dissatisfaction with the results of surgery was found in some participants. Those responses tended to be few and were more idiosyncratic. The findings of this study were more qualitative and gave a more individualized view of outcomes of the surgery, specifically on adolescents.

Inge, Xanthakos, & Zeller (2007) report early findings on a sample of 16 adolescents (63% female, mean BMI 59.9kg/m), which at 12-months post-surgery expressed significant improvements in health related quality of life and depressive symptomology, despite continued
obesity (mean BMI 36.9 kg/m). Burgner et al. (2007) studied a group of 149 adults (ages 19 to 64) undergoing restrictive obesity surgery and determined that in addition to considerable weight loss post-surgery, depressive symptoms and self-esteem improved significantly. Such effects were noticeable one year after surgery, though tended to plateau by the second year follow-up.

Clearly, obesity is an increasing problem across the United States and worldwide. It has far reaching physical, economic, and psychological consequences. Bariatric weight loss surgery has become an increasingly common weight-loss treatment in both adults and adolescents, and preliminary research indicates positive outcomes in weight reduction. However, less is known about the psychosocial outcomes associated with such weight loss, thus there is a need for research investigating the related complex psychosocial constructs of this surgery and resulting weight loss, in order to determine the psychological risks and benefits of the procedure, and to optimize pre-surgery evaluation and post-surgery treatment.

Further absent throughout the literature is research on physical self-efficacy, described as one’s confidence in the ability to be physically active (Felton et al., 2002), in obese individuals, especially obese adolescents. Given the limited available literature, it is assumed that physical self-efficacy is lower in obese adolescents. This may be due to a history of criticisms during physical activity leading to decreased confidence in one’s actual ability to perform, and/or a physical inability to participate because of shape and size leading to decreased confidence in ability. These assumptions are based on theories, such as cognitive evaluation theory, that propose motivation is based largely on perceptions of competence (Whitehead, 1995). According to this theory, self-perceptions are developed from four sources of information, including past performances, modeling, verbal persuasion, and physiological state (Bandura, 1986). Further, research has shown that targeting individual’s perceptions of competence can
result in significant effects on intrinsic motivation in the physical domain (Prong, Rutherford, & Corbin, 1992). This is particularly relevant to patients undergoing bariatric surgery because participation in physical activity is vital to success post-surgery, thus assessing physical self-efficacy can contribute to the patient selection process, as well as guide interventions post-surgery.

Body-esteem, defined by Mendelson, Mendelson, & White (2001) as an individual’s self-evaluation of his or her body or appearance, was the second focus of this study, as it has been found to be related to other measureable constructs. French et al. (1995) hypothesized that body image may contribute to a significant portion of self-esteem for obese youth and that programs may affect body-image first, then leading to changes in self-esteem. Klaczynski, Goold, & Mudry (2004) reported that among Caucasian adolescents and adults that self-esteem and body-esteem are clearly correlated. This knowledge may also help to guide interventions post-surgery.

The purpose of the current study was to contribute to the available literature on the psychosocial effects experienced by adolescents achieving weight loss through bariatric surgery, focusing on body-esteem, and physical self-efficacy. Specifically, the present study investigated what, if any, effect does surgical weight loss intervention have on adolescents’ perception of their bodies; both how they view their physical appearance and their perception of their physical capabilities. The study also explored the role of gender on an adolescent’s perceptions of the body, and finally, the impact of the amount of weight lost on these perceptions.
Method

Participants

Participants were part of two larger prospective longitudinal studies examining psychosocial outcomes of adolescents undergoing laparoscopic Roux-en-Y gastric bypass surgery (RYGBP) at a Midwestern Children’s Hospital. The participants in the present study included 24 consecutive adolescents who underwent RYGBP between May 2004 and March 2006. To be considered for this surgery, an adolescent had to be obese with a Body Mass Index \( \geq 40 \). The adolescents underwent a multidisciplinary evaluation and were approved for surgery prior to being contacted about participation in the study. Study inclusion criteria required participants to be 13-17 years of age and have neither physical impairments unrelated to obesity nor developmental disability. Of the 25 consecutive patients meeting inclusion criteria, 24 (96%) agreed to participate in the study and completed baseline measures. One patient declined due to lack of interest in research participation. A summary of demographic characteristics of participants at baseline is presented in Table 1.

The study was approved by the Institutional Review Boards of the medical center (see Appendices A & B) and Xavier University (see Appendix C).

Measures

In order to measure adolescents’ body-esteem and physical self-efficacy, participants completed the Impact of Weight on Quality of Life- Kids (Kolotkin et al., 2006), the Children’s Physical Self-Perception Profile [(C-PSPP) Whitehead, 1995], and the Stunkard (1983) Figure Rating Scale.

The Impact of Weight on Quality of Life- Kids Version [IWQOL-Kids (Kolotkin et al., 2006)], assesses the impact of an adolescent’s weight on his or her quality of life. Participants
are oriented to answer in a weight-specific manner, as each question begins with the phrase “Because of my weight,” and possible responses ranged from always true (1) to never true (5). The raw score of the scales is calculated as an unweighted sum of its component items and is then transformed to 0 to 100 scoring, with 100 representing the best quality of life, and 0 representing the worst. The initial measure consisted of 73 items that were developed and pilot tested on patients who were recruited from weight loss studies and community samples. Based on factor analyses, the initial 73 items were reduced to 27 and yielded four factors (Physical Comfort, Body Esteem, Social Life, Family Relations), as well as a Total Score. The measure exhibits excellent psychometric properties. Internal consistency ranged from .88 to .96. Convergent validity (r= .76, p<.0001) was shown, with strong correlations between the IWQOL-Kids total score and the Pediatric Quality of Life scale. The measure is sensitive, with significant differences appearing across BMI groups and between the clinical and community samples. For the present study, the entire measure was completed, though only the Body Esteem scale, consisting of nine items, was utilized. This scale reflects an adolescent’s preoccupation with weight and appearance, in addition to how he or she feels about self and body.

The Physical Self Perception Profile- Children’s Edition [C-PSPP (Whitehead, 1995)] is a 32-item measure created to assess physical self-efficacy across four subdomains, including sports competence (i.e., some kids do very well at all kinds of sports, BUT other kids don’t feel that they are very good when it comes to sports), condition/stamina (i.e., some kids feel uneasy when it comes to doing vigorous physical exercise, BUT other kids feel confident when it comes to doing vigorous physical exercise), body attractiveness (i.e., some kids find it difficult to keep their bodies looking good physically, BUT other kids find it easy to keep their bodies looking good physically), and physical strength (i.e., some kids feel that they lack strength compared to
other kids their age, BUT other kids feel that they are stronger than other kids their age). An additional scale, physical self-worth, is included in the measure and is taken directly from Susan Harter’s Self-Perception Profile (Harter, 1985). Participants are given two options of attributes or behaviors and are asked to choose the response that best represents them, and then indicate if the response is “really true” or “sort of true.” Scores range from 1 to 4, with some items using reverse scoring to account for use of negative words. Total scores for each subscale are determined by summing the total points and dividing by the number of items in that scale.

Whitehead (1995) tested this measure, and the results supported the reliability of the construct and its concurrent validity. The scales are shown to be moderately correlated with each other, with r values ranging from .33 to .66, with the exception of a .77 correlation between the Physical Condition Adequacy and Sport/Athletic Competence for a specific grade of girls. Reliability coefficients for the scales ranged from .80 to .88 for males, and .86 to .90 for females.

The Stunkard Figure Rating Scale consists of nine silhouettes ranging in size from very underweight to very overweight. As part of written instructions, respondents were asked to identify which figure looks most like them currently and which they would prefer to look like, and circle the response corresponding to the chosen figure. Any difference between the two is interpreted as a measure of body dissatisfaction. At the time of its development, the measure was novel and no investigation of psychometric properties was performed. However, the measure continues to be widely used and accepted. In 2001, Bulik et. al conducted a study with the intention of establishing BMI norms for the scale and to determine the effectiveness of the figural stimuli in classifying individuals as obese or thin. The authors reported that the scale was significantly and highly correlated with measured percentage overweight (r = 0.79). The polyserial correlations between the log of BMI and the figural stimuli were 0.81 for women and
0.73 for men. The measure also appears to be valuable in correctly identifying individuals as obese (0.93 for women and 0.88 for men) or thin (0.87 for women and 0.88 for men). One factor that might limit the generalization of Stunkard’s study to the current study is his entirely Caucasian sample.

