



Complete Summary

GUIDELINE TITLE

Expert panel on weight loss surgery.

BIBLIOGRAPHIC SOURCE(S)

Betsy Lehman Center for Patient Safety and Medical Error Reduction. Expert panel on weight loss surgery executive report. Boston (MA): Massachusetts Department of Public Health; 2007 Dec 12. 106 p. [77 references]

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: Betsy Lehman Center for Patient Safety and Medical Error Reduction. Expert panel on weight loss surgery. Boston (MA): Massachusetts Department of Public Health; 2004 Aug 4. 70 p.

** REGULATORY ALERT **

FDA WARNING/REGULATORY ALERT

Note from the National Guideline Clearinghouse: This guideline references a drug(s) for which important revised regulatory and/or warning information has been released.

- [February 28, 2008, Heparin Sodium Injection](#): The U.S. Food and Drug Administration (FDA) informed the public that Baxter Healthcare Corporation has voluntarily recalled all of their multi-dose and single-use vials of heparin sodium for injection and their heparin lock flush solutions. Alternate heparin manufacturers are expected to be able to increase heparin production sufficiently to supply the U.S. market. There have been reports of serious adverse events including allergic or hypersensitivity-type reactions, with symptoms of oral swelling, nausea, vomiting, sweating, shortness of breath, and cases of severe hypotension.

COMPLETE SUMMARY CONTENT

** REGULATORY ALERT **

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SCOPE

DISEASE/CONDITION(S)

Obesity

GUIDELINE CATEGORY

Counseling
Evaluation
Management
Risk Assessment
Treatment

CLINICAL SPECIALTY

Anesthesiology
Family Practice
Gastroenterology
Internal Medicine
Nursing
Nutrition
Pediatrics
Plastic Surgery
Psychiatry
Psychology
Sleep Medicine
Surgery

INTENDED USERS

Advanced Practice Nurses
Allied Health Personnel
Dietitians
Health Care Providers
Health Plans
Hospitals
Managed Care Organizations
Nurses
Patients
Physician Assistants
Physicians
Psychologists/Non-physician Behavioral Health Clinicians
Public Health Departments
Social Workers

GUIDELINE OBJECTIVE(S)

- To improve the safety of weight loss surgery (WLS) in the state of Massachusetts and protect the well-being of patients who undergo it
- To prevent medical errors with evidence-based standards of care

TARGET POPULATION

Patients in Massachusetts and nationwide, including children and adolescents, who are candidates for weight loss surgery

INTERVENTIONS AND PRACTICES CONSIDERED

1. Patient selection criteria, including:
 - Body mass index (BMI)
 - Presence of obesity-related complications (e.g., hypertension, diabetes, hyperlipidemia, sleep apnea, coronary heart disease, stroke)
 - Patient characteristics, such as motivation, history with other nonsurgical weight loss approaches, operative risks, age
2. Surgical care, including:
 - Roux-en-Y gastric bypass (RYGB) including; open, laparoscopic (LRYGB), long-limb (LL-RYGB), very very long-limb (VVLL-RYGB), and banded
 - Biliopancreatic diversion (BPD) with duodenal switch (DS)
 - Laparoscopic adjustable gastric banding (LAGB)
 - Laparoscopic sleeve gastrectomy (LSG) (investigational only)
 - Vertical banded gastroplasty (VBG) in limited cases
 - Revisional weight loss surgery (WLS)
 - Intraoperative techniques
3. Multidisciplinary (medical, nutritional) pre- and postoperative care, including:
 - Medical care, such as identification and coordination of necessary preoperative testing and evaluation
 - Nutritional care, such as monitoring of micronutrient deficiencies
 - Post-WLS body contouring
4. Behavioral and psychological care
5. Pediatric/adolescent care
6. Anesthetic perioperative care and pain management
7. Nursing perioperative care
8. Informed consent and patient education
9. Policy and access (coding and reimbursement)
10. Specialized facilities and resources, including physician and facility credentialing
11. Data collection registries
12. Endoscopic interventions

MAJOR OUTCOMES CONSIDERED

- Patient safety
- Medical error reduction

- Complication rates
- Surgical outcomes, such as long-term weight loss, quality of life and health outcomes, and mortality rates

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
 Hand-searches of Published Literature (Secondary Sources)
 Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

The Expert Panel was divided into task groups.

A medical librarian, aided by a clinical epidemiologist with experience in systematic reviews, carried out literature searches for each task group. Studies were included or excluded based on *a priori* criteria (i.e., written protocols that defined research questions and search parameters, including patient characteristics, study designs, surgical interventions, and outcomes).

MEDLINE searches were limited to English-language studies published from April 2004 to May 2007. (Some groups searched other databases or focused on more recent literature.) References in retrieved articles, guidelines from national organizations, and systematic reviews from the Cochrane Library were also examined. Task group coordinators, with input from the clinical epidemiologist, screened all titles and abstracts; they selected only those most relevant to the review questions.

NUMBER OF SOURCE DOCUMENTS

Surgical Care

The Surgical Care Task Group identified more than 135 papers; the 65 most relevant were reviewed in detail. These included randomized control trials, prospective and retrospective cohort studies, meta-analyses, case reports, prior systematic reviews, and expert opinion.

Multidisciplinary Evaluation and Treatment

The Multidisciplinary Care Task Group identified over 150 abstracts related to weight loss surgery (WLS) in general, and to medical, nutritional, and multidisciplinary care in particular; 112 of these studies were reviewed in detail.

The task group identified and reviewed in detail 80 relevant articles on body contouring, ranging from case reports and expert opinion to prospective randomized trials.

Behavioral and Psychological Care

The Behavioral and Psychological Care Task Group identified 17 papers; the 13 more relevant were reviewed in detail. These included randomized controlled trials, prospective and retrospective cohort studies, meta-analyses, case reports, and prior systematic reviews.

Pediatric/Adolescent Care

The Pediatric/Adolescent WLS Task Group identified more than 1,085 papers; 186 or the most relevant were reviewed in detail.

Anesthetic Perioperative Care and Pain Management

The Anesthetic Perioperative Care and Pain Management Task Group's literature search yielded 1,788 abstracts, with 162 potentially relevant titles. Following full-text evaluation of the latter, 45 articles were reviewed in detail.

Nursing Perioperative Care

A systematic review of MEDLINE, nursing journals, and the CINHALL database for nursing and allied health literature identified more than 54 papers; the most relevant were reviewed in detail.

Informed Consent and Patient Education

This Task Group's literature search identified 120 papers, 38 of which were reviewed in detail. No articles were specific to informed consent and WLS.

