Washington State Health Care Authority
Health Technology Assessment

FINAL Key Questions and Background

Bariatric Surgery

Background

It is estimated that more than one-third of adults and about 17% of adolescents are obese (Ogden, 2014). The health effects of obesity are myriad, and include the development of type 2 diabetes, hypertension, cardiovascular disease, high blood pressure, and sleep apnea. Obesity and its sequelae are estimated to generate $147 billion in health care costs in the U.S. alone (Finkelstein, 2009).

Historically, options for treating obesity have been limited to lifestyle modifications such as dietary changes and exercise as well as the use of weight-loss medications and dietary supplements, many of which have been shown to pose significant health risks of their own (National Institutes of Health, 2013). More recently, options for surgical intervention have become more widespread. The term "bariatric surgery" refers to a collective group of procedures that involve modifications to the digestive system that promote weight loss, and include gastric bypass, gastric banding, sleeve gastrectomy, and biliopancreatic diversion (with or without duodenal switch) (National Institutes of Health, 2009). Procedures can be performed via open or laparoscopic surgery; the choice of procedure and method primarily depends on the severity of obesity, the presence of comorbid conditions, the experience of the surgeon, and the patient's individual preferences or other contraindications (Colquitt, 2009).

In certain settings and populations, bariatric surgical procedures have shown reductions in body weight and reduced risks of obesity-related conditions. Early use of the procedures focused on individuals meeting criteria for severe or morbid obesity (body mass index [BMI] ≥35.0 kg/m^2) who had at least one obesity-related condition (e.g., diabetes). Subsequent studies have been conducted in individuals at lower levels of BMI, which has led to regulatory approval specific to this population: in 2011, the FDA approved the use of a laparoscopic adjustable gastric banding device (LAP-BAND®, Apollo Endosurgery, Inc.) for use in patients with lower levels of obesity (BMI 30.0-34.9) and at least one obesity-linked condition (U.S. Food and Drug Administration, 2011). The most common application of bariatric surgery in less obese individuals has been in patients with type 2 diabetes. Clinical interest in expanding the use of bariatric surgery to individuals with lower levels of obesity is high; questions remain, however, regarding the performance of these procedures in these patients versus those with higher levels of obesity, the health-system impact given the higher prevalence of moderate obesity versus severe/morbid obesity, and the durability of clinical benefit in all populations.

There are also specific risks associated with bariatric procedures, which may include bowel obstruction, development of gallstones or hernias, stomach perforation and ulcer, "dumping syndrome" (diarrhea and other related symptoms caused by rapid movement of undigested food to the small bowel), and in

some cases, death (Mayo Clinic, 2014). Additional surgeries may be required as part of a multi-phase procedure (as with biliopancreatic diversion), to implement an entirely new treatment modality, remedy a complication, or reverse the procedure altogether if complications are life-threatening (Brethauer, 2014). Surgical revisions comprise about 6% of all weight loss surgeries performed annually in the U.S. (American Society for Metabolic and Bariatric Surgery, 2014). Also, as with any surgical procedure, there are general surgical risks, including hemorrhage, wound infection, deep vein thrombosis and/or pulmonary embolism, and anesthesia reactions (Mayo Clinic, 2014).

Policy Context

About 93 million Americans are classified as obese (Obesity Action Coalition, 2014). While the number of obese individuals has remained stable in recent years, obesity continues to be one of the most prevalent public health issues in the U.S. (Ogden, 2014). In June 2012, the American Medical Association officially recognized obesity as a chronic disease, believing it would more effectively address the issue; however, the new classification remains controversial among advocates, policymakers, and the medical community, who feel that such a designation may distance patients from responsibility for their condition (Pollack, 2012).

Compounding the problem is the lack of viable treatment alternatives. Success rates from lifestyle modifications alone have been modest at best, and the risk-benefit tradeoffs for weight-loss medications are questionable. Clinical interest in expanding the use of bariatric surgery is therefore justifiably high, but there are uncertainties regarding the relative performance of each type of procedure in specific patient populations (e.g., adult versus pediatric patients, moderately versus severely/moderately obese, etc.). There are also conflicting data on long-term benefit. Earlier findings from retrospective chart review as well as prospective observational study suggested a sustained reduction in all-cause mortality at 7-11 years of follow-up (Adams, 2007; Sjostrom, 2007), but data from a more recently-published study of a cohort of U.S. veterans indicated no mortality benefit at a mean of 6.7 years of follow-up (Maciejewski, 2011).

