The new cardiovascular disease prevention guidelines: What you need to know

A new, partially tested CVD risk-assessment tool significantly increases the number of individuals who would qualify for statin therapy. Treating to a target LDL-C value has given way to reducing the level by different percentages based on patient characteristics.

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A significant milestone in evidence-based practice was reached in November 2013, when the American Heart Association and American College of Cardiology (AHA/ACC) published 4 clinical practice guidelines on the prevention of cardiovascular disease.[1-4] These guidelines—on obesity, lifestyle management, cardiovascular disease (CVD) risk assessment, and cholesterol—were developed under the auspices of the National Heart, Lung, and Blood Institute (NHLBI) to update its prior guidelines on the treatment of hypertension, high cholesterol, and obesity that were published more than a decade ago.[5-7] After the NHLBI had organized the respective guideline panels and progressed through most of the guideline development process (which lasted several years each), it arranged for the AHA/ACC to assume sponsorship and publication of the guidelines. The NHLBI decided its role should be to develop evidence reports, leaving the development of guidelines to professional organizations.

While the prior guidelines on hypertension and hypercholesterolemia were influential and widely cited as the standard of care, they were heavily influenced by expert opinion and were not strictly evidence based. The NHLBI sought to develop the new guidelines using more contemporary and rigorous evidence-based processes to meet standards set by the Institute of Medicine (IOM). The group started with key clinical questions, conducted comprehensive systematic reviews of the evidence, and then rated the quality of the evidence and assigned strength of recommendation ratings.[8] The guidelines and evidence reports are lengthy, and are summarized below.

In December 2013, the Eighth Joint National Committee (the 5th panel organized by the NHLBI to address CVD prevention) published its updated guideline on the treatment of hypertension, which has also generated controversy. Visit www.jfponline.com to listen to an audiocast summary of these recommendations.[9]

Obesity and overweight

The guideline on managing obesity and overweight adults has 17 recommendations, only 3 of which are based on expert opinion.[1] (**TABLE 1** summarizes the strong [A] and moderate [B] recommendations.) The recommendations stress screening, diagnosis, and treatment using diet, exercise, and lifestyle modification. They also address bariatric surgery for those with a body mass index (BMI) ≥40 or a persisting BMI ≥35 despite weight loss interventions. This set of recommendations, like those of the United States Preventive Services Task Force,

New hypertension guideline: Two numbers to remember

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TABLE 1

Recommendations to address obesity and overweight[1]

Recommendation	NHLBI grade*
Identify those who need to lose weight	
Refer to cutpoints for overweight (BMI >25-29.9) and obesity (≥30) in determining risk of CVD; use obesity BMI to determine risk of all-cause mortality.	A
Inform overweight and obese adults that risk of CVD, T2DM, and all-cause mortality increases as BMI increases.	A
Advise overweight and obese adults with high BP, hyperlipidemia, or hyperglycemia that achieving even 3%-5% sustained weight loss with lifestyle changes can yield clinically meaningful reductions in triglycerides, blood glucose, HbA1c, and risk of developing T2DM. Greater weight loss will reduce BP, improve LDL-C and HDL-C, and reduce the need for medications to control these complications.	A
Urge dietary measures	
Advocate decreased calorie intake as part of a comprehensive lifestyle intervention. Prescribe: -a 1200-1500 kcal/d diet for women and a 1500-1800 kcal/d for men (usually adjusted for body weight); **or** -a daily energy deficit of 500 kcal or 750 kcal; **or** -an evidence-based diet restricting foods high in fats or carbohydrates or low in fiber, to create an energy deficit.	A
Initiate a calorie-restricted diet appropriate for an individual's preferences and health status, and consider referring for professional nutritional counseling.	A
Encourage lifestyle interventions	
Advise participation for ≥6 months in a comprehensive lifestyle program that uses behavioral strategies to support adherence to a lower calorie diet and increased physical activity.	A
Suggest an onsite, high-intensity, comprehensive weight-loss program with individual or group sessions led by a trained interventionist.	A
Consider electronic or telephone support programs, though keep in mind that they generally are less effective than onsite programs. Confirm that any commercial program claiming comprehensive lifestyle intervention has peer-reviewed evidence of safety and efficacy.	B
Resort to a very low calorie diet (<800 kcal/d) in limited circumstances, with a trained practitioner and adequate medical monitoring.	A
Advise individuals who have lost weight to join a long-term weight loss maintenance program (face-to-face or by phone) that includes conversations with an interventionist who can help patients engage in high levels of physical activity, monitor body weight, and follow a reduced-calorie diet.	A
Assess the need for bariatric surgery	
Consider bariatric surgery for adults with a BMI ≥40 or a BMI ≥35 with obesity-related comorbid conditions who have not lost sufficient weight with conservative and pharmacologic interventions. Offer referral to an experienced bariatric surgeon for consultation and evaluation.	A

