Health Technology Assessment

Bariatric Surgery in Pediatric Patients

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Presented by:

ECRI Institute
The Discipline of Science. The Integrity of Independence.

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This technology assessment report is based on research conducted by ECRI Institute, as contracted by the Washington State Health Care Authority. This report is an independent assessment of the technology question(s) described based on accepted methodological principles. The findings and conclusions contained herein are those of the investigators and authors who are responsible for the content. These findings and conclusions may not necessarily represent the views of the HCA/Agency and thus, no statement in this report shall be construed as an official position or policy of the HCA/Agency.

The information in this assessment is intended to assist health care decision makers, clinicians, patients and policy makers in making sound evidence-based decisions that may improve the quality and cost-effectiveness of health care services. Information in this report is not a substitute for sound clinical judgment. Those making decisions regarding the provision of health care services should consider this report in a manner similar to any other medical reference, integrating the information with all other pertinent information to make decisions within the context of individual patient circumstances and resource availability

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Executive Summary

This technology assessment was commissioned by the Washington State Health Technology Assessment program for use by the Health Technology Clinical Committee (HTCC). The HTCC uses evidence, primarily as assessed in this report to determine whether health technologies are safe, effective, and cost effective, and therefore should be covered by state programs that pay for health care.

This report evaluates relevant published research describing bariatric surgery in the pediatric population. ECRI Institute's technology assessment provides an independent, in-depth, formal evaluation of the strength of evidence for the safety and efficacy of bariatric surgery for treatment of co-morbid conditions associated with obesity in patients under age 21. It is based on systematic review of the published, peer reviewed scientific literature and methodological precepts described in Appendix C.

Recent years have seen substantial increases in the prevalence of morbid obesity (defined as BMI $\geq$40 kg/m^2 or $\geq$35 kg/m^2 in the presence of one or more medical comorbidities) in both the adult and pediatric populations. (1-3) Between 1988 and 1994, 2.9% of adults in the United States were morbidly obese; this percentage rose to 4.9% (10.8 million people) between 1999 and 2002. The condition was more common among women (6.4%) than among men (3.3%). Epidemiological data are not available on the percentage of the pediatric population who meet the definition of morbid obesity; however the prevalence of morbid obesity in the pediatric population is estimated at 2%-3%.

Obese individuals are at increased risk of type 2 diabetes, hypertension, coronary artery disease, stroke, gallbladder disease (cholelithiasis), osteoarthritis, sleep apnea, respiratory problems, and many types of cancer (including endometrial, breast, prostate, and colon). Obesity is also associated with pregnancy complications, menstrual irregularities, hirsutism, stress incontinence, and psychosocial impairments (e.g., binge eating, altered perception of body image, depression, social stigmatization).(1,10) These health risks contribute to obesity-related increases in all-cause mortality. Studies in pediatric populations have demonstrated the health risks of obesity in pediatric populations.(14-25), and that obesity during adolescence is highly likely to persist into adulthood and creates greater risks of adult health problems (18, 30, 31). Pediatric obesity may also be associated with reduced quality-of-life and social marginalization. (26-28)

Medical intervention for obesity is intended to promote weight loss and thereby reduce comorbid conditions associated with excess weight. Categories of treatment include diet, exercise, behavioral modifications, pharmacotherapy, and bariatric surgery. The goal of bariatric surgery in pediatric patients with morbid obesity is to halt the progression of obesity into adulthood to improve or eliminate medical conditions associated with obesity, and to improve quality of life. An individual considering whether to undergo bariatric surgery must take into consideration not only these potential improvements as compared to the risks of persistent severe obesity, but also the risks associated with the surgical procedure both in the short and long term and the need to comply with lifelong dietary and lifestyle changes. Use of bariatric surgery to treat morbid obesity has increased dramatically in recent years, from approximately 13,000 operations in 1998 to approximately 121,000 operations in 2004.(34) Patients under age 18 comprise about 0.1 - 1%

of patients reported to have received bariatric surgery for morbid obesity at various centers. It is estimated that over 2,000 pediatric patients ages 21 and younger in the United States received bariatric surgery in 2004, and based on a 2005 survey of bariatric surgeons in the United States indicating 75% were planning to perform adolescent bariatric surgery in the coming year, this number is likely to rise. Many different types of bariatric surgical procedures are performed, so "bariatric surgery" cannot be considered a single procedure. Some bariatric surgeries are purely restrictive—they cause weight loss by limiting the amount of food that can be consumed in one meal. Others are malabsorptive—they cause weight loss by reducing the amount of food that is absorbed into the body. The two most common bariatric surgical procedures are laparoscopic adjustable gastric banding (LAGB), which is a purely restrictive procedure, and Roux-en-Y gastric bypass (RYGB), which is both restrictive and malabsorptive. While the mechanism of action differs from procedure to procedure, all bariatric procedures are intended to induce weight loss, improve medical comorbidities, enhance quality of life, and (ultimately) extend survival.

Overall, data from 17 studies that enrolled a total of 553 pediatric patients are included. (Table 2) Eight studies reported outcomes after laparoscopic adjustable gastric banding (LAGB), six after Roux-en-Y gastric bypass (RYGB), two after vertical banded gastroplasty (VBG), and one after banded bypass. One study reported data separately for RYGB and VBG. Additional study characteristics and patient characteristics are listed in **Table 19** and **Table 20** of Appendix E, respectively.

Our detailed assessments of the quality (defined as internal validity) of the literature appear in **Table 21** and **Table 22** of Appendix E. Quality was addressed in the context of the specific outcome(s) being examined and the specific time points at which each outcome was measured. Briefly, only one study was clearly prospective. Although the remaining studies appeared to have collected data retrospectively, 13 studies did include data on consecutive patients, Consecutive enrollment helps ensure that authors did not specially select patients who experienced desired outcomes. Of note in regard to generalizability of the information is that the majority of studies were conducted in academic medical centers, and at least four of the centers had multidisciplinary pediatric bariatric surgery programs. Consequently, we believe that this evidence is most generalizable to similar care settings. Also, although the mean number of pediatric bariatric surgeries performed by surgeons in the studies was generally low, whether these surgeons had more extensive experience in the adult population was not reported.

The average age of patients in the included studies ranged from 15.6 years to 18.1 years, with little difference in mean age among bariatric procedures. None of the studies focused exclusively on patients aged 18-21, or on patients aged 12 or less. Four studies enrolled only patients aged 13-17: the Nadler study of LAGB, the Barnett study of RYGB and VBG, the Strauss study of RYGB, and the Capella study of banded bypass.

For pre-surgical BMI the weighted average was lower for LAGB (BMI = 45.8 kg/m^2) than for RYGB (BMI = 51.8 kg/m^2). This observation conforms to the conventional use of purely restrictive procedures (such as LAGB) for less obese patients, or the use of more malabsorptive procedures (such as RYGB) for those who are more obese. For reference, a 17-year-old boy of average height with a BMI of 48 kg/m^2weighs approximately 334 pounds (152 kilograms), and the corresponding 17-year-old girl weighs approximately 289 pounds (131 kilograms). This report defines "clinically significant" weight loss as 7% of body weight (see *Methods* section). In the included LAGB studies, 7% of body weight in the enrolled patients corresponds to 3.5 BMI

units. For RYGB, it corresponds to 4 BMI units; for VBG or banded bypass, it corresponds to 3.9 BMI units.

Prior to surgery, all patients had undergone multiple unsuccessful attempts at weight loss using non-surgical methods (see studies' descriptions of prior attempts in **Table 19** of Appendix E). We believe that it is reasonable to assume that these patients would not have lost any weight if they had received additional non-surgical treatments. One of the 17 studies reported a control group of patients who were not treated with bariatric surgery; however the control group patients weighed statistically significantly less at baseline than surgical patients, and the study did not report any medical comorbidities among control group patients, as compared to surgical patients who had several comorbidities at baseline. These factors mean that the groups were not well-matched at baseline; thus we excluded the data from this control group, and included only the data from the surgical group.

We examined this evidence in the context of five clinical questions, which are listed below, along with our evidence-based conclusions. Our strength of evidence ratings take into consideration not only the individual study quality for each outcome and time point, but also the quantity, consistency, and robustness of the evidence, in addition to the magnitude of observed effects.

1. Does pediatric bariatric surgery lead to sustained and clinically significant weight loss compared to non-operative approaches?

   a. In patients aged 21 or less

   b. Specifically in patients aged 18-21

   c. Specifically in patients aged 13-17

   d. Specifically in patients aged 12 or less

ECRI Institute evidence assessments:

Laparoscopic Adjustable Gastric Banding (LAGB) for morbidly obese patients aged 21 or less does lead to sustained and clinically significant weight loss compared to non-operative approaches.

- Strength of evidence at longest followup after surgery (1.7 to 3.3 years): Weak
- Strength of evidence at one year after surgery: Moderate

Roux-en-Y Gastric Bypass (RYGB) for morbidly obese patients aged 21 or less does lead to sustained and clinically significant weight loss compared to non-operative approaches.

- Strength of evidence at longest followup after surgery (1 to 6.3 years): Weak;
- Strength of evidence at one year after surgery: Moderate

The evidence is insufficient to permit quantitative estimates of the precise amount of weight loss after any bariatric surgical procedure for pediatric patients.

The evidence is insufficient to permit any conclusions about weight loss after other bariatric surgical procedures for pediatric patients.

The evidence is insufficient to permit any conclusions about weight loss in specific age

subgroups (18-21, 13-17, 12 or less) within the pediatric population.

Five of eight LAGB studies reported BMI data that met inclusion criteria. The length of followup ranged from 1.7 to 3.3 years, and the percentage of patients in our analysis of longest-follow-up BMI was 100% in four studies and 64% in the fifth study. Our study quality assessments for this analysis indicated that the overall quality was low. All five studies observed statistically and clinically significant weight loss after surgery. We performed seven tests to confirm the robustness of the finding, including an alternate assumption that patients might lose as many as 1.7 BMI units without surgery (change in weight as measured by kilograms per meter of height squared). All analyses still indicated clinically significant weight loss. Based on the overall quality of the studies as well as the quantity, consistency, and robustness of the evidence, we rated the strength of the evidence at longest followup after LAGB as Weak. Also, three of the studies had reported BMI specifically at one year after LAGB. The overall quality of the one-year BMI data was moderate, and each reported statistically and clinically significant weight loss. All seven qualitative robustness tests analyses were passed; therefore the strength of this evidence for one-year BMI reduction after LAGB was Moderate.

Five of six RYGB studies reported BMI data that met inclusion criteria. One study's BMI data were very low quality, and consequently we excluded it from further consideration. For the remaining four studies, the percentage followup ranged from 60% to 90%, and the mean length of followup ranged from 1 year to 6.3 years. The overall quality was low. All four studies observed statistically and clinically significant weight loss after surgery, and the analysis passed all seven robustness tests. Thus, as with LAGB, we rated the strength of the evidence as Weak for longest-follow-up BMI after RYGB. Also, three of the studies had reported BMI specifically at one year after LAGB. The overall quality of the one-year BMI data was moderate, and each reported statistically and clinically significant weight loss. All seven qualitative robustness tests analyses were passed; therefore the strength of this evidence for one-year BMI reduction after RYGB was Moderate.

The evidence did not permit precise quantitative estimates of the number of BMI units lost after either LAGB or RYGB, because studies did not generally report sufficient information for us to calculate the pre-post correlation for BMI. Also, the evidence on weight loss after other bariatric procedures (e.g., VBG) did not support conclusions due to low quantity and quality of evidence. For specific age groups of pediatric patients (e.g., 13-17), there were not enough studies of any single age group to permit conclusions.

2. Does bariatric surgery for patients a-d (as above) improve comorbid conditions linked to obesity (e.g., diabetes, hypertension, obstructive sleep apnea, and musculoskeletal disorders), quality of life, or survival, as compared to non-operative approaches?

   ECRI Institute evidence assessments:

   Laparoscopic Adjustable Gastric Banding (LAGB) for morbidly obese patients aged 21 or less does resolve comorbid conditions linked to obesity (diabetes, hypertension) compared to non-operative approaches. (Strength of evidence for comorbidity data: Weak).

   Roux-en-Y Gastric Bypass for morbidly obese patients aged 21 or less does resolve comorbid conditions linked to obesity (hypertension) compared to non-operative approaches. (Strength of evidence for comorbidity data: Weak).

The evidence is insufficient to permit quantitative estimates of the likelihood of comorbidity resolution, quality of life improvement, or survival after any bariatric surgical procedure for pediatric patients.

The evidence is insufficient to permit any conclusions about comorbidity resolution after other bariatric surgical procedures for pediatric patients.

The evidence is insufficient to permit any conclusions about comorbidity resolution in specific age subgroups (18-21, 13-17, 12 or less) within the pediatric population.

Four of eight LAGB studies met inclusion criteria for comorbidity and quality of life outcomes. The mean length of follow-up ranged from 1.3 years to 2.9 years. No studies evaluated changes in medical conditions or quality of life using validated instruments or long term survival. The evidence was sufficient to permit conclusions only for diabetes (two studies, with resolution rates of 80% and 100%) and hypertension (three studies, with resolution rates of 50%, 100%, and 100%). These are large rates, but due to the moderate quality and limited quantity, we rated the strength of evidence as Weak for these outcomes. The evidence on other comorbidities and quality of life was too sparse to permit conclusions.

Four of six RYGB studies met inclusion criteria for comorbidity and quality of life outcomes. The mean length of followup ranged from 5 months to 2.7 years. The evidence was sufficient to permit a conclusion only for hypertension (three studies, with resolution rates of 50%, 82% and 100%). Due to the moderate quality and limited quantity, we rated the strength of evidence as Weak for hypertension resolution. One other comorbidity had at least two studies (sleep apnea), but the data were of overall low quality, therefore we drew no conclusions. The evidence on other outcomes was too sparse to permit conclusions.

We drew no conclusions about other bariatric procedures or specific age groups, due to a limited quantity of evidence.

3. What are the relative safety profiles of bariatric surgery and non-operative approaches for patients a-d (as above)?

ECRI Institute evidence assessments:

Our review of the eight LAGB studies (the procedures were performed between 1996 and 2006; the individual patient follow-up times ranged from one month to 85 months) found:

No reported in-hospital or postoperative death.

The most frequently reported complication after LAGB was band slippage.

Reoperations were performed on 26 (7.92%) of the 328 LAGB patients to correct various complications.

Our review of the six RYGB studies (the procedures were performed between 1978 and 2005; the individual patient follow-up times ranged from two weeks to six years) found:

One postoperative death was reported for RYGB; no in-hospital death was reported.

The most frequently reported complication after RYGB was related to protein-calorie malnutrition and micronutrient deficiency.

Potentially life-threatening complications such as shock, pulmonary embolism, severe

malnutrition, immediate postoperative bleeding, and gastrointestinal obstructions were reported in the RYGB studies.

The evidence is insufficient to permit any conclusions on potential impacts of bariatric surgery on growth and development of pediatric patients.

The evidence is insufficient to permit any conclusions on potential harms in specific age groups (18-21, 13-17, 12 or less).

Systematic reviews on pediatric obesity management did not provide sufficient data for the development of a safety profile of non-operative approaches.

All 17 studies were included for data on complications. The overall evidence quality was rated as Moderate for these outcomes. Given the low patient enrollment, we did not attempt to estimate the rate of any complication. For LAGB, the primary concern is the need for reoperation, which was necessary for 26 pediatric patients (7.92%) overall. Reasons for reoperation include band slippage, intragastric migration, and port/tubing problems. For RYGB, there is a different profile of complications, varying from mild events (e.g., slight malnutrition, correctable by supplements) to severe events (e.g., pulmonary embolism, severe malnutrition, immediate postoperative bleeding, and gastrointestinal obstruction).

4. What are the relative cost profiles of bariatric surgery and non-operative approaches for patients a-d (as above)?

ECRI Institute evidence assessments:

Nationally, the median inpatient hospital cost for bariatric surgeries performed in pediatric patients in 2004 was $8,651; the median hospital charge was $25,021. Nationally, the median inpatient hospital cost for restrictive bariatric procedures performed in pediatric patients in 2004 was $6,688; the median inpatient hospital cost for bypass procedures was $8,893.

Nationally, for those aged 13-17, the median inpatient hospital cost for bariatric procedures performed in 2004 was $7,973; the median inpatient hospital cost for those aged 18-21 was $8,945. No conclusions can be drawn regarding the cost of patients aged 12 and less due to lack of data.

Data were not sufficient to permit a comparison of inpatient hospital cost between the State of Washington and the rest of the nation.

Data were not sufficient to permit an analysis of the costs for professional services and post-surgery care.

The evidence was not sufficient to permit the development of a comprehensive cost profile of non-operative approaches to pediatric obesity management.

Due to the inadequacy of published evidence on the costs of bariatric surgery in pediatric patients with morbid obesity, we conducted our own analyses of publicly available data to estimate inpatient hospital costs. However, due to lack of data, we were unable to conduct similar primary analyses to estimate the costs for professional services and postoperative care.

5. Do the effectiveness, safety and cost of bariatric surgery for patients a-d (as above) vary based on patients' characteristics, including:

    a. Chronological age

    b. Physiologic/skeletal age

    c. Pre-surgical BMI

    d. Pre-surgical BMI categories (35-40, 40-50, 50+)

    e. Sex

    f. Race

    g. Comorbid conditions (e.g., hypertension)

    h. Other factors (e.g., psychosocial or socioeconomic factors)

ECRI Institute evidence assessments:

The evidence is insufficient to permit any conclusions for this question

Studies' data were included for four of the eight patient characteristics: chronological age (a), pre-surgical BMI (c), pre-surgical BMI category (d), and sex (e). However, none of these associations were addressed by more than two studies of any given bariatric procedure, and the low quantity of evidence precluded conclusions. The association between chronological age and surgical outcome was addressed by only one study of LAGB, one study of RYGB, and one study of banded bypass. Similarly, the association between sex and outcome was addressed by only one study each for LAGB, RYGB, and VBG. There were two studies of LAGB addressing the association between pre-surgical BMI and surgical outcome (and also the association between pre-surgical BMI category and surgical outcome), but the overall low quality precluded conclusions.

Overall assessment

Both LAGB and RYGB led to clinically significant weight loss in morbidly obese pediatric patients over the followup times reported. While reporting of comorbid conditions was limited, there was evidence that diabetes and hypertension resolved following LAGB and that hypertension resolved after RYGB. A number of complications were reported following both procedures, including one postoperative death following RYGB. Variations in outcomes based on patient characteristics such as age, baseline BMI, sex, race or socioeconomic variables could not be determined from the available literature.

Individuals who work with morbidly obese children and adolescents have expressed concern about the appropriateness of bariatric surgery in this population. In particular, many question the ability of pediatric patients to give informed consent not only to an invasive procedure, but also to the long-term lifestyle and dietary changes necessary following the surgery. Future research should examine methods of presenting the complex information necessary for truly informed consent in pediatric individuals considering bariatric surgery. More evidence is needed on outcomes such as physical growth and quality of life. Longer term prospective collection of data on weight loss, persistence or resolution of comorbid conditions, and long-term survival would be valuable for understanding more fully the role of these surgical procedures in treating morbidly obese

pediatric patients. Data collection on a large population (e.g., a national registry) could provide enough data to improve our ability to identify individuals most likely to benefit long term from a surgical approach, and to determine which surgical approach is best suited to individuals with specific characteristics.

Introduction

Morbid Obesity in Pediatric Patients

Definitions

Morbid obesity is generally defined as having a body mass index (BMI) of at least 40 kg/m^2 or at least 35 kg/m^2 in the presence of one or more medical comorbidities.(1-3) BMI is computed as the weight in kilograms divided by the height in square meters.

For this report, we defined the "pediatric" population as patients aged 21 or younger, corresponding to the definition of the American Association of Pediatrics.(4) The Centers for Disease Control and Prevention (CDC) have noted that BMI is a "reliable indicator of body fatness in most children and teens."(5)[1] For illustrative purposes, Table 1 shows four hypothetical pediatric patients of average height (a 13-year-old girl, a 13-year-old boy, a 17-year-old girl, and a 17-year-old boy) along with two weights: the weight corresponding to a BMI of 40, and the weight corresponding to a BMI of 50.

Body fat is most accurately measured using hydrodensitometry or dual-energy X-ray absorptiometry (DXA),(6) but these methods are highly labor-intensive and costly. BMI, on the other hand, is more feasible because it only requires measurements of height and weight. An important question is whether BMI correlates well with body fatness *in the pediatric population*. Field et al. (2003)(6) addressed this question by measuring both body fat (using DXA) and BMI in 596 children and adolescents. They found that BMI explained 72% of the variance in body fat (corresponding to a Pearson r correlation of 0.85). This finding suggests that in pediatric patients, BMI is a reasonably accurate surrogate for body fatness.

[1] The interpretation of BMI for children and teenagers depends on age and sex, and the CDC definition of an "overweight" pediatric patient is when the BMI is at or above the 95th percentile for that age and sex.(5) For bariatric surgery, however, the key weight criteria are tied to "morbid obesity"; a person at the threshold for morbid obesity is much heavier than a person at the CDC threshold for "overweight."

Table 1. Examples of Weights Corresponding to High BMIs Assuming Average Height

Age	Sex	Average height[a]	Weight corresponding to a BMI of 40 kg/m^2	Weight corresponding to a BMI of 50 kg/m^2
13	Girl	5 feet, 1.3 in.	217 lbs (98.8 kg)	272 lbs (123.6 kg)
13	Boy	5 feet, 0.9 in.	215 lbs (97.6 kg)	268 lbs (122.0 kg)
17	Girl	5 feet, 3.5 in.	234 lbs (106.1 kg)	292 lbs (132.7 kg)
17	Boy	5 feet, 8.4 in.	270 lbs (122.9 kg)	338 lbs (153.7 kg)

a Average heights are based on CDC growth charts.

BMI – Body Mass Index
kg – kilograms
in – inches
m – meters

Epidemiology

The prevalence of obesity has increased sharply in recent years. Between 1988 and 1994, 2.9% of adults in the United States were morbidly obese; this percentage rose to 4.9% (10.8 million people) between 1999 and 2002. The condition was more common among women (6.4%) than among men (3.3%). Approximately 26% of U.S. adults had nonmorbid obesity; an additional 34.7% were overweight but not obese.(7,8)

Epidemiological data are not available on the percentage of the pediatric population who meet the definition of morbid obesity (as defined in the previous section). However, the phrase "overweight" has been applied to adolescents to denote those with BMIs above the 95th percentile for age and sex based on CDC growth charts. Using this definition, percentage of adolescents who were "overweight" nearly tripled between 1970 and 1999 (from 5% to 14%).(9) Hedley et al. (2004) used data from the National Health and Nutrition Examination Survey (NHANES) for 1999-2002 to estimate that 16% of pediatric patients aged 6-19 were "overweight" (the study did not report the percentage of pediatric patients who had morbid obesity).(8) However, our analysis of CDC growth charts estimates that a 17-year-old girl of average height who barely meets this threshold for "overweight" has a BMI of only 30. Therefore, the true prevalence of morbid obesity in the pediatric population is much lower than the ~14%-16% figures for "overweight". Based on the distribution of adult BMIs, the prevalence of morbid obesity in the pediatric population may be 2%-3%.[2]

[2] This estimation is based the observations that 31% of adults are obese and 5% are morbidly obese. This corresponds in the pediatric population to 15% obese and 2.5% morbidly obese.

Health Implications of Obesity

Overweight and obese individuals are at increased risk of type 2 diabetes, hypertension, coronary artery disease, stroke, gallbladder disease (cholelithiasis), osteoarthritis, sleep apnea, respiratory problems, and many types of cancer (including endometrial, breast, prostate, and colon). Obesity is also associated with pregnancy complications, menstrual irregularities, hirsutism, stress incontinence, and psychosocial impairments (e.g., binge eating, altered perception of body image perceptions, depression, social stigmatization).(1,10)

These health risks contribute to obesity-related increases in all-cause mortality. In 2000, about 365,000 deaths in the United States were attributed specifically to poor diet and physical inactivity.(11,12) Approximately seven years of life are lost due to obesity in a 40-year-old white female with a BMI over 45 kg/m^2.(13)

Many studies in pediatric populations have demonstrated the health risks of obesity in pediatric populations.(14-25) Becque(25) determined that 35 of 36 (97%) obese adolescents had four or more serious cardiovascular[3] risk factors. Weiss(22) found that 97 of 195 severely obese adolescents (50%) met criteria for the metabolic syndrome, as compared to 0 of 20 non-obese adolescents. Rhodes(23) studied 14 morbidly obese children and adolescents and found that five of them (36%) had sleep apnea, which was associated with more neurocognitive deficits (learning, memory). Additional risks of obesity among adolescents include musculoskeletal problems, asthma, gastroesophageal reflux disease (GERD), pseudotumor cerebri, gallstones, and menstrual abnormalities.(14,17,24)

Research has also demonstrated reduced quality of life(26) and social marginalization among obese pediatric patients.(27,28) Schwimmer(26) surveyed the quality of life of 106 obese patients aged 5-18, and found an average score of only 67, as compared to 83 for non-obese pediatric patients (on their pediatric QOL scale, 100 indicated excellent quality of life, and 0 indicated extremely poor quality of life). The impact of obesity was persistent for both psychosocial health and physical health. In another study of over 90,000 adolescents in the National Longitudinal Study of Adolescent Health,(27) the authors measured the number of friendship nominations[4] received by other adolescents. The average was lower for overweight adolescents (3.4) than for non-overweight adolescents (4.8). Also, obese adolescents were more likely to receive zero friendship nominations (which was true for 12% of overweight adolescents as compared to 7% of non-overweight adolescents), suggesting social marginalization.

Long-Term Risks

Obese pediatric patients are more likely to become obese adults than their non-obese peers.(18,29-31) In a review of 15 studies, Serdula(29) estimated that 42%-63% of obese school-age children become obese adults; the comparative risk of becoming an obese adult was 4 to 6.5 times higher for obese school-age children than non-obese school-age children. Power(18) used data from a 1958 birth cohort and found similar relative risks of adulthood obesity based on

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[3] The factors under consideration were: 1) serum triglyceride >100 mg/dL; 2) HDL cholesterol below the 10th percentile for age and sex; 3) total cholesterol >200 mg/dL; 4) systolic BP above the 90th percentile for age and sex; 5) dystolic BP above the 90th percentile for age and sex; 6) maximal oxygen consumption <24 mL/kg of body weight; and 7) strong immediate family history of cardiovascular disease.

[4] This study defined a "friendship nomination" as when the obese adolescent is cited by another adolescent as a friend.

adolescent obesity. Whitaker(30) found that 23 of 30 patients (77%) who had been severely obese at age 15-17 were still obese as adults, and this same percentage (77%) was observed in a study by Freedman(31) that included 186 obese adolescents.

Obesity during adolescence has also been tied directly to health problems in adulthood.(18,31-33) Power(18) reviewed five pertinent studies and found correspondence between adolescent obesity and adulthood all-cause mortality, coronary heart disease, atherosclerosis, colorectal cancer, gout, arthritis, and menstrual problems. Also, Abraham(33) found higher prevalence rates of four medical conditions (diabetes, atherosclerosis, hypertension, and cardiovascular disease) among 19 men whose weight was ≥120% of the average weight for age and height.

Principles and Goals of Treatment

Obesity treatments are intended to promote weight loss, reduce the risks of health problems, improve the quality of life, and (ultimately) extend survival. The categories of treatment include diet, exercise, behavioral modification, pharmacotherapy, and bariatric surgery. Because bariatric surgery is the topic of this assessment, we describe it first, and then we describe non-surgical obesity treatments.

Bariatric Surgery

Bariatric surgery is a specialty area of general surgery devoted to the treatment of obesity. Use of bariatric surgery to treat morbid obesity has increased dramatically in recent years, from approximately 13,000 operations in 1998 to approximately 121,000 operations in 2004.(34)

Patients under age 18 comprise about 0.1 - 1% of patients reported to have received bariatric surgery for morbid obesity at various centers.(35-37) The estimated adolescent bariatric rate (per 100,000 population) in the U.S. increased from 0.7 in 2000 to 2.3 in 2003.(38) Based on our analysis of the Nationwide Inpatient Sample (NIS) of the Healthcare Cost and Utilization Project (HCUP), we estimated that over 2,000 pediatric patients ages 21 and younger in the United States received bariatric surgery in 2004. A 2005 survey of bariatric surgeons in the United States found that 49% of them (45/92) had performed bariatric surgery on one or more adolescents in the previous year, 75% (69/92) were planning to perform adolescent bariatric surgery in the coming year, and 55% (51/92) either had a bariatric program with pediatric specialists or were creating one.(39)

Underlying Theory

A wide variety of surgical procedures have been used to treat obesity. Surgeons distinguish between these procedures based on the presence of restrictive or malabsorptive features.(3) Restrictive features are intended to cause weight loss by restricting the amount of food that can be consumed. By contrast, malabsorptive features are intended to cause weight loss by limiting the amount of food that is absorbed by the digestive tract. A procedure can have restrictive features, malabsorptive features, or both.

All bariatric surgical procedures can be performed using either an open or laparoscopic approach. Whereas the open approach involves making a large abdominal incision to enable direct access to the stomach and intestines, the laparoscopic approach utilizes several small incisions, and the operation is performed using specialized instruments and monitors. This less invasive approach is intended to improve short-term operative and perioperative outcomes including blood loss, complications, length of hospital stay, and patient recovery time. However,

the laparoscopic approach adds technical complexity which commonly lengthens the time required to perform the surgery. For a given procedure, the open and laparoscopic approaches intend to create the same anatomic structure of the patient's digestive system. The difference lies only in the manner in which the procedure is performed.

Basic Procedure

The two most commonly performed bariatric surgical procedures are laparoscopic adjustable gastric banding (LAGB) and the Roux-en-Y (RYGB) gastric bypass (illustrated in **Figure 1** below). LAGB is a purely restrictive procedure in which the surgeon places a silicone band around the entire upper portion of the stomach, creating a tiny pouch where food empties from the esophagus to the upper stomach. Because of the tiny pouch and the narrow channel through the band, patients feel satiated after only a small amount of food is eaten. Adjusting the diameter of the band allows more or less food to pass to the lower portion of the stomach. These adjustments permit some flexibility in treatment: the band can be narrowed if weight loss is insufficient, or it can be expanded if the patient experiences severe complications.

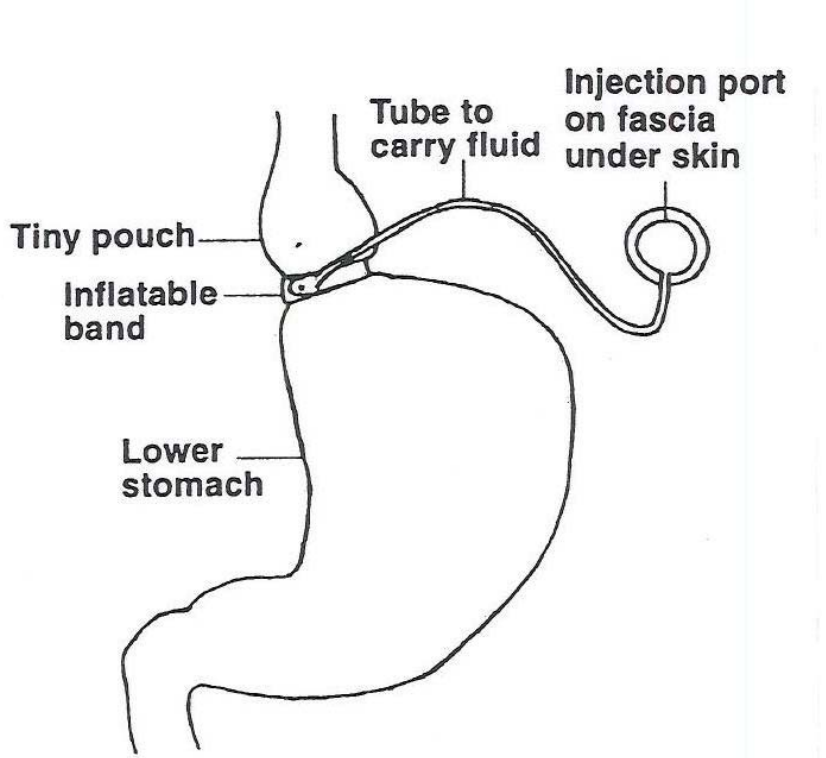
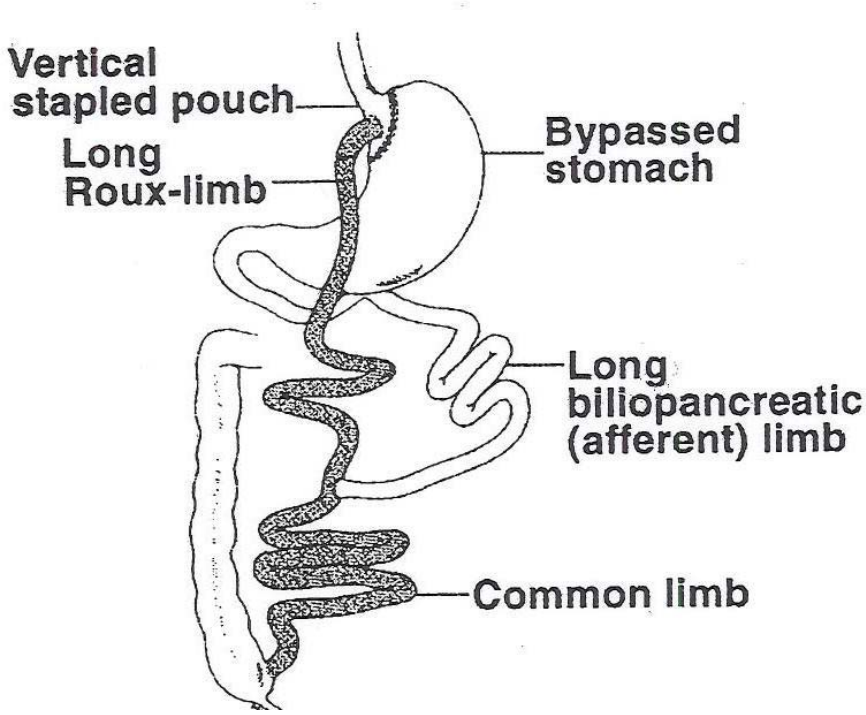
Five types of bands are currently being used: the LAP-BAND® (Inamed Health, Santa Barbara, CA), the Swedish Adjustable Gastric Band (SAGB; Ethicon Endo-Surgery, Cincinnati, OH), the Midband (Medical Innovation Development, Lyon, France), the Heliogast band (Heliogast HAGA, Helioscopie, Veinne Cedex, France), and the AMI band (AMI, GmbH, Feldkirch, Austria). Of these, in the United States only the LAP-BAND® has received FDA clearance for marketing.

