Summary of Evidence-Bariatric Surgery – November 4, 2004

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TABLE OF CONTENTS

Executive Summary

An estimated 27% of the US population is obese and an additional 34% is overweight. Morbid obesity increased from 2.9 to 4.7 percent of the US population from the early nineties to 2000. In 1999 to 2000, 33% of men and 39% of women aged 65 to 74 were obese as were 20% and 25% over the age of 74. Overweight and obese persons have an increased risk of a number of diseases compared to persons with normal weight and waist circumference. Some of the most important co-morbidities include hypertension, dyslipidemia, type 2 diabetes, coronary heart disease, stroke, gallbladder disease, osteoarthritis, sleep apnea, respiratory problems, and endometrial, breast, prostate, and colon cancers.

The relative lack of success of most weight loss programs has induced persons with morbid obesity to turn to bariatric surgery at an exponentially increasing rate. This rate increased from approximately 1/100,000 population in the 80's and early 90's to an estimated 30/100,000 in 2003. Successful bariatric surgical procedures affect weight loss by restricting intake of food, by controlled malabsorption of food, or a combination of these mechanisms. At present, the more common and well-known restrictive procedures are Vertical Banded Gastroplasty (VBG), and LAGB. The most common malabsorptive procedure is a Roux-en-Y gastric bypass (RYGBP) which has a restrictive component, followed by the much less common Biliopancreatic Diversion with and without duodenal switch (BPD, DS). The banding procedures are currently performed laparoscopically, while the other bariatric procedures may be performed laparoscopically or as an open procedure. Laparoscopic adjustable silicone gastric banding (LAGB) is currently becoming more popular than VBG.

The Centers for Medicare and Medicaid Services (CMS) currently has a national coverage determination (NCD) that allows bariatric surgery if the surgery is to correct an illness which caused the obesity or was aggravated by the obesity. CMS has asked the Medicare Coverage Advisory Committee (MCAC) to make recommendations as to the adequacy of the evidence for bariatric surgery. both in those Medicare beneficiaries who have co-morbidities (currently covered) as well as those Medicare beneficiaries who are obese but do not have co-morbidities.

There have been a number of technology assessments (TA) produced in the last several years reviewing the literature on bariatric surgery. The most recent TA was published by the Agency for Healthcare Research and Quality (AHRQ) in October 2004. CMS reviewed each of these TAs and searched the literature for publications after March 2003. June 2003 was the publication date of the most recent TA when we started the project. We updated the search as recently as October 13, 2004, and this included the recent RAND-AHRQ TA.

In general, there is evidence that weight loss is much higher in those patients with obesity who have bariatric surgery as compared to controls who do not have surgery. Weight loss following gastric bypass is significantly higher than weight loss from purely restrictive procedures. Studies show co-morbidities in many post-bariatric-surgery patients are generally improved or resolved when compared to controls. Long-term weight loss is, therefore, likely to result in long-term improvement of co-morbidities.

Studies report a substantial benefit of surgery in reducing sleep apnea, symptoms of dyspnea and chest pain as well as diabetes and hypertension. A maintained weight reduction of 16% strongly counteracted the development of diabetes over 8 years of follow-up, indicating that diabetes incidence can be decreased by sufficient weight loss. In fact, unadjusted and adjusted odds ratios

for developing diabetes and hypertension in surgically treated patients compared with control subjects demonstrated that controls were six times more likely to develop diabetes over 8 years than those in the surgical group. There is strong evidence that lowering weight decreases elevated levels of total cholesterol, LDL-cholesterol and triglycerides, and raises low levels of HDL-cholesterol in overweight and obese persons with dyslipidemia. Weight loss lowers elevated blood glucose levels in overweight and obese persons with type 2 diabetes. Medical co-morbidities, in one study, either improved (47%) or resolved (43%), representing 90% of the patients following satisfactory weight loss.

There is some evidence that bariatric surgery patients have prolonged longevity as expressed in Years of Life Lost (YLL). This appeared to be different in whites and blacks, with whites having an advantage at younger ages and white males having an advantage over black males, while black females had an advantage over all the others at higher ages. One finding was that in females aged 40-64, intentional weight loss of any amount was associated with a statistically significant, 20% reduction in all-cause mortality, primarily due to lowered incidence of obesity related cancers.

Short-term mortality, that occurring within 30 days of surgery, is estimated to be less than 1 in 200 cases in the laparoscopically performed restrictive procedures and as high as 1.9% for bariatric surgery overall. Increased surgeon experience was associated with a lower short-term mortality rate.

There is substantial evidence that the overall surgical complication rate after gastric bypass is significantly higher than that of purely restrictive procedures. However, for some types of complications, restrictive procedures may have a higher complication rate due to the fundamental differences in procedure. Laparoscopic procedures have a lower complication rate than their corresponding open procedures in general. In particular, LAGB has a lower complication rate than the other bariatric surgery procedures.

The relative paucity of data relating to bariatric surgery in the Medicare population is remarkable. There is some evidence of sustained weight loss five years post-operatively in the older age groups, though it is not as marked as it is in younger patients. However, acceptable data on short-term mortality in elderly persons were not found. Nonetheless, bariatric surgery was considered acceptable in older patients if close attention were to be paid to co-morbidities that increase surgical risk. Preoperative co-morbidity is higher in patients greater than or equal to 60 years of age, but these co-morbidities were noted to be decreased in elderly patients after RYGBP.

Finally, using the outcomes of short-term mortality, long-term mortality, sustained weight loss, and complications of surgery we noted an extreme paucity of data that might allow post-operative bariatric surgery comparisons of groups of persons who had no pre-operative co-morbidities with groups of persons who had at least one pre-operative co-morbidity.

Bariatric surgery appears to have a place in the medical armamentarium for physicians treating obesity in the general population. Sustained weight loss may be an attainable goal, with combination or malabsorptive procedures showing greater weight loss than restrictive procedures. Sustained and sufficient weight loss may improve or resolve co-morbid conditions.

Short-term mortality is low and experienced surgeons performing bariatric surgery have a lower rate of short-term mortality in their patients than inexperienced surgeons. There is some

indication that the years of life lost (YLL) are increased in persons with a high Body Mass Index (BMI), helping to justify any increased risk in having the surgery.

The currently available data does not allow generalization of these results to the Medicare population.

More high quality studies on clinically important gaps in the scientific evidence are indicated. In particular, evidence is needed with respect to short-term mortality, long-term survival, co-morbidities, sustained weight loss, complications, and in persons over age 65.

Introduction

Obesity is a growing epidemic in the United States with over 60% of the population classified as overweight or obese.[1] One form of treatment for obesity, bariatric surgery, is the focus of this summary of evidence. Questions for evaluation of evidence regarding the subject of bariatric surgery and its relationship to Medicare beneficiaries focus on types of surgery and their outcomes, in persons that have at least one pre-operative co-morbidity as compared to those that have surgery and no pre-operative co-morbidities.

Overweight people are classified into four groups based on BMI:

Overweight	= 25-29.9
Class I obesity	= 30.0-34.9
Class II obesity	= 35.0-39.9
Class III (Extreme) Obesity	≥ 40.0

By these definitions, approximately 27% of the US population is obese and an additional 34 % are overweight.[2] Obesity is more common in women and overweight is more common in men. Obesity is especially common in African Americans, Native Americans, Native Hawaiians, and some Hispanic populations.[3] Data for the extent of obesity in the Medicare population indicate that, in 1999-2000, 33% of men and 39% of women aged 65-74 were obese as were 20% and 25% respectively over the age of 74.

