Morbid Obesity Task Force
Final Report

Executive Summary

Act 2007-565 of the Alabama Legislature established the Legislative Task Force on Morbid Obesity. The Task Force had five (5) meetings from September 2007 through February 2008. The meetings were held in the State Health Officers' Board Room and the SEIB Board Room. Discussions at these meetings were recorded in minutes.

The Task Force recommendation is for an outside research firm to review insurance claims to address the research question:

"Based on insurance claims data and chart reviews, does bariatric surgery result in short-term and long-term cost savings in those insured by the State Employees Insurance Board (SEIB) and the Public Education Employees Health Insurance Plan (PEEHIP)?"

The study's calculated costs will determine the cost savings, increased costs, or cost neutral effects for bariatric surgery.

Committee Charge

Act 2007-565 of the Alabama Legislature established the Legislative Task Force on Morbid Obesity. The bill specified organizations to form the Task Force. The purpose of the Task Force, as outlined in the bill, was "to study the feasibility of implementing a pilot program to increase the funding formula of the State Employee's Health Insurance Plan for bariatric surgery in the morbidly obese as a treatment option in an effort to reduce the financial and clinical burden of morbid obesity upon the citizens of Alabama and study the long term cost of coverage for morbid obesity versus the cost of bariatric surgery by a provider, certified by either the American College of Surgeons or the American Society of Bariatric Surgery- Surgical Review Corporation Bariatric Surgery Center of Excellence program".

Background and History

The 2010 National Health Objectives include reducing the prevalence of obesity among adults to less than 15 percent; however, current data indicate that obesity is increasing rather than decreasing. In 2008, Alabama was ranked as the third most obese state in the nation.

Obesity is defined by using the Body Mass Index (BMI) which is a number calculated from a person's weight and height. BMI does not measure body fat directly, but research has shown that BMI correlates to direct measures of body fat, such as underwater weighing and dual energy x-ray absorptiometry (DXA). For adults 20 years old and older, BMI is interpreted using standard weight status categories that are the same for all ages and for both men and women. For children and teens, on the other hand, the interpretation of BMI is both age- and sex- specific.

Chart 1, on the following page, reflects the guidelines provided by the National Heart, Lung, Blood Institutes (NHLBI) of the National Institutes of Health. The standard adult classifications are Class I (mild), Class II (moderate), or Class III (severe) obesity.[1] The World Health Organization (WHO) uses the same classification system of overweight and obesity with one notable exception. The BMI range of 25 to 29.9 kg/m2 is termed pre-obese instead of overweight to reflect the higher risk potential for those with a BMI in this range.

Chart 1

NIH Classification of Overweight and Obesity by BMI

	Obesity Class	BMI (kg/m^2)
Underweight		<18.5
Normal		18.5-24.9
Overweight		25.0-29.9
Obesity	I	30.0-34.9
	II	35.0-39.9
Extreme Obesity	III	≥40

Taken directly from "The Practical Guide: Identification, Evaluation, and Treatment of Overweight and Obesity in Adults"[1]

The term morbid obesity was replaced with newer descriptive terms, including Class III obesity, extreme obesity, or clinically severe obesity. However, the term morbid obesity is still listed in the International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM), where it is used for coding and classing morbidity data from the inpatient and outpatient records, physician offices, and most National Center for Health Statistics (NCHS) surveys.

Risks

Obesity is of concern because of its implications to health and health care costs. Being obese increases the risk of many diseases and health conditions, including hypertension, dyslipidemia (for example, high total cholesterol or high levels of triglycerides), type 2 diabetes, coronary heart disease, strokes, gallbladder disease, osteoarthritis, sleep apnea and other respiratory problems, and some cancers (endometrial, breast, and colon). [2]

Obesity related health care costs have been estimated at $92.6 billion per year accounting for 9.1 percent of the total United State health expenditures. [3] Approximately half of these costs were paid by Medicaid and Medicare. A more recent study focused on state-level estimates of total Medicare and Medicaid obesity attributable medical expenditures. [4] In Alabama, the Medicare and Medicaid adult medical expenses that are attributable to obesity is estimated at $1,320 million. [2, 4] These state-estimated data are limited to direct medical costs and not indirect costs such as absenteeism and decreased productivity, attributed to obesity. [4]

Even though it is well accepted that obesity is one of the most important threats to good health and longevity, its treatment remains difficult. Bariatric

surgery procedures have been noted as an intervention that consistently helps patients achieve significant weight loss. [5] Most expert panels recommend bariatric surgery as the final treatment option after diet, exercise, lifestyle modifications, and pharmacotherapy have been exhausted. [6] The research indicates most surgery candidates have made multiple weight loss efforts. Bariatric surgery, also called gastric bypass, includes gastric restriction and gastrointestinal bypass. Gastric bypass is a hybrid operation causing both intake restriction and food malabsorption. The results are weight loss. Although there are risks associated with surgery, it is an option for well-informed, motivated patients who have clinically severe obesity (BMI ≥ 40) or a BMI ≥ 35 with serious comorbid conditions.

Studies indicate that when the surgery outcomes are as planned, bariatric surgery helps reduce health care costs. Improvements in diabetes, hypertension, hyperlipidemia, and sleep apnea are all documented.[7] Decreased use of prescription drugs alone results in a cost savings.[8] Currently, there is no evidence of increases in health care costs due to the surgery; some data indicates increased costs would occur without the surgery; and some data reflects cost reductions after the surgery. Current data from Alabama is inconclusive on the time it takes after the surgery for cost neutrality or cost savings.

Though bariatric surgery has been performed since the 1960s, research into its long term pros and cons is still in its infancy and concerns continue. The concern surrounding this surgery is two fold. First, the surgery is cost prohibitive for many and insurance coverage varies. Secondly, studies during the first two years post surgery are favorable for health improvements and cost savings; however, health problems may be noted later and surgical patients should be monitored for complications and lifestyle adjustments throughout their lives. The impressive health benefits should be balanced by the incidence of complications.[9]

The common complications are dumping syndrome, which includes vomiting, reflux, and diarrhea; anastomosis complications (resulting from the surgical joining of the intestine and stomach), such as leaks or strictures; abdominal hernias; infections; and pneumonia. These complications increase overall costs.[10] Long term health concerns, such as failure to lose weight or to regain weight and developing nutritional deficiencies, are typically attributed to non-compliance to the postoperative diet. Weight regain is not insignificant and often begins at the two year mark postoperatively and is estimated at 15% of the maximum weight loss.[9,11,12] Nutritional deficiencies can lead to irreversible health problems. Despite these concerns, the number of operations continues to increase and a possible cost savings exists.

To improve the quality of care and promote positive outcomes, the American College of Surgeons developed requirements for facilities. A hospital meeting the requirements is certified as a Bariatric Center of Excellence. [13] In addition, BlueCross BlueShield Association has a certification process, the Blue Distinction Center for Bariatric Surgery. To further enhance the quality of care, BlueCross BlueShield of Alabama established a Bariatric Surgical Network that requires physicians to meet specific requirements along with other credentialing criteria. However, in Alabama patients may select the surgeon and facility, regardless of the credentialing or training.