The RYGB has both restrictive and malabsorptive features. For restriction, the stomach is separated (using staples or other method) into a small upper portion and a large lower portion. Food enters only the upper portion (the gastric pouch). The small intestine is cut 15 to 50 cm distal to the ligament of Treitz. The distal small intestine is connected to the gastric pouch, permitting the emptying of food. This creates one limb (the "Roux," or alimentary limb) of a Y-shaped construction. Completion of the Y portion of the reconstruction involves performing an anastomosis (jejunojejunostomy) to connect the proximal end to the side of the roux limb at least 45 cm downstream to prevent reflux of bile and pancreatic juices into the proximal gastric pouch. The two limbs meet and form a common limb at the most distal section of the small intestine, where food and digestive fluids mix.

Other bariatric surgical procedures include vertical banded gastroplasty (VBG), banded bypass, biliopancreatic diversion with duodenal switch (BPD/DS), and laparoscopic sleeve gastrectomy (LSG). In VBG, the surgeon creates a small gastric pouch in the upper portion of the stomach using vertically aligned staples. The pouch is drained through a narrow band (stoma) into the rest of the stomach. VBG maintains the anatomic and functional continuity of the gastrointestinal tract; thus, its mechanism of weight loss is purely restrictive. Banded bypass, also called the Fobi pouch procedure or the Fobi-Capella procedure, employs the restrictive properties of VBG and the malabsorptive proportions of RYGB. In recent years, the BPD/DS has been used with increasing frequency.(40) This procedure is considered to be more malabsorptive than the RYGB, and surgeons remove the greater curvature of the stomach. The alimentary limb is created by connecting the distal small intestine to the duodenum distal to the stomach. A second limb (biliopancreatic) permits the emptying of digestive fluids. The two limbs meet in a common channel measuring only 75 to 100 cm, thereby permitting relatively little absorption. In some morbidly obese patients, the risk of complications of a full BPD/DS is particularly high. These

may include patients with “super” obesity (i.e., those with BMIs of 50 or higher) or heart conditions. Due to these risks, some surgeons first perform only the restrictive portion of BPD/DS. This restrictive portion is laparoscopic sleeve gastrectomy (LSG).(41,42) Weight loss may be sufficient with this operation alone, but if not, the patient may potentially undergo the second half of the operation.

Figure 1. Diagrams of LAGB and RYGB

Laparoscopic Adjustable Gastric Banding (LAGB)	Roux-en-Y Gastric Bypass (RYGB)
	

Diagrams used with the permission of Mervyn Deitel, MD. The Roux-en-Y diagram is specifically of the Torres Roux-en-Y procedure.(43)

Non-Surgical Treatments for Morbid Obesity

In general, pediatric patients who receive bariatric surgery have previously had unsatisfactory weight loss with non-surgical methods. In this section, we describe non-surgical methods of weight reduction including dietary modification, physical activity, behavioral modification, and pharmacotherapy. Any of these methods can be used simultaneously to optimize weight loss.

Dietary modification can cause weight loss by limiting energy intake below energy expenditure. This modification is individualized per patient based on age, sex, previous calorie intake, and weight-loss goals. Generally, the emphasis in obesity treatment is on limiting overall quantities as well as the intake of fat, sugar, and salt. Further, in the pediatric population, nutrient recommendations differ based on age. The recommended percentage of daily calories for fat, carbohydrates and protein are:(44)

- Fat: 30%-40% for ages 1-3 and 25%-35% for ages 4-18.
- Carbohydrates: 45%-65% for all ages
- Protein: 5%-20% for ages 1-3 and 10%-30% for ages 4-18.

Increasing physical activity and exercise also promote weight loss. Current recommendations vary regarding the amount of necessary exercise in pediatric patients. In 2005, a panel of 13 experts reviewed evidence on exercise and concluded that "school-age youth should participate daily in 60 minutes or more of moderate to vigorous physical activity that is developmentally appropriate, enjoyable, and involves a variety of activities."(45) However, because obese patients are often sedentary before beginning an exercise program, such recommendations only represent a long-term exercise target.

Behavioral modification is also a component of some weight-loss programs.(46,47) This intervention addresses the psychological component of eating and is intended to promote weight loss by helping people make better decisions about eating. Several aspects of behavior are addressed, including when, where, and what to eat and when to stop eating.(46) For example, obese people may be encouraged to avoid certain environments that contribute to weight gain (e.g., fast-food restaurants that serve mostly fatty foods).

Pharmacotherapy employs pharmacologic agents to cause weight loss. These agents may be used in conjunction with diet, exercise, or other weight management programs. Antiobesity agents that have been approved by FDA include orlistat, sibutramine, benzphetamine HCl, diethylpropion HCl, mazindol HCl, phendimetrazine tartrate, and phentermine HCl.(48) These agents affect the noradrenergic pathway or both the noradrenergic pathway and the serotonergic pathway. The only two agents approved for six or more months of use are orlistat and sibutramine. With orlistat, commonly cited gastrointestinal side effects include oily/loose stool and flatulence; for sibutramine, side effects include dry mouth and nausea. Standard dosing for adolescents is 120 mg three times a day for orlistat, or 5-15 mg/day for sibutramine.(49) However, orlistat is only approved for those aged 12 and older, and sibutramine is only approved for those aged 16 and older. Therefore, some obese pediatric patients do not meet indications for long-term pharmacotherapy.

The primary concerns with the effectiveness of non-surgical weight methods for obese pediatric patients involve high dropout rates, and the minimal weight loss among those who do not drop out. For example, two recent trials (Chanoine et al. (2005)(50) and Savoye et al. (2007)(51)) followed obese pediatric patients for one year after initiation of treatment. Chanoine et al.

(2005)(50) enrolled 357 pediatric patients in a group to receive orlistat, hypocaloric diet, exercise and behavioral modification, but only 232 of them (65%) completed one-year followup, and their average BMI loss was only 0.55 units (from a baseline BMI of 35.6). Similarly, Savoye et al. (2007)(51) observed one-year completion in only 71% (75/105) of patients assigned to a weight management program, and the average one-year BMI reduction was only 1.7 units (baseline BMI 35.9).

Methods

Key Questions and Outcomes Assessed

In this report, we address the following five Key Questions:

1. Does pediatric bariatric surgery lead to sustained and clinically significant weight loss compared to non-operative approaches?
    a. In patients aged 21 or less
    b. Specifically in patients aged 18-21
    c. Specifically in patients aged 13-17
    d. Specifically in patients aged 12 or less
2. Does bariatric surgery for patients a-d (as above) improve comorbid conditions linked to obesity (e.g., diabetes, hypertension, obstructive sleep apnea, musculoskeletal disorders), quality of life, or survival, as compared to non-operative approaches?
3. What are the relative safety profiles of bariatric surgery and non-operative approaches for patients a-d (as above)?
4. What are the relative cost profiles of bariatric surgery and non-operative approaches for patients a-d (as above)?
5. Do the effectiveness, safety and cost of bariatric surgery for patients a-d (as above) vary based on patients' characteristics, including:
    a. Chronological age
    b. Physiologic/skeletal age
    c. Pre-surgical BMI
    d. Pre-surgical BMI categories (35-40, 40-50, 50+)
    e. Sex
    f. Race
    g. Comorbid conditions (e.g., hypertension)
    h. Other factors (e.g., psychosocial or socioeconomic factors)

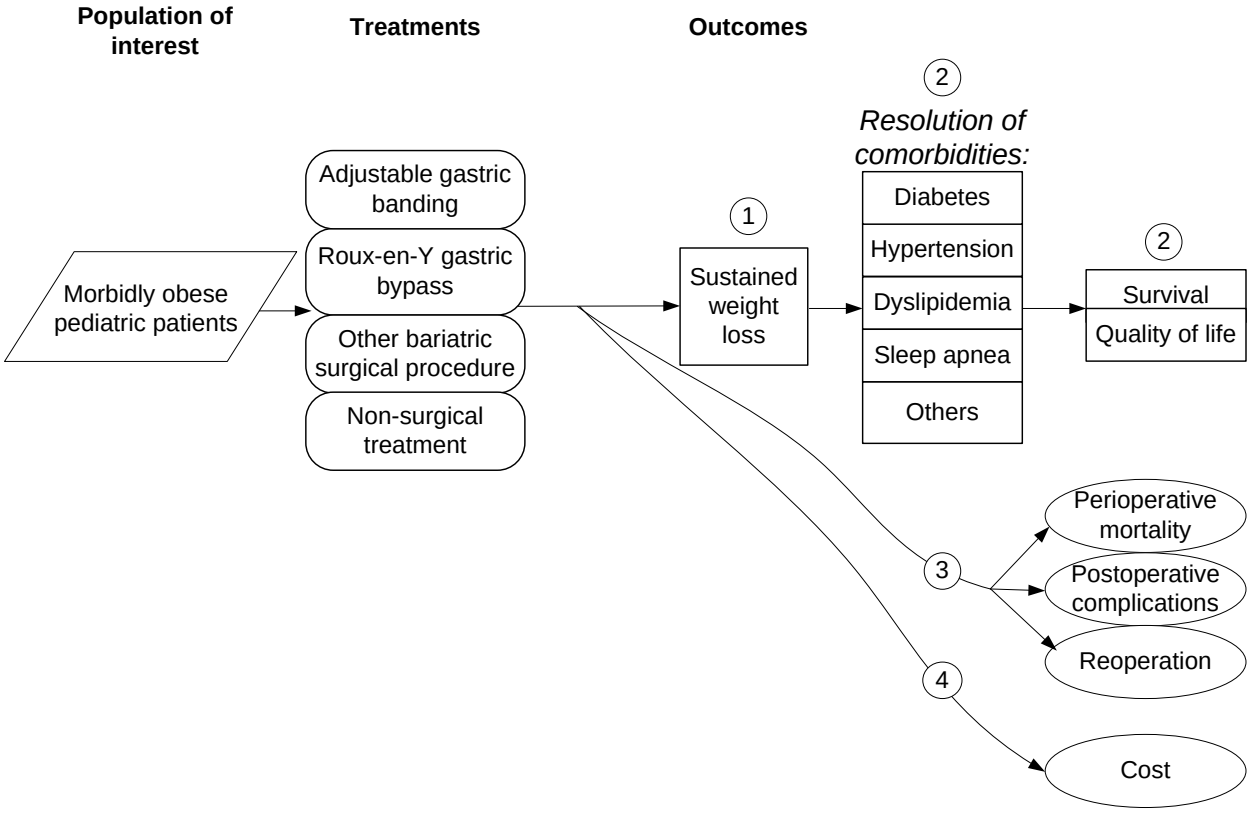
Bariatric surgery for the treatment of morbid obesity in pediatric patients is diagrammed in **Figure 2** below. This figure is called an analytic framework. Such frameworks help clarify the scope of the review, the key clinical questions addressed, and the relationships between outcomes. Pediatric patients with morbid obesity enter the framework from the left and progress through treatment and outcomes to the right. The Key Questions delineate four age categories: 1) all those aged 21 or younger; 2) patients between 18 and 21; 3) patients between 13 and 17; and 4) patients 12 and younger.

For treatment, patients can either receive bariatric surgery (LAGB, RYGB, or other procedure) or non-surgical treatment for obesity (e.g., diet, exercise, pharmacological agents, behavioral modification). In the long term, the chosen intervention may lead to weight loss, which is addressed in Key Question 1. This report defines "long term" as one year or more. Surgery could also result in improvement or resolution of comorbidities (e.g., diabetes, hypertension, dyslipidemia, sleep apnea, musculoskeletal pain in weight-bearing joints). Finally, the weight loss and any consequent comorbidity resolution may improve quality of life and increase long-

term survival. These outcomes of potential benefit are addressed in Key Question 2.
Key Question 3 involves safety, including perioperative mortality, complications, and the need for re-operation to correct problems with the original operation. Additional Key Questions involve costs (Key Question 4) and whether certain patient characteristics are associated with differences in outcomes (Key Question 5).

For all Key Questions, we examined outcome data separately for different bariatric procedures. This is due to variation among procedures in the mechanism(s) for inducing weight loss. Consequently, different procedures would be expected to result in different amounts of weight loss, different rates of comorbidity resolution, different types of harms and complications, different costs, and different associations between patient characteristics and outcomes.

Figure 2. Analytic Framework



Literature Searches

The clinical studies included in this technology assessment were identified using a multi-staged study selection process, and were based on inclusion criteria that were determined *a priori*. Use of *a priori* inclusion criteria reduces the risk of bias because the decision to include or exclude each study is independent of the results of the study. In the first stage of the selection process, we performed a comprehensive literature search using broad criteria. In the second stage, we retrieved all articles that appeared to meet the *a priori* inclusion criteria, based on their published abstracts. In the final stage of the study selection, we reviewed the full text of each retrieved article, assessed its quality, and verified whether or not it met the *a priori* inclusion criteria.

One characteristic of a good technology assessment is a systematic and comprehensive search for information. Such searches distinguish systematic reviews from traditional literature reviews. Traditional literature reviews use a less rigorous approach to identifying and obtaining literature, making it possible for a reviewer to include primarily articles that agree with a particular perspective, and to ignore articles that do not. Our approach precludes this potential reviewer bias because we obtained and included articles according to explicitly determined *a priori* criteria.

Briefly, we searched 15 external and internal databases, including PubMed and Embase, for relevant studies. In addition, we searched more than 1,600 journals and supplements maintained in ECRI Institute's collections to determine if they contained relevant information. We also examined the bibliographies/reference lists from peer-reviewed and gray literature. (Gray literature includes reports and studies produced by local government agencies, private organizations, educational facilities, and corporations that do not appear in the peer-reviewed literature.) A complete list of the databases searched and the search strategy used to identify relevant studies are presented in Appendix A. The last search was conducted on August 6, 2007.

Study Inclusion Criteria

Use of explicit inclusion criteria, decided upon before data have been extracted, is a vital tool in preventing reviewer biases. Some of these *a priori* criteria are based on study design, and other criteria ensure that the evidence is not derived from unusual patients or interventions and/or outmoded technologies. Finally, we also developed criteria to ensure that we focused our analysis on the outcomes that are of most interest to patients.

The inclusion criteria were:

1. Study must have reported on at least one of the outcomes that are the focus of this report. *Other outcomes are beyond the scope of this report.*
2. Study must be published in English.
   Moher et al. have demonstrated that exclusion of non-English language studies from meta-analyses has little impact on the conclusions drawn.(52) Juni et al. found that non-English studies typically were of lower methodological quality and that excluding them had little effect on effect size estimates in the majority of meta-analyses they examined.(53) Although we recognize that there may be situations in which exclusion of non-English studies could lead to bias, we believe that it is insufficiently likely that we

cannot justify the time and cost of translations to identify studies of acceptable quality for inclusion in our reviews.

3. Study must be published as a peer-reviewed full article. Meeting abstracts will not be included.
   Published meeting abstracts have not been peer-reviewed and often do not include sufficient details about experimental methods to permit one to verify that the study was well designed.(54,55) In addition, it is not uncommon for abstracts that are published as part of conference proceedings to describe studies that are never published as full articles.(56-59)
4. The study must have enrolled three or more individuals per treatment arm.
   The results of case studies are typically more variable and less generalizable than those of larger studies.
5. When several sequential reports from the same study center are available, only outcome data from the largest and most recent report will be included. However, we will use relevant data from earlier and smaller reports if the report presents pertinent data not presented in the larger, more recent report.
   This criterion prevents the double-counting of patients.
6. If the study was a controlled trial directly comparing a surgical approach to a non-surgical approach, the groups must have been well-matched at baseline (for age, sex, and pre-surgical BMI) in order to include the data from the non-surgical group.
   This criterion protects against selection bias.
7. If the study enrolled patients who received different procedures, data must have been reported separately for each procedure, or at least 85% of patients must have received the same procedure.
   Because different procedures may have different patient indications and may result in different outcomes, combined data may not be easily interpreted.
8. For weight outcomes, the study must have reported data for at least half of the pertinent enrolled patients at one or more years after surgery.
   If data were reported for less than half of the enrolled patients, the reported data may be unrepresentative of the experience of typical patients. Short-term weight loss can be transient, and sustained weight loss is defined in this report as one year or more after surgery.
9. For other outcomes, the study must have reported data for at least half of the enrolled patients, and there was no minimum length of followup.
   For other outcomes (e.g., improvements in comorbidities, complications), all time points are of interest.
10. For quality-of-life outcomes, the study must have measured quality of life before and after surgery using a previously validated instrument.
    This criterion means that quality of life data would not depend on patients' memory of their quality-of-life before surgery.
11. All patients must have been age 21 or less.
    This report only considers pediatric patients.

12. Study must report data on one of the following surgical procedures:
    - Adjustable gastric banding (AGB)
    - Roux-en-Y gastric bypass (RYGB)
    - Vertical banded gastroplasty (VBG)
    - Silastic ring vertical gastroplasty (SRVG)
    - Mini gastric bypass (MGB)
    - Banded bypass (also called the Fobi pouch procedure)
    - Biliopancreatic diversion (BPD)
    - Biliopancreatic diversion with duodenal switch (BPD/DS)
    - Laparoscopic sleeve gastrectomy (LSG)

    The above-listed procedures are currently being performed. Some bariatric procedures, such as horizontal gastroplasty and jejunoileal bypass (JIB), are not currently performed and were therefore outside the scope of this report.

Evaluation of the Stability and Strength of the Body of Evidence

To rate the quality of case series of bariatric surgery, we considered six criteria: 1) whether the study was prospective; 2) whether the study had enrolled consecutive patients; 3) whether the outcome assessment was performed by an independent party; 4) whether the study was not funded by a financially interested party; 5) whether the outcome was objective; and 6) whether the data for the outcome contained at least 85% of the pertinent enrolled patients. Based on these criteria, we categorized the quality of each study, separately for the different outcomes and timepoints reported by that study (for further details, see Appendix C). The reason for multiple quality assessments for each study is that two of the criteria (85% completion, outcome objectivity) can vary by outcome or timepoint.

After assessing quality, we evaluated the overall stability and strength of the evidence using a formal rating system.(60) The system incorporates the quality, quantity, consistency, robustness of the evidence, as well as the magnitude of observed effects. Quality refers to the degree of potential bias in the design or conduct of studies. Quantity refers to the number of studies and the number of enrolled patients. Consistency addresses the degree of agreement among the results of available studies. Robustness involves the constancy of conclusions in the face of minor hypothetical alterations in the data. Magnitude of effect concerns the quantitative amount of benefit that patients experience after treatment, and it is only considered in the qualitative section of the system. These concepts, and the rules we used to incorporate the concepts in this report, are described more fully in Appendix C.

Our system employs decision points that collectively yield an overall category that describes the strength of the evidence for a *quantitative* estimate and *qualitative* conclusion as strong, moderate, weak, or inconclusive. The qualitative conclusion addresses the question, "Does it work?" The quantitative estimate addresses the question, "How well does it work?" This distinction allows flexibility in ratings of different aspects of the evidence. For example, an evidence base can be considered weak in terms of the precise *quantitative* estimate of effect (e.g., if estimates vary widely among studies), but strong or moderate with respect to the qualitative conclusion (e.g., if all studies nevertheless demonstrate the same direction of effect).

Statistical Methods

When three or more studies of the same surgical procedure reported data on the same outcome, we performed DerSimonian and Laird random-effects meta-analysis.(61) We analyzed weight data using body mass index (BMI). Meta-analysis allows the pooling of data from different studies to maximize the informativeness of the evidence. The purpose of meta-analysis can be to estimate the size of the overall effect (i.e., quantitative estimate), or to determine the general direction of the effect (i.e., qualitative conclusion). In this report, reporting deficiencies precluded precise estimates of an overall effect, but we still used meta-analysis in an attempt to reach qualitative conclusions and perform sensitivity analyses.

One important caveat to meta-analysis is that it does not influence the quality of the evidence. In other words, if the studies entered into a meta-analysis are susceptible to bias, then the meta-analysis will be similarly susceptible to bias. Thus, meta-analysis cannot somehow transform a low-quality evidence base into an evidence base of higher quality. In our strength of evidence rating system, the quality of the evidence is the most important factor, regardless of whether meta-analysis is performed.

Because all patients in all studies had undergone multiple unsuccessful attempts at weight loss prior to surgery, our analyses assumed that they would not have lost weight without surgery.[5] This assumption was tested in robustness analyses; specifically, we investigated alternative assumptions that without surgery patients might have lost a small amount of weight (up to 1.7 BMI units).

For weight loss, a clinically significant amount was defined as 7% of body weight, because patients who lose this amount of weight have been shown by other researchers to yield substantial reductions in medical comorbidities of obesity (e.g., diabetes).(62,63) This criterion is more stringent than the definition of clinically significant weight loss of 5% body weight that is used by the U.S. FDA.(64)

For meta-analysis of before-after studies of change in BMI, the computation of an effect size requires a patient-level correlation between pre-surgical BMIs and post-surgical BMIs. Some studies reported such individual patient data, so we calculated the correlation for each of these studies, and then performed a random-effects meta-analysis of these correlations. We then used the summary correlation (0.60) as an imputed correlation in studies that had not provided individual patient data. In subsequent robustness tests, we used the 95% confidence bounds of this correlation to determine sensitivity to the choice of correlation.

Other statistical robustness tests included the removal of one study at a time to determine whether the conclusion was driven by any single study; cumulative meta-analysis to determine sensitivity to publication date; assessment of the width of the confidence interval around a summary effect size to determine the robustness of a quantitative estimate; imputation of a small amount of BMI loss (0.55 to 1.7 units) without surgery to determine sensitivity of conclusions to the assumption of no weight loss without surgery; and removal of studies with less than 75% followup to determine sensitivity of conclusions to the inclusion of studies with 50%-74% followup.

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[5] Studies of non-surgical weight loss methods in obese adolescents have not shown the potential for reversing medical comorbidities, and the observed long-term weight loss is minimal (e.g., 1.7 BMI units at one year).(51)

For the resolution of comorbidities, we determined statistical significance by computing the odds ratio separately for each comorbidity for each procedure. This was computed by assuming that non-surgical methods would not resolve comorbidities, and by adding 0.5 to all cells of the 2x2 table to permit calculation of the odds ratio (as is standard practice). For Key Question 5, we calculated correlations between patient characteristics and outcomes in included studies that reported patient-level data.

Specific Methods for Key Question 4

A preliminary review of the clinical studies potentially included for Key Questions 1-3 and 5 indicated that none of these studies provided cost data regarding bariatric surgeries. An extensive search of other literature on the topic identified two U.S. studies(34,38) reporting cost (or charge) data regarding pediatric bariatric surgeries. However, the data from these two studies alone were inadequate to address Key Question 4 for two reasons. First, the two studies covered patients aged 10 to19 and patients aged 12 to17, respectively; however, this evidence report was intended to cover the 21-and-under age group as well as three sub-groups: 12-and-under, 13-17 and 18-21. Second, the two studies did not report cost data separately for different bariatric procedures (e.g., restrictive procedures and bypass procedures). Therefore, to address Key Question 4, we conducted a primary analysis of hospital inpatient cost using the Healthcare Cost and Utilization Project (HCUP) data.

In addition, we attempted to identify studies on the costs for professional services and post-surgery care in the pediatric population, but no such studies exist. Neither did we identify a reliable data source (like the HCUP data sets) that would permit us to conduct a primary analysis. As a result, we did not cover the costs for professional services and post-surgery care in this report despite the potential significance of these costs.

Identifying Hospital Inpatient Cost

To identify hospital inpatient cost, we used the Healthcare Cost and Utilization Project (HCUP) data.

HCUP Data

The HCUP databases are developed through a Federal-State-Industry partnership and sponsored by the Agency for Healthcare Research and Quality (AHRQ). HCUP includes the largest collection of longitudinal hospital care data in the United States, with all-payer, encounter-level information beginning in 1988, which enables research on a broad range of health policy issues including cost and quality of health services. HCUP consists of several databases including the Nationwide Inpatient Sample (NIS), the State Inpatient Database (SID), the Kids' Inpatient Database (KID), the State Ambulatory Surgery Databases (SASD), and the State Emergency Department Databases (SEDD).

For our inpatient cost analyses, we utilized the NIS for 2004. NIS is the largest all-payer inpatient care database in the United States. It contains data from approximately 8 million hospital stays each year and is the only national hospital database with charge information on all patients, regardless of payer. The NIS 2004 data set was the most recent NIS available to the public. It contains discharge data from 1,004 hospitals located in 37 states, approximating a 20-percent stratified sample of U.S. community hospitals in 2004. We decided to use NIS instead of the Kids' Inpatient Database (KID) for two reasons. First, NIS is updated more frequently

than KID (the most recent KID data set is for 2003). Second, KID only contains data for patients of up to 20 years of age, while this evidence report covers a population of up to 21 years of age. Our analysis of the 2004 NIS data showed that nearly a quarter (103) of the identified 415 pediatric patients who received bariatric surgery were 21 years old.

In addition to NIS 2004, we also used the State Inpatient Database (SID) 2002-2004 databases for the State of Washington (SID WA) to analyze the state-specific inpatient costs. The SID WA data sets contained the universe of the inpatient discharge abstracts in the State of Washington for all payer types. SID WA 2004 is the most recent SID available to the public.

Case Selection

HCUP data sets use the International Classification of Diseases, Ninth Revision (ICD-9), coding system to classify procedures and diagnoses. Since the ICD-9 system does not have specific codes for all bariatric procedures currently performed, we consulted previous studies(34,38,65,66) and the Centers for Medicare & Medicaid Services' billing guidelines to develop the following criteria to select bariatric surgery cases in the HCUP databases:

- To be selected, a case must have a diagnosis code for obesity (278.0, 278.00, 278.01, 278.1, or 278.8) and a procedure code for gastric bypass (44.31 and 44.39), gastroplasty (44.69), laparoscopic gastric bypass (44.38), laparoscopic gastroplasty (44.68), or laparoscopic gastric restrictive procedures (44.95).
- Cases with diagnosis codes for gastrointestinal tract neoplasm (150.0-159.9), in-situ cancers (230.1-130.9), inflammatory bowel disease (555.0-556.9), or noninfectious colitis (557.0-558.9), and emergent admission codes (admission-type variable = emergent or urgent and/or admission-source variable = emergency department or other hospital) were excluded because they were unlikely to be elective bariatric surgeries.

Because different bariatric procedures (e.g., LAGB and VBG; standard RYGB and long-limb gastric bypass) might be coded under the same ICD-9 codes in 2004, a clear-cut differentiation between these procedures included in the HCUP data sets is impossible. To make the procedure-level cost analysis possible, we created two procedure categories—bypass procedures and restrictive procedures—based on the similarity in resource consumption and involved surgical techniques. The bypass category would mostly consist of RYGB, long-limb gastric bypass and biliopancreatic diversion (with or without duodenal switch) cases. The restrictive category would mostly consist of LAGB and VBG cases. We used ICD-9 procedure codes 44.31, 44.39, and 44.38 to capture the cases in the bypass category and used codes 44.69, 44.68, and 44.95 to capture the cases in the restrictive category.

Within each procedure category, we further created two sub-categories: procedures performed laparoscopically and those performed via the open approach. On October 1, 2004, three codes for laparoscopic bariatric procedures (44.38, 44.68 and 44.95) were added to the ICD-9 system. In addition to using these three codes, we used concurrent procedure coding to capture the laparoscopic cases performed before October 1, 2004. We considered concurrent procedure coding with any laparoscopic code—including 54.21, 47.01, 47.11, 51.23, 54.51, 65.01, 65.25, 65.31, 65.39, 65.41, 65.63, 65.64, 65.81, or 68.51—as evidence that the procedure was performed laparoscopically. Appendix D contains the information on the codes discussed in this section.

Data Analyses

We analyzed both charge and cost data using SPSS 15.0. Because HCUP data sets do not provide cost values directly, we converted HCUP charge values to cost values using HCUP hospital-specific cost-to-charge ratios (CCRs). The CCRs were based on hospital accounting reports from the Centers for Medicare and Medicaid Services (CMS) and had factored in both operating costs and capital-related costs. Because the hospital-specific CCR values were missing for 32% of the cases, we used group average CCRs to substitute the missing hospital-specific values. The HCUP hospital groups are defined by state, urban/rural, investor-owned/other, and number of beds. The group average CCR is a weighted average for the hospitals in the group, using the proportion of group beds as the weight for each hospital.

Specific Methods for Non-surgical Approaches in Key Questions 3 and 4

Given the vast amount of published literature available on non-surgical interventions for nonmorbid obesity, our time and resource limitations, and the emphasis of this report on surgical approaches, we restricted our evaluation of the safety profile of non-surgical approaches to recently published systematic reviews. To be included, a systematic review had to meet the following criteria:

- The review was published in English.
- The review was published in 2000 or later.
- The review was on treatments for obesity/morbid obesity in the pediatric population with a dedicated section on potential harms of non-surgical approaches.
- A comprehensive literature search was performed using at least two electronic sources (e.g., Central, EMBASE, and MEDLINE).
- Inclusion and exclusion criteria for study selection were provided.

The quality of included systematic reviews would be evaluated using a measurement tool for assessment of multiple systematic reviews (AMSTAR).(67) We decided to summarize the findings from these reviews qualitatively.

For the cost profile of non-surgical approaches, we included all published materials that have a cost component for non-surgical approaches to obesity management in the pediatric population. To be included, a published material must meet the following criteria:

- Published in 2000 or later.
- The cost data were reported for treatments conducted in U.S settings. Foreign studies were excluded.
- The cost data reported reflect the national or a regional pattern or trend. Publications containing cost data only for an individual institution or provider were excluded.
- Information on data collection and analysis were provided to permit an evaluation of the quality of the study.

We decided to summarize the cost data reported in published materials qualitatively.

Results

Evidence Base

Included Studies

The results of literature searches, abstract reviewing, full-article retrieval, and study exclusion are depicted in **Figure 3** below. Of the 153 abstracts identified by searches, we retrieved 38 articles, and we excluded 14 of these because they did not meet the inclusion criteria. The list of excluded studies appears in Appendix B.

After these exclusions, 17 unique studies in 24 publications comprised the evidence base (**Table 2**). Eight studies reported outcomes after laparoscopic adjustable gastric banding (LAGB), six after Roux-en-Y gastric bypass (RYGB), two after vertical banded gastroplasty (VBG), and one after banded bypass. One study (Barnett)(68) reported data separately for RYGB and VBG. Additional study characteristics and patient characteristics are listed in **Table 19** and **Table 20** of Appendix E, respectively.

Patients' ages and pre-surgical BMIs are displayed graphically in **Figure 4** and **Figure 5**. The average age ranged from 15.6 years to 18.1 years, with little difference in mean age among bariatric procedures. None of the studies focused exclusively on patients aged 18-21, or on patients aged 12 or less. Four studies enrolled only patients aged 13-17: the Nadler study of LAGB, the Barnett study of RYGB and VBG, the Strauss study of RYGB, and the Capella study of banded bypass.

For pre-surgical BMI (**Figure 5**), the weighted average was lower for LAGB (BMI = 45.8 kg/m^2) than for RYGB (BMI = 51.8 kg/m^2). This observation conforms to the conventional use of purely restrictive procedures (such as LAGB) for less obese patients, or the use of more malabsorptive procedures (such as RYGB) for those who are more obese. For reference, a 17-year-old boy of average height with a BMI of 48 kg/m^2weighs approximately 334 pounds (152 kilograms), and the corresponding 17-year-old girl weighs approximately 289 pounds (131 kilograms).

This report defines "clinically significant" weight loss as 7% of body weight (see *Methods* section). In the included LAGB studies, 7% of body weight in the enrolled patients corresponds to 3.5 BMI units. For RYGB, it corresponds to 4 BMI units; for VBG or banded bypass, it corresponds to 3.9 BMI units.[6]

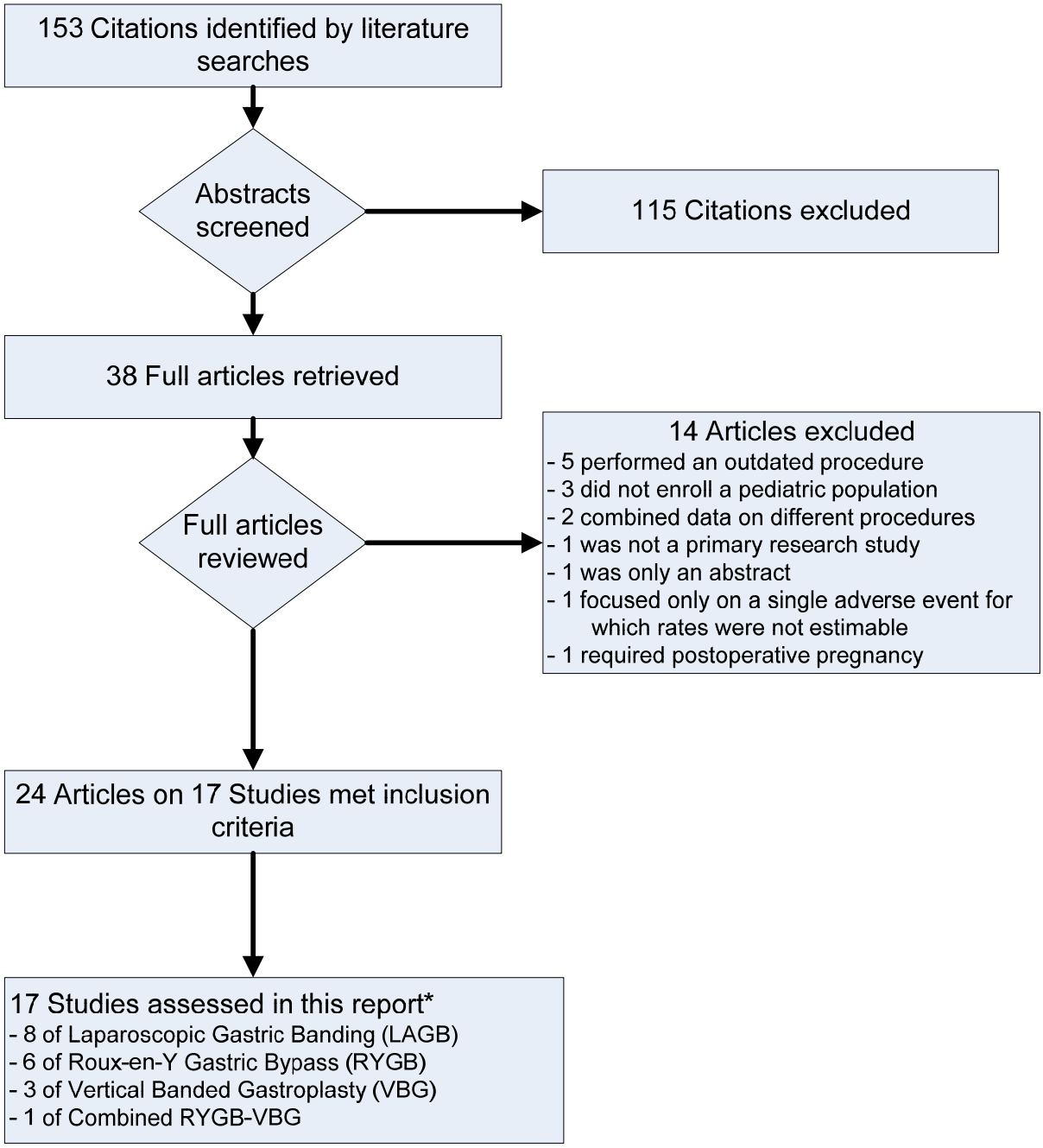
Prior to surgery, all patients had undergone multiple unsuccessful attempts at weight loss using non-surgical methods (see studies' descriptions of prior attempts in **Table 19** of Appendix E). We believe that it is reasonable to assume that these patients would not have lost any weight if they had received additional non-surgical treatments. One of the 17 studies reported a control group of patients who were not treated with bariatric surgery (the Lawson study of RYGB).(69) This control group included 12 patients who had completed one year in a non-surgical pediatric weight management program. However, patients in the control group were much different from

[6] These BMI units are based on baseline BMIs and calculations of the average heights of patients, which was possible in studies that reported both BMI and weight data.

those who received surgery. Specifically, the control group patients weighed statistically significantly less at baseline than surgical patients, and the study did not report any medical comorbidities among control group patients, as compared to surgical patients who had several comorbidities at baseline. These factors mean that the groups were not well-matched at baseline, thus we excluded the data from this control group, and included only the data from the surgical group.

