



**OREGON HEALTH AND SCIENCE UNIVERSITY  
OFFICE OF CLINICAL INTEGRATION AND EVIDENCE-BASED PRACTICE**

Evidence-Based Practice Summary  
Follow-up Strategies for Patients Outside of Normal BMI Parameters

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**BACKGROUND AND RATIONALE**

The Physician Quality Reporting System (PQRS 128, 2015) requires that patients aged 18 years and older receive body mass index (BMI) screening and follow-up to address weight conditions outside the normal parameters (age 65 years and older; BMI  $\geq 23$  and  $< 30 \text{ kg/m}^2$ ; age 18-64 years; BMI  $\geq 18.5$  and  $< 25 \text{ kg/m}^2$ ). In order for providers to meet this performance measure, they must document a patient's BMI during the current encounter or during the previous six months. Additionally, if the patient's BMI is outside the normal parameters, a follow-up plan must be documented. A follow-up plan may include, but is not limited to: (1) Documentation of education; (2) Referral; (3) Pharmacological interventions; (4) Dietary supplements; (5) Exercise counseling; or (6) Nutrition Counseling.

This requirement is in response to the national increase of adults who are considered overweight or obese, where according to the Centers for Disease Control and Prevention, more than one-third (36.5%) of U.S. adults have a BMI  $\geq 30 \text{ kg/m}^2$  (CDC, 2015). Obesity causes an estimated annual medical cost of \$147 billion, with the annual medical costs for people who are obese \$1,429 higher than those of normal weight (Finkelstein, 2009). This is due to the fact that obesity causes deadly and costly preventable conditions such as heart disease, stroke, type 2 diabetes and certain types of cancer (NHLBI, 2013).

**BMI Above Normal Parameters**

Obesity is also associated with an increased risk of death, particularly in adults younger than age 65 years and has been shown to reduce life expectancy by 6 to 20 years depending on age and race (LeBlanc et al., 2011). Masters, et al. (2013) also showed mortality due to obesity varied by race and gender. They estimated adult deaths between 1986 and 2006 associated with overweight and obesity was 5.0% and 15.6% for Black and White men, and 26.8% and 21.7% for Black and White women, respectively. They also found a stronger association than previous research demonstrated between obesity and mortality risk at older ages. Padula, Allen and Nair (2014) examined data from a commercial claims and encounters database to estimate the cost for obesity and associated comorbidities among working-age adults who had a claim with a primary or secondary diagnosis of obesity in 2006-2007. The mean net expenditure for inpatient and outpatient claims was \$1,907 per patient per visit. The increases in cost for comorbidities ranged from \$527 for obesity with CHF to \$15,733 for the combination of obesity, diabetes mellitus, hypertension and depression. In addition to a high prevalence rate of obesity, less than 50% of obese adults in 2010 received advice to exercise or perform physical activity (Barnes & Schoenborn, 2012).

**BMI Below Normal Parameters**



In the National Center for Health Statistics (NCHS) Health E-Stat, Fryer and Ogden (2012) reported that poor nutrition or underlying health conditions can result in underweight. Results from the 2007-2010 National Health and Nutrition Examination Survey (NHANES), using measured heights and weights, indicate an estimated 1.7% of U.S. adults are underweight with women more likely to be underweight than men (2012). In a cohort study conducted by Borrell and Samuel (2014), data from NHANES III (1988-1994) was linked to the National Death Index mortality file with follow-up to 2006, and showed that when compared to their normal weight counterparts (BMI 18.5-25 kg/m<sup>2</sup>), underweight (BMI <18.5 kg/m<sup>2</sup>) had significantly higher death rates (Hazard Ratio= 2.27; 95% confidence interval (CI) = 1.78, 2.90). Ranhoff, Gjoen and Mowe (2005) recommended using BMI < 23 kg/m<sup>2</sup> for the elderly to identify positive results with malnutrition screens and poor nutritional status.

### **Normal Parameters for Age 65 Years and Older**

Winter et al. (2014) performed a meta-analysis looking at the relationship between BMI and all-cause mortality among adults 65 and older. They identified a higher risk of mortality among those with a BMI <23 kg/m<sup>2</sup> and recommended monitoring weight status in this group to address any modifiable causes of weight loss promptly with due consideration of individual comorbidities. Dahl et al. (2013) reported that old persons (70-79) who were overweight had a lower mortality risk than old persons who were of normal weight, even after controlling for weight change and multimorbidity. The study also shows that persons who increased or decreased in BMI had a greater mortality risk than those who had a stable BMI, particularly those aged 70 to 79. Their results provide support to the belief that the World Health Organization guidelines for BMI are overly restrictive in old age.

### **ASK THE QUESTION**

In patients 18 years and older with a Body Mass Index (BMI) outside of normal parameters (Age 65 years and older BMI  $\geq$ 23 and <30 kg/m<sup>2</sup>; Age 18 – 64 years BMI  $\geq$ 18.5 and <25 kg/m<sup>2</sup>), what are the most effective clinical tools and strategies for implementing follow-up on weight loss?