Livingston used the 2000 NHIS data base to estimate the number of persons with obesity eligible for surgery, using the standard definition of morbid obesity, to be over 5 million persons (2.8% of US population). Of that number, 4.6 million were class III obese persons and 9 million had a BMI in the class II range. [4] In his recent JAMA article, Buchwald et al. estimated the number to be 5% at present.[5]

The Massachusetts TA reported that weight loss in bariatric surgery studies was an order of magnitude greater than weight loss in pharmaceutical or diet studies. They cited a weight loss of 20-40 kg at one or two years in surgical studies versus 2-5 kg in pharmaceutical studies.[6] Extremely obese persons often do not benefit from the non-surgical treatments for weight loss and weight maintenance.[7]

In a study of the National In-patient Survey (NIS), Pope reported that the rate of bariatric surgery procedures increased from 2.7 to 6.3 per100,000 adults from 1990 to 1997.[8] During the same time period gastric bypass surgery increased from 54% to 84% of all bariatric surgery in the US.[9]

Weight loss surgery may be an option for certain selected patients with clinically severe obesity (a BMI ≥ 40 or ≥ 35 with co-morbid conditions), when less invasive methods of weight loss treatment have failed and the patient is at high risk for obesity-associated morbidity or

mortality.[10] Due to this increase in obesity and the increased rate of bariatric surgery, CMS has elected to ask the MCAC, in a public forum, to review and assess the evidence for bariatric surgery. The questions posed to MCAC by CMS are in Appendix A.

History of Medicare Coverage of Obesity

Medicare policy for the treatment of obesity alone has been and continues to be one of non-coverage. In 2001, CDC contacted CMS and asked that the language in the National Coverage Determination (NCD) Manual be revised to reflect current social and clinical concerns about obesity. On July 15, 2004, Secretary Tommy Thompson announced that CMS would remove the language "obesity itself cannot be considered an illness" in the manual, and by doing so remove barriers to covering anti-obesity interventions if scientific and medical evidence demonstrate their effectiveness in improving the health outcomes of Medicare beneficiaries.
CMS does not believe it is appropriate to address the definition of illness in the manual since the manual is intended to address the coverage of particular care and services rather than the definition of illness. Medicare does reimburse for treatments of diseases resulting in or made worse by obesity, particularly for morbidly obese individuals.

The policy on obesity may be found in the NCD Manual, Section 40.5, *Treatment of Obesity:*

> *Obesity may be caused by medical conditions such as hypothyroidism, Cushing's disease, and hypothalamic lesions or can aggravate a number of cardiac or respiratory diseases as well as diabetes and hypertension. Services in connection with the treatment of obesity are covered services when such services are an integral and necessary part of a course of treatment for one of these medical conditions. However, program payment may not be made for treatment of obesity unrelated to such a medical condition since treatment in this context has not been determined reasonable and necessary.*

Gastric bypass surgery for extreme obesity is covered under the program if (1) it is medically appropriate for the individual to have such surgery; and (2) the surgery is performed to correct an illness that caused the obesity or was aggravated by the obesity.

Other bariatric surgical procedures may be covered under contractor discretion if they meet the requirements of the local contractors and are consistent with the national policy on obesity.

Epidemiology of Obesity

According to the Centers for Disease Control and Prevention (CDC), the prevalence of adult obesity (Classes I and II; see Table below) rose nearly 50% in the period between 1976-1980 and 2001-2002, when an estimated 63 million people were classified as obese.[11] An estimated 55% of adults age 20 or over are considered overweight or obese. Extreme Obesity increased from 2.9 to 4.7 percent of the US population from the early nineties to 2000.[12] Overweight and obese persons have an increased to extremely high relative risk of disease relative to normal weight and waist circumference. That risk increases, within these categories, as BMI and waist circumference increase.[13] The prevalence of a BMI $\geq$35 in the population over 75 years of age in the United States is estimated to be 6.4%, or approximately 2,000,000 persons.[14] Extreme (Class III) obesity grew at an even faster rate—nearly 4-fold between 1986 and 2000. In 2001-2002,

some 11 million individuals had severe obesity (more than 100 lbs overweight) and that number is recently estimated to be as much as 5% of the US population.[15]

CLASSIFICATION OF OVERWEIGHT AND OBESITY BY BMI, WAIST CIRCUMFERENCE AND ASSOCIATED DISEASE RISK*

			Disease Risk* Relative to Normal Weight and Waist Circumference	
	BMI (kg/m²)	Obesity Class	Men ≤ 102 cm (≤ 40 in) Women ≤ 88 cm (≤ 35 in)	> 102 cm (> 40 in) > 88 cm (> 35 in)
Underweight	<18.5		—	—
Normal†	18.5 –24.9		—	—
Overweight	25.0 – 29.9		Increased	High
Obesity	30.0 – 34.9	I	High	Very High
	35.0 – 39.9	II	Very High	Very High
Extreme Obesity	≥40	III	Extremely High	Extremely High

* Disease risk for type 2 diabetes, hypertension, and CVD.
\+ Increased waist circumference can also be a marker for increased risk even in persons of normal weight.

To lose that extra weight, persons with morbid obesity have been turning to bariatric surgery at an exponentially increasing rate. This rate has increased from approximately 1/100,000 population in the 80's and early 90's to an estimated 30/100,000 in 2003.[16,17]

Obesity is associated with an increased risk for coronary heart disease, hypertension, stroke, type 2 diabetes, sleep apnea, certain cancers, and musculoskeletal disorders.[18] NHANES data showed that, in persons with obesity being black and male sex were independently associated with increased (YLL).[19] Much of this difference is lost after age 60.

Bariatric Surgery

Several modifications of bariatric surgery have developed over the last several years. Two major types of surgery have developed. One diverts food from the stomach to a lower part of the digestive tract where the normal mixing of digestive fluids and adsorption of nutrients cannot occur – a malabsorptive procedure. The other restricts the size of the stomach and decreases intake–a restrictive procedure. Other surgeries combine both. Bariatric surgery initially developed as an open procedure, but in recent years successful attempts have been made to convert some of the procedures to a laparoscopic procedure and new procedures have been developed solely as laparoscopic ones. Descriptions of the commonly performed procedures follow. Diagrams can be found in Appendix C.

1. RYGBP (Open/Lap)

RYGB achieves weight loss through both gastric restriction and malabsorption. Reduction of the stomach to a small gastric pouch (30 cc) results in feelings of satiety following even small meals.

This small pouch is connected to a segment of the jejunum, bypassing the duodenum and very proximal small intestine, thereby reducing absorption.

The RYGB procedure has been performed regularly since the early 1980s and was first performed laparoscopically in the early 1990s. RYGB is one of the most common types of weight loss procedures in current use, with approximately 50,000 cases performed in 2001. This procedure may result in more sustained weight loss than banding procedures.

