Journal of the American College of Cardiology
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Published by Elsevier Inc.

Vol. 63, No. 25, 2014
ISSN 0735-1097/$36.00
http://dx.doi.org/10.1016/j.jacc.2013.11.004

2013 AHA/ACC/TOS Guideline for the Management of Overweight and Obesity in Adults☆

A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines and The Obesity Society

Endorsed by the American Association of Cardiovascular and Pulmonary Rehabilitation, American Pharmacists Association, American Society for Nutrition, American Society for Parenteral and Enteral Nutrition, American Society for Preventive Cardiology, American Society of Hypertension, Association of Black Cardiologists, National Lipid Association, Preventive Cardiovascular Nurses Association, The Endocrine Society, and WomenHeart: The National Coalition for Women With Heart Disease

Expert Panel Members

Michael D. Jensen, MD, *Co-Chair*
Donna H. Ryan, MD, *Co-Chair*

Caroline M. Apovian, MD, FACP
Jamy D. Ard, MD
Anthony G. Comuzzie, PHD
Karen A. Donato, SM*
Frank B. Hu, MD, PHD, FAHA
Van S. Hubbard, MD, PHD*
John M. Jakicic, PHD
Robert F. Kushner, MD
Catherine M. Loria, PHD, FAHA*
Barbara E. Millen, DRPH, RD
Cathy A. Nonas, MS, RD
F. Xavier Pi-Sunyer, MD, MPH
June Stevens, PHD
Victor J. Stevens, PHD
Thomas A. Wadden, PHD
Bruce M. Wolfe, MD
Susan Z. Yanovski, MD*

*Ex-Officio Members.

Methodology Members

Harmon S. Jordan, SCD
Karima A. Kendall, PHD
Linda J. Lux
Roycelynn Mentor-Marcel, PHD, MPH
Laura C. Morgan, MA
Michael G. Trisolini, PHD, MBA
Janusz Wnek, PHD

ACC/AHA Task Force Members

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E. Magnus Ohman, MD, FACC
Susan J. Pressler, PHD, RN, FAAN, FAHA
Frank W. Sellke, MD, FACC, FAHA
Win-Kuang Shen, MD, FACC, FAHA

Subcommittee on Prevention Guidelines

Sidney C. Smith, JR, MD, FACC, FAHA, *Chair*
Gordon F. Tomaselli, MD, FACC, FAHA, *Co-Chair*

This document was approved by the American College of Cardiology Board of Trustees, the American Heart Association Science Advisory and Coordinating Committee, and The Obesity Society Board of Trustees in November 2013. The Academy of Nutrition and Dietetics affirms the value of this guideline.

The American College of Cardiology requests that this document be cited as follows: Jensen MD, Ryan DH, Apovian CM, Ard JD, Comuzzie AG, Donato KA, Hu FB, Hubbard VS, Jakicic JM, Kushner RF, Loria CM, Millen BE, Nonas CA, Pi-Sunyer FX, Stevens J, Stevens VJ, Wadden TA, Wolfe BM, Yanovski SZ. 2013 AHA/ACC/TOS guideline for the management of overweight and obesity in adults: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines and The Obesity Society. J Am Coll Cardiol 2014;63:2985–3023.

This article is copublished in *Circulation* and *Obesity*.

Copies: This document is available on the World Wide Web sites of the American College of Cardiology (http://www.cardiosource.org) and the American Heart Association (my.americanheart.org). For copies of this document, please contact the Elsevier Inc. Reprint Department, fax (212) 462-1935, e-mail reprints@elsevier.com.

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Preamble and Transition to ACC/AHA Guidelines to Reduce Cardiovascular Risk

The goals of the American College of Cardiology (ACC) and the American Heart Association (AHA) are to prevent cardiovascular diseases (CVD); improve the management of people who have these diseases through professional education and research; and develop guidelines, standards, and policies that promote optimal patient care and cardiovascular health. Toward these objectives, the ACC and AHA have collaborated with the National Heart, Lung, and Blood Institute (NHLBI) and stakeholder and professional organizations to develop clinical practice guidelines for assessment of cardiovascular risk, lifestyle modifications to reduce cardiovascular risk, management of blood cholesterol in adults, and management of overweight and obesity in adults.

In 2008, the NHLBI initiated these guidelines by sponsoring rigorous systematic evidence reviews for each topic by expert panels convened to develop critical questions (CQs), interpret the evidence, and craft recommendations. In response to the 2011 report from the Institute of Medicine on the development of trustworthy clinical guidelines (1), the NHLBI Advisory Council recommended that the NHLBI focus specifically on reviewing the highest-quality evidence and partner with other organizations to develop recommendations (2,3). Accordingly, in June 2013 the NHLBI initiated collaboration with the ACC and AHA to work with other organizations to complete and publish the 4 guidelines noted above and make them available to the widest possible constituency. Recognizing that the Expert Panels/Work Groups did not consider evidence beyond 2011 (except as specified in the methodology), the ACC, AHA, and collaborating societies plan to begin updating these guidelines starting in 2014.

The joint ACC/AHA Task Force on Practice Guidelines (Task Force) appointed a subcommittee to shepherd this transition, communicate the rationale and expectations to the writing panels and partnering organizations, and expeditiously publish the documents. The ACC/AHA and partner organizations recruited a limited number of expert reviewers for fiduciary examination of content, recognizing that each document had undergone extensive peer review by representatives of the NHLBI Advisory Council, key federal agencies, and scientific experts. Each writing panel responded to comments from these reviewers. Clarifications were incorporated where appropriate, but there were no substantive changes because the bulk of the content was undisputed.

Although the Task Force led the final development of these prevention guidelines, they differ from other ACC/AHA guidelines. First, as opposed to an extensive compendium of clinical information, these documents are significantly more limited in scope and focus on selected CQs on each topic based on the highest-quality evidence available. Recommendations were derived from randomized trials, meta-analyses, and observational studies evaluated for quality and were not formulated when sufficient evidence was not available. Second, the text accompanying each recommendation is succinct, summarizing the evidence for each question. The Full Panel/Work Group Reports include more detailed information about the evidence statements (ESs) that serve as the basis for recommendations. Third, the format of the recommendations differs from other ACC/AHA guidelines. Each recommendation has been mapped from the NHLBI grading format to the ACC/AHA Classification of Recommendation/Level of Evidence (COR/LOE) construct (Table 1) and is expressed in both formats. Because of the inherent differences in grading systems and the clinical questions driving the recommendations, alignment between the NHLBI and ACC/AHA formats is in some cases imperfect. Explanations of these variations are noted in the recommendation tables, where applicable.

In consultation with NHLBI, the policies adopted by the writing panels to manage relationships of authors with industry and other entities (RWI) are outlined in the methods section of each panel report. These policies were in effect when this effort began in 2008 and throughout the writing process and voting on recommendations, until the process was transferred to ACC/AHA in 2013. In the interest of transparency, the ACC/AHA requested that panel authors resubmit RWI disclosures as of July 2013. Relationships relevant to this guideline are disclosed in Appendix 1. None of the ACC/AHA expert reviewers had relevant RWI (Appendix 2). See Appendix 3 for a list of abbreviations used in this guideline.

Systematic evidence reports and accompanying summary tables were developed by the expert panels and NHLBI. The guideline was reviewed by the ACC/AHA Task Force and approved by the ACC Board of Trustees, the AHA Science Advisory and Coordinating Committee, and The Obesity Society. In addition, ACC/AHA sought endorsement from other stakeholders, including professional organizations. It is the hope of the writing panels, stakeholders, professional organizations, NHLBI, and Task Force that the guidelines will garner the widest possible readership for the benefit of patients, providers, and the public health.

These guidelines are meant to define practices that meet the needs of patients in most circumstances and are not a replacement for clinical judgment. The ultimate decision about care of a particular patient must be made by the healthcare provider and patient in light of the circumstances presented by that patient. As a result, situations might arise in which deviations from these guidelines may be appropriate. These considerations notwithstanding, in caring for most patients, clinicians can employ the recommendations confidently to reduce the risks of atherosclerotic CVD events.

Table 1. Applying Classification of Recommendation and Level of Evidence

ESTIMATE OF CERTAINTY (PRECISION) OF TREATMENT EFFECT ↓ / SIZE OF TREATMENT EFFECT →	CLASS I *Benefit >>> Risk* Procedure/Treatment **SHOULD** be performed/ administered	CLASS IIa *Benefit >> Risk* *Additional studies with focused objectives needed* **IT IS REASONABLE** to perform procedure/administer treatment	CLASS IIb *Benefit ≥ Risk* *Additional studies with broad objectives needed; additional registry data would be helpful* Procedure/Treatment **MAY BE CONSIDERED**	CLASS III *No Benefit* or CLASS III *Harm* Procedure/Test / Treatment COR III: No benefit — Not Helpful / No Proven Benefit COR III: Harm — Excess Cost w/o Benefit or Harmful / Harmful to Patients
LEVEL A Multiple populations evaluated* Data derived from multiple randomized clinical trials or meta-analyses	■ Recommendation that procedure or treatment is useful/effective ■ Sufficient evidence from multiple randomized trials or meta-analyses	■ Recommendation in favor of treatment or procedure being useful/effective ■ Some conflicting evidence from multiple randomized trials or meta-analyses	■ Recommendation's usefulness/efficacy less well established ■ Greater conflicting evidence from multiple randomized trials or meta-analyses	■ Recommendation that procedure or treatment is not useful/effective and may be harmful ■ Sufficient evidence from multiple randomized trials or meta-analyses
LEVEL B Limited populations evaluated* Data derived from a single randomized trial or nonrandomized studies	■ Recommendation that procedure or treatment is useful/effective ■ Evidence from single randomized trial or nonrandomized studies	■ Recommendation in favor of treatment or procedure being useful/effective ■ Some conflicting evidence from single randomized trial or nonrandomized studies	■ Recommendation's usefulness/efficacy less well established ■ Greater conflicting evidence from single randomized trial or nonrandomized studies	■ Recommendation that procedure or treatment is not useful/effective and may be harmful ■ Evidence from single randomized trial or nonrandomized studies
LEVEL C Very limited populations evaluated* Only consensus opinion of experts, case studies, or standard of care	■ Recommendation that procedure or treatment is useful/effective ■ Only expert opinion, case studies, or standard of care	■ Recommendation in favor of treatment or procedure being useful/effective ■ Only diverging expert opinion, case studies, or standard of care	■ Recommendation's usefulness/efficacy less well established ■ Only diverging expert opinion, case studies, or standard of care	■ Recommendation that procedure or treatment is not useful/effective and may be harmful ■ Only expert opinion, case studies, or standard of care
Suggested phrases for writing recommendations	should is recommended is indicated is useful/effective/beneficial	is reasonable can be useful/effective/beneficial is probably recommended or indicated	may/might be considered may/might be reasonable usefulness/effectiveness is unknown/unclear/uncertain or not well established	COR III: No Benefit: is not recommended; is not indicated; should not be performed/ administered/ other; is not useful/ beneficial/ effective COR III: Harm: potentially harmful; causes harm; associated with excess morbidity/mortality; should not be performed/ administered/ other
Comparative effectiveness phrases†	treatment/strategy A is recommended/indicated in preference to treatment B treatment A should be chosen over treatment B	treatment/strategy A is probably recommended/indicated in preference to treatment B it is reasonable to choose treatment A over treatment B		

A recommendation with Level of Evidence B or C does not imply the recommendation is weak. Many important clinical questions addressed in the guidelines do not lend themselves to clinical trials. Even when 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.

See Tables 2 and 3 for an explanation of the NHLBI recommendation grading methodology.

1. Introduction/Scope of Guideline

More than 78 million adults in the United States were obese in 2009 and 2010 (4). Obesity raises the risk of morbidity from hypertension, dyslipidemia, type 2 diabetes mellitus (diabetes), coronary heart disease (CHD), stroke, gallbladder disease, osteoarthritis, sleep apnea and respiratory problems, and some cancers. Obesity is also associated with increased risk of all-cause and CVD mortality. The biomedical, psychosocial, and economic consequences of obesity have substantial implications for the health and well-being of the U.S. population.

According to the 1998 "Clinical Guidelines on the Identification, Evaluation, and Treatment of Overweight and Obesity in Adults—The Evidence Report" (5), overweight is defined as a body mass index (BMI) of 25 kg/m^2 to 29.9 kg/m^2 and obesity as a BMI of ≥30 kg/m^2. Current estimates are that 69% of adults are either overweight or obese, with approximately 35% obese (6). These latest data from the National Health and Nutrition Examination Surveys indicate that for both men and women, obesity estimates for 2009 and 2010 did not differ significantly from estimates for 2003 to 2008 and that increases in the prevalence rates of obesity appear to be slowing down or leveling off (6). Nevertheless, overweight and obesity continue to be highly prevalent, especially in some racial and ethnic minority groups, as well as in those with lower

Table 2. NHLBI Grading of the Strength of Recommendations

Grade	Strength of Recommendation*
A	**Strong recommendation** There is high certainty based on evidence that the net benefit† is substantial.
B	**Moderate recommendation** 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.
C	**Weak recommendation** There is at least moderate certainty based on evidence that there is a small net benefit.
D	**Recommendation against** There is at least moderate certainty based on evidence that there is no net benefit or that risks/harms outweigh benefits.
E	**Expert opinion ("There is insufficient evidence or evidence is unclear or conflicting, but this is what the Work Group 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 Work Group 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 Work Group thought no recommendation should be made. Further research is recommended in this area.

*In most cases, the strength of the recommendation should be closely aligned with the quality of the evidence; however, under some circumstances, there may be valid reasons for making recommendations that are not closely aligned with the quality of the evidence (e.g., strong recommendation when the evidence quality is moderate, such as smoking cessation to reduce CVD risk or ordering an ECG as part of the initial diagnostic work-up for a patient presenting with possible MI). Those situations should be limited and the rationale explained clearly by the Work Group.

†Net benefit is defined as benefits minus risks/harms of the service/intervention.

CVD indicates cardiovascular disease; ECG, electrocardiogram; MI, myocardial infarction; and NHLBI, National Heart, Lung, and Blood Institute.

Table 3. NHLBI Quality Rating of the Strength of Evidence

Type of Evidence	Quality Rating*
• Well-designed, well-executed† RCT that adequately represent populations to which the results are applied and directly assess effects on health outcomes. • Meta-analyses of such studies. **Highly certain about the estimate of effect. Further research is unlikely to change our confidence in the estimate of effect.**	High
• RCT with minor limitations‡ affecting confidence in, or applicability of, the results. • Well-designed, well-executed nonrandomized controlled studies§ and well-designed, well-executed observational studies‖. • Meta-analyses of such studies. **Moderately certain about the estimate of effect. Further research may have an impact on our confidence in the estimate of effect and may change the estimate.**	Moderate
• RCT with major limitations. • Nonrandomized controlled studies and observational studies with major limitations affecting confidence in, or applicability of, the results. • Uncontrolled clinical observations without an appropriate comparison group (e.g., case series, case reports). • Physiological studies in humans. • Meta-analyses of such studies. **Low certainty about the estimate of effect. Further research is likely to have an impact on our confidence in the estimate of effect and is likely to change the estimate.**	Low

*In some cases, other evidence, such as large all-or-none case series (e.g., jumping from airplanes or tall structures), can represent high- or moderate-quality evidence. In such cases, the rationale for the evidence rating exception should be explained by the Work Group and clearly justified.