Policy and Access (Coding and Reimbursement)

The Policy and Access group identified 51 publications in its literature search; the 20 most relevant were examined in detail. These included reviews, cost-benefit analyses, and trend and cost studies from administrative databases.

Specialized Facilities and Resources

The Specialized Facilities and Resources Task Group identified 1,647 papers in its literature search; the 46 most relevant were reviewed in detail. The literature in the area was very sparse. There were no randomized control trials or prospective or retrospective cohort studies. Most of the available literature was in the form of retrospective reviews, prior systematic reviews, and expert or consensus opinion.

Data Collection (Registries)/Future Considerations

This Task Group identified 212 papers and reviewed the 63 most relevant in detail.

Endoscopic Interventions

This Task Group's literature search identified 18 related articles, all of which were reviewed in detail.

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Grading System for Evidence-Based Recommendations*

Category A: Evidence obtained from at least one well-conducted randomized clinical trial (RCT) or a systematic review of all relevant RCTs

Category B: Evidence from well-conducted prospective cohort studies, registry or meta-analysis of cohort studies, or population-based case-control studies

Category C: Evidence obtained from uncontrolled or poorly controlled clinical trials, or retrospective case-control analyses, cross-sectional studies, case series, or case reports

Category D: Evidence consisting of opinion from expert panels or the clinical experience of acknowledged authorities

*Adapted from the criteria used by the U.S. Preventive Services Task Force (USPSTF) and the American Diabetes Association.

METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses
Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Data Extraction and Tabulation

The panel developed a data extraction sheet and used it to cull detailed information from selected full articles after review. Key data included study design; size; patient demographics; follow-up time; drop-out rate; description of the intervention; outcome measures, including adverse effects; and main conclusions. Information was tabulated in a format suitable for publication.

Synthesis of Evidence

Narrative (or qualitative) summaries primarily were used for the literature review because study designs and outcomes were too dissimilar to combine results in a formal meta-analysis. All selected studies were critically assessed for internal validity or methodological rigor. They were ranked according to levels of evidence based on study design (see "Rating Scheme for the Strength of the Evidence" field). For example, well-conducted randomized clinical trials (RCTs) (Category A evidence) provided the strongest evidence on the effectiveness of a surgical weight loss procedure. Expert opinion (Category D evidence), including clinical experience, the opinions of respected authorities, reports from expert committees,

and consensus of the Expert Panel, was used in conjunction with evidence from RCTs or observational studies to develop recommendations.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Framework for Evidence-Based Recommendations

The Betsy Lehman Center for Patient Safety and Medical Error Reduction (Lehman Center) convened an Expert Panel to study patient-related safety issues in the state's weight loss surgery (WLS) programs and procedures.

The 35-member panel included experienced weight loss surgeons, nurses, psychologists, and nutritionists who counsel patients before and after the procedures; other physicians who care for patients with obesity (an anesthesiologist, internist, and pediatrician); a hospital patient safety officer; a health plan medical director; an ethicist; and a consumer.

The 35-member Expert Panel was divided into eleven task groups:

- Surgical care
- Multidisciplinary evaluation and treatment
- Behavioral and psychological care
- Pediatric/adolescent
- Anesthetic perioperative care and pain management
- Nursing perioperative care
- Informed consent and patient education
- Policy and access (coding and reimbursement)
- Specialized facilities and resources
- Data collection (registries)/future considerations
- Endoscopic interventions

Panel members joined one or two task groups, each with an assigned coordinator. Members were asked to update reports from the prior Lehman Center supplement based on the best available evidence, including randomized controlled trials (RCTs), observational studies, and expert opinion.

Each task group prepared a critical summary of its literature review and developed updated best practice recommendations based on the most current available evidence. The reports were reviewed and approved by the Expert Panel.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

Obesity, particularly abdominal obesity, is associated with increased risk of hypertension, diabetes, hyperlipidemia, sleep apnea, coronary heart disease, and strokes. In 1998, medical costs attributable to overweight and obesity accounted for 9.1% of total U.S. medical expenditures, and may have reached as high as \$78.5 billion (\$92.6 billion in 2002 dollars).

Obesity is linked to higher health care costs than smoking or drinking, and plays a major role in disability (Category B evidence). Accurate short- and long-term cost savings (and risk/benefits) for employers and insurance companies need to be collected and disseminated. Clinical pathways that reduce unnecessary costs to providers should also be developed (Category D evidence).

METHOD OF GUIDELINE VALIDATION

Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

The Executive Report, a summary of key recommendations from all the task groups, was approved by the Expert Panel at its final meeting on July 19, 2007.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Definitions for the level of evidence categories (A-D) are provided at the end of the "Major Recommendations" field.

I. Surgical Care **A. Overview**

Roux-en-Y gastric bypass (RYGB) remains the predominant, gold standard weight loss surgery (WLS) in the U.S., accounting for 93% of all such operations in 2000. Laparoscopic adjustable gastric banding (LAGB) is the second most commonly performed procedure. RYGB is known to safely improve or reverse obesity-related comorbidities and produce significant long-term weight loss. Long-term data on weight loss after LAGB vary.

B. Types of Weight Loss Surgery

Combination Procedures

Combination procedures join a restrictive component (e.g., gastric stapling) with some form of duodenal bypass. They include RYGB, biliopancreatic diversion (BPD), and duodenal switch (DS).

Roux-en-Y Gastric Bypass (Open and Laparoscopic)

Most gastric bypass operations are now done laparoscopically. Laparoscopic Roux-en-Y gastric bypass (LRYGB) reduces pulmonary, wound, hernia-related complications, and postoperative pain (Category B), but may have higher internal hernia rates than RYGB (Category C). Weight loss is similar with both approaches (Category B).

Roux-en-Y Gastric Bypass Modifications

Long-limb RYGB (LL-RYGB) and very very long-limb RYGB (VVLL-RYGB) extend the length of the Roux limb to enhance weight loss. The procedures may increase risk of protein and micronutrient deficiencies (Category C); it has yet to be determined if they produce superior weight loss (Category C).

Banded RYGB may be subject to long-term complications related to reintervention, reoperation, and quality of life (Categories C and D). There is insufficient evidence to make a recommendation (Category D). Long-term drawbacks of mini-gastric bypass might include bile reflux and the need for revisional surgery (Category C). As with banded RYGB, more data are needed to develop recommendations.

Biliopancreatic Diversion and Duodenal Switch

Biliopancreatic diversion (BPD) and duodenal switch (DS) produce effective weight loss (Category B). In patients with a BMI > 50, it may be superior to that achieved with RYGB (Category C). However, the procedures may increase severe complications (e.g., protein and micronutrient deficiencies) (Category B). They also require diligent lifelong patient follow-up (Category D).

