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. Boston (MA): Massachusetts Department of Public Health; 2004 Aug 4. 70 p. [89 references]

GUIDELINE STATUS

Note: This guideline has been updated. The National Guideline Clearinghouse (NGC) is working to update this summary.

** 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.
- May 2, 2007, Antidepressant drugs: Update to the existing black box warning on the prescribing information on all antidepressant medications to include warnings about the increased risks of suicidal thinking and behavior in young adults ages 18 to 24 years old during the first one to two months of treatment.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Obesity

GUIDELINE CATEGORY

Management
Treatment

CLINICAL SPECIALTY

Family Practice
Gastroenterology
Internal Medicine
Pediatrics
Surgery

INTENDED USERS

Advanced Practice Nurses
Allied Health Personnel
Dietitians
Health Care Providers
Health Plans
Hospitals
Nurses
Physician Assistants
Physicians
Public Health Departments

GUIDELINE OBJECTIVE(S)

- To provide evidence-based recommendations to the Lehman Center for improving the safety and well-being of patients who undergo weight loss surgery in the Commonwealth of Massachusetts
- To advance patient care across the Commonwealth based on the medical literature, to reduce unnecessary variability, and to improve surgical and patient outcomes

TARGET POPULATION

Patients in Massachusetts, 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., cardiovascular disease, type 2 diabetes, sleep apnea)
    - Patient characteristics, such as motivation, history with other nonsurgical weight loss approaches, and operative risks
2. Surgical procedures
    - Roux-en-Y gastric bypass (RYGB) (open and laparoscopic)
    - Biliopancreatic diversion with or without duodenal switch
    - Laparoscopic adjustable gastric banding (LAGB)
    - Vertical banded gastroplasty (VBG)
3. Multidisciplinary (psychological, nutritional, medical) pre- and postoperative care, including:
    - Behavioral and psychological care to support behavior changes
    - Nutritional care, such as monitoring of protein intake and adequate hydration
    - Medical care, such as identification and coordination of necessary preoperative testing and evaluation
4. Anesthetic perioperative care and pain management
5. Nursing perioperative care
6. Pediatric/adolescent care
7. Patient education (informed consent)
8. Strategies for medical error reduction
9. Credentialing of facilities and personnel
10. Coding and reimbursement
11. Development of data collection registries

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 nine task groups. An expert in library science, 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 January 1980 to April 2004 (Some groups have 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.

The literature searches focused on commonly performed procedures (e.g., Roux-en-Y gastric bypass, vertical banded gastroplasty, gastric banding, and biliopancreatic diversion). Data on other types of surgeries were very limited or irrelevant. Some procedures are no longer performed.

NUMBER OF SOURCE DOCUMENTS

Surgical Care

The Surgical Care Task Group identified more than 100 papers, but only the 26 most relevant studies were reviewed in detail. It also relied on literature from the 2003 Society of American Gastrointestinal Endoscopic Surgeons (SAGES) Appropriateness Conference that included a review of some 50 studies and a summary of the state-of-the-art in open and laparoscopic weight loss surgery (WLS) operations.

Criteria for Patient Selection and Multidisciplinary (Psychological, Nutritional, Medical) Evaluation and Treatment

The Multidisciplinary Care Task Group identified more than 3,000 abstracts related to WLS in general, and to nutritional, medical, and psychological care in particular; 104 of these studies were reviewed in detail.

Patient Education/Informed Consent

The Patient Education/Informed Consent Task Group found no empirical data on the informed consent process for WLS. Recommendations are based on three review articles, materials from six Massachusetts WLS programs, discussions with WLS program leaders, and the consensus of task group members.

Anesthetic Perioperative Care and Pain Management

The Anesthetic Perioperative Care and Pain Management Task Group's literature search identified 195 scientific abstracts, 35 of which were reviewed in detail and evidence graded. An additional 10 references provided general information or indirectly related trial results.

Nursing Perioperative Care

For the Nursing Perioperative Care Task Group, a systematic review of MEDLINE, nursing journals, and the CINAHL® database for nursing and allied health literature identified 134 articles; 16 of them were relevant to this report.

Pediatric/Adolescent Care

The Pediatric/Adolescent Care Task Group identified eight pertinent case series reports on vertical banded gastroplasty (VBG), jejunoileal bypass (JIB), laparoscopic adjustable gastric band (LAGB), and open and laparoscopic Roux-en-Y gastric bypass (RYGB).

Facility and Quality Assurance and Quality Improvement (QA/QI) Resources

The Facility and QA/QI Resources Task Group found scant data on facility resources, all purely descriptive. A search of multiple databases identified 14 relevant papers.

