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ASMBS, SOARD, outcome reporting standards

Standardized outcomes reporting in metabolic and bariatric surgery

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Executive summary of American Society for Metabolic and Bariatric Surgery (ASMBS) outcome reporting standards

The purpose of this document is to provide guidance to authors and editors who write, review, and publish manuscripts focusing on bariatric and metabolic surgery. In addition to providing consistency within the field of bariatric and metabolic surgery, standardized outcome reporting will provide a uniform method of communicating our findings throughout the medical literature.

1. Follow-up

% Follow-up. When appropriate for the study design, the percentage of patients comprising the original study group who complete each follow-up period reported for the study should be reported (i.e., report the numerator and denominator available for follow-up at each time point reported).

For prospective studies, % follow-up should represent the percentage of patients from the original study group(s) who remained in the study until the study endpoint(s) are reached or for the final reported follow-up interval. The reasons for patient attrition from the study should be reported when possible. For retrospective studies, the total number of patients in the database(s) who meet the inclusion criteria should be reported in addition to the percentage available for data analysis for the study endpoints.

Duration of follow-up. *Short-term* follow-up is defined as <3 years after intervention. *Medium-term* follow is defined as >3 and <5 years after intervention. *Long-term* follow-up is defined as >5 years after intervention.

2. Diabetes

Definitions of glycemic outcomes after bariatric surgery

Outcome	Definition
Remission (complete)	Normal measures of glucose metabolism (HbA_{1c} $<6\%$, FBG <100 mg/dL) in the absence antidiabetic medications
Remission (partial)	Subdiabetic hyperglycemia (HbA_{1c} 6%–6.4%, FBG 100–125 mg/dL)

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	in the absence antidiabetic medications
Improvement	Statistically significant reduction in HbA_{1c} and FBG not meeting criteria for remission or decrease in antidiabetic medications requirement (by discontinuing insulin or one oral agent, or ½ reduction in dose)
Unchanged	The absence of remission or improvement as described earlier
Recurrence	FBG or HbA_{1c} in the diabetic range ($\geq$126 mg/dL and $\geq$6.5%, respectively) *or* need for antidiabetic medication after any period of complete or partial remission

HbA_{1c} = glycosylated hemoglobin; FBG = fasting blood glucose.

3. Hypertension

Stage of hypertension before and after bariatric surgery at the defined follow-up intervals are as follows:

Prehypertension (120–140/80–89 systolic/diastolic)
Stage 1 hypertension (140–159/90–99)
Stage 2 hypertension (>160/>100)

Antihypertensive medication use should be reported (clearly define indication for medication as treatment of hypertension). Reporting medication type or class and duration of therapy is also recommended with the understanding that this may not be feasible in retrospective studies.

Improvement:	Defined as a decrease in dosage or number of antihypertensive medication or decrease in systolic or diastolic blood pressure (BP) on the same medication (better control).
Partial remission:	Defined as prehypertension values (120–140/80–89) when off medication.
Complete remission:	Defined as being normotensive (BP <120/80) off antihypertensive medication.
	If medication such as beta-blockade is used for another indication (atrial fibrillation), this needs to be clearly described but cannot be included as complete remission because of the dual therapeutic effect of some medications.

4. Dyslipidemia

It is recommended that reporting practice for dyslipidemia after bariatric surgery follow the *Adult Treatment Panel III Guidelines, 2001,* of the National Heart, Lung and Blood Institute. These values reflect fasting blood samples:

LDL cholesterol	<100 mg/dL = optimal (or <40 mg/dL if another risk factor is present)
	100–129 mg/dL = near optimal
	130–159 mg/dL = borderline high
	160–189 mg/dL = high
	>190 mg/dL = very high
HDL cholesterol	<40 mg/dL = low
	>60 mg/dL = high
Total cholesterol	<200 mg/dL = desirable
	200–239 mg/dL = borderline high
	>240 mg/dL = high
Triglycerides	<150 mg/dL = normal
	150–199 mg/dL = borderline high
	200–499 mg/dL = high
	>500 mg/dL = very high

LDL = low-density lipoprotein; HDL = high-density lipoprotein.

Cardiovascular risk may then be calculated as the total cholesterol/HDL ratio:

½ average risk = 3.27
average risk = 4.44
2× average risk = 7.05
3× average risk = 11.04

Indication for cholesterol and lipid-lowering medication use should be clearly stated.

Improvement:	Decrease in number or dose of lipid-lowering agents with equivalent control of dyslipidemia *or* improved control of lipids on equivalent medication.
	Authors must specify which components of the lipid profile are being studied and report them as individual outcomes when possible.
	Cardiovascular risk based on total cholesterol (TC)/HDL or other risk scoring systems can be used to provide a more global assessment of lipid changes after surgery.
Remission:	Normal lipid panel (or specific component being studied) off medication.

5. Obstructive sleep apnea (OSA)

Recognizing that not all patients will undergo repeat testing, a "subjective" category is included here in addition to the "objective" findings. Reporting complete remission or objective improvement is preferred over subjective improvement.

Complete remission:	In those patients with preoperative polysomnography (PSG) with diagnosis of OSA, complete remission would be defined as AHI/RDI of <5 off CPAP/BI-PAP on repeat objective testing with PSG.
Improvement Objective:	Requires some form of measurable improvement:
	Reduced pressure settings on CPAP/BI-PAP as recommended by a sleep medicine provider.
	Decreased severity of disease on repeat objective testing with PSG (e.g., going from severe to mild).
	Improved repeat score on screening tool compared with preoperative.

Subjective:	Patients with preoperative documentation of OSA who have not or will not undergo repeat objective testing with PSG. Document personal or witnessed improvement in sleep hygiene and symptoms of sleep apnea. Have self-discontinued the use of sleep apnea treatment CPAP/BiPAP based on improved symptoms.

CPAP = continuous positive airway pressure; Bi-PAP = bilevel positive airway pressure.

6. Gastroesophageal reflux disease (GERD)

In the evaluation and reporting of GERD after bariatric surgery, the following recommendations are made:

1. Use of a validated questionnaire pre- and postsurgery
2. Recording and reporting medication use and specific indication
3. Minimum of 1-year follow-up and, ideally, long-term follow-up that is procedure-specific

Like OSA, there may be subjective self-reported criteria to define improvement of GERD after surgery as well as objective criteria. Objective, procedure-specific criteria are preferred. Authors should specify whether their outcomes are based on objective or subjective criteria.

Complete resolution (objective):	Absence of symptoms (normal symptom score) *and* No medication use *and* Normal physiologic test (24- or 48-hr pH study, impedance study [preferred], and/or endoscopy])
Complete resolution (subjective):	Absence of symptoms *and* No medication use
Improvement (objective):	Improved symptom score on validated testing *or* Decreased or as needed medication use* *or* Improved physiologic test (24- or 48-hour pH study, impedance study, and/or endoscopy)
Improvement (self-reported):	Improved symptom severity or frequency *or* Decreased or as needed medication use*

*Decreased or as-needed medication associated with improvement of symptoms and not ineffectiveness of medication, cost, or other reasons.

7. Complications

Complication	Major	Minor
Early <30 days	Early major	Early minor
Late >30 days	Late major	Late minor

Major complications include any complication that result in a prolonged hospital stay (beyond 7 days), administration of an anticoagulant, reintervention, or reoperation.