2. Biliopancreatic Diversion (BPD) wi/wo Duodenal Switch (DS)

BPD, like RYGB, combines both restrictive and malabsorptive mechanisms. The stomach is partially resected, but the remaining capacity is generous compared to that achieved with the RYGB. As such, patients eat relatively normal-sized meals and do not need to radically restrict intake. Because the most proximal areas of the small intestine (i.e., the duodenum and jejunum) are bypassed, substantial malabsorption occurs. Although this procedure is less commonly performed than either banding procedures or RYGB, the approach is strongly favored by some bariatric surgeons. The partial biliopancreatic diversion with duodenal switch is a variant of the BPD procedure. Recently, a number of centers in the United States and Canada have begun to perform this procedure, which involves resection of the greater curvature of the stomach, preservation of the pyloric sphincter, and transection of the duodenum above the ampulla of Vater with a duodeno-ileal anastamosis and a lower ileo-ileal anastamosis.

3. Laparoscopic Adjustable Gastric Banding (LABG)

Gastric banding achieves weight loss by gastric restriction, not malabsorption. A band creating a gastric pouch with a capacity of approximately 15 to 30 cc encircles the uppermost portion of the stomach. The band is an inflatable doughnut-shaped balloon, the diameter of which can be adjusted in the clinic by adding or removing saline via a port that is positioned beneath the skin. The bands used today are adjustable, allowing the size of the gastric outlet to be modified as needed, depending on the rate of a patient's weight loss. Today, essentially all of the banding procedures are performed laparoscopically.

4. Vertical Gastric Banding (VBG)

VBG uses mechanical restriction to cause weight loss, a similar mechanism to that used in LAGB, with no malabsorption component. However, the upper part of the stomach is stapled (see diagram below) creating a narrow gastric inlet or pouch that remains connected with the remainder of the stomach. In addition, a non-adjustable band is placed around this new inlet in an attempt to prevent future enlargement of the stoma (opening). As a result, patients experience a sense of fullness after eating small meals. Weight loss from this procedure results entirely from eating less. VBG was one of the more common surgical procedures for weight loss in the late 1980s and early 1990s but has been largely supplanted by LAGB since 1995 and now its role in the treatment of patients with severe obesity is limited.

Evidence Review

CMS performed two literature searches:

1. The complete Medline database on the terms ((Bariatric or Obesity) AND Surgery) AND (Elderly OR Older).
2. Medline from 4April 2003 to the present using the terms ((Bariatric or Obesity) AND Surgery) since existing Technology Assessments (TAs) covered data through June 2003. We updated our search as recently as October 12, 2004.

Inclusion criteria

1. Published in the English language between April 2003 and the present for all ages.
2. Technology assessments and papers included in them that had data on bariatric surgery and were published in the last 7 years.
3. Data on outcomes of short-term mortality, initial and sustained weight loss, co-morbidities, long-term survival.
4. Published at any time in the English language and having data on persons 50 years of age and older.
5. Not having to do with bariatric surgery in adolescents with obesity.

A team of four analysts graded all 184 papers located by our search as either unacceptable or acceptable. Fifty of these referenced the elderly and 42 of those papers were published earlier than April of 2003. Of all 184 papers, 22 were considered acceptable. Only data from acceptable papers were utilized in our Summary of Evidence. Of special note is that many of the studies reported to date have not had population samples representative of the general severely overweight population with respect to race, ethnicity, cultural or socioeconomic background, gender or age.

Number and Percentage of Acceptable Papers by Search type				
	Acceptable	**Not Acceptable**	**Total**	**% Acceptable**
Elderly/Older Before 04/03*	3	39	**42**	**7%**
Elderly After 04/03	8	23	**31**	**25%**
Total Elderly	11	62	**73**	**15%**
Others	11	100	**111**	**10%**
TOTAL Papers	22	162	**184**	**13%**
* Paper mentions the word elderly or older				

Numbers and Percentages of Acceptable Papers by Type of Study				
Type of study	**Acceptable**	**Not Acceptable**	**Total**	**% Acceptable**
RCT	0	0	**0**	**0%**
NRCT	2	2	**4**	**50%**
Cohort/Observational	20	81	**101**	**20%**
Expert Opinion/Case Study/Review	1	71	**72**	**1%**
Other		7	**7**	**0%**

Unacceptable Papers by Main Reason for Rejection and Type							
Unacceptable Papers by Type ↓	**Indeterminate Results not well handled**	**Sample size small**	**Sample selection inadequate**	**Confounders not well handled**	**Follow-up insufficient**	**Other**	**Total**
NRCT			2				**2 (1%)**
Cohort/Obs.	30	18	19	4	7	3	**81 (50%)**
Expert Opinion						72	**72 (44%)**
Other language						7	**7 (4%)**
Total							**162**

.

The 22 articles are summarized in evidence tables in Appendix D

Technology Assessments Reviewed

1**. "Clinical Guidelines On The Identification, Evaluation, And Treatment Of Overweight And Obesity In Adults : The Evidence Report." 1998. National Heart Lung and Blood Institute (NHLBI).**

The NHLBI report examined articles from January 1980 through September 1997 regarding gastric bypass, gastroplasty with diet, VBG, horizontal-banded gastroplasty (HBG), BPD, and RYGB. According to the report, co-morbid conditions improved after VBG and RYGB. Complications following surgery, however, were frequent and substantial: readmission, depression, staple line failure, dilated pouch, and dehydration/malnutrition. If less invasive weight loss treatments have failed in patients at high risk for obesity-related morbidity or mortality, NHLBI recommends that bariatric surgery is an option for carefully selected patients with a BMI >40 or >35 with co-morbidities.

2. "Pharmacological and Surgical Treatment of Obesity." Southern California Evidence-Based Practice Center RAND Corp. July, 2004: for Agency for Healthcare Research and Quality, U.S. Department of Health and Human Services.

Rand reviewed articles dating from 1966 to 2003 regarding gastric banding, VBG and other gastroplasty, jejunoileal bypass, RYGB, and BPD. The report found that surgery controls obesity-related co-morbid conditions more effectively than non-surgical treatments. No clear differences in mortality or complications exists between different surgical procedures. Overall mortality for bariatric surgery remains between 1 and 2%, but may be higher in some settings than others. No recommendations are made beyond future research priorities.

3. "Newer Techniques in Bariatric Surgery For Morbid Obesity." Blue Cross Blue Shield. September, 2003.

The Blue Cross Blue Shield Technology Evaluation Center (TEC) examined articles from January 1985 through August 2003 regarding open and laparoscopic gastric banding, BPD, and long-limb gastric bypass. Due to insufficient data, the committee remained unable to confidently evaluate the safety and net health benefit of any of the bariatric surgeries except RYGB. The report placed mortality associated with RYGB mortality between .5-.6%. No recommendations are made beyond the acceptance of Roux-en Y as the sole procedure meeting BCBS criteria for coverage.

4. "Executive Report." August 4, 2004. Commonwealth of Massachusetts Betsy Lehman Center for Patient Safety and Medical Error Reduction Expert Panel on Weight Loss Surgery.

The Massachusetts expert panel reviewed articles published between January 1980 and February 2004 regarding RYGB, VBG , gastric banding, and BPD. The report maintained that laparoscopic and open RYGB improve or resolve many co-morbid conditions but benefits of LAGB remain unclear. RYGB risks are substantial and include pulmonary embolism, intestinal leak, wound infection, staple line failure and long-term nutritional deficiencies. Laparoscopic techniques have a steeper learning curve than other equivalent open procedures. LAGB risks include band and port related problems, GERD, and esophagitis. The LAGB revision rate may be as high as 10%. LAGB mortality (< 0.5%) was found lower than RYGB or BPD. The Expert

panel provided extensive and specific recommendations regarding credentialing of surgeons and bariatric surgery programs.