Coding and Reimbursement

For the Coding and Reimbursement Task Group, seventy-six publications were identified in the literature search, and 28 were found to be relevant to the issues of coding and reimbursement; none, however, dealt directly with coding or reimbursement policy issues. The Task Group searched the Internet and trade press and found substantial additional information relevant to these issues. The Massachusetts Dietetics Association provided information about reimbursement for medical nutrition therapy.

Data Collection (Registries)/Future Considerations

The Data Collection (Registries)/Future Considerations Task Group identified over 150 publications in the literature search; 16 of these were reviewed in detail. There were few, if any, studies on the effect of data registries on the care of WLS patients. To compensate for the lack of data, the search was broadened to include databases from related fields (such as cardiac and thoracic surgery), as well as cancer data registries.

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

Evidence Grading System*

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 American Diabetes Association.

METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses
Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Data Extraction and Tabulation

The panel developed a data extraction sheet and used it to pull 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 were primarily used for the literature review because study designs and outcomes are 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) provide 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 24-member panel included experienced weight loss surgeons; nurses, a psychologist, and a nutritionist 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 24-member Expert Panel was divided into nine task groups:

- Surgical care
- Criteria for patient selection and multidisciplinary (psychological, nutritional, medical) evaluation and treatment
- Patient education/informed consent
- Anesthetic perioperative care and pain management
- Nursing perioperative care
- Pediatric/adolescent care
- Facility and quality assurance/quality improvement (QA/QI) resources
- Coding and reimbursement
- Data collection (registries)/future considerations

Panel members joined one or two task groups, each with an assigned coordinator. In developing recommendations, they were asked to focus on five topics: patient safety, medical errors, credentialing, systems improvements, and research needed for the future.

The panel met six times between February and July 2004. There were also several task group meetings, and numerous telephone conferences and e-mail communications. The core group, composed of the panel chairs and Department of Public Health personnel, met five times. Members from the Massachusetts Coalition for the Prevention of Medical Errors participated in two Expert Panel meetings.

Each task group prepared a critical summary of its literature review and developed recommendations based on the best available evidence.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

The Expert Panel reviewed published cost analyses.

METHOD OF GUIDELINE VALIDATION

Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

The Executive Report of key recommendations was approved by the full expert panel at the last meeting on July 19, 2004.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Note: This guideline has been updated. The National Guideline Clearinghouse (NGC) is working to update this summary. The recommendations that follow are based on the previous version of the guideline.

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

The guideline developers present recommendations pertaining to the following 9 topic areas:

- Surgical care
- Criteria for patient selection and multidisciplinary (psychological, nutritional, medical) evaluation and treatment
- Patient education/informed consent
- Anesthetic perioperative care and pain management
- Nursing perioperative care
- Pediatric/adolescent care
- Facility and quality assurance/quality improvement (QA/QI) resources
- Coding and reimbursement
- Data collection (registries)/future considerations

For each one of these topic areas, recommendations are provided for 1 or more of 5 focus areas: patient safety, medical errors, system improvements, credentialing, and future research needs. The clinical practice recommendations pertaining to "patient safety," "medical errors," and "system improvements" are provided below. Interested readers are directed to the original full text guideline for recommendations pertaining to "credentialing" and "future research needs."

I. **Surgical Care**

A. **Patient Safety**

1. **Risks**

Refer to the "Potential Harms" field for information on complications of weight loss surgery (WLS).

B. **Types of Weight Loss Surgery**

A large body of evidence suggests that commonly performed WLS procedures, such as Roux-en-Y gastric bypass (RYGB), are effective in producing long-term weight loss, improved quality of life and health outcomes, and reduced mortality (Category B).

The task group recommends use of the Society of American Gastrointestinal Endoscopic Surgeons (SAGES) Appropriateness

Conference statement in selecting types of WLS. Evidence below reflects the panel's statements on the Appropriateness Conference and the consensus of task group members.

1. **Gastric Bypass**

Roux-en-Y Gastric Bypass (open and laparoscopic)

Roux-en-Y gastric bypass (RYGB) produces greater long-term weight loss than gastric partitioning alone or vertical banded gastroplasty (VBG) (Categories A and B), and it is substantially safer than jejunoileal bypass.

Open and laparoscopic RYGB produce similar short-term weight loss and improvements in comorbid medical conditions. The laparoscopic approach improves short-term recovery from surgery and has a lower incidence of incisional hernias than the open RYGB (Long-term data are not yet available) (Categories A and B).