†"Well-designed, well-executed" refers to studies that directly address the question; use adequate randomization, blinding, and allocation concealment; are adequately powered; use intention-to-treat analyses; and have high follow-up rates.

‡Limitations include concerns with the design and execution of a study that result in decreased confidence in the true estimate of the effect. Examples of such limitations include but are not limited to: inadequate randomization, lack of blinding of study participants or outcome assessors, inadequate power, outcomes of interest that are not prespecified for the primary outcomes, low follow-up rates, and findings based on subgroup analyses. Whether the limitations are considered minor or major is based on the number and severity of flaws in design or execution. Rules for determining whether the limitations are considered minor or major and how they will affect rating of the individual studies will be developed collaboratively with the methodology team.

§Nonrandomized controlled studies refer to intervention studies where assignment to intervention and comparison groups is not random (e.g., quasi-experimental study design).

‖Observational studies include prospective and retrospective cohort, case-control, and cross-sectional studies.

NHLBI indicates National Heart, Lung, and Blood Institute; and RCT, randomized controlled trial.

incomes and less education. Overweight and obesity are major contributors to chronic diseases in the United States and present a major public health challenge. Compared with normal-weight individuals, obese patients incur 46% higher inpatient costs, 27% more physician visits and outpatient costs, and 80% higher spending on prescription drugs (7). The medical care costs of obesity in the United States are staggering. In 2008 dollars, these costs totaled about $147 billion (7).

The Expert Panel was first convened in September 2008 by the NHLBI in cooperation with the National Institute of Diabetes and Digestive and Kidney Diseases to update the 1998 Clinical Guidelines Report (5). The Expert Panel considered new evidence related to key issues on overweight and obesity evaluation and treatment, particularly in individuals with other risk factors for CVD and diabetes. The key issues identified included the appropriateness of the current BMI and waist circumference cutpoints that are used for determining risk in overweight and obese adults across diverse populations; the impact of weight loss on risk factors for CVD and type 2 diabetes, as well as CVD morbidity and mortality; optimal behavioral, dietary intervention, and other lifestyle treatment approaches for weight loss and weight loss maintenance; and benefits and risks of various bariatric surgical procedures. The Expert Panel's ultimate goal was to systematically develop ESs and recommendations for 5 CQs to assist clinicians in primary care. The recommendations are based on evidence from a rigorous systematic review and synthesis of recently published medical literature.

This guideline is based on the Full Panel Report, which is provided as an online-only data supplement to the guideline. The Full Panel Report contains background and additional material related to content, methodology, evidence synthesis, rationale, and references and is supported

by the NHLBI Systematic Evidence Review, which can be found at http://www.nhlbi.nih.gov/guidelines/obesity/ser/. Refer to the "2013 ACC/AHA Guideline on the Treatment of Blood Cholesterol to Reduce Atherosclerotic Cardiovascular Risk in Adults," "2013 AHA/ACC Guideline on Lifestyle Management to Reduce Cardiovascular Risk," and "2013 ACC/AHA Guideline on the Assessment of Cardiovascular Risk" (8–10) for topics outside the scope of the 2013 AHA/ACC/TOS Obesity Guideline.

1.1. Rationale for Updating Obesity Clinical Guidelines

The NHLBI, in cooperation with the National Institute of Diabetes and Digestive and Kidney Diseases, released the 1998 "Clinical Guidelines on the Identification, Evaluation, and Treatment of Overweight and Obesity in Adults—The Evidence Report" (11) as a systematic review of the published scientific literature found in MEDLINE from January 1980 to September 1997 on important topics reviewed by the Expert Panel. The published literature was evaluated to determine appropriate treatment strategies that would constitute evidence-based clinical guidelines on overweight and obesity. The San Antonio Cochrane Center assisted in literature abstraction and in organizing the data into evidence tables, and a methodology consultant worked with the Expert Panel to develop ESs and recommendations.

In 2005, the NHLBI initiated the process to update the overweight/obesity guidelines and convened stakeholder groups to provide input on what should be the next-generation guideline development process. The resulting recommendations were used to design the process. To continually improve the quality and impact of the guidelines, the process was updated to assure rigor and minimize bias through the use of strict, evidence-based methodologies to guide the development of ESs and recommendations based on a systematic review of the biomedical literature for a specific period of time.

1.2. CQ-Based Approach

The Expert Panel began its deliberations by developing 23 possible CQs, and after considerable discussion, narrowed the possibilities to 5 targeted CQs. Questions were chosen to aid primary care practitioners (PCPs) and providers who frequently work with obese patients to identify patients at health risk of weight-related comorbidities and to update them on the benefits and risks of weight loss achieved by various approaches. Examples of CQs that were not included for this review included consideration of genetics of obesity, binge-eating disorders, pharmacotherapy, and cost-effectiveness of interventions to manage obesity. For each of the chosen CQs, Expert Panel members reviewed the final list of included and excluded articles, along with the quality ratings, and had the opportunity to raise questions and appeal the ratings to the methodology team. The team then reexamined these articles and presented their rationale for either keeping or changing the quality rating of the articles. Expert Panel members also played a key role in examining the evidence tables and summary tables to be certain the data from each article were accurately displayed.

The body of the present report is organized by CQ and the following information is included for each CQ:

- The rationale for its selection is provided, and methods are described.
- The body of evidence is summarized, and ESs are presented, which include a rating for quality and a supportive narrative summary.
- Recommendations and their strength are accompanied by a narrative summary of how the recommendation was derived from the evidence and a discussion of issues considered by the Expert Panel in formulating the recommendation.

CQ1 and CQ2 were chosen to help providers determine the appropriate criteria to guide a weight loss recommendation. CQ1 addresses the expected health benefits of weight loss as a function of the amount and duration of weight loss. CQ2 addresses the health risks of overweight and obesity and seeks to determine if the current waist circumference cutpoints and the widely accepted BMI cutpoints defining persons as overweight (BMI 25–29.9 kg/m^2) and obese (BMI $\geq$30 kg/m^2) are appropriate for population subgroups. Because patients are interested in popular diets that are promoted for weight loss and see the PCP as an authoritative source of information, CQ3 asks which dietary intervention strategies are effective for weight loss efforts. CQ4 seeks to determine the efficacy and effectiveness of a comprehensive lifestyle approach (diet, physical activity, and behavior therapy) to achieve and maintain weight loss. CQ5 seeks to determine the efficacy and safety of bariatric surgical procedures, including benefits and risks. CQ5 also seeks to determine patient and procedural factors that may help guide decisions to enhance the likelihood of maximum benefit from surgery for obesity and related conditions.

1.3. Organization of the Panel

In 2007, the NHLBI sought nominations for panel membership that would ensure adequate representation of key specialties and appropriate expertise. The NHLBI staff reviewed the nominees and selected potential chairs and co-chairs for the panels. A Guidelines Executive Committee was formed, consisting of the chairs from each of the 3 panels (obesity, high blood pressure [BP], and high blood cholesterol) and 3 cross-cutting working groups (lifestyle, risk assessment, and implementation). This committee worked with the NHLBI to select panel members from the list of nominees.

The Obesity Expert Panel comprised 15 members and 3 ex-officio members, including individuals with specific expertise in psychology, nutrition, physical activity,

bariatric surgery, epidemiology, internal medicine, and other clinical specialties. The full Obesity Expert Panel met 23 times throughout the years (5 times face-to-face and 18 times via Webinar). Expert Panel chairs asked all members to disclose any conflicts of interest to the full Expert Panel in advance of the deliberations; members with conflicts were asked to recuse themselves from voting on any aspect of the guideline for which a conflict might exist. Each of the 5 CQs had working groups consisting of a leader and various Expert Panel members who met via conference calls to discuss all aspects of the CQ; to review the list of included and excluded articles along with the quality ratings; to review the evidence tables and summary tables; and to develop spreadsheets, ESs, resulting recommendations, and research/evidence gaps. Expert Panel members had the opportunity to raise questions about the included and excluded articles, submit additional articles that were not identified in the original search, appeal the quality ratings on articles, and question articles that were excluded. Each working group presented their findings to the full Expert Panel for all final decisions on ESs and recommendations, including the strength of the evidence.

The evidence-based process followed most of the standards from the Institute of Medicine's report, *Clinical Practice Guidelines We Can Trust* (1). The process had support from a methodology contractor and a systematic review and general support contractor and included the following steps:

- Constructed CQs relevant to clinical practice.
- Identified (a priori) inclusion/exclusion (I/E) criteria for each CQ.
- Developed a literature search strategy, based on I/E criteria, for each CQ.
- Executed a systematic electronic search of the published literature from relevant bibliographic databases for each CQ. The date range for the overall literature search was from January 1998 to December 2009. Because CQ1 and CQ2 used systematic reviews and meta-analyses, the literature search included those published from January 2000 to October 2011. CQ3 and CQ4 added major randomized controlled trials (RCTs) published after 2009 with >100 people per treatment arm. CQ5 added some major studies published after 2009 that met the I/E criteria.
- Screened, by 2 independent reviewers, thousands of abstracts and full-text articles returned from the search to identify relevant original articles, systematic reviews, and meta-analyses. Rigorous validation procedures were applied to ensure that the selected articles met the pre-established detailed I/E criteria before being included in the final review results.
- Determined, by 2 independent raters on the methodology team, the quality of each included study (good, fair, and poor).
- Abstracted relevant information from the included studies into an electronic central repository database using common templates and types of data elements.
- Constructed detailed evidence tables, which organized the data from the abstraction database.
- Analyzed the evidence tables and constructed summary tables, which display the evidence in a manageable format to answer specific parts of each CQ.
- Used summary tables to develop ESs for each CQ. The quality of evidence for each ES was graded as high, moderate, or low on the basis of scientific methodology, scientific strength, and consistency of results. For CQ1 and CQ2, spreadsheets with relevant data from systematic reviews and meta-analyses were developed rather than summary tables.
- Used the graded ESs to write clinical recommendations, and graded the strength of each recommendation. Recommendations were graded as Strong Recommendation (Grade A), Moderate Recommendation (Grade B), Weak Recommendation (Grade C), Recommendation Against (Grade D), Expert Opinion (Grade E), or No Recommendation For or Against (Grade N).
- Performed Guideline Implementability Appraisals, planned and coordinated by the NHLBI Implementation Work Group, to identify and address barriers to guideline implementation.

1.4. Document Review and Approval

A formal peer review process was initially completed under the auspices of the NHLBI and included 10 expert reviewers and representatives from multiple federal agencies. This document was also reviewed by 6 expert reviewers nominated by the ACC, AHA, and The Obesity Society after the management of the guideline transitioned to the ACC/AHA. The ACC, AHA, and The Obesity Society reviewers' RWI information is published in this document (Appendix 2).

This document was approved for publication by the governing bodies of the ACC, the AHA, and The Obesity Society and is endorsed by the American Association of Cardiovascular and Pulmonary Rehabilitation, American Pharmacists Association, American Society for Nutrition, American Society for Parenteral and Enteral Nutrition, American Society for Preventive Cardiology, American Society of Hypertension, Association of Black Cardiologists, National Lipid Association, Preventive Cardiovascular Nurses Association, The Endocrine Society, and WomenHeart: The National Coalition for Women With Heart Disease.

2. Obesity Recommendations and Algorithm

2.1. Summary of Evidence-Based Recommendations

The recommendations in Table 4 serve as a guide for PCPs in making evaluations and treatment decisions for

Table 4. Summary of Recommendations for Obesity

Recommendations	NHLBI Grade	NHLBI ES	ACC/AHA COR	ACC/AHA LOE
Identifying Patients Who Need to Lose Weight (BMI and Waist Circumference)				
1a. Measure height and weight and calculate BMI at annual visits or more frequently.	E (Expert Opinion)	CQ2	I	C
1b. Use the current cutpoints for overweight (BMI 25.0–29.9 kg/m^2) and obesity (BMI $\geq$30 kg/m^2) to identify adults who may be at elevated risk of CVD and the current cutpoints for obesity (BMI $\geq$30 kg/m^2) to identify adults who may be at elevated risk of mortality from all causes.	A (Strong)	CQ2	I	B
1c. Advise overweight and obese adults that the greater the BMI, the greater the risk of CVD, type 2 diabetes, and all-cause mortality.	A (Strong)	CQ2	I	B
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.	E (Expert Opinion)	CQ2	IIa	B
Matching Treatment Benefits With Risk Profiles (Reduction in Body Weight Effect on Risk Factors for CVD, Events, Morbidity and Mortality)				
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.	A (Strong)	CQ1	I	A
Diets for Weight Loss (Dietary Strategies for Weight Loss)				
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.	A (Strong)	CQ3	I	A
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.	A (Strong)	CQ3	I	A

Continued on the next page

overweight and obese patients. The CQs answered by evidence-based recommendations summarize current literature on the risks of overweight and obesity and the benefits of weight loss. They also summarize knowledge on the best diets for weight loss, the efficacy and effectiveness of comprehensive lifestyle interventions on weight loss and weight loss maintenance, and the benefits and risks of bariatric surgery. This information will help PCPs decide who should be recommended for weight loss and what health improvements can be expected. The Expert Panel did not choose a CQ that dealt with various aspects of pharmacotherapy for a comprehensive evidence assessment, because at the time the CQs were chosen there was only one approved medication (orlistat) for weight loss. However, CQ1 includes some ESs on the efficacy of orlistat because the effect of pharmacotherapy on weight loss was included in its evidence review.

2.2. Chronic Disease Management Model for Primary Care of Patients With Overweight and Obesity—Treatment Algorithm

The Expert Panel provides a treatment algorithm, Chronic Disease Management Model for Primary Care of Patients With Overweight and Obesity (Figure), to guide PCPs in the evaluation, prevention, and management of excess body weight in their patients. The algorithm incorporates, wherever possible, the recommendations derived from the 5 CQs that yielded ESs and recommendations. However, because the 5 CQs that were considered did not cover the entire scope of evaluation, prevention, and management of overweight/obesity, the panelists provided advice based on other guidelines and expert opinion to give providers a more comprehensive approach to their patients with weight-related issues.

Table 4. Summary of Recommendations for Obesity

Recommendations	NHLBI Grade	NHLBI ES	ACC/AHA COR	ACC/AHA LOE
Lifestyle Intervention and Counseling (Comprehensive Lifestyle Intervention)				
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.	A (Strong)	CQ4	I	A
4b. Prescribe on-site, high-intensity (i.e., ≥14 sessions in 6 mo) comprehensive weight loss interventions provided in individual or group sessions by a trained interventionist.†	A (Strong)	CQ4	I	A
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.	B (Moderate)	CQ4	IIa	A
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.	B (Moderate)	CQ4	IIa	A
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.	A (Strong)	CQ4	IIa‡	A
4f. Advise overweight and obese individuals who have lost weight to participate long term (≥1 year) in a comprehensive weight loss maintenance program.	A (Strong)	CQ4	I	A
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).	A (Strong)	CQ4	I	A
Selecting Patients for Bariatric Surgical Treatment for Obesity (Bariatric Surgical Treatment for Obesity)				
5a. Advise adults with a BMI ≥40 kg/m^2 or BMI ≥35 kg/m^2 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.	A (Strong)	CQ5	IIa§	A
5b. For individuals with a BMI <35 kg/m^2, there is insufficient evidence to recommend for or against undergoing bariatric surgical procedures.	N (No Recommendation)	CQ5	—	—
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).	E (Expert Opinion)	CQ5	IIb	C

*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.

