

American College of Surgeons

# BSCN

Bariatric Surgery Center Network



# Accreditation Program Manual

*ACS Division of Research and Optimal Patient Care*

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# American College of Surgeons Bariatric Surgery Center Network Manual

## Chapter 1. Introduction

Surgeons from Canada and the United States founded the American College of Surgeons in 1913 for the purpose of improving surgical care with education and setting standards. The organizing surgeons established a Hospital Standards Committee which became the Joint Commission on Accreditation of Healthcare Organizations in 1951. In 1922 the College established the Committee on Trauma to focus on the care of the injured and by 1976 had codified the principles of trauma care in a publication, "Optimal Hospital Resources for the Care of the Injured Patient". Because of increasing quantity of injuries, increasing complexity of injuries, increasing complexities of care, and the lessons learned from Military Surgery the Committee on Trauma recognized the need for trauma centers and began to implement them. They also recognized the need for guidelines and clinical pathways and instituted the Advanced Trauma Life Support education programs. The ATLS program continues to save lives throughout North America and the world and establishes the effectiveness of guidelines and pathways. Trauma Centers promoted by the Committee on Trauma continued to flourish and by 1987 adapted the Verification Process to document the application of the standards of care. The Verification Process also includes consultation to assist Centers to provide the best resources and practices. Nationwide, 197 Trauma Centers apply best practices verified periodically. Effective trauma care requires more than Trauma Centers, it requires systems of integrated resources and processes. The Committee on Trauma defined the systems approach in 1993. High quality care requires evaluation of outcomes. The National Trauma Data Bank now provides a database of 1.5 million patient records to evaluate the safety and effectiveness of trauma care.

The American College of Surgeons and the American Cancer Society organized the Commission on Cancer in 1922. The Commission on Cancer includes 100 members representing 38 national professional organizations. The Commission therefore represents all disciplines engaged in providing cancer care. It effectively establishes standards for cancer programs and evaluates programs according to those standards; coordinates the collection, analysis and dissemination of cancer data; coordinates the activities of a national network of 1,500 physician-volunteers; provides oversight for cancer education programs; and establishes standards for cancer care. The Commission on Cancer oversees 1,425 Cancer Centers nationwide with an Approvals Program to review every center with a site-visit and data evaluation every 3 years. The National Cancer Database, established in 1986, contains records of 16 million cancer patients representing 80% of cancer care in the United States. The NCDB represents a vital tool for quality improvement, research, and direction of national policy. So, the Commission on Cancer has established centers, established standards, established processes of care, and used outcome data to improve the quality of cancer care in the United States.

For many decades the Committee on Trauma and the Commission on Cancer have practiced the principles of surgical care quality improvement. They established standards of care and organized centers to carry out those standards. Quality improvement requires identification and implementation of

best practices, documentation of application of best practices, reliable outcome data, and the safe, timely introduction of new knowledge and new technology into the standard of care. The Committee on Trauma and the Commission on Cancer have done these things and led the way.

The leaders of the American College of Surgeons recognize the urgent and pressing need to extend these established quality improvement practices beyond Trauma and Cancer into all disciplines of surgical care. For that reason, on February 12, 2005, the Board of Regents instructed the College Staff to develop additional center networks, establish standards of care, provide reliable outcome data, develop approvals/verification processes for hospitals and outpatient facilities, and to establish credentialing criteria for surgeons. These additional centers could address diseases, procedures, or disciplines. Because of the timeliness of the matter, the Board of Regents indicated highest priority for developing Bariatric Surgery Center Networks.

In the United States more than 11 million people suffer from severe obesity and the numbers continue to increase. Obesity increases the risks of morbidity and mortality because of its serious associated co-morbidities such as type II diabetes, hypertension, dyslipidemia, cardiovascular disease, stroke, sleep apnea, gallbladder disease, fatty liver, osteoarthritis, and some forms of cancer. In addition, obesity interferes with the activities of daily living and invites social stigmatization. At the present time, surgery provides the only effective, lasting relief from severe obesity. This document describes the necessary physical resources, human resources, clinical standards, surgeon credentialing standards, data reporting standards, and verification/approvals processes required for the designation of American College of Surgeons Bariatric Surgery Centers. The American College of Surgeons Bariatric Surgery Center Committee may change or modify the processes, standards, and stipulations set forth in this document as new knowledge, new technology, and experience require.

## **Chapter 2. American College of Surgeons Bariatric Surgery Centers**

Most, if not all, patients with severe obesity fail to achieve and maintain healthy weight with non-surgical treatments. In 1991 an NIH Consensus Conference recognized these assertions, acknowledged the usefulness for surgical treatment in selected patients, and recommended criteria to assist selecting patients for surgical treatment of morbid obesity. These criteria include a BMI  $\geq 40$  kg/m<sup>2</sup>, or a BMI  $\geq 35$  kg/m<sup>2</sup> associated with major medical complications of obesity such as cardiovascular disease, type II diabetes, and sleep apnea. Some patients undergoing weight loss surgery have higher risks of complications. Increased risks of mortality include revisional surgery, increased BMI, male gender, and increased age. Patients older than 50 with a BMI  $\geq 50$  kg/m<sup>2</sup> have elevated risk. Type II diabetes, hypertension, obstructive sleep apnea and other co-morbidities may also contribute to increased operative risk.

Scrutiny of contemporary weight loss surgery reveals a need for organization, standards, and data on outcomes. The decision to recommend surgery for obese patients requires multidisciplinary input to evaluate the indications for operation and to define and manage co morbidities properly. Institutions providing weight loss surgery must have certain commitment, organization, leadership, human resources, and physical resources to provide optimal care. The professionals must have the necessary training, skills, and experience demonstrable. And, high quality surgical care requires documentation with reliable measurements of outcomes. For all of these reasons, the American College of Surgeons will recognize and commend those facilities, which implement defined standards of care, document their outcomes, and participate in periodic reviews and verifications of their programs in bariatric surgery.

To improve quality and facilitate access to care for morbidly obese patients the American College of Surgeons will acknowledge, as Bariatric Centers, facilities which implement and maintain certain physical resources, human resources, standards of practice, and documentation of outcomes of care. This document describes those standards delineating four levels of inpatient facilities as well as standards for outpatient surgical care.

