Expert Panel on Weight Loss Surgery: Executive Report Update

George L. Blackburn[1], Matthew M. Hutter[2], Alan M. Harvey[3], Caroline M. Apovian[4], Hannah R.W. Boulton[5], Susan Cummings[6], John A. Fallon[7], Isaac Greenberg[8], Michael E. Jiser[9], Daniel B. Jones[1], Stephanie B. Jones[10], Lee M. Kaplan[11], John J. Kelly[12], Rayford S. Kruger Jr[13], David B. Lautz[14], Carine M. Lenders[4], Robert LoNigro[15], Helen Luce[16], Anne McNamara[17], Ann T. Mulligan[18], Michael K. Paasche-Orlow[19], Frank M. Perna[20], Janey S.A. Pratt[2], Stancel M. Riley Jr[21], Malcolm K. Robinson[14], John R. Romanelli[22], Edward Saltzman[23], Roman Schumann[24], Scott A. Shikora[25], Roger L. Snow[26,27], Stephanie Sogg[28], Mary A. Sullivan[29], Michael Tarnoff[25], Christopher C. Thompson[30], Christina C. Wee[31], Nancy Ridley[32], John Auerbach[32], Frank B. Hu[32], Leslie Kirle[32], Rita B. Buckley[32] and Catherine L. Annas[32]

Rapid shifts in the demographics and techniques of weight loss surgery (WLS) have led to new issues, new data, new concerns, and new challenges. In 2004, this journal published comprehensive evidence-based guidelines on WLS. In this issue, we've updated those guidelines to assure patient safety in this fast-changing field. WLS involves a uniquely vulnerable population in need of specialized resources and ongoing multidisciplinary care. Timely best-practice updates are required to identify new risks, develop strategies to address them, and optimize treatment. Findings in these reports are based on a comprehensive review of the most current literature on WLS; they directly link patient safety to methods for setting evidence-based guidelines developed from peer-reviewed scientific publications. Among other outcomes, these reports show that WLS reduces chronic disease risk factors, improves health, and confers a survival benefit on those who undergo it. The literature also shows that laparoscopy has displaced open surgery as the predominant approach; that government agencies and insurers only reimburse procedures performed at accredited WLS centers; that best practice care requires close collaboration between members of a multidisciplinary team; and that new and existing facilities require wide-ranging changes to accommodate growing numbers of severely obese patients. More than 100 specialists from across the state of Massachusetts and across the many disciplines involved in WLS came together to develop these new standards. We expect them to have far-reaching effects of the development of health care policy and the practice of WLS.

Obesity (2009) **17,** 842–862. doi:10.1038/oby.2008.578

[1]Department of Surgery, Beth Israel Deaconess Medical Center, Boston, Massachusetts, USA; [2]Department of Surgery, Massachusetts General Hospital, Boston, Massachusetts, USA; [3]Department of Anesthesiology, Mercy Medical Center/Catholic Health East, Springfield, Massachusetts, USA; [4]Department of Medicine, Boston Medical Center, Boston, Massachusetts, USA; [5]Department of Nursing, South Shore Hospital, Weymouth, Massachusetts, USA; [6]Massachusetts General Hospital Weight Center, Massachusetts General Hospital, Boston, Massachusetts, USA; [7]Blue Cross Blue Shield of Massachusetts, Boston, Massachusetts, USA; [8]Obesity Consult Center, Tufts-New England Medical Center, Boston, Massachusetts, USA; [9]Department of Surgery, Saints Medical Center, Lowell, Massachusetts, USA; [10]Department of Anesthesiology, Beth Israel Deaconess Medical Center, Boston, Massachusetts, USA; [11]Department of Medicine, Massachusetts General Hospital, Boston, Massachusetts, USA; [12]Department of Surgery, University of Massachusetts Memorial Medical Center, Worcester, Massachusetts, USA; [13]Department of Surgery, Tobey Hospital, Wareham, Massachusetts, USA; [14]Department of Surgery, Brigham and Women's Hospital, Boston, Massachusetts, USA; [15]Care Management, Tufts Health Plan, Boston, Massachusetts, USA; [16]Consumer Representative, Boston, Massachusetts, USA; [17]Department of Nursing and Surgery, Beth Israel Deaconess Medical Center, Boston, Massachusetts, USA; [18]Department of Nursing, Newton-Wellesley Hospital, Newton, Massachusetts, USA; [19]Department of Medicine, Boston University School of Medicine, Boston, Massachusetts, USA; [20]Health Promotion Research Branch Divison of Cancer Control and Population Sciences, National Cancer Institute, Bethesda, Maryland, USA; [21]Patient Care Assessment Division, Massachusetts Board of Registration in Medicine, Boston, Massachusetts, USA; [22]Department of Surgery, Baystate Medical Center, Springfield, Massachusetts, USA; [23]Department of Medicine, Tufts-New England Medical Center, Boston, Massachusetts, USA; [24]Department of Anesthesiology, Tufts-New England Medical Center, Boston, Massachusetts, USA; [25]Department of Surgery, Tufts-New England Medical Center, Boston, Massachusetts, USA; [26]University of Massachusetts Medical School, Worcester, Massachusetts, USA; [27]MassHealth, Boston, Massachusetts, USA; [28]Behavioral Medicine Services and MGH Weight Center, Massachusetts General Hospital, Boston, Massachusetts, USA; [29]Division of Medical Specialties, Lahey Clinic and Massachusetts Coalition for the Prevention of Medical Errors, Burlington, Massachusetts, USA; [30]Department of Medicine, Brigham and Women's Hospital, Boston, Massachusetts, USA; [31]Department of Medicine, Beth Israel Deaconess Medical Center, Boston, Massachusetts, USA; [32]Betsy Lehman Center for Patient Safety and Medical Error Reduction, Commonwealth of Massachusetts, Boston, Massachusetts, USA. Correspondence: George L. Blackburn (gblackbu@bidmc.harvard.edu)

Received 26 June 2007; accepted 6 September 2007; published online 19 February 2009. doi:10.1038/oby.2008.578

INTRODUCTION

Foreword

Sharp increases in the prevalence of severe obesity (BMI >40 and BMI >50) have continued to fuel demand for weight loss surgery (WLS) (**Figure 1**). In 2004, the Betsy Lehman Center for Patient Safety and Medical Error Reduction (Lehman Center) formed an Expert Panel to assess WLS procedures, identify issues related to patient safety, and develop evidence-based best practice recommendations to address those issues.

The resulting document, published as a supplement in *Obesity* in 2005, set the standard for WLS across the state and well beyond it. The Agency for Healthcare Research and Quality abstracted the report for broad use, and the American College of Surgeons adopted it as the blueprint for its Bariatric Surgery Network Center Accreditation Program. Its recommendations influenced health care policy and medical practice at home and abroad.

Since 2004, the literature on WLS has expanded rapidly. New data have been published; new procedures have been developed; and new issues have been brought to our attention. In Massachusetts, weight loss operations increased from over 2,700 in Fiscal Year 2003 to nearly 3,500 in Fiscal Year 2006 (**Figure 2**). We saw a shift from open to laparoscopic operations, and changes in reimbursement policies.

The safety of WLS continues to be of concern. In response, the Lehman Center reconvened the Expert Panel to update the literature review and evidence-based recommendations developed in 2004. Several new members joined the 2007 Expert Panel as well its task groups. All told, there were two additional task groups, bringing the total from 9 to 11. We separated the Psychology Task Group from Multidisciplinary Evaluation and Treatment, and formed a new group, Endoscopic Interventions, to develop best practice guidelines for that emerging technology. In addition, we changed the name of the Coding and Reimbursement Task Group to Policy and Access to better reflect its focus.

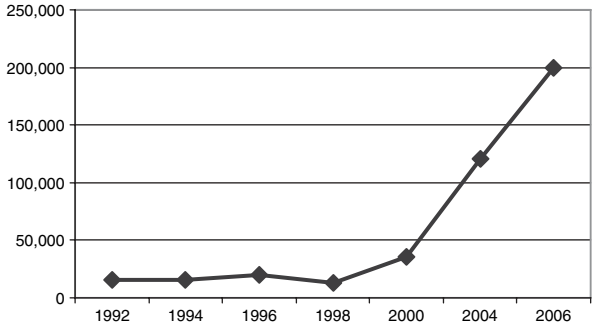


Figure 1 Estimated number of weight loss procedures performed in the United States, 1992–2006 (Adapted from refs. 20,25,36).

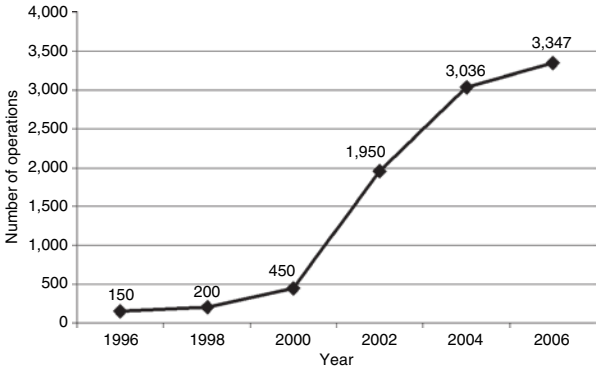


Figure 2 The number of weight loss operations performed in Massachusetts, 1996–2006 (Department of Public Health).

