Oregon Health Resources Commission

Bariatric Surgery

MedTAP Report
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Health Resources Commission

The State of Oregon’s Health Resources Commission is a volunteer commission appointed by the Governor. The Health Resources Commission provides a public forum for discussion and development of consensus regarding significant emerging issues related to medical technology. Created by statute in 1991, it consists of four physicians experienced in health research and the evaluation of medical technologies and clinical outcomes; one representative of hospitals; one insurance industry representative; one business representative; one representative of labor organizations; one consumer representative; two pharmacists. All Health Resources Commissioners are selected with conflict of interest guidelines in mind. Any minor conflict of interest is disclosed.

The Commission is charged with conducting medical assessment of selected technologies, including prescription drugs. The commission may use MedTAP or subcommittees, the members to be appointed by the chairperson of the commission subject to approval by a majority of the commission. The appointees have the appropriate expertise to develop a medical technology assessment. Subcommittee meetings and deliberations are public, where public testimony is encouraged. MedTAP or subcommittee recommendations are presented to the Health Resources Commission in a public forum. The Commission gives strong consideration to the recommendations of the advisory subcommittee meetings and public testimony in developing its final reports.

Overview

The 1993 ORS 442.583 statute authorized the creation of the Medical Technology assessment program (MedTAP) that specifically directs the Health Resources Commission (HRC) to encourage the rational, responsible and appropriate allocation and use of health technology in Oregon. The HRC MedTAP report will be used to inform and influence decision makers, including consumers, through the collection, analysis, synthesis, and dissemination of information concerning the use, effectiveness and cost of health technologies.

In the spring of 2006 the Oregon Health Resources Commission (HRC) appointed an Obesity Management MedTAP to perform an evidence-based review and two reports on:

1. The use of Bariatric Surgery for the treatment of Morbid Obesity in adults

2. The comparison of surgical and non-surgical therapy for obesity

Members of the subcommittee consisted of an Internist, a Medical Director from an Oregon physician-owned liability carrier, a Cardiologist, an Endocrinologist, the Medical Director of the Health Services Commission, the Medical Director for Oregon Medicare, a Registered Dietician, a Nurse Practitioner, a Gastroenterologist, and a Pediatrician. The subcommittee held five meetings for the initial report on Bariatric Surgery. All meetings were held in public with appropriate notice provided.

MedTAP members developed and finalized key questions for the review of Bariatric Surgery specifying patient populations, interventions to be studied and outcome measures for analysis, considering both effectiveness and safety. Evidence was specifically sought for subgroups of patients based on co-morbidities, age, and other demographics.

The EPC's report, "Bariatric Surgery" prepared for the Public Employees Benefits Board (PEBB), State of Oregon was completed in May, 2005, circulated to subcommittee members and posted on the web. The EPC report was a summation of systematic reviews through 2004 and served as a basis for this report. However, since there has been considerable literature since then, the MedTAP subcommittee used the EPC's standardized methods to review and grade the medical literature through September 2006. The subcommittee met on April 24, 2006 to review the document and by consensus agreed to adopt the EPC's report. The MedTAP report was finalized at the September 26, 2006 HRC meeting. Time was allotted for public comment, questions and testimony at each meeting.

This report does not recite or characterize all the evidence that was discussed by the OH&SU EPC or the Health Resources Commission. This report is not a substitute for any of the information provided during the subcommittee process, and readers are encouraged to review the source materials. This report is prepared to facilitate the Health Resources Commission in providing recommendations to the Health Services Commission, public and private health plans, and public in general.

The Health Resources Commission will seek medical evidence for new developments in obesity management. Working cooperatively with Oregon Health Policy and Research (OHPR) Data Unit, the commission will obtain Oregon data needed to monitor the utilization of Bariatric Surgery and its effects on the health system. Substantive changes will be brought to the attention of the Health Resources Commission who may choose to reconvene an Obesity Management MedTAP. The Bariatric Surgery report will be periodically updated if indicated.

The full OHSU Evidence-based Practice Center's report, *Bariatric Surgery* is available on the Office for Oregon Health Policy & Research Medical Technology Evaluation web site. Information regarding the Oregon Health Resources Commission and its subcommittee policy and process can be found on the Office for Oregon Health Policy & Research website:
http://www.oregon.gov/DAS/OHPPR/HRC/MedTap_page.shtml
You may request more information including copies of the draft report, minutes and tapes of subcommittee meetings, from:

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Quality of the Evidence:

For quality of evidence the Obesity Management subcommittee took into account the number of studies, the total number of patients in each study, the length of the study period, and the end points of the studies. Statistical significance was an important consideration. The subcommittee utilized the EPC's ratings of "good, fair or poor" for grading the body of evidence. Poor evidence was excluded. Overall quality ratings for an individual study were based on the internal and external validity of the trial.

Internal validity of each trial was based on:

1) Methods used for randomization
2) Allocation concealment and blinding
3) Similarity of compared groups at baseline and maintenance of comparable groups
4) Adequate reporting of dropouts, attrition, and crossover
5) Loss to follow-up
6) Use of intention-to-treat analysis

External validity of trials was assessed based on:

1) Adequate description of the study population
2) Similarity of patients to other populations to whom the intervention would be applied
3) Control group receiving comparable treatment
4) Funding source that might affect publication bias.

A particular randomized trial might receive two different ratings: one for efficacy and another for adverse events. The overall strength of evidence for a particular key question reflects the quality, consistency and power of the body of evidence relevant to that question.

Key Questions:

1. What is the evidence for the effectiveness of bariatric surgery in improving objective outcomes for morbid obesity in adult (≥18) patients?

2. What are the short- and long-term adverse effects associated with bariatric surgery in adult patients? Does the incidence of adverse effects vary with duration of follow-up, specific surgical intervention, or patient characteristics?

3. Is there evidence that safety of bariatric surgery varies for specific patient subgroups and with surgical centers of excellence.

4. What is the cost-effectiveness of bariatric surgery measured in $/QALY (quality adjusted years)?

Inclusion criteria:

1. Populations:

- Adult (≥ 18) patients with morbid obesity (BMI ≥40)

$$\textbf{BMI} = \frac{\textbf{weight in pounds}}{\textbf{Height in inches}^2} \times 703$$

- Or BMI >35 with serious long term complications of:
  - Diabetes Type 2
  - Obstructive sleep apnea
  - Hyperlipidemia
  - Hypertension
  - Cardiovascular disease
  - Osteoarthritis hips/knees
- Medical and behavioral management have not been successful in sustained weight loss
- Secondary types of obesity are excluded, e.g. hypothyroidism, Cushing's disease.