Minor complications include everything else that is not included under *major.*

Examples of major complications

- Examples of major complications include the following:
- Venous thrombotic event (VTE) requiring administration of anticoagulant or intervention, such as embolectomy, inferior vena caval (IVC) filter
- Anastomotic leak requiring reoperation, percutaneous drainage of abscess, stent placement or conservative management with parenteral nutrition and nothing per os (NPO)
- Gastrointestinal hemorrhage requiring transfusion or intervention
- Small bowel obstruction requiring reoperation
- Bowel perforation requiring reoperation
- Trocar site hernia requiring reoperation
- Death
- Myocardial infarction
- Cerebrovascular accident
- Renal failure requiring dialysis
- Respiratory failure requiring intervention such as intubation
- Prolonged hospitalization (>7 d)
- Chronic nausea and vomiting not responsive to conservative management and requiring total parenteral nutrition (TPN)
- Gastric sleeve stenosis/obstruction requiring revision to a gastric bypass
- Surgical site infection (superficial, deep, or organ space) requiring debridement or washout in the operating room or percutaneous intervention
- Small bowel stenosis, stricture, or obstruction requiring revision of the jejunojejunostomy

Examples of minor complications. Examples of minor complications include the following:

- Marginal ulcer diagnosed with upper endoscopy
- Anastomotic stricture requiring endoscopic dilation
- Nausea and vomiting requiring intravenous fluids (IVF) but not TPN
- Acute renal failure managed with IVF without the need of dialysis
- Gastrointestinal ileus managed conservatively
- Incisional hernia (diagnosed during routine follow-up)
- Trocar site surgical site infection managed with drainage and local wound care
- Negative re-exploration (e.g., diagnostic laparoscopy to rule out leak or for unexplained tachycardia)
- Urinary tract infection managed with antibiotics
- Dehydration requiring IV hydration as an inpatient
- Vitamin or mineral deficiency requiring IV supplementation (e.g., severe anemia requiring IV iron infusion or severe vitamin B12 requiring vitamin B12 injections or symptomatic thiamine deficiency requiring IV thiamine)
- Nephrolithiasis
- Symptomatic cholelithiasis

8. Weight Loss

Reporting of weight loss outcomes after bariatric surgery should include the following parameters (in which *initial weight* is the patient's weight as measured closest to the time of surgery and *initial BMI* is the body mass index (BMI) determined closest to the time of surgery in the preoperative period):

Complete reporting is recommended as follows:

1. Mean initial BMI of the cohort
2. Change in BMI (ΔBMI):
   ΔBMI = (Initial BMI) – (Postop BMI)
3. Percent of total weight loss (%TWL):
   %TWL = [(Initial Weight) – (Postop Weight)] / [(Initial Weight)] × 100
4. Percent excess BMI loss (%EBMIL):
   %EBMIL = [ΔBMI / (Initial BMI – 25)] × 100
   and/or
   Percent excess weight loss (%EWL)
   %EWL = [(Initial Weight) – (Postop Weight)] / [(Initial Weight) – (Ideal Weight)]
   (in which *ideal weight* is defined by the weight corresponding to a BMI of 25 kg/m^2; see Appendix A)

9. Quality of life

Currently, psychological testing in bariatric surgery has been used primarily as a descriptive measure or to determine treatment effects in well-defined populations. Consequently, in the context of evaluating program outcomes, no specific recommendations are supported by the current literature. In the context of reporting treatment effects, the need for a generic instrument, a system- and condition-specific instrument, an obesity-specific instrument, or a combination of tools should be made based on the specific research aims. However, we recommend the use of a validated instrument is for all published reports.

Standardized outcomes reporting in metabolic and bariatric surgery

To date, there has been no standardized or systematic method of reporting outcomes in the bariatric surgery literature. As a result, weight loss is commonly reported differently throughout the medical and surgical literature. Additionally, the definitions of co-morbidity improvement and remission have been inconsistent and this has made interpretation of these results across studies difficult.

Several systematic reviews of the bariatric and metabolic surgery literature have been conducted. The conclusions obtained from these reviews have been weakened by the quality of the data included and the variability of endpoints for weight and co-morbidities throughout the studies reviewed.

The purpose of this document is to provide guidance to authors and editors who write, review, and publish manuscripts focusing on bariatric and metabolic surgery. In addition to providing consistency within the field of bariatric and metabolic surgery, standardized outcome reporting will provide a uniform method of communicating our findings throughout the medical literature.

1. Follow-up

Obesity is a chronic disease and its treatment requires close follow-up to accurately assess the efficacy and durability of any treatment strategy. It is widely accepted that bariatric surgery patients require lifetime follow-up to assess for weight loss, co-morbidity changes, and nutritional deficiencies. The type and frequency of follow-up depends on the specific operation, but a standardized approach to postoperative follow-up schedules has been required for programs to participate in accreditation and quality improvement programs.

Current practices. Current methods of reporting follow-up in the bariatric literature vary widely, and this presents significant challenges in interpreting the results of many published studies. To date, there has not been a uniform method or even a requirement to report follow-up rates for cohorts of patients. Follow-up rates are most often reported for prospective studies. Retrospective studies, however, most often do not report the percentage of patients included in a study as a percentage of patients in the database who were eligible for inclusion. The duration of follow-up (short, medium, and long term) is not presented in a uniform manner across the bariatric literature.

Challenges. The primary challenge is in achieving consistency in follow-up reporting across various types of bariatric publications in various journals. The requirement and necessity for reporting follow-up rates for prospective studies is clear. Enforcing the requirement to include the total patient number (denominator) for retrospective studies presents a greater challenge but is worth pursuing to address the large amount of selection bias in the current bariatric literature.

Recommended reporting. % Follow-up. When appropriate for the study design, the percentage of patients comprising the original study group who complete each follow-up period reported for the study should be reported (i.e., report the numerator and denominator available for follow-up at each time point reported). For prospective studies, percent follow-up should represent the percentage of patients from the original study group(s) who remained in the study until the study endpoints are reached or for the final reported follow-up interval. The reasons for patient attrition from the

study should be reported when possible. For retrospective studies, the total number of patients in the database who meet the inclusion criteria should be reported in addition to the percentage available for data analysis for the study endpoints.

Duration of follow-up. Short-term follow-up is defined as <3 years after intervention. *Medium-term* follow-up is defined as >3 and <5 years after intervention. *Long-term* follow-up is defined as >5 years after intervention.

2. Diabetes

The field of metabolic and bariatric surgery has advanced rapidly over the last decade and this is due in large part to the effect of these operations on type 2 diabetes mellitus (T2DM). There is a large body of literature demonstrating the early and mid-term effects of bariatric procedures on diabetes remission and improvement and several that have reported the durability of these effects beyond 5 years. Over time, definitions of diabetes remission based on biochemical parameters have changed and there is a wide variety of definitions for remission used throughout the bariatric literature. As this field continues to progress, clear biochemical endpoints and definitions of diabetes improvement, remission, and recurrence must be established and reported consistently in the bariatric literature.

Current practices

There is no consistency in how diabetes remission has been reported in the bariatric literature. Definitions have ranged from patient-reported medication discontinuation to strict biochemical parameters. The American Diabetes Association (ADA) publishes clear criteria to define the disease of T2DM and prediabetes [1]. The current ADA target of therapy is an HbA_{1c} $<7\%$, but this target of therapy implies only adequate control with or without medication. Normoglycemia based on HbA_{1c} and fasting blood glucose off medication has been used more commonly in recent publications, but even some recent publications in high-impact journals have used subdiabetic hyperglycemia in their definition of remission.

Challenges. Even though obtaining fasting glucose levels and HbA_{1c} levels are routine and considered standard of care for diabetic patients, it can be difficult to obtain these parameters from retrospective studies. Prospective trials that are evaluating diabetic outcomes as a primary or secondary endpoint, however, should include these biochemical parameters as well as medication usage in their study design if appropriate. One major challenge potentially encountered in longer-term studies, particularly retrospective studies, is that patients who achieve complete remission of their diabetes are no longer considered diabetic by their primary physician or insurance company and either don't have these laboratory measurements drawn annually or don't have insurance coverage for them any longer. In prospective trials, these laboratory measurements should be included in the budgeting for long-term follow-up because they may no longer be considered "standard of care" for some patients in remission.