Procedure

Participants were recruited for the current study by the Principal Investigator (PI) of the larger study. Recruitment took place during a clinic visit, after the family had been approved for surgery. The PI explained the procedure and the value of the study and was available to answer any questions. After agreeing to participate, a baseline data collection appointment was scheduled, during which time families were met by a member of the PI’s research team and the consent form was reviewed (see Appendices A & B). As all participants were minors, consent was obtained from their parents and assent was given by the patients. The initial data collection session was conducted in a private room. All procedures were explained to the adolescent and his or her caregiver(s) and the research assistant was available throughout to answer any questions. One or two research assistants administered the packet of measures to the adolescent and his or her caregiver(s) (See Appendix D). Adolescents and caregivers were seen individually if two assistants were available, or together if only one was available. Adolescents and caregivers were not able to view each others’ responses. Directions of each individual measure were read to the participants (see Appendix D). All measures were self-report and were completed by the appropriate individual. However, if a participant was unable to read the information but was capable of understanding the questions, the questionnaires were read to the participant. (One participant had the questionnaires read to him due to difficulty reading.) After the questionnaires were completed the participants signed a receipt and were given
compensations for their time. Participants were compensated at the rate of $45 per adolescent and $30 per caregiver(s) for participation in the baseline data collection.

Prior to the patients' scheduled six month follow-up in the clinic, the family was contacted by a member of the research team and the second data collection session was scheduled. In this session, another packet of the same questionnaires was administered to both the patient and his or her caregiver(s). A research assistant again administered the questionnaires and was available to answer any questions. At the completion of the second visit the patient and caregiver(s) signed another receipt, acknowledging receiving the $60 offered to the adolescent and the $40 offered to the parent for their time and participation. If a patient and/or family did not return to the hospital for the six month follow-up, a member of the research team contacted the family and made arrangements to send the measures via Federal Express to the family. A member of the research team then called the family, reviewed the measures, and answered any questions. The family then completed and returned the measures in the pre-paid, self-addressed Federal Express envelope and was compensated upon completion of their participation. Data were collected via Federal Express with three participants in this sample.

Data Analysis

Change in adolescents' view of their bodies and how they feel about their bodies six months after surgery were measured using repeated administration of the Stunkard Figural Stimuli scale, the body-esteem scale from the Impact of Weight on Quality of Life-Kids (IWQL-Kids) version, and the body attractiveness scale of the Physical Self-Perception Profile, Children's edition (C-PSPP). Changes in what the adolescents believe their bodies are physically able to do six months after surgery were measured using the sports competence, condition/stamina, and physical strength scales of the C-PSPP. The correlation between
individual BMIs and the scores obtained on the measures above were investigated using each adolescent’s height and weight and his or her scores on the measures. Impact of gender was investigated using mean scores by gender and time point on each of the above scales.

Tests of mean group differences (t tests) were performed to compare mean group scores at the baseline visit versus mean group scores at the six month, post-operative follow-up on measures of weight-related body-esteem, physical self-efficacy (e.g., sports competence, condition competence, attractive adequacy, strength competence, physical self-worth) and the body dissatisfaction scores on the Stunkard Figure Rating Scale. A bivariate correlation was run between mean change in each of the above mentioned scales and mean change in BMI from baseline to 6 months. Finally, two-way, repeated measures mixed between-within subjects ANOVA tested if change in adolescent weight-related body-esteem, physical self-efficacy and body dissatisfaction varied by gender and time point.

Results

Physical Self – Efficacy

On measures assessing physical self-efficacy, significant differences were found on the condition competence and physical self-worth scales of the PSPP-C (Whitehead, 1995) when comparing mean scores at baseline with mean scores obtained at the six month follow-up. No significant differences were found on the sports competence or strength competence scales of that measure. (See Table 2 for means and t-test results.)

Body – Esteem

On measures assessing weight-related body-esteem, a significant difference was found between mean score at baseline compared to mean score at follow-up on the body-esteem scale of the IWQL-Kids, as well as the attractive adequacy composite of the C-PSSPP. A significant
difference was also found on the Stunkard Figure Rating Scale when comparing mean baseline scores with those at follow-up. (See table 2 for means and \( t \)-test results.) Of note, the distribution of scores on this measure was further examined and the adolescents appear to have an accurate perception of their body size, both before and six-months after surgery. Further, the figures they find most desirable remained consistent from baseline to follow-up (see Table 6 for distribution of scores).

In order to assess for differences between the obtained sample means on measures of body-esteem and physical self-efficacy, both at baseline and at six month follow-up, and means observed in the population, \( z \) scores were computed. Significant differences were found at both time points on attractive adequacy, sports competence, condition competence, physical self-worth, body-esteem in the thinnest sub-set (11\(^{th}\) to 84.9\(^{th}\) percentile), and on the middle-weight sub-set (85\(^{th}\) to 94.9\(^{th}\) percentile), and at baseline in the heaviest sub-set (95\(^{th}\) to 100\(^{th}\) percentile) of population norms on the body-esteem scale. No significant differences were found at either time point between sample means and population norms on the strength competence scale.

*Relationship between Change in Scores and Change in Weight*

Bivariate correlations were conducted to examine the relationship between the change in BMI during the six month period and the change in scores on each of the scales. These correlations yielded no significant results at the .01 level. (See Table 3 for correlation values.)

*Impact of Gender on Change in Scores*

To evaluate whether changes in physical self-efficacy and weight related body-esteem scores from baseline to six month follow-up varied by sex, a time (baseline vs. six month follow-up) X gender (male vs. female) analysis of variance (ANOVA) was conducted. A significant interaction was observed between gender and the change in strength competence, \( F (1, 21) = \)
13.88, p = .001. There were no other significant interactions found. A significant main effect for
gender was found on the sports competence scale [F(1, 21)=8.75, p=.007]. (See Table 4 for
mean scores by gender and time point. See Table 5 for ANOVA results.)

Discussion

Obesity is currently described as one of the most chronic medical conditions of childhood
and its prevalence continues to increase rapidly (Jonides, Buschbacher, & Barlow, 2002). The
reasons behind this increase are complex and multifaceted, as genetic factors as well as culture,
environment, and lifestyles influence overweight and obesity (Rautstorp, Mattson, Svensson, &
Stahle, 2006). Given the complicated factors contributing to obesity, finding appropriate
treatments resulting in significant and prolonged weight loss has been difficult. Bariatric weight
loss surgery is an increasingly common intervention which "has proven to be an exceptionally
effective and durable solution in morbidly obese adults," though its application in youth remains
controversial (Collins et al., 2007). However, Tsai, Inge, & Burd (2007) reported on a surge in
these procedures in adolescents representing a threefold increase nationwide from 2000 to 2003.
They further report that current evidence indicates the procedure results in significant weight
loss, and improvements in obesity-related medical and psychosocial conditions.

Previous research on the detrimental effects of obesity on individuals’ psychological
functioning and self-concept has been inconsistent. The construct of self-concept can be further
delineated into the dimensions that comprise it, including physical self-efficacy and body-
esteeem. These variables have been studied to a limited degree among overweight populations,
usually in comparison to normal weight controls, though are receiving increasing attention as
obesity continues to be increasingly prevalent in this country and around the world. The present
study did not directly examine the psychosocial functioning of obese adolescents compared to
standardized norms, but rather investigated the presence and direction of changes in body perception occurring after bariatric surgery. Specifically, did surgery-induced weight loss improve adolescents' view of their physical appearance and physical ability?

Data from the current study does suggest improvements in all areas of body-esteem and physical self-efficacy assessed. In the area of physical self-efficacy, significant improvements were found in the adolescents' perception of their ability to participate in and sustain physical activity, as well as their overall physical self-worth, a scale comprised of multiple physical self-efficacy domains. Improvements were also demonstrated in the adolescents' confidence in their physical strength and ability to participate in athletic activities, though not to a significant degree. Significant improvements were seen in all areas of body-esteem assessed, indicating noteworthy improvements in the adolescents' evaluation of their physical appearance. All improvements exhibited were found to be independent of amount of weight lost, or change in BMI, and generally were not affected by gender, with the exception of strength competence, on which males improved at a higher trajectory than females, and on sports competence, on which boys scored significantly higher than girls.