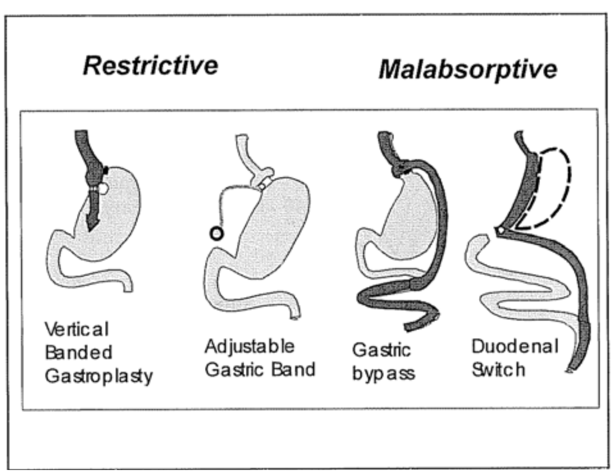
2. Exclusions

- Comorbidity causing excessive operative risk

3. Interventions

- Surgical (See Fig. 1.)
  - Gastroplasty (no longer being done in US)
    - Horizontal
    - Vertical (**VBG**)
  - Gastric Banding
    - Adjustable gastric band (**AGB**)
    - Laparoscopic adjustable gastric band (**LAGB**)
  - Roux-en-Y Bypass (**RYGB**)
    - Open RYGB
    - Laparoscopically (**LRYGB**)
  - Biliopancreatic diversion (**BPD**) or duodenal switch (**DS**)

Fig. 1



4. **Outcomes**
   - Sustained weight loss
   - Decreased mortality
   - Reduction or resolution of:
     - Diabetes Type 2
     - Hyperlipidemia
     - Hypertension
     - Mortality
     - Cardiovascular events
     - Obstructive sleep apnea
     - Disability due to hip or knee osteoarthritis
   - Reduced use of medications for:
     - Diabetes
     - Hyperlipidemia
     - Cardiovascular disease
     - Osteoarthritis
   - Higher work productivity (e.g. change in days of work lost)
   - Quality of life (QOL)
   - Ability to exercise
5. **Safety and Adverse Effects:**
   - Mortality
   - Morbidity
     - Surgical
       - Ventral hernia
       - Anastomotic leaks
       - Bleeding
       - Re-operation for stenosis
       - Wound infection
       - Splenic injury
     - Medical
       - Myocardial infarction (MI)
       - Cerebral vascular accident (CVA)
       - Pneumonia/atelectesis/respiratory insufficiency
       - Deep vein thrombophlebitis (DVT), Pulmonary embolus (PE)
     - Gastrointestinal symptoms (e.g. vomiting, dysphagia, dumping syndrome)
     - Nutritional (e.g. anemia, metabolic bone disease, and vitamin deficiency)
     - Cholelithiasis

Clinical Overview

The increased prevalence of obesity among both children and adults in the US has received much publicity. Despite the calls for action at various levels, the obesity epidemic is progressive. It is estimated that at least 5% of the adult population experiences severe obesity defined as a BMI > 40. Multiple epidemiological studies have demonstrated increasing BMI is a causative factor in many life threatening co-morbidities including type 2 DM, cardiovascular disease and cancer. Thus, it is recommended that the fourth vital sign be a calculation of BMI as part of health maintenance with weight loss therapy prescribed for all patients who have a BMI>25.

Combinations of diet therapy, behavior modification, prescribed exercise programs, and pharmacotherapy in various combinations are widely used and generally accomplish some degree of weight loss. Unfortunately, the weight loss is usually transient. The typical patient who presents for surgical evaluation has participated in multiple combinations of these interventions with variable success, with weight regain commonly occurring after treatment cessation.

Despite a 10 fold increase in the use of bariatric surgical procedures, research on these interventions continues to be reported primarily through the case series of bariatric surgeons and has focused only on selected outcomes. As a result there is a gap between the proliferation of these procedures and the evidence base needed to understand key components of their use. This gap includes an assessment of the effectiveness of bariatric surgery in the population at-large, the total impact of bariatric surgery on patients and the health care system, identification of which patients are best suited for the procedures, and the physiological mechanisms that promote weight loss after surgery.

The most important barrier to effective bariatric surgical research has been the absence of an adequate control group with meaningful long-term outcomes. Many surgeons believe that randomization to be "unethical." Patients who are considering bariatric surgery may not agree to randomization because they feel they have spent a lifetime in the "non-interventional" arm. Moreover, randomization to interventions with significant difference in the nature and timing of risk raises ethical problems involving informed consent and would not pass an Institutional Review Board (IRB). There are differences between the anticipated long-term risks of non-operative interventions including progressive weight gain and its effect on organ systems vs. the short-term and potentially life-threatening operative risk and complications.

Longitudinal follow-up in bariatric surgical research is essential. Surgical bariatric interventions are associated with different amounts of weight loss over time e.g. weight loss with adjustable gastric banding may take more time than weight loss with the Roux-en-Y gastric bypass. Older studies of bariatric surgery reveal long-term results of transient weight loss, but the majority of the procedures reported were vertical gastroplasty that has been abandoned in the US. Evaluation of the newer surgical procedures suggests greater excess weight loss maintained over time.

With the growth in the use of bariatric surgery has come increasing scrutiny of its safety. Obesity poses a long-term rather than a short-term health risk. The "elective" nature of these surgeries demands a low risk. While laparoscopic procedures have appealed to patients, they are challenging to perform and have a considerable learning curve. Media exposure of less invasive procedures has heightened the public's awareness, yet reports of adverse outcomes, the closing of bariatric surgery programs because of perceived safety problem, and the sense that inexperienced surgeons are involved in this procedure has made evaluation of bariatric surgical safety paramount.

According to the Swedish Obesity Subjects (SOS) report on obesity, there are at least ten different surgical procedures used to treat morbid obesity and several variations on these procedures. The surgical interventions can be divided into two types of procedures: malabsorptive (bypassing parts of the gastrointestinal tract to limit the absorption of nutrients) and restrictive (decreasing the size of the stomach). The two most common procedures are the Roux-en-Y gastric bypass (**RYGB**) and the Adjustable Gastric Banding (**AGB**). (See Figure 1)

RYGB is now the most commonly performed bariatric procedure in the US (75%), although the **LAGB** (20%) is increasing in popularity. Growth in the use of any type of bariatric procedure over the last decade has been truly remarkable; with more than 150,000 procedures performed in 2004 (six times those performed a decade earlier.) Oregon data confirmed that during the same decade there was an eight-fold increase in bariatric surgery.[1] This growth is likely related to the obesity epidemic, less invasive laparoscopic techniques, the availability of high volume bariatric surgical centers with improved surgical outcomes, and by increased media exposure of celebrity patients who have had successful bariatric procedures.

As the prevalence of obesity has increased in the US (33% increase in past decade), it is expected that obesity will likely overtake tobacco as the leading preventable cause of mortality.[2] Healthcare costs from obesity, now estimated at $92.6 billion/year, account for 9.1% of the total US health expenditures.[3] Cost-effective analyses (CEAs) of bariatric operations are important given the high cost of the procedures, its potential for saving future costs related to comorbidities, and the growing population of operative candidates.

In recent years, less-invasive techniques have been applied to bariatric surgery, and offer potential benefits compared to open gastric bypass, especially for lowering the complication rate. Another trend is the use of variations on gastric bypass e.g. **BPD** in attempts to maximize weight loss in patients with super-obesity (BM > 50 kg/m^2).

The desirability for prevention of morbid obesity and application of effective medical intervention for morbid obesity is recognized. Effective treatment of morbid obesity is challenging and is expected to require major advances in pharmacotherapy as well as appropriate changes in public policy. The Longitudinal Assessment of Bariatric Surgery (LABS) is a National Institutes of Health (NIH)-funded consortium of six clinical centers and a data coordinating center working in cooperation with NIH scientific staff to plan, develop, and conduct coordinated clinical, epidemiological, and behavioral research in the field of bariatric surgery. Topics include improving patient safety, more detailed identification of optimal candidates for specific bariatric surgical procedures, responses of specific co-morbidities to surgical intervention, and the mechanism of action of the different surgical procedures.