†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.

‡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.

§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.

ACC indicates American College of Cardiology; AHA, American Heart Association; BMI, body mass index; BP, blood pressure; COR, Class of Recommendation; CQ, critical question; CVD, cardiovascular disease; ES, evidence statement; HDL-C, high-density lipoprotein cholesterol; IDF, International Diabetes Federation; LDL-C, low-density lipoprotein cholesterol; LOE, Level of Evidence; NHLBI, National Heart, Lung, and Blood Institute; NIH, National Health Institute; WHO, World Health Organization; and —, not applicable.

The algorithm is not intended to supplant initial assessment for cardiovascular risk factors or diseases but rather focuses on the identification of patients with excess body weight and those at risk for obesity-related health problems. Its purpose is to guide weight management decision making.

The algorithm incorporates the recommendations from CQ3 and CQ4 that patients who have sufficient health risk from overweight or obesity receive comprehensive lifestyle intervention. These approaches were all found effective under conditions in which multidisciplinary teams of medical, nutrition, and behavioral experts and other highly trained professionals worked intensively with individuals on weight management. This intervention should be foundational to additional weight management efforts, such as medications or bariatric surgery. It also emphasizes

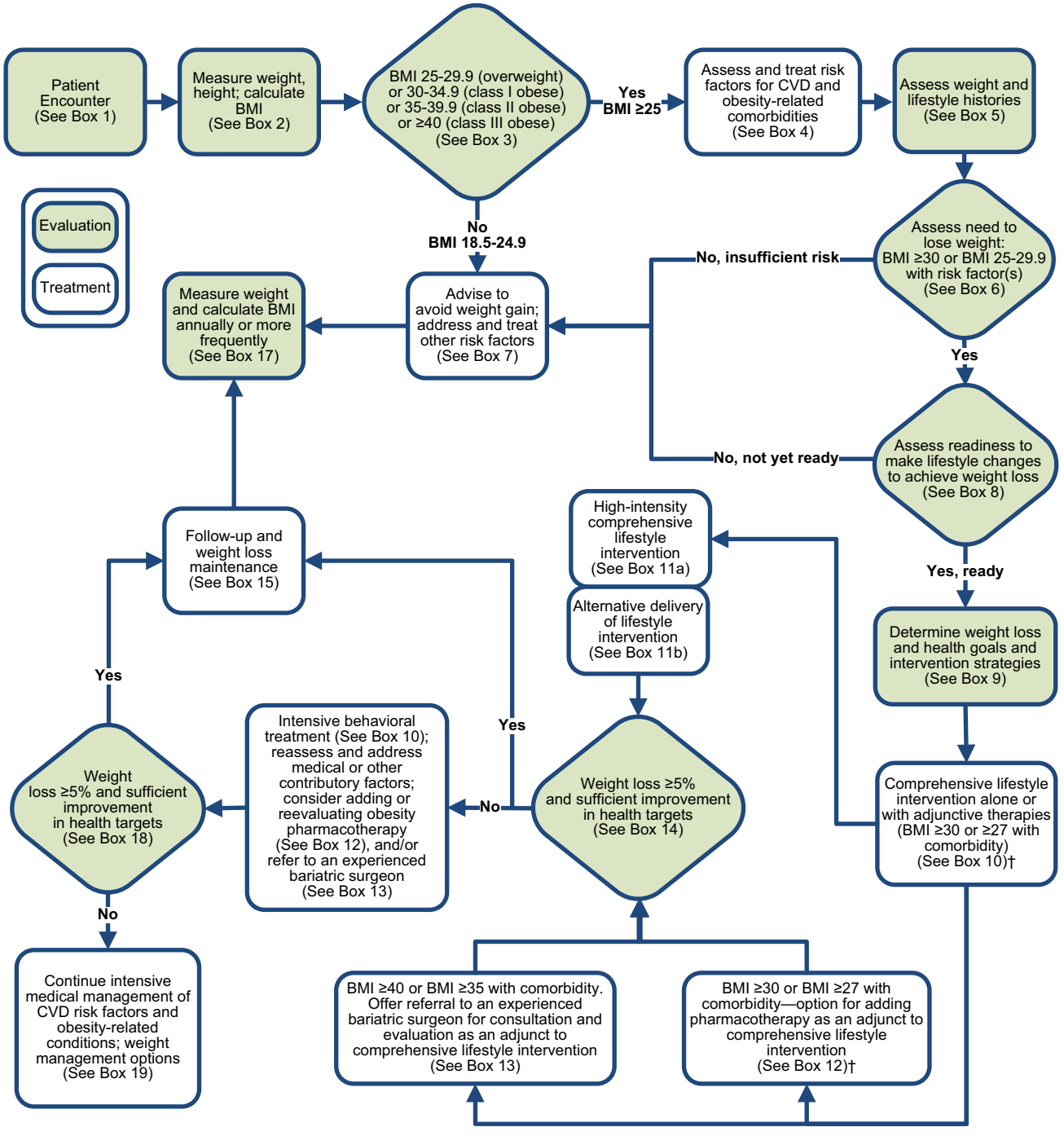

Figure 1. Treatment Algorithm—Chronic Disease Management Model for Primary Care of Patients With Overweight and Obesity*

*This algorithm applies to the assessment of overweight and obesity and subsequent decisions based on that assessment. Each step (designated by a box) in this process is reviewed in Section 2.2 and expanded on in subsequent sections.

†BMI cutpoint determined by the FDA and listed on the package inserts of FDA-approved obesity medications.

BMI indicates body mass index; CVD, cardiovascular disease; and FDA, U.S. Food and Drug Administration.

Box 1: Patient Encounter for Obesity Prevention and Management
A patient encounter for obesity prevention and management is defined as an interaction with a PCP who assesses a patient's weight status to determine presence of overweight or obesity and need for further assessment and treatment.

Box 2: Measure Weight and Height; Calculate BMI
With the patient wearing light clothing or an examination gown and no shoes, weight and height are measured and the BMI calculated. BMI can be calculated manually (weight in kg/[height in meters]^2) or electronically by using the electronic medical record or other resources. The BMI should be documented in the patient medical record.

Box 3: BMI 25-29.9 (overweight), BMI 30-34.9 (class I obese), BMI 35-39.9 (class II obese), or BMI ≥40 (class III obese [extreme obesity])
These BMI cutpoints define overweight and class I to III obese individuals and identify adults who may be at increased risk for CVD and other obesity-related conditions. Within these categories, additional personal risk assessment is needed because degree of risk can vary (Box 4 and CQ2).

Box 4: **Assess and Treat Cardiovascular Risk Factors and Obesity-Related Comorbidities**
Assess risk of CVD and/or presence of obesity-related comorbidities. Risk assessment for CVD and diabetes in a person with overweight or class I to III obesity includes history; physical examination; and clinical and laboratory assessments, including BP, fasting blood glucose, and fasting lipid panel (expert opinion). A waist circumference measurement is recommended for individuals with BMI 25-34.9 kg/m^2 to provide additional information on risk. It is unnecessary to measure waist circumference in patients with BMI ≥35 kg/m^2 because the waist circumference will likely be elevated and will add no additional risk information. The Expert Panel recommends, by expert opinion, using the current cutpoints (>88 cm [>35 in] for women and >102 cm [>40 in] for men) as indicative of increased cardiometabolic risk.

Because obesity is associated with increased risk of hypertension, dyslipidemia, diabetes, and a host of other comorbidities, the clinician should assess for associated conditions. The Expert Panel recommends, by expert opinion, that intensive management of cardiovascular risk factors (hypertension, dyslipidemia, prediabetes, or diabetes) or other obesity-related medical conditions (e.g., sleep apnea) be instituted if they are found, regardless of weight loss efforts.

Box 5: Assess Weight and Lifestyle Histories
The Expert Panel recommends, by expert opinion, that the clinician assess weight and lifestyle histories and determine other potential contributory factors: Ask questions about history of weight gain and loss over time, details of previous weight loss attempts, dietary habits, physical activity, family history of obesity, and other medical conditions or medications that may affect weight. Answers to these questions may provide useful information about the origins of or maintaining factors for overweight and obesity, including success and difficulties with previous weight loss or maintenance efforts. This information can help the clinician determine any adjustments to the patient's medical regimen that can assist weight management efforts and provide appropriate advice on lifestyle change. The information may also impact recommendations for treatment.

Box 6: Assess Need to Lose Weight

YES: **BMI ≥30 or BMI 25-29.9 with additional risk factor(s)**:
Weight loss treatment is indicated for 1) obese individuals and 2) overweight individuals with ≥1 indicators of increased cardiovascular risk (e.g., diabetes, prediabetes, hypertension, dyslipidemia, elevated waist circumference) or other obesity-related comorbidities.

NO: **BMI <25 or BMI 25-29.9 without additional risk**.
Normal-weight patients (BMI 18.5-24.9 kg/m^2) should be advised to avoid weight gain (Box 7). Patients who are overweight (BMI 25-29.9 kg/m^2) who do not have indicators of increased cardiovascular risk (e.g., diabetes, prediabetes, hypertension, dyslipidemia, elevated waist circumference) or other obesity-related comorbidities should be advised to avoid additional weight gain (Box 7).

Box 7: Advise to Avoid Weight Gain and Address Other Risk Factors

A. Normal weight: Individuals who are normal weight (BMI 18.5-24.9 kg/m^2) and do not have a history of overweight or obesity should be counseled on the desirability of avoiding weight gain to prevent the health risks of increased body weight.

B. Overweight without additional risk factors or normal weight with a history of overweight or obesity: For individuals who are overweight (BMI 25-29.9 kg/m^2) and who do not have indicators of increased cardiovascular risk (e.g., diabetes, prediabetes, hypertension, dyslipidemia, elevated waist circumference) or other obesity-related comorbidities, and for individuals who have a history of overweight and are now normal weight with risk factors at acceptable levels, advise patients to frequently measure their own weight and to avoid weight gain by adjusting their food intake if they start to gain more than a few pounds. Also, advise patients that engaging in regular physical activity will help them avoid weight gain.

C. Overweight or obese individuals who would benefit from weight loss but who are not currently prepared or able to lose weight: Periodically assess the patient's interest in and readiness for weight loss as shown in Box 8, and counsel the patient on the desirability of avoiding additional weight gain to prevent greater health risk. Regardless of patient's interest in or readiness for weight loss intervention, any cardiovascular risk factors and obesity-related health conditions should be evaluated and treated.

Box 8: Assess Readiness to Make Lifestyle Changes to Achieve Weight Loss and Identify Barriers to Success

The Expert Panel advises (expert opinion) that the clinician and patient agree on whether weight loss is appropriate. The clinician, together with the patient, should assess whether the patient is prepared and ready to undertake the measures necessary to succeed at weight loss before beginning comprehensive counseling efforts. The clinician can ask, "How prepared are you to make changes in your diet, to be more physically active, and to use behavior change strategies such as recording your weight and food intake?" These are the components of a comprehensive lifestyle intervention.

The decision to undertake weight loss efforts must be made in the context of competing priorities (e.g., smoking cessation may supersede a weight loss effort; life events may make the effort at weight reduction futile until a future time). If the patient is not prepared to undertake these changes, attempts to counsel the patient on how to make lifestyle changes are likely to be counterproductive.

Box 9: Determine Weight Loss and Health Goals and Intervention Strategies

Clinician and patient devise weight loss and health goals and comprehensive lifestyle treatment strategies to achieve these goals.

Recommended goals for weight loss: A realistic and meaningful weight loss goal is an important first step. Although sustained weight loss of as little as 3%-5% of body weight may lead to clinically meaningful reductions in some cardiovascular risk factors, larger weight losses produce greater benefits. The Expert Panel recommends as an initial goal the loss of 5%-10% of baseline weight within 6 months.

Recommended methods for weight loss: Weight loss requires creating an energy deficit through caloric restriction, physical activity, or both. An energy deficit of ≥500 kcal/d typically may be achieved with dietary intake of 1,200-1,500 kcal/d for women and 1,500-1,800 kcal/d for men. The choice of calorie-restricted diet can be individualized to the patient's preferences and health status (CQ3). Very-low-calorie diets (<800 kcal/d) should be used only in limited circumstances in a medical care setting where medical supervision and a high-intensity lifestyle intervention can be provided. If a specialized diet for CVD risk reduction, diabetes, or other medical conditions is also prescribed, referral to a nutrition professional* is recommended (CQ3).

Recommendations for management of medical conditions during weight loss: While weight loss treatment is ongoing, manage risk factors such as hypertension, dyslipidemia, and other obesity-related conditions. This includes monitoring the patient's requirements for medication change as weight loss progresses, particularly for antihypertensive medications and diabetes medications that can cause hypoglycemia.

Box 10: Weight Loss Options—Comprehensive Lifestyle Intervention Alone or With Adjunctive Therapies‡

All patients for whom weight loss is recommended should be offered or referred for comprehensive lifestyle intervention (Box 11a and 11b). Comprehensive lifestyle intervention, preferably with a trained interventionist† or nutrition professional*, is foundational to weight loss (Box 11a) regardless of augmentation by medications or bariatric surgery.

By expert opinion, if the weight and lifestyle history indicates that the patient has never participated in a comprehensive lifestyle intervention program as defined in CQ4 and in Box 11a, it is recommended that he or she be encouraged to undertake such a program before the addition of adjunctive therapies since a substantial proportion of patients will lose sufficient weight to improve health with comprehensive lifestyle treatment alone. This recommendation may be modified by the availability of comprehensive lifestyle intervention or by patient factors, such as medical conditions that warrant earlier initiation of more intensive treatment.

If the patient has been unable to lose weight or sustain weight loss with comprehensive lifestyle intervention and he or she has a BMI ≥30 kg/m^2 or BMI ≥27 kg/m^2 with comorbidity, adjunctive therapies may be considered.

Patients who are otherwise appropriate candidates for obesity drug treatment or bariatric surgery, whose weight and lifestyle history indicate a history of inability to achieve or sustain weight loss and who have previously participated in a comprehensive lifestyle intervention, may be offered the option to add pharmacotherapy at the time of initiation of a lifestyle intervention program (BMI ≥30 kg/m^2 or BMI ≥27 kg/m^2 with comorbidity) or to be referred for evaluation for bariatric surgery (BMI ≥40 kg/m^2 or BMI ≥35 kg/m^2 with comorbidity) (expert opinion).‡

Box 11a. Offer or Refer for High-Intensity Comprehensive Lifestyle Intervention

The most effective behavioral weight loss treatment is an in-person, high-intensity (i.e., ≥14 sessions in 6 months) comprehensive weight loss intervention provided in individual or group sessions by a trained interventionist† (CQ4). The principal components of an effective high-intensity, on-site comprehensive lifestyle intervention include 1) prescription of a moderately reduced-calorie diet, 2) a program of increased physical activity, and 3) the use of behavioral strategies to facilitate adherence to diet and activity recommendations. As shown in CQ4, comprehensive lifestyle intervention consisting of diet, physical activity, and behavior therapy produces average weight losses of approximately 8 kg in a 6-month period of frequent, in-person treatment. This approximates losses of 5%-10% of initial weight. The observed average weight loss of approximately 8 kg includes people who have variable weight loss (i.e., some more and some less than average), so accurate prediction of individual weight loss is not possible. After 6 months, most patients will equilibrate (caloric intake balancing energy expenditure) and will require adjustment of energy balance if they are to lose additional weight. As demonstrated in CQ4, continued intervention contact after initial weight loss treatment is associated with better maintenance of lost weight (Box 15).

