General

Guideline Title

2013 AHA/ACC guideline on lifestyle management to reduce cardiovascular risk: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines.

Bibliographic Source(s)


Guideline Status

This is the current release of the guideline.

This guideline meets NGC's 2013 (revised) inclusion criteria.

Recommendations

Major Recommendations

Note from the National Guideline Clearinghouse (NGC): National Heart, Lung and Blood Institute (NHLBI) Evidence Statements are included for each recommendation. See detail in the original guideline document under each critical question review.

Each recommendation has been mapped from the NHLBI grading format to the American College of Cardiology/American Heart Association Class of Recommendation/Level of Evidence (ACC/AHA COR/LOE) construct 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. Definitions for the NHLBI strength of recommendation (A-E, N) and quality of evidence (High, Moderate, Low) and the ACC/AHA levels of the evidence (LOE: A-C) and classes of recommendations (COR: I-III) are provided at the end of the "Major Recommendations" field.

Summary of Recommendations for Lifestyle Management

Diet

Low-density lipoprotein cholesterol (LDL-C): Advise adults who would benefit from LDL-C lowering* to:

1. Consume a dietary pattern that emphasizes intake of vegetables, fruits, and whole grains; includes low-fat dairy products, poultry, fish, legumes, nontropical vegetable oils, and nuts; and limits intake of sweets, sugar-sweetened beverages, and red meats. NHLBI Grade: A (Strong); ACC/AHA COR: I; ACC/AHA LOE: A
Adapt this dietary pattern to appropriate calorie requirements, personal and cultural food preferences, and nutrition therapy for other medical conditions (including diabetes).

Achieve this pattern by following plans such as the Dietary Approaches to Stop Hypertension (DASH) dietary pattern, the U.S. Department of Agriculture (USDA) Food Pattern, or the AHA Diet.

Blood pressure (BP): Advise adults who would benefit from BP lowering to:

1. Consume a dietary pattern that emphasizes intake of vegetables, fruits, and whole grains; includes low-fat dairy products, poultry, fish, legumes, nontropical vegetable oils, and nuts; and limits intake of sweets, sugar-sweetened beverages, and red meats. NHLBI Grade: A (Strong); ACC/AHA COR: I; ACC/AHA LOE: A
   a. Adapt this dietary pattern to appropriate calorie requirements, personal and cultural food preferences, and nutrition therapy for other medical conditions (including diabetes).
   b. Achieve this pattern by following plans such as the DASH dietary pattern, the USDA Food Pattern, or the AHA Diet.

2. Lower sodium intake. NHLBI Grade: A (Strong); ACC/AHA COR: I; ACC/AHA LOE: A
   a. Consume no more than 2,400 mg of sodium/d; b. Further reduction of sodium intake to 1,500 mg/d can result in even greater reduction in BP; and c. Even without achieving these goals, reducing sodium intake by at least 1,000 mg/d lowers BP. NHLBI Grade: B (Moderate); ACC/AHA COR: IIa; ACC/AHA LOE: B

3. Combine the DASH dietary pattern with lower sodium intake. NHLBI Grade: A (Strong); ACC/AHA COR: I; ACC/AHA LOE: A

Physical Activity

Lipids

1. In general, advise adults to engage in aerobic physical activity to reduce LDL-C and non-high-density lipoprotein cholesterol (non–HDL-C): 3–4 sessions per week, lasting on average 40 minutes per session, and involving moderate- to vigorous-intensity physical activity. NHLBI Grade: B (Moderate); ACC/AHA COR: IIa; ACC/AHA LOE: A

BP

1. In general, advise adults to engage in aerobic physical activity to lower BP: 3 to 4 sessions per week, lasting on average 40 minutes per session, and involving moderate- to vigorous-intensity physical activity. NHLBI Grade: B (Moderate); ACC/AHA COR: IIa; ACC/AHA LOE: A


See Tables 7-10, 13, 15, and 16 in the original guideline document for additional diet and physical activity guidelines and resources.

Definitions:

NHLBI Grading of the Strength of Recommendations

<table>
<thead>
<tr>
<th>Grade</th>
<th>Strength of Recommendation*</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>Strong recommendation</td>
</tr>
<tr>
<td></td>
<td>There is high certainty based on evidence that the net benefit† is substantial.</td>
</tr>
<tr>
<td>B</td>
<td>Moderate recommendation</td>
</tr>
<tr>
<td></td>
<td>There is moderate certainty based on evidence that the net benefit is moderate to substantial, or there is high certainty that the net benefit is moderate.</td>
</tr>
<tr>
<td>C</td>
<td>Weak recommendation</td>
</tr>
<tr>
<td></td>
<td>There is at least moderate certainty based on evidence that there is a small net benefit.</td>
</tr>
<tr>
<td>D</td>
<td>Recommendation against</td>
</tr>
<tr>
<td>Grade</td>
<td>Strength of Recommendation*</td>
</tr>
<tr>
<td>-------</td>
<td>-----------------------------</td>
</tr>
<tr>
<td>E</td>
<td>Expert opinion (&quot;There is insufficient evidence or evidence is unclear or conflicting, but this is what the Work Group recommends.&quot;)</td>
</tr>
</tbody>
</table>

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 cardiovascular disease [CVD] risk or ordering an electrocardiogram [ECG] as part of the initial diagnostic work-up for a patient presenting with possible myocardial infarction [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.