As the Washington State Health Care Authority reviews its coverage policy for bariatric surgery, it is therefore timely to assess the evidence on the clinical benefits and cost-effectiveness of common weight loss procedures across all relevant populations, including those defined by level of obesity, age, and levels of comorbidity.

Project Scope

This project will involve a systematic review of the published literature on the use of bariatric surgery for the four types of procedures that are most commonly utilized in the U.S.: gastric bypass, gastric banding, sleeve gastrectomy, and biliopancreatic diversion (with or without duodenal switch) (National Institutes of Health, 2009). Evidence specifically in pediatric populations will build on a review conducted for the Health Care Authority in 2007, which examined studies published through June 2007 (ECRI Institute, 2007).

Specific details on the proposed scope (Population, Intervention, Comparators, and Outcomes, or PICO) are detailed in the following sections.

Population

The target population for this review will include both adults and children undergoing surgical treatment for obesity; evidence from adult and pediatric studies will be evaluated separately. All classifications of obesity (i.e., moderately, severely, and morbidly obese) within these categories will be considered; among those who are moderately or severely obese (i.e., BMI 30.0 – 34.9), studies will be categorized according to major comorbidities present (e.g., Type 2 diabetes, hypertension), as feasible. As with the original HCA pediatric report, updated evidence for specific age categories (i.e., 12 or less, 13-17, 18-20) will be assessed.

Intervention

We will evaluate the effectiveness of gastric bypass, gastric banding, sleeve gastrectomy, and biliopancreatic diversion (with or without duodenal switch). Studies that focus on the combination of bariatric surgery with pre- and post-operative psychotherapy and/or nutritional counseling will also be included. We will evaluate studies that compare these procedures to each other as well as those that compare bariatric procedures individually and collectively against conventional weight-loss treatments (see below). Finally, to the extent feasible, we will characterize detailed aspects of the intervention in each study, including components of pre-procedure preparation, level of post-procedure support, members of the treatment team, and definitions of treatment success or failure.

Comparators

The primary comparison of interest will be to conventional weight-loss treatments. Those treatments deemed to be conventional will include prescription medication, dietary supplements, diet-control programs, exercise, psychotherapy, and nutritional counseling. Conventional treatments may be delivered individually or in combination. While it is unlikely that we will identify studies employing sham procedures or placebo treatments for surgeries of this type, we will nevertheless include such studies if found.

Outcomes

Outcomes of primary interest will include rapid and sustained weight loss, changes in BMI, reduction of comorbidities (and associated medication use), improvements in health-related quality of life, and rates of complications, surgical revision and/or reversal, other longer-term procedure-related morbidity (e.g., malabsorption), and mortality. Reduction of comorbidities will include objective findings (e.g., blood glucose, cholesterol levels, blood pressure) as well as measures of positive and/or negative change in both physical (e.g., musculoskeletal pain) and psychiatric (e.g., depression, eating disorders) symptoms. Mortality will be evaluated on both a peri-procedural (i.e., during the procedure or the 30 days following) and longer-term basis. Finally, given the interest in documenting specific components of the treatment approach in each study, we will seek to identify those components correlated with higher levels of treatment success.