Restrictive Procedures

Laparoscopic Adjustable Gastric Banding

Short-term data show promising outcomes with laparoscopic adjustable gastric banding (LAGB) but long-term studies raise questions on durability and reoperative rates (Category B). The authors recommend monitoring of long-term data and continuation of current practice patterns, with yearly follow-up of patients (Category D).

LAGB should be performed in accredited, multidisciplinary settings by experienced surgeons. They should have advanced laparoscopic skills, including those needed to revise LAGB to an alternate procedure. Barring that, WLS programs should be able to provide appropriate referrals to facilities that can provide that level of care (Category D). It is safe for obesity medicine specialists, nurse practitioners, physician assistants, residents, and bariatric nurse specialists to adjust bands under the supervision of a weight loss surgeon (Category D).

Laparoscopic Sleeve Gastrectomy

Several short-term studies suggest safe and effective weight loss with laparoscopic sleeve gastrectomy (LSG) (Categories B and C), but long-term data on safety and efficacy are needed to recommend the approach as anything other than investigational (Category D). If other WLS options are ruled out for reasons of preference or safety, LSG may be considered (Category D).

Vertical Banded Gastroplasty

Vertical banded gastroplasty (VBG) is associated with increased peri- and postoperative complications compared with LAGB. Evidence suggests that it should not be used as a primary surgical treatment for obesity (Categories A and B). However, it can be considered when alternative weight loss surgeries are not safe or possible (Category D).

C. **Revision of WLS**

Revisional WLS can address unsatisfactory weight loss or complications after primary WLS. It may also enhance weight loss and further improve comorbidities (Category B). Complications, length of stay, and mortality are higher for revisional WLS (Category B), but it can be safe and effective when performed by experienced weight loss surgeons (Category D).

D. **Intraoperative Techniques**

The authors recommend the following as standard practice:

- Testing of gastrojejunal anastomosis for leaks intraoperatively or within 48 hours (Category C)
- Strong consideration of whether to close mesenteric defects to avoid internal hernia (Category C)

E. **Patient Selection**

Emerging issues in patient selection include treatment of those with a BMI >50 and individuals age >60. Although procedure-specific recommendations for extremely obese patients have yet to be determined (Category C), the literature suggests that combination procedures (e.g., RYGB, BPD, DS) lead to greater excess weight loss (EWL) and resolution of comorbidities than restrictive procedures (e.g., LAGB) (Category D).

Age may remain an independent risk factor following WLS (Category C), but evidence suggests that WLS can be safe and effective in patients >60 (Categories B and C). The authors recommend that older patients not be denied improvements in health and quality of life associated with WLS (Category D).

F. **Facility and Surgeon Credentialing Standards**

Facilities

- All WLS centers should have, or be in the process of obtaining, accreditation by external review
- They should meet WLS volume standards specified by credentialing bodies
- Centers with lower volume should be endorsed if risk-adjusted outcomes fall within benchmarks determined by credentialing body data.

Surgeon—Credentialing

General Requirements

All surgeons seeking WLS credentials for the first time should:

- Complete an accredited general surgery program and be board-certified, board-eligible, or the equivalent
- Have documented training in the fundamentals of WLS, including pre-, peri-, and postoperative care of the WLS patient

Open Privileges

Most weight loss surgeries are performed laparoscopically. Those who want *only* open privileges should complete the general credentialing requirements above, and:

- Be proctored by an experienced weight loss surgeon until proficient
- Have their first 10 cases reviewed by the chief of service and an experienced weight loss surgeon
- Count fellowship cases toward individual surgeon volume requirements

Full Privileges (Open and Laparoscopic)

It is no longer practical to require specific and mandatory experience in open WLS prior to applying for laparoscopic privileges. Those seeking full laparoscopic privileges should complete the general requirements and a laparoscopic fellowship of 50 WLS procedures. As an alternative, they can be proctored for a minimum of 25 cases by an experienced (>200 laparoscopic cases) weight loss surgeon with full privileges.

In addition, surgeons should:

- Have their first 10 cases reviewed by the chief of staff and an experienced weight loss surgeon
- Count fellowship cases toward individual surgeon volume requirements

Fundamentals of Laparoscopic Surgery (FLS) certification is also highly recommended for newly trained laparoscopic surgeons.

Surgeon—Recredentialing

- Institutions should develop in-house standards for recredentialing based on procedure-specific and risk adjusted outcomes (benchmarks) rather than volume alone
- An annual volume of 25 cases may be sufficient if outcomes are within accepted standards, reported to a central database, and performed at an accredited institution
- Weight loss surgeons should complete at least 12 continuing medical education (CME) credits related to WLS or obesity every 2 years

Procedure-Specific Credentialing

Rapid changes in technologies and techniques warrant disclosure of procedure-specific information to patients, and selection of those with lower risk profiles for the first 25 cases. As part of the educational process, surgeons should disclose:

- The type and approximate number of procedures they perform (Category D)
- Alternative WLS options available (Category D)
- Risks, potential benefits, and program outcomes (Category D)

II. Multidisciplinary Evaluation and Treatment

A. Multidisciplinary Care

The American Society for Bariatric Surgery (ASBS) recently changed its name to the American Society for Metabolic and Bariatric Surgery (ASMBS), reflecting growing knowledge that WLS has benefits beyond the treatment of severe obesity. This change expands the scope of multidisciplinary expertise required to provide optimal care for WLS patients. As the nature of multidisciplinary care changes, the authors recommend:

- Development of uniform minimum standards of multidisciplinary care for WLS patients (Category D)
- Further research on the effectiveness of general medical, surgical, anesthetic, nutritional, and psychological aspects of multidisciplinary treatment (Category D)

B. Preoperative Education and Patient Selection

Preoperative education allows for more appropriate matching of patients and procedures. It can dispel misperceptions and unrealistic expectations, and help clarify issues related to resolution of comorbid conditions, differences between surgical procedures, and required lifestyle changes after WLS (Category D).

C. **Operative Risk**

Higher BMI and medical comorbidities (e.g., obstructive sleep apnea and coronary heart disease risk factors) increase operative risk and postoperative complications. The authors recommend assessment of risk factors in each patient (Category C).

Preoperative Weight Loss

Preoperative weight loss of 5% to 10% of initial body weight can decrease operation time and may reduce surgical risk. Patients, especially those with a BMI ≥ 50 , should be encouraged to achieve weight loss of 5% to 10% of initial body weight prior to surgery (Category C). Prospective randomized controlled trials are needed to determine optimal preoperative weight loss and improve supervision of preoperative weight reduction (Category C).