NHLBI Quality Rating of the Strength of Evidence

<table>
<thead>
<tr>
<th>Type of Evidence</th>
<th>Quality Rating*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Well-designed, well-executed† randomized controlled trials (RCTs) that adequately represent populations to which the results are applied and directly assess effects on health outcomes.</td>
<td>High</td>
</tr>
<tr>
<td>Meta-analyses of such studies.</td>
<td></td>
</tr>
</tbody>
</table>

Highly certain about the estimate of effect. Further research is unlikely to change confidence in the estimate of effect.

- RCTs 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.

Moderate certainty about the estimate of effect. Further research may have an impact on confidence in the estimate of effect and may change the estimate.

- RCTs 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 confidence in the estimate of effect and is likely to change the estimate.

*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.

Applying Classification of Recommendations and Level of Evidence

<p>| Size of Treatment Effect | |
|--------------------------|</p>
<table>
<thead>
<tr>
<th>CLASS I</th>
<th>CLASS IIa</th>
<th>CLASS IIb</th>
<th>CLASS III No Benefit of Class III Harm</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benefit &gt;&gt; Risk Procedure/Treatment SHOULD be performed/administered</td>
<td>Benefit &gt;&gt; Risk Additional studies with focused objectives needed IT IS REASONABLE to perform procedure/administer treatment</td>
<td>Benefit &gt; Risk Additional studies with broad objectives needed; additional registry data would be helpful Procedure/Treatment MAY BE CONSIDERED</td>
<td></td>
</tr>
</tbody>
</table>

**Estimate of Certainty (Precision) of Treatment Effect**

<table>
<thead>
<tr>
<th>LEVEL A</th>
<th>LEVEL B</th>
<th>LEVEL C</th>
</tr>
</thead>
<tbody>
<tr>
<td>Multiple populations evaluated*</td>
<td>Limited populations evaluated*</td>
<td>Very limited populations evaluated*</td>
</tr>
<tr>
<td>Data derived from multiple randomized clinical trials or meta-analyses</td>
<td>Data derived from single randomized trial or nonrandomized studies</td>
<td>Only consensus opinion of experts, case studies, or standard of care</td>
</tr>
</tbody>
</table>

- 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

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.

**Clinical Algorithm(s)**

None provided

**Scope**

**Disease/Condition(s)**

- Cardiovascular disease (CVD)
- Hypercholesterolemia
- Hypertension

**Guideline Category**

Counseling
Management
Prevention

**Clinical Specialty**
Guideline Objective(s)

To evaluate evidence that particular dietary patterns, nutrient intake, and levels and types of physical activity can play a major role in cardiovascular disease (CVD) prevention and treatment through effects on modifiable CVD risk factors (i.e., blood pressure [BP] and lipids)

Target Population

Adults 18 years of age and older

Interventions and Practices Considered

1. Providing dietary advice to lower low-density lipoprotein cholesterol (LDL-C) and blood pressure (BP), including use of dietary plans such as the Dietary Approaches to Stop Hypertension (DASH) dietary pattern, the U.S. Department of Agriculture (USDA) Food Pattern, or the American Heart Association (AHA) Diet
   - Reducing percent of calories from saturated fat
   - Reducing percent of calories from trans fat
   - Adapting dietary pattern to appropriate calorie requirements, personal and cultural food preferences, and nutrition therapy for other medical conditions
2. Advising adults to reduce sodium intake
3. Advising adults to engage in aerobic physical activity to reduce LDL-C and non-high-density lipoprotein cholesterol (non–HDL-C) and to lower BP

