Appropriateness Criteria for Bariatric Surgery: Beyond the NIH Guidelines

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Careful selection of bariatric patients is critical for successful outcomes. In 1991, the NIH first established patient selection guidelines; however, some surgeons operate on individuals outside of these criteria, i.e., extreme age groups. We developed appropriateness criteria for the spectrum of patient characteristics including age, BMI, and severity of eight obesity-related comorbidities. Candidate criteria were developed using combinations of patient characteristics including BMI: ≥40 kg/m^2, 35–39, 32–34, 30–31, <30; age: 12–18, 19–55, 56–64, 65+ years old; and comorbidities: prediabetes, diabetes, hypertension, dyslipidemia, sleep apnea, venous stasis disease, chronic joint pain, and gastroesophageal reflux (plus severity level). Criteria were formally validated on their appropriateness of whether the benefits of surgery clearly outweighed the risks, by an expert panel using the RAND/UCLA modified Delphi method. Nearly all comorbidity severity criteria for patients with BMI ≥40 kg/m^2 or BMI = 35–39 kg/m^2 in intermediate age groups were found to be appropriate for surgery. In contrast, patients in the extreme age categories were considered appropriate surgical candidates under fewer conditions, primarily the more severe comorbidities, such as diabetes and hypertension. For patients with a BMI of 32–34, only the most severe category of diabetes (Hgb A1c >9, on maximal medical therapy), is an appropriate criterion for those aged 19–64, whereas many mild to moderate severity comorbidity categories are "inappropriate." There is overwhelming agreement among the panelists that the current evidence does not support performing bariatric surgery in lower BMI individuals (BMI <32). This is the first development of appropriateness criteria for bariatric surgery that includes severity categories of comorbidities. Only for the most severe degrees of comorbidities were adolescent and elderly patients deemed appropriate for surgery. Patient selection for bariatric procedures should include consideration of both patient age and comorbidity severity.

INTRODUCTION

Obesity has recently reached epidemic proportions in the United States. Fifteen million people, or 1 out of every 20, in this country have a BMI >35 kg/m^2 (normal <25) (1–3). Obesity is not only a medical problem, but also a social, psychological, and economic problem. Severely obese individuals are typically refractory to diet and drug therapy, but bariatric surgery offers them an option for significant and sustainable weight loss (4–13). For example, weight loss following Roux-en-Y gastric bypass is >40 kg and is sustainable out to at least 8 years (14). Additionally, findings support that many preexisting comorbidities improve or resolve following the procedure, particularly diabetes (type 2) and hypertension (15).

The NIH in 1991 first established guidelines for patient selection based on the literature at that time. The criteria included BMI ≥40 or BMI = 35–39 with one or more obesity-related comorbidities. In addition, patients should have attempted, and failed, several structured methods of weight loss. As these criteria were established >17 years ago and both experience with these procedures and the literature have considerably increased, there is a need to develop updated guidelines for patients who are appropriate surgical candidates.

Patient selection criteria for bariatric surgery currently include BMI, presence of comorbidities, and past history of attempted weight loss. The NIH guidelines consider neither age nor comorbidity severity. With surgeons now operating on patients at the extremes of age and BMI, there is a need to expand our indications for surgery. Furthermore, particularly for the lower BMI range, considering the severity of the coexisting comorbidities is warranted. For example, consider two patients with the diagnosis of diabetes in their charts: one would make a case that the patient with uncontrolled diabetes despite treatment would be more likely to be a candidate for bariatric procedures, as compared to the patient with

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diet-controlled diabetes. Additionally, the same arguments can be made for age and BMI ranges; just as the patient selection criteria for a 65-year old should not be the same as those for a 15-year old, the selection criteria for a patient with a BMI of 30 should not be equivalent to those of a patient with a BMI of 40. Given these patient differences, our project aimed at developing appropriateness criteria, stratified by comorbidity severity, age, and BMI.

Despite the increased availability of new studies, there is a lack of high level evidence in the bariatric surgery literature, which is not uncommon for surgical disorders or treatments. In this situation, methodology such as the RAND appropriateness method that combines the available evidence with expert opinion is a valid technique. This methodology has been used successfully for various surgical procedures, including carotid endarterectomy and coronary revascularization. In fact, studies have shown that adherence to the appropriateness criteria is associated with better outcomes (16).