Box 11b. Options for Alternative Modes of Delivery of Lifestyle Intervention

In primary care offices where frequent, in-person individual or group sessions led by a trained interventionist† or a nutrition professional* are not possible or available by referral, the physician may consider alternative modes of delivery. As found in CQ4, emerging evidence supports the efficacy, albeit with less weight loss, of electronically delivered interventions (e.g., by Internet or telephone) that provide personalized feedback by a trained interventionist† and of some commercial programs that provide counseling (face-to-face or telephonic) with or without prepackaged meals. The Expert Panel recommends, by expert opinion, that physicians may refer to these alternative sources provided their outcomes are supported by scientific evidence of safety and efficacy. An additional option if a high-intensity comprehensive lifestyle intervention program is not available or feasible is referral to a nutrition professional* for dietary counseling.

Box 12. Option for Adding Pharmacotherapy as an Adjunct to Comprehensive Lifestyle Intervention‡

The Expert Panel did not review comprehensive evidence for pharmacotherapy for weight loss. On the basis of expert opinion, the panelists recommend that for individuals with BMI ≥ 30 kg/m^2 or BMI ≥27 kg/m^2 with ≥1 obesity-associated comorbid condition(s) who are motivated to lose weight, pharmacotherapy can be considered as an adjunct to comprehensive lifestyle intervention to help achieve targeted weight loss and health goals. Medications should be FDA approved, and clinicians should be knowledgeable about the product label. The provider should weigh the potential risks of the medication being considered against the potential benefits of successful weight loss for the individual patient. The rationale for use of medications is to help patients adhere to a lower-calorie diet more consistently to achieve sufficient weight loss and health improvements when combined with increased physical activity. The available medications work through effects on appetite or fat absorption. Medications work to reinforce lifestyle change and should be prescribed as an adjunct to lifestyle interventions as defined in Boxes 11a and 11b.

Box 13. Offer Referral to an Experienced Bariatric Surgeon for Consultation and Evaluation

For adults with a BMI ≥40 kg/m^2 or BMI ≥35 kg/m^2 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, advise that bariatric surgery may be an appropriate option to improve health and offer referral to an experienced bariatric surgeon for consultation and evaluation (CQ5 for additional information). Because bariatric surgery leads to improvements in both weight-related outcomes and many obesity-related comorbid conditions, the benefit-to-risk ratio may be favorable in appropriately selected patients at high risk for obesity-related morbidity and mortality. In the absence of RCTs to identify the optimal duration and weight loss outcomes of nonsurgical treatment before bariatric surgery is recommended, the decision to proceed to surgery should be based on multiple factors: patient motivation, treatment adherence, operative risk, and optimization of comorbid conditions, among others. Bariatric surgery should be considered an adjunct to lifestyle treatment: behavioral treatment, appropriate dietary modification, and physical activity.

Box 14. Weight Loss ≥5% of Initial Body Weight and Sufficient Improvement in Health Targets?

Achieving the goals noted in Box 9 of approximately 5%-10% of initial weight with a comprehensive lifestyle intervention should be considered successful weight reduction that leads to decreased risk for development of or amelioration of obesity-related medical conditions and cardiovascular risk factors for many patients. Some patients will require additional weight loss to achieve targeted health outcome goals.

If the patient achieves the weight loss and health outcome goals previously identified by clinician and patient, the clinician should consider the weight loss maintenance strategies described in Box 15 using the disease management model of obesity treatment. If these weight loss or health outcome goals are not achieved with current treatment, the clinician can consider intensification of behavioral treatment (Box 16), and/or the addition or reevaluation of obesity pharmacotherapy (Box 12), or referral for evaluation for bariatric surgery (Box 13) in patients otherwise meeting BMI and comorbidity criteria.

Box 15: Weight Loss Maintenance

Typically, obesity is a chronic condition that develops over an individual's lifetime. The prevalence of obesity has greatly increased over the past 30 years, most likely because of environmental changes that promote increased consumption of high-calorie palatable foods, decreased physical activity, and more sedentary behavior. In this environment, it is difficult to maintain a healthy weight and prevent weight gain. Long-term research has shown that continuing weight loss maintenance interventions produce better long-term results than limited-term intervention programs. Clinicians must acknowledge the lifelong challenge that patients experience with obesity, provide support and encouragement, be prepared to assist patients with addressing small weight gains before they become larger ones, and reinstitute weight management efforts as early as possible in the course of regain.

The usual pattern of weight loss in patients undergoing a lifestyle intervention is that maximum weight loss is achieved at 6 months, followed by plateau and gradual regain over time. This is also true for medication-assisted weight loss, although weight regain may be slower with continued medication use. For bariatric surgery patients, it may take much longer for weight to plateau (CQ3, CQ4, and CQ5).

The strategies for weight maintenance after successful loss differ from the strategies for achieving weight loss. Flexibility and willingness to try different approaches are recommended. Patients should be advised that participation in a long-term (≥1 y) comprehensive weight loss maintenance program with monthly or more frequent contact, in person or by telephone, can improve successful weight maintenance. Strategies such as frequent self-weighing (at least weekly), consumption of a reduced-calorie diet, and high levels of physical activity (>200 min/wk) are associated with better weight maintenance over time.

Box 16: Unable to Lose Enough Weight With Current Treatment to Meet Weight or Targeted Health Goals
By expert opinion, if patients are unable to lose enough weight to meet weight or targeted health outcome goals with their current treatment, consider offering or referring for more intensive behavioral treatment than is currently being attempted, an alternative diet including options for meal replacement, referral to a nutrition professional*, addition of obesity pharmacotherapy, or referral for evaluation for bariatric surgery if otherwise appropriate. The clinician should also assess the patient's medication regimen for drugs that may contribute to weight gain and consider adjustments if medically appropriate. If the patient is currently taking an obesity medication but has not lost at least 5% of initial body weight after 12 weeks on a maximal dose of the medication, the provider should reassess the risk-to-benefit ratio of that medication for the patient and consider discontinuation of that drug.

Box 17: Measure Weight and Calculate BMI Annually or More Frequently
Weight should be measured and BMI calculated and documented by the clinician at least annually in all patients. For those who have never been overweight or who are weight stable, a 1-year interval is appropriate for the reassessment of BMI. For overweight or obese individuals or those of normal weight with a history of overweight, more frequent monitoring may be appropriate. Although these follow-up intervals are not evidence based, they are a reasonable compromise between the need to identify weight gain at an early stage and the need to limit the time, effort, and cost of repeated measurements.

Box 18. Weight Loss ≥5% of Initial Body Weight *and* Sufficient Improvement in Health Targets?
Determine if the intensified treatment strategies instituted in Box 16 have led to both successful weight loss and sufficient risk factor/comorbidity reduction to achieve the health goals determined by patient and clinician.

Box 19. Continue Intensive Medical Management of Cardiovascular Risk Factors and Obesity-Related Conditions and Periodic Assessment of Weight Management Options
Actively and intensively manage cardiovascular risk factors and obesity-related conditions, regardless of the patient's ability to achieve or sustain weight loss. Periodically reassess and address medical or other contributory factors and the potential to institute or reinstitute additional weight management options as shown in Box 16.

*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.
†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.
‡BMI cutpoint determined by the FDA and listed on the package inserts of FDA-approved obesity medications.

BMI indicates body mass index; BP, blood pressure; CQ, critical question; CVD, cardiovascular disease; FDA, U.S. Food and Drug Administration; PCP, primary care practitioner; and RCT, randomized controlled trial.

a fundamental principle of chronic disease management—that is, the need to complement a committed patient with informed providers to effectively manage a chronic condition like obesity and its associated cardiovascular risk factors.

3. CQs and Corresponding ESs

Each of the CQs are stated below, together with the number of articles screened against their individual I/E criteria and the number of articles that met the inclusion criteria and were rated as fair or good quality. For CQs that did not have many articles rated fair or good, the articles rated as poor were used (i.e., CQ2). The resulting ESs reflect the Expert Panel's review of the literature. The stated strength of evidence applies to the overall ES, including any bulleted items, unless noted otherwise.

3.1. CQ1: Statement of the Question

Among overweight and obese adults, does achievement of reduction in body weight with lifestyle and pharmacological interventions affect cardiovascular risk factors, CVD events, morbidity, and mortality?

1a. Does this effect vary across population subgroups defined by the following demographic and clinical characteristics:
- Age
- Sex
- Race/ethnicity
- Baseline BMI
- Baseline waist circumference
- Presence or absence of comorbid conditions
- Presence or absence of cardiovascular risk factors

1b. What amount (shown as percent lost, pounds lost, etc.) of weight loss is necessary to achieve benefit with regard to cardiovascular risk factors, morbidity, and mortality?
- Are there benefits of cardiovascular risk factors, CVD events, morbidity, and mortality from weight loss?
- What are the benefits of more significant weight loss?

1c. What is the effect of sustained weight loss for ≥2 years in individuals who are overweight or obese, on cardiovascular risk factors, CVD events, and health and psychological outcomes?
- What percent of weight loss needs to be maintained at ≥2 years to be associated with health benefits?

CQ1 was initially intended to be a de novo systematic review of original studies plus systematic reviews and meta-analyses. Because of resource and time constraints, CQ1 was restricted to systematic reviews and meta-analyses published only between January 2000 and October 2011. The titles and abstracts of 1,630 publications were screened against the I/E criteria independently by 2 reviewers, which resulted in 669 publications being excluded and 697 publications being retrieved for full-text review to further assess eligibility.* Six hundred ninety-seven full-text publications were independently screened by 2 reviewers, who assessed eligibility by applying the I/E criteria; 669 of these publications were excluded on the basis of ≥1 of the I/E criteria. Of the 697 full-text publications, 42 publications met the criteria and were included. The quality (internal validity) of these 42 publications was assessed using the quality assessment tool developed to assess systematic reviews, meta-analyses, or RCTs. Of these, 14 publications were rated as poor quality. The remaining 28 publications were rated to be of good or fair quality and were included in the evidence base that was used to formulate the ESs and recommendations (12–39). Although the issue of pharmacotherapy was not by itself a CQ, CQ1 was tasked to evaluate this evidence, and several meta-analyses included the effect of orlistat on weight loss and risk factors. None of the systematic reviews or meta-analyses included the Look AHEAD (Action for Health in Diabetes) trial data, which the Expert Panel considered unique in that the number of participants equaled or exceeded the total number of observations in most systematic reviews and meta-analyses. The Look AHEAD papers were included in the database as a critical supplement to the systematic review and meta-analysis information. The ESs were developed from the published literature available as of October 2011 and could not take into account published or unpublished reports of outcomes subsequent to the approval of the statements.

The following ESs reflect the Expert Panel's review of the literature. See the Full Panel Report supplement for the supportive evidence and spreadsheets.

3.1.1. Weight Loss and Risk of Diabetes

ES1. In overweight and obese adults at risk for type 2 diabetes, average weight losses of 2.5 kg to 5.5 kg at ≥2 years achieved with lifestyle intervention (with or without orlistat) reduce the risk of developing type 2 diabetes by 30% to 60%.

- ***Strength of Evidence: High***

ES2. In overweight and obese adults with type 2 diabetes, 2% to 5% weight loss achieved with 1 to 4 years of lifestyle intervention (with or without orlistat) results in modest reductions in fasting plasma glucose concentrations and lowering of hemoglobin A1c by 0.2% to 0.3%.

- ***Strength of Evidence: High***

*Some papers were not appropriate for inclusion for reasons other than the criteria, i.e., they did not address the question.

ES3. In overweight and obese adults with type 2 diabetes, those who achieve greater weight loss at 1 year with lifestyle intervention (with or without orlistat) have greater improvements in hemoglobin A1c. Weight loss of 5% to 10% is associated with hemoglobin A1c reductions of 0.6% to 1.0% and reduced need for diabetes medications.

- ***Strength of Evidence: High***

ES4. In overweight and obese adults with type 2 diabetes treated for 1 year with lifestyle intervention (with or without orlistat), those who lose more weight achieve greater reductions in fasting plasma glucose concentrations. Those who achieve weight losses of 2% to 5% are more likely to have clinically meaningful (>20 mg/dL) reductions in fasting glucose than those who remain weight stable (defined as gaining ≤2% or losing <2%).

- ***Strength of Evidence: High***

ES5. As comprehensive lifestyle treatment of overweight and obese adults with type 2 diabetes continues over 4 years, some weight regain will occur on average; partial weight regain is associated with an increase in hemoglobin A1c, but hemoglobin A1c remains below preintervention levels, and the reduction remains clinically meaningful (23).

- ***Strength of Evidence: Moderate***

ES6. In observational cohort studies, overweight and obese adults with type 2 diabetes who intentionally lost 9 kg to 13 kg had a 25% decrease in mortality rate compared with weight-stable controls.

- ***Strength of Evidence: Low***

ES7. In overweight and obese adults with type 2 diabetes, orlistat with lifestyle intervention results in 2 kg to 3 kg greater weight loss at 1 and 2 years than placebo with lifestyle intervention. The addition of orlistat is associated with greater reductions in fasting blood glucose, averaging 11 mg/dL and 4 mg/dL at 1 and 2 years, as well as an average greater reduction in hemoglobin A1c of 0.4% at 1 year.

- ***Strength of Evidence: High***

3.1.2. Weight Loss and Impact on Cholesterol/Lipid Profile

ES1. In overweight or obese adults with or without elevated cardiovascular risk, there is a dose–response relationship between the amount of weight loss achieved by lifestyle intervention and the improvement in lipid profile. The level of weight loss needed to observe these improvements varies by lipid as follows:

- At a 3 kg weight loss, a weighted mean reduction in triglycerides of at least 15 mg/dL is observed.
- At 5 kg to 8 kg weight loss, low-density lipoprotein cholesterol (LDL-C) reductions of approximately 5 mg/dL and high-density lipoprotein cholesterol (HDL-C) increases of 2 to 3 mg/dL are achieved.
- With <3 kg weight loss, more modest and more variable improvements in triglycerides, HDL-C, and LDL-C are observed.

- ***Strength of Evidence: High***

ES2. Among overweight and obese adults with type 2 diabetes, 8.0% weight loss at 1 year and 5.3% weight loss over 4 years, compared with usual care control, results in greater average increases (2 mg/dL) in HDL-C and greater average reductions in triglycerides.

- ***Strength of Evidence: Moderate***

ES3. A mean 5% weight loss achieved over 4 years by lifestyle intervention in overweight or obese adults with type 2 diabetes is associated with a reduction in newly prescribed lipid-lowering medications compared with controls.

- ***Strength of Evidence: Moderate***

ES4. Among overweight and obese adults with type 2 diabetes, there is a dose–response relationship between the amount of weight loss and the increase in HDL-C, which is most pronounced in those who are the least overweight at baseline.

- ***Strength of Evidence: Low***

ES5. Compared with placebo, the addition of orlistat to lifestyle intervention in overweight and obese adults results in an average 3 kg greater weight loss together with an 8 to 12 mg/dL reduction in LDL-C, a 1 mg/dL reduction in HDL-C, and variable changes in triglycerides.