The charge to the 2007 Expert Panel was to update the evidence-based best practice recommendations for WLS developed 3 years ago. Toward that end, its members reviewed weight loss surgical procedures, analyzed the medical literature published since 2004, recommended specific steps to reduce medical errors and improve patient safety, developed credentialing and training standards, identified best practices, and established clinical guidelines and directions for future research.

What follows is a comprehensive evidence-based update to the original best practice recommendations. As with the first report, we hope that these guidelines will have far-reaching effects on clinical practice and health care policy, not only in the Commonwealth, but also nationwide. We hope that they will equalize access and reduce variability in performance and outcomes. Ultimately, our objective is to improve the safety of WLS in the state of Massachusetts and protect the well-being of patients who undergo it.

More than 100 individuals created this report. I express my deepest appreciation to the Expert Panel and task group members for the monumental work that went into this project. I especially thank George Blackburn, Chair, Matt Hutter, Vice Chair, Frank Hu, our clinical epidemiologist, and Rita Buckley, our librarian and medical editor, for their continued leadership and commitment to this project. Last but not least, I thank the Department of Public Health and Betsy Lehman Center staff, especially our project manager, Leslie Kirle, and Katie Annas for their diligent efforts in coordinating and facilitating the work of this project.

Preface

Overwhelming data demonstrate a reduction in known disease risk factors and improvements in health after WLS (1–3). Recent studies also indicate that WLS confers a survival advantage on patients who undergo it compared with community controls (1,2). Landmark findings from the Swedish Obese Subjects study show an estimated 28% reduction in the adjusted overall mortality rate in the surgical groups compared with conventionally treated controls (4).

Similar outcomes have been cited in other reports. A collaborative research project in Utah compared 7,925 gastric bypass patients with the same number of age-, gender-, and BMI-matched controls. Data showed that the rate of death from all diseases was 52% lower in the surgery group than in the control group ($P < 0.001$) (ref. 5). In a case study that compared 821 obese patients who received laparoscopic adjustable gastric banding (LAGB) with 821 controls treated with medical

therapy, Favretti *et al.* (6) found a statistically significant survival difference in favor of the surgically treated group.

Perry *et al.* (7) compared a cohort of extremely obese Medicare beneficiaries who underwent WLS to a similar cohort of extremely obese Medicare beneficiaries who did not. At the 2-year follow-up, younger (<65 years old) and older patients (≥65) in the surgical group had significantly reduced mortality compared with those in the nonsurgical group. Similarly, Sowemimo *et al.* (8) reported 50–85% mortality reductions with surgical intervention.

Decreased total mortality in the Swedish Obese Subjects study (4) surgical groups was primarily due to fewer deaths from cardiovascular disease (especially myocardial infarction) and cancer. In the Utah study (5), significant reductions in mortality were linked to fewer deaths from coronary artery disease (CAD), diabetes, and cancer. These results, which show substantial and consistent evidence of a survival advantage for severely obese patients who undergo WLS, are in line with those of earlier reports by Christou *et al.* (9) and Flum and Dellinger (10). They also confirm previous case series and epidemiologic observations on mortality after weight loss operations in more diverse populations (1,11).

But despite reductions in disease-related mortality after WLS, death rates from other causes, such as accidents and suicides, exceed those of nonsurgery patients. In Adams *et al.* (5), rates of death not caused by disease were 58% higher in the surgery group than in the control group. Reports reveal that a substantial number of severely obese persons have unrecognized presurgical mood disorders or post-traumatic stress disorder, or have been victims of childhood sexual abuse (12).

Data on the association between presurgical psychological status and postsurgical outcomes are limited (13). Although research shows an improved quality of life (QOL) after gastric bypass surgery (14–17), certain unrecognized presurgical conditions may reappear after surgery (18). Some WLS centers recommend that all patients undergo psychological evaluation, and, if necessary, treatment before surgery and psychologically related surveillance postoperatively (12,13,19). Adams *et al.* (5) note the need for further research on the optimal approach to evaluating candidates for WLS, including possible presurgical assessment, psychiatric treatment, and diligent postoperative follow-up.

We know from a substantial body of literature that WLS achieves significant and durable weight loss with minimal mortality or complications. We know that laparoscopy shortens length of stay and makes for a faster, easier recovery (20). Now reliable evidence is starting to accumulate on the survival advantage conferred by WLS on those who undergo it. The field is dynamic (21), with surgical approaches being developed and refined at a rapid pace. Yet technical performance of the operations, critical though it may be, is only one of many challenges.

WLS deals with a uniquely vulnerable population in need of specialized resources and ongoing multidisciplinary care. Timely best practice updates are critical to identify new risks, develop strategies to address them, and optimize treatment of WLS patients. As before (22), members of this panel have come together to protect patient safety and prevent medical errors with evidence-based standards of care. This update of best practice guidelines is part of our continued efforts to improve the efficacy and safety of WLS procedures.

Background

More than 33% of US adults are classified as obese based on objectively measured weight (23), and one-third of American children are either obese or at risk of becoming so (24). Between 2000 and 2005, the proportion of Americans with a BMI ≥40 increased by 50%, although those with a BMI ≥50 increased by 75% (25). Severe obesity has been growing at the fastest rate for the past 20 years (23,25).

Obesity, particularly abdominal obesity, is associated with increased risk of hypertension, diabetes, hyperlipidemia, sleep apnea, coronary heart disease, and strokes (26,27). In 1998, medical costs attributable to overweight and obesity accounted for 9.1% of total US medical expenditures, and may have reached as high as $78.5 billion ($92.6 billion in 2002 dollars) (28,29). In 2000, there were ~360,000 deaths associated with obesity (30). It has been suggested that in the 21st century, increasing rates of obesity may lead to a decline in overall life expectancy in the United States (31).

METHODS AND PROCEDURES

Update on common WLS procedures

Overview. WLS reduces caloric intake by modifying the anatomy of the gastrointestinal tract via restriction, malabsorption, or a combination of the two techniques. Ensuing changes in the gut–brain axis alter peptides that may regulate appetite and satiety (32) (e.g., ghrelin, glucagon-like peptide, and pancreatic polypeptide). Among the several competing approaches for the management of severe obesity, the general trend is toward combined restrictive–malabsorptive procedures (33). Over the past few decades, the number of weight loss surgeries performed in the United States has increased significantly (34,35). Between 1998 and 2004, weight loss operations rose by 900% to 121,055 (ref. 36). In 2006, the estimated total climbed to 200,000 (refs. 20,25).

Laparoscopic Roux-en-Y gastric bypass (LRYGB) is considered the gold standard operation for long-term weight control in United States (35,37). Rates of RYGB per 100,000 adults rose significantly from 1998 to 2002, from 7.0 to 38.6. This increase may be attributed, in part, to improved surgical techniques, better patient outcomes, and growing popularity of the procedure (38). LAGB is the second most commonly performed operation in the United States. Despite rapid growth in LRYGB and other weight loss procedures, only an estimated 1% of patients who are eligible for WLS receive it in any given year (39).

Common WLS procedures

LRYGB. Gastric bypass involves the creation of a small (20–30 ml) gastric pouch and a Roux limb (typically 75–105 cm) (34) that reroutes a portion of the alimentary tract to bypass the distal stomach and proximal small bowel (**Figure 3**). Following LRYGB, a pleiotropic endocrine response may contribute to improved glycemic control, appetite reduction, and long-term changes in body weight (40). LYRGB also has a profoundly positive impact on obesity-related comorbidities and QOL (41). Other advantages include established long-term effectiveness for sustained weight loss, reduction of comorbidities, minimal risk for long-term nutritional sequelae, and effective relief of gastroesophageal reflux disease (21). LRYGB is not without risks. Common causes of death include pulmonary embolism and anastomotic leaks. Nonfatal perioperative complications include

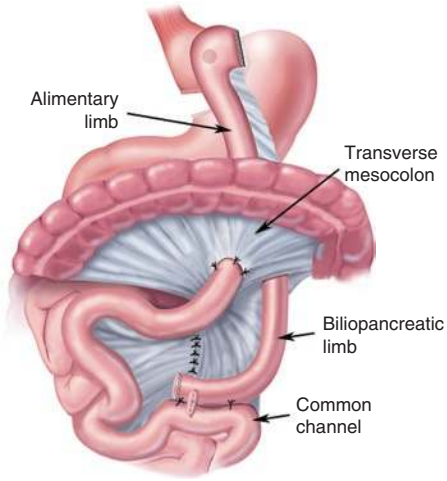


Figure 3 Roux-en-Y gastric bypass (RYGB). RYGB involves the creation of a small (<30 ml) gastric pouch and a Roux limb (typically 75–105 cm) that reroutes a portion of the alimentary tract to bypass the distal stomach and proximal small bowel. (Reprinted with permission of Atlas of Metabolic and Weight Loss Surgery, Jones *et al.* Cine-Med, 2008.) Copyright of the book and illustrations are retained by Cine-Med.