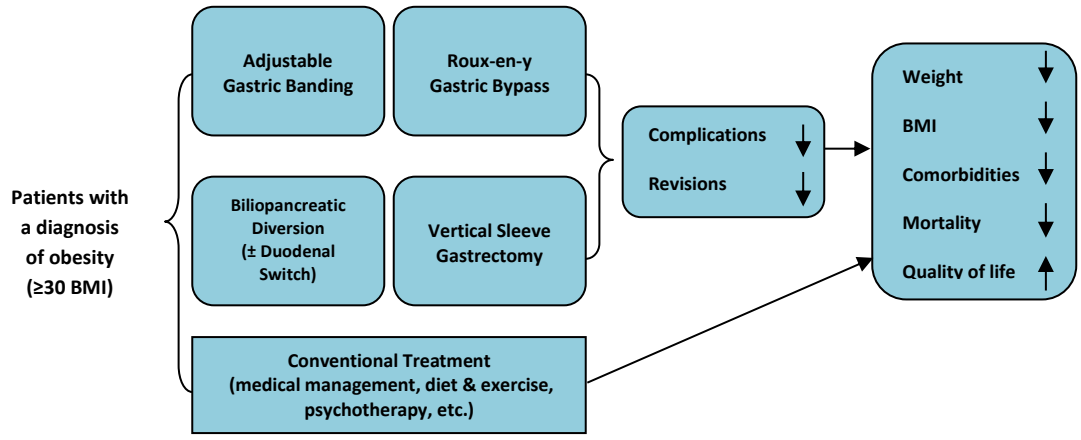
While we will not place any study duration thresholds on the evidence base, previous systematic reviews have noted that most bariatric surgery studies do not evaluate outcomes beyond two years of follow-up (Colquitt, 2009; Cohen, 2013; Maggard-Gibbons, 2013; Ribaric, 2014); in addition, longer-term studies have been criticized for inconsistent standards for evaluating changes in comorbidity, as well as insufficient study power to detect between-treatment differences.

Information on the costs and cost-effectiveness of bariatric surgery procedures relative to each other and collectively compared to conventional treatment will be assessed where available. We will also develop a decision-analytic model evaluating the potential cost-effectiveness of these treatments and budgetary impact in a setting germane to the Washington HCA. Although our model will primarily focus on the direct medical costs associated with the various treatment approaches (i.e., initial treatment, management of complications, re-treatment), we will also include a sensitivity analysis that accounts for the impact of each treatment approach on work productivity (e.g., hours of work loss, days absent).

Analytic Framework

The proposed analytic framework for this project is depicted below. Because it is expected that there will be limited data directly comparing all bariatric procedures of interest in any one study, judgments about the effectiveness of these interventions will likely rest predominantly upon individual consideration of each type of surgery versus non-surgical interventions, and evaluation of procedure-specific risks. We also expect that conceptual links will need to be made between shorter-term outcomes and long-term effects of treatment.

Analytic Framework: Bariatric Surgery



FINAL Key Questions

1) What is the comparative clinical effectiveness of bariatric surgery procedures versus conventional weight-loss management in:
    a. Adults (i.e., age 21 years and older)?
    b. Children (age <21), on an overall basis and by specific age groups (i.e., 18-20, 13-17, 12 or less)?

2) What components of the management of patients undergoing bariatric surgery (e.g., selection of candidates for surgery, multi-disciplinary care team, pre- and/or post-procedure counseling and support) appear to be correlated with higher levels of "treatment success" (e.g., sustained weight loss, reduction in comorbidity burden, etc.)?

3) What are the potential short- and long-term harms of bariatric surgery procedures, including rates of procedure-specific and general surgical complications, longer-term morbidity, mortality, and requirements for procedure revision and/or reversal?

4) What is the differential effectiveness and safety of bariatric surgery procedures according to health-system and/or program factors such as:
    a. Surgeon experience
    b. Procedure volume
    c. Type of procedure
    d. Certification of surgery center
    e. Members of core team
    f. Type of pre-procedure preparation/post-procedure support

5) What is the differential effectiveness and safety of bariatric surgery procedures according to patient and/or clinical factors such as:
    a. Age (both chronological and physiologic/skeletal)
    b. Gender
    c. Race/ethnicity
    d. BMI (assessed as both continuous and categorical variable)
    e. Presence of comorbidities (e.g., hypertension, type 2 diabetes)
    f. Prior event history (e.g., myocardial infarction, stroke)
    g. Smoking status
    h. Psychosocial health
    i. Pre/ post procedure adherence with program recommendations

6) What are the costs and cost-effectiveness of the major bariatric surgery procedures of focus in this evidence review?

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Public Comment & Response

See Draft Key Questions: Public Comment and Response document published separately.