The aim of this study is to develop appropriateness criteria for bariatric surgery. Specifically, the goals are threefold: to establish severity categories for comorbidities, to stratify appropriateness criteria by BMI, age, and comorbidity severity, and to test the extremes of age by investigating the appropriateness of bariatric surgery in the pediatric and elderly populations. By developing and validating appropriateness criteria for bariatric surgery through literature review and expert panel, we hope to improve the quality of care by guiding clinicians to select patients for whom the procedure is likely to have benefits exceeding the risks, as well as to identify those patients for whom the risks may exceed the benefits.

METHODS AND PROCEDURES
Semistructured interviews
Semistructured interviews were completed with 12 leaders in the field of bariatric surgery. Experts were identified through bariatric surgery societies and published literature. Interviews were performed both locally and at several national meetings.

Criterion development and literature reviews
Based on the semistructured interviews, a list of candidate criteria was compiled. Appropriateness criteria were designed to establish the guidelines that should be used to identify appropriate candidates for surgery. These criteria were rated on whether or not the benefits of bariatric surgery clearly outweighed the risks of the specific patient characteristics. The characteristics selected included BMI, age, and obesity-related comorbidities.

Using various combinations for each category, candidate appropriateness criteria were developed. Five groups based on BMI were created: BMI ≥40, 35–39, 32–34, 30–31, and <30. We selected these five BMI categories following semistructured interviews with experts in bariatric surgery. The main issue we hoped to address was the appropriateness of surgery for the lower BMI categories (as some surgeons support lowering the limits for these patients). As a significant number of the superobese patients undergo staged procedures, we felt that it would not be possible to incorporate the superobese BMI categories into the matrix of clinical characteristics.

Within each BMI group, four age ranges were applied: 12–18, 19–55, 56–64, and 65+ years old. Additionally, the presence of obesity-related comorbidities was assessed. Severity categories of the comorbidities

were included in the criteria. Eight comorbidities were considered: (i) prediabetes, (ii) diabetes (hemoglobin (Hgb) A1c <7, Hgb A1c = 7–9, and Hgb A1c >9), (iii) hypertension (systolic blood pressure (SBP) >140/diastolic blood pressure (DBP) >90 and SBP <140/DBP <90), (iv) dyslipidemia (levels either elevated or normal), (v) sleep apnea (mild, moderate, severe), (vi) venous stasis disease, (vii) degenerative joint disease (whether or not symptoms severely affected work or leisure), and (viii) quality of life. Seven of the comorbidities were selected based on the semistructured interviews. They felt that these were the most frequent clinically relevant factors. Reflux disease was added by the experts during the panel meeting. Factors such as that coronary artery disease, smoking, and congestive heart failure are important in determining the operative risk and outcomes following surgery, but they were felt to be relatively infrequent in this population of patients.

Comorbidity categories, with the exception of those for prediabetes, sleep apnea, venous stasis disease, reflux, and impaired quality of life, were evaluated separately for patients on maximal medical therapy and those who were not. Maximal medical therapy was considered to be two or more medications. Degenerative joint disease was renamed chronic joint pain by the expert panel. Detailed definitions of comorbidities, severity categories, and therapy are provided in **Table 1**.

Next, a systematic review of the relevant literature was performed. The levels of evidence for each indicator were assigned: (i) randomized controlled trial, (ii) nonrandomized controlled trials, cohort or case analysis, or multiple time series, and (iii) textbooks, opinions, or descriptive studies. The literature with the highest level of evidence was selected for each candidate criterion, and a detailed summary of the evidence was compiled. For each BMI and age combination there were 24 comorbidity categories to consider; as such, for the five BMI groups and four age categories we had a total of 480 combinations of criteria that were rated. An example of one of these criteria is a 40-year old patient with a BMI of 37 with mild sleep apnea. The list of candidate criteria and summary of the literature review were provided to each participant of the expert panel meeting.

Expert panel
An expert panel (consisting of 11 bariatric surgeons, two internists, and one endocrinologist) was used to evaluate and rate the candidate criteria. We used the validated RAND/UCLA appropriateness method, which is a modified Delphi method developed at RAND and UCLA (17). The RAND/UCLA appropriateness method has been shown to have reproducibility consistent with that of well-accepted diagnostic tests such as the interpretation of coronary angiography and screening mammography and has been shown to have content, construct, and predictive validity (17–20). This method quantitatively assesses the expert judgment of a group of physicians regarding the criteria by using a scale from 1 to 9. A detailed description of this scoring method is available in a study documenting the development of quality indicators in bariatric surgery by Maggard *et al.* (21). In brief, panelists were asked to rate whether or not it is appropriate, or that the risks outweighed the benefits to perform a procedure for a given candidate criterion. A score of ≥7 was considered appropriate and ≤3 inappropriate. The degree of agreement in ratings among panelists was also measured by evaluating the spread of the ratings.

