ICSI Institute for Clinical Systems Improvement

Health Care Guideline

Prevention and Management of Obesity for Adults

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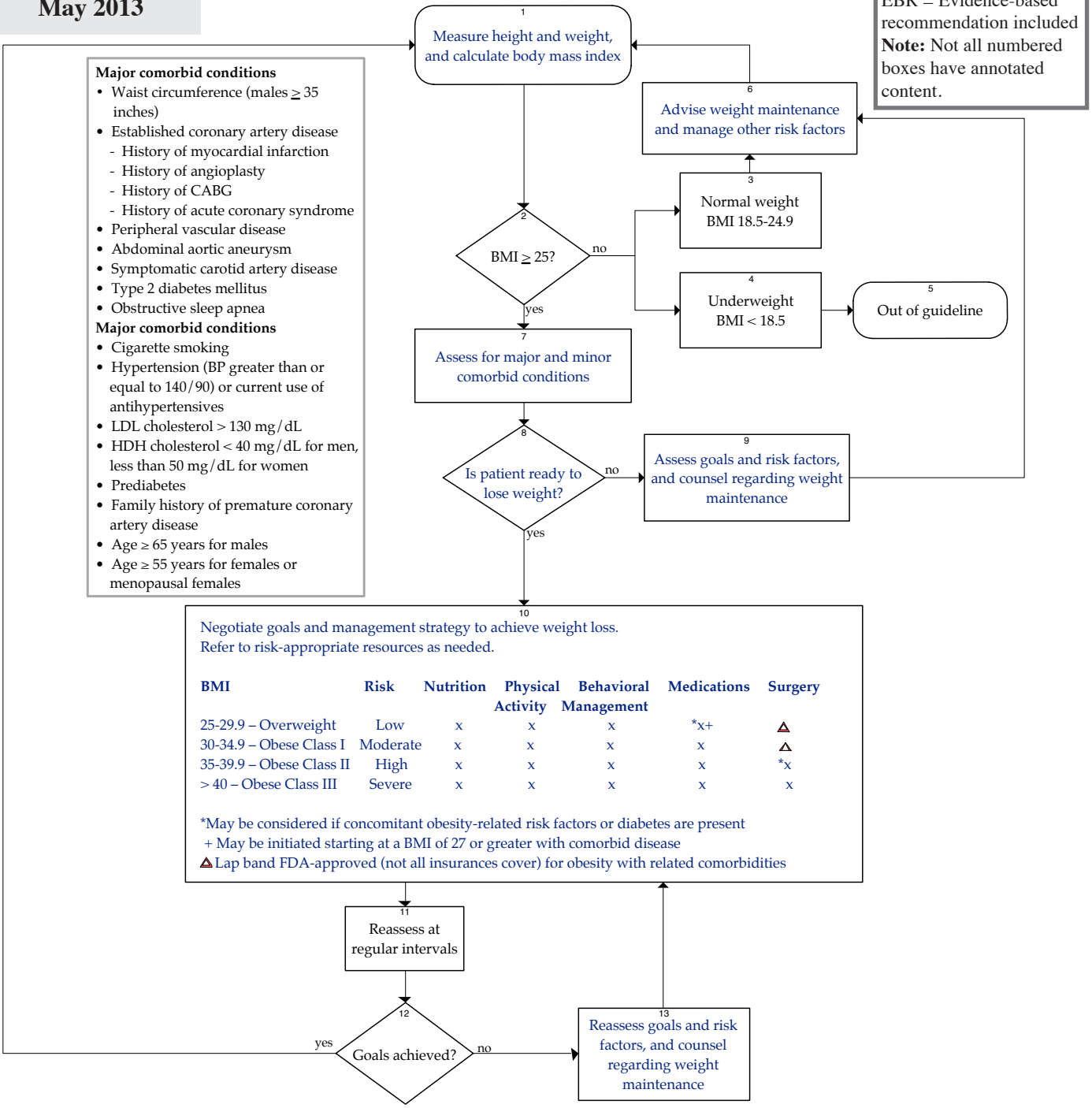
ICSI
Institute for Clinical Systems Improvement

Health Care Guideline:
Prevention and Management of Obesity for Adults

Prevention and Diagnosis Algorithm

Sixth Edition
May 2013

EBR = Evidence-based recommendation included
Note: Not all numbered boxes have annotated content.



Major comorbid conditions
- Waist circumference (males ≥ 35 inches)
- Established coronary artery disease
  - History of myocardial infarction
  - History of angioplasty
  - History of CABG
  - History of acute coronary syndrome
- Peripheral vascular disease
- Abdominal aortic aneurysm
- Symptomatic carotid artery disease
- Type 2 diabetes mellitus
- Obstructive sleep apnea

Major comorbid conditions
- Cigarette smoking
- Hypertension (BP greater than or equal to 140/90) or current use of antihypertensives
- LDL cholesterol > 130 mg/dL
- HDH cholesterol < 40 mg/dL for men, less than 50 mg/dL for women
- Prediabetes
- Family history of premature coronary artery disease
- Age ≥ 65 years for males
- Age ≥ 55 years for females or menopausal females

BMI	Risk	Nutrition	Physical Activity	Behavioral Management	Medications	Surgery
25-29.9 – Overweight	Low	x	x	x	*x+	△
30-34.9 – Obese Class I	Moderate	x	x	x	x	△
35-39.9 – Obese Class II	High	x	x	x	x	*x
> 40 – Obese Class III	Severe	x	x	x	x	x

*May be considered if concomitant obesity-related risk factors or diabetes are present
\+ May be initiated starting at a BMI of 27 or greater with comorbid disease
△ Lap band FDA-approved (not all insurances cover) for obesity with related comorbidities

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Text in blue in this algorithm indicates a linked corresponding annotation.

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Evidence Grading

Literature Search

A consistent and defined process is used for literature search and review for the development and revision of ICSI guidelines. Literature search terms for the current revision of this document included adults (18 years and older), published since January 2005 – systematic reviews, randomized control trials, meta-analysis restricted to human studies, in the following topic areas: prevention, screening, treatments/drug studies, medications, gastric bypass and/or bariatric surgery, lipid and cholesterol screening, activity recommendations, genetic studies, activity recommendations, family-based therapy, readiness for change, motivational interviewing, goal setting, managing chronic conditions, binge eating disorders, binge eating disorder assessment and scale, and obesity with diabetes.

GRADE Methodology

Following a review of several evidence rating and recommendation writing systems, ICSI has made a decision to transition to the Grading of Recommendations Assessment, Development and Evaluation (GRADE) system.

GRADE has advantages over other systems including the current system used by ICSI. Advantages include:

- developed by a widely representative group of international guideline developers;
- explicit and comprehensive criteria for downgrading and upgrading quality of evidence ratings;
- clear separation between quality of evidence and strength of recommendations that includes a transparent process of moving from evidence evaluation to recommendations;
- clear, pragmatic interpretations of strong versus weak recommendations for clinicians, patients and policy-makers;
- explicit acknowledgement of values and preferences; and
- explicit evaluation of the importance of outcomes of alternative management strategies.

In the GRADE process, evidence is gathered related to a specific question. Systematic reviews are utilized first. Further literature is incorporated with randomized control trials or observational studies. The evidence addresses the same population, intervention, comparisons and outcomes. The overall body of evidence for each topic is then given a quality rating.

Once the quality of the evidence has been determined, recommendations are formulated to reflect their strength. The strength of a recommendation is either strong or weak. Low quality evidence rarely has a strong recommendation. Only outcomes that are critical are considered the primary factors influencing a recommendation and are used to determine the overall strength of this recommendation. Each recommendation answers a focused health care question.

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Category	Quality Definitions	Strong Recommendation	Weak Recommendation
High Quality Evidence	Further research is very unlikely to change our confidence in the estimate of effect.	The work group is confident that the desirable effects of adhering to this recommendation outweigh the undesirable effects. This is a strong recommendation for or against. This applies to most patients.	The work group recognizes that the evidence, though of high quality, shows a balance between estimates of harms and benefits. The best action will depend on local circumstances, patient values or preferences.
Moderate Quality Evidence	Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.	The work group is confident that the benefits outweigh the risks but recognizes that the evidence has limitations. Further evidence may impact this recommendation. This is a recommendation that likely applies to most patients.	The work group recognizes that there is a balance between harms and benefits, based on moderate quality evidence, or that there is uncertainty about the estimates of the harms and benefits of the proposed intervention that may be affected by new evidence. Alternative approaches will likely be better for some patients under some circumstances.
Low Quality Evidence	Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change. The estimate or any estimate of effect is very uncertain.	The work group feels that the evidence consistently indicates the benefit of this action outweighs the harms. This recommendation might change when higher quality evidence becomes available.	The work group recognizes that there is significant uncertainty about the best estimates of benefits and harms.

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Recommendations Table

The following table is a list of evidence-based recommendations for the Prevention and Management of Obesity for Adults.

Note: Other recommendation language may appear throughout the document as a result of work group consensus but is not included in this evidence-based recommendations table.

Topic	Quality of Evidence	Recommendations	Strength of Recommendation	Annotation Number	Relevant Resources
Measure height and weight, and calculate body mass index	High	Clinicians should calculate body mass index (BMI) for their patients on an annual basis for screening and as needed for management. Classify BMI based on the body mass categories (see Table 3). Educate patients about their body mass index and associated risks for them.	Strong	1	*LeBlanc, 2011; McTigue, 2003*
Measure height and weight, and calculate body mass index	Moderate	Clinicians should consider waist circumference measurement to estimate disease risk for patients who have normal or overweight BMI scores. Refer to Table 2 for disease risk relative to weight and waist circumference.	Strong	1	*National Heart, Lung and Blood Institute, 2013; LeBlanc, 2011*
Measure height and weight, and calculate body mass index	Moderate	Clinicians need to carefully consider BMI and its associated mortality risk across different ethnicity, sex and age groups.	Strong	1	*LeBlanc, 2011*
Assess for major and minor comorbid conditions	Moderate	Waist circumference greater than or equal to 40 inches for males and 35 inches for females is an additional risk factor for complications related to obesity. Measuring waist circumference is recommended to further assess the patient.	Weak	7	*National Heart, Lung and Blood Institute, 2013*
Is the patient ready to lose weight?	Moderate	Clinicians should use motivational interviewing techniques as a tool for encouraging behavior change.	Strong	8	*Rollnick, 2000*

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Foreword

Introduction

Obesity is a chronic, multifactorial disease with complex psychological, environmental (social and cultural), genetic, physiologic, metabolic and behavioral causes and consequences. The prevalence of overweight and obese people is increasing worldwide at an alarming rate in both developing and developed countries. Environmental and behavioral changes brought about by economic development, modernization and urbanization have been linked to the rise in global obesity. The health consequences are becoming apparent.

Obesity is a national epidemic in the United States with 78 million obese adults *(Ogden, 2012 [Reference])*. In 2009-2010, the prevalence of obesity was 35.5% among men and 35.8% among women *(Flegal, 2012 [Reference])*. The prevalence of extreme obesity has also increased. Approximately 6% of U.S. adults now have a BMI of 40 kg/m2 or higher *(The Surgeon General's Vision for a Healthy and Fit Nation, 2010 [Reference])*. One in every three children (31.7%) is overweight or obese (*White House Task Force on Childhood Obesity, 2010 [Reference])*. More than one quarter of all Americans ages 17-24 are unqualified for military service because they are too heavy *(White House Task Force on Childhood Obesity, 2010 [Reference])*. Specifically, 16.9% of children were considered obese in 2009-2010 *(Ogden, 2012 [Reference])*. This data is concerning, for the Healthy People 2010 goals for obesity prevalence in the United States were not met *(National Center for Health Statistics, 2012 [Reference])*.

Medical costs associated with obesity were estimated at as much as $147 billion to $210 billion a year *(Robert Wood Johnson Foundation, 2012 [Reference])*. Obese persons had estimated medical costs that were $1,429 higher per person, per year than persons of normal weight *(Finkelstein, 2009 [Reference])*.

Obesity is the second leading cause of preventable death in the U.S., with only tobacco use causing more deaths *(New York State Department of Health, 2011 [Reference])*. More than 112,000 preventable deaths per year are associated with obesity *(Surgeon General's Vision for a Healthy and Fit Nation, 2010 [Reference])*.

Obesity and major depression frequently co-occur. A meta-analysis study showed obesity was found to be an increased risk of depression, and depression was found to be a predictor of developing obesity *(Floriana, 2010 [Reference])*.

Several of the comorbidities associated with obesity include type 2 diabetes, heart disease, hypertension, dyslipidemia and certain cancers *(Withrow, 2010 [Reference])*. The prevalence of various medical conditions increases with those who are overweight and obese as shown in Tables 1 and 2.

Note: Some studies show significant ethnic variability *(Flegal, 2012 [Reference]; Hedley, 2004 [Reference]; Ogden, 2002 [Reference])*.

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Table 1. Prevalence of Comorbid Conditions by Body Mass Index Category, Adults Aged ≥ 18, United States, 2000-2002 Behavioral Risk Factor Surveillance System

	Body Mass Index				
	Normal (18.5-24.9)	**Overweight (25.0-29.9)**	**Obese – Class 1 (30.0-34.9)**	**Obese – Class 2 (35.0-39.9)**	**Obese – Class 3 (≥ 40.0)**
Diabetes	4.8 (4.7-5.0)	7.5 (7.3-7.7)	13.4 (13.0-13.8)	19.8 (18.9-20.7)	26.4 (25.0-27.8)
Asthma	9.6 (9.4-9.8)	9.9 (9.7-10.1)	12.6 (12.2-13.0)	16.0 (15.2-16.8)	21.9 (20.5-23.2)
Arthritis	22.3 (21.9-22.6)	25.6 (25.2-26.0)	32.3 (31.8-32.9)	38.5 (37.4-39.5)	47.1 (45.4-48.7)
High blood pressure	19.1 (18.6-19.6)	28.9 (28.3-29.4)	39.5 (38.6-40.5)	46.7 (44.9-48.4)	53.5 (51.0-55.9)
High cholesterol	24.7 (24.1-25.3)	32.5 (31.9-33.2)	37.6 (36.5-38.7)	37.0 (35.1-39.0)	36.0 (33.4-38.7)
Fair/Poor Health	13.1 (12.8-13.3)	14.7 (14.5-15.0)	20.9 (20.4-21.4)	28.6 (28.6-30.6)	39.4 (37.9-40.9

Jenkins TM. Prevalence of overweight, obesity, and comorbid conditions among U.S. and Kentucky adults, 2000-2002. *Prev Chronic Dis* 2005 Jan. Available from URL: http://www.cdc.gov/pcd/issues/2005/jan/04_0087.htm.

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Scope and Target Population

This guideline addresses the prevention, diagnosis and management of obesity in adult patients, and includes behavioral approaches, drug treatment and surgery.

This guideline does not address pregnant women or bodybuilders/weight trainers.

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Aims

1. Increase percentage of patients 18 years and older who have an annual screening for obesity using body mass index (BMI) measure specific for age and gender. *(Annotation #1)*
2. Increase the percentage of patients age 18 years and older with BMI > 25 kg/m^2 who have received education and counseling regarding weight management. *(Annotations #8, 10)*
3. Increase the percentage of patients age 18 years and older with BMI > 25 who have improved outcomes from the treatment. *(Annotations #8, 10)*

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Clinical Highlights

- Obesity is a chronic disease that is a multifactorial, growing epidemic with complex political, social, psychological, environmental, economic and metabolic causes and consequences. Obesity affects essentially every organ system in the body. Health consequences increase across the body mass index span, not just for the extremely obese. *(Introduction)*
- Calculate the body mass index; classify the individual based on the body mass index categories. Educate patients about their body mass index and their associated risks. *(Annotation #1; Aim #1)*
- Effective weight management strategies are available and include nutrition, physical activity, lifestyle changes, medication and surgery. *(Annotation #6; Aim #2)*

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- A 5-10% weight loss can reduce a patient's risk of heart disease and diabetes that is clinically significant, and should be encouraged for all patients who are overweight and obese. This amount of weight loss and maintenance should be considered a clinical success and commended. This can be achieved and maintained with a high-intensity medical weight loss program even for the morbidly obese. *(Annotation #8; Aim #2)*
- The clinician should follow the 5 A's (Ask, Advise, Assess, Assist, Arrange). Physician intervention can be effective, the clinician can have an important influence, and successful weight management is possible. *(Annotation #8; Aim #3)*
- Weight management requires a team approach. Be aware of clinical and community resources. The patient needs to have an ongoing therapeutic relationship and follow-up with a health care team. Weight control is a lifelong commitment, and the health care team can assist with setting specific goals with the patient. *(Annotations #10, 13; Aim #2)*
- Beyond their clinical role, primary care clinicians should be aware of their roles as community leaders and public health advocates. *(Annotations #10, 13; Aim #4)*

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Implementation Recommendation Highlights

The following system changes were identified by the guideline work group as key strategies for health care systems to incorporate in support of the implementation of this guideline.

- Establish a system for using a Patient Readiness Scale to determine if the patient is ready to talk about weight loss and/or would like information.
- Establish a system for staff to efficiently calculate BMI prior to the clinician entering the exam room. The BMI may provide more health risk information than traditional vital signs and should be built into the patient assessment protocol. A BMI chart should be placed by each scale in the clinic. All organizations with electronic medical records should build BMI calculators as a component for immediate calculation.
- Develop a tracking system that periodically reviews patient charts to identify patients who are overweight or obese so that clinicians are aware of the need to discuss the issue with the patient.
- Establish a system for staff and clinician training around skills and knowledge in the areas of motivational interviewing; brief, focused advice on nutrition, physical activity and lifestyle changes; and evaluation of evidence of effectiveness of treatment options.
- Establish a system for continuing education on evidence-based obesity management for clinicians, nurses and ancillary clinic staff.
- Remove barriers to referral programs for weight loss by understanding where programs are and what process is required for referrals.
- Develop medical record systems to track status of patients under the clinician's care with the capability to produce an outpatient tracking system for patient follow-up by clinician/staff.
- Use tools such as posters and brochures throughout the facility to assist with identifying and notifying patients about health risk in relationship to NIH-based categories of BMI. Promote a healthy lifestyle around nutrition and activity while encouraging patient knowledge of his or her BMI.
- Develop patient-centered education and self-management programs, which may include self-monitoring, self-management and skills such as journaling.
- Build systems to track outcomes measures, as well as ongoing process measures. Track the response rate to various treatments/strategies. Improvement rates – the BMI is stable or has decreased over time.

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- Systems to coordinate care ensure continuity and keep clinicians informed of progress.
  - Develop electronic tracking systems for panel or population management.
  - Educate patients to foster awareness and knowledge of BMI for self-monitoring and reporting.
  - Structure follow-up visits with patient per guideline recommendations.

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Related ICSI Scientific Documents

Guidelines

- Hypertension Diagnosis and Treatment
- Diagnosis and Management of Type 2 Diabetes Mellitus in Adults
- Lipid Management in Adults
- Major Depression in Adults in Primary Care
- Preventive Services for Adults
- Assessment and Management of Chronic Pain

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Definition

Clinician – All health care professionals whose practice is based on interaction with and/or treatment of a patient.

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Algorithm Annotations

1. Measure Height and Weight, and Calculate Body Mass Index

Recommendations:

- Clinicians should calculate body mass index (BMI) for their patients on an annual basis for screening, and as needed for management. Classify BMI based on the National Institute of Health categories (see Table 3). Educate patients about their BMI and associated risks for them *(Strong Recommendation, High Quality Evidence) (McTigue, 2003; LeBlanc, 2011)*.
- Clinicians should consider waist circumference measurement to estimate disease risk for patients who have normal or overweight BMI scores. Refer to Table 2 for disease risk relative to weight and waist circumference *(Strong Recommendation, Moderate Quality Evidence) (National Heart, Lung and Blood Institute, 2013; LeBlanc, 2001)*.
- Clinicians need to carefully consider BMI and its associated mortality risk across different ethnicity, sex and age groups *(Strong Recommendation/Moderate Quality Evidence) (LeBlanc, 2011)*.

BMI continues to be a common and reasonably reliable measurement to identify overweight and obese adults who may be at an increased risk for future morbidity. Although good quality evidence supports obtaining a BMI, it is important to recognize it is not a perfect measurement. BMI is not a direct measure of adiposity and as a consequence it can over- or underestimate adiposity. BMI is a derived value that correlates well with total body fat and markers of secondary complications, e.g., hypertension and dyslipidemia *(Barlow, 2007 [Reference])*. An abnormally high body mass index does not address the distribution of body fat, i.e., central versus peripheral or visceral versus subcutaneous. Central or visceral fat carry greater risk for morbidity and mortality. BMI is solely dependent on height and weight, and does not consider other factors such as a person's physical activity level, sex or age.

In contrast, waist circumference is positively associated with abdominal fat, which is an independent predictor of risk factors and morbidity of obesity-related diseases *(Anuradha, 2012 [Reference])*. Waist circumference should be measured midway between the lowest ribs and the iliac crest *(Ma, 2013 [Reference])*. At BMIs > or equal to 35, waist circumference provides little value over BMI value in predicting disease risk. Waist circumference cut points can generally be applied to all adult ethnic or racial groups *(National Heart, Lung and Blood Institute, 2013 [Moderate Quality Evidence])*.

In contrast with waist circumference, BMI and its associated disease and mortality risk appear to vary among ethnic subgroups. Female African American populations appear to have the lowest mortality risk at a BMI of 26.2-28.5 kg/m^2 and 27.1-30.2 kg/m^2 for women and men, respectively. In contrast, Asian populations may experience lowest mortality rates starting at a BMI of 23 to 24 kg/m^2. The correlation between BMI and diabetes risk also varies by ethnicity *(LeBlanc, 2011 [Moderate Quality Evidence])*. In addition, in adults older than 65 years, waist circumference, but not BMI, is associated with greater mortality risk. It is important to not rely solely on BMI scores to predict future mortality risk across different populations.

Other screening tools are available, as well. These include waist-to-hip ratio (WHR) measurement, bioimpedance (BIA), dual-energy x-ray absorptiometry (DXA) and the recently proposed Body Adiposity Index (BAI= [hip circumference]/[height] 1.5-18 *(Suchanek, 2012 [Reference])*. Some research indicates if BMI is known, BAI provides little additional information of CHD risk factors and is not shown to be a

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replacement for BMI in the Caucasian population *(Freedman, 2012 [Reference]; Suchanek, 2012 [Reference])*. Further BAI measurement research is needed. In the clinical setting, BMI and waist circumference measurements are not associated with any direct physical harm; one must consider possible secondary harms – for example, potential negative self-esteem and associated stigma from BMI category label. Research is extremely limited in this area but must be considered *(LeBlanc, 2011 [Reference])*.

Table 2: Classification of Overweight and Obesity by BMI, Waist Circumference and Associated Disease Risk*

			Disease Risk* Relative to Normal Weight and Waist Circumference	
	BMI (kg/m^2)	Obesity Class	Men ≤ 102 cm (≤ 40 in.) Women ≤ 88 cm (≤ 35 in.)	Men > 102 cm (> 40 in.) Women > 88 cm (> 35 in.)
Underweight	18.5		-----	-----
Normal+	18.5-24.9		-----	-----
Overweight	25.0-29.9		Increased	High
Obesity	30.0-34.9	I	High	Very High
	35.0-39.9	II	Very High	Very High
Extreme Obesity	≤ 40	III	Extremely High	Extremely High

* Disease risk for type 2 diabetes, hypertension, and CVD.
+Increased waist circumference can also be a marker for increased risk even in persons of normal weight.

Recommendation: For adult patients with a BMI of 25 to 34.9 kg/m^2, sex-specific waist circumference cutoffs should be used in conjunction with BMI to identify increased disease risk.

Table 3: Adult BMI Categories

BMI	Category
Less than 18.5	Underweight
18.5-24.9	Normal weight
25-29.9	Overweight
30-34.9	Obese – class I
35-39.9	Obese – class II
40 or more	Extreme obesity – class III

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6. Advise Weight Maintenance and Manage Other Risk Factors

Lifetime risk of obesity is high for residents of the United States. Lifetime risk of diabetes is about 32.4% for men and 35.5% for women, and lifetime risk for obesity is higher than this *(Flegal, 2010 [Referemce])*. Therefore, it is important to address the issue of weight maintenance for those with body mass index in the normal range (18.5 to 24.9 kg/m^2). Successful weight management requires a lifestyle approach that integrates physical activity, nutrition, behavioral management and attention to psychosocial needs.