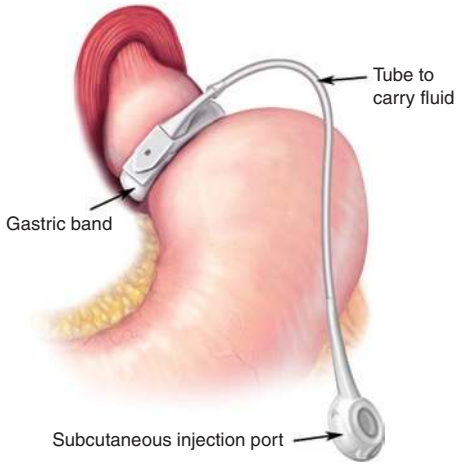


Figure 4 Adjustable gastric band (LAGB). LAGB involves the placement of a band or collar around the upper stomach 1–2 cm below the gastroesophageal junction, thereby creating an ~30 ml upper gastric pouch. The band is imbricated to prevent slippage of the stomach in a retrograde manner through the band. Degree of stomach constriction can be adjusted by modifying the amount of saline injected into a subcutaneous port, which is linked to a balloon within the band. (Reprinted with permission of Atlas of Metabolic and Weight Loss Surgery, Jones *et al.* Cine-Med, 2008.) Copyright of the book and illustrations are retained by Cine-Med.

venous thromboembolism, wound infections, small bowel obstruction, and bleeding. Postoperative gastrointestinal complications include nausea and vomiting, micronutrient deficiencies, (35) and possible weight regain (22).

LAGB. LAGB involves the placement of a band or collar around the upper stomach 1–2 cm below the gastroesophageal junction, thereby creating an ~30 ml upper gastric pouch. Degree of stomach constriction can be adjusted by modifying the amount of saline injected into a subcutaneous port, which is linked to a balloon within the band (34) (**Figure 4**). Parikh *et al.* (42) found that LAGB had fewer

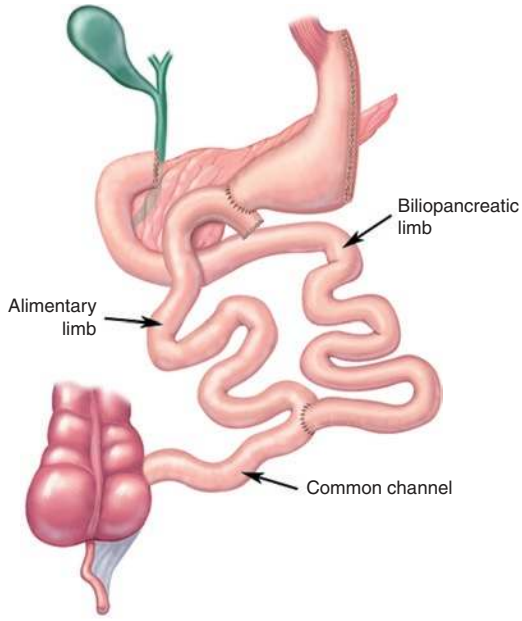


Figure 5 Biliopancreatic diversion (BPD) with duodenal switch. BPD creates malabsorption by maintaining a flow of bile and pancreatic juice through the biliopancreatic limb. The procedure is commonly performed with a duodenal switch in which a distal, common-channel length of small intestine severely limits caloric absorption. The extent of malabsorption is thought to be a function of the length of the common channel. (Reprinted with permission of Atlas of Metabolic and Weight Loss Surgery, Jones *et al.* Cine-Med, 2008.) Copyright of the book and illustrations are retained by Cine-Med.

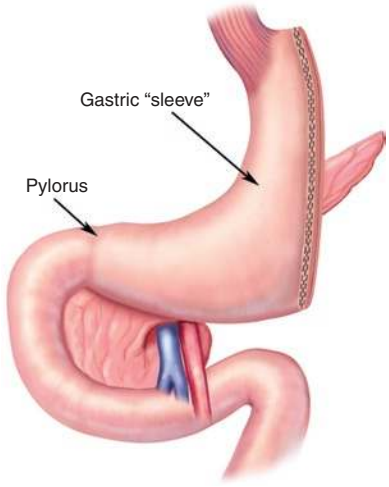


Figure 6 Sleeve gastrectomy (SG). SG consists of the restrictive component of the duodenal switch, a vertical resection of the greater curvature of the stomach creating a long tubular stomach along the lesser curvature. The pylorus and part of the antrum are preserved. (Reprinted with permission of Atlas of Metabolic and Weight Loss Surgery, Jones *et al.* Cine-Med, 2008.) Copyright of the book and illustrations are retained by Cine-Med.

and less severe complications compared with LRYGB or laparoscopic malabsorptive procedures. But other 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 (43,44).

Biliopancreatic diversion. Biliopancreatic diversion (BPD) creates malabsorption by maintaining a flow of bile and pancreatic juice through the biliopancreatic limb (45). The procedure is commonly performed with a duodenal switch (DS) in which a distal, common-channel length of small intestine severely limits caloric absorption (35). The extent of malabsorption is thought to be a function of the length of the common channel (34). The procedure is combined with a sleeve gastrectomy (SG) in which the greater curvature of the stomach is resected, creating a tubular section along the lesser curvature of the stomach (34) (**Figure 5**). The BPD described by Scopinaro (45) is capable of producing substantial and sustained weight loss, perhaps associated with markedly suppressed ghrelin levels (46). However, increased incidence of stomal ulceration, severe protein-energy malnutrition, diarrhea, and dumping has limited its broad acceptance (21).

Laparoscopic SG. Laparoscopic SG (LSG) is a new purely restrictive treatment for severe obesity. The technique consists of the restrictive component of the DS, a resection of the greater curvature of the stomach over a 45–50 F bougie positioned along the lesser curvature. The pylorus and part of the antrum are preserved, resulting in a lesser curvature-based "restrictive" gastric sleeve (21) (**Figure 6**). Early reports of SG have shown it to be safe and effective (47,48), with marked weight loss and significant reduction of major obesity-related comorbidities (49,50). LSG can be performed as a stand-alone operation or as a bridge to more complex WLS. Following the operation, the stomach empties its contents rapidly into the small intestine, but with little or no vomiting (characteristic of restrictive procedures) (51). There is also a significant reduction in ghrelin associated with resection of the gastric fundus, the predominant area of human ghrelin production (46,52).

Framework for evidence-based recommendations

We divided the 35-member Expert Panel into 11 task groups:

- Surgical Care (53).
- Multidisciplinary Evaluation and Treatment (54).
- Behavior and Psychological Care (55).
- Pediatric/Adolescent (56).
- Anesthetic Perioperative Care and Pain Management (57).
- Nursing Perioperative Care (58).
- Informed Consent and Patient Education (59).
- Policy and Access (Coding and Reimbursement) (60).
- Specialized Facilities and Resources (61).
- Data Collection (Registries)/Future Considerations (62).
- Endoscopic Interventions (63).

Panel members joined one or two task groups, each with an assigned coordinator. Participants were asked to update recommendations from the first Lehman Center report (22) based on the best available evidence, including randomized controlled trials, observational studies, and expert opinion. A medical librarian performed systematic literature reviews for each group. Searches were limited to English-language studies published between April 2004 and May 2007 in MEDLINE, EMBASE, and the Cochrane Library. Some groups also searched other databases (e.g., CINHAL). The process used to extract data, assess the literature, and grade evidence has been previously described (22).

Each task group prepared a critical summary of its literature review and developed updated best practice recommendations (individual studies are published in this issue of *Obesity*) based on the most current evidence. Their reports were reviewed and approved by the Expert Panel. This Executive Report, a summary of key recommendations from all the task groups, was approved by the Expert Panel at its final meeting on 19 July 2007.

RESULTS AND DISCUSSION

Summary of evidence-based recommendations

I. Surgical Care

The Surgical Care Task Group identified >135 papers; the 65 most relevant were reviewed in detail (53). These included randomized control trials, prospective and retrospective cohort studies, meta-analyses, case reports, prior systematic reviews, and expert opinion.

A. Overview

RYGB remains the predominant gold standard WLS in the United States, accounting for 93% of all such operations in 2000 (ref. 64). LAGB is the second most commonly performed procedure (65,66). RYGB is known to safely improve or reverse obesity-related comorbidities and produce significant long-term weight loss (21). Long-term data on weight loss after LAGB vary (42,67,68).

B. Types of WLS

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

RYGB (open and laparoscopic): Most gastric bypass operations are now done laparoscopically. 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).

RYGB modifications: Long-limb RYGB and very very long-limb 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 whether they produce superior weight loss (category C).

Banded RYGB may be subject to long-term complications related to reintervention, reoperation, and QOL (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.

BPD and DS: BPD and 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. Restrictive WLS (e.g., LAGB) has no malabsorptive or maldigestive components.

LAGB: Short-term data show promising outcomes with LAGB, but long-term studies raise questions on durability and reoperative rates (category B). We 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).

LSG: Several short-term studies suggest safe and effective weight loss with 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 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

We recommend the following as standard practice:

- testing of gastrojejunal anastomosis for leaks intraoperatively or within 48 h (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 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). We recommend that older patients not be denied improvements in health and QOL associated with WLS (category D).

F. Facility and surgeon credentialing standards

The following are best practice updates to guidelines in our prior report (69). These recommendations are all based on category D evidence, unless otherwise noted.

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 (70) (>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 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 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

The Multidisciplinary Care Task Group identified over 150 abstracts related to WLS in general, and to medical, nutritional, and multidisciplinary care in particular; 112 of these studies were reviewed in detail (54).

A. Multidisciplinary care

The American Society for Bariatric Surgery recently changed its name to the American Society for Metabolic and Bariatric Surgery, 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, we 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 (OSA) and coronary heart disease risk factors) increase operative risk and postoperative complications. We recommend assessment of risk factors (71) in each patient (category C).