First round ratings
The first round of candidate criteria was rated by the individual panelists, prior to the expert panel meeting. Panelists were encouraged to comment on the literature reviews, definitions of key terms, and the criteria. They also could make additions or deletions to the criteria. For the 480 criteria rated, 27.1% had a median score ≥7, which is considered "appropriate," that is, the benefits of bariatric surgery clearly outweigh the risks; 23.7% had a median score of 4–6, which means that under those conditions the benefits did not clearly outweigh the risks ("inappropriate" indication), and 49.2% had a median score of

Table 1 Definitions of obesity-related comorbidities, corresponding severity categories, and therapy

	Definition	Severity categories	Therapy
Prediabetes	Fasting plasma glucose test >100 but ≤125 mg/dl or oral glucose tolerance test ≥140 but <200 mg/dl	Not defined	Regardless of therapy
Diabetes	Individuals taking insulin and/or oral hypoglycemic medications or have a fasting glucose >126 mg/dl	1. Hgb A1c >9, on maximal medical therapy 2. Hgb A1c >9, not on maximal medical therapy 3. Hgb A1c 7–9, on maximal medical therapy 4. Hgb A1c 7–9, not on maximal medical therapy 5. Hgb A1c <7, regardless of therapy	Maximal medical therapy = taking insulin or maximally tolerated dose of at least two different classes of oral hypoglycemic medications
Hypertension	SBP >140 or DBP >90 or the use of an antihypertensive medication	1. SBP >140 or DBP >90, on maximal medical therapy 2. SBP >140 or DBP >90, not on maximal medical therapy 3. SBP <140 or DBP <90, on maximal medical therapy 4. SBP <140 or DBP <90, not on maximal medical therapy	Maximal medical therapy = maximally tolerated dose of at least three different classes of antihypertensive medications
Dyslipidemia	Triglycerides >250 mg/dl or cholesterol >220 mg/dl or HDL <35 mg/dl or LDL >200 or use of lipid lowering medication	1. Dyslipidemic on maximal medical therapy 2. Dyslipidemic not on maximal medical therapy 3. Nondyslipidemic on maximal medical therapy 4. Nondyslipidemic, not on maximal medical therapy	Maximal medical therapy = maximally tolerated dose of at least two different classes of lipid lowering medications
Sleep apnea	A formal sleep study test consistent with this diagnosis: • Epworth Sleepiness Scale ≥6; • Polysomnography with Respiratory Disturbance Index ≥10 hyponeic and/or apneic episodes per hour of sleep	1. Severe (e.g., apnea–hypoapnea index >30 per hour) 2. Moderate (e.g., apnea–hypoapnea index 16–30 per hour) 3. Mild (e.g., apnea–hypoapnea index 5–15 per hour)	Regardless of therapy
Venous stasis disease	Presence or history of pretibial venous stasis ulcers	Not defined	Regardless of therapy
Chronic joint disease	Deterioration of the joint cartilage and the formation of new bone (bone spurs) at the margins of the joints	1. Symptoms severely affect work or leisure activities, on maximal medical therapy 2. Symptoms severely affect work or leisure activities, not on maximal medical therapy 3. Symptoms do not severely affect work or leisure activities, on maximal medical therapy 4. Symptoms do not severely affect work or leisure activities, not on maximal medical therapy	Maximal medical therapy = maximally tolerated dose of an NSAID or COX-II inhibitor or Acetaminophen, and the completion at least one physical therapist- supervised exercise program
Quality of life	Impaired quality of life is defined as poor quality of life as measured by a formal and previously validated quality of life (QOL) questionnaire. Examples include: SF-36, IW QOL-lite, and Moorehead-Ardelt QOL Questionnaire	Abnormal relative to age, gender, and weight normative controls (varies depending on validated instrument of measure)	Regardless of therapy
Reflux, gastro-esophageal	Heartburn, regurgitation, or pain with swallowing, and chest pain. Symptoms relieved by antiacid medications	Not defined	Regardless of therapy

DBP, diastolic blood pressure; HDL, high-density lipoprotein; Hgb, hemoglobin; LDL, low-density lipoprotein; SBP, systolic blood pressure.