The other major challenge is to communicate consistently in the literature and present accurate biochemical parameters that are agreeable to our medical colleagues. More mechanistic evaluations such as euglycemic hyperinsulinemic clamp studies are extremely helpful in communicating our findings to endocrinologists, though this type of study is not always practical or feasible.

Recommended reporting.

Definitions of glycemic outcomes after bariatric surgery*

Outcome	Definition
Remission (complete)	Normal measures of glucose metabolism (HbA_{1c} $<6\%$, FBG <100 mg/dL) in the absence of antidiabetic medications
Remission (partial)	Subdiabetic hyperglycemia (HbA_{1c} 6%–6.4%, FBG 100–125 mg/dL) in the absence of antidiabetic medications
Improvement	Statistically significant reduction in HbA_{1c} and FBG not meeting criteria for remission or decrease in antidiabetic medications requirement (by discontinuing insulin or 1 oral agent, or ½ reduction in dose)
Unchanged	The absence of remission or improvement as described earlier
Recurrence	FBG or HbA_{1c} in the diabetic range ($\geq$126 mg/dL and $\geq$6.5%, respectively) *or* need for antidiabetic medication after any period of complete or partial remission

HbA_{1c} = glycosylated hemoglobin; FBG = fasting blood glucose.

Adapted from Buse JB, Caprio S, Cefalu WT, et al. How do we define cure of diabetes? Diabetes Care 2009;32 (11):2133–5; and Schauer PR, Burguera B, Ikramuddin S, et al. Effect of laparoscopic Roux-en-Y gastric bypass on type 2 diabetes mellitus. Ann Surg 2003;238(4):467–84.

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3. Hypertension

Reporting of the effects of weight loss and its impact on hypertension is rather confusing because of the wide range of definitions used to quantify hypertension, prehypertension, and hypertensive crisis. Another point of conflict is the use of hypertension medications for their secondary effects such as for treatment of atrial fibrillation, migraines, and so on. Lastly, the accepted ranges of normal systolic and diastolic pressure change over the course of life, and changing "normal" values must be considered when reporting the data.

Hypertension affects 1 billion individuals worldwide and carries an increased risk of mortality and morbidity because of its association with strokes, coronary heart disease, congestive heart failure, and end-stage renal disease. Hypertension, as defined by the American Heart Association, is divided into stages. Stage 1 hypertension occurs when the systolic blood pressure (BP) is between 140 and 159 mm Hg or the diastolic range falls between 90 and 99 mm Hg. Stage 2 hypertension occurs when systolic readings are consistently >160 mm Hg or diastolic readings are >100 mm Hg. Hypertensive crisis requiring immediate intervention occurs when systolic readings are >180 mm Hg or diastolic readings are >110 mm Hg. Normotensive values are reported as a systolic <120 mm Hg and a diastolic <80 mm Hg. Prehypertension occurs when a systolic reading falls between 120 and 139 mm Hg or a diastolic reading falls between 80 and 89 mm Hg.

Treatment of hypertension, regardless of the degree or stage, begins with lifestyle management (dietary restriction, behavior modification, and increased activity). Currently there are >75 antihypertensive medications available in the United States in 9 classes with continued interest in newer targeted therapies. Although traditional thought was to begin pharmacologic therapy for stage 1 hypertension, the new paradigm suggests that pharmacologic treatment begin during the prehypertensive stage because it can reduce the risk of major cardiovascular events by 18%–42%. The Canadian Hypertension Education Program Evidence-Based Recommendations Task Force recommended pharmacotherapy targets of BP $<140/90$ mm Hg in all patients but $<130/80$ mm Hg in those with diabetes mellitus or chronic kidney disease. In the United States, 33% of the population has hypertension and is under medical treatment. The trend to treat prehypertension with pharmacotherapy is rapidly gaining favor, and the target blood pressure ranges are also trending lower. There is a wealth of literature that indicates that treating obesity with lifestyle management alone or in conjunction with bariatric surgery has major effects on improving hypertension and its associated sequelae.

Current reporting practices. Various studies have documented the significant impact bariatric surgery has on the improvement and resolution of hypertension. Currently there is no standard definition of hypertension or stage of hypertension to be used in the bariatric literature. Additionally, stating that a patient decreased medication use does not provide the important details needed to understand the effects of the intervention (surgery) on the disease of hypertension because many of these medications have multiple indications.

Challenges and controversies. Multiple issues exist when reporting the impact of surgery on hypertension, including patient compliance. Because many hypertensive medications have multiple indications beyond hypertension, it is important to ensure that the initial indication for the specific hypertensive was to treat a specific stage of hypertension. There is also a relative lack of data comparing the efficacy of different bariatric procedures on hypertension or discussions regarding mechanisms beyond weight loss. Additionally, reporting of hypertension outcomes in the bariatric literature may be confounded by differences in age, sex, and usage of nicotine products among a study cohort.

Recommended reporting practices. For consistency in reporting and comparing data, defined parameters should be followed. Patient age; gender; the presence of diabetes, chronic kidney disease, or collagen disorders; ethnicity; and smoking history should carefully be outlined, because each of these factors may play an important role in hypertension management. When reporting hypertension outcomes after metabolic and bariatric procedures, the following staging system should be used:

Stage of hypertension before and after bariatric surgery at defined follow-up intervals:	Prehypertension (120–140/80–89) Stage 1 hypertension (140–159/90–99) Stage 2 hypertension ($>60/>100$)
Antihypertensive medication use:	Clearly define indication for medication as treatment of hypertension. Reporting medication type or class and duration of therapy is also recommended, with the understanding that this may not be feasible in retrospective studies.

Improvement:	Decrease in dosage or number of antihypertensive medication or decrease in systolic or diastolic blood pressure on same medication (better control).
Partial remission:	Prehypertension values (120–140/80–89) off medication.
Complete remission:	Normotensive (BP $<120/80$) off antihypertensive medication. If medication such as beta-blockade is used for another indication (e.g., atrial fibrillation), this needs to be clearly described but cannot be included as complete remission because of the dual therapeutic effect of some medications.

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4. Dyslipidemia

The words *hyperlipidemia* and *dyslipidemia* are used interchangeably and refer to an abnormal amount of one or more lipids in the blood. Dyslipidemia may be seen in 50%–80% of obese persons. Although it is commonly seen in conjunction with other weight-related co-morbidities such as diabetes mellitus and hypertension, dyslipidemia is a primary major risk factor for both cardiovascular disease and cerebrovascular disease, and therefore its improvement or resolution has been deemed important to study after weight loss surgery.

The general recommendation for screening of blood lipids is a complete fasting lipoprotein profile, including total cholesterol, LDL cholesterol, HDL cholesterol, and triglycerides. A secondary option would be to collect nonfasting total cholesterol and HDL cholesterol; if total cholesterol is ≥ 200 mg/dL or if the HDL is <40 mg/dL, then the recommendation would be to proceed to the full fasting panel.

There are many possible causes for dyslipidemia, including overweight and obesity, physical inactivity, alcohol abuse, smoking, a diet high in carbohydrates, type II diabetes mellitus, chronic renal insufficiency, various drugs such as steroids and beta-blockers, and a variety of genetic disorders, including monogenic familial hypercholesterolemia, type III hyperlipidemia, familial defective apolipoprotein B-100, and polygenic hypercholesterolemia.

Once a diagnosis has been made, the treatment of dyslipidemia generally starts with lifestyle changes, such as a decrease in the dietary intake of cholesterol-raising nutrients, overall reduction in saturated fats, use of soluble fiber, weight reduction, and increase in exercise. When such measures are insufficient, or in the presence of other risk factors, medications may be started, and include such substances as statins, bile acid sequestrants, nicotinic acid, omega-3 fatty acids, and the fibric acids.

Weight loss surgery is not generally discussed as a specific treatment for dyslipidemia in the same way it is used as a treatment for diabetes mellitus, and as such there are no controlled trials looking specifically at improvement of blood lipids after weight loss surgery. Nonetheless, there is a large body of literature, mostly reviews and retrospective studies, demonstrating in a variety of ways how dyslipidemia can improve after weight loss surgery.