Medical Evaluation

Specific consideration should be given to WLS patients with a history of coronary artery disease (CAD) or deep vein thrombosis/pulmonary embolism (DVT/PE), those who are current smokers, and those with known or suspected abnormal liver function. *Helicobacter pylori* (*H. pylori*) testing and treatment may also be useful, but more evidence is needed to determine its importance. Other risk factors include postprandial hypoglycemia, chronic renal disease, and HIV.

Coronary Artery Disease (CAD)

Patients with a history of CAD should receive preoperative assessment of cardiovascular conditions as indicated (Category C). Those with stable or suspected CAD should receive perioperative beta blockade unless contraindicated (Category C).

Abnormal Liver Function

Patients with known or suspected liver disease should be evaluated to assess severity of cirrhosis and/or portal hypertension (Category B). Intraoperative liver biopsy at the time of surgery may be useful for diagnosis and assessment of liver disease (Category C). WLS is not recommended in patients with Child's Class C cirrhosis (Category B).

Deep Vein Thrombosis/Pulmonary Embolism (DVT/PE)

The authors recommend perioperative use of anticoagulants and sequential compression devices to reduce the risk of DVT/PE unless clinically contraindicated (Category B). In patients with increased risk of DVT/PE extended prophylaxis should also be considered (Category D).

Smokers

Smokers should be strongly encouraged to stop smoking prior to WLS (Category B). Smoking cessation advice and treatment should be available at the institution or through the WLS program (Category D).

Hypoglycemia

Patients with known or suspected hypoglycemia should be assessed by an endocrinologist prior to WLS. In that gastric bypass surgery is already being used to treat diabetes, purely restrictive procedures should be considered for WLS patients with a documented history of hypoglycemia (Category D).

Chronic Renal Disease

Pre- and postoperative monitoring of renal function is recommended in patients with diabetes and hypertension (Categories A and B). Patients with significant renal disease should be evaluated by a nephrologist prior to WLS (Category D). Special consideration should be given to pre- and postoperative monitoring of fluid and intravascular volume status (Category A).

Human Immunodeficiency Virus (HIV) Infection

Patients with HIV should be evaluated by an infectious disease specialist prior to WLS (Category D). Special consideration should be given to preoperative assessment of viral loads, CD4 counts (Category D), and weight gain from antiretroviral medications (Category D).

D. Nutrition

Preoperative and Postoperative Micronutrients

WLS, especially malabsorptive procedures, can cause multiple micronutrient deficiencies. Patients should be monitored pre- and postoperatively for deficiencies in vitamin D, thiamine, calcium, iron, vitamin B12, and folic acid, with repletion as indicated (Categories A, B, and C).

E. Exercise and Physical Activity

WLS patients should be encouraged to increase pre- and postoperative physical activity (Category D) and low-to-moderate intensity exercise (Category A). Guidance and periodic monitoring should be used to help WLS patients remain physically active (Category D).

F. Pregnancy

WLS should not be performed in patients who are known to be pregnant; the authors strongly recommend preoperative testing for women of childbearing age (Category C). Patients should be strongly

counseled to not get pregnant for at least 18 months after surgery (Category C).

G. Post-WLS Body Contouring

Post-WLS body contouring is an emerging field.

Body contouring can be considered after a patient has achieved a stable weight, generally 18 months (or more) after WLS. Facilities should be accredited, with ready access to intensive care personnel and equipment (Category D).

Surgeon Criteria

Body contouring should only be performed by board-eligible or board-certified surgeons with training and experience in the relevant procedures (Category D).

III. Behavioral and Psychological Care

A. Patient Selection and Preoperative Evaluation

WLS patients are an emotionally vulnerable population. All candidates for WLS should undergo psychosocial evaluation by a credentialed expert in psychology and behavior change (Category C). Evaluations should be carried out by a social worker, psychologist, or psychiatrist with a strong background in the current literature on obesity and WLS, and some experience in the pre- and postoperative assessment and care of WLS patients (Category D). Though not essential, it is preferable that the evaluator be on staff or affiliated with the WLS center to facilitate communication, maintain the support network, and provide continuity of care (Category D).

To address long-term complications, mental health resources should be made available to patients beyond the standard postoperative period of 6 months (Category D). This recommendation can be met in a variety of ways (e.g., staff mental health professional, referral network).

Mental illness, including eating pathology, should not necessarily be a contraindication to WLS. Evaluations should determine the degree to which mental illness, including eating pathology, may jeopardize the safety or efficacy of WLS (Category C). They should be used to identify patients in need of preoperative psychosocial intervention, and develop recommendations on if, how, and when to best address significant psychosocial risk factors (Category C).

Psychological assessment and support have become essential components of multidisciplinary care in WLS. The authors recommend that organizations that provide education on obesity and WLS (e.g., The North American Association for the Study of Obesity) offer continuing education units (CEUs) to mental health care providers.

This will facilitate the development of continuing education standards for mental health specialists in the fields of obesity and WLS (Category D).

B. Binge Eating Disorder (BED)

BED in patients seeking WLS is clinically important, especially in the long-term. It should be taken into account in the development of treatment plans. Assessment should be done in a standardized, empirically validated way (e.g., screening with the Eating Disorder Examination Questionnaire [EDE-Q] and follow-up with a brief, standardized interview based on The Diagnostic and Statistical Manual of Mental Disorders, 4th edition, text revision [DSM-IV-TR] criteria) (Category C). The disorder should not be considered a contraindication for WLS, but rather, a potential complication that may need to be addressed before or after surgery to ensure optimal outcome (Category C).

Patients should know that eating pathology can recur after WLS, and that they may need professional help to deal with recurring patterns of binge eating. BED should be included in the informed consent process and as part of the WLS program's standard educational component (Category C).

C. Night Eating Syndrome (NES)

In that there is no clear evidence that NES has any impact on surgical outcome, the condition should not be considered a contraindication for WLS. Rather, it should be seen as a potentially complicating factor that may need to be addressed before or after surgery to ensure optimal outcome (Category D).

D. Emotional Eating

Data are insufficient to make recommendations on the assessment and treatment of emotional eating. As with NES, the issue should be considered a potentially complicating factor that may need to be addressed before or after WLS to assure optimal outcome (Category D).

E. Substance Abuse

Findings on the prevalence of substance abuse among those seeking WLS are conflicting, and there are few studies on the subject. Evidence is insufficient to conclude that the problem is a frequent one after WLS. Further research is needed to establish the prevalence of substance abuse after WLS as well as its predictors, its relation to surgical outcome, and effective treatment approaches (Category D).

F. Psychotropic Medications

Data indicate significantly higher use of psychotropic medications in WLS patients compared with the general population. Further research is needed to determine the relation between various psychotropic medications and their impact on postoperative weight loss and psychosocial adjustment (Category D).

