Complete Summary

GUIDELINE TITLE

Disorders of lipid metabolism evidence-based nutrition practice guideline.

BIBLIOGRAPHIC SOURCE(S)

American Dietetic Association. Disorders of lipid metabolism evidence-based nutrition practice guideline. Chicago (IL): American Dietetic Association; 2005 Aug. 17 p.

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: American Dietetic Association. Hyperlipidemia medical nutrition therapy protocol. Chicago (IL): American Dietetic Association; 2001 Jun. Various p.

COMPLETE SUMMARY CONTENT

SCOPE
METHODOLOGY - including Rating Scheme and Cost Analysis
RECOMMENDATIONS
EVIDENCE SUPPORTING THE RECOMMENDATIONS
BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS
CONTRAINDICATIONS
QUALIFYING STATEMENTS
IMPLEMENTATION OF THE GUIDELINE
INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES
IDENTIFYING INFORMATION AND AVAILABILITY
DISCLAIMER

SCOPE

DISEASE/CONDITION(S)

Lipid metabolism disorders including elevated low-density lipoprotein (LDL) cholesterol, total cholesterol, and triglyceride levels

GUIDELINE CATEGORY

Counseling
Management

Prevention
Risk Assessment

CLINICAL SPECIALTY

Cardiology
Endocrinology
Geriatrics
Internal Medicine
Nutrition
Pharmacology
Physical Medicine and Rehabilitation
Preventive Medicine

INTENDED USERS

Dietitians

GUIDELINE OBJECTIVE(S)

- To provide medical nutrition therapy guideline recommendations for disorders of lipid metabolism that support improvement in lipid levels and risk factor management of cardiovascular disease
- To define evidence based recommendations within the scope of practice for registered dietitians (RDs) that are carried out in collaboration with other healthcare providers
- To guide practice decisions that integrate medical, nutritional, and behavioral elements
- To reduce variations in practice among RDs
- To promote self-management strategies that empower the patient to take responsibility for day-to-day management and provide the RD with data to make recommendations to adjust medical nutrition therapy, or recommend other therapies to achieve clinical outcomes
- To enhance the quality of life for the patient, utilizing customized meal planning strategies based on the individual's eating preferences, lifestyle, and goals to improve metabolic control
- To develop content for intervention that can be tested for impact on clinical outcomes
- To define highest quality of care within cost constraints of the current healthcare environment

TARGET POPULATION

Adult patients 19 years of age and older with lipid metabolism disorders including those at risk of coronary heart disease

INTERVENTIONS AND PRACTICES CONSIDERED

1. Referral to a registered dietitian
2. Medical history and assessment of risk factors

3. Laboratory tests including fasting lipid profile (blood cholesterol, low-density and high-density lipoprotein cholesterol, triglycerides), glucose, blood pressure, and other tests as needed
4. Nutrition-specific assessment including
    - Body mass index (BMI), waist circumference, waist-hip ratio
    - Assessment of client's readiness to learn
    - Comprehensive diet history, including current dietary intake (calories, total fat, and sources of fat, cholesterol, sugar, sodium, vitamin E, folate, B-vitamins and alcohol)
    - Physical activity pattern
    - Psychosocial/economic issues impacting nutrition therapy
    - Consideration of comorbid conditions and need for additional modifications in nutrition care plan.
5. Individualized medical nutrition therapy
    - Calories
    - Macronutrients: major dietary fat components (includes carbohydrate and protein consideration): fat composition- trans-fatty acids, omega-3 fatty acids, and fiber
    - Micronutrients: homocysteine, folate, B12 antioxidants, vitamins E and C, beta-carotene, selenium
    - Food recommendations: nuts, fish, soy products, plant stanol/sterol products
    - Healthful habits: limiting alcohol, increasing physical activity

MAJOR OUTCOMES CONSIDERED

- Risk factors of dyslipidemia
- Efficacy of medical nutrition therapy

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Searches of PUBMED MEDLINE database, the Database of Abstracts of Reviews of Effects (DARE), and the Agency for Healthcare Research and Quality (AHRQ) database were performed.

Inclusion criteria:

1. English only
2. Human subjects
3. Sample >10 in each treatment group
4. Drop-out <20%

Refer to Attachment #1 of the original guideline document for more information on inclusion/exclusion criteria for each recommendation.