Summary of Results

Bariatric surgery is potentially an option for patients with morbid obesity when less invasive methods of weight loss such as dietary, exercise, pharmacotherapy, and/or behavior modification have failed or the patient is at high risk for obesity related morbidity or mortality. Common comorbidities relating to obesity include, but are not limited to, hypertension, sleep apnea, diabetes, dyslipidemia, arthritis that limits function, and gastroesophogeal reflux disease (GERD).

Key Question 1 ***What is the evidence of the effectiveness for bariatric surgery for adult patients with morbid obesity(BMI>40 or BMI >35 with comorbidities) in improving: a) weight loss, b)diabetes, c) hyperlipidemia, d) hypertension, e) mortality, f) cardiovascular disease, g)obstructive sleep apnea, , and h)osteoarthritis of hips and knees.***

1a. For weight loss

Three head-to-head studies compared bariatric surgery with a non-surgically treated controlgroup. A 1988 non-randomized study of 60 patients compared horizontal gastroplasty (early form of gastric stapling) and diet with diet alone at 6 months, 24 months, and 5 years. At 6 months weight loss did not differ between the 2 groups, but at 24 months the net weight change from baseline greatly favored surgical therapy (30.5 kg surgical vs. 8.0 kg non-surgical) and this difference persisted at 5 years.[4] A second study compared jejuno-ileal bypass in 196 patients with medical treatment at 24 months greatly favored surgical therapy (mean difference 37 kg).[5] This study, conducted more than 20 years ago, assessed procedures that are not currently considered relevant, and would not pass a current IRB as the patients did not receive informed consent prior to randomization.

A good recent randomized controlled trial (80 patients) from Australia assessed treatment of mild to moderate obesity (BMI 30-35) assigned either laparoscopic banding (LAGB) or an intensive medical program revealed that at 2 years the surgical group had greater excess weight loss of 21.6% (CI, 77.7% to 96.6%) while the non-surgical groups had a loss of 5.5% (CI, 11.9% to 31.6%) ($p<0.001$).[6] They did not study patients with a BMI >35 because “current observational data suggest that outcomes after non-surgical treatment were unlikely to be equal to those after surgical care for these patients.” However our review requires BMI ≥ 35, thus this data is not relevant, though interesting.

Reports from the long-term prospective controlled intervention trial SOS study of 2010 patients reported a significant maximum weight loss at 1 year follow-up in the surgical subgroups compared to controls: **RYGB** 32%, **VBG** 25%, and **AGB** 20%[7]. After 10 years weight loss for the groups was 25%, 16%, and 14% respectively.[8]

Weight loss varies by type of procedure. One systematic review compared **RYGB** to **LAGB** and concluded **RYGB** had more loss up to 2 years after surgery, but from 2-4 years after surgery, there was no significant difference between these two groups.[9]

Key Question 1a.

The Bariatric Surgery MedTAP agrees by consensus that:

- **There is good evidence that Bariatric surgery produces a sustained weight loss for adult patients with morbid obesity (BMI ≥ 40 or with BMI ≥ 35 with significant co-morbidities).**

1b. For Type 2 Diabetes Mellitus?

A systematic review and meta-analysis by Buchwald of 136 studies that included a total of 22,094 patients showed that morbidly obese individuals have a 10-28% incidence of type 2 non-insulin dependent diabetes mellitus (DM). After surgery DM was completely ameliorated in 76.8% (95% CI 70.7%-82.9%) of patients and hyperglycemia resolved or improved in 86.0% (95% CI, 78.4%-93.7%).[10] A landmark article in bariatric surgery demonstrated that resolution or marked improvement in type 2 DM begins within days after surgery even before weight loss has begun.[11] The correction of plasma insulin and glucose levels is due to changes in gastrointestinal hormones after surgery. At a 2 and 10 year follow-up a 60% decrease in the plasma glucose was seen in the surgical weight loss group of the SOS study.[12,13] Surgery also reduced the onset of diabetes after 5 years in the SOS study. Rates of *new* onset diabetes were 3.6% for the surgery group and 18.5% for the conventional group.

The Buchwald systematic review reported a gradation of diabetes resolution as a function of the operative procedure itself: 98.9% (95% CI, 96.8%-100%) for **BPD/DS**; 83.7% (95% CI, 77.3%-90.1%) for **RYGB**; 71.6% (95% CI, 55.1%-88.2%) for **VGB**; and 47.9% (95% CI, 29.1%-66.7%) for **AGB**. The study of the impact of the various bariatric procedures on incretins is receiving increasing attention.[14]

In the Maggard meta-analysis of 114 case series of surgical treatment of obesity commissioned by AHRQ through RAND 21 studies reported quantitative information on the control of diabetes.[15] The proportion of patients who had preoperative diabetes (11%) and showed improvement or resolution of diabetes after surgery ranged from 64% to 100%.

Key Question 1b.

The Bariatric Surgery MedTAP agrees by consensus that:

- **There is good evidence that Type 2 Diabetes resolves or improves after Bariatric surgery for adult patients with BMI ≥ 35.**
- **There is good evidence the onset of Type 2 Diabetes decreases after Bariatric surgery for adult patients with BMI ≥ 35.**

1c. For hyperlipidemia?

The Buchwald meta-analysis revealed improvement of hyperlipidemia, hypercholesterolemia, and hypertriglyceridemia by all bariatric surgical procedures. The percentage of patients improved was typically 70% or higher with some variation as a function of the measure used and the procedures performed. Meta analysis showed the greatest improvements in hyperlipidemia with **BPD/DS** (99.1%, 95% CI, 97.6-100%) and with **RYGB** (96.9%, 95% CI, 93.6%-100%). [16]

In the Maggard meta-analysis of the impact of bariatric surgery on dyslipidemia, 32% of patients in the 11 studies had dyslipidemia at baseline and 60%-100% reported improvement or resolution of dyslipidemia following surgery. These reported improvements are substantial, but a cause-and-effect relationship cannot be conclusively proven from case series data alone. Still these results are consistent with the improvement reported by the SOS study at 10 years for diabetes, hypertension in the **RYGB** subset for diabetes, hypertension, and sleep apnea.[17] In the SOS **RYGB** subset triglycerides were decreased by 29.9% ($p<0.001$) and cholesterol was decreased by13% ($p<0.05$)

> **Key Question 1c.**
>
> **The Bariatric Surgery MedTAP agrees by consensus that:**
>
> - **There is good evidence that Bariatric surgery improves hypertriglyceridemia and to a lesser extent hypercholesterolemia.**

1d. For hypertension?

By both meta-analysis and weighted proportions, blood pressure significantly normalized in the total patient population across all surgical procedures 61.7% (95% CI, 55.6%-67.8%). The percentage of patients in the total population whose blood pressure normalized or improved was 78.5% (95% CI, 70.8%-86.1%).[18] The rank order of efficacy among surgical groups was variable for both resolution of hypertension and resolution plus improvement.