5. "Diagnosis and Treatment of Obesity in the Elderly." University of Pittsburgh. December 18, 2003: for Agency for Healthcare Research and Quality, U.S. Department of Health and Human Services.

AHRQ reviewed articles published between January 1980 and February 2003 regarding gastric bypass, LAGB, VBG and DS. According to this assessment, current data are insufficient to evaluate safety or efficacy of bariatric surgery in the elderly . In young obese patients, surgery has been shown to improve diabetes, hypertension, dyslipidemia and quality of life (QOL), but age may increase perioperative risk of bariatric surgery. Surgical data is poor and adverse events can be very serious, including death. No recommendations are made beyond future research suggestions to analyze effects of surgery in elderly.

Outcomes after Bariatric Surgery

Sustained Weight loss

With respect to sustained weight loss, 4 of 22 acceptable articles contained data on sustained weight loss and 1of 22 articles had data on sustained weight loss in persons over the age of 65. Of the 5 TAs none had sustained weight loss data on persons over age 65 and 4 of 5 had data on sustained weight loss. We did not find data comparing sustained weight loss in persons having bariatric surgery and at least one pre-op co-morbidity, with those having bariatric surgery and no pre-operative co-morbidities**.**

The Swedish Obese Subjects (SOS) study, a case-control study with respect to outcomes from bariatric surgery,[20] reported statistically significant long-term weight loss after different types of bariatric surgery (banding and gastric bypass) as compared to controls. The study matched subjects on 18 variables, including gender, age, height, and weight. At eight years of follow-up, among 251 surgically treated patients, the average weight loss was 20 kg (or 16 percent of body weight) as compared to no change in the control group of 232 medically treated patients. Weight loss in the operated group ranged from 4.4-35kg. [21] The SOS study, the only carefully controlled trial with long-term results, also demonstrated that there was approximately 8-9 kg more sustained weight loss in VBG as compared to gastric bypass. Their results provide strong evidence of the superiority of surgical treatment for the patients that were enrolled (37-57 year olds with an average BMI of about 41kg/m^2).[22]

The NLHBI TA reported that bariatric surgery (gastric restriction [vertical gastric banding] or gastric bypass [Roux-en Y]) could result in substantial weight loss, and therefore is an available weight loss option for well-informed and motivated patients with a BMI ≥ 40 or ≥ 35, who have co-morbid conditions and acceptable operative risks.[23] They also added that RYGB produced greater long-term weight loss than gastric partitioning alone or VBG and was substantially safer than jejunoileal bypass.[24] The Massachusetts TA reported that open and laparoscopic RYGB produced short-term weight loss and improvements in co-morbid medical conditions.[25]

BPD with or without duodenal switch is effective in producing weight loss.[26] LAGB produces variable short-term weight loss and improvements in obesity-related co-morbidities and has

lower average mortality rates than RYGB or malabsorptive procedures.[27] In a case-control study by Dolan et al., it was determined that weight loss was higher in BPD than in LAGB, 64% excess weight loss (EWL) vs 48%EWL at 24 months.[28] In a study by Shen, LAGB was compared to RYGBP and it was pointed out that in LAGB, if patients had more than 6 visits postoperatively, they had 8% more EWL (50% vs. 42%), whereas there was no difference in the RYGBP group.[29]

The one acceptable paper that we found with sustained weight loss in persons close to age 65 was by Sugerman (2004). He reported on a cohort of 80 patients over age 60 with an average age of 63 years. His paper reported that, at 5 years after bypass surgery, there was an average of 27% EWL, and 50% EWL.[30] Finally, in the Gonzalez study of bypass surgery for obesity in persons over age 50, weight loss plateaued at 18 months with EWL averaging 68%, similar to that in younger age groups.[31]

Short-term mortality

In our CMS overall review 6 of 22 acceptable papers and 3 TAs reported data on short-term mortality results, none of which pertained solely to persons over 65. We were unable to locate any data comparing short-term mortality in persons having bariatric surgery and at least one pre-op co-morbidity, with those having bariatric surgery and no pre-op co-morbidities.

The Buchwald article reported the rates of short-term mortality to be 0.1% for purely restrictive procedures, 0.5 % for gastric bypass, and 1.1% for BPD or DS.[32] Flum reported a short-term mortality rate in Medicaid bariatric surgery (gastric bypass) patients of 1.9% and that 81% of the short-term mortality cases were associated with surgeon inexperience. Nineteen percent of all surgical cases in that study were performed by inexperienced bariatric surgeons defined in this study as a bariatric surgeon who had performed less than 20 operations.[33] Data from that paper yielded an approximately 8.5% short-term mortality rate in the hands of inexperienced surgeons, while the rate for experienced bariatric surgeons was 0.5%. In Herron's review short-term mortality relating to gastric banding and gastric bypass was in the range of 0.0-1.0%, while in BPD or DS, it was higher at 0.5%-2.5%.[34] In the Pope study of the National In-hospital Survey, in-hospital mortality for all bariatric surgery was reported to be 0.37% from 1990 to 1991.[35] In the Massachusetts TA, LAGB had a short term mortality rate of < 0.5%.[36] The overall VBG range of short-term mortality was 0-1.4%[37,38,39,40] and for all of bariatric surgery, short-term mortality ranged from 0.1% to 2.0%.[41,42,43,44]

In two cohort studies by Fernandez, risk factors for peri-operative death in open or laparoscopic gastric bypass were postoperative leak, pulmonary embolus, higher pre-operative weight, and hypertension. Other risk factors for mortality were age, male gender, having diabetes, and having had a a specific surgical procedure with RYGBP having a 2.7% short-term mortality rate, open RYGBP a 1.5% short-term mortality rate and LRYGBP a 0.5% rate. There were no deaths in persons older than 60 (number of cases over age 60 not shown in paper) despite the fact that being a higher age was predictive of a higher chance of mortality.[45,46] Livingston found that male gender is a predictor of mortality for patients undergoing gastric bypass surgery.[47]

Longevity

With respect to longevity, 2 of 22 of our acceptable articles had data on longevity and 1 of 22 had longevity data on person over the age of 65. Of the 5 TAs we reviewed, none had any data on longevity. We were unable to locate any data comparing longevity in persons having bariatric

surgery and at least one pre-operative co-morbidity, with those having bariatric surgery and no pre-operative co-morbidities.

There is some evidence that bariatric surgery patients have prolonged longevity and less YLL. Black males aged 30, with a BMI of 40, have 8YLL as compared to 5YLL for white males aged 30 with the same BMI. White females age 30 with BMI 40 had roughly the same YLL as white males (4-5). These differences almost disappear for person aged 60 and above with BMI 40, with black females actually having negative years of life lost at higher ages.[48] Flum reported an increase in longevity in those post-bariatric surgery Medicaid patients given that they survived to year one after the surgery.[49]

Co-morbidities

Nine of 22 of our acceptable reviewed articles had data on co-morbidities and none had co-morbidity data on persons over the age of 65. Of the 5 TAs we reviewed, none had co-morbidity data on persons over age 65 and 3 of 5 had data on co-morbidities in the general population.