Major Outcomes Considered

- Cholesterol/lipid-related measurements: low-density lipoprotein cholesterol (LDL-C), high-density lipoprotein cholesterol (HDL-C), triglycerides, non-HDL-C, apolipoprotein B (ApoB), lipoprotein (a) [Lp (a)], particle number (LDL-P), Apo A–1, % at lipid goal
- Blood pressure (BP)-related measurements: systolic BP, diastolic BP, or hypertensive/nonhypertensive, % at BP goal
- Incident hypertension
- Cardiovascular disease (CVD)-related morbidity or mortality including:
  - Acute coronary syndrome: unstable angina, myocardial infarction (MI)
  - Fatal or nonfatal stroke
• Fatal or nonfatal MI (ST-segment elevation myocardial infarction [STEMI] and non-ST elevation myocardial infarction [NSTEMI]).
• Coronary revascularization procedures: angioplasty, coronary stent placement, coronary artery bypass
• Other atherosclerotic revascularization procedures (carotid endarterectomy)
• Fatal heart failure or hospitalization for heart failure
• Hospitalization for any coronary heart disease (CHD)/CVD cause
• Urinary excretion of albumin sodium (Na) or potassium (K)
• Change in medication dose

Methodology

Methods Used to Collect/Select the Evidence

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

Literature Search Infrastructure, Search Strategy Development, and Validation

The literature search was performed using an integrated suite of search engines that explored a central repository of citations and full-text journal articles. The central repository, search engines, search results, and Web-based modules for literature screening and data abstraction were integrated within a technology platform called the Virtual Collaborative Workspace (VCW). The VCW was custom-developed for the National Heart, Lung and Blood Institute (NHLBI) guidelines initiative.

The central repository consisted of 1.9 million citations and 71,000 full-text articles related to cardiovascular disease (CVD) risk reduction. Citations were acquired from the PubMed, EMBASE, CINAHL®, Cochrane, PsycINFO®, Wilson Science, and Biological Abstracts® databases. Literature searches were conducted using a collection of search engines including TeraText®, Content Analyst, Collexis, and Lucene. These engines were used for executing search strategies, and Lucene was used in correlating the search with screening results.

For every critical question (CQ), a literature search and screening were conducted according to the understanding of the question and the inclusion and exclusion (I/E) criteria that provided specific characteristics of studies relevant to the question. Criteria were framed in the PICOTS format specifying population, intervention, comparator, outcomes, timing, settings, and study design. The question and PICOTS components were translated into a search strategy involving Boolean and conceptual queries.

A Boolean query encodes both inclusion and exclusion rules. It grants access to the maximum quantity of citations, which are then analyzed by text analytics tools and ranked to produce a selection for literature screening that was conducted by two independent reviewers in the VCW's Web-based module. Boolean queries select citations by matching words in titles and abstracts, as well as Medical Subject Headings (MeSH) and subheadings. The number of citations resulting from Boolean queries has ranged from a few hundred to several thousand depending on the question. The text analytics tools suite included:

• A natural language processing module for automated extraction of data elements in support of application of I/E criteria. Frequently extracted and utilized data elements were study size and intervention follow-up period.
• Content Analyst for automatically expanding vocabulary of queries, conceptual retrieval, and conceptual clustering. The conceptual query engine employed in Content Analyst leverages word frequency features and co-occurrence in similar contexts to index, select, and rank results. The indexing utilizes the Singular Value Decomposition (SVD) algebraic method.
• TeraText for ranking search results and a variety of fast operations on the inverted index.

Search strategy development was intertwined with the results of literature screening, which provided feedback on search quality and context. Screened literature was categorized into two subsets: relevant or not relevant to the question. Next, results were analyzed to determine the characteristics of relevant versus not relevant citations. Additional keywords and MeSH terms were used to expand or contract the scope of the query as driven by characteristics of relevant citations. If the revised search strategy produced citations that did not undergo the screening process, then a new batch of citations was added for review. The search strategy refinement/literature review cycle was repeated until all citations covered by the most recent Boolean query had been screened.

Each search strategy was developed and implemented in the VCW. The search strategy was reviewed by the methodologist and Workgroup
members, and was available for viewing and printing at any time by Workgroup members and staff collaborating on the systematic review. It was available for execution and supplying literature updates until the literature search and screening cut-off date.

Search strategies for a sample of questions were validated by an independent methodology team. This validation process involved the methodology team developing and executing a separate search strategy and screening a random sample of citations against I/E criteria; these results were compared to the search and screening results developed by the systematic review team. As an additional validation method, studies identified in systematic reviews and meta-analyses were cross-checked against a CQ's "include" list to ensure completeness of the search strategy.

**Process for Literature Review and Application of I/E Criteria**

Using results from the search strategy, criteria were applied to screen literature for inclusion or exclusion in the evidence base for the CQ. I/E criteria address the parameters in the PICOTS framework and determine what types of studies are eligible and appropriate to answer the CQ. Additional criteria such as sample size restrictions were included by the Panel to fit the context of the CQ.