- ***Strength of Evidence: High***

3.1.3. Weight Loss and Hypertension Risk

ES1. In overweight or obese adults with elevated cardiovascular risk (including type 2 diabetes and hypertension), there is a dose–response relationship between the amount of weight loss achieved at up to 3 years by lifestyle intervention (alone or with orlistat) and the lowering of BP.

- At a 5% weight loss, a weighted mean reduction in systolic and diastolic BP of approximately 3 and 2 mm Hg, respectively, is observed.
- At <5% weight loss, there are more modest and more variable reductions in BP.

- ***Strength of Evidence: High***

ES2. A 5% mean weight loss difference achieved over 4 years by intensive lifestyle intervention in overweight or obese adults with type 2 diabetes is associated with a lower

prevalence of patients who are prescribed antihypertensive medications compared with controls.

- ***Strength of Evidence: Moderate***

3.2. CQ2: Statement of the Question

2a. Are the current cutpoint values for overweight (BMI 25.0 to 29.9 kg/m^2) and obesity (BMI ≥30 kg/m^2), compared with BMI 18.5 to 24.9 kg/m^2, associated with elevated CVD-related risk (defined below)? Are the waist circumference cutpoints of >102 cm (male) and >88 cm (female) associated with elevated CVD-related risk? How do these cutpoints compare with other cutpoints in terms of elevated CVD-related risk and overall mortality?
- Fatal and nonfatal CHD, stroke, and CVD (CHD and stroke)
- Overall mortality
- Incident type 2 diabetes
- Incident dyslipidemia
- Incident hypertension

2b. Are differences across population subgroups in the relationships of BMI and waist circumference cutpoints with CVD, its risk factors, and overall mortality sufficiently large to warrant different cutpoints? If so, what should they be?
- Fatal and nonfatal CHD, stroke, and CVD
- Overall mortality
- Incident type 2 diabetes
- Incident dyslipidemia
- Incident hypertension

Groups being considered include:
- Age
- Sex (both male and female)
- Race/ethnicity (African American, Hispanic, Native American, Asian, white)

2c. What are the associations between weight maintenance and weight gain with elevated CVD-related risk in normal-weight, overweight, and obese adults?

Because of resource limitations, the literature search for CQ2 was limited to studies published between 2000 and 2011, and the evidence review limited to systematic reviews, meta-analyses, and pooled analyses, to limit the number of individual articles to be searched, reviewed, and quality rated. Expert Panel members excluded studies that focused on specific subpopulations with a disease or condition (e.g., women with breast cancer, adults on maintenance hemodialysis) and constructed summary evidence tables from the identified articles, and these tables were reviewed and checked by contractor staff for accuracy. Of the 1,571 articles initially screened, 15 of the 482 full-text publications met the I/E criteria and were included. The quality (internal validity) of these 15 publications was assessed using the quality assessment tool developed to assess systematic reviews and meta-analyses. Of these, 3 publications were rated as fair (40–42); the rest were rated as poor quality but were included in the evidence base because the NHLBI policy indicated that poor studies could be used as part of the evidence base if the majority of included studies were not rated good or fair. The following ESs reflect the Expert Panel's review of the literature.

3.2.1. Current BMI Cutpoints and CVD-Related Risk and All-Cause Mortality

ES1. Among overweight and obese adults, analyses of continuous BMI show that the greater the BMI, the higher the risk of fatal CHD and combined fatal and nonfatal CHD. The current cutpoints for overweight (BMI ≥25.0 kg/m^2) and obesity (BMI ≥30 kg/m^2) compared with normal weight (BMI 18.5 to <25.0 kg/m^2) are associated with elevated risk of combined fatal and nonfatal CHD.

- ***Strength of Evidence: Moderate***

ES2. Among overweight and obese adults, analyses of continuous BMI show that the greater the BMI, the higher the risk of fatal CHD and combined fatal and nonfatal CHD in both men and women. The current BMI cutpoints for overweight (BMI ≥25.0 kg/m^2) and obesity (BMI ≥30.0 kg/m^2) compared with normal weight (BMI 18.5 to <25.0 kg/m^2) are associated with elevated risk of fatal CHD in both sexes.

- ***Strength of Evidence: Moderate***

ES3. Among overweight or obese adults, analyses of continuous BMI show that the greater the BMI, the higher the risk of fatal stroke overall, as well as ischemic and hemorrhagic stroke. The same relationship holds for combined fatal and nonfatal ischemic stroke but across the entire BMI range, not just in overweight and obese adults. There is no evidence from meta-analyses, pooled analyses, or systematic reviews to change current BMI cutpoints as they relate to risk of stroke.

- ***Strength of Evidence: Moderate***

ES4. Among overweight and obese adults, analyses of continuous BMI show that the greater the BMI, the higher the risk of combined fatal and nonfatal CVD. The current cutpoint for obesity (BMI ≥30 kg/m^2) compared with normal weight (BMI 18.5 to 24.9 kg/m^2) is associated with an elevated risk of fatal CVD in men and women.

- ***Strength of Evidence: Moderate***

ES5. In men only, the current BMI cutpoint for overweight (BMI 25.0 to 29.9 kg/m^2) compared with normal weight (BMI 18.5 to <25.0 kg/m^2) is associated with an elevated risk of fatal CVD. In both men and women, obesity (BMI ≥30.0 kg/m^2) compared with normal weight is associated with an elevated risk of fatal CVD.

- ***Strength of Evidence: Low***

ES6. With current BMI cutpoints, the relative risk of fatal CVD was higher in obese white women than in obese African-American women compared with normal-weight women. In overweight women, there was no increase in risk of fatal CVD compared with normal-weight women in either race group.

- ***Strength of Evidence: Low***

ES7. Analyses of continuous BMI across the entire BMI range show that the greater the BMI, the higher the risk of type 2 diabetes without an indication of a threshold effect.

- ***Strength of Evidence: Moderate***

ES8. Among overweight and obese adults, analyses of continuous BMI show that the higher the BMI, the greater the risk of all-cause mortality. The current category for overweight (BMI 25.0 to 29.9 kg/m^2) is not associated with elevated risk of all-cause mortality, but a BMI at or above the current cutpoint for obesity (BMI $\geq$30 kg/m^2) is associated with an elevated risk of all-cause mortality, compared with normal weight (18.5 to 24.9 kg/m^2).

- ***Strength of Evidence: Moderate***

ES9. Sex-specific analyses of continuous BMI among overweight and obese men and women show that the greater the BMI, the higher the risk of all-cause mortality. The risk of all-cause mortality associated with the current cutpoints of obesity was similar for men and women.

- ***Strength of Evidence: Moderate***

3.2.2. Areas of Insufficient Evidence With Regard to Cutpoints for BMI and for Waist Circumference

The Expert Panel was not able to address parts of CQ2 because of the lack of systematic reviews, meta-analyses, and pooled analyses identified in the systematic search. Expert Panel members were aware of a large body of literature from individual studies examining the associations between BMI or waist circumference and hypertension or dyslipidemia, but these studies have not been summarized in meta-analyses, pooled analyses, or systematic reviews that met the criteria. In addition, no studies in the search compared alternative cutpoints with current cutpoints as they relate to risk of CHD, stroke, CVD, overall mortality, and diabetes. No systematic reviews, meta-analyses, or pooled analyses were identified that examined current waist circumference cutpoints as they relate to the risk of all outcomes addressed in CQ2, but the Expert Panel examined meta-analyses of studies that used waist circumference as a continuous variable. There is evidence from systematic reviews, meta-analyses, and pooled analyses that risk factors increase in a continuous manner with waist circumference. Because the Expert Panel was unable to address issues of the adequacy of current waist circumference cutpoints for overweight and obesity in comparison with alternative cutpoints, the choice of cutpoints to apply in patient evaluation is somewhat arbitrary. The Expert Panel was also unable to determine if age-, sex-, or race-specific waist circumference cutpoints for overweight and obesity are warranted to delineate elevated risk of all outcomes examined in CQ2. The absence of evidence from the available systematic reviews, meta-analyses, and pooled analyses for waist circumference cutpoints is not the same as the evidence of absence of usefulness. The Expert Panel acknowledges that this absence does not mean that waist circumference does not provide useful information in certain circumstances. For several of the outcomes, there were no analyses in the studies retrieved that examined current BMI and waist circumference cutpoints stratified by age, sex, and race-ethnicity. Finally, there was a lack of these types of analyses examining the associations between weight maintenance and weight gain with elevated cardiovascular risk in normal-weight, overweight, and obese adults. For this reason, the Expert Panel did not develop ESs addressing questions related to these areas. The methodology team and systematic review team worked closely with Expert Panel members to ensure the accuracy of data and the application of systematic evidence-based methodology.

3.3. CQ3: Statement of the Question

3a. In overweight or obese adults, what is the comparative efficacy/effectiveness of diets of differing forms and structures (macronutrient content, carbohydrate and fat quality, nutrient density, amount of energy deficit, and dietary pattern) or other dietary weight loss strategies (e.g., meal timing, portion-controlled meal replacements) in achieving or maintaining weight loss?

3b. During weight loss or weight maintenance after weight loss, what are the comparative health benefits or harms of the aforementioned diets and other dietary weight loss strategies?

Of the 1,422 articles screened against the I/E criteria, 438 full-text articles were retrieved to further assess eligibility. Of the 438 full-text publications, 77 publications met the criteria and were included. A total of 17 trials (23 articles) satisfied the final inclusion criteria for CQ3 and were rated to be of fair or good quality (43–65). The following ESs reflect the Expert Panel's review of the literature.

3.3.1. Overall Dietary Intervention and Composition—Creating Reduced Dietary Energy Intake

ES1. To achieve weight loss, an energy deficit is required. The techniques for reducing dietary energy intake include the following:

- Specification of an energy intake target that is less than that required for energy balance, usually

1,200 to 1,500 kcal/d for women and 1,500 to 1,800 kcal/d for men (kilocalorie levels are usually adjusted for the individual's body weight and physical activity levels);
- Estimation of individual energy requirements according to expert guidelines (66–68) and prescription of an energy deficit of 500 kcal/d or 750 kcal/d or 30% energy deficit; and
- *Ad libitum* approaches, in which a formal energy deficit target is not prescribed, but lower calorie intake is achieved by restriction or elimination of particular food groups or provision of prescribed foods.

- ***Strength of Evidence: High***

ES2. A variety of dietary approaches can produce weight loss in overweight and obese adults. All of the following dietary approaches (listed in alphabetical order) are associated with weight loss if reduction in dietary energy intake is achieved:

- A diet from the European Association for the Study of Diabetes Guidelines, which focuses on targeting food groups, rather than formal prescribed energy restriction, while still achieving an energy deficit. Descriptions of the diet can be found in the Full Panel Report supplement.
- Higher-protein diet (25% of total calories from protein, 30% of total calories from fat, and 45% of total calories from carbohydrate), with provision of foods that realize an energy deficit.
- Higher-protein Zone™-type diet (5 meals/d, each with 40% of total calories from carbohydrate, 30% of total calories from protein, and 30% of total calories from fat) without formal prescribed energy restriction but with a realized energy deficit.
- Lacto–ovo–vegetarian–style diet with prescribed energy restriction.
- Low-calorie diet with prescribed energy restriction.
- Low-carbohydrate diet (initially <20 g/d carbohydrate) without formal prescribed energy restriction but with a realized energy deficit.
- Low-fat vegan-style diet (10% to 25% of total calories from fat) without formal prescribed energy restriction but with a realized energy deficit.
- Low-fat diet (20% of total calories from fat) without formal prescribed energy restriction but with a realized energy deficit.
- Low–glycemic–load diet, either with formal prescribed energy restriction or without formal prescribed energy restriction, but with realized energy deficit.
- Lower-fat (≤30% fat), high-dairy (4 servings/d) diets with or without increased fiber and/or low-glycemic-index (low–glycemic-load) foods with prescribed energy restriction.
- Macronutrient-targeted diets (15% or 25% of total calories from protein; 20% or 40% of total calories from fat; 35%, 45%, 55%, or 65% of total calories from carbohydrate) with prescribed energy restriction.
- Mediterranean-style diet with prescribed energy restriction.
- Moderate-protein diet (12% of total calories from protein, 58% of total calories from carbohydrate, and 30% of total calories from fat) with provision of foods that realize an energy deficit.
- Provision of high–glycemic-load or low–glycemic-load meals with prescribed energy restriction.
- The AHA-style Step 1 diet (prescribed energy restriction of 1,500 to 1,800 kcal/d, <30% of total calories from fat, <10% of total calories from saturated fat).

- ***Strength of Evidence: High***

3.3.2. Overall Dietary Intervention and Composition—Pattern of Weight Loss Over Time With Dietary Intervention

ES3. With dietary intervention in overweight and obese adults, average weight loss is maximal at 6 months, with smaller losses maintained for up to 2 years, while treatment and follow-up tapers. Weight loss achieved by dietary techniques aimed at reducing daily energy intake ranges from 4 kg to 12 kg at 6-month follow-up. Thereafter, slow weight regain is observed, with total weight loss at 1 year of 4 kg to 10 kg and at 2 years of 3 kg to 4 kg.

- ***Strength of Evidence: High***

3.3.3. Low-Fat Approaches

ES4a. In overweight and obese adults, there is comparable weight loss at 6 to 12 months with instruction to consume a calorie-restricted (500- to 750-kcal deficit/d) lower-fat diet (<30% of total calories from fat) compared with a higher-fat diet (>40% of total calories from fat). Comprehensive programs of lifestyle change were used in all trials. Comparator diets had ≥40% of total calories from fat, either with a low-carbohydrate or low-glycemic-load diet or one that targets higher fat with either average or low protein.

- ***Strength of Evidence: Moderate***

ES4b. With moderate weight loss, lower-fat, higher-carbohydrate diets, compared with higher-fat, lower-carbohydrate diets, have the following differential effects:

- Greater reduction in LDL-C,
- Lesser reduction in serum triglycerides, and
- Lesser increases in HDL-C.

- ***Strength of Evidence: Moderate***

ES4c. Evidence is inconsistent with regard to BP differences between lower-fat, higher-carbohydrate diets and higher-fat, lower-carbohydrate diets.

- ***Strength of Evidence: Low***

3.3.4. Higher-Protein Approaches (25% to 30% of Energy)

ES5a. In overweight and obese adults, recommendations to increase dietary protein (25% of total calories) as part of a comprehensive weight loss intervention results in weight loss equivalent to that achieved with a typical protein diet (15% of total calories) when both diets are calorie restricted (500- to 750-kcal/d deficit).

- ***Strength of Evidence: High***

ES5b. In overweight and obese adults, high-protein diets (25% of total calories) do not result in more beneficial effects on cardiovascular risk factors than typical protein diets (15% of total calories) in the presence of weight loss and other macronutrient changes.

- ***Strength of Evidence: Low***

ES5c. On the basis of studies conducted in settings where all food is provided to deliver increased protein (25% of total calories) either as part of caloric restriction or with *ad libitum* energy consumption, there is insufficient evidence to inform recommendations for weight loss interventions in free-living overweight or obese individuals.

