

IFSO Guidelines for Safety, Quality, and Excellence in Bariatric Surgery

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Introduction

Surgery is now recognized as the only effective treatment for the morbidly obese patient with long-term sustained weight loss and postoperative complete resolution or significant improvement in the obesity comorbidities. However, this highly demanding and challenging surgical therapy necessitates the appropriate training and experience on the part of the surgeon. It is vital that the surgeon, beyond the optimal theoretical knowledge, also has the necessary technical skills in open and/or laparoscopic surgery, performs meticulous pre- and postoperative care, and is committed to long-term patient follow-up.

Moreover, institutional commitment to the excellent multidisciplinary care of the morbidly and super-obese patient, who have an exceptional surgical and anesthetic risk, is essential to ensure the safe and effective performance of bariatric surgery. The necessary ancillary services, including specialized nursing staff, dietitians, psychologists and exercise advisors, and a multidisciplinary bariatric medical team of surgeons, cardiologists, anesthesiologists, ICU specialists and psychiatrists, etc., may be extremely valuable. Modern medical and surgical facilities, such as operating room tables, instruments, furniture, and radiology

equipment capable of handling morbidly obese patients, are of course essential resources for any institution that seeks to treat bariatric patients.

Background

Bariatric surgeons, like general surgeons in other subspecialty areas of surgery, have been involved in the assessment of their own profession for many decades. In this era of evidence-based medicine, pressure to improve the overall quality of care delivered is greater than ever. In an effort to improve the quality of service offered to bariatric patients worldwide, IFSO elected to form an international board that will advise and endorse national and regional 'centers of excellence' programs. The creation of guidelines that could be applied to different global areas and define surgeon's credentials and institutional requirements for safe and efficient management of morbidly obese patients was the main task. The implementation of the guidelines, and their evolution to Centers of Excellence (COE) programs, in countries or geographically homogeneous areas, would be the responsibility of IFSO Accreditation Council in collaboration with IFSO regional chapters or national societies.

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Rationale

IFSO's Safety Quality and Excellence Guidelines have three main objectives:

1. To offer advice to institutions and surgeons worldwide regarding the requirements when beginning bariatric surgery to proceed with an acceptable degree of safety

and efficiency. In other words, to prepare new centres (Primary Bariatric Institutions, PBIs) willing to be involved in the treatment of epidemic obesity, ensuring a safety level and thus avoiding risks during early surgical experience in the severely obese patient group. This effort is equally important as the upgrading of the existing centres to COE, taking into account the number of surgeons and centers required to treat the ever-growing number of obese individuals. Unfortunately, because of the enormous demand for bariatric surgery, many surgeons are entering into bariatric surgical practice without the necessary training and experience in inadequate or under-equipped institutions. This is certainly not approved professional behavior and may have unpleasant consequences. A clear definition of the minimum requirements for surgeons and institutions before accepting bariatric patients would, therefore, be of tremendous importance for the safety of obese patients seeking medical attention.

2. To advise existing bariatric institutions (BIs) already performing surgical treatment for morbidly and super obese patients with Laparoscopically Adjustable Gastric Banding (LAGB) and/or more complex techniques requiring division and stapling of the stomach and intestine (gastric bypass, RYGBP; biliopancreatic diversion, BPD with or without duodenal switch) as well as revisional cases on how to improve the quality of their services offered to the severely obese patients, thereby ensuring highly efficient and safe management. Bariatric procedures particularly in the super and super-super obese patients or revisional surgery requires accumulated surgical experience, completely equipped institutions with full in-house consultative services, specializing in the care of bariatric patients, including intensive care services. It is IFSO's responsibility to precisely define both surgeons' credentials and institutional facilities for performing advanced bariatric surgery.
3. To advise existing bariatric institutions to upgrade their status to level of excellence (Center of Excellence Bariatric Institution, COEBI), thus, optimizing patient outcomes. This mission does not aim at limiting the bariatric centers to a few academic or specialized institutions. On the contrary, IFSO accepts that an enormous demand exists for bariatric facilities and that there are far more patients in need of surgical intervention for weight loss than the existing centers can currently cope with. The aim of establishing IFSO Centers of Excellence is, therefore, to further improve the quality of bariatric service treatment, with increased emphasis on safe, efficacious, and efficient patient care. This result would also help the public and payers to

further trust and support the bariatric surgical community in its difficult task dedicated to optimal surgical management of severely obese patients.

IFSO Guidelines for (1) PBIs

Institutional Requirements

For any medical institution considering the surgical management of morbidly obese patients, it would be necessary to:

1. Ensure that surgeons performing bariatric surgery have the appropriate certification, training, and experience to treat severely obese patients as described in the surgeon's credentials.
2. Ensure that individuals who provide services in the bariatric surgery program are adequately qualified to provide such services.
3. Provide ancillary services such as specialized nursing care, dietary instruction, counseling, and psychological assistance if and when needed.
4. Have readily available consultants in cardiology, pulmonology, psychiatry, and rehabilitation with previous experience in treating bariatric surgery patients.
5. Have trained anesthesiologists with experience in treating bariatric surgery patients.
6. Keep records of the adverse events that occur during the management of the patients.
7. Ensure that basic equipment necessary for the obese patients such as scales, operating room tables, instruments, and supplies specifically designed for bariatric laparoscopic and open surgery, laparoscopic towers, wheelchairs, various other articles of furniture, and lifts that can accommodate stretchers are available, as well as a recovery room capable of providing critical care to morbidly obese patients and an intensive care unit with similar capacity.
8. Ensure that radiology department facilities can perform emergency chest x-rays with portable machinery, abdominal ultrasonography, and upper GI series.
9. Ensure that blood tests can be performed on a 24-h basis.
10. Ensure that blood bank facilities are available and blood transfusion can be carried out at any time.