**Pilot Literature Screening Mode**

In the Pilot Literature Screening Mode, two reviewers independently screened the first 50 titles/abstracts in the search strategy results by applying I/E criteria. Reviewers voted to include or exclude the publication for full-text review. Reviewers compared their results to ensure that I/E criteria were applied consistently. Discrepancies in votes were discussed, and clarification on criteria was sought from the Panel where appropriate. For example, if criteria were not specific enough to be clearly applied to include or exclude a citation, guidance was sought to more explicitly word criteria.

During this phase, reviewers provided feedback to the Literature Search team about the relevance of search strategy results; this feedback was used to further refine and optimize the search.

**Phase 1: Title and Abstract Screening Phase**

After the completion of the Pilot Mode phase, two reviewers independently screened search results at the title and abstract level by applying I/E criteria. Reviewers voted to include or exclude the publication for full-text review.

Titles and abstracts where one or both reviewers voted to include the publication advanced to Phase 2, Full-Text Screening. Titles and abstracts where both reviewers voted to exclude were excluded and not reviewed further; these citations were maintained in the VCW and marked as "excluded at title/abstract phase."

**Phase 2: Full-Text Screening Phase**

Titles and abstracts where at least one reviewer voted to include were reviewed at the full-text level in phase 2. In this phase, two reviewers independently applied I/E criteria to the full-text article and voted for "include," "exclude," or "undecided." The reviewer had to specify the rationale for exclusion (i.e., population, intervention, etc.) in this phase.

Articles where both reviewers voted to include were moved to the "include" list. Articles where both reviewers voted to exclude were moved to the "exclude" list; these citations were maintained in the VCW and identified as "excluded at the full article phase" and the rationale for exclusion was noted. Any article with discrepant votes (i.e., one include and one undecided, one include and one exclude, etc.) advanced to phase 3.

**Phase 3: Resolution and Consultation Phase**

In this phase, reviewers discussed their vote for "include," "exclude," or "undecided" and cited the relevant criteria for their decision. The two reviewers attempted to achieve consensus through collaborative discussion. If a decision was not reached between the two reviewers, input was sought from the methodologist. If a decision was not reached after consultation with the methodologist, input was sought from the Panel; however, the methodologist had the final decision. The final disposition of the article ("include" or "exclude") was recorded in the VCW along with comments from the adjudication process.

Similar to search strategies being posted and available for viewing on the VCW, all citations screened for a critical question were maintained in the VCW with their reviewer voting status and all collected comments.

**CQ 1 and CQ 2 Search Strategy Results**

The below listed databases were searched for randomized controlled trials (RCTs), controlled clinical trials, and observational or epidemiologic studies with a time difference between interventions/exposures and outcomes (i.e., cohort studies, case-control studies) and systematic reviews and meta-analyses of these study designs to answer CQ1 and CQ2. Observational and epidemiologic studies or systematic reviews of such studies were eligible for hard health outcomes only.
• PubMed from January 1998 to December 2009 (to April 2012 for CQ2)
• CINAHL from January 1998 to July 2008
• EMBASE from January 1998 to July 2008
• PsycINFO from January 1998 to July 2008
• EBM (Evidence-based Medicine) Cochrane Libraries from January 1998 to July 2008
• Biological Abstracts from January 2004 to July 2008
• Wilson Social Sciences Abstracts from January 1998 to July 2008

Duplicate citations which arise from the same citation being found in more than one database were removed from the Central Repository prior to screening.

CQ3 Search Strategy Results

CQ3 was restricted to systematic reviews and meta-analyses. The following databases were searched for evidence to answer this question:

• PubMed from January 2001 to January 2010
• CINAHL from January 2001 to July 2008
• EMBASE from January 2001 to July 2008
• PsycINFO from January 2001 to July 2008
• EBM (Evidence-based Medicine) Cochrane Libraries from January 2001 to July 2008
• Biological Abstracts from January 2001 to July 2008
• Wilson Social Sciences Abstracts from January 2001 to July 2008

Duplicate citations which arise from the same citation being found in more than one database were removed from the Central Repository prior to screening.

See additional details regarding search strategy and criteria in the full panel report supplement Appendices (see the "Availability of Companion Documents" field).

Number of Source Documents

Critical Question (CQ) 1 Search Strategy Results

The search produced 6,084 citations. This number of citations includes results from a supplemental search of PubMed for systematic reviews and meta-analyses focused on fatty acids, with publication dates between 1990 and 2009. A natural language processing (NLP) filter was used to identify studies with sample sizes less than 500, for studies reporting hard health outcomes and sample sizes less than 50, for biomarker assessment and risk factor studies. The NLP filter was executed against titles and abstracts, and 2,318 publications were automatically excluded because they were of studies with less than the required sample size. The titles and abstracts of the 3,768 remaining publications were screened against the inclusion/exclusion (I/E) criteria independently by two reviewers, which resulted in the retrieval of 1,237 full-text papers. These papers were independently screened by two reviewers and 1,209 of these publications were excluded on one or more of the I/E criteria. An additional 27 publications were excluded because they were rated as poor quality; 17 were randomized controlled trials (RCTs), 4 were cohort studies, and 6 were systematic reviews or meta-analyses. Twenty-eight articles were included in the Question 1 Evidence Base. Twenty-four were RCTs, 1 was a cohort study, and 3 were systematic reviews or meta-analyses.