Regarding the prevalence of co-morbidities in the population eligible for bariatric surgery, Pope demonstrated that the percentage of persons that had obesity surgery and had at least one major pre-operative co-morbidity was estimated to be 20.8% in 1990 and 31.4% in 1997. [50] Yet in Gonzalez' cohort study, for persons 50 years old or older, 47 of 52 (90%) had co-morbidities such as degenerative joint disease 60%, diabetes and gastroesphageal reflux disease (GERD) 40%, and hypertension 56%.[51] Approximately 90% of each type improved post-operatively with the exception of hypertension where 56% improved. In a study by Residori, 57% of patients had at least one metabolic complication with 30% having diabetes, 38% dyslipidemia, and 38% hypertension. [52] Approximately one-third of the diabetes cases and one-half of the dyslipidemia and hypertension cases were previously undiagnosed. Dindo calculated, after adjustment for BMI and age, that the occurrence of dyslipidemia was higher in Caucasians than Hispanics or African Americans, while hypertension rates were about the same.[53]

In the Swedish Obesity Study (SOS), ten-year follow-up of 1006 post-bariatric surgery patients aged 37 to 57 years showed that the two-year incidence rates of diabetes, hypertension, and low high density lipoproteins (HDL's) were statistically significantly higher in the control group (diabetes 16% vs. 0.5%, hypertension 23% vs. 6.0%, and elevated HDL's 16% vs. 5.0%).[54] From the SOS Sjostrom reported that the post-op prevalence of hypertension, after 8 years follow-up, showed no difference between VBG cases and controls, while there was a statistically significant lowering of hypertension in the group that had GBP as compared to the control group.[55] One important study, the Adelaide Study (Dixon-1988), showed that medical co-morbidities ether improved (47%) or resolved (43%) in all but 4 cases (9% of patients who all had unsatisfactory weight loss). They reported that 60 percent of the patients who initially had any obesity-related co-morbidity were free of medication for those co-morbidities 3 years after surgery.[56] Buchwald reported that for all types of bariatric surgery, diabetes completely resolved in 77% of cases, and improved or resolved in 86%; hypertension completely resolved in 62% and improved or resolved in 78%; hyperlipidemia improved in 70%; and obstructive sleep apnea (OSA) was resolved in 85%. [57] In Dolan's case-control study the resolution of co-morbidities was similar across groups having BPD as compared to those having LAGB, ranging from 66% in hypertension to 100% of OSA.[58]

Complications

In our CMS review 5 of 22 acceptable papers and 3 of 5TAs reported data on complication results in patients, while 2 of 22 acceptable papers and no TAs reported data on persons over 65 years. We were unable to locate any data comparing complication rates in persons having bariatric surgery and at least one pre-op co-morbidity, with those having bariatric surgery and no pre-op co-morbidities.

Laparoscopic adjustable silicone gastric banding (LAGB) has a lower complication rate than the other bariatric surgery procedures.[59] The Dolan study showed that LapBPD had a markedly higher rate of complication (56%) as compared to 6.3% in LAGB.[60] Heron's review underscored the difference in rates of complications from RYGB and BPD versus VBG. For example, bypass procedures had lower re-operation rates in and LAGB had lower wound infection rates. Overall, the LAGB complications are somewhat lower than those in either RYGBP, BPD, or VBG. A known complication of LRYGBP is conversion from LRYGBP to the open procedure during surgery. A study by Felix showed that 3% of laparoscopic procedures were converted to open, while other studies showed a range of 1.6% re-operations in RYGBP, 11.3% in VBG, and 7.7 to 10% in LAGB.[61,62] In the converted group, risk factors for conversion were higher age, higher weight, and male gender.[63]

In other types of complications, Fernandez identified risk factors for having a leak as male gender, having diabetes, and RYGBP> LRYGBP> open RYGBP.[64] In general, wound infections ranged from 2.3% in laparoscopic cases to 11.4% in open cases.[65] In the Livingston study on procedure and in-hospital complication rates using NHIS data, risk factors for complications were higher age, and being male. In that study, the most frequent complication was pneumonia (at 2.6%), while the short-term mortality rate was 0.4% .[66] Over the 1990 to 1997 period Pope found significant decreases of in-hospital reoperations for bleeding, abscess, or dehiscence (2.2% to 1.4%); respiratory complications (7.4% to 5.9%); and a trend toward decreased in-hospital complications.[67] The Rand TA reported reduced occurrence of wound and incisional hernia complications in patients treated laparoscopically, compared to open procedures.[68] Malnutrition occurred in 2.5% in VBG to 16.9% in RYGBP and 5.8% for all bariatric surgery.[69,70] Notable in another Livingston study was that male gender is a predictor of morbidity for patients undergoing gastric bypass surgery.[71]

Conclusions

In general, for outcomes of short-and long-term mortality, co-morbidities, sustained weight loss and complications of surgery, we found there is little or no data enabling comparisons of persons who had at least one pre-operative co-morbidity with those who had none.

In the general populations we found that sustained weight loss may be an attainable goal with combination or malabsorptive procedures showing greater weight loss than restrictive procedures, which, in turn, demonstrate much more weight loss than no surgery. Sustained and sufficient weight loss may improve or resolve co-morbid conditions. We also found that short-term mortality is low, and that experienced surgeons performing bariatric surgery have a lower rate of short-term mortality than inexperienced surgeons. We also found an indication that longevity was decreased in persons with high BMI's, and increased in persons having bariatric

surgery if they survived to one-year post surgery. Laparoscopic procedures may have fewer complications than open ones.

We were unable to find any significant amount of data that apply these results to the Medicare population age 65 or more. The one TA addressing the Medicare population was also unable to locate sufficient data.

CMS sees the need for more high quality studies on clinically important gaps in the scientific evidence are indicated. In particular, evidence is needed with respect to short-term mortality, long-term survival, co-morbidities, sustained weight loss, and complications, and persons over age 65. Finally, we think that a registry for bariatric surgery patients warrants consideration.

Appendix A -

Evaluative Questions for MCAC

Medicare Coverage Advisory Committee – Evaluative Questions
Obesity Patients With One or More Co-morbidities

1. How well does the evidence address the effectiveness of Bariatric Surgery in the treatment of obesity in patients with one or more co-morbidities compared to non-surgical medical management?

** 1 – Poorly * 2 * 3 – Reasonably Well * 4 * 5 – Very Well*

1 2 3 4 5

	2. How confident are you in the validity of the scientific data on the following outcomes? *1 - No confidence* *2* *3 - Moderate Confidence* *4* *5 - High Confidence*	**3. How likely is it that the Bariatric Surgery, including RYGBP, banding and BPD will positively affect the following outcomes in obese patients with one or more co-morbidities compared to non-surgical medical management?** *1 – Not Likely* *2* *3 – Reasonable Likely* *4* *5 – Very likely*
Wt Loss (sustained)	1 2 3 4 5	1 2 3 4 5
Long-term Survival	1 2 3 4 5	1 2 3 4 5
Short-Term Mortality	1 2 3 4 5	1 2 3 4 5
Co-morbidities	1 2 3 4 5	1 2 3 4 5

4. How confident are you that the following bariatric surgeries will produce a clinically important net health benefit in the treatment of obese patients with one or more co-morbidities?