### **SEARCH FOR EVIDENCE**

**Databases** included Ovid MEDLINE, Cochrane Database of Systematic Reviews, PsycINFO, and National Guideline Clearinghouse, also looked at references and citing articles

**Ovid MEDLINE search strategy** included:

1. exp Primary Health Care/ (99822)
2. exp General Practitioners/ (3657)
3. exp Family Practice/ (34047)
4. exp Physicians, Family/ (9745)
5. exp Ambulatory Care/ (26085)
6. exp Ambulatory Care Facilities/ (27945)
7. exp Office Visits/ (5050)
8. exp "Referral and Consultation"/ (44155)



9. exp outpatients/ (9712)
10. (appointment\* or (((office\* or schedul\* or clinic or clinics) adj5 visit\*) or ((house or home or homes) adj5 (call\* or visit\*))))).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms] (41421)
11. 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 (256253)
12. exp overweight/dh, dt, nu, rh, su, th [Diet Therapy, Drug Therapy, Nursing, Rehabilitation, Surgery, Therapy] (34024)
13. limit 12 to yr="2007 - 2017" (24645)
14. exp "Outcome and Process Assessment"/ (849232)
15. 13 and 14 (5808)
16. exp Mortality/ (256207)
17. mo.fs. (345531)
18. 16 or 17 (479083)
19. 13 and 18 (583)
20. 15 or 19 (6146)
21. limit 20 to (meta analysis or systematic reviews) (473)
22. limit 21 to english language (437)
23. limit 21 to abstracts (436)
24. 22 or 23 (464)
25. 11 and 24 (25)
26. 11 and 20 (268)
27. limit 26 to (comparative study or controlled clinical trial or meta-analysis or practice guideline or randomized controlled trial or systematic reviews) (107)
28. exp Epidemiologic Studies/ (1647442)
29. 26 and 28 (121)
30. 27 or 29 (192)
31. limit 30 to english language (186)
32. limit 30 to abstracts (186)
33. 31 or 32 (192)
34. 33 not 25 (167)
35. limit 25 to yr="2012 -Current" (17)

**Filters/limits** included research articles published in English in the last 5 years



### **CRITICALLY ANALYZE THE EVIDENCE**

The search resulted in 192 of primary research articles. Due to the large volume of literature, we focused on systematic reviews addressing treatment and follow-up in the clinical office setting. Seventeen systematic reviews reporting on various interventions are included in the analysis. To simplify the review process, we grouped the evidence into three categories: (1) Pharmacologic interventions; (2) Non-pharmacologic interventions; and (3) Documentation.

1. **Pharmacologic**: Two systematic reviews studied the effects of pharmacologic interventions on long-term weight loss which overall showed that drug interventions were effective at reducing weight and BMI, especially in the short-term. One systematic review with meta-analysis (Ara, 2012) evaluated the clinical effectiveness and cost-effectiveness of three pharmacological interventions compared with each other and with standard care in obese patients in primary care. The meta-analysis included 94 studies of 24,808 individuals.. The results showed that the active drug interventions are all effective at reducing weight and BMI compared with placebo. At 3 months from baseline, all active treatments were associated with significant reductions in BMI compared with placebo (0.50 kg/m<sup>2</sup>, CrI -0.51kg/m<sup>2</sup> to 1.48 kg/m<sup>2</sup>). However, at 6 months none of the active treatments or standard care was significantly better than placebo. For example, metformin was associated with an increase in BMI compared with placebo (0.18 kg/m<sup>2</sup>, 95% CrI -4.05 kg/m<sup>2</sup> to 4.37 kg/m<sup>2</sup>). At 12 months orlistat and sibutramine 15 mg resulted in significantly greater BMI loss than placebo. No difference was seen between sibutramine 10 mg and placebo or standard care. Sibutramine 15 mg had the largest probability (62.4%) of being the best intervention in terms of BMI loss. Another systematic review (LeBlanc, 2011) studied effectiveness and harms of primary care – relevant weight-loss interventions for overweight and obese adults. Orlistat treatment with accompanying behavioral component resulted in weight loss of 11 to 22 lb; (8% of baseline weight) compared to 7 to 13 lb; (5% of baseline weight) with placebo and the same behavioral component. In the 12 trials that could be combined by meta-analysis, participants randomly assigned to orlistat lost 6.6lb more (95% CI, -3.9 to -2.0 kg) than those receiving placebo after 12 months. Weight loss was maintained with up to 24 to 36 months of orlistat therapy. Metformin plus a behavioral intervention was associated with a smaller degree of weight loss (4.4 to 8.8lb), although the best evidence was limited to patients with prediabetes.  
*Quality of Evidence: Low*
2. **Non-Pharmacologic**: Five systematic reviews studied non-pharmacologic interventions on long-term weight loss, a majority included various behavioral interventions. One systematic review (Barnes, 2014) examined motivational interviewing (MI) as an intervention for weight loss among adult patients in a primary care setting. When comparing the studies that implemented the MI intervention in addition to typical primary care appointments to those that incorporated MI into regularly scheduled appointments, 9 of 17 studies (52.9%) versus 2 of 7 (28.6%) studies reported the MI group experienced significant weight loss compared with control groups, respectively. Two systematic reviews examined the effects of behavioral interventions. One (Booth, 2014) conducted a meta-analysis estimating the effect of behavioral interventions on body weight. Weight change at 12 months in 8 studies was -1.36 kg (-2.10 to -0.63; P <0.0001) favoring the intervention over the control. Another review (Yoong, 2012) found that none of the interventions targeting providers' behavior resulted in statistically significant weight loss in their patients. Three studies targeting patients reported statistically significant difference in amount of weight loss between the intervention and control group at end of intervention, but no significant weight loss at 9 or 12 months. Another review (LeBlanc, 2011) summarized the effectiveness and harms of primary-care relevant weight-loss interventions. In 21 trials that could be combined by meta-analysis, patients receiving behavioral interventions lost 6.6 lbs more (95% CI, -4.0 to 2.0 kg) than controls after 12 to 18 months. Behavioral interventions lasting longer (24 to 54 months) continued to show greater weight loss (4.4 to 8.8 lb) compared with controls.