NUMBER OF SOURCE DOCUMENTS

Total number of studies included: 200

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

Quality and Strength of the Evidence

Conclusion Grades

I. **Good/Strong**
- Studies of strong design for question; free from design flaws, bias and execution problems.
- Findings generally consistent in direction and size of effect or degree of association, and statistical significance with minor exceptions at most.
- One to several good quality studies; large number of subjects studied. Studies with negative results have sufficiently large sample size for adequate statistical power.
- Studied outcome relates directly to the question. Size of effect is clinically meaningful. Significant (statistical) difference is large.
- Studied population, intervention and outcomes are free from serious doubts about generalizability.

II. **Fair**
- Studies of strong design for question with minor methodological concerns OR only studies of weaker study design for question.
- Inconsistency among results of studies with strong design OR consistency with minor exceptions across studies of weaker design.
- Several studies by independent investigators. Doubts about adequacy of sample size to avoid Type I and Type II error
- Some doubt about the statistical or clinical significance of the effect
- Minor doubts about generalizability

III. **Limited/Weak**
- Studies of weak design for answering the question OR inconclusive findings due to design flaws, bias or execution problems.
- Unexplained inconsistency among results from different studies OR single study unconfirmed by other studies.
- Limited number of studies; low number of subjects studied and/or inadequate sample size within studies.
- Studied outcome is an intermediate outcome or surrogate for the true outcome of interest OR size of effect is small or lacks statistical and/or clinical significance.
- Serious doubts about generalizability due to narrow or different study population, intervention or outcomes studied.

IV. **Expert Opinion Only**
- No studies available; conclusion based on usual practice, expert consensus, clinical experience, opinion, or extrapolation from basic research.

- Conclusion supported solely by statements of informed nutrition or medical commentators.
- Unsubstantiated by published research studies
- Objective data unavailable
- Generalizability limited to scope of experience.

V. **V Grade Not Assignable**

- No evidence that pertains to question being addressed
- Relevant studies have not been done.
- Indicates area for future research.

*Adapted by the American Dietetic Association from Grier, Mosser, Logam, & Wagstrom Halaas. A practical approach to evidence grading. *Jt Comm J Qual Improv*. 2000;26:700-712. http://www.adaevidencelibrary.com/topic.cfm?cat=1330, downloaded 6/12/06.

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

Step One: Formulate the question

Specify a question in a defined area of practice; or state a tentative conclusion or recommendation that is being considered. Formulate questions using PICO format which includes population, intervention, comparison, and outcomes of interest. Determine inclusion and exclusion criteria.

Step Two: Gather and classify evidence reports

Conduct a systematic search of the literature in electronic databases to find evidence related to the question, gather studies and reports, and classify them by type of evidence. Classes differentiate primary reports of new data according to study design, and distinguish them from reports that are a systematic review and synthesis of primary reports.

Step Three: Critically appraise each report

Review each report for relevance to the question and critique for scientific validity. Abstract key information from the report and document. Assign a code to indicate the quality of the study by completing quality criteria checklist.

Step Four: Summarize evidence in a conclusion statement

Combine findings from ALL reports to arrive at a concise conclusion statement, taking into account the synthesis of all relevant studies and reports, their class, and quality ratings.

Step Five: Grade the strength of evidence supporting the conclusion

Assign a grade to indicate the overall strength or weakness of evidence informing the conclusion statement.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Formulation of Recommendations

Recommendations are formulated by reviewing the graded evidence, taking into consideration issues such as cost implications, patient preference, conditions of application, and any potential risks/harms associated with application.

Narrative

Brief narrative of the supporting evidence is developed using the evidence summaries, quality criteria checklists, and abstracted article information related to the recommendation.

Rating

Recommendations are rated using the recommendation rating scale adapted from the American Academy of Pediatrics, and agreed upon by consensus of the expert panel. Any minority opinions are documented.

Label Conditional versus Imperative

Conditional statements clearly define a specific situation, while imperative statements are broadly applicable to the target population without restraints on their pertinence. A conditional recommendation can be stated in if/then terminology, with the condition of application listed.

Recommendation Strength Rationale

The rationale for the recommendation rating is documented and is based on the grades of the supporting evidence.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Rating Scheme for the Strength of the Recommendation

Strong

A **Strong** recommendation means that the workgroup believes that the benefits of the recommended approach clearly exceed the harms (or that the harms clearly exceed the benefits in the case of a strong negative recommendation), and that the quality of the supporting evidence is excellent/good (grade I or II). In some

clearly identified circumstances, strong recommendations may be made based on lesser evidence when high-quality evidence is impossible to obtain and the anticipated benefits strongly outweigh the harms.

