Citation

This slide set is adapted from the 2013 AHA/ACC Guideline for the Management of Overweight and Obesity in Adults. E-Published on November 12, 2013, available at:


http://circ.ahajournals.org/lookup/doi/10.1161/01.cir.000043739.71477.ee


The full-text guidelines are also available on the following Web sites: ACC (www.cardiosource.org) and AHA (my.americanheart.org)
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Helping Cardiovascular Professionals
A recommendation with Level of Evidence B or C does not imply that the recommendation is weak. Many important clinical questions addressed in the guidelines do not lend themselves to clinical trials. Although randomized trials are unavailable, there may be a very clear clinical consensus that a particular test or therapy is useful or effective.

*Data available from clinical trials or registries about the usefulness/efficacy in different subpopulations, such as sex, age, history of diabetes, history of prior myocardial infarction, history of heart failure, and prior aspirin use.

†For comparative effectiveness recommendations (Class I and IIa; Level of Evidence A and B only), studies that support the use of comparator verbs should involve direct comparisons of the treatments or strategies being evaluated.
<table>
<thead>
<tr>
<th>Grade</th>
<th>Strength of Recommendation</th>
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<tr>
<td>A</td>
<td><strong>Strong recommendation:</strong> There is high certainty based on evidence that the net benefit is substantial.</td>
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<tr>
<td>B</td>
<td><strong>Moderate recommendation:</strong> There is moderate certainty based on evidence that the net benefit is moderate to substantial, or there is high certainty that the net benefit is moderate.</td>
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<tr>
<td>C</td>
<td><strong>Weak recommendation:</strong> There is at least moderate certainty based on evidence that there is a small net benefit.</td>
</tr>
<tr>
<td>D</td>
<td><strong>Recommendation against:</strong> There is at least moderate certainty based on evidence that it has no net benefit or that risks/harms outweigh benefits.</td>
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| E     | **Expert opinion ("There is insufficient evidence or evidence is unclear or conflicting, but this is what the Panel recommends.")**  
Net benefit is unclear. Balance of benefits and harms cannot be determined because of no evidence, insufficient evidence, unclear evidence, or conflicting evidence, but the Panel thought it was important to provide clinical guidance and make a recommendation. Further research is recommended in this area. |
| N     | **No recommendation for or against ("There is insufficient evidence or evidence is unclear or conflicting.")**  
Net benefit is unclear. Balance of benefits and harms cannot be determined because of no evidence, insufficient evidence, unclear evidence, or conflicting evidence, and the Panel thought no recommendation should be made. Further research is recommended in this area. |
### Quality Rating the Strength of Evidence

<table>
<thead>
<tr>
<th>Quality Rating</th>
<th>Type of Evidence</th>
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<tr>
<td><strong>High</strong></td>
<td>• Well-designed, well-executed RCTs that adequately represent populations to which the results are applied and directly assess effects on health outcomes.</td>
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<td>• Met-analyses of such studies.</td>
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<td>Highly certain about the estimate of effect. Further research is unlikely to change the Panel’s confidence in the estimate of effect.</td>
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<tr>
<td><strong>Moderate</strong></td>
<td>• RCTs with minor limitations affecting confidence in, or applicability of, the results.</td>
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<td>• Well-designed, well-executed nonrandomized controlled studies and well-designed, well-executed observational studies.</td>
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<td>• Meta-analyses of such studies.</td>
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<td>Moderately certain about the estimate of effect. Further research may have an impact on the Panel’s confidence in the estimate of effect and may change the estimate.</td>
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<tr>
<td><strong>Low</strong></td>
<td>• RCTs with major limitations.</td>
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<td>• Nonrandomized controlled studies and observational studies with major limitations affecting confidence in, or applicability of, the results.</td>
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<td>• Uncontrolled clinical observations without an appropriate comparison group (e.g., case series, case reports).</td>
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<td></td>
<td>• Physiological studies in humans.</td>
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<tr>
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<td>• Meta-analyses of such studies.</td>
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<tr>
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<td>Low certainty about the estimate of effect. Further research is likely to have an impact on the Panel’s confidence in the estimate of effect and is likely to change the estimate.</td>
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Obesity Background

• Process began January 2008
• NHLBI formed 15-member Expert Panel
• Followed IOM reports “Clinical Guidelines We Can Trust” and “Finding What Works in Health Care – Standards for Systematic Reviews”
• 5 Critical Questions → Evidence Review → Evidence Statements → Recommendations
• ACC, AHA, and TOS partnering to promote and publish the Guidelines
Obesity Context