Lastly, one review (Olson, 2015) studied the effects of mindfulness interventions on weight loss. In 13 of 19 studies, significant weight loss was documented among participants in mindfulness interventions. However, studies did not clarify the degree to which changes in mindfulness are a mechanism responsible for weight loss in mindfulness interventions.

*Quality of Evidence: Low*

3. Documentation: No research articles were found that studied improving the documentation of BMI screening and follow-up.

<b>PICO Question:</b> In patients 18 years and older with a Body Mass Index (BMI) outside of normal parameters (Age 65 years and older BMI $\geq 23$ and $< 30$ kg/m <sup>2</sup> ; Age 18 – 64 years BMI $\geq 18.5$ and $< 25$ kg/m <sup>2</sup> ), what are the most effective clinical tools and strategies for implementing follow-up on weight loss?						<b>Lower Quality Rating if:</b> <input checked="" type="checkbox"/> Studies inconsistent (wide variation of treatment effect across studies, populations, interventions, or outcomes varied)  <input type="checkbox"/> Studies are indirect (PICO question is quite different from the available evidence in regard to population, intervention, comparison, or outcome)  <input type="checkbox"/> Studies are imprecise (When studies include few patients and few events and thus have wide confidence intervals and the results are uncertain)  <input type="checkbox"/> Publication Bias (e.g. pharmaceutical company sponsors study on effectiveness)
<b>Outcome:</b> Decrease BMI; <b>Modality:</b> Pharmacologic						
Author/Date	Purpose of Study	Study Design & Methods	Sample	Outcomes	Design Limitations	
<b>Total # of Studies: 2 # of Systematic Reviews: 2 # of RCTs: 0 # of Non-Randomized Studies: 0; # of Diagnostic Studies: 0</b>						
Ara, R., et al., 2012, <i>Health Technology Assessment</i>	To evaluate the clinical effectiveness and cost-effectiveness of three pharmacological interventions in obese patients	Systematic Review with meta-analysis	94 studies involving 24,808 individuals were included in the clinical meta-analysis. A total of 83 trials included data on weight change, 41 trial data on BMI change and 45 and 36 trial data on 5% and 10% body weight loss, respectively.	Overall, the results show that the active drug interventions are all effective at reducing weight and BMI compared with placebo.  <u>Body mass index change from baseline</u> <b>3 months:</b> In line with the results for weight change at 3 months, all active treatments were associated with significant reductions in BMI compared with placebo. No difference was seen between standard care and placebo (0.50 kg/m <sup>2</sup> , 95% CrI -0.51 kg/m <sup>2</sup> to 1.48 kg/m <sup>2</sup> ).  <b>6 months:</b> At 6 months none of the active treatments or standard care was significantly better than placebo. For example, metformin was associated with an increase in BMI compared with placebo (0.18 kg/m <sup>2</sup> , 95% CrI -4.05 kg/m <sup>2</sup> to 4.37 kg/m <sup>2</sup> ).  <b>12 months:</b> At 12 months orlistat and sibutramine 15 mg resulted in significantly greater BMI loss than placebo. No	Study Limitations = <input type="checkbox"/> None <b>Systematic Review</b> <input type="checkbox"/> Review did not address focused clinical question <input type="checkbox"/> Search was not detailed or exhaustive <input checked="" type="checkbox"/> Quality of the studies was not appraised or studies were of low quality <input checked="" type="checkbox"/> Methods and/or results were inconsistent across studies	