Regarding the surgical procedures, six of the eight LAGB studies used the LAP-BAND® (Inamed Health, Santa Barbara, CA) one used the Swedish Adjustable Gastric Band (SAGB; Ethicon Endo-Surgery, Cincinnati, OH), and one used the SAGB in 74% of patients and the LAP-BAND® in the remaining 26%. Of the six RYGB studies, two used a laparoscopic approach, three used an open approach, and one used an open approach for 94% of procedures and a laparoscopic approach for the remaining 6%. The three VBG studies were all performed using an open approach. Additional procedure details, along with the center locations and surgical date ranges, appear in **Table 19** of Appendix E.

Figure 3. Study Attrition Diagram



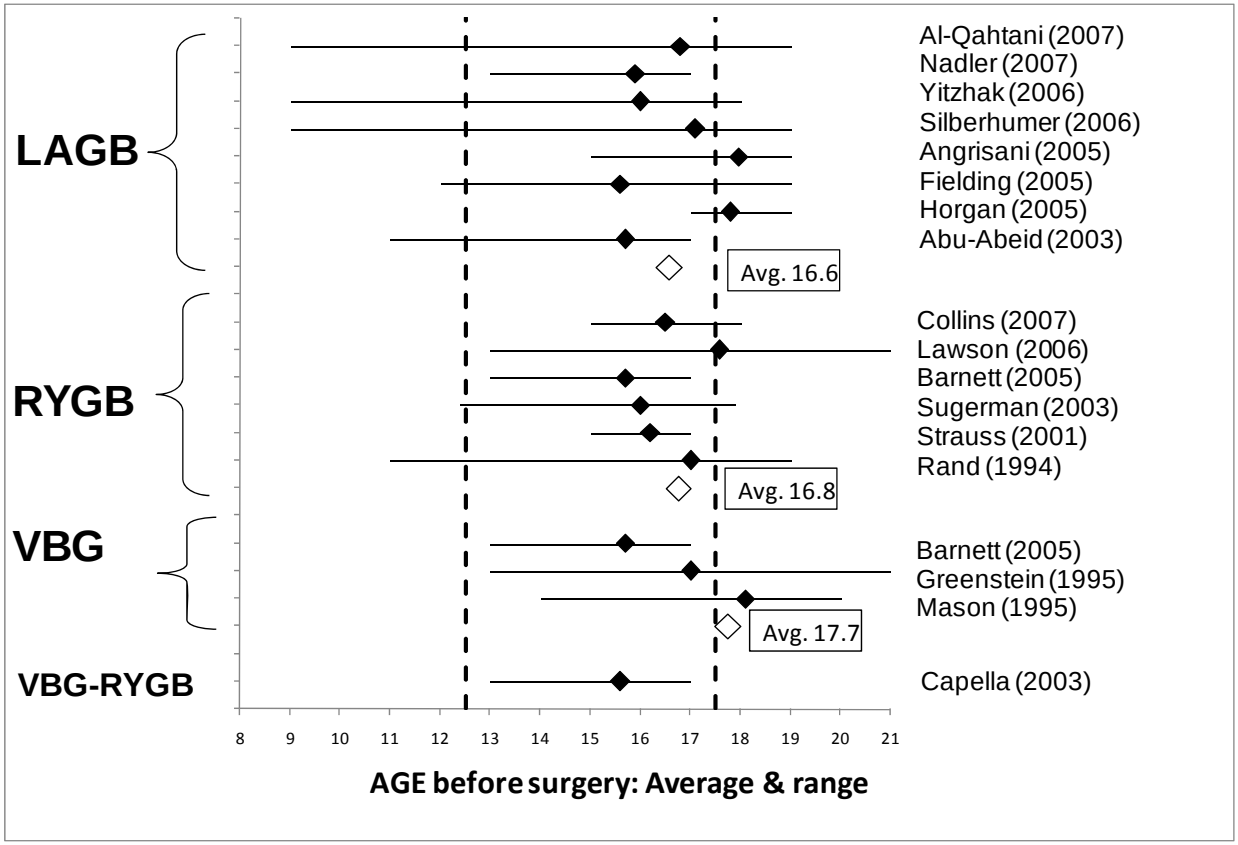
* One of the 17 studies reported data on both RYGB and VBG, so the procedure counts add to 18

Table 2. Included Studies

Study	Dates of surgery	Number of patients	Mean age before surgery (range)	Mean BMI in kg/m² before surgery (range)
Studies of Laparoscopic Adjustable Gastric Banding (LAGB)				
Al-Qahtani (2007)(70)	1/2003 – 12/2005	51	16.8 (9 - 19)	49.9 (38 - 63)
Nadler (2007)(71)	9/2001 – 2/2006	53	15.9 (13 - 17)	47.6 (Range NR)
Yitzhak (2006)(72)	2000 – 2006	60	16 (9 - 18)	43 (35 - 61)
Silberhumer (2006)(73,74)	1998 - 2004	50	17.1 (9 - 19)	45.2 (32.5 - 76.6)
Angrisani (2005)(75)	1/1996 – 12/2003	58	18.0 (15 - 19)	46.1 (34.9 - 69.25)
Fielding (2005)(76-78)	1998 – 2003	41	15.6 (12 - 19)	42.4 (31 - 71)
Horgan (2005)(79)	2001 - 2003	4	17.8[a] (17-19)	50.5[a] (40 - 61)
Abu-Abeid (2003)(80)	Not reported	11	15.7 (11 - 17)	46.6 (38 to 56.6)
Studies of Roux-en-Y Gastric Bypass (RYGB)				
Collins (2007)(81,82)	1999 - 6/2005	11	16.5 (15-18)	50.5 (42 - 66)
Lawson (2006)(69,83-85)	5/2001 – 10/2003	39	17.6 (13 - 21)	56.5 (41.9 - 95.5)
Barnett (2005)[b](68)	1978 – 2001	14	15.7 (13 - 17)	51 (Range NR)
Sugerman (2003)(35)	1981 – 1/2002	33	16.0 (12.4 - 17.9)	52 (38 - 91)
Strauss (2001)(36)	4/1985 – 5/1999	10	16.2[a] (15 - 17)	53.6[a] (41.4 - 70.5)
Rand (1994)(37)	1/1979 – 12/1990	34	17 (11 - 19)	47 (38 - 66)
Studies of Vertical Banded Gastroplasty (VBG)				
Barnett (2005)[b](68)	1978 – 2001	14	15.7 (13 - 17)	60 (Range NR)
Greenstein (1995)(86)	3/1982 – 6/1994	18	17 (13 - 21)	47.8[a] (41 - 60)
Mason (1995)(87)	1980 – 1994	47	18.1 (14 - 20)	48.4 (Range NR)
Studies of Banded bypass				
Capella (2003)(88)	5/1990 – 1/2001	19	15.6[a] (13 - 17)	49 (38 - 67)

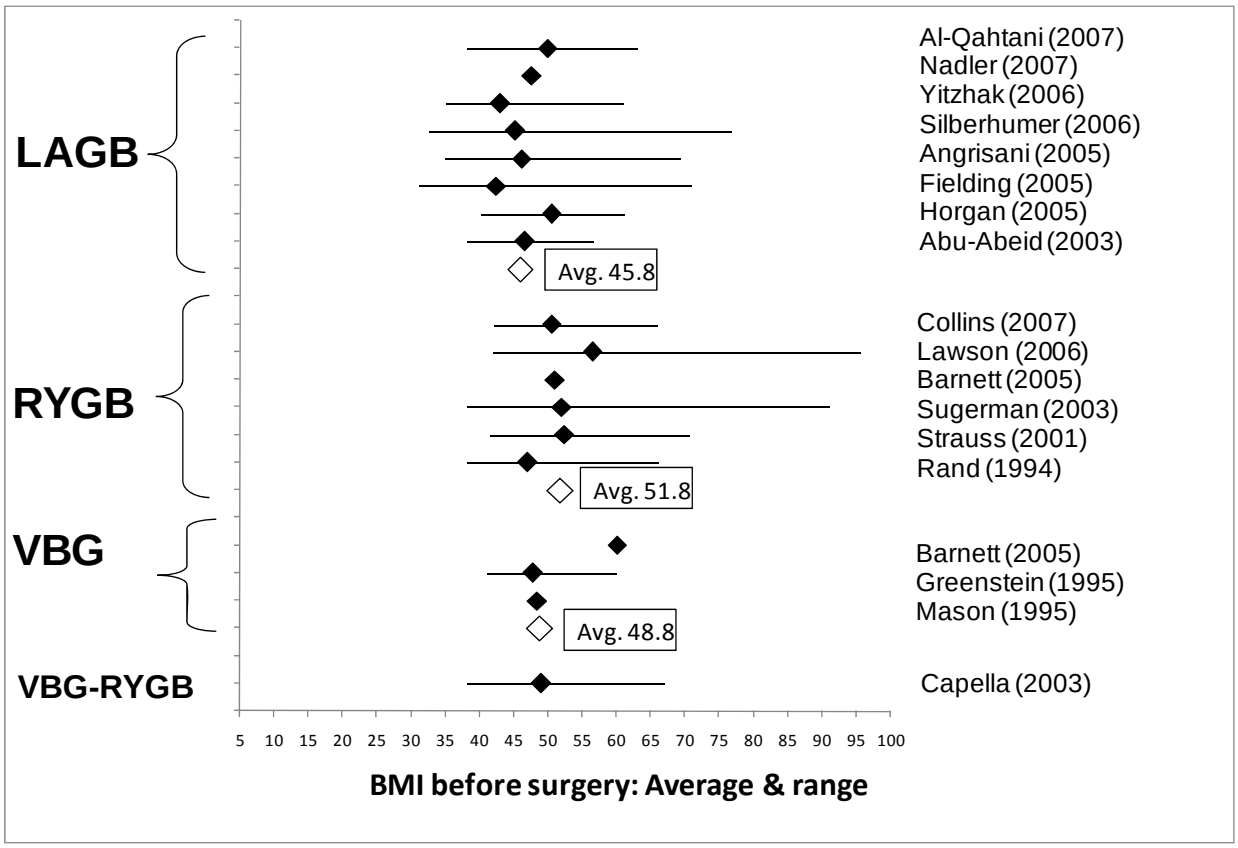
[a] Calculated by ECRI based on reported information
[b] The study by Barnett reported data on both RYGB and VBG, thus it is listed twice.

Figure 4. Patient Age Before Surgery



BB Banded bypass.
LAGB Laparopscopic adjustable gastric banding.
RYGB Roux-en-Y gastric bypass.
VBG Vertical banded gastroplasty.

Figure 5. Patient BMI Before Surgery



BB	Banded bypass.
LAGB	Laparopscopic adjustable gastric banding.
RYGB	Roux-en-Y gastric bypass.
VBG	Vertical banded gastroplasty.

Note: The studies by Nadler, Barnett, and Mason did not report the range of BMIs.

Internal Validity

Our detailed assessments of the quality of the literature appear in **Table 21** and **Table 22** of Appendix E. This section provides some insight into the quality limitations of the 17 studies. For example, only one study was clearly conducted prospectively (the Nadler study). Retrospective design may introduce bias because when authors decided to publish the data, they were armed with the knowledge of the favorable (or unfavorable) outcomes experienced by patients. Other potential authors may have decided not to publish their analyses. If so, the *reported* outcomes would overestimate (or underestimate) the benefits of surgery. Retrospective analyses may also fail to detect certain complications that would have been caught with prospective data collection.

One strategy to counteract the problem of retrospectivity is to enroll all eligible patients consecutively, which was performed in 13 studies, not performed in three studies, and unclear in the remaining study. Consecutive enrollment helps ensure that authors did not specially select patients who experienced desired outcomes. A related quality factor is study completion rate: studies would ideally report long-term outcome data on *all* patients enrolled. However, with any long-term followup, there will be patients whose outcomes are not known or patients who have not reached longer timepoints. Usually it is unclear whether dropouts experienced similar outcomes as those remaining in the study, or whether recently-treated patients will eventually experience similar outcomes.

Outcome objectivity is another quality criterion we examined. Patient weight is easily measured objectively, and of the 12 studies we included for Key Question 1, eight stated that patients attended follow-up visits in the clinic, suggesting that the weight data were based on actual weighings rather than patients' self-reporting. Three other studies did not report sufficient information on this criterion, and the other study (the study by Greenstein) based weight data on patient self-reporting.

Two other quality criteria that we applied involved the independence of outcome assessors and the study funding source. None of the 17 studies utilized independent outcome assessment (e.g., weights recorded at a center independent from the surgeon and surgical staff), which raises the possibility of outcome recording bias. Also, only one of the 17 studies reported the study funding source.[7] However, studies were generally conducted by bariatric surgeons, who do have financial interest in the outcomes of surgery.

Generalizability

Generalizability involves the extent to which the patients and treatments in published studies are representative of typical practice. In this section, we discuss four aspects of generalizability:

- Characteristics of the patients enrolled
- Prior experience of the bariatric surgeons
- Surgical techniques used
- The setting of care

[7] The Lawson study of RYGB reported that the study was partially funded by Ethicon-EndoSurgery, the manufacturer of a gastric stapling device and the Swedish Adjustable Gastric Band.

The population of interest is pediatric patients in the U.S. who are morbidly obese, willing to undergo bariatric surgery, and meet all other surgical criteria (e.g., informed consent). Our inclusion criteria ensured that all patients in all studies were among this population. Also, the included studies generally used the NIH criteria for adult bariatric surgery for patient selection (**Table 19** in Appendix E). Further, no evidence from the included studies indicated any significant difference between the studied population and the population of interest in demographic, socioeconomic, or cultural aspects. These observations support the generalizability of the patients enrolled.

Studies of adult bariatric surgery have suggested that more experienced surgeons may produce better surgical outcomes than less experienced surgeons.(89,90) The duration of the learning curve may be different for different procedures. For LAGB, Shapiro et al. (2003)(89) found that the rate of complications dropped from 37% in the first 30 cases to 7% in the next 30 cases. For laparoscopic RYGB, a study by Schauer et al. (2003)(90) found a decrease in complications from 42% in the first 50 cases, to 30% in the next 50 cases, and to 22% in the next 50 cases.

As shown in **Table 3**, the average number of pediatric cases performed by the surgeons in the included studies was generally low. However, because many of these surgeons were affiliated with a surgical department that also has adult patients, they might have experience with adult surgery cases before they started to perform on pediatric patients. Unfortunately, the studies did not report the prior number of surgeries performed by the surgeons, which precludes assessments of this aspect of generalizability.

With respect to the surgical techniques used, 14 of 17 studies performed either LAGB or RYGB, which are the two most commonly performed bariatric procedures in the U.S. Three other studies described less commonly performed procedures (VBG and banded bypass). Regarding the use of laparoscopic techniques, all bands were placed laparoscopically, which conforms to standard practice. RYGBP was performed laparoscopically for all patients in two studies, and using an open approach for most or all patients in the other four studies. Bariatric surgery techniques have been continually refined. Many changes in the techniques have helped to improve clinical outcomes and reduce the complication rates. For example, the adoption of the 'pars flaccida' technique that keeps the band above the apex of the lesser sac, the use of more stitches on the gastric serosa and the creation of smaller pouches reduced the complications after LAGB.(91-93) These incremental changes in surgical techniques might limit the generalizability of the findings of this evidence report to bariatric surgeries performed in the future.

Studies have suggested that multidisciplinary support is crucial for satisfactory long-term outcomes of bariatric surgeries.(84) Sixteen of the 21 medical centers involved in the included studies were university-based academic medical centers (The Italian study(75) was not counted because it reported multi-center results). Academic medical centers offer good accessibility to expertise in various disciplines needed for a comprehensive pediatric bariatric surgery program. Four studies explicitly stated that the involved medical centers had a multidisciplinary pediatric bariatric program.(71,80,81,84) In general, we feel that the findings of our study are generalizable to those procedures performed in academic centers or other settings that had a multidisciplinary pediatric bariatric surgery program. Likely, the care setting at these institutions was more advanced than in other settings in which pediatric bariatric surgery might occur.

In addition, six of the eight LAGB studies were conducted at non-U.S. institutions (two in Israel, and one each in Austria, Australia, Italy, and Saudi Arabia). Only fifty-seven (17%) of the 328

LAGB cases were from the two U.S. studies. Nonetheless, there was no evidence from these studies suggesting any demographic, clinical, or socioeconomic, differences between U.S. and non-U.S. populations. Further, there was no evidence either suggesting that LAGB procedures were performed differently in different regions. All of the studies on RYGB, VBG, and banded bypass were conducted at U.S. institutions.

Table 3. Characteristics of Centers and Surgeons in Included Studies

Study	Country	Center and bariatric program	Type of surgical department	Number of surgeons involved	Total patient number	Case number per surgeon
Studies of Laparoscopic Adjustable Gastric Banding (LAGB)						
Al-Qahtani (2007)(70)	Saudi Arabia	One academic medical center with a multi-disciplinary bariatric surgery team	Division of Pediatric Surgery	Not reported	51	≤51
Nadler (2007)(71)	USA	One academic medical center with a comprehensive bariatric program	Division of Pediatric Surgery	3	53	18
Yitzhak (2006)(72)	Israel	One academic medical center	Department of Surgery	1	60	60
Silberhumer (2006)(73,74)	Austria	Three centers, including one academic medical center	Departments of Surgery	≥2	50	≤25
Angrisani (2005)(75)	Italy	Multicenter	Not reported	≥2	58	≤29
Fielding (2005)(76-78)	Australia	One private center with a comprehensive bariatric program	Department of Surgery	1	41	41
Horgan (2005)(79)	USA	One academic medical center	Division of General Surgery and Minimally Invasive Surgery, and Division of Pediatric Surgery	Not reported	4	≤4
Abu-Abeid (2003)(80)	Israel	One academic medical center with a multidisciplinary bariatric program	Department of Surgery B and Endoscopic Surgery	Not reported	11	≤11
Studies of Roux-en-Y Gastric Bypass (RYGB)						
Collins (2007)(81,82)	USA	One academic medical center with a multidisciplinary bariatric surgery program	Division of Minimally Invasive Surgery	Not reported	11	≤11
Lawson (2006)(69,83,84)	USA	Three pediatric academic centers with a comprehensive weight management program	Division of Pediatric Surgery, Department of Surgery, Division of Pediatric Surgery	≥3	39	≤13
Barnett (2005)(68)	USA	One academic medical center	Department of Surgery	1	14	14
Sugerman (2003)(35)	USA	One academic medical center	Department of Surgery	Not reported	33	≤33

Study	Country	Center and bariatric program	Type of surgical department	Number of surgeons involved	Total patient number	Case number per surgeon
Strauss (2001)(36)	USA	One academic medical center	Department of Surgery	1	10	≤10
Rand (1994)(37)	USA	One regional medical center	Department of Surgery	1	34	34
Studies of Vertical Banded Gastroplasty (VBG)						
Barnett (2005)(68)	USA	One academic medical center	Department of Surgery	1	14	14
Greenstein (1995)(86)	USA	Two centers including one academic medical center	Department of Surgery	1	18	18
Mason (1995)(87)	USA	One academic medical center	Department of Surgery	Not reported	47	≤47
Studies of banded bypass						
Capella (2003)(88)	USA	One academic medical center	Department of Surgery	Not reported	19	≤19

Note: Barnett reported data on both RYGB and VBG, thus it is listed twice

Key Questions Addressed by Included Studies

The studies included for each Key Question are listed in **Table 4** below. For weight loss (Key Question 1), we included the data from five of eight LAGB studies, five of six RYGB studies, two of three VBG studies, and one study of the banded bypass. For comorbidities and quality of life (Key Question 2), we included data from four LAGB studies and four RYGB studies. For complications (Key Question 3), data from all 17 studies were included. None of the studies were included for cost data (Key Question 4), thus we used alternative data sources for that question (see *Results* section below). For the association between patient characteristics and outcomes (Key Question 5), we included data from two LAGB studies, one RYGB study, one VBG study, and the banded bypass study.

Table 4. Key Questions Addressed

Study	Key Question				
	1[b]	2[c]	3	4	5[d]
Studies of Laparoscopic Adjustable Gastric Banding (LAGB)					
Al-Qahtani (2007)(70)		✓	✓		
Nadler (2007)(71)			✓		
Yitzhak (2006)(72)	✓	✓	✓		
Silberhumer (2006)(73,74)	✓	✓	✓		
Angrisani (2005)(75)	✓		✓		
Fielding (2005)(76-78)	✓		✓		✓
Horgan (2005)(79)			✓		
Abu-Abeid (2003)(80)	✓	✓	✓		✓
Studies of Roux-en-Y Gastric Bypass (RYGB)					
Collins (2007)(81,82)	✓	✓	✓		
Lawson (2006)(69,83-85)	✓	✓	✓		
Barnett (2005)[a](68)			✓		
Sugerman (2003)(35)	✓	✓	✓		
Strauss (2001)(36)	✓	✓	✓		✓
Rand (1994)(37)	✓		✓		
Studies of Vertical Banded Gastroplasty (VBG)					
Barnett (2005)[a](68)			✓		
Greenstein (1995)(86)	✓		✓		✓
Mason (1995)(87)	✓		✓		
Studies of banded bypass					
Capella (2003)(88)	✓		✓		✓

[a] Barnett reported data on both RYGB and VBG, thus it is listed twice.

[b] Four studies reported BMI data that did not meet inclusion criteria for the following reasons: The study by Al-Qahtani did not report the number of patients followed for 1+ years. The study by Nadler did not report 1+ year data for at least 50% of patients. The study by Horgan did not report 1+ year data for at least three patients. The study by Barnett did not report the length of followup of patients receiving specific procedures.

[c] Four studies reported quality-of-life data that did not meet inclusion criteria for the following reasons. In three studies (Yitzhak, Rand, Greenstein), the quality of life instrument was not previously validated, and only *post*operative data were reported. In the fourth study (Collins), the quality of life instrument was not administered both before and after surgery. Barnett reported comorbidity resolution data, but these data were combined for three bariatric procedures, and therefore were excluded. Three other studies (Fielding, Horgan, Greenstein) reported data for comorbidity resolution, but there were no more than three patients for any single comorbidity, so the data did not meet inclusion criteria.

[d] Key Question 5 was addressed by studies reporting individual patient data or studies that reported the necessary correlation between a patient characteristics and an outcome. Three studies had reported some individual patient data, but these data were excluded for the following reasons. A secondary publication(74) of the Silberhumer study reported individual patient data, but 1+ year individual weight data were only reported for three of eight patients. A secondary publication(82) of the Collins study reported individual patient data, but 1+ year individual weight data were only reported for three of 11 patients. Horgan reported individual patient data, but only reported 1+ year individual weight data for two of four patients.

Key Question 1: Does pediatric bariatric surgery lead to sustained and clinically significant weight loss compared to non-operative approaches?

a. In patients aged 21 or less
b. Specifically in patients aged 18-21
c. Specifically in patients aged 13-17
d. Specifically in patients aged 12 or less

ECRI Institute evidence assessments:

- Laparoscopic Adjustable Gastric Banding (LAGB) for morbidly obese patients aged 21 or less does lead to sustained and clinically significant weight loss compared to non-operative approaches.(Strength of evidence at longest followup after surgery (1.7 to 3.3 years): Weak; Strength of evidence at one year after surgery: Moderate).
- Roux-en-Y Gastric Bypass (RYGB) for morbidly obese patients aged 21 or less does lead to sustained and clinically significant weight loss compared to non-operative approaches. (Strength of evidence at longest followup after surgery (1 to 6.3 years): Weak; Strength of evidence at one year after surgery: Moderate).
- The evidence is insufficient to permit quantitative estimates of the precise amount of weight loss after any bariatric surgical procedure for pediatric patients.
- The evidence is insufficient to permit any conclusions about weight loss after other bariatric surgical procedures for pediatric patients.
- The evidence is insufficient to permit any conclusions about weight loss in specific age groups (18-21, 13-17, 12 or less)

Patients Aged 21 or Less

The sections below describe the details of our analyses, separately for each bariatric surgical procedure. All evidence tables appear in Appendix E, including study and treatment details (**Table 19**), patient characteristics (**Table 20**), quality assessments (**Table 21**), BMI data at longest followup (**Table 23**), and BMI data at specific timepoints (**Table 24**).

Laparoscopic Adjustable Gastric Banding (LAGB). Five of eight LAGB studies reported BMI data that met inclusion criteria. **Table 5** (below) lists specific information for each study pertaining to mean pre-surgical BMI, the percentage of surgical patients who were included in the analysis, the length of followup, the postsurgical BMI at longest followup, the pre-post change in BMI, and whether this change was statistically and/or clinically significant.

The mean length of followup ranged from 1.7 years to 3.3 years; the percentage of patients with follow-up BMI data was 100% in four studies and 64% in the fifth study. All five studies found that weight loss was statistically and clinically significant. We performed a random-effects meta-analysis that confirmed this finding. To investigate the robustness of this finding, we performed seven tests (see Appendix C). The analysis passed all seven tests, indicating good robustness.

Our study quality assessments indicated that the quality scores for the five studies' data at longest followup ranged from 4.5 to 7.5, with a median of 5.5 (on a scale from 0 to 10). This falls into the category of low quality. To rate the strength of the evidence, we considered jointly

the quality, quantity, consistency and robustness of the evidence. Based on these considerations, we rated the strength of the evidence for weight loss at longest followup as Weak.

We also examined BMI data at specific timepoints (e.g., at exactly one year after surgery). For one-year BMI, there were three studies reporting the pertinent data (Angrisani, Fielding, Abu-Abeid), and all three found statistically and clinically significant weight loss. The median quality of one-year BMI data among these three studies was 6.5, which falls into the moderate quality category. As with longest-follow-up BMI, all seven qualitative robustness tests analyses were passed; therefore the strength of this evidence for 1-year BMI reduction was Moderate.

The evidence for longer timepoints did not permit conclusions because there was no more than one LAGB study for any single longer timepoint (i.e., lack of replication of study findings). Also, the evidence did not permit precise quantitative estimates of the amount of BMI units lost after LAGB, because only two of five studies (40%) reported sufficient information for us to calculate the pre-post correlation for BMI. Such information is necessary to permit accurate effect size estimates of weight change after surgery.

Roux-en-Y Gastric Bypass (RYGB). Five of six RYGB studies reported BMI data that met inclusion criteria; **Table 6** (below) lists the relevant specifics for each study. When we assessed the quality of the studies, one study's BMI data (the study by Rand et al.) was rated as very low quality (score 3.5), and consequently we excluded it from further consideration.

For the remaining four studies, the percentage followup ranged from 60% to 90%, and the mean length of followup ranged from 1 year to 6.3 years. As with LAGB, we first performed an analysis of longest follow-up BMI. In this analysis, all four studies found that weight loss was statistically and clinically significant. The analysis passed all seven robustness tests, indicating good robustness.

Quality scores for the four studies ranged from 4.0 to 6.5, with a median of 4.5, which falls into the low quality category. To rate the strength of the evidence, we considered jointly the quality, quantity, consistency and robustness of the evidence. Based on these considerations, we rated the strength of the evidence for weight loss at longest followup as Weak.

As with LAGB, we also examined BMI data at specific timepoints. For one-year BMI, there were three studies reporting the pertinent data (Lawson, Sugerman, Strauss), and all three found statistically and clinically significant weight loss (the one-year BMI data appear in **Table 24** of Appendix E). The quality scores for these three studies at one-year followup were 6.5 for two studies (moderate), and 4.0 for one study (low). All seven qualitative robustness tests analyses were passed. Considering the quality, quantity, consistency, and robustness, we rated the strength of the evidence for one-year BMI loss as Moderate.

The evidence for longer timepoints did not permit conclusions due to the presence of only one RYGB study per timepoint. Also, the evidence did not permit precise quantitative estimates of the amount of BMI units lost after RYGB, because only one of five studies (20%) reported sufficient information for us to calculate the pre-post correlation for BMI.

Vertical Banded Gastroplasty (VBG). Two of three VBG met inclusion criteria for BMI data (the studies by Greenstein and Mason). Both were rated very low quality for BMI data (quality scores of 1.5 and 2.5), and therefore we excluded them from further consideration. Due to the lack of evidence of sufficient quality, we did not draw conclusions about weight loss after VBG.

Banded bypass. The single study of this procedure met inclusion criteria for BMI data, but it was of very low quality. Thus, we drew no conclusions about weight loss after banded bypass.

Specific Age Groups (18-21, 13-17, 12 or Less)

The evidence was insufficient to permit conclusions for any specific age group (18-21, 13-17, ≤12) for any procedure. No studies enrolled only patients aged 18-21 or only patients aged 12 or less (refer again to **Figure 4**). Four studies enrolled only patients aged 13-17, but only two studies' BMI data met inclusion criteria (the Strauss study of RYGB, and the Capella study of banded bypass). Considering the lack of replication for any single procedure in the 13-17 age group, the evidence was insufficient to permit conclusions.

Table 5. Weight Loss after LAGB (at Longest Followup)

Study	% of patients receiving surgery who were included in this analysis (N/N)	Length of followup (years)	Pre-surgical BMI in kg/m^2 (SD)	Post-surgical BMI in kg/m^2 at longest followup (SD)	BMI units lost in kg/m^2 (95% CI)	Was weight loss statistically significant?	Was weight loss clinically significant?*
Yitzhak (2006)(72)	100% (60/60)	3.3 (range 2.1 to 5.4)	43 (SD: 7.4)	30 (SD: 8.4)[a]	-13 (-14.8 to -11.2)[b]	Yes	Yes
Silberhumer (2006)(73,74)	100% (50/50)	2.9 (range 0.3 to 7.2)	45.2 (SD: 7.6)	32.6 (SD: 6.8)	-12.6 (-14.4 to -10.8)[b]	Yes	Yes
Angrisani (2005)(75)	64% (37/58)	3	46.1 (SD: 6.31)	37.8 (SD: 11.27)	-8.3 (-11.2 to -5.4)[b]	Yes	Yes
Fielding (2005)[c](76-78)	100% (17/17)	1.7 (range 1 to 2)	43.1 (SD: 9.6)	30.2 (SD: 7.3)	-12.9 (-15.5 to -10.3)	Yes	Yes
Abu-Abeid (2003)(80)	100% (11/11)	1.9 (range 1 to 3)	46.5 (SD: 5.1)	32.5 (SD: 4)	-14 (-16.5 to -11.5)	Yes	Yes

* Clinical significance was determined by whether the amount of weight loss was statistically significantly larger than 3.5 BMI units (which represents approximately 7% of body weight in these patients).

[a] Imputed SD based on a pooled SD from other studies.

[b] Imputed pre-post correlation based on a pooled correlation from other studies.

[c] Data for a secondary publication(77) were used because the weight data from the more recent publication did not include at least 50% of patients with 1+ years followup.

CI Confidence interval.

Note: Three LAGB studies reported BMI data that did not meet inclusion criteria for the following reasons: 1) The study by Al-Qahtani did not report the number of patients followed for 1+ years; 2) The study by Nadler did not report 1+ year data for at least 50% of patients; 3) The study by Hogan did not report 1+ year data for at least three patients.

Table 6. Weight Loss after RYGB (at Longest Followup)

Study	% of patients receiving surgery who were included in this analysis (N/N)	Length of followup (years)	Pre-surgical BMI in kg/m^2 (SD)	Post-surgical BMI in kg/m^2 at longest followup (SD)	BMI units lost in kg/m^2 (95% CI)	Was weight loss statistically significant?	Was weight loss clinically significant?*
Collins (2007)[b](81,82)	75% (3/4)	1.8 (range 1.7 to 1.8)	52 (SD: 12.1)	28 (SD: 8.7)	-24 (-35.1 to -12.9)[a]	Yes	Yes
Lawson (2006)(69,83-85)	77% (30/39)	1	56.5 (SD: 10.1)	35.8 (SD: 6.9)	-20.7 (-23.6 to -17.8)[a]	Yes	Yes
Sugerman (2003)(35)	60% (20/33)	5	52 (SD: 11)	33 (SD: 11)	-19 (-22.9 to -15.1)[a]	Yes	Yes
Strauss (2001)(36)	90% (9/10)	6.3 (range 1 to 13)	52 (SD: 9.4)	35.2 (SD: 12.4)	-16.8 (-24.3 to -9.3)	Yes	Yes
Rand (1994)(37)	87% (34/39)	6 (range 2 to 13)	47 (SD: 7)	32 (SD: 7)	-15 (-17.1 to -12.9)[a]	Yes	Yes

* Clinical significance was determined by whether the amount of weight loss was statistically significantly larger than 4 BMI units (which represents approximately 7% of body weight in these patients).