Findings from the National Weight Control Registry show that maintenance of successful weight loss for five years substantially decreases the risk for subsequent weight regain. It is likely that the investments that improve the opportunities for long term maintenance provide a good return in terms of health gain. Cost benefit and cost effectiveness analyses are being used to evaluate various medical treatments, of which surgery is one treatment. Quality–adjusted life year (QALY) studies provide a common currency to assess the extent of the health gained that results from healthcare interventions and when combined with costs associated with the interventions, can be used to assess their relative worth from an economic perspective. [14] The process makes it possible to compare the health profile of a patient receiving an intervention with that of a patient who does not receive the intervention. The use of QALY in resource allocation decisions provides the information needed for explicit choices to be made between patient groups competing for medical care. Because of limited resources, this method meets the demands that are placed on healthcare services. [14,15]

Questions the Task Force discussed that were beyond the scope of this proposal included the process of approving patients for the surgery, counseling prior and post surgery, and follow up procedures. It was noted that research indicates certain groups of patients tend to have poor outcomes. Those groups were listed as African Americans, the poor, those with substance abuse histories, and those with certain mental health issues.[9,16] Future research will need to address the methodological limitations of previous studies to establish the relationship between psychopathology and postoperative outcome. [9] Even though all causes of death may be lower after the surgery, suicide rates and coronary heart disease have increased in the gastric bypass population. [17] Other concerns raised were the transfer of addictions, or replacing eating with other "vices" such as alcohol abuse, uncontrolled gambling, and sexual behaviors. Large prospective studies that include widely used, standardized assessment methods and follow patients for several years are needed to best characterize this relationship.

Committee Process

Organizations to have membership in the Task Force were designated in the bill. Members included: Donald E. Williamson, MD (Chair), State Health Officer; Jamy Ard, MD, representing the Medical Association of the State of Alabama; Donald Jones, RN, representing the Alabama Hospital Association; Edward Facundus, MD, representing the bariatric surgery subspecialty of Medical Association of the State of Alabama; Representative Blaine Galliher, representing the Alabama State House of Representatives; Lee Hayes, representing PEEHIP; Debbie Strong, RD, representing the Alabama Dietetic Association; Olivia Thomas, PhD, representing the UAB School of Public Health; Deborah Unger, representing SEIB; Tim Vines, representing BlueCross BlueShield of Alabama; Helen Wilson, RN, representing the Alabama State Nurses Association; Miriam Gaines, MACT, RLD, staff assistant; and Dechelle Merritt, staff support. Senator Linda Coleman, representing the Alabama State Senate, was not able to attend the meetings but received the correspondence.

There were five (5) meetings from September 2007 through February 2008. The meetings were held in the State Health Officers' Board Room and the SEIB Board Room. Discussions at these meeting were recorded in minutes. The minutes are found in Attachment 1 through Attachment 5.

Morbid Obesity Task Force
February 19, 2008
Proposal Executive Summary:

The Morbid Obesity Task Force is recommending a well-designed and controlled review of insurance claims to address the research question:

"Based on insurance claims data and chart reviews, does bariatric surgery result in short-term and long-term cost savings in those insured by the State Employees Insurance Board (SEIB) and the Public Education Employees Health Insurance Plan (PEEHIP)?"

The study's calculated costs will determine the cost savings, increased costs, or cost neutral effects for bariatric surgery. Medical claims from members of the State Employees Insurance Board (SEIB) and the Public Education Employees Health Insurance Plan (PEEHIP) having bariatric surgery in 2007 will be reviewed. The baseline data will capture medical costs for 18 months prior to the surgery. The records will be tracked for 5 years post-surgical. The control data will be composed of medical claims from patients from the same sources having the same diagnosis codes but not undergoing the surgery.

Morbid Obesity Task Force Proposal

Introduction

The Morbid Obesity Task Force recommends the State of Alabama evaluate outcomes of bariatric surgery. The results from this study can assist state policy makers to determine how best to allocate resources and provide information concerning the economic impact of obesity in Alabama.

Proposals will be considered from independent research entities having the capability to conduct scientific research through data reviews. These entities will have no association with the Morbid Obesity Task Force. A review committee appointed by the State Health Officer will select the proposal which best meets the specifications and needs as outlined below.

Background

Obesity-related health care costs have been estimated at $92.6 billion per year accounting for 9.1 percent of the total United State health expenditures.[3] Approximately half of these costs were paid by Medicare and Medicaid. A more recent study focused on state-level estimates of total Medicare and Medicaid obesity-attributed medical expenditures. [4] In Alabama, the Medicare and Medicaid adult medical expenses that are attributable to obesity are estimated at $ 1.3 billion. [2, 4]

Gastric bypass is performed for treatment of obesity. Cost of the surgery and related care is often cited as a major barrier to payors and other interested parties. Balanced against the benefits of the surgery are the risks of peri-operative death and short-term adverse outcomes. [5]

Purpose

The concern surrounding this surgery is two-fold. First, the surgery is cost-prohibitive for many and insurance coverage varies. Secondly, although studies during the first two years post surgery are favorable for cost savings, health concerns are noted after this time. The review will address both concerns.

This study will address the research question: "Based on insurance claims data and chart reviews, does bariatric surgery result in short-term and long-term cost savings in those insured by the State Employees Insurance Board (SEIB) and the Public Education Employees Health Insurance Plan (PEEHIP)?"

This will be a case-cohort study that compares the health care costs of morbidly obese patients treated with bariatric surgery in Alabama to that of matched morbidly obese controls that were not treated surgically. Cost effectiveness will be determined by using a cost-analysis technique. The study's calculated costs will determine the cost savings, increased costs, or cost neutral

effects for bariatric surgery. Through the claims after the surgery, complications will be evaluated.

Medical Claims Reviewed

The study will follow medical claims of all members in the State Employees Insurance Board (SEIB) and the Public Education Employees Health Insurance Plan (PEEHIP) having bariatric surgery in 2007. The Alabama Medicaid Agency also has expressed an interest in the study. The baseline data will capture medical costs for 18 months prior to the surgery and five (5) years post-surgery.

Patients will be identified has having a bariatric surgery if they had a claim for any of the following procedures, as indicated by the CPT codes below. (Note: These are inclusive of procedures that may or may not be used on a routine basis. This listing includes more codes than were used for the preliminary data gathered for the committee to review.)

43842 Vertical-Banded Gastroplasty

43843 Other gastric restrictive procedures, without gastric bypass, and other than Vertical Banded Gastroplasty

43846 Gastric restrictive procedure with gastric bypass for morbid obesity; with short limb (<150 cm) Roux-en-Y

43847 Gastric restrictive procedure with gastric bypass for morbid obesity; with long limb (>150 cm) Roux-en-Y

43659 Mini -gastric bypass

43847 Biliopancreatic bypass procedure (Scopinaro)

43845 Biliopancreatic bypass with duodenal switch

43644 Laparoscopy, surgical, gastric restrictive procedure; with gastric bypass and Roux-en-Y gastroenterostomy (roux limb 150 cm or less)

43645 Laparoscopy with gastric bypass and small intestine reconstruction to limit absorption

43770 Laparoscopy, surgical, gastric restrictive procedure; placement of adjustable gastric band

43771 Revision of adjustable gastric band component only

43772 Removal of adjustable gastric band component only

43773 Removal and replacement of adjustable gastric band component only

43774 Removal of adjustable gastric band and subcutaneous port components

43886 Gastric restrictive procedure, open; revision of subcutaneous port component only

43887 Removal of subcutaneous port component only

43888 Removal and replacement of subcutaneous port component only

43848 Revision, open of gastric restrictive procedure for morbid obesity, other than adjustable gastric band (separate procedure)

S2083 Adjustment of gastric band diameter

The control data will be compiled from selected SEIB and PEEHIP cost claims from patients having the same diagnosis codes (ICD9 codes) and not undergoing the surgery. A close match between the surgical group and the control group will lessen the magnitude of difference between the groups.

Time Span

Proposals for the study will reflect a well designed, systemic review of the databases for the period June 1, 2005 through June 1, 2012.

The Proposal

The study will have two phases.

Phase 1 - Data review

The research team will compare data sets to determine exactly what data is available for Alabama, what data from different sets can be used in comparison studies, and what data sets are needed to have a consistent reporting system.