				difference was seen between sibutramine 10 mg and placebo or standard care. Sibutramine 15 mg had the largest probability (62.4%) of being the best intervention in terms of BMI loss.		<i>of drug, only small, positive studies found)</i>
LeBlanc, E.S., et al., 2011, <i>Annals of Internal Medicine</i>	To summarize effectiveness and harms of primary care-relevant weight-loss interventions for overweight and obese adults	Systematic Review with Meta-analysis	21 Studies; 2,908 participants. 18 (256 participants) involving orlistat plus behavioral interventions and 3 (2,652 participants) involving metformin plus behavioral interventions	Orlistat treatment with accompanying behavioral component resulted in weight loss of 11 to 22 lb; 8% of baseline weight) compared to 7 to 13 lb; 5% of baseline weight with placebo and the same behavioral component. In the 12 trials that could be combined by meta-analysis, participants randomly assigned to orlistat lost 6.6lb more (95% CI, -3.9 to -2.0 kg) than those receiving placebo after 12 months. Weight loss was maintained with up to 24 to 36 months of orlistat therapy. Metformin plus a behavioral intervention was associated with a smaller degree of weight loss (4.4 to 8.8lb), although the best evidence was limited to patients with prediabetes.	Study Limitations = <input type="checkbox"/> None <b>Systematic Review</b> <input type="checkbox"/> Review did not address focused clinical question <input type="checkbox"/> Search was not detailed or exhaustive <input checked="" type="checkbox"/> Quality of the studies was not appraised or studies were of low quality <input type="checkbox"/> Methods and/or results were inconsistent across studies	<u>Increase Quality Rating if:</u> <input type="checkbox"/> Large Effect <input type="checkbox"/> Dose-response gradient <input type="checkbox"/> Plausible confounders or other biases increase certainty of effect  Quality (certainty) of evidence for studies as a whole: <input type="checkbox"/> High <input type="checkbox"/> Moderate <input checked="" type="checkbox"/> Low <input type="checkbox"/> Very Low

The GRADE criteria were used to evaluate the quality of evidence presented in research articles reviewed during the development of this guideline. For more detailed information, see Appendix A.

<b>PICO Question:</b> In patients 18 years and older with a Body Mass Index (BMI) outside of normal parameters (Age 65 years and older BMI $\geq$ 23 and $<$ 30 kg/m <sup>2</sup> ; Age 18 – 64 years BMI $\geq$ 18.5 and $<$ 25 kg/m <sup>2</sup> ), what are the most effective clinical tools and strategies for implementing follow-up on weight loss?						<u>Lower Quality Rating if:</u> <input checked="" type="checkbox"/> Studies inconsistent (wide variation of treatment effect across studies, populations, interventions, or outcomes varied)  <input type="checkbox"/> Studies are indirect (PICO question is quite different from the available evidence in regard to population,
<b>Outcome:</b> Decrease BMI; <b>Modality:</b> Non-Pharmacologic						
<i>Author/Date</i>	<i>Purpose of Study</i>	<i>Study Design &amp; Methods</i>	<i>Sample</i>	<i>Outcomes</i>	<i>Design Limitations</i>	
<b>Total # of Studies: 5 # of Systematic Reviews: 5 # of RCTs: 0 # of Non-Randomized Studies: 0 ; # of Diagnostic Studies: 0</b>						
Barnes, R.D., et al., 2014, <i>Obesity Reviews</i>	To examine motivational interviewing as an intervention for weight loss among adults	Systematic Review	24 RCTs	When examining all 24 studies, 12 studies (50.0%) reported no significant weight loss compared with UC, 9 studies (37.5%) reported significant weight loss compared with UC or control groups, 1 (4.2%) reported a trend towards significance ( 26), P = 0.053) and 2 (8.3%)	Study Limitations = <input type="checkbox"/> None <b>Systematic Review</b> <input checked="" type="checkbox"/> Review did not address focused clinical question <input type="checkbox"/> Search was not detailed or exhaustive	