Preoperative weight loss. Preoperative weight loss of 5–10% 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 5–10% 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 CAD or DVT/PE, those who are current smokers, and those with known or suspected abnormal liver function. *Helicobacter 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.

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 β 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).

DVT/PE: We 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 (72), 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).

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 (including PTH), 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; we 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. The task group identified and reviewed in detail 80 relevant articles, ranging from case reports and expert opinion to prospective randomized trials.

Insurance coverage. Body contouring should generally be reserved until a patient has achieved a stable weight. This usually happens at 18 months (or more) after WLS. There are no widely accepted guidelines for insurance coverage of body contouring after substantial weight loss. We recommend third party coverage of excess skin excision, if medically indicated (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

The Behavioral and Psychological Care Task Group identified 17 papers; the 13 most relevant were reviewed in detail (55). These included randomized controlled trials, prospective and retrospective cohort studies, meta-analyses, case reports, and prior systematic reviews.

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. We recommend that organizations that provide education on obesity and WLS (e.g., North American Association for the Study of Obesity) offer continuing education units to mental health 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

Binge eating disorder 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 EDE-Q and follow-up with a brief, standardized interview based on 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. This disorder 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

In that there is no clear evidence that night eating syndrome 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 night eating syndrome, 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, we recommend close postoperative monitoring of WLS patients, especially after gastric bypass (category D).

G. Future research needs

The needs of future research are

- adequately powered and controlled prospective trials that examine the relation between psychosocial factors and surgical outcomes;
- randomized controlled trials on the effectiveness of treatments to reduce the impact of psychosocial risk factors on outcomes.

IV. Pediatric/Adolescent

The Pediatric/Adolescent WLS Task Group identified >1,085 papers; 186 of the most relevant were reviewed in detail (56).

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 has not been approved by the FDA for use in adolescents, and therefore, should be considered investigational. Off-label use can be considered, if done in an 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).

SG 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 OSA with AHI ≥15 (category C), severe and/or progressive NASH (category C), and pseudotumor cerebri (category C). Other indications for WLS in adolescents include mild OSA, mild NASH, hypertension, dyslipidemia, and significantly impaired QOL (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).

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 QOL 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, we 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 1 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 four or five professionals who are colocated 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—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 outcomes

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

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. Best practice recommendations integrate the latest research on obesity and collaborative multidisciplinary care (57).

A. Preoperative evaluation and preparation

Mandatory polysomnography for WLS patients has been proposed (category C). However, we recommend that it be used in selected patients as indicated. 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 CPAP treatment should be strongly considered for patients with a polysomnography diagnosis of moderate to severe OSA (categories B and C). We 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° 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 ~10 cm H_2O may be considered during preoxygenation to prolong nonhypoxic 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. 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 α-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. We recommend initial treatment of intraoperative hypoxemia with recruitment maneuvers and positive end-expiratory pressure while monitoring their potential hemodynamic effects (categories A and B).

Other interventions. Postoperative nausea and vomiting in laparoscopic WLS patients is related to the volume and rate of intraoperative fluid replacement. To reduce postoperative nausea and vomiting, we 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 United States), 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 noninvasive positive pressure ventilatory support (NIV) in nonobese, non-OSA patients at high risk of respiratory failure. A joint decision between the surgeon, anesthesiologist, respiratory therapist, and nurse should determine NIV use on selected WLS patients (categories A, B, and C). LRYGB and LAGB have been performed safely as 23-h stay and outpatient procedures. However, patients with OSA should not be considered candidates for outpatient WLS (category C); we recommend adherence to the American Society of Anesthesiologists Practice Guidelines for the Perioperative Management of Patients with OSA (category C).

Postoperative pain management. Based on new evidence of efficacy and safety specific to WLS patients, we 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. We 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 C) and needs further refinement for WLS patients.

F. Future research needs

Research is needed in the following areas:

- the role and parameters of preoperative OSA treatment for perioperative safety outcomes in WLS;
- intra- and perioperative drug dosing, including prophylactic antibiotic tissue pharmacokinetic assessment;
- appropriate use of α-2 agonists in the perioperative care of WLS patients;
- strategies for intra- and postoperative glycemic management;
- impact of advanced monitoring of anesthetic effects on outcomes;
- evidence-based postoperative care guidelines for WLS patients with OSA;
- optimal anesthetic care for WLS patients with increased BMI, age, and quantity and severity of comorbidities;
- impact of an organized multidisciplinary care team on WLS safety outcomes;
- effect of surgical and overall care team pathways to decrease and/or treat perioperative anesthetic and surgical complications.

VI. Nursing Perioperative Care

A systematic review of MEDLINE, nursing journals, and the CINHAL database for nursing and allied health literature identified >54 papers; the most relevant were reviewed in detail. Recommendations are based on published evidence and the consensus of the Task Group members (58).

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, we 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). We also recommend use of the Association of Perioperative Registered Nurses Bariatric Surgery Guideline (category D) and the American Society of Anesthesiologists Practice Guidelines for the Perioperative Management of Patients with OSA (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 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. We 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 Association of Perioperative Registered Nurses 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 that 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 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 conditions most likely to occur in the early discharge phase. Later complications 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 has developed national certification criteria for Clinical Bariatric Nurse Specialists. We recommend certification (category D).

F. Future research needs

Studies are needed in the following areas:

- clinical pathways for WLS, including emergency departments;
- comprehensive ergonomics programs;
- teach-to-goal educational methods for pre- and postoperative education;
- program retention tools and outcome measures;
- nursing research and involvement in pediatric WLS programs.

VII. 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. Recommendations are extrapolated from, and supported by, existing data (59).

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 QOL 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 consenting 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).

D. Future research needs

Future research is needed to better identify factors that affect short- and long-term outcomes so that patients can be cited appropriate and individualized outcome information. Research should focus on important gaps in knowledge on outcomes and consequences of WLS, and the different approaches that facilitate patient understanding of, and decision making about, WLS.

VIII. 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 (60). These included reviews, cost–benefit analyses, and trend and cost studies from administrative databases.

A. Policy and access

Access disparities (all category D). Public health policy should be aligned with long-term goals for the treatment of severe obesity. Barriers to WLS in populations with high prevalence of severe obesity should be identified and eliminated, and there should be uniform standards of coverage for all WLS candidates. We recommend advocacy for increased access to WLS for underserved regions and population groups; support for community-based efforts to fight health disparities; and public education about the obesity epidemic and the risks/benefits of WLS.

Childhood obesity (categories C and D). Sharp increases in childhood obesity lend urgency to the need to address the problem (category C). Policy initiatives to identify pediatric and adolescent populations most likely to benefit from surgical treatment of obesity are needed. Surgical treatment should be considered a potentially effective option for appropriately selected individuals, and there should be uniform standards of coverage for adolescent patients. We need to educate legislators, community leaders, and other stakeholders on the costs and benefits of WLS for extremely obese adolescents, and leverage opportunities for collaboration between teachers, parents, and community leaders (category D).

Insurance policies (category A, B, C, and D). Controversial issues include required documentation of prior weight loss attempts through more conservative means; access to WLS for those with a BMI of 35–40 and obesity-related comorbidities; and proof of extreme obesity for at least 5 years. We recommend

- routine examination of weight loss histories during behavioral evaluation to determine whether additional attempts at nonsurgical weight loss are advisable;
- coverage of WLS for those with a BMI of 35–40 and comorbid conditions that require ongoing treatment (e.g., CPAP, medication);
- research to characterize weight loss histories of surgical candidates, and explore the relation between dieting history and postoperative outcomes;
- ongoing collection and dissemination of data on WLS costs, risks, and benefits;
- collaborative efforts between government, industry, and other stakeholders to promote safe and effective delivery of WLS.

Cost-effectiveness issues. Obesity is linked to higher health care costs than smoking or drinking, and plays a major role in disability (category B). 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).

Innovation, evidence-based medicine, and cost containment. The application of standard cost-containment policies to surgical innovations may stifle new developments. We recommend the use of evidence-based medicine to both guide clinical decisions and show reasonable trends for health care cost containment (category C).

Legislation. We need to keep legislators apprised of the personal and economic costs of obesity in the communities they serve. Dissemination of evidence-based information on the risks, benefits, and cost-effectiveness of WLS can bring these issues to their attention (categories C and D).

Stigma (all category D). The highest BMI groups are the fastest growing and the most stigmatized. To address this problem, we recommend targeted education campaigns; community-level public information/education; and sensitivity training for hospital personnel. Hospitals should also acquire obese-appropriate products (e.g., gowns, chairs, commodes).

B. Coding and reimbursement

Centers for Medicare and Medicaid Services. Centers for Medicare and Medicaid Services allows national coverage for RYGB (open and laparoscopic), LAGB, and BPD with DS (open and laparoscopic). Nationally covered procedures and new 2006 CPT codes are available.

C. Potential pathways to new codes

Category III and S codes. CPT category III Codes are a temporary set of tracking codes used to identify new and emerging technologies. CPT category III codes (T codes) support data collection on new services and procedures. CPT category III codes may be converted to CPT category I codes if the FDA and CPT Editorial Panel approve the clinical efficacy of the particular service or procedure. Blue Cross/Blue Shield and other commercial payers have developed the category of S codes, which were added to HCPCS Level II to report drugs, services, and supplies. S codes are typically used in conjunction with a nonspecific CPT code.