The Swedish Obesity Study looked at outcomes with 10 years of follow-up, which was in part successfully completed because of a national healthcare system. The reporting of large collective groups of patients who underwent "bariatric surgery" is confusing and unhelpful; improvement of dyslipidemia should be reported in the context of which surgical procedure was performed, including but not limited to the various limb lengths in gastric bypass. Patient age and gender have both been reported to have differential effects on various blood lipids before and after surgery, so these populations should be described separately. In addition, improvement of dyslipidemia should be reported in the context of amount of weight lost. How weight loss or BMI loss is reported is another topic of discussion. Finally, whether or not patients are using lipid-lowering medication at the time of drawn lipid levels is essential information. Because this can confound the data, controlled studies of lipid levels before and after surgery in patients not taking lipid-lowering medications will be most helpful in clarifying exactly how weight loss operations affect blood lipid levels.

Current reporting practices. Dyslipidemia is common in the severely obese population and studies in the surgical literature generally document improvement of dyslipidemia after weight loss surgery. Unfortunately, current reporting practices are not standardized and may include a simple reported history of the presence or absence of dyslipidemia, surveys of medication usage, or comparisons of lipid profiles at different time points before and after surgery. Not all studies state whether blood lipid levels were taken in a fasting or nonfasting state. Not all studies differentiate improvement from complete resolution. Many papers, including some meta-analyses, do not define dyslipidemia or state how the diagnosis was arrived at in any particular study. Some studies use various models of risk, such as the Regicor model, or the Framingham model to assess cardiovascular risk, which is closely tied to dyslipidemia.

Challenges. One challenge with simple reporting of medication use is that patients may have refused medication treatment before surgery despite the presence of dyslipidemia, either because of side effects or a general dislike of taking medications. This phenomenon would tend to underreport improvement in dyslipidemia. In addition, there are other indications for various lipid-lowering medications; for example, not all patients taking statins are using them for dyslipidemia but for other established diagnoses, including osteoporosis, some cancers, cerebrovascular events, cardiac arrhythmias, renal disease, rheumatoid arthritis, and others. Statins are sometimes used for the prevention of certain diseases such as Alzheimer's and Parkinson's disease. In this sense, a study of medication use could tend to overreport the presence of dyslipidemia. Statin use is also widely recommended in the setting of diabetes to achieve an even lower LDL level than commonly recommended because of increased risk for coronary events; in this sense a patient may be taking a statin but may not have dyslipidemia by strict definitions. Comparison of the efficacy of various operations in improving dyslipidemia will also be clouded by the presence of genetic causes of abnormal blood lipids, which may not improve simply with weight loss.

Recommended reporting practices. It is recommended that reporting practice for dyslipidemia after bariatric surgery follow the *Adult Treatment Panel III Guidelines, 2001,* of the National Heart, Lung and Blood Institute. These values reflect fasting blood samples:

LDL cholesterol	<100 mg/dL = optimal (or <40 mg/dL if another risk factor is present)
	100–129 mg/dL = near optimal
	130–159 mg/dL = borderline high
	160–189 mg/dL = high
	>190 mg/dL = very high
HDL cholesterol	<40 mg/dL = low
	>60 mg/dL = high
Total cholesterol	<200 mg/dL = desirable
	200–239 mg/dL = borderline high
	>240 mg/dL = high
Triglycerides	<150 mg/dL = normal
	150–199 mg/dL = borderline high
	200–499 mg/dL = high
	>500 mg/dL = very high
Cardiovascular risk may then be calculated as the cholesterol/HDL ratio:	½ average risk = 3.27
	average risk = 4.44
	2× average risk = 7.05
	3× average risk = 11.04

Indication for cholesterol and lipid-lowering medication should be clearly stated.

Improvement:	Decrease in number or dose of lipid-lowering agents with equivalent control of dyslipidemia *or* improved control of lipids on equivalent medication.
	Authors must specify which components of the lipid profile are being studied and report them as individual outcomes when possible.
	Cardiovascular risk based on TC/HDL or other risk scoring systems can be used to provide a more global assessment of lipid changes after surgery.
Remission:	Normal lipid panel off medication.

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5. Obstructive sleep apnea

Obstructive sleep apnea is a common chronic respiratory condition that is estimated to affect up to 17%–24% of North American Adults and severely affect 2%–6%. The incidence of OSA is thought to be significantly higher in the morbidly obese population although variably reported between 41%–98% in published literature.

OSA results in the periodic reduction (hypopnea) or cessation (apnea) of breathing as a result of narrowing or occlusion of the upper airway during sleep. The repetitive collapse of the upper airway leads to sleep fragmentation, hypoxemia, hypercapnia, and changes in intrathoracic pressure. OSA has been documented to be an independent

risk factor for the development of diabetes, acute and chronic cardiovascular events, cardiac arrhythmias, hypertension as well as sudden death. Although some patients may be asymptomatic, classic symptoms of sleep apnea include daytime sleepiness, loud snoring, witnessed apneic events or awakenings caused by gasping or choking. The diagnosis of OSA may be suggested but cannot be made on symptoms or physical examination alone.

Screening tools such as the Epworth Sleepiness Score and Berlin Questionnaire (BQ) are commonly used; however, no screening tool to date has been validated in the morbidly obese or bariatric population. These screening tools in conjunction with a comprehensive sleep history are generally used to help assess and stratify a patient's risk for OSA. A BMI >35 or preoperative status for bariatric surgery alone is sufficient to be considered high risk for OSA by the American Academy of Sleep Medicine (AASM) and would prompt further evaluation to determine severity. There is no clinical method available to predict the severity of OSA, which is necessary to determine treatment strategies, including continuous positive airway pressure (CPAP) or bi-level positive airway pressure (BI-PAP). The 2 objective methods of testing severity of sleep apnea include in-laboratory polysomnography (PSG) (gold standard) and home testing with portable monitors (PM) to assess for the presence of apneic and hypopneic events. A preoperative clinical sleep evaluation that includes PSG is recommended by the AASM for patients before they undergo bariatric surgery. The apnea hypoxia index (AHI) or respiratory disturbance index (RDI) is used to classify the severity of OSA, with <5 events as normal, 5 to <15 as mild, 15–30 events as moderate, and >30 as severe.

Current reporting practices

As mentioned earlier, the only method of determining the severity and presence of sleep apnea in bariatric patients is through objective testing with PSG. Although it is thought that the prevalence of sleep apnea is several-fold higher in the bariatric population, the true prevalence is unknown. Underdiagnosis is likely, in part because of the added potential cost, time, and discomfort associated with undergoing a PSG. In a study by Chung et al., $<9\%$ of patients invited to undergo a preoperative PSG participated. Testing with PSG has also been recommended to be considered after successful weight loss (although there is not a direct correlation between the degree of weight loss and remission of OSA) in patients with preoperative OSA as well as those patients with significant weight regain or those considering revisional/repeat bariatric surgery.

Current and historical reporting practices often label subjective or self-reported improvement (self- and witnessed reports of reduced symptoms of OSA) as an endpoint. Because of varying degrees in the loss of soft tissue adiposity (truncal losses are generally greater than in the neck and airway), as well as varying degree of overall weight loss after bariatric procedures and the presence of other associated risk factors for OSA, the complete resolution of OSA after bariatric surgery is likely to be less than previously thought. It is also likely that postbariatric patients may prematurely abandon primary treatment (CPAP/BI-PAP) before it would otherwise be recommended based on objective testing.

Challenges and controversies

Preoperative testing for sleep apnea before bariatric surgery is not a mandated practice and likely underutilized. Because of this, it is difficult to determine true prevalence of the disease in the bariatric population.