The American College of Surgeons will recognize certain hospitals as Level 1a and 1b Bariatric Centers. Such hospitals will provide complete tertiary care, physical and human resources devoted to bariatric surgery. These hospitals can manage the most challenging and complex patients with optimal opportunity for safe and effective outcome. They will have high volume practices conducted by professional services of breadth and depth.

Recognizing the need for access to Bariatric Surgery and recognizing that high quality surgical care occurs in other than high volume tertiary centers, the American College of Surgeons will designate certain facilities as Level 2a and 2b Bariatric Surgery Centers. These centers will provide high quality care to a lower volume of patients having lesser obesity and lesser co morbidities.

Outpatient surgery centers will provide for the application and adjustment of laparoscopic gastric bands. Furthermore, laparoscopic gastric bypass can be done with discharge from the unit in less than 24 hours. For those reasons the American College of Surgeons will recognize as Outpatient Bariatric Surgery Centers those facilities which implement stipulated standards, maintain physical and human resources, and document their outcomes.

## **Chapter 3. Level 1a and 1b Bariatric Surgery Centers**

### **Level 1a Centers:**

A full service JCAHO or AOA approved tertiary hospital will house Level 1a Bariatric Surgery Centers. These centers will engage all levels of obesity, standard of care weight loss operations, all ages, co morbid conditions, and reoperations. They will have provided bariatric surgery services for 24 months prior to approval and will provide outcome data and description of existing resources and personnel in their application. A Level 1a Center will have provided and continue to provide no less than 125 primary weight loss operations annually. A Bariatric Surgeon Director will lead the program and will report to the Department of Surgery or to the Hospital Administration depending on the institution's organization. The training and volume standards stipulated elsewhere in this document define "Bariatric Surgeon". A Level 1a Center must have 2 or more bariatric surgeons on staff. A Bariatric Surgery Program Coordinator (a nurse or a physician assistant) will report to the Director to implement all stipulated processes and practices of Bariatric Surgery care and to assure submission of related outcome data.

Surgeons performing the weight-loss operations (Bariatric Surgeons) will be certified or recertified by the American Board of Surgery (ABS). At least 2 Bariatric Surgeons must perform 50 weight loss operations annually and abide by the Surgeon Credentialing Criteria in Chapter 9. It is strongly encouraged but not required to have all Bariatric Surgeons perform 50 weight loss operations annually.

All surgeons caring for Bariatric Surgery patients will be certified by the ABS and experienced in the care of bariatric surgical patients. They will be capable of managing the full range of complications associated with surgery of the obese. Such qualified surgeons and the bariatric surgeons will be responsible for bariatric surgery patients 24/7/365. The Bariatric Surgeons and the Bariatric Surgery Program Coordinator will maintain a call schedule establishing those responsibilities.

Following weight-loss surgery patients need life-long health surveillance. For that reason, postoperatively the Bariatric Surgeon will refer each patient to a physician of the patient's choice to assist with long-term medical management. The long term metabolic consequences of weight-loss surgery remain unknown, but the history of gastric surgery predicts nutritional disturbances, hematological disorders, and metabolic bone disease, for example.

## **SERVICES**

### **Multispecialty Services:**

The list of obesity-related sequelae continues to grow and includes type II diabetes mellitus, obstructive sleep apnea, pseudo tumor cerebri, hypertension, dyslipidemias, nonalcoholic steatohepatitis, venous stasis disease, impaired daily living activities, intertriginous soft-tissue infections, urinary stress incontinence, gastroesophageal reflux disease, weight-related arthropathies, and obesity related psychosocial distress. Therefore, the preoperative and postoperative care of bariatric surgery patients requires comprehensive multispecialty services. The Level 1a Bariatric Surgery Center Hospital active staff must include pulmonology, cardiology, intensivists, infectious disease, nephrology, psychiatry/psychology, gastroenterology, thoracic surgery, otorhinolaryngology, and orthopedics.

### **Anesthesiology Services:**

The Level 1a Bariatric Surgery Center requires board certified anesthesiologists with special competence in managing obese patients and complex airway problems, and anesthesiologists with major time commitments to bariatric surgery patients. Anesthesiology must provide perioperative and postoperative active pain control services including drug management, patient controlled analgesia, and epidural techniques.

### **Critical Care Services:**

The Critical Care Unit will have physician/surgeon staffing 24/7/365 and a trained Critical Care Nursing Staff. The Critical Care Unit will be equipped for obese patients.

The Level 1a Bariatric Surgery Center must have a full-service, full-time Emergency Room staffed with Emergency Room Physicians.

### **Comprehensive Endoscopy Services:**

Trained nursing staff will manage complete facilities for upper GI endoscopy and bronchoscopy equipped for obese patients. These facilities will be available 24/7/365.

### **Comprehensive Minimally Invasive Surgery:**

Complete staff, equipment, and experience in minimally invasive surgery of the GI tract, biliary system, and abdominal organs including anastomotic procedures. The Center will have a dedicated nursing team with training, experience and interest in bariatric surgery and minimally invasive surgery.

### **Comprehensive Imaging Services:**

The Radiology Unit will have equipment for morbidly obese patients with over-sized CT and MR equipment (adequate for patients undergoing bariatric surgery) and provides complete interventional radiology services.

## **FACILITIES**

### **Full Service Operating Rooms:**

The Level 1a Bariatric Surgery Center will provide special operating room tables and equipment to accommodate morbidly obese patients such as retractors suitable for bariatric surgical procedures, specifically designed stapling instruments, and long surgical instruments.

The center will provide other special supplies unique to the procedure identified, and a dedicated nursing team with special training and interest in bariatric surgery and minimally invasive surgery.

### **Recovery Room:**

The Recovery Room nursing staff will be experienced in managing obese patients and will have special stretchers, lifting devices, and other equipment for managing obese patients.

### **Emergency Room:**

The Center will maintain a staffed Emergency Room 24/7.

### **Dialysis Facilities for Acute Renal Failure:**

The Renal Unit provides care for acute renal failure including hemodialysis.