Laparoscopic RYGB has become increasingly common, but it needs to be performed by appropriately trained, qualified laparoscopic weight loss surgeons (Category D).

Long limb (>150 cm) RYGB may produce superior short-term weight loss in patients who are more than 200 lbs overweight or have a body mass index (BMI) $\geq$ 50. Optimal limb length is unknown, but long-term follow-up indicates that the benefit of longer limb length decreases over time and may disappear completely (Category C).

2. **Malabsorptive Procedures**

Biliopancreatic Diversion with Duodenal Switch

Biliopancreatic diversion with or without duodenal switch is effective in producing weight loss (These procedures are still considered investigational, however, due to limited data on long-term safety and metabolic side effects) (Category C).

3. **Restrictive Procedures**

Laparoscopic Adjustable Gastric Band (LAGB)

LAGB produces variable short-term weight loss and improvements in obesity-related comorbidities (Category B). It has lower average mortality rates than RYGB or malabsorptive procedures (Categories B and C).

Placement of the LABG in the pars flaccida path rather than the retrogastric position may reduce the incidence of postoperative complications (Category C).

Vertical Banded Gastroplasty (VBG)

The role of VBG in the treatment of patients with severe obesity is limited (Category D). This procedure has been largely supplanted by LAGB.

C. Strategies for Medical Error Reduction

Risk of medical errors and complications are most likely to be minimized under the following conditions (Category D, unless otherwise noted):

- Rigorous training that puts a strong emphasis on patient safety and includes close monitoring and early supervision of surgeons in their learning curves
- Ongoing training and accumulation of experience that takes place in a supportive setting, with extended proctoring by experienced weight loss surgeons
- High-volume surgeons (50 to 100 cases per year) operating in properly equipped, high-volume weight loss centers (>100 cases per year) with integrated and multidisciplinary treatment. High-volume surgeons tend to have better short-term outcomes (Category B).

II. Criteria for Patient Selection and Multidisciplinary (Psychological, Nutritional, Medical) Evaluation and Treatment

A. Patient Safety

1. Criteria for Patient Selection

The Expert Panel recommends use of patient selection guidelines from the 1991 National Institutes of Health (NIH) Consensus Development Conference on Gastrointestinal Surgery for Severe Obesity. These criteria, paraphrased below, include:

- BMI $\geq$ 40 kg/m^2, or BMI $\geq$ 35 kg/m^2 in association with major medical complications of obesity (e.g., cardiovascular disease, type 2 diabetes, sleep apnea)
- A well-informed and motivated patient
- A strong desire for substantial weight loss
- Failure of other nonsurgical approaches to long-term weight loss
- Acceptable operative risks

Most patients with severe obesity are unlikely to achieve and maintain a healthy weight with nonsurgical treatment (Category A). We were unable to recommend specific criteria for

demonstrating prior unsuccessful efforts at long-term weight loss via nonsurgical means (Category D).

Increased risk of complications: Refer to the "Potential Harms" field for information.

2. **Multidisciplinary Care**

The Expert Panel strongly recommends preoperative and postoperative medical, nutritional, and behavioral/psychological care for weight loss surgery (WLS) patients. Recommendations in each area are listed below, along with the categories of supporting evidence. Preferred providers are those who specialize in, or have substantial experience with, the care of WLS patients (Category D).

Behavioral/Psychological Care

The Expert Panel recommends evaluation by a credentialed expert in psychology and behavior change, preferably a psychiatrist, psychologist, or social worker. He or she must be skilled at identifying psychological contraindications to WLS and potential barriers to success (e.g., inability to make needed behavior changes). They must be able to develop plans and implement treatments to address these barriers (Category D).

Nutritional Care

The Expert Panel recommends preoperative education and counseling by a registered dietitian, with a well-defined diet progression after surgery. Early postoperative priority should be placed on maintenance of adequate hydration and protein intake (Category D). Blood levels of micronutrients should be assessed for deficiencies prior to surgery, 6 months after surgery, and at least annually thereafter (Category D). All patients should take a daily multivitamin (Category A) and calcium supplement with added vitamin D (Category D). Thiamine supplementation should be considered for patients with persistent vomiting or poor intake (Category C). Prenatal multivitamins are an option for patients at risk of deficiencies in iron and/or folic acid. Regular use of additional iron supplements is also likely to minimize iron deficiency in at-risk patients (Category A). Patients who have had RYGB or malabsorptive procedures should be considered at risk for metabolic bone disease, and patients who have additional risk factors for metabolic bone disease should be assessed periodically after WLS (Category A).