CQ2 Search Strategy Results

The search produced 1,382 citations. This number of citations includes results from a supplemental search of PubMed that was extended to April 2012, and which was focused on sodium and hard health outcomes. An NLP filter was used to identify studies with sample sizes less than 500 for studies reporting hard health outcomes and for sample sizes less than 50 for biomarker assessment and risk factor studies. The NLP filter was executed against titles and abstracts. Six hundred and thirty-three publications were automatically excluded using the NLP filter because they were of studies with less than the required sample size. The titles and abstracts of the 749 remaining publications were screened against the I/E criteria independently by two reviewers, which resulted in the retrieval of 271 full-text papers. These papers were independently screened by two reviewers and 225 of these publications were excluded on one or more of the I/E criteria. An additional 5 publications were excluded because they were rated as poor quality; all 5 poor quality studies were RCTs. 46 articles were included in the Question 2 Evidence Base. Sixteen were RCTs, 25 were cohort studies, 1 was a case-control study, and 4 were systematic reviews or meta-analyses.
CQ3 Search Strategy Results

The search produced 843 systematic reviews and meta-analyses. An additional 24 citations published between January 2010 and May 2011 were retrieved from PubMed for review. The titles and abstracts of these 867 publications were screened against the I/E criteria independently by two reviewers which resulted in the retrieval of 184 full-text papers. These papers were independently screened by two reviewers, and 158 of these publications were excluded on one or more of the I/E criteria. The majority of full-text articles that were excluded were excluded because the outcomes did not meet those specified in the criteria. An additional 16 publications were excluded because they were rated as poor quality using the National Heart, Lung and Blood Institute (NHLBI) Quality Assessment Tool for Systematic Reviews and Meta-Analyses. Twenty-six systematic reviews and meta-analyses were eligible for inclusion in the Question 3 Evidence Base. Twenty-five of the 26 included systematic reviews and meta-analyses were published between January 2001 and January 2010. One systematic review by Lin et al. that was published in December 2010 was retained in the body of evidence.

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Applying Classification of Recommendations and Level of Evidence

<table>
<thead>
<tr>
<th>Size of Treatment Effect</th>
<th>CLASS I</th>
<th>CLASS IIa</th>
<th>CLASS IIb</th>
<th>CLASS IIIa</th>
<th>CLASS IIIb</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benefit &gt;&gt; Risk</td>
<td>Procedure/Treatment SHOULD be performed/administered</td>
<td>Recommendation that procedure or treatment is useful/effective</td>
<td>Recommendation in favor of treatment or procedure being useful/effective</td>
<td>Recommendation's usefulness/efficacy less well established</td>
<td>Recommendation that procedure or treatment is not useful/less effective and may be harmful</td>
</tr>
<tr>
<td>Procedure/Treatment MAY BE CONSIDERED</td>
<td>IT IS REASONABLE to perform procedure/administer treatment</td>
<td>Some conflicting evidence from multiple randomized trials or meta-analyses</td>
<td>Greater conflicting evidence from multiple randomized trials or meta-analyses</td>
<td>Sufficient evidence from multiple randomized trials or meta-analyses</td>
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</tr>
</tbody>
</table>

A recommendation with Level of Evidence B or C does not imply that the recommendation is weak. Many important clinical questions addressed in the guidelines do not lend themselves to clinical trials. Although randomized trials are unavailable, there may be a very clear clinical consensus that a particular test or therapy is useful or effective.

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

†For comparative-effectiveness recommendations (Class I and IIa; Level of Evidence A and B only), studies that support the use of comparator verbs should involve direct comparisons of the treatments or strategies being evaluated.

National Heart, Lung and Blood Institute (NHLBI) Quality Rating of the Strength of Evidence
<table>
<thead>
<tr>
<th>Type of Evidence</th>
<th>Quality Rating*</th>
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<tr>
<td>• Well-designed, well-executed† randomized controlled trials (RCTs) that adequately represent populations to which the results are applied and directly assess effects on health outcomes. Meta-analyses of such studies.</td>
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<td></td>
</tr>
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<td>• RCTs 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.</td>
<td>Moderate</td>
</tr>
<tr>
<td>Moderately certain about the estimate of effect. Further research may have an impact on confidence in the estimate of effect and may change the estimate.</td>
<td></td>
</tr>
<tr>
<td>• RCTs 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.</td>
<td>Low</td>
</tr>
<tr>
<td>Low certainty about the estimate of effect. Further research is likely to have an impact on confidence in the estimate of effect and is likely to change the estimate.</td>
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</tr>
</tbody>
</table>

*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.