3.3.5. Low-Carbohydrate Approaches (<30 g/d)

ES6a. In overweight and obese adults, there are no differences in weight loss at 6 months with instructions to consume a carbohydrate-restricted diet (20 g/d for up to 3 months, followed by increasing levels of carbohydrate intake up to a point at which weight loss plateaus) in comparison with instruction to consume a calorie-restricted, low-fat diet. The comparator diets on which this statement is based were either a calorie-restricted, higher-carbohydrate, and lower-protein diet (55% of total calories from carbohydrate, 30% of total calories from fat, and 15% of total calories from protein) or a lower-fat European Association for the Study of Diabetes food group dietary pattern (40% of total calories from carbohydrate, 30% of total calories from fat, and 30% of total calories from protein).

- ***Strength of Evidence: Low***

ES6b. There is insufficient evidence to comment on the cardiovascular risk factor effects of low-carbohydrate diets.

3.3.6. Complex Versus Simple Carbohydrates

ES7. There is insufficient evidence to comment on the value of substituting either simple or complex carbohydrates for dietary fat in overweight or obese adults for the purpose of weight reduction.

3.3.7. Glycemic Load Dietary Approaches

ES8. In overweight and obese adults, both high– and low–glycemic-load diets produce a comparable weight loss with a similar rate of loss over 6 months.

- ***Strength of Evidence: Low***

3.3.8. Dietary Patterns (Mediterranean Style, Vegetarian, and Other Dietary Pattern Approaches)

ES9. In overweight and obese adults, a variety of calorie-restricted dietary patterns (e.g., Mediterranean-style diet, lower-fat lacto–ovo-vegetarian or vegan-style diet, or lower-fat diet with high dairy/calcium with added fiber and/or low–glycemic-index [low–glycemic-load] foods) produce weight loss and cardiovascular benefits that are comparable to an energy-restricted, lower-fat dietary pattern (25% to 30% of total calories from fat; Adult Treatment Panel III or AHA Step 1).

- ***Strength of Evidence: Low***

3.3.9. Meal Replacement and Adding Foods to Liquid Diets

ES10a. In overweight and obese women, the use of liquid and bar meal replacements is associated with increased weight loss at up to 6 months, in comparison with a balanced deficit diet using only conventional food. Longer-term evidence of continued weight loss advantage is lacking.

- ***Strength of Evidence: Low***

ES10b. There is insufficient evidence to comment on the value of adding various types of foods to a low-calorie liquid diet.

3.3.10. Very-Low-Calorie Diet Approaches

ES11a. There is insufficient evidence to comment on the value of liquid protein supplementation after the very–low-calorie diet induction of weight loss as an aid to weight loss maintenance.

ES11b. There is insufficient evidence to comment on strategies to provide more supervision of very–low-calorie diet adherence or to liberalize very–low-calorie diet therapy with the addition of conventional foods as an aid to the induction of weight loss.

3.4. CQ4: Statement of the Question

4a. Among overweight and obese adults, what is the efficacy/effectiveness of a comprehensive lifestyle intervention program (i.e., comprised of diet, physical activity, and behavior therapy) in facilitating weight loss or maintenance of lost weight?

4b. What characteristics of delivering comprehensive lifestyle interventions (e.g., frequency and duration of treatment, individual versus group sessions, on site versus telephone/email contact) are associated with greater weight loss or weight loss maintenance?

The wording of the CQ evolved over time, from a comprehensive intervention initially including 2 or more components (dietary prescription, physical activity, or behavioral therapy) to all 3 components being required. Additional exclusion criteria were later put in place to remove trials that included comprehensive lifestyle interventions but were designed principally to compare different dietary interventions. The Expert Panel decided that such trials were more appropriately addressed under CQ3. The titles and abstracts of 2,160 publications were screened against the I/E criteria independently by 2 reviewers (i.e., independent contractors), which resulted in 1,776 publications being excluded and 384 publications being retrieved for full-text review to further assess eligibility. Three hundred eighty-four full-text publications were independently screened by 2 reviewers who assessed eligibility by applying the I/E criteria; 215 of these publications were excluded on the basis of ≥1 of the I/E criteria.

Out of 384 full-text publications, 146 publications met the criteria and were included. The quality (internal validity) of these 146 publications was assessed using the quality assessment tool developed to assess RCTs. Of these, 74 publications were excluded because they were rated as poor quality; of those 74 publications, 43 studies were rated poor because of the intention-to-treat and attrition rates. The remaining 51 trials (72 articles) were rated to be of good or fair quality (22,23,69–138) and were included in the evidence base that was used to formulate the following ESs and recommendations.

3.4.1. Description of the Diet, Physical Activity, and Behavior Therapy Components in High-Intensity, On-Site Lifestyle Interventions

ES1. The principal components of an effective high-intensity, on-site comprehensive lifestyle intervention include 1) prescription of a moderately reduced-calorie diet, 2) a program of increased physical activity, and 3) the use of behavioral strategies to facilitate adherence to diet and activity recommendations. All 3 components should be included:

- **Reduced-calorie diet:** In comprehensive lifestyle interventions, overweight/obese individuals typically are prescribed a diet designed to induce an energy deficit of ≥500 kcal/d. This deficit often is sought by prescribing 1,200 to 1,500 kcal/d for women and 1,500 to 1,800 kcal/d for men. Alternatively, dietary energy deficits can be determined by one of the methods described in CQ3.
- **Increased physical activity:** Comprehensive lifestyle intervention programs typically prescribe increased aerobic physical activity (such as brisk walking) for ≥150 min/wk (equal to ≥30 min/d most days of the week). Higher levels of physical activity, approximately 200 to 300 min/wk, are recommended to maintain lost weight or minimize weight regain in the long term (>1 year).
- **Behavior therapy:** Comprehensive lifestyle interventions usually provide a structured behavior change program that includes regular self-monitoring of food intake, physical activity, and weight. These same behaviors are recommended to maintain lost weight, with the addition of frequent (i.e., weekly or more often) monitoring of body weight.

- ***Strength of Evidence: High***

3.4.2. Comprehensive Interventions Compared With Usual Care, Minimal Care, or No-Treatment Control

ES2a (Short-Term Weight Loss). In overweight and obese individuals in whom weight loss is indicated and who wish to lose weight, comprehensive lifestyle interventions consisting of diet, physical activity, and behavior therapy (all 3 components) produce average weight losses of up to 8 kg in 6 months of frequent (i.e., initially weekly) on-site treatment provided by a trained interventionist† in group or individual sessions. Such losses (which can approximate reductions of 5% to 10% of initial weight) are greater than those produced by usual care (i.e., characterized by the limited provision of advice or educational materials). Comparable 6-month weight losses have been observed in treatment-comparison studies of comprehensive lifestyle interventions, which did not include a usual-care control group.

- ***Strength of Evidence: High***

ES2b (Intermediate-Term Weight Loss). Longer-term comprehensive lifestyle interventions, which additionally provide weekly to monthly on-site treatment for another 6 months, produce average weight losses of up to 8 kg at 1 year, losses that are greater than those resulting from usual care. Comparable 1-year weight losses have been observed in treatment-comparison studies of comprehensive lifestyle interventions, which did not include a usual-care control group.

- ***Strength of Evidence: Moderate***

ES2c (Long-Term Weight Loss). Comprehensive lifestyle interventions that, after the first year, continue to provide bimonthly or more frequent intervention contacts, are associated with gradual weight regain of 1 to 2 kg/y (on average) from the weight loss achieved at 6 to 12 months. Long-term (>1 y) weight losses, however, remain larger than those associated with usual care.

†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.

Comparable findings have been observed in treatment-comparison studies of comprehensive lifestyle interventions, which did not include a usual-care control group.

- ***Strength of Evidence: High***

3.4.3. Efficacy/Effectiveness of Electronically Delivered, Comprehensive Interventions in Achieving Weight Loss

ES3. Electronically delivered, comprehensive weight loss interventions developed in academic settings, which include frequent self-monitoring of weight, food intake, and physical activity—as well as personalized feedback from a trained interventionist†—can produce weight loss of up to 5 kg at 6 to 12 months. This loss is greater than that resulting from no or minimal intervention (i.e., primarily knowledge based) offered on the Internet or in print.

- ***Strength of Evidence: Moderate***

3.4.4. Efficacy/Effectiveness of Comprehensive, Telephone-Delivered Lifestyle Interventions in Achieving Weight Loss

ES4. In comprehensive lifestyle interventions that are delivered by telephone or face-to-face counseling and that also include the use of commercially-prepared prepackaged meals or an interactive Web-based program, the telephone-delivered and face-to-face–delivered interventions produce similar mean net weight losses of approximately 5 kg at 6 months and 24 months, compared with a usual-care control group.

- ***Strength of Evidence: Low***

3.4.5. Efficacy/Effectiveness of Comprehensive Weight Loss Programs in Patients Within a Primary Care Practice Setting Compared With Usual Care

ES5. In studies to date, low- to moderate-intensity lifestyle interventions for weight loss provided to overweight or obese adults by primary care practices alone have not been shown to be effective.

- ***Strength of Evidence: High***

3.4.6. Efficacy/Effectiveness of Commercial-Based, Comprehensive Lifestyle Interventions in Achieving Weight Loss

ES6. Commercial-based, comprehensive weight loss interventions that are delivered in person have been shown to induce an average weight loss of 4.8 kg to 6.6 kg at 6 months in 2 trials when conventional foods are consumed and 6.6 kg to 10.1 kg at 12 months in 2 trials with provision of prepared food. These losses are greater than those produced by minimal-treatment control interventions.

- ***Strength of Evidence: Low***

3.4.7. Efficacy/Effectiveness of Very–Low-Calorie Diets as Used as Part of a Comprehensive Lifestyle Intervention in Achieving Weight Loss

ES7a. Comprehensive, high-intensity, on-site lifestyle interventions that include a medically supervised very–low-calorie diet (often defined as <800 kcal/d), as provided by complete meal replacement products, produce total weight loss of approximately 14.2 kg to 21.0 kg over 11 to 14 weeks, which is larger than that produced by no intervention or usual care (i.e., advice and education only).

- ***Strength of Evidence: High***

ES7b. After the cessation of a high-intensity lifestyle intervention with a medically supervised very–low-calorie diet of 11 to 14 weeks, weight regain of 3.1 kg to 3.7 kg has been observed during the ensuing 21 to 38 weeks of nonintervention follow-up.

- ***Strength of Evidence: High***

ES7c. The prescription of various types (resistance or aerobic training) and doses of moderate-intensity exercise training (e.g., brisk walking 135 to 250 min/wk) delivered in conjunction with weight loss maintenance therapy does not reduce the amount of weight regained after the cessation of the very–low-calorie diet, compared with weight loss maintenance therapy alone.

- ***Strength of Evidence: Low***

3.4.8. Efficacy/Effectiveness of Comprehensive Lifestyle Interventions in Maintaining Lost Weight

ES8a. After initial weight loss, some weight regain can be expected, on average, with greater regain observed over longer periods of time. Continued provision of a comprehensive weight loss maintenance program (on site or by telephone) for periods of up to 2.5 years after initial weight loss reduces weight regain, as compared with the provision of minimal intervention (i.e., usual care). The optimal duration of weight loss maintenance programs has not been determined.

- ***Strength of Evidence: Moderate***

ES8b. Of overweight/obese adults who participate in a high-intensity long-term comprehensive lifestyle intervention, 35% to 60% maintain a loss of ≥5% of initial body weight at ≥2 years' follow-up (after randomization).

- ***Strength of Evidence: Moderate***

3.4.9. Characteristics of Lifestyle Intervention Delivery That May Affect Weight Loss: Intervention Intensity

ES9a (Moderate-Intensity Interventions). Moderate-intensity, on-site comprehensive lifestyle interventions, which provide an average of 1 to 2 treatment sessions per

month, typically produce mean weight losses of 2 kg to 4 kg in 6 to 12 months. These losses generally are greater than those produced by usual care (i.e., minimal-intervention control group).

- *Strength of Evidence: High*

ES9b (Low-Intensity Interventions). Low-intensity, on-site comprehensive lifestyle interventions, which provide less-than-monthly treatment sessions, do not consistently produce weight loss when compared with usual care.

- *Strength of Evidence: Moderate*

ES9c (Effect of Intervention Intensity). When weight loss with each intervention intensity (i.e., low, moderate, and high) is compared with usual care, high-intensity lifestyle interventions (≥14 sessions in 6 months) typically produce greater net-of-control weight losses than do low- to moderate-intensity interventions.

- *Strength of Evidence: Moderate*

3.4.10. Characteristics of Lifestyle Intervention Delivery That May Affect Weight Loss or Weight Loss Maintenance: Individual Versus Group Treatment

ES10. There do not appear to be substantial differences in the size of the weight losses produced by individual- and group-based sessions in high-intensity, comprehensive lifestyle intervention delivered on site by a trained interventionist.†

- *Strength of Evidence: Low*

3.4.11. Characteristics of Lifestyle Intervention Delivery That May Affect Weight Loss or Weight Loss Maintenance: On-Site Versus Electronically Delivered Interventions

ES11. Weight losses observed in comprehensive lifestyle interventions, which are delivered on site by a trained interventionist† in initially weekly and then biweekly group or individual sessions, are generally greater than weight losses observed in comprehensive interventions that are delivered by Internet or email and that include feedback from a trained interventionist.

- *Strength of Evidence: Low*

3.5. CQ5: Statement of the Question

5a. Bariatric Surgery Efficacy. What are the long-term effects of the following surgical procedures on weight loss, weight loss maintenance, cardiovascular risk factors, related comorbidities, and mortality?
- Laparoscopic adjustable gastric banding (LAGB)
- Laparoscopic Roux-en-Y gastric bypass (RYGB)
- Open RYGB
- Biliopancreatic diversion (BPD) with and without duodenal switch
- Sleeve gastrectomy

What are the long-term effects of these surgical procedures in patients with different BMIs and comorbidities?
- BMI <35
- BMI 35 to <40 with no comorbidities
- BMI ≥35 with comorbidities
- BMI ≥40 with no comorbidities

5b. Predictors. What are the predictors associated with long-term effects of the following surgical procedures on weight loss, weight loss maintenance, cardiovascular risk factors, related comorbidities, and mortality?
- LAGB
- Laparoscopic RYGB
- Open RYGB
- BPD with and without duodenal switch
- Sleeve gastrectomy

What are the predictors associated with long-term effects of these surgical procedures in patients with different BMIs and comorbidities?
- BMI <35
- BMI 35 to <40 with no comorbidities
- BMI ≥35 with comorbidities
- BMI ≥40 with no comorbidities

5c. Complications: What are the short-term (<30 days) and long-term (≥30 days) complications of the following bariatric surgical procedures? What are the predictors associated with complications?
- LAGB
- Laparoscopic RYGB
- Open RYGB
- BPD with and without duodenal switch
- Sleeve gastrectomy

What are the complications of these surgical procedures in patients with different BMIs and comorbidities?
- BMI <35
- BMI 35 to <40 with no comorbidities
- BMI ≥35 with comorbidities
- BMI ≥40 with no comorbidities

Many, if not most, patients with extreme obesity have tried to lose weight numerous times. Some have lost substantial amounts of weight successfully, only to regain it. Although lifestyle intervention is the mainstay of all weight management treatment, there is increasing recognition of the need for adjunctive treatments for patients with obesity who are at high medical risk and who are unable to achieve or

†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.

maintain sufficient weight loss to improve their health. Bariatric surgery is one treatment option that has been increasingly used in patients with extreme obesity or with lesser degrees of obesity but with obesity-related comorbid conditions. Bariatric surgery is, by definition, invasive and has inherent short-term risks as well as adverse effects that may become apparent only during longer-term follow-up. Incurring these risks may be acceptable if health benefits are sustained over time. Therefore, the Expert Panel believed that evaluation of efficacy endpoints for weight loss and change in cardiovascular risk factors and other health outcomes required studies with a minimum postsurgical follow-up of 2 years and inclusion of a nonsurgical comparator group. Studies evaluating predictors of weight change or medical outcomes, including patient factors (e.g., presence or absence of diabetes) or surgical factors (e.g., RYGB versus BPD) required studies that directly compared these factors plus a minimum 2-year follow-up. Studies evaluating complications of bariatric surgery required at least 30-day postsurgical follow-up. For observational studies with ≥10 years of follow-up or for studies on BPD or sleeve gastrectomy procedures, sample size ≥100 was required, and for all other observational studies the sample size requirement was ≥500. This sample size requirement was instituted because the most important complications are infrequent (e.g., perioperative mortality <1%), such that smaller studies could give inaccurate estimates of complication rates.