Medical Care

Physicians and nonphysician providers (e.g., nurses and physicians assistants) provide unique contributions to patient care; all should be considered important members of the multidisciplinary WLS treatment team. Extreme obesity is associated with several conditions known or suspected to increase operative risk. The following are recommendations for assessment and treatment for specific conditions:

Obstructive sleep apnea (witnessed or daytime symptoms): The Expert Panel recommends preoperative assessment of patients with signs or symptoms of sleep apnea (e.g., increased neck circumference, daytime sleepiness, or other symptoms), as well as patients with hypertension, lower extremity edema, or cardiac dysfunction. There are insufficient data to recommend specific perioperative measures, although oxygen saturation monitoring appears prudent (Category D).

Deep vein thrombosis/pulmonary embolism (DVT/PE): WLS patients are at high risk for venous thromboembolism (VTE) and should receive perioperative DVT/PE prophylaxis. Except where contraindicated, prophylaxis should be carried out via combined use of mechanical methods and anticoagulant strategies (Categories A and B). Patients at particularly high risk for DVT/PE should be considered for preoperative inferior vena cava filter placement (Category D).

Liver disease: Patients with unexplained elevations of hepatic transaminases should undergo preoperative evaluation for common etiologies of liver disease. Patients with preoperative or intraoperative evidence of fibrosis, cirrhosis, or hepatic dysfunction should undergo intraoperative liver biopsy. Those with evidence of insulin resistance should also be considered for intraoperative liver biopsy. In cases where cirrhosis is found, decisions on whether to proceed with WLS should be made on a case-by-case basis; factors to consider include the overall health of the patient, the presence of gastric or intestinal varices or ascites, and the physical or histologic appearance of the liver (Category B).

Smoking cessation: All patients who smoke cigarettes should be encouraged to quit, preferably at least 6 to 8 weeks prior to surgery (Category D). Use of nicotine replacements and/or bupropion may help minimize weight gain with smoking cessation. To reduce long-term health effects from smoking, patients should not resume tobacco use after surgery (Category A).

Preoperative weight loss: All patients should be encouraged to lose weight prior to surgery (Category D). Those with BMI > 50 or comorbidities such as sleep apnea, type 2 diabetes, glucose intolerance, and hypertension should attempt to lose 5 to 10% of initial weight. Some patients (e.g., those already maintaining

significant losses or taking medications that promote weight gain) may be unable to reduce weight prior to surgery. Decisions on whether to proceed with surgery in these patients should be made on a case-by-case basis given the limited data linking preoperative weight loss to safety or efficacy outcomes (Categories C and D).

Coronary Artery Disease (CAD): WLS patients with known or suspected CAD should receive perioperative beta blockers to reduce cardiovascular complications (Category D). Current guidelines from the American College of Cardiology and the American Heart Association recommend use of beta blockers prior to, during, and after surgery in patients with a history of CAD or with two or more CAD risk factors, such as hypertension or high cholesterol (if use is not contraindicated).

B. **Strategies for Medical Error Reduction**

Refer to the "Contraindications" field for information on contraindications to WLS.

Patient care should be coordinated by regular meetings of the multidisciplinary team. In centers where this is not possible, specific procedures should be established to insure timely communication of patient care information among participating providers (Category D).

C. **Systems Improvements**

Weight loss outcome after WLS should be measured as change in BMI or percent excess body weight loss (Categories C and D).

III. **Patient Education/Informed Consent**

A. **Patient Safety**

1. **Understanding vs. disclosure**

The informed consent process can make a significant contribution to patient safety and long-term outcomes. It should include an assessment of the patient's understanding of the content of the informed consent. Informed consent based on comprehension (vs. just disclosure) better promotes patient safety.

2. **Educational objectives**

Educational objectives of the informed consent process include:

- Maximizing participation in preoperative program by the patient
- Helping patients make informed decisions about surgery
- Improving each patient's short- and long-term health and well-being

3. **Appropriate content**

WLS programs should include information on the following topics as part of their informed consent process:

- Health risks associated with obesity
- Alternatives to WLS for treatment of obesity
- Alternative forms of WLS and our current understanding of their respective risks and benefits
- Potential complications in the postoperative period and beyond
- Presurgical strategies to reduce surgical risks, including preoperative weight loss when possible
- Potential impact of WLS on family, friends, and relationships
- Common psychological adjustment issues after WLS
- Postsurgical requirements, especially those related to diet and medications
- Aftercare programs and sources of support

4. **Teaching and learning**

WLS programs should use active teaching and learning techniques that may include:

- Videotapes that prospective patients can take home and share with their family and friends
- Participation of patient's support network (family or friends) in education programs and discussions with the WLS clinical team
- Practice with a mock postsurgical diet regimen to improve understanding of long-term implications

5. **Assessment of learning**

Assessment of learning should be an integral part of the informed consent process. Some programs have used diet preparation and documentation exercises, oral or written tests, and tools to evaluate the effectiveness of their education programs.