BMI, body mass index; BP, blood pressure; CVD, cardiovascular disease; HbA1c, glycated hemoglobin; HDL-C, high-density lipoprotein cholesterol; LDL-C, low-density lipoprotein cholesterol; NHLBI, National Heart, Lung, and Blood Institute; T2DM, type 2 diabetes mellitus.

* A, strong recommendation; B, moderate recommendation. See Tables 2 & 3 at http://circ.ahajournals.org/content/early/2013/11/11/01.cir.0000437739.71477.ee for more information on the ACC/AHA rating of evidence and recommendations.

advises intensive interventions for weight management and additionally offers much more detail on recommended diet and exercise.

Lifestyle management

The 10 recommendations on lifestyle management to reduce cardiovascular risk, all evidence based, are limited to diet and exercise as a means to control hypertension and hypercholesterolemia.[2] They do not cover other important lifestyle modifications for preventing CVD, such as smoking cessation. The guideline panel acknowledged that the interventions are aimed at those with high blood pressure and elevated cholesterol, but they encour-

TABLE 2

A new approach: Using high-, moderate-, or low-intensity statin therapy to reduce cardiovascular events[4]

These drugs were studied in randomized controlled trials at the specified doses and found to reduce major cardiovascular events.

High-intensity therapy (Lowers LDL-C by ≥50%)	Moderate-intensity therapy (Lowers LDL-C by 30% to <50%)	Low-intensity therapy (Lowers LDL-C by <30%)
Atorvastatin 40-80 mg Rosuvastatin 20 mg	Atorvastatin 10 mg Rosuvastatin 10 mg Simvastatin 20-40 mg Pravastatin 40 mg Lovastatin 40 mg Fluvastatin 40 mg bid	Pravastatin 10-20 mg Lovastatin 20 mg

LDL-C, low-density lipoprotein cholesterol.

age all adults to follow them. Although these recommendations are not particularly controversial, the 2 recommendations to reduce sodium intake are said to be based on strong or moderate strength evidence, in contrast to a recent IOM report that concluded evidence for the health benefits of salt intake <2.3 g/d is weak.[10] This illustrates how separate authoritative groups can rate the strength of the same evidence differently.

Summary highlights:

- Encourage adults who would benefit from lowering either blood pressure (BP) or low-density lipoprotein cholesterol (LDL-C) to eat a diet that emphasizes vegetables, fruits, whole grains, low-fat dairy products, and other notably healthful foods, and to cut down on products high in sugar content and on red meats.
- Review, as appropriate, such options as the DASH (dietary approaches to stop hypertension) eating plan, US Department of Agriculture Food Patterns, or the American Heart Association's diet.
- Establish a dietary plan that also incorporates nutritional requirements for an existing comorbidity, such as type 2 diabetes mellitus (T2DM).
- Lower saturated-fat intake to 5% to 6% of total calories, and reduce trans fats.
- Advise patients with high BP to reduce sodium consumption to ≤2400 mg/d; or, at the very least, to reduce daily consumption by 1000 mg.
- Promote aerobic activity to reduce either LDL-C or BP, at moderate or vigorous intensity 3 to 4 times a week with 40-minute sessions.

CVD risk assessment

The CVD risk assessment guideline[3] has generated a lot of controversy. It proposes a new tool for assessing an individual's 10-year risk of developing an atherosclerotic cardiovascular disease (ASCVD) event, defined as a fatal or nonfatal heart attack or stroke. While the tool is new, the risk factor categories it uses have been known for decades: age, gender, race, lipid levels, diabetes, smoking status, and BP. It has not performed better in validation studies than other existing tools (all of which are suboptimal), and it may be worse.[11,12] Moreover, this new tool has been tested only in African Americans and non-Hispanic whites. Using it could classify 33 million adults age 40 to 79 years as having a 10-year risk of 7.5%, and 13 million a risk between 5% and 7.5%.[12] The significance of this is discussed in the next section on the management of high cholesterol levels.