### **Accommodations for the Morbidly Obese:**

The Center's patient care units will include shower rooms large enough for super obese patients, and furniture, beds, scales, wheel chairs, litters, floor mounted toilets, doorways, blood pressure cuffs, abdominal binders, gowns, walkers, SCD boots, and patient movement and transport systems for morbidly obese patients.

## **PERSONNEL**

### **Surgeons:**

Surgeon criteria are described in chapter 9.

### **Trained Staff:**

The staff will include nurses, nurse practitioners, physician assistants, physical therapy/exercise, nutritionist/dietician all with dedicated training and experience in the care of bariatric surgical patients. Individuals specifically designated to coordinate the care of bariatric surgery patients will provide staff leadership and organization.

## **PROCESSES**

### **Mandatory Outcomes Reporting:**

All American College of Surgeons Bariatric Surgery Centers will report outcomes on all patients undergoing weight loss surgery. Level 1a Centers will use the American College of Surgeons National Surgical Quality Improvement Program (ACS NSQIP) adapted for bariatric surgery (as described in Chapter 10). In addition to the criteria listed in Chapter 9: Credentialing, the Center will review their outcomes data as part of the surgeon credentialing process.

### **Quality Improvement Program:**

Level 1a Centers will establish a Quality Improvement Program including establishing best practices and monitoring their implementation. The ACS NSQIP will provide the cornerstone of the quality improvement efforts. Enrollment as a Level 1a center requires documentation of ACS NSQIP membership.

### **Use of Best Evidence Guidelines, Clinical Pathways, and Algorithms:**

Level 1a Bariatric Surgery Centers will employ practice guidelines, and will develop and implement clinical pathways. The guidelines and clinical pathways will be reviewed during the Verification Process.

### **Education and Training of Bariatric Surgeons:**

Level 1a Bariatric Surgery Centers will agree to participate in training surgeons in weight loss operations. The Center may have a Bariatric Surgery Fellowship. The Center will allow selected and mutually acceptable surgeons to observe for educational and quality improvement purposes.

### **Patient Selection Process:**

A multidisciplinary group of clinicians will review bariatric surgery candidates to evaluate the indications for surgery, the contraindications for surgery, the co morbidities, and the operative risks.

### **Patient Education/Counseling/Informed Consent:**

Level 1a Centers will establish procedures for patient education, counseling, and obtaining informed consent and informed assent as described in Chapter 6.

### **Discharge and Follow-Up Plan:**

Weight loss operations carry known and unknown long term risks. At discharge from the hospital the patient should receive instructions regarding activity, diet, wound care, symptoms of complications. Follow up visits should occur at 2 weeks post operatively, several weeks later as indicated, 3 months, 6 months, 1 year, then annually.

### **Postoperative Rehabilitation and Long Term Follow-up:**

Postoperative rehabilitation and long term follow up as described in Chapter 7.

### **Level 1b Bariatric Surgery Centers:**

Level 1b Bariatric Surgery Centers have the same standards as Level 1a Bariatric Centers except that ACS NSQIP is not required. Level 1b Bariatric Surgery Centers must report outcomes data to the American College of Surgeons Bariatric Surgery Database as described in Chapter 10.

## **Chapter 4. Level 2a and 2b Bariatric Surgery Centers**

### **Level 2a Centers:**

JCAHO or AOA approved general acute care hospitals will house Level 2a Bariatric Surgery Centers for primary weight loss operations for morbidly obese patients under the age of 60 years in the absence of cardiac or pulmonary co morbidities. Level 2a Bariatric Surgery Centers are not approved for operations on high-risk patients, such as males with a BMI  $\geq$  55, females with a BMI  $\geq$  60, and the medically disabled. They will have performed bariatric surgery for the previous 24 months and will have performed no less than 25 primary weight loss operations annually. The Bariatric Surgeons are certified or recertified by the ABS and performed 50 weight loss operations during the previous 2 years. ABS certified surgeons capable of managing the full range of complications associated with surgery of the obese would be available for bariatric surgery patients 24/7. The Bariatric Program Coordinator, a nurse or physicians assistant will report to the Bariatric Surgeons and organize the Bariatric Program. All patients will have a physician assisting in the patient's long-term medical management. Medical specialty services will be readily available..

### **SERVICES**

#### **Anesthesiology Services:**

Board certified anesthesiologists with special competence in managing obese patients and complex airway problems will provide anesthesia services.

#### **Critical Care Services:**

The Critical Care Services will provide physician/surgeon/intensivist staffing and a trained Critical Care Nurse staff. The Intensive Care Unit will be equipped for obese patients.

#### **Availability of Other Services:**

The Center will have endoscopy services, minimally invasive surgery facilities, and imaging services suitable for morbidly obese patients.

### **FACILITIES**

#### **Operating Rooms:**

Operating rooms will provide tables and equipment to accommodate morbidly obese patients, retractors suitable for bariatric surgical procedures, specifically designed stapling instruments, appropriately long surgical instruments, and other special supplies unique to the procedure. The Operating Room nursing staff will be trained in performance of bariatric surgical procedures.

### **Recovery Room:**

The Recovery Room Nursing staff will have experience in managing obese patients. The Recovery Room will provide special stretchers, lifting devices, and other equipment for managing obese patients.

### **Emergency Room:**

The Center will maintain a staffed Emergency Room 24/7.

### **Accommodations:**

Accommodations for the morbidly obese patients will include furniture, beds, scales, wheel chairs, litters, toilets, doorways, blood pressure cuffs, abdominal binders, walkers, SCD boots, patient movement and transport systems for obese patients.

## **PERSONNEL**

### **Surgeons:**

Surgeon criteria are described in chapter 9.

### **Trained Staff:**

The trained staff will include nurses, nurse practitioners or physician assistants as needed, physical therapists, nutritionists, and dieticians.

## **PROCESSES**

### **Use of Best Evidence Guidelines, Clinical Pathways, and Algorithms:**

Level 2a Bariatric Surgery Centers will employ guidelines, clinical pathways, and algorithms. The guidelines and clinical pathways will be reviewed during the Verification Process.

### **Quality Improvement Program:**

Quality improvement programs will include promotion and documentation of the use of best practices and measuring outcomes. The ACS NSQIP will form the foundation of the quality improvement program. The Quality Improvement Program will be reviewed during the Verification Process.