[a] Imputed pre-post correlation based on a pooled correlation from other studies.

[b] Data for a secondary publication(82) were used because the weight data from the more recent publication did not include at least 50% of patients with 1+ years followup.

CI Confidence interval.

Note: The study by Barnett reported BMI data, but did not report the length of followup of patients receiving specific procedures; therefore, it was excluded from this analysis.

Key Question 2: Does bariatric surgery for patients a-d (as above) improve comorbid conditions linked to obesity (e.g., diabetes, hypertension, obstructive sleep apnea, musculoskeletal disorders), quality of life, or survival, as compared to non-operative approaches?

ECRI Institute evidence assessments:

- Laparoscopic Adjustable Gastric Banding (LAGB) for morbidly obese patients aged 21 or less does resolve comorbid conditions linked to obesity (diabetes, hypertension) compared to non-operative approaches. (Strength of evidence for comorbidity data: Weak).
- Roux-en-Y Gastric Bypass for morbidly obese patients aged 21 or less does resolve comorbid conditions linked to obesity (hypertension) compared to non-operative approaches. (Strength of evidence for comorbidity data: Weak).
- The evidence is insufficient to permit quantitative estimates of the likelihood of comorbidity resolution, quality of life, or survival after any bariatric surgical procedure for pediatric patients.
- The evidence is insufficient to permit any conclusions about comorbidity resolution after other bariatric surgical procedures for pediatric patients.
- The evidence is insufficient to permit any conclusions about comorbidity resolution in specific age groups (18-21, 13-17, 12 or less)

Patients Aged 21 or Less

The sections below describe the details of our analyses, separately for each bariatric surgical procedure. Quality assessments appear in **Table 22** of Appendix E, the comorbidity data appear in **Table 25** of Appendix E, and the quality of life data appear in Table 26 of Appendix E.

Laparoscopic Adjustable Gastric Banding (LAGB). Four of eight LAGB studies met inclusion criteria for comorbidity and/or quality of life outcomes.(70,72,73,80) The mean length of followup ranged from 1.3 to 2.9 years, and a summary of the data appears in **Table 7** below. Two studies(70,73) reported rates of diabetes resolution of 100% (7/7) and 80% (4/5); both studies were of moderate quality for comorbidity data (quality scores of 6.5 and 7.5). Three studies(70,72,73) reported rates of hypertension resolution of 50% (6/12), 100% (6/6), and 100% (3/3); two were of moderate quality (quality scores of 6.5 and 7.5), and one was of low quality for comorbidity data (5.5). Considering the magnitude of effect, along with the quality, quantity and consistency of the data, we rated the strength of the evidence Weak for the resolution of diabetes and hypertension after LAGB.

Data on the resolution of other comorbidities (dyslipidemia, sleep apnea, asthma, GERD, musculoskeletal problems) and quality of life were too sparse to permit conclusions, due to evidence from only a single study and/or small numbers of patients with each specific comorbidity.

Roux-en-Y Gastric Bypass (RYGB). Four of six RYGB studies reported comorbidity data that met inclusion criteria. The mean length of followup ranged from 5 months to 2.7 years, and a summary of the data appears in **Table 7** below. Only one study(81) met inclusion criteria for diabetes resolution data, therefore we drew no conclusions about this comorbidity. Three

studies(35,36,81) reported hypertension resolution rates of 50% (3/6), 82% (9/11), and 100% (3/3); all three scored 6.5 on the quality assessment for comorbidities (moderate). Considering the magnitude of effect, and the quality, quantity, and consistency, we rated the strength of the evidence Weak for the resolution of hypertension after RYGB. Two studies(35,69) reported sleep apnea resolution rates of 100% (10/10) and 100% (6/6); the quality scores were 4.0 and 6.5, for an overall quality of 5.25 (low). Due to overall low quality and only two studies reported sleep apnea outcomes, we drew no conclusion.

Data on the resolution of other comorbidities (diabetes, dyslipidemia, asthma, GERD, musculoskeletal problems) were too sparse to permit conclusions, due to evidence from only a single study and/or small numbers of patients with each specific comorbidity. Similarly, we drew no conclusions for either VBG or banded bypass for this Key Question, due to the paucity of evidence.

Specific Age Groups (18-21, 13-17, 12 or Less)

Only one study (the Strauss study) enrolled a specific age group and was also included for comorbidity data. Due to the existence of only one study on this outcome for this age group, the evidence was insufficient to permit conclusions.

Table 7. Summary of Results of Comorbidity Resolution

Bariatric procedure	Comorbidity	Diabetes	Hypertension	Dyslipidemia	Sleep Apnea	Asthma	GERD	Musculoskeletal	Other
Laparoscopic Adjustable Gastric Banding (LAGB)	Amount of Evidence[a]	2 studies, 12 patients	3 studies, 21 patients	2 studies, 7 patients	1 study, 10 patients	2 studies, 6 patients	-	1 study, 8 patients	1 study, 3 patients[b]
	Mean followup (years)	1.3 and 2.9	1.3, 2.9, and 3.3	1.9 and 2.9	3.3	2.9 and 3.3	-	2.9	2.9
	% Resolved	80%-100%	50%-100%	67%-100%	100%	100%	-	38%	100%[b]
Roux-en-Y Gastric Bypass (RYGB)	Amount of Evidence[a]	1 study, 6 patients	3 studies, 20 patients	-[c]	2 studies, 16 patients	-	1 study, 5 patients	1 study, 11 patients	1 study, 3 patients[d]
	Mean followup (years)	0.96	0.96, 1, 2.7	-[c]	0.43 and 1	-	1	1	1
	% Resolved	50%	50%-100%	-[c]	100%	-	60%	36%	100%[d]

Note: "-" indicates that there were no studies of this bariatric procedure that reported the postsurgical status of comorbidities for at least three patients who had the condition before surgery. The Barnett study of RYGB and VBG reported comorbidity resolution data, but these data were combined for three bariatric procedures, and therefore were excluded. Three other studies (the Fielding study of LAGB, the Horgan study of LAGB, and the Greenstein study of VBG) reported data for comorbidity resolution, but there were no more than 3 patients for any single comorbidity, so the data were excluded. The studies of VBG and banded bypass did not report any comorbidity data that met inclusion criteria.

The data for individual studies appear in Table 25 in Appendix E.

[a] This row refers to the number of studies that had reported resolution results in at least 3 patients who had the condition before surgery (along with the combined number of patients with that condition at baseline). Some studies reported data on conditions with fewer than 3 patients, which did not meet our inclusion criteria.

[b] Cholecystitis

[c] The only study RYGB that reported results for dyslipidemia (the Lawson study at one year followup) did not report in terms of resolution, but instead in terms of statistically significant postoperative improvements in triglyceride, total cholesterol, fasting blood glucose, and fasting insulin.

[d] 100% resolution for both pseudotumor cerebri and polycystic ovary syndrome.

Key Question 3: What are the relative safety profiles of bariatric surgery and non-operative approaches for patients aged a) 21 or less, b) 18-21, c) 13-17, and d) 12 or less?

ECRI Institute evidence assessments:

- Our review of the eight LAGB studies (the procedures were performed between 1996 and 2006; the individual patient follow-up times ranged from one month to 85 months) found:
    - No reported in-hospital or postoperative death.
    - The most frequently reported complication after LAGB was band slippage.
    - Reoperations were performed on 26 (7.92%) of the 328 LAGB patients to correct various complications.
- Our review of the six RYGB studies (the procedures were performed between 1978 and 2005; the individual patient follow-up times ranged from two weeks to six years) found:
    - One postoperative death was reported for RYGB; no in-hospital death was reported.
    - The most frequently reported complication after RYGB was related to protein-calorie malnutrition and micronutrient deficiency.
    - Potentially life-threatening complications such as shock, pulmonary embolism, severe malnutrition, immediate postoperative bleeding, and gastrointestinal obstructions were reported in the RYGB studies.
- The evidence is insufficient to permit any conclusions on potential impacts of bariatric surgery on growth and development of pediatric patients.
- The evidence is insufficient to permit any conclusions on potential harms in specific age groups (18-21, 13-17, 12 or less).
- Systematic reviews on pediatric obesity management did not provide sufficient data for the development of a safety profile of non-operative approaches.

Patients Aged 21 or Less

The sections below describe the details of our analyses, separately for each bariatric surgical procedure. Quality assessments appear in **Table 22** of Appendix E, and the reported data for this Key Question appear in **Table 27**, **Table 28**, and **Table 29** of Appendix E.

Laparoscopic Adjustable Gastric Banding (LAGB). All eight LAGB studies (11 publications) reported complications and met the inclusion criteria. For this Key Question, the overall evidence quality was rated as Moderate. The surgical procedures reported in the studies were performed between 1996 and 2006. All but one study(71) had an average postoperative follow-up time longer than one year. At individual case level, follow-up time in the eight studies ranged from one month to 7.1 years.

Reported complications are summarized in **Table 8** below. No in-hospital or postoperative death was reported in any LAGB study. Reoperations were performed on 26 (7.92%) of the 328 LAGB patients to correct various complications. Band slippage was the most frequently reported post-LAGB complication, which occurred on 12 (3.66%) of the 328 patients. Eight of the 12 cases occurred in one center using SAGB, while the other four cases occurred in three centers using LAP-BAND. In addition, eight cases of iron deficiency and five cases of mild hair loss were reported in the LAGB studies; the remaining reported complications had a case number equal to

or less than three. None of the LAGB studies reported any results regarding potential impacts of the LAGB procedure on growth or development of the patients.

Roux-en-Y Gastric Bypass (RYGB). Six RYGB studies reported complications and met inclusion criteria. For this Key Question, the overall evidence quality was rated as Moderate. The RYGB procedures reported in the studies were performed between 1978 and 2005. Average postoperative follow-up time of the studies ranged from 11.5 months to six years. At individual case level, follow-up time in the six studies ranged from two weeks to six years.

The complications reported in the studies are summarized in **Table 8** below. One postoperative death was reported in Lawson's study.(69,83,84) This 18-year-old patient initially presented with hypercholesterolemia, hyperinsulinemia, hypertension, sleep apnea, and degenerative joint disease at a BMI of 80 kg/m^2 and weight of 630 lb. Three months after surgery, the patient developed severe infectious colitis because of *Clostridium difficile*. Severe diarrhea and an extended period of profound hypovolemia associated with the colitis resulted in multiorgan failure and subsequent death nine months after surgery. In addition, one patient in Barnett's study(68) died four years after surgery and two patients in Sugerman's study(35) died two years and six years after surgery of causes that were unlikely to be directly related to the bariatric surgeries. No in-hospital death was reported in any of the RYGB study.

Although the RYGB studies had a smaller patient pool, they had a longer list of postoperative complications than the LAGB studies. Reported complications included some potentially life-threatening conditions such as shock, pulmonary embolism, severe malnutrition, immediate postoperative bleeding, and gastrointestinal obstruction. The most frequently reported complication was the group of problems related to protein-calorie malnutrition and micronutrient deficiency. The inconsistency in data reporting among the six studies prevented a calculation of a combined reoperation rate for RYGB.

Five of the six RYGB studies did not report any outcomes regarding potential impacts of the procedure on growth or development of the patients. The remaining one(37) reported the patients' preoperative and postoperative heights and concluded that there was no evidence of growth retardation after surgery. However, the authors of the study also stated that "the question as to whether these adolescents achieved their expected growth could not be extracted from data available".

Other Procedures. Three VBG studies and one banded bypass study reported complications and met the inclusion criteria for this Key Question. For complications data, the overall evidence quality for the three VBG studies was rated as low, while the banded bypass study was rated as Moderate quality. The VBG procedures were performed between 1978 and 2001; the postoperative follow-up time was between 3 months to 21.75 years. The banded bypass procedures were performed between 1990 and 2001 and had an average follow-up time of 5.5 years.

In the VBG studies, recurrent gastric ulceration (in two patients), enlarged pouches (in two patients) and staple line disruption (in one patient) were reported. In the banded bypass study, two revisions for gastro-gastric fistula, one cholecystectomy, one recurrent marginal ulcer requiring antacids, and three plastic surgeries for excess skin were reported as post-surgery complications. No in-hospital or postoperative deaths were reported in any of these four studies.

None of the VBG and banded bypass studies reported any outcomes regarding potential impacts of the procedures on growth or development of the patients. Although one VBG study(87) and the banded bypass study(88) documented patients' heights at surgery, neither of the studies reported post-surgery height data. To explain why post-surgery height data were not recorded, the authors of the banded bypass study stated that "most of the patients were fully-grown at the time of initial visit". For reference, the average patient age before surgery in the banded bypass study was 15.6 years (range 13-17).

Specific Age Groups (18-21, 13-17, 12 or Less)

No study included for the Key Question enrolled only patients aged 18-21 or only patients aged 12 or less. One LAGB study(71) and two RYGB studies(36,68) enrolled only patients aged 13-17. Other studies all reported outcomes for mixed age groups. The evidence was insufficient to permit any conclusions about potential harms in specific age groups (18-21, 13-17, 12 or less).

Table 8. Reported Postoperative Complications for LAGB and RYGB

LAGB	RYGB
Number of studies: 8 **Total number of patients**: 328 **Reported complications (number of events):** • Band slippage (12) • Iron deficiency (8) • Mild hair loss (5) • Intragastric migrations (3) • Gastric pouch dilatation (2) • Hiatal hernia (2) • Nephrolithiasis and cholelithiasis (2) • Port/tubing problems (2) • Gastroesophageal reflux (1) • Wound infection (1) **Number of reoperations:** 26[a] **Reported in-hospital death(s):** 0 **Reported postoperative death(s)**: 0	**Number of studies**: 6 **Total number of patients**: 125[b] **Reported complications (number of events)**: • Protein-calorie malnutrition and micronutrient deficiency including iron deficiency ,vitamin deficiency , hypokalemia, hypoglycemia, and beriberi (16) • Incisional hernia (7) • Wound infection (≥6) • Cholecystectomy (6) • Marginal ulcer (6) • Stomal stenoses and food obstruction (≥5) • Pouch dilation (5) • Dumping syndrome (≥3) • Other complaints including nausea and diarrhea (≥2) • Small bowel obstruction (2) • Anastomotic stricture/gastrojejunostomy stricture (≥1) • Deep vein thrombosis (≥1) • Dehydration (≥1) • Gastrostomy revision (≥1) • Internal hernia (≥1) • Melena (≥1) • Shock (≥1) • Staple line leak (≥1) • Immediate postoperative bleeding (1) • Pulmonary embolism (1) **Number of reoperations:** Not summarizable[c] **Reported in-hospital death(s):** 0 **Reported postoperative death(s)**: 1[d]

[a] Reoperations were performed to correct postoperative complications including band slippage, gastric dilation, intragastric band migration, psychological intolerance of band, hiatal hernia, cholecystitis, and tubing crack. See Table 27 in Appendix E.

[b] Among the 142 patients in the six studies, only 125 received RYGB procedures.

[c] Inconsistencies in data reporting among the six studies prevented a calculation of a combined reoperation rate for RYGB.

[d] One patient died nine months after RYGB in Lawson's study.(69,83,84) The one death in Barnett's study(68) and the two deaths in Sugerman's study(35) were not counted because the causes of death were unlikely to be directly related to the bariatric surgeries.

Safety Profile of Non-operative Approaches

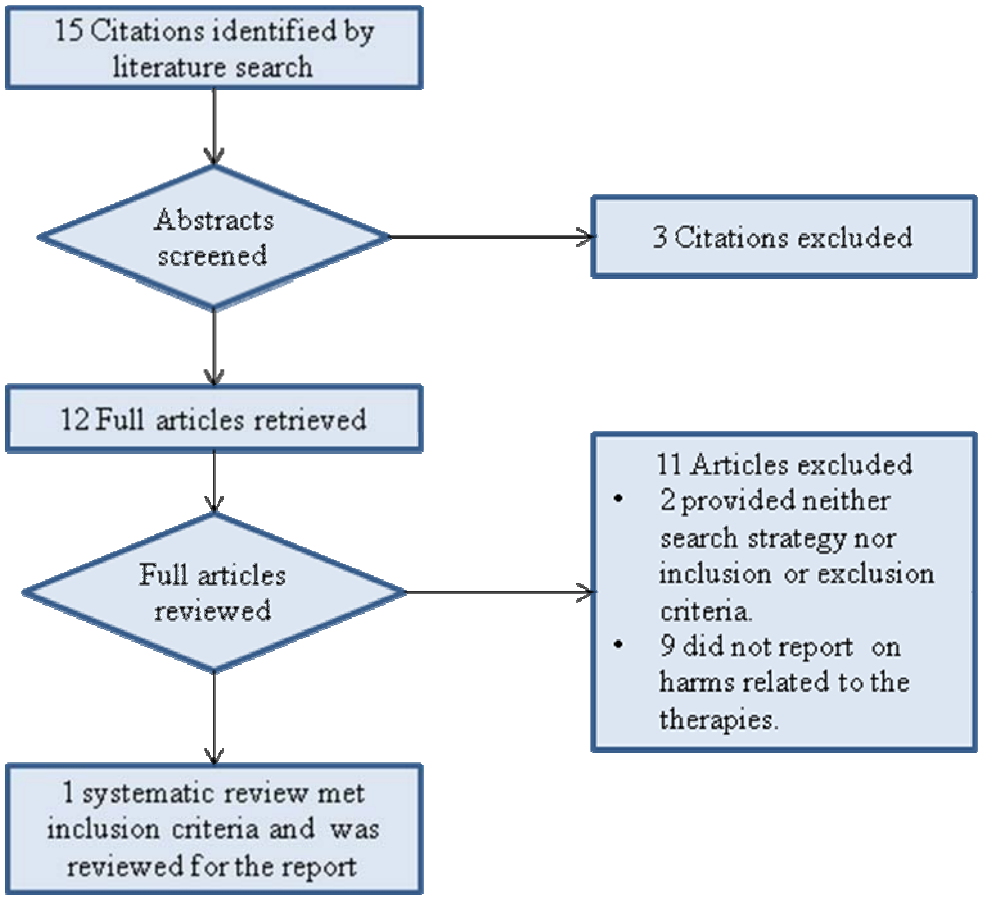
We searched four electronic sources (Medline, PsycINFO, EMBASE, and CINAHL) on April 19, 2007 and also conducted a manual search for systematic reviews on non-operative approaches to obesity management in pediatric patients. Search results are depicted in **Figure 6** below.

Our searches identified one systematic review that met our inclusion criteria(94), which we rated as High quality using the AMSTAR tool. This evidence report for the U.S. Preventive Services Task Force (USPSTF) assessed adverse events associated with behavioral counseling interventions, pharmacotherapy, and surgical treatments for overweight. Potential harms associated with diet therapy and physical exercise were not addressed.

Potential eating problems or weight management behaviors were the only harms addressed in the two trials of behavioral counseling included in the USPSTF report. One trial reported no adverse effects on problematic eating after primary care-based comprehensive behavioral treatment in 37 of 44 adolescent trial completers. The other trial reported no effect on eating disorder symptoms, weight dissatisfaction, or purging/restricting behaviors in 47 8-12 year-olds in a family-based comprehensive behavioral treatment program. The USPSTF report only included one trial (n = 43) that reported on the potential harms of pharmacotherapy. In the placebo-controlled phase of this sibutramine trial, 44% (19/43) of patients in the active medication group reduced or discontinued the medication due to elevated blood pressure, pulse rate, or both.

Our search of systematic reviews did not yield sufficient results for building a comprehensive safety profile for non-surgical approaches to obesity management. To achieve this goal, several separate evidence reports would need to be done on different diet therapies, physical exercise programs, behavioral therapy, and weight-loss medications (e.g., orlistat and sibutramine).

Figure 6. Systematic Review Attrition Diagram



Key Question 4: What are the relative cost profiles of bariatric surgery and non-operative approaches for patients aged a) 21 or less, b) 18-21, c) 13-17, and d) 12 or less?

ECRI Institute evidence assessments:

- Nationally, the median inpatient hospital cost for bariatric surgeries performed in pediatric patients in 2004 was $8,651; the median hospital charge was $25,021.
- Nationally, the median inpatient hospital cost for restrictive bariatric procedures performed in pediatric patients in 2004 was $6,688; the median inpatient hospital cost for bypass procedures was $8,893.
- Nationally, for those aged 13-17, the median inpatient hospital cost for bariatric procedures performed in 2004 was $7,973; the median inpatient hospital cost for those aged 18-21 was $8,945. No conclusions can be drawn regarding the cost of patients aged 12 and less due to lack of data.
- Data were not sufficient to permit a comparison of inpatient hospital cost between the State of Washington and the rest of the nation.
- Data were not sufficient to permit an analysis of the costs for professional services and post-surgery care.
- The evidence was not sufficient to permit the development of a comprehensive cost profile of non-operative approaches to pediatric obesity management.

The sections below describe the details of our analyses of inpatient hospital costs and charges. As described in the *Methods* section, this evidence report does not cover the costs for professional services and post-surgery care. In Appendix F in **Table 30**, we provide a summary of the Medicare physician fee amounts for bariatric surgeries in 2007 (that summary is only for the purpose of information and should not be considered as part of our analysis).

Inpatient Hospital Cost and Charge

Using the case selection criteria previously described, we identified a total of 415 pediatric (patients aged 21 or less) bariatric surgery cases in the HCUP NIS 2004 data (**Table 9**). Three hundred and forty-two (82.4%) of these pediatric cases were in the 18-21 age group, while the remaining 73 (17.6%) cases were in the 13-17 age group. No patients aged 12 or less were identified in the data set.

Of the 415 pediatric cases, 412 (99.3%) had morbid obesity as the primary diagnosis; the remaining three cases had morbid obesity as one of the secondary diagnoses. Over 60 percent of the 415 pediatric cases had ICD-9 code 44.39 (gastroenterostomy including bypass other than high gastric bypasses) as the primary procedure code, followed by 17 percent with ICD-9 code 44.31 (high gastric bypass) and 10 percent with ICD-9 code 44.38 (laparoscopic bypass) as the primary procedure code.

Table 10 summarized the inpatient charges and costs for the pediatric cases. The median inpatient hospital charge was $25,021, whereas the mean charge was $30,594. The median cost

was $8,651, while the mean cost was $10,913. The median charge was nearly three times as high as the median cost (**Figure 7**). The significant discrepancies between the mean and the median values, as well as the statistics, indicated that the charge and cost data distributions were positively skewed. Therefore, median values are better measures of central tendency for charges and costs.

Table 11, **Figure 8**, and **Figure 9** provide an overview of inpatient charge and cost by age group. Nationally, for those aged 13-17, the median inpatient hospital cost for bariatric procedures performed in 2004 was $7,973; the median inpatient hospital cost for those aged 18-21 was $8,945. No results were obtained regarding the cost or charge of patients aged less than 12 due to lack of data.

Table 12, **Figure 10**, and **Figure 11** provide an overview of inpatient charge and cost by procedure. The median and mean charge amounts for the restrictive procedures are $20,051 and $22,758, respectively, compared to $26,150 and $31,853, respectively, for the bypass procedures. The median and mean costs for the restrictive procedures are $6,688 and $7,899, respectively, compared to $8,893 and $11,276, respectively, for the bypass procedures.

Table 13 is a summary of inpatient charge for the pediatric bariatric procedures performed in the State of Washington in 2002-2004. Using the same case selection criteria that we used with the NIS 2004 data set, we only identified 14, 25 and 15 pediatric bariatric surgery cases, respectively, for 2002, 2003 and 2004 in the SID (WA) data sets. We were unable to obtain the cost data for the State because the data file containing CCRs could not be linked to the file containing the charge data. **Figure 12** shows that the inpatient charge (both the median and the mean) rose slightly from 2002 to 2004. In 2004, the median and mean inpatient charges were $21,688 and $26,483, respectively, for the State of Washington, compared to $25,021 and $30,594, respectively, for the nation. The small case numbers did not permit a reliable analysis of charge data by age group or procedure for the State.

Table 9. Summary of Pediatric Bariatric Surgery Cases in NIS 2004

	Number of Patients	Percentage
Age		
<13	0	0
13-17	73	17.6
18-21	342	82.4
Total	415	100.0
Primary Diagnosis (ICD-9 Codes)		
Morbid obesity (278.01)	412	99.3
Other hyperalimentation (278.8)	1	.2
Digestive system complications (997.4)	1	.2
Complications due to implant or internal device (996.59)	1	.2
Total	415	100.0
Primary Procedure (ICD-9 Codes)		
Other gastroenterostomy (bypass) (44.39)	255	61.4
High gastric bypass (44.31)	71	17.1
Laparoscopic gastroenterostomy (bypass) (44.38)	44	10.6
Other operation on stomach (44.69)	30	7.2
LAGB (44.95)	11	2.7
Laparoscopic gastroplasty (vertical banding) (44.68)	3	.7
Small-to-small intestinal anastomosis (45.91)	1[a]	.2
Total	**415**	**100.0**

[a] The case had ICD-9 Code 44.69 as one of the five secondary procedure codes.

Table 10. Overview of Inpatient Charge and Cost in NIS 2004

		Charges	Cost
N		415	391[a]
Mean		$30,594	$10,913
Median		$25,021	$8,651
Skewness		4.471	3.239
Standard error of skewness		0.120	0.123
Percentiles	25	$19,182	$6,976
	75	$37,390	$12,379

[a] Both hospital-specific and group average CCRs were missing for 24 of the 415 cases.

Figure 7. Median Inpatient Cost and Charge in NIS 2004

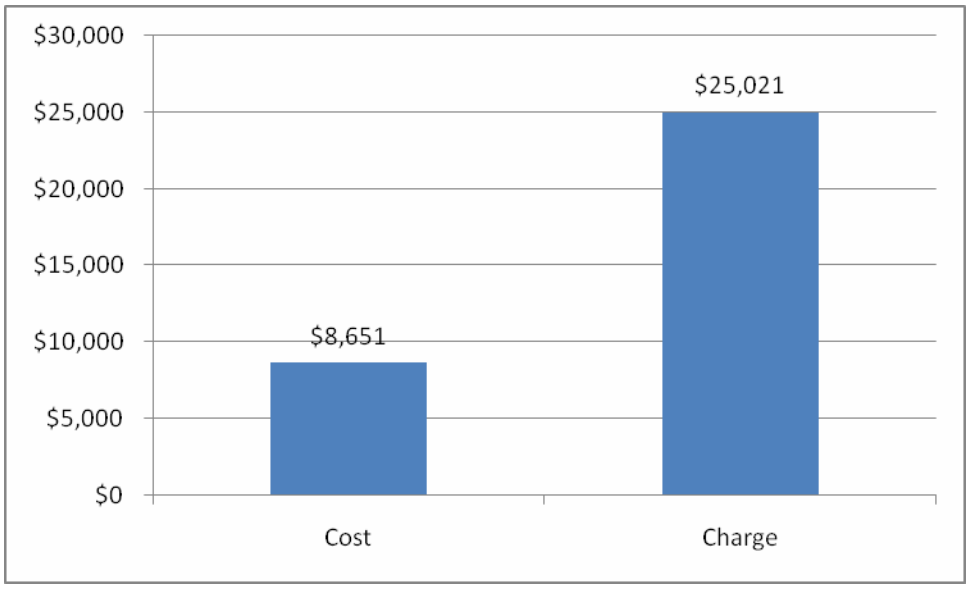


Table 11. Inpatient Charge and Cost by Age Group in NIS 2004

Age		Charge			Cost		
		Case number (%)	Median	Mean[a]	Case number (%)	Median	Mean[a]
≤21		415	$25,021	$30,594	391[b]	$8,651	$10,913
	≤12	0	N/A	N/A	0	N/A	N/A
	13-17	73 (17.59%)	$23,311	$29,867	65 (16.62%)	$7,973	$9,873
	18-21	342 (82.41%)	$25,161	$30,749	326 (83.38%)	$8,945	$11,121

[a] p >0.10 for 13-17 group vs. the 18-21 group

[b] Both hospital-specific and group average CCRs were missing for 24 of the 415 cases.

Table 12. Inpatient Charge and Cost by Procedure in NIS 2004

Procedure		Charge			Cost		
		Case number	Median	Mean	Case number	Median	Mean
Bypass Procedures		370	$26,150	$31,547	349	$8,893	$11,276
	Open	245	$26,152	$31,853	235	$9,179	$11,463
	Laparoscopic	125	$26,147	$30,946	114	$8,634	$10,892
Restrictive Procedures		45	$20,051	$22,758	42	$6,688	$7,899
	Open	22	$19,220	$21,086	21	$6,180	$7,004
	Laparoscopic	23	$20,624	$24,358	21	$7,178	$8,793