The literature search for CQ5 included an electronic search for RCTs, controlled clinical trials, and observational studies published in the literature from January 1998 to December 2009. The search produced 2,317 citations, with 9 additional citations identified from nonsearch sources—that is, by Expert Panel members or hand search of systematic reviews and meta-analyses (obtained through the electronic search). Of the 2,317 citations identified through the database search, 811 citations were automatically excluded, and the titles and abstracts of the 1,515 remaining citations were screened against the I/E criteria for each of the 3 components (efficacy, predictors, and complications) independently by 2 reviewers, which resulted in 1,062 publications being excluded. Of the remaining 453 full-text publications, 64 met the I/E criteria, underwent full text review, and were included. The quality (internal validity) of these 64 publications was assessed, and of these, 29 publications were excluded because they were rated as poor quality; 18 studies were rated poor because of the intent-to-treat and/or attrition rates. The remaining 22 studies (35 articles) that met the criteria for at least 1 of the 3 components were rated good or fair quality and included in the evidence base (139–173). For the efficacy, predictors, and complications components, 5 studies (17 articles), 10 studies (12 articles) and 14 studies (15 articles) were rated as good/fair, respectively. A total of 8 articles were used across more than 1 component (141,142,144,148,156,159,168,169).

3.5.1. Component 1: Efficacy

A total of 5 studies (17 articles) met the criteria for determining the efficacy of bariatric surgery for weight loss and the impact on obesity-related comorbidities, were rated as good or fair quality, and are included in the summary table. The number of studies meeting inclusion criteria was limited because of the requirement that surgical treatment be compared with a nonsurgical comparator group with a minimum postsurgical follow-up of 2 years.

ES1. In obese adults, bariatric surgery produces greater weight loss and weight loss maintenance than that produced by usual care, conventional medical treatment, lifestyle intervention, or medically supervised weight loss, and weight loss efficacy varies depending on the type of procedure and initial body weight.

- Weight loss at 2 to 3 years after a variety of surgical procedures in adults with presurgical BMI ≥30 varies from a mean of 20% to 35% of initial weight and mean difference from nonsurgical comparators of 14% to 37%, depending on procedure.

- ***Strength of Evidence: High***

- Mean weight loss at 10 years after a variety of bariatric surgical procedures (predominantly vertical banded gastroplasty) is approximately 16% of initial weight, representing a mean weight regain of 7%.

- ***Strength of Evidence: Low***

ES2. In obese adults, bariatric surgery generally results in more favorable impact on obesity-related comorbid conditions than that produced by usual care, conventional medical treatment, lifestyle intervention, or medically supervised weight loss.

- At 2 to 3 years after a variety of bariatric surgical procedures in adults with BMI ≥30 who achieve mean weight loss of 20% to 35%, fasting glucose and insulin are reduced and incidence of type 2 diabetes is decreased, and there is a greater likelihood of diabetes remission among those with type 2 diabetes at baseline.

- ***Strength of Evidence: High***

- At 10 years, incidence and prevalence of type 2 diabetes are lower in those who have undergone surgery. However, among those in whom type 2 diabetes remits after surgery, diabetes may recur over time.

- ***Strength of Evidence: Low***

- At 2 to 3 years after a variety of bariatric surgical procedures in adults with BMI ≥30 who achieve mean weight loss of 20% to 35%, BP or use of BP medication is reduced compared with nonsurgical management. BP tends to increase over time, and at 10 years after surgery, there is no difference in mean systolic BP or the incidence of new cases of hypertension in those who have undergone bariatric surgery compared with those who have not undergone surgery.

- ***Strength of Evidence: Low***

  - Among obese adults with baseline hypertension, a greater percentage are in remission at 2 to 3 years and 10 years after bariatric surgery compared with nonsurgical management.‡

- ***Strength of Evidence: Low***

  - At 2 to 3 years and 10 years after a variety of bariatric surgical procedures in adults with BMI ≥30 who achieve mean weight loss of 20% to 35%, serum triglyceride levels are lower, HDL-C levels are higher, ratio of total cholesterol to HDL-C is lower, and changes in total cholesterol or LDL levels are inconsistent, compared with nonsurgical management.

- ***Strength of Evidence: Low***

  - Most measures of health-related quality of life are improved at 2 and 10 years after bariatric surgery.

- ***Strength of Evidence: Moderate***

  - Total mortality is decreased compared with nonsurgical management at mean follow-up of 11 years after undergoing a variety of bariatric surgical procedures (predominantly vertical banded gastroplasty) in patients with mean BMI >40 who achieve a mean long-term weight loss of 16%.

- ***Strength of Evidence: Low***

ES3. There are insufficient data on the efficacy of bariatric surgical procedures for weight loss and maintenance or risk factors for CVD ≥2 years after surgery in patients with a BMI <35.

3.5.2. Component 2: Predictors

A total of 10 studies (12 articles) met the inclusion criteria, were rated as good or fair quality, and are included in the summary table (141,142,144,148,151,155,156,159,161,168,169,172). The studies were required to have a comparator group but not necessarily a nonsurgical comparator, as well as outcomes of specific bariatric operative procedures.

‡Remission was defined variously depending on the study.

ES4. Weight loss after bariatric surgery expressed as percentage of total body weight loss varies by procedure.

In direct comparative studies at 2 to 3 years after surgery:

- Weight loss after gastric bypass exceeds that achieved after LAGB.

- ***Strength of Evidence: Moderate***

  - Weight losses after BPD, gastric bypass, and sleeve gastrectomy are similar.

- ***Strength of Evidence: Low***

In direct comparative studies at 5 to 10 years after surgery:

- Weight loss after gastric bypass exceeds that achieved after LAGB.

- ***Strength of Evidence: Low***

ES5. The remission of obesity-related comorbidities varies by procedure.

- Type 2 diabetes remission or improved glycemic control occurs with increasing frequency according to procedure as follows: LAGB, gastric bypass, BPD.

- ***Strength of Evidence: Low***

  - Reduction in the prevalence of hypertension is more frequent after gastric bypass than after LAGB.

- ***Strength of the Evidence: Low***

  - The prevalence of dyslipidemia is lower after gastric bypass than after LAGB.

- ***Strength of Evidence: Low***

3.5.3. Component 3: Complications

Fourteen studies met the inclusion criteria for complications. The complication evidence base included those studies from the efficacy and predictors searches that included complication data (141,156), as well as those studies that met the expanded search criteria (139,143,145,146,152,153,160,170,171).

3.5.3.1. LAPAROSCOPIC ADJUSTABLE GASTRIC BANDING

ES6. Perioperative (≤30 day) and longer-term (>30 days) complications after bariatric surgery vary by procedure and patient-derived risk factors. When LAGB is performed by an experienced surgeon:

- Perioperative complications are infrequent and do not tend to be life-threatening: major adverse outcomes (1%), such as deep venous thrombosis and reoperations, and minor complications (3%), such as wound infection.

- *Strength of Evidence: Moderate*

  - Longer-term complications continue to occur over time and may require operative correction: misplacement of band, approximately 3% to 4%; erosion of gastric wall, approximately 1%; and port complication, 5% to 11%.

- *Strength of Evidence: Moderate*

  - The rate of longer-term LAGB failure leading to removal of the band with or without conversion to another bariatric procedure varies from 2% to 34%. Inadequate weight loss is the most often reported basis for removal of band.

- *Strength of Evidence: Moderate*

3.5.3.2. ROUX-EN-Y GASTRIC BYPASS

ES6 (continued). Perioperative (≤30 days) and longer-term (>30 days) complications after bariatric surgery vary by procedure and patient-derived risk factors. When gastric bypass is performed by an experienced surgeon:

  - Perioperative complications consist of a major adverse outcome in approximately 4% to 5% of patients, including mortality (0.2%), deep vein thrombosis and/or pulmonary embolism (0.4%), and a need for reoperation (3% to 5%). The rate of any complication, major or minor, is 2% to 18%.

- *Strength of Evidence: Moderate*

  - Perioperative complications are less frequent for the laparoscopic approach than for open incision.

- *Strength of Evidence: Moderate*

When open gastric bypass is performed by an experienced surgeon:

  - Perioperative complications consist of a major adverse outcome in approximately 8% of patients, including mortality (2%), deep vein thrombosis or pulmonary embolism (1%), and a need for reoperation (5%).

- *Strength of Evidence: Low*

  - Perioperative complications are associated with extremely high BMI, inability to walk 200 feet, history of deep vein thrombosis or pulmonary embolism, and history of obstructive sleep apnea.

- *Strength of the Evidence: Low*

3.5.3.3. BILIOPANCREATIC DIVERSION

ES6 (continued). Perioperative (≤30 days) and longer-term (>30 days) complications after bariatric surgery vary by procedure and patient-derived risk factors. The mortality rate for BPD was reported by 2 of the 3 included studies. When BPD is performed by an experienced surgeon:

  - Perioperative complications occur in 2% to 8% of cases and include mortality (<1%) and deep vein thrombosis or pulmonary embolism (0.4%). The frequency of anastomotic leak, hemorrhage, and wound complication is variable.

- *Strength of the Evidence: Low*

  - One- to three-year complications include: anemia (13% to 20%); deficiency of protein (0.3% to 3.0%), iron (17%), or zinc (6%); and neuropathy (0.4%). Deficiency of vitamin D and elevated parathyroid hormone may exceed 40%.
  - When BPD is performed by open incision, the rate of ventral hernia can be as high as 72%.

- *Strength of the Evidence: Low*

3.5.3.4. LAPAROSCOPIC SLEEVE GASTRECTOMY

ES6 (continued). Perioperative (≤30 days) and longer-term (>30 days) complications after bariatric surgery vary by procedure and patient-derived risk factors. When laparoscopic sleeve gastrectomy is performed by an experienced surgeon:

  - There is insufficient evidence to establish the incidence of perioperative and longer-term complications.

4. Gaps in Evidence and Future Research Needs

The Expert Panel identified gaps in evidence supporting the 5 chosen CQs. For each CQ, the Expert Panel summarized recommendations for future research. See the Full Panel Report supplement for a more detailed and comprehensive discussion.

4.1. CQ1 (Benefits of Weight Loss)

The literature available in systematic reviews and meta-analyses did not specifically address whether age, sex, race, or baseline BMI or waist circumference modifies the beneficial effects of weight loss on cardiovascular risk factors. Likewise, the systematic reviews and meta-analyses did not specifically address the issue of how baseline comorbid conditions and cardiovascular risk factors modify the response to weight loss. Nevertheless, high-quality literature that addresses these issues could exist. Given that caveat and the present evidence review, future research in this area should address the following issues:

1. Do the observed improvements in cardiovascular risk factors, need for medications, and improved quality

of life associated with weight loss differ by age, sex, race, or BMI or waist circumference?
2. What is the cost-effectiveness of modest weight loss as a preventive strategy for those at risk of developing type 2 diabetes?
3. What is the best approach to identify and engage those who can benefit from weight loss?

4.2. CQ2 (Risks of Overweight and Obesity)

Because evidence-based methods to identify patients with elevated risk for CVD, its risk factors, and all-cause mortality are essential for healthcare practitioners, more systematic reviews, meta-analyses, and pooled analyses are needed to inform future guidelines in the following areas:

- Studies are needed that compare current BMI and waist circumference cutpoints with alternative cutpoints for predicting risk to optimize the specificity of cutpoints.
  - Studies should examine the independent and combined effects of BMI and waist circumference to determine if both in combination are better at predicting elevated risk than either alone.
  - Such studies should explicate the methods and logical framework that guides the choice of optimal cutpoints.
  - Studies comparing the predictive ability of BMI and waist circumference with more objective measures of percent body fat, such as dual-energy x-ray absorptiometry or magnetic resonance imaging, may enhance risk prediction of cutpoints and/or combinations of BMI and waist circumference.
- Similar studies are needed to assess whether overall cutpoints are appropriate for population subgroups stratified by age, sex, and race/ethnicity.
  - Studies that compare risk across different age groups should report absolute risk estimates. This is especially important when examining age.
  - Studies are needed on racial-ethnic differences in risk within Western countries, particularly in Asian Americans and Hispanic Americans.
- Longitudinal studies are needed that assess the risks associated with weight change (accounting for intentionality) in normal-weight, overweight, and obese adults to determine the role of weight change trajectory in risk assessment.

4.3. CQ3 (Dietary Interventions for Weight Loss)

More research is needed to inform future guidelines about dietary interventions for weight loss.

Because long-term dietary adherence is problematic in weight management, to determine the best dietary approach to sustain weight loss over the long term, studies are needed that:

- Test the impact of tailoring choice of dietary interventions on the individual's ability to adhere in the long term.
- Test pragmatic approaches to diet intervention delivery in free-living individuals for at least 2 years duration.
- Evaluate the physiological and biological adaptations to weight loss, so as to refine methods of caloric restriction during weight reduction and maintenance.

4.4. CQ4 (Lifestyle Interventions for Weight Loss)

More research is needed to inform future guidelines focusing on improvements in efficiency and efficacy, optimizing delivery and dissemination, and targeting special populations. The research is needed in the following areas:

- On-site (face-to-face), comprehensive, high-intensity lifestyle interventions (14 or more contacts in first 6 months) represent the standard for behavioral weight loss interventions. Further research can help improve efficiency of these interventions with studies that:
  - Evaluate optimal frequency (and duration) of contact.
  - Evaluate characteristics of those who lose less weight in response to a standard, comprehensive behavioral intervention, and develop alternative approaches for their treatment.
  - Evaluate effective methods of delivering lifestyle interventions remotely (e.g., Internet, mobile phone, text messaging, telephone, DVDs, or some combination of these) to achieve and maintain clinically meaningful weight loss.
- Because of changing demographics, there is a need for further research to understand the most appropriate strategies and prescriptions for weight loss for some key populations, including older adults and racial/ethnic groups.
- Because the efficacy of on-site (face-to-face), comprehensive, high-intensity lifestyle intervention has been established in academic settings, translational studies are needed that:
  - Evaluate programs that can be delivered in community, work-site, and other settings (including commercial programs).
  - Determine the personal characteristics, skills, and training required of a lifestyle interventionist.
  - Identify the optimal role for PCPs to play in the management of obesity by lifestyle modification.

- Evaluate head-to-head comparisons of the relative effectiveness and associated costs of delivering interventions on site (face-to-face), remotely, or by a combination of approaches (i.e., hybrid delivery).