### **Mandatory Outcomes Database:**

All American College of Surgeons Bariatric Surgery Centers will report outcomes on all patients undergoing weight loss surgery. Level 2a Centers will use the American College of Surgeons National Surgical Quality Improvement Program

(ACS NSQIP) adapted for bariatric surgery (as described in Chapter 10). In addition to the credentialing criteria listed in Chapter 9, the Center will review their outcomes data as part of the surgeon credentialing process.

**Patient Education/Counseling/Informed Consent:**

Level 2a Centers will establish procedures for patient education, counseling, and obtaining informed consent and informed assent as described in Chapter 6.

**Patient Selection Process:**

A multidisciplinary group will review the selection of patients for weight-loss surgery according to the standards described in this document.

**Discharge and Follow-Up Plan:**

Weight loss operations carry known and unknown long term risks. At discharge from the hospital the patient should receive instructions regarding activity, diet, wound care, symptoms of complications. Follow up visits should occur at 2 weeks post operatively, several weeks later as indicated, 3 months, 6 months, 1 year, then annually.

**Postoperative Rehabilitation and Long Term Follow-up:**

Postoperative rehabilitation and long term follow-up as described in Chapter 7.

**Level 2b Bariatric Surgery Centers:**

Same standards as Level 2a Bariatric Surgery Center except these Centers must report outcome data to the American College of Surgeons Bariatric Surgery Database.

## **Chapter 5. American College of Surgeons Outpatient Bariatric Surgery Centers**

The American College of Surgeons will recognize JCAHO, AAAHC, or AOA approved outpatient surgical centers for specific procedures such as surgical placement of laparoscopic adjustable gastric band. These centers will meet full criteria for outpatient surgical centers and an inpatient surgical center must be available for patient transfer whenever the need arises 24/7/365. A Surgeon Director will oversee the program and will work with a nurse or physician's assistant serving as the Bariatric Program Coordinator. The Bariatric Surgeons will be certified or recertified by the ABS and will perform no less than 50 weight loss operations annually. The Bariatric Surgeons must have experience in performing laparoscopic adjustable band procedures and have operating privileges at the available inpatient facility for managing the full range of complications of laparoscopic banding. The designated inpatient facility will maintain a staff of qualified surgeons to manage the complications of lap banding 24/7/365.

Identified physician teams (can include physician's assistant or nurse practitioner) will provide long-term medical management of lap banded patients.

Anesthesiology services, operating rooms, recovery rooms, accommodations, trained staff, best evidence guidelines, clinical pathways, algorithms, quality improvement program, outcomes database, data-based surgeon credentialing, patient selection process, patient education counseling/informed consent, discharge and follow-up plan, and long-term follow-up all same as for Level 2b Center.

Gastric bands will be adjusted in these approved facilities having a Surgeon Director and a Bariatric Program Coordinator. The facility will provide radiology facilities, a certified radiologist experienced in band adjustment, and radiology equipment accommodating morbidly obese patients. The Bariatric Surgeon must perform  $\geq 50$  band adjustments annually.

The facility will provide office equipment, toilets, doorways, wheelchairs, scales, stretchers, examination tables, blood pressure cuffs, and gowns available for morbidly obese patients.

### **Outcomes Database:**

The American College of Surgeons Outpatient Bariatric Surgery Centers will report data on all patients and all procedures to the American College of Surgeons Bariatric Surgery Database as described in Chapter 10. The Outpatient Centers will use their outcomes data in the surgeon credentialing process.

### **Patient Education/Counseling/Informed Consent:**

Outpatient Centers will establish procedures for patient education, counseling, and obtaining informed consent and informed assent as described in Chapter 6.

### **Discharge and Follow-Up Plan:**

Weight loss operations carry known and unknown long term risks. At discharge from the hospital the patient should receive instructions regarding activity, diet, wound care, symptoms of complications. Follow up visits should occur at 2 weeks post operatively, several weeks later as indicated, 3 months, 6 months, 1 year, then annually.

### **Postoperative Rehabilitation and Long Term Follow-up:**

Postoperative rehabilitation and long term follow-up as described in Chapter 7.

## **Chapter 6. Patient Education/Counseling/Informed Consent:**

Centers will establish procedures for patient education, counseling, and obtaining informed consent and informed assent.

### **Informed Consent (for all levels):**

Informed consent will include communication with the patient providing description of the planned procedure, its risks, and benefits. The patient should understand what to expect during the early post operative period as well as during the long term. A discussion of long-term follow up will include reviewing quality of life and life style issues as well as what late complications can occur. The informed consent should document the educational materials used to inform the patient and should document that the patient knows about the signs and symptoms of complications common to the operation provided plus the signs and symptoms that require emergency attention: a sustained heart rate  $\geq 120$ b/min during the first 30 days post operatively and uncontrollable vomiting, abdominal pain during the remaining lifetime. The informed consent should include an explanation of alternative procedures including an alternative of no operation. The informed consent should include evidence that the patient made an educated choice of free will.

## **Chapter 7. Postoperative Rehabilitation and Follow-up**

Bariatric surgery and its resulting weight loss produce dramatic changes in anatomy, physiology, life style, body image, and health considerations. Following weight loss patients can engage in activities previously denied them and on the other hand will be denied certain activities they previously enjoyed such as over eating.

### **Dietary Counseling:**

Patients may need help in adjusting to the quantity and quality of food ingested post operatively. Counseling may smooth out the bumps of trial and error. Also, they may need help with advice about vitamins and micronutrients.

### **Exercise Counseling:**

Good health requires proper exercise. Morbid obesity precludes proper exercise so reintroducing physical activity into the life-style becomes an important feature of rehabilitation. The co morbidities of obesity such as joint disease and cardiovascular disease deserve professional monitoring during the resumption of physical activity.

### **Psychological Counseling:**

Some patients have difficulty with the changes in their self-image, relationships, how their life has changed, or not changed, as a result of the surgery. Patients may need counseling to address these issues and should get help with referrals.

### **Plastic Surgery Consultation:**

Extensive weight loss produces changes in body structure, function, and appearance. Plastic surgery can enhance the quality of life from both the cosmetic and functional standpoint. Patients should get help with referrals.