Methods Used to Analyze the Evidence

Review of Published Meta-Analyses

Systematic Review with Evidence Tables

Description of the Methods Used to Analyze the Evidence

Directed by the National Heart, Lung and Blood Institute (NHLBI), with input from the Panels and Workgroups, the contractor staff:

- Determined the quality of each included study through the use of two independent raters. For the most part, these were the same reviewers who had screened the literature previously. However, due to limited resources, this was not always possible. The methodology staff, with input from the NHLBI, adapted study-rating instruments and trained study raters on the use of these instruments.
- Abstracted relevant information from the included studies into an electronic database. Templates with lists of data elements pertinent to the established inclusion/exclusion (I/E) criteria were constructed and used to support abstraction.
- 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 the critical question (CQ).

The Expert Panels and Workgroups:
• Used summary tables to develop evidence statements for each CQ. The quality of evidence for each evidence statement was graded as high, moderate, or low based on scientific methodology, scientific strength, and consistency of results (see the "Rating Scheme for the Strength of the Evidence" field).

See the Appendices of the full panel report supplement (see the "Availability of Companion Documents" field) for more details on the evidence-based process for each CQ. The strength of the body of evidence represents the degree of certainty, based on the overall body of evidence, that an effect or association is correct. Appendix A describes how four domains of the body of evidence—risk of bias, consistency, directness, and precision—were used to grade the strength of evidence.

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

The American College of Cardiology (ACC) and the American Heart Association (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, the NHLBI Advisory Council recommended that the NHLBI focus specifically on reviewing the highest-quality evidence and partner with other organizations to develop recommendations. 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 (see the "Availability of Companion Documents" field). 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 (see the "Rating Scheme for the Strength of the Evidence" field) 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.

CQ-Based Approach

The Lifestyle Workgroup developed an initial set of questions based on their expertise and a brief literature review to identify topics of the greatest relevance and impact for the target audience of the guideline, primary care providers. Due to time and resource limitations, the Workgroup prioritized the final three critical questions below.

The body of the report is organized by CQ. For each CQ:

• The rationale for its selection is provided, and methods are described.
The ESs are presented, which include a rating for quality, a rationale that supports each item of evidence, and a statement. A detailed description of methods is provided in the NHLBI Lifestyle Systematic Evidence Review Report (see the "Availability of Companion Documents" field). The Full Work Group Report supplement presents documentation for search strategies and results from the search of the published literature (see the "Availability of Companion Documents" field).

Recommendations include recommendation strength, accompanied by a summary of how the recommendation derives from the evidence and a discussion of issues considered by the Work Group in formulating the recommendation. The ACC/AHA COR/LOE ratings have also been added.

The ESs and recommendations are presented by CQ and grouped by topic:

- CQ1 presents evidence on dietary patterns and macronutrients and their effect on blood pressure (BP) and lipids. The dietary recommendations for low-density lipoprotein cholesterol (LDL-C) lowering are described at the end of CQ1.
- CQ2 presents the evidence on the effect of dietary sodium and potassium intake on BP and cardiovascular disease (CVD) outcomes. The dietary recommendations for BP lowering are located at the end of CQ2.
- Finally, CQ3 presents evidence on the effect of physical activity on lipids an activity recommendations for BP and lipid lowering. The physical activity recommendations for BP and lipid lowering are located at the end of CQ3.

It should be recognized that formulating recommendations derived from evidence reviews in response to CQs has some advantages as well as limitations. Because of its desire to adhere to the highest quality of evidence, the Work Group was restricted to using evidence that met inclusion/exclusion and quality criteria established by the Work Group in partnership with the methodologists. When the phrase "there is insufficient evidence" is used, the reader must distinguish between "insufficient" evidence where no studies meeting inclusion/exclusion and quality criteria were found to answer a CQ and "insufficient" evidence where RCTs or observational studies were conducted but the available data do not provide sufficient information to formulate a recommendation. This perspective is important because clinicians could see fewer recommendations derived from expert opinion.

Organization of Work Group

The Work Group was composed of 12 members and 4 ex-officio members, including physicians and experts in BP, blood cholesterol, obesity, and lifestyle management. The authors came from the primary care, nursing, pharmacology, nutrition, exercise, behavioral science, and epidemiology disciplines and also included senior scientific staff from NHLBI and the National Institutes of Health.