Practitioners should follow a **Strong** recommendation unless a clear and compelling rationale for an alternative approach is present.

Fair

A **Fair** recommendation means that the workgroup believes that the benefits exceed the harms (or that the harms clearly exceed the benefits in the case of a negative recommendation), but the quality of evidence is not as strong (grade II or III). In some clearly identified circumstances, recommendations may be made based on lesser evidence when high-quality evidence is impossible to obtain and the anticipated benefits outweigh the harms.

Practitioners should generally follow a **Fair** recommendation but remain alert to new information and be sensitive to patient preferences.

Weak

A **Weak** recommendation means that the quality of evidence that exists is suspect or that well-done studies (grade I, II, or III) show little clear advantage to one approach versus another.

Practitioners should be cautious in deciding whether to follow a recommendation classified as **Weak**, and should exercise judgment and be alert to emerging publications that report evidence. Patient preference should have a substantial influencing role.

Consensus

A **Consensus** recommendation means that Expert opinion (grade IV) supports the guideline recommendation even though the available scientific evidence did not present consistent results, or controlled trials were lacking.

Practitioners should be flexible in deciding whether to follow a recommendation classified as **Consensus,** although they may set boundaries on alternatives. Patient preference should have a substantial influencing role.

Insufficient Evidence

An **Insufficient Evidence** recommendation means that there is both a lack of pertinent evidence (grade V) and/or an unclear balance between benefits and harms.

Practitioners should feel little constraint in deciding whether to follow a recommendation labeled as **Insufficient Evidence** and should exercise judgment and be alert to emerging publications that report evidence that clarifies the balance of benefit versus harm. Patient preference should have a substantial influencing role.

COST ANALYSIS

Guideline developers reviewed published cost analyses.

METHOD OF GUIDELINE VALIDATION

External Peer Review
Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Each guideline is reviewed internally and externally using the Appraisal of Guidelines for Research and Evaluation (AGREE) instrument as the evaluation tool. The external reviewers consist of a multidisciplinary group of individuals (may include dietitians, doctors, psychologists, pharmacists, nurses, etc.). The review is done electronically. The guideline is adjusted by consensus of the expert panel and approved by American Dietetic Association's Evidence-Based Practice Committee prior to publication on the Evidence Analysis Library.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Ratings for the strength of the recommendations (Strong, Fair, Weak, Consensus, Insufficient Evidence), conclusion grades (I-V), and statement labels (Conditional versus Imperative) are defined at the end of "Major Recommendations"

Recommendation 1. Referral to a Registered Dietitian for Medical Nutrition Therapy (MNT) and Disorders of Lipid Metabolism

(R1.1) Referral to a registered dietitian for MNT is recommended whenever an individual has an abnormal lipid profile, based on the National Cholesterol Education Program (NCEP) Adult Treatment Panel (ATP) III Risk category and low-density lipoprotein cholesterol (LDL-C) goals, or has coronary heart disease (CHD). A planned initial visit lasting from 45 to 90 minutes and at least two to six planned follow-up visits (30 to 60 minutes each, with a registered dietitian [RD]) can lead to improved dietary pattern; improved lipid profile; reduced plasma total cholesterol, LDL-C, and triglycerides; and improved weight status.
Strong
Conditional

(R1.2) The number and duration of visits in the course of MNT will need to be greater if the client is in a higher risk category, if there is a large number of therapeutic lifestyle changes (TLC) that need to be made, and if the individual is not motivated to make TLC changes. Increasing the number of visits and length of time spent with a dietitian can improve serum lipid levels and cardiovascular disease (CVD) risk.
Fair
Conditional

(R1.3) Re-evaluate the dosage and necessity of lipid-lowering medications throughout the course of MNT. MNT may successfully improve the lipid levels to the point where medication doses can be lowered or discontinued.
Fair
Imperative

Recommendations were based on evidence conclusion statements with Grades I, III, and V

Recommendation 2. Body Mass Index (BMI), Waist Circumference or Waist-to-Hip Ratio (WHR) and Disorders of Lipid Metabolism