**Body-Esteem**

The improvements seen in body-esteem are expected, and consistent with previous research findings indicating positive impact of weight loss on body image (Rand & MacGregor, 1994; Stunkard, 1983). Specific to bariatric surgery, Masheb, Grile, Burke-Martindale, & Rothschild (2006) reported improved body dissatisfaction after gastric bypass surgery. Braet et al. (2004) found that body dissatisfaction decreased significantly in adolescents ages 7-17 during a 10-month inpatient weight loss program, and remained significantly lower than baseline at a 14-month follow-up. Annis, Cash, & Hrabosky (2004) compared previously overweight women
with those who were obese at the time of the study. Their results supported previous research (Cash, 1994; Foster, Wadden & Vogt, 1997), indicating that those women who had lost weight showed improved scores on measures of body image distraction/distress, and their scores were higher than those obtained by the women who were overweight at the time of the study, indicating improvements related to weight loss.

Collins et al. (2007) obtained follow-up quality of life data from 9 adolescents having laparoscopic Roux-en-Y surgery, and all patients described either "improved" or "greatly improved" self-esteem, physical function, social interactions, and function at work. Research supporting improvements in global self-esteem is relevant to this study, as French et al. (1995) hypothesized that body image may contribute to a significant portion of self-esteem for obese youth and that programs may affect body-image first, then leading to changes in self-esteem. Klaczynski, Goold, & Mudry (2004) reported that, among Caucasian adolescents and adults self-esteem and body-esteem are clearly correlated.

**Physical Self-Efficacy**

Relatively little data have been published on physical self-efficacy, and that which has been is generally unrelated to obesity. Thus, the improvements in physical self-efficacy seen in this study are compared with related measures throughout the literature, and have been found to be consistent with improvements in related areas assessed. Collins et al. (2007) obtained follow-up quality of life data from nine adolescents having laparoscopic Roux-en-Y surgery, and all patients described either "improved" or "greatly improved" physical functioning following surgery. Boan, Kolotkin, Westman, McMahon, & Grant (2004) and Isacsson, Frederiksen, Nilsson, & Hedenbro, (1997) also found increases in physical activity after weight loss.
Dymek, le Grange, Neven, & Alverdy (2002) found a significant difference in scores on the physical functioning subscale of the IWQOL-Lite from several weeks prior to gastric bypass surgery to several weeks after, and the scores continued to increase significantly at six months and one year post surgery. Sabbioni et al., (2002) investigated health-related quality of life in 82 patients undergoing vertical banded gastroplasty. The final data collection took place 24 months post-surgery, and the results consistently indicated that weight reduction, perceived health, physical well-being and physical performance continued to be higher than before surgery.

Assessment of changes in physical self-efficacy is important in bariatric surgery patients, as an individual’s beliefs about his or her ability to be physically active likely affect the extent to which he or she participates in physical activity. Prong, Rutherford, & Corbin (1992) found that addressing perceptions of competence can result in significant effects on intrinsic motivation in the physical domain. This is important in the present study, as patients’ participation in physical activity post-surgery has important implications for successful outcomes. The observed changes in scores suggest increased confidence in patients’ abilities which can be expected to result in increased participation in the recommended exercise regimen.

The body-dissatisfaction scores on the Stunkard Figure Rating Scale (Stunkard, Sorensen, Schulsinger, 1983) were further examined and it was found that the adolescents have an accurate perception of their body size before and six-months after surgery. This is an important observation in light of the improvements found in each area assessed, as it suggests that these adolescents recognize their continued overweight status, and they are experiencing improvements in their perceptions of both their physical appearance and capabilities in spite of their large size.
Impact of Change in BMI

While much research has shown that BMI and constructs of self-concept and body-image are inversely related (Klaczyński, Goold, & Mudry, 2004; Kolotkin et al., 2006; Marsh, Hau, Sung, & Yu, 2007; O’Dea & Abraham, 1999; O’Dea, 2006; Pritchard, King & Czajka-Narins, 1997), the role of weight loss, or change in BMI, and the impact on these concepts is less clear and the published findings are inconsistent.

In a review of the literature on psychological outcomes of weight loss treatment over the past 30 years, Blaine, Rodman, & Newman (2007) indicated that weight loss treatments improved participants’ self-esteem significantly more when a large amount of weight was lost than when little or no weight was lost. This finding was not true in the other variable assessed, as improvements in depression were found to be independent of amount of weight lost. Similarly, Guisado et al. (2002) reported that greater weight loss subsequent to bariatric surgery is strongly correlated with improvements in quality of life, less disturbed eating behavior, and lower psychopathology, compared to less weight loss (weight loss > 30% versus weight loss < 30%).

As no significant correlations were found between the change in BMI and changes in scores on the measures of body-esteem and physical self-efficacy, the findings of the present study support contrary research indicating there is no relationship between weight loss and improvements in self-concept. Similarly, Dixon & O’Brien (2002) indicated that after LAP-BAND surgery, the improvement in quality of life was greater in those with premorbid disability, and was not dependent on the amount of weight lost. Dymek, le Grange, & Alverdy (2002) studied a group of 316 individuals undergoing bariatric surgery at four different time points, and while significant improvements were found in physical functioning, self-esteem, sexual life, and
public distress after surgery, the improvements did not parallel improvements in BMI. The authors suggested that a mechanism other than weight loss may play a role in said improvements. Sabbioni et al., (2002) found that weight loss did not predict changes in scores on measures of health-related quality of life in 82 patients undergoing vertical banded gastroplasty.

The true relationship between change in BMI and improvements in perception of psychological functioning deserves further attention. The lack of significant correlation at the 6-month follow-up is hypothesized by this author to be related to the positive feelings experienced after the initial significant weight loss. At this point in time, the individuals are losing large amounts of weight and likely possess the expectation that they will continue to do so, thus they are not considering the fact that they remain obese. It is worth investigating whether physical self-concept and body-esteem scores continue to improve over time and whether or not these changes begin to correlate with changes in BMI.

Role of Gender

Previous research has found that gender impacts individuals’ evaluation of their own physical abilities and appearance, with females typically endorsing more distress than males in these areas (Kolotkin et al., 2006; Marsh, Hau, Sung, & Yu, 2007; Mendelson & White, 1985; Schwartz & Brownell, 2004). Klaczynski, Goold, & Mudry (2004) found a clear, though indirect, relationship between body-esteem and gender, indicating that females are more likely to have an external locus of control over their weight and have internalized cultural messages about the importance of thinness to personal success. While the exact cognitive mechanisms behind these differences among gender are unknown, following the published data, it was expected that differences in gender would be found in the present population. However, in general, this was not the case. A significant main effect for gender was only observed on the sports competence
scale in the domain of physical self-efficacy, and an interaction between gender and time was observed only on the strength competence scale. These findings may not be truly representative, as there were nearly double the number of girls in the study as boys (n=15 and n=9, respectively). This demographic alone deserves further attention, as it could be said that the mere fact that more females than males present for surgery may support the published data indicating females experience more negative self-perceptions than males.

Bariatric weight loss surgery is increasingly being used to create significant and lasting weight loss in obese individuals, including adolescents. While weight loss outcomes are clear-cut and measurable, as are improvements in a multitude of comorbidities, the impact of this weight loss and the associated, significant and life-long changes in lifestyle are less concise.

The field of literature in this area is expanding and the present study served to contribute to the available knowledge through its investigation of body-esteem and physical self-efficacy. In addition to the unique contribution of information, there are several other strengths of this study, as well. The choice of measures allowed for content specific investigation, permitting examination of researched constructs (i.e. body-esteem and physical self-efficacy) to be applied to a unique population. Further, while each of the measures used is relatively new, they have exhibited good psychometric properties. Another strength of the present study is the high retention rate, with each adolescent evaluated at baseline also having six-month follow-up data.