### **Long-Term Follow-Up:**

As stated previously, many of the sequelae of weight-loss surgery remain unknown. So, the patients' interests will be served by lifelong periodic health examinations. Centers must either document at least one year of personal contact with patients or document contact effort. An attempt to contact a patient should include 2 letters to the patient, one of which is certified, along with a phone call to the patient and a letter to the patient's doctor.

## **Chapter 8. Bariatric Surgery for Adolescents**

The prevalence of obesity in children and adolescents in the United States has tripled since the mid 1970's. Because of the increasing need to address treatment of morbid obesity in adolescents, physicians have begun to employ weight-loss surgery in some cases. The management of morbid obesity on children and adolescents requires evaluation by a multidisciplinary weight management team. While the non operative management fails to correct morbid obesity in adults, in some instances progressive obesity can be deflected in children. The criteria for weight-loss surgery in adolescents deserve special consideration.

### **Criteria for Bariatric Surgery in Adolescents:**

Bariatric surgery should be considered in adolescents if the patient has: failed  $\geq 6$  months of organized attempts at weight management, as determined by primary care provider; attained or nearly attained physiologic maturity; a BMI  $\geq 40$  with serious co morbidities or BMI  $\geq 50$ ; committed to comprehensive medical and psychological evaluations before and after surgery; agreed to avoid pregnancy for a year postoperatively; committed to adhere to nutritional guidelines postoperatively; provided informed assent to surgical treatment; demonstrated decisional capacity; a supportive family environment; and agreed to long-term follow-up.

### **Relative Contraindications to Bariatric Surgery in Adolescents:**

Bariatric surgery should not be performed in adolescents in the following circumstances: medically correctable cause of obesity; substance abuse within the preceding year; psychiatric or cognitive impairment; lactation, pregnancy, or planned pregnancy; inability of the patient or parents to comprehend the procedure and its medical consequences.

## **Chapter 9. Surgeon Credentialing Criteria for American College of Surgeons Bariatric Surgery Center Network**

These criteria will be procedure specific. For example, laparoscopic does not qualify for open, open does not qualify for laparoscopic, band does not qualify for gastric bypass, and gastric bypass does not qualify for band. An explanation is required for any surgeon who has not met the corresponding criteria.

### **Newly Trained Surgeons:**

Newly trained surgeons must have satisfactorily completed a General Surgery Residency and performed  $\geq 25$  laparoscopic bariatric operations and some open bariatric operations or  $\geq 10$  open bariatric operations during residency. If these newly trained surgeons have performed open bariatric operations only, they may not be credentialed for laparoscopic bariatric operations.

OR satisfactorily completed a General Surgery Residency followed by Bariatric Surgery Fellowship if performed  $\geq 25$  laparoscopic bariatric operations and some open bariatric operations or  $\geq 10$  open bariatric operations during residency. If newly trained surgeons have performed open bariatric operations only, they may not be credentialed for laparoscopic bariatric operations.

OR satisfactorily performed at least 10 open bariatric operations during a General Surgery Residency followed by a Minimally Invasive Surgery Fellowship with  $\geq 25$  bariatric operations as the operating fellow.

### **Established Surgeons who want to perform Bariatric Surgery:**

Credentialing an established surgeon in Bariatric surgery first requires completion of an established didactic course on Bariatric Surgery. Then successful completion of 10 open cases proctored by a credentialed bariatric surgeon or successful completion of 25 laparoscopic cases proctored by a surgeon credentialed for laparoscopic weight loss surgery and successful completion of some open cases proctored by a credentialed bariatric surgeon. Then a committee including the institution's chief of surgery will review the first 5 cases performed independently by the surgeon. If these surgeons have performed open bariatric operations only, they may not be credentialed for laparoscopic bariatric operations.

### **Surgeon Recredentialing:**

Rec credentialing of established Bariatric Surgeons requires maintenance of ABS certification, performance of 50 primary weight loss operations during the previous 2 years, documented long-term patient follow up, no substantial deviation of weight loss surgery outcomes from accepted norms or benchmarks, and at least 12 weight loss surgery CME credits every 2 years from bariatric surgery meetings or other accredited obesity courses annually.

## **Chapter 10. Outcomes Data Collection**

Level 1a and 2a Centers will employ the American College of Surgeons National Surgical Quality Improvement Program (ACS NSQIP)

### **The ACS NSQIP:**

In 1990 the Veterans Administration Health System (VA) introduced the National Surgical Quality Improvement Program (NSQIP). This became the first peer-controlled, reliable, biostatistically rigorous, validated, risk-adjusted quality improvement in surgery. The NSQIP served the VA very well and for that reason in 2000 the VA and the ACS began collaboration to employ the NSQIP in the private sector by studying General and Vascular Surgery. This collaboration produced the ACS NSQIP, now available to private hospitals.

The ACS NSQIP depends on a database including preoperative, intraoperative, and 30-day postoperative data. Multiple logistic regressions identify the significant risk factors for morbidity and mortality allowing prediction of expected outcomes. Comparing the expected outcome to the observed outcomes (O/E ratio) provides quantification of surgical quality and permits valid comparisons of outcomes between hospitals.

The ACS NSQIP requires a surgeon leader in each participating hospital. A trained, dedicated Surgical Clinical Nurse Reviewer (SCNR) collects and submits the required data. A carefully defined data collection process provides a statistically valid sample of each hospital's operations. The effectiveness of the program depends on the accuracy, quality, and reliability of the submitted data. The SCNRs receive initial and continuing training, as well as annual quality evaluation.

The ACS NSQIP maintains a website for surgeons to examine their data and compare their performance with the averages of the hospitals in the program. The website provides to participants continuously updated Clinical Performance Improvement Reports; Online Reports and Benchmarking; Post Operative Occurrence(complication) Reports; Wound Class Reports; Pre-Operative Risk Factors Reports; Mortality Reports; Length of Stay Reports; Procedure Reports; and Surgical Performance Measures Reports. In addition, each hospital receives a semi-annual written report with an analysis of their outcomes and a confidential comparison with all other hospitals in the program.