Phase II - Once data sets are compared and determined, an analytic review will be used to do comparisons.

- Patient records meeting the criteria of the specific CPT Codes will be evaluated for listed ICD9 Codes. The ICD9 Codes will be used to track costs for symptoms, diseases, conditions, and other reasons for seeking healthcare services.
- All obesity-related health care costs including hospitalizations, outpatient visits, physician office visits, prescription medications, other paramedical services, and home health devices will be calculated for 18 months before and 5 years after the operation.
    - Hospitalization costs will include the reimbursable costs allowed for hospital bed use, intensive care unit stay, nursing, medications, food, operating room costs, diagnostic procedures including all radiology and laboratory tests, disposable equipment, physician's fees, surgeon's fees, anesthesiologist's fees, preoperative evaluation fees, dietitian's consultation fees, psychiatric evaluation fees, and all paramedical services including physiotherapy.
    - The costs for the subsequent related care, including the management of complications, will be included in the total cost estimate of the bariatric surgery. Because complications following

the surgery may occur in four out of ten procedures, charges associated with the care after hospital discharge will be tracked.[18] Complications include but are not limited to leakage or bleeding of the stomach, wound-related problems, stomal stenosis, ulcers, and gallstones.

  - Problems after surgery, from patient non-compliance or education, will also be tracked. These include costs associated with addressing and treating nutritional deficiencies.

- Medication changes (prescription drugs and doses) will be reviewed to compare the costs prior to the surgery to costs after the surgery.

- Mortality rates have been documented greatest during the first 30 days after surgery. It has also been noted that for Medicaid patients or patients over 65 years, the 30 day mortality rate was greater. These higher-than-expected mortality rates are important because to date, no survival benefit has been established prospectively in patients undergoing bariatric procedures.

- Patient demographics or characteristics, such as age, weight, Body Mass Index (BMI), gender, race, socioeconomic status, and marital status will be reviewed for patterns.

Facility and Surgeon Inclusion

Facilities will be analyzed by cataloging hospitals as

a. Centers of Excellence or as Level IA Bariatric Centers of Excellence by the American College of Surgeons or non accredited facilities performing the surgery
b. Blue Distinction Centers for Bariatric Surgery or non recognized facilities performing the surgery
c. Academic based hospitals or community centers
d. Large capacity or small capacity
e. Urban or rural

Individual surgeon information will be reviewed based on their Unique Physician Identification Number. The number of claims for bariatric procedures for each surgeon will be used as a surrogate measure of surgeon volume.

Evaluations

Assessments of cost and outcomes will be made using modeled analyses that anticipate the effects of cost averaging, variability in local billing patterns and capitation issues, and allow for sensitivity testing of each assumption.

Budget Considerations

Budget projections from research entities will be reviewed for accuracy and conservative estimates. However, it is projected the total cost of the medical claims data review will be approximately $350,000. If the chart review is added, the cost will be increased to approximately $500,000.

Attachment 1

MINUTES OF THE MEETING OF THE MORBID OBESITY TASK FORCE
September 19, 2007

Attendees:
Dr. Williamson (Chair), Dr. D. Jamy Ard, Rosemary Blackmon for Donald Jones Dr. Edward Facundus, Representative Blaine Galliher, Lee Hayes, Debbie Strong Dr. Olivia Thomas, Deborah Unger, Tim Vines, Miriam Gaines (staff assistant), and Dechelle Merritt (staff assistant)

Others Invited:
Senator Linda Coleman, Helen Wilson

The first meeting of the Morbid Obesity Task Force was held September 19, 2007, in the Alabama Department of Public Health's Board Room.

Dr. Donald E. Williamson, State Health Officer, provided introductory remarks and thanked everyone for attending. Introductions followed.
Dr. Williamson reviewed the charge to the Task Force. The charge is to "study the feasibility of implementing a pilot program to increase the funding formula of the State Employees' Health Insurance Plan for bariatric surgery in the morbidly obese as a treatment option in an effort to reduce the financial and clinical burden of morbid obesity upon the citizens of Alabama and study the long-term cost of coverage for morbid obesity versus the cost of bariatric surgery by a provider, certified by either the American College of Surgeons or the American Society of Bariatric Surgery - Surgical Review Corporation Bariatric Surgery Center of Excellence program."

Dr. Williamson opened the meeting for comments. Representative Galliher explained the background of this bill and discussed a prior task force that addressed broad obesity issues. He stated this group had a much narrower scope in evaluating the cost benefits of bariatric surgery. He stated the intent of the bill is to find the statistical numbers or point where health care costs to the state are reduced, while making bariatric surgery affordable for the patient. He referred to studies indicating bariatric surgery improves patient health and stated bariatric surgery with certain conditions can result in cost savings. He acknowledged surgery complications occur but felt this study would identify the parameters needed for the state to get a return on its investments.

Dr. Williamson stated that the State Employees' Insurance Board (SEIB) had looked at their experience. Ms. Unger explained that a review was conducted in 2004 that compared data from 1999 surgeries to four years post surgery. The claims were two times higher in the second four years. The data excluded the cost of the actual surgery. Based on that study, SEIB members elected to reduce payment to 50 percent of the costs.

Dr. Facundus stated that in 1999 most surgeons were performing open bariatric surgery. He explained the review of procedure outcomes done by the Centers of Excellence showed laparoscopic surgery procedures had reduced complications. In 2003, a large shift to the laparoscopic procedure started. The number of surgeons in Alabama doing open versus laparoscopic surgery was not available at the meeting.

Dr. Thomas asked if favorable outcomes were noted with an intensive program that includes lifestyle changes and nutrition education. Dr. Facundus agreed that pre-surgery and follow-up counseling were important. Dr. Ard made additional comments concerning the need for nutritional counseling and lifestyle interventions in follow up programs. It was unknown if this type of follow up was completed in all Centers of Excellence. The need for this component in an Alabama pilot project was interjected. Mr. Vines agreed that unless wellness issues are addressed, the long term results will bring a new set of potential problems. Ms. Unger stated rewarding persons with incentives for completing scheduled appointments was also successful. An example was a 10 to 20 percent reimbursement. Mr. Vines stated Blue Cross Blue Shield (BCBS) had success with physician-directed programs. He also noted that some co-morbidities are not paid by Blue Cross and have to be covered by the patient.

Dr. Williamson posed the question of whether it was possible to compare health claims costs data of Alabama citizens who had laparoscopic surgery at a Center of Excellence for the year before to the year after surgery. The comparison would serve two purposes: to review the cost of the individuals at a Center of Excellence to see if a decrease in cost occurs after surgery and to see if patient outcome costs are less if treated by a Center of Excellence.

Mr. Vines supported the idea that the Centers of Excellence are best to use when looking for life style changes. He agreed to review BCBS data to identify the Centers. Mr. Vines, Ms. Unger, and Ms. Hayes will provide data at the next meeting as described above.

Dr. Facundus stated Louisiana had started a pilot program, but details were not available at the meeting.

Representative Galliher noted that after the data was reviewed it would help with the charge of "studying the feasibility of implementing a pilot program." Depending on the data, this task force will be responsible for constructing a pilot program for selected patients to go through sites, such as a Center of Excellence. At this point, while developing the pilot program, the group will need to decide on the key components.
Dr. Williamson stated that the pilot should be the model of how to do the entire process correctly from referrals, to skill level of the surgeons, to follow-up sessions. Alabama standards can be above the Excellence of Practice Standards if so desired.

Next Meeting Date: November 7, 2007, 2 – 4 p.m.