Initial treatment of OSA in the overweight, severely obese, and bariatric surgery population should include CPAP/BI-PAP treatment as a primary treatment regardless of planned weight loss. Stratifying disease severity of OSA with PSG, however, does not imply that all preoperative patients will be compliant with CPAP/BI-PAP treatment. Although it is recommended that bariatric surgeons consider the use of preoperative PSG to determine the severity of OSA, it is also understood that the resolution of OSA can only be determined by repeat objective testing. Many patients discontinue using their CPAP/BI-PAP after losing significant weight after surgery but do not undergo repeat testing to assess the presence, severity, or absence of disease. This is partially because of the fact that it is unclear what the optimal time is to retest postbariatric patients with repeat PSG, particularly with procedures such as the laparoscopic adjustable gastric band (LAGB), where long plateaus can be encountered and greatest weight loss may average $>$ 18 months. It is likely safe to consider retesting after procedures that provide rapid, predictable weight loss and in patients who have achieved a stable weight regardless of whether this occurs at 12 or 18+ months.

Complete resolution or improvement of OSA as documented on repeat PSG would be defined as a normal AHI or RDI of <5/hr or a lower AHI from baseline, respectively, but the definition currently reported in the literature is often subjective based on patient discontinuance of CPAP or sleeping better on lower CPAP settings.

OSA is a chronic disease. Therefore, despite documentation of complete resolution of symptoms, the disease should be considered to be in remission and still requires ongoing surveillance regarding return of symptoms after weight regain, which should prompt consideration for additional objective testing.

Recommended reporting practices

Recognizing that not all patients will undergo repeat testing, a *subjective* category is included here in addition to the *objective* findings. Reporting complete remission or objective improvement is preferred over subjective improvement.

Complete remission:	In those patients with preoperative PSG with diagnosis of OSA, complete remission is defined as AHI/RDI of <5 off CPAP/BI-PAP on repeat objective testing with PSG.
Improvement	
Objective:	Requires some form of measurable improvement. Reduced pressure settings on CPAP/BI-PAP as recommended by a sleep medicine provider. Decreased severity of disease on repeat objective testing with PSG (e.g., going from severe to mild). Improved repeat score on screening tool compared with preoperative score.
Subjective:	Patients with preoperative documentation of OSA who have not or will not undergo repeat objective testing with PSG. Document personal or witnessed improvement in sleep hygiene and symptoms of sleep apnea. Have self-discontinued the use of sleep apnea treatment CPAP/BI-PAP based on improved symptoms.

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6. Gastroesophageal reflux disease (GERD)

GERD is a condition that develops when the reflux of stomach contents causes symptoms and/or complications. Symptoms related to gastroesophageal reflux become troublesome when they adversely affect an individual's well-being (mild symptoms occurring ≥ 2 d/wk; moderate/severe symptoms occurring >1 d/wk). Prevalence of at least weekly GERD in North America ranges from 18% to 28%. GERD is related to 22% of primary care visits. Heartburn (burning sensation in the retrosternal area) and regurgitation (perception of flow of refluxed gastric content into the mouth or hypopharynx) are the characteristic symptoms of GERD. Other symptoms of GERD include epigastric pain, chest pain, and dysphagia. Extraesophageal symptoms of GERD include chronic cough, laryngitis, and asthma. Obesity increases the risk for GERD and its complications, such as erosive esophagitis and esophageal adenocarcinoma.

Current reporting practices. Diagnosis of GERD can be achieved with a variety of methods, including typical symptoms and response to medications, symptom scales, endoscopy, radiographic studies, and physiologic studies (24- or 48-hr pH studies, impedance study). A 24-hour pH study is considered by many as "the gold standard" for diagnosis of GERD. There are >20 symptom scales that have been designed as screening, evaluative, and diagnostic tools, including health-related quality-of-life instruments. These instruments have undergone various degrees of psychomotor testing and only a few have been designed or used to evaluate GERD before and after surgical intervention.

Published studies evaluating the effect of bariatric surgery on GERD have used all of the aforementioned diagnostic methods. There is no widely accepted definition of remission of GERD; one of the best attempts includes both parameters from physiology and quality of life: "GERD patients are in remission when they are no longer exposed to the risk of physical complications from gastroesophageal reflux and have no clinically significant impairment of health-related well-being (quality of life) due to reflux-related symptoms." Currently, MBSAQIP instructs reporting postoperative GERD in patients who carry the diagnosis of GERD and are being treated with either a protein pump inhibitor (PPI) or histamine-2 (H2) blocker on a regular basis (PPIs or H2 blockers may be prescription or over the counter). This definition includes in the remission group patients who have occasional symptoms or use medications on an as-needed (PRN) basis.

Challenges/controversies. GERD symptoms often overlap with symptoms of other disorders, and antacid use and PPI prescriptions are often given for vague symptoms or symptoms that are atypical for GERD. Additionally, the diagnostic methods for GERD have limitations because there are patients with typical GERD symptoms but a normal esophagus on endoscopy and normal pH studies (these patients are often labeled as having functional heartburn).

Approximately 50%–60% of patients suffering from heartburn and regurgitation have no esophagitis, and <20% of patients with endoscopically confirmed esophagitis experience heartburn; there is no consensus regarding the routine use of endoscopy or GERD evaluation before bariatric surgery.

A 24-hour pH study, which is considered the "gold standard" for diagnosis of GERD, is an invasive test and not easily accepted by patients. It also adds to the cost of healthcare for these patients and may not be necessary in the setting of classic GERD symptoms or a mechanical defect such as hiatal hernia.

There are a many scoring systems and scales designed to assess GERD symptoms but not a single "gold standard" to provide a subjective evaluation of GERD. There are also no established definitions of GERD remission in the bariatric surgery population.

GERD can develop de novo after bariatric surgery, particularly after sleeve gastrectomy or after complications of an LAGB. There is little guidance on the evaluation or management of these patients. Patients can also develop GERD after a Roux-en-Y gastric bypass (RYGB), and this can present a clinical challenge if related to a large gastric pouch or a refractory marginal ulcer.

Medications that are typically prescribed to treat GERD, such as PPI or H2 blockers, are also used to treat or prevent complications (anastomotic ulcer) and gastrointestinal symptoms that may develop after bariatric surgery. There is no consensus regarding the use of these agents after bariatric surgery or the appropriate duration of ulcer prophylaxis after surgery. Also, many postbariatric surgery patients will develop intermittent epigastric symptoms at some point in their life after surgery and the empiric use of acid-reducing medication is a confounding factor when assessing the incidence of GERD in this population.

Finally, there are few long-term evaluations of GERD after bariatric surgery in the literature, so the true incidence of GERD after commonly performed procedures is unknown and confounded by different surgical techniques and variable weight loss patterns. The evaluation and reporting of GERD after bariatric surgery, then, needs to be procedure specific to draw meaningful conclusions.

Recommended reporting practices. In the evaluation of GERD after bariatric surgery, the following recommendations are made:

1. Use of a validated questionnaire pre- and postsurgery
2. Recording and reporting medication use and specific indication
3. Minimum of 1-year follow-up and, ideally, long-term follow-up that is procedure specific

As in OSA, there may be subjective self-reported criteria to define improvement of GERD after surgery as well as objective criteria. Objective, procedure-specific criteria are preferred. Authors should specify whether their outcomes are based on objective or subjective criteria.

Complete resolution (objective):	1. Absence of symptoms (normal symptom score) *and* 2. No medication use *and* 3. Normal physiologic test (24- or 48-hr pH study, impedance study) (preferred) and/or endoscopy
Complete resolution (subjective):	1. Absence of symptoms *and* 2. No medication use
Improvement (objective):	1. Improved symptom score on validated testing *or* 2. Decreased or as needed medication use* *or* 3. Improved physiologic test (24- or 48-hr pH study, impedance study) and/or endoscopy
Improvement (self-reported):	1. Improved symptom severity or frequency *or* 2. Decreased or as needed medication use*

*Decreased or as needed medication associated with improvement of symptoms and not ineffectiveness of medication, cost or other reasons.