(R2.1) In addition to BMI, use waist circumference or WHR to assess obesity and CVD risk. BMI alone is not a good predictor of CVD risk in persons over 65 years old. Increases in waist circumference, WHR, and BMI are associated with CHD events and CVD mortality.
Strong
Imperative

Recommendations were based on evidence conclusion statements with Grades II and III

Recommendation 3. Major Dietary Fat Components and Lipid Metabolism Disorders

(R3.1) The cardioprotective dietary pattern should be tailored to the individual's needs to provide a fat intake of 25 to 35% of calories, <7% of calories from saturated fat and trans-fatty acids, and <200 mg cholesterol per day. This dietary pattern can lower LDL-cholesterol up to 16% and decrease risk of CHD.
Strong
Imperative

(R3.2) The cardioprotective dietary pattern should be as low as possible in saturated and trans fatty acids and less than 7% of calories. For individuals at their appropriate body weight without elevated LDL-cholesterol or triglyceride levels and with normal HDL-cholesterol levels, saturated fatty acid calories could be replaced by unsaturated fat and/or complex carbohydrate. Replacing saturated fats with mono- and polyunsaturated fat lowers LDL-cholesterol, without lowering HDL-cholesterol or increasing triglycerides, although the ideal replacement percentages are unclear. Research is needed on how best to titrate these recommendations.
Strong
Imperative

Recommendations were based on evidence conclusion statements with Grade I

Recommendation 4. Trans-Fatty Acid Intake and Disorders of Lipid Metabolism

(R4.1) Trans-fatty acids consumption should be as low as possible. A cardioprotective dietary pattern should contain less than 7% of calories from saturated fat and trans-fatty acids. Trans-fatty acids raise total cholesterol (TC) and LDL-C and may decrease HDL-C, thereby increasing the TC/HDL-C and LDL-C/HDL-C ratios. Increasing trans-fatty acid intake increases risk of CHD events.
Strong
Imperative

Recommendation was based on evidence conclusion statements with Grades I and II

Recommendation 5. Omega-3 Fatty Acids and Disorders of Lipid Metabolism

(R5.1) If consistent with patient preference and not contraindicated by risks or harms, omega-3 fatty acids, preferably from both marine and plant sources, should be included in a cardioprotective diet. Consuming dietary sources of omega-3 fatty acids from fish (two 4-oz servings of fish per week [preferably fatty fish such as mackerel, salmon, herring, trout, sardines, or tuna]) and plant-based foods of 1.5g alpha-linolenic acids (1 Tb canola or walnut oil, 0.5 Tb ground flax seed, <1 tsp flaxseed oil) are recommended. Consumption of increased omega-3 fatty acids is associated with a decreased risk of death from cardiac events and non-fatal myocardial infarctions (MIs). Some fatty fish can be high in methylmercury and should be limited, according to the US Food and Drug Administration (FDA).
Fair
Conditional

(R5.2) If an individual does not eat food sources of omega-3 fatty acids, then 1g of eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA) omega-3 fatty acid supplements *may* be recommended for secondary prevention.
Fair
Conditional

Recommendations were based on evidence conclusion statements with Grades II and III

Recommendation 6. Carbohydrates and Protein, Including Dietary Fiber, and Disorders of Lipid Metabolism

(R6.1) The cardioprotective dietary pattern should be as low as possible in saturated and trans fatty acids and less than 7% of calories. Saturated fatty acid and trans-fatty acid calories may be replaced by unsaturated fatty acids, complex carbohydrates and protein. However, studies to determine the ideal percentages of these macronutrients as replacements for saturated fat are needed.
Strong
Imperative

(R6.2) Include foods containing 25 to 30 grams of fiber per day, with special emphasis on soluble fiber sources (7 to 13 grams), as part of a cardioprotective diet. Foods rich in soluble fiber include: fruits, vegetables, and whole grains, especially high-fiber cereals, oatmeal, beans, and prunes. Risk factors associated

with CHD (blood pressure, lipoprotein subclasses and particle sizes, insulin resistance, and post-prandial glucose) and CVD (fatal and non-fatal MI and stroke) are decreased as dietary fiber intake increases. Diets high in total and soluble fiber, as part of a cardioprotective diet, can further reduce TC by 2 to 3% and LDL up to 7%.
Strong
Imperative

Recommendations were based on evidence conclusion statements with Grades I, II, and III