1–3, meaning the risks outweighed the benefits. Of the criteria that fell into the 1–3 range score, 78.8% had a high level of agreement between panelists, and predominately represented the criteria for the low BMI values (BMI <30, BMI = 30–31).

Expert panel meeting and second round ratings
At the panel meeting, 14 participants discussed each of the clinical areas, focusing on the evidence, or lack thereof, supporting or refuting each criterion. They were encouraged to discuss any relevant published information that the literature reviews had potentially omitted. Panelists

were provided a summary of the panel's first round ratings and a confidential reminder of their own ratings.

Panelists added reflux esophagitis as an obesity-related comorbidity. They did not feel that a definition of severity was needed for reflux esophagitis, as it was their impression that medical treatments were ineffective in obese individuals. They also agreed to rename the term degenerative joint disease as chronic joint pain because they felt the former was too restrictive.

Following the expert panel discussion, all criteria were rerated (second round) by each panelist for appropriateness, and statistical

Table 2 Appropriateness criteria for patients with BMI ≥40: benefits outweigh risks

Comorbidity	Severity	12–18 years		65+ years	
		On max medical therapy	Not on max medical therapy	On max medical therapy	Not on max medical therapy
Diabetes	Hgb A1c >9	✓	✓	✓	✓
	Hgb A1c 7–9	✓	—	✓	—
	Hgb A1c <7*	—[a]		—[a]	
Hypertension	SBP >140, DBP >90	✓	—	✓	✓
	SBP <140, DBP <90	—	—	✓	✓
Dyslipidemia	Levels elevated	✓	✓	✓	✓
	Levels normal	—	—	—	—
Chronic joint pain	Severely affects work/leisure	✓	✓	✓	—
	Does not severely affect work/leisure	—	—	—	—
		Regardless of therapy		Regardless of therapy	
Prediabetes	Fasting blood glucose 101–125 mg/dl	✓		—	
Sleep apnea	Severe	✓		✓	
	Moderate	✓		✓	
	Mild	✓		—	
Venous	Venous stasis disease	✓		✓	
QOL	Impaired quality of life	✓		—	
Reflux esophagitis	Any symptoms	—		✓	
>2 Comorbidities	Two or more of above comorbidities	✓		✓	
No Comorbidities	None of the above	X		X	

Of note, patients with BMI 32–34, the only condition found to be appropriate for surgery was diabetes with Hgb A1c >9 on maximal medical therapy and for patients with BMI ≥40 (19–64 years old), all conditions were found to be appropriate for surgery.

✓Indicates appropriate, benefits outweigh risks; rating ≥7. X indicates inappropriate; risks outweigh benefits; rating ≤3.

[a]For Hgb A1c <7* the panelists rated for "regardless of medical therapy."

analysis was performed. One panelist did not complete the appropriateness indicator discussion or second round ratings. The two lowest BMI categories (BMI <30, BMI 30–31) were not rerated, as none of these criteria passed the first round. After the panelists' changes were made, there were 104 criteria to rate in each of three BMI categories (BMI ≥40, 35–39, 32–34). Of these 312 items, 46.5% received a median score of ≥7, 32.0% had a median score of 4–6, and 21.5% had a median score of 1–3. Of the 145 criteria with favorable ratings (≥7), 64.8% were scored with sufficient agreement between panelists, 35.2% were indeterminate, and none had disagreement.

RESULTS
The results are provided in the following sections as a summary for the final appropriateness indicators for each age group.

BMI ≥40 kg/m²
Intermediate age groups. For patients with BMI ≥40, 19–55, and 56–64 years old, it is appropriate to undergo surgery for all the comorbidity severity categories. Additionally, surgery is appropriate for individuals without any obesity-related comorbidities (ratings ≥7 with adequate agreement). These results, not surprisingly, are consistent with the NIH consensus guidelines.