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7. Complications

The issue of reporting surgical complications can be confusing and controversial. The lack of agreement on the definition of a surgical complication and what constitutes an actual surgical complication in addition to the issue of time frame of the occurrence add to the confusion. This section is intended to review the current practices of reporting bariatric complications and to recommend a standard framework for reporting complications that can be easily adopted and used in the bariatric literature.

Current reporting practices

When evaluating the general surgical literature, one classification system developed to define complications

was described by Clavien in 1992. This classification was subsequently modified to make it more inclusive and comprehensive. However, those changes made the system more difficult to use. Briefly, the grading system includes 5 grades (I–V) that are based on the therapy used to correct a specific complication after surgery. Some grades have subgrades; for example grade III includes IIIa and IIIb. Although this system is very inclusive and was reported to be reliable, it is confusing, inflexible, and does not take into consideration the time frame of the occurrence. For example, the administration of an antiemetic for nausea after a sleeve is considered a grade I complication. Bariatric literature reporting on surgical complications does not include a consistent or a well-defined grading system.

In its 2009 report on perioperative safety profile of bariatric surgery, the Longitudinal Assessment of Bariatric Surgery (LABS) Consortium reported a 30-day composite endpoint including death, VTE, reintubation, reintervention using endoscopic, percutaneous or operative technique, and failure of discharge after 30 days. However, when the Surgical Review Committee (SRC) presented its summary of key statistics of patient data collected and entered in a national database of centers participating in the Bariatric Surgery Center of Excellence (BSCOE) program, it used 2 separate definitions of complications: *serious* and *others*. Serious complications include death, deep venous thrombosis (DVT), stroke/cerebrovascular accident, heart attack, pulmonary embolus, heart failure or pulmonary edema, renal failure, liver failure, multisystem organ failure, sepsis from leak or other abdominal source, and systematic inflammatory response. The remaining complications were bundled under *others.* This system leaves a wide variety of postoperative complications open to interpretation. For example, a patient with low-grade fever and tachycardia after a gastric bypass can be considered as having a systematic inflammatory response and therefore included under serious complications.

Recommended practice

We recommend using 2 separate methods of reporting complications: one based on the time frame—that is, *early* (<30 d) versus *late* (>30 d)—and another based on the complication itself: *major* versus *minor* (or serious versus nonserious).

Complication	Major	Minor
Early <30 d	Early major	Early minor
Late >30 d	Late major	Late minor

An early complication will be any complication that occurs within 30 days and a late complication will be any complication that occurs after 30 days. This is based on the knowledge that most of the bariatric complications, such as leak, infection, and obstruction, will occur within a few days or weeks of the operation. However, other complications, such as stricture, delayed leak with a sleeve, ulcers, symptomatic cholelithiasis, anastomotic strictures, and so on, often occur after 30 days.

In terms of the actual complication, we recommend dividing those into major and minor.

Major complications include any complication that results in a prolonged hospital stay (>7 d), administration of an anticoagulant, reoperation, or reintervention. For example, a leak that requires reoperation will be obviously included as a major complication and a leak that is managed nonoperatively by placing the patient NPO and starting TPN would also be considered major because it required reintervention (peripherally inserted central catheter [PICC] placement), possible percutaneous drainage, or prolonged hospital stay (TPN administration). A DVT or a pulmonary embolism (PE) would also be included because it requires anticoagulation or reintervention (IVC filter placement). Gastrointestinal bleeding that requires transfusion or endoscopy or reoperation to control the bleeding would also be included as a major complication. A slight drop in hemoglobin (Hb), which may be secondary to bleeding that is only observed and managed without further intervention, would not be included in this category.

Minor complications include everything that is not included under *major*. Vitamin deficiency, urinary tract infection, dehydration requiring intravenous fluid, and so on, are all examples of minor complications. Some further examples of major and minor complications are listed next, but these lists are not intended to address every possible complication that can occur after bariatric procedures.

Examples of major complications

- VTE requiring administration of anticoagulant or intervention such as embolectomy
- Anastomotic leak requiring reoperation, percutaneous drainage of abscess, stent placement, or conservative management with parenteral nutrition and NPO
- Gastrointestinal hemorrhage requiring transfusion or intervention
- Small bowel obstruction requiring reoperation
- Bowel perforation requiring reoperation
- Trocar site hernia requiring reoperation
- Death
- Myocardial infarction
- Cerebrovascular accident
- Renal failure requiring dialysis
- Respiratory failure requiring intubation
- Prolonged hospitalization (>7 d)
- Chronic nausea and vomiting not responsive to conservative management and requiring TPN administration or enteral access
- Gastric sleeve stenosis/obstruction requiring revision to a gastric bypass

- Surgical site infection (superficial, deep, or organ space) requiring debridement or washout in the operating room or percutaneous intervention
- Small bowel stenosis, stricture, or obstruction, requiring revision of the jejunojejunostomy

Examples of minor complications

- Marginal ulcer diagnosed with upper endoscopy but not requiring endoscopic intervention
- Anastomotic stricture requiring endoscopic dilation
- Nausea and vomiting requiring IVF but not TPN
- Acute renal failure managed with IVF without the need of dialysis
- Gastrointestinal ileus managed conservatively but requiring prolonged hospital stay
- Incisional hernia (diagnosed during routine follow-up)
- Trocar site surgical site infection managed with drainage and local wound care.
- Negative reexploration (e.g., diagnostic laparoscopy to rule out leak or for unexplained tachycardia)
- Urinary tract infection managed with antibiotics
- Dehydration requiring IV hydration as an inpatient
- Vitamin or mineral deficiency requiring IV supplementation (e.g., severe anemia requiring IV iron infusion or severe vitamin B12 requiring vitamin B12 injections or symptomatic thiamine deficiency requiring IV thiamine)
- Nephrolithiasis
- Symptomatic cholelithiasis

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8. Weight Loss

Weight loss is the most commonly reported outcome after bariatric surgery. The efficacy of a specific bariatric operation and a patient's progress is often measured and compared in terms of weight loss. Indeed, a primary goal of weight loss surgery and the measure of its success is the attainment of significant and durable weight loss. The number of bariatric operations performed annually worldwide has increased to $>340{,}000$ with a corresponding increase in the number of publications reporting bariatric surgery outcomes in the medical and surgical literature. A well-established and widely accepted reporting standard for weight loss is needed to communicate effectively between different clinical specialties and to provide consistency in the medical and surgical literature.

Current reporting practices. Although percent excess weight loss (%EWL) is currently the most often measured and reported weight loss outcome measure in the bariatric surgical literature, other commonly used metrics include total weight loss and percent total weight loss (%TWL), body mass index (BMI) reduction, and percent excess BMI loss (%EBMIL). There is currently no consensus regarding the ideal reporting method for medical or surgical weight loss. Here are some of the most commonly reported methods.

Total absolute weight loss (TWL in kg) and percent total weight loss (%TWL):

$$\%\text{TWL} = [(\text{Initial Weight}) - (\text{Postop Weight})]/[(\text{Initial Weight})] \times 100$$

Absolute weight loss provides a metric that is easy to measure and easy to comprehend by physicians as well as patients and is commonly reported in the medical literature as a percentage of total initial weight.

Percent excess weight loss (%EWL):

$$\%\text{EWL} = [(\text{Initial Weight}) - (\text{Postoperative Weight})] / [(\text{Initial Weight}) - (\text{Ideal Weight})] \times 100$$

Percent excess weight loss is a quotient that is calculated from initial weight, postoperative weight, and ideal weight and represents the amount of excess weight (EW) lost as % of total EW. This outcome measure allows for comparison of individuals with varying initial weights and varying excess weights, making it useful as a standard measure across populations, and some have argued it should be the standard metric for reporting in general. It is the most common method of reporting weight loss in the bariatric surgical literature. The disadvantage of using %EWL is that it may not reflect successful weight loss in very high BMI patients. In fact, patients with super-obesity often have lower %EWL than lower BMI groups despite achieving greater absolute weight loss. Therefore, %EWL has limitations when used as the sole measure of success after bariatric surgery.