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- First, encourage regular physical activity at recommended levels. Regular physical activity is strongly related to maintaining normal weight. In selecting types of physical activity, it is important to consider the age of the patient, musculoskeletal limitations and availability of exercise facilities. For inactive patients, this may include as little as 10 minutes of physical activity a day. Ideally, 30 to 60 minutes of moderate physical activity on most days of the week is recommended (> 150 minutes a week). However, for those who have lost a considerable amount of weight, higher amounts of physical activity may be required for weight maintenance (> 275 minutes a week). Enjoyment and variety of physical activity are also key features for adherence *(Jakicic, 2011 [Reference]; Donnelly, 2009 [Reference])* .
- Second, provide structured lifestyle modification suggestions that include specific nutrition recommendations, educational sessions and frequent contact with health care clinicians, such as a dietitian. Focus on calorie balancing, using a combination of decreased caloric intake with increased calorie expenditure. Include nutrition education (e.g., interpreting food labels); managing restaurant and social eating situations; making healthy, nutritious food choices; using portion control; and recipe modifiying.

  There is considerable evidence that individuals consuming low-fat, low-calorie diets are successful at maintaining weight loss for 12 months and longer. Data from the National Weight Control Registry demonstrates that successful weight maintainers consume a low-calorie diet containing ~40 g fat (24% of calories), 200 g carbohydrate (56% of calories) and 70 g protein (19% of calories). A low-fat diet (25-30% calories from fat) is considered the conventional therapy for treating obesity *(Klein, 2004 [Reference])*. Data is emerging to suggest that patients who are insulin resistant may respond better to a lower carbohydrate diet (< 30% carbohydrate). This may also be linked to genetics *(Gardner, 2007 [Reference])*.
- Third, encourage behavior management strategies that may include weekly weight checks, food journals and monitoring daily routine that focuses on a balanced lifestyle. Balance includes eating a nutritionally balanced breakfast soon after awakening and eating balanced meals at regular intervals thereafter; incorporating fun physical activity into the day; and scheduling the week to include rest, play and social interactions along with work, school and family responsibilities.

  Specific behavioral strategies to promote behavior change include self-monitoring some aspect of behavior that, in itself, typically results in behavior change; non-food rewards and positive reinforcements; reminders; stimulus control (changing social or environmental cues that trigger eating behavior); stress management, problem solving and helping patients believe they can be successful.

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7. Assess for Major and Minor Comorbid Conditions

Recommendation:

- Waist circumference greater than or equal to 40 inches for males and 35 inches for females is an additional risk factor for complications related to obesity. Measuring waist circumference is recommended to further assess the patient *(Weak Recommendation, Moderate Quality Evidence) (National Heart, Lung and Blood Institute, 2013)*.

It is important to assess for comorbid conditions as treatment decisions and outcomes may be influenced by their presence. Evaluation for depression, eating disorders and sleep disorders in particular are encouraged. Assessment should include a complete medical history including identification of medications that may include weight gain or interfere with weight loss.

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Table 4. Prevention and Management of Obesity Interventions

Comorbid Condition	BMI			
	25-30 kg/m^2	**30-35 kg/m^2**	**35-40 kg/m^2**	**40 + kg/m^2**
0	Counsel and educate: • Lifestyle changes • Behavioral management	Counsel and educate: • Lifestyle changes • Behavioral management • Medication considerations	Counsel and educate: • Lifestyle changes • Behavioral management • Medication considerations	Counsel and educate: • Lifestyle changes • Behavioral management • Medication and surgical considerations
1-2 Minor Comorbid Conditions	Counsel and educate: • Lifestyle changes • Behavioral management	Counsel and educate: • Lifestyle changes • Behavioral management • Medication considerations	Counsel and educate: • Lifestyle changes • Behavioral management • Medication therapy • Surgical options	Counsel and educate: • Lifestyle changes • Behavioral management • Medication and surgical considerations
Major Comorbid Conditions OR 3 Minor Comorbid Conditions	Counsel and educate: • Lifestyle changes • Behavioral management • Medication considerations The FDA approves drug therapy only for BMI greater than 27 kg/m^2.	Counsel and educate: • Lifestyle changes • Behavioral management • Medication and surgical considerations	Counsel and educate: • Lifestyle changes • Behavioral management • Medication and surgical considerations	Counsel and educate: • Lifestyle changes • Behavioral management • Medication and surgical considerations

Minor Comorbid Conditions

- Cigarette smoking
- Hypertension (BP greater than or equal to 140/90) or current use of antihypertensives†
- LDL cholesterol > 130 mg/dL
- HDL cholesterol < 40 mg/dL for men; less than 50 mg/dL for women†
- Prediabetes*†
- Family history of premature coronary artery disease
- Age ≥ 65 years for males
- Age ≥ 55 years for females or menopausal females

Major Comorbid Conditions

- Waist circumference (males ≥ 40 inches, females ≥ 35 inches) †
- Established coronary artery disease
  - History of myocardial infarction
  - History of angioplasty
  - History of CABG
  - History of acute coronary syndrome
- Peripheral vascular disease
- Abdominal aortic aneurysm
- Symptomatic carotid artery disease
- Type 2 diabetes mellitus
- Obstructive sleep apnea

* The term pre-diabetes has been adopted by the American Diabetes Association and others, and refers to those who have a fasting plasma glucose of 100 mg/dL to 125 mg/dL, those with a two-hour plasma glucose post- 75-gram-oral-glucose tolerance test value of 140 mg/dL to 199 mg/dL or those with a hemoglobin A1C in the range of 5.7-6.4%.

†The clustering of these symptoms has been described as the metabolic syndrome. Several formal definitions exist *(National Heart, Lung and Blood Institute, 2013 [Moderate Quality Evidence]; de Ferranti, 2004 [Reference]; World Health Organization, 2004 [Reference])*.

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Assessing for Depression

The evidence showing the linkage between depression and obesity is mixed *(Jorm, 2003 [Reference]; Roberts, 2003 [Reference]; Friedman, 1995 [Reference]; DiPietro, 1992 [Reference])*. Higher rates of depression have been found in severely obese people, especially younger women with poor body image *(Dixon, 2003 [Reference]; Onyike, 2003 [Reference])*. It is difficult to study whether the depression is secondary to the obesity or to existing comorbid conditions *(Stunkard, 2003 [Reference])*. Weight loss often leads to improvement of depression scores *(Dixon, 2003 [Reference])*.

Depression is identified more often in obese women and teenagers and is less likely to be diagnosed in men *(Jorm, 2003 [Reference]; Stunkard, 2003 [Reference]; Palinkas, 1996 [Reference]; Istvan, 1992 [Reference])*. Depression in the elderly is often associated with weight loss, while depression in younger females can be associated with weight gain *(DiPietro, 1992 [Reference])*.

In the past, depression has been associated with poor weight-loss outcomes *(Linde, 2004 [Reference])*. However, this is not necessarily the case. People with depression can do well in weight-loss treatment, and their symptoms can improve *(Linde, 2011 [Reference])*.

Bariatric surgery patients with poorly managed depression or anxiety are at greater risk for weight regain within the first five postoperative years *(Waters, 1991 [Reference])*. One explanation for this may be found in a line of research investigating biological pathways that link depressive symptomatology to increased adiposity and weight gain *(Miller, 2003 [Reference])*. Weight-loss studies have often excluded people with depression *(Linde, 2004 [Reference])*. More studies to address this issue are warranted.

Screening for depression can include asking the following questions.

Over the past month, have you been bothered by:

- little interest or pleasure in doing things?
- feeling down, depressed or hopeless?

If the patient answers "yes" to either one of the above questions, consider using a questionnaire to further assess whether the patient has sufficient symptoms to warrant a full clinical interview and a diagnosis of clinical major depression. An example of such a questionnaire is the PHQ-9 (Patient Health Questionnaire).

This should not be considered a comprehensive screening for depression, which is beyond the scope of this guideline. See the ICSI Major Depression in Adults in Primary Care guideline for more information.

The work group's opinion is that patients who are clinically depressed should undergo treatment with medication and/or psychotherapy to maximize their ability to lose weight. An antidepressant that does not contribute to weight gain should be chosen. Medications such as bupropion, venlafaxine and sertraline have been shown in clinical studies to be associated with the least weight gain over time.

Assessing for an Eating Disorder

Eating disorders, particularly binge eating disorder, may complicate the treatment of obesity.

Assessing for eating disorders can include asking the following questions:

- Do you eat a large amount of food in a short period of time – like eating more food than another person may eat in, say, a two-hour period of time?
- Do you ever feel like you can't stop eating even after you feel full?
- When you overeat, what do you do (e.g., Have you ever tried to "get rid of" the extra calories that you've eaten by doing something like: Take laxatives? Take diuretics [or water pills]? Smoke cigarettes? Take street drugs like cocaine or methamphetamine? Make yourself sick [induce vomiting]?)

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If the patient answers "yes" to any of the above questions, consider further evaluation or a referral to a dietitian or a behavioral health specialist who specializes in eating disorders or in health psychology and working with bariatric patients.

More comprehensive assessment tools include the SCOFF Questionnaire or Eating Attitudes Test (EAT-24).

Assessing for Medication Use That Contributes to Weight Gain

The assessment of the obese patient should include a complete medication history to identify medications that may induce weight gain or interfere with weight loss. Non-steroidal anti-inflammatory drugs and calcium channel blockers may cause peripheral edema rather than body fat weight gain. HIV protease inhibitors are associated with lipodystrophy (central obesity) that is actually a change in body fat distribution rather than a body fat weight gain. If possible, alternative medications that are weight-neutral or that induce weight loss should be selected *(Kushner, 2003b [Reference]; Vanina, 2002 [Reference]; Ganguli, 1999 [Reference])*. A common belief exists among women and clinicians that there is an association between the use of combination hormonal contraceptives and weight gain. This belief may prevent some women from starting hormonal contraception or cause early discontinuation of medication. A review of 42 clinical trials – including three randomized, placebo-controlled trials – did not find evidence to support a causal relationship between the use of combination oral contraceptives and weight gain. The authors of the review concluded that current evidence is not sufficient to determine the effect of combination contraceptives on weight, but no large effect is evident *(Gallo, 2004 [Reference])*.

Please see Appendix A, "Medications Associated with Weight Gain and Weight Loss," and the ICSI Diagnosis and Management of Type 2 Diabetes Mellitus in Adults guideline for more information.

Assessing for a Sleep Disorder

Overweight and obese patients who have not had a sleep study should be encouraged to do so if they show signs of sleep disturbance such as daytime somnolence, snoring, evidence of apnea episodes provided by a partner, or issues with daytime memory and attention.

Assessing for sleep disorders such as sleep apnea and sleep-related eating disorder is important. Patients with documented sleep apnea need to be encouraged to be compliant with their treatment plan in order to improve their ability to lose weight. Sleep duration is important for weight loss, as well. Sleep curtailment decreased the proportion of weight lost as fat by a total of 2.4% if patients slept for 5.5 hours compared to 5.4% if the patient slept for 8.5 hours *(Nedeltcheva, 2010 [Reference])*.

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8. Is Patient Ready to Lose Weight?

Recommendation:

- Clinicians should use motivational interviewing techniques as a tool for encouraging behavior change *(Strong Recommendation, Moderate Quality Evidence) (Rollnick, 2000)*.

Knowing the patient's readiness to change can help the clinician understand a patient's level of motivation and how to tailor communication about weight loss. Patients will need to set realistic, achievable goals and be held accountable to practice new behaviors that produce and maintain weight loss.

Introduction to Weight Management/Lifestyle Change

Weight management is a skill. Patients need to set realistic, achievable goals and to be held accountable to practicing the new behaviors that produce and maintain weight loss. Recordkeeping or self-monitoring of progress on specific behaviors is key to successful weight management.

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The ICSI Patient Advisory Council reviewed this guideline and supports the value of the clinician initiating the conversation and suggested that patients were more likely to act on the recommendations of their clinician. Also, because obesity can be an overwhelming condition for the patient, creating small achievable goals and celebrating those achievements are important for continued success and healthy choices. We recommend that clinicians guide goals using the acronym "SMART" (specific, measurable, action based, realistic, and time based).

Refer to Appendix K for a SMART Goal example tool.

Stages of Change Model

When evaluating a patient with obesity, it is recommended to get a general sense of his or her readiness to change specific dietary and physical activity habits.

The Transtheorectical Model of Change, also known as the Stages of Change model, can be helpful to understand where in the process of change the patient stands. This can be organized into five stages including precontemplation, contemplation, preparation, action and maintenance.

During the precontemplation stage, patients are not willing to change at all. They may have tried to lose weight unsuccessfully and given up. They may not see that a clinician's advice to change their poor health habits may apply to them directly.

In the contemplation stage, patients are starting to think about change but fearful about moving forward. They know they should but have reservations perhaps about giving up something they enjoy very much. The patient is interested in learning ways to lose weight. This is when the patient thinks about the pros and cons of changing his or her behavior. The patient is not considering the change in the near future.

During the preparation stage, the patients are ready to make a change in their life but they do so in small ways. They experiment with these changes. The patient may make the change in the next month.

The action stage occurs when a patient has made a determined effort to reach a goal. This should be recognized by clinicians, and the patient should be encouraged to continue these good health practices. This is usually about three to six months long.

The maintenance stage involves continuing to maintain the new behavior over time and therefore reinforcing healthy habits. This stage is more than six months long.

Table 5. Stages of Change

Stage of Change	Definition
Pre-Contemplation	Not interested in changing behavior
Contemplation	Starting to think about change but not ready
Preparation	Planning to change behavior
Action	Practicing new behavior for a few months
Maintenance	Continuing the new behavior for more than six months

Overview of Motivational Interviewing (MI)

Motivational interviewing is an empathy-based, patient-centered approach to behavior modification. It has been shown to help patients set realistic, achievable goals and be held accountable to practicing new behaviors. This is a reversal from the traditional role of the physician as advisor and expert "problem solver" *(Rollnick, 2008 [Reference])*.

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The "spirit" of MI is to elicit from patients their own good motivations for making behavior changes; it is collaborative, evocative and honors a patient's autonomy. It recognizes that there is something in human nature that resists being told what to do or being coerced *(Rollnick, 2008 [Reference])*.

The Guiding Principles of MI = RULE:

- **R:** Resist the righting reflex. Rather, seek to "fix" a patient, recognize the natural human tendency to resist persuasion (especially the ambivalent). Aim to support the patient's own discovery of the reasons for change.
- **U:** Understand your patient's motivations. If your consultation time is limited, you are better off asking patients why they would want to make a change and how they might do it, rather than telling them that they should.
- **L:** Listen to your patient. MI involves as much listening as informing; maintain empathetic interest and acknowledge that the answers most likely lie within the patient.
- **E:** Empower your patient. MI helps patients explore how they can make a difference in their health. A patient who is active in the consultation, thinking aloud about the why and how of change, is more likely to do something about this afterward. Recognize and guide through "change talk" in which the patient states the good reasons for and steps toward change, rather than resisting change.

(Rollnick, 2008 [Reference])

The goal of motivational interviewing is to move the patient along the "stages of change," from one stage to the next. The majority of patients in the primary care office are either precontemplation, or contemplative *(Prochaska, 1992 [Reference])*. As such, the success of motivational interviewing lies in the physician allowing the patient to "set the agenda" regarding which health behavior he or she is willing to address.

Once a topic has been identified, Rollnick, et al. emphasize separating readiness to change into two basic elements: "importance" and "confidence." The patient is asked to rate his or her perception of the importance of habit change on a scale, for example: from 1-10. The same is done for confidence in successful habit change. Patients who attribute little importance to behavior change can be asked to assess what they like about the particular behavior and what bothers them. Patients can then be asked to assess the pros and cons of making the behavior change. Scaling questions can again be asked, as well as "come-back" queries such as "You rated (X) a 5 …why not a 2?"

Patients who lack confidence in their ability to effect a behavior change may benefit from investigation of past successes and identification of obstacles. In discussion of how the patient might overcome identified obstacles, it is important that the patient himself or herself generate solutions to his or her own problem, and that the clinician refrain from slipping into the familiar role of advisor. In the event of a "mental block," patients can be given "brainstorming homework," to be addressed at a subsequent interval *(Simons, 2007 [Reference])*.

Refer to Appendix L for a sample of motivational interviewing scripting for adults.

See the Implementation Tools and Resources Table for links to video examples of motivational interviewing techniques.

The clinician should follow the 5 A's (Ask, Advise, Assess, Assist, Arrange). Clinician intervention can be effective and the influencial, and successful management is possible.

- *ASK* about weight, measure height and weight and calculate BMI.
- *ADVISE* to lose weight. In a clear, strong but sensitive and personalized manner, urge every overweight or obese patient to lose weight.

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- *ASSESS* readiness to lose weight. Ask every overweight or obese patient if he or she is ready to make a weight loss attempt at the time, e.g., within the next 30 days.
- *ASSIST* in weight-loss attempt. Help the patient with a weight-loss plan. Refer to appropriate resources.
- *ARRANGE* follow-up. Schedule follow-up contact, either in person or via telephone.

(See Appendix M for details on the 5 A's.)

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9. Assess Goals and Risk Factors, and Counsel Regarding Weight Maintenance

See Annotation #13, "Reassess Goals and Risk Factors, and Counsel Regarding Weight Maintenance," for additional information.

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10. Negotiate Goals and Management Strategy to Achieve Weight Loss. Refer to Risk-Appropriate Resources as Needed.

Nutrition

Appropriate nutrition therapy for weight management will be developed collaboratively with the patient. Assessment and education may require a clinician with expertise in nutrition therapy. It is important that clinicians understand and support the general principles of nutrition recommendations for weight management.

Diet history or eating pattern history. A food/beverage frequency checklist, three-day food/beverage record and weekly food/beverage diary are common tools used to collect information about dietary habits.

Nutrition assessment. Evaluate the patient's current food and beverage choices, and eating and drinking habits. Assessment may include the following:

- Current intake of food and beverage calories and fat
- Portion sizes and inclusion of all food groups
- Under- or overconsumption of nutrients
- Use of supplements
- Use of meal replacements
- Stage of behavior change for specific behaviors, such as fruit and vegetable consumption
- Symptoms of possible eating disorder – triggers for overeating
- Timing/consistency of meals and snacks

For more information, including interactive guidance for evaluating portion sizes and calorie analysis, the work group recommends the Center for Nutrition Policy and Promotion Web site at http://www.usda.gov/cnpp and choosemyplate.gov.

Nutrition recommendations. Select a meal planning approach that the patient is willing and ready to incorporate into present lifestyle. Dietary guidance should be individualized and tailored to food and beverage preferences; it should allow for flexible approaches to reducing calorie intake. The initial goal of weight loss therapy should be to reduce body weight by about 5-10% from baseline. With success, and if warranted, further weight loss can be attempted *(National Heart, Lung and Blood Institute, 2013 [Moderate Quality Evidence])*.

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Recommend:

- Achieving weight loss by a reduction in calorie intake. A moderate decrease in calories (500-1,000 kcal per day) can result in a progressive weight loss of 1-2 pounds per week. Weight loss should be about one to two pounds per week for a period of six months, with the subsequent strategy based on the amount of weight lost *(National Heart, Lung and Blood Institute, 2013 [Moderate Quality Evidence])*.
- A weight-loss eating plan that supplies at least 1,000-1,200 kcal/day for women and 1,200-1,600 kcal/day for men *(National Heart, Lung and Blood Institute, 2013 [Moderate Quality Evidence])*.

A useful tool is the BMR calculator and can be accessed at bwsimulator.niddk.nih.gov.

Table 6: *Lower-Calorie Meal Plan for Weight Loss *(NHLBI, 2000; NHLBI 2002)*

Nutrient	Recommended Intake
Calories	500-1,000 kcal/day reduction from usual intake
Total fat	30% or less of total calories
Trans fat	Less than or equal to 1% of total calories
Saturated fat	7-10% of total calories
Monounsaturated fat	Up to 15% of total calories
Protein	15% of total calories
† Carbohydrates, complex, from variety of vegetables, fruits and whole grains	55% of total calories
Fiber	Equal to or greater than 25-35 grams

Interactive tool for meal planning is at nhbli: http://hp2010.nhlbihin.net/menuplanner/menu.cgi

* The macronutrient composition of weight loss diets continues to be controversial and the subject of ongoing research.

- An eating plan that is balanced and consistent with other national dietary guidelines *(Esposito, 2003 [Reference])*. Encourage at least five servings of fruits and vegetables per day. Limit fat intake to 30% of calories from fat, 7-10% of calories from saturated fat, less than or equal to 1% trans fat. Emphasize whole grains, with a fiber intake of 35 grams or more daily.
- Keep trans fat intake below about 1% of calories. The lower the combined intake of saturated and trans fat and the lower the dietary cholesterol intake, the greater the cardiovascular benefit will be *(USDA, 2005 [Reference])*. Reduce the amount of trans fat by limiting foods that contain "partially hydrogenated" vegetable oils that may be found in some margarines, shortenings, crackers, candies, baked goods, cookies, snack foods, fried foods, salad dressings and other processed foods.
- All low-calorie diets will produce weight loss in the short term (3 to 12 months) *(Bravata, 2003 [Reference]; Freedman, 2001 [Reference]; National Heart, Lung and Blood Institute, 2013 [Moderate Quality Evidence])*. More studies are needed to determine long-term efficacy of weight loss and maintenance of low-carbohydrate (less than 100 grams) diets. Guidelines from the American Diabetes Association state that for short-term weight loss, either a low-carbohydrate or low-fat calorie-restricted diet may be effective. Initiated with a two-week phase of carbohydrate restriction of 20-25 g daily depending on baseline weight, participants lost weight and were able to increase carbohydrate intake at 5 g increments each week. Patients who are insulin resistant may respond better to a lower-carbohydrate meal plan (< 30% carbohydrate) *(Garder, 2007 [Reference])*.

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Low-carbohydrate diets have been found to result in more rapid short-term weight loss than conventional low-calorie diets at three and six months, but the difference was not significant at one year. Over a one-year period, low-carbohydrate diets have been found to result in greater improvements than conventional diets in triglycerides and HDL cholesterol levels but not LDL cholesterol. Long-term safety and effectiveness of low-carbohydrate diets for weight loss and cardiovascular risk factor improvements are not yet known.

- For information on popular diets, see the Implementation Tools and Resources Table.
- Weight-loss recommendations that exclude food groups and/or restrict macronutrients substantially below the dietary reference intakes and RDAs can cause nutrient deficiencies and increase health risks *(Bonow, 2003 [Reference]; Freedman, 2001 [Reference])*. A dietitian can assess food and beverage records using a variety of tools. A quick method is to evaluate portion sizes and number of servings recommended for food groups http://www.choosemyplate.gov. There are also food guide assessment tools available on the USDA Web site that calculate calories and total nutrients from food records that are entered. See the Implementation Tools and Resources Table for more information.
- There are reviews of low-cost, moderate-cost and high-cost food plans available at the USDA Web site that evaluate the weekly cost of healthy eating plans. The Web site is http://www.cnpp.usda.gov/USDAFoodPlansCostofFood.htm.
- Another meal planning approach is utilizing meal replacements. This typically involves using frozen meals, formula shakes or bars or prepackaged meals to control portion sizes and simplify food decisions. Drinks and bars are used to replace two meals and one snack per day. Most meal replacements contain 200-400 calories, and additional servings of fruits and vegetables are recommended. Weight maintenance usually involves replacing one meal per day *(Delahanty, 2002 [Reference]; Heymsfield, 2003 [Reference]; Kushner, 2003a [Reference])*.
- Low-calorie diets (LCD) are less than 1,000 calories/day for weight loss in overweight and obese persons. Reducing fat as part of an LCD is a practical way to reduce calories *(Clinical Guidelines on the Identification, Evaluation and Treatment of Overweight and Obesity in Adults; Evidence Report, 1998 [Reference])*.
- VLCDs (very low calorie diets) should be used only for weight-loss therapy by experienced practitioners with specialized monitoring and use of supplements *(National Heart, Lung and Blood Institute, 2000 [Reference])*. If VLCDs are used, weight loss can be expected in the first six months (~20 kg); (on less than 800 calories/day) however, there is rapid weight regain between 6 to 12 months if a maintenance program is not included. Weight loss is typically not maintained without ongoing dietary and behavioral support *(Paisey 2002 [Reference]; Torgerson, 1999 [Reference])*.
- Successful weight-loss maintenance is sustained by a combination of lower calorie intake and increased physical activity *(Franz, 2007 [Reference]; Freedman, 2001 [Reference]; Wing, 2001 [Reference]; McGuire, 1998 [Reference])*. Analysis of data from the National Weight Control Registry indicates weight-loss maintainers have an average intake of 1,400 kcal/day, get one hour of moderate activity per day and eat breakfast daily.
- A low-glycemic-index diet is not more effective than traditional low-fat diet for weight loss or weight maintenance in general but may be beneficial for patients with certain risk factors such as insulin resistance *(Gardner, 2007 [Reference])*. More studies are needed to determine long-term effect on hunger and satiety, as well as possible genetic predictors of dietary success *(Ebbeling, 2005 [Reference]; Thompson, 2005 [Reference])*.