** 1 – No Confidence * 2 * 3 – Moderate Confidence * 4 * 5 – High Confidence*

RYGBP – open	1 2 3 4 5	**RYGBP – lap**	1 2 3 4 5
BPD - open	1 2 3 4 5	**BPD - lap**	1 2 3 4 5
Banding - open	1 2 3 4 5	**Banding - lap**	1 2 3 4 5

5. Based on the scientific evidence presented, how likely is it that the results of Bariatric Surgery in obese patients with one or more co-morbidities can be generalized to:

** 1 – Not Likely * 2 * 3 – Reasonably Likely * 4 * 5 – Very Likely*

a. The Medicare population (aged 65+): 1 2 3 4 5

b. Providers (facilities/ physicians) in community practice: 1 2 3 4 5

Glossary:

Obesity refers to "Class II Obesity" and "Class III Extreme Obesity." NIH defines "Class II Obesity" as BMI = 35.0 to 39.9 and Class III Extreme Obesity as BMI ≥ 40.

Co-morbidity. includes but is not limited to high risk factors such as MI, Type 2 diabetes, Hypertension and sleep apnea, etc, and may include reversal &/or prevention of same.

Validity. CMS uses "validity" here as defined by Meinert, "Validity, in the context of a treatment difference, refers to the extent to which that difference can be reasonably attributed to a treatment assignment." (Meinert CL. Clinical Trials, Overview. In: Redmond CK, Colton T, eds. Biostatistics in clinical trials. Wiley and Sons, 2001. pp. 37-51). This encompasses all issues of methodologic framework, study design, observed results, biological rationale, etc.

Net health benefit. Balance between risks and benefits including complications of surgery

RYGBP = Roux-en-Y Gastric Bypass, open and laproscopic

Banding = Laparoscopic & open

BPD = Biliopancreatic Diversion with or without Duodenal Switch, open and laproscopic

Medicare Coverage Advisory Committee – Evaluative Questions
Obesity Patients Without Co-morbidities

1. How well does the evidence address the effectiveness of Bariatric Surgery in the treatment of obesity in patients without co-morbidities compared to non-surgical medical management?

** 1 – Poorly * 2 * 3 – Reasonably Well * 4 * 5 – Very Well*

1 2 3 4 5

	2. How confident are you in the validity of the scientific data on the following outcomes? *1 - No confidence* *2* *3 - Moderate Confidence* *4* *5 - High Confidence*	**3. How likely is it that the Bariatric Surgery, including RYGBP, banding and BPD will positively affect the following outcomes in obese patients without co-morbidities compared to non-surgical medical management?** *1 – Not Likely* *2* *3 – Reasonable Likely* *4* *5 – Very likely*
Wt Loss (sustained)	1 2 3 4 5	1 2 3 4 5
Long-term Survival	1 2 3 4 5	1 2 3 4 5
Short-Term Mortality	1 2 3 4 5	1 2 3 4 5
Co-morbidities	1 2 3 4 5	1 2 3 4 5

4. How confident are you that the following bariatric surgeries will produce a clinically important net health benefit in the treatment of obese patients without co-morbidities?

** 1 – No Confidence * 2 * 3 – Moderate Confidence * 4 * 5 – High Confidence*

RYGBP – open	1 2 3 4 5	**RYGBP – lap**	1 2 3 4 5
BPD - open	1 2 3 4 5	**BPD - lap**	1 2 3 4 5
Banding - open	1 2 3 4 5	**Banding - lap**	1 2 3 4 5

5. Based on the scientific evidence presented, how likely is it that the results of Bariatric Surgery in obese patients without co-morbidities can be generalized to:

** 1 – Not Likely * 2 * 3 – Reasonably Likely * 4 * 5 – Very Likely*

c. The Medicare population (aged 65+): 1 2 3 4 5

d. Providers (facilities/ physicians) in community practice: 1 2 3 4 5

Glossary:

Obesity refers to "Class II Obesity" and "Class III Extreme Obesity." NIH defines "Class II Obesity" as BMI = 35.0 to 39.9 and Class III Extreme Obesity as BMI ≥ 40.

Co-morbidity. includes but is not limited to high risk factors such as MI, Type 2 diabetes, Hypertension and sleep apnea, etc, and may include reversal &/or prevention of same.

Validity. CMS uses "validity" here as defined by Meinert, "Validity, in the context of a treatment difference, refers to the extent to which that difference can be reasonably attributed to a treatment assignment." (Meinert CL. Clinical Trials, Overview. In: Redmond CK, Colton T, eds. Biostatistics in clinical trials. Wiley and Sons, 2001. pp. 37-51). This encompasses all issues of methodologic framework, study design, observed results, biological rationale, etc.

Net health benefit. Balance between risks and benefits including complications of surgery

RYGBP = Roux-en-Y Gastric Bypass, open and laproscopic

Banding = Laparoscopic & open

BPD = Biliopancreatic Diversion with or without Duodenal Switch, open and laproscopic

Appendix B

Definitions

BMI = Kg body weight/m^2 body height – This definition is used to assess overweight and obesity. [72]

Overweight/Obesity Classification[13]

		BMI
i.	Overweight	= 25-29.9
ii.	Class I obesity	= 30.0-34.9
iii.	Class II obesity	= 35.0-39.9
iv.	Class III (Extreme) Obesity	≥ 40.0

Morbid Obesity (MO)
2x ideal Body Weight, or
BMI≥35 with co-morbidity or BMI≥40 without co-morbidity, or
100 lbs above ideal body weight

Ideal Body Weight – Body weight considered normal according to a standard (e.g., Metropolitan Life Tables), for a given height and weight**.**

Excess Weight Loss (EWL) - % of weight above ideal body weight that is lost from the intervention. E.g., if a person has an ideal body weight of 60kg, and they weigh 100 kg they are overweight by (100-60) =40 kg. If they lose 30kg after bariatric surgery they have lost 30/40 = 75% of their excess weight, written as 75%EWL.

Appendix C

Bariatric Surgery Procedures – *Used with permission of the American Society for Bariatric Surgeons*

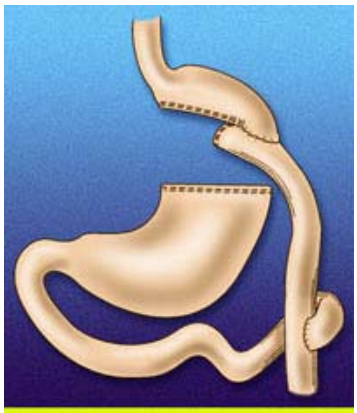

FIGURE 8
TRANSECTED ROUX-EN-Y GASTRIC BYPASS

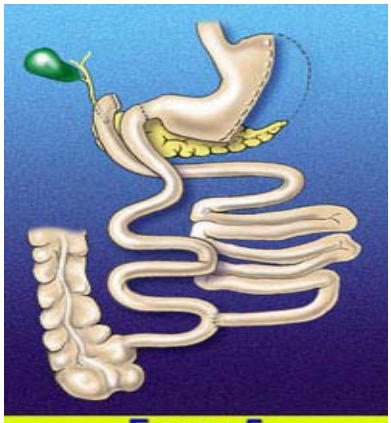

FIGURE 5
BILIOPANCREATIC DIVERSION (BPD) WITH DUODENAL SWITCH (HESS/MARCEAU)