The SOS long-term observational trial reported that hypertension benefits diminished by the 8th year of follow-up and were no longer statistically significant. However, significant decrease in both systolic and diastolic blood pressure persisted in the SOS **RYGB** subset (5% of the total—34 cases). These patients lost significantly more weight compared to the total of all bariatric surgery patients.[19]

> **Key Question 1d.**
>
> **The Bariatric Surgery MedTAP agrees by consensus that although there is good evidence that hypertension is initially improved, this benefit may not be sustained in patients who have undergone bariatric surgery.**

1e. For mortality

A recently published abstract from the ongoing SOS study reported a 31.6% ($p<0.01$) reduction in adjusted overall mortality for the surgical group.[20] Although the HRC generally does not rely on abstracts, this is an ongoing report of the SOS study using the same methods for the past 18 years. A recently reported cohort study conducted in Utah compared mortality in 8,172 patients who had gastric bypass surgery in a single practice with the same number of community controls matched for age, sex, and BMI.[21] The gastric bypass cohort had a 40% reduction in mortality ($p<0.001$) related to coronary artery disease, diabetes and cancer. This long-term study, with up to 18 years follow-up represents the largest gastric bypass cohort followed for mortality.

> **Key Question 1e.**
>
> **The Bariatric Surgery MedTAP agrees by consensus that:**
>
> - **There is evidence that Bariatric Surgery decreases mortality in adult patients with BMI ≥ 40 or with BMI≥35 with significant co-morbidities.**

1f. For cardiovascular disease

Data from the SOS study revealed a reduction in cardiovascular (especially myocardial infarction) deaths. A 5 year recent observational study with 1,035 morbidly obese patients treated with bariatric surgery compared to a matched cohort of 5,746 morbidly obese non-surgically treated controls by Sampalis revealed that bariatric patients had a significant reduction in myocardial infarctions (RR+0.71, P=0.05) and angina (RR+0.53, p <0.001.) as compared to controls [22]

> **Key Question 1f.**
>
> **The Bariatric Surgery MedTAP agrees by consensus that:**
>
> - **There is no direct evidence that Bariatric surgery significantly improves cardiovascular disease, but it may prevent future cardiovascular events.**

1g. For obstructive sleep apnea?

Two systematic reviews reported on sleep apnea outcomes. Meta-analysis on the outcome of obstructive sleep apnea found significant improvement in the total patient population group and for each surgical procedure group. [23] Obstructive sleep apnea resolved in 85.7% (95% CI, 79.2%-92.2%) of the total population and resolved or improved in 83.6% (95% CI, 71.8%-95.4%) of the population. **RYGB** was associated with the greatest reduction in resolution or improvement of sleep apnea (94.8%), followed by

VGP (90.7 %), **BPD/DS** (71.2%) and **AGB** (71.2%). The second systematic review[24] reported 95-100% of patients improved or resolved.

> **Key Question 1g.**
>
> **The Bariatric Surgery MedTAP agrees by consensus that:**
>
> - **There is evidence that Bariatric surgery improves obstructive sleep apnea.**

1h. For osteoarthritis of the hips and knees.

There were no systematic reviews, cohort studies, or case series reports that specifically addressed osteoarthritis of the hips and knees as to improving function or outcome from joint replacement after bariatric surgery.

> **Key Question 1h.**
> **The Bariatric Surgery MedTAP agrees by consensus that:**
>
> - **There is no evidence that Bariatric surgery significantly improves function or surgical outcome after joint replacement surgery.**

Key Question 2 **What are the short- and long-term mortality and morbidity associated with bariatric surgery in adult patients? Does the incidence of adverse effects vary with duration of follow-up, specific surgical interventions, or patient characteristics?**

2a. Mortality

The early (≤ 30 days) mortality rate for obesity surgery varied by type of surgery and type of study. A recent meta-analysis reported a mortality rate of 0.1% following **LAGB** compared to 0.5% for **RYGB** and 1.1% for **BPD/DS**.[25] Pooling from 15 controlled trials (907 patients) for **RYGB** shows a mortality rate of 1.0% (95% CI, 0.5% to 1.9%). Pooling of 50 case series (11,290 patients) showed 0.3% (95% CI, 0.2% to 0.4%). Pooling for **AGB** showed an early mortality rate of 0.4% (95% CI 0.01% to 2.1%) for 6 controlled trials (268 patients) and 0.02% (97.5% one-sided CI, 0% to 0.78%) for 35 case series (9222 patients) data. **BPD** data were only available in 7 case series (2808 patients). Pooled data showed an early mortality rate of 0.9% (95% CI, 0.5% to 1.3%).[1]

Five studies report the 30 day mortality rates in unselected patients from administrative data bases. Flum's report on 3328 procedures performed in the state of Washington between 1987 and 2001 found a mortality rate of 1.9%.[26] Mortality rates were significantly greater in men than women (5% and 1.2% respectively). This study also revealed a marked survival advantage after year 1 as compared to matched controls (adjusted hazard for death was 33% lower than non-operated patients).

A more recent report by Flum on **RYGB** patients (2033) performed from 2000-2002 in the state of Washington revealed a 30 day mortality rate of 1.92%.[27] A third Flum study reports mortality rates among Medicare beneficiaries in the 65 and older population as 4.8% compared to 1.7% for those under 65 years of age.[28] However, 90% of the patients were < 65 years of age and qualified for Medicare because of disability.

In 2003 Liu reported data from the California inpatient database and found that among 16,232 gastric bypass cases, the in-hospital mortality rate was 0.3%.[29] Courcoulas and associates examined administrative data from Pennsylvania and found the in-hospital mortality rate was 0.6% in 4685 patients who had gastric bypass.[30]

In 2005 Zingmond[31] using the California database and death statistics found the all-cause 30-day mortality rate for all bariatric sugery to be 0.33% for 60,077 patients and the one year mortality was 0.91%.

There are several disadvantages to using administrative data because important clinical details such as whether the patient had laparoscopic bypass or an open bypass could not be determined from the data set. Also some administrative data are not sensitive enough to differentiate which components of outcome variability are based on hospital and surgeon rather than patient features or co-morbidities.

Key Question 2a

The Bariatric Surgery MedTAP agrees by consensus that there is fair evidence for mortality:

- **Short-term mortality (≤ 30 days) for all bariatric surgery ranged from 0.3% to 1.9% depending on the source of the data (case reports vs. administrative data bases).**
- **Short-term mortality following bariatric surgery varied by procedure from 0.1% for AGB, 0.5% for RYGB, to 1.1% for BPD/duodenal switch.**
- **Mortality rates declined with increased surgical experience.**

2 b. Morbidity

The types of complications following bariatric surgery can be categorized as gastrointestinal symptoms (reflux, vomiting, dysphagia, dumping syndrome, and cholelithiasis); nutritional abnormalities (anemia, metabolic bone disease, and vitamin deficiencies); surgical complications (anastomotic leaks, stenosis, bleeding, wound infections, and incisional hernia); and medical complications such as cardiovascular or respiratory (MI, CVA, PE DVT, atelectesis, pneumonia, respiratory insufficiency, or need for ventilator support).

Reports of adverse events other than mortality varied among studies. A recent meta-analysis revealed the pooled results from 5 controlled trials comparing **RYGB** with **VBG** failed to yield any statistically significant differences between rates of adverse events.[32] Pooled results from all studies (mostly case series) revealed electrolyte and nutritional abnormalities in 17% of patients treated with **RYGB** but 0% for **LAGB**; and all GI symptoms 16.9% for **RYGB**, 7.0% for **LAGB**, and 37.7% for **BPD**. At a minimum these data indicate that the proportion of patients with adverse events may be approximately 10%-40% and that the occurrence may differ among procedures in clinically important ways.