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Physical Activity

Physical activity refers to all types and intensities of body movement, including activities of daily living. Exercise, physical fitness and training are terms that suggest elevated intensity, a sense of obligation or sports participation. These terms may have negative connotations for some obese patients. Physical activity is a more inclusive, attainable and acceptable term.

Physical inactivity, or sedentary lifestyle, has been previously identified as an independent risk factor for cardiovascular disease (CVD) by the American Heart Association *(Fletcher, 1992 [Reference])*. Physical inactivity is currently seen as a key contributor to the obesity problem. With approximately 60% of adults in the United States overweight *(Flegal, 2002 [Reference])*, it is essential to improve physical activity levels for the prevention and management of obesity.

While physical activity has long been recognized as an important component of a healthy lifestyle and longevity *(Paffenbarger, 1986 [Reference])*, the work group recognizes that the literature on physical activity in obesity prevention and management is extensive and the overall results are variable. Some of the confusion arises from inherent individual variability in response to exercise *(Skinner, 2001 [Reference])*. There is also significant interstudy variability (e.g., self-reported physical activity compared to measured physical activity). There are variable exercise regimens and research designs that confound comparison of results. This would suggest that selecting physical activity for weight loss is still largely patient preference and compatibility with lifestyle.

Evidence still remains that increasing calorie expenditure by increasing physical activity is necessary for improved weight-loss outcomes and weight maintenance *(Esposito, 2003 [Reference]; Rejeski, 2002 [Reference]; National Heart, Lung and Blood Institute, 2000 [Reference]; Miller, 1997 [Reference])*.

Improved outcomes for long-term weight reduction occur when a low-calorie intake is combined with increased physical activity and behavior therapy *(Diabetes Prevention Program Research Group, 2002 [Reference]; Rejeski, 2002 [Reference]; Freedman, 2001 [Reference]; Tuomilehto, 2001 [Reference]; Chao, 2000 [Reference]; National Heart, Lung and Blood Institute, 2000 [Reference]; National Heart, Lung and Blood Institute, 1998 [Reference]; Miller, 1997 [Reference])*.

Specific Roles for Physical Activity in Obesity

Physical activity has several potential roles in obesity: prevention, acute weight loss, long-term weight loss, weight maintenance and metabolic fitness with or without weight loss. A brief review of the literature will be done for each potential role.

- **Prevention of obesity**

  There is general consensus that energy expended in physical activity has the potential to affect energy balance and weight regulation. There is some evidence that physical activity can minimize weight gain *(Jakicic, 2002 [Reference])*. However, physical activity alone cannot be expected to overcome unhealthy eating habits. Both must be balanced to prevent excessive weight gain. Evidence has shown that it takes > 250 minutes/week to maintain weight after weight loss *(Donnelly, 2009 [Reference])*. Individual requirements will likely vary, given age, gender, occupational energy expenditure and habitual caloric intake. The current activity recommendation of 30 to 60 minutes of moderate intensity, five days per week, is a reasonable point of departure for an individualized activity prescription *(Jakicic, 2001 [Reference])*. However, 200-300 minutes/week of moderate-intensity physical activity is recommended for long-term weight loss *(Donnelly, 2009 [Reference])*. Becoming physically active is recognized as an important component of overall behavioral change in obesity. See "Behavioral Management" further in this section.

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- **Acute weight loss**

  Without some control of caloric intake, studies suggest limited weight loss with exercise alone. There is a 2 kg weight loss that is additive to dietary loss when patients exercise more than 150 minutes per week *(Jakicic, 2011 [Reference])*. There appear to be gender differences in exercise effect while on ad libitum diets. Men were more likely to lose weight while women only prevented weight gain *(Donnelly, 2003 [Reference])*. In the HERITAGE Family Study, men and women of various ages (16-65), two races (black and white), and variable body composition were given 20 weeks of cycle ergometry endurance training, three days per week. All measures of body fat decreased with training, and fat-free mass increased. The magnitude of the changes was judged of limited biological significance. Gender differences in training response were noted *(Wilmore, 1999 [Reference])*.

- **Long-term weight maintenance**

  The literature shows more support for the role of physical activity in preventing weight regain *(Pronk, 1994 [Reference]; Jeffery, 1984 [Reference])*. A 16-week randomized controlled trial with a one-year follow-up data on 40 obese women found that diet plus lifestyle activity was a suitable alternative to diet plus structured aerobic activity *(Andersen, 1999 [Reference])*. Total weight loss was not improved with aerobic exercise or strength training, but regular exercisers regained significantly less weight at the one-year follow-up *(Wadden, 1998 [Reference])*. Evidence shows that weight maintenance is improved with > 250 minutes/week of moderate physical activity after weight loss. However, no evidence from well-designed randomized controlled trials exists to judge the effectiveness of physical activity for prevention of weight regain after weight loss *(Donnelly, 2009 [Reference])*.

  Long-term weight maintenance may require as much physical activity as expended during the weight-loss phase. As cited previously, data from the National Weight Control Registry indicates that weight-loss maintainers get one hour or more of moderate activity per day.

- **Metabolic fitness with or without weight loss**

  The beneficial effects of physical activity extend beyond weight loss. There is very strong evidence that physical activity is important in the prevention and management of cardiovascular disease (and related risk factors) and type 2 diabetes mellitus. The literature supports a role for physical activity in improving metabolic syndrome with 5 to 10% weight loss *(Goldstein, 1992 [Reference])*. Intermittent exercise, two 15-minute brisk walks five days per week, did not result in weight loss but did significantly improve HDL and insulin levels in moderately obese females *(Donnelly, 2000 [Reference])*. In men, weight loss induced by increased daily physical activity without caloric restriction reduced abdominal obesity and insulin resistance. Exercise without weight loss reduced abdominal fat and improved cardiovascular fitness but not insulin levels *(Ross, 2000 [Reference])*.

  Obese men and women with impaired glucose tolerance who received lifestyle intervention and exercise counseling had improved weight loss and significantly reduced progression to diabetes *(Tuomilehto, 2001 [Reference])*.

  There are studies of physical activity that do not show an independent metabolic effect beyond weight loss. In obese women, aerobic exercise and resistance exercise had no additional affect over diet alone on weight loss, change in regional adiposity nor improvement in insulin or lipid levels *(Janssen, 2002 [Reference])*.

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Physical activity prescription

Over 20 years ago it was suggested that clinicians write individualized exercise prescriptions *(Gibson, 1983 [Reference])*. The previously introduced National Heart, Lung and Blood Institute and AMA clinician guides on obesity management contain sections on physical activity. Please see Appendix B, "Physical Activity Prescription," for an example of a physical activity prescription.

Certain commercially available products such as pedometers and heart rate monitors may be helpful to patients in order to monitor the daily physical activity levels *(Stovitz, 2005 [Reference])*.

Frequency

In general, three days per week is a minimum frequency to induce physiologic adaptations. Direct improvements in blood pressure or insulin sensitivity require almost daily exercise. Many current activity regimens recommend five or more days per week to reap exercise benefits. From a behavioral perspective, it is better to start with an attainable frequency goal and progress as exercise capacity improves. Having a variety of activities augments greater frequency without onset of boredom or burnout. Enjoyment of physical activity is also a key feature for adherence.

Duration

The recommended duration of activity **for fitness** effects is variable. The traditional cardiovascular fitness guideline was 30 minutes of continuous exercise at 60-80% of maximal heart rate for three to five days per week. The current American College of Sports Medicine position is 30 minutes of moderate-intensity activity on most days per week *(Jakicic, 2001 [Reference])*. Multiple short bouts of exercise for 10 minutes duration also achieved cardiovascular improvement and weight loss with better program adherence *(Jakicic, 1995 [Reference])*. It has been found that moderate-intensity physical activity between 150 and 200 minutes/week will improve weight loss in conjunction with moderate diet restriction. If this amount of physical activity is used alone without diet restriction, there is only modest weight loss *(Donnelly, 2009 [Reference])*.

The Institute of Medicine has recommended 60 minutes a day of total physical activity time t**o control body weight**. Prescribing a weekly energy expenditure of 2,500 kcal (~ 300 cal /day) improved weight loss for overweight men and women compared to the standard 1,000 kcal/week (~150 cal/day) *(Jeffery, 2003 [Reference])*.

Intensity

The appropriate intensity of activity is difficult to adjust for individual patients. The obese, physically deconditioned patient will have greater effort and perceived exertion at lower levels of exercise. At-risk, obese patients with cardiovascular disease may warrant a treadmill evaluation to benchmark their current exercise tolerance. Appropriate intensity may be estimated by the patient's ability to talk during activity. Inability to converse suggests a fairly rigorous effort that will be difficult to sustain. Excessive intensity of activity increases the risk of injury and likelihood of lost activity time. It is better to start at a sustainable intensity level and progress as tolerated to continue improvement. Varying the intensity level by adding intermittent hills or stairs will also improve capacity. Slowing the pace to recover breathing and complete the duration of the exercise session is preferable.

Physical activity intensity can be quantified by caloric expenditure per minute or hour. The estimation of calories used depends on weight and intensity of movement. There are extensive reference tables for caloric expenditure by occupation, household activities, recreation and sports *(Katch, 1993 [Reference])*. See Table 7 as an example.

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Table 7: Energy Expended in Common Physical Activities

Light (less than 3.0 metabolic equivalent task (METs)or less than 4 kcal/min)	Moderate (3.0-6.0 METs or 4-7 kcal/min)	Hard/Vigorous (greater than 6.0 METs or greater than 7 kcal/min)
Walking slowly (strolling) (1-2 mph)	Walking briskly (3-4 mph)	Walking briskly uphill or with a load
Cycling, stationary (less than 50 W)	Cycling for pleasure or transportation (less than or equal to 10 mph)	Cycling, fast or racing (greater than 10 mph)
Swimming, slow treading	Swimming, moderate effort	Swimming, fast treading or crawl
Conditioning exercise, light stretching	Conditioning exercise, general calisthenics	Conditioning exercise, stair ergometer, ski machine
——	Racquet sports, table tennis	Racquet sports, single tennis, racquetball
Golf, power cart	Golf, pulling cart or carrying clubs	——
Bowling	——	——
Fishing, sitting	Fishing, standing/casting	Fishing in stream
Boating, power	Canoeing leisurely (2.0-3.9 mph)	Canoeing rapidly (greater than or equal to 4 mph)
Home care, carpet sweeping	Home care, general cleaning	Moving furniture
Mowing lawn, riding mower	Mowing lawn, power mower	Mowing lawn, hand mower
Home repair, carpentry	Home repair, painting	——

Source: Journal of the American Medical Association, 1995 Feb 1; 273(5):404.

As a rule of thumb, sitting at rest or reading consumes ~ 1 kcal/minute. An average-weight person burns approximately 5 kcal/minute walking, 10 kcal/minute jogging a 10-minute mile and 15 kcal/minute running a 7-minute mile. These same activities done by someone weighing 300 lbs. approximately double the energy expenditures.

Another measure of activity intensity is the metabolic equivalency. The metabolic equivalency is defined as the energy expenditure for sitting quietly at rest. For the average adult this is 1 kcal/kg body weight/hour. A compendium of activities with their metabolic equivalency values can be used to estimate total energy expenditure: (metabolic equivalency value for the activity) x (weight in kgs) x (activity time) *(Ainsworth, 2000 [Reference]; Ainsworth, 1993 [Reference])*.

The recommended daily goal for physical activity ranges from 150 calories (kcal) to 300 calories. An initial level of physical fitness must be established to sustain the duration of activity at moderate levels that is required for weight loss. A pound of body fat contains 3,500 kcal of energy and can sustain 35 miles of walking for the average-weight person. Energy expenditure by physical activity is easily negated by uncontrolled caloric intake. A moderate level of physical activity (5 kcal/min) for 30 minutes expends 150 kcal. This is equivalent to 15 french fries, 15 snack chips or one 12-ounce can of sugared beverage. Physical activity and nutritional recommendations must be coordinated in any weight-management effort.

Although there is consensus on the value of physical activity in obesity management, there is not a standard format for recommending physical activity. The closest examples in the literature are Project PACE (Physician-based Assessment and Counseling for Exercise) *(Patrick, 1994 [Reference])* and the Activity Pyramid developed by Norstrom at Park Nicollet HealthSource *(Park Nicollet Medical Foundation, 1999 [Reference])*.

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Office-based assessment of physical activity was pioneered by Project PACE. The one-page questionnaire determines the patient's level of physical activity and readiness to increase activity. The counseling protocols are designed to tailor the message to different patient needs. The program may be administered by clinicians, nurses or other health professionals *(Patrick, 1994 [Reference])*.

Written advice to exercise was found to be more effective than just verbal recommendation *(Swinburn, 1998 [Reference])*. Yet, activity prescriptions seem more difficult to write than drug prescriptions. Individualized activity prescriptions appear to be very context-dependent. They must take into account individual motivation, self-efficacy, type of activity, available resources, potential physical constraints or possible medical contraindications *(CME Resource, 2004 [Reference])*. The "dosages" must be individualized to current patient capacity and then titrated toward improvement *(Bhaskarabhatla, 2004 [Reference]; Ward, 1991 [Reference])*. The time course for expected improvement also varies across patients.

Patient handouts for improving physical activity can be very informative and helpful but often have a target population in mind. Handouts for older patients *(Barry, 1993 [Reference])*, "Walking Your Way to Feeling Better" and "Getting Stronger by Using Weights," can be extended to obese patients with similar current activity capacity.

A prototype general Physical Activity Prescription is offered in Appendix B. It represents a composite of key features suggested from the literature *(CME Resource, 2004 [Reference]; Patrick, 1994 [Reference])*. It has not been evaluated and is intended only as a suggestion for operationalizing the written physical activity prescription. The ICSI Obesity Guideline work group will continue to search for an evidence-based activity prescription format.

An example of a physical activity questionnaire can be found in the American Medical Association's "Road Maps for Clinical Practice – Assessment and Management of Adult Obesity" at http://www.ama-assn.org/ama/pub/category/10931.html, booklet 5, figure 5.1.

Behavioral Management

Self-monitoring of weight, nutrition and activity

A key component of successful weight loss and maintenance is regular self-monitoring of energy intake, expenditure and body weight. Participants in weight-loss trials who regularly self-monitor their diet and activity tend to lose more weight compared to those who don't *(Boutelle, 1999 [Reference]; Boutelle, 1998 [Reference])*. Regular monitoring of weight is also a predictor of successful weight control. Evidence from the National Weight Control Registry (NWCR), which was created to compile data on individuals who were successful at losing at least 13.6 kg and maintaining that loss for one year or more, shows that over 75% of these successful weight-loss maintainers report weighing themselves at least once a week *(Klem, 1997 [Reference])*.

Patients should be encouraged to keep track of their dietary intake, physical activity level and body weight. Dietary intake and activity should be recorded on a daily basis, and weight should be recorded on a weekly basis. For example, see the American Medical Association's "Road Maps for Clinical Practice – Assessment and Management of Adult Obesity," http://www.ama-assn.org/ama/pub/category/10931.html, booklet 8, figures 4.2 and 5.7.

Additional behavioral modification strategies that play a key role in successful weight loss and maintenance include:

Stimulus control: Stimulus control refers to a set of behavioral procedures designed to help people reduce environmental cues associated with eating behavior and inactivity. Individuals should be taught to limit the presence of high-calorie/high-fat foods in the home; to reduce the visibility of unhealthy food choices in the home; to limit where and when they eat; to avoid distractions when eating, such as television watching; and to eat more slowly.

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Cognitive restructuring: Negative thinking (e.g., perfectionistic thinking, dichotomous/"all-or-none" thinking, pessimistic thinking and self-doubt) often interferes with behavior change efforts. Individuals need to be taught to identify negative thoughts that interfere with their weight-loss efforts and counter them with positive self-statements that promote adherence to healthy eating and activity patterns.

Goal setting: Individuals need to be taught the importance of setting short-term goals for enhancing motivation; setting daily and weekly goals that are reasonable and attainable for eating, physical activity and weight loss should be encouraged.

Problem solving: Teaching problem-solving strategies to deal with barriers to changing eating and physical activity patterns is an important component of weight-loss intervention. Strategies such as defining the problem, brainstorming solutions, selecting a solution, and evaluating the success of the solution are recommended.

Social support: Spouses, family members, friends and co-workers can serve as both barriers and facilitators of successful weight loss. Individuals need to be able to engage their social support systems in ways that facilitate weight loss, eating and physical activity behavior change. Participants may also benefit from learning how to be assertive in social situations involving eating and physical activity so that they can adhere to their behavior change efforts.

Relapse prevention: Restarts are common in behavior change. Patients who relapse should be encouraged to try again when they are ready. In fact, a permanent change may never be achieved.

The relapse prevention model (RPM), originally developed to address cognitive and behavioral factors associated with the relapse process for addictive behaviors (e.g., alcohol abuse) *(Marlatt, 1984 [Reference]),* has been shown to be helpful for long-term weight management *(Baum 1991 [Reference]; Perri, 1984 [Reference])*. A key component of relapse prevention model is its distinction between "lapses" and "relapse." Lapses are defined as a "single event, a reemergence of a previous habit, which may or may not lead to the state of relapse," whereas "relapse" refers to a full return to an unhealthy state. An individual's response to a "lapse" is thought to determine the likelihood of relapse. The "abstinence violation effect" is the reaction to a behavioral slip, guilt and perceived loss of control; when this occurs an individual is more likely to experience a full relapse. Alternatively, when framed as a "lapse," people can respond proactively to a slip in behavior, thus avoiding complete relapse. Additional relapse prevention strategies may include helping individuals manage lapses in behavior, identifying high-risk situations for relapse, enhancing skills for coping with these situations and increasing self-efficacy for avoiding relapse *(Larimer, 1999 [Reference])*.

Behavior therapy: includes nutrition and physical activity; for the treatment of obesity it has often produced poor long-term results and has led to an increased interest in a drug treatment component.

Follow-up

Weight loss requires frequent follow-up (initially weekly) with planned education/counseling by health care clinicians to be most effective (i.e., improve adherence) *(Rejeski, 2002 [Reference]; Tuomilehto, 2001 [Reference]; Chao, 2000 [Reference]; National Heart, Lung and Blood Institute, 2000 [Reference])*.

Pharmacologic Therapy

Pharmacotherapy, when used for six months to one year, along with lifestyle modification including nutrition and physical activity, produces weight loss in obese adults. Behavioral modification programs including dietary and exercise counseling typically result in a 5% weight loss *(Klein, 2002 [Reference])*. The average weight loss with pharmacological agents is 10-15% of initial weight *(Frank, 2004 [Reference])* or 2-10 kg (4.4 to 22 lbs). However, it is not possible to predict the exact amount of weight an individual may lose. Most of the weight loss with these agents will occur during the first six months of therapy. The amount of weight lost with medications is more likely to be maintained if medications are able to be continued long term. Therefore, medications for obesity are most effective if they are continued indefinitely, unless weight is regained or if significant side effects develop.

Weight-loss drugs should only be used as part of a comprehensive weight-loss regimen that includes a low-calorie diet, increased physical activity and behavior therapy. If a patient has been on a combination regimen that includes nutrition therapy, physical activity and behavior modification and has not lost 1 lb./week, the addition of pharmacotherapy should be considered.

Patients considered for pharmacotherapy should have a body mass index of greater than or equal to 30 or a body mass index of greater than or equal to 27 with concomitant obesity-related risk factors or diseases. The risk factors and diseases that are serious enough to support pharmacotherapy at a body mass index of 27 to 29.9 include hypertension, dyslipidemia, CVD, type 2 diabetes, fatty liver disease and sleep apnea.

Medication therapy should consist of an initial trial period with a single drug to establish efficacy in a given patient. If a patient does not respond to a drug with reasonable weight loss, the patient should be evaluated to determine adherence with the medication regimen and adjunctive therapies, or to consider the need for a dosage adjustment. If the patient continues to be unresponsive to the medication, or serious adverse effects occur, the medication should be discontinued.

Patients who respond to pharmacotherapy should lose at least 2 kg (4.4 lb.) in the first four weeks after initiating therapy. If a patient has not lost 2 kg (4.4 lb.) in the first four weeks, the chance of a long-term response is low and they may be considered non-responders. The amount of weight lost in the first four weeks may be used as a guide to subsequent therapy. Medication can be continued in patients meeting the appropriate response criteria. Consideration should be given to stopping medication in those patients who fail to meet the four-week weight-loss guide. Successful therapy is characterized by weight loss in the first six months of therapy or weight maintenance after the initial weight-loss-phase, and consideration should be given to continued use of medication. Drug therapy may be continued as long as there is a clinical response and there are no serious or unmanageable adverse effects. Patients should be monitored for adverse events as long as they continue on a medication regimen.

Patient monitoring

Patient monitoring is important once weight-loss medications have been initiated. A suggested monitoring schedule would include return visits between two and four weeks, then monthly for three months, and then every three months for the first year after starting the medication regimen. The purpose of these visits would be to measure weight, BMI, waist circumference, blood pressure and heart rate to assess any adverse effects, and to conduct laboratory tests and answer questions.

Therapy should be considered successful if, after six months of therapy, a weight loss of greater than or equal to 10% of body weight is achieved and there have been no serious adverse effects from the medication. After six months of drug therapy, the rate of weight loss generally reaches a plateau, and weight maintenance should take priority. To achieve additional weight loss, lifestyle modifications to further decrease caloric intake and increase energy expenditure should be implemented.

To be considered successful weight maintenance, weight regain should be less than 3 kg (6.6 lb.) in two years and there should be a sustained reduction in waist circumference of at least 4 cm *(National Heart, Lung and Blood Institute/NIH, 1998 [Reference])*.

Please see Appendix C, "FDA-Approved Medications for the Treatment of Obesity," for more information.

Phentermine

Phentermine is an appetite suppressant with stimulant-like properties that is approved for the treatment of obesity. It is widely available in the United States and is effective in weight loss. In one large meta-analysis study, phentermine was associated with an average of 3.6 kg (7.9 pounds) additional weight loss at six months as compared to placebo *(Pharmacological and Surgical Treatment of Obesity, Shekelle, 2003 (Reference))*. Three long-term studies have been done with phentermine, ranging from 14 weeks to 36 weeks and showing an average weight loss of 8.7 to 13% body weight compared to 2 to 5.1% with placebo.

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Patients taking phentermine or any other anorexiant should have their blood pressure monitored carefully during treatment due to the possibility of increased blood pressure as a side effect of this medication. However, one study showed no significant differences in blood pressure between placebo-treated patients and patients treated with phentermine *(Kim, 2006 [Reference])*.

Due to its anticholenergic effects, phentermine can cause severe constipation and severe dry mouth. Usually however, these side effects are relatively mild and are manageable. Insomnia can also occur but usually resolves if the patient continues to take this medication; it can be minimized by prescribing any afternoon dose to be taken by 3:00 p.m.

While phentermine is indicated as short-term monotherapy as an adjunct in the management of exogenous obesity in patients with initial body mass index (BMI) of > or = 30 or > or = 27 in the presence of other risk factors, it is often prescribed long term (off-label use). As mentioned earlier, most of the weight loss with these agents will occur during the first six months of therapy. The amount of weight lost with medications is more likely to be maintained if it is possible for these medications to be continued long term. Therefore, medications for obesity are most effective if they are continued indefinitely, unless weight is regained or if significant side effects develop.

As also mentioned earlier, anorexiant medications are typically less effective if not combined with dietary and exercise counselling. It is recommended that anorexiant medications be stopped if the patient does not continue appropriate dietary changes and a documented exercise program or is not maintaining weight loss.

Amphetamines have been used in the past to treat obesity but are not approved and may have dangerous side effects. Fenfluramine was combined with phentermine in the late 1990s (phen-fen) and resulted in significant weight loss but was associated with cardiac valvular insufficiency and pulmonary hypertension, and was withdrawn from the market. Phentermine, when used in isolation, is not associated with a significant risk of pulmonary hypertension or regurgitant valvular heart lesions.However, patients who receive long-term anorexiant therapy (off-label use) should be carefully evaluated for dyspnea, chest pain, syncope and edema.