Adolescents. For adolescents (12–18 years old) with BMI ≥40, surgery is appropriate only for the severe to moderate degrees of comorbidities (Table 2). These criteria include: prediabetes

and diabetes with Hgb A1c >9, regardless of therapy, or 7–9 on maximal medical therapy. Only the most severe degree of hypertension is an appropriate criterion for this group. Elevated lipids and sleep apnea, regardless of level of treatment, are also deemed appropriate criteria for surgery in adolescents. Chronic joint pain, in its most severe state, venous stasis disease, and impaired quality of life are also considered appropriate for this young age group.

Elderly. When compared to those of the adolescents, the appropriateness criteria for surgery in the elderly (65+ years old) include the more severe comorbidity categories (Table 2). Only the most severe degrees of diabetes are appropriate criteria in the elderly with BMI ≥40, including, Hgb A1c >9, regardless of therapy, or 7–9 on maximal medical therapy. The presence of hypertension, regardless of treatment, is considered an appropriate criterion, as are elevated lipids, regardless of treatment. Severe to moderate sleep apnea and venous stasis disease are also appropriate criteria for surgery. However, only the most severe degree of chronic joint pain, not on maximal medical therapy, is considered appropriate for these patients. Impaired quality of life is not considered to be an appropriate criterion in this age and BMI grouping.

In general, most criteria in the BMI category ≥40 passed as appropriate selection criteria for bariatric surgery. However,

Table 3 Appropriateness criteria for patients with BMI = 35–39: benefits outweigh risks

Comorbidity	Severity	12–18 years		65+ years	
		On max medical therapy	Not on max medical therapy	On max medical therapy	Not on max medical therapy
Diabetes	Hgb A1c >9	✓	✓	✓	✓
	Hgb A1c 7–9	✓	✓	✓	—
	Hgb A1c <7*	—ᵃ		—ᵃ	
Hypertension	SBP >140, DBP >90	✓	—	✓	—
	SBP <140, DBP <90	—	—	—	—
Dyslipidemia	Levels elevated	—	—	—	—
	Levels normal	—	—	—	—
Chronic joint pain	Severely affects work/leisure	—	—	—	—
	Does not severely affect work/leisure	—	—	—	—
		Regardless of therapy		**Regardless of therapy**	
Prediabetes	Fasting blood glucose 101–125 mg/dl	—		—	
Sleep apnea	Severe	✓		✓	
	Moderate	✓		✓	
	Mild	—		—	
Venous	Venous stasis disease	—		—	
QOL	Impaired quality of life	—		—	
Reflux esophagitis	Any symptoms	—		—	
>2 Comorbidities	Two or more of above comorbidities	✓		—	
No Comorbidities	None of the above	—		—	

Of note, patients with BMI 32–34 kg/m², the only condition found to be appropriate for surgery was diabetes with Hgb A1c >9 on maximal medical therapy and for patients with BMI ≥40 kg/m² (19–64 years old), all conditions were found to be appropriate for surgery.

✓Indicates appropriate, benefits outweigh risks; rating ≥7.

ᵃFor HgbA1c <7* the panelists rated for "regardless of medical therapy."

only for the severe to moderate comorbidity categories did the panel determine that the risks of surgery outweigh the benefits for adolescent and elderly individuals.

BMI = 35–39 kg/m²

Intermediate age groups. For patients aged 19–64 with BMI 34–39, nearly all the comorbidity criteria were determined to be appropriate to undergo surgery. However, in individuals without any obesity-related comorbidities the panel determined that the benefits of surgery do not clearly outweigh the risks. The ratings are not such that surgery is considered inappropriate in this group; rather, it is unknown whether or not the benefits outweigh the risks (median ratings 4–6). In addition, the mildest form of chronic joint pain, i.e., "symptoms do not severely affect work or leisure, not on maximal medical therapy," does not pass as a criterion to perform bariatric surgery.

Adolescents. For adolescents with BMI = 35–39, surgery is considered to be appropriate for only the most severe comorbidity categories (**Table 3**). Prediabetes, dyslipidemia, venous stasis disease, chronic joint pain, impaired quality of life, and reflux esophagitis are not appropriate criteria for bariatric surgery. Diabetes (except for those with Hgb A1c <7), severe hypertension, (despite maximal medical therapy), and moderate to severe sleep apnea are criteria for this age group. Additionally, the presence of two or more comorbidities is an appropriate criterion for surgery. Only the lack of comorbidities is an inappropriate criterion for surgery (risks of surgery outweigh the benefits, rating ≤3).