FIGURE 16
ADJUSTABLE GASTRIC BAND "LAP BAND" (KUZMAK)

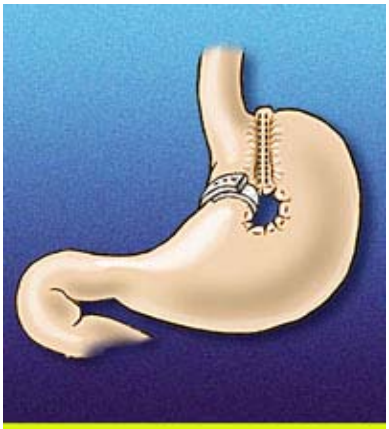

FIGURE 13
VERTICAL BANDED GASTROPLASTY (MASON)

Appendix D –

CMS Review Table of Papers and Selected Characteristics

Author, Year and Title	Study design	Demographics	Interventions (I) and Outcome measures (O)	Results	
				Intervention group	Control group
Buchwald H 2004. Bariatric surgery: A systematic review and meta-analysis	review and meta-analysis	bariatric surgery patients mean age = 39 female = 72.6% N = 22,094	I = bariatric surgery O =weight loss, operative mortality	Excess weight loss averaged 61.2% overall, 47.5% for gastric banding, 61.2% for gastric bypass, 68.2% gastroplasty, and 70.1% for BPD or DS. Rates of operative mortality were 0.1% for purely restrictive procedures, 0.5 % for gastric bypass, and 1.1% for BPD ± DS. Diabetes was completely resolved in 78.6% of cases, while improved or resolved in 86%; hypertension was completely resolved in 61.7% and improved or resolved in 78%; hyperlipidemia was improved in 70%; and OSA was resolved in 86%.	NA
Dindo D 2003 Obesity in General Elective Surgery	Retrospective cohort N = 239	Zurich Switzerland mean age = 49 female = 72%	O = many surgical procedures I= rate of complications	Obesity not a risk factor for complications with the exception of wound infection in open surgery (non-obese = 3%, obese = 4%)	NA
Dolan K 2004. A comparison of laparoscopic adjustable gastric banding and biliopancreatic diversion in superobesity	prospective case-control; matched to 23 BPD patients to 1319 LAGB patients	mean age = 39 female = 69.6% all superobese patients matched on sex, BMI and age	I = open and lap BPD vs. LAGB O= EWL, complication rate, re-operation rate, LOS, resolution of OSA, DM, HTN	BPD EWL at 24 months = 64.4%; complications = 56.6%; re-operations = 30.4%; OSA = 75%; HTN = 66%; diabetes = 100%	lap: EWL at 24 months = 48.4%; complications = 8.7%; OSA = 66%; HTN = 66%; DM =75%

Author, Year and Title	Study design	Demographics	Interventions (I) and Outcome measures (O)	Results	
				Intervention group	Control group
Felix E 2003. Conversion of laparoscopic Roux-en-Y gastric bypass	retrospective cohort N = 1236	non-converted group: mean age = 40; female = 87% converted group: mean age = 48; female = 63%	I= LRYGBP O = conversion rate	conversion rate 3 reasons for conversion: 25% technical difficulty, 10% bleeding, 10% massive liver males and older age increase chance for conversion	NA
Fernandez AZ 2003. Experience with over 3,000 open and Laparoscopic Bariatric procedures: multivariate analysis of factors related to leak and resultant mortality	Retrospective cohort N= 3073	Patients at VA Commonwealth University mean age=40.4 female= 81%	I=RYGBP O=short-term mortality	Mortality = 1.5% Leak = 3.2%	NA
Fernandez AZ 2004. Multivariate risk factors for death following gastric bypass for treatment of morbid obesity	retrospective cohort N = 2011	open group: mean age = 40.7, female = 7% lap group: mean age = 41.8, female = 86.4%	I = open or lap bypass O = death rate, SBO, leak, pulmonary embolism	lap: mortality = .7% ; leak = 4.1%; SBO = 3.3%; pulmonary embolism = 1% open: mortality = 1.9%; leak = 2.5%; SBO = 3.3%; pulmonary embolism = 1.2% leak, pulmonary embolism and pre-operative weight are risk factors for death	NA

Author, Year and Title	Study design	Demographics	Interventions (I) and Outcome measures (O)	Results	
				Intervention group	Control group
Flum D 2004. Impact of gastric bypass on operation survival: A population based analysis	retrospective cohort N = 3328	Washington state patients unoperated: mean age = 47, female = 63% operated: mean age = 43, female = 80%	I = bariatric surgery O = short term mortality, long-term survival	overall short-term mortality = 1.9%; surgeon inexperience leads to 4.7 times higher short-term mortality mortality at 15 years: non-operated = 16.3% operated = 11.8%	NA
Fontaine K 2003. Years of life lost due to obesity	retrospective cohort	U.S. population 18-85 years old NHANES	I = none O = years of life lost (YLL)	obese males have more YLL than obese females, especially at younger ages	NA
Gonzalez R 2003. Gastric bypass for morbid obesity patients 50 years or older: Is laparoscopic technique safer?	retrospective cohort N = 52	mean age = 55 female = 87%	I = LRYGBP vs. ORYGBP O = EWL, co-morbidities: HTN, hyperglycemia, LOS, mortality, morbidity	overall: decrease in HTN, hyperglycemia, EWL at 3- months = 68% lap: LOS = 3.4; morbidity = 18%; mortality = 2.6%; ICU stay = 5% open: LOS = 5.9; morbidity = 26%; mortality = 0%; ICU stay = 36%	NA
Herron D 2004. The surgical management of severe obesity	review	U.S. population	I = bariatric surgery, medication O = weight loss	long-term weight loss less than 10% with diet and medication	NA

Author, Year and Title	Study design	Demographics	Interventions (I) and Outcome measures (O)	Results	
				Intervention group	Control group
Lee WJ 2003. Clinical significance of central obesity in laparoscopic bariatric surgery	retrospective cohort	national Taiwan hospital catchment area mean age = 30.9 female = 74.8%	I = laparoscopic bariatric surgery O = comorbidities: hyperglycemia, triglyceride levels, EWL, major complications, hospital stay	central group: hospital stay = 4.3 (male), 4 (female); EWL at 3 years = 55% (male), 57.5% (female) peripheral group: hospital stay = 4.1 (male), 3.8 (female); major complications =3.06% (male), .44% (female); EWL at 3 years = 59% (male), 56% (female)	NA
Livingston EH 2002. Male gender is a predictor of morbidity and age a predictor of mortality for patients undergoing gastric bypass surgery	retrospective cohort N = 1067	female = 78% mean age = 42.3	I = gastric bypass O = mortality	renal failure = 2.2% (male), .5% (female); mortality = 3% (male), .8% (female); leak =-3.5% (male), .8% (female)	NA
Livingston EH 2004. Socioeconomic characteristics of the population eligible for obesity surgery	retrospective cohort	U.S. population National Health Information Survey (NHIS) 84% < 60 years old female = 64%	I = bariatric surgery O= eligibles for surgery	2.8% of U.S. population eligible for bariatric surgery eligibles more likely to be impoverished, less-educated and African-American	NA