- Because maintenance of lost weight over the long term has been challenging, studies are needed that:
  - Evaluate strategies to promote additional weight loss beyond the first 6 months, the time at which weight loss plateaus in most individuals.
  - Evaluate novel methods of improving the maintenance of lost weight.
- Further study is needed on the effect of weight loss treatment on healthcare utilization and cost.

4.5. CQ5 (Surgical Procedures for Weight Loss)

More research is needed to inform future guidelines in the following areas:

- Because bariatric surgery offers the potential for prevention or remission of diabetes, better control of cardiovascular risk factors, improvement in quality of life and possibly decreased mortality, there is a need for research to better characterize those patients who are most likely to benefit from and least likely to suffer adverse consequences of bariatric surgical procedures.
- Large and well-designed experimental, quasi-experimental, and observational studies with long-term follow-up are needed to determine whether the risks and benefits of bariatric surgery are sustained over time. Studies are needed that:
  - Evaluate which surgical procedures are best applied to different populations, on the basis of factors such as presence and duration of comorbid conditions, age, sex, race/ethnicity, degree and duration of obesity, underlying genetic etiologies, and psychosocial or behavioral characteristics.
  - Evaluate the implementation of bariatric surgery in nonacademic settings, which may be more reflective of real-world clinical practice.

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National Heart, Lung, and Blood Institute
Glen Bennett, MPH
Melinda Kelley, PhD
Melissa McGowan, MHS, CHES
Kathryn Y. McMurry, MS
Denise Simons-Morton, MD, PhD

Acknowledgment
The CQ2 Working Group of the Obesity Expert Panel acknowledges the valuable contributions of Eva Erber, MS, Graduate Research Assistant at the University of North Carolina at Chapel Hill.

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Key Words: ACC/AHA Practice Guidelines ■ bariatric surgery ■ behavior therapy ■ blood pressure ■ body mass index ■ diabetes mellitus ■ diet ■ dyslipidemia ■ lifestyle ■ waist circumference ■ weight loss.

Appendix 1. Author Relationships With Industry and Other Entities (Relevant)—2013 AHA/ACC/TOS Guideline for the Management of Overweight and Obesity in Adults

Committee Member	Employment	Consultant	Speakers Bureau	Ownership/ Partnership/ Principal	Personal Research	Expert Witness
Michael D. Jensen *(Co-Chair)*	Mayo Clinic Endocrine Research Unit—Professor of Medicine, Endocrinology, Metabolism, Diabetes, Nutrition, and Internal Medicine Division	**2008–2012** None **2013** • Eisai • Novo Nordisk • Vivus	**2008–2012** None **2013** None	**2008–2012** None **2013** None	**2008–2012** None **2013** None	**2008–2012** None **2013** None
Donna H. Ryan *(Co-Chair)*	Pennington Biomedical Research Center—Associate Executive Director for Clinical Research	**2008–2012** • Alere Wellbeing • Amylin • Arena Pharmaceuticals • Eisai • Novo Nordisk • Nutrisystem • Orexigen • Takeda • Vivus **2013** • Arena Pharmaceuticals • Eisai • Novo Nordisk • Takeda • Vivus	**2008–2012** None **2013** None	**2008–2012** None **2013** • Scientific Intake	**2008–2012** None **2013** None	**2008–2012** None **2013** None
Caroline M. Apovian	Boston Medical Center—Professor of Medicine and Pediatrics; Center for Nutrition and Weight Management—Director	**2008–2012** • Amylin • Arena Pharmaceuticals • Johnson & Johnson • Merck • Nutrisystem • Orexigen • Sanofi-aventis • Zafgen **2013** • Abbott Nutrition • Allergan • Amylin • Arena Pharmaceuticals • GI Dynamics • Johnson & Johnson • Merck • Novo Nordisk • Nutrisystem • Orexigen Therapeutics • Pfizer • Sanofi-aventis • Zafgen	**2008–2012** None **2013** None	**2008–2012** None **2013** None	**2008–2012** • Amylin • Dr. Robert C. and Veronica Atkins Foundation • Eli Lilly • MetaProteomics • Orexegin • Pfizer • Sanofi-aventis **2013** • Amylin† • Aspire Bariatrics† • Dr. Robert C. and Veronica Atkins Foundation† • Eli Lilly† • GI Dynamics† • GlaxoSmithKline • MetaProteomics • Orexigen Therapeutics† • Pfizer† • Sanofi-aventis	**2008–2012** None **2013** None
Jamy D. Ard	Wake Forest University—Assistant Professor of Epidemiology and Prevention; Weight Management Center—Co-Director	**2008–2012** • Arena Pharmaceuticals • Nestle Healthcare Nutrition • OPTIFAST Division • Vivus **2013** • Eisai • Nestle Healthcare Nutrition • OPTIFAST Division • Vivus	**2008–2012** None **2013** None	**2008–2012** None **2013** None	**2008–2012** • OPTIFAST—Medical Director **2013** None	**2008–2012** None **2013** None

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Appendix 1. Continued

Committee Member	Employment	Consultant	Speakers Bureau	Ownership/ Partnership/ Principal	Personal Research	Expert Witness
Anthony G. Comuzzie	Southwest Foundation for Biomedical Research—Scientist, Department of Genetics	**2008–2012** None **2013** None	**2008–2012** None **2013** None	**2008–2012** None **2013** None	**2008–2012** None **2013** None	**2008–2012** None **2013** None
Karen A. Donato	NHLBI—Acting Director, Division for the Application of Research Discoveries	**2008–2012** None **2013** None	**2008–2012** None **2013** None	**2008–2012** None **2013** None	**2008–2012** None **2013** None	**2008–2012** None **2013** None
Frank B. Hu	Harvard University School of Public Health—Professor, Nutrition and Epidemiology	**2008–2012** • Amgen • Novo Nordisk • Nutrition Impact • Unilever **2013** • Bunge	**2008–2012** None **2013** None	**2008–2012** None **2013** None	**2008–2012** • Merck **2013** • Merck	**2008–2012** None **2013** None
Van S. Hubbard *(Ex-officio)*	NIDDK—Director, NIH Division of Nutrition Research Coordination	**2008–2012** None **2013** None	**2008–2012** None **2013** None	**2008–2012** None **2013** None	**2008–2012** None **2013** None	**2008–2012** None **2013** None
John M. Jakicic	University of Pittsburgh—Professor and Chair, Physical Activity and Weight Management Research Center	**2008–2012** • Alere Wellbeing • Jenny Craig • Nestle Nutrition **2013** • Calorie Control Council	**2008–2012** None **2013** None	**2008–2012** None **2013** None	**2008–2012** • BodyMedia—PI **2013** • BodyMedia—PI	**2008–2012** None **2013** None
Robert F. Kushner	Northwestern University Feinberg School of Medicine—Professor, Division of General Internal Medicine	**2008–2012** • Abbott • Amylin • Novo Nordisk • Orexigen • Retrofit • Sanofi-aventis • Zafgen **2013** None	**2008–2012** None **2013** None	**2008–2012** None **2013** None	**2008–2012** • Novo Nordisk • Weight Watchers **2013** • Aspire Bariatrics	**2008–2012** None **2013** None
Catherine M. Loria *(Ex-officio)*	NHLBI—Nutritional Epidemiologist	**2008–2012** None **2013** None	**2008–2012** None **2013** None	**2008–2012** None **2013** None	**2008–2012** None **2013** None	**2008–2012** None **2013** None
Barbara E. Millen	Boston Nutrition Foundation—Chairman; Millennium Prevention—President	**2008–2012** None **2013** None	**2008–2012** None **2013** None	**2008–2012** • Boston Nutrition Foundation* • Millennium Prevention* **2013** • Boston Nutrition Foundation* • Millennium Prevention*	**2008–2012** None **2013** None	**2008–2012** None **2013** None
Cathy A. Nonas	NYC Dept of Health and Mental Hygiene—Senior Advisor, Bureau for Chronic Disease Prevention and Tobacco Control	**2008–2012** None **2013** None	**2008–2012** None **2013** None	**2008–2012** None **2013** None	**2008–2012** None **2013** None	**2008–2012** None **2013** None

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Appendix 1. Continued

Committee Member	Employment	Consultant	Speakers Bureau	Ownership/ Partnership/ Principal	Personal Research	Expert Witness
F. Xavier Pi-Sunyer	Columbia University—Professor of Medicine, College of Physicians and Surgeons	**2008–2012** • Amylin • AstraZeneca • Eisai • Eli Lilly • McNeil • Novo Nordisk • Weight Watchers • Zafgen	**2008–2012** None	**2008–2012** None	**2008–2012** • Arena Pharmaceuticals • Novo Nordisk • Orexigen • Roche • Vivus	**2008–2012** None
		2013 • AstraZeneca • Eisai • McNeil • Novo Nordisk • Vivus • Weight Watchers • Zafgen	**2013** None	**2013** None	**2013** • Novo Nordisk	**2013** None
June Stevens	University of North Carolina at Chapel Hill—Chair, Department of Nutrition; Department of Epidemiology Schools of Public Health and Medicine—Professor	**2008–2012** • CMeducation Resources	**2008–2012** None	**2008–2012** None	**2008–2012** • Dannon • PepsiCo, Gatorade • Sanofi-aventis • Wyeth Nutrition	**2008–2012** None
		2013 None	**2013** None	**2013** None	**2013** • PepsiCo, Gatorade • Sanofi-aventis • Wyeth Nutrition	**2013** None
Victor J. Stevens	Kaiser Permanente Center for Health Research—Assistant Director, Epidemiology and Disease Prevention	**2008–2012** None	**2008–2012** None	**2008–2012** None	**2008–2012** None	**2008–2012** None
		2013 None	**2013** None	**2013** None	**2013** None	**2013** None
Thomas A. Wadden	Perelman School of Medicine at the University of Pennsylvania—Professor of Psychology in Psychiatry; Center for Weight and Eating Disorders—Director	**2008–2012** • Alere Wellbeing • BMIQ • Novo Nordisk • Orexigen • Vivus	**2008–2012** None	**2008–2012** None	**2008–2012** • Novo Nordisk • Nutrisystem • Weight Watchers	**2008–2012** None
		2013 • Novo Nordisk • Orexigen	**2013** None	**2013** None	**2013** None	**2013** None
Bruce M. Wolfe	Oregon Health and Science University—Professor of Surgery	**2008–2012** • Crospon • EnteroMedics	**2008–2012** None	**2008–2012** None	**2008–2012** None	**2008–2012** None
		2013 • EnteroMedics	**2013** None	**2013** None	**2013** None	**2013** None
Susan Z. Yanovski *(Ex-officio)*	NIDDK—Co-Director, Office of Obesity Research, Division of Digestive Diseases and Nutrition	**2008–2012** None	**2008–2012** None	**2008–2012** None	**2008–2012** None	**2008–2012** None
		2013 None	**2013** None	**2013** None	**2013** None	**2013** None

This table reflects the relevant healthcare-related relationships of authors with industry and other entities provided by the Expert Panel during the document development process (2008–2012). Both compensated and uncompensated relationships are reported. These relationships were reviewed and updated in conjunction with all meetings and conference calls of the Expert Panel during the document development process. Authors with relevant relationships during the document development process recused themselves from voting on recommendations relevant to their relationships. In the spirit of full transparency, the ACC and AHA asked Expert Panel members to provide updates and approve the final version of this table, which includes current relevant relationships (2013). To review the NHLBI and ACC/AHA's current comprehensive policies for managing relationships with industry and other entities, please refer to http://www.nhlbi.nih.gov/guidelines/cvd_adult/coi-rwi_policy.htm and http://www.cardiosource.org/Science-And-Quality/Practice-Guidelines-and-Quality-Standards/Relationships-With-Industry-Policy.aspx.

Per ACC/AHA policy: A person is deemed to have a significant interest in a business if the interest represents ownership of ≥5% of the voting stock or share of the business entity, or ownership of ≥$10,000 of the fair market value of the business entity; or if funds received by the person from the business entity exceed 5% of the person's gross income for the previous year. Relationships that exist with no financial benefit are also included for the purpose of transparency. Relationships in this table are modest unless otherwise noted.

*Significant relationship.

†No financial benefit.

ACC indicates American College of Cardiology; AHA, American Heart Association; NHLBI, National Heart, Lung, and Blood Institute; NIDDK, National Institute of Diabetes and Digestive and Kidney Diseases; NIH, National Health Institute; PI, principal investigator; and TOS, The Obesity Society.

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Appendix 2. Expert Reviewer Relationships With Industry and Other Entities—2013 AHA/ACC/TOS Guideline for the Management of Overweight and Obesity in Adults

Reviewer	Representation	Employment	Consultant	Speakers Bureau	Ownership/ Partnership/ Principal	Personal Research	Institutional, Organizational, or Other Financial Benefit	Expert Witness
William H. Dietz	ACC/AHA	Centers for Disease Control and Prevention—Director, Division of Nutrition and Physical Activity	None	None	None	None	None	None
Penny Gordon-Larsen	TOS	University of North Carolina, Gillings School of Global Public Health—Professor, Department of Nutrition	None	None	None	None	None	None
Lee M. Kaplan	TOS	Massachusetts General Hospital—Director, Weight Center	• AMAG Pharmaceuticals • Bristol-Myers Squibb • Eisai • Ethicon* • Fractyl • Gelesis • GI Dynamics† • MedImmune • Novo Nordisk • Pfizer • Rhythm† • USGI Medical • Vivus • Zafgen	None	None	• Ethicon*	None	None
Paul Poirier	ACC/AHA	Laval University, Institut Universitaire de Cardiologie et Pneumologie, Hôpital Laval—Faculty of Pharmacy	• AstraZeneca • Bristol-Myers Squibb • Merck	None	None	None	None	None
Susan J. Pressler	ACC/AHA Task Force on Practice Guidelines	University of Michigan School of Nursing—Professor	None	None	None	None	• Pfizer*	None
Rena R. Wing	TOS	Brown University—Professor, Psychiatry & Human Behavior	None	None	None	None	None	None

This table represents the relationships of reviewers with industry and other entities that were self-disclosed at the time of peer review. It does not necessarily reflect relationships with industry at the time of publication. To review the NHLBI and ACC/AHA's current comprehensive policies for managing relationships with industry and other entities, please refer to http://www.nhlbi.nih.gov/guidelines/cvd_adult/coi-rwi_policy.htm and http://www.cardiosource.org/Science-And-Quality/Practice-Guidelines-and-Quality-Standards/Relationships-With-Industry-Policy.aspx.

*No financial benefit.

†Significant relationship.

ACC indicates American College of Cardiology; AHA, American Heart Association; and TOS, The Obesity Society.

Appendix 3. Abbreviations

BMI = body mass index
BP = blood pressure
BPD = biliopancreatic diversion
CHD = coronary heart disease
CVD = cardiovascular disease
COR = Class of Recommendation
CQ = critical question
ES = evidence statement
HDL-C = high-density lipoprotein cholesterol
I/E = inclusion/exclusion
LAGB = laparoscopic adjustable gastric banding
LDL-C = low-density lipoprotein cholesterol
LOE = Level of Evidence
NHLBI = National Heart, Lung, and Blood Institute
PCP = primary care practitioner
RWI = relationships of authors with industry and other entities
RYGB = laparoscopic Roux-en-Y gastric bypass