Orlistat

Orlistat is another FDA approved medication for the treatment of obesity.

The adverse events of orlistat are mainly gastrointestinal. Absorption of the drug is minimal.

Table 8: Incidence of Adverse Events Commonly Observed During the First Year of Treatment

Adverse Event	Orlistat	Placebo
Oily spotting	26.6%	1.3%
Flatulence	23.9%	1.4%
Fecal urgency	22.1%	6.7%
Oily stool	20.0%	2.9%
Oily evacuation	11.9%	0.8%
Increased defecation	10.8%	4.1%
Fecal incontinence	7.7%	0.9%

Most common adverse reactions were mild and transient, and decreased during the second treatment year. Events usually began within the first three months of therapy. Approximately 50% of all episodes of GI adverse events lasted for less than one week, and most lasted for no more than four weeks. However, adverse GI events may occur in some individuals over a period of six months or longer.

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Adherence with a low-fat diet containing less than 30% of calories derived from fat can lessen or avoid the fat-intake-related adverse effects. Since orlistat is useful only if taken with a meal containing some fat, a dose should be skipped when a meal is fat-free. Cardiac abnormalities have not been reported in association with the use of orlistat.

In May 2010, the FDA approved a revised label for orlistat that included new safety information about cases of severe liver injury that are reported rarely with use of the drug. New warnings about reports of rare liver injury were also added to the label of the over-the-counter version of orlistat.

The new safety information is based on an FDA review that identified 13 total reports of severe liver injury with orlistat: 12 foreign reports and one U.S. report with the over-the-counter version. A cause and effect relationship of severe liver injury with orlistat use has not been definitively established because of the following factors:

- One U.S. case with Alli and 12 foreign cases with Xenical reported between 1999 and 2009 out of an estimated 40 million people who have used one of the two products.
- Some patients in the reported cases also used other drugs or had other conditions that may have contributed to the development of severe liver injury.
- Severe liver injury can occur in people not taking drugs and without a distinct cause.

The primary intent of the FDA in requiring the addition of the information about reported cases of liver injury to the label of orlistat is to educate the public about the signs and symptoms of liver injury and the need to see a clinician promptly should they occur.

Efficacy

Patients taking orlistat as part of a program of nutritional and physical activity changes can expect a weight loss of 3.9 to 10.6 kg after one year of treatment and 4.6 to 7.6 kg after two years of treatment. A weight loss of at least 5% of initial body weight at one year is reported by 30 to 73% (vs. 13 to 45% of patients taking placebo); a weight loss of at least 10% of initial body weight at one year is reported by 10 to 41% (vs. 4 to 21% of patients taking placebo *(Torgeson, 2004 [Reference]; Rissanen, 2003 [Reference]; Hauptman, 2000 [Reference]; Rössner, 2000 [Reference]; Sjöström, 1998 [Reference])*.

Drug interactions

The potential for drug-drug interactions should be assessed before initiating therapy with weight-loss agents.

Phentermine is contraindicated for use with MAO inhibitors, and it should not be started within 14 days of discontinued MAOI. Phentermine should be used with caution with SSRIs or stimulant medications.

Orlistat has also been shown to reduce serum concentrations of fat-soluble vitamins (vitamins A, D, E and K). Although most patients' plasma levels remained within normal ranges during clinical trials, a daily multivitamin supplement containing fat-soluble vitamins at bedtime is recommended. Caution should also be exercised with concomitant use of orlistat and other lipophilic drugs, as their overall bioavailability may be compromised.

With orlistat, patients should have their cyclosporine levels monitored more frequently. Increased monitoring should also apply to patients taking other medications with a narrow therapeutic index, such as warfarin, that could be affected by fat malabsorption.

Summary

- As an adjunct to intensive nutritional and lifestyle changes, both phentermine and orlistat are associated with greater weight loss than placebo.

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- When on orlistat, gastrointestinal side effects are common, but the frequency and severity decrease over time (typically after one week) and can be reduced by careful attention to dietary fat content.
- Medical opinion is currently shifting toward the need for chronic pharmacological therapy in obesity, as it is a chronic disease. However, with the current paucity of weight-loss medications available, this remains a clinical challenge.
- The long-term safety of phentermine and other anorexiants, as well as orlistat, is unknown. Therefore, more studies need to be done on the safety and efficacy of weight-loss medications used for the long-term treatment of obesity.

Qsymia

Qsymia is a combination of two FDA-approved drugs, phentermine and topiramate in an extended-release formulation. The drug was approved in July 2012.

Regulatory history

The original New Drug Application (NDA) for phentermine/topiramate was submitted to the Food and Drug Administration under the brand name QNEXA in December 2009 and was reviewed in July 2010. The medication name was later changed and approved under the brand name Qsymia.

The NDA included results of a clinical development program conducted by the manufacturer involving the efficacy and safety of three doses of QNEXA for the treatment of obesity. FDA found no deficiencies pertaining to the establishment of QNEXA efficacy in the NDA. FDA did, however, issue a Complete Response Letter (CRL) for QNEXA in October 2010 based on two safety concerns related to the approved component products.

The CRL requested a comprehensive assessment of the teratogenic potential of topiramate and phentermine/topiramate, including a plan and strategy to evaluate and mitigate potential teratogenic (orofacial cleft) risks in women of childbearing potential. The CRL also requested evidence that the QNEXA-associated heart rate elevations (mean of 1.6 bpm at the highest dose) do not increase the risk for major adverse cardiovascular events.

Significant improvements were noted in blood pressure, waist circumference, lipids, blood glucose and inflammatory biomarkers with phentermine/topiramate compared to placebo. Improvements were most pronounced in patients with pre-existing comorbid diseases *(Gadde, 2011 [Reference])*.

The FDA approved Qsymia with a Risk Evaluation and Mitigation Strategy (REMS), which includes a Medication Guide advising patients about important safety information, a patient brochure and a formal training program for prescribers. The purpose of the REMS is to inform prescribers and their patients about the increased risk of birth defects associated with first-trimester exposure to Qsymia, the need for pregnancy prevention and the need to discontinue therapy if pregnancy occurs. For prescribing processes, see http://www.qsymia.com/hcp/pharmacists.aspx.

In addition, Vivus Inc., the sponsor, will be required to conduct several post-marketing requirements, including a long-term cardiovascular outcomes trial to assess the effect of Qsymia on the risk for major adverse cardiac events such as heart attack and stroke.

Indications and use

Phentermine is indicated for short-term weight loss in overweight or obese adults who are exercising and eating a reduced-calorie diet. Topiramate is indicated to treat certain types of seizures in people who have epilepsy and to prevent migraine headaches.

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Phentermine is a sympathomimetic amine with pharmacologic activity similar to amphetamine and is commonly known as anorectice or anorexigenic. The mechanism of action on weight management is mediated by release of catecholamines resulting in reduced appetite and decreased food consumption. Because of the phentermine component, Qsymia is a CIV controlled substance.

The exact mechanism of action of topiramate on chronic weight management is unknown but may be due to both appetite suppression and satiety enhancement through a variety of actions.

Qsymia is indicated as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adults with:

- A body mass index of 30 kg/m^2 or greater (obese)
- 27 kg/m^2 or greater (overweight) who also have at least one weight-related comorbidity such as hypertension, type 2 diabetes mellitus, or dyslipidemia

Qsymia is available in four combination capsule strengths and is taken once daily in the morning. Evening administration should be avoided due to the possibility of insomnia. Treatment is started with the lowest strength combination (phentermine 3.75 mg/topiramate 23 mg extended-release) for 14 days and then increased to the next higher strength (phentermine 7.5 mg/ topiramate 46 mg extended-release). Clinicians may prescribe a 30-day supply with five refills.

Patients should be evaluated for weight loss after 12 weeks of treatment. If a patient has not lost at least 3% of baseline body weight on Qsymia 7.5 mg/46 mg, the medication should either be discontinued or the dosage should be increased.

For dose escalation, Qsymia is increased to 11.25 mg/69 mg daily for 14 days, followed by 15 mg/92 mg daily.

Weight loss should be evaluated following dose escalation to 15 mg/92 mg after an additional 12 weeks of treatment. If the patient has not lost at least 5% of baseline body weight, it is unlikely that the patient will achieve and sustain clinically significant weight loss with continued treatment, and the medication should be discontinued. The 3.75 mg/23 mg and 11.25 mg/69 mg strengths are intended only for titration purposes.

Qsymia 15 mg/92 mg should be discontinued gradually by dosing every other day for at least one week before stopping completely because of the possibility of inducing a seizure. Dosing adjustments are necessary for patients with renal or hepatic impairment.

Contraindications, warnings and precautions

Qsymia is contraindicated in patients who are pregnant or who have glaucoma, hyperthyroidism, a known hypersensitivity or idiosyncrasy to sympathomimetic amines, or who are taking or have taken within the past 14 days a monoamine oxidase inhibitor.

Qsymia must not be used during pregnancy because it can cause harm to a fetus. Data from pregnancy registries and epidemiology studies show that a fetus exposed to topiramate, which is a component of Qsymia, in the first trimester of pregnancy has an increased risk of oral clefts (cleft lip with or without cleft palate).

Females of reproductive potential must not be pregnant when starting Qsymia or become pregnant while taking Qsymia. Females of reproductive potential should have a negative pregnancy test before starting Qsymia and every month while using the drug, and should use effective contraception consistently while taking Qsymia. If a patient becomes pregnant while taking Qsymia, treatment should be immediately discontinued.

Qsymia can increase resting heart rate; this drug's effect on heart rate in patients at high risk for heart attack or stroke is not known. The use of Qsymia in patients with recent (within the last six months) or unstable heart disease or stroke is not recommended. Regular monitoring of heart rate is recommended for all patients taking Qsymia, especially when starting Qsymia or increasing the dose.

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Antiepileptic drugs including topiramate can increase the risk of suicidal thoughts or behavior in patients who are taking them for any indication. Patients on Qsymia should be monitored for the development or worsening of depressing, suicidal thoughts or behavior and any unusual changes in mood or behavior. Qsymia use should be avoided in patients with a history of suicidal attempts or active suicidal ideation and should be discontinued if a patient experiences suicidal thoughts or behavior.

Qsymia can also cause mood disorders, including depression and anxiety, insomnia and cognitive dysfunction (such as impaired concentration and attention, memory difficulties, and problems with language and speech). Dosage reduction or drug discontinuation may be required.

Acute myopia associated with secondary angle closure glaucoma has been reported in patients taking topiramate. Symptoms include acute onset of decreased visual acuity with or without ocular pain. The primary treatment is to discontinue topiramate-containing Qsymia.

Hyperchloremic, non-anion gap, metabolic acidosis with a decreased serum bicarbonate level (below the normal reference range and not related to chronic respiratory alkalosis) has been reported. Concomitant use of Qsymia and a carbonic anhydrase inhibitor may increase the severity of metabolic acidosis and may also increase the risk of kidney stone formation. It is recommended that serum electrolytes including bicarbonate be measured prior to and during therapy with Qsymia.

Qsymia may also increase serum creatinine, and measurement of serum creatinine prior to and during therapy is recommended.

Patients with hypertension or type 2 diabetes should be monitored closely. Qsymia has been shown to improve glucose control and blood pressure. Thus, patients may need to have medications adjusted or discontinued as they lose weight.

The most common adverse reactions identified during clinical trials and occurring at a rate of greater than or equal to 5% and at a rate of at least 1.5 times greater than placebo include paresthesia, dizziness, dysgeusea, insomnia, constipation and dry mouth.

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Qsymia Clinical Trial Results

Table 9. 56-Week Trial Results

Analysis	EQUIP (BMI greater than 35 kg/m^2)			CONQUER (BMI 27-45 mg/m^2 plus two or more comorbidities)		
	Placebo	Qsymia 3.75 mg/23 mg	Qsymia 15 mg/92 mg	Placebo	Qsymia 7.5 mg/46 mg	Qsymia 15 mg/92 mg
Number	514	241	512	994	498	995
Baseline mean weight in kg	115.7	118.6	115.2	103.3	102.8	103.1
Weight loss as a percentage of baseline weight	1.6%	5.1%	10.9%	1.2%	7.8%	9.8%
Percentage of patients with ≥ 5% Weight loss	17.3%	44.9%	66.7%	21%	62%	70%
Percentage of patients with ≥ 10% weight loss	7%	19%	47%	7%	37%	48%

Table 10. 108-Week Extension Trial Results

Analysis	SEQUEL (52 week extension trial for patients completing the CONQUER trial)		
	Placebo	Qsymia 7.5 mg/46 mg	Qsymia 15 mg/92 mg
Number	227	153	295
Weight loss as a percentage of baseline weight	1.8%	9.3%	10.5%
Percentage of patients with ≥ 5% Wt loss	30%	75.2%	79.3%
Percentage of patients with ≥ 10% weight loss	11.5%	50.3%	53.9%

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2013 review Lorcaserin (Belviq)

Lorcaserin is intended for weight management as an adjunct to life style changes of reduced calorie intake and increased activity. Patients with a BMI of > 30 kg/m^2 or a BMI of > 27 kg/m^2 with an additional weight related comorbid condition (hypertension, type 2 diabetes, dyslipidemia) qualify for lorcaserin.

Pharmacology: Lorcaserin is a selective serotonin 2C receptor agonist. The exact mechanism of action is not known; however, it is believed to achieve satiety by selectively activating the 5-HT2c receptors on anorexigenic pro-opiomelonocortin neurons in the hypothalamus.

Extensively metabolized by the liver, lorcaserin has a half-life of 11 hours and is primarily excreted in the urine.

Dose: Recommended adult dose and maximum dose for lorcaserin is 10 mg twice daily with or without food. Weight-loss progress should be monitored after 12 weeks. Discontinue lorcaserin if patients have not lost > 5% of their baseline weight. No dosage change has been recommended for the elderly. Lorcaserin is not recommended for children under the age of 18. Do not use lorcaserin in severe renal impairment (Cl_{cr} < 30 mL/minute) and use with caution in severe hepatic impairment. Use in ESRD is not recommended as this has not been studied.

Cautions: Lorcaserin has the potential to cause serotonin syndrome like effects and should not be used with other drugs that can cause this potentially life-threatening syndrome. If symptoms of serotonin syndrome appear, lorcaserin should be discontinued.

Mitral valve regurgitation has been linked with lorcaserin through its seratonergic pathway. If signs and symptoms of valvular disease appear, it may be necessary to discontinue lorcaserin. Use with caution in patients with a history of bradycardia or heart block greater than first degree.

Lorcaserin can cause cognitive impairment, leading to memory and attention changes. Caution patients with the operation of hazardous machinery when starting lorcaserin.

Do not exceed the maximum dose of 10 mg twice daily, as psychiatric disorders of euphoria and dissociation have been reported. Monitor patients for suicidal thoughts.

Lorcaserin has abuse potential when taken in dosages exceeding the maximum dose of 10 mg twice daily. The U.S. Drug Enforcement Agency (DEA) is evaluating lorcaserin for abuse potential and possible controlled classification.

Monitor blood glucose when taking lorcaserin with antidiabetic drugs, as additional weight loss can cause hypoglycemia.

Priapism has been associated with lorcaserin. Use with caution in patients predisposed to priapism.

Lorcaserin can cause a decrease in red and white blood cell count. Monitor patient's complete blood count while taking this drug.

Lorcaserin moderately elevates prolactin. Prolactin should be measured when patient's exhibit signs and symptoms of excessive prolactin.

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Table 11. Incidence of Adverse Reactions

Adverse Reactions	Percent
Headache, hypoglycemia, decrease in lymphocytes, back pain, upper respiratory tract infection, nasopharyngitis	> 10%
Peripheral edema, hypertension, valvulopathy, dizziness, fatigue, anxiety, insomnia, depression, cognitive impairment, psychiatric disorders, rash, diabetes melatis exacerbation, prolactin increased, nausea, diarrhea, constipation, xerostomia, vomiting, gastroenteritis, toothache, appetite decreased, UTI, hemoglobin decreased, neutrophils decreased, muscle spasm, muscle pain, eye disorders, oropharyngeal pain, sinus congestion, seasonal allergy, stress	1-10%
Bradycardia, dissociation, euphoria, serotonin syndrome, suicidal ideation	< 1%

Contraindications: Lorcaserin is contraindicated in pregnancy, risk factor X, and should not be taken by nursing mothers.

Drug/Drug Interactions: Lorcaserin is a selective serotonin 2C receptor agonist with the potential to cause serotonin syndrome (sweating, hyperthermia, tachycardia). Care should be taken when prescribing lorcaserin with other drugs that work through the seratonergic pathway, as the potential for serotonin syndrome can be enhanced.

Clinical Trials: Approval of lorcaserin was based on three one-year randomized double-blind studies in obese and overweight adults.

In the Bloom trial, subjects who lost > 5% of their body weight in the first year were randomized to continue lorcaserin in year two or switch to a placebo. At the end of year, two patients who continued with lorcaserin had regained 25% of their initial weight loss and those who took lorcaserin during year one and were switched to a placebo for year two lost an average of 1.2 kg more than those who took placebo during year one.

Table 12. 52-week trial results

Trial	Average baseline weight	Mean weight loss (52 wks)	Dose	Number	Percentage of patients with ≥ 5% weight loss
BLOOM	100 kg	5.8 kg	10 mg twice daily	1,538	47.5%
Placebo		2.2 kg		1,499	20.3%
BLOSSOM	100 kg	4.7 kg 5.8 kg	10 mg daily 10 mg twice daily	801 1,602	40.2% 47.2%
Placebo		2.9 kg		1,601	25%
BLOOM DM	102-106 kg	5 kg 4.7 kg	10 mg daily 10 mg twice daily	95 251	44.7% 37.5%
Placebo		1.6 kg		248	16.1%

Conclusion: As an adjunct to diet and exercise, lorcaserin offers some success with increased weight loss during the first year of therapy. However, further weight loss is not seen in year two of therapy.

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Non-Prescription and alternative medicine

Numerous products, touted as weight-loss preparations, are available to patients without a prescription. These products contain a wide range of ingredients either alone or in combination.

Alternative therapy agents have become attractive options for the treatment of obesity. Herbal and dietary supplements are thought to be natural products and perceived to be safer than prescription medications. Also, patients do not perceive a need to seek professional assistance with these products. Obese patients with limited financial resources may find this to be a cheaper solution. Other patients choose alternative therapies after previous failed attempts at weight loss with more conventional treatments.

No long-term data (longer than one year) is available for any of these herbal agents. While there has been a growing popularity and interest in herbal therapies, there is no adequate data to support their use for weight loss. The short- and long-term adverse effects of these agents are largely unknown. Since many herbal products are not standardized, the content of the ingredients can vary substantially from the label and among lots of the same product *(Gurley, 2000 [Reference])*. Patients who use non-prescription or herbal preparations should be cautioned about adverse effects, drug interactions and the potential impurities of herbal products *(Miller 1998 [Reference]; Winslow, 1998 [Reference])*. The combination of these agents with 500-calorie diets is not safe and should be discouraged.

Safety and adverse effects

The safe and effective use of any weight-loss drug beyond two years has not been established.

Clinicians considering pharmacotherapy should obtain complete medication histories on their patients including the use of other prescription, non-prescription or herbal preparations for weight loss before recommending or prescribing prescription weight-loss medications.

Adverse side effects from the use of weight-loss drugs have been observed in patients. Dose-related minor effects may occur soon after beginning therapy. These effects are often mild and spontaneously resolve over time. Initial adverse effects can be avoided or minimized by:

- adjusting dosage and administration schedules,
- identifying patients at high risk for adverse effects and selecting drug therapy accordingly, and
- providing patient education and monitoring for adverse effects at the beginning of therapy or when making dosage adjustments

Infrequent, but potentially serious, effects can also occur much later in the course of therapy.

The practice of combination drug therapy for obesity may increase the frequency of adverse events. Using the lowest possible effective dose may also reduce the chance of an adverse event.

None of the weight-loss drugs is approved for use in pregnant or lactating women, and the safe use of these drugs in pregnant or lactating women has still not been determined.

Surgery for Obesity

Introduction

Bariatric operations are tools designed to produce substantial weight loss in patients who are morbidly obese. Bariatric surgery should be considered as an adjunct to the overall treatment paradigm, rather than as a separate and independent therapy for obesity. Please see Table 13, "Overview of Bariatric Procedures" and Appendix D, "Overview of Bariatric Procedures" for more information.

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Patient selection

Patients undergoing bariatric surgery must be aware of operative and longer-term risks. While BMI criterion may be a starting point for determining appropriate candidates to undergo surgery, additional factors contribute to determining appropriate candidacy for surgery.

The current indications, for bariatric surgery include:

- Body mass index greater than 40 kg/m^2.
- Body mass index greater than 35 kg/m^2 with significant comorbid illness including diabetes, hypertension, dyslipidemia, sleep apnea, cardiovascular disease, gastroesophageal reflux disease and pseudotumor cerebri.
- Other indications may include need for significant weight loss in order to facilitate solid organ transplant operations, abdominal wall hernia repair or joint replacement.
- Medical management to (a) exclude untreated endocrinopathies, (b) stabilize medical problems including hypertension and type 2 diabetes, and (c) demonstrate patient compliance, including preoperative weight loss and smoking cessation.
- Psychologic stability as determined in health and behavioral assessment performed by an experienced practitioner.

Shared decision-making

Surgery of any sort is a significant decision for any patient. The informed consent process, while providing a simple framework for explaining the procedure, risks and benefits, doesn't provide a deeper understanding of the patient values, lifestyle changes, or implications for the future. Shared decision-making between the clinician and the patient for bariatric surgery can include some decision support tools to guide the patient as he or she considers this surgery. One resource for evaluating the patient's readiness for shared decision-making is the Ottawa Personal Decision Aid. A decision aid specifically for guiding the patient and family through the pros and cons of surgery and to support the discussion with the clinician can be found here: http://www.healthwise.net/cochranedecisionaid/Content/StdDocument.aspx?DOCHWID. For more discussion on shared decision-making, see Appendix N.

Bariatric surgery for patients with class I obesity (BMI of 3.0-34.9 kg/m^2)

Bariatric surgery might be indicated for a select group of patients with BMI of 30-34.9 kg/m^2, with severe associated comorbid illness.

In a recent randomized trial from Shauer and colleagues, 150 obese patients (BMI 27-43 kg/m^2) with uncontrolled type 2 diabetes were enrolled. Patients were randomized into three arms, including medical therapy, sleeve gastrectomy and Roux-en-gastric bypass. Glycemic control, measured by normalization of HbA1c, was superior in both surgical arms.

A randomized study from O'Brien and colleagues in patients with class I obesity, BMI 30-34.9 kg/m^2 undergoing adjustable banding compared to lifestyle modification, there are substantial improvements over two years in both weight loss and improvement of the metabolic syndrome in the surgical group compared to those who are medically managed *(O'Brien, 2006 [Reference])*.

In a slightly heavier cohort of patients, BMI 30-40 kg/m^2, dramatic improvements were seen in patients with mild (less than two-year history) diabetes. Clearly there are indications that may suggest a role for use of bariatric surgery in patients with obesity who may not meet traditional criteria *(Dixon, 2008 [Reference])*. Laparoscopic adjustable gastric (lap banding) has been approved by the FDA for these patients. More research is needed to clarify which patients would benefit and which procedures are optimal for bariatric surgery.

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Review of bariatric procedures

The most common bariatric procedures performed in the United States include the Roux-en-Y gastric bypass, laparoscopic adjustable gastric banding, the sleeve gastrectomy, and the duodenal switch (SRC). At this juncture, there is little justification for primary bariatric surgery to be done in an open fashion except in the setting of a reoperative abdomen *(Nguyen, 2001 [Reference])*. Functionally speaking, procedures are divided into either a restrictive or a malabsorptive category. The restrictive operations include laparoscopic adjustable banding for which there are two types of bands available on the market, and the vertical sleeve gastrectomy. The malabsorptive group includes the gastric bypass and the duodenal switch operation. The latter group involves varying components of restriction and malabsorption. Table 13, "Overview of Bariatric Procedures," provides selected information about the advantages and limitations of various bariatric procedures. Additional information on each procedure can also be found in Appendix D, "Overview of Bariatric Procedures." See Appendix H, "Band Assessment Protocol," for band adjustment scheduling.