The ACS NSQIP has developed a Bariatric Surgery Module to accommodate Bariatric Surgery Centers who wish to use it. It requires inclusion of all weight loss operations and will include long-term follow up data. Level 1a and 2a Centers are required to collect their outcomes data via the ACS NSQIP.

## **The American College of Surgeons Bariatric Surgery Database:**

Level 1b, Level 2b, and Outpatient Bariatric Surgery Centers will report their outcomes data to the American College of Surgeons Bariatric Surgery database using a web-based data entry system. A designated nurse of the Bariatric Surgery Service will enter the data using the established protocol. The entered data will be subjected to quality control. The data will enter the database encrypted and deidentified to protect the confidentiality of the patients, the hospital, the outpatient facility, and the surgeons. When the hospital or outpatient facility receives the data reports, they can identify the patients and surgeons. The hospitals and outpatient facilities will receive annual data reports. Center verification visits will include audits of the data, which include chart reviews. This data does not have the same rigor as ACS NSQIP and is not risk adjusted. It will not be used to make comparisons or for research due to the lack of rigor. This data will only report on a center's outcomes to the ACS for accreditation.

## **Chapter 11. Verification Program**

### **The enrollment process for the American College of Surgeons Bariatric Surgery Centers for centers currently providing bariatric surgery services:**

Hospitals wishing to participate in the American College of Surgeons Bariatric Surgery Center Network will contact the College and signify their interest in enrolling and designate their intended level. The hospital or outpatient surgery center will receive a form to assist in describing their resources, case volumes, and outcomes.

The applying unit will provide certain information such as hospital data, JCAHO, AAAHC, or AOA status and will provide a letter of support from the CEO. The application will include the annual volume of weight loss operations performed during the previous 2 years. An inventory will include descriptions of inpatient and outpatient facilities, operating rooms, recovery rooms, intensive care units, endoscopy facilities, and radiology facilities. The application will document surgeon certification and qualifications. Nursing services, dietetic and nutrition services, social services, and psychology services will be documented. Medical specialty services will be described.

Following receipt of the completed application, the American College of Surgeons will complete a Business Agreement with the applicant hospital. This Business Agreement will delineate both parties' responsibilities. It will delineate the College's obligations to the participating hospital and will delineate the hospital's obligations to maintain the standards and stipulations of the American College of Surgeons Bariatric Surgery Center designation. The Business Agreement will enroll the designated hospital in the American College of Surgeons Bariatric Surgery Database but not the ACS NSQIP. Level 1a and 2a Centers will apply to the ACS NSQIP separately.

Upon receipt of the enrollment fee and the signed business associate agreement, the hospital will then receive provisional approval as an American College of Surgeons Bariatric Surgery Center or an American College of Surgeons Outpatient Bariatric Surgery Center. Centers have provisional status until they complete and pass their first site visit. Site visits for new hospitals must take place within six months of start date of the business associate agreement. The application process is detailed in Appendix B.

## **Approvals Processes for the American College of Surgeons Bariatric Surgery Center Network:**

The American College of Surgeons endorses safety, and quality improvement. Those issues require structure, process, and outcomes measurement. The College will organize these centers to establish and sustain structure, process, and outcome measurement to enable surgical care of the highest value to patients and to the public. This is not an instrument of punishment, harassment, or embarrassment. This is a manifestation of our professional responsibility to encourage, to support, to enable, *to measure* and *to acknowledge* safe, high quality surgical care.

The Approvals Process requires setting standards and verifying the standards. From an operational standpoint verification requires 2 efforts. The first is the analysis and reporting of data on processes and especially on outcomes. The second is on-site verification of structure, process, and data quality.

### **1. Data Monitoring:**

#### ACS NSQIP Participants

ACS NSQIP participants can monitor their data 24/7/365 using the ACS NSQIP website. They can compare their data with the average of the other centers in the program. These centers will receive a semi-annual report of their risk-adjusted outcomes in confidential ranking with other center programs. This data will also undergo confidential review by the ACS NSQIP Advisory Committee and the American College of Surgeons Bariatric Surgery Center Committee. If these reviews reveal trends or variances of concern, the concerns will be communicated to the hospital CEO, the Surgeon Director, and the Program Coordinator. Each ACS NSQIP Center will have an annual Inter-rater Reliability visit from a trained, experienced Surgical Clinical Nurse Reviewer. This involves a medical record review to assess the reliability of the submitted data and the variability of data collection and submission.

#### American College of Surgeons Bariatric Center Network Database Participants

The Hospital CEO, the Bariatric Surgery Director, and the Bariatric Surgery Coordinator will receive a report of their non risk-adjusted outcome data annually. The American College of Surgeons Bariatric Surgery Center Committee will review each hospital's deidentified data annually. If these reviews reveal trends or variances of concern, the concerns will be communicated in a special report to the Hospital CEO, the Bariatric Surgery Director, and the Bariatric Surgery Coordinator.

## **2. Verification:**

The second component of the Approvals Process is on-site verification of structure, process, and data quality. For that reason, each American College of Surgeons Bariatric Surgery Center will undergo a Verification Site Visit every 3 years except for new centers, which must complete a review within the first six months of provisional approval.

Following application for a scheduled site visit and the completion of the pre-review questionnaire and hospital resources checklist, a surgeon reviewer acceptable to the hospital will be selected, and a mutually acceptable date for the review will be established. All reviewers will be from out-of-state or province unless there are special requests. Bariatric Surgeon leaders will be selected from the Fellowship of the American College of Surgeons to serve as reviewers. Several steps will facilitate the review process:

- A Pre-Review Questionnaire will allow the site visitors to understand the existing bariatric care capabilities and the performance on the hospital or outpatient surgery center and medical staff before beginning the review.
- Guidelines for the site visit have been developed that will allow the visitors to conduct the review consistently and emphasize the evaluation of quality improvement activities and review of medical records.
- An Organized Agenda will be developed for the site visit, which will encourage an efficient review.
- The site reviewers will use a standardized report/feedback form to improve communication.

### **Pre-review Meetings:**

A pre-review meeting will facilitate an efficient on-site review. The review team will meet with the Bariatric Surgery Director, the Bariatric Surgery Coordinator, and the Hospital CEO at the beginning of the site visit. Other individuals may participate, as needed, to clarify the Pre-Review Questionnaire and to describe existing bariatric center activities. The meeting will include discussion of the overall bariatric surgery program, clarification of the Pre-Review Questionnaire, specific concerns, unique features of the institution, discussion of the local care of obese patients, and clarification of the review process.