Body mass index (BMI) and change in BMI (ΔBMI)

BMI, expressed as kg/m^2, is a common method for reporting weight as a function of height; $\text{BMI} = (\text{weight}) / (\text{height})^2$. It is used to define the classes of obesity, as well as candidacy for bariatric surgery. A BMI of 25 kg/m^2 is regarded as the upper limit of normal weight and the threshold of overweight. It has been used as a convenient proxy for "ideal weight" and is simply determined by height

and weight alone. It is easy to calculate BMI from available clinical data and it has been reported to correlate with total body fat content. Thus, BMI is generally a convenient measure of weight burden and can be readily used to compare individuals, populations, and specific treatment outcomes. Like %TWL, change in BMI is a useful comparison tool for treatment efficacy.

Percent excess BMI loss (%EBMIL):

$$\%EBMIL = [\text{change in BMI} / (\text{Initial BMI} - 25)] \times 100$$

Compared with %EWL, the %EBMIL is not yet used routinely in medical and surgical literature. Similar to % EWL, %EBMIL depends on initial weight measurements that can be variable and inconsistent, as described earlier. However, it is a measurement of weight loss that avoids the difficulties of determining ideal weight, as defined by Metropolitan Life tables. Rather, it sets ideal BMI at 25 kg/m^2, greatly simplifying the calculation.

Challenges/controversies. While there are several methods of reporting weight loss outcomes after bariatric surgery, there is no established standard for reporting of a single weight loss metric. Although the goal is to achieve outcome reporting that is reproducible, easy to use, and clinically meaningful, each of the commonly used metrics is associated with a shortcoming or limitation.

The data obtained from %TWL may be clinically misleading, especially in the setting of variable clinically ideal and initial weights. A heavier individual with greater excess weight needs to lose more weight than a less-heavy individual to attain a similar clinical impact and approach a normal weight range. For example, a 30-kg weight loss in an individual with super-obesity is likely to be inadequate and less clinically relevant compared with a similar amount of total weight loss in a severely obese individual. Thus, reporting of absolute or percent total weight loss (%TWL) may not provide sufficient clinically relevant information to reflect weight loss success or failure.

Percent excess weight loss (%EWL) relies on a measurement of initial weight and determination of ideal weight. However, the values of *initial weight* and *ideal weight,* on which the calculation of %EWL relies, are not uniform and can lead to wide variability in the meaning of reported outcomes. "Initial weight" can mean different things in different studies. It may reflect a measurement taken months before surgery or may reflect a measurement taken on the day of surgery. There is no established standard, and the method used to measure the initial weight is rarely specifically specified in literature reports.

"Ideal weight" has historically been determined based on the Metropolitan height and weight tables published in 1983. Determining ideal weight from these tables depends on gender, body frame (small, medium, large), and height. When these tables were established, "ideal" was linked to mortality data obtained from 4.2 million individuals over an 18-year period. These data, however, were > 40 years old at the time and were restricted to individuals 25–29 years old who had no significant co-morbid conditions, thus bringing into question the validity of these data for a contemporary population. Also, the ideal weights in each body-frame category are reported as a range rather than a single number, further adding variability to the value of ideal weight. The importance of the %EWL, despite its limitations, has been described previously in ASMBS guidelines.

Because of these shortcomings, some authors advocate the use of a BMI of 25 kg/m^2, instead of Metropolitan Life tables, for determining the clinically desirable weight. BMI measurements, however, also exclude variables such as gender, age, or race, which have been reported to have clinically significant effects on the measurement of obesity. Percent excess BMI loss (%EBMIL) is determined from easily available clinical data, is readily reproducible, and is consistent with other bariatric metrics that rely on body mass index, such as obesity classification and thresholds for surgery, making it clinically relevant.

Recommended reporting practices. Reporting of weight loss outcomes after bariatric surgery should include the following parameters (in which *initial weight* is the patient's weight as measured closest to the time of surgery and *initial BMI* is the BMI determined closest to the time of surgery in the preoperative period):

Complete reporting is recommended as follows:

1. Initial mean BMI of the cohort
2. Change in BMI (ΔBMI):
   $\Delta BMI = (\text{Initial BMI}) - (\text{Postop BMI})$
3. Percent of total weight loss (%TWL):
   $\%TWL = [(\text{Initial Weight}) - (\text{Postop Weight})] / [(\text{Initial Weight})] \times 100$
4. Percent excess BMI loss (%EBMIL):
   $\%EBMIL = [\Delta BMI/(\text{Initial BMI} - 25)] \times 100$
   and/or

   Percent excess weight loss (%EWL)
   $\%EWL = [(\text{Initial Weight}) - (\text{Postop Weight})] / [(\text{Initial Weight}) - (\text{Ideal Weight})]$
   (in which *ideal weight* is defined by the weight corresponding to a BMI of 25 kg/m^2; see Appendix A)

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9. Quality-of-life outcomes

Morbid obesity has significant detrimental effects on both physical and psychosocial health. The adverse impact of obesity on psychosocial health is reflected in a reduction in health-related quality of life (HR-QOL). Although bariatric surgery produces marked weight loss and improvement of co-morbidities, the impact on HR-QOL is less well established. One factor hampering this effort is the lack of guidelines for reporting psychosocial outcomes.

Current practices. A list of commonly used health-related quality-of-life instruments for bariatric surgery is found in Table 1. These instruments have been categorized as generic, system- and condition-specific, and obesity-specific instruments. Generic tools measure overall HR-QOL, system- and condition-specific tools measure the HR-QOL related to a specific body system or health condition, and obesity-specific tools measure the HR-QOL related to obesity. Based on a recent study, the most commonly used instruments in bariatric surgery publications are the Moorehead-Ardelt Quality of Life Questionnaire (MAQOL) in 21%, 36-item Short-Form Health Survey (SF-36) in 20%, Gastrointestinal Quality of Life Index (GIQOL) in 9%, European Quality of Life-5 D (EQ-5 D) in 5% and Impact of Weight on Quality of Life-Lite (IWQOL-Lite) in 4%. Two newer obesity-specific instruments (Laval questionnaire, Bariatric Quality of Life Index [BQL]) were not included in Table 1 because of their currently limited clinical use.

All of the tabulated tools were evaluated for validity—the ability to measure what it claims to measure—and reliability —the degree to which the instrument is free of measurement error. Reliability is assessed 2 ways: reproducibility and internal consistency. Reproducibility is typically reported using the test-retest reliability—the ability of the instrument to obtain the same result when testing is repeated without intervention. A test-retest reliability coefficient $\geq .7$ is considered satisfactory. Internal consistency reliability evaluates whether items that are intended to measure the same general concept produce similar scores. Internal consistency is typically reported as Cronbach's α, and the instrument is considered to have acceptable internal consistency if Cronbach's α is $\geq .7$. In general, the tabulated tools are valid, have acceptable test-retest reliable, and have acceptable internally consistency. All instruments were initially validated in specific culturally distinct populations, which may limit general applicability. However, many instruments are in the process of being validated or modified for expanded use.

Challenges. Unfortunately, no single instrument is ideal for all clinical situations. Each instrument attempts to balance scope of the survey, ease of administration, and statistical properties. By necessity every instrument represents a compromise between these factors.

The scope of the survey is determined by the type of instrument. Generic instruments are designed to measure how multiple factors influence the HR-QOL but tend to be less sensitive to the impact of any specific factor, such as obesity. One advantage of this approach is that it provides a framework for comparing HR-QOL of differing etiologies. Obesity-specific instruments are designed to measure the impact of obesity on the quality of life while minimizing the influence of other factors. Consequently, these instruments are able to discern changes in HR-QOL caused by small changes in obesity-related factors. The main disadvantage of using obesity-specific instruments is the loss of context; specifically, the relationship of obesity-related quality of life to the overall HR-QOL is uncertain. This limits the ability to determine the impact of obesity on HR-QOL relative to the impact of other disorders.