Figure 8. Median Inpatient Charge by Age Group in NIS 2004

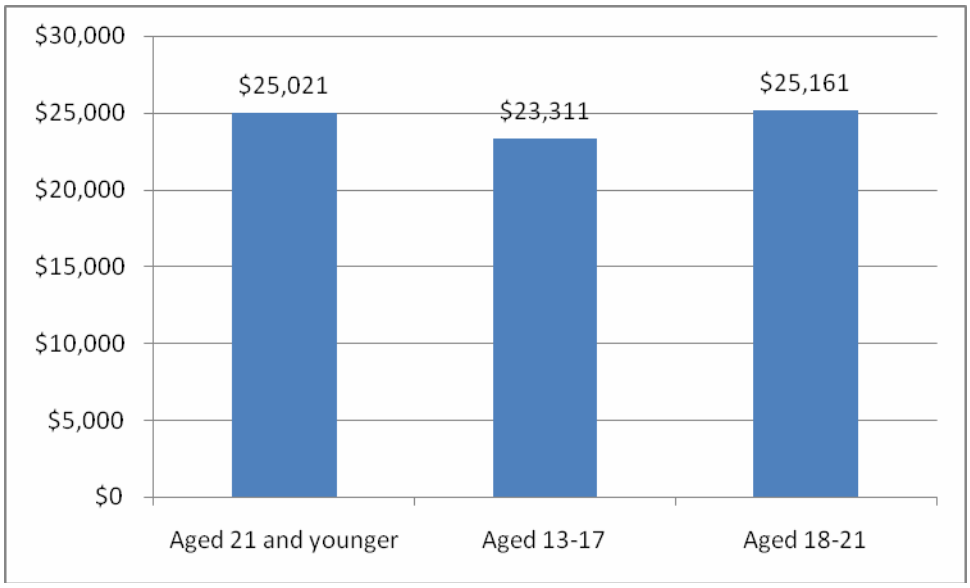


Figure 9. Median Inpatient Cost by Age Group in NIS 2004

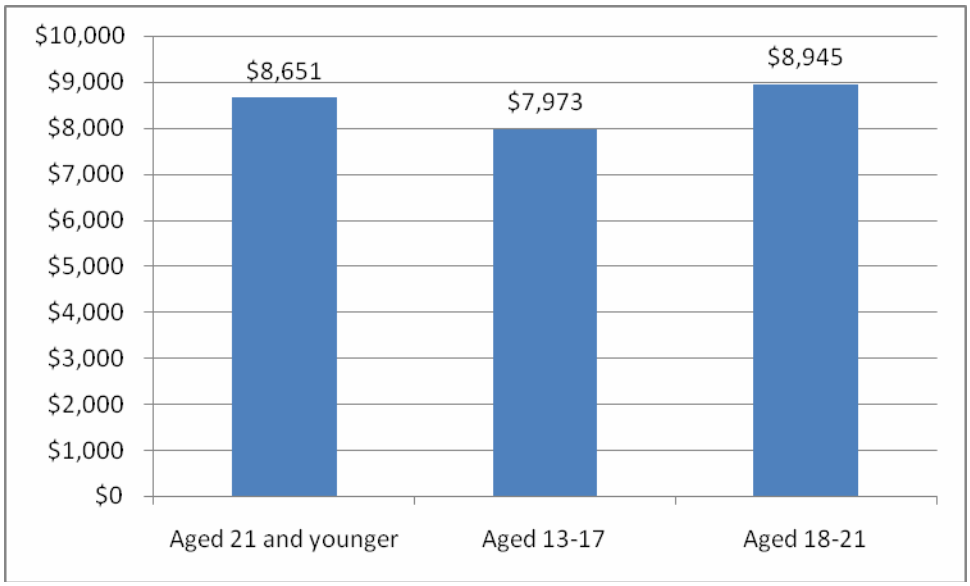


Figure 10. Median Inpatient Charge by Procedure in NIS 2004

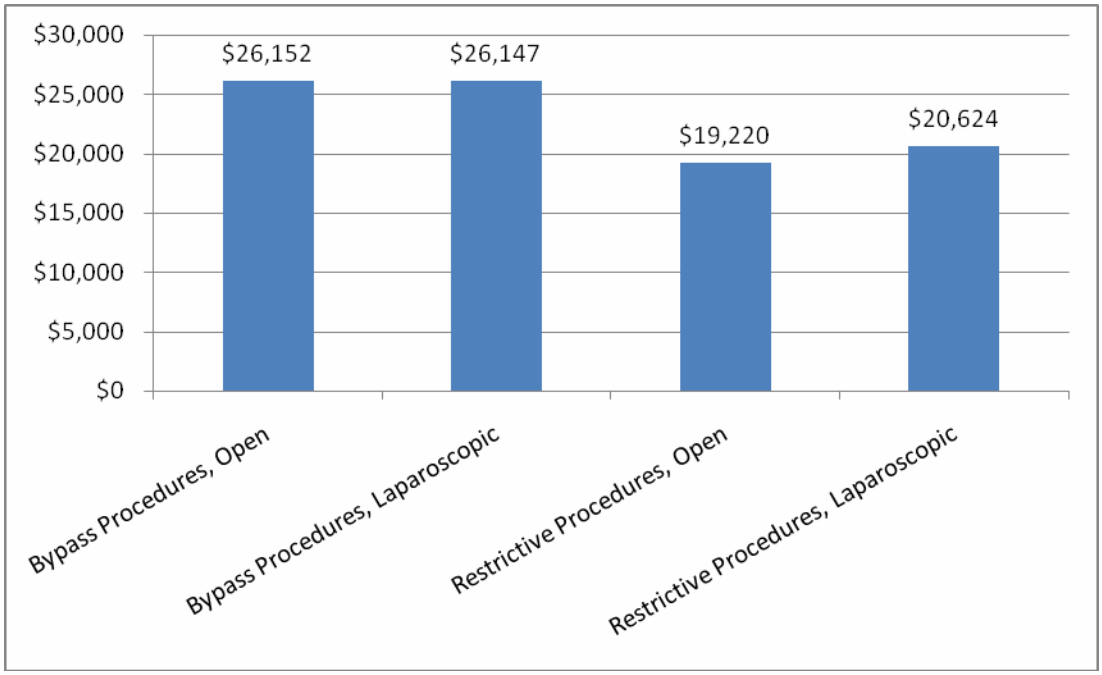


Figure 11. Median Inpatient Cost by Procedure in NIS 2004

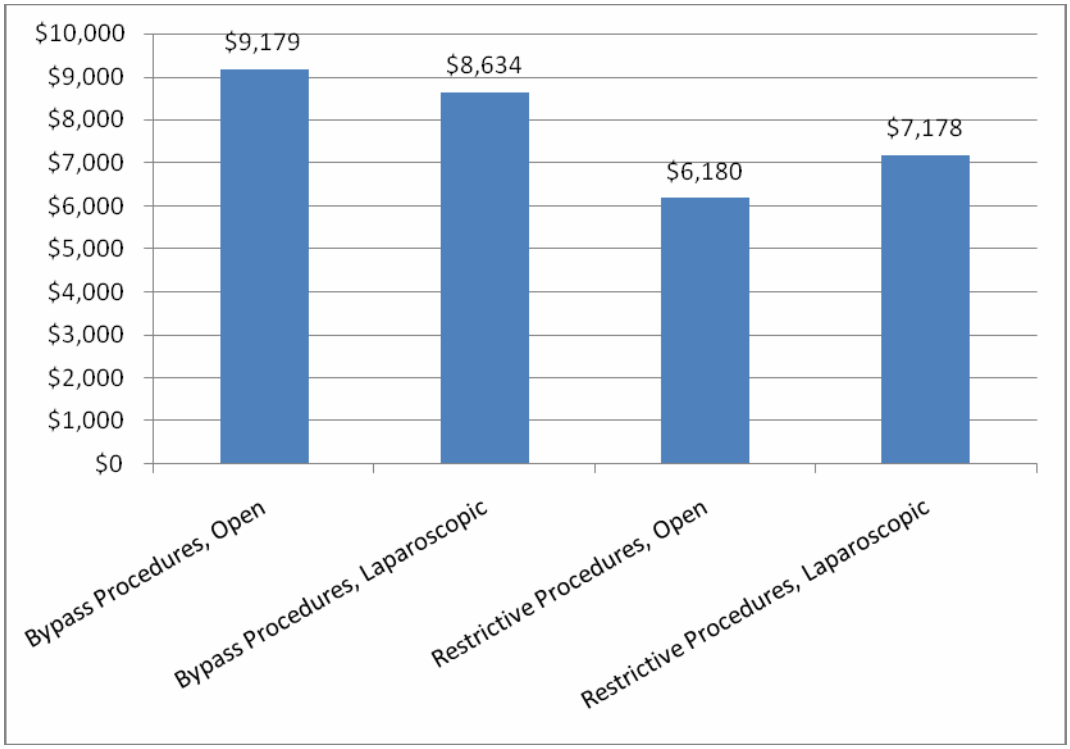
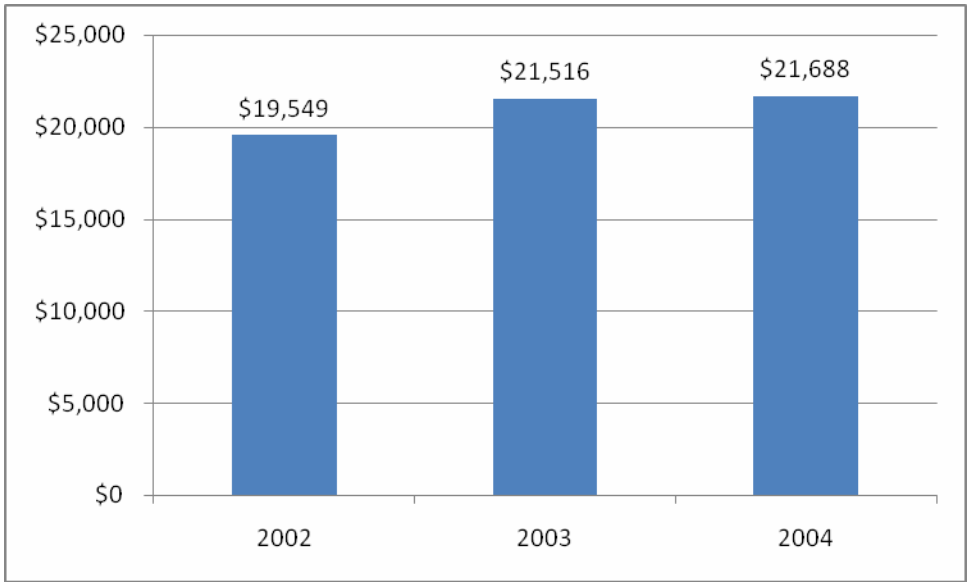


Table 13. 2002-2004 Inpatient Charge, Washington State

Year	Case number	Median	Mean
2004	15	$21,688	$26,483
2003	25	$21,516	$22,143
2002	14	$19,549	$20,494

Note: Charge amounts are all in 2004 dollars.

Figure 12. 2002-2004 Median Inpatient Charge, Washington State



Note: Charge amounts are all in 2004 dollars.

Cost of Non-operative Approaches

Non-operative approaches to pediatric obesity management include dietary therapies, physical exercise, psychological and family support, residential treatment, behavioral interventions, and pharmacotherapy. These non-operative approaches are usually combined into a comprehensive weight management program because evidence supports that the combination therapy is more successful than any single intervention.(95)

According to a survey by Marketdata (a market research organization), hundreds of weight loss programs existed in the United States in 2004.(96) Findings from the same survey indicate that a typical customized, six-month weight loss program would cost $802 on average. Such programs are typically led by a well-trained dietitian and based in either hospitals or health clubs. For a less medically-oriented program led by a nutritionist holding a bachelor's degree, the average cost would be $643. The weight loss programs surveyed by Marketdata might enroll both adult and pediatric patients. Our literature search did not identify any cost information regarding a weight loss program specifically designed for pediatric patients with obesity/morbid obesity.

Our searches found only one study containing information on pediatric pharmacotherapy charges. Encinosa and colleagues analyzed the 2002 Medstat data for pharmacotherapy costs and found that, of the 4 million patients who had prescription drug coverage, 21,931 used medications for weight loss.(97) These patients spent $304 per year on average on weight loss medications in 2002 (26 percent was paid out of pocket and 74 percent covered by insurers). Average annual spending for weight loss medications was found to increase with age, from $192 per person for ages 8-17 to $361 for ages 55-64.

Key Question 5: Do the effectiveness, safety and cost of bariatric surgery for patients a-d (as above) vary based on patients' characteristics, including:

a. Chronological age
b. Physiologic/skeletal age
c. Pre-surgical BMI
d. Pre-surgical BMI categories (35-40, 40-50, 50+ kg/m^2)
e. Sex
f. Race
g. Comorbid conditions (e.g., hypertension)
h. Other factors (e.g., psychosocial or socioeconomic factors)

ECRI Institute evidence assessments:

- The evidence is insufficient to permit any conclusions for this question

Five studies met the inclusion criteria for this Key Question. Of the eight patient characteristics (a) through (h), the studies addressed four: chronological age (a), pre-surgical BMI (c), pre-surgical BMI category (d), and sex (e). Quality assessments appear in **Table 22** of Appendix E, and a summary of the data appears in **Table 14** below. The patient-level data for each of these four patient characteristics are plotted against individual BMI units lost and appear in Appendix E (starting with **Figure 17**).

Among the five studies, there were two studies of LAGB; the quality scores were 6.5 (moderate) and 5.5 (low), for an average of 6.0 (low). Because the evidence was severely limited in both quality and quantity, the evidence was insufficient to permit conclusions. For the other procedures, there was only one study for this Key Question. Quality scores were 6.5 (moderate) for the Strauss study of RYGB; 2.5 (very low) for the Greenstein study of VBG, and 3.5 (very low) for Capella study of banded bypass. Again, due to limitations in the evidence, we did not draw conclusions for this Key Question.

Table 14. Data for Key Question 5 (Patient Characteristics to Predict Outcomes)

Study	N	Correlation between patient characteristic and BMI units lost[a]			
		Age	Pre-surgical BMI	Pre-surgical BMI category	Sex
Studies of Laparoscopic Adjustable Gastric Banding (LAGB)					
Fielding (2005)[b](76-78)	17	+0.08 (-0.42 to 0.54)	+0.66 (0.26 to 0.87)	+0.61 (0.18 to 0.84)	-0.20 (-0.62 to 0.31)
Abu-Abeid (2003)(80)	11	NR	+0.65 (0.08 to 0.90)	+0.70 (0.17 to 0.92)	NR
Studies of Roux-en-Y Gastric Bypass (RYGB)					
Strauss (2001)(36)	9	-0.51 (-0.88 to 0.24)	+0.31 (-0.45 to 0.81)	+0.04 (-0.64 to 0.69)	-0.37 (-0.83 to 0.39)
Studies of Vertical Banded Gastroplasty (VBG)					
Greenstein (1995)(86)	14	NR	+0.49 (-0.05 to 0.81)	+0.49 (-0.05 to 0.81)	-0.54 (-0.83 to -0.01)
Studies of banded bypass					
Capella (2003)(88)	15[c]	-0.12 (-0.63 to 0.46)	+0.50 (-0.02 to 0.81)	+0.49 (-0.03 to 0.80)	NR

a Each cell shows the patient-level Pearson r correlation (with 95% confidence interval) between a patient characteristic and the number of BMI units lost. For age, a positive correlation (+) means that older patients lost more BMI units. For the two BMI characteristics, a positive correlation means that patients with higher pre-surgical BMIs lost more BMI units than those with lower pre-surgical BMIs. The six categories of pre-surgical BMI were <40, 40-44.99, 45-49.99, 50-54.99, 55-59.99, and 60+ kg/m^2. For sex, a positive correlation means that boys lost more BMI units than girls. Figures in Appendix E show the individual patient data for all of the studies above.

b Individual patient data reported in a secondary publication(77)

c In the Capella study, the correlations with pre-surgical BMI and pre-surgical BMI category are based on all 15 patients, and the age correlation is based on 13 patients, because age was reported for only those 13.

NR – Not reported

Note: Key Question 5 was addressed by studies reporting individual patient data or studies that reported the necessary correlation between a patient characteristics and an outcome. Three studies had reported some individual patient data, but these data were excluded for the following reasons. A secondary publication(74) of the Silberhumer study reported individual patient data, but 1+ year weight data were reported for only three of eight patients. Horgan reported individual patient data, but only reported 1+ year weight data for only two of four patients.

Discussion

General Considerations

Researchers have raised several special considerations about the appropriateness of bariatric surgery in a pediatric population.(35) These include informed consent, interference with physical growth/maturation, and compliance with post-surgical diets.

Regarding informed consent, Inge et al.(2004)(98) stated that one important ethical consideration is whether the pediatric patient has "decisional capacity." Determining decisional capacity often requires consultation with the family, and patients without such capacity should not be treated surgically. Even with good decisional capacity when surgery is elected, some pediatric bariatric patients may later regret the decision to undergo surgery. If so, bariatric procedures that are more easily reversed (such as LAGB) may receive greater consideration in the pediatric population.

Another concern is the potential for bariatric surgery to interfere with physical growth and/or sexual maturation. Therefore, these additional outcomes should be considered in pediatric patients who receive bariatric surgery. In Key Question 3, we examined the published evidence for these outcomes. Only one study formally evaluated the growth of patients in post-operative followups.(37) The authors stated that "there was no evidence of growth retardation after surgery," but they also stated that "the question as to whether these adolescents achieved their expected growth could not be extracted from data available."(37) Two additional studies documented patients' pre-surgical height, but did not report height data after surgery.(87,88) Thus, the available evidence does not clarify whether bariatric surgery impairs the growth and development of pediatric patients.[8]

Another consideration is compliance with post-surgical dietary regimens, dietary supplements, and exercise recommendations. Pediatric patients may have lower levels of compliance than adults. One study included in our review reported that only 13% of pediatric patients continued taking nutritional supplements as instructed.(37) No other included studies examined the issue. To adequately address concerns about low compliance, additional evidence is needed from future studies.

Previous Systematic Reviews

The United Kingdom National Institute for Health and Clinical Excellence (NICE) published a systematic review in 2006 on obesity in children and adolescents.(49) The review contained 16 evidence statements specific to bariatric surgery in the pediatric population, and these statements correspond well to the conclusions in our report. We summarize their statements in the context of the five Key Questions in this report. For weight loss (our Key Question 1), the NICE report concluded than "Evidence appears to suggest that an approximate change in BMI of -20 kg/m^2 (after approximately two years) can occur in obese adolescents who underwent bariatric surgery."(49) For comorbidities and quality of life (our Key Question 2), it stated that "Evidence suggests that bariatric surgery can have an impact on psychosocial adjustment of severely obese

[8] Radiographs of epiphyses may help determine whether the majority of bone growth has been achieved prior to surgery. (M. Deitel, personal communication, 7/11/2007).(99)

adolescents", and that "Some evidence suggests that bariatric surgery can reduce significant comorbidities in severely obese adolescents."(49) For our Key Question 3 on harms, the NICE report contained four evidence statements concerning harms that may occur, including micronutrient deficiencies, revisional surgery, and band slippage or port infection/leakage after LAGB. For all outcomes, authors graded the evidence based only on study design, ignoring the quantity, consistency and robustness of the evidence. Thus, because the studies employed single-arm designs, the evidence grades were all 3 on a scale from 1 (representing systematic reviews or meta-analyses of randomized controlled trials) to 4 (representing expert opinion). No evidence statements were provided about costs (our Key Question 4) or the correspondence between patient characteristics and outcomes (our Key Question 5).

The Belgian Health Care Knowledge Center reported a systematic review in 2006 that included an assessment of the evidence on bariatric surgery in patients under age 18. Based on six studies, authors concluded that "long-term efficacy and safety of bariatric surgery in patients under 18 remain to be properly documented and demonstrated" and that "this procedure should be strictly limited to few specialized centres of excellence."(100)

A systematic review by the Institute for Clinical Systems Improvement in 2005 addressed bariatric surgery in children and adolescents.(101) After describing three studies, the review concluded that "in the short term, bariatric surgery appears to lead to significant weight loss with resolution of comorbidities." "Based on small case series, bariatric surgical complications in adolescents (age 11 years or greater) are no higher than in adults, although the impact of bariatric surgery on growth, development, metabolic homeostasis, and nutritional balance is unknown."(101)

A 2004 systematic review by the Southern California-RAND Evidence-Based Practice Center specifically examined data on bariatric surgery for adolescents.(102) They discussed eight case series, and concluded that "these reports document benefits in terms of weight loss and resolution of complications as well as harms in terms of surgical complications."(102) However, the authors also noted that the literature is "almost bereft of data" on the topic, and that "no studies have compared these benefits and harms to those of similar patients who received nonsurgical therapies such as diet or medication".

Another 2004 systematic review, performed by the Health Technology Assessment Unit in Malaysia, included four studies of bariatric surgery in patients aged 0-18.(103) Based on four studies, authors stated that "surgery is recommended for treatment of morbidly obese children."(103)

Ongoing Clinical Trials

Our searches of clinicaltrials.gov located three ongoing studies of bariatric surgery in pediatric patients, all of which were recruiting patients as of 4/13/07:

- One study (clinicaltrials.gov identifier NCT00289705) at Göteborg University in Sweden started in February of 2006 involves the use of laparoscopic Roux-en-Y gastric bypass with an expected enrollment of 80 patients aged 13-17.
- Another study (clinicaltrials.gov identifier NCT00447590) by the Allergan Medical Corporation (Irvine, CA) is planned to enroll 150 obese patients aged 14-17 who will undergo LAGB with the LAP-BAND® (start date not included in the trial record).

- A third study (clinicaltrials.gov identifier NCT00360373), sponsored by the National Institute of Diabetes and Digestive Kidney Disease (NIDDK) and being conducted at the Cincinnati Children's Hospital Medical Center, started in August of 2005. The investigators plan to perform gastric bypass on 50 patients with BMI >40 in two groups (aged 15-21 or aged 30-45).

Clinical Practice Guidelines and Position Statements

This section reviews nine guidelines and position statements that addressed bariatric surgery for morbidly obese pediatric patients.

The Institute for Clinical Systems Improvement (ICSI) published a Health Care Guideline in 2006 pertaining to the prevention and management of obesity in mature adolescents and adults.(104) They defined "mature adolescents" as those who have reached Tanner stage 5 of sexual maturity (of five stages total). For this population as well as adults, the authors of the guideline concluded that "Bariatric surgery is indicated in carefully selected patients: a) with a BMI greater than or equal to 40 kg/m^2, or b) with a BMI of 35-39.9 kg/m^2 and who are at a very high absolute risk for increased morbidity or premature mortality. Patients are to be motivated, well-informed in disease management, psychologically stable, and accepting of operative risks."(104)

In a 2005 guideline, the American Heart Association (AHA) mentioned surgical treatment as one option in the treatment of overweight in children and adolescents. Authors recommended more stringent BMI indications for pediatric patients than for adults: a minimum BMI of 50 kg/m^2 or a BMI of at least 40 kg/m^2 in the presence of serious comorbidities. The guideline stated that "weight loss goals and reduction of morbidity are often achieved with gastric bypass surgery. The rates of short-term mortality appear to be low, but significant complications can occur".(44) The guideline further recommended that "surgical therapy should be reserved for full-grown adolescents with the severest obesity-related morbidity, offered only by experienced multidisciplinary teams, and presented to families with appropriate informed consent procedures."(44)

The North American Society for Pediatric Gastroenterology, Hepatology and Nutrition published a 2005 guideline on overweight children and adolescents.(105) Bariatric surgery was listed in a set of "intensive therapies for severely obese children". The guideline stated that "until more data are available, gastric bypass surgery should be considered only for well-informed and motivated adolescents who meet the following criteria: severe obesity (BMI ≥40 kg/m^2), failure of ≥6 months of organized attempts at weight loss, near-complete skeletal maturity and significant comorbidities that would be responsive to sustained weight loss."(105)

Inge et al.(2004)(98) published bariatric surgery recommendations for adolescents who are severely overweight. Like the AHA, the publication recommended that for this patient population, the BMI criteria should be more stringent than those for adults (minimum BMI of 50 kg/m^2 or a BMI of at least 40 kg/m^2 in the presence of serious comorbidities). Other indications for adolescent bariatric surgery included the attainment of physical maturity, demonstrated decisional capacity, a supportive family environment, and other criteria that are also applied to adults, such as the documented failure of previous non-surgical attempts at weight loss.

The 2004 Consensus Conference Statement of the American Society for Bariatric Surgery states that "Bariatric surgery, performed only by experienced centers, should be considered in morbidly obese adolescents "(106) The statement also noted that since the 1991 NIH Consensus Conference on bariatric surgery, there has been "increased experience with bariatric surgery in adolescent and elderly populations."(106) Further, the statement notes that "BMI guidelines for adolescents should be identical to those advocated for adults,"(106) and it includes recommendations such as "physiologic maturity should be complete", "adolescents should indicate their desire for the operation and should have sufficient cognitive and psychologic development to participate in decision-making", and "adolescents should first undergo a trial of dietary and behavior modification for at least 6 months."(106)

The 2004 Singapore Ministry of Health clinical practice guidelines for obesity stated that "Bariatric surgery cannot be recommended for most adolescents, but only for those at the highest risk of mortality from obesity, and with both patient and parental understanding of the consequences of surgery."(107)

In 2004, the Betsy Lehman Center for Patient Safety and Medical Error Reduction (Boston, MA) convened an Expert Panel on Weight Loss Surgery.(108) The report recommended more stringent BMI criteria for adolescents than for adults (the same BMI criteria recommended by the Inge document discussed above).(98) About the effectiveness of bariatric surgery, the panel concluded that "the limited data available indicate that Roux-en-Y Gastric Bypass (RYGB) and laparoscopic adjustable gastric banding (LAGB) are generally safe and produce durable weight loss when used in adolescents."(108)

The University of Texas at Austin published a 2004 guideline on the evaluation and treatment of obesity in children and adolescents.(109) One of the statements on patient management stated "Referral to specialty weight reduction clinics including consideration of medication and/or bariatric surgery (needed in less than 1% of children and adolescents identified as obese)."(109)

In 2003, the Australian National Health and Medical Research Council (NHMRC) published clinical practice guidelines for the management of overweight and obesity in children and adolescents.(110) With respect to bariatric surgery, the guideline concluded that "There is limited evidence that gastric bypass or gastric restrictive surgery in obese adolescents induces a weight loss comparable to that shown in adult studies. There are, however, no established criteria for determining which subjects would benefit from such a procedure."(110)

Third Party Payers

Our searches of company websites located ten coverage policies pertaining to bariatric surgery. All policies stated that surgery is only covered for patients with a BMI of 40+ or with a BMI of 35+ in the presence of significant medical comorbidity, as well as unsuccessful prior attempts at weight loss through non-surgical methods. Other details of these polices, especially age-related restrictions, appear in **Table 15** below. Six of the 10 policies did not cover bariatric surgery for patients aged 17 or under. The other four policies covered these younger patients under certain circumstances (see table).

We also searched the CMS website, and located a National Coverage Determination on bariatric surgery.(111) This determination covers LAGB, RYGB, and BPD/DS for Medicare patients who have a BMI of at least 35, have significant medical comorbidity, have had previous unsuccessful non-surgical treatment, and are treated at approved facilities. The document does not mention the

use of bariatric surgery in pediatric patients, and does not restrict coverage to those aged 18 and older. Some procedures were explicitly mentioned as non-covered: open adjustable gastric banding, open and laparoscopic sleeve gastrectomy, and open and laparoscopic VBG.

Public Comment

A draft of this report was made available for public review and comment on the Washington State Health Care Authority Web site. No public comments were received on the draft report.

Table 15. Coverage Policies Identified in Web Searches

(✓ indicates a covered procedure; **X** indicates a non-covered procedure; ? indicates a procedure that was not mentioned explicitly in the policy)

Company	Age-related restrictions on coverage of bariatric surgery	LAGB	RYGB	VBG	Banded bypass	Other explicitly INCLUDED procedures	Other explicitly EXCLUDED procedures
Aetna(112)	Age ≥18 OR "documentation of completion of bone growth"	✓	✓	✓[a]	**X**	BPD/DS, BPD	MGB, HBG, IGB, Loop, LSG
BCBS-Alabama(113)	Age ≥18	✓	✓	✓	**X**	None	BPD, BPD/DS, GES, GW, IGB, JIB, LLRYGB, Loop, LSG, MGB, Open SG
BCBS – Massachusetts(114)	Age ≥18 OR "documentation of complete bone growth"	✓	✓	✓	?	None	BPD, BPD/DS, GES, GW, HBG, IGB, JIB, LLRYGB, LSG, MGB, Open SG
BCBS-Wisconsin(115)	Age ≥18 OR "A bariatric surgeon with experience in the pediatric population may request further consideration of a case of an individual under 18 years old with severe morbid obesity and unique circumstances by contacting a Medical Director"	✓	✓	✓	**X**	BPD/DS	MGB, BPD, HBG, IGB, JIB, LLRYGB, Loop, LSG
Cigna(116)	Age ≥18 OR "has reached full expected skeletal growth"	✓	✓	✓	**X**	None	MGB, BPD/DS,
HealthPartners(117)	Age ≥18	✓	?	?	?	None	GES, IGB, MGB
Humana(118)	Age ≥18	✓	✓	✓	?	BPD/DS, BPD	IGB, LSG, Open AGB, Open SG

Company	Age-related restrictions on coverage of bariatric surgery	LAGB	RYGB	VBG	Banded bypass	Other explicitly INCLUDED procedures	Other explicitly EXCLUDED procedures
Medica(119)	Age ≥18	✓	✓	✓[b]	**X**	BPD/DS[b]	BPD, MandM, HBG, JIB, MGB
Regence(120)	Age ≥18	✓	✓	**X**	?	None	BPD, BPD/DS, LSG, LLRYGB, MGB
Wellmark(121)	Age ≥18	✓[c]	✓	✓	?	None	BPD, BPD/DS, MGB

[a] Additional restrictions on coverage of VBG in the Aetna policy: Covered for patients who meet other criteria but are at "increased risk of adverse consequences of a RYGB due to the presence of any of the following comorbid medical conditions: A) Hepatic cirrhosis with elevated liver function tests; B) Inflammatory bowel disease (Crohn's disease or ulcerative colitis), C) Radiation enteritis; D) Demonstrated complications from extensive adhesions involving the intestines from prior major abdominal surgery, multiple minor surgeries, or major trauma; E) Poorly controlled systemic disease (American Society of Anesthesiology (ASA) Class IV)".

[b] Medica only covers VBG and BPD/DS if the operation is performed using an open approach. Also, open VBG requires medical director review.

[c] Wellmark only covers LAGB if the patient's BMI is between 35 and 50 and the Lap-Band is used.

BPD	Biliopancreatic diversion.
BPD/DS	Biliopancreatic diversion with duodenal switch.
GES	Gastric electrical stimulation.
GW	Gastric wrapping.
HBG	Horizontal banded gastroplasty.
IGB	Intragastric balloon.
JIB	Jejunoileal bypass.
LAGB	Laparoscopic adjustable gastric banding.
LLRYGB	Long limb gastric bypass.
Loop	Loop gastric bypass.
LSG	Laparoscopic sleeve gastrectomy.
MandM	Magenstrasse and Mill procedure.
MGB	Mini-gastric bypass.
Open AGB	Open adjustable gastric banding.
Open SG	Open sleeve gastrectomy.
RYGB	Roux-en-Y gastric bypass.
VBG	Vertical banded gastroplasty.

Table 16 provides information on Medicaid coverage of bariatric surgery in all 50 states and the District of Columbia. To obtain this information, we first looked for information from state-specific agencies, and secondarily from Lexis-Nexis.

Table 16. Medicaid Policies Pertaining to Pediatric Bariatric Surgery

State	Covered	Age restrictions	General restrictions	Source
Alabama	Yes	None mentioned	Prior authorization	Alabama Medicaid Agency, Fact sheet--coverage of gastric bypass surgery
Alaska	No			Alaska Adm. Code, Title 7, part 3, ch. 48.050
Arizona	Not mentioned			
Arkansas	Yes	16-60	Prior authorization	Arkansas Provider manual, sect. II
California	Yes	None mentioned	Prior authorization	Medi-Cal update, Feb. 2007, bulletin 388
Colorado	Not specifically mentioned under new pilot program			Colorado revised statutes, 25.5-5-317
Connecticut	Not mentioned			
DC	Depends on plan	None mentioned		District of Columbia Medicaid Managed Care Programs
Delaware	Yes	None mentioned	Prior authorization	Provider policy manual, 2.3.5.2
Florida	Yes	None mentioned	Medically necessary/Prior authorization	Physicain services coverage and limitations handbook and Provider reimbursement handbook
Georgia	Yes	None mentioned		Official Code of Georgia, 33-24-59.7
Hawaii	Yes (Gastric bypass) No (Jejunoileal bypass)	None mentioned	Prior authorization	Medicaid provider manual, ch. 6, 6.16.3 & 6.16.4
Idaho	Yes	None mentioned	Medically necessary/Prior authorization	Idaho Adm. Code IDAPA 16.03.09
Illinois	Yes	None mentioned	Physician certified as morbid obesity (2X normal body weight)	Illinois Compiled Statutes, 215 ILCS 105/8
Indiana	Yes	None mentioned	Prior authorization	Indiana Health Coverage Programs Provider Manual, ch 6: Prior authorization
Iowa	Yes	None mentioned	Prior authorization	Coverage and limitations: acute hospital services, ch. E-2
Kansas	Not mentioned			
Kentucky	Yes	None mentioned		Physician Fee Schedule

State	Covered	Age restrictions	General restrictions	Source
Louisiana	Not specifically mentioned under program on obesity prevention & management			Louisiana Revised Statutes, 46:2612
Maine	Yes	Will do under 21 with restrictions	Prior authorization	Code of Maine Rules, 10-144-101
Maryland	Yes	None mentioned	Prior authorization	Code of Maryland Regulations, 10.09.06.06
Massachusetts	Yes	Over 18	Medically necessary/Prior authorization	MassHealth. Guidelines for Medical Necessity Determination for Bariatric Surgery
Michigan	Yes	None mentioned	Medically necessary/Prior authorization/Psychiatric evaluation	Medicaid provider manual Hospital, p. 32-3 & Practitioner, p.4, 40
Minnesota	Yes	None mentioned	Prior authorization	MHCP Provider Manual--Authorization, ch. 5
Mississippi	No			General description of the Mississippi Medicaid Program, 1.14
Missouri	Not mentioned			
Montana	No			Adm. Rules of Montana, 37.85.207
Nebraska	Yes	None mentioned	Prior authorization	Neb. Adm. Code Title 471, Ch. 10
Nevada	Yes	21-55	Prior authorization	Medicaid Services Manual, Physicians, Policy 6-07
New Hampshire	Not mentioned			
New Jersey	No, unless specifically approved			New Jersey Administrative Code, 10:49-5.7 & 10:74-3.11
New Mexico	Not mentioned			
New York	Yes	None mentioned	Medically necessary	DOH Medicaid Update, Jan. 2005, Vol. 20(1)
North Carolina	Yes	19 or older	Medically necessary/Prior authorization	NC Div. of Medical Assistance, clinical coverage policy no. 1A-15: Surgery for clinically severe obesity
North Dakota	Yes	None mentioned	Prior authorization	ND General Information for Providers: Medicaid and other medical assistance programs
Ohio	No			Ohio Administrative Code, 5101:3-4-28
Oklahoma	Yes	18-65	Prior authorization	Oklahoma Health Care Authority Medicaid Rules, Part 10: Bariatric surgery, 317:30-5-137-141
Oregon	Yes	None mentioned		Oregon Health Services Commission current prioritized list

State	Covered	Age restrictions	General restrictions	Source
Pennsylvania	Yes	None mentioned		Medical Assistance Program Fee Schedule Revisions
Rhode Island	Yes	18-60	Prior authorization	RI DHS Physician Provider Manual, Prior approval (PA) criteria for surgical procedures, p. 5
South Carolina	Yes	None mentioned	Medically necessary	SC DHHS, Hospital Services Provider Manual, sect. 2, p. 56
South Dakota	No, unless certain conditions met	None mentioned	Medically necessary/Prior authorization	Obesity and gastric procedures, Provider Information, SD Dept. of Social Services
Tennessee	Yes	Under 21	Medically necessary	Tenn. Comp. R. & Regs. R 1200-12-14-.04
Texas	Not mentioned			
Utah	No			Utah Medicaid Provider Manual, Hospital Services, p. 27
Vermont	Not mentioned			
Virginia	Yes	None mentioned	Prior authorization	VA Dept. of Medical Assistance Services, Hospital manual, ch. 4
Washington	Yes	Ages 21-59	Medically necessary	WAC 388-550-2301
West Virginia	Yes	Ages 18-65	Medically necessary/Prior authorization	West VA [Medicaid] Provider Manuals, vol. 10, ch. 500-15
Wisconsin	Yes	18 or older	Prior authorization	Wisconsin Medicaid and BadgerCare update, Dec. 2005
Wyoming	No			Wyoming Medicaid Rules, ch. 26

Conclusions

In this section, we first summarize the five clinical questions and the conclusions we drew based on the evidence (for more detailed descriptions of the evidence, please consult the *Results* section). Then, we provide general comments on the overall picture of the evidence pertaining to bariatric surgery for morbidly obese pediatric patients.

1. Does pediatric bariatric surgery lead to sustained and clinically significant weight loss compared to non-operative approaches?
    a. In patients aged 21 or less
    b. Specifically in patients aged 18-21
    c. Specifically in patients aged 13-17
    d. Specifically in patients aged 12 or less

ECRI Institute evidence assessments:

- Laparoscopic Adjustable Gastric Banding (LAGB) for morbidly obese patients aged 21 or less does lead to sustained and clinically significant weight loss compared to non-operative approaches. (Strength of evidence at longest followup after surgery (1.7 to 3.3 years): Weak; Strength of evidence at one year after surgery: Moderate).
- Roux-en-Y Gastric Bypass (RYGB) for morbidly obese patients aged 21 or less does lead to sustained and clinically significant weight loss compared to non-operative approaches. (Strength of evidence at longest followup after surgery (1 to 6.3 years): Weak; Strength of evidence at one year after surgery: Moderate).
- The evidence is insufficient to permit quantitative estimates of the precise amount of weight loss after any bariatric surgical procedure for pediatric patients.
- The evidence is insufficient to permit any conclusions about weight loss after other bariatric surgical procedures for pediatric patients.
- The evidence is insufficient to permit any conclusions about weight loss in specific age subgroups (18-21, 13-17, 12 or less) within the pediatric population.

2. Does bariatric surgery for patients a-d (as above) improve comorbid conditions linked to obesity (e.g., diabetes, hypertension, obstructive sleep apnea, musculoskeletal disorders), quality of life, or survival, as compared to non-operative approaches?

ECRI Institute evidence assessments:

- Laparoscopic Adjustable Gastric Banding (LAGB) for morbidly obese patients aged 21 or less does resolve comorbid conditions linked to obesity (diabetes, hypertension) compared to non-operative approaches. (Strength of evidence for comorbidity data: Weak).
- Roux-en-Y Gastric Bypass for morbidly obese patients aged 21 or less does resolve comorbid conditions linked to obesity (hypertension) compared to non-operative approaches. (Strength of evidence for comorbidity data: Weak).

- The evidence is insufficient to permit quantitative estimates of the likelihood of comorbidity resolution, quality of life, or survival after any bariatric surgical procedure for pediatric patients.

- The evidence is insufficient to permit any conclusions about comorbidity resolution after other bariatric surgical procedures for pediatric patients.