Development and Prioritization of Questions

After Panels were convened, members were invited to submit topic areas or questions for systematic review. Members were asked to identify topics of the greatest relevance and impact for the target audience of the guideline, primary care providers.

Proposed questions and topic areas were collected from Panel members over a period of several months. The number of critical questions was scoped, and questions were prioritized based on resource constraints. After group discussion, Panel members ranked priority critical questions through a combination of collaborative dialogue and voting. The rationale for each priority critical question is in the main body of the report.

With support from the methodologist and systematic review team, priority critical questions were formulated. Inclusion/exclusion (I/E) criteria were defined and formatted using the PICOTS framework. PICOTS is a framework for developing a structured research question. It includes the following components in the statement of the critical question or in the question's I/E criteria: population, intervention/exposure, comparator, outcome, timing, setting.

I/E criteria define the parameters for the selection of literature for a particular critical question. I/E criteria were developed with input from the methodologist and systematic review team to ensure that criteria were clear and precise and could be applied consistently across literature identified in the search.

The final critical questions and criteria were submitted to the Literature Search team for search strategy development:

CQ1. Among adults, what is the effect of dietary patterns and/or macronutrient composition on CVD risk factors, when compared with no treatment or with other types of interventions?

CQ2. Among adults, what is the effect of dietary intake of sodium and potassium on CVD risk factors and outcomes, when compared with no treatment or with other types of interventions?

CQ3. Among adults, what is the effect of physical activity on blood pressure and lipids when compared with no treatment or with other types of interventions?
Process for the Development of Evidence Statements, Recommendations, and Panel Voting

Using the summary tables (and evidence tables as needed), evidence statements were collaboratively written by Work group or Panel members with input from methodology staff and oversight of the process by NHLBI staff. Evidence statements aimed to summarize key messages from the evidence that could be provided to primary care physicians and other stakeholders. In some cases, the evidence was too limited or inconclusive, so no evidence statement was developed, or a statement of insufficient evidence was made.

Methodology staff provided Panels with overarching guidance on how to grade the level of evidence (high, moderate, or low), and the Panels used this guidance to grade each evidence statement.

Panel members who had relationships with industry (RWI) or other possible conflicts of interest (COI) were allowed to participate in discussions leading up to voting as long as they declared their relationships, but they recused themselves from voting on any issue relating to their RWI or potential COI. Voting occurred by a Panel Chair asking each member to signify his or her vote. The NHLBI project staff and contractors did not vote.

Once evidence statements were finalized, attention turned to developing recommendations. Recommendations were developed using a similar process to evidence statements. For approval of a recommendation rated E (expert opinion), at least 75 percent of the Workgroup/Panel members had to vote "yes." For both evidence statements and recommendations, voting could be open so that differing viewpoints could be identified easily and facilitate further discussion and revisions to address areas of disagreement (e.g., by wordsmithing or dividing an evidence statement into more than one statement). Voting could be by confidential ballot if the group chose.

For both evidence statements and recommendations, a record of the vote count (for, against, or recusal) was made without attribution. The ideal was 100 percent consensus, but a two-thirds majority was considered acceptable.

Rating Scheme for the Strength of the Recommendations

*Note:* Each recommendation has been mapped from the National Heart, Lung and Blood Institute (NHLBI) grading format below to the American College of Cardiology/American Heart Association (ACC/AHA) Classification of Recommendation/Level of Evidence (COR/LOE) construct (see the "Rating Scheme for the Strength of the Evidence" field) and is expressed in both formats.

NHLBI Grading of the Strength of Recommendations

<table>
<thead>
<tr>
<th>Grade</th>
<th>Strength of Recommendation*</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>Strong recommendation</td>
</tr>
<tr>
<td></td>
<td>There is high certainty based on evidence that the net benefit† is substantial.</td>
</tr>
<tr>
<td>B</td>
<td>Moderate recommendation</td>
</tr>
<tr>
<td></td>
<td>There is moderate certainty based on evidence that the net benefit is moderate to substantial, or there is high certainty that the net benefit is moderate.</td>
</tr>
<tr>
<td>C</td>
<td>Weak recommendation</td>
</tr>
<tr>
<td></td>
<td>There is at least moderate certainty based on evidence that there is a small net benefit.</td>
</tr>
<tr>
<td>D</td>
<td>Recommendation against</td>
</tr>
<tr>
<td></td>
<td>There is at least moderate certainty based on evidence that there is no net benefit or that risks/harms outweigh benefits.</td>
</tr>
<tr>
<td>E</td>
<td>Expert opinion (&quot;There is insufficient evidence or evidence is unclear or conflicting, but this is what the Work Group recommends.&quot;)</td>
</tr>
<tr>
<td></td>
<td>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.</td>
</tr>
<tr>
<td>N</td>
<td>No recommendation for or against (&quot;There is insufficient evidence or evidence is unclear or conflicting.&quot;)</td>
</tr>
<tr>
<td></td>
<td>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.</td>
</tr>
</tbody>
</table>
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 cardiovascular disease [CVD] risk or ordering an electrocardiogram [ECG] as part of the initial diagnostic work-up for a patient presenting with possible myocardial infarction [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.