6. **Promoting realistic expectations**

It is important to emphasize that surgery is only one component of a lifetime weight management program. An "agreement," signed by the patient and a member of the clinical team, may be helpful in reinforcing the patient's commitment to long-term follow up and self-management. The "agreement" is not legally binding.

IV. Anesthetic Perioperative Care and Pain Management

A. **Patient Safety**

1. **Preanesthesia evaluation**

At least one day before scheduled WLS, an anesthesia clinician should conduct a preanesthesia evaluation. Each patient should be clinically evaluated for, and specifically asked about, signs and symptoms of sleep apnea. Baseline routine laboratory testing within 6 months of WLS should include hematocrit, glucose, creatinine, and blood urea nitrogen (BUN).

2. **Anesthesia induction and emergence**

The 30 degrees reverse Trendelenburg (head up) position—with additional upper body and airway positioning measures as needed to facilitate successful tracheal intubation—is recommended for routine use unless medically contraindicated. This anesthesia induction positioning helps to maintain oxygenation during the apneic (non-breathing) period and possibly decreases the risk of aspiration.

3. **Equipment and personnel**

The anesthesia practitioner should be proficient in the use of a variety of airway management devices and techniques for the management of a difficult airway; these devices should be immediately available to him or her during induction and emergence of anesthesia. An additional anesthesia clinician, the operating surgeon, and an operating room nurse should be immediately available to the anesthesia care team during induction of, and emergence from, anesthesia.

4. **Dosing of medication**

Proper dosing of many medications for patients with severe obesity is uncertain. The task group recommends that clinicians should begin with doses close to the estimated lean body mass (approximately 120% of ideal body weight) and adjust as needed.

5. **Intraoperative monitoring**

In addition to standard American Society of Anesthesiologists (ASA) standard intraoperative monitoring protocols (including an electrocardiogram, blood pressure, oxygen saturation, inspired oxygen concentration, and end-tidal carbon dioxide values), assessment of body temperature and measures to maintain normothermia are recommended during WLS. Use of alternate sites for noninvasive blood pressure measurements (e.g., the forearm) should be considered as needed. Invasive hemodynamic measurements should be used as medically indicated.

6. **Postanesthesia care**

The ASA *Standards for Postanesthesia Care* should be followed taking into consideration the patient's overall medical condition and the presence or absence of sleep apnea. Continuous positive airway pressure/bi-level positive airway pressure (CPAP/BiPAP) should be available to patients as needed for noninvasive positive pressure ventilation.

7. **Postoperative pain management**

Major postoperative pain treatment strategies include thoracic epidural analgesia (TEA) and patient controlled intravenous analgesia (PCA).

When TEA is preferred, the Expert Panel recommends a combination of local anesthetics with opioids (narcotics), with or without epinephrine in the epidural solution, unless any of these agents is specifically contraindicated. Standardized nursing protocols should be established for monitoring, maintaining, and troubleshooting epidural management daily, and an acute pain service should be available to provide assistance or oversight as needed. TEA is not typically needed following laparoscopic procedures.

When PCA management is preferred, the combination of an opioid-based PCA with local anesthetic wound infiltration and adjunct (non-narcotic) analgesic medications is recommended, unless any of these agents is specifically contraindicated. The routine use of a continuous opioid background infusion PCA mode should be avoided.

B. **Strategies for Medical Error Reduction and Systems Improvement**

1. **Effective communication**

Effective and unimpaired intraoperative and perioperative communication between the anesthesia and surgical members of the WLS care team is essential to promote patient safety.

2. **Equipment and skills**

Throughout the perioperative period, at least one portable storage unit with specialized equipment for difficult airway management should be readily available; it should be maintained and operated by anesthesia clinicians. A clinician with advanced airway management skills should be immediately available.

3. **Patient monitoring**

Patients with documented or suspected sleep apnea may require continued close perioperative monitoring to protect against respiratory depression beyond the recovery room; the Expert Panel encourages the formulation of, and adherence to, institutional protocols of continued close monitoring as clinically indicated. A national task force from the American Society of Anesthesiologists (ASA) is currently developing recommendations for the perioperative care of patients with sleep apnea. These should be followed when they become available.