Ease of administration reflects the ability to obtain useful psychosocial data and is influenced by method of administration (e.g., self-administered, structured interview, etc.), scoring (e.g., hand scoring versus computer scoring, proprietary versus nonproprietary, etc.), and length of the instrument. In general, instruments with more items (e.g., SF-36, QOLI) are useful for examining treatment responses in individual patients but are less likely to be completed by patients, whereas instruments with fewer items (e.g., SF-12) are completed at higher rates but tend to be most useful for examining populations.

The cost of administering these instruments is beyond the scope of this review but is most strongly influenced by the method of administration and type of scoring. The use of structured interviews or proprietary instruments can be expensive. Fortunately, some of the proprietary tools are available for limited use for low or no cost.

Recommended reporting. Currently, psychological testing in bariatric surgery has been used primarily as a descriptive measure or to determine treatment effects in well-defined populations. Consequently, in the context of evaluating program outcomes, no specific recommendations are supported by the current literature. In the context of reporting treatment effects, the need for a generic instrument, a system-

Table 1
Health-related quality of life instruments

Test	Description	Origin	Reliability / internal consistency	Strengths	Limitations
Generic Instruments					
Short Form Health Survey 36 (SF-36)	• Self-administered • 36 items in 8 domains: Physical Functioning, Bodily Pain, Role Limitations Due to Physical Health Problems, Role, Limitations Due To Personal or Emotional Problem, Emotional Well-Being, Social Functioning, Energy/Fatigue, General Health Perceptions, Perceived Change in Health	USA	• Test-retest • reliability, $r = .74$-$.91$ • Internally consistency, Cronbach's α 0.85	Useful for measuring: 1. Individual patient improvemen t or decline 2. Treatment effects 3. Populations	Lengthy administration
Short Form Health Survey 12 (SF-12) Short Form Health Survey 8 (SF-8)	• Self-administered • Same 8 health domains			• Administration brief (2–3 minutes) • Useful for measuring populations only	
European Quality of Life-5D (EQ5D)	• Self-administered • 5 items in 5 dimensions: Mobility, Self-Care, Usual Activities, Pain / Discomfort, Anxiety/Depression	Finland, the Netherlands, Norway, Sweden, the United Kingdom	• Test-retest reliability, $r = .73$-$.78$ • Internally consistency, Cronbach's α .73	Translated into >60 languages	
System-/condition-specific Instruments					
Gastrointestinal Quality of Life Index (GIQLI)	• Self-administered • 36 items in 3 domains: Physicial, Emotional, Social, Symptoms • Recall: last 2 wks	Germany	• Internal consistency, Cronbach's α .91		
Obesity-specific instruments					
The Obesity-related Psychosocial Problems scale (OP-scale)	• Self-administered • 8 items assessing the impact of obesity on psychosocial function • 4 point scale	Sweden	• Test-retest reliability: not done • Internal consistency, Cronbach's $\alpha = .89$–$.92$	Brief administration	
Impact of Weight on Quality of Life (IWQOL)	• Self–administered • 74 items in 8 domains: Health, Social / Interpersonal, Work, Mobility, Self-esteem, Sexual life, Activities of daily living, Comfort with food • 5 point Likert scale	USA	• Test–retest reliability • Items: $r = .75$ • Domains: $r = .89$ • Internal consistency Cronbach's $\alpha = .87$		
Impact of Weight on Quality of Life-Lite (IWQOLLite)	• Self-administered • 31 items in 5 domains: Physical Function, Self-esteem, Sexual life, Public distress, Work. • 5-point Likert scale	USA	• Test-retest reliable $r = 0.94$ • Internal consistency, Cronbach's $\alpha = 0.96$	Widely available (culturally adapted and translated)	
Bariatric Analysis and Reporting Outcomes System (BAROS)	• Self-administered • 7 items in 3 domains: Weight loss, Medical Conditions, Quality of Life (Self-esteem, Physical Well-being, Social Relationships, Work, Sexuality)	USA	• Test-retest reliability "satisfactory" • Internal consistency: not done	Brief administration	
Moorehead-Ardelt Quality of Life Questionnaire II (M-AQoLQII)	• Self-administered • 6 items in 6 domains: Selfesteem, Physical Well-being, Social Relationships, Work, Sexuality, Eating Behavior • 10-point Likert scale	USA (Austria)	• Test retest reliability "satisfactory" • Internal consistency cronbach's $\alpha = .84$	Brief administration	

Table 1
Continued.

Test	Description	Origin	Reliability / internal consistency	Strengths	Limitations
Obesity and Weight Loss Quality of Life (OWL-QOL)	• Designed to be used with WRSM • Self-administered • 17 items "evaluates obesity and trying to lose weight in terms of feelings that unobservable. • 7-point Likert scale • Recall period: at this time, presently	USA & Europe	• Test-retest reliability, $r = .95$ • Internally consistency, Cronbach's $\alpha = .93$	• Multicultural • Brief administration	
Weight-Related Symptom Measure (WRSM)	• Designed to be used with OWL-QOL • Self-administered • 20 items assessing "presence and bothersomeness of symptoms" • Yes/no (Presence) and 7 point Likert scale (bothersomeness) • Recall period: last 4 weeks	USA & Europe	• Test-retest reliability, $r = 0.83$ • Internally consistency, Cronbach's α .87	Multicultural	
Lewin-Technology Assessment Group (Lewin-TAG)	• Self-administered • 55 items with global domains (General health, Comparative health) and obesity-specific domains (Overweight distress, Depression, Self-esteem)	USA	• Test-retest reliability, $r = 0.70$ (0.59-0.90) • Internal Consistency, Cronbach's α .85–.94		
Obesity-Related Well-Being Scale (ORWELL97)	• Self-administered • 18 items in 3 domains: Symptoms, Discomfort, Impact. • 4-point Likert scale	Italy	• Test-retest reliability, $r = .92$ • Internally consistency, Cronbach's α .83	Scores age independent	
Obesity Coping (OC) &	• Self-administered • 16 items in 3 OC scales: social trust, fighting spirit, wishful thinking	Sweden	• Test-retest Reliablity $r = 0.71$-0.77 • Internal consistency, Cronbach's α .69–.77	• Derived from a subset of SOS participants • Scales were developed using factor analysis. • Validated in an independent group.	
Obesity Distress (OD)	• 13 items in 2 OD Scales: Helplessness, Intrusion		• Test-retest Reliablity, $r = .84$–.89 • Internal consistency, Cronbach's α .51–.78		
Obesity Adjustment Survey-Short Form (OAS-SF)	• Self-administered • 20 items in 1 domain: psychological distress over obesity • 5 point Likert scale	Canada	• Test-retest reliablity, $r = .87$ • Internally consistency, Cronbach's $\alpha = .72$		Items chosen by individual statistical properties; not from factor analysis
Obesity Specific Quality of Life (OSQOL)	• Self-administered • 11 items in 4 domains: Physical State; Vitality/Desire to Do Thing; Relations with Other People; Mood/ Psychological State • 5-point Likert scale	France	• Test–retest reliability: Not done • Internal consistency, Cronbach's $\alpha = 0.77$	Brief administration	

and condition-specific instrument, an obesity-specific instrument, or combination of tools should be made based on the specific research aims. However, we recommend the use of a validated instrument is for all published reports.[1–20]

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Appendix A

"Ideal weight": weight that corresponds to a body mass index of 25 kg/m^2

Height (inches)	Weight (lbs)
58	119
59	124
60	128
61	132
62	136
63	141
64	145
65	150
66	155
67	159
68	164
69	169
70	174
71	179
72	184
73	189
74	194
75	200
76	205

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