Recommendation 7. Plant Stanols and Sterols and Disorders of Lipid Metabolism

(R7.1) If consistent with patient preference and not contraindicated by risks or harms, then plant sterol and stanol ester enriched foods consumed two or three times per day, for a total consumption of two or three grams per day, may be used in addition to a cardioprotective diet to further lower TC by 4 to 11% and LDL-C by 7 to 15%. For maximal effectiveness, foods containing plant sterols and stanols (spreads, juices, yogurts) should be eaten with other foods. To prevent weight gain, isocalorically substitute stanol- and sterol-enriched foods for other foods. Plant stanols and sterols are effective in people taking statin drugs.
Strong
Conditional

Recommendation was based on evidence conclusion statements with Grades I, II, and III

Recommendation 8. Soy Protein and Disorders of Lipid Metabolism

(R8.1) If consistent with patient preference and not contraindicated by risks/harms, then soy (e.g., isolated soy protein, textured soy, tofu) may be included as part of a cardioprotective diet. Consuming 26 to 50g of soy protein per day in place of animal protein can reduce TC by 0 to 20% and LDL-C by 4 to 24%. Evidence is insufficient to establish a beneficial role of isoflavones as an independent component.
Fair
Conditional

Recommendation was based on evidence conclusion statements with Grades II and III

Recommendation 9. Nuts, Disorders of Lipid Metabolism, and CHD

(R9.1) If consistent with patient preference and not contraindicated by risks or harms, then nuts (walnuts, almonds, peanuts, macadamia, pistachios, and pecans) may be isocalorically incorporated into a cardioprotective dietary pattern. Consuming five ounces of nuts per week is associated with a reduced risk of CHD. Because of their beneficial fatty acid profile as well as other nutritional components, nuts may be incorporated into a cardioprotective dietary pattern low in saturated fat and cholesterol to reduce TC by 4 to 21% and LDL-C by 6 to 29%.

Fair
Conditional

Recommendation was based on evidence conclusion statements with Grade II

Recommendation 10. Alcohol Intake and Disorders of Lipid Metabolism

(R10.1) Current evidence does *not* justify encouraging those who do not drink alcohol to start doing so. If a patient currently drinks alcohol, and if not contraindicated, then a maximum of one drink per day for women and up to two drinks per day for men *may* be incorporated into a cardioprotective dietary pattern with meals within recommended calorie levels. This level of alcohol consumption has been demonstrated to be associated with a reduced risk of CVD.

There is no evidence that one type of alcohol is better than another.
Fair
Conditional

Recommendations were based on evidence conclusion statements with Grades II and III

Recommendation 11. Antioxidants (Vitamin E, Vitamin C, and Beta-Carotene), Disorders of Lipid Metabolism, and CHD

(R11.1) Antioxidants such as vitamin E, vitamin C, and beta-carotene (or carotenoids) should be specifically planned into a cardioprotective dietary pattern. Antioxidant-rich fruits, vegetables, and whole grains have been shown to be associated with reduced disease risk.
Fair
Imperative

Recommendations were based on evidence conclusion statements with Grade III

(R11.2) Vitamin E, vitamin C, and beta-carotene supplements should not be recommended to reduce the risk of CVD. These supplements have shown no protection for CVD events or mortality.
Strong
Imperative

Recommendation was based on evidence conclusion statements with Grade I and II

(R11.3) Supplemental vitamin E, vitamin C, beta-carotene, and selenium should not be taken with a simvastatin/niacin drug combination. Supplemental beta-carotene cannot be recommended in individuals with a smoking habit. Research indicates that in these situations there is an increased risk.
Fair
Imperative

Recommendation was based on evidence conclusion statements with Grade II

Recommendation 12. Homocysteine, Folate, or Vitamin B6 or B12 and Prevention of CHD

(R12.1) Folate, vitamin B6, and vitamin B12 should be planned into the cardioprotective dietary pattern to meet the DRI. If an individual has high serum homocysteine levels (usually greater than 13 umol/L), these B vitamins may lower serum homocysteine levels by 17 to 34%.
Fair
Imperative

(R12.2) Supplemental folate, given alone or in combination with B6 and B12, may or may not be beneficial. If a patient with CVD is taking supplemental B vitamins to lower homocysteine, then dietetics professionals may decide to discuss the evidence for supplemental B vitamin and CVD events. Research has shown that after six months to two years, supplemental folate and B-vitamins did not reduce the risk for coronary events. Consultation with the patient's physician is warranted.
Weak
Conditional