Comparisons of open and laparoscopic procedures show differences in adverse event rates favoring laparoscopic approaches for wound infections (13.1% open vs. 0.0% laparoscopic) and incisional hernia (8.2% vs. 0.0%).

A recent, long (39 month), prospective RCT that compared laparoscopic vs. open RYGB revealed less postoperative pain, shorter hospital length of stay (LOS), fewer wound related complications, and faster convalescence for patients who underwent LRYGB.[33] There were no significant differences in the percent of excess body weight loss, rate of improvement or resolution of co-morbidities between groups, and improvement in quality of life. Late complications were similar between groups except for the rate of incisional hernia (39% open vs. 5% laparoscopic, $p<0.01$) and the rate of subsequent cholecystectomy (5% open vs. 28% laparoscopic, $p=0.03$).

A recent AHRQ study[34] using a national insurance data-base claims for 2522 bariatric surgeries in a non-elderly population from 2001-2002 reported the complication rate as 39.6% (95% CI, 37.7-41.5%) over the 180 days after discharge. The top five complications included: dumping syndrome (19.50%), complications of anastomosis (12.33%), abdominal hernias (7.09%), infections (5.67%), and pneumonia (4.10%).

Key Question 2b.

The Bariatric Surgery MedTAP agrees by consensus there is mixed evidence for morbidity:

- **Overall adverse events (including mild and reversible) range from 10-40% in observational studies.**
- **LRYGB as compared to open RYGB decreases postoperative pain, hospital LOS, wound complications, convalescence and late adverse events including infections and incisional hernia.**

Key Question 3 ***Is there evidence that safety of bariatric surgery varies for specific patient subgroups or with surgeon and/or hospital experience.***

Recently Flum compared unselected patients from administrative data bases in Washington and reported the following serious adverse events: re-operation rate of 7.9% (range 0.0% to 16.67%), post-op bleeding 1.2% (range 0.0% to 8.3%), readmission with 90 days 11.8% (range 0.0% to 18.2%) and ventilator use 2.4% (0.0% to 8.3%). In addition the re-operation rate was 12.8% in patients ≥ 60 vs. 7.5% age <60 (p=0.02); the re-admission rate was 19.9% for age ≥ 60 vs. 11.1% for age <60 (p=0.001); and ventilator use was 6.4% for age ≥ 60 vs. 1.4% for age <60 (p<0.001). Male patients were significantly more likely than female patients to suffer 30 day mortality (5% vs.1.2% [p<0.001]), re-admission (16.3% vs.10.7%[p=0.002]), and ventilator use (5% vs. 1.8% [p<0.001]). Medicaid patients did not tolerate bariatric surgery as well as non-Medicaid. Although there was no significant difference between Medicaid and non-Medicaid (adjusted for age, sex and co-morbid conditions) for 30 day mortality and re-operation rate, there was a 2.2 odds ratio (1.5-3.1) for re-admission and a 2.9 odds ratio (1.4-6.3) for ventilator use. Patients with chronic pulmonary heart disease were uncommon (n=8), however 2 of the deaths occurred in this group resulting in an adjusted odds ratio of 21 (3.9-11.3)

Using New York State's inpatient discharge data base Weller found that there was a considerably higher likelihood of postoperative complications among surgeons performing ≤100 bariatric procedures compared to those performing >100 procedures (OR 2.39, 95% CI, 1.59-3.59) after risk adjustment.[35] Likewise for each of the four hospital volume cut-off points (>100, >125, >150, or >200 bariatric procedures), there was a notably higher likelihood of postoperative complications in the lower volume hospitals. Analysis of interaction between surgeon and hospital volume indicated a markedly higher likelihood of postoperative complications among patients operated on by a low-volume surgeon (≤100 bariatric procedures) in a low-volume hospital (≤ 150 bariatric procedures) or a low-volume surgeon in a high-volume hospital than among patients operated on by a high-volume surgeon in a high-volume hospital.

Five case studies support the existence of a technical learning curve. One study[36] found that surgeons who had performed fewer than 20 procedures had patient mortality rates of 5%, compared with rates near zero for those who had performed more than 250 procedures. Schauer[37] reported an anastomotic leak rate of 10% following laparoscopic RYGB in the first 50 procedures as compared to 0% in the subsequent 100-150 procedures; Wittgrove[38] reported a 3% leak in the first 300 procedures, and 1% thereafter. Higa[39] and colleagues reported in 2000 that operative times for LAGB stabilized after 150 procedures. Suter[40] and colleagues reported major complication rates of 12.5% for the first two thirds of procedures and 2.7% for the last third. Some of these studies reported on surgeons who were instrumental in developing new techniques; thus it is possible that the potential learning curve for surgeons currently being trained will be lower because the details of the procedures have become optimized. In addition the potentially higher complication rates of low-volume surgeons may not be represented in the literature because poor results are less likely to be reported or published as case reports.

Key Question 3

The Bariatric Surgery MedTAP agrees by consensus that:

- **There is fair evidence that patients who are elderly (>65), Medicare (90% disabled and <65), Medicaid, male, or have chronic pulmonary heart disease have significantly higher mortality and morbidity rates following bariatric surgery.**
- **There is a good body of evidence that high-volume surgeons and high-volume hospitals have significantly better mortality and morbidity rates than low-volume surgeons or low-volume hospitals**

Key Question 4 ***What is the cost-effectiveness of bariatric surgery measured in $/QALY (quality adjusted years) or by other methods?***

Cost Analysis

Decision and cost analysis are powerful analytic tools that take into account probability and cost estimates associated with different management strategies using actual and modeled data. Cost effectiveness measure in $/quality adjusted years **(QALYs**) takes into account both the quantity and quality of life generated by an intervention, providing a common currency to asses the benefits gained. **QALY**s help policy makers prioritize resource allocation across programs of varying types. Interventions that have a cost/**QALY** < $50,000 (typically assigned to dialysis therapy) have, by convention, been considered cost effective. A recent systematic review assessed the cost effectiveness of bariatric surgery based on previously published reports to determine if these constitute a compelling argument for cost effectiveness.[41]

Only 3 publications reported the cost effectiveness of surgery as cost per **QALY**. In all of them surgery was found to be cost effective at < $50,000/QALY, and in one, bariatic surgery was cost saving at $4,000 per **QALY**.[42] The most comprehensive analysis used data on effectiveness based on RCTs, prospective clinical trials, and economic evaluations of different surgical procedures and nonsurgical management for morbid obesity. The calculated costs after 20 years of treatment concludes that surgery was cost effective at $20,000 per **QALY**. The impact on comorbidities was limited to diabetes and the analysis assumed only benefits in the short term (<8years).[43]

Another cost effectiveness analysis (CEA)[44] used a deterministic decision analysis model and compared the lifetime expected costs and outcomes of **RYGB** with controls receiving no treatment of their severe obesity. It demonstrated that surgery was a cost-effective alternative to no treatment in the severely obese at $5,000-$16,000 per **QALY** for women and $10,000-$35,600 per **QALY** for men. In the subpopulation of older (>45), less obese (BMI ≤ 40) men, variations in parameters such as loss of excess weight, obesity-related quality of life, complication rates, and perioperative mortality affected the cost-effectiveness ratios. In this subpopulation bariatric surgery was associated with higher cost/**QALY** than is considered cost-effective. In this analysis costs for treatment for many obesity-related diseases (GERD, sleep apnea, and degenerative joint disease) were not included. Inclusion of patients with comorbidities would probably increase complications, costs, and mortality associated with the operation, but might also be expected to result in even greater long term improvements in health-related quality of life.