V. Nursing Perioperative Care

A. Patient Safety

1. Education

Nursing care is a critical factor to ensure patient safety in WLS. Those who care for patients with severe obesity should complete a competency-based orientation that enables them to identify potential complications and prevent adverse outcomes. Core curriculum should cover the physiological and psychological effects of obesity, associated comorbidities, surgical options, and benefits and risks of surgery. Nurses should be able to demonstrate skill and knowledge in the use of special equipment for patients with severe obesity.

Educational in-service sessions should be available to increase understanding of obesity-related psychological issues and to promote awareness of and to minimize intended or unintended bias (e.g., groans during transport). Nurses should take great care to ensure patient confidentiality.

2. Preoperative care

Preoperative nursing care should include a comprehensive admission assessment, identification of the patient's support system (family and/or friends), and education of the patient and family about the surgery and postoperative care.

Other responsibilities include ensuring a safe physical environment; ensuring protection of patient privacy; provision of size-appropriate materials (e.g., patient gowns); helping patients with activities of daily living, especially those made more difficult because of severe obesity, taking vital signs; checking lab work; and ensuring the completeness of paperwork. Nurses involved in the perioperative assessment should be prepared to review the planned procedure with the patient and to provide him or her with ample opportunity to ask questions. The nurse's assessment should help secure an appropriate bed designed to facilitate the recovery of patients with severe obesity.

3. Operating room

Operating room nurses should help position the patient with severe obesity properly to avoid nerve damage or other pressure-related injury. The circulating nurse must be aware of the need for extra support and should secure the patient's extremities to prevent movement or nerve plexus injuries.

4. **Postanesthesia nursing**

The Postanesthesia Care Unit (PACU) nurse is responsible for monitoring the patient according to hospital standards of care. Additionally, the nurse must pay special attention to airway stability, hemodynamic stability, and postoperative pain management.

When any ventilated patient travels out of the PACU or intensive care unit (ICU) for testing, a respiratory therapist should accompany the nurse.

The Expert Panel recommends continuous oxygen saturation monitoring for patients receiving continuous positive airway pressure (CPAP) and using patient controlled analgesia (PCA).

5. **Discharge and follow-up**

Nurses should provide thorough discharge instructions, including detailed plans for follow-up care. A phone call to the patient 48 hours after discharge enables nurses to clarify instructions, determine progress, provide encouragement, and give patients an opportunity to ask additional questions.

6. **Communication channels**

Communication among the nurse, surgeon, and other members of the WLS care team must be open and clear.

7. **Summary**

Safe and competent nursing care requires assessment of, and provision for, the complex physical and psychological needs of patients undergoing WLS. Potential complications that could result from obesity-related comorbid conditions call for special attention and vigilant perioperative monitoring. In addition, nurses should consistently use proper body mechanics and take necessary precautions to avoid self-injury.

B. **Strategies for Medical Error Reduction**

Standardized order sets and/or clinical pathways minimize medical errors. Clinical pathways, used in acute care settings to outline care plans and define expectations, also improve coordination and delivery of appropriate care.

C. **Systems Improvements**

Use of a dedicated area, fully and appropriately equipped for the care of patients with severe obesity, will improve the quality of care, the patient's experience, and the productivity and morale of participating clinicians (Refer to The Facility and QA/QI Resources section for more detail).

VI. Pediatric/Adolescent Care

A. Patient Safety

1. Eligibility

Inclusion criteria:

- BMI $\geq$ 40 kg/m^2 with one serious comorbidity (such as diabetes mellitus, obstructive sleep apnea, severe or complicated hypertension, or pseudotumor cerebri)

OR

- BMI $\geq$ 50 kg/m^2 with less serious comorbidities
- Failure of nonsurgical treatments for obesity
- Adolescents with lower BMI and life-threatening comorbidities should be considered for WLS on a case-by-case basis (Category D).

Exclusion criteria:

- Patient has not attained Tanner stage IV (Category D).
- Patient has not attained 95% of adult height based on estimates from bone age (Category D).
- Female adolescents who are pregnant, breast feeding, or plan to become pregnant within two years of surgery (Category D)

2. Eligibility Evaluations

WLS requires comprehensive evaluation of the prospective patient and his or her family.