	within primary care settings			provided MI to both conditions. When comparing the studies that implemented the MI intervention in addition to typical primary care appointments to those that incorporated MI into regularly scheduled appointments, 9 of 17 studies (52.9%) versus 2 of 7 (28.6%) studies reported the MI group experienced significant weight loss compared with control groups, respectively.	<input checked="" type="checkbox"/> Quality of the studies was not appraised or studies were of low quality <input checked="" type="checkbox"/> Methods and/or results were inconsistent across studies	<i>intervention, comparison, or outcome)</i>  <input type="checkbox"/> Studies are imprecise ( <i>When studies include few patients and few events and thus have wide confidence intervals and the results are uncertain</i> )  <input type="checkbox"/> Publication Bias ( <i>e.g. pharmaceutical company sponsors study on effectiveness of drug, only small, positive studies found</i> )  <u>Increase Quality Rating if:</u> <input type="checkbox"/> Large Effect <input type="checkbox"/> Dose-response gradient <input type="checkbox"/> Plausible confounders or other biases increase certainty of effect  Quality (certainty) of evidence for studies as a whole: <input type="checkbox"/> High <input type="checkbox"/> Moderate <input checked="" type="checkbox"/> Low <input type="checkbox"/> Very Low
Booth, H.P., 2014, Family Practice	To estimate the effect of behavioral interventions delivered in primary care on body weight in overweight and obese adults. Interventions include behavioral change counseling through individual or group sessions, telephone counseling sessions, and diet, exercise, and lifestyle management counseling.	Systematic Review with meta-analysis	15 RCTs; 4,539 participants	All of the studies reported change in weight at 12 months in the control and intervention groups, but not all of these could be included in a meta-analysis. The meta-analysis of weight change at 12 months in eight studies was -1.36 kg (-2.10 to -0.63; P <0.0001) favoring the intervention over the control.  Five lifestyle studies reported weight change at 24 months, all of which provided complete data and were included in a meta-analysis. The pooled results was -1.23 kg (-2.23 to -0.18; P = 0.002).	Study Limitations = <input type="checkbox"/> None <b>Systematic Review</b> <input type="checkbox"/> Review did not address focused clinical question <input type="checkbox"/> Search was not detailed or exhaustive <input checked="" type="checkbox"/> Quality of the studies was not appraised or studies were of low quality <input checked="" type="checkbox"/> Methods and/or results were inconsistent across studies	
LeBlanc, E.S., et al., 2011, <i>Annals of Internal Medicine</i>	To summarize effectiveness and harms of primary care-relevant weight-loss interventions	Systematic Review with meta-analysis	38 studies; 13,495 participants	In 21 trials that could be combined by meta-analysis, patients receiving behavioral interventions lost 6.6 lb more (95% CI, -4.0 to 2.0 kg) than controls after 12 to 18 months. Behavioral interventions lasting longer (24 to 54 months) continued to show greater weight loss (4.4 to 8.8 lb)	Study Limitations = <input type="checkbox"/> None <b>Systematic Review</b> <input type="checkbox"/> Review did not address focused clinical question <input type="checkbox"/> Search was not detailed or exhaustive <input type="checkbox"/> Quality of the studies was	



	for overweight and obese adults			compared with controls. Interventions with more weight loss – patients receiving 12 to 26 intervention sessions generally lost 8.8 to 15.4 lb (6% of baseline weight) compared with 3.3 to 8.8 lb (2.8% of baseline weight) in intervention groups with fewer than 12 sessions in the first year, none of the following demonstrated a relationship with effect size: physical activity sessions, group sessions, individual sessions, technology-based intervention, specific weight-loss goals, spouse or family involvement, addressing barriers to weight loss, motivational assessment, self-monitoring, incentives, or support after active intervention phase.	not appraised or studies were of low quality <input checked="" type="checkbox"/> Methods and/or results were inconsistent across studies
Olson, K.L., et al., 2015, <i>Psychosomatic Medicine</i>	To determine if the current evidence supports mindfulness interventions for weight loss	Systematic Review	19 studies; 13 RCTs and 6 observational studies	Significant weight loss was documented among participants in mindfulness interventions for 13 of the 19 studies. However, studies did not clarify the degree to which changes in mindfulness are a mechanism responsible for weight loss in mindfulness interventions.	Study Limitations = <input type="checkbox"/> None <b>Systematic Review</b> <input type="checkbox"/> Review did not address focused clinical question <input type="checkbox"/> Search was not detailed or exhaustive <input checked="" type="checkbox"/> Quality of the studies was not appraised or studies were of low quality <input checked="" type="checkbox"/> Methods and/or results were inconsistent across studies
Yoong, S.L., 2012, <i>Public Health Nutrition</i>	To examine the effectiveness of behavioral weight-loss interventions involving primary-care physicians in producing weight loss in overweight and obese primary-care patients	Systematic Review	15 different studies	None of the interventions targeting providers' behavior resulted in statistically significant weight loss in their patients. Three studies targeting patients reported a statistically significant difference in amount of weight loss between the intervention and control group at end of intervention, but no significant weight loss at 9 or 12 months. None of the studies reported that clinically significant weight loss was achieved.	Study Limitations = <input type="checkbox"/> None <b>Systematic Review</b> <input checked="" type="checkbox"/> Review did not address focused clinical question <input type="checkbox"/> Search was not detailed or exhaustive <input checked="" type="checkbox"/> Quality of the studies was not appraised or studies were of low quality <input checked="" type="checkbox"/> Methods and/or results were inconsistent across studies



				<p>Nine studies reported on the effectiveness of lifestyle counselling delivered by non-primary-care physicians with support from primary care physicians. The types of interventions included meal replacements, nurse- or dietitian-delivered counseling, weight-loss websites, and counselling delivered by non-medical health coaches. Two studies compared two interventions, without a control group. One of the two comparative effectiveness studies reported statistically significant findings. Six studies compared the intervention with usual care. Of them, four reported statistically significant results between usual care and intervention groups and that clinically significant weight loss was achieved.</p>		
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The GRADE criteria were used to evaluate the quality of evidence presented in research articles reviewed during the development of this guideline. For more detailed information, see Appendix A.