Recommendations were based on evidence conclusion statements with Grade II

Recommendation 13. Coenzyme Q10 and Disorders of Lipid Metabolism

(R13.1) If a patient is taking coenzyme Q10 supplements, then the practitioner *may* discuss the lack of evidence for the association of Q10 and CHD events. Research is inconclusive regarding the relationship between co-Q10 and risk of disease.
Insufficient Evidence
Conditional

Recommendation was based on evidence conclusion statements with Grade III

Recommendation 14. Physical Activity and Lipid Metabolism Disorders and CHD

(R14.1) Moderate intensity physical activity (e.g., brisk walking, swimming laps, bicycling) should be incorporated for at least 30 minutes most, if not all, days of the week, if not contraindicated. Many individuals will have to start slowly and increase gradually to achieve goals. Moderately intense physical activity reduces the risk of CVD events, decreases LDL-C and triglycerides, and increases HDL-C.
Strong
Imperative

Recommendations were based on evidence conclusion statements with Grade II

Recommendation 15. Disorders of Lipid Metabolism and Hypertension

(R15.1) A cardioprotective dietary pattern should be planned to include 9 to 12 servings of fruits and vegetables, 2 to 3 servings of low-fat dairy products, <2.3 g sodium, weight loss if necessary, and increased physical activity (moderate intensity 3 times per week) if individuals also need to lower their blood pressure. Following this type of lifestyle change has been demonstrated to lower systolic blood pressure by at least 4 to 12 mmHg.
Strong
Imperative

Recommendation was based on evidence conclusion statements with Grade I

Recommendation 16. Disorders of Lipid Metabolism and Metabolic Syndrome

(R16.1) A calorie-controlled cardioprotective dietary pattern that avoids extremes in carbohydrate and fat intake, limits refined sugar, and includes physical activity at a moderate-intensity level for at least 30 minutes on most (preferably all) days of the week, should be used for individuals with metabolic syndrome. Weight loss of 7 to 10% of body weight should be encouraged if indicated. These lifestyle changes improve risk factors of metabolic syndrome.
Fair
Imperative

Recommendation was based on evidence conclusion statements with Grade II

Definitions:

Ratings of the Strength of the Recommendations

Strong

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Fair

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Weak

A **Weak** recommendation means that the quality of evidence that exists is suspect or that well-done studies (grade I, II, or III) show little clear advantage to one approach versus another.

Consensus

A **Consensus** recommendation means that Expert opinion (grade IV) supports the guideline recommendation even though the available scientific evidence did not present consistent results, or controlled trials were lacking.

Insufficient Evidence

An **Insufficient Evidence** recommendation means that there is both a lack of pertinent evidence (grade V) and/or an unclear balance between benefits and harms.

Grading of Evidence Conclusion Statements

I. **Good/Strong**
- Studies of strong design for question; free from design flaws, bias and execution problems.
- Findings generally consistent in direction and size of effect or degree of association, and statistical significance with minor exceptions at most.
- One to several good quality studies; large number of subjects studied. Studies with negative results have sufficiently large sample size for adequate statistical power.
- Studied outcome relates directly to the question. Size of effect is clinically meaningful. Significant (statistical) difference is large.
- Studied population, intervention and outcomes are free from serious doubts about generalizability.

II. **Fair**
- Studies of strong design for question with minor methodological concerns OR only studies of weaker study design for question.
- Inconsistency among results of studies with strong design OR consistency with minor exceptions across studies of weaker design.
- Several studies by independent investigators. Doubts about adequacy of sample size to avoid Type I and Type II error
- Some doubt about the statistical or clinical significance of the effect
- Minor doubts about generalizability

III. **Limited/Weak**
- Studies of weak design for answering the question OR inconclusive findings due to design flaws, bias or execution problems.
- Unexplained inconsistency among results from different studies OR single study unconfirmed by other studies.
- Limited number of studies; low number of subjects studied and/or inadequate sample size within studies.
- Studied outcome is an intermediate outcome or surrogate for the true outcome of interest OR size of effect is small or lacks statistical and/or clinical significance.

- Serious doubts about generalizability due to narrow or different study population, intervention or outcomes studied.