Attachment 2

MINUTES OF THE MEETING OF THE MORBID OBESITY TASK FORCE
November 7, 2007

Task Force Members in Attendance:
Dr. Williamson (Chair), Dr. D. Jamy Ard, Dr. Edward Facundus, Representative Blaine Galliher, Lee Hayes, Donald Jones, Debbie Strong, Dr. Olivia Thomas, Deborah Unger, Tim Vines, Miriam Gaines (staff assistant), and Dechelle Merritt (staff assistant)

Others Invited: Senator Linda Coleman, Helen Wilson

Dr. Donald E. Williamson, State Health Officer, opened the second meeting of the Morbid Obesity Task Force on November 7, 2007, in the Alabama Department of Public Health's Board Room.

Ms. Lee Hayes provided data from the Public Education Employees' Health Insurance Plan (PEEHIP) claims. (Attachment 2 A) Handouts were provided. The summary indicated the claims cost did not reduce after the surgery, however, the cost for the medications did decrease. Based on other studies, it was explained the time of the study was not long enough to see the expected decrease.

Ms. Unger provided the data from the State Employees' Insurance Board (SEIB) had looked at their experience. (Attachment 2B) Ms. Unger explained that SEIB dropped the pre-surgery requirement of participating in a supervised weight loss program due to the lack of programs available. SEIB covered a smaller population base than PEEHIP and only covered only 50 percent of the surgery costs, but had more surgeries. Ms. Unger stated with the limited time the data represents, it was not possible to make a recommendation.

Dr. Facundus provided an overview of the obesity problem in Alabama with studies supporting the cost savings and health benefits from bariatric surgery. (His Power Point is located for view at ftp://ph.state.al.us/NPA/ . The link goes to the log on page. The user name should be public, and no password is required. After clicking the "log on" button, the nutrition page opens with various power point presentations.
Dr. Facundus' Power Point is saved as "Facundus Morbid Obesity Surgery".)

During the presentation, questions were raised concerning cost benefits, patient successes, and long term follow up. Selecting appropriate criteria used to approve surgery for candidates that include a follow up component was raised as a possibility to consider. The UAB clinic works with patients ten (10)

years after the surgery versus the three to five years used in published studies and is facing nutritional concerns not documented in the short term studies.

Blaine Galliher recommended that the deadline for the report not prevent the committee from reviewing all needed materials.

Next Meeting Date: December 11, 2007, 1 – 4 p.m., State Employees Insurance Meeting Room

Quantification of Morbid Obesity and Bariatric Surgery: Roux-en-Y and Vertical Banding
PEEHIP
FY2003-2004

Total Claims paid in FY03 and FY04 for Gastric Bypass Surgery or Morbid Obesity:

	Stats			Dollars		
	FY2003	**FY2004**	**% Change**	**FY2003**	**FY2004**	**% Change**
Inpatient hospital admissions	461	683	48%	$2,315,534.34	$3,019,560.83	30.40%
Surgeon – stats only include primary surgeon	410	563	37%	$1,083,347.63	$1,421,583.30	31.22%
Anesthesiologist fees				$289,648.19	$474,904.87	63.96%
Other fees/procedures, etc.				$739,257.26	$702,599.43	-4.96%
Total spent on Diagnosis codes 278, 2780 27800 and 27801 – Per query of Access database				$4,427,787.42	$5,618,648.43	26.90%

Note: The above costs do not include sleep studies, psychiatric evaluations and nutritional counseling for potential bariatric surgery candidates. Limited CPT codes were used for these preliminary results.

PEEHIP
Public Education Employees' Health Insurance Plan

Legislative Task Force on Morbid Obesity

November 7, 2007

PEEHIP Coverage

- Payment for surgery for morbid obesity is considered if medically necessary and in compliance with guidelines of the claims administrator, Blue Cross and Blue Shield of Alabama
- Benefits will only be provided for one surgical procedure for obesity (morbid) in a lifetime.
- Benefits will not be provided for subsequent surgery for complications related to a covered surgical procedure for obesity (morbid) if the complications arise from non-compliance with medical recommendations regarding patient activity and lifestyle following the procedure.

2

Blue Cross Medical Criteria

- The condition of morbid obesity (BMI ≥ 40 or BMI ≥ 35 with presence of co-morbid conditions) must be at least 3 years of duration. Documented medical records are required.
- BMI ≥ 40, or BMI ≥ 35 with co-morbid conditions.
- Documentation of participation in medically supervised weight loss program. At least one attempt in a weight loss program must occur during the year prior to request for surgery or date of surgery.

3

Blue Cross Medical Criteria (cont'd)

- Documentation must support participation in the weight loss program for **six consecutive** months.
- A complete history and physical must be performed by the bariatric surgeon.
- The patient must be at least 18 years of age.
- Surgery will not be covered for anyone who has smoked in less than eight weeks prior to surgery.

4

PEEHIP Claims Data for Gastric Bypass Surgery

- Procedure codes used: 43644 and 46846
- Surgeries incurred for the calendar year 2005

Looked at claims data in three buckets:

1. Claims cost 18 months prior to surgery
2. Claims cost for the surgery
3. Claims cost 18 months post surgery

5

PEEHIP Results

- 84 surgeries incurred in 2005
- Claims Results:
  1. 18 months prior to surgery: $641,735.32/$7,639 per patient
  2. Surgery Cost: $573,646.87/$6,829
  3. 18 months post surgery: $832,480.00/$9,910

6

Factors to Consider

- One patient had $130,000 in post- surgery costs.
- Drug costs went down for PEEHIP patients by $76,992 or 33%.
- 105 surgeries were incurred in 2005 but 21 were not paid until 2006.

7

Conclusions

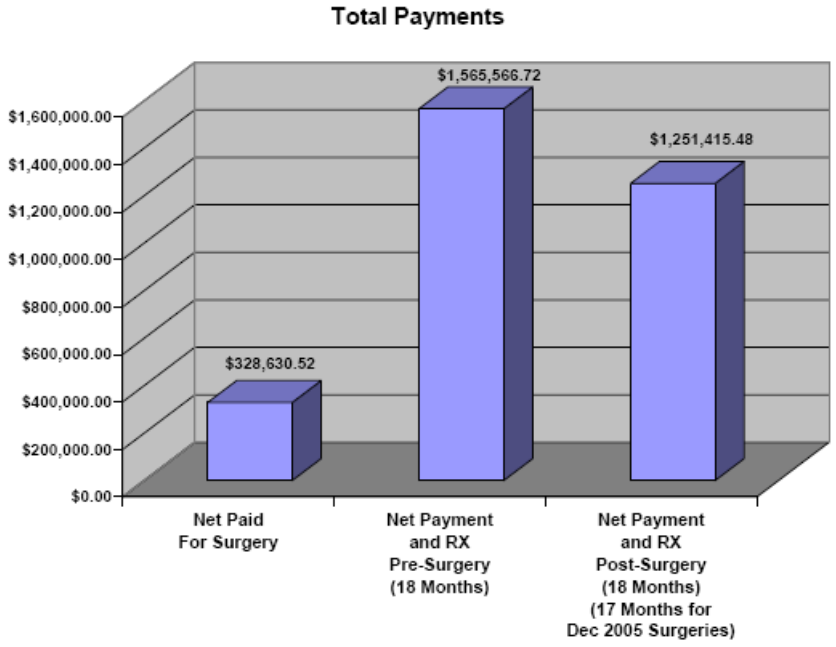
Blue Cross:

- Changed the medical criteria for bariatric surgery effective 1/1/05
- Established a bariatric provider network effective 4/1/05

Based on these two changes, PEEHIP has experienced a reduction in the number of surgical procedures and enhanced the quality of care for members with severe obesity.