Surgeon's Credentials

1. Appropriate certification to perform general surgery.

2. Training and experience in gastrointestinal open and/or laparoscopic surgery.
 3. Successful completion of a training course in an existing bariatric Institution or at least a minimum of 2 days bariatric training course including live demonstrations and laboratory hands-on-training.
 4. Testimonials by mentors (proctors) of satisfactory bariatric surgical ability.
 5. Careful maintenance of a database of all bariatric cases, including outcomes, which can be audited by the appropriate national authorities.
 6. Commitment to postoperative lifetime follow-up of the patients.
 7. Carrying out of operations in approved facilities as described above.
4. Have a written informed consent process that informs each patient of the surgical procedure, the risk for complications and mortality rate, alternative treatments, the possibility of failure to lose weight and his/her right to refuse treatment.
 5. Maintain details of the treatment and outcome of each patient in a digital database.
 6. Provide all necessary assistance and advise the staff to attend relevant meetings, subscribe to international journals and become members of a national bariatric society.
 7. Have experienced interventional radiologists available to take over the non- surgical management of possible anastomotic leaks and strictures.

IFSO strongly advises PBIs not to accept super obese patients for the first period (1–2 years) of their practice. It is also recommended for this early period that the management of morbidly obese patients be confined to more simple bariatric procedures. PBIs may proceed to more complex bariatric techniques and to treat super obese patients only when significant experience has been gained (i.e. after performing of a minimum of 50 cases). Obviously, more technically demanding procedures requiring stapling and division of the stomach and gut and revisional surgery should not be carried out until the conditions described for BI are completely reached.

IFSO Guidelines for (2) BIs

Institutional Requirements

Any medical institution undertaking the management of morbidly obese, super obese, and super-super obese patients with LABG and/or bariatric procedures requiring stapling of the stomach and the gut such as sleeve gastrectomy, RYGBP and BPD/DS or revisional cases should, apart from points described in guidelines for PBIs, ensure they fulfil the following additional conditions:

1. Ensure that the director of bariatric surgery has at least 5 years experience in the field and is capable of performing advanced bariatric procedures successfully.
2. Have comprehensive and full in-house consultative services required for the care of the bariatric surgical patients, including critical care services.
3. Have the complete line of necessary equipment, instruments, items of furniture, wheel chairs, operating room tables, beds, radiology facilities such as CT scan and other facilities specially designed and suitable for morbidly and super obese patients.

Surgeon's Credentials

Each interested surgeon should:

1. Have performed at least 50 bariatric cases per year.
2. Be able to perform revisional surgery by open and/or laparoscopic approach.
3. Be committed to a long-term (lifetime) follow-up of his patients.
4. Attend bariatric meetings regularly, subscribe to at least one bariatric journal, and report his/her experience by presenting at local or international congresses or by publishing articles in peer-reviewed Journals.
5. Perform advanced bariatric surgery at the appropriate facilities.

IFSO Guidelines for COEBIs

Institutional Requirements

Apart from the described requirements for BIs, every medical center willing to be evaluated and approved as an IFSO Center of Excellence Bariatric Institution, should prove to the IFSO authorized Review Committee that:

1. It is committed to the highest level of excellence in bariatric surgical patient care and maintains a regular program of education for medical, nursing, administrative and allied health staff in bariatric surgery.
2. Performs at least 100 bariatric surgical cases per year including revisional cases. The perioperative care and the surgical procedures have to be standardized for each surgeon.
3. Has a bariatric surgeon who spends the main portion of his or her effort in the field of bariatric surgery.

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4. Has supervised support groups for bariatric patients.
 5. Provides lifetime follow-up for the majority and not less than 75% of all bariatric surgical patients. Details of the patients' outcome should be included in a digital database and confidential information should be available on request by IFSO authorities.
 2. Be involved in the training and the accreditation of less-experienced bariatric surgeons.
 3. Be committed to complete and life time follow-up of his/her patients and prove that his/her follow-up for at least 75% of them for five or more years.
 4. Report his/her results in international conferences and publish articles in international peer-reviewed journals.

Surgeon's Credentials

Each surgeon in addition to the above described BIs credentials should:

1. Perform at least 50 bariatric cases per year including a number of revisional cases among them.

The application for IFSO approval as Center of Excellence, is voluntary and initiated when the surgical team believes that it fulfils the requirements. The IFSO approval would be based on the achievements of acceptable and documented patient outcomes. The process for recognition as an IFSO Bariatric Center of Excellence is still to be defined by IFSO Accreditation Council.