A third study[45] detailed a prospective cohort of 21 operated patients, simulated lifelong follow-up using modeled decision analysis, and compared them with a hypothetical untreated cohort. This study used a societal perspective taking into account costs to society (caretakers, productivity, travel, etc) accounting for both direct and indirect costs, including those related to comorbid conditions and surgical complications, and accounted for the productivity-gain associated with significant weight loss. Unfortunately this was a small cohort undergoing **VBG** which is no longer done.

Other evaluations of utilization

Other studies have evaluated important components of cost and resource use in bariatric surgery without performing formal cost analyses. The SOS study, the largest long-term prospective controlled intervention trial of surgical and non-surgical treatment of obesity, reported that after exclusion of hospitalizations for surgical intervention and condition, there were no significant differences found between the groups in number of hospital days or hospitalization costs. Unfortunately it excluded outpatient visits and the weight loss was 16% as compared to the 35% weight loss reported with **RYGB** due to now seldom used procedures (Only 5% of the SOS study or **RYGB** patients).

In the VA system, cost of bariatric surgery has also been evaluated.[46] In a retrospective review of 25 VA patients who underwent **RYGB**, all obesity related health-care cost including hospitalizations, out-patient visits, medications and home health devices were calculated for 12 months pre- and 12 months post-surgery. The total cost of postoperative care (excluding perioperative charges) was \$2,840 compared to \$10,800 preoperatively. This was mainly due to marked reduction in outpatient visits from 55 to 18. Recent work by Sampalis and colleagues[47] in Canada demonstrated that based on calculated costs, the "break-even" point for bariatric surgery was 3.5 years. Another report by Finkelstein[48] reported that 9% of the full-time US workforce is eligible for bariatric surgery. Obese workers have 5.1 additional days of work loss and \$2230 higher annual medical costs. They calculate that the breakeven point from bariatric surgeries that assumes a 75% reduction in obesity-attributable costs is 5.0 years.

A recent administrative data base study[49] that was a retrospective study of 60,077 Californians receiving **RYGB** from 1995-2004 revealed the rate of hospitalization in the year following **RYGB** was more than double the rate in the year preceding **RYGB** (19.3% vs. 7.9%, P<.001). Furthermore a subset of patients (n=24,678) followed for 3 years, a mean of 8.4% were readmitted a year before **RYGB** while 20.2% were readmitted in the year after **RYGB**, 18.4% in the second year after **RYGB**, and 14.9% in the third year after **RYGB**. Hospitalizations prior to gastric bypass were generally for treatment of obesity-related disease; whereas following gastric bypass were diagnostic endoscopy, late complications of the procedure eg hernia repair, and plastic surgery eg panniculectomy that accounted for the majority of re-hospitalizations. Several factors may have contributed to increased rates of postoperative hospitalization that may not be sustained in the future. Zigmond et al noted that patients undergoing operation by high-volume surgeons experience fewer postoperative re-hospitalizations. Technical innovations such as the laparoscopic approach have been shown to reduce wound infections, pulmonary complications, and incisional hernias.[50]

Although an increasing number of persons with extreme obesity are undergoing bariatric surgical procedures, there has been little systematic research to help determine the risks and benefits of bariatric surgery, or to provide guidance on appropriate patient selection. To facilitate and accelerate research in this area, the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) established a bariatric surgery clinical research consortium, now known as the Longitudinal Assessment of Bariatric Surgery (LABS).

Key Question 4

The Bariatric Surgery MedTAP agrees by consensus that:

- **there is insufficient evidence at this time that bariatric surgery is cost-effective for the treatment of morbid obesity in patients with a BMI ≥40 or with BMI ≥35 with significant co-morbidities.**

Conclusion

It is the decision of the Obesity Management MedTAP that:

- **Bariatric surgery is effective for weight loss and improving the co-morbidity of diabetes for patients with BMI ≥40, or for BMI ≥35 with significant co-morbidities.**
- **Bariatric surgery is effective for reduced mortality in long-term (18 years) studies.**
- **Significant adverse outcomes are minimized with increased surgical experience.**
- **Subpopulations of elderly, male, Medicaid, and those with chronic pulmonary heart disease are at higher risk for mortality and morbidity.**
- **High volume bariatric surgeons and high-volume hospitals have significantly improved outcomes.**
- **We will await LABS reports before deciding if bariatric surgery is cost-effective for the treatment of morbid obesity in patients with a BMI ≥40 or BMI ≥35 with significant co-morbidities.**

Eligibility Criteria

Consideration of both patient and provider eligibility criteria is a key factor in benefit design for bariatric surgery. Recent outcome research points to wide variability in rates of morbidity and mortality after surgery. These rates are influenced by patient and provider factors that can be modified with plan design. For example, studies have shown that more experienced surgeons and centers have lower rates of adverse events and morbidity. In a 2004 retrospective study using administrative discharge data on patients who had gastric bypass surgery in Washington, hospitals where surgeons perform more than 100 procedures over a 3-year period had better outcomes even after adjustment for some important patient variables. Patient factors that affected outcomes included advanced age, male gender, and comorbid pulmonary hypertension.

These recommended criteria reflect those used to choose patients who have participated in bariatric surgery studies (our evidence base) and those developed by groups outside Oregon. These criteria are proposed as a foundation for discussion and not as a definitive guide, as the process of identifying appropriate candidates for bariatric surgery is not an exact science. Requiring step evaluations and program compliance over time screens for patient motivation, the ability to make life-long lifestyle changes, and minimizes adverse selection. Participation in a comprehensive life-management program with support from several health disciplines offering weight loss approaches seem to offer patients the best chance for a successful outcome from bariatric surgery.

Discussion of the current distribution of Oregon Bariatric Surgeries by hospital included the clustering of cases within the Willamette valley. See Figure 2. The data over the past 10 years suggests a trend towards discontinuation of bariatric surgery in low volume hospitals favoring higher volume centers. Since 2002 no hospitals reported performing fewer than 25 bariatric surgeries. There was discussion of the impact of recommending Centers of Excellence.