Medicare does not recognize or reimburse for services reported under S codes, and may or may not reimburse for CPT category III codes, depending on the service or procedure.

Individual commercial insurers may or may not reimburse for S codes or CPT category III codes as medical policies and reimbursement polices are specific to each insurer.

D. Issues and recommendations

Alignment of reimbursement policies with clinical objectives. Reimbursement policies should reflect the importance of comprehensive, multidisciplinary care. There should be full coverage for medical, nutritional, and psychological preoperative evaluation as well as pre-, peri-, and postoperative care required by insurers (category D).

CPT codes for WLS and related clinical services (all category D). CPT codes for WLS should be updated to reflect current practice. New CPT category I codes should be requested and approved as evidence accumulates in favor of new procedures (e.g., vertical SG, endoscopic interventions). T codes should be considered for evolving technologies, and procedures. The use of T codes may create a pathway for reimbursement by supporting consistent data collection and development of evidence. Evidence indicating that a promising technology or new procedure leads to improved health outcomes could support conversion of category III codes to category I codes. There should be support for the development of appropriate CPT codes for each component of multidisciplinary care (e.g., exercise therapy, pre- and postoperative support groups).

Data collection, tracking, and reporting systems. There are several national data collection, tracking, and reporting databases (see Data Collection) (62) as well as proprietary systems. We recommend standardized collection, tracking, and reporting of tiered and risk-adjusted data (category D).

IX. 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 (61). These included randomized control trials, prospective and retrospective cohort studies, meta-analyses, case reports, prior systematic reviews, and expert opinion.

A. Personnel

All medical and support staff must be adequately trained and credentialed as specified in the following task group reports: Surgical Care (53), Anesthesia Perioperative Care and Pain Management (57), Behavioral and Psychological Care (55), and Nursing Care (58). 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. We 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 the following.

Ancillary

- Wide wheelchairs, stretchers, and walkers.
- Wide 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 retractors;
- 43–46 cm laparoscopes.

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

- CT scanners with 400 lb weight capacity;
- 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 h a day, 7 days a week.

C. Physical plant

Size-appropriate facilities should be available in both postanesthesia and intensive care units; postoperative, dedicated in-patient 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 (73).

D. Extent of facility changes

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

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. We 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

We 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 (53,57,58). 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 Accreditation of Healthcare Organizations in 2004 (ref. 74) emphasize safety. We recommend that facilities follow these recommendations, as well as those specified in our prior report (61). We 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 (75). 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. We recommend risk-adjusted outcomes to adequately evaluate performance.

X. Data Collection (Registries)/Future Considerations

This Task Group identified 212 papers and reviewed the 63 most relevant in detail. Recommendations are based on available evidence as well as consensus of opinions from Task Group and Expert Panel members (62,76).

A. Administrative and nonadministrative databases

Administrative databases have inherent problems, including unreliable coding and lack of WLS-specific data points. Clinical databases that are not WLS-specific have other shortcomings (e.g., short-term follow-up, sampling of WLS procedures), and single-institution, WLS-specific databases lack standardized definitions and appropriate quality benchmarks. Rather, we recommend collection of WLS-specific data (categories B and D) on 100% of weight loss surgeries performed (category D).

B. New developments

Longitudinal assessment of bariatric surgery. The NIH-funded Longitudinal Assessment of Bariatric Surgery consortium has developed a database of standardized information on WLS patients at six clinical centers. Data are being collected on patient characteristics, surgical procedures, medical and psychosocial outcomes, and economic factors.

Accreditation programs. The Centers for Medicare and Medicaid Services made a national decision to cover WLS, but only if performed by institutions and surgeons that are accredited by either the American College of Surgeons Bariatric Surgery Center Network or the American Society for Metabolic and Bariatric Surgery/Surgical Review Corporation Centers of Excellence program. WLS-specific, longitudinal data collection systems are a major part of each of these accreditation programs. The optimal data collection system should gather information on all WLS procedures using a longitudinal, universal database system. It should be prospective, risk adjusted, and benchmarked, with WLS-specific data points that track clinical effectiveness and complications following WLS (categories B and D).

The American College of Surgeons Bariatric Surgery Network Data Collection System, the Society of American Gastrointestinal Endoscopic Surgeons Bariatric Data Collection System, and the American Society for Metabolic and Bariatric Surgery/Surgical Review Corporation system should meet these criteria. If these systems are not compatible (i.e., cannot agree on the same definitions), an interface should be developed that makes them so (category D).

C. Areas that need more data

Risk adjustment. Risk adjustment helps control for differences in patient risk factors and case mix. Appropriate risk adjustment models should be developed and refined over time to account for these variables (categories C and D).

Determining the best data collector. Data entered into the system must be of the highest quality to ensure accurate analyses on quality of care. To avoid bias, data should be collected by audited, trained data collectors not directly involved in patient care (categories B and C). That data, in turn, should be analyzed

to see whether information collected by audited, trained non-nurse reviewers is as valid as that collected by nurse reviewers (category D).

Defining data points. High inter-rater reliability requires data points that are clinically relevant, objective, and easy to identify. Data points, definitions, and systems training programs should be developed that optimize clinical relevance and minimize subjectivity, and in so doing, maximize inter-rater reliability (categories C and D).

Quality indicators and benchmarking capabilities. Definitions of quality and benchmark indicators of progress can be difficult to develop. To advance patient safety, quality indicators and metrics should be appropriate and actionable (category D).

Outliers. Accurate determination of what constitutes an outlier, or bad performer, can have a direct effect on patient safety and access to WLS. Responsible analysis of data and careful definition of outliers is essential to improve quality of care. The means to regularly report that data to stakeholders should be determined (categories C and D). Poor performers, or high outliers, should be identified, and a mechanism for corrective action developed (category D).

Novel therapies. Safe introduction of novel technologies and assessment of the appropriateness of those procedures in new patient populations are critical for patient safety. Novel and experimental therapies, new patient populations, and expanded indications for WLS should be carefully studied through comprehensive data collection and analysis (category D). Experimental therapies should be performed with IRB approval, and data collected and audited by a data monitoring board to assess clinical effectiveness and patient safety (category D).

Cost-effectiveness and utility analyses. There is a critical need for well-designed prospective studies that evaluate the cost-effectiveness, cost utility, return on investment, and economic impact of WLS. Cost utility studies should be carried out to guide decision-making on the appropriate allocation of resources (category D).

State coalition. We propose the development of a statewide coalition to collectively gather and share data, and determine quality indicators and processes of care that could lead to best practices in WLS (categories C and D).

XI. Endoscopic Interventions

This Task Group's literature search identified 18 related articles, all of which were reviewed in detail. All of our recommendations are based on expert opinion (63).

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).

G. Coding and reimbursement

As new devices and minimally invasive surgical therapies for obesity and its complications are approved for clinical use, a new category of provisional billing codes should be established for these interventions. Reimbursement for novel therapies for obesity should be determined on the basis of scientific evidence of their safety and efficacy (category D).

H. Future research

Randomized, blinded, sham-controlled clinical trials should be the standard for investigation of the safety and efficacy of endoscopic interventions for the treatment of obesity and its complications (category D).

ACKNOWLEDGMENTS

This Expert Panel on Weight Loss Surgery report was prepared for the Betsy Lehman Center for Patient Safety and Medical Error reduction. The report was commissioned by N.R., Director, Betsy Lehman Center for Patient Safety and Medical Error Reduction. We thank all Expert Panel and Task Group members for their important contributions to the report. We also acknowledge Eileen McHale at the Betsy Lehman Center and Jane Guilfoyle at the Department of Public Health.

DISCLOSURE

The authors declared no conflict of interest.

APPENDIX I

To view Task Group Appendices, go to http://www.mass.gov.dph and search "weight loss surgery."

Framework and methodology for evidence-based systematic reviews of literature on weight loss surgery

The Expert Panel was charged with reviewing WLS operations, identifying potential safety issues, and recommending specific actions to reduce safety risks and improve patient outcomes. It used the methodology of evidence-based medicine to systematically search available literature on the subject, and developed a classification system from established models to grade the quality of evidence.

The systematic review involved a MEDLINE search of studies published from April 2004 to May 2007. These included prior systematic reviews on the subject, randomized controlled trials, prospective cohort studies, cross-sectional surveys, case reports, and existing guidelines on WLS procedures from national organizations. The panel based its grading classification system on those used by the US Preventive Services Task Force, the American Diabetes Association, and the National Heart, Lung, and Blood Institute (NHLBI) Obesity Education Initiative Expert Panel on the Identification, Evaluation, and Treatment of Overweight and Obesity in Adults.

Randomized controlled trials (RCTs) are considered the highest-level evidence of clinical efficacy and safety, but there are few such studies on WLS operations. The Expert Panel's recommendations are based on the best available evidence. The sections below detail the procedures and methodology used to develop recommendations.

1. Panel selection

At the request of Massachusetts Public Health Commissioner, Christine Ferguson, 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 WLS programs and procedures.

The 35-member panel included experienced weight loss surgeons, nurses, psychologists, and a nutritionist who counsels 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 panel delivered a report on its progress to the Lehman Center and the Department of Public Health in mid-July 2007.