The effects of WLS on the dissolution, absorption, and clinical response to psychotropic drugs are not well understood. For this reason, the authors recommend close postoperative monitoring of WLS patients, especially after gastric bypass (Category D).

IV. **Pediatric/Adolescent**

A. **Types of Surgery**

RYGB is considered a safe and effective option for extremely obese adolescents as long as appropriate long-term follow-up is provided (Category B). The adjustable gastric band (AGB) has not been approved by the Food and Drug Administration (FDA) for use in adolescents, and therefore, should be considered investigational. Off-label use can be considered, if done in an Institutional Review Board (IRB)-approved study (Category C).

BPD and DS procedures cannot be recommended in adolescents. Current data suggest substantial risks of protein malnutrition, bone loss, and micronutrient deficiencies. These nutritional risks are of particular concern during pregnancy. In addition, several late maternal deaths have been reported (Category C).

Sleeve gastrectomy should be considered investigational; existing data are not sufficient to recommend widespread and general use in adolescents (Category D).

B. **Comorbidities**

Strong indications for WLS in adolescents include established type 2 diabetes (Category B), moderate to severe obstructive sleep apnea (OSA) with apnea hypopnea index (AHI) ≥ 15 (Category C), severe and/or progressive nonalcoholic steatohepatitis (NASH) (Category C), and pseudotumor cerebri (Category C). Other indications for WLS in adolescents include mild OSA, mild NASH, hypertension, dyslipidemia, and significantly impaired quality of life (Categories C and D).

All adolescents with obesity should be formally assessed for depression. If found to be depressed, they should be treated prior to WLS (Category B). The presence of eating disturbances is not an exclusion criterion for WLS, but adolescents with such disorders should be treated prior to surgery (Category B).

C. **Patient Selection**

When combination procedures are used in adolescents, physical maturity (completion of 95% of adult stature based on radiographic study) should be documented. In most cases, this criterion will limit surgery to children over age 12 (Category D). Psychological maturity—demonstrated by understanding of the surgery, mature motivations for the operation, and compliance with preoperative therapy—should be assessed prior to WLS (Category D).

Body mass index (BMI) cutpoints in children and adolescents who meet other criteria should be ≥ 35 with major comorbidities (i.e., type 2 diabetes mellitus, moderate to severe sleep apnea [AHI >15], pseudotumor cerebri, or severe NASH) and ≥ 40 with other comorbidities (e.g., hypertension, insulin resistance, glucose intolerance, substantially impaired quality of life or activities of daily living, dyslipidemia, sleep apnea with AHI >5) (Categories B and C).

There are no data available to suggest that prolonged preoperative weight management programs are of benefit to adolescents who undergo WLS. However, children and adolescents should demonstrate the ability to comply with treatment regimens and medical monitoring before WLS. In many cases, consistent attendance in a prolonged weight management program will provide important assurance of postoperative compliance (Category D).

Individuals with mental retardation vary in their capacity to demonstrate knowledge, motivation, and compliance; they should, therefore, be evaluated for WLS on a case-by-case basis. For these children, the authors suggest including an ethicist on the multidisciplinary evaluation team (Category D).

Others who should be screened on a case-by-case basis include: patients with syndromic obesity, endocrine disorders, obesity that appears to be related to the use of weight-promoting medications, and those in whom obesity cannot be controlled through medical interventions and/or carefully designed environmental and behavioral management. Very limited information is available about the outcomes of WLS for such patients (Category D). Patients with uncontrolled psychosis (presence of hallucinations and delusions), bipolar disorder (extreme mood lability), or substance use disorders can be considered for WLS on a case-by-case basis after they have been in remission for one year (Category C).

D. Team Member Qualifications

Although few hospitals have sufficient volume for a stand-alone pediatric surgical center, the ideal WLS team should include a minimum of 4 or 5 professionals who are co-located and have at least one preoperative face-to-face meeting to prepare a treatment plan for each patient (Category D). Staff should include:

- Surgeon – experienced adult bariatric surgeon or pediatric surgeon with bariatric fellowship or the equivalent experience

- Pediatric specialist – internist or pediatrician with adolescent and obesity training and experience
- Registered dietician – with weight management certificate and experience in treating obesity and working with children and families
- Mental health professional – with specialty training in child, adolescent, and family treatment, and experience treating eating disorders and obesity
- Coordinator – Registered nurse (RN), social worker, or one of the other team members who has the responsibility of coordinating each child or adolescent's care and assuring compliance and follow-up

The ideal setting would be in an adult/pediatric hospital, with a pediatric program, partnered with an adult program that has full access to pediatric specialists (Category D). A comprehensive family-based evaluation should be provided to parents seeking surgery for their adolescent children (Category D).

E. Risks and Outcome

Early WLS may reduce obesity-related mortality and morbidity. However, early timing must be weighed against the patient's possible psychological immaturity and the risk of decreased compliance and long-term follow-up (Category C). All adolescents undergoing WLS should be included in prospective longitudinal data collection to improve the evidence base for evaluating the risks and benefits of WLS in this age group (Category D).

Emphasis on compliance strategies, careful monitoring of vitamin and mineral intake, and periodic laboratory surveillance to detect deficiencies is crucial (Category D). Adolescent girls are particularly vulnerable to nutritional deficiencies; this group is at substantial risk of developing iron deficiency anemia and vitamin B deficiencies during menstruation and pregnancy (Category C), and should receive special attention.

Risk of pregnancy increases after WLS. All female adolescents should be informed about increased fertility following weight loss, and possible risks associated with pregnancy during the first 18 months after surgery. They should be counseled to avoid pregnancy during this period, and offered contraception (Category D). In addition to risks for deficiencies of iron, calcium, and vitamin B12 after WLS, adolescents may also be at particular risk for osteopenia and thiamine deficiency (Category C).

F. Informed Consent

Informed assent by the adolescent should be obtained separately from the parents to avoid coercion (as in other pediatric chronic illnesses that require surgical intervention) (Category D). The patient's knowledge of the risks and benefits of the procedure and the

importance of postoperative follow-up should be formally evaluated to ensure true informed assent (Category C). The parental permission process should include discussion of the risks of adult obesity (Category C), available medical treatments (Category B), surgical alternatives, and the specific risks and outcomes of the proposed WLS in the proposed institution.

V. Anesthetic Perioperative Care and Pain Management

A. Preoperative Evaluation and Preparation

Mandatory polysomnography (PSG) for WLS patients has been proposed (Category C). However, the authors recommend that it be used in selected patients as indicated (Category D). When uncertain of the indication for such testing, clinical assessment should be supplemented to include gender, waist-to-hip ratio, and neck circumference (Category B). Preoperative continuous positive airway pressure (CPAP) treatment should be strongly considered for patients with a PSG diagnosis of moderate to severe OSA (Category C). The authors recommend smoking cessation at least 6 weeks prior to surgery (Category C); the WLS program should provide active support to help patients achieve and sustain compliance (Category D).