Fig 3. Oregon Hospitals' Bariatric Surgery Data 1995-2004

Facility Name	1995	1996	1997	1998	1999	2000	2001	2002	2003	2004	Total
Sacred Heart Medical Center Eugene	88	88	114	133	106	111	151	165	90	79	1125
Legacy Good Samaritan Hospital				1	19	64	121	179	278	231	893
OHSU Hospital		4	8	15	55	114	111	157	215	145	824
Bay Area Hospital				3	8	15	37	150	138	76	427
Merle West Medical Center						5	55	94	146	105	405
Kaiser Sunnyside Medical Center	1	2	2	3	4	1	29	40	69	59	210
St. Charles Medical Center (Bend)								44	67	50	161
Providence Portland Medical Center	4	7	8	17	22	29	41	24			152
Good Samaritan Medical Corvallis					1	10	27	29	4	16	87
Woodland Park Hosp		1					5	15	29		50
Mercy Medical Center								14	18	6	38
Adventist Medical Center									6	19	25
Salem Hospital				1	4	10	1				16
Legacy Emanuel Hospital				2	1		1		2		6
Mid-Columbia Medical Center	1	2									3
Rogue Valley Medical			1					1	1		3
Legacy Mt. Hood Medical Center			1	1							2
Providence Milwaukie Hospital				1		1					2
Providence St. Vincent Medical						1		1			2
Samaritan Lebanon Hospital			2								2
Lower Umpqua Hosp						1					1
TOTAL	**94**	**104**	**136**	**177**	**220**	**362**	**579**	**913**	**1063**	**786**	**4434**

HRC Recommend Patient Eligibility Criteria

1. **Age** ≥ 18
2. **BMI** ≥ 35 with co-morbid conditions that impose medical risk and have evidence showing benefit of surgery outweighing risk
3. **BMI** ≥ 40 with or without co-morbid conditions
4. **Participate in the following four evaluations and meet criteria as described.**
   a. **Psychosocial evaluation:** (Conducted by a licensed mental health professional)
      i. Evaluation to assess compliance with post-operative requirements.
      ii. No current substance abuse or dependence. Must be free of abuse or dependence for at least a year. Discontinue smoking.
      iii. No mental or behavioral disorder that may interfere with postoperative outcomes *
      iv. Patient with previous psychiatric illness must be stable for at least 6 months.
   b. **Medical evaluation:** (Conducted by primary care provider)
      i. Pre-operative physical condition and mortality risk assessed with patient found to be an appropriate candidate.
      ii. Maximize medical control of diabetes, hypertension, or other co-morbid conditions.
      iii. Female patient not currently pregnant with no plans for pregnancy for at least 2 years post-surgery. Contraception methods reviewed with patient agreement to use effective contraception through 2nd year post-surgery.
   c. **Surgical evaluation:** (Conducted by a licensed bariatric surgeon associated with program)
      i. Patient found to be an appropriate candidate for surgery.
      ii. Received counseling by a credentialed expert on the team regarding the risks and benefits of the procedure and understands the many potential complications of the surgery (including death) and the realistic expectations of post-surgical outcomes.
   d. **Dietician evaluation** (Conducted by licensed dietician)
      i. Evaluation of adequacy of prior dietary efforts to lose weight
      ii. Counseling in dietary lifestyle changes
5. **Participate in additional evaluations:** (Conducted after completion of medically supervised weight reduction program)
      i. Post-surgical attention to lifestyle, an exercise program and dietary changes and understands the need for post-surgical follow-up with all applicable professionals (e.g. nutritionist, psychologist/psychiatrist, exercise physiologist or physical therapist, support group participation, regularly scheduled physician follow-up visits).

* Many patients (>50%) have depression as a co-morbid diagnosis that if treated would not preclude their participation in the bariatric surgery program.

HRC Recommended Hospital Selection Guidelines

1. **Surgeon experience**
   Every participating bariatric surgeon:
   Option A**:** has performed at least 100 bariatric surgeries over the last 5 years (may include previous practice location)
   Option B: has performed at least 125 bariatric cases in a lifetime
2. **Hospital surgery volume**
   Hospital has performed at least:
   Option A**:** 100 bariatric surgeries in past 5 years
   Option B**:** 125 bariatric surgeries total
3. **Has developed a team** of committed people experienced with bariatric patients including:
   a. Medical Director
   b. Dedicated on-call surgeon when bariatric surgeon unavailable
   c. 30 minute availability of consultant
4. **Surgeon's patient mortality rate**
   Mortality rate (30 day PO $\leq$ 2%.)
5. **Outcome documentation**
   Documented system for patient follow-up for at least 5 years.

OR

The surgeon and hospital are approved as a Center of Excellence by the Surgical Review Corporation (SRC) of American Society of Bariatric Surgeons (ASBS) or by the American College of Surgeons (ACS). (See appendix A)

APPENDIX A

***CMS requires SRC or ACS Level 1 certification**

Surgical Review Corporation
American Society of Bariatric Surgeons Criteria

1. Center 125 cases/yr
2. At least one bariatric surgeon
3. Multidisciplinary team
4. Processes of care
5. Outcomes data

American College of Surgeons

Level 1 Criteria:

1. Center 125 cases/yr
2. Two bariatric surgeons, 50 cases each/yr
3. Board certified general surgery
4. Multidisciplinary team
5. Processes of care
6. Outcomes data