- The evidence is insufficient to permit any conclusions about comorbidity resolution in specific age subgroups (18-21, 13-17, 12 or less) within the pediatric population.

3. What are the relative safety profiles of bariatric surgery and non-operative approaches for patients a-d (as above)?

ECRI Institute evidence assessments:

- Our review of the eight LAGB studies (the procedures were performed between 1996 and 2006; the individual patient follow-up times ranged from one month to 85 months) found:
    - No reported in-hospital or postoperative death.
    - The most frequently reported complication after LAGB was band slippage.
    - Reoperations were performed on 26 (7.92%) of the 328 LAGB patients to correct various complications.
- Our review of the six RYGB studies (the procedures were performed between 1978 and 2005; the individual patient follow-up times ranged from two weeks to six years) found:
    - One postoperative death was reported for RYGB; no in-hospital death was reported.
    - The most frequently reported complication after RYGB was related to protein-calorie malnutrition and micronutrient deficiency.
    - Potentially life-threatening complications such as shock, pulmonary embolism, severe malnutrition, immediate postoperative bleeding, and gastrointestinal obstructions were reported in the RYGB studies.
- The evidence is insufficient to permit any conclusions on potential impacts of bariatric surgery on growth and development of pediatric patients.
- The evidence is insufficient to permit any conclusions on potential harms in specific age groups (18-21, 13-17, 12 or less).
- Systematic reviews on pediatric obesity management did not provide sufficient data for the development of a safety profile of non-operative approaches.

4. What are the relative cost profiles of bariatric surgery and non-operative approaches for patients a-d (as above)?

ECRI Institute evidence assessments:

- Nationally, the median inpatient hospital cost for bariatric surgeries performed in pediatric patients in 2004 was $8,651; the median hospital charge was $25,021.

- Nationally, the median inpatient hospital cost for restrictive bariatric procedures performed in pediatric patients in 2004 was $6,688; the median inpatient hospital cost for bypass procedures was $8,893.
- Nationally, for those aged 13-17, the median inpatient hospital cost for bariatric procedures performed in 2004 was $7,973; the median inpatient hospital cost for those aged 18-21 was $8,945. No conclusions can be drawn regarding the cost of patients aged 12 and less due to lack of data.
- Data were not sufficient to permit a comparison of inpatient hospital cost between the State of Washington and the rest of the nation.
- Data were not sufficient to permit an analysis of the costs for professional services and post-surgery care.
- The evidence was not sufficient to permit the development of a comprehensive cost profile of non-operative approaches to pediatric obesity management.

5. Do the effectiveness, safety and cost of bariatric surgery for patients a-d (as above) vary based on patients' characteristics, including:
    a. Chronological age
    b. Physiologic/skeletal age
    c. Pre-surgical BMI
    d. Pre-surgical BMI categories (35-40, 40-50, 50+)
    e. Sex
    f. Race
    g. Comorbid conditions (e.g., hypertension)
    h. Other factors (e.g., psychosocial or socioeconomic factors)

ECRI Institute evidence assessments:

- The evidence is insufficient to permit any conclusions for this question

General Comments

The potential benefits of LAGB and RYGB for pediatric patients with morbid obesity are the substantial weight loss (Key Question 1) and the resolution of medical conditions associated with obesity (Key Question 2). The limited evidence available suggests these potential benefits in pediatric populations. However, direct evidence on enhanced quality of life and extended long-term survival is too sparse (or simply unavailable) to support conclusions. Also, current evidence does not permit conclusions about whether certain patient characteristics (e.g., age, sex, pre-surgical BMI) are predictive of surgical outcomes (Key Question 5).

The potential benefits of bariatric surgery must be weighed against the complications (Key Question 3). For LAGB, the primary concern is the need for reoperation to correct problems associated with the band and port. Reasons for reoperation include band slippage, intragastric migration, and port/tubing problems. For RYGB, there is a different profile of complications, varying from mild events (e.g., slight malnutrition, correctable by supplements) to severe events (e.g., pulmonary embolism, severe malnutrition, immediate postoperative bleeding, digestive obstruction, staple line leak). Precisely how often these events occur in pediatric patients is unknowable, due to the sparseness of the evidence.

The costs associated with bariatric surgery (Key Question 4) include not only the hospital inpatient costs of the procedure, but also the costs for professional services and postoperative management. Unfortunately, no published data exists covering all such costs for bariatric surgery in pediatric patients. Although we conducted our own analyses of publicly available data to estimate hospital inpatient costs, we did not conduct similar analyses on the costs for professional services and postoperative care due to lack of data.

Future research on the use of bariatric surgery should be performed to provide greater clarity about bariatric risks and benefits in the pediatric population. The most easily interpreted study design would be one where patients were randomized to receive either bariatric surgery or non-surgical weight loss methods. Longer followup in prospective studies of larger populations could provide insights into key issues of informed consent, compliance with post-surgical regimens, the impact on physical growth, influence on medical comorbidities, quality of life, and long-term survival.

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Appendix A. Literature Search Methods

Electronic Database Searches

The following databases have been searched for relevant information:

Name	Date limits	Platform/provider
CINAHL (Cumulative Index to Nursing and Allied Health Literature)	2003 through June 4, 2007	OVID
The Cochrane Central Register of Controlled Trials (CENTRAL)	2003 through 2007, Issue 2	http://www.thecochranelibrary.com
The Cochrane Database of Methodology Reviews (Methodology Reviews)	2003 through 2007, Issue 2	http://www.thecochranelibrary.com
The Cochrane Database of Systematic Reviews (Cochrane Reviews)	2003 through 2007, Issue 2	http://www.thecochranelibrary.com
Database of Abstracts of Reviews of Effects (DARE)	2003 through 2007, Issue 2	http://www.thecochranelibrary.com
Embase (Excerpta Medica)	2003 through June 4, 2007	OVID
Health Technology Assessment Database (HTA)	2003 through 2007, Issue 2	http://www.thecochranelibrary.com
Healthcare Standards	1975 through April 10, 2007	ECRI
International Health Technology Assessment (IHTA)	2003 through April 10, 2007	ECRI
MEDLINE	2003 through June 4, 2007	OVID
metaRegister of Controlled Trials (mRCT)	Searched April 13, 2007	http://www.controlled-trials.com/mrct/
PsycINFO	2003 through June 4, 2007	OVID
PubMed (PREMEDLINE)	Premedline[sb] Searched April 16, 2007	http://www.pubmed.gov
U.K. National Health Service Economic Evaluation Database (NHS EED)	2003 through 2007, Issue 2	http://www.thecochranelibrary.com
U.S. National Guideline Clearinghouse™ (NGC™)	2003 through April 10, 2007	http://www.ngc.gov

Detailed Search Strategies

The search strategies employed combinations of freetext keywords as well as controlled vocabulary terms including (but not limited to) the following concepts. The strategy below is presented in OVID syntax; the search was simultaneously conducted across Embase, MEDLINE, and PsycINFO. A parallel strategy was used to search the databases comprising the Cochrane Library.

Medical Subject Headings (MeSH), Emtree, PsycINFO and Keywords

Conventions:

OVID

$ = truncation character (wildcard)

exp = "explodes" controlled vocabulary term (e.g., expands search to all more specific related terms in the vocabulary's hierarchy)

.de. = limit controlled vocabulary heading

.fs. = floating subheading

.hw. = limit to heading word

.md. = type of methodology (PsycINFO)

.mp. = combined search fields (default if no fields are specified)

.pt. = publication Type

.ti. = limit to title

.tw. = limit to title and abstract fields

PubMed

[mh] = MeSH heading

[majr] = MeSH heading designated as major topic

[pt] = Publication Type

[sb] = Subset of PubMed database (PreMedline, Systematic, OldMedline)

[sh] = MeSH subheading (qualifiers used in conjunction with MeSH headings)

[tiab] = keyword in title or abstract

[tw] = Text word

CINAHL/Embase/Medline/PsycINFO
English language, human
Date range 2003 - 2007

Set Number	Concept	Search statement
1	Bypass surgery	Exp bariatric surgery/ or roux y anastomosis.de. or anastomosis, roux-en-y.de. or stomach bypass.de. or biliopancreatic bypass.de. or biliopancreatic diversion.de. or gastric bypass or intestinal bypass or fobi pouch or silastic pouch or bariatrics.de.
2	Gastric banding	(silastic or vertical or silicone ring or horizontal or collis) and (band$ or gastroplasty)
3	Specific products	Lap band or lapband or lap-band
4	Surgery	Obesity morbid/su or morbid obesity/su
5	Specific trials	“assess cost-effectiveness in obesity project”
6	Combine sets	or/1-5
7	General Limits	6 and 2003-2007 publication date, human, and English language
8	Limit by population	7 and (exp child/ or adolescent.de. or child$ or pediatr$ or paediatr$ or juvenile$ or adolescen$ or teen$ or youth$) Note: We may consider using the term age factors as another means of addressing this subject.
9	Limit by study type	8 and ((Randomized controlled trials or random allocation or double-blind method or single-blind method or placebos or cross-over studies or crossover procedure or double blind procedure or single blind procedure or placebo or latin square design or crossover design or double-blind studies or single-blind studies or triple-blind studies or random assignment or exp controlled study/ or exp clinical trial/ or exp comparative study/ or cohort analysis or follow-up studies.de. or intermethod comparison or parallel design or control group or prospective study or retrospective study or case control study or major clinical study).de. or random$.hw. or random$.ti. or placebo$ or ((singl$ or doubl$ or tripl$ or trebl$) and (dummy or blind or sham)) or latin square or ISRTCN)
10	Economic analyses	8 and (Exp economic evaluation/ or exp costs and cost analysis/ or ec.fs. or cost$.sh. or (econom$ or cost$).ti.)
11	Combine sets	or/9-10
12	Limit by publication type	11 not ((letter or editorial or news or comment or case reports or review or note or conference paper).de. or (letter or editorial or news or comment or case reports or review).pt.)
13	Eliminate overlap	Remove duplicates from 12

PubMed
(PREMEDLINE/Publisher Sub-files)
English language, human

Set Number	Concept	Search statement
1	Obesity	Bariatric*[ti] OR obes*[ti]
2	Surgery	#1 AND surg*
3	Specific procedures	"gastric bypass" OR (band* AND (silastic OR vertical OR "silicone ring" OR horizontal OR collis))
4	Combine sets	#2 OR #3
5	Limit by population	#4 AND (child* OR pediatr* OR paediatr* OR juvenile OR teen OR adolescen*)
6	Limit by sub-file	#5 AND (in process[sb] OR publisher[sb])
7	Limit by publication type	#6 NOT (letter[pt] OR editorial[pt] OR news[pt] OR comment[pt] OR case reports[pt])

Reimbursement

The following websites were searched for reimbursement policies:

Aetna US Healthcare
(http://www.aetnaushc.com/cpb/cpb_alpha.html)

Blue Cross/Blue Shield of Alabama
(http://www.bcbsal.org/providers/policies/final)

Blue Cross/Blue Shield of Massachusetts
(http://www.bcbsma.com/common/en_US/hresource/medcat.jsp)

Blue Cross/Blue Shield of Wisconsin
(http://www2.bluecrosswisconsin.com/provider/medpolicy/policies/SURG/severe_obesity.html)

Cigna
(http://www.cigna.com/health/provider/medical/procedural/coverage_positions/medical/index.html)

HealthPartners
(www.healthpartners.com/policies/)

Humana
(http://apps.humana.com/tad/tad_new/returnContent.asp?mime=application/pdf&id=5306&issue=132)

Medica
(http://provider.medica.com/router/default.pdf?doc=/C10/PolicyUtilization/Document%20Library/IIISUR30.pdf)

Regence Blue Cross/Blue Shield
(http://www.regence.com/trgmedpol/contents/)

Wellmark Blue Cross/Blue Shield
(http://www.wellmark.com/e%5Fbusiness/provider/medical%5Fpolicies/policies/)

We also searched the CMS website (http://www.cms.gov)

We also used the Google and Vivisimo internet search engines to locate reimbursement information, using a combination of topic-specific keywords and the following search terms: (reimburs* OR coverage OR "medical policy").

Hand Searches of Journal and Nonjournal Literature

Journals and supplements maintained in ECRI's collections were routinely reviewed. Nonjournal publications and conference proceedings from professional organizations, private agencies, and government agencies were also screened. Other mechanisms used to retrieve additional relevant information included review of bibliographies/reference lists from peer-reviewed and gray literature. (Gray literature consists of reports, studies, articles, and monographs produced by federal and local government agencies, private organizations, educational facilities, consulting firms, and corporations. These documents do not appear in the peer-reviewed journal literature.)

Appendix B. Excluded Studies

Table 17. Excluded Studies

Study	Reason for exclusion
Anderson et al. (1980)(122)	Patients did not receive a bariatric surgical procedure of interest
Benotti et al. (2006)(123)	Not a pediatric population
Breaux et al. (1995)(124)	39% of surgical procedures were VBG or BPD, and the remaining 61% were RYGB, but authors did not report separate data for RYGB patients
Haby et al. (2006)(125)	Not a primary research study
Inge et al. (2004)(126)	Abstract only
Metzelder et al. (2006)(127)	Not bariatric surgery
Organ et al. (1984)(128)	Patients did not receive a bariatric surgical procedure of interest
Randolph et al. (1974)(129)	Patients did not receive a bariatric surgical procedure of interest
Roehrig et al. (2007)(130)	Patients must have gotten pregnant after surgery; pregnancy was not an outcome of interest
Silber (1986)(131)	Patients did not receive a bariatric surgical procedure of interest
Soper et al. (1975)(132)	Patients did not receive a bariatric surgical procedure of interest
Towbin et al. (2004)(133)	Only examined one complication; no indication of the frequency of this complication in the population
Tsai et al. (2007)(38)	Study did not report the number of patients who received different bariatric procedures, and also did not report data separately for different procedures.
Vishne et al. (2004)(134)	Not a pediatric population

Appendix C. Quality of Literature and Evidence Strength

Study Quality Assessment

The prior unsuccessful attempts at non-surgical weight loss in patients who choose to undergo bariatric surgery mean that it is a reasonable assumption that patients would not have lost weight without surgery. Therefore, we did not require that studies enroll a control group of patients who received non-surgical treatment.

To rate the quality of case series of bariatric surgery, we considered six criteria: 1) whether the study was prospective; 2) whether the study had enrolled consecutive patients; 3) whether the outcome assessment was performed by an independent party; 4) whether the study was not funded by a financially interested party; 5) whether the outcome was objective; and 6) whether the data for the outcome contained at least 85% of the pertinent enrolled patients. Each item was coded as Yes (indicating no potential for bias on that criterion), or No (indicating a potential for bias on that criterion), or NR (indicating that the publication did not provide enough information to determine the potential for bias on that criterion. Items 1-4 were completed once per study, item 5 was completed once per outcome of each study (because the objectivity of the outcome can vary by outcome), and item 6 was completed once per outcome/timepoint of each study (because completion rates can vary by outcome or by timepoint).

We then scored the quality for each outcome/timepoint by coding +1 for each Yes, -1 for each No, and 0 for each NR. Items 4 and 5 were coded as +0.5 for Yes, -0.5 for No, and 0 for NR, because these items both address the general issue of potential investigator bias. The six numbers were then added, and then we added five to the total so that the best possible study would score 10 (i.e., all Yes's), and the worst possible study would score 0 (i.e., all No's). If the resulting combined score was less than 4, we considered the study very low quality and excluded that data from further consideration (but the study may have been included for other outcomes or other timepoints). If the score was at least 4 but 6 or lower, we categorized the quality as low; if it was more than 6 but 8 or lower, we categorized quality as moderate; if it was above 8, we categorized the quality as high. We then used these quality categories to proceed through the Strength of Evidence system, described next.

Strength of Evidence System

In evaluating the stability and strength of a body of literature, we used the ECRI Institute strength-of-evidence system.(60) This system employs decision points that collectively yield an overall category that describes the strength of the evidence for a quantitative estimate and qualitative conclusion as strong, moderate, weak, or inconclusive. The qualitative conclusion addresses the question, "Does it work?" The quantitative estimate addresses the question, "How well does it work?" This distinction allows an evidence base to be considered weak in terms of the quantitative estimate of effect (e.g., if estimates vary widely among studies) but strong or moderate with respect to the qualitative conclusion (e.g., if all studies nevertheless demonstrate the same direction of effect).

The system addresses five general aspects of the evidence: quality, quantity, consistency, robustness, and magnitude of effect. Quality refers to the degree of potential bias in the design or conduct of studies. Quantity refers to the number of studies and the number of enrolled patients. Consistency addresses the degree of agreement among the results of available studies. Robustness involves the constancy of conclusions in the face of minor hypothetical alterations in the data. Magnitude of effect concerns the quantitative amount of benefit (or harm) that patients experience after treatment, and it is only considered in the qualitative section of the system.

The output of the system is two ratings: a stability rating (which pertains to a quantitative conclusion) and a strength rating (which pertains to a qualitative conclusion). Interpretations of the two types of ratings appear in the table below.

Table 18. Interpretation of Different Categories of Strength of Evidence Supporting Conclusion

Strength of Evidence	Interpretation
Qualitative Conclusion (Direction of Effect)	
Strong Evidence	Evidence supporting the qualitative conclusion is convincing. It is highly unlikely that new evidence will lead to a change in this conclusion.
Moderate Evidence	Evidence supporting the qualitative conclusion is somewhat convincing. There is a small chance that new evidence will overturn or strengthen our conclusion. ECRI recommends regular monitoring of the relevant literature at this time.
Weak Evidence	Although some evidence exists to support the qualitative conclusion, this evidence is tentative and perishable. There is a reasonable chance that new evidence will overturn or strengthen our conclusions. ECRI recommends frequent monitoring of the relevant literature at this time.
Inconclusive	Although some evidence exists, this evidence is not of sufficient strength to warrant drawing an evidence-based conclusion from it. ECRI recommends frequent monitoring of the relevant literature at this time.
Quantitative Conclusion (Magnitude of Effect)	
High Stability	The estimate of diagnostic test performance included in the conclusion is stable. It is highly unlikely that the magnitude of this estimate will change substantially as a result of the publication of new evidence.
Moderate Stability	The estimate of diagnostic test performance included in the conclusion is somewhat stable. There is a small chance that the magnitude of this estimate will change substantially as a result of the publication of new evidence. ECRI recommends regular monitoring of the relevant literature at this time.
Low Stability	The estimate of diagnostic test performance included in the conclusion is likely to be unstable. There is a reasonable chance that the magnitude of this estimate will change substantially as a result of the publication of new evidence. ECRI recommends frequent monitoring of the relevant literature at this time.
Unstable	Estimates of the diagnostic test performance are too unstable to allow a quantitative conclusion to be drawn at this time. ECRI recommends frequent monitoring of the relevant literature.

To arrive at these strength and stability ratings, we applied the ECRI Strength and Stability of Evidence System. The methods we used to resolve these decision points appear below.

Decision Point 1: Determining Quality of Individual Studies

For this decision point, we excluded any study that was considered very low quality (see previous section). The remaining studies constituted the evidence base for the rest of the system.

Decision Point 2: Determine Quality of Evidence Base

We classified the overall quality of the evidence base by taking the median quality score of the individual studies. We used the median because it is the appropriate measure of central tendency to represent the "typical" quality category, and is less sensitive to outliers than the mean. Depending on the overall quality, we then followed the high, moderate, or low quality branch of the system. If the median fell between two categories, we proceeded with the lower quality category. Because the quality was determined separately for each outcome, a study that scored as moderate quality for one outcome might score as low quality for another outcome.

Decision Point 3: Is Quantitative Analysis Possible?

The answer to Decision Point 3 depends upon the adequacy of reporting in available studies as well as the number of available studies. In order to conduct a quantitative analysis of a given outcome, the data for that outcome must be reported in at least three studies in a manner that allows the data to be pooled in a meta-analysis. For pre-post designs, this requires that the study either report the correlation between pre- and post values, or the study report sufficient information for the reader to calculate the correlation (e.g., if the study reports individual patient data). If so, we proceeded to Decision Point 4. If less than three studies are available, no quantitative analysis is usually possible regardless of reporting. Another situation that does not allow a quantitative analysis is when three or more studies are available, but fewer than 75% of them permit determination of the effect size and its dispersion, either by direct reporting from the trial or calculations based on reported information. If no quantitative analysis was possible, then we moved directly to Decision Point 8 to determine whether the data permitted a qualitative conclusion.

Decision Point 4: Are Data Quantitatively Consistent (Homogeneous)?

This decision point was used only if the answer to Decision Point 3 was Yes. Consistency refers to the extent to which the results of studies in an evidence base agree with each other. The more consistent the evidence, the more precise a summary estimate of treatment effect derived from the evidence base. Quantitative consistency refers to consistency tested in a meta-analysis using Higgins and Thompson's I^2 statistic.(135) We considered the evidence base to be quantitatively consistent when I^2 <50%.(135)

If the evidence base was quantitatively consistent (i.e., homogeneous), we combined the results to yield a meta-analytic summary statistic. We then tested the robustness of this summary estimate in Decision Point 5. If it was not homogeneous, then Decision Point 5 was not applicable, and we proceeded to Decision Point 6.

Decision Point 5: Are Findings Stable (Quantitatively Robust)?

To be considered ***quantitatively*** robust, the summary estimate must have met all six of the following conditions:

1) Sufficiently narrow confidence interval around the summary effect size. This is defined as an interval that is not bigger than twice the level of clinical significance (clinical significance is defined below in the section labeled "Informative").
2) After removal of one study at a time, the summary effect size never strays further than 1 unit of clinical significance away from the all-study effect size.
3) Cumulative robustness test by year, using the same criterion as for removal of one study at a time.
4) After the use of a before-after correlation at the lower bound of the 95% confidence for an imputed correlation, the summary effect size never strays further than 1 unit of clinical significance away from the original effect size.
5) After the use of a before-after correlation at the upper bound of the 95% confidence for an imputed correlation, the summary effect size never strays further than 1 unit of clinical significance away from the original effect size.
6) After the exclusion of studies with less than 75% of patients represented in the analysis, the summary effect size never strays further than 1 unit of clinical significance away from the original effect size.

If the summary estimate did not meet all six of these conditions, it was deemed not quantitatively robust.

Decision Points 6 and 7: Exploration of Heterogeneity

Decision Points 6 and 7 are relevant only when one has, during a quantitative analysis, found that the findings of the studies that comprise an evidence base are determined to be heterogeneous (see Decision Point 4).

Decision Point 6: Does Meta-regression Explain Heterogeneity?

If we observed heterogeneity, we next attempted (if there were at least 5 studies) to explain the heterogeneity using meta-regression. If there were fewer than 5 studies in this situation, we did not arrive at a quantitative estimate. A priori, we planned to use the following factors as predictor variables in meta-regression:

- Whether the study was prospective (Yes, No, or not reported)
- Whether the study enrolled consecutive patients in a time period
- The actual percentage of patients with reported data to the timepoint of interest
- The overall quality category (high, moderate, low)
- For weight data on longest followup, the length of followup.
- For LAGB, the proportion of patients who received LAP-BAND® (as opposed to SAGB).
- For RYGB, the length of the roux limb
- For VBG, the size of the gastric pouch

We decided that a meta-regression could be considered to have explained the heterogeneity if the covariate was statistically significant, and if the resulting I^2 was less than 50%.

Decision Point 7: Is Meta-regression Model Stable?

The purpose of Decision Point 7 is to test the stability of any quantitative findings that may emanate from meta-regression analysis. We used the same robustness tests as in Decision Point 5.

Decision Point 8: Are Qualitative Findings Robust?

To be considered ***qualitatively*** robust, the conclusion must have met all seven of the following conditions:

1) After removal of one study at a time, the qualitative conclusion remains the same.
2) Under a cumulative robustness test by year, the qualitative conclusion remains the same.
3) Under the assumption that patients would lose 0.55 BMI units at one year if they had not had surgery, the qualitative conclusion remains the same. This number is based on a randomized trial by Chanoine et al. (2005)(136), in which 539 adolescents (age 12-16, average baseline BMI 35) were randomized to either orlistat (N = 357) or placebo (N = 182) (all patients also received diet, exercise, and behavioral therapy). Among 232 adolescents who were in the orlistat group and completed one-year followup, the average BMI reduction was 0.55.
4) Under the assumption that patients would lose 1.7 BMI units at one year if they had not had surgery, the qualitative conclusion remains the same. This number is based on the one-year BMI loss in a non-surgical weight management group in Savoye et al. (2007).(51) This study randomized 209 participants aged 8-16 with an average baseline BMI of 35 to either weight management with structured meal plan (N = 35), weight management with better food choices (N = 105), or a control group (N = 69) (patients also received diet, exercise, and behavioral therapy). The structured meal plan arm was discontinued. Among the 75 patients who completed followup in the group receiving weight management with better food choices, the average number of BMI reduction at 1 year was 1.7.
5) After the use of a before-after correlation at the lower bound of the 95% confidence for an imputed correlation (i.e., 0.36), the qualitative conclusion remains the same.
6) After the use of a before-after correlation at the upper bound of the 95% confidence for an imputed correlation (i.e., 0.76), the qualitative conclusion remains the same.
7) After the exclusion of studies with less than 75% of patients represented in the analysis, the qualitative conclusion remains the same.

If the analysis did not meet all seven of these conditions, it was deemed not qualitatively robust.

Decision Point 9: Are Data Qualitatively Consistent?

This Decision Point is used only when the evidence base for an outcome consists of two studies. For this report, the two studies were considered qualitatively consistent if they reached the same statistical conclusion.

Decision Point 10: Is Magnitude of Treatment Effect Extremely Large?

When considering the strength of evidence supporting a qualitative conclusion based on only one or two studies, magnitude of effect becomes very important. The more positive the findings, the more confident one can be that new evidence will not overturn a general conclusion that the treatment is beneficial.

The system divides the magnitude of effect into two categories: large and not large. Determining the threshold above which the observed magnitude of effect can be considered to be "extremely large" cannot usually be determined *a priori*. The lead analyst presented the findings to other methodologists who independently determined whether an effect was "large" (blinded to each other's judgments). Disagreements were resolved in committee using a modified Delphi technique.

Other parts of the system

Some parts of the system are not formally called "Decision Points", and yet some decisions must be made in order to apply them. These are described next.

Informative?

When there are only a small number of patients in an evidence base, statistical tests generally do not perform well. Under such circumstances, statistics cannot determine whether a true difference exists between treatments. This means that no clear conclusion can be drawn. For this decision point, we determined whether the precision of an evidence base was sufficient to permit a conclusion. Statistically significant results are potentially conclusive because they mean that a treatment effect may exist. Statistically non-significant results are also potentially conclusive, but only if they exclude the possibility that a clinically significant treatment effect exists.

When considering the summary effect size from a meta-analysis (or the effect size from a single study), there are three ways in which the effect can be "informative":

1) The summary effect size is statistically significantly different from 0. This would be indicated whenever the confidence interval does not overlap 0.
2) The summary effect size is not statistically significantly different from 0, but the confidence intervals are narrow enough to exclude the possibility that a *clinically significant difference* exists (see below for definitions of clinical significance).
3) The summary effect size is not statistically significantly different from 0, but the confidence intervals are narrow enough to exclude the possibility that a *substantial difference* exists. This possibility is included to address situations when even a very small effect can be considered "clinically significant" (e.g., a difference in mortality rates), but the effect may not be "substantial".

For weight loss, a clinical significant amount was defined as 7% of body weight, because patients who lose this amount of weight have been shown by other researchers to yield substantial reduction in medical comorbidities of obesity.(62,63) This is more stringent than the definition of clinically significant weight loss of 5% body weight that is used by the U.S. FDA and by the U.K. NICE.(64) In the included LAGB studies, 7% of body weight in the enrolled patients corresponds to 3.5 BMI units. In the included RYGB studies, 7% of body weight in the enrolled patients corresponds to 4 BMI units. In the included VBG studies, 7% of body weight in the enrolled patients corresponds to 3.9 BMI units.

Sufficient Data for Meta-Regression?

We required a minimum of five studies before attempting meta-regression.

Mega-Trial?

We defined a mega-trial as any trial that reported data on 1,000 or more patients.

Meta-Analysis Possible?

For continuous outcomes, meta-analysis is possible when the pertinent studies either report effect sizes and standard errors, or there is sufficient reported information for both effect sizes and standard errors to be calculated. For dichotomous outcomes, meta-analysis is possible when the pertinent studies report the total number of patients in each group as well as the number of events in each group.