### **On-Site Review:**

The On-site Review requires approximately six hours and includes an exit interview to discuss the reviewers' findings and conclusions. All bariatric surgery care areas of the unit will be visited with an emphasis on evaluating medical records of bariatric surgery patients and correlating patient care with performance improvement. The reviewers will request medical records 7 -10 days prior to the site visit. The reviewers will prepare a report to reflect the

statements made at the exit interview. The reviewers will forward the report to the College's Division of Research and Optimal Patient Care.

The Division of Research and Optimal Patient Care will reserve final approval to ensure consistency of the reports, accurate interpretation of the findings, well-documented conclusions, and professionalism in the final report. This final process may modify the conclusions of the individual site reviewer's report to maintain a consistent interpretation of the resources documented.

Confidentiality of the whole review process ensures an institution that the program is designed to be a constructive process in which a hospital or outpatient surgical center can place its trust.

**Appeal Process:**

If the hospital or outpatient surgery center does not agree with the review process or the final report, it may appeal to the College's Division of Research and Optimal Patient Care. The Division may refer the appeal to the College's Bariatric Surgery Center Committee. Unresolved disagreements can prompt a repeat review.

## **Chapter 12. Consultation Services**

American College of Surgeons Bariatric Surgery Center Start-up Services (no bariatric surgery services currently being provided)

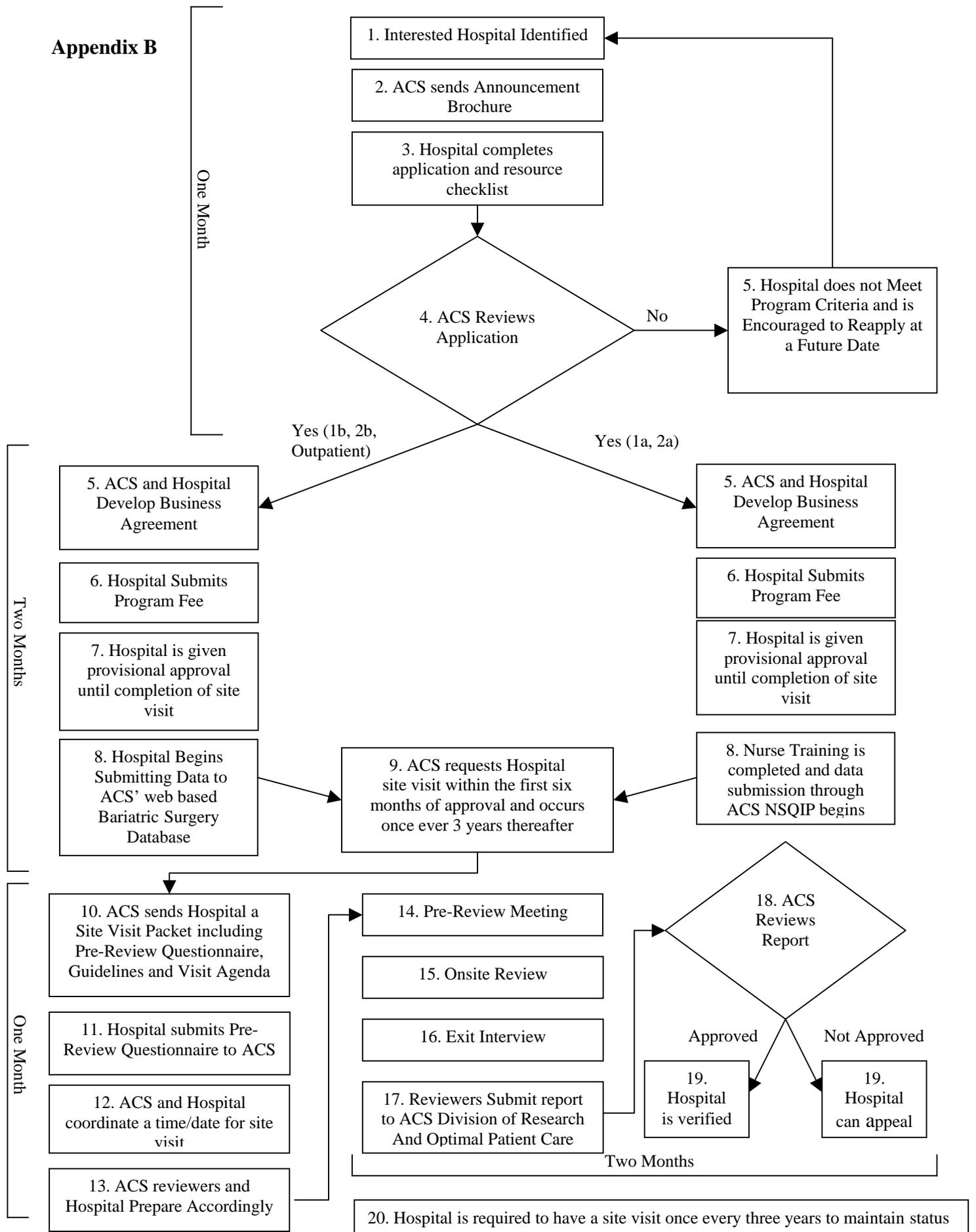
Some hospitals and Outpatient Surgical Centers without bariatric services may wish to initiate a bariatric surgery program. If so, the American College of Surgeons will offer consultation services to assist program development. This could involve a site visit in some instances. The College will assist in identifying opportunities for surgeon training, proctoring, and preceptoring. The College offers courses in bariatric surgery at present. The College can assist in building a bariatric surgery team and organizing consultation with nursing, anesthesiology, bariatricians, and other essential team members including dietitians, social workers, and clinical psychologists.