Summary highlights:

- Use race- and sex-specific Pooled Cohort Equations to predict 10-year risk for a first hard ASCVD event (nonfatal myocardial infarction, coronary death, or nonfatal or fatal stroke) in non-

Hispanic African Americans and non-Hispanic Whites, 40 to 79 years of age.

- Consider assessing a patient's family history, high-sensitivity C-reactive protein, coronary artery calcium, or ankle-brachial index to help guide treatment decisions if quantitative risk assessment has led to uncertainty. (This recommendation is based on expert opinion.)
- Consider evaluating ASCVD risk factors every 4 to 6 years in individuals 20 to 79 years of age who do not have ASCVD, and calculating the 10-year risk of an ASCVD event in those 40 to 79 years of age.
- Consider evaluating 30-year or lifetime ASCVD risk using traditional risk factors in individuals 20 to 59 years of age who do not have ASCVD and have no high short-term risk. (This is based on low-level evidence.)

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Cholesterol management

The guideline on lowering blood cholesterol[4] is a significant departure from the previous one.[6] It contains 54 recommendations, 21 based on expert opinion. Using an unusual methodology that considered only randomized controlled trials in the evidence report, the guideline panel stated that the evidence demonstrates that 4 groups will benefit from treatment with statins:

- patients with established ASCVD
- individuals whose LDL-C is ≥190 mg/dL
- patients with diabetes and no established ASCVD who are 40 to 75 years of age and have an LDL-C between 70 and 189 mg/dL
- anyone with an estimated 10-year ASCVD risk of ≥7.5% (based on the new risk-assessment tool) and an LDL-C of 70 to 189 mg/dL.

The major departure from the old guideline is an abandonment of "treating to target" that attempts to lower LDL-C to a specified level. The panel concluded that the evidence does not show any benefit in achieving a specified level of LDL-C and that this approach can lead to either over- or under-treatment. The proposed new approach is to use high-, moderate-, or low-intensity statin treatment based on a patient's age and reason for treatment, and the dose that they can tolerate (**TABLE 2**).[4]

Absent any contraindications, high-intensity treatment is indicated for:

- patients ≤75 years old with established ASCVD
- patients with an LDL-C level ≥190mg/dL
- patients 40 to 75 years old with diabetes and a ≥7.5% 10-year risk of ASCVD.

Moderate-intensity treatment is indicated for those who cannot tolerate a high-intensity regimen, and for those ages 40 to 75 with diabetes and <7.5% 10-year ASCVD risk.

Low-intensity treatment is recommended for those who should receive moderate-intensity treatment but cannot tolerate it.

For those >75 years of age, the guideline makes only 2 recommendations:

- Prescribe a statin at the highest tolerable intensity for an LDL-C ≥190mg/dL.
- Assess those with established ASCVD for potential benefits and risks of moderate- to high-intensity statin treatment. (It is reasonable to continue statin therapy for those already on it and tolerating it.)

Value of nonstatin drugs is questionable. In another significant departure from the previous guideline, the panel said that other cholesterol-lowering drugs can be considered when LDL-C remains high after statin treatment, but the benefit of these agents in preventing ASCVD is not proven.

Several objections to the new guideline have been raised in the short time since its release. Criticisms center on the large number of adults who would now qualify for statin treatment based on the new risk-assessment tool. Using the 7.5% 10-year risk cutoff, the number needed to treat to prevent one ASCVD event over 10 years would be 67. Also of concern to many is the fact that 7 out of 16 members of the guideline panel had financial ties to the pharmaceutical industry.[12]

Commentary

The new guidelines reflect a more rigorous evidence-based approach than those of the

past. That some of them diverge significantly from previous recommendations that relied heavily on expert opinion reveals the pitfalls of making authoritative recommendations based on weak evidence. Such recommendations, especially those emerging from the National Institutes of Health, are used as national and international standards and serve as the basis of performance measures. When they do not stand the test of time because of a weak evidence base, medicine's reputation is damaged. Notably, the new set of cholesterol recommendations, while an improvement from an evidentiary perspective, is founded partly on a questionable risk-assessment tool, and it is possible it will suffer the same long-term fate as its predecessor. (For more on these guidelines, see "The new cholesterol guideline: Beyond the headlines," [*J Fam Pract*. 2013;62:730.]) JFP

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