There are limitations associated with this study, as well. The limited sample size makes it difficult to determine the generalizability of the results. Further, the demographic makeup of the sample (65% female, 37% male, and 83% Caucasian, 17% African American) limit its generalizability, as this is not representative of obese individuals in the general population. Another limitation of the study is the presence of only one time point post-surgery, occurring at
six month follow-up. This does not allow for monitoring of change over time as patients continue to lose weight, but also as they potentially become more adjusted to their new figure, as well as to the adherence with the dietary restrictions and expectations of physical activity.

In summary the present study investigated body-esteem and physical self-efficacy in a unique population of adolescents undergoing bariatric weight loss surgery. Individuals were assessed in the week prior to surgery and at six-month follow-up. Significant improvements were seen in all areas of body-esteem assessed and in the area of physical self-concept significant improvements were seen on condition competence and physical self-worth. Improvements were also seen in sports and strength competence, however, not at a statistically significant level. No correlation was found between the change in scores and change in BMI, and in terms of gender, a significant main effect was found only in sports competence, and an interaction in strength competence. Continued assessment over an extended period of time will be necessary to determine sustainability of these findings.
References


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<thead>
<tr>
<th>Demographics</th>
<th>N</th>
<th>M(SD)</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age* at Baseline</td>
<td>24</td>
<td>15.79(1.41)</td>
<td></td>
</tr>
<tr>
<td>BMI at Baseline</td>
<td>24</td>
<td>62.09(9.17)</td>
<td></td>
</tr>
<tr>
<td>BMI at Follow-up</td>
<td>24</td>
<td>43.60(7.72)</td>
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</tr>
<tr>
<td>Sex</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>15</td>
<td></td>
<td>62.5</td>
</tr>
<tr>
<td>Male</td>
<td>9</td>
<td></td>
<td>37.5</td>
</tr>
<tr>
<td>Race</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Caucasian</td>
<td>20</td>
<td></td>
<td>83.33</td>
</tr>
<tr>
<td>African American</td>
<td>4</td>
<td></td>
<td>16.67</td>
</tr>
</tbody>
</table>

*Age in measured in years.
Table 2

*Comparisons of group means on measures assessing Weight Related Body-Esteem, Physical Self-Efficacy and Body Satisfaction at time one and time two*

<table>
<thead>
<tr>
<th>Scales (N)</th>
<th>Baseline</th>
<th>Follow-Up</th>
<th>p</th>
<th>Norm</th>
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</thead>
<tbody>
<tr>
<td>Sports Competence (23)</td>
<td>2.06</td>
<td>2.22</td>
<td>.093</td>
<td>2.85**</td>
</tr>
<tr>
<td>Condition Competence (23)</td>
<td>1.72</td>
<td>2.13</td>
<td>.001*</td>
<td>2.73**</td>
</tr>
<tr>
<td>Attractive Adequacy (23)</td>
<td>1.59</td>
<td>1.98</td>
<td>.006*</td>
<td>2.59**</td>
</tr>
<tr>
<td>Strength Competence (23)</td>
<td>2.60</td>
<td>2.75</td>
<td>.139</td>
<td>2.73**</td>
</tr>
<tr>
<td>Physical Self-Worth (23)</td>
<td>1.81</td>
<td>2.30</td>
<td>.002*</td>
<td>2.96**</td>
</tr>
<tr>
<td>Body-Esteem Scale (24)</td>
<td>44.44</td>
<td>65.44</td>
<td>p&lt;.001*</td>
<td>94.52#</td>
</tr>
<tr>
<td>Stunkard Dissatisfaction (10)</td>
<td>4.40</td>
<td>2.60</td>
<td>p&lt;.001*</td>
<td>63.84#</td>
</tr>
</tbody>
</table>

*Significant at p < .01  
**Established normative data from Whitehead (1995)  
# Established normative data from Kolotkin et al., based on BMI groups, increasing in weight from 11th to 84.9th percentile, 85th to 94.9th percentile, and 95th to 100th percentile, respectively
Table 3

*Bivariate correlations examining the relationship between change in BMI and change in scale scores*

<table>
<thead>
<tr>
<th>Subscale</th>
<th>BE</th>
<th>SC</th>
<th>CC</th>
<th>AA</th>
<th>StC</th>
<th>PSW</th>
<th>DS</th>
<th>BMI</th>
</tr>
</thead>
<tbody>
<tr>
<td>BE</td>
<td>1</td>
<td>.204</td>
<td>-.015</td>
<td>.276</td>
<td>.149</td>
<td>.212</td>
<td>-.632</td>
<td>.361</td>
</tr>
<tr>
<td>SC</td>
<td>.204</td>
<td>1</td>
<td>.275</td>
<td>.344</td>
<td>.006</td>
<td>.389</td>
<td>-.475</td>
<td>-.022</td>
</tr>
<tr>
<td>CC</td>
<td>-.015</td>
<td>.275</td>
<td>1</td>
<td>.345</td>
<td>-.138</td>
<td>.187</td>
<td>-.398</td>
<td>-.077</td>
</tr>
<tr>
<td>AA</td>
<td>.276</td>
<td>.344</td>
<td>.345</td>
<td>1</td>
<td>-.229</td>
<td>.815**</td>
<td>-.255</td>
<td>.138</td>
</tr>
<tr>
<td>StC</td>
<td>.149</td>
<td>.006</td>
<td>-.138</td>
<td>-.229</td>
<td>1</td>
<td>-.235</td>
<td>-.260</td>
<td>-.077</td>
</tr>
<tr>
<td>PSW</td>
<td>.212</td>
<td>.389</td>
<td>.187</td>
<td>.815**</td>
<td>-.235</td>
<td>1</td>
<td>-.219</td>
<td>.149</td>
</tr>
<tr>
<td>DS</td>
<td>-.632</td>
<td>-.475</td>
<td>-.398</td>
<td>-.255</td>
<td>-.260</td>
<td>-.219</td>
<td>1</td>
<td>.308</td>
</tr>
<tr>
<td>BMI</td>
<td>.361</td>
<td>-.022</td>
<td>-.077</td>
<td>.138</td>
<td>-.077</td>
<td>.149</td>
<td>.308</td>
<td>1</td>
</tr>
</tbody>
</table>

**Significant at p< .01
Table 4
*Means for the measures of body-esteeem and physical efficacy scores based on gender and time points*

<table>
<thead>
<tr>
<th>Gender</th>
<th>Time Point</th>
<th>N</th>
<th>Mean(SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Body-Esteem Scale</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>Baseline</td>
<td>15</td>
<td>32.41(32.71)</td>
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<tr>
<td></td>
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<tr>
<td>Male</td>
<td>Baseline</td>
<td>9</td>
<td>64.51(22.30)</td>
</tr>
<tr>
<td></td>
<td>6-Month Follow-up</td>
<td>9</td>
<td>80.56(24.69)</td>
</tr>
<tr>
<td><strong>Sports Competence</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>Baseline</td>
<td>15</td>
<td>1.70(.51)</td>
</tr>
<tr>
<td></td>
<td>6-Month Follow-up</td>
<td>14</td>
<td>1.94(.66)</td>
</tr>
<tr>
<td>Male</td>
<td>Baseline</td>
<td>9</td>
<td>2.57(.81)</td>
</tr>
<tr>
<td></td>
<td>6-Month Follow-up</td>
<td>9</td>
<td>2.67(.72)</td>
</tr>
<tr>
<td><strong>Condition Competence</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>Baseline</td>
<td>15</td>
<td>1.68(.52)</td>
</tr>
<tr>
<td></td>
<td>6-Month Follow-up</td>
<td>14</td>
<td>1.98(.39)</td>
</tr>
<tr>
<td>Male</td>
<td>Baseline</td>
<td>9</td>
<td>1.87(.59)</td>
</tr>
<tr>
<td></td>
<td>6-Month Follow-up</td>
<td>9</td>
<td>2.37(.37)</td>
</tr>
<tr>
<td><strong>Attractive Adequacy</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>Baseline</td>
<td>15</td>
<td>1.34(.45)</td>
</tr>
<tr>
<td></td>
<td>6-Month Follow-up</td>
<td>14</td>
<td>1.81(.84)</td>
</tr>
<tr>
<td>Male</td>
<td>Baseline</td>
<td>9</td>
<td>1.96(.56)</td>
</tr>
<tr>
<td></td>
<td>6-Month Follow-up</td>
<td>9</td>
<td>2.24(.56)</td>
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</table>
## Strength Competence