Impact on mortality

Long-term data suggests that bariatric surgery in properly selected patients may reduce overall mortality over a 15-year period compared to conservative medical management. The Swedish obesity study (SOS) demonstrated less percentage chance of mortality for those who underwent surgery. 6.3% in the control group died as compared with 5.0% in the surgery group *(Sjöström, 2007 [Reference])*. Another study by Christou and colleagues reported the mortality rate in the bariatric surgery cohort to be 0.68% compared with 6.17% in controls *(Christou, 2004 [Reference])*. Another study by Adams did note a small increase in suicide rate and accidental death in patients who have undergone gastric bypass operation. Rates of accidental death and suicide were 0.11% in the surgical group and 0.064% in the control group *(Adams, 2007 [Reference])*.

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Table 13. Overview of Bariatric Procedures

		Adjustable Band	Sleeve Gastrectomy	Gastric Bypass	Duodenal Switch
Mechanism	Restrictive	+	+		
	Malabsorptive				
	Both			+	+
Estimated weight loss		45.1% at 1 year	45% at 1 yr	49% at 14 yrs	75% at 12 yrs
Readmission rate		1%	5%	6%	12%
Mortality		0.02	0.2	0.2%	0.4
Contraindications	All procedures: unstable psychological conditions, endocrine disorders, and pregnancy	Esophageal dysmotility Inflammatory bowel disease		Hx of gastric cancer Need for NSAID bile duct pathology, Inflammatory bowel disease	Vegetarians, inflammatory bowel disease
¤Effect comorbid illness					
	Diabetes	++	++	+++	++++
	Hypertension	++	++	+++	++++
	Sleep Apnea	++	++	++	+++
	GERD	+	—	++++	—
¤Failure rate		20-35%	-	9-18%	-
Complications and Side Effects	All procedures: hair loss, excess skin, nausea, vomiting and dehydration	Slippage Erosion Concentric dilation Port-related problems	Leak Stenosis Bowel obstruction	Nutritional Leak Stricture Marginal ulcer Bowel obstruction Internal hernia	Malnutrition Leak Stricture Bowel obstruction
Common Nutritional Deficiencies *(See Appendix G)*		N/A Except in the presence of complications		Iron B12 Thiamine	Vitamins A, D, E, K
Anatomical workups		UGI including motility	No	H-Pylori EGD if hx of ulcer	
Preoperative workup	Three months to document compliance	Psychological Nutritional Mandatory weight-loss Sleep study			
Medical follow-up		Band assessment protocol *(See Appendix I)*	1, 3, 6 and 12 months, then annually	1, 3, 6 and 12 months, then annually	1, 3, 6 and 12 months, then annually
Radiology		Annual UGI			
Follow-up labs *(See Appendix I)*	Three months after surgery, then annually	+	+	+	+

If bariatric patient presents in emergency department **do not** provide glucose-containing IV fluids

¤ At five years patients with BMI > 35

• % EWL = (current weight – IBW / initial weight – IBW) x 100

+ - ++++ Relative effectiveness, less to greater

— No effect

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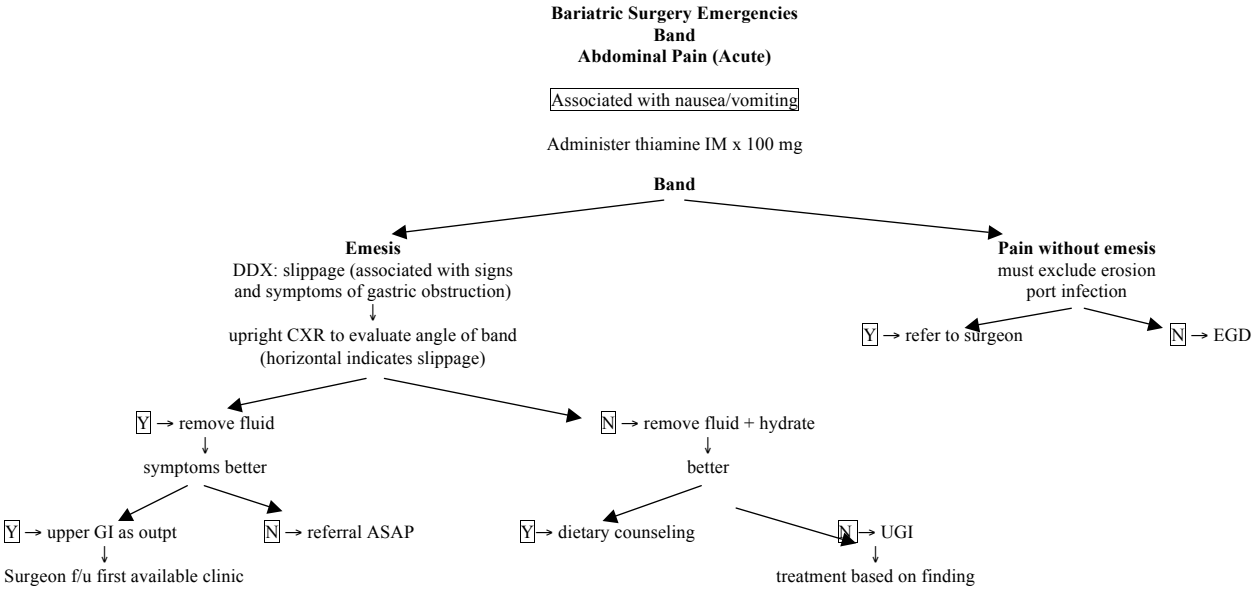
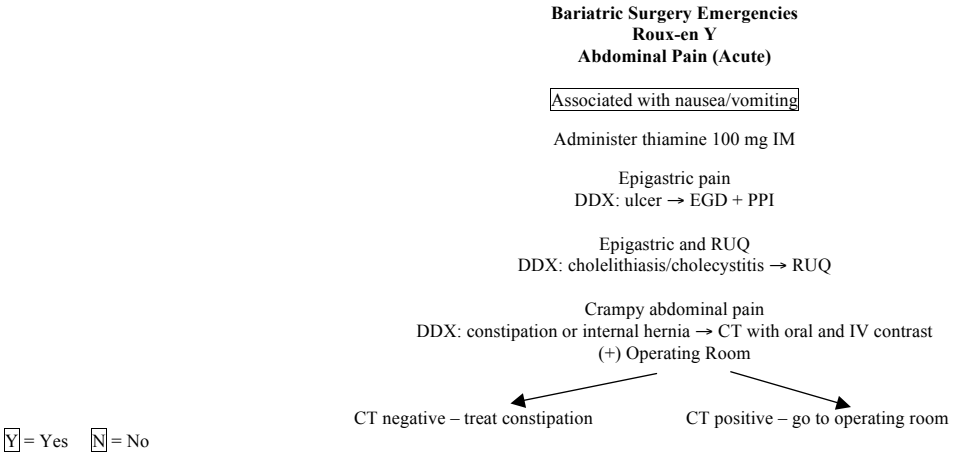
Preoperative workup of the bariatric surgical patient

As mentioned, once it has been determined that a patient has met the preoperative requirements and has undergone the necessary weight loss, it is important to prepare patients and screen them for surgery. For patients undergoing laparoscopic adjustable gastric banding it is helpful, though not mandatory, to obtain a preoperative upper-GI study. Though not specific, the presence of esophageal anatomic abnormality may preclude a band. The presence of preoperative dysphagia or atypical gastroesophageal reflux disease may warrant workup including pH probe studies and manometry. All patients who are obese, regardless of intended procedure, should undergo careful nutritional screening including vitamin status and an albumin level. For those patients undergoing malabsorptive procedures, a vitamin B panel should be checked to include thiamine, riboflavin, folic acid and cyanocobalamin (B12). For patients planning Roux-en-Y gastric bypass, careful history of ulcers or family history of gastric cancer would suggest the need for preoperative upper endoscopy. Whether such patients should have biopsy and screening for *H. Pylori* is unknown. Please see Appendix I, "Sample Weight Loss Surgery Preoperative Laboratory – SUR and Checkout Orders."

Medical Emergencies Following Bariatric Surgery





Y = Yes N = No

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Postoperative nutritional follow-up

Please see Appendix G, "Nutritional Supplement Recommendations," for more information. Also, please see Appendix J, "Sample Post-Bariatric-Surgery Patient Diet," for more information.

The final phase introduces the lifelong way of eating for patients. Patients should focus on eating protein first as they add solid foods back into their diet. Tougher foods like fruits, vegetables and whole grains should be introduced more slowly. These foods, unless chewed well, have a tendency to plug the outlet from the stomach pouch. Patients should be advised to introduce new foods at separate times to assess for tolerance.

To maintain success with weight management, patients need to do the following:

- Drink fluids 30 minutes before and/or 30 minutes after meals, *not* during the meal.
- Eat lean sources of protein first, followed by fruits, vegetables and whole grains.
- Aim for a minimum of 50 to 60 grams of protein per day.
- Avoid high-fat or high-sugar foods.
- Drink at least six to eight cups of non-calorie fluids daily (choose water most often).
- Drink two glasses skim or 1% milk daily in addition to water (between meals).
- Limit fluids with calories to skim or 1% milk (two cups daily).
- Eat three meals a day.
- Take multivitamins and supplements daily.

Protein. The newly formed anatomy of the stomach reduces availability of rennin, pepsin and hydrochloric acid, consequently limiting protein digestion. These alterations in anatomy, coupled with a significantly reduced intake of food, make it difficult to meet the requirements for protein and prevent catabolism immediately following surgery. Protein supplements should be considered, especially in the early postoperative phase, to prevent excess loss of lean tissue *(Moize, 2003 [Reference])*.

Counseling patients on adequate protein intake is pertinent both before and after surgery. Many patients cannot tolerate high-protein foods, which may jeopardize their ability to take in recommended amounts. These intolerances may be long term, particularly with red meat *(Avinoah, 1992 [Reference]; Kushner, 2000 [Reference])*. Supplements are often used until adequate protein intake through solid foods can be maintained, usually about six months after surgery *(Deitel, 2002 [Reference]; Moize, 2003 [Reference])*.

Gastric bypass nutritional deficiencies. Because gastric bypass surgery excludes critical portions of the gastrointestinal tract, including the fundus, duodenum and upper portion of the jejunum, nutrient deficiencies are predictable and should be proactively treated. Patients should be advised to take a multivitamin or prenatal vitamin in addition to the nutrients discussed below.

Calcium and vitamin D. Calcium deficiency is difficult to detect because a normal blood calcium level can be maintained despite poor intake. Several factors affect calcium intake following surgery, including reduced dairy intake as a result of decreased stomach capacity or as a result of lactose intolerance, food dislikes and patient adherence with the meal plan. Since the primary absorption pathway for calcium has been removed with gastric bypass, supplementation is vital to bone health *(Elliot, 2003 [Reference])*. Calcium citrate with added vitamin D would be the preferable source, since it does not rely on stomach acidity for absorption *(Elliot, 2003 [Reference]; Kushner, 2000 [Reference])*. Fifty-eight percent of people have vitamin D deficiency when they present *(Gemmel, 2009 [Reference])*. The American Association of Clinical Endocrinologists Guideline recommends 400-800 IU of vitamin D per day *(Mechanick, 2008 [Reference])*.

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Iron. Iron deficiency post gastric bypass occurs in 33% to 50% of patients *(Deitel, 2002 [Reference])*. Deficiency may be due to several factors, including possible food intolerance (patients may not be taking in sufficient heme iron), bypassed absorption site (duodenum and upper jejunum) and reduced stomach acidity. Iron should be supplemented to prevent deficiency *(Elliot, 2003 [Reference]; Avinoah, 1992 [Reference])*, with special attention to premenopausal women *(Klein, 2002 [Reference])*. In addition, the iron may need to be administered either by intravenous or intramuscular methods due to absorption change. Ferritin levels may need to be monitored annually as the levels can decline for up to seven years post bypass *(Buchwald, 2004 [Reference])*. After six weeks of oral repletion, iron infusions can be instituted. Provide sodium ferric gluconate (125 mg in 100 cc of normal saline) and infuse for over one hour once per week in six doses for a total of six infusions. Follow-up with patient includes checking CBC and ferritin in two to three months.

B vitamins

B12

B12 deficiency occurs in greater than 30% of patients with gastric bypass *(Kushner, 2000 [Reference])*, and the American Gastroenterological Association reports it may reach greater than 50% if supplemental B12 is not used *(Klein, 2002 [Reference])*. Of note, most multivitamins do not have enough B12 to return post-gastric bypass patients to their normal plasma levels *(Buchwald, 2004 [Reference])*. Vitamin B12 has a complex method of absorption, which is greatly impaired by gastric bypass surgery. Additionally, patients may have difficulty tolerating foods rich in B12 (meat, eggs and milk) and consume very little, if any, of these. Supplemental B12 greater than the recommended daily intake has been found to maintain normal plasma cobalamin levels *(Elliot, 2003 [Reference]; Kushner, 2000 [Reference])*.

Thiamine

Thiamine deficiency can occur as a result of bypass of the jejunum, where thiamine is primarily absorbed, or as a result of impaired nutritional intake from recurrent emesis. Neurologic symptoms one to three months after surgery are the predominant indication for thiamine deficiency. Parenteral supplementation with thiamine (100 mg/d) should be initiated in patients with active neurologic symptoms. After a 7-14 day course, an oral preparation (10 mg/d) can be used until neurologic symptoms resolve *(Mechanick, 2008 [Reference])*.

Duodenal switch nutritional deficiencies

Further considerations exist for the duodenal switch patients due to fat malabsorption, particularly for vitamins A, D, E, K. Water miscible preparations exist as a combination and patients can take these. Additional supplementation is warranted when levels dip. Additionally, hypoalbuminemia can be observed in duodenal switch patients manifested by postoperative edema. Therapy is to institute pancrelipase 1-3 tablets/meal for six weeks until prealbumin and albumin have normalized.

Medications

It is important to individually evaluate every post-procedure bariatric patient on an ongoing basis to determine whether or not chronic medications should be continued. In addition, certain medications require dosing adjustments due to their method of absorption or narrow therapeutic window. Changes in a patient's weight may require dose modifications to avoid toxicity and increased side effects.

Extended-release medications may be problematic in some patients since the mechanism by which delayed absorption occurs might be affected. Drugs with narrow therapeutic windows should be monitored especially closely. For example, warfarin dosing may need to be monitored due to alterations in dietary intake post-procedure or due to any possible changes in absorption. Until more research is done in this area, there are no standard rules for adjustments of medications following bariatric surgery. Patients taking any medications

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should be closely monitored for both toxicity and increased side effects. Also drugs with weight requirements for dosing should be reevaluated frequently as patients experience weight loss. Since many drugs are monitored for a therapeutic outcome, the dose can be titrated to this outcome *(Buchwald, 2004 [Reference])*.

Surgery for adolescents

Bariatric surgery in adolescents is highly controversial and must be carried out on a case-by-case basis for patients in a high-volume center *(O'Brien, 2010 [Reference])*.

Failed bariatric surgery

Bariatric surgery can fail. At 10 years it is estimated that 23% of patients with a BMI less than 50 fail bariatric surgery. Also at 10 years, it is estimated that 58% of patients with a BMI greater than 50 fail bariatric surgery. Failed bariatric surgery is when the patient will achieve less than 25% of excess weight lost *(Christou, 2006 [Reference])*. Besides beginning BMI, we have no good indicator for prediction of weight-loss.

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13. Reassess Goals and Risk Factors, and Counsel Regarding Weight Maintenance

Patients need regular follow-up for obesity, which is a lifelong problem in most cases. Regular follow-up conveys the message that the condition is important to the patient, and it affords the opportunity for monitoring body mass index, as well as evaluation and management of any of the common complications that are often associated with obesity.

Intensive intervention with weekly contact for the first three months and then continued support out to four years such as the Look AHEAD program is the most successful at creating and maintaining the 5-10% weight loss needed to reduce clinically significant health risks *(Wadden, 2009 [Reference])*.

Patients on pharmacotherapy for obesity need ongoing evaluation for blood pressure, adequacy of nutrition, and surveillance for specific nutrient deficiencies such as low levels of fat-soluble vitamins in those on orlistat.

Patients who have had bariatric surgery may also need procedure-specific follow-up.

Ongoing reinforcement of important behavior strategies may include provision of new information on obesity management, control of local food environment, strategies to cope with restaurant eating, strategies to limit perimeal snacking and high-calorie beverages, and strategies for achieving regular physical activity.

See Annotation #6, "Advise Weight Maintenance and Manage Other Risk Factors."

The primary care clinician also may serve as community leader and public health advocate. Such advocacy may occur in a variety of forms and settings:

Schools: Priorities for school activities that limit risk of obesity include control of the food environment, enhancement of regular physical activity including lifelong forms of physical activity as a regular part of the school curriculum, and education of students on advantages and practical approaches for healthy eating and regular physical activity.

Work sites: Advocate for healthy food choices at worksites, including both healthy food choices in cafeterias and healthy food choices in vending machines. Especially consider limiting availability of sweetened carbonated beverages and high-calorie, high-fat snacks in vending machines.

Other community settings: There are opportunities for political advocacy and community health education that emphasize the importance of healthy lifestyle. Issues such as availability of sidewalks, pedestrian access to commercial establishments, and availability of public affordable exercise facilities of different sorts are among the issues that may be relevant.

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The Aims and Measures section is intended to provide protocol users with a menu of measures for multiple purposes that may include the following:

- population health improvement measures,
- quality improvement measures for delivery systems,
- measures from regulatory organizations such as Joint Commission,
- measures that are currently required for public reporting,
- measures that are part of Center for Medicare Services Physician Quality Reporting initiative, and
- other measures from local and national organizations aimed at measuring population health and improvement of care delivery.

This section provides resources, strategies and measurement for use in closing the gap between current clinical practice and the recommendations set forth in the guideline.

The subdivisions of this section are:

- Aims and Measures
- Implementation Recommendations
- Implementation Tools and Resources
- Implementation Tools and Resources Table

Aims and Measures

1. Increase percentage of patients age 18 years and older who have an annual screening for obesity using body mass index (BMI) measure specific for age and gender documented. *(Annotation #1)*

   Measure for accomplishing this aim:

   a. Percentage of patients who have an annual body mass index (BMI) measured and documented.

2. Increase the percentage of patients age 18 years and older with a BMI ≥ 25 who have received education and counseling regarding weight management. *(Annotations #8, 10)*

   Measure for accomplishing this aim:

   a. Percentage of patients with a BMI ≥ 25 who received education and counseling for weight-management strategies that include nutrition, physical activity, lifestyle changes, medication and/or surgical considerations. Each education/counseling strategy is based on the BMI level as follows:

      - BMI 25-29.9: Lifestyle changes and behavioral management.
      - BMI 30-34.9: Lifestyle changes, behavioral management and medication considerations.
      - BMI 35-39.9: Lifestyle changes, behavioral management, medication and surgical considerations.
      - BMI 40+: Lifestyle changes, behavioral management, medication and surgical considerations.
      - Percentage of patients with BMI ≥ 25 who set an individualized goal along with target date for reduction in BMI.
      - Percentage of patients with BMI ≥ 25 who reach their goal BMI by the set target date.

3. Increase the percentage of patients age 18 years and older with a BMI ≥ 25 who have improved outcomes from the treatment. *(Annotations #8, 10)*

   Measures for accomplishing this aim:

   a. Percentage of patients with a BMI ≥ 25 who have reduced their weight by 5%.

   b. Percentage of patients with a BMI ≥ 25 who have 30 minutes of any type of physical activity documented five times per week documented.

   c. Percentage of patients with a BMI ≥ 25 who have reduced their weight by 10%.

   d. Percentage of patients with a BMI ≥ 40 who have been provided with a referral to a bariatric specialist.

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Measurement Specifications

Measurement #1a

Percentage of patients who have an annual body mass index (BMI) measured and documented.

Population Definition

Patients age 18 years and older in the primary care panel.

Data of Interest

$$\frac{\text{\# patients who have an annual body mass index (BMI) documented}}{\text{\# patients in the primary care panel}}$$

Numerator/Denominator Definitions

Numerator: Number of patients age 18 years and older who have an annual BMI documented.

Denominator: Total number of patients age 18 years and older in the clinic's primary care panel.

Method/Source of Data Collection:

Query electronic medical records for the total number of patients in the clinic's primary care panel who were age 18 years and older in the last 12 months from the measurement period date. The measurement period can be monthly, quarterly, semi-annually or annually. Determine the number of those patients who had an annual BMI documented.

Time Frame Pertaining to Data Collection

Monthly, quarterly, semi-annually or annually. Select time frame that aligns best with your clinic's quality improvement activities.

Notes

This is a process measure, and improvement is noted as an increase in the rate.

National Committee for Quality Assurance (NCQA) also has a HEDIS measure for annual BMI screening for patients age 18-74 years old. Full specifications for this measure can be obtained from NCQA at http://www.ncqa.org.

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Measurement #2a

Percentage of patients with a BMI ≥ 25 who received education and counseling for weight-management strategies that include nutrition, physical activity, lifestyle changes, medication therapy and/or surgical considerations *(each education/counseling strategy is based on the BMI level)*:

- BMI 25-29.9: Lifestyle changes and behavioral management.
- BMI 30-34.9: Lifestyle changes, behavioral management and medication considerations.
- BMI 35-39.9: Lifestyle changes, behavioral management, medication therapy and surgical considerations.
- BMI 40+: Lifestyle changes, behavioral management, medication and surgical considerations.
- Percentage of patients with BMI ≥ 25 who set an individualized goal along with target date for reduction in BMI.
- Percentage of patients with BMI ≥ 25 who reach their goal BMI by the set target date.

Population Definition

Patients age 18 years and older with BMI ≥ 25.

Data of Interest

$$\frac{\text{\# of patients who receive education and counseling for weight management strategies appropriate to their BMI}}{\text{Patients with BMI} \geq 25}$$

Numerator/Denominator Definitions

Numerator: Number of patients with a BMI ≥ 25 who receive education and counseling for weight management appropriate to their BMI level, including nutrition, physical activity, lifestyle changes, medication and/or surgical considerations.

- BMI 25-29.9: Lifestyle changes and behavioral management.
- BMI 30-34.9: Lifestyle changes, behavioral management and medication considerations.
- BMI 35-39.9: Lifestyle changes, behavioral management, medication therapy and surgical considerations.
- BMI 40+: Lifestyle changes, behavioral management, medication and surgical considerations.
- Percentage of patients with BMI ≥ 25 who set an individualized goal along with target date for reduction in BMI.
- Percentage of patients with BMI ≥ 25 who reach their goal BMI by the set target date.

Denominator: Number of patients with a BMI ≥ 25.

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Method/Source of Data Collection:

Query electronic medical records for patients who have BMI ≥ 25. Focus your query for patients who had BMI done 12 months earlier from the measurement period date and were age 18 years or older at the time. The measurement period can be monthly, quarterly, semi-annually or annually. Determine the number of those patients who had one or more of the weight-management strategies appropriate to their BMI at any time over a 12-month period from the date of BMI done to the measurement period date.

Time Frame Pertaining to Data Collection

Monthly, quarterly, semi-annually or annually. Select time frame that aligns best with your clinic's quality improvement activities.

Notes

This is a process measure, and improvement is noted as an increase in the rate.

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Measurement #3a

Percentage of patients with a BMI ≥ 25 who have reduced their weight by 5%.

Population Definition

Patients age 18 years and older with a BMI ≥ 25.

Data of Interest

$$\frac{\text{\# of patients with a BMI} \geq 25 \text{ who have reduced their weight by 5\%}}{\text{\# of patients with BMI} \geq 25}$$

Numerator/Denominator Definitions

Numerator: Number of patients who have reduced their weight by 5%.

Denominator: Number of patients with a BMI ≥ 25.

Method/Source of Data Collection

Query electronic medical records for patients who have BMI ≥ 25. Focus your query for patients who had BMI done 12 months earlier from the measurement period date and were age 18 years or older at the time. The measurement period can be monthly, quarterly, semi-annually or annually. Determine the number of those patients who reduced their BMI by 5% over a 12-month period from the date of BMI done to the measurement period date.

Time Frame Pertaining to Data Collection

Monthly, quarterly, semi-annually or annually. Select time frame that aligns best with your clinic's quality improvement activities.

Notes

This is an outcome measure, and improvement is noted as an increase in the rate.

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Measurement #3b

Percentage of patients with a BMI ≥ 25 who have 30 minutes of any type of physical activity five times per week documented.

Population Definition

Patients age 18 years and older with a BMI ≥ 25.

Data of Interest

$$\frac{\text{\# of patients who have 30 minutes of physical activity five times per week documented}}{\text{\# of patients with a BMI} \geq 25}$$

Numerator/Denominator Definitions

Numerator: Number of patients with a BMI ≥ 25 who have 30 minutes of physical activity five times per week documented.

Denominator: Number of patients with a BMI ≥ 25.