- Knowledge, motivation, and compliance should be assessed by interview and written examination of the adolescent and at least one parent or legal guardian; exam content should evaluate understanding of the planned procedure, the potential risks and benefits, the nature of the potential complications, and responsibility for self-care (Category D).
- Psychological maturity should be evaluated to determine if the patient is able to understand the consequences of WLS, provide informed consent, and comply with

medical care and lifestyle changes required prior to and after surgery (Category D).

- Psychological factors that present a contraindication to WLS or that could interfere with treatment, such as eating and/or mood disorders, psychosis, borderline personality disorder, sexual or physical abuse, cigarette smoking, substance abuse and post traumatic stress disorder (PTSD) should be evaluated and treated as appropriate (Category D).
- Eligibility evaluations should include a workup for syndromic or genetic obesity (e.g., Prader-Willi syndrome) for candidates suspected of these syndromes and careful consideration on a case-by-case basis to proceeding with surgery in case of a diagnosis of syndromic or genetic obesity (Category D).

3. **Required counseling**

Female adolescents who undergo WLS must be counseled on the need to postpone pregnancy until at least 2 years after surgery to avoid potential birth defects from nutrient deficiencies. Family planning, including methods of contraception, should be offered to fertile female patients (Category D).

4. **Recommended procedures**

The limited available data indicate that Roux-en-Y gastric bypass (RYGB) and laparoscopic adjustable gastric banding (LABG) are generally safe and produce durable weight loss when used in adolescents (Evidence is from eight Category C studies and large-scale adult case series reports).

The Expert Panel recognizes RYGB as the procedure with the best long-term data and LABG as the procedure with the least apparent risk for adolescent patients. More aggressive (e.g., malabsorptive) procedures should be viewed with great caution in this population (Category C).

Because there are currently no criteria to determine which of the two procedures (RYGB or LAGB) is better for any given patient, the decision should rest with the patient and his or her parents or guardians upon recommendation of the WLS surgeon and other members of the WLS clinical care team.

B. **Strategies for Medical Error Reduction**

The Expert Panel recommends a peer review process for all programs offering WLS to adolescents every two years. Refer to the original guideline document for more information.

VII. Facility and Quality Assurance and Quality Improvement (QA/QI) Resources

A. Patient Safety

1. Personnel

The Expert Panel recommends that all medical staff be adequately trained and credentialed in accordance with recommendations from the surgical care, anesthesia perioperative care, and nursing perioperative care task groups.

A team of designated medical subspecialists, fully aware of the problems and sensitivities of patients with severe obesity, should be readily available.

A dedicated hospital administrator should be identified to provide consistent support and oversight. All personnel who interact with WLS patients should attend educational programs focused on the care of patients with severe obesity that include sensitivity training.

2. Equipment

Operating rooms

A specially-equipped operating room and ancillary equipment should be available to accommodate patients with severe obesity. Equipment should include:

- An automated extra-wide operating table with appropriate weight capacity
- Extra-long abdominal instrument sets
- Appropriately sized retractors
- 43 to 46 cm laparoscopes

Other equipment should include:

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

Special diagnostic and interventional equipment

Special diagnostic and interventional equipment is required to accommodate WLS patients, including appropriate x-ray and ultrasound, computed tomography (CT), magnetic resonance imaging (MRI), fluoroscopy, interventional facilities, and longer needles.

3. **Physical Plant**

Postanesthesia and ICU

Dedicated beds and specially trained personnel should be available in both the Postanesthesia and Intensive Care Units.

Relief staff

A minimum of two designated floor units are required to provide assigned nurses and attendants intermittent relief from exceptional demands required for the care of patients with severe obesity.

Specially-equipped patient rooms

Rooms must have sufficiently wide entrances and bathroom doors, and bathroom facilities must have floor-mounted toilets and wide shower stalls.

Patient transport

Patient transport elevators must have sufficiently wide doors and weight capacity to accommodate patients with severe obesity.

B. **Strategies for Medical Error Reduction**

Blame-free culture

The Expert Panel recommends three initiatives to establish a blame-free environment conducive to reporting of adverse events:

- Executive walk-rounds, encouraging communication between executives with decision-making authority and frontline caregivers
- A sentinel event reporting system, enabling and encouraging staff to let the designated hospital administrator and risk manager know about concerns
- A Web-based incident reporting system to provide a fast and easy way to report actionable information

Dedicated pharmacy committee

An institutional Pharmacy & Therapeutics Committee must be empowered to establish and disseminate appropriate weight-based dosing of drugs commonly used during and after WLS including:

- Analgesics
- Epidural regimens
- Patient-controlled analgesia

- Anxiolytics
- DVT prophylaxis (low molecular weight heparin).