Figure 13. Entry into System

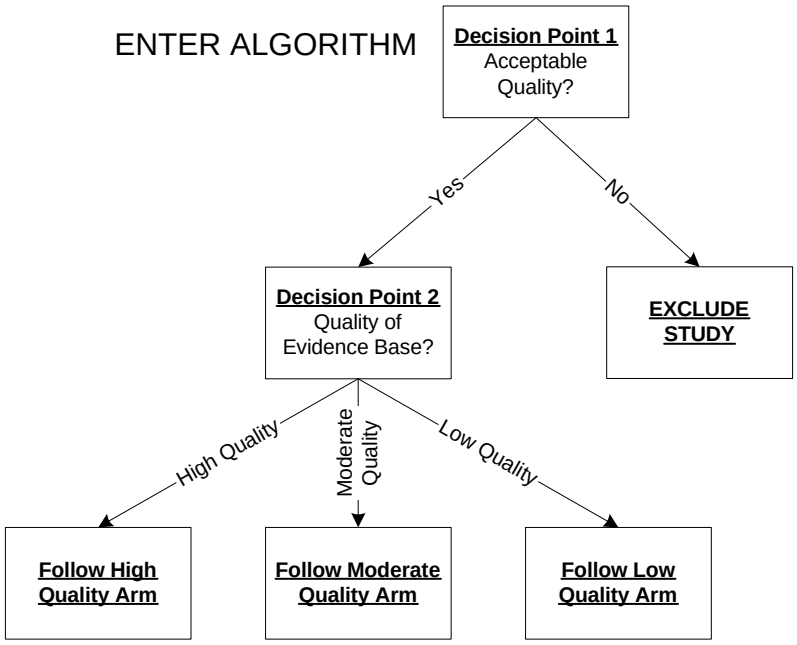


Figure 14. High-Quality Arm

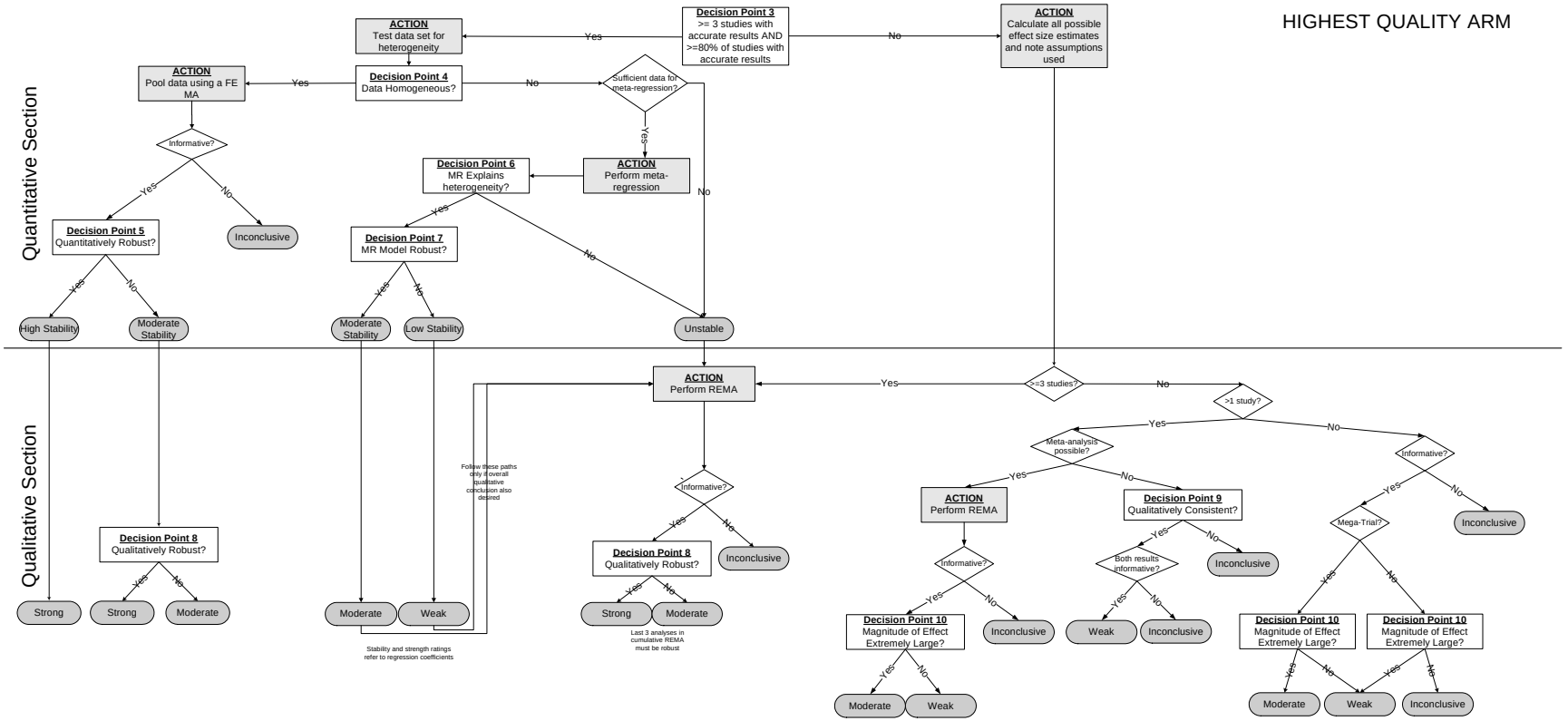


Figure 15. Moderate-Quality Arm

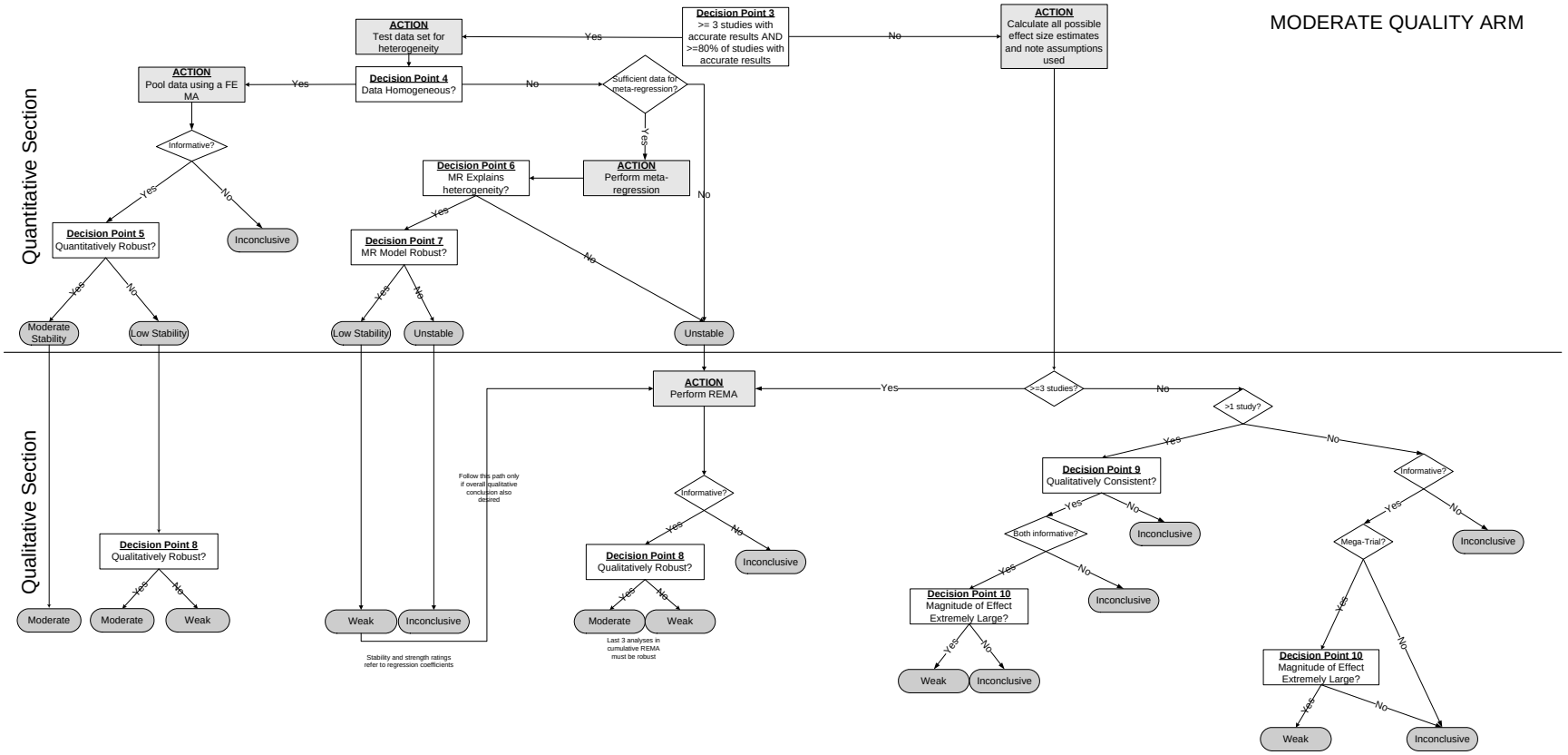
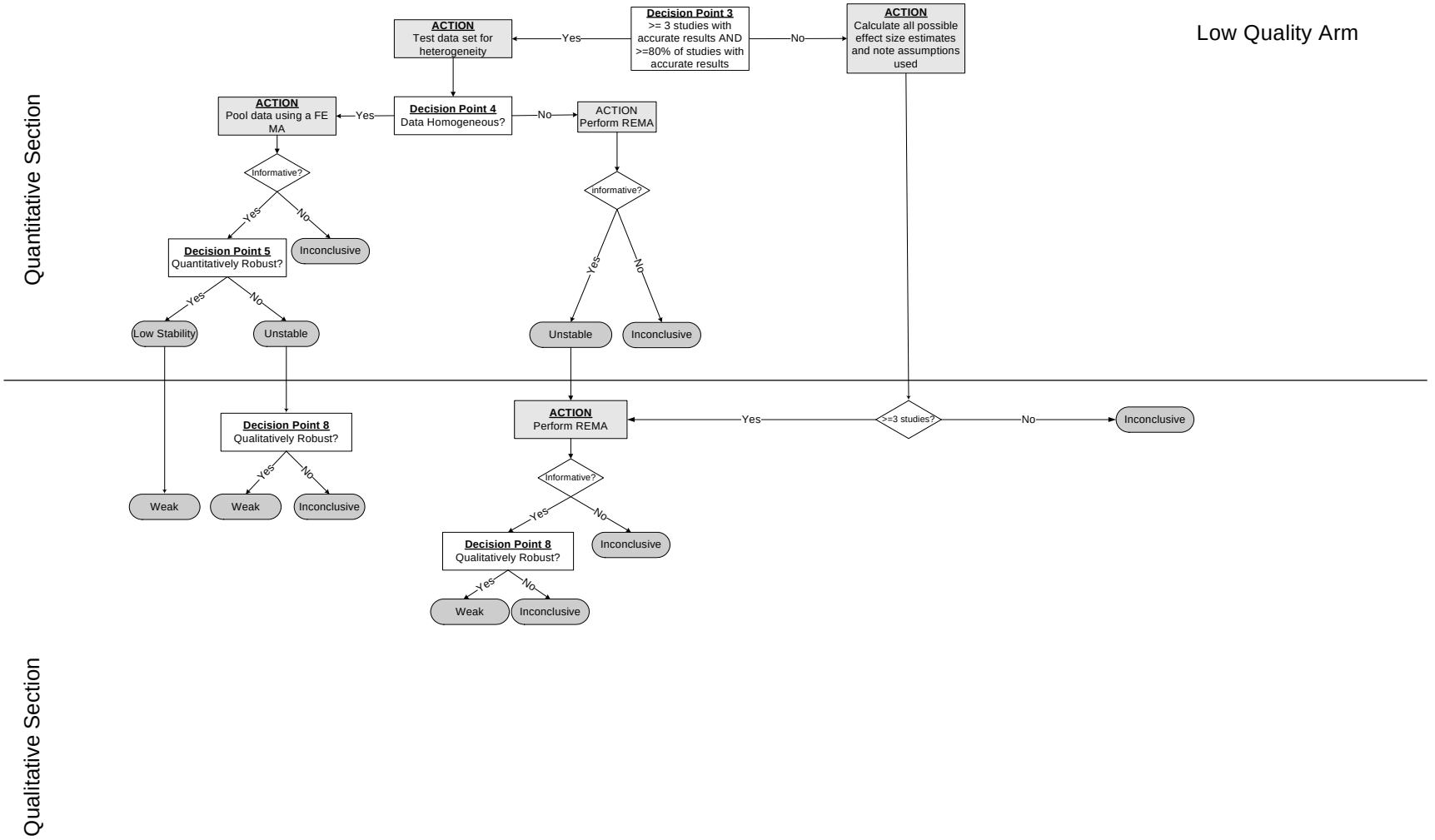


Figure 16. Low-Quality Arm



Appendix D. ICD-9-CM Codes

The following is a list of the ICD-9-CM codes that we used to select bariatric surgery cases and exclude nonbariatric surgery cases.

Diagnosis Codes:

278.0 Overweight and obesity
Excludes:
adiposogenital dystrophy (253.8)
obesity of endocrine origin NOS (259.9)
Use additional code to identify Body Mass Index (BMI) if known (V85.0-V85.54)
278.00 Obesity, unspecified
Obesity NOS
278.01 Morbid obesity
Severe obesity
278.1 Localized adiposity
Fat pad
278.8 Other hyperalimentation
1500 to 1599 Stomach and intestinal cancers
2301 to 2309 In-situ cancers

Procedure Codes for Bariatric Surgeries:

44.31 High gastric bypass
Printen and Mason gastric bypass
44.38 Laparoscopic gastroenterostomy
Bypass: gastroduodenostomy
gastroenterostomy
gastrogastrostomy
Laparoscopic gastrojejunostomy without gastrectomy NEC
Excludes:
gastroenterostomy, open approach (44.39)
44.39 Other gastroenterostomy
Bypass:
gastroduodenostomy
gastroenterostomy
gastrogastrostomy
Gastrojejunostomy without gastrectomy NOS
44.68 Laparoscopic gastroplasty
Banding
Silastic vertical banding
Vertical banded gastroplasty (VBG)
Code also any synchronous laparoscopic gastroenterostomy (44.38)
Excludes:
insertion, laparoscopic adjustable gastric band (restrictive procedure) (44.95)
other repair of stomach, open approach (44.61-44.65, 44.69)
44.69 Other
Inversion of gastric diverticulum
Repair of stomach NOS
44.95 Laparoscopic gastric restrictive procedure
Adjustable gastric band and port insertion
Excludes:
laparoscopic gastroplasty (44.68)

other repair of stomach (44.69)

44.96 Laparoscopic revision of gastric restrictive procedure

Revision or replacement of:
adjustable gastric band
subcutaneous gastric port device

44.97 Laparoscopic removal of gastric restrictive device(s)

Removal of either or both:
adjustable gastric band
subcutaneous port device
Excludes:
nonoperative removal of gastric restrictive device(s) (97.86)
open removal of gastric restrictive device(s) (44.99)

44.98 (Laparoscopic) adjustment of size of adjustable gastric restrictive device

Infusion of saline for device tightening
Withdrawal of saline for device loosening
Code also any:
abdominal ultrasound (88.76)
abdominal wall fluoroscopy (88.09)
barium swallow (87.61)

Codes for Concurrent Laparoscopic Procedures:

54.21 Laparoscopy

Peritoneoscopy
Excludes:
laparoscopic cholecystectomy (51.23)
that incidental to destruction of fallopian tubes (66.21-66.29)

47.01 Laparoscopic appendectomy
47.11 Laparoscopic incidental appendectomy
51.23 Laparoscopic cholecystectomy

That by laser

54.51 Laparoscopic lysis of peritoneal adhesions
65.01 Laparoscopic oophorotomy
65.25 Other laparoscopic local excision or destruction of ovary
65.31 Laparoscopic unilateral oophorectomy
65.39 Other unilateral oophorectomy

Excludes:
that by laparoscope (65.31)

65.41 Laparoscopic unilateral salpingo-oophorectomy
65.63 Laparoscopic removal of both ovaries and tubes at same operative episode
65.64 Laparoscopic removal of remaining ovary and tube
65.81 Laparoscopic lysis of adhesions of ovary and fallopian tube
68.51 Laparoscopically assisted vaginal hysterectomy (LAVH)

Appendix E. Evidence Tables

Table 19. General Aspects of Included Studies

Study	Location	Prior non-surgical attempts at weight loss	Dates of surgery	Procedural details
Studies of Laparoscopic Adjustable Gastric Banding (LAGB)				
Al-Qahtani (2007)(70)	King Khalid University Hospital, Saudi Arabia	Patients had to meet National Institutes of Health (NIH) criteria for surgery. All patients experienced "failure to obtain weight loss for at least 6 months with conservative medical treatment".	1/2003 – 12/2005	Lap-Band®, with band size 10 or 11cm, placed using pars flaccida technique..
Nadler (2007)(71)	New York University School of Medicine, USA	"All patients met National Institutes of Health (NIH) consensus development conference criteria for bariatric surgery" (NIH criteria include multiple prior attempts at weight loss using non-surgical methods)	9/2001 – 2/2006	Lap-Band®, placed using pars flaccida technique at 1-2 cm below the gastroesophageal junction. Band sizes were 9.75cm, 10cm, or 11cm.
Yitzhak (2006)(72)	Ben-Gurion University of the Negev, Israel	"All the patients fulfilled the NIH criteria for bariatric surgery, and had failed conservative means of weight reduction before turning to surgery"	2000 – 2006	SAGB, before 7/2002 placement was using "pars flaccida technique but through a lower tunnel which passed freely in the lesser sac". After 7/2002, "a higher pars flaccida technique with extraperitoneal dissection was used."
Silberhumer (2006)(73,74)	Medical University of Vienna, Austria	"All referred patients failed to reduce and maintain weight loss by resorting to several methods of therapeutic procedures, such as diet camps, behavioral and drug therapy. After some time, all patients gained weight again and showed severe psychological problems and social withdrawal".	1998 - 2004	Lap-Band® in 13/50 patients, and SAGB in 37/50 patients.
Angrisani (2005)(75)	Citta della Scienza, via Coroglio, Italy	One of the inclusion criteria was "failure to obtain weight loss after ≥1 year of conservative medical treatment".	1/1996 – 12/2003	Lap-Band® placement via perigastric access in 55 patients and pars flaccida in 3 patients.
Fielding (2005)(76-78)	Wesley Hospital, Australia	Used NIH criteria for bariatric surgery.	1998 – 2003	Lap-Band®. "Since 1999 we have placed the band posteriorly behind the esophagus and not the stomach, to create a smnall anterior pouch of stomach in an attempt to prevent slippage of the band into the lesser sac"
Horgan (2005)(79)	University of Illinois at Chicago, USA	All had failed medically supervised attempts at weight loss for at least 6 months.	2001 - 2003	Lap-Band®, placed using pars flaccida technique.

Study	Location	Prior non-surgical attempts at weight loss	Dates of surgery	Procedural details
Abu-Abeid (2003)(80)	Tel-Aviv University, Israel	"Before referral to our center, the adolescents had been under the care of a dietician for at least 1 year and had failed to reduce weight despite a low calorie diet of about 800 Kcal/d."	Not reported	Lap-Band® placed 2cm below the gastroesophageal junction
Studies of Roux-en-Y Gastric Bypass (RYGB)				
Collins (2007)(81,82)	University of Pittsburgh Medical Center, USA	"All patients met, at a minimum, the established criteria set by the National Institutes of Health (NIH) for candidacy for bariatric surgery"."All have attempted to lose weight by conventional means".	1999 - 6/2005	Laparoscopic RYGB via Schauer-Okramuddin technique.
Lawson (2006)(69,83-85)	Cincinnati Children's Hospital Medical Center, USA	"Failure of at least 6 months of medically supervised weight loss attempts"	5/2001 – 10/2003	Laparoscopic RYGB in 34/39, 3 open RYGB, and 2 converted to open. Roux limb lengths ranged from 75 cm (for BMI <50) to 150 cm (for BMI ≥50). Gastric pouch estimated 30-45 mL.
Barnett (2005)[a](68)	University of Minnesota School of Medicine, USA	"All patients were considered eligible for bariatric surgery according to the National Institutes of Health adult criteria"	1978 – 2001	Open RYGB
Sugerman (2003)(35)	Virginia Commonwealth University, USA	Used NIH criteria for bariatric surgery.	1981 – 1/2002	30 RYGB, 2 VBG, 1 HBG.
Strauss (2001)(36)	Robert Wood Johnson Medical School, USA	"All had demonstrated serious attempts at weight loss in diet and behavior modification programs"	4/1985 – 5/1999	Open RYGB, with gastric pouch volumes estimated at 20 ±5 mL
Rand (1994)(37)	North Florida Regional Medical Center, USA	Not reported	1/1979 – 12/1990	Open RYGB in 30 patients and open VBG in 4 patients. For RYGB, pouch size range from less than 50 mL to 70 mL.
Studies of Vertical Banded Gastroplasty (VBG)				
Barnett (2005)[a](68)	University of Minnesota School of Medicine, USA	"All patients were considered eligible for bariatric surgery according to the National Institutes of Health adult criteria"	1978 – 2001	Open VBG
Greenstein (1995)(86)	Mount Sinai School of Medicine CUNY, USA	Not reported	3/1982 – 6/1994	Open Mason VBG
Mason (1995)(87)	University of Iowa College of Medicine, USA	Not reported	1980 – 1994	Open Mason VBG, pouch size average 17.3 mL, range 9-40 mL. The band was a 7 x 1.5 cm Marlex mesh

Study	Location	Prior non-surgical attempts at weight loss	Dates of surgery	Procedural details
Studies of Banded bypass				
Capella (2003)(88)	Hackensack University Medical Center, USA	All patients had attempted several weight-reducing regimes that included medically supervised diets, exercise, behavior modification, commercial diets, psychological interventions, and pharmacological agents.	5/1990 – 1/2001	Banded bypass

[a] The study by Barnett reported data on both RYGB and VBG, thus it is listed twice.

SAGB Swedish Adjustable Gastric Band.

Table 20. Characteristics of Patients in Included Studies

Study	N	Mean age in years (range)	% female	Mean BMI in kg/m^2 (SD and range)	Race	Number of patients with specific medical comorbities before surgery[d]						
						Diabetes	Hypertension	Dyslipidemia	Sleep apnea	Asthma	GERD	Musculoskeletal
Studies of Laparoscopic Adjustable Gastric Banding (LAGB)												
Al-Qahtani (2007)(70)	51	16.8 (9-19)	53% (27/51)	49.9 (Range 38-63)	NR	7	6	NR	10	NR	NR	7
Nadler (2007)(71)	53	15.9 (13 - 17)	77% (41/53)	47.6 (SD: 6.7; Range NR)	81% white, 13% Hispanic, 6% black	NR	NR	NR	NR	NR	NR	NR
Yitzhak (2006)(72)	60	16 (9 - 18)	70% (42/60)	43 (SD: NR; Range 35 to 61)	NR	2	3	NR	10	3	NR	NR
Silberhumer (2006)(73,74)	50	17.1 (9 - 19)	62% (31/50)	45.2 (SD: 7.6; Range 32.5 to 76.6)	NR	5	12	4	NR	3	1	8
Angrisani (2005)(75)	58	17.96 (15 - 19)	81% (47/58)	46.1 (SD: 6.31; Range 34.9 to 69.25)	NR	8	8	6	10	NR	NR	12
Fielding (2005)(76-78)	41	15.6 (12 - 19)	73% (30/41)	42.4 (SD: 8.2; Range 31 to 71)	NR	2	2	NR	1	NR	NR	1
Horgan (2005)(79)	4	17.8[a] (17-19)	50% (2/4)	50.5[a] (SD: 8.8[a]; Range 40 to 61)	NR	NR	NR	NR	NR	NR	NR	2
Abu-Abeid (2003)(80)	11	15.7 (11 - 17)	73% (8/11)	46.6 (SD: 5.1[a]; Range 38 to 56.6)	NR	NR	NR	3	NR	NR	NR	NR

Study	N	Mean age in years (range)	% female	Mean BMI in kg/m² (SD and range)	Race	Number of patients with specific medical comorbities before surgery[d]						
						Diabetes	Hypertension	Dyslipidemia	Sleep apnea	Asthma	GERD	Musculoskeletal
Studies of Roux-en-Y Gastric Bypass (RYGB)												
Collins (2007)(81,82)	11	16.5 (15-18)	64% (7/11)	50.5 (SD: 2; Range 42 to 66)	NR	6	6	7	2	4	1	8
Lawson (2006)(69,83-85)	38	17.57 (13 - 21)	66% (23/35)[f]	56.5 (SD: 10.1; Range 41.9 to 95.5)	90% white	NR	NR	NR	19[e]	NR	NR	NR
Barnett (2005)[c](68)	14	15.7 (13 - 17)	57% (8/14)	51 (SD: 9; Range NR)	NR	1	5	NR	2	3	NR	3
Sugerman (2003)(35)	33	16 (12.4 - 17.9)	58% (19/33)	52 (SD: 11; Range 38 to 91)	81% white, 19% black	2[b]	11[b]	NR	6	NR	5	11
Strauss (2001)(36)	10	16.2[a] (15 - 17)	70% (7/10)	53.6[a] (SD: 10.2[a]; Range 41.4 to 70.5)	NR	NR	3	NR	2	NR	NR	1
Rand (1994)(37)	34	17 (11 - 19)	79% (27/34)	47 (SD: 7; Range 38 to 66)	NR	NR	NR	NR	NR	NR	NR	NR
Studies of Vertical Banded Gastroplasty (VBG)												
Barnett (2005)[c](68)	14	15.7 (13 - 17)	57% (8/14)	60 (SD: 20; Range NR)	NR	1	5	NR	2	3	NR	3
Greenstein (1995)(86)	18	17 (13 - 21)	79% (11/14)	47.8[a] (SD: 7.2[a]; Range 41 to 60)	NR	NR	2	NR	1	NR	NR	NR
Mason (1995)(87)	47	18.1 (14 - 20)	68% (32/47)	48.4 (SD: 6.92; Range NR)	NR	NR	NR	NR	NR	NR	NR	NR

Study	N	Mean age in years (range)	% female	Mean BMI in kg/m² (SD and range)	Race	Number of patients with specific medical comorbities before surgery[d]						
						Diabetes	Hypertension	Dyslipidemia	Sleep apnea	Asthma	GERD	Musculoskeletal
Studies of banded bypass												
Capella (2003)(88)	19	15.6[a] (13 - 17)	63% (12/19)	49 (SD: 5.7[a]; Range 38 to 67)	NR	2	3	3	3	NR	NR	NR

GERD Gastroesophageal reflux disease.
NR Information not reported.

[a] Calculated by ECRI based on reported information

[b] Sugerman reported inconsistent numbers for the number of patients who had diabetes and/or hypertension at baseline. We used the numbers reported in the results section because they served the basis for comorbidity outcomes.

[c] The study by Barnett reported data on both RYGB and VBG, thus it is listed twice.

[d] Additional comorbidities before surgery included:
Al-Qahtanii (2007): Metabolic syndrome 15
Silberhumer (2006): Cholecystolithiasis 3;
Angrisani (2005): Anxiety/depression 1, amenorrhea 4
Horgan (2005): Heartburn without GERD: 2
Abu-Abeid (2003): Cholecystolithiasis 1
Collins (2007): Insulin resistance 1, fatty liver/steatosis 5, hepatomagaly 1, depression 4, hypothyroidism 2, migraines 1, polycystic ovary syndrome 3, anemia 2, gynecomastia 1
Barnett (2005): Attention deficit disorder 5, depression 1, hypothyroidism 1
Sugerman (2003): Psuedotumor cerebri 2, polycystic ovary syndrome 1
Strauss (2001): Hypoventilation 1, dyspnea 1

[e] Sleep apnea reported by a secondary publication.(83)

[f] Sex distribution reported by a secondary publication.(83)

Table 21. Study Quality Assessments for Key Question 1

Study	All outcomes				BMI	Longest follow-up BMI	1-year BMI	2-year BMI	3-year BMI	4-year BMI	5-year BMI	Quality scores and quality categories
	Prospective?	Consecutive?	Outcome assessor independent?	Not funded by a financially interested party?	Outcome objectively measured?	≥85% completion?	≥85% completion?	≥85% completion?	≥85% completion?	≥85% completion?	≥85% completion?	
Studies of Laparoscopic Adjustable Gastric Banding (LAGB)												
Yitzhak (2006)(72)	No	Yes	No	NR	NR	Yes	NA	NA	NA	NA	NA	5.5 (Low)
Silberhumer (2006)(73,74)	NR	Yes	No	NR	Yes	Yes	NA	NA	NA	NA	NA	7.5 (Moderate)
Angrisani (2005)(75)	No	Yes	No	NR	Yes	No	Yes	NA	No	NA	NA	6.5 (Moderate) for 1-year BMI 4.5 (Low) for Longest follow-up BMI and 3-year BMI
Fielding (2005)(76-78)	No	Yes	No	NR	Yes	Yes	Yes	No	NA	NA	NA	6.5 (Moderate) for Longest follow-up BMI and 1-year BMI 4.5 (Low) for 2-year BMI
Abu-Abeid (2003)(80)	No	NR	No	NR	Yes	Yes	Yes	No	NA	NA	NA	5.5 (Low) for Longest follow-up BMI and 1-year BMI 3.5 (Very Low) for 2-year BMI
Studies of Roux-en-Y Gastric Bypass (RYGB)												
Collins (2007)(81,82)	No	Yes	No	NR	Yes	No	NA	NA	NA	NA	NA	4.5 (Low)
Lawson (2006)(69,83-85)	No	Yes	No	No	Yes	No	No	NA	NA	NA	NA	4 (Low)

Study	All outcomes				BMI	Longest follow-up BMI	1-year BMI	2-year BMI	3-year BMI	4-year BMI	5-year BMI	Quality scores and quality categories
	Prospective?	Consecutive?	Outcome assessor independent?	Not funded by a financially interested party?	Outcome objectively measured?	≥85% completion?	≥85% completion?	≥85% completion?	≥85% completion?	≥85% completion?	≥85% completion?	
Sugerman (2003)(35)	No	Yes	No	NR	Yes	No	Yes	NA	NA	NA	No	6.5 (Moderate) for 1-year BMI 4.5 (Low) for Longest follow-up BMI and 5-year BMI
Strauss (2001)(36)	No	Yes	No	NR	Yes	Yes	Yes	No	No	No	NA	6.5 (Moderate) for Longest follow-up BMI and 1-year BMI 4.5 (Low) for 2-4 year BMI
Rand (1994)(37)	No	No	No	NR	NR	Yes	NA	NA	NA	NA	NA	3.5 (Very Low)
Studies of Vertical Banded Gastroplasty (VBG)												
Greenstein (1995)(86)	No	No	No	NR	No	Yes	NA	NA	NA	NA	NA	2.5 (Very Low)
Mason (1995)(87)	No	No	No	NR	NA	No	NA	NA	NA	NA	No	1.5 (Very Low)
Studies of banded bypass												
Capella (2003)(88)	No	Yes	No	NR	NR	No	NA	NA	No	No	NA	3.5 (Very Low)

Note: The studies not listed in this table (Al-Qahtani, Nadler, Horgan, Barnett) did not meet inclusion criteria for Key Question 1.

NA Not applicable because either the study did not report the pertinent data, or the reported data did not meet inclusion criteria.
NR Not reported.

Table 22. Study Quality Assessments for Key Questions 2, 3, and 5

Study	All outcomes				Comorbidities		Quality of life		Complications		Patient characteristics to predict outcomes		Quality scores and quality categories
	Prospective?	Consecutive?	Outcome assessor independent?	Not funded by a financially interested party?	Outcome objectively measured?	≥85% completion?	Outcome objectively measured?	≥85% completion?	Outcome objectively measured?	≥85% completion?	Outcome objectively measured?	≥85% completion?	
Studies of Laparoscopic Adjustable Gastric Banding (LAGB)													
Al-Qahtani (2007)(70)	No	Yes	No	NR	Yes	Yes	NA	NA	Yes	Yes	NA	NA	6.5 (Moderate)
Nadler (2007)(71)	Yes	Yes	No	NR	NA	NA	NA	NA	Yes	Yes	NA	NA	8.5 (High)(only included for complication data)
Yitzhak (2006)(72)	No	Yes	No	NR	NR	Yes	NA	NA	NR	Yes	NA	NA	5.5 (Low)
Silberhumer (2006)(73,74)	NR	Yes	No	NR	Yes	Yes	No	Yes	Yes	Yes	NA	NA	7.5 (Moderate) for comorbidities and complications; 5.5 (Low) for quality of life
Angrisani (2005)(75)	No	Yes	No	NR	NA	NA	NA	NA	Yes	Yes	NA	NA	6.5 (Moderate)
Fielding (2005)(76-78)	No	Yes	No	NR	NA	NA	NA	NA	Yes	Yes	Yes	Yes	6.5 (Moderate)
Horgan (2005)(79)	No	Yes	No	NR	NA	NA	NA	NA	Yes	Yes	NA	NA	6.5 (Moderate)
Abu-Abeid (2003)(80)	No	NR	No	NR	Yes	Yes	NA	NA	Yes	Yes	Yes	Yes	5.5 (Low)

Study	All outcomes				Comorbidities		Quality of life		Complications		Patient characteristics to predict outcomes		Quality scores and quality categories
	Prospective?	Consecutive?	Outcome assessor independent?	Not funded by a financially interested party?	Outcome objectively measured?	≥85% completion?	Outcome objectively measured?	≥85% completion?	Outcome objectively measured?	≥85% completion?	Outcome objectively measured?	≥85% completion?	
Studies of Roux-en-Y Gastric Bypass (RYGB)													
Collins (2007)(81,82)	No	Yes	No	NR	Yes	Yes	NA	NA	Yes	Yes	NA	NA	6.5 (Moderate)
Lawson (2006)(69,83-85)	No	Yes	No	No	Yes	No	NA	NA	Yes	Yes	NA	NA	6 (Low) for complications; 4 (Low) for comorbidities
Barnett (2005)[a](68)	No	Yes	No	NR	NA	NA	NA	NA	Yes	Yes	NA	NA	6.5 (Moderate)
Sugerman (2003)(35)	No	Yes	No	NR	Yes	Yes	NA	NA	Yes	Yes	NA	NA	6.5 (Moderate)
Strauss (2001)(36)	No	Yes	No	NR	Yes	Yes	NA	NA	Yes	Yes	Yes	Yes	6.5 (Moderate)
Rand (1994)(37)	No	No	No	NR	NA	NA	NA	NA	Yes	Yes	NA	NA	4.5 (Low)
Studies of Vertical Banded Gastroplasty (VBG)													
Barnett (2005)[a](68)	No	Yes	No	NR	NA	NA	NA	NA	Yes	Yes	NA	NA	6.5 (Moderate)
Greenstein (1995)(86)	No	No	No	NR	NA	NA	NA	NA	Yes	Yes	No	Yes	4.5 (Low) for complications; 2.5 (very low) for Key Question 5
Mason (1995)(87)	No	No	No	NR	NA	NA	NA	NA	Yes	Yes	NA	NA	4.5 (Low)

Study	All outcomes				Comorbidities		Quality of life		Complications		Patient characteristics to predict outcomes		Quality scores and quality categories
	Prospective?	Consecutive?	Outcome assessor independent?	Not funded by a financially interested party?	Outcome objectively measured?	≥85% completion?	Outcome objectively measured?	≥85% completion?	Outcome objectively measured?	≥85% completion?	Outcome objectively measured?	≥85% completion?	
Studies of banded bypass													
Capella (2003)(88)	No	Yes	No	NR	NA	NA	NA	NA	Yes	Yes	NR	No	6.5 (Moderate) for complications; 3.5 (very low) for Key Question 5

Note: The study by Barnett reported data on both RYGB and VBG, thus it is listed twice.

NA Not applicable because either the study did not report the pertinent data, or the reported data did not meet inclusion criteria.
NR Not reported.

Table 23. Data for Key Question 1 (BMI) for Longest Followup

Study	N at followup	Pre-surgical BMI in kg/m² (SD)	Length of followup (years)	Post-surgical BMI in kg/m² at longest followup (SD)	BMI units (kg/m²) lost (95% CI)
Studies of Laparoscopic Adjustable Gastric Banding (LAGB)					
Yitzhak (2006)(72)	60	43 (SD: 7.4)	3.3 (range 2.1 to 5.4)	30 (SD: 8.4) [a,b]	-13 (-14.8 to -11.2)
Silberhumer (2006)(73,74)	50	45.2 (SD: 7.6)	2.9 (range 0.3 to 7.2)	32.6 (SD: 6.8)[b]	-12.6 (-14.4 to -10.8)
Angrisani (2005)(75)	37	46.1 (SD: 6.31)	3	37.8 (SD: 11.27) [b]	-8.3 (-11.2 to -5.4)
Fielding (2005)[c](76-78)	17	43.1 (SD: 9.6)	1.7 (range 1 to 2)	30.2 (SD: 7.3)	-12.9 (-15.5 to -10.3)
Abu-Abeid (2003)(80)	11	46.5 (SD: 5.1)	1.9 (range 1 to 3)	32.5 (SD: 4)	-14 (-16.5 to -11.5)
Studies of Roux-en-Y Gastric Bypass (RYGB)					
Collins (2007)[d](81,82)	3	52 (SD: 12.1)	1.8 (range 1.7 to 1.8)	28 (SD: 8.7) [b]	-24 (-35.1 to -12.9)
Lawson (2006)(69,83-85)	30	56.5 (SD: 10.1)	1	35.8 (SD: 6.9) [b]	-20.7 (-23.6 to -17.8)
Sugerman (2003)(35)	20	52 (SD: 11)	5	33 (SD: 11) [b]	-19 (-22.9 to -15.1)
Strauss (2001)(36)	9	52 (SD: 9.4)	6.3 (1 to 13)	35.2 (SD: 12.4)	-16.8 (-24.3 to -9.3)
Rand (1994)(37)	34	47 (SD: 7)	6 (range 2 to 13)	32 (SD: 7) [b]	-15 (-17.1 to -12.9)

Study	N at followup	Pre-surgical BMI in kg/m² (SD)	Length of followup (years)	Post-surgical BMI in kg/m² at longest followup (SD)	BMI units (kg/m²) lost (95% CI)
Studies of Vertical Banded Gastroplasty (VBG)					
Greenstein (1995)(86)	14	47.8 (SD: 7.2)	5.6 (range 1 to 10)	32.5 (SD: 8.9)	-15.3 (-20.4 to -10.2)
Mason (1995)(87)	25	48.1 (SD: 7.01)	5	36.2 (SD: 5.99)[b]	-11.9 (-14.2 to -9.6)
Studies of banded bypass					
Capella (2003)(88)	15	46.7 (SD: 5.7)	5.5 (range 1 to 10)	28.9 (SD: 5.5)	-17.8 (-20.4 to -15.2)

[a] Imputed SD based on other studies
[b] Imputed pre-post correlation based on other studies
[c] Data for a secondary publication(77) were used because the weight data from the primary publication did not include at least 50% of patients with 1+ years followup
[d] Data for a secondary publication(82) were used because the weight data from the primary publication did not include at least 50% of patients with 1+ years followup

CI Confidence interval.

Note: Four studies reported BMI data that did not meet inclusion criteria, for the following reasons. The study by Al-Qahtani did not report the number of patients followed for 1+ years. The study by Nadler did not report 1+ year data for at least 50% of patients. The study by Hogan did not report 1+ year data for at least three patients. The study by Barnett did not report the length of followup of patients receiving specific procedures.