**Guideline Recommendations:**

The **American College of Cardiology/American Health Association Task Force** recommends the following:

1. **Identifying patients who need to lose weight** (BMI and Waist Circumference)
  - a. Measure height and weight and calculate BMI at annual visits or more frequently. *Recommendation – Class I; Level of Evidence – C*
  - b. Use the current cutpoints for overweight (BMI>25.0-29.9 kg/m<sup>2</sup>) and obesity (BMI ≥30 kg/m<sup>2</sup>) to identify adults who may be at elevated risk of CVD and the current cutpoints for obesity (BMI ≥30) to identify adults who may be at elevated risk of mortality from all causes. *Recommendation – Class I; Level of Evidence – B*
  - c. Advise overweight and obese adults that the greater the BMI, the greater the risk of CVD, type 2 diabetes, and all-cause mortality. *Recommendation – Class I; Level of Evidence – B*
  - d. Measure waist circumference at annual visits of more frequently in overweight and obese adults. Advise adults that the greater the waist circumference, the greater the risk of CVD, type 2 diabetes, and all-cause mortality. The cutpoints currently in common use (from either NIH/NHLBI or WHO/IDF) may continue to be used to identify patients who may be at increased risk until further evidence becomes available. *Recommendation – Class IIa; Level of Evidence – B*
2. **Matching treatment benefits with risk profiles** (reduction in body weight effect on CVD risk factors, events, morbidity and mortality)
 

Counseling overweight and obese adults with CV risk factors (high BP, hyperlipidemia and hyperglycemia), that lifestyle changes that produce even modest, sustained weight loss of 3% - 5% produce clinically meaningful health benefits, and greater weight losses produces greater benefits. *Recommendation – Class I; Level of Evidence – A*



- a. Sustained weight loss of 3% - 5% is likely to result in clinically meaningful reductions in triglycerides, blood glucose, HbA1C, and the risk of developing type 2 diabetes;
  - b. Greater amounts of weight loss will reduce BP, improve LDL-C and HDL-C, and reduce the need for medications to control BP, blood glucose and lipids as well as further triglycerides and blood glucose.
3. **Diets for Weight Loss** (Dietary Strategies for Weight Loss)
- a. Prescribe a diet to achieve reduced calorie intake for obese or overweight individuals who would benefit from weight loss, as part of a comprehensive lifestyle intervention. Any 1 of the following methods can be used to reduce food and calorie intake: *Recommendation – Class I; Level of Evidence – A*
    - i. Prescribe 1,200-1,500 kcal/day for women and 1,500-1,800 kcal/day for men (kcal levels are usually adjusted for the individual's body weight);
    - ii. Prescribe a 500 kcal/day or 750 kcal/day energy deficit; or
    - iii. Prescribe one of the evidence-based diets that restricts certain food types (such as high-carbohydrate foods, low-fiber foods, or high-fat foods) in order to create an energy deficit by reduced food intake.
  - b. Prescribe a calorie-restricted diet, for obese and overweight individuals who would benefit from weight loss, based on the patient's preferences and health status and preferably refer to a nutrition professional for counseling. A variety of dietary approaches can produce weight loss in overweight and obese adults.
4. **Lifestyle Intervention and Counseling** (Comprehensive Lifestyle Intervention)
- a. Advise overweight and obese individuals who would benefit from weight loss to participate for  $\geq 6$  months in a comprehensive lifestyle program that assists participants in adhering to a lower calorie diet and in increasing physical activity through the use of behavioral strategies. *Recommendation – Class I; Level of Evidence - A*
  - b. Prescribe on site, high-intensity (i.e.,  $\geq 14$  sessions in 6 months) comprehensive weight loss interventions provides in individual or group session by a trained interventionist. *Recommendation – Class I; Level of Evidence – A*
  - c. Electronically delivered weight loss programs (including by telephone) that include personalized feedback from a trained interventionist can be prescribed for weight loss but may results in smaller weight loss than face-to-face interventions. *Recommendation – Class IIa; Level of Evidence – A*
  - d. Some commercial-based programs that provide a comprehensive lifestyle intervention can be prescribed as an option for weight, provided there is peer-reviewed published evidence of their safety and efficacy. *Recommendation – Class IIa; Level of Evidence – A*
  - e. Use a very low calorie diet (defined as  $< 800$  kcal/day) only in limited circumstances and only when provided by trained practitioners in a medical care setting where medical monitoring and high intensity lifestyle intervention can be provided. Medical supervision is required because of the rapid rate of weight loss and potential for health complications. *Recommendation – Class IIa; Level of Evidence – A*