B. Intraoperative Management

Induction and Emergence

The ≥ 30 degree reverse Trendelenburg position prolongs the ability of severely obese patients to tolerate apnea during induction of (Category A), and emergence from (Category D), anesthesia. CPAP of approximately 10 cm of water may be considered during preoxygenation to prolong non-hypoxic apnea (Category A). Intubating laryngeal mask airway devices provide an alternative mechanical approach to securing the airway (Categories A and B), and may also improve success when attempting ventilation prior to securing the airway (Category D). Intubating laryngeal mask airway devices should be included among the alternative airway management devices immediately available in the operating room (Categories A and B).

Maintenance of Anesthesia

Preoperative oral administration of clonidine (an alpha-2 agonist) to obese patients with OSA is associated with reduced anesthetic requirements as well as reduced intra- and postoperative opioid requirements. Its use may be considered unless medically or surgically contraindicated (Categories A and C).

Intraoperative Oxygenation

Several methods to improve intraoperative oxygenation during WLS have been evaluated. The authors recommend initial treatment of intraoperative hypoxemia with recruitment maneuvers and positive

end-expiratory pressure (PEEP) while monitoring their potential hemodynamic effects (Categories A and B).

Other interventions

Postoperative nausea and vomiting (PONV) in laparoscopic WLS patients is related to the volume and rate of intraoperative fluid replacement. To reduce PONV, the authors recommend maintenance of euvolemia (Category C).

Intraoperative Drug Dosing

Pharmacodynamic studies in severely obese patients have suggested optimal dosing requirements for different neuromuscular blocking agents. Cisatracurium and rocuronium should be dosed according to ideal body weight during standard induction of general anesthesia (Category A). The muscle relaxant succinylcholine should be dosed at 1 mg/kg total body weight (Category A). For target controlled infusion (not yet approved in the U.S.), propofol dose should be calculated to more closely reflect total body weight (Category C).

C. Postanesthesia Care

Positive outcomes have been reported with early treatment of postoperative hypoxemia employing non-invasive positive pressure ventilatory support (NIV) in non-obese, non-OSA patients at high risk of respiratory failure (Categories A, B, and C). A joint decision between the surgeon, anesthesiologist, respiratory therapist, and nurse should determine NIV use in selected WLS patients (Category D). LRYGB and LAGB have been performed safely as 23-hour stay and outpatient procedures (Category C). However, patients with OSA should not be considered candidates for outpatient WLS (Category D); the authors recommend adherence to the American Society of Anesthesiologists Practice Guidelines for the Perioperative Management of Patients with OSA (Category D).

Postoperative Pain Management

Based on new evidence of efficacy and safety specific to WLS patients, the authors recommend use of opioid sparing multimodal analgesic strategies, including local anesthetic wound infiltration and nonsteroidal anti-inflammatory medications, unless contraindicated (Categories A and C). Solutions for thoracic epidural pain management in OSA patients should be opioid-free to reduce the risk of respiratory depression (Category C).

D. Credentialing

No evidence indicates that specific credentialing of anesthesia personnel for WLS will improve patient safety or outcomes. The authors recommend the selection of a board-certified anesthesiologist

to coordinate intradepartmental staff education and proctoring to establish proficiency. This individual will also serve as an interdepartmental liaison to WLS programs and the multidisciplinary WLS care team (Category D).

E. Medical Error Reduction and Systems Improvement

Optimal outcomes require unimpaired intra- and perioperative multidisciplinary communication among WLS caregivers (Category D). Development of perioperative care pathways for patients with OSA is at an early stage (Category D) and needs further refinement for WLS patients.

VI. Nursing Perioperative Care

A. Planning and Communication

Effective communication between all members of the health care team is paramount in the delivery of quality care. It requires sufficient time for the collection of information from patients, site verification in the operating room, timely and concise reporting of symptoms, and the "repeating back" of information exchanged between team members. To optimize communication, the authors recommend:

- Continued development of clinical pathways (Category D)
- An Advanced Practice Nurse or Clinical Bariatric Nurse Specialist on staff in WLS programs (Category D)
- Development and fostering of good communication skills between patients and practitioners and between members of the health care team (Category D)
- Promotion of collaboration between nurses, physical therapists, discharge planners, social workers, nutritionists, and facilitators of support groups (Category D)

B. Perioperative Management

Unit-specific triage based on individual comorbidities can promote patient safety (Category D). The authors also recommend use of the Association of Perioperative Registered Nurses (AORN) Bariatric Surgery Guideline (Category D) and the American Society of Anesthesiologists Practice Guidelines for the Perioperative Management of Patients with Obstructive Sleep Apnea (Category C). Preferably, a dedicated operative team of nurses and surgical technicians should regularly assist in WLS procedures (Category D).

Preventing Complications

Risk of venous thromboembolic events (VTE) after gastric bypass is significant. Other postoperative complications include those associated with monitoring of fluid balance, hypoxemia, anastomotic leak, tachycardia, peripheral nerve injury, and risk of skin irritation, infection, ulceration in skinfolds, and decubitus ulcers. The authors

recommend ambulation on the day of surgery, and deep breathing/coughing (Category D); careful positioning to decrease risk of peripheral nerve injury (Categories C and D); and education of emergency department staff on early and late complications in WLS patients (Category D).

Perianesthesia

Obese patients present with distinct respiratory care considerations. They should be closely monitored for rapid oxyhemoglobin desaturation and respiratory depression after extubation. Facilities should reference the AORN Bariatric Surgery Guideline (Category D) and educate staff on pulmonary pathophysiology in obese patients (Category D).

Postoperative Analgesia

The goal of postoperative pain management is to promote participation in activity, ambulation, incentive spirometry, deep breathing, and coughing. Nursing staff should consult with a pharmacist on equianalgesic agents and dosing (Category D), and use multimodal, opioid-sparing strategies to keep patients comfortable (Category D).

C. Patient and Staff Safety

WLS patients move through many areas of hospitals for tests and procedures. Facilities should review each area and its equipment to make certain they can accommodate extremely obese patients. The weight capacity of tables, beds, stretchers, and wheelchairs should be clearly marked (Categories C and D). A comprehensive ergonomics program, including lifting and transferring equipment, should be used to prevent patient handling injuries (Category B). A designated nurse or back injury resource nurse (BIRN) should coordinate equipment selection, maintenance, staff training, and reporting (Category D).