Table 24. Data for Key Question 1 (BMI) for Specific Timepoints

Study	N	Pre-surgical Mean BMI in kg/m² (SD)	Mean BMI after surgery									
			One year		Two years		Three years		Four years		Five years	
			N	Mean BMI in kg/m² (SD)	N	Mean BMI in kg/m² (SD)	N	Mean BMI in kg/m² (SD)	N	Mean BMI in kg/m² (SD)	N	Mean BMI in kg/m² (SD)
Studies of Laparoscopic Adjustable Gastric Banding (LAGB)												
Yitzhak (2006)(72)	60	43 (SD: 7.4)	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
Silberhumer (2006)(73,74)	50	45.2 (SD: 7.6)	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
Angrisani (2005)(75)	58	46.1 (SD: 6.31)	48	35.9 (SD: 8.4)	NR	NR	37	37.8 (SD: 11.27)	NR	NR	NR	NR
Fielding (2005)[a](76-78)	17	43.1 (SD: 9.6)	17	33 (SD: 7)	11	29.5 (SD: 4.8)	NR	NR	NR	NR	NR	NR
Abu-Abeid (2003)(80)	11	46.5 (SD: 5.1)	11	34 (SD: 3.4)	NI	NI	NR	NR	NR	NR	NR	NR
Studies of Roux-en-Y Gastric Bypass (RYGB)												
Collins (2007)[b](81,82)	3	52 (SD: 12.1)	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
Lawson (2006)(69,83-85)	30	56.5 (SD: 10.1)	30	35.8 (SD: 6.9)	NR	NR	NR	NR	NR	NR	NR	NR
Sugerman (2003)(35)	24	52 (SD: 11)	32	36 (SD: 10)	NR	NR	NR	NR	NR	NR	24	33 (SD: 11)
Strauss (2001)(36)	9	52 (SD: 9.4)	9	34 (SD: 7.7)	7	31.2 (SD: 7.8)	7	32.2 (SD: 9.8)	5	35.2 (SD: 14.7)	NR	NR
Rand (1994)(37)	34	47 (SD: 7)	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR

Study	N	Pre-surgical Mean BMI in kg/m² (SD)	Mean BMI after surgery									
			One year		Two years		Three years		Four years		Five years	
			N	Mean BMI in kg/m² (SD)	N	Mean BMI in kg/m² (SD)	N	Mean BMI in kg/m² (SD)	N	Mean BMI in kg/m² (SD)	N	Mean BMI in kg/m² (SD)
Studies of Vertical Banded Gastroplasty (VBG)												
Greenstein (1995)(86)	14	47.8 (SD: 7.2)	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
Mason (1995)(87)	25	48.1 (SD: 7.01)	NR	NR	NR	NR	NR	NR	NR	NR	25	36.2 (SD: 5.99)[b]
Studies of banded bypass												
Capella (2003)(88)	15	46.7 (SD: 5.7)	NR	NR	NR	NR	10	26.5 (SD: 2.4)	9	28.5 (SD: 6.5)	NR	NR

BMI Body mass index.
N Number of patients.
NI Data not included because of very low quality for this timepoint.
NR Not reported.
SD Standard deviation.

[a] Data for a secondary publication(77) were used because the weight data from the primary publication did not include at least 50% of patients with 1+ years followup

[b] Data for a secondary publication(82) were used because the weight data from the primary publication did not include at least 50% of patients with 1+ years followup

Note: Four studies reported BMI data that did not meet inclusion criteria, for the following reasons. The study by Al-Qahtani did not report the number of patients followed for 1+ years. The study by Nadler did not report 1+ year data for at least 50% of patients. The study by Hogan did not report 1+ year data for at least three patients. The study by Barnett did not report the length of followup of patients receiving specific procedures.

Table 25. Data for Key Question 2 on Resolution of Comorbidities

Study		Diabetes	Hypertension	Dyslipidemia[b]	Sleep Apnea	Asthma	GERD	Musculoskeletal[c]	Notes
Studies of Laparoscopic Adjustable Gastric Banding (LAGB)									
Al-Qahtani (2007)(70)	Baseline N	7	6	-	10	-	-	7	Metabolic syndrome 15
	Resolved %	100% (7/7)	100% (6/6)	-	See notes	-	-	See notes	The mean length of followup was 1.3 years (range 0.25 to 2.8). "Patients with diabetes and hypertension were cured of their disease, and other comorbidities improved or resolved with discontinuation of their therapy"(70)
Yitzhak (2006)(72)	Baseline N	2	3	-	10	3	-	-	-
	Resolved %	*	100% (3/3)	-	100% (10/10)	100% (3/3)	-	-	The mean length of followup was 3.3 years (range 2.1 to 5.4).
Silberhumer (2006)(73,74)	Baseline N	5	12	4	-	3	1	8	3 cholelithiasis
	Resolved %	80% (4/5)	50% (6/12)	100% (4/4)	-	100% (3/3)	*	38% (3/8)	The mean length of followup was 2.9 years (range 0.3 to 7.2). 100% resolution for cholelithiasis. Cases that improved but not resolved included one for diabetes, six for hypertension, and five for musculoskeletal problems.
Fielding (2005)(76-78)	Baseline N	2	2	-	1	-	-	1	-
	Resolved %	*	*	-	*	-	-	*	-
Horgan (2005)(79)	Baseline N	-	-	-	-	-	-	2	Also, two patients had heartburn without GERD.
	Resolved %	-	-	-	-	-	-	*	Heartburn outcomes not reported

Abu-Abeid (2003)(80)	Baseline N	-	-	3	-	-	-	-	1 Heart failure and pulmonary hypertension; 3 recurrent boil, 2 skin rashes; 7 stretch marks; 2 amenorrhea;1 cholelithiasis; offensive body odor and unpleasant appearance.
	Resolved %	-	-	67% (2/3)	-	-	-	-	The mean length of followup was 1.9 years (range 1 to 3). Heart failure, pulmonary hypertension, and amenorrhea resolved; others not reported
Studies of Roux-en-Y Gastric Bypass (RYGB)									
Collins (2007)(81,82)	Baseline N	6	6	7	2	4	1	8	4 depression/anxiety; 5 fatty liver/steatosis; 1 hepatomegaly; 2 hypothyroidism; 1 migraines; 3 polycystic ovarian syndrome; 2 iron deficiency anemia; 1 gynecomastia; and 1 insulin resistance
	Resolved %	50% (3/6)	50% (3/6)	NR	*	NR	NR	NR	The mean length of followup was 0.96 years (range 0.25 to 2.7). Cases that improved but not resolved included 3 for hypertension, two for diabetes, and two for sleep apnea cases. 2 out of 3 polycystic ovarian syndrome improved; other comorbidities not reported
Lawson (2006)(69,83-85)	Baseline N	-	-	-	19[a]	-	-	-	-
	Resolved %	See notes	-	See notes	100% (10/10)	-	-	-	For sleep apnea, the mean length of followup was 0.43 years (SD 0.1; range not reported). For diabetes and dyslipidemia, study did not report resolution or improvement rates, but instead reported overall statistically significant postoperative improvements in fasting blood glucose, and fasting insulin, triglycerides, total cholesterol, but no statistically significant changes in random glucose, HDL, or LDL.
Sugerman (2003)(35)	Baseline N	2	11	-	6	-	5	11	3 pseudotumor cerebri; 3 polycystic ovarian syndrome
	Resolved %	*	82% (9/11)	-	100% (6/6)	-	60% (3/5)	36% (4/11)	The length of followup for comorbidity data was one year for all patients. 100% resolution in the 3 cases of pseudotumor cerebri and also in the 3 cases of polycystic ovarian syndrome

Strauss (2001)(36)	Baseline N	-	3	-	2	-	-	1	1 progressive dyspnea on exertion; obesity-hypoventilation syndrome1; 1 refusing to attend school because of teasing
	Resolved %	-	100% (3/3)	-	*	-	-	NR	The mean length of followup for hypertension data was 2.7 years (range 0.67 to 3.75). The patient reentered school; other comorbidities not reported
Studies of Vertical Banded Gastroplasty (VBG)									
Greenstein (1995)(86)	Baseline N	-	2	-	1	-	-	-	-
	Resolved %	-	NR	-	*	-	-	-	-

* Study reported comorbidity resolution data on only one or two patients, therefore the data did not meet inclusion criteria for this report.

[a] Sleep apnea outcomes reported by a secondary publication.(83) Nineteen patients had sleep apean before surgery, but sleep apnea status was reported for only 10 of the 19. This noncompletion was considered in our quality assessment.

[b] Dyslipidemia includes those reported as dyslipidemia, hyperglyceridemia and hypercholesterolemia.

[c] Reported musculoskeletal conditions included those reported as arthropathy, orthopedic problems, osteoarthropathy, joint and musculoskeletal complaints, degenerative joint disease, back pain, arthralgia, and vertebra fractures.

GERD Gastroesophageal reflux disease.

NR or – indicate that the study did not report any patient outcomes for this comorbidity

Table 26. Data for Key Question 2 on Quality of Life

Study	N	Length of followup	Instrument[a]	QOL score before surgery	QOL score after surgery	P value[b]
Studies of Laparoscopic Adjustable Gastric Banding (LAGB)						
Silberhumer(2006)(73,74)	50	Mean 34.7 months, SD 17.5, Range 3.6 to 85.4 months	Moorehead-Ardelt	0.8 (SD 0.3)	2.1 (SD 0.8)	P <0.0001

[a] Scores on the Moorehead-Ardelt quality-of-life instrument range from -3 to 3 where 3 represents excellent quality-of-life and -3 represents very poor quality-of-life.(137)
[b] p value calculated by ECRI Institute based on a t-test.

SD Standard deviation.
QOL Quality of life.

Note: Four studies reported quality-of-life data that did not meet inclusion criteria for the following reasons: In three studies (Yitzhak, Rand, Greenstein), the quality of life instrument was not previously validated, and only postoperative data were reported. In the fourth study (Collins), only postoperative data were reported. The Silberhumer study also reported BAROS data, but these data were not included because BAROS is only used after surgery.

Table 27. Data for Key Question 3 on Reported Complications for LAGB[a]

Study	Number of patients	Band used	Dates of surgery	Followup time	Reported complications (case number)	Treatments for complications
Al-Qahtani (2007)(70)	51	LAP-BAND	1/2003-12/2005	16 (3-34) months	One patient required port repositioning under fluoroscopic guidance, and one patient required readmission and rehydration because of an overly tight adjustment. Nine patients complained of repeated attacks of vomiting especially when eating fast or eating foods that are supposed to be avoided during the early postoperative period.	See the adjacent cell on the left Number of reoperations:1
Nadler (2007)(71)	53	LAP-BAND	9/2001-2/2006	At 6 (n = 33), 12 (n = 18), 18 (n = 6), and 24 (n = 2) months	Band slippage (2), hiatal hernia (2); wound infection (1), nephrolithiasis and cholelithiasis (1), gastroesophageal reflux (1), mild hair loss (5), iron deficiency (4)	Laparoscopic band reposition, laparoscopic hiatal hernia repair, medical therapy for GERD, and nutritional counseling and supplementations Number of reoperations: 4
Yitzhak (2006)(72)	60	SAGB[b]	2000-2006	39.5 (25-65) months	Band slippage (8)	Band reposition for 6 patients and band removal for 2 patients Number of reoperations: 8
Silberhumer (2006)(73,74)	50	SAGB & LAP-BAND	1998-2004	34.7 (3.6-85.4) months	Dislocated port (1)	Not reported Number of reoperations: 0
Angrisani (2005)(75)	58	LAP-BAND	1/1996-12/2003	At 1, 3, 5, and 7 years	Band slippage (1), gastric pouch dilatation (2), intragastric migrations (3), psychological intolerance of band (2), Conversion to laparoscopic GB in 2 years (1), biliopancreatic diversion with gastric preservation and band left in situ (2)	Band reposition for band slippage and gastric pouch dilations, band removal for intragastric migration and psychological intolerance Number of reoperations: 11
Fielding (2005)(76-78)	41	LAP-BAND	1998-2003	33.8 (1-70) months	Band slippage (1), tubing crack (1)	Laparoscopic band reposition for band slippage and exploratory procedure to repair the tubing crack Number of reoperations: 2
Horgan (2005)(79)	4	LAP-BAND	2001-2003	13.3 (4-30) months	Cholecystitis (1)	Outpatient laparoscopic cholecystectomy Number of reoperations: 0
Abu-Abeid (2003)(80)	11	LAP-BAND	Not reported	23 (6-36) months	Iron deficiencies (4)	Iron supplementation Number of reoperations: 0

[a] No perioperative death attributable to the surgical procedure was reported in the studies.

[b] SAGB - Swedish Adjustable Gastric Band

Table 28. Data for Key Question 3 on Reported Complications for RYGB[a]

Study	Number of patients	Approach	Date of surgery	Followup time	Reported complications (case number)	Treatments for complications
Collins (2007)(81,82)	11	Laparoscopic	1999 - 6/2005	11.5 (3-32) months	Immediate postoperative bleeding (1), marginal ulcer (2)	Laparoscopic re-exploration for postoperative bleeding and use of proton pump inhibitor for marginal ulcers
Lawson (2006)(69,83,84)	39	Laparoscopic (n = 36) and open (n = 3)	5/2001-10/2003	Within 1 year	There were neither perioperative death nor severe surgical complications. Two patients had at least one of the following: death[b] and severe beriberi. Four patients had at least one of the following: persistent iron deficiency anemia, peripheral neuropathy secondary to vitamin deficiency, reoperation (for staple line leak, obstruction, or gastrostomy revision), shock, and internal hernia. Nine patients had at least one of the following: endoscopy (for melena, suspected obstruction, or stricture), food obstruction, wound infection, anastomotic stricture/gastrojejunostomy stricture, nausea, dumping syndrome secondary to overeating, diarrhea, dehydration, mild beriberi, hypokalemia, deep vein thrombosis.	Not reported
Barnett (2005)(68)	15 procedures on 14 patients (including 5 RYGBs)	Open	1978 – 2001	6 years (9 month.-21.75 years)	The following were linked to the 5 RYGB cases: Dumping syndrome (2); hypoglycemia (1)	Both dumping syndrome cases were resolved within 1 year without further surgical intervention. The hypoglycemia case was treated medically without difficulty.
Sugerman (2003)(35)	33 (1 HGP, 2 VBG, 17 standard GBPs, 10 LL-GBPs, 3 D-GBPs)	Open (n = 31) and laparoscopic (on 2 standard GBPs)	1981 – 1/2002	2 weeks, 3, 6, 12 , 18 months, and yarely thereafter	Early complications: pulmonary embolism (1), major wound infection (1), minor wound infection (4), stomal stenoses (3), marginal ulcer (4) Late complications: small bowel obstruction (1), incisional hernia (6) Conversion from D-GBP to standard gastric bypass due to severe protein-calorie malnutrition (1)	Endoscopic dilation for stomal stenoses, medical treatments for marginal ulcers, adhesiolysis for small bowel obstruction, and herniorrhaphy with polypropylene for incisional hernias

Study	Number of patients	Approach	Date of surgery	Followup time	Reported complications (case number)	Treatments for complications
Strauss (2001)(36)	10	Open	4/1985 – 5/1999	Followup >1 year was present in 9 patients	No early complications Late complications: incisional hernia (1), symptomatic cholelithiasis (2), protein-calorie malnutrition and micronutrient deficiency (1), and small bowel obstruction caused by adhesion and internal hernia (1), minor nutritional complications include iron deficiency anemia (5), transient folic acid deficiency (3)	Laparoscopic cholecystectomy for symptomatic cholelithiasis, TPN and Abx for protein-calorie malnutrition, operative correction for small bowel obstruction, operative repair of incisional hernia, vitamin and mineral supplementation for iron and folic acid deficiencies
Rand (1994)(37)	34 (30 RYGBs and 4 VBGs)	Open	1/1979 – 12/1990	6 years	There were no major postoperative complications.	Revisional surgery to reduce size of the pouch for better weight loss results (3 performed, 2 scheduled), cholecystectomy (4), and abdominal panniculectomy (1)

[a] No perioperative death attributable to the surgical procedure was reported in the studies.

[b] The patient initially presented with hypercholesterolemia, hyperinsulinemia, hypertension, sleep apnea, and degenerative joint disease at a BMI of 80 kg/m^2 and weight of 630 lb. After an initial uncomplicated 3-month postoperative course, the patient developed severe infectious colitis because of Clostridium difficile. This illness was contracted while undergoing inpatient rehabilitation of his weight-related lower extremity osteoarthropathy in a long-term care facility distant from the bariatric center. Severe diarrhea and extended period of profound hypovolemia associated with the colitis resulted in multiorgan failure and subsequent death 9 months after RYGB.

D-GBP Distal gastric bypass.
GPS Gastric bypass.
HGP Horizontal gastroplasty.
LL-GBP Long-lime gastric bypass.
VBG Vertical banded gastroplasties.

Table 29. Data for Key Question 3 on Reported Complications for Other Bariatric Surgeries[a]

Study	Number of patients	Procedure	Date of surgery	Followup time	Reported complications (case number)	Treatments for complications
Barnett[b] (2005)(68)	15 procedures on 14 patients (including 7 VBG)	VBG	1978 – 2001	6 years (9 months - 21.75 years)	No complications related to the VBG procedures were reported.	Not reported.
Greenstein (1995)(86)	18	VBG	3/1982 – 6/1994	3-120 months	Major morbidities included recurrent gastric ulceration in two female patients who were heavy cigarette smokers.	Not reported.
Mason (1995)(87)	47	VBG	1980 – 1994	Up to 5 year (n = 35) or 10 years (n = 19)	No operation-related deaths; no leaks or instances of peritonitis; no pneumonia nor wound infections 3 late revisions for unsatisfactory weight loss results (2 due to enlarged pouches and 1 due to disrupted staple line)	Surgical revisions for enlarged pouches and disrupted staple line
Capella (2003)(88)	19	Banded bypass	5/1990 – 1/2001	5.5 (1-10) years	No postoperative mortality or serious morbidity.	Two revisions for gastro-gastric fistula, one cholecystectomy, one recurrent marginal ulcer requiring antacids, three plastic surgeries for excess skin

[a] No perioperative death attributable to the surgical procedure was reported in the studies.

[b] The study was also reported in Table 28 because it covered more than one type of bariatric surgery.

D-GBP Distal gastric bypass.
GPS Gastric bypass.
HGP Horizontal gastroplasty.
LL-GBP Long-lime gastric bypass.
VBG Vertical banded gastroplasties.

Figure 17. Age and BMI Change: Individual Patient Data

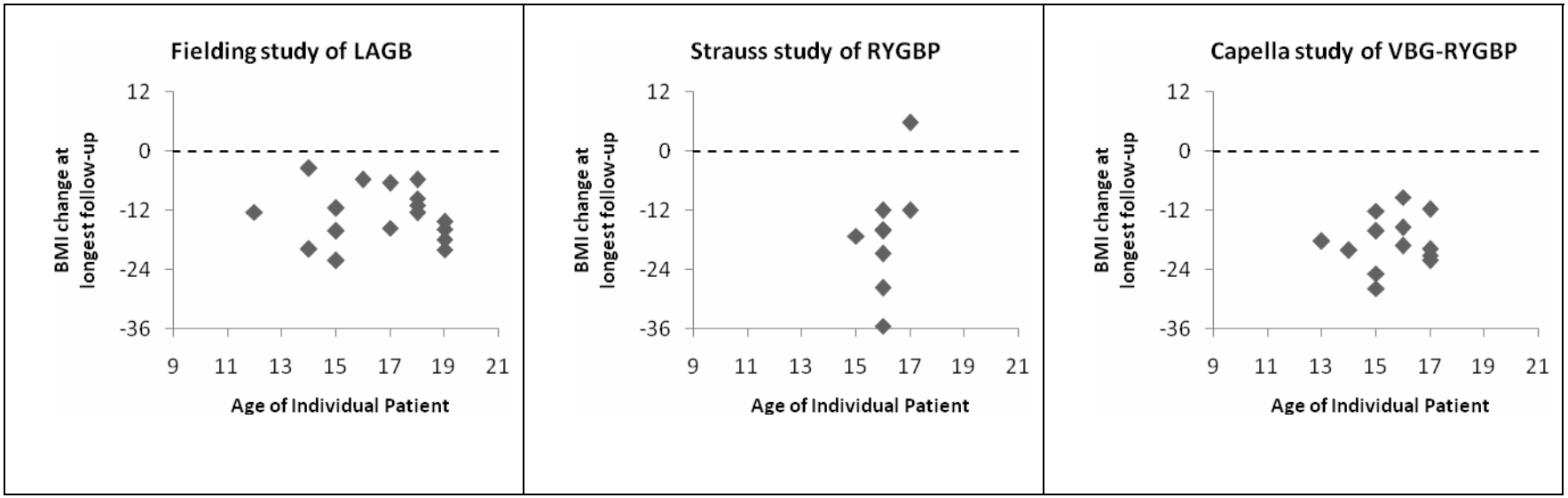


Figure 18. Pre-surgical BMI and BMI Change: Individual Patient Data

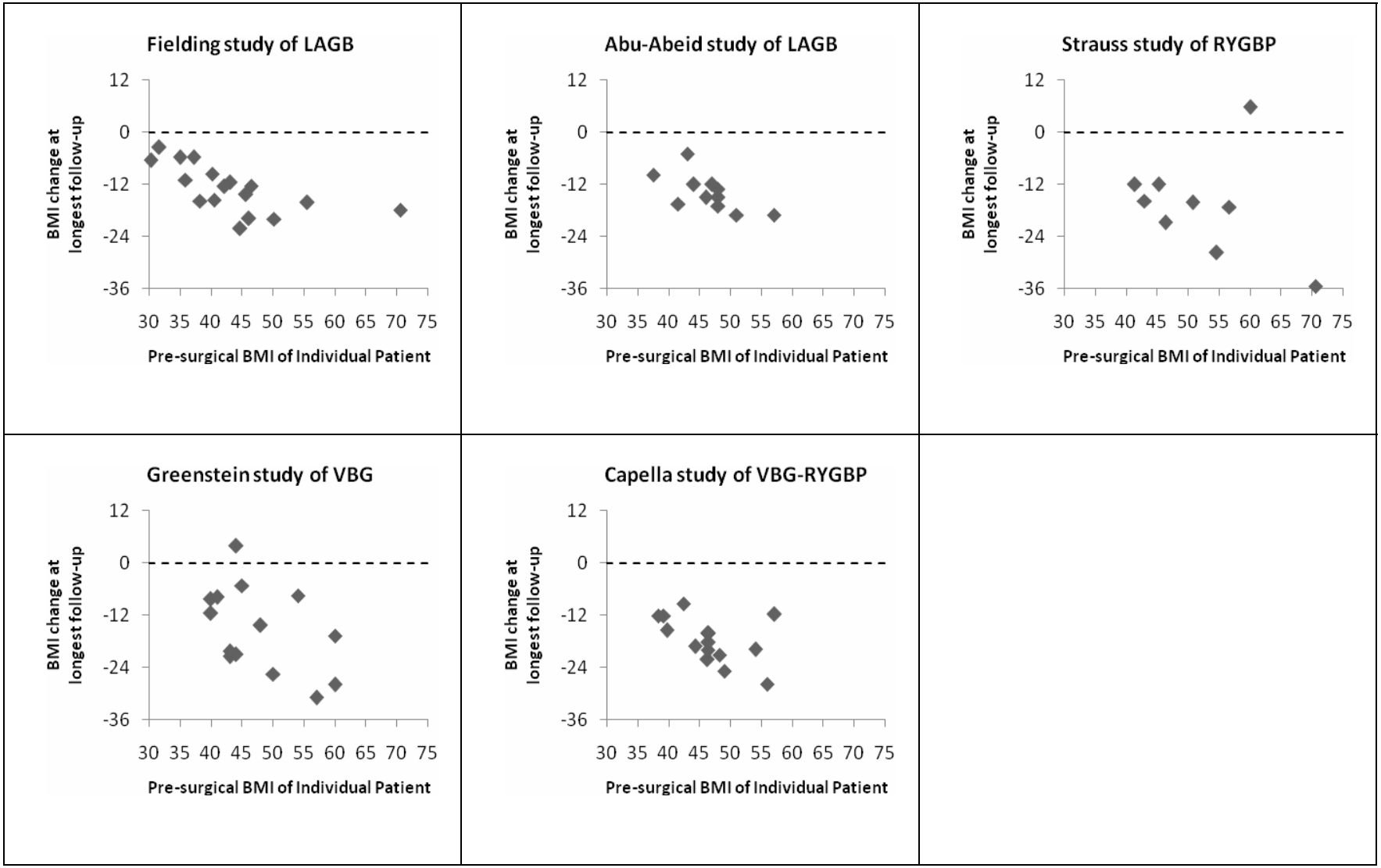


Figure 19. Pre-surgical BMI Category and BMI Change: Individual Patient Data

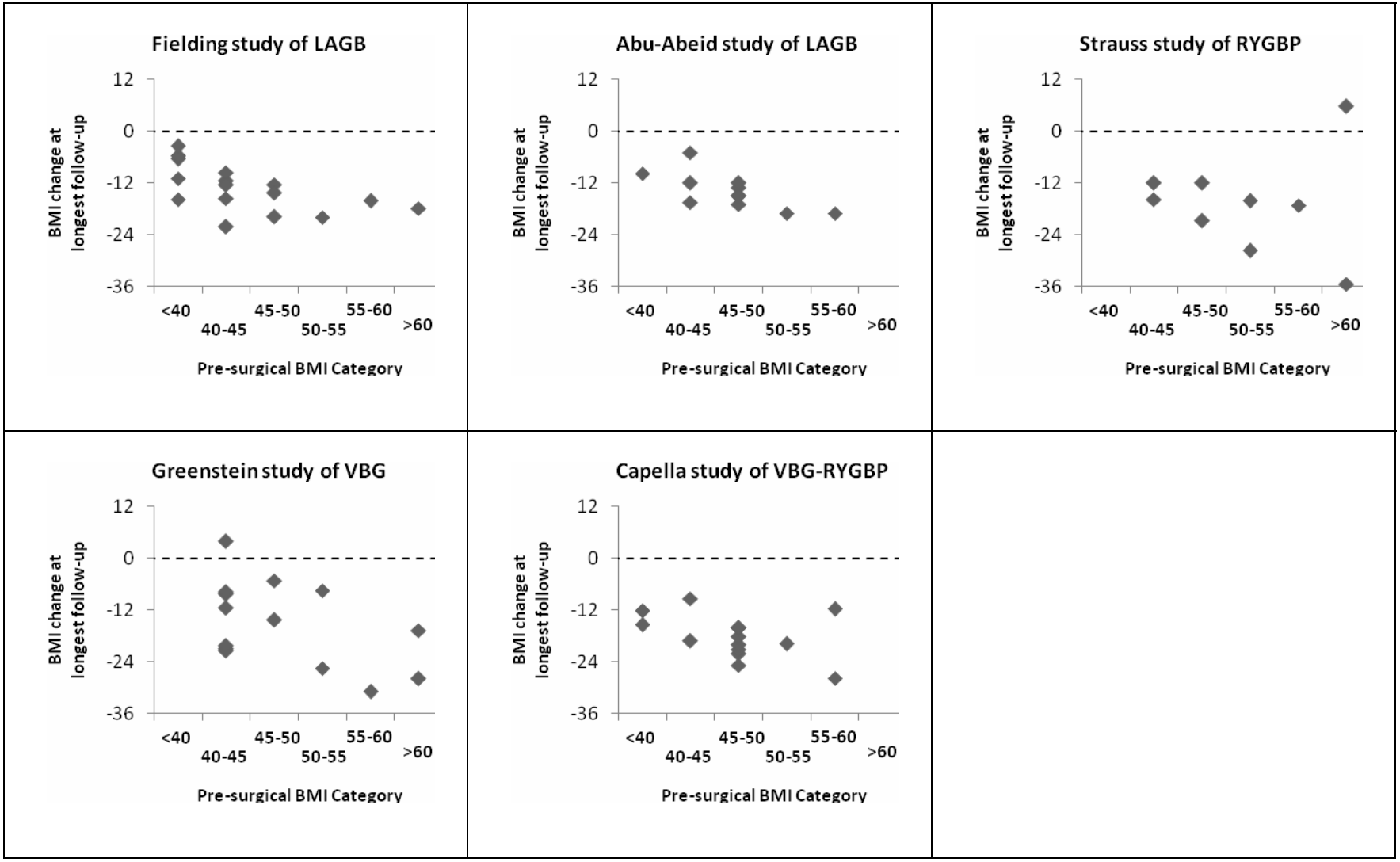
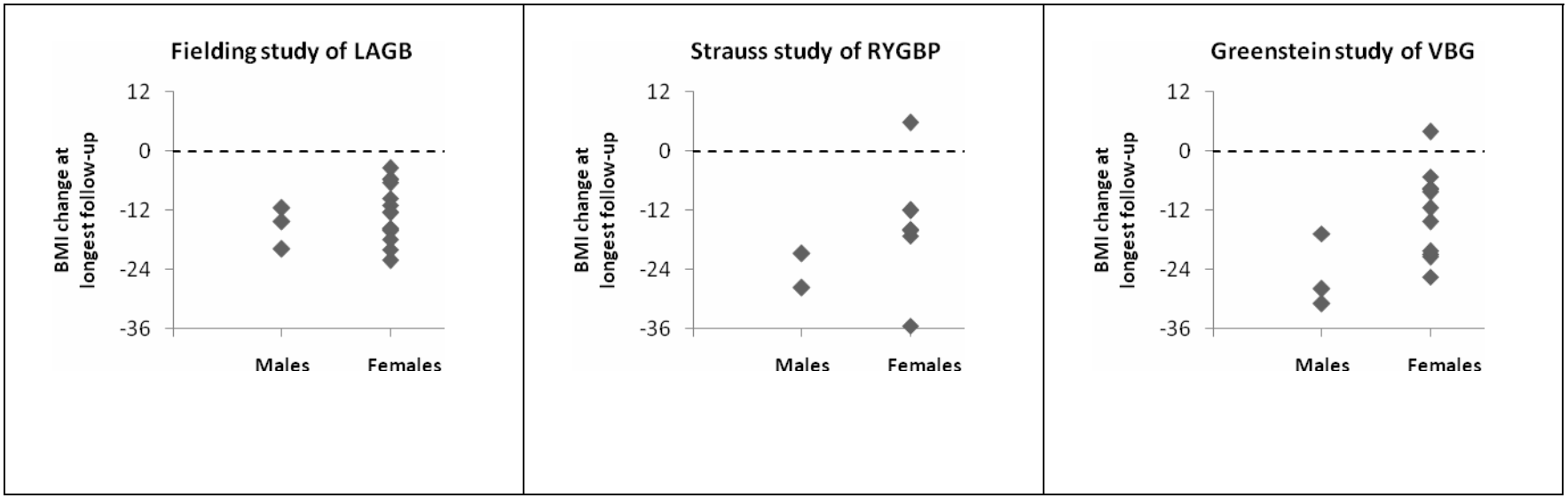


Figure 20. Sex and BMI Change: Individual Patient Data



Appendix F. Reference on Cost

Table 30. Medicare Professional Fee Schedule for Bariatric Surgeries, 2007

HCPCS Code[a]	Code Description	Medicare Payment[b]			Procedure
		National	Seattle, WA	Rest of WA	
RYGB procedures					
43846	Gastric restrictive procedure, with gastric bypass for morbid obesity; with short limb (150 cm or less) Roux-en-Y gastroenterostomy	$1429.11	$1469.09	$1397.94	RYGB, open
43644	Laparoscopy, surgical, gastric restrictive procedure; with gastric bypass and Roux-en-Y gastroenterostomy (roux limb 150 cm or less)	Not available	$1578.09	$1500.53	RYGB, laparoscopic
LAGB-related procedures					
43770	Laparoscopy, surgical, gastric restrictive procedure; placement of adjustable gastric band (gastric band and subcutaneous port components)	$981.17	$1012.06	$959.18	LAGB
43771	Laparoscopy, surgical, gastric restrictive procedure; revision of adjustable gastric band component only	$1121.39	$1155.13	$1096.12	See code description
43772	Laparoscopy, surgical, gastric restrictive procedure; removal of adjustable gastric band component only	$844.74	$869.73	$825.69	See code description
43773	Laparoscopy, surgical, gastric restrictive procedure; removal and replacement of adjustable gastric band component only	$1121.77	$1155.44	$1096.42	See code description
43774	Laparoscopy, surgical, gastric restrictive procedure; removal of adjustable gastric band and subcutaneous port components	$848.53	$874.88	$829.96	See code description
43886	Gastric restrictive procedure, open; revision of subcutaneous port component only	$284.99	$301.39	$280.72	See code description
43887	Gastric restrictive procedure, open; removal of subcutaneous port component only	$270.21	$282.63	$264.31	See code description
43888	Gastric restrictive procedure, open; removal and replacement of subcutaneous port component only	$386.18	$403.13	$378.13	See code description
Restrictive procedures other than LAGB					
43842	Gastric restrictive procedure, without gastric bypass, for morbid obesity; vertical-banded gastroplasty	Not available	$1120.51	$1066.88	VBG, open
43843	Gastric restrictive procedure, without gastric bypass, for morbid obesity; other than vertical-banded gastroplasty	$1106.23	$1137.27	$1082.16	Gastric restrictive procedure other than VBG, open

HCPCS Code[a]	Code Description	Medicare Payment[b]			Procedure
		National	Seattle, WA	Rest of WA	
Other procedures					
43847	Gastric restrictive procedure, with gastric bypass for morbid obesity; with small intestine reconstruction to limit absorption	$1571.61	$1614.30	$1537.08	Biliopancreatic bypass procedure (Scopinaro)
43845	Gastric restrictive procedure with partial gastrectomy, pylorus-preserving duodenoileostomy and ileoileostomy (50 to 100 cm common channel) to limit absorption (biliopancreatic diversion with duodenal switch)	$1706.90	$1749.11	$1668.42	Biliopancreatic bypass with duodenal switch
43999	Unlisted procedure, stomach	Not available	Not available	Not available	Long- limb gastric bypass (>100 cm) (which has no specific code.
43659	Unlisted laparoscopy procedure, stomach	Not available	Not available	Not available	Mini-gastric bypass (which has no specific code)
43645	Laparoscopy, surgical, gastric restrictive procedure; with gastric bypass and small intestine reconstruction to limit absorption	$1650.06	$1698.29	$1614.96	See code description
43848	Revision, open, of gastric restrictive procedure for morbid obesity, other than adjustable gastric band (separate procedure)	$1700.46	$1746.30	$1662.92	See code description

[a] The coding information regarding bariatric surgeries was from Wellmark Blue Cross and Blue Shield, available at http://www.wellmark.com/e_business/provider/medical_policies/policies/obesity_surgery.htm, accessed on May 2, 2007.

[b] The HCPCS code and Medicare payment information was from the CMS Web site, available at http://www.cms.hhs.gov/apps/ama/license.asp?file=/pfslookup/02_PFSsearch.asp, accessed on May 2, 2007.