Author, Year and Title	Study design	Demographics	Interventions (I) and Outcome measures (O)	Results	
				Intervention group	Control group
Livingston EH-2004. Procedure incidence and in-hospital complication rates of bariatric surgery	retrospective cohort	U.S. population National Hospital Discharge Survey (NHDS)	I = none O = national incidence and complication rates; LOS; intestinal complications; cardiac and respiratory failure	in-hospital complication rate = 9.6%; procedure incidence = 125.2 per 100,000 discharges; LOS = 4.6; intestinal complications = 2.3%; cardiac and respiratory failure = .9%	NA
Pope GD 2002. National trends in utilization and in-hospital outcomes of bariatric surgery	National Inpatient Survey(NIS) N= 12203	US population having had bariatric surgery mean age = 40.2 female = 83.6%	I = none O= rates of bariatric surgery, co-morbidities, mortality, re-operation rate, LOS, pulmonary embolism	rate of bariatric surgery increased from 2.7 to 6.3/100,000 , co-morbidities ranged from 20.9% in 1990 to 31.6% in 1997; bypass comprised 86.1% of bariatric surgeries in 1997; In-hospital mortality = 0.37%; LOS = 4; pulmonary embolism = .07%; re-operations = 1.4%	NA
Residori L 2003. Prevalence of comorbidities in obese patients before bariatric surgery: Effect of race	retrospective cohort N = 300	mean age = 37.5 female = 86.8 40% Hispanic 34% Caucasian 25% African American 1% Asian	I = none O = pre-operative comorbidity prevalence rates	57% of patients had at least one metabolic complication; diabetes prevalence = 30%; hyperlipidemia = 71.4%; hypertension = 68.8%	NA

Author, Year and Title	Study design	Demographics	Interventions (I) and Outcome measures (O)	Results	
				Intervention group	Control group
Shen R. 2004. Impact of patient follow-up on weight loss after bariatric surgery	retrospective cohort N = 355	mean age = 40.4	I = LAGB, RYGBP, patient follow-up O = EWL	LAGB patients had increased EWL on average if they had 7 or more post-op visits; no difference in RYGBP group > 7 visits = 50.4% EWL < 6 visits = 41.9% EWL	NA
Sjostrom C 2000. Differentiated long-term effects of intentional weight loss on diabetes and hypertension	Case-control N = 692	mean age = 47 (control), 46 (surgery) female = 65.9% Swedish morbid obese patients	I= bypass and restrictive surgery (VBG) O = long-term weight loss, co-morbidities	surgical group lost an average of 20.1kg at 8 years; OR for diabetes, for cases compared to controls = .16; OR for HTN, for cases compared to controls = 1.01	control group lost no weight over 8 years; diabetes 7.8 - 24.9 at 8 years
Steinbrook R 2004. Surgery for severe obesity	Expert Opinion	U.S. Population	I = none O = projected bariatric procedure rates	100,000 expected from 2003	NA
Sugerman H 2004. Effects of bariatric surgery in older patients	retrospective cohort N = 80	age $\geq$ 60 at time of bariatric surgery. mean age = 63 female = 78%	I = banding, RYGBP O = EWL, weight loss, mortality, complications, co-morbidity	EWL 49% after surgery; long-term mortality unclear, diabetes decreased 30% at 5 years; HTN decreased 30%, GERD decreased 51% wound infection in 4/88; leak in 2/88; pulmonary embolus in 1/88	

Author, Year and Title	Study design	Demographics	Interventions (I) and Outcome measures (O)	Results	
				Intervention group	Control group
Szold A 2001. Laparoscopic adjustable silicone gastric banding for morbid obesity: results and complications in 715 patients	retrospective cohort N=715	mean age=34.6 female= 76%	I= LAGB O= Complications	complications= 1.7% re-operation rate= 7.9%	NA
Zizza C 2003. Bariatric surgeries in North Carolina, 1990-2001: A gender comparison	retrospective cohort	North Carolina Hospital Discharge Data Base ≥18 years of age 78-79% state residents of NC female = 86%	I= bariatric procedures O =odds ratio of women to men having surgery	OR female: male of having bariatric surgery was 4.96 (4.39, 5.59), controlling for age and year of procedure, and residence in NC; mortality = 1.1% (female), 1.95% (male)	

Appendix E

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Appendix F
Tables of Outcomes for Summary of Evidence

Bariatric Surgery Outcomes (all ages)						
		RYGB	BPD	Vertical Banding	Lap Banding	Overall
Sustained Weight loss	Open	-	-	-	-	4.4-35.8kg[1]
	Lap	-	-	-		
	Combined	-	-	-		
Short-term Mortality	Open	-	-	-	< 0.5%[2]	.1-2%[3]
	Lap	-	-	-		
	Combined	0-1.9%[4]	.5- 2.5%[5]	0-1.4%[6]		
Long term mortality	Open	-	-	-	-	-
	Lap	-	-	-		
	Combined	-	-	-		
Comordities	Open	-	-	-	-	improved or resolved[7]
	Lap	-	-	-		
	Combined	improved or resolved[8]	improved or resolved[9]	improved or resolved[10]		

Bariatric Surgery Outcomes Age >65						
		RYGB	BPD	Vertical Banding	Lap Banding	Overall
Sustained Weight loss	Open	-	-	-	-	-
	Lap	-	-	-		
	Combined	-	-	-		
Short-term Mortality	Open	-	-	-	-	-
	Lap	-	-	-		
	Combined	-	-	-		
Long term mortality	Open	-	-	-	-	-
	Lap	-	-	-		
	Combined	-	-	-		
Comordities	Open	-	-	-	-	improved (60+)[11]
	Lap	-	-	-		
	Combined	improved (50+)[12]	-	-		

Bariatric Surgery Complications						
		RYGB	BPD	Vertical Banding	Lap Banding	Overall
N&V; dysphagia, dumping	Open	-	-	-	7%[13]	-
	Lap	-	-	-		
	Combined	[14]	37.7%[15]	17.5 %[16]		
Reflux	Open	16.9% -	-	-	4.7%[17]	-
	Lap	-	-	-		
	Combined	10.9%[18]	-	2.2%[19]		
Metabolic	Open	-	-	-	-	-
	Lap	-	-	-		
	Combined	-	-	-		
Reoperation	Open	-	-	-	7.7-10%[20]	1.4%[21]
	Lap	-	-	-		
	Combined	1.6%[22]	4.2%[23]	11.3%[24]		

Bariatric Surgery Complications (Continued)						
		RYGB	BPD	VBG	Lap Banding	Overall
Surgical (wound, hernia, stenosis)	Open	-	-	-	13.2%[25]	-[26]
	Lap	-	-	-		
	Combined	18.7-23.9%[27]	5.9%[28]	23.7%[29]		
Respiratory	Open	-	-	-	-	5.9%[30]
	Lap	-	-	-		
	Combined	2.6%[31]	-	-		
Wound Infection	Open	-	-	-	-	Open: 11.4%[32] Lap: 2.3%[33]
	Lap	-	-	-		
	Combined	-	-	-		
Malnutrition	Open	-	-	-	-	5.8%[34]
	Lap	-	-	-		
	Combined	16.9%[35]	-	2.5%[36]		

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