2. Task groups

We divided the panel into 11 task groups:

- Surgical Care (53).
- Multidisciplinary Evaluation and Treatment (54).
- Behavioral and Psychological Care (55).
- Pediatric/Adolescent (56).
- Anesthetic Perioperative Care and Pain Management (57).
- Nursing Perioperative Care (58).
- Informed Consent and Patient Education (59).
- Policy and Access (Coding and Reimbursement) (60).
- Specialized Facilities and Resources (61).
- Data Collection (Registries)/Future Considerations (62).
- Endoscopic Interventions (63).

Panel members joined one or two task groups, each with an assigned coordinator. They were asked to update reports from the prior Lehman Center supplement (22).

3. Literature search

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.

4. 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; dropout rate; description of the intervention; outcome measures, including adverse effects; and main conclusions. Information was tabulated in a format suitable for publication.

5. Synthesis of evidence

We primarily used narrative (or qualitative) summaries 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

(Table 1). For example, well-conducted RCTs (category A) provide the strongest evidence on the effectiveness of a surgical weight loss procedure. We used expert opinion (category D) (including clinical experience, the opinions of respected authorities, reports from expert committees, and consensus of the Expert Panel) in conjunction with evidence from RCTs or observational studies to develop recommendations.

6. Developing evidence-based recommendations

Each task group prepared a critical summary of the literature (Table 2) and developed evidence-based recommendations on its assigned topic; these were presented to the full group for comments. This Executive Report of key recommendations from all groups was approved by the Expert Panel at its last meeting on 19 July 2007.

Table 1 Grading system for evidence-based recommendations

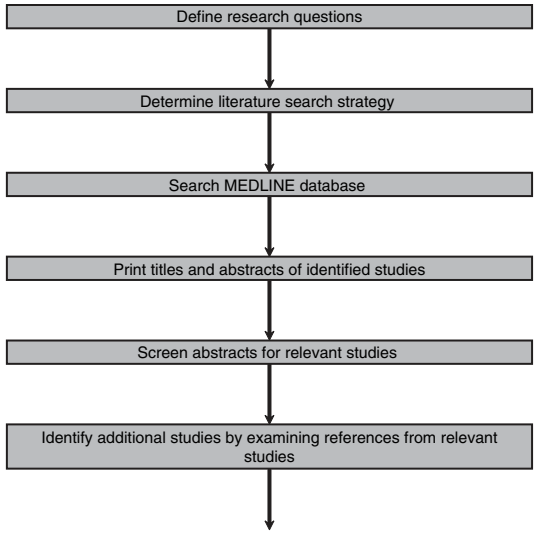
Category A	Evidence obtained from at least one well-conducted randomized clinical trial or a systematic review of all relevant RCTs
Category B	Evidence from well-conducted prospective cohort studies, registry or meta-analysis of cohort studies, or population-based case–control studies
Category C	Evidence 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 US Preventive Services Task Force (USPSTF) and the American Diabetes Association.

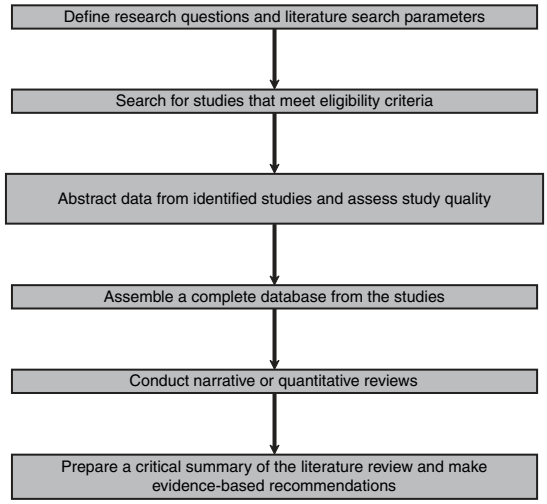
Table 2 Inclusion/exclusion criteria—example used in literature search, laparoscopic vs. open gastric bypass surgery

Inclusion criteria
English language
Published between April 2004 and May 2007
RCTs or controlled trials without randomization, cohort studies
Surgical procedures: gastric bypass, Roux-en-Y gastric bypass, open vs. laparoscopic
Minimum follow-up: 6 months
Outcomes: change in body weight, excess weight, and BMI; mortality and major morbidity
Exclusion criteria
Selection criteria not indicated
Small sample size ($n < 10$ for each intervention)
Dropout rate >50%

Literature search process



Literature review process



REFERENCES FOR THE FRAMEWORK

1. Oxford Centre for Evidence-based Medicine Levels. <http://www.musckids.com/~annibald/ebm/oxford_levels_of_evidence.pdf> (2001). Accessed 23 August 2007.
2. Clinical Guidelines on the Identification, Evaluation, and Treatment, of Overweight and Obesity in Adults. The Evidence Report: National Institutes of Health. National Heart, Lung, and Blood Institute; 1998. No. 98-4083.
3. Introduction. *Diabetes Care* 2004;27:S1–S2.
4. Agency for Healthcare Research and Quality. Current Methods of the US Preventive Services Task Force: a Review of the Process. <http://www.ahrq.gov/clinic/ajpmsuppl/harris1.htm>. Accessed 24 August 2007.
5. Harris RP, Helfand M, Woolf SH *et al*. Current methods of the US Preventive Services Task Force: a review of the process. *Am J Prev Med* 2001;20(3 Suppl):21–35.
6. Naylor CD, Guyatt GH. Users' guides to the medical literature. X. How to use an article reporting variations in the outcomes of health services. The Evidence-Based Medicine Working Group. *JAMA* 1996;275:554–558.
7. Barton MB, Miller T, Wolff T *et al*. How to read the new recommendations statement: methods update for the U.S. Preventive Services Task Force. *Ann Intern Med* 2007;147:123–127.
8. Guirguis-Blake J, Calonge N, Miller T *et al*. Current processes of the U.S. Preventive Services Task Force: refining evidence-based recommendation development. *Ann Intern Med* 2007;147:117–122.

APPENDIX II

Task Groups for Lehman Center Report on Weight Loss Surgery

Surgical Care

Coordinator

John Kelly, M.D., University of Massachusetts Memorial Medical Center

Co-chair

Scott Shikora, M.D., Tufts-New England Medical Center
George L. Blackburn, M.D., Ph.D., Beth Israel Deaconess Medical Center
Frederick Buckley, M.D., North Shore Medical Center
Matthew Hutter, M.D., Massachusetts General Hospital
Daniel B. Jones, M.D., M.S., Beth Israel Deaconess Medical Center
David Lautz, M.D., Brigham and Women's Hospital
Andrew B. Lederman, M.D., Berkshire Medical Center
Malcolm K. Robinson, M.D., Brigham and Women's Hospital
John Romanelli, M.D., F.A.C.S., Baystate Medical Center

Multidisciplinary Evaluation and Treatment

Coordinator

Caroline Apovian, M.D., Boston Medical Center

Co-chair

Susan Cummings, M.S., R.D., L.D.N., Massachusetts General Hospital
Wendy Anderson, R.D., L.D.N., Boston Medical Center
Loren J. Borud, M.D., Beth Israel Deaconess Medical Center
Kelly Moore, R.D., L.D.N., Beth Israel Deaconess Medical Center
Kristina Day, R.D., L.D.N., Beth Israel Deaconess Medical Center
Edward Hatchigian, M.D., Beth Israel Deaconess Medical Center
Barbara Hodges. R.D., M.P.H., L.D.N., Brigham and Women's Hospital
Mary Elizabeth Patti, M.D., Joslin Diabetes Center
Frank Perna, Ph.D., National Cancer Institute
Mark Pettus, M.D., Berkshire Medical Center
Daniel Rooks, Ph.D., Beth Israel Deaconess Medical Center
Edward Saltzman, M.D., Tufts-New England Medical Center
June Skoropowski, R.D., L.D.N., Beth Israel Deaconess Medical Center
Michael B. Tantillo, M.D., Private Practice, Brookline, MA
Phyllis Thomason, M.S., R.D., L.D.N., Faulkner Hospital

Behavioral and Psychological Care

Coordinator

Isaac Greenberg, Ph.D., Tufts-New England Medical Center

Co-chair

Stephanie Sogg, Ph.D., Massachusetts General Hospital
Frank Perna, Ph.D., National Cancer Institute

Pediatric/Adolescent

Coordinator

Janey S.A. Pratt, M.D., Massachusetts General Hospital

Co-chair

Carine Lenders, M.D., M.S., Boston Medical Center
Emily Dionne, Massachusetts General Hospital
Alison G. Hoppin, M.D., Massachusetts General Hospital
George Hsu, M.D., Tufts-New England Medical Center
Thomas Inge, M.D., Ph.D., Cincinnati Children's Hospital Medical Center
David Lawlor, M.D., Massachusetts General Hospital
Margaret Marino, Ph.D., Boston Medical Center
Alan Meyers, M.D., Boston Medical Center
Jennifer Rosenblum, M.D., Massachusetts General Hospital
Vivian Sanchez, M.D., Beth Israel Deaconess Medical Center

Anesthetic Perioperative Care and Pain Management

Coordinator

Roman Schumann, M.D., Tufts-New England Medical Center

Co-chair

Stephanie Jones, M.D., Beth Israel Deaconess Medical Center
Daniel B. Carr, M.D. (Advisor), Tufts-New England Medical Center
Kathy Connor, M.D., Newton-Wellesley Hospital
Bronwyn Cooper, M.D., University of Massachusetts Memorial Medical Center
Alan M. Harvey, M.D., M.B.A., Brigham and Women's Hospital
Michael Kaufman, M.D., Lahey Clinic
Scott Kelley, M.D., Brigham and Women's Hospital
Vilma E. Ortiz, M.D., Massachusetts General Hospital
Mark Vanden Bosch, M.D., Berkshire Medical Center