<table>
<thead>
<tr>
<th></th>
<th>Female</th>
<th>Male</th>
</tr>
</thead>
<tbody>
<tr>
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<td>Baseline</td>
<td>Baseline</td>
</tr>
<tr>
<td></td>
<td>15</td>
<td>9</td>
</tr>
<tr>
<td>6-Month Follow-up</td>
<td>14</td>
<td>9</td>
</tr>
</tbody>
</table>

|        | Female Baseline | 1.58(.60) | 6-Month Follow-up | 2.17(1.0) |
|        | Male Baseline   | 2.20(.53) | 6-Month Follow-up | 2.52(.56) |

## Physical Self-Worth

|        | Female Baseline | 2.27(.71) | 6-Month Follow-up | 2.63(.67) |
|        | Male Baseline   | 3.13(.63) | 6-Month Follow-up | 2.93(.44) |

## Stunkard Body Dissatisfaction Score

|        | Female Baseline | 4.57(1.40) | 6-Month Follow-up | 2.71(1.38) |
|        | Male Baseline   | 4.00(1.00) | 6-Month Follow-up | 2.33(.58) |

Note: The standard deviation appears in parentheses after the mean.
Table 5

**Analysis of Variance for Weight Related Body-Esteem and Physical Self-Efficacy Measures by gender and time point**

<table>
<thead>
<tr>
<th>Source</th>
<th>df</th>
<th>SS</th>
<th>F</th>
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<tr>
<td><strong>Body Esteem Scale</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Between subjects</td>
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</tr>
<tr>
<td>Gender</td>
<td>1</td>
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<td>22</td>
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<td>Within subjects</td>
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<td></td>
<td></td>
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<tr>
<td>Time point</td>
<td>1</td>
<td>4504.04</td>
<td>22.48*</td>
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<td>176.38</td>
<td>.880</td>
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<tr>
<td>Between subjects</td>
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<td></td>
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<td>Within subjects</td>
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<tr>
<td>Between subjects</td>
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<td>Within subjects</td>
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### Adolescents' Body Perceptions

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|                   | 21                  | 2.86    |

### Attractive Adequacy Scale

#### Between subjects

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<tr>
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</table>

|                   | 21     | 12.76   |

### Strength Competence

#### Between subjects

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<tr>
<td></td>
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<td>3.70</td>
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</table>

|                   | 21     | 16.13   |

#### Within subjects

<table>
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<th></th>
<th>Time point</th>
<th>Time point x Gender</th>
<th>Error 2</th>
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<tbody>
<tr>
<td></td>
<td>1</td>
<td>.08</td>
<td>1.16</td>
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</tbody>
</table>

|                   | 1          | .90                 | 13.88*  |

|                   | 21         | 1.36                |         |

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### Physical Self-Worth

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<td>Time point x Gender</td>
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### Stunkard Dissatisfaction Scale

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*p < .01
Table 6

*Distribution of Actual and Ideal Scores on the Stunkard Figure Rating at Baseline and Six-Month Follow-Up*

<table>
<thead>
<tr>
<th>Figure</th>
<th>Baseline</th>
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<th>Six-Month Follow-Up</th>
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<tr>
<td></td>
<td>Actual</td>
<td>Ideal</td>
<td></td>
<td>Actual</td>
<td>Ideal</td>
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</tr>
<tr>
<td>A (thinnest)</td>
<td>0</td>
<td>0</td>
<td></td>
<td>0</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>B</td>
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<td>1</td>
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<td>5</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>H</td>
<td>4</td>
<td>0</td>
<td></td>
<td>0</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>I (heaviest)</td>
<td>4</td>
<td>0</td>
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<td>0</td>
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</tr>
</tbody>
</table>
Appendix A

OUTLOOK Consent Form

CINCINNATI CHILDREN'S HOSPITAL MEDICAL CENTER
CONSENT TO PARTICIPATE IN A RESEARCH STUDY

STUDY TITLE: Observing Unique Teens Living With Obesity: Outcomes and Knowledge
(The OUTLOOK Study)

SPONSOR NAME: National Institutes of Health
CCHMC IRB # 05-04-34

IRB APPROVAL STAMP:

Protocol No: 05-04-34
Approved: 04-08-05

INVESTIGATOR INFORMATION:
Meg Zeller, Ph.D.
(513) 636-2712 (phone)
(513) 636-4200 (On-call service)

Subject Name: ___________________________ Date of Birth: ___/___/___

Throughout this document, references to "You" may stand for either the research study subject
or for the parents or legal guardians of the research study subject if the subject is under 18 years
of age or otherwise unable to legally give informed consent to participate in the research study.
The signature(s) at the end will clarify whether the research study subject is signing this consent
form on their own behalf or via a legal guardian or legal personal representative.

INTRODUCTION:
You have been asked to participate in a research study. Before agreeing to participate in this
study, it is important that you read and understand the following explanation. It describes, in
words that can be understood by a lay person, the purpose, procedures, benefits, risks and
discomforts of the study and the precautions that will be taken. It also describes the alternatives
available and the right to withdraw from the study at any time. No guarantee or assurance can
be made as to the results of the study. Also, participation in the research study is completely
voluntary. Refusal to participate will involve no penalty or loss of benefits to which you are
otherwise entitled. You may withdraw from the study at any time without penalty.

Version 2 - June 2006
WHY IS THIS RESEARCH BEING DONE?
The main purposes of this study are to describe: 1) psychosocial health and quality of life experienced by adolescents who are overweight and their families, 2) the changes in these factors over time associated with weight change. The researchers are interested in your viewpoint and have called this the "Outlook Study".

WHY HAVE YOU BEEN ASKED TO TAKE PART IN THIS RESEARCH STUDY?
You are being asked to take part in this research study because you were referred to the Comprehensive Weight Management Center (CVMC) or the HealthWorksI program of Cincinnati Children's Hospital Medical Center.

WHO SHOULD NOT BE IN THE RESEARCH STUDY?
Only adolescents and families referred to the CVMC or HealthWorksI program with a Body Mass Index $> 40 \text{ kg/m}^2$ (a weight to height ratio) are eligible to participate. Adolescents under age 13 and adolescents older than 17 who were referred to these programs are not eligible to participate in this research study.

HOW LONG WILL YOU BE IN THE RESEARCH STUDY?
Adolescents and their primary caregivers will be in the research study for approximately 1 year. This consent, unless you choose to withdraw it, shall remain in effect until the end of the research study. The researcher may decide to take you off this research study at any time.

WHO IS CONDUCTING THE RESEARCH STUDY?
The study is directed by Dr. Meg Zeller, a clinical psychologist and researcher at Cincinnati Children's Hospital Medical Center. This study is sponsored by the National Institutes of Health.

HOW MANY PEOPLE WILL TAKE PART IN THE RESEARCH STUDY?
Approximately 48 adolescents and their families will take part in this study at Cincinnati Children's Hospital Medical Center.

WHAT IS INVOLVED IN THE RESEARCH STUDY?
If you agree that you will participate in this study you will be asked to complete questionnaires and height/weight measurements will be obtained from all participants. At the first or baseline visit, the adolescent will complete 11 questionnaires. Each parent will complete 8 questionnaires. Height/weight measurements will be completed. It is understood that these assessments will require approximately 2½ hours for the adolescent and 2 hours for a parent or caregiver. Parents and adolescents will complete questionnaires in separate testing areas. Follow-up visits will be scheduled at 6- and 12-months following the baseline visit. At these follow-up visits, each parent and the adolescent will complete all the same questionnaires and again height/weight measurements will be completed. Therefore, it is understood that the 6- and 12-month assessments will require approximately 2½ hours for the adolescent and 2 hours for a parent or caregiver. All assessments will be conducted in the Division of Psychology at Cincinnati Children's Hospital Medical Center and will be scheduled at a time convenient for your family.