IV. **Expert Opinion Only**

- No studies available; conclusion based on usual practice, expert consensus, clinical experience, opinion, or extrapolation from basic research.
- Conclusion supported solely by statements of informed nutrition or medical commentators.
- Unsubstantiated by published research studies
- Objective data unavailable
- Generalizability limited to scope of experience.

V. **V Grade Not Assignable**

- No evidence that pertains to question being addressed
- Relevant studies have not been done.
- Indicates area for future research.

Statement Labels (Conditional versus Imperative)

Conditional statements clearly define a specific situation, while imperative statements are broadly applicable to the target population without restraints on their pertinence. A conditional recommendation can be stated in if/then terminology, with the condition of application listed.

CLINICAL ALGORITHM(S)

Four clinical algorithms based on the major recommendations are available to American Dietetic Association (ADA) members at www.adaevidencelibrary.com.

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of evidence supporting each recommendation is identified and graded for each recommendation (see "Major Recommendations").

The guideline contains conclusion statements that are supported by evidence summaries and evidence worksheets. These resources summarize the important studies pertaining to the conclusion statement and provide the study details. Each study is given a quality rating (positive, negative, neutral) and the type of study is also identified.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Overall Benefits

Increased percentage of individuals with lipid disorders, with or without coronary heart disease (CHD), who meet their treatment goal

Specific Benefits

Medical nutrition therapy (MNT) is effective in managing dyslipidemia and reducing risk factors associated with cardiovascular disease. Studies indicate that the amount of time dyslipidemia patients spend with the registered dietitian is associated with a reduction in total serum cholesterol, a reduction in low-density lipoprotein (LDL)-cholesterol levels, and decreased dependence on drug therapy. Evidence supports the need for three to four visits with the registered dietitian to achieve optimal outcomes. The nutrition prescription goes beyond the realm of fat intake, integrating the use of food sources providing key nutrients that have been demonstrated to improve lipid management and cardiovascular disease outcomes.

POTENTIAL HARMS

Omega-3 Fatty Acids

- Some fatty fish can be high in methylmercury and should be limited, according to US Food and Drug Administration (FDA).
- An increased risk for cardiac events has been noted with omega-3 supplements in some populations including: individuals being treated for angina and individuals with a recent episode of sustained ventricular tachycardia or ventricular fibrillation with implantable defibrillators. Therefore, eating foods rich in omega-3 fatty acids, rather than taking supplements is the preferable method for obtaining omega-3 fatty acids.

Plant Stanols and Sterols

- Margarines are a common source of plant sterols/stanols, and can contain considerable calories. Caloric content should be considered and these foods should only be recommended when weight can be maintained.
- Consideration should be given to individuals with financial limitations, as these foods can be expensive.

Soy Protein

- Soy protein may not be recommended in some individuals with breast cancer. Individuals with breast cancer or at high risk for breast cancer should speak with their physician.
- Levels greater than 50 g of soy protein with isoflavones may cause gastrointestinal distress in some individuals.
- Care should also be taken, as patient may have an undiagnosed allergy to soy protein.

Nuts

- Nuts contain a high level of calories and should only be included in a cardioprotective diet if weight can be maintained.
- Brazil nuts are higher in saturated fat and should not be consumed regularly as part of a cardioprotective diet.

Alcohol Intake

Possible adverse effects of alcohol include:

- Fetal alcohol syndrome
- Cardiomyopathy
- Hypertension
- Cardiac arrhythmia
- Sudden death
- 60 g alcohol per day (long-term) is associated with risk for strokes of all types.
- Increases in serum triglyceride and very low density lipoprotein (VLDL) cholesterol, resulting in increased risk for pancreatitis in some individuals
- Increased risk of automobile accident, trauma, and suicide

Physical Activity

- Intense physical activity in individuals with lipid disorders may contribute to disability or death, thus consultation with a physician prior to beginning an exercise program should be recommended.