Method/Source of Data Collection

Query electronic medical records for patients who have BMI ≥ 25. Focus your query for patients who had BMI done 12 months earlier from the measurement period date and were age 18 years or older at the time. The measurement period can be monthly, quarterly, semi-annually or annually. Determine the number of those patients who have 30 minutes of physical activity five times per week over a 12-month period from the date of BMI done to the measurement period date.

Time Frame Pertaining to Data Collection

Monthly, quarterly, semi-annually or annually. Select time frame that aligns best with your clinic's quality improvement activities.

Notes

This is an outcome measure, and improvement is noted as an increase in the rate.

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Measurement #3c

Percentage of patients with a BMI ≥ 25 who have reduced their weight by 10%.

Population Definition

Patients age 18 years and older with a BMI ≥ 25.

Data of Interest

$$\frac{\text{\# of patients who reduced their BMI by 10\%}}{\text{\# of patients with a BMI} \geq 25}$$

Numerator/Denominator Definitions

Numerator: Number of patients with a BMI ≥ 25 who have reduced their BMI by 10%.

Denominator: Number of patients with a BMI ≥ 25.

Method/Source of Data Collection

Query electronic medical records for patients who have BMI ≥ 25. Focus your query for patients who had BMI done 12 months earlier from the measurement period date and were age 18 years or older at the time. The measurement period can be monthly, quarterly, semi-annually or annually. Determine the number of those patients who reduced their BMI by 10% over a 12-month period from the date of BMI done to the measurement period date.

Time Frame Pertaining to Data Collection

Monthly, quarterly, semi-annually or annually. Select time frame that aligns best with your clinic's quality improvement activities.

Notes

This is an outcome measure, and improvement is noted as an increase in the rate.

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Measurement #3d

Percentage of patients with a BMI ≥ 40 who have been provided with a referral to a bariatric specialist.

Population Definition

Patients age 18 years and older with a BMI ≥ 40.

Data of Interest

$$\frac{\text{\# of patients were provided referrals to bariatric specialist}}{\text{\# of patients with BMI} \geq 40}$$

Numerator/Denominator Definitions

Numerator: Number of patients with BMI ≥ 40 who provided referrals to a bariatric specialist.

Denominator: Number of patients with a BMI ≥ 40.

Method/Source of Data Collection

Query electronic medical records for patients who have BMI ≥ 40. Focus your query for patients who had BMI done 12 months earlier from the measurement period date and were age 18 years or older at the time and whose set goal target date is within 12 months of the BMI done. The measurement period can be monthly, quarterly, semi-annually or annually. Determine the number of those patients who received a referral to a bariatric specialist over a 12-month period from the date of BMI done to the measurement period date.

Time Frame Pertaining to Data Collection

Monthly, quarterly, semi-annually or annually. Select time frame that aligns best with your clinic's quality improvement activities.

Notes

This is an outcome measure, and improvement is noted as an increase in the rate.

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Implementation Recommendations

Prior to implementation, it is important to consider current organizational infrastructure that addresses the following:

- System and process design
- Training and education
- Culture and the need to shift values, beliefs and behaviors of the organization.

The following system changes were identified by the guideline work group as key strategies for health care systems to incorporate in support of the implementation of this guideline:

- Establish a system for using a Patient Readiness Scale to determine if the patient is ready to talk about weight loss and/or would like information.
- Establish a system for staff to efficiently calculate BMI prior to the clinician entering the exam room. The BMI may provide more health risk information than traditional vital signs and should be built into the patient assessment protocol. A BMI chart should be placed by each scale in the clinic. All organizations with electronic medical records should build BMI calculators as a component for immediate calculation.
- Develop a tracking system that periodically reviews patient charts to identify patients who are overweight or obese so that clinicians are aware of the need to discuss the issue with the patient.
- Establish a system for staff and clinician training around skills and knowledge in the areas of motivational interviewing; brief, focused advice on nutrition, physical activity and lifestyle changes; and evaluation of evidence of effectiveness of treatment options.
- Establish a system for continuing education on evidence-based obesity management for clinicians, nurses and ancillary clinic staff.
- Remove barriers to referral programs for weight loss by understanding where programs are and what process is required for referrals.
- Develop medical record systems to track status of patients under the clinician's care with the capability to produce an outpatient tracking system for patient follow-up by clinician/staff.
- Use tools such as posters and brochures throughout the facility to assist with identifying and notifying patients about health risk in relationship to NIH-based categories of BMI. Promote a healthy lifestyle around nutrition and activity while encouraging patient knowledge of his or her BMI.
- Develop patient-centered education and self-management programs, which may include self-monitoring, self-management and skills such as journaling.
- Build systems to track outcomes measures, as well as ongoing process measures. Track the response rate to various treatments/strategies. Improvement rates – the BMI is stable or has decreased over time.
- Systems to coordinate care ensure continuity and keep clinicians informed of progress.
  - Develop electronic tracking systems for panel or population management.
  - Educate patients to foster awareness and knowledge of BMI for self-monitoring and reporting.
  - Structure follow-up visits with patient per guideline recommendations.

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Implementation Tools and Resources

Criteria for Selecting Resources

The following tools and resources specific to the topic of the guideline were selected by the work group. Each item was reviewed thoroughly by at least one work group member. It is expected that users of these tools will establish the proper copyright prior to their use. The types of criteria the work group used are:

- The content supports the clinical and the implementation recommendations.
- Where possible, the content is supported by evidence-based research.
- The author, source and revision dates for the content are included where possible.
- The content is clear about potential biases and when appropriate conflicts of interests and/or disclaimers are noted where appropriate.

Resources Available to ICSI Members Only

ICSI has knowledge resources that are ***only*** available to ICSI members (these are indicated with an asterisk in far left-hand column of the Resources Table). In addition to the resources listed in the table, ICSI members have access to a broad range of materials including tool kits on Continuous Quality Improvement processes and Rapid Cycling that can be helpful. To obtain copies of these or other Resources, go to Education and Quality Improvement on the ICSI Web site. To access these materials on the Web site, you must be logged in as an ICSI member.

The resources in the table on the next page that are not reserved for ICSI members are available to the public free-of-charge unless otherwise indicated.

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Implementation Tools and Resources Table

*	Author/Organization	Title/Description	Audience	Web sites/Order Information
	America On the Move	**America On the Move (AOM):** Challenges you, your family and your community to take small steps and make small changes to a healthier way of life. Get involved!	Patients and Families	http://www.americaonthemove.org
	American Academy of Family Physicians	**American Family Physician:** Patient education article, "Exercise: How to Get Started"	Patients and Families	http://www.aafp.org/afp/20030115/367ph.html
	American Dietetic Association	**American Dietetic Association:** Provides information on nutrition and current research	Patients and Families; Health Care Professionals	http://www.eatright.org
	Calorie King	**Calorie King:** Provides a review of the most popular diets	Patients and Families	http://www.calorieking.com
	Centers for Disease Control (CDC)	**Overweight and Obesity:** an overview. Includes a body mass index calculator. **Physical Activity Guidelines for Americans**	Patients and Families; Health Care Professionals	http://www.cdc.gov/nccdphp/dnpa/obesity/contributing_factors.htm http://www.cdc.gov/nccdphp/dnpa/physical/pdf/PA_Fact_Sheet_Adults.pdf
	Crowley and Lodge	**Younger Next Year for Men** **Younger Next Year for Women**	Patients and Families; Health Care Professionals	http://www.youngernextyear.com/books.php
	Department of Food Science and Human Nutrition, University of Illinois at Urbana-Champaign	**NAT (Nutritional Assessment Tools for Good Health):** Provides a free Web-based program that allows one to perform a nutritional analysis of one's diet	Patients and Families	http://www.nat.uiuc.edu
	Department of Health and Human Services	**President's Council on Physical Fitness and Sports:** Online pamphlet providing information on physical fitness fundamentals **Physical Activity Guidelines for Americans**	Patients and Families	http://www.fitness.gov http://www.health.gov/paguidelines/factsheetprof.aspx
	Dole Company	**Dole Super Kids:** Provides basic nutrition education for kids and classroom ideas for teachers	Patients and Families	http://www.dole5aday.com

* Available to ICSI members only.

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*	Author/Organization	Title/Description	Audience	Web sites/Order Information
	Health Wise	Obesity: Should I have weight-loss surgery?	Patients and Families; Health Care Professionals	http://www.healthwise.net/cochranedecisionaid/Content/StdDocument.aspx?DOCHWID=ug2364#ug2364-Intro
*	Institute for Clinical Systems Improvement	**Prevention and Management of Obesity Guideline Pilot Summary:** Affiliated Community Medical Centers and St. Mary's/Duluth Clinic Health System participated in a guideline pilot from mid-2005 to early 2006. This summary will tell their story and provide information around strategies for implementation, measurement/outcomes and overall improvement in processes.	Health Care Professionals	http://www.icsi.org
	Institute for Research and Education - PNC	More Flavor, Less Fat – Easy Low Fat Cooking; Nutrition pamphlet	Patients and Families	800-372-7776
	Institute for Research and Education - PNC	**Simple Strategies for Meal Planning:** Nutrition pamphlet	Patients and Families	800-372-7776
	Institute for Research and Education - PNC	**Simple Strategies for Eating Out:** Nutrition pamphlet	Patients and Families	800-372-7776
	Institute for Research and Education - PNC	**Simple Strategies for Weight Management:** Nutrition pamphlet	Patients and Families	800-372-7776
	Krames - Health and Safety Education	**Understanding Bariatric Surgery:** Your Surgical Options for Weight Loss; Surgery pamphlet	Patients and Families	Call 1-800-333-3032
	Let's Move	**Let's Move:** Michelle Obama's Web site to reduce obesity in kids.	Patients and Families; Health Care Professionals	http://www.letsmove.gov
	Mayo Clinic	**Mayo Clinic:** Provides a wide variety of information on nutrition, programs and a food pyramid placing fruits and vegetables at the bottom vs. carbohydrates. **The Mayo Clinic Diet: Eat Well, Enjoy Life, Lose Weight**	Patients and Families	http://www.mayoclinic.com Book
	National Heart, Lung and Blood Institute	**Aim for a Healthy Weight:** provides key recommendations from the National Heart, Lung and Blood Institute national guidelines, how to get started and links to other publications.	Patients and Families	http://www.nhlbi.nih.gov/health/public/heart/obesity/lose_wt/index.htm

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Implementation Tools and Resources Table

*	Author/Organization	Title/Description	Audience	Web sites/Order Information
	National Institutes of Health	**The National Institute of Diabetes and Digestive and Kidney Diseases:** Provides science-based information on obesity, weight management and nutrition.	Patients and Families; Health Care Professionals	http://www.niddk.nih.gov/index.htm
	Paths to Healthy Weight	At Paths to Healthy Weight, the Health Care Innovations Exchange presents new approaches for helping communities and clinicians prevent overweight and obesity, in a joint effort of the Agency for Healthcare Research and Quality and the Health Resources and Services Administrations.	Patients and Families; Health Care Professionals	http://www.innovations.ahrq.gov/healthyweight.aspx
	Shape Up America	**Shape Up America:** Provides information on an interactive personalized weight-loss program with links to a support center, recipes and fitness information.	Patients and Families	http://www.shapeup.org
	The Discovery Health Channel	**Discovery Health:** Provides information on nutrition, fitness and weight management.	Patients and Families	http://www.health.discovery.com
	U.S. Department of Agriculture	**Choose My Plate:** Use the plate as an interactive nutrition education tool.	Patients and Families; Health Care Professionals	http://www.choosemyplate.gov
	We Can (Ways to Enhance Children's Activity and Nutrition)	**We Can:** National Heart, Lung and Blood Institutes national movement designed to give parents, caregivers and entire communities a way to help children ages 8-13 stay at a healthy weight.	Patients and Families; Health Care Professionals	http://wecan.nhlbi.nih.gov

* Available to ICSI members only.

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- References
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Links are provided for those new references added to this edition (author name is highlighted in blue).

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Appendix A – Medications Associated with Weight Gain and Weight Loss

Therapeutic Class	Mechaism of Action or Pharmaceutical Class	Medication	Weight Neutral	Related to Weight Gain	Related to Weight Loss
Antidepressants *(Masand, 2000 [Reference]; Sussman, 2001[Reference])*	Norepinephrine and Dopamine RI	Bupropion Venlafaxine			X (especially when combined with naltrexone) X
	SSRI	Fluoxetine Sertraline	X		X (initially but may gain over time)
	Tricyclics			X	
	Monamine oxidase inhibitors			X	
	Multiple	Mirtazapine		X	
Hypoglycemics *(The Diabetes Control and Complications Trial Research Group; 1993 [Reference]; Purnell, 1998 [Reference]; Williams, 1999 [Reference])*	GLP-1 analogs	Exenatide Liraglutide			X X
	Biguanides	Metformin			X
	Amylin analog	Pramlitide			X
	Alpha-Glucosidase inhibitors	Acarbose Miglitol			X X
	Insulin secretagogues – meglitinides	Nateglinide Repaglinide		X X	
	Insulin secretagogues – sulfonylureas			X	
	Thiazolidine-diones	Pioglitazone	Weight neutral if used with metformin	X (when used alone or in combination with sulfonylurea)	
	Insulin			X	
	DPP-4 inhibitors	Sitagliptin Saxagliptin	X X		
Anticonvulsants *(Nemeroff, 2003 [Reference]; Isojarvi, 1996 [Reference]; DeToledo, 1997 [Reference]; Biton, 2001 [Reference]; Ben-Menachem, 2003 [Reference])*		Topiramate Zonisamide Valproate Gabapentin Lamotrigine	X	X – extreme X – extreme	X X
Opioid Antagonist		Naltrexone			X
Mood Stabilizer		Lithium		X	
Antihypertensives	Beta and alpha-l adrenergic blocking agents			X	
Antipsychotics (consider empiric use of metformin to minimize weight gain) *(Aronne, 2003 [Reference])*		Risperidone Sertindole Olanzapine Clozapine Ziprasidone		X X X X X (small increase)	

Sources: (Aronne, 2009 [Reference]; Astrup, 2009 [Reference]; Moyers, 2005 [Reference])

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Appendix B – Physical Activity Prescription

Name _____
Date _____
Follow-up interval _____

Health Status for Physical Activity:

Current Diagnoses (see contraindications):
1. _____
2. _____
3. _____

Current Medications:
1. _____
2. _____
3. _____

Assessment:
_____ OK for a self-monitored activity program
_____ OK for a supervised activity program (referral)
_____ Needs exercise tolerance testing (referral)

Activity Planner: Season(s) of Year _____

Indoors - Alone

1. Activity _____
   Resources
   a._____
   b. _____
   c. _____

2. Activity _____
   Resources
   a._____
   b. _____
   c. _____

Indoors - with Others

1. Activity _____
   Resources
   a._____
   b. _____
   c. _____

2. Activity _____
   Resources
   a._____
   b. _____
   c. _____

Outdoors – Alone

1. Activity _____
   Resources
   a. _____
   b. _____
   c. _____

2. Activity _____
   Resources
   a._____
   b. _____
   c. _____

Outdoors – with Others

1. Activity _____
   Resources
   a. _____
   b. _____
   c. _____

2. Activity _____
   Resources
   a. _____
   b. _____
   c. _____

Patient should identify at least two possible *activities* under each circumstance to achieve variety.

For each selected activity, identify key *resources* needed to make it happen. Resources include both physical (e.g., equipment, coach, time) and psychological (e.g., social support, goals).

Goals are to adjust activity plans for seasons and weather, minimize boredom, develop social support and personalize activity selection, given resources.

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Appendix B – Physical Activity Prescription

Dimensions for Physical Activity Improvement:
Frequency – recommended number of days per week to perform selected activities.

1. Cardiovascular – Start at 3x/week and advance to most days per week.
2. Strength – Start at 2-3 x/week and advance to every other day for a given muscle group.
3. Flexibility – Start at every other day and advance to most days per week; especially stretch after aerobic or resistance activities during the cool-down phase.

Duration – recommended amount of time or total work per activity session. Frequency and duration are more important for total caloric expenditure and weight management. They should be increased *before* intensity.

Intensity – recommended speed of movement (walking pace) or amount of weight to be lifted for each repetition. Increasing intensity creates continued improvement after physiologic adaptation to a given frequency and duration of activity. Intensity can be monitored with the Borg Perceived Exertion Scale. Typical target intensity on the Borg 6-20 scale is: 10-12 Fairly Light to 13-14 Somewhat Hard.

Also, the "talk test" indicates need to decrease intensity if difficulty in talking during aerobic activity.

Activity Prescription: Record prescribed activity and amount of time for each day of the week.

Week 1

	Sun.	Mon.	Tues.	Wed.	Thurs.	Fri.	Sat.
Indoors: (Activity)	_____	_____	_____	_____	_____	_____	_____
(Activity)	_____	_____	_____	_____	_____	_____	_____
Outdoors: (Activity)	_____	_____	_____	_____	_____	_____	_____
(Activity)	_____	_____	_____	_____	_____	_____	_____

Week 2

	Sun.	Mon.	Tues.	Wed.	Thurs.	Fri.	Sat.
Indoors: (Activity)	_____	_____	_____	_____	_____	_____	_____
(Activity)	_____	_____	_____	_____	_____	_____	_____
Outdoors: (Activity)	_____	_____	_____	_____	_____	_____	_____
(Activity)	_____	_____	_____	_____	_____	_____	_____

Work up to _____ minutes for (activity) in ____ weeks. Work up to _____lbs. for (activity) in ____ weeks.

I agree to this activity prescription and to keep an activity log on my calendar from _____to _____.

Patient's Signature _____ Provider's Signature _____

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Appendix C – FDA-Approved Medications for the Treatment of Obesity

Generic Name	Mechanism of Action
Diethylpropion	Sympathomimetic amine; causes central nervous system stimulation and acts as an anorectic.
Locaserin	Selective agonist of the serotonin (5-hydroxytryptamine) 2C ($5\text{-}HT_{2c}$) receptor that reduces body weight by reducing food intake.
Orlistat	Reversible inhibitor of lipases; exerts its therapeutic activity in the lumen of the stomach and small intestine by forming a covalent bond with gastric and pancreatic lipases and a subsequent reduction in triglyceride hydrolysis and absorption of dietary fat, including cholesterol.
Phentermine	Sympathomimetic amine; causes central nervous system stimulation and acts as an anorectic.
Phentermine and topiramate extended release	Sympathomimetic amine; causes central nervous system stimulation and acts as an anorectic/antiepileptic that has effects on both appetite suppression and satiety enhancement through multiple actions.

*Orlistat 60, TN Alli, available for over-the-counter use.

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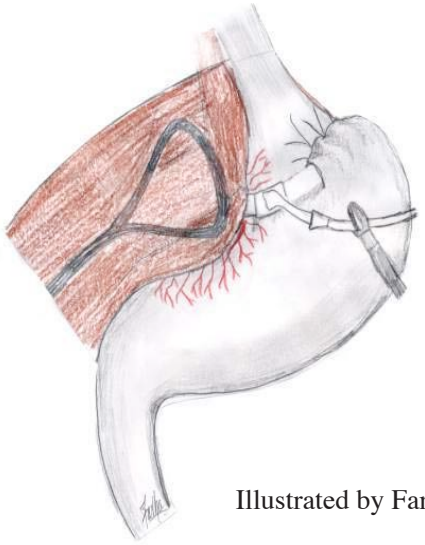
Appendix D – Overview of Bariatric Procedures

Restrictive procedures (adjustable band)

Figure 1: Adjustable Band



Illustrated by Farha Ikramuddin

The most common restrictive procedure that is performed today is the adjustable band. At present there are two types available in the United States, the Lap Band™ and the Realize Band™. In principle both devices function as circumferential balloons that are placed just below the level of the gastroesophageal junction and then secured in a way to prevent migration. The band balloons are connected to a port (similar to a chemotherapy port) that is secured to the anterior abdominal wall fascia below the skin, providing access for saline placement. In most cases patients will have an overnight stay and beginning six weeks postoperatively fluid will be introduced into the band either in the office setting or under direct radiologic guidance. Initially adjustment protocols were designed to produce a maximal amount of restriction, lending some advantage to the radiologic adjustment model. However, the actual mechanism may also be related to the direct pressure placed externally. Some studies show no actual delay in the progression of food from the pouch into the remainder of the stomach *(Burton, 2011 [Reference])*. The bands differ slightly in terms of the pressure generated on the stomach in relation to the same amount of fluid in the band. There are no good control studies to suggest differences in outcomes of weight loss between the two groups *(Cunneen, 2008 [Reference])*. The weight-loss from banding is typically 45 to 55% of excess weight. Unlike other bariatric operations, the weight loss is far more gradual and in many cases will reach the nadir between two and three years following surgery.

Complications following adjustable banding and suggestions for management

Laparoscopic adjustable banding carries the best safety profile of any operation performed in the short term. The mortality rate is 0.05% (*Longitudinal Assessment of Bariatric Surgery [LABS[Consortium, The, 2009 [Reference])*. Despite this, appropriate preoperative workup including deep venous thrombosis (DVT) prophylaxis has been shown to be a benefit *(Scholten, 2002 [Reference])*. Four types of technical complications exist following banding; these include slippage, concentric dilatation, erosion, and port-related problems. In aggregate, this results in a substantial need postoperatively for re-operation. In most cases including erosion, the patients will present with subacute symptoms. However, acute gastric distention, necrosis and perforation can occur. Access of the patient and the primary care clinician to the original team or an experienced team that is receptive to managing complications is imperative to minimize the long-term sequelae of these complications. There is a great deal of variability in how complications are managed.

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Slippage is defined by passage of stomach, usually fundus and body, underneath the band and above the band. In almost all cases the slippage occurs anteriorly. The classic presentation is obstruction usually preceded by an episode of vomiting. Diagnostically, this can be suggested by a change in the angle of the band on plain x-ray. Usually the band is oriented at a 45° angle from the left down to the right. In slippage, the band takes a more horizontal orientation. The mainstay of therapy is fluid removal from the band, and observation. If symptoms are immediately improved and the slippage is small, fluid may be reintroduced after a period of four weeks with careful dietary counseling. In case of large slippage or persistent obstruction, emergent surgery is performed. The stomach should be decompressed and the band either replaced, repositioned or removed, with conversion to alternative procedure if weight loss has been inadequate.

Impact on comorbid illness

Despite being one of the more recently introduced procedures, some of the best data (randomized) exists for laparoscopic adjustable banding. Dixon, et al. reported two studies looking at weight loss and improvement of patients with type 2 diabetes *(Dixon, 2008 [Reference])*. The effect of the laparoscopic adjustable band was demonstrably superior to medical management alone.

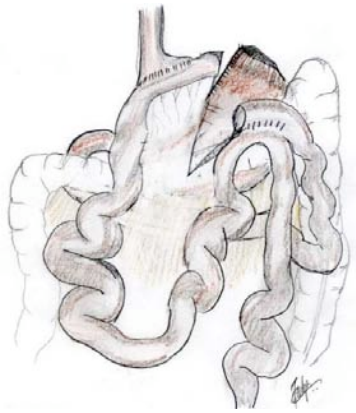
Vertical sleeve gastrectomy

This is a relatively new procedure that has gained considerable growth over the last five to six years. In principle this operation involves removal of the greater curvature of the stomach including the fundus while preserving the antrum. Unlike the laparoscopic adjustable band, this restrictive procedure does not require adjustments. It does, however, involve construction of a long staple line. This increases the potential for leakage. Additionally, there is uncertainty about the best way to construct the sleeve in terms of size of the sleeve caliber. This results in variations in both weight loss and complications. At present, use of the sleeve gastrectomy is not covered by CMS. It remains, however, an intriguing procedure to use in select circumstances. In patients with inflammatory bowel disease (IBD), this may have advantages over the gastric bypass. The laparoscopic adjustable band includes IBD as a contraindication for surgery. The relative lack of malabsorption, the lack of need for adjustments, and the potential for converting this to a more robust operation such as the gastric bypass and the duodenal switch remain promising. The initial draw for the sleeve gastrectomy was in patients considered high risk secondary to cardiopulmonary disease or extremes of obesity. Many authors have found that preoperative liquid diets can easily and more safely substitute as a first step in the treatment of this patient population *(Still, 2007 [Reference])*.

Complications of the sleeve gastrectomy

These are similar to those found in the Roux-en-Y gastric bypass. Complications include leakage, stricture and significant issues with nausea and vomiting.

Figure 2: Roux-en-Y gastric bypass



Illustrated by Farha Ikramuddin

The gastric bypass represents the gold standard bariatric surgical operation. It produces a durable weight loss, is the most intensively studied, and has the most predictable set of complications. It is, therefore, reasonable that operations be compared to this in terms of superiority or inferiority. The gastric bypass was first used as an operation to treat ulcer disease. Observations that it produced massive weight loss in obese patients prompted its use as a primary operation to treat obesity. Currently, the operation is performed laparoscopically.