- f. Advise overweight and obese individuals who have lost weight to participate long-term (>=1 year) in a comprehensive weight loss maintenance program. *Recommendation – Class I; Level of Evidence – A*
  - g. For weight loss maintenance, prescribe face-to-face or telephone-delivered weight loss maintenance programs that provide regular contact (monthly more frequent) with a trained interventionist who helps participants engage in high levels of physical activity (i.e., 200-300 minutes/week), monitor body weight regularly (i.e., weekly or more frequent), and consume a reduced-calorie diet (needed to maintain lower body weight). *Recommendation – Class I; Level of Evidence – A*
- 5. Selecting Patients for Bariatric Surgical Treatment for Obesity** (Bariatric Surgical Treatment for Obesity)
- a. Advise adults with a BMI >=40 or BMI >=35 with obesity-related comorbid conditions who are motivated to lose weight and who have not resulted to behavioral treatment with or without pharmacotherapy with sufficient weight loss to achieve targeted health outcome goals that bariatric surgery may be appropriate option to improve health and offer referral to an experienced bariatric surgeon for consultation and evaluation. *Recommendation – Class IIa; Level of Evidence – A*
  - b. For individuals with a BMI <35, there is sufficient evidence to recommend for or against undergoing bariatric surgical procedures. *Recommendation – N/A; Level of Evidence – N/A*
  - c. Advise patients that choice of a specific bariatric surgical procedure may be affected by patient factors, including age, severity of obesity/BMI, obesity-related comorbid conditions, other operative risk factors, risk of short- and long-term complications, behavioral and psychosocial factors, and patient tolerance for risk as well as provider factors (surgeon and facility). *Recommendation – Class IIb; Level of Evidence – C*

The **U.S. Preventive Services Task Force (USPSTF)** recommends screening all adults for obesity. Clinicians should offer or refer patients with a body mass index (BMI) of 30 kg/m<sup>2</sup> or higher to intensive, multicomponent behavioral interventions.

**Guideline Ratings**

Guideline Issuer and Date	AHA/ACC/TOS	USPSTF
1. Transparency	A	A
2. Conflict of interest	A	A
3. Development group	A	A
4. Systematic Review	A	A
5. Supporting evidence	A	A



6. Recommendations	A	A
7. External Review	A	A
8. Currency and updates	B	A

See appendix B for full description of the Trustworthy Guideline grading system.



### **References:**

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## Appendix A. GRADE criteria for rating a body of evidence on an intervention

Developed by the GRADE Working Group

### ***Grades and interpretations:***

High: Further research is very unlikely to change our confidence in the estimate of effect.

Moderate: Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.

Low: 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.

Very low: Any estimate of effect is very uncertain.

### ***Type of evidence and starting level***

Randomized trial—high

Observational study—low

Any other evidence—very low

### ***Criteria for increasing or decreasing level***

#### **Reductions**

Study quality has serious (–1) or very serious (–2) problems

Important inconsistency in evidence (–1)

Directness is somewhat (–1) or seriously (–2) uncertain

Sparse or imprecise data (–1)

Reporting bias highly probable (–1)

#### **Increases**

Evidence of association† strong (+1) or very strong (+2)

†Strong association defined as significant relative risk (factor of 2) based on consistent evidence from two or more studies with no plausible confounders Very

strong association defined as significant relative risk (factor of 5) based on direct evidence with no threats to validity.



## Appendix B. Trustworthy Guideline rating scale

The University of Pennsylvania's Center for Evidence-Based Practice Trustworthy Guideline rating scale is based on the Institute of Medicine's "Standards for Developing Trustworthy Clinical Practice Guidelines" (IOM), as well as a review of the AGREE Enterprise and Guidelines International Network domains.

The purpose of this scale is to focus on the weaknesses of a guideline that may reduce the trust a clinical user can have in the guideline, and distinguish weaknesses in documentation (e.g. guide-line does not have a documented updating process) from weaknesses in the guidance itself (e.g. recommendations are outdated). Current quality scales like AGREE emphasize documentation. They are important checklists for developers of new guidelines, but are less useful for grading existing guidelines. These scales also are harder for clinicians and other persons who are not methodology experts to apply, and their length discourages their use outside formal technology assessment reports. This new scale is brief, balanced, and easy and consistent to apply.

We do not attempt to convert the results of this assessment into a numeric score. Instead we present a table listing the guidelines and how they are rated on each standard. This facilitates qualitative understanding by the reader, who can see for what areas the guideline base as a whole is weak or strong as well as which guidelines are weaker or stronger.