Elderly. For elderly patients with BMI = 35–39, as in the adolescent group, prediabetes, dyslipidemia, venous stasis disease, chronic joint pain, impaired quality of life, and reflux esophagitis are not sufficient criteria to identify patients for surgery (**Table 3**). Diabetes (except Hgb A1c 7–9, not on maximal therapy), severe hypertension, (hypertension despite maximal medical therapy), and moderate to severe sleep apnea are all appropriate criteria in the elderly. Unlike the adolescent group, the presence of two or more comorbidities is not a criterion for surgery. However, similar to the adolescent group, only a lack of comorbidities is deemed an inappropriate criterion for surgery.

In summary, most of the comorbidity criteria in the BMI category 35–39 pass as appropriate selection criteria to consider bariatric surgery in the intermediate age groups. For adolescent and elderly patients, only the presence of severe comorbidities is deemed appropriate, with the adolescent criteria being somewhat more liberal.

BMI = 32–34 kg/m²

For individuals with BMI 32–34 in any age group, very few criteria are appropriate for patients undergoing surgery. Only the most severe category of diabetes (Hgb A1c >9, on maximal medical therapy), is an appropriate criterion for those aged 19–55 and 56–64 years old. In fact, many mild to moderate severity comorbidity categories are inappropriate as criteria for surgery, particularly in the extreme age groups. Examples include most categories of diabetes, hypertension, dyslipidemia, sleep apnea, venous stasis disease, chronic joint pain, impaired quality of life, and the presence of no comorbidities. For the adolescent and elderly patients, the presence of two or more obesity-related comorbidities is not an appropriate selection criterion for bariatric surgery.

BMI = 30–31 or BMI <30 kg/m²

There is overwhelming agreement among the panelists that the current evidence does not support performing bariatric surgery in lower BMI individuals (BMI <32). In fact, for patients of any age with BMI <30, regardless of severity of the obesity-related comorbidity, the use of surgery is considered inappropriate, (median rating ≤3 with "agreement" for all scores). The only exception in this BMI category are patients in the 19–55 years-old group who have severe diabetes, dyslipidemia, or sleep apnea; for these individuals there is disagreement (median score of 4–5), which states that the panel could not determine whether surgery was appropriate or inappropriate. For all other comorbidities, it is inappropriate to consider these patients for surgery, for which there was virtual agreement among panelists.

DISCUSSION

We have developed a set of appropriateness criteria for bariatric surgery procedures for patients ranging in age from adolescent to elderly, with BMI's of <30 to >40, taking into account multiple comorbidity severity categories and treatment intensity. Our focus was to assess the lower BMI categories as well as the extreme age groups. These criteria will allow clinicians to help identify both appropriate surgical candidates as well as those patients for whom the risks of surgery outweigh the benefits.

In summary, for patients in the 19–64 age group, who fall in the lower BMI category of 32–34, surgery is considered appropriate only for the most severe of obesity-related comorbidities (poorly controlled diabetes despite maximal medical therapy). For patients in the 35–39 BMI range in this age group, the presence of most of the obesity-related comorbidities is considered appropriate for surgery. Lastly, as stated by the NIH guidelines, BMI ≥40, without comorbidities, is an appropriate criterion for surgery in and of itself.

Our data defined appropriateness criteria for the more common surgical candidates in the intermediate age range of 19–64 years old, and addressed the adolescent and elderly age ranges to determine when the benefits of bariatric surgery outweigh the risks. Currently, there are surgeons pushing the limits established by the 1991 NIH guidelines by operating on lower BMI patients as well as adolescents or elderly individuals. Our findings suggest that lower BMI (<32) individuals should not be considered appropriate candidates for these procedures based on current evidence, regardless of age or comorbidities. As such, operations on these individuals should only be conducted within a clinical trial, such as for those with diabetes. In general, adolescent and elderly patients in the higher BMI categories with moderate to severe obesity-related comorbidities were considered appropriate surgical candidates. For comorbidities that are severe in condition or that lack effective treatment beyond those achieved through weight loss, the selection criteria are somewhat loosened and may be performed for preventative purposes. For example, severe to moderate sleep apnea is an appropriate criterion for the adolescent and elderly in the BMI 35–39 category, whereas dyslipidemia is not.