In addition, it is understood that the adolescent's medical record will be reviewed for medical information related to his/her obesity-related health status, including the presence/absence of Type II diabetes, insulin resistance, sleep apnea, hypertension, and dyslipidemia, all which are routinely assessed as part of the medical care of the CVMC or HealthworksI programs.
WHAT ARE THE RISKS AND DISCOMFORTS OF THE RESEARCH STUDY?
There are minimal risks to adolescent or adult participants in this study. All questionnaires and interviews have been used in research without any reported negative effects. If problems should occur, you will be encouraged to discontinue any of the procedures that cause you to feel uncomfortable in any way. Dr. Zeller will meet with you to discuss your concerns, and if appropriate, assist in making appropriate clinical referrals. In addition, given the length of time needed to complete questionnaires (i.e., 2–4 hours at each visit) participants may become fatigued. Participants will be allowed brief rest breaks at the end of each hour. Another risk may be loss of confidentiality. Please see the section of this consent form entitled How Will Information About You Be Kept Private and Confidential to learn steps that will be taken to reduce the risk of loss of confidentiality. Finally, there may be unknown or unforeseen risks associated with study participation.

ARE THERE DIRECT BENEFITS TO TAKING PART IN THE RESEARCH STUDY?
If you agree to take part in this research study, there are no direct benefits to you. However, the information that the researchers acquire from this study will allow professionals to have a better understanding of the psychosocial health issues that face adolescents who are overweight and their families. Through your efforts and honest participation, researchers hope to influence the manner in which health professionals work with families to provide more optimal care.

WHAT OTHER CHOICES FOR CARE ARE THERE?
You may choose not to participate in the study and this will not affect your adolescent’s care at Cincinnati Children’s Hospital Medical Center.

HOW WILL INFORMATION ABOUT YOU BE KEPT PRIVATE AND CONFIDENTIAL?
Every effort will be made to maintain the confidentiality of your medical and research information ("Protected Health Information" or "PHI"), consisting of your responses to questionnaires, your and height and weight measurements, and medical information related to your adolescent’s treatment at the CWMC or HealthworksI program.

Protected Health Information is defined as health information, whether verbal or recorded in any form (such as on a piece of paper or entered in a computer), that identifies you as an individual or offers a reasonable basis to believe that the information could be used to identify you.

By signing this consent form you are giving permission for representatives of the Cincinnati Children’s Hospital Medical Center ("CCHMC"), the Investigator and CCHMC employees involved with the research study including the Institutional Review Board and the Office for Research Compliance, and any sponsoring company or their appointed agent as well as the National Institutes of Health to be allowed to inspect sections of your medical and research records related to this study. The information from the research study may be published; however, you will not be identified in such publication. The publication will not contain information about you that would enable someone to determine your identity as a research participant without your authorization.

Cincinnati Children’s Hospital Medical Center and/or the Investigator will take the following precautionary measures to protect your privacy and confidentiality of your research and/or medical records. All questionnaires and the results of the study will be treated in strict confidence. Participants will remain anonymous as all information is coded to a number, not to you or your adolescent’s name. The information will be kept in locked cabinets in the Principal Investigators’ offices at Children’s Hospital Medical Center. The names associated with the identifying numbers will be kept in a locked cabinet separate from the questionnaires.
A copy of this consent form will be included in your medical record. You will be registered in the Children’s Hospital Medical Center’s computer system as a research subject which may be beneficial for future clinical care.

USE AND DISCLOSURE OF YOUR PROTECTED HEALTH INFORMATION
The Protected Health Information described in the section above will be used /disclosed for the purpose of research by CHMCC to the other persons or entities identified above. “Use” of an individual's health information is defined as the sharing, examination or analysis (break down) of the information that is collected and maintained for the length of the research study. “Disclosure” of an individual's health information is defined as the release, transfer, providing access to, or to reveal in any other manner, the information outside the persons or entity holding the information as described in the section "How Will Information About You Be Kept Private And Confidential" in this consent form. Once your Protected Health Information is disclosed, the information may be subject to re-disclosure and may no longer be protected by the federal privacy regulations.

AVAILIBILITY OF INFORMATION? If you have questions or would like more information about the study you may contact Dr. Meg Zeller (513-636-2712).

WHAT ARE YOUR COSTS TO BE IN THIS STUDY?
There are no costs for participating in this research study. You will be responsible for the usual costs your adolescent’s medical care, but you will not be charged any additional costs for participation in this study.

WILL YOU BE PAID TO PARTICIPATE IN THIS RESEARCH STUDY?
Participating adolescents will be compensated with a cash payment of $45, and parents $30 (for a total of $75) upon completion of the first study visit. Participating adolescents will be compensated with a cash payment of $60, and parents $40 (for a total of $100) upon completion of the 6-month follow-up study visit. Participating adolescents will be compensated with a cash payment of $75, and parents $50 (for a total of $125) upon completion of the 12-month follow-up visit. The total combined compensation is $300 for adolescents and parents who complete all three study visits.

WHAT ARE YOUR RIGHTS AS A PARTICIPANT?
Your participation in this study is completely voluntary. You may choose either to take part or not to take part in this research study. Your decision whether or not to participate will not result in any penalty or loss of benefits to you and the standard medical care for your condition will remain available to you. If you decide to take part in the research study, you are free to withdraw your consent and discontinue participation in this research study at any time. Leaving the study will not result in any penalty or loss of benefits to you.

You may revoke (choose to withdraw) this Authorization as provided under the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”) at any time after you have signed it by providing Dr. Meg Zeller (Cincinnati Children’s Hospital Medical Center, Mail Location D-3015) with a written statement that you wish to withdraw this Authorization. Your withdrawal of this Authorization will be effective immediately and your Protected Health Information can no longer be used/disclosed for research purposes by CCHMC and the other persons or entities that are identified in the “Use or Disclosure of Your Protected Health Information” section of this consent, except to the extent that CCHMC and/or the other persons or entities identified above have already taken action in reliance upon your consent. In addition, your Protected Health Information may continue to be used/disclosed to preserve the integrity of this research study. The investigators will tell you about significant new findings developed during the course of the research and new information that may affect your health, welfare, or willingness to stay in this study.
study. If you are an employee at Cincinnati Children's Hospital Medical Center, refusal to participate or withdrawal from the study will not jeopardize any of your employee rights, benefits, or opportunities.

If you have questions about the study, you will have a chance to talk to one of the study staff or your regular doctor. Do not sign this form unless you have had the chance to ask questions and have received satisfactory answers. Nothing in this consent form waives any legal rights you may have nor does it release the investigator, the sponsor, the institution, or its agents from liability for negligence. For further information about your rights, please see CCHMC Notice of Privacy Practices.

ABILITY TO CONDITION TREATMENT ON PARTICIPATION IN THIS STUDY
You have a right to refuse to sign this consent to use/disclose your Protected Health Information for research purposes. If you refuse to sign this consent, your rights concerning treatment, payment for services, enrollment in a health plan or eligibility for benefits will not be affected.

WHO DO YOU CALL IF YOU HAVE QUESTIONS OR PROBLEMS?
For questions about this research study or to report a research-related injury, you can contact the researcher, Dr. Meg Zeller at 513-636-2712. (Researchers are available to answer any questions you may have about the research at any time.) If you have general questions about your rights as a research participant in this research study, you can call the Cincinnati Children’s Hospital Medical Center Institutional Review Board at 513-636-8039.

WITNESSING AND SIGNATURES
I have read the information given above. The investigator or his/her designee have personally discussed with me the research study and have answered my questions. I am aware that, like in any research, the investigators cannot always predict what may happen or possibly go wrong. I have been given sufficient time to consider if I (or my adolescent) should participate in this study.

I hereby consent for myself (or my adolescent) to take part in this study as a research study subject.

Adolescent's signature indicating assent

Date:________________________

Parent/Legal Guardian (Signature)

Date:________________________

Parent/Legal Guardian (Signature)

Date:________________________

I have witnessed the voluntary signing of this document by the research subject, or the legally authorized representative of the research subject.

Investigator or specific individual who has been designated to obtain consent (Signature)

Date:________________________

Investigator (Signature)

Date:________________________

This research study and consent form have been reviewed and approved by the Cincinnati Children's Hospital Medical Center Institutional Review Board (telephone number 513-636-8039).