Cost Analysis
A formal cost analysis was not performed and published cost analyses were not reviewed.

Method of Guideline Validation
Peer Review

Description of Method of Guideline Validation
A formal peer review process initially was completed under the auspices of the National Heart, Lung, and Blood Institute (NHLBI) and included 6 expert reviewers and representatives of federal agencies. This document was also reviewed by 4 expert reviewers nominated by the American College of Cardiology (ACC) and the American Heart Association (AHA) when the management of the guideline transitioned to the ACC/AHA.

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

This document was approved by the ACC Board of Trustees and the AHA Science Advisory and Coordinating Committee in November 2013. The Academy of Nutrition and Dietetics affirms the value of this guideline.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations
The type of supporting evidence is identified and graded for each recommendation (see the "Major Recommendations" field).

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits
Appropriate lifestyle management, including dietary patterns, nutrient intake, and levels and types of physical activity to prevent cardiovascular disease (CVD)

Potential Harms
In one study, the Dietary Approaches to Stop Hypertension (DASH) diet had favorable effects on blood pressure (BP) and low-density lipoprotein cholesterol (LDL-C), yet it had neutral or slightly adverse effects on triglycerides and high-density lipoprotein cholesterol (HDL-C).

Qualifying Statements
Qualifying Statements

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 cardiovascular disease (ASCVD) events.

Implementation of the Guideline

Description of Implementation Strategy

An implementation strategy was not provided.

Implementation Tools

Patient Resources
Pocket Guide/Reference Cards
Resources
Slide Presentation
Staff Training/Competency Material

For information about availability, see the Availability of Companion Documents and Patient Resources fields below.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need
Staying Healthy

IOM Domain
Effectiveness
Patient-centeredness

Identifying Information and Availability

Bibliographic Source(s)

Adaptation
Not applicable: The guideline was not adapted from another source.

Date Released
2014 Jul 1

Guideline Developer(s)
American College of Cardiology Foundation - Medical Specialty Society
American Heart Association - Professional Association

Source(s) of Funding
Development of the systematic review (see the "Availability of Companion Documents" field) was funded by the United States Government.

Development of the guideline was funded by the American College of Cardiology and the American Heart Association.

Guideline Committee
Lifestyle Expert Work Group
American College of Cardiology/American Heart Association (ACC/AHA) Task Force on Practice Guidelines

Subcommittee on Prevention Guidelines

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Financial Disclosures/Conflicts of Interest
In consultation with National Heart, Lung and Blood Institute (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 American College of
Cardiology/American Heart Association (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 of the original guideline document. None of the ACC/AHA expert reviewers had relevant RWI (see Appendix 2 in the original guideline document).

Panel members who had RWI or other possible conflicts of interest (COI) were allowed to participate in discussions leading up to voting as long as they declared their relationships, but they recused themselves from voting on any issue relating to their RWI or potential COI.

Guideline Endorser(s)

American Association of Cardiovascular and Pulmonary Rehabilitation - Medical Specialty Society
American Pharmacists Association - Professional Association
American Society for Nutrition - Nonprofit Organization
American Society for Preventive Cardiology - Medical Specialty Society
American Society of Hypertension - Disease Specific Society
Association of Black Cardiologists - Medical Specialty Society
Preventive Cardiovascular Nurses Association - Medical Specialty Society
WomenHeart: The National Coalition for Women with Heart Disease - Nonprofit Organization

Guideline Status

This is the current release of the guideline.

This guideline meets NGC's 2013 (revised) inclusion criteria.

Guideline Availability

Electronic copies: Available from the Journal of the American College of Cardiology (ACC) Web site and from the Circulation Web site.

Print copies: Available from the ACC, 2400 N Street NW, Washington DC, 20037; (800) 253-4636 (US only).

Availability of Companion Documents

The following are available:

- 10 points to remember. Available from the American College of Cardiology (ACC) Web site. Also available as a video from the ACC Web site.
A pocket guideline is available from the Guideline Central Web site.

Print copies: Available from the ACC, 2400 N Street NW, Washington DC, 20037; (800) 253-4636 (US only).

Patient Resources

The following is available:


Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

NGC Status

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