Nursing Perioperative Care

Coordinator

Ann Mulligan, R.N., Newton-Wellesley Hospital

Co-chair

Anne McNamara, R.N., Beth Israel Deaconess Medical Center
Hannah Boulton, R.N., M.S.N., South Shore Hospital
Ann Mullen, R.N., B.S.N., Newton-Wellesley Hospital
Carol Raiano, R.N., C.C.R.N., Newton-Wellesley Hospital
Linda Trainor, R.N., B.S.N., Beth Israel Deaconess Medical Center

Informed Consent and Patient Education

Coordinator

Christina C. Wee, M.D., M.P.H. Beth Israel Deaconess Medical Center

Co-chair

Michael Paasche-Orlow, M.D., M.P.H. Boston University School of Medicine
Robert Fanelli, M.D., Berkshire Medical Center
Janey Pratt, M.D., Massachusetts General Hospital
Patricia Samour, M.M.Sc., R.D., L.D.N., Beth Israel Deaconess Medical Center
Linda Trainor, R.N., B.S.N., Beth Israel Deaconess Medical Center

Policy and Access (Coding and Reimbursement)

Coordinator

Scott Shikora, M.D., Tufts-New England Medical Center

Co-chair

Rayford Kruger M.D., F.A.C.S., Tobey Hospital
George L. Blackburn, M.D., Ph.D., Beth Israel Deaconess Medical Center
John A. Fallon, M.D., M.B.A., F.A.C.P., Blue Cross Blue Shield of Massachusetts
Alan M. Harvey, M.D., M.B.A., Mercy Medical Center/ Catholic Health East
Elvira Johnson, M.S., R.D., C.D.E., L.D.N., Massachusetts Dietetics Association
Lee Kaplan, M.D., Ph.D., Massachusetts General Hospital
David Lautz, M.D., Brigham and Women's Hospital
Robert LoNigro, M.D., M.S., Tufts Health Plan
Edward C. Mun, M.D., Brigham and Women's Hospital
Malcolm K. Robinson, M.D., Brigham and Women's Hospital
Roger L. Snow, M.D., M.P.H., University of Massachusetts Medical School and MassHealth
Lee Steingisser, M.D., Blue Cross Blue Shield of Massachusetts
James Sabin, M.D., Harvard Pilgrim Health Care
Stancel M. Riley Jr., M.D., Massachusetts Board of Registration in Medicine

Specialized Facilities and Resources

Coordinator

David Lautz, M.D., Brigham and Women's Hospital

Co-chair

Michael E. Jiser, M.D., Saints Memorial Medical Center
Robert J. Cella, M.D., Berkshire Medical Center
John Kelly, M.D., University of Massachusetts Medical Center
Sheila K. Partridge, M.D., Newton-Wellesley Hospital
John Romanelli, M.D., F.A.C.S., Baystate Medical Center
John P. Ryan, R.N., Beth Israel Deaconess Medical Center
Scott Shikora, M.D., Tufts-New England Medical Center

Data Collection (Registries)/Future Considerations

Coordinator

Matthew M. Hutter, M.D., Massachusetts General Hospital

Co-Chair

Daniel B. Jones, M.D., M.S., Beth Israel Deaconess Medical Center
Robert J. Cella, M.D., Berkshire Medical Center
Stancel M. Riley Jr., M.D., Massachusetts Board of Registration in Medicine
Benjamin Schneider, M.D., Beth Israel Deaconess Medical Center
Roger L. Snow, M.D., M.P.H., University of Massachusetts Medical School and MassHealth
Kerri Clancy, R.N., Brigham and Women's Hospital

Endoscopic Interventions

Coordinator

Lee Kaplan, M.D., Ph.D., Massachusetts General Hospital

Co-chair

Christopher C. Thompson, M.D., M.H.E.S., Brigham and Women's Hospital
William R. Brugge, M.D., Massachusetts General Hospital
Ram Chuttani, M.D., Beth Israel Deaconess Medical Center
David Desilets, M.D., Baystate Medical Center
James C. Ellsmere, M.D., Beth Israel Deaconess Medical Center
David W. Rattner, M.D., Massachusetts General Hospital
Michael Tarnoff, M.D., Tufts-New England Medical Center

SUPPLEMENTARY MATERIAL

To review task group appendices, go to www.mass.gov/dph and search "Weight Loss Surgery."

DISCLOSURE

The authors declared no conflict of interest.

REFERENCES

1. Bray GA. The missing link—lose weight, live longer. *N Engl J Med* 2007;357:818–820.
2. Dixon J. Survival advantage with bariatric surgery: report from the 10th International Congress on Obesity. *Surg Obes Relat Dis* 2006;2:585–586.
3. Maggard MA, McGory ML, Shekelle PG, Ko CY. Quality indicators in bariatric surgery: improving quality of care. *Surg Obes Relat Dis* 2006;2:423–429.
4. Sjöström L, Narbro K, Sjöström CD *et al*. Effects of bariatric surgery on mortality in Swedish obese subjects. *N Engl J Med* 2007;357:741–752.
5. Adams TD, Gress RE, Smith SC *et al*. Long-term mortality after gastric bypass surgery. *N Engl J Med* 2007;357:753–761.
6. Favretti F, Segato G, Ashton D *et al*. Laparoscopic adjustable gastric banding in 1,791 consecutive obese patients: 12-year results. *Obes Surg* 2007;17:168–175.
7. Perry CD, Hutter MM, Smith DB, Newhouse JP, McNeil BJ. Survival and changes in comorbidities after bariatric surgery. *Ann Surg* 2008;247:21–27.
8. Sowemimo OA, Yood SM, Courtney J *et al*. Natural history of morbid obesity without surgical intervention. *Surg Obes Relat Dis* 2007;3:73–77.
9. Christou NV, Sampalis JS, Liberman M *et al*. Surgery decreases long-term mortality, morbidity, and health care use in morbidly obese patients. *Ann Surg* 2004;240:416–423.
10. Flum DR, Dellinger EP. Impact of gastric bypass operation on survival: a population-based analysis. *J Am Coll Surg* 2004;199:543–551.
11. Kral JG. Studies show reduction in mortality after bariatric surgery. *Surg Obes Relat Dis* 2006;2:564.
12. McMahon MM, Sarr MG, Clark MM *et al*. Clinical management after bariatric surgery: value of a multidisciplinary approach. *Mayo Clin Proc* 2006;81(10 Suppl):S34–S45.
13. Clark MM, Balsiger BM, Sletten CD *et al*. Psychosocial factors and 2-year outcome following bariatric surgery for weight loss. *Obes Surg* 2003;13:739–745.
14. Sarwer DB, Wadden TA, Fabricatore AN. Psychosocial and behavioral aspects of bariatric surgery. *Obes Res* 2005;13:639–648.
15. Herpertz S, Kielmann R, Wolf AM *et al*. Does obesity surgery improve psychosocial functioning? A systematic review. *Int J Obes Relat Metab Disord* 2003;27:1300–1314.
16. Arcila D, Velázquez D, Gamino R *et al*. Quality of life in bariatric surgery. *Obes Surg* 2002;12:661–665.
17. Kolotkin RL, Crosby RD, Pendleton R *et al*. Health-related quality of life in patients seeking gastric bypass surgery vs non-treatment-seeking controls. *Obes Surg* 2003;13:371–377.
18. Elkins G, Whitfield P, Marcus J *et al*. Noncompliance with behavioral recommendations following bariatric surgery. *Obes Surg* 2005;15:546–551.
19. Collazo-Clavell ML, Clark MM, McAlpine DE, Jensen MD. Assessment and preparation of patients for bariatric surgery. *Mayo Clin Proc* 2006 81(10 Suppl):S11–S17.
20. Belle SH, Berk PD, Courcoulas AP *et al*. Safety and efficacy of bariatric surgery: Longitudinal Assessment of Bariatric Surgery. *Surg Obes Relat Dis* 2007;3:116–126.
21. Kendrick ML, Dakin GF. Surgical approaches to obesity. *Mayo Clin Proc* 2006;81(10 Suppl):S18–S24.