Tracking and management

Effective tracking and management of medication dispensing and administration requires the following equipment:

- Computerized order entry with decision support
- Automated medication dispensing devices
- Electronic medication administration that incorporates bar-code technology (Categories A, B, and C)

C. **Systems Improvements**

Personnel

Strategies to implement and monitor systems improvements must include the appointment of a Medical Director of the WLS Program to work closely with the designated Hospital Administrator.

Information

A statewide risk-adjusted WLS Data Registry needs to be established and maintained in an accessible outcome tracking system (see Data Collection/Registries Section).

Quality Assurance

- Critical pathways should be developed, implemented, and monitored for adherence; and
- A quality assurance (QA) program specific to WLS should be established.

VIII. Coding and Reimbursement

Refer to the original guideline document for recommendations specific to coding and reimbursement.

IX. Data Collection (Registries)/Future Considerations

Refer to the original guideline document for specific recommendations.

Definitions

Level of Evidence Grading System*

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 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:

Roux-en-Y Gastric Bypass (% of patients)

- Deep vein thrombophlebitis 1-2%
- Pulmonary embolus 0.5%
- Splenectomy 1%
- Gastrointestinal leak 1-3%
- Postoperative bleeding 1-5%
- Stomal obstruction 5-15%

- Small bowel obstruction 1-3%
- Mortality (within 30 days) 0.5–1%
- Protein-calorie malnutrition <1%

Laparoscopic Adjustable Gastric Band (LAGB) (% of patients)

- Injury to adjacent organs 0.5%
- Band erosion 1%
- Band slippage/stomach herniation 2-3%
- Port infection 1%
- Mortality (within 30 days) <0.5%

The revision rate for LAGB patients may be as high as 10%; such operations are performed to replace the port and/or tubing and, possibly, to replace, reposition, or remove the band.

Subgroups Most Likely to Experience Harms

The risk of complications and mortality is greater with revisional surgery, increased weight or body mass index (BMI), male gender, and increased age. In particular, patients older than 50 years, with a BMI > 50 kg/m^2 appear to have a significantly elevated risk (Category B)*. Severe medical conditions that may contribute to increased risk include type 2 diabetes, hypertension, and obstructive sleep apnea (Category C)*. Use of hospitals with qualified 24-hour, in-house coverage for airway and resuscitative management should be considered for such patients (Category D)*.

**See the Rating Scheme for the Strength of Evidence field for level of evidence category definitions.*

CONTRAINDICATIONS

CONTRAINDICATIONS

Contraindications to weight loss surgery include:

- Unstable coronary artery disease
- Severe pulmonary disease
- Portal hypertension with gastric or intestinal varices
- Other conditions thought to seriously compromise anesthesia or wound healing risk
- Inability to comprehend basic principles of the procedure or to follow basic postoperative instructions

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

Randomized controlled trials (RCTs) are considered the highest-level evidence of clinical safety and efficacy, but there are few such studies available on weight loss surgery (WLS).

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. Boston (MA): Massachusetts Department of Public Health; 2004 Aug 4. 70 p. [89 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2004 Aug 4

GUIDELINE DEVELOPER(S)

Massachusetts Department of Public Health - State/Local Government Agency [U.S.]

SOURCE(S) OF FUNDING

Massachusetts Department of Public Health

GUIDELINE COMMITTEE

Expert Panel on Weight Loss Surgery

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

Note: This guideline has been updated. The National Guideline Clearinghouse (NGC) is working to update this summary.

GUIDELINE AVAILABILITY

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

AVAILABILITY OF COMPANION DOCUMENTS

The following is available:

- Massachusetts expert panel on weight loss surgery summary. Boston (MA): Massachusetts Department of Public Health; 2004.

Electronic copies: Available from the Massachusetts Department of Public Health Web site.

PATIENT RESOURCES

The following is available:

- Weight loss surgery: a primer for patients. Boston (MA): Massachusetts Department of Public Health; 2004.

Electronic copies: Available from the Massachusetts Department of Public Health Web site.

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

NGC STATUS

This NGC summary was completed by ECRI on October 27, 2004. The information was verified by the guideline developer on November 29, 2004. This summary was updated by ECRI Institute on June 22, 2007 following the U.S. Food and Drug Administration (FDA) advisory on heparin sodium injection. This summary was updated by ECRI Institute on November 9, 2007, following the U.S. Food and Drug Administration advisory on Antidepressant drugs. This summary was updated by ECRI Institute on March 14, 2008 following the updated FDA advisory on heparin sodium injection.

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Date Modified: 9/29/2008