D. Outpatient Postoperative Nursing Follow-up

Dehydration, pulmonary embolisms, and anastomotic leaks are the serious complications most likely to occur in the early discharge phase. Later conditions can include hyperinsulinemic hypoglycemia, metabolic bone disease, problems with redundant skin, nutritional deficiencies, suboptimal weight loss, issues with psychosocial adjustment, and pregnancy.

Medications and vitamin supplements should be reviewed at each postoperative outpatient visit (Categories C and D). Nurses should be knowledgeable about possible late complications, know how to support patients, and be prepared to make referrals to appropriate caregivers (Category D). WLS patients should be encouraged to continue treatment through ongoing WLS support groups and networks (Categories A and D).

E. **Credentialing**

The American Society for Metabolic and Bariatric Surgery (ASMBS) has developed national certification criteria for Clinical Bariatric Nurse Specialists (CBN). The authors recommend certification (Category D).

VII. **Informed Consent and Patient Education**

A. **Content**

Risks/Complications

Informed consent should include realistic risk estimates that take into account patient factors (Category C) and relevant institutional and health provider characteristics that might affect risk (e.g., experience and outcomes for specific WLS procedures) (Category B). Short- and long-term risks and complications, and the potential for unknown or unforeseeable long-term risks, should be discussed (Category D).

Benefits/Effectiveness

Patients should receive realistic estimates of short- and long-term weight loss, including the potential for weight regain and modest benefits (Category B). They should also be informed if long-term data (>5 years) are unavailable (Category D). They should be advised of the long-term health benefits of weight loss produced by WLS (Category B), but also be made aware that not all pre-existing medical and psychosocial consequences of obesity (including eating disorders) will improve with WLS (Category C). Candidates for WLS should be given realistic estimates for health outcomes if they decline surgical treatment (Categories B and C), and be advised of known factors and interventions that might optimize benefits (Category D). Informed consent and education should consider patient expectations, the value placed on different outcomes, and the risks each candidate is willing to accept. It should also address unrealistic expectations or other misconceptions patients might have (Category C).

Consequences

Patients should be advised of required behavioral and dietary changes and other reasonable and foreseeable consequences of WLS that could affect health or quality of life in a substantive way, e.g., gastrointestinal symptoms, cosmetic effects, nutritional restrictions (Category D).

B. **Alternative Treatments**

Patients should be advised about alternative WLS procedures and nonsurgical treatment options (e.g., medical and behavioral) (Category C). They should be informed about them even if they are not available through the consent-seeking health provider or institution (Category C).

C. **Patient Comprehension**

Each patient should have their comprehension of the risks, benefits, consequences, and alternatives to WLS evaluated (Category C). Confirmation of comprehension should be included as a protection for patients engaged in the informed consent process (Category C).

VIII. **Policy and Access (Coding and Reimbursement)**

Refer to the original guideline document for recommendations specific to policy and access (coding and reimbursement).

IX. **Specialized Facilities and Resources**

A. **Personnel**

All medical and support staff must be adequately trained and credentialed as specified in the following task group reports: Surgical Care, Anesthesia Perioperative Care and Pain Management, Behavioral and Psychological Care, and Nursing Care. A team of dedicated medical specialists—fully aware of the problems and sensitivities of patients with severe obesity—should be readily available, and all personnel (including ancillary and nonclinical staff) should have obesity-specific education focused on sensitivity training.

B. **Equipment**

All facilities performing WLS, including pediatric WLS centers, require the same equipment. The authors strongly recommend that WLS centers have well-defined plans for the evaluation and treatment of post-WLS surgery patients with potential complications who cannot fit into available diagnostic equipment. Recommended equipment includes:

Ancillary

- Wide wheelchairs, stretchers, and walkers
- Wide blood pressure (BP) cuffs
- Biphasic defibrillators
- Size-appropriate sequential compression devices
- Emergency airway equipment
- Wide examination tables bolted to the floor
- Scales of appropriate size and capacity

Operating Room

Specially-equipped operating room and ancillary equipment should be available to support patients with severe obesity, including:

- An automated extra-wide operating table with appropriate weight capacity
- Extra-long abdominal instrument sets

- Appropriately sized retractor
- 43- to 46-cm laparoscopes

Radiology Equipment

Special diagnostic and interventional equipment is required to support and accommodate WLS patients. Such equipment should include:

- Computed tomography (CT) scanners with 400 pound (lb) weight capacity
- Magnetic resonance imaging (MRI) magnet with 400 lb weight capacity
- Fluoroscopic equipment with 300 lb capacity that can study patients in a standing position with high beam voltages
- Interventional facilities available 24 hours a day, 7 days a week

C. Physical Plant

Size-appropriate facilities should be available in both post-anesthesia and intensive care units (ICUs); postoperatively, dedicated inpatient floors with specially trained personnel should be available. Patient rooms and elevators must have sufficiently wide entrances. Floor-mounted commodes are recommended, but support systems can be used as an alternative. Design of new facilities that will accommodate the WLS patient must comply with the American Institute of Architects Planning and Design Guidelines for Bariatric Healthcare Facilities.

D. Extent of Facility Changes

WLS patients travel throughout hospitals for tests and procedures; there should be size-appropriate accommodations in all inpatient and outpatient points of service. These should include chairs and bathroom facilities, transferring equipment (stretchers and wheelchairs), and monitoring equipment.

E. Investment

Specialized resources for WLS patients require a significant investment, the size of which depends on everything from geography to patient population. Capital investments are preferred for renovations to existing facilities, and strongly recommended for new construction. WLS centers with lower volume or storage space problems should consider renting equipment.

F. Staff Injury Reduction

Health care consistently ranks among the top fields for back injuries. Well-established, agreed-upon, and well-known plans for transferring severely obese patients at all points of care can help reduce injuries. The authors also recommend that proper equipment, as well as training on how to use it, should be immediately available for the

transfer of WLS patients. Staff should be well educated in the use, location, and operation of available lift equipment. Portable equipment is more useful than ceiling lifts, but requires more room clearance. Trained and available on call "lift team" alternatives to equipment (as appropriate) should be considered.

G. Medical Error Reduction

The authors recommend dedicated facilities and staff to reduce risk of medical errors, including a dedicated hospital administrator to provide consistent support and oversight. All medical staff should be adequately trained and credentialed in best practice care of WLS patients. A team of designated medical subspecialists, fully aware of the problems and sensitivities of extremely obese patients, should be readily available, and all personnel who interact with WLS patients should attend obesity-specific education programs focused on sensitivity training.

H. Medication Error Reduction

Medication guidelines released by the Joint Commission on Healthcare Organizations (JCAHO) in 2004 emphasize safety. The authors recommend that facilities follow these recommendations, as well as those specified in our prior report. The authors also recommend an Institutional Pharmacy and Therapeutics Committee to oversee WLS medical dosing regimens, and further research on medication use in the WLS patient.