22. Lehman Center Weight Loss Surgery Expert Panel.Commonwealth of Massachusetts. Betsy Lehman Center for Patient Safety and Medical Error Reduction. Expert Panel on Weight Loss Surgery: Executive Report. *Obes Res* 2005;13:206–226.
23. Rand Corporation. Research Briefs.Obesity and Disability: The Shape of Things to Come. <http://www.rand.org/pubs/research_briefs/RB9043-1/> (2007). Accessed 9 June 2007.
24. Desjardins E, Schwartz AL. Collaborating to combat childhood obesity. *Health Aff (Millwood)* 2007;26:567–571.
25. Sturm R. Increases in morbid obesity in the USA: 2000–2005. *Public Health* 2007;121:492–496.
26. Haslam DW, James WP. Obesity. *Lancet* 2005;366:1197–1209.
27. Li Z, Bowerman S, Heber D. Health ramifications of the obesity epidemic. *Surg Clin North Am* 2005;85:681–701.
28. Finkelstein EA, Fiebelkorn IC, Wang G. National medical spending attributable to overweight and obesity: how much, and who's paying? *Health Aff (Millwood)* 2003;W3:219–226.
29. Economic Consequences. Centers for Disease Control and Prevention. <http://www.cdc.gov/nccdphp/dnpa/obesity/economic_consequences.htm> (2007). Accessed 9 June 2007.
30. Mokdad AH, Marks JS, Stroup DF, Gerberding JL. Actual causes of death in the United States, 2000. *JAMA* 2004;29:1238–1245. [Erratum in: *JAMA* 2005;293:293–294. *JAMA* 2005;293:298].
31. Olshansky SJ, Passaro DJ, Hershow RC *et al*. A potential decline in life expectancy in the United States in the 21st century. *N Engl J Med* 2005;352:1138–1145.
32. de Fatima, Haueisen Sander, Diniz M, de Azeredo, Passos VM, Diniz MT. Gut-brain communication: how does it stand after bariatric surgery? *Curr Opin Clin Nutr Metab Care* 2006;9:629–636.
33. Samuel I, Mason EE, Renquist KE *et al*. Bariatric surgery trends: an 18-year report from the International Bariatric Surgery Registry. *Am J Surg* 2006;192:657–662.
34. Elder KA, Wolfe BM. Bariatric surgery: a review of procedures and outcomes. *Gastroenterology* 2007;32:2253–2271.
35. DeMaria EJ. Bariatric surgery for morbid obesity. *N Engl J Med* 2007;356:2176–2183.
36. Zhao Y, Encinosa W. Bariatric Surgery Utilization and Outcomes in 1998 and 2004. Statistical Brief #23. Agency for Healthcare Research and Quality: Rockville, MD, 2007.
37. Kim TH, Daud A, Ude AO *et al*. Early U.S. outcomes of laparoscopic gastric bypass versus laparoscopic adjustable silicone gastric banding for morbid obesity. *Surg Endosc* 2006;20:202–209.
38. Smoot TM, Xu P, Hilsenrath P, Kuppersmith NC, Singh KP. Gastric bypass surgery in the United States, 1998–2002. *Am J Public Health* 2006;96:1187–1189.
39. Wolfe BM, Morton JM. Weighing in on bariatric surgery: procedure use, readmission rates, and mortality. *JAMA* 2005;294:1960–1963.
40. le Roux CW, Aylwin SJ, Batterham RL *et al*. Gut hormone profiles following bariatric surgery favor an anorectic state, facilitate weight loss, and improve metabolic parameters. *Ann Surg* 2006;243:108–114.
41. Peluso L, Vanek VW. Efficacy of gastric bypass in the treatment of obesity-related comorbidities. *Nutr Clin Pract* 2007;22:22–28.
42. Parikh MS, Laker S, Weiner M, Hajiseyedjavadi O, Ren CJ. Objective comparison of complications resulting from laparoscopic bariatric procedures. *J Am Coll Surg* 2006;202:252–261.
43. Chapman AE, Kiroff G, Game P *et al*. Laparoscopic adjustable gastric banding in the treatment of obesity: a systematic literature review. *Surgery* 2004;135:326–351.
44. Olbers T, Fagevik-Olsen M, Maleckas A, Lonroth H. Randomized clinical trial of laparoscopic Roux-en-Y gastric bypass versus laparoscopic vertical banded gastroplasty for obesity. *Br J Surg* 2005;92:557–562.
45. Scopinaro N, Gianetta E, Civalleri D, Bonalumi U, Bachi V. Bilio-pancreatic bypass for obesity: II. Initial experience in man. *Br J Surg* 1979;66:618–620.
46. Kotidis EV, Koliakos G, Papavramidis TS, Papavramidis ST. The effect of biliopancreatic diversion with pylorus-preserving sleeve gastrectomy and duodenal switch on fasting serum ghrelin, leptin and adiponectin levels: is there a hormonal contribution to the weight-reducing effect of this procedure? *Obes Surg* 2006;16:554–559.
47. Cottam D, Qureshi FG, Mattar SG *et al*. Laparoscopic sleeve gastrectomy as an initial weight-loss procedure for high-risk patients with morbid obesity. *Surg Endosc* 2006;20:859–863.
48. Roa PE, Kaidar-Person O, Pinto D *et al*. Laparoscopic sleeve gastrectomy as treatment for morbid obesity: technique and short-term outcome. *Obes Surg* 2006;16:1323–1326.
49. Silecchia G, Boru C, Pecchia A *et al*. Effectiveness of laparoscopic sleeve gastrectomy (first stage of biliopancreatic diversion with duodenal switch) on co-morbidities in super-obese high-risk patients. *Obes Surg* 2006;16:1138–1144.
50. Mognol P, Chosidow D, Marmuse JP. Laparoscopic sleeve gastrectomy (LSG): review of a new bariatric procedure and initial results. *Surg Technol Int* 2006;15:47–52.
51. Melissas J, Koukouraki S, Askoxylakis J *et al*. Sleeve gastrectomy: a restrictive procedure? *Obes Surg* 2007;17:57–62.
52. Langer FB, Reza Hoda MA, Bohdjalian A *et al*. Sleeve gastrectomy and gastric banding: effects on plasma ghrelin levels. *Obes Surg* 2005;15:1024–1029.
53. Kelly J, Shikora S, Jones DB *et al*. Best practice updates for surgical care in weight loss surgery. *Obes*, in press.
54. Apovian CM, Cummings S, Anderson W *et al*. Best practice updates for multidisciplinary care in weight loss surgery. *Obes*, in press.
55. Greenberg I, Sogg S, Perna F. Behavioral and psychological care in weight loss surgery—best practice update. *Obes*, in press.
56. Pratt J, Lenders CM, Dionne E *et al*. Best practice updates for pediatric/adolescent weight loss surgery. *Obes*, in press.
57. Schumann R, Jones SB, Cooper B *et al*. Update on best practice recommendations for anesthetic preioperative care and pain management in weight loss surgery, 2004–2007. *Obes*, in press.
58. Mulligan A, McNamara A, Boulton H *et al*. Best practice updates for nursing care in weight loss surgery. *Obes*, in press.
59. Wee CC, Pratt J, Fanelli R *et al*. Best practice updates for informed consent and patient education in weight loss surgery. *Obes*, in press.
60. Shikora SA, Kuger RS Jr, Blackburn GL *et al*. Best practices in policy and access for weight loss surgery. *Obes*, in press.
61. Lautz DB, Jiser ME, Kelly J *et al*. An update on best practice guidelines for specialized facilities and resources necessary for bariatric surgical programs. *Obes*, in press.
62. Hutter MM, Jones DB, Riley S *et al*. Best practice updates for weight loss surgery data collection. *Obes*, in press.
63. Ellsmere JC, Thompson CC, Brugge WR *et al*. Best practices in endoscopic intervention for weight loss surgery. *Obes*, in press.
64. Trus TL, Pope GD, Finlayson SR. National trends in utilization and outcomes of bariatric surgery. *Surg Endosc* 2005;19:616–620.
65. Galvani C, Gorodner M, Moser F *et al*. Laparoscopic adjustable gastric band versus laparoscopic Roux-en-Y gastric bypass: ends justify the means? *Surg Endosc* 2006;20:934–941.
66. DeMaria EJ, Jamal MK. Laparoscopic adjustable gastric banding: evolving clinical experience. *Surg Clin North Am* 2005;85:773–787.
67. Suter M, Giusti V, Worreth M, Heraief E, Calmes JM. Laparoscopic gastric banding: a prospective, randomized study comparing the Lapband and the SAGB: early results. *Ann Surg* 2005;241:55–62.
68. Suter M, Calmes JM, Paroz A, Giusti V. A 10-year experience with laparoscopic gastric banding for morbid obesity: high long-term complication and failure rates. *Obes Surg* 2006;16:829–835.
69. Kelly J, Tarnoff M, Shikora S *et al*. Best practice recommendations for surgical care in weight loss surgery. *Obes Res* 2005;13:227–233.
70. Schirmer BD, Schauer PR, Flum DR, Ellsmere J, Jones DB. Bariatric surgery training: getting your ticket punched. *J Gastrointest Surg* 2007;11:807–812.
71. Lautz DB, Jackson TD, Clancy KA *et al*. Bariatric operations in Veterans Affairs and selected university medical centers: results of the patient safety in surgery study. *J Am Coll Surg* 2007;204:1261–1272.
72. American Society for Metabolic and Bariatric Surgery. <http://www.asbs.org/> (2007). Accessed 23 August 2007.
73. Andrade SD. Planning and Design Guidelines for Bariatric Healthcare Facilities.American Institute of Architects. AIA Academy Journal. <http://www.aia.org/journal_aah.cfm?pagename=aah_jrnl_20061018_award_winner&dspl=1&article=article> (2006). Accessed 6 August 2007.
74. Rich DS. New JCAHO medication standards for 2004. *Am J Health-Syst Pharm* 2004;61:1349–1358.
75. ACS Division of Research and Optimal Patient Care. American College of Surgeons Bariatric Surgery Center Network (BSCN) Accreditation Program Manual.American College of Surgeons. <http://facs.org/index.html>. Accessed 23 August 2007.
76. Commonwealth of Massachusetts. Betsy Lehman Center for Patient Safety and Medical Error Reduction. Expert Panel on Weight Loss Surgery: Executive Report update. *Obes*, in press.