Version 2 - June 2006
Appendix B

CReff Consent Form

CINCINNATI CHILDREN'S HOSPITAL MEDICAL CENTER
CONSENT TO PARTICIPATE IN A RESEARCH STUDY

STUDY TITLE: Psychosocial Health and Quality of Life in Adolescents Pursuing Bariatric Surgery
CCHMC IRB # 04-1-53 IRB Approval Date: 03/04/04
Principal Investigator:
Meg Zeller, Ph.D.
(513) 736-4995 (24-hour pager)
(513) 636-2712 (phone)

Subject Name: ______________________ Date of Birth: ____________

Throughout this document, references to "You" may stand for either the research study subject or for the parents or legal guardians of the research study subject if the subject is under 18 years of age or otherwise unable to legally give informed consent to participate in the research study. The signature(s) at the end will clarify whether the research study subject is signing this consent form on their own behalf or via a legal guardian or legal personal representative.

INTRODUCTION:
You have been asked to participate in a research study. Before agreeing to participate in this study, it is important that you read and understand the following explanation. It describes, in words that can be understood by a lay person, the purpose, procedures, benefits, risks and discomforts of the study and the precautions that will be taken. It also describes the alternatives available and the right to withdraw from the study at any time. No guarantee or assurance can be made as to the results of the study. Also, participation in the research study is completely voluntary. Refusal to participate will involve no penalty or loss of benefits to which you are otherwise entitled. You may withdraw from the study at any time without penalty.

WHY IS THIS RESEARCH BEING DONE?
The aims of the present study are to describe: 1) psychosocial health and quality of life experienced by adolescents who are overweight and pursuing surgical weight loss, 2) the changes in these factors associated with weight reduction.

WHY HAVE YOU BEEN ASKED TO TAKE PART IN THIS RESEARCH STUDY?
You are being asked to take part in this research study because your adolescent has been referred to the Comprehensive Weight Management Program at Cincinnati Children's Hospital Medical Center.

WHO SHOULD NOT BE IN THE RESEARCH STUDY?
Only adolescents with who are referred to the Comprehensive Weight Management Program are eligible to participate. Children under age 13 and adolescents older than 18 who are referred to the Comprehensive Weight Management Program are not eligible to participate in this research study.
HOW LONG WILL YOU BE IN THE RESEARCH STUDY?
Surgery patients and their primary caregivers will be in the research study for approximately twenty-four months after their surgery. This consent, unless you choose to withdraw it, shall remain in effect until the end of the research study. The researcher may decide to take you off this research study at any time.

WHO IS CONDUCTING THE RESEARCH STUDY?
The study is directed by Dr. Meg Zeller, a researcher at Cincinnati Children's Hospital Medical Center. Medical supervision for the study is provided by Dr. Stephen Daniels and Dr. Thomas Inge. This study being sponsored in part by the General Clinical Research Centers Program, National Center for Research Resources of the National Institutes of Health.

HOW MANY PEOPLE WILL TAKE PART IN THE RESEARCH STUDY?
Approximately 30 adolescents will take part in this study at Cincinnati Children's Hospital Medical Center.

WHAT IS INVOLVED IN THE RESEARCH STUDY?
If I agree that I, or my adolescent, will participate in this study we will be asked to complete questionnaires and height/weight measurements will be obtained from myself and my adolescent. At the first visit, I understand that my adolescent will complete 9 questionnaires and I will complete 4 questionnaires. Height/weight measurements will be completed for my adolescent and parent(s). We understand that these assessments will require approximately 25 minutes for adults and 1 hour for our adolescent. We also agree that our responses to the psychological questionnaires administered as part of my adolescent's initial evaluation in the CWMP will be included in the present study.

For those who undergo surgery, follow-up visits will be scheduled at 3-, 6-, 12-, 18-, and 24-months post surgery. At these follow-up visits, my adolescent will complete 10 questionnaires and I will complete 4 questionnaires. Height/weight measurements will be completed for my adolescent and parent(s). We understand that these assessments will require approximately 40 minutes for adults and 1 1/2 hours for my adolescent.

All assessments will be conducted in the Division of Psychology at Cincinnati Children's Hospital Medical Center and will be scheduled at a time convenient for my family. In addition, I understand that my adolescent's medical record will be reviewed for medical information related to my adolescent's treatment at the Comprehensive Weight Management Program.

WHAT ARE THE RISKS AND DISCOMFORTS OF THE RESEARCH STUDY?
There are minimal risks to adolescent or adult participants in this study. All questionnaires and interviews used in this study are standardized and have been used in research without any reported negative effects as asking adolescents and adults about their quality of life and psychological adjustment typically does not result in distress. If problems should occur, you or your adolescent will be encouraged to discontinue any of the procedures that cause you to feel uncomfortable in any way. Dr. Zeller will meet with you to discuss your concerns, and if appropriate, assist in making appropriate clinical referrals. In addition, given the length of time needed to complete questionnaires (i.e., 1 1/4 hours at each visit) participants may become fatigued. Another risk may be loss of confidentiality. Please see the section of this consent form entitled How Will Information About You Be Kept Private And Confidential to learn steps that will be taken to reduce the risk of loss of confidentiality. Finally, there may be unknown or unforeseen risks associated with study participation.
ARE THERE DIRECT BENEFITS TO TAKING PART IN THE RESEARCH STUDY?
If you agree to take part in this research study, there are no direct benefits to you or your adolescent. However, the information that the researchers acquire from this study will allow professionals and parents to have a better understanding of the psychological health issues that are faced by adolescents who are overweight. Through our efforts and honest participation, researchers hope to influence the manner in which health professionals work with families to provide more optimal care.

WHAT OTHER CHOICES FOR CARE ARE THERE?
We may choose not to participate in the study and this will not affect my adolescent's care at Cincinnati Children's Hospital Medical Center.

HOW WILL INFORMATION ABOUT YOU BE KEPT PRIVATE AND CONFIDENTIAL?
Every effort will be made to maintain the confidentiality of your medical and research information ("Protected Health Information" or "PHI"), consisting of you and your adolescent's responses to questionnaires, you and your adolescent's height and weight measurements, and medical information related to your adolescent's treatment at the Comprehensive Weight Management Program.

Protected Health Information is defined as health information, whether verbal or recorded in any form (such as on a piece of paper or entered in a computer), that identifies you as an individual or offers a reasonable basis to believe that the information could be used to identify you.

By signing this consent form you are giving permission for representatives of the Cincinnati Children's Hospital Medical Center ("CCHMC"), the Investigator and CCHMC employees involved with the research study including the Institutional Review Board and the Office for Research Compliance, and any sponsoring company or their appointed agent to be allowed to inspect sections of your medical and research records related to this study.

The information from the research study may be published; however, you will not be identified in such publication. The publication will not contain information about you that would enable someone to determine your identity as a research participant without your authorization.

Cincinnati Children's Hospital Medical Center and/or the Investigator will take the following precautionary measures to protect your privacy and confidentiality of your research and/or medical records. All questionnaires and the results of the study will be treated in strict confidence. Participants will remain anonymous as all information is coded to a number, not to you or your child's name. The information will be kept in locked cabinets in the Principal Investigators' offices at Children's Hospital Medical Center. The names associated with the identifying numbers will be kept in a locked cabinet separate from the questionnaires. A copy of this consent form will be included in your medical record. You will be registered in the Children's Hospital Medical Center's computer system as a research subject which may be beneficial for future clinical care.

USE AND DISCLOSURE OF YOUR PROTECTED HEALTH INFORMATION
The Protected Health Information described in the section above will be used /disclosed for the purpose of research by CCHMC to the other persons or entities identified above.

"Use" of an individual's health information is defined as the sharing, examination or analysis (break down) of the information that is collected and maintained for the length of the research study.
"Disclosure" of an individual's health information is defined as the release, transfer, providing access to, or to reveal in any other manner, the information outside the persons or entity holding the information as described in the section “How Will Information About You Be Kept Private And Confidential” in this consent form.

Once your Protected Health Information is disclosed, the information may be subject to re-disclosure and may no longer be protected by the federal privacy regulations.