I. Systems Improvements

Clinical pathways are required by WLS accreditation programs, such as the American College of Surgeons Bariatric Surgery Center Network Accreditation Program and American Society of Metabolic and Bariatric Surgery's Surgical Review Corporation. Clinical pathways specific to WLS patients should be established. These should be procedure-specific, updated frequently, and consistent with order sets. Regular meetings by the WLS team to review patient outcomes and address possible systems changes are essential, as is investment in a WLS database. The database should track patient outcomes and be compatible with the needs of the credentialing body that certifies the center. The authors recommend risk-adjusted outcomes to adequately evaluate performance.

X. Data Collection (Registries)/Future Considerations

The authors recommend collection of WLS-specific data (Categories B and D) on 100% of weight loss surgeries performed (Category D). Refer to the original guideline document for recommendations specific to data collection (registries)/future considerations.

XI. Endoscopic Interventions

A. **Overview**

Endoscopic interventions may provide valuable approaches to the management of WLS complications, and should be a high priority for development and investigation. Similarly, endoscopic interventions, endoscopically-placed devices, and other minimally invasive, image-guided techniques may also provide valuable approaches to the primary management of obesity; they too should be a high priority for development and investigation (Category D).

B. **Experimental Status**

Until formally approved by appropriate regulatory bodies, novel endoscopic interventions and endoscopically-placed devices should only be used in the setting of IRB-approved clinical trials (Category D).

C. **Credentials**

Treatment with endoscopic and other image-guided interventions should be performed only by clinicians with specialized training and expertise in their effective and appropriate use (Category D).

D. **Clinical Application**

As is the standard for other medical and surgical therapies for obesity, endoscopic interventions should be studied and used only in the context of comprehensive patient evaluation and treatment that reflects the complex medical, nutritional, and behavioral contributors to obesity.

E. **Risks and Benefits**

As new technologies become available, choice among therapeutic options for obesity should be determined by the comparative risk-benefit profiles of each modality. These considerations should be matched to the specific clinical characteristics, needs, and treatment goals of each patient (Category D).

F. **Data Collection**

To facilitate tracking of utilization, adverse events, and comparative outcomes, all patients who undergo endoscopic and other minimally-invasive interventions for obesity and its complications should be entered into a standard registry. Methods of tracking should be compatible with those used for patients undergoing WLS (Category D).

Definitions:

Grading System for Evidence-Based Recommendations*

Category A: Evidence obtained from at least one well-conducted randomized clinical trial (RCT) or a systematic review of all relevant RCTs

Category B: Evidence from well-conducted prospective cohort studies, registry or meta-analysis of cohort studies, or population-based case-control studies

Category C: Evidence obtained from uncontrolled or poorly controlled clinical trials, or retrospective case-control analyses, cross-sectional studies, case series, or case reports

Category D: Evidence consisting of opinion from expert panels or the clinical experience of acknowledged authorities

*Adapted from the criteria used by the U.S. Preventive Services Task Force (USPSTF) and the American Diabetes Association.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The recommendations are based on the best available evidence, including randomized controlled trials (RCTs), observational studies, and expert opinions.

The type of supporting evidence is specifically identified for selected recommendations (see "Major Recommendations").

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

- Identification of credentials, tools, and procedures required for best practice in the care of weight loss surgery patients.
- Enhanced public health policies and scientific research in the area of weight loss surgery.
- Optimized patient safety and high quality care.

POTENTIAL HARMS

The complications of commonly performed weight loss surgery (WLS) procedures are well defined. They include:

Laparoscopic Roux-en-Y Gastric Bypass (LRYGB)

Common causes of death include pulmonary embolism and anastomotic leaks. Nonfatal perioperative complications include venous thromboembolism, wound infections, small bowel obstruction, and bleeding. Postoperative gastrointestinal

complications include nausea and vomiting, micronutrient deficiencies, and possible weight regain.

Laparoscopic Adjustable Gastric Band (LAGB)

Data link LAGB with intermediate and long-term complications (e.g., band erosion or slippage, failure to achieve or maintain weight loss) that require reoperation in up to 20% of patients LAGB has been linked to intermediate and long-term complications.

Biliopancreatic Diversion (BPD)

BPD is capable of producing substantial and sustained weight loss, perhaps associated with markedly suppressed ghrelin levels. However, increased incidence of stomal ulceration, severe protein-energy malnutrition, diarrhea, and dumping has limited its broad acceptance

Subgroups Most Likely to Experience Harms

- Higher body mass index (BMI) and medical comorbidities (e.g., obstructive sleep apnea and coronary heart disease risk factors) increase operative risk and postoperative complications.
- Specific consideration should be given to WLS patients with a history of coronary artery disease (CAD) or deep vein thrombosis/pulmonary embolism (DVT/PE), those who are current smokers, and those with known or suspected abnormal liver function. *Helicobacter pylori* (*H. pylori*) testing and treatment may also be useful, but more evidence is needed to determine its importance. Other risk factors include postprandial hypoglycemia, chronic renal disease, and HIV.

CONTRAINDICATIONS

CONTRAINDICATIONS

There are some circumstances where the risks of the surgery may outweigh the potential benefits. For example, weight loss surgery (WLS) may be contraindicated for patients with severe pulmonary disease, unstable coronary artery disease, and other conditions that may seriously compromise anesthesia or wound healing. It is recommended that women of child-bearing age be tested for pregnancy before WLS. Women who are pregnant planning to become pregnant within 18 months, or are currently breastfeeding should not be considered for WLS. Many people considering WLS suffer from obstructive sleep apnea (OSA), and while this is not a contraindication to surgery, it is recommended that they not have WLS as an outpatient.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

IMPLEMENTATION TOOLS

Patient Resources

For information about [availability](#), see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better

IOM DOMAIN

Effectiveness
Patient-centeredness
Safety

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Betsy Lehman Center for Patient Safety and Medical Error Reduction. Expert panel on weight loss surgery executive report. Boston (MA): Massachusetts Department of Public Health; 2007 Dec 12. 106 p. [77 references]

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GUIDELINE COMMITTEE

Expert Panel on Weight Loss Surgery

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Not stated

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This is the current release of the guideline.

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GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from the [Massachusetts Department of Public Health Web site](#).

AVAILABILITY OF COMPANION DOCUMENTS

None available

PATIENT RESOURCES

The following is available:

- Frequently Asked Questions: Patient Primer. Massachusetts Department of Public Health; Dec. 12, 2007.

Electronic copies: Available from the [Massachusetts Department of Public Health Web site](#).

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