There are a number of technical complications that can follow the gastric bypass. A high index of suspicion should be maintained in patients, and prompt bariatric surgical input should be obtained *(Podnos, 2003 [Reference])*.

- Leaks (3%) occur early within the first week.
- Internal bleeding (1%) occurs within the first week and can be in the GI tract.
- Anastomotic stenosis (2-20%) occurs most often by three-four weeks.
- Internal hernia formation (1-5%) occurs most often beyond six months.
- Wound infections can occur in up to 6.6% of patients.
- Anastomotic marginal ulceration can be as high as 15%, but the true incidence is likely unknown. Recalcitrant ulcers raise the concern of gastrogastric fistula formation that can be seen even following a divided gastric bypass.

Severe life-threatening complications appear to be influenced by gender and by weight and age. Overall mortality of the gastric bypass is 0.5% *(Schauer, 2000 [Reference])*. Livingston, et al. found that patients older than 55 years had a threefold higher mortality from surgery than younger patients, although the complication rate (5.8%) was the same in both groups *(Livingston, 2002 [Reference])*. The risk for severe life-threatening adverse outcomes in women increased from 4% for a 200 lb. female patient to 7.5% for a 600 lb. patient. In males, the risk increased from 7% for a 200 lb. male to 13% for a 600 lb. patient *(Livingston, 2002 [Reference])*.

The waist-to-hip ratio may also correlate with the difficulty of surgery, as it may correlate to increased visceral fat stores and may contribute to possible respiratory difficulty *(Schwartz, 2003 [Reference])*.

The incidence of serious respiratory complications varies from 0% to 4.5% in both laparoscopic and open procedures *(Podnos, 2003 [Reference])*.

Dealing with the excluded limb following the gastric bypass can be a significant issue. Usually concern is warranted to evaluate the excluded stomach in patients with unexplained pain or the presence of a mass. In some cases it becomes useful to access the stomach to perform an ERCP in order to remove common duct stones. The stomach can be accessed using interventional radiologic techniques, laparoscopy or conventional surgery.

Pregnancy after the bypass operation is possible. Fertility can be increased following the bypass in some patients. Patients should wait until weight loss has ceased prior to conceiving, which usually occurs at 18 months after surgery. Patients should undergo a thorough nutritional evaluation prior to and during pregnancy *(Wittgrove, 1998 [Reference])*.

Post-gastric-bypass hypoglycemia

This is a rare condition associated with low blood sugar following the ingestion of concentrated sweets. It begins usually after maximal weight loss has been achieved and patients' beginning to resume higher quantity of food intake. It is characterized by symptoms of neuroglycopenia, which include dizziness, syncope, confusion, blurred or double vision, or even seizure activity *(Bantle, 2007 [Reference])*. It is a variant of the dumping syndrome. There are two phases. The earlier phase is associated with initial ingestion of

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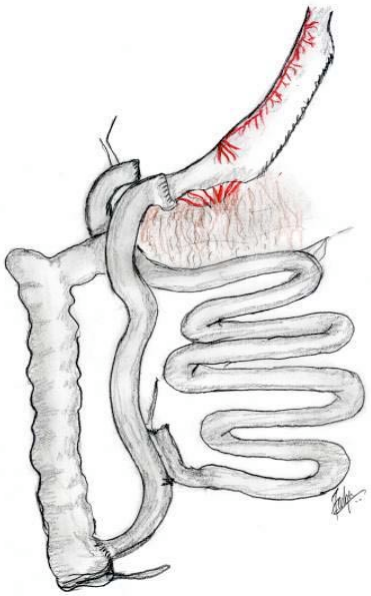
concentrated carbohydrates – symptoms include nausea, abdominal pain, palpitations, and the urge to lie down. These are mediated by a number of intestinal peptides such as vip and neurotensin. Workup should include determination that fasting hypoglycemia due to insulinoma is present. Phase two is associated with increased insulin secretion and hypoglycemia in some patients. In patients who have neuroglycopenia, e.g., associated neurologic change, further workup is indicated. Please see Appendix E, "Meal Tolerance Test Orders: High CHO Meals," and Appendix F, "Meal Tolerance: Low CHO Meals."

Figure 3: Duodenal switch



Illustrated by Farha Ikramuddin

The duodenal switch procedure is a combination of the sleeve gastrectomy and a long intestinal bypass. The common channel, which is the length of the bowel exposed to both food and bilio-pancreatic fluid, is between 50 and 150 cm. The pylorus and most proximal portion of the duodenum are left intact. This allows for improved food processing by the stomach and thus little if any dumping syndrome. The small segment of duodenum, 1-4 cm, is quite resistant to the development of marginal ulceration, a common problem associated with the gastric bypass. The presence of a large sleeve facilitates more food intake over time than the gastric bypass. DS patients tend to suffer from diarrhea in comparison to patients with the gastric bypass, who have constipation.

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Appendix E – Meal Tolerance Test Orders: High CHO Orders

Patient name: _____

Diagnosis: Symptomatic Hypoglycemia

Patient should be fasting for at least 8 hours prior to testing.

Time Intervals	Chart Time	Action	Document BP/HR/Symptoms
Baseline (Pre-meal)		Obtain blood samples*	
O min.**		Ask patient to eat High CHO meal within 10 minutes.	
+ 15 min.		Obtain blood samples*	
+ 30 min.		Obtain blood samples*	
+ 45 min.		Obtain blood samples*	
+ 60 min.		Obtain blood samples*	
+ 90 min.		Obtain blood samples*	
+ 120 min.		Obtain blood samples*	
+ 180 min.		Obtain blood samples*	
+ 240 min.		Obtain blood samples*	

* Blood samples for plasma glucose (2 ml blood in grey-top tube) and serum insulin (3 ml in red-top tube).

** Time zero starts when patient is eating meal. Patient must eat the entire meal.

Record amount eaten: _____

High CHO meal: 8 oz. orange juice, 6 oz Yoplait fat-free fruit-flavored yogurt, 1 slice bread or toast with 1 tsp. margarine and 2 tsp. jam. For patients who are lactose intolerant, ¾ cup applesauce can be substituted for the yogurt.

If patient becomes confused, check finger prick blood glucose; if < 45 mg/dL, treat with 3 glucose tablets and note in record. Continue drawing blood samples according to schedule.

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Appendix F – Meal Tolerance: Low CHO Meals

Patient name: _____

Diagnosis: Symptomatic Hypoglycemia

Patient should be fasting for at least eight hours prior to testing.

Time Interval	Chart Time	Action	Document BP/HR/Symptoms
Baseline (Pre-meal)		Obtain blood samples*	
O min.**		Ask patient to eat Low CHO meal within 10 minutes.	
+ 15 min.		Obtain blood samples*	
+ 30 min.		Obtain blood samples*	
+ 45 min.		Obtain blood samples*	
+ 60 min.		Obtain blood samples*	
+ 90 min.		Obtain blood samples*	
+ 120 min.		Obtain blood samples*	
+ 180 min.		Obtain blood samples*	
+ 240 min.		Obtain blood samples*	

* Blood samples for plasma glucose (2 ml blood in grey-top tube) and serum insulin (3 ml in red-top tube).

** Time zero starts when patient is eating meal. Patient must eat the entire meal and within 10 minutes.

Record amount eaten:_____

Low CHO meal: decaffeinated black coffee or tea, one scrambled egg, two ounce sausage patties, one slice (1.0 oz.) cheese. No sugar or cream with coffee.

If patient becomes confused, check finger prick blood glucose: if < 45 mg/dL, treat with three glucose tablets and note in record. Continue drawing blood samples according to schedule.

At each blood draw: document symptoms, check pulse and blood pressure.

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Appendix G – Nutritional Supplement Recommendations

Supplement	Amount recommended
Multivitamin containing thiamine and 400 mcg folic acid	1-2 each day
Vitamin B12	IM: Either mcg weekly, 1,000 mcg monthly or 3,000 mcg every six months or Sublingual: 350 mcg per day
Iron (ferrous sulfate, fumarate or gluconate)	150-300 mg per day (for menstruating women)
Calcium citrate + vitamin D	400-800 mg twice daily (to achieve total dose of 1,200-2,000 mg per day)
Vitamin A	5,000 to 10,000 units per day
Vitamin D	600-50,000 units per day
Vitamin E	400 international units per day

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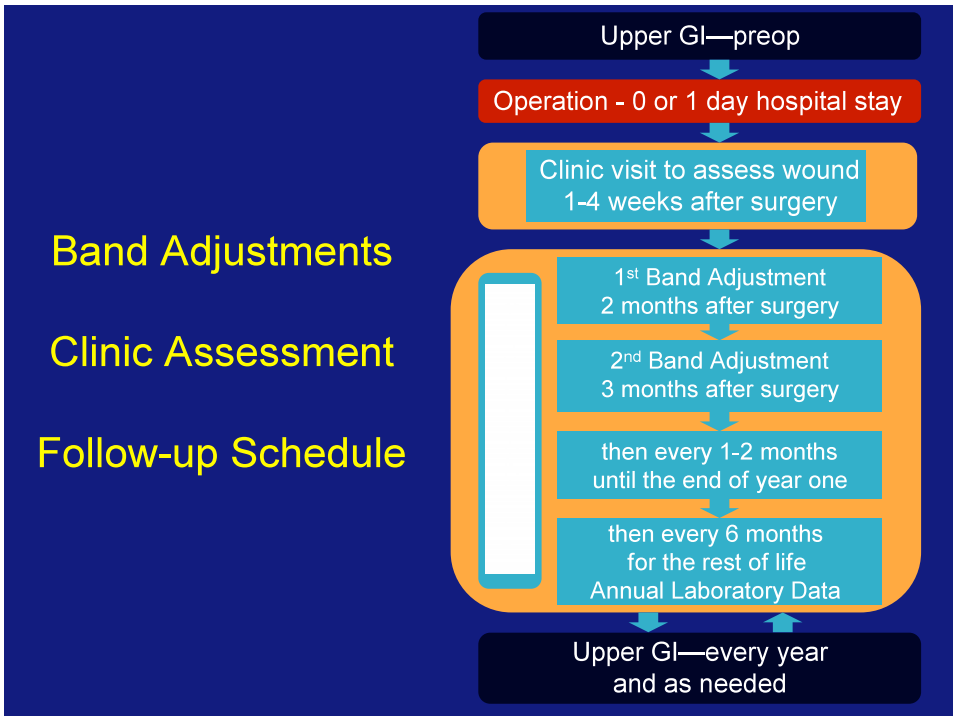
Appendix H – Band Assessment Protocol



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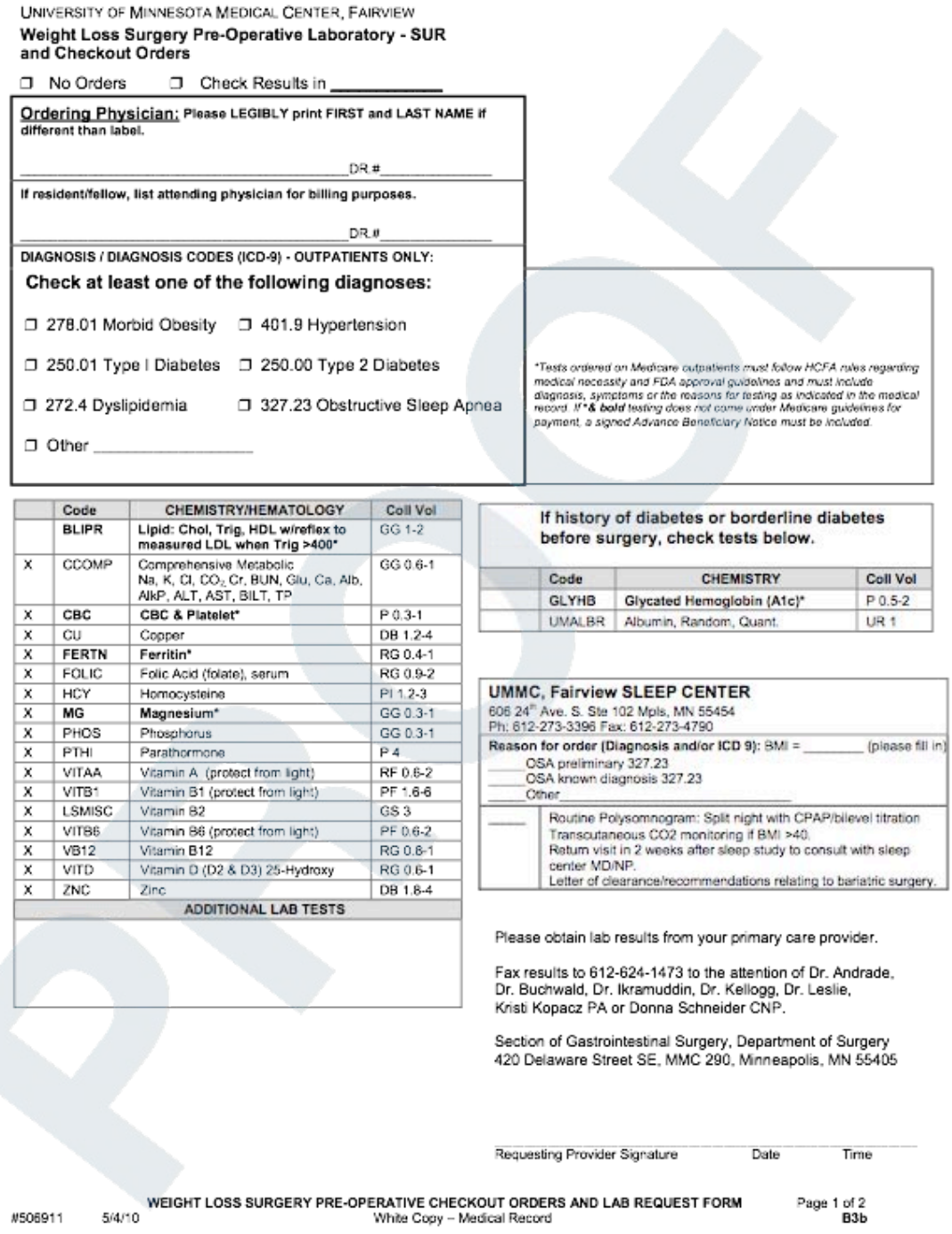
Appendix I – Sample Weight-Loss Surgery Preoperative Laboratory – SUR and Checkout Orders



UNIVERSITY OF MINNESOTA MEDICAL CENTER, FAIRVIEW

Weight Loss Surgery Pre-Operative Laboratory - SUR and Checkout Orders

❒ No Orders ❒ Check Results in _____

Ordering Physician: Please LEGIBLY print FIRST and LAST NAME if different than label.

_____ DR.#_____

If resident/fellow, list attending physician for billing purposes.

_____ DR.#_____

DIAGNOSIS / DIAGNOSIS CODES (ICD-9) - OUTPATIENTS ONLY:

Check at least one of the following diagnoses:

❒ 278.01 Morbid Obesity ❒ 401.9 Hypertension

❒ 250.01 Type I Diabetes ❒ 250.00 Type 2 Diabetes

❒ 272.4 Dyslipidemia ❒ 327.23 Obstructive Sleep Apnea

❒ Other _____

Tests ordered on Medicare outpatients must follow HCFA rules regarding medical necessity and FDA approval guidelines and must include diagnosis, symptoms or the reasons for testing as indicated in the medical record. If *& bold** testing does not come under Medicare guidelines for payment, a signed Advance Beneficiary Notice must be included.*

	Code	CHEMISTRY/HEMATOLOGY	Coll Vol
	BLIPR	**Lipid: Chol, Trig, HDL w/reflex to measured LDL when Trig >400***	GG 1-2
X	CCOMP	Comprehensive Metabolic Na, K, Cl, CO_2, Cr, BUN, Glu, Ca, Alb, AlkP, ALT, AST, BILT, TP	GG 0.6-1
X	**CBC**	**CBC & Platelet***	P 0.3-1
X	CU	Copper	DB 1.2-4
X	**FERTN**	**Ferritin***	RG 0.4-1
X	FOLIC	Folic Acid (folate), serum	RG 0.9-2
X	HCY	Homocysteine	PI 1.2-3
X	**MG**	**Magnesium***	GG 0.3-1
X	PHOS	Phosphorus	GG 0.3-1
X	PTHI	Parathormone	P 4
X	VITAA	Vitamin A (protect from light)	RF 0.6-2
X	VITB1	Vitamin B1 (protect from light)	PF 1.6-6
X	LSMISC	Vitamin B2	GS 3
X	VITB6	Vitamin B6 (protect from light)	PF 0.6-2
X	VB12	Vitamin B12	RG 0.6-1
X	VITD	Vitamin D (D2 & D3) 25-Hydroxy	RG 0.6-1
X	ZNC	Zinc	DB 1.8-4
		ADDITIONAL LAB TESTS	

If history of diabetes or borderline diabetes before surgery, check tests below.

	Code	CHEMISTRY	Coll Vol
	GLYHB	**Glycated Hemoglobin (A1c)***	P 0.5-2
	UMALBR	Albumin, Random, Quant.	UR 1

UMMC, Fairview SLEEP CENTER
606 24th Ave. S. Ste 102 Mpls, MN 55454
Ph: 612-273-3396 Fax: 612-273-4790

Reason for order (Diagnosis and/or ICD 9): BMI = _____ (please fill in)
____ OSA preliminary 327.23
____ OSA known diagnosis 327.23
____ Other_____

____ Routine Polysomnogram: Split night with CPAP/bilevel titration
Transcutaneous CO2 monitoring if BMI >40.
Return visit in 2 weeks after sleep study to consult with sleep center MD/NP.
Letter of clearance/recommendations relating to bariatric surgery.

Please obtain lab results from your primary care provider.

Fax results to 612-624-1473 to the attention of Dr. Andrade, Dr. Buchwald, Dr. Ikramuddin, Dr. Kellogg, Dr. Leslie, Kristi Kopacz PA or Donna Schneider CNP.

Section of Gastrointestinal Surgery, Department of Surgery
420 Delaware Street SE, MMC 290, Minneapolis, MN 55405

Requesting Provider Signature Date Time

WEIGHT LOSS SURGERY PRE-OPERATIVE CHECKOUT ORDERS AND LAB REQUEST FORM Page 1 of 2
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Appendix J – Sample Post-Bariatric-Surgery Patient Diet

Step 1: Clear Liquid Diet: Two Days

- Water or sugar-free clear liquid drinks
- Sugar-free Jell-O
- Vegetable, chicken or beef broth (regular or low-sodium)
- Diluted juice (50:50) (recommend apple, white grape or white cranberry juices)

Step 2: Full Liquid Diet: Two Weeks

- Skim, 1% no-sugar-added soy, or lactose-free milk **(no more than two cups per day)**
- Healthy Choice, Healthy Request Campbell's or other low-fat strained cream soups
- Thinned light yogurt, sugar-free puddings, and unsweetened applesauce
- Other protein-rich, low-sugar liquir drinks (at least 15 grams of protein per 6-8 ounces)

Step 3: Pureed Diet: One Week

- Smooth, light yogurt (no lumps or food particles present)
- Hot cereal made with milk, protein powder or non-fat dry milk powder
- Canned tuna, chicken or salmon, blenderized
- Blenderized tender meats and cottage cheese
- Thinned instant mashed potatoes (made with dry milk powder or protein powder)
- Blenderized fruits and vegetables (avoid skins, peels and membranes)

Step 4: Soft Solids: Six to Eight Weeks

- Tender, moist meats
- Canned/cooked vegetables (fresh vegetables as tolerated – skins, peels, membranes not tolerated well in the beginning)
- Baked fish (non-breaded and without bones)
- Low-fat or fat-free refried beans
- Tuna, chicken, crab or egg salad (made with fat-free or light mayonnaise), blenderized
- Banana, seedless melons or canned fruit in its own juice
- Advance textures as tolerated (try one new food every other day)

Step 5: Regular Bariatric Diet – Avoid Foods with Skins, Peels, Membranes and Seeds for the First Three Months After Surgery

- Skinless, boneless **moist** chicken and turkey breasts
- Pork loin, pork tenderloin
- Lean ground meats
- Lean and extra-lean cuts of beef and turkey (sirloin, round, flank, 93-96% hamburger)
- Cottage cheese or part-skim ricotta cheese
- Cooked or canned vegetables
- Fresh, frozen or canned fruit in its own juice
- Cooked cereals, potatoes, whole grain crackers, etc.

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Appendix K – Example SMART Goal

Go For Your Goal

It is important to set goals and make a plan when it comes to managing your diabetes, because having a plan makes it easier to make daily choices.

Goals need to be **SMART.** They need to make SENSE and answer why you are setting the goal. They need to be MEASURABLE and answer what will happen and where. Goals need to be ATTAINABLE and answer how you are going to achieve your goal. They need to be REALISTIC and show yourself responsible as in "I will" – not "I will *try*." Goals include a TIME or when you will do something.

Sensible	makes sense, answers "why"
Measurable	"what and where"
Attainable	answers "how"
Realistic	"I will" – not "I will *try*"
Time	"when"

SMART Goal Sample

To increase my physical activity, *I will walk three times a week on the exercise trail outside of my apartment complex in the morning between 7 and 8 a.m. for the next three months and wear my pedometer to track my steps.*

- What is your long-term goal to improve your life with diabetes? (check one)

  ☐ manage blood glucose ☐ manage cholesterol ☐ manage stress

  ☐ manage weight ☐ establish support network ☐ _____

	Not important				Very important
• How important is it to you? (circle one)	1	2	3	4	5

  Why is this important to you?

	Not confident				Very confident
• How confident are you that you can do it? (circle one)	1	2	3	4	5

- What is one thing you can start doing to work toward your long-term goal? For example: I will walk 20 minutes three times a week after lunch.

- Write down a question for your health care team about reaching your goal.

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Appendix L – Readiness to Change – Motivational Interviewing Sample Scripting for Adults

I. Suggestions for Using Motivational Interviewing to Address Weight Management

1. Why is now a good time for you to lose weight?
2. What have you tried in the past to lose weight?
3. How would you do things differently this time?
4. How would you feel if you were successful losing weight?
5. What's one thing we can do together to make a step towards your weight-loss goals?
6. Help me understand why you want to lose weight.
7. What could work? To what extent would this affect your life?

II. Sample Script for 10-minute Motivational Interview for Weight Loss:

1. **LISTEN:** Ask open-ended questions. Exhibit curiosity versus being judgmental (Remember W.A.I.T. = Why am I talking?)
2. **ASK PERMISSION:** Acknowledge that the right and freedom not to change sometimes makes the change possible.
3. **ENGAGE:** Take off the expert hat.
4. **REFLECT:** Clarify that you heard correctly.

Ask what patient wants to work on today.

Tell what you heard the patient say.

Ask patient if it is okay to provide information/input.

Set the agenda for the visit.

- **ASK: What concerns you most about your weight?**
- **1-2 minutes ELICIT:**
  - "Tell me what you know (or what you've tried) about losing weight."
- **½ minute REFLECT:**
  - "It sounds like you are having trouble losing weight."
- **2 minutes PROVIDE:**
  - In non-judgmental fashion…"May I share with you what has worked for other patients to lose weight?"
- **1-2 minutes ELICIT:**
  - "How do you feel about these ideas?"

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- **2-3 minutes GOAL:**
  - "What would be one small step that you think you might be able to do moving forward?"
  - "I heard you say you will start keeping a food record. On a scale of 1-10, how confident are that you you will be able to do this? (A score or 7 or higher indicating success in this goal) "If a 5 …why not a 2?" or "What would it take to get you from a 5 to a 7?"
- **You said:**

(Clinician or patient writes goals on a paper that goes home with patient.)

- I will keep a food record for two weeks.
- I will schedule a follow-up appointment in two weeks to review my food records.
- I will post my goals on the bathroom mirror.
- I will weigh myself once a week and record it.

Clarify: "Is that correct?"

- 1/2 minute SESSION CLOSE:

"Thank you for your time today. I can hear excitement in your voice about starting (or continuing) on the path to losing weight. I am confident that you will do this! In two weeks, I look forward to seeing you to follow up and ask some questions about your action goal."

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Appendix M – How to Utilize the 5 A's Approach

ASK

Implement an officewide system to ensure that for every patient, preferably on an annual basis, weight is measured, body mass index is calculated, and patients are educated about their body mass index and risk status. See Annotation #1, "Measure Height and Weight, and Calculate Body Mass Index."