Level 1-a Criteria

1. Participates in ACS-NSQIP

Level 1-b

1. Does not participate in ACS-NSQIP

Level 2 Criteria

1. Center 25 cases/yr
2. Two bariatric surgeons, 50 cases each/yr

Outpatient Center

1. Same criteria as inpatient
2. transfer arrangement

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References

[1] Day H and Edund T. Oregon Health Policy and Research Data Unit (un-published)August 2006
[2] Mokdad AH, Marks JS, Stroup DF, et al. Actual cause of death in the United States 2000, *JAMA* 2004;291"1238-1245.
[3] Finkelstein EA, Fiebelkorn IC, Wang G. National medical spending attributable to overweigh and obesity: how much and who's paying? *Health Affairs(Milwood)* 2003; [Suppl W3]:219-226.
[4] Andersen T, Stokholm KH, Backer OG, et al. Long-term (5-year) results after either horizontal gastroplasty or very-low calorie diet for morbid obesity. *Int. J. Obes*. 1988:12:277-84
[5] Sjöström L, Randomized trial of jejunoileal bypass versus medical treatment in morbid obesity. The Danish Obesity Project. *Lancet.* 1979;2:1255-8
[6] O'Brien PE, Dixon JB, Laurie C, et al. Treatment of mild to moderate obesity with laparoscopic adjustable gastric banding or an intensive medical program. *Annals of Int. Medicine* May 2006;144(9):625-633.
[7] Sjöström L, Lindroos AK, Petonen M, et al. Lifestyle, diabetes, and cardiovascular risk factors 10 years after bariatric surgery *NEJM*. 2004;351:2683-93.
[8] Sjöström L Soft and hard endpoints over 5 to 18 years in the intervention trial Swedish Obese Subjects *Obesity Review* 2006;7 SA:27
[9] Maggard MA, Shugarman LR, Suttorp M, et al. Meta-Analysis: Surgical Treatment of Obesity. *Annals of Int. Medicine* - *Clinical Guidelines* April 2005;142(7):547-559. AHRQ RAND study.
[10] Buchwald H, Avidor Y, Braunwald E, et al. Bariatric Surgery: A Systematic Review and Meta-analysis. *JAMA* October 2004;292(14):1724-1728
[11] Pories WJ, Swanson MS, MacDonald KG, et al. Who would have thought it? An operation proves to be the most effective therapy for adult-onset diabetes mellitus. Ann Surg 1995;222:339-352.
[12] Sjöström L, Lissner L, Wedel H, et al. Reduction in incidence of diabetes, hypertension and lipid disturbances after intentional weight loss induced by bariatric surgery: the SOS Intervention Study. Obes Res../ 1999;7:477-484.
[13] Sjöström L Soft and hard endpoints over 5 to 18 years in the intervention trial Swedish Obese Subjects *Obesity Review* 2006;7 SA:27
[14] Hickey MS, Pories WJ, MacDonald KG et al. A New Paradigm for Type 2 Diabetes Mellitus, *Annals of Surgery,* 1998; 227:637-644
[15] Maggard M, Shugarman LR, Suttorp M, et al. Meta-Analysis: Surgical Treatment of Obesity- Clinical Guidelines *Annals of Internal Medicine* April 2005;142(7):547-559. AHRQ RAND EPC study.
[16] Buchwald H, Avidor Y, Braunwald E, et al. Bariatric Surgery: A Systematic Review and Meta-analysis. *JAMA* October 2004;292(14):1724-1728
[17] Sjöström L, Lindroos AK, Petonen M, et al. Lifestyle, diabetes, and cardiovascular risk factors 10 years after bariatric surgery *NEJM*. 2004;351:2683-93
[18] Buchwald H, Avidor Y, Braunwald E, et al. Bariatric Surgery: A Systematic Review and Meta-analysis. *JAMA* October 2004;292(14):1724-1728
[19] Sjöström L, Lindroos AK, Petonen M, et al. Lifestyle, diabetes, and cardiovascular risk factors 10 years after bariatric surgery *NEJM*. 2004;351:2683-93
[20] Sjöström L Soft and hard endpoints over 5 to 18 years in the intervention trial Swedish Obese Subjects Abstracts of the 10th International Congress on Obesity (ICO) 3-8 September 2006 Sydney, Australia; Obes Rev 2006: 7(S2); 1-370.
[21] Adams T, Gress R, Smith S, et al. Long-term mortality following gastric bypass surgery. Obesity Reviews 2006; 7 S2:94.
[22] Sampalis JS, Sampalis F, Liberman M, et al. Impact of Bariatric Surgery on Cardiovascular and Musculoskeletal Morbidity *Surgery for Obesity and Related Diseases* September 2006 E Published ahead of print.
[23] Buchwald H, Avidor Y, Braunwald E, et al. Bariatric Surgery: A Systematic Review and Meta-analysis. *JAMA* October 2004;292(14):1724-1728
[24] Shekelle PG , Morton SC, Maglione M, et al. Pharmacological and surgical treatment of *obesity. Evid Rep Technol Assess (Summ)* 2004 Jul;(103):1-6
[25] Buchwald H, Avidor Y, Braunwald E, et al. Bariatric Surgery: A Systematic Review and Meta-analysis. *JAMA* October 2004;292(14):1724-1728
[26] Flum DR, Dellinger EP Impact of gastric bypass operation on survival: a population-based analysis. *J Am Coll Surg.* 2004 Oct;199(4):543--51.
[27] Flum DR Final Report Washington State Gastric Bypass Outcomes Assessment *Prepared for DSHS* August 2004
[28] Flum DR, Salem L, Elrod JA, et al. Early mortality among Medicare beneficiaries undergoing bariatric surgical procedures. *JAMA* 2005 Oct;294(15):1903-8.

[29] Liu JH, Zingmond D, Etzioni DA, et al. Characterizing the performance and outcomes of obesity surgery in California. *Am. Surg*. 2003;134:613-21
[30] Courcoulas A, Schuchert M, Gatti G, et al. The relationship of surgeon and hospital volume to outcome after gastric bypass surgery in Pennsylvania: a 3-year summary *Surgery*. 2003;134:613-21.
[31] Zingmond Hospitalization Before and After Gastric Bypass Surgery *JAMA* October 19, 2005;294(15):1918-1924.
[32] Maggard MA, Shugarman LR, Suttorp M, et al. Meta-Analysis: Surgical Treatment of Obesity. *Annals of Int. Medicine - Clinical Guidelines* April 2005;142(7):547-559
[33] Puzziferri N. Austrheim-Smith IT, Wolfe BM, et al. Three-year follow-up of a prospective randomized trial comparing laparoscopic versus open gastric bypass. *Ann Surg.* 2006 Feb'243(2):181-8
[34] Encinosa WE, Bernard DM, Chen, CC, et al. Healthcare Utilization and Outcomes After Bariatric Surgery *Medical Care* 2006 August;44(8):706-712
[35] Weller WE, Rosati C, and Hannan EL Predictors of In-Hospital Postoperative Complications among Adults Undergoing Bariatric Procedures in New York State, 2003 *Obesity Surgery* 2006;16:702-708
[36] Flum DR, Dellinger EP Impact of gastric bypass operation on survival: a population-based analysis. *J Am Coll Surg.* 2004 Oct;199(4):543--51
[37] Schauer P, Ikramuddin S, Hamad G, et al. The learning curve for laparoscopic Rous-en-Y gastric bypass is 100 cases. *Surg endosc*. 2003;17:212-5.
[38] Wittgrove AC and Clark GW. Laparoscopic gastric bypass Roux-en-Y 500 patients, technique and results with 3-60 month follow-up. *Obes Surg.* 2000;10:233-9
[39] Higa KD, Boone KB, Ho T, et al. Laparoscopic Roux-en-Y gastric bypass for morbid obesity: technique and preliminary results of our first 400 patients. *Arch Surg.* 2000;135:1029-33.
[40] Suter M, Giusti V. Heraief E, et al. Laparoscopic Roux-en-Y gastric bypass: initial 2-year experience. *Surg Endosc*. 2003;17:603-9.
[41] Salem L, Jensen CC, and Flum DR. Are Bariatric Surgical Outcomes Worth Their Cost? A Systematic Review. J *Am Coll Surg*. 2005 Feb;200(2):270-8
[42] Van Gemert WG, Adang EM, Eop M, et al. A prospective cost-effectiveness analysis of vertical banded gastroplasty for the treatment of morbid obesity. *Obes. Surgery* 1999;9:484-491.
[43] Clegg A. Colquitt J, Sidhu M, et al. The clinical effectiveness of surgery for people with morbid obesity: a systematic review and economic evaluation. *Health Technology Assess. 2002;6:1-153*
[44] Craig BM. Tsent DS. Cost-effectiveness of gastric bypass for severe obesity. *Am. J. Med* 2002;113:491-498
[45] Van Gemert WG, Adang EM, Eop M, et al. A prospective cost-effectiveness analysis of vertical banded gastroplasty for the treatment of morbid obesity. *Obes. Surgery* 1999;9:484-491.
[46] Gallagher SF, Banasiak M, Gonzalvo JP, et al. The impact of bariatric surgery on the Veterans Administration healthcare system: a cost analysis. *Obes. Surg.* 2003;13:245-248
[47] Sampalis JS, Liberman M, Auger S, Christou NV. The impact of weight reduction surgery on health-care costs in morbidly obese patients. *Obes Surg*2004;14:939-947.
[48] Finkelstein EA, Brown DS A cost-benefit simulation model of coverage for bariatric surgery among full-time employees. *AJ Managed Care* Oct 2005;11(10):641-6
[49] Zingmond, DS,, McGory ML, and Ko CY, Hospitalization before and after gastric bypass surgery. *JAMA*; October 2005;294(15):1918-1924.
[50] Puzziferri N, Austrehim IT, Wolfe BM, et al. Three-year follow-up of a prospective randomized trial comparing laparoscopic versus open gastric bypass. *Ann Surg.* Feb 2006;243(2):181-188