8

SEIB


Total Payments
$1,565,566.72
$1,251,415.48
$328,630.52
$1,600,000.00
$1,400,000.00
$1,200,000.00
$1,000,000.00
$800,000.00
$600,000.00
$400,000.00
$200,000.00
$0.00
Net Paid For Surgery
Net Payment and RX Pre-Surgery (18 Months)
Net Payment and RX Post-Surgery (18 Months) (17 Months for Dec 2005 Surgeries)

BARIATRIC SURGICAL NETWORK

- Effective April 1, 2005, Blue Cross and Blue Shield of Alabama established a Bariatric Surgical Network to further enhance the quality of care for members with severe obesity. Physicians had to meet the necessary requirements along with other credentialing criteria to be included in the network.

- Blue Cross and Blue Shield of Alabama sent applications to all providers (both in and out of state) who had performed any bariatric procedures in the last 12 months.

- If Blue Cross and Blue Shield of Alabama received an application from a surgeon, they reviewed that surgeon's documentation that he/she was compliant with Blue Cross and Blue Shield of Alabama's pre- and post-op evaluation requirements.

- Additionally, the application required examples of the providers teaching materials and also the provider had to agree that Blue Cross and Blue Shield of Alabama could oversee the medical management of each case.

- Each network surgeon is reimbursed at the PMD rate and the facility charges are reimbursed with no change. Services received from non-PPO providers are paid at 80%. If a sub uses a PPO non-bariatric network provider, the doctor is paid at the PPO fee schedule minus 20%, and member is responsible for the 20%.

- There are 35 surgeons who have agreed to join the Blue Cross network. There are 63 surgeons in the state who perform this procedure.

- Attached is the required criterion that Blue Cross and Blue Shield of Alabama is using in the network to provide this service.

Attachment 3

MINUTES OF THE MEETING OF THE MORBID OBESITY TASK FORCE
December 11, 2007

Attendees:
Dr. Williamson (Chair), Dr. D. Jamy Ard, Dr. Edward Facundus, Representative Blaine Galliher, Lee Hayes, Debbie Strong, Deborah Unger, Tim Vines, Helen Wilson, Miriam (Mim) Gaines (staff assistant) and Dechelle Merritt (staff assistant)

Others Invited:
Senator Linda Coleman, Donald Jones, Dr. Olivia Thomas

The third meeting of the Morbid Obesity Task Force was held December 11, 2007, in the State Employees' Insurance Board (SEIB) Conference Room.

Dr. Donald E. Williamson, State Health Officer, opened the meeting. Minutes from September 19 and November 7 meetings were reviewed and adopted.

Dr. Williamson summarized the committee reports provided. The committee agreed on three points:

1. There is no evidence of increases in health care costs due to the surgery.

2. Some data indicates increased costs would occur without the surgery.

3. Some data reflects cost reductions after the surgery.

Dr. Williamson turned the meeting over to Dr. Jamy Ard. Dr. Ard presented research identifying existing and potential outcome problems that must be considered in designing a pilot study. Those four areas are summarized below.

1. Positive health outcomes for the patient should include quality of life issues in addition to cost savings factors.

Dr. Ard explained quality–adjusted life year (QALY) studies. This research compares years of life extended versus the quality of life a patient can expect. He encouraged the committee to consider the baseline data as presented in the article provided, "What is a QALY?" from the www.evidence-based-medicine.co.uk web site.

2. Patients with known adverse indicators should be denied surgery.

Those patients with known poor outcomes, or who are considered high risk groups, include African Americans, economically disadvantaged, and those with mental health issues, such as manic depression.

In explaining mental health issues, Dr. Ard stated it was not clear whether bariatric surgeries unmasked an inability to cope with unmet expectations, resulting in increased stress that had previously been dealt with using food as the coping mechanism. Deborah Unger reminded the group that mental concerns, including depression, are not always assessed by the best qualified physician. The uses of certain medications, such as Zoloft or Prozac, have increased.

Rep. Blaine Galliher noted the Michigan study used health care dollars for maximum effect, making sure that the best qualified would receive the intervention. Noting that additional funds would be requested from the Legislature to fund this pilot, he reminded the group that we need to determine the point at which health care costs to the state are reduced, while making bariatric surgery affordable for certain patients. He reminded us that this surgery is not a cure-all for addressing other life issues, and that all patients may not benefit from the surgery.

Tim Vines reminded the committee that the pilot must have standardized criteria which all physicians and facilities follow. Not doing so would cause a challenge for insurance policies.

Rep. Blaine Galliher asked if existing guidelines could be strengthened for the pilot to be designed as a comprehensive program.

3. The patients' total health needs should be addressed instead of focusing only on obesity concerns.

Dr. Ard discussed the quality of life for patients may not be as high as expected in all cases. Even though all causes of death may be lower after the surgery, suicide rates have increased in this population by 30 percent according to two large cohort studies as quoted in the New England Journal of Medicine. Other concerns are the transfer of addictions, or replacing eating with other "vices" such as alcohol abuse, uncontrolled gambling, and sex habits.

Dr. Ard stated binge eating is a disqualifying criterion for the surgery. Therefore, eating disorders may not be uncovered prior to the surgery because the patient may not acknowledge the problem. Dr. Facundus

echoed the need to have a strong dietary assessment and felt the patient should be obese for three or more years to qualify. This time factor would indicate the patient had tried to lose weight and would help control for patients intentionally gaining weight to qualify for surgery. Dr. Ard reminded the committee that a person can have eating disorders and be obese for many years. The need to have an effective screening tool to clearly delineate best outcomes was repeated.

Dr. Ard urged the committee to broaden the follow-up period in order to capture potential problems outside the previously investigated follow-up periods of about three years. In considering state employees, it was surmised there was a stability of the work force; employees tend to stay in state based jobs rather than leaving for a private industry position. This stability would enable the state to recognize the cost savings benefit of long term follow-up as a reduction in health care costs.

Dr. Facundus stated the surgery is a tool and not the end all cure. He felt the programs with strong support systems before and after the surgery had the best outcomes.

4. The design of the study should have a valid control group without withholding appropriate care standards.

The public health model of health prevention targets the majority of persons in the mid-range section, instead of only focusing on the high-risk population. Dr. Ard stated the pilot should provide an alternative intervention for those not accepted for surgery. Data indicates this obese population will continue to gain weight with no intervention.

Dr. Ard recommended all patients accepted in the pilot should go through the lifestyle intervention, whether selected for surgery or not. Lifestyle interventions, as in the *Diabetes Mellitus* study, would improve the quality of life. He reminded us the typical Western health care model does not include in-depth preventive counseling, perhaps due to reimbursement and time issues.

Dr. Facundus felt the pilot should have a true control group, which means no intervention would be provided.

Tim Vines reminded the group that intervention programs, coaching, and disease management are currently available through BCBS and SEIB. Internet MD coaching may be a possibility for part of the lifestyle intervention.

The question of how to get subjects to go through the class if not selected for the surgery was discussed. Incentive rewards were decided to be effective.

As recommended by Dr. Williamson's, the committee agreed to have Mim Gaines draft an outline of a pilot program based on the discussion. The pilot would include:

- Statewide availability through Centers of Excellence. Dr. Facundus recommended considering only those with high volume.

- An incentive for follow-up compliance.

- Inclusion criteria based on SEIB existing criteria; however, it may be stronger.
- A time frame of two to five years. As in the DM study, if the pilot proves effective, the study could be discontinued before the five years.

- A set number of participants enrolled. The cost estimate for providing intensive interventions and the number of existing surgery requests will be used to determine the number of patients accepted. (A pilot would accept fewer patients than the current number of surgeries completed.)

SEIB could continue to absorb the costs for surgery that are currently experienced, if their same criteria are used. The requested funds will cover the additional costs associated with the pilot. These costs factors include, but are not limited to, pre- and post-surgery counseling, administrative overhead of the pilot, and data collection.