**AVAILIBILITY OF INFORMATION?**
If we have questions or would like more information about the study we may contact Dr. Meg Zeller (513-636-2712).

**WHAT ARE YOUR COSTS TO BE IN THIS STUDY?**
There are no costs for participating in this research study. You will be responsible for the usual costs of you or your adolescent's medical care, but you will not be charged any additional costs for participation in this study.

**WILL YOU BE PAID TO PARTICIPATE IN THIS RESEARCH STUDY?**
Participating adolescents will be compensated with a payment of $25 upon completion of each visit. Participating parent(s) will be compensated with a payment of $10 upon completion of each visit.

**WHAT ARE YOUR RIGHTS AS A PARTICIPANT?**
Your participation in this study is completely voluntary. You may choose either to take part or not to take part in this research study. Your decision whether or not to participate will not result in any penalty or loss of benefits to you and the standard medical care for your condition will remain available to you. If you decide to take part in the research study, you are free to withdraw your consent and discontinue participation in this research study at any time. Leaving the study will not result in any penalty or loss of benefits to you.

You may revoke (choose to withdraw) this Authorization as provided under the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") at any time after you have signed it by providing Dr. Meg Zeller (Cincinnati Children's Hospital Medical Center, Mail Location D-3015) with a written statement that you wish to withdraw this Authorization. Your withdrawal of this Authorization will be effective immediately and your Protected Health Information can no longer be used/disclosed for research purposes by CCHMC and the other persons or entities that are identified in the "Use or Disclosure of Your Protected Health Information" section of this consent, except to the extent that CCHMC and/or the other persons or entities identified above have already taken action in reliance upon your consent. In addition, your Protected Health Information may continue to be used/disclosed to preserve the integrity of this research study.

The investigators will tell you about significant new findings developed during the course of the research and new information that may affect your health, welfare, or willingness to stay in this study. If you have questions about the study, you will have a chance to talk to one of the study staff or your regular doctor. Do not sign this form unless you have had the chance to ask questions and have received satisfactory answers. Nothing in this consent form waives any legal rights you may have nor does it release the investigator, the sponsor, the institution, or its agents from liability for negligence. For further information about your rights, please see CCHMC Notice of Privacy Practices.
ABILITY TO CONDITION TREATMENT ON PARTICIPATION IN THIS STUDY
You have a right to refuse to sign this consent to use/disclose your Protected Health Information for research purposes. If you refuse to sign this consent, your rights concerning treatment, payment for services, enrollment in a health plan or eligibility for benefits will not be affected.

WHO DO YOU CALL IF YOU HAVE QUESTIONS OR PROBLEMS?
For questions about this research study or to report a research-related injury, you can contact the researcher, Dr. Meg Zeller at 513-636-2712. Researchers are available to answer any questions you may have about the research at any time. If you have general questions about your rights as a research participant in this research study, you can call the Cincinnati Children's Hospital Medical Center Institutional Review Board at 513-636-8039.

WITNESSING AND SIGNATURES
I have read the Information given above. The investigator or his/her designee have personally discussed with me the research study and have answered my questions. I am aware that, like in any research, the investigators cannot always predict what may happen or possibly go wrong. I have been given sufficient time to consider if I (or my child) should participate in this study. I hereby consent for myself (or my child) to take part in this study as a research study subject.

Check box if verbal assent is obtained from the child who is the research subject □

Subject Signature Indicating consent or assent

Parent/Legal Guardian (Signature)

Date: 3-24-05

Date: 3-24-05

Date:

Parent/Legal Guardian (Signature)

Date:

I have witnessed the voluntary signing of this document by the research subject, or the legally authorized representative of the research subject.

Date:

Witness as to the voluntary nature of the Signatures noted above (Signature)

Investigator or specific individual who has been designated to obtain consent (Signature)

Investigator (Signature)

Date: 3-24-05

Date: 4-5-05

This research study and consent form have been reviewed and approved by the Cincinnati Children's Hospital Medical Center Institutional Review Board (telephone number 513-636-8039).
Appendix C

Approval Letter from Xavier University IRB

April 6, 2006

Kate Grampp
3534 A Brookstone Drive
Cincinnati, OH 45209

Dear Ms. Grampp,

The IRB reviewed your protocol #0384-1 Change in Adolescents’ Body Perception Pre and Post Bariatric Surgery at its March 29 meeting. Subsequently, you supplied the questionnaires and measures being used in the research and clarified your roles in the research study. As a research assistant for Children’s Hospital Medical Center on a study approved by their IRB, you are consenting participants and collecting data. As a Xavier University student, you are using pre-existing anonymized data from three of the questionnaires from that study for your dissertation research. As such, your dissertation research is exempt from review. Your protocol is approved in the exempt category.

We wish you success in your research.

Sincerely,

Robert C. Baumiller, S.J.
Chair and Administrator

cc: Dr. Janet R. Schultz, MI 6511
Appendix D
Directions for Administration

**IWQOL-Kids**

This measure assesses the impact of weight on quality of life for kids. It asks how weight affects their day-to-day life across a number of domains, including their ability to be physically active, their self-esteem, their social relations and family relationships, school, and whether it causes them distress. This measure is always administered **LAST**. The directions should be read directly from the questionnaire.

"Please answer the following statements by circling the number that best applies to you in the past seven days. Be as open as possible. There are no right or wrong answers."

When the child has completed this measure and you are checking it over for completeness, casually check their response to item #10/DISTRESS/PG 4.

If the participant endorsed "BECAUSE OF MY WEIGHT I HAVE THOUGHTS OF HARMING MYSELF OR DYING" **A 5 OR 4** ("Always true" or "Usually true"), please refer to the CDI and IWQOL-Kids Lethality procedures in the back of this manual and follow those procedures.
**What I Am Like – CPSPP / PIP**

This measure looks just like the Harter but is the Children's Physical Self-Perception Profile, and the Children's Perceptions of Importance Profile. The directions are the same for but should be reviewed.

**Fill out this questionnaire just like you did the first.** So first decide whether you are more like the teen on the left side who would rather go to a sports event, or whether you are more like the teen on the right who would rather go to the movies. Which one is more like you?

Now the second thing I want you to decide is whether that is “really true” for you or only “sort of true” for you. If it’s only “sort of true”, put an X or a check under “sort of true”. If it’s “really true”, put a mark in that box.

For each sentence only check one box. Sometimes it will be on one side of the page, and other times on the other side. You don’t ever check both sides.

Do you have any questions?
• Make sure you take a male protocol when seeing male patients and a female protocol when seeing females.

• At the baseline visit ONLY the first page, with questions 1 & 2 will be needed. At 6 month and 12 month follow-up, the first and second pages, questions 1, 2 & 3 will be needed. They are attached because the copyright information is on the second page.

• Read “Below are some drawings of (fe)male figures of the same height, but different weight or shape. Please circle the letter below the figure in response to the following questions.” Hand the protocol to the patient. Make sure they have circled a letter for each question (1 & 2 at baseline; 1, 2 & 3 at follow up).

• For scoring, the letters (A-I) will correspond to numbers (1-9).

<table>
<thead>
<tr>
<th>Letter</th>
<th>Number</th>
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<tbody>
<tr>
<td>A</td>
<td>1</td>
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<td>H</td>
<td>8</td>
</tr>
<tr>
<td>I</td>
<td>9</td>
</tr>
</tbody>
</table>

• At baseline you will record three numerical scores
  - 1. The answer to number 1
  - 2. The answer to number 2
  - 3. The discrepancy score (the difference between 1 & 2).

• At 6 month and 12 month follow up you will record four numerical scores
  - 1. The answer to number 1
  - 2. The answer to number 2
  - 3. The discrepancy score (the difference between 1 & 2).
  - 4. The answer to number 3
Weight/Height - Adolescent

1. Obtain height and weight from clinic charts.

2. Patient charts are located across from Dr. Inge’s office (Sabin 3rd floor).

3. When obtaining height and weight from patient charts it is important that you copy this information from the Nutritional Report. When obtaining data from the Nutritional Report make sure that you are getting the current height and weight and not the surgery height and weight. Also, it is important to make sure that date of which the visit occurred matches the date on the Medical Label.