• Most PCPs are not trained in obesity etiology, pathogenesis, diagnosis and treatment
• Culture promotes supplements and dietary approaches that promise quick and easy weight loss
• PCPs need authoritative recommendations for managing weight to improve their patient’s health
Obesity Guidelines

• Backed by stringent methodology
• Therefore, speak with authority
• But limited in scope:
  • Who needs to lose weight?
  • What are the benefits of weight loss and how much weight loss is needed?
  • What is the best diet?
  • What is the efficacy of lifestyle intervention?
  • What are the benefits and risks of the bariatric surgical procedures?
Treatment Algorithm
The Chronic Care Model of Weight Management by PCPs

Patient Encounter (See Box 1) → Measure weight, height; calculate BMI (See Box 2) → BMI 25-29.9 (overweight) or 30-34.9 (class I obese) or 35-39.9 (class II obese) or ≥40 (class III obese) (See Box 3) → Yes BMI ≥25 → Assess and treat risk factors for CVD and obesity-related comorbidities (See Box 4) → Assess weight and lifestyle histories (See Box 5)

BMI 18.5-24.9 → No → Evaluate weight and calculate BMI annually or more frequently (See Box 17) → Advise to avoid weight gain; address and treat other risk factors (See Box 7)

Assess need to lose weight: BMI ≥30 or BMI 25-29.9 with risk factor(s) (See Box 6)

Assess readiness to make lifestyle changes to achieve weight loss (See Box 8)

No, insufficient risk → No, not yet ready → Yes, ready
The Chronic Care Model of Weight Management by PCPs

Follow-up and weight loss maintenance (See Box 15)

- Weight loss ≥5% and sufficient improvement in health targets (See Box 18)
  - Yes
    - Intensive behavioral treatment (See Box 10); reassess and address medical or other contributory factors; consider adding or reevaluating obesity pharmacotherapy (See Box 12), and/or refer to an experienced bariatric surgeon (See Box 13)
  - No
    - Continue intensive medical management of CVD risk factors and obesity-related conditions; weight management options (See Box 19)
  - Yes, ready
    - Weight loss ≥5% and sufficient improvement in health targets (See Box 14)
  - No
    - BMI ≥40 or BMI ≥35 with comorbidity. Offer referral to an experienced bariatric surgeon for consultation and evaluation as an adjunct to comprehensive lifestyle intervention (See Box 13)
    - BMI ≥30 or BMI ≥27 with comorbidity—option for adding pharmacotherapy as an adjunct to comprehensive lifestyle intervention (See Box 12)†

High-intensity comprehensive lifestyle intervention (See Box 11a)

- Alternative delivery of lifestyle intervention (See Box 11b)

Determine weight loss and health goals and intervention strategies (See Box 9)

- Yes
  - Comprehensive lifestyle intervention alone or with adjunctive therapies (BMI ≥30 or ≥27 with comorbidity) (See Box 10)†
Recommendation 1

1a. Measure height and weight and calculate BMI at annual visits or more frequently.

1b. Use the current cutpoints for overweight (BMI 25.0-29.9 kg/m²) and obesity (BMI ≥30 kg/m²) to identify adults who may be at elevated risk of CVD and the current cutpoints for obesity (BMI ≥30 kg/m²) to identify adults who may be at elevated risk of mortality from all causes.

1c. Advise overweight and obese adults that the greater the BMI, the greater the risk of CVD, type 2 diabetes, and all-cause mortality.

1d. Measure waist circumference at annual visits or 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 2

Counsel overweight and obese adults with cardiovascular 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 produce greater benefits.

a. Sustained weight loss of 3%–5% is likely to result in clinically meaningful reductions in triglycerides, blood glucose, hemoglobin A1c, 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 reduce triglycerides and blood glucose.
Recommendation 3a

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 one of the following methods can be used to reduce food and calorie intake:

a. Prescribe 1,200–1,500 kcal/d for women and 1,500–1,800 kcal/d for men (kilocalorie levels are usually adjusted for the individual’s body weight);

b. Prescribe a 500-kcal/d or 750-kcal/d energy deficit; or

c. 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.
Recommendation 3b

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, as presented in CQ3, ES2.

*Nutrition professional: In the studies that form the evidence base for this recommendation, a registered dietitian usually delivered the dietary guidance; in most cases, the intervention was delivered in university nutrition departments or in hospital medical care settings where access to nutrition professionals was available.
**Recommendation 4**

4a. Advise overweight and obese individuals who would benefit from weight loss to participate for ≥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.