At the end of the meeting, the question was if the pilot, by providing an incentive, would simply prove incentives work rather than trying to determine the statistical number or point where health care costs to the state are reduced, while making bariatric surgery affordable for certain patients. It was decided that Mim Gaines would provide the outline to be used as for future discussion. This question, as well as others that committee members were urged to formulate, will be discussed at the January meeting.

Next Meeting Date: January 15, 2008, in the SEIB Conference Room, 5th floor of the RSA Tower

Attachment 4

MINUTES OF THE MEETING OF THE MORBID OBESITY TASK FORCE
January 15, 2008

Attendees:
Dr. Williamson (Chair), Dr. D. Jamy Ard, Dr. Edward Facundus, Representative Blaine Galliher, Lee Hayes, Debbie Strong, Dr. Olivia Thomas, Deborah Unger, Tim Vines, Helen Wilson, Miriam (Mim) Gaines (staff assistant), Frances Kennamer and Michele Jones (ADPH Staff), and Dechelle Merritt (staff assistant)

Others Invited:
Senator Linda Coleman, Donald Jones

The fourth meeting of the Morbid Obesity Task Force was held January 15, 2008, in the State Employees' Insurance Board (SEIB) Conference Room.

Dr. Donald E. Williamson, State Health Officer, joined the meeting after Miriam Gaines opened the meeting. Minutes from December 11, 2007 meeting were reviewed and adopted after two changes were made. (Corrected minutes were redistributed on January 16, 2008.)

As recommended by Dr. Williamson, Miriam Gaines presented two draft proposals for a pilot program. The proposals served as the basis for the discussion. The two proposals are found in Attachments A and B.

Both proposals were tabled because of the desire on the part of the Task Force to focus on cost containment. It was agreed that a less expensive study design could be developed to review statistical data to measure outcomes, which would also provide Alabama specific data. It was felt a proposal should be written for a health care analyst to follow data in a study with retrospective and prospective capabilities. The concept of including Medicaid as part of the review was discussed. This would provide a review of costs. The study would focus on determining if bariatric surgery saved the State money. The first step would be to determine what data sets are available. A proposal will be drafted and distributed to all members.

Future work for the committee will be achieved via email unless an assembled meeting is requested. The report is due on the fifth legislative day of the 2008 Regular Session.

Executive summary: Proposal A

The Morbid Obesity Task Force is seeking funding from the Alabama Legislature to fund a well designed, prospective, controlled pilot study to address the research question:

Which method of care provides the best outcome for bariatric surgery as measured by:
(1) reduced complications
(2) cost savings from health claims (long term included) and
(3) long term weight loss maintenance?

The study involves four groups. Group One will have intensive pre and post surgery counseling. Group Two will have routine pre surgery and intensive post surgery counseling. Group Three will be patients' data compiled from selected SEIB files of patients having the same diagnosis codes and undergoing the surgery at a comparable site but not participating in the intensive pre or post follow up. Group Four will be patients' data compiled from selected SEIB files of patients having the same diagnosis codes who do not undergoing the surgery.

Groups One and Two will have100 study participants with a diagnosis of morbid obesity for three consecutive years, or be obese with co-morbid conditions; be 18 years or older; be a non smoker; have an impaired glucose tolerance; and have no history of mental illness.

The facilities will be recruited from hospitals that are a Center of Excellence or a Level IA Bariatric Center of Excellence located in Montgomery, Birmingham, Huntsville, Tuscaloosa, and Mobile.

Evaluations will include, but not be limited to the Quality–Adjusted Life Year (QALY) model.

Committee Proposal

The Morbid Obesity Task Force recommends the State of Alabama provide funding for a study to evaluate and determine criteria used for patients who undergo bariatric surgery. This recommendation will ensure people electing to pursue bariatric surgery as a weight control option will be assured of cost effectiveness of the procedures and treatment plan, and positive, quality of life outcomes.

The State will provide authority and funding to the Alabama Department of Public Health in order to accept proposals from independent research entities having the capabilities to conduct controlled scientific research in a pilot study. These entities will have no association with the Morbid Obesity Task Force. A review committee appointed by the Morbid Obesity Task Force will select the proposal designed to best meet the specifications and needs as outlined below.

The State will provide funding to State Employees Insurance Board (SEIB) to cover the additional costs for reimbursement issues as associated with direct care in the pilot.

Purpose

Gastric bypass is performed for treatment of obesity. It is a hybrid operation causing both intake restriction and food malabsorption. The results are weight loss.

The concern surrounding this surgery is two fold. First, the surgery is cost prohibitive for many and insurance coverage varies. Secondly, studies during the first two years post surgery are favorable for cost savings; however, health concerns are noted after this time period. The pilot study will address both concerns.

Proposals for the pilot study will reflect a well designed, prospective, controlled study to address the research question: Which method of care provides the best outcome for bariatric surgery as measured by (1) reduced complications (2) cost savings from health claims (long term included) and (3) long term weight loss maintenance? The method of care refers to the study groups of intensive counseling as described below.

Pilot Study

The proposal for the pilot study shall have the following components:

I. Study Participants

- The study involves four groups.
    - Group One will have fifty participants accepted for bariatric surgery, and have intensive pre and post surgery counseling from a qualified team.
    - Group Two will have fifty participants accepted for bariatric surgery, and have routine pre-surgery counseling and intensive post surgery follow up from a qualified team.
    - Group Three will be patient's data compiled from selected SEIB files of patients having the same diagnosis codes and undergoing the surgery at a comparable site but not participating in the intensive pre or post follow up.
    - Group Four will be patient's data compiled from selected SEIB files of patients having the same diagnosis codes who do not undergo the surgery. This will serve as the control.
    - A close match between the intervention surgical groups and the control group will lessen the magnitude of difference between the groups.
- Participants approved for the surgery as administered by the State Employees Insurance Board (SEIB) at the current 50 percent reimbursement rate, will be recruited for the pilot study and be eligible to receive reimbursements over the five years of the pilot to equal 100 percent of the cost covered.
- Group One and Group Two will be limited to a total of 100 participants, 50 in each group. Participants will be randomly assigned.
- Participants selected to be in Group One and Group Two will meet both SEIB criteria for the surgery and additional criteria. The criteria are:
    - Class III level of obesity (BMI $\geq$ 40) for three (3) years or $\geq$ 35 and < 39.9 with co-morbid conditions) (SEIB)
    - Age $\geq$18 (SEIB)
    - Has not smoked for one (1) year and will not be able continue participation if tobacco is used after the study starts
    - Impaired Glucose Tolerance, which is a well recognized risk factor for the development of type 2 diabetes
    - Has no history or diagnosis of mental illness * as determined by a presurgical psychological assessment, such as the

Structured Clinical Interview of DSM Disorders, or the Minnesota Multiphasic Personality Inventory (MMPI). *(IF not excluded, we will need to be able to identify them or filter them out for the results to address the methodological limitations of previous studies to establish the relationship between psychopathology and postoperative outcome.)*

- By being accepted into the study, the participant is agreeing to undergo more intensive counseling and follow up over a five year period.

Those members who apply, but are not accepted into the study due to limited space, will be referred back to SEIB.

II. Team members

The qualified team will include the surgeon, physician assistant or nurse practitioner, registered nurse, registered dietitian, psychiatric counselor/ psychologist, and exercise counselor.

III. Intervention counseling

The intensive pre and post intervention counseling will include psychological testing and counseling, healthy lifestyle counseling, and chronic disease management. The pre intervention counseling will be over a two (2) week period and the post intervention counseling will be 16 weeks.

The psychological testing and counseling will use a standardized assessment method. Refer to evaluation section.

The lifestyle intervention will be implemented with a 16- lesson core curriculum covering diet, exercise, and behavior modification that is taught on a one to one basis, followed by monthly individual and group sessions, as in the Diabetes Prevention Program (DPP).