## Appendix A

### Consolidated Criteria Checklist

Standard	Level 1a	Level 1b	Level 2a	Level 2b	Outpatient
JCAHO or AOA approved	Yes	Yes	Yes	Yes	Yes/AAAHC
Accepts all cases or selects cases	All	All	Selected	Selected	Band only
Performed weight loss operations for the past 24 months	Yes	Yes	Yes	Yes	Yes/AAAHC
Surgery Center performs at least X weight loss operations annually	125	125	25	25	50
Has a Director of Bariatric Surgery	Yes	Yes	Yes	Yes	Yes
Has a Coordinator for Bariatric Surgery	Yes	Yes	Yes	Yes	Yes
Director and active Bariatric surgeons are ABS certified	Yes	Yes	Yes	Yes	Yes
Active surgeons must perform X weight loss surgeries annually	50	50	25	25	50
Provides the following specialty services: Pulmonologist, Cardiologist, Intensivist, Infectious Disease, Nephrologist, Otorhinolaryngologist, Psychiatrist/Psychologist, Gastroenterologist, Thoracic surgeon, and an Orthopedist	Yes	Yes	Selected	Selected	Selected
Has a FT anesthesiologist providing full coverage for all weight loss procedures	Yes	Yes	Selected	Selected	Selected
Full coverage of Pain Service	Yes	Yes	Optional	Optional	Optional
Fully staffed and medically equipped Operating Room for morbidly obese patients	Yes	Yes	Yes	Yes	Yes
Fully staffed and medically equipped Recovery Room for morbidly obese patients	Yes	Yes	Yes	Yes	Yes
Fully staffed and medically equipped Emergency Room for morbidly obese patients	Phys. 24hrs	Phys. 24hrs	Staff 24hrs	Staff 24hrs	Staff 24hrs
Fully staffed and medically equipped Intensive Care Unit for morbidly obese patients	Phys. 24hrs	Phys. 24hrs	Phys. PM schedule	Phys. PM schedule	Phys. PM schedule
Performs endoscopy procedures for morbidly obese	Yes	Yes	Yes	Yes	Optional
Performs minimally invasive procedures for morbidly obese	Yes	Yes	Yes	Yes	Yes
Imaging service is equipped for morbidly obese	Yes	Yes	Yes	Yes	Selected
General accommodations for morbidly obese	Yes	Yes	Yes	Yes	Yes
Implementing Clinical Practice Guidelines	Yes	Yes	Yes	Yes	Yes
Agrees to report outcomes data	ACS NSQIP	ACS	ACS NSQIP	ACS	ACS
Implementing Quality Improvement Programs	Yes	Yes	Yes	Yes	Yes
Database fueled surgeon credentialing	Yes	Yes	Yes	Yes	Yes
Multidisciplinary group monitoring patient selection process	Yes	Yes	Yes	Yes	Yes
Patient education pre and post surgery	Yes	Yes	Yes	Yes	Yes
Extensive explanation of informed consent	Yes	Yes	Yes	Yes	Yes
Protocol in place for patient discharge including instructions for activity, diet, wound care, and symptoms of complications	Yes	Yes	Yes	Yes	Yes
Protocol in place for patient follow up at 2 weeks, 3 months, 6 months, 1 year, and annually thereafter	Yes	Yes	Yes	Yes	Yes
Protocol of patient rehabilitation including dietary, exercise, and plastic surgery counseling	Yes	Yes	Yes	Yes	Yes

**Appendix B**



## Appendix C

### Other Bariatric Resources

Name of Organization	Website
American Heart Association	<a href="http://www.americanheart.org/">http://www.americanheart.org/</a>
American Board of Bariatric Medicine	<a href="http://www.abbmcertification.org/">http://www.abbmcertification.org/</a>
American College of Nutrition	<a href="http://www.amcollnutr.org/">http://www.amcollnutr.org/</a>
American College of Surgeons	<a href="http://www.facs.org/">http://www.facs.org/</a>
American Dietetic Association	<a href="http://www.eatright.org/Public/">http://www.eatright.org/Public/</a>
American Obesity Association	<a href="http://www.obesity.org/">http://www.obesity.org/</a>
American Society for Bariatric Surgery	<a href="http://www.asbs.org">http://www.asbs.org</a>
American Society for Clinical Nutrition	<a href="http://www.ascn.org/">http://www.ascn.org/</a>
American Society for Nutritional Sciences (ASNS, formerly known as AIN)	<a href="http://www.asns.org/">http://www.asns.org/</a>
American Society of Bariatric Physicians	<a href="http://www.asbp.org">http://www.asbp.org</a>
Food and Drug Administration (FDA)	<a href="http://www.fda.gov/">http://www.fda.gov/</a>
International Association for the Study of Obesity	<a href="http://www.iaso.org/">http://www.iaso.org/</a>
International Obesity Task Force	<a href="http://www.ietf.org/">http://www.ietf.org/</a>
National Coalition for Promoting Physical Activity	<a href="http://www.ncppa.org/">http://www.ncppa.org/</a>
National Heart, Lung, and Blood Institute	<a href="http://www.nhlbi.nih.gov/">http://www.nhlbi.nih.gov/</a>
National Institute of Diabetes, and Digestive and Kidney Diseases	<a href="http://www.niddk.nih.gov/">http://www.niddk.nih.gov/</a>
National Institutes of Health	<a href="http://www.nih.gov/">http://www.nih.gov/</a>
North American Association for the Study of Obesity	<a href="http://www.naaso.org/">http://www.naaso.org/</a>
Obesity Law and Advocacy Center	<a href="http://www.obesitylaw.com/">http://www.obesitylaw.com/</a>
The Society of American Gastrointestinal and Endoscopic Surgeons	<a href="http://www.sages.org/">http://www.sages.org/</a>
The Surgeon's General Call To action To Prevent and Decrease Overweight and Obesity (2001)	<a href="http://www.surgeongeneral.gov/topics/obesity/">http://www.surgeongeneral.gov/topics/obesity/</a>

### Journals

- Annals of Surgery
- Obesity Reviews
- Surgical Endoscopy
- Journal of Surgical Research
- American Journal of Surgery
- Journal of the American College of Surgeons
- British Journal of Surgery
- International Journal of Obesity
- Obesity Surgery
- Obesity Research
- Diabetes, Obesity and Metabolism
- International Journal of obesity and related metabolic disorders: journal of the International Association for the Study of Obesity
- Journal of Gastrointestinal Surgery