ADVISE to lose weight

Patients who are in the normal weight range should be encouraged to be physically active and eat a healthy diet to help prevent future weight gain. If a patient is overweight or obese, physicians need to communicate this in a direct but sensitive manner and also make the recommendation to consider losing weight. Research suggests that adults who report that their physician advised them to lose weight are more likely to initiate weight loss attempts. Obese patients who reported receiving advice to lose weight have been shown to be almost three times as likely to report trying to lose weight compared with those who did not receive advice. *(Abid, 2005 [Reference])*. The next important step will be to engage the patient in a discussion regarding his/her current level of motivation for losing weight.

ASSESS readiness to change/motivation for weight loss

Although definitive evidence regarding the prognostic significance of an individual's stage of change is not available, assessment of an individual's readiness to make a weight-loss attempt is a key step in encouraging weight-loss efforts. There is evidence that moving into and/or staying longer in the "action" stage for weight loss is associated with better weight outcomes. For example, Prochaska and colleagues found that the more clients progressed into the action stage early in weight-loss therapy, the more successful they were in losing weight by the end of treatment *(Prochaska, 1992 [Reference])*. A study showed that the elapsed time in action or maintenance for multiple weight-loss-related target behaviors is longitudinally related to weight loss over a two-year period *(Logue, 2004 [Reference])*. However, others have found no association between baseline stage of change for weight loss and short- *(Macqueen, 2002 [Reference])* and long-term (e.g., three years) weight outcomes *(Jeffery, 1999 [Reference])*. The only published randomized trial specifically evaluating the efficacy of a primary-case based, transtheoretical model, stage-matched weight-loss intervention delivered was associated with weight maintenance, but not weight loss at one-year follow-up *(Logue, 2005 [Reference])*. The authors note that their intervention (e.g., monthly telephone advice) was not intensive enough to produce clinically significant weight losses, which is consistent with a large body of evidence suggesting that intervention intensity and frequency of contact are strongly associated with successful outcomes *(Jeffery, 2000 [Reference])*.

Additional psychological and lifestyle factors clearly have an influence on weight-loss success. For example, research suggests that depression status may adversely affect treatment outcome *(Linde, 2004 [Reference])* and should be considered when making recommendations for weight loss to patients. It is recommended that physicians assess patient motivation and support, stressful life events, psychiatric status, time availability and constraints, and appropriateness of goals and expectations to help establish the likelihood of lifestyle change in the area of nutrition and physical activity. Assessing readiness to change involves more than simply asking patients, "Are you ready to lose weight?"

One helpful strategy to begin an assessment is to anchor patients' interest and confidence for change on a numerical scale. "On a scale from 0 to 10, with 0 being not interested and 10 being very interested, how interested are you in losing weight at this time?" See MI example in Appendix L. Ask patients, "On a scale of 0 to 10, with 0 being not important and 10 being very important, how important is it for you to lose weight at this time?" Follow this by asking, "Also, on a scale of 0 to 10, with 0 being not confident and 10 being very confident, how confident are you that you can lose weight at this time?" Physicians can also ask patients: "On a scale of 0 to 10, with 0 being not interested and 10 being very interested, how interested are you in losing weight at this time?"

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To obtain further information about patient readiness to change, a Patient Readiness Checklist can be administered. For example, see the American Medical Association's "Road Maps for Clinical Practice – Assessment and Management of Adult Obesity" (http://www.ama-assn.org/ama/pub/category/10931.html, booklet 3, figure 3.2.). This checklist assesses multiple domains including patient motivation/support for change, stressful life events that may hinder change efforts, psychiatric issues (e.g., depression, binge eating), time availability/constraints, and weight-loss goals/expectations. Figure 3.3 of the AMA guideline is a weight-loss questionnaire that may also be a useful tool.

Another useful tool can be the Patient Activation Measure or PAM. The PAM is a tool designed to assess an individual's knowledge, skill and confidence with respect to managing his or her health. It has been used and studied in several chronic disease management programs. Based on a 13-item scale, each patient is assigned an "activation score" from Level 1 to 4, with 1 being the lowest health activation (patients tend to be overwhelmed and unprepared to play an active role in their own health) to 4 being the highest (patients have adopted many of the behaviors needed to support a healthy lifestyle). Using this measure can help guide a clinician as to where to begin the assessment process. Patients with lower activation need a different approach and more health coaching to get them to a point where they can consider weight management. *(Hibbard, 2009 [Reference]; Schmittdiel, 2007 [Reference]; Hibbard, 2005 [Reference]; Hibbard, 2004 [Reference]).*

ASSIST in weight-loss attempt

- Patient not currently interested/motivated for weight loss? Patients may fit into this category either because they are unaware that their weight status is a problem, or they are not interested in changing (pre-contemplator), or they are aware of the problem but are just starting to think about changing (contemplator). Providing information about the health risks of obesity and the potential health benefits of weight loss may be most appropriate for those who are not yet interested in changing. For patients who are just beginning to contemplate change, discussion of ambivalence about change and of barriers to change may be helpful strategies. Patient readiness to lose weight should be reassessed at regular intervals.
- Patient interested/motivated for weight loss? Patients who are interested and motivated to lose weight likely need information about appropriate nutrition, activity and behavioral recommendations and support in making these lifestyle changes. The sections below describe in detail recommendations for eating, physical activity and behavioral modification. Physicians need to be aware of resources and appropriate referral sources within their clinics and/or local communities for their patients. See the Quality Improvement Support section, Implementation Tools and Resources Table, for Web sites and further information about weight management.

ARRANGE follow-up

Although physicians may not necessarily be directly involved in weight-management counseling, it is recommended that a follow-up appointment to evaluate progress be scheduled approximately three months following initiation of a weight-loss program by a patient, and progress should be reassessed at appropriate intervals thereafter.

Studies have shown that weekly follow-up for the first three months and gradually decreasing to monthly for the next six months to four years can produce successful weight loss and maintenance *(Wing, 2005 [Reference])*. A successful intensive lifestyle intervention program such as the Look AHEAD (Action for Health in Diabetes) program (a study of weight loss and maintenance in diabetic patients) produced 9% weight loss in one year and maintained a 6% weight loss at four years. Institutions wishing to start an intensive lifestyle intervention program for overweight and obese patients should consider modeling it after this successful program *(Wadden, 2009 [Reference])*.

See Annotation #13, "Reassess Goals and Risk Factors, and Counsel Regarding Weight Maintenance."

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Appendix N – ICSI Shared Decision-Making Model

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The technical aspects of Shared Decision-Making are widely discussed and understood.

- **Decisional conflict** occurs when a patient is presented with options where no single option satisfies all the patient's objectives, where there is an inherent difficulty in making a decision, or where external influencers act to make the choice more difficult.
- **Decision support** clarifies the decision that needs to be made, clarifies the patient's values and preferences, provides facts and probabilities, guides the deliberation and communication and monitors the progress.
- **Decision aids** are evidence-based tools that outline the benefits, harms, probabilities and scientific uncertainties of specific health care options available to the patient.

However, before decision support and decision aids can be most advantageously utilized, a Collaborative Conversation™ should be undertaken between the provider and the patient to provide a supportive framework for Shared Decision-Making.

Collaborative Conversation™

A collaborative approach toward decision-making is a fundamental tenet of Shared Decision-Making (SDM). The Collaborative Conversation™ is an inter-professional approach that nurtures relationships, enhances patients' knowledge, skills and confidence as vital participants in their health, and encourages them to manage their health care.

Within a Collaborative Conversation™ , the perspective is that both the patient and the provider play key roles in the decision-making process. The patient knows which course of action is most consistent with his/her values and preferences, and the provider contributes knowledge of medical evidence and best practices. Use of Collaborative Conversation™ elements and tools is even more necessary to support patient, care provider and team relationships when patients and families are dealing with high stakes or highly charged issues, such as diagnosis of a life-limiting illness.

The overall framework for the Collaborative Conversation™ approach is to create an environment in which the patient, family and care team work collaboratively to reach and carry out a decision that is consistent with the patient's values and preferences. A rote script or a completed form or checklist does not constitute this approach. Rather it is a set of skills employed appropriately for the specific situation. These skills need to be used artfully to address all aspects involved in making a decision: cognitive, affective, social and spiritual.

Key communication skills help build the Collaborative Conversation™ approach. These skills include many elements, but in this appendix only the questioning skills will be described. (For complete instruction, see O'Connor, Jacobsen "Decisional Conflict: Supporting People Experiencing Uncertainty about Options Affecting Their Health" [2007], and Bunn H, O'Connor AM, Jacobsen MJ "Analyzing decision support and related communication" [1998, 2003].)

1. **Listening skills:**

   Encourage patient to talk by providing prompts to continue such as "*go on, and then?, uh huh,*" or by repeating the last thing a person said, "*It's confusing*."

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Paraphrase content of messages shared by patient to promote exploration, clarify content and to communicate that the person's unique perspective has been heard. The provider should use his/her own words rather than just parroting what he/she heard.

Reflection of feelings usually can be done effectively once trust has been established. Until the provider feels that trust has been established, short reflections at the same level of intensity expressed by the patient without omitting any of the message's meaning are appropriate. Reflection in this manner communicates that the provider understands the patient's feelings and may work as a catalyst for further problem solving. For example, the provider identifies what the person is feeling and responds back in his/her own words like this: "*So, you're unsure which choice is the best for you*."

Summarize the person's key comments and reflect them back to the patient. The provider should condense several key comments made by the patient and provide a summary of the situation. This assists the patient in gaining a broader understanding of the situations rather than getting mired down in the details. The most effective times to do this are midway through and at the end of the conversation. An example of this is, "*You and your family have read the information together, discussed the pros and cons, but are having a hard time making a decision because of the risks*."

Perception checks ensure that the provider accurately understands a patient or family member, and may be used as a summary or reflection. They are used to verify that the provider is interpreting the message correctly. The provider can say "*So you are saying that you're not ready to make a decision at this time. Am I understanding you correctly?*"

2. **Questioning Skills**

Open and closed questions are both used, with the emphasis on open questions. Open questions ask for clarification or elaboration and cannot have a yes or no answer. An example would be "*What else would influence you to choose this?*" Closed questions are appropriate if specific information is required such as "*Does your daughter support your decision?*"

Other skills such as summarizing, paraphrasing and reflection of feeling can be used in the questioning process so that the patient doesn't feel pressured by questions.

Verbal tracking, referring back to a topic the patient mentioned earlier, is an important foundational skill (Ivey & Bradford-Ivey). An example of this is the provider saying, "*You mentioned earlier…*"

3. **Information-Giving Skills**

Providing information and **providing feedback** are two methods of information giving. The distinction between providing information and giving advice is important. Information giving allows a provider to supplement the patient's knowledge and helps to keep the conversation patient centered. Giving advice, on the other hand, takes the attention away from the patient's unique goals and values, and places it on those of the provider.

Providing information can be sharing facts or responding to questions. An example is "*If we look at the evidence, the risk is…*" Providing feedback gives the patient the provider's view of the patient's reaction. For instance, the provider can say, "*You seem to understand the facts and value your daughter's advice*."

Additional Communication Components

Other elements that can impact the effectiveness of a Collaborative Conversation™ include:

- Eye contact
- Body language consistent with message
- Respect

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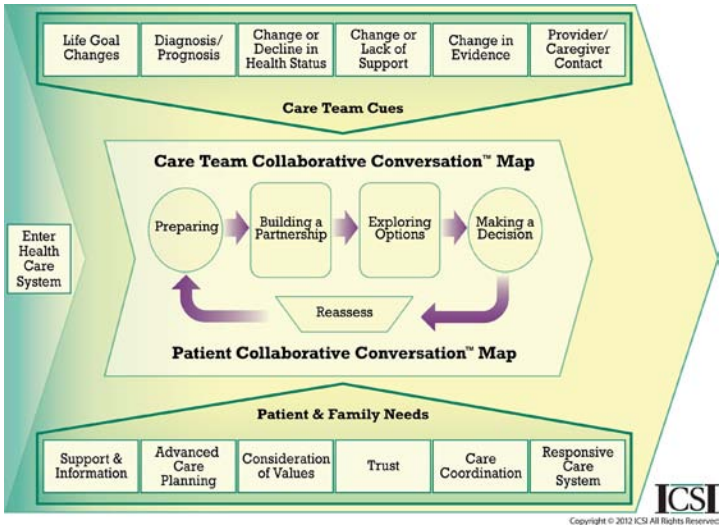
- Empathy
- Partnerships

Self-examination by the provider involved in the Collaborative Conversation™ can be instructive. Some questions to ask oneself include:

- Do I have a clear understanding of the likely outcomes?
- Do I fully understand the patient's values?
- Have I framed the options in comprehensible ways?
- Have I helped the decision-makers recognize that preferences may change over time?
- Am I willing and able to assist the patient in reaching a decision based on his/her values, even when his/her values and ultimate decision may differ from my values and decisions in similar circumstances?

When to Initiate a Collaborative Conversation™

A Collaborative Conversation™ can support decisions that vary widely in complexity. It can range from a straightforward discussion concerning routine immunizations to the morass of navigating care for a life-limiting illness. Table 1 represents one health care event. This event can be simple like a 12 year-old coming to the clinic for routine immunizations, or something much more complex like an individual receiving a diagnosis of congestive heart failure. In either case, the event is the catalyst that starts the process represented in this table. There are cues for providers and patient needs that exert influence on this process. They are described below. The heart of the process is the Collaborative Conversation™. The time the patient spends within this health care event will vary according to the decision complexity and the patient's readiness to make a decision.



Regardless of the decision complexity there are cues applicable to all situations that indicate an opportune time for a Collaborative Conversation™. These cues can occur singularly or in conjunction with other cues.

Cues for the Care Team to Initiate a Collaborative Conversation™

- **Life goal changes:** Patient's priorities change related to things the patient values such as activities, relationships, possessions, goals and hopes, or things that contribute to the patient's emotional and spiritual well-being.

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- **Diagnosis/prognosis changes:** Additional diagnoses, improved or worsening prognosis.
- **Change or decline in health status:** Improving or worsening symptoms, change in performance status or psychological distress.
- **Change or lack of support:** Increase or decrease in caregiver support, change in caregiver, or caregiver status, change in financial standing, difference between patient and family wishes.
- **Change in medical evidence or interpretation of medical evidence:** Providers can clarify the change and help the patient understand its impact.
- **Provider/caregiver contact:** Each contact between the provider/caregiver and the patient presents an opportunity to reaffirm with the patient that his/her care plan and the care the patient is receiving are consistent with his/her values.

Patients and families have a role to play as decision-making partners, as well. The needs and influencers brought to the process by patients and families impact the decision-making process. These are described below.

Patient and Family Needs within a Collaborative Conversation™

- **Request for support and information:** Decisional conflict is indicated by, among other things, the patient verbalizing uncertainty or concern about undesired outcomes, expressing concern about choice consistency with personal values and/or exhibiting behavior such as wavering, delay, preoccupation, distress or tension. Generational and cultural influencers may act to inhibit the patient from actively participating in care discussions, often patients need to be given "permission" to participate as partners in making decisions about his/her care.

  Support resources may include health care professionals, family, friends, support groups, clergy and social workers. When the patient expresses a need for information regarding options and his/her potential outcomes, the patient should understand the key facts about options, risks and benefits, and have realistic expectations. The method and pace with which this information is provided to the patient should be appropriate for the patient's capacity at that moment.

- **Advance Care Planning:** With the diagnosis of a life-limiting illness, conversations around advance care planning open up. This is an opportune time to expand the scope of the conversation to other types of decisions that will need to be made as a consequence of the diagnosis.
- **Consideration of Values:** The personal importance a patient assigns potential outcomes must be respected. If the patient is unclear how to prioritize the preferences, value clarification can be achieved through a Collaborative Conversation™ and by the use of decision aids that detail the benefits and harms of potential outcomes in terms the patient can understand.
- **Trust:** The patient must feel confident that his/her preferences will be communicated and respected by all caregivers.
- **Care Coordination:** Should the patient require care coordination, this is an opportune time to discuss the other types of care-related decisions that need to be made. These decisions will most likely need to be revisited often. Furthermore, the care delivery system must be able to provide coordinated care throughout the continuum of care.
- **Responsive Care System:** The care system needs to support the components of patient- and family-centered care so the patient's values and preferences are incorporated into the care he/she receives throughout the care continuum.

The Collaborative Conversation™ Map is the heart of this process. The Collaborative Conversation™ Map can be used as a stand-alone tool that is equally applicable to providers and patients as shown in Table 2.

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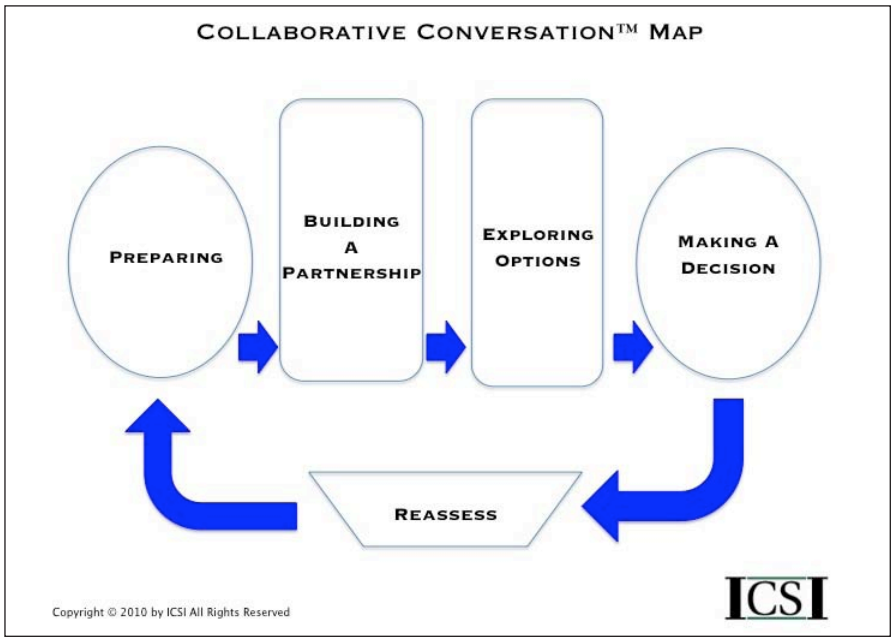
Providers use the map as a clinical workflow. It helps get the Shared Decision-Making process initiated and provides navigation for the process. Care teams can used the Collaborative Conversation™ to document team best practices and to formalize a common lexicon. Organizations can build fields from the Collaborative Conversation™ Map in electronic medical records to encourage process normalization. Patients use the map to prepare for decision-making, to help guide them through the process and to share critical information with their loved ones.



Evaluating the Decision Quality

Adapted from O'Connor, Jacobsen "Decisional Conflict: Supporting People Experiencing Uncertainty about Options Affecting Their Health" [2007].

When the patient and family understand the key facts about the condition and his/her options, a good decision can be made. Additionally, the patient should have realistic expectations about the probable benefits and harms. A good indicator of the decision quality is whether or not the patient follows through with his/her chosen option. There may be implications of the decision on patient's emotional state such as regret or blame, and there may be utilization consequences.

Decision quality can be determined by the extent to which the patient's chosen option best matches his/her values and preferences as revealed through the Collaborative Conversation™ process.

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ICSI has long had a policy of transparency in declaring potential conflicting and competing interests of all individuals who participate in the development, revision and approval of ICSI guidelines and protocols.

In 2010, the ICSI Conflict of Interest Review Committee was established by the Board of Directors to review all disclosures and make recommendations to the board when steps should be taken to mitigate potential conflicts of interest, including recommendations regarding removal of work group members. This committee has adopted the Institute of Medicine Conflict of Interest standards as outlined in the report, Clinical Practice Guidelines We Can Trust (2011).

Where there are work group members with identified potential conflicts, these are disclosed and discussed at the initial work group meeting. These members are expected to recuse themselves from related discussions or authorship of related recommendations, as directed by the Conflict of Interest committee or requested by the work group.

The complete ICSI policy regarding Conflicts of Interest is available at http://bit.ly/ICSICOI.

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ICSI facilitates and coordinates the guideline development and revision process. ICSI, member medical groups and sponsoring health plans review and provide feedback but do not have editorial control over the work group. All recommendations are based on the work group's independent evaluation of the evidence.

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Research Grants: None
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All ICSI documents are available for review during the revision process by member medical groups and sponsors. In addition, all members commit to reviewing specific documents each year. This comprehensive review provides information to the work group for such issues as content update, improving clarity of recommendations, implementation suggestions and more. The specific reviewer comments and the work group responses are available to ICSI members at http://Obesity.

The ICSI Patient Advisory Council meets regularly to respond to any scientific document review requests put forth by ICSI facilitators and work groups. Patient advisors who serve on the council consistently share their experiences and perspectives in either a comprehensive or partial review of a document, and engaging in discussion and answering questions. In alignment with the Institute of Medicine's triple aims, ICSI and its member groups are committed to improving the patient experience when developing health care recommendations.

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Acknowledgements

ICSI Patient Advisory Council

The work group would like to acknowledge the work done by the ICSI Patient Advisory Council in reviewing the Prevention and Management of Obesity (Adults) guideline. ICSI would like to recognize two ICSI Patient Advisory Council members who participated in the work group review and revision: Lynn Everling and Erika Kennedy.

Invited Reviewers

During this revision, the following groups reviewed this document. The work group would like to thank them for their comments and feedback.

Allina Medical Clinic, Mineapolis, MN
CentraCare Health System, St. Cloud, MN
HealthPartners Health Plan
Marshfield Clinic, Marshfield, WI
Mayo Clinic, Rochester, MN
Medica Health Plans, Minnetonka, MN
Minnesota Association of Community Health Centers, Minneapolis, MN

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ICSI
Institute for Clinical Systems Improvement

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Document History

- *Statewide Health Improvement Program selected ICSI Obesity guideline for implementation.*

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ICSI Document Development and Revision Process

Overview

Since 1993, the Institute for Clinical Systems Improvement (ICSI) has developed more than 60 evidence-based health care documents that support best practices for the prevention, diagnosis, treatment or management of a given symptom, disease or condition for patients.

Audience and Intended Use

The information contained in this ICSI Health Care Guideline is intended primarily for health professionals and other expert audiences.

This ICSI Health Care Guideline should not be construed as medical advice or medical opinion related to any specific facts or circumstances. Patients and families are urged to consult a health care professional regarding their own situation and any specific medical questions they may have. In addition, they should seek assistance from a health care professional in interpreting this ICSI Health Care Guideline and applying it in their individual case.

This ICSI Health Care Guideline is designed to assist clinicians by providing an analytical framework for the evaluation and treatment of patients, and is not intended either to replace a clinician's judgment or to establish a protocol for all patients with a particular condition.

Document Development and Revision Process

The development process is based on a number of long-proven approaches and is continually being revised based on changing community standards. The ICSI staff, in consultation with the work group and a medical librarian, conduct a literature search to identify systematic reviews, randomized clinical trials, meta-analysis, other guidelines, regulatory statements and other pertinent literature. This literature is evaluated based on the GRADE methodology by work group members. When needed, an outside methodologist is consulted.

The work group uses this information to develop or revise clinical flows and algorithms, write recommendations, and identify gaps in the literature. The work group gives consideration to the importance of many issues as they develop the guideline. These considerations include the systems of care in our community and how resources vary, the balance between benefits and harms of interventions, patient and community values, the autonomy of clinicians and patients and more. All decisions made by the work group are done using a consensus process.

ICSI's medical group members and sponsors review each guideline as part of the revision process. They provide comment on the scientific content, recommendations, implementation strategies and barriers to implementation. This feedback is used by and responded to by the work group as part of their revision work. Final review and approval of the guideline is done by ICSI's Committee on Evidence-Based Practice. This committee is made up of practicing clinicians and nurses, drawn from ICSI member medical groups.

Implementation Recommendations and Measures

These are provided to assist medical groups and others to implement the recommendations in the guidelines. Where possible, implementation strategies are included that have been formally evaluated and tested. Measures are included that may be used for quality improvement as well as for outcome reporting. When available, regulatory or publicly reported measures are included.

Document Revision Cycle

Scientific documents are revised every 12-24 months as indicated by changes in clinical practice and literature. ICSI staff monitors major peer-reviewed journals every month for the guidelines for which they are responsible. Work group members are also asked to provide any pertinent literature through check-ins with the work group midcycle and annually to determine if there have been changes in the evidence significant enough to warrant document revision earlier than scheduled. This process complements the exhaustive literature search that is done on the subject prior to development of the first version of a guideline.

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