The chronic disease management will be provided for Type 2 diabetes, coronary artery disease, hypertension, and chronic obstructive pulmonary disease. SEIB's utilization management vendor can be used for this follow up and tracking of member compliance.

All participants will receive standard lifestyle recommendation through written information and individual counseling sessions. The individual counseling will be annually, 20 to 30 minutes, to emphasize the importance of healthy lifestyles for the duration of the pilot (5 years).

Participants will have a written agreement to follow instructions through a patient- provider contract system. All team members will reinforce adherence.

IV. Time Span

The study will be conducted for three to five (3 to 5) years, with year one (1) used for recruitment of participants and collection of baseline data. The following four (4) years will be for the procedures and follow up.

V. Facility Inclusion

The goal of statewide availability will be achieved through hospitals that qualify as a Center of Excellence or as a Level IA Bariatric Center of Excellence by the American College of Surgeons. Facilities located in Montgomery, Birmingham, Huntsville, Tuscaloosa, and Mobile will be contacted. Centers willing to participate will receive training and technical assistance for pilot concerns for all of the team members involved.

With 100 total slots available, study site limitations and population data will be imposed to ensure equal statewide coverage.

VI. Standards of Care

The Standards of Care are *those required as a Center of Excellence..... CHECK these requirements. Not sure what they are*

The facility and team members must agree to provide vitamin supplementation for a minimum of iron, vitamin B12, folate, calcium, and vitamin D.

VII. Data collection

Medical data collection will include anthropometrics, resting metabolic rate, cholesterol, blood glucose, blood pressure, serum nutrient levels, bone turnover markers, co morbidity status, and prescription usage. A standardized assessment method such as the Structural Clinical Interview for DSM Disorders will be utilized for mental health issues. Data on the patient's gender, race/ethnicity, marital status, education, and socioeconomic status will be collected. Data on the patient's gender, race/ethnicity, marital status, and socioeconomic status will be collected.

Information on body weight, BMI, fat distribution, blood pressure, cholesterol, and blood glucose will be reported at each time point. Changes in patient characteristics, such as age, socioeconomic status, and marital status will be reviewed at each time point and reported if

changed. All complications will be recorded. Readmissions and visits to the emergency room will be recorded.

VIII. Evaluations

Failure to lose weight, to regain weight within the first two years postoperative, and to develop nutritional deficiencies and disease complications due to inappropriate nutrient intake are typically attributed to poor adherence to the postoperative diet.

At end of this 5 year study, the groups with intense counseling will be compared to the control and standard counseling groups. Outcome evaluations will be completed for weight loss, weight maintenance, and weight gain; medication usages through prescription refills; all complications, including the peri operative and post operative for the entire five years; percent co morbid conditions controlled; quality of life and the Quality–Adjusted Life Year (QALY); and mortality will be tracked.

Additional outcomes may also include body image and self acceptance as based on appropriate psychometric measures such as the Multidimensional Body Self Relations Questionnaire or Body Shape Questionnaire. As with improvements in health, most studies showing an improved image after the surgery have investigated changes during the first and second years. This evaluation will provide a five year follow up to better determine true self- acceptance.

The cost associated with the additional counseling will be compared to the outcome for cost to determine the cost savings, increased costs, or cost neutral effects.

<u>Budget Considerations:</u> (Note: I did not do the budget. I wanted to wait until the proposal direction is known.)

Current benefits in place at the time of the pilot will be covered as any other requests under the SEIB health plan. All additional costs as noted below will be appropriated by legislation from the general fund. As noted above, funds will be provided to SEIB for additional coverage items. Funds will be provided to ADPH for the grant award to conduct the pilot study.

NOT A COMPLETE LIST: "Shall include but not be limited to":
Additional material costs for pre and post counseling
Salary for additional team members doing the counseling, 16 weeks plus annual follow up
Data collection and lab tests,
Initial Psychological counseling/ testing
Vitamin supplements?
Incentive rewards

Attachment 4B

Executive summary: Proposal B

The Morbid Obesity Task Force is seeking funding from the Alabama Legislature to fund a well designed, prospective, and controlled pilot study to address the research question:

> Is there a way to predict who will have the best outcome with surgery for obesity? (What criteria are needed before surgery is covered?)

The pilot study will track outcomes of 100 patients undergoing intensive pre-surgery assessments. The assessment results, as compared to the surgery's five year outcome, will be used to determine which characteristics are needed to ensure quality outcomes. The comparison data will be compiled from selected SEIB files of patients having the same diagnosis codes and undergoing the surgery at a comparable site but not participating in the intensive pre assessments. The control group will be compiled of data from selected SEIB files of patients having the same diagnosis codes but selecting not to have the surgery.

The study participants will meet the current SEIB criteria and be approved for surgery. By agreeing to participate in the pilot for the entire five years, 100 percent of the costs will be covered.

The facilities will be recruited from academic based and community center hospitals having a Center of Excellence or a Level IA Bariatric Center of Excellence accreditation. Hospitals will be located in Montgomery, Birmingham, Huntsville, Tuscaloosa, and Mobile.

Committee Proposal

The Morbid Obesity Task Force recommends the State of Alabama provide funding for a pilot study to evaluate and determine criteria used for bariatric surgery. This recommendation will ensure people electing to pursue bariatric surgery as a weight control option will be assured of cost effectiveness of the procedures and treatment plan, and positive quality of life outcomes.

The State will provide authority and funding to the Alabama Department of Public Health in order to accept proposals from independent research entities having the capabilities to conduct controlled scientific research in a pilot study. These entities will have no association with the Morbid Obesity Task Force. A review committee appointed by the State Health Officer will select the proposal designed to best meet the specifications and needs as outlined below.

The State will provide funding to SEIB to cover the additional costs for reimbursement issues as associated with direct care in the pilot.

Purpose

Gastric bypass is performed for treatment of obesity. The concern surrounding this surgery is two fold. First, the surgery is cost prohibitive for many and insurance coverage varies. Secondly, studies during the first two years post surgery are favorable for cost savings; however, health concerns are noted after this time period, perhaps due to patient compliance. The pilot study will address both concerns.

Proposals for the pilot study will reflect a well designed, prospective, controlled study to address the research question:

Is there a way to predict who will have the best outcome with surgery for obesity? (What criteria are needed before surgery is covered?)

This study will have three components.

1. Study participants accepted into the pilot project
2. SEIB case files of members having bariatric surgery at comparable sites
3. SEIB case files of members having similar diagnosis codes, who do not select surgery as a treatment.

The proposal for the pilot study should include but not be limited to the following:

I. Study participants accepted into the pilot project

One hundred members of the insurance plan, as administered by the State Employees Insurance Board (SEIB), will be recruited to participate in the study. This number is flexible, dependent upon statistician's advice or may be determined by the awarded research entity.

- Participants will meet the SEIB inclusion criteria for bariatric surgery.

II. Study Outline

- Participants approved for the surgery at the current 50 percent reimbursement rate, will be recruited for the pilot study and be eligible to receive reimbursements over the five years of the pilot to equal 100 percent of the cost covered.
- By being accepted into the study, the participant is agreeing to undergo more intensive pre-surgery assessments administered by qualified team members as specified below.
- The pre-surgery assessments include: a pre-surgical physiological assessment i.e. Minnesota Multiphasic Personality Inventory (MMPI), an eating factor inventory, depression scale, eating disorder survey, and evaluation of dietary intake with calorie and nutrient count with post surgery diet counseling.
- Those members who apply, but are not accepted into the study because of the limited space, can opt to have the surgery with the 50 percent coverage.
- Comparison data will be compiled from selected SEIB files of patients having the same diagnosis codes and undergoing the surgery at a comparable site (volume wise) but not participating in the intensive pre-surgery pilot. A close match between the intervention surgical group and the comparison group will lessen the magnitude of difference between the groups.
- The control group will be compiled of data from selected SEIB files of patients having the same diagnosis codes who do not select surgery as a treatment method. A close match between the surgical groups and the control group will lessen the magnitude of difference between the groups.