In general, we did find some differences in the appropriateness of surgery between the adolescent and elderly age groups, and the reasons behind them are complex. First, the adolescents have lower operative risk than the elderly, and therefore, the benefit to risk comparison for some comorbidities, like chronic joint pain, was rated as less for the older group. Second, comorbidities that have limited treatment options, like mild sleep apnea, were more appropriate indications for surgery in the younger age group. Third, the long-term benefits may not be as great for the elderly as compared to the adolescents who have longer life expectancy, which explains the differences seen for diabetes as an indicator of appropriateness between the two age groups. There needs to be clear evidence that the associated condition will be likely to improve for the elderly. For example, the presence of impaired quality of life alone (for both BMI ≥40 or 35–39 groups) was not a sufficient indication for surgery. Impaired quality of life may be associated with other issues like untreated depression, social support, and other nonobesity related health issues. Additionally, there were some scenarios for which preventative benefits of the surgery on future comorbidities was rated to be more beneficial in the younger patients, like prediabetes. Likewise, as the degree of weight loss achieved tends to be less for the elderly, the potential benefits will in turn be lower for certain comorbidities.

Our study is unique in that we have defined comorbidity severity categories, taking into account the level of treatment and included them in the appropriateness to undergo bariatric surgery. Without these categories, we are amiss at comparing data where the degree of severity of the comorbidity is unknown. For example, patients with diet controlled diabetes tend to get grouped with those with markedly elevated Hgb A1c, despite the degree of medical therapy. Given the differences in implications of performing surgery, these two different diabetes patients, creating definitions for comorbidity severity categories is one of the first steps in ensuring appropriate patient selection.

Although much focus has been placed on diet, exercise, and medications for the treatment of diabetes, a cure, in fact, may lie in a surgical procedure (6). Following bariatric procedures, resolution of diabetes has been seen independent of weight loss. The American Society of Bariatric Surgery has even renamed itself the American Society for Metabolic and Bariatric Surgery, recognizing bariatric surgery as a treatment for diabetes, however, at this time, diabetes as an indication for bariatric surgery in the nonobese population is only performed under the supervision of clinical trials.

There are several limitations with our study. The main limitation is the lack of adequate level I evidence found in the literature review. As such, for areas where the literature is limited, the makeup of the criterion relies heavily on the opinions of the expert panel. Additionally, there may be concern that the criteria may not be valid for the surgeon outside of the academic setting. This could potentially limit the degree to which the final criteria are accepted into practice. In order to maximize acceptance in the community, we selected a panel composed of leaders in bariatric surgery in academics as well as in the community (five community based surgeons). Many of the members are actively involved with training future bariatric surgeons. Furthermore, we plan to test our criteria in several clinical settings.

Another potential concern is whether our results would vary if the candidate criteria were posed to a different expert panel. Previous work has suggested that if the makeup of the panel is consistent with regard to the area of clinical expertise, then the results tend to be quite similar. One criticism regarding the makeup of our panel was that it was overrepresented with surgeons. However, in light of the fact that the overwhelming number of bariatric programs are established and maintained by surgeons, it is reasonable that they were overrepresented on the panel. In addition, this fact will help us to gain acceptance into the community at large to use the criteria. Of note, the three nonsurgeons on the panel did not rate the criteria in a pattern uniquely different than the surgeons. Finally, these appropriateness criteria form a foundation on which to base patient selection. However, given the constantly evolving nature of surgical care, we recommend that these criteria are updated as new data become available.

We have explicitly defined severity categories for the obesity-related comorbidities. Although these categories can be utilized on a prospectively followed patient population, it may be difficult to utilize these criteria in a retrospective chart review. In a recent meta-analysis on the surgical treatment of obesity that reviewed a total of 114 cases, only 21 reported information on diabetes, 19 commented on hypertension, 11 documented data on lipids, and 14 noted the presence of sleep apnea (14). Additionally, often, if comorbidities are mentioned in a patient chart, information like an Hgb A1c is difficult to find. In order to determine a patient's appropriateness for surgery, it is important to document not only the patient's comorbidities, but also the severity.

We have developed a list of formally developed appropriateness criteria to use for bariatric surgery. These indicators were based on explicitly defined, evidence-based literature, and validated by an expert panel consisting of both surgeon and nonsurgeon experts in the fields of obesity and bariatrics. These criteria focus on the assessing of the lower BMI categories and the extreme age groups. Important structural and process measures of care have been defined for establishing the floor of providing good quality of care. In the future, it would be instructive to see how current care is being delivered relative to these criteria in various practice environments.

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