### 1. Transparency

A	Guideline development methods are fully disclosed.
B	Guideline development methods are partially disclosed.
C	Guideline development methods are not disclosed.

The grader must refer to any cited methods supplements or other supporting material when evaluating the guideline. Methods should include:

Who wrote the initial draft

How the committee voted on or otherwise approved recommendations

Evidence review, external review and methods used for updating are not addressed in this standard.

### 2. Conflict of interest

A	Funding of the guideline project is disclosed, disclosures are made for each individual panelist, and financial or other conflicts do not apply to key authors of the guideline or to more than 1 in 10 panel members).
B	Guideline states that there were no conflicts (or fewer than 1 in 10 panel members), but does not disclose funding source.
C	Lead author, senior author, or guideline panel members (at least 1 in 10) have conflict of interest, or guideline project was funded by industry sponsor with no assurance of independence.



NR	Guideline does not report on potential conflict of interests.
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For purposes of this checklist, conflicts of interest include employment by, consulting for, or holding stock in companies doing business in fields affected by the guideline, as well as related financial conflicts. This definition should not be considered exclusive. As much as anything, this is a surrogate marker for thorough reporting, since it may be assumed that guideline projects are funded by the sponsoring organization and many authors think it unnecessary to report a non-conflict.

### 3. Guideline development group

A	Guideline development group includes 1) methodological experts and clinicians and 2) representatives of multiple specialties.
B	Guideline development group includes one of the above, but not both.
C	Guideline developers all from one specialty or organization, and no methodologists.
NR	Affiliations of guideline developers not reported

The purpose of this standard is to ensure that supporters of competing procedures, or clinicians with no vested interest in utilization of one procedure or another, are involved in development of the guideline. Both AGREE II and IOM call for patient or public involvement: very few guideline panels have done so to date, so this is not necessary for guidelines to be rated A. Involvement of methodologists or HTA specialists in the systematic review is sufficient involvement in the guideline development group for our purposes. In the absence of any description of the guideline group, assume the named authors are the guideline group.

### 4. Systematic review

A	Guideline includes a systematic review of the evidence or links to a current review.
B	Guideline is based on a review which may or may not meet systematic review criteria.
C	Guideline is not based on a review of the evidence.

In order to qualify as a systematic review, the review must do all of the following:

Describe itself as systematic or report search strategies using multiple databases

Define the scope of the review (including key questions and the applicable population)

Either include quantitative or qualitative synthesis of the data or explain why it is not indicated

Note: this element does not address the quality of the systematic review: simply whether or not it exists. Concerns about quality or bias of the review will be discussed in text, where the analyst will explain whether the weaknesses of the review weaken the validity or reliability of the guideline.



Note: a guideline may be rated B on this domain even if the review on which it is based is not available to us. This potential weakness of the guideline should be discussed in text of the report.

## 5. Grading the supporting evidence

A	Specific supporting evidence (or lack thereof) for each recommendation is cited and graded
B	Specific supporting evidence (or lack thereof) for each recommendation is cited but the recommendation is not graded.
C	Recommendations are not supported by specific evidence.

To score a B on this domain there should be specific citations to evidence tables or individual references for each relevant recommendation in the guideline, or an indication that no evidence was available. Any standardized grading system is acceptable for purposes of this rating. If a guideline reports that there is no evidence available despite a thorough literature search, it may be scored B on this domain, or even A if evidence for other recommendations is cited and graded.

## 6. Recommendations

A	Considerations for each recommendation are documented (i.e. benefits and harms of a particular action, and/or strength of the evidence); and recommendations are presented in an actionable form.
B	Either one or the other of the above criteria is met.
C	Neither of the above criteria are met

In order to be actionable, the guideline should specify the specific population to which the guideline applies, the specific intervention in question, and the circumstances under which it should be carried out (or not carried out). The language used in the recommendations should also be consistent with the strength of the recommendation (e.g. directive and active language like “should” or “should not” for strong recommendations, and passive language like “consider” for weak recommendations). A figure or algorithm is considered actionable as long as it is complete enough to incorporate all the applicable patients and interventions. Please see the forthcoming NICE manual (24) for a good discussion of actionability in guidelines.

## 7. External review

A	Guideline was made available to external groups for review.
B	Guideline was reviewed by members of the sponsoring body only.
C	Guideline was not externally reviewed.
NR	No external review process is described.

**8. Updating and currency of guideline**

A	Guideline is current and an expiration date or update process is specified.
B	Guideline is current but no expiration date or update process is specified.
C	Guideline is outdated.

A guideline is considered current if it is within the developers' stated validity period, or if no period or expiration data is stated, the guideline was published in the past three years (NOTE: the specific period may be changed at the analyst's discretion, based on whether the technology is mature and whether there is a significant amount of recent evidence). A guideline must address new evidence when it is updated. A guideline which is simply re-endorsed by the panel without searching for new evidence must be considered outdated