4b. Prescribe on-site, high-intensity (i.e., ≥14 sessions in 6 months) comprehensive weight loss interventions provided in individual or group sessions by a trained interventionist.†

4c. Electronically delivered weight loss programs (including by telephone) that include personalized feedback from a trained interventionist† can be prescribed for weight loss but may result in smaller weight loss than face-to-face interventions.

†Trained interventionist: In the studies reviewed, trained interventionists included mostly health professionals (e.g., registered dietitians, psychologists, exercise specialists, health counselors, or professionals in training) who adhered to formal protocols in weight management. In a few cases, lay persons were used as trained interventionists; they received instruction in weight management protocols (designed by health professionals) in programs that have been validated in high-quality trials published in peer-reviewed journals.
Recommendation 4 (con’t)

4d. Some commercial-based programs that provide a comprehensive lifestyle intervention can be prescribed as an option for weight loss, provided there is peer-reviewed published evidence of their safety and efficacy.

4e.‡ Use a very-low-calorie diet (defined as <800 kcal/d) 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.

4f. Advise overweight and obese individuals who have lost weight to participate long term (≥1 year) in a comprehensive weight loss maintenance program.

‡There is strong evidence that if a provider is going to use a very-low-calorie diet, it should be done with high levels of monitoring by experienced personnel; that does not mean that practitioners should prescribe very-low-calorie diets. Because of concern that an ACC/AHA Class I recommendation would be interpreted to mean that the patients should go on a very-low-calorie diet, it was the consensus of the Expert Panel that this maps more closely to an ACC/AHA Class IIa recommendation.
Recommendation 4 (con’t)

4g. For weight loss maintenance, prescribe face-to-face or telephone-delivered weight loss maintenance programs that provide regular contact (monthly or more frequently) with a trained interventionist† who helps participants engage in high levels of physical activity (i.e., 200–300 min/wk), monitor body weight regularly (i.e., weekly or more frequently), and consume a reduced-calorie diet (needed to maintain lower body weight).

†Trained interventionist: In the studies reviewed, trained interventionists included mostly health professionals (e.g., registered dietitians, psychologists, exercise specialists, health counselors, or professionals in training) who adhered to formal protocols in weight management. In a few cases, lay persons were used as trained interventionists; they received instruction in weight management protocols (designed by health professionals) in programs that have been validated in high-quality trials published in peer-reviewed journals.
5a. § Advise adults with a BMI ≥40 kg/m² or BMI ≥35 kg/m² with obesity-related comorbid conditions who are motivated to lose weight and who have not responded to behavioral treatment with or without pharmacotherapy with sufficient weight loss to achieve targeted health outcome goals that bariatric surgery may be an appropriate option to improve health and offer referral to an experienced bariatric surgeon for consultation and evaluation.

§ There is strong evidence that the benefits of surgery outweigh the risks for some patients. These patients can be offered a referral to discuss surgery as an option. This does not mean that all patients who meet the criteria should have surgery. This decision-making process is quite complex and is best performed by experts. The ACC/AHA criterion for a Class I recommendation states that the treatment/procedure should be performed/administered. This recommendation as stated does not meet the criterion that the treatment should be performed. Thus, the ACC/AHA classification criteria do not directly map to the NHLBI grade assigned by the Expert Panel.
Recommendation 5 (con’t)

5b. For individuals with a BMI <35 kg/m², there is insufficient evidence to recommend for or against undergoing bariatric surgical procedures.

5c. 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).
Gaps and Topics for Future Guidelines

• No Critical Question on pharmacotherapy
  • When Critical Questions developed only sibutramine and orlistat were on the market and sibutramine was removed shortly after
  • The algorithm offers Expert Panel recommendations on pharmacotherapy + comprehensive lifestyle intervention

• No Critical Question on physical activity protocols
• No Critical Question on weight gain with medications
• Evidence review required for waist circumference and BMI as categorical variables to establish additional recommendations regarding cutpoints
Conclusions

• High quality treatments are available and can result in medically important weight loss for patients who need to lose weight

• Translation will depend upon
  o Providing primary care providers with information regarding success rates of the programs they work with for obesity treatment
  o Reimbursement practices for successful treatment programs, primary care physicians and specialists
  o Education of the primary care provider workforce, which will require great effort

• The AHA, ACC, TOS, and appropriate partners must address these translational needs