CONTRAINDICATIONS

CONTRAINDICATIONS

- Plant sterol/stanol products should not be used in individuals with sitosterolemia.
- Contraindications to alcohol include suspicion or history of alcohol abuse.
- Supplemental vitamin E, vitamin C, beta-carotene, and selenium should not be taken with a simvastatin/niacin drug combination.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

This nutrition practice guideline is meant to serve as a general framework for handling clients with particular health problems. It may not always be appropriate to use these nutrition practice guidelines to manage clients because individual circumstances may vary. For example, different treatments may be appropriate for clients who are severely ill or who have co-morbid, socioeconomic, or other complicating conditions. The independent skill and judgment of the health care provider must always dictate treatment decisions. These nutrition practice guidelines are provided with the express understanding that they do not establish or specify particular standards of care, whether legal, medical, or other.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

This publication of this guideline is an integral part of the plans for getting the American Dietetic Association Medical Nutrition Therapy (ADA MNT) evidence-based recommendations on lipid metabolism disorders to all dietetics practitioners

engaged in, teaching about, or researching lipid metabolism disorders as quickly as possible. National implementation workshops at various sites around the country and during the ADA Food Nutrition Conference Expo (FNCE) have been conducted and more are planned for the future. Additionally, there are recommended dissemination and adoption strategies for local use of the *ADA Disorders of Lipid Metabolism Evidence-Based Nutrition Practice Guideline*

The guideline development team recommended multi-faceted strategies to disseminate the guideline and encourage its implementation. Management support and learning through social influence are likely to be effective in implementing guidelines in dietetic practice. However, additional interventions may be needed to achieve real change in practice routines.

Implementation of the disorders of lipid metabolism guideline will be achieved by announcement at professional events, presentations and training. Some strategies include:

- **National and Local Events** – State dietetic association meetings, an ADA House of Delegates training session and media coverage will help promote the guideline
- **Local Feedback Adaptation** – Presentation by members of the work group at peer review meetings and opportunities for continuing education unites (CEUs) for courses completed
- **Education Initiatives** – The guideline and supplementary resources are freely available for use in the education and training of dietetic interns and students in approved Commission on Accreditation of Dietetics Education (CADE) programs
- **Champions** – Local champions have been identified and expert members of the guideline team will prepare articles for publications. Resources are provided that include PowerPoint presentations, full guidelines, and pre-prepared case studies.
- **Practical Tools** – A toolkit has been developed to help implement the guideline, which includes specially designed resources such as medical record documentation forms, case studies, client education resources, outcomes monitoring forms. The MNT protocol for disorders of lipid metabolism is also available as a companion document to the guideline.

Specific distribution strategies include:

Publication in Full – The guideline will be available electronically at the ADA Evidence Analysis Library (www.adaevidencelibrary.com) and has been announced to all the ADA dietetic practice groups. The ADA website also provides downloadable supporting information and presentations for navigating.

IMPLEMENTATION TOOLS

Clinical Algorithm
Tool Kits

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

Getting Better
Staying Healthy

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

American Dietetic Association. Disorders of lipid metabolism evidence-based nutrition practice guideline. Chicago (IL): American Dietetic Association; 2005 Aug. 17 p.

ADAPTATION

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

DATE RELEASED

2001 Jun (revised 2005 Aug)

GUIDELINE DEVELOPER(S)

American Dietetic Association - Professional Association

SOURCE(S) OF FUNDING

American Dietetic Association

GUIDELINE COMMITTEE

Disorders of Lipid Metabolism Evidence-Based Guideline Workgroup

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Workgroup Members: Mikelle McCoin MPH, RD (*Lead Analyst*); Wahida Karmally DrPH, RD, CDE (*Chair*); Frances Burke MS, RD; JoAnn Carson PhD, RD, LD; Catherine Champagne PhD LDN, FADA; Elvira Johnson, MS, RD, CDE, LDN; Penny Kris-Etherton PhD, RD; Geeta Sikand MA, RD, FADA, CDE; Linda Van Horn PhD, RD

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No work group members have potential conflicts of interest to disclose.

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: American Dietetic Association. Hyperlipidemia medical nutrition therapy protocol. Chicago (IL): American Dietetic Association; 2001 Jun. Various p.

GUIDELINE AVAILABILITY

Electronic and print copies: Available from the American Dietetic Association Web site.

AVAILABILITY OF COMPANION DOCUMENTS

The following is available:

- Disorders of lipid metabolism toolkit. A companion to the disorders of lipid metabolism evidence-based nutrition practice guideline. 2006 Jun.

Available for purchase from the American Dietetic Association Web site.

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI on July 27, 2006. The information was verified by the guideline developer on September 29, 2006.

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When modifying the guidelines for local circumstances, significant departures from these comprehensive guidelines should be fully documented and the reasons for the differences explicitly detailed.

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