III. Team members

The qualified team will include the surgeon, registered nurse, registered dietitian, and psychiatric counselor/ psychologist.

IV. Time Span

The study will be conducted for five (5) years, with year one (1) used for recruitment of participants and collection of baseline data. The following four (4) years will be for the procedures and follow up.

V. Facility Inclusion

Statewide availability will be met through recruiting a mixed group of hospitals containing both academic centers and community centers. Preference will be given to Centers of Excellence or Level IA Bariatric Centers of Excellence as accredited by the American College of Surgeons. This criterion will assure experienced surgeons are available. Facilities located in Montgomery, Birmingham, Huntsville, Tuscaloosa, and Mobile will be contacted. Centers willing to participate will receive training and technical assistance for pilot concerns for all of the team members involved. *(Note to committee: Do we limit to the accredited centers? The study could include a variable for where the surgery was done if accreditation is not required. Do you want to look for surgeon experience versus site accreditation?)*

With 100 total slots available, study site limitations and population data will be imposed to ensure equal statewide coverage.

VI. Data collection

Medical data collection will include anthropometrics, resting metabolic rate, cholesterol, blood glucose, blood pressure, serum nutrient levels, bone turnover markers, co morbidity status, and prescription usage. A standardized assessment method such as the Structural Clinical Interview for DSM Disorders will be utilized for mental health issues. Data on the patient's gender, race/ethnicity, marital status, education, and socioeconomic status will be collected.

Information on body weight, BMI, fat distribution, blood pressure, cholesterol, and blood glucose will be reported at each time point. Changes in patient characteristics, such as age, socioeconomic status, and marital status will be reviewed at each time point and reported if changed. All complications will be recorded. Readmissions and visits to the emergency room will be recorded.

VII. Evaluations

At end of 5 year study the group with advanced screening will be compared to the control or standard screening. Outcome evaluations will be completed for weight loss, weight maintenance, and weight gain; medication usages through prescription refills; all complications, including

the peri operative and post operative for the entire five years; percent co morbid conditions controlled; quality of life and the Quality–Adjusted Life Year (QALY); and mortality will be tracked.

The cost associated with the additional assessment screenings will be compared to the outcome for cost to determine the cost savings, increased costs, or cost neutral effects.

Additional outcomes may also include body image and self acceptance as based on appropriate psychometric measures such as the Multidimensional Body Self Relations Questionnaire or Body Shape Questionnaire. As with improvements in health, most studies showing an improved image after the surgery have investigated changes during the first and second years. This evaluation will provide a five year follow up to better determine true self- acceptance.

Budget Considerations: (Note: I did not do the budget. I wanted to wait until the proposal direction is known.)

Current benefits in place at the time of the pilot will be covered as any other requests under the SEIB health plan. All additional costs as noted below will be appropriated by legislation from the general fund. As noted above, funds will be provided to SEIB for additional coverage items. Funds will be provided to ADPH for the grant award to conduct the pilot study.

NOT A COMPLETE LIST: "Shall include but not be limited to":
Salary for additional team members doing the screening (psychological and dietary assessment)
Annual follow up, data collection, and lab tests
Incentive rewards
Payment for lifestyle coaching referral

Attachment 5

MINUTES OF THE MEETING OF THE MORBID OBESITY TASK FORCE
February 12, 2008

Attendees:
Dr. Williamson (Chair), Representative Blaine Galliher, Dr. Olivia Thomas, Deborah Unger, Tim Vines, Helen Wilson, Miriam (Mim) Gaines (staff assistant), Frances Kennamer, Donna Joyner (PEEHIP)

Others Invited:
Dr. Jamy Ard, Lee Hayes, Senator Linda Coleman, Dr. Edward Facundus, Debbie Strong, and Donald Jones

The fifth and last meeting of the Morbid Obesity Task Force was held February, 2008, in the State Health Officers' Board Room.

Dr. Donald E. Williamson, State Health Officer, opened meeting. Minutes from January 15, 2008 meeting were approved.

The proposal was reviewed and approved.

The meeting concluded the Morbid Obesity Task Force's charge, and the Task Force disbanded.

References

1. The Practical Guide: Identification, Evaluation, and Treatment of Overweight and Obesity in Adults. NIH Publication Number 00-4084. October 2000.
2. Centers for Disease Control and Prevention http://www.cdc.gov/nccdphp/dnpa/obesity/economic_consequences.htm
3. Salem, L. MD, Jesen, C. MD, and Flum, D. MD. Are Bariatric Surgical Outcomes Worth Their Cost? A Systemic Review. *Journal of American College of Surgeons.* 2005; 200(2): 270 - 278.
4. Finkelstein, EA, Fiebelkorn, IC, Wang, G. State-level Estimates of Annual Medical Expenditures Attributable to Obesity. *Obesity Research.* 2004; 12(1): 18 - 24.
5. Flum, D. MD, Salem, L. MD, Elrod, J. PhD. Early Mortality Among Medicare Beneficiaries Undergoing Bariatric Surgical Procedures. *JAMA*. 2005; 294(15): 1903 - 1908.
6. Roadmaps for Clinical Practice: Assessment and Management of Adult Obesity. A Primer for Physicians. American Medical Association. NC 426203
7. Buchwald,H. MD, PhD, Avidor,Y. MD, et al., Bariatric Surgery: A Systematic Review and Meta-analysis. *JAMA*. 2004; 292: 1724 - 1737.
8. Snow, L. MD, Weinstein, L.MD, et al. The Effect of Roux-en Y Gastric Bypass on Prescription Drug Costs. Obesity Surgery. 2004; 14: 1031-1035.
9. Wadden T, Sarwer D. Behavioral Assessment of Candidates for Bariatric Surgery: A Patient-Oriented Approach. Obesity. 2006; 14 Supplement: 53S - 62S.
10. Smith, B, RN, BSN. Bariatric Surgery: It's No Easy Fix. RNWeb. 2005; http://www.rnweb.com/rnweb/content/printContentPopup.jsp?id=163354
11. Shah M, Simha V, and Garg A. Review: Long-Term Impact of Bariatric Surgery on Body Weight, Co-morbidities, and Nutritional Status. The Journal of Clinical Endocrinology and Metabolism. 2006; 91(11): 4223 – 4231.
12. Sarwer, D, Wadden,T, Fabricatore,A. Psychosocial and Behavioral Aspects of Bariatric Surgery. Obesity Research. 2005; 13(4): 639 – 648.
13. American Society for Metabolic and Bariatric Surgery. www.asbs.org

14. Phillips C, Thompson G. What is a QALY? May 2001. ONC 195058. www.evidence-based-medicine.co.uk
15. Encinosa WE, Bernard DM, Chen CC, Steiner CA. Healthcare Utilization and Outcomes After Bariatric Surgery. Med Care. 2006; 44(8): 706 - 12.
16. Herman W, Hoerger T, et al. The Cost-Effectiveness of Lifestyle Modifications or Metformin in Preventing Type 2 Diabetes in Adults with Impaired Glucose Tolerance. Ann Intern Med. 2005; 142(5): 323 - 332.
17. Omalu B, Ives DG, Buhari A, et al. Obesity, Mortality, and Bariatric Surgery Death Rates. Arch Surg. 2007; 142(10): 923 - 928.
18. Kaufman, S. Esq. Bariatric Surgery Claims - A Medico-Legal Perspective. Obesity Surgery. 2006; 16: 1555 -1558.