Complete Summary

GUIDELINE TITLE

Diabetes type 1 and 2 evidence-based nutrition practice guideline for adults.

BIBLIOGRAPHIC SOURCE(S)

American Dietetic Association (ADA). Diabetes type 1 and 2 evidence-based nutrition practice guideline for adults. Chicago (IL): American Dietetic Association (ADA); 2008. Various p. [21 references]

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: American Dietetic Association. Nutrition practice guidelines for type 1 and type 2 diabetes mellitus. Chicago (IL): American Dietetic Association; 2001 Dec. Various p.

The guideline will undergo a complete revision every three to five years.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Type 1 and type 2 diabetes mellitus

GUIDELINE CATEGORY

Assessment of Therapeutic Effectiveness
Counseling

Evaluation
Management
Treatment

CLINICAL SPECIALTY

Cardiology
Endocrinology
Family Practice
Internal Medicine
Nephrology
Nutrition

INTENDED USERS

Advanced Practice Nurses
Dietitians
Health Care Providers
Nurses
Pharmacists
Physician Assistants
Physicians
Students

GUIDELINE OBJECTIVE(S)

Overall Objectives

- To help dietetic practitioners, patients and consumers make shared decisions about health care choices in specific clinical circumstances
- To provide evidence-based recommendations for effective medical nutrition therapy (MNT) in the management of type 1 and type 2 diabetes in adults that assist in the normalization and maintenance of glycemia, lipid profiles, and blood pressure

Specific Objectives

- To define evidence-based diabetes nutrition recommendations for registered dieticians (RDs) that are carried out in collaboration with other health care providers
- To guide practice decisions that integrate medical, nutritional, and behavioral strategies
- To reduce variations in practice among RDs
- To promote self-management strategies that empower the adult with diabetes to take responsibility for day-to-day management
- To provide the RD with data to make recommendations to adjust MNT or recommend other therapies to achieve desired outcomes
- To enhance the quality of life for the adult with diabetes, utilizing customized strategies based on the individual's preferences, lifestyle, and goals
- To develop guidelines for interventions that have measurable clinical outcomes

- To define the highest quality of care within cost constraints of the current health care environment

TARGET POPULATION

Adults (>19 years) with type 1 or type 2 diabetes mellitus

INTERVENTIONS AND PRACTICES CONSIDERED

Diagnosis/Evaluation

1. Referral to a registered dietitian
2. Nutritional assessment
    - Medical/health history
    - Medication and supplement history
    - Social history
    - Personal history

3. Biochemical data
4. Anthropometric measurements
    - Height, weight, body mass index (BMI), waist circumference
    - Weight change rate

5. Food and nutrition history
    - Food intake
    - Nutrition and health awareness
    - Physical activity and exercise
    - Food availability
    - Psychosocial and economic issues impacting nutrition therapy
    - Consideration of comorbid conditions and need for additional modifications in nutrition care plan

Management/Treatment

1. Individualized prescription for medical nutrition therapy based on:
    - Food/nutrition intervention
    - Physical activity interventions
    - Behavioral interventions
    - Pharmacotherapy, when indicated

MAJOR OUTCOMES CONSIDERED

- Morbidity
- Mortality
- Quality of life
- Lipid and lipoprotein levels
- Serum blood glucose level
- Hemoglobin A1C level
- Blood pressure
- Weight loss
- Incidence of cardiovascular disease

- Cost of medical care

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Searches of PubMed and CENTRAL databases, and hand searches of other relevant literature were performed on the following topics:

- Process for providing medical nutrition therapy (MNT) for adults with diabetes
- Carbohydrate -- distribution/amount, sucrose, glycemic index, fiber
- Protein
- Blood glucose monitoring
- Prevention and treatment of cardiovascular disease
- Weight management
- Physical activity

General Exclusion Criteria

As a general rule, studies are excluded if the:

- Study sample size is less than 10 in each treatment group
- Drop-out rate was >20%

Inclusion Criteria

- Study design preferences: randomised controlled trials or clinical controlled studies, large nonrandomized observational studies, and cohort, case-control studies
- Limited to articles in English

The American Dietetic Association (ADA) has determined that for narrowly focused questions dealing with therapy or treatment, six well designed randomized controlled trials that demonstrate similar results is sufficient to draw a conclusion.

No one study design was preferred for all questions. The preferred study design depended on the type of question. The ADA uses the following principles in the table below for identifying preferred study design.

Type of Question	Preferred Study Designs (in order of preference)
Diagnosis questions	Sensitivity & specificity of diagnostic test Cross-sectional study

Type of Question	Preferred Study Designs (in order of preference)
Etiology, causation, or harm questions	Prospective Cohort Case Control Study Cross-sectional study
Therapy and prevention questions	Randomized controlled trial Nonrandomized trial
Natural history and prognosis questions	Cohort study

NUMBER OF SOURCE DOCUMENTS

Not stated

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

Grading the Strength of the Evidence for a Conclusion Statement or Recommendation Conclusion Grading Table

Strength of Evidence Elements	Grade I Good/Strong	Grade II Fair	Grade III Limited/Weak	Grade IV Expert Opinion Only	Grade Grade Assigna
Quality • Scientific rigor/validity • Considers design and execution	Studies of strong design for question Free from design flaws, bias and execution problems	Studies of strong design for question with minor methodological concerns OR Only studies of weaker study design for question	Studies of weak design for answering the question OR Inconclusive findings due to design flaws, bias or execution problems	No studies available Conclusion based on usual practice, expert consensus, clinical experience, opinion, or extrapolation from basic research	No evidence that pertains question being addresse
Consistency	Findings generally	Inconsistency among results	Unexplained inconsistency	Conclusion supported	NA

Strength of Evidence Elements	Grade I Good/Strong	Grade II Fair	Grade III Limited/Weak	Grade IV Expert Opinion Only	Grade Grade Assigna
Of findings across studies	consistent in direction and size of effect or degree of association, and statistical significance with minor exceptions at most	of studies with strong design OR Consistency with minor exceptions across studies of weaker designs	among results from different studies OR Single study unconfirmed by other studies	solely by statements of informed nutrition or medical commentators	
Quantity • Number of studies • Number of subjects in studies	One to several good quality studies Large number of subjects studies Studies with negative results having sufficiently large sample size for adequate statistical power	Several studies by independent investigators Doubts about adequacy of sample size to avoid Type I and Type II error	Limited number of studies Low number of subjects studies and/or inadequate sample size within studies	Unsubstantiated by published studies	Relevan studies have no been do
Clinical Impact • Importance of studies outcomes • Magnitude of effect	Studied outcome relates directly to the question Size of effect is clinically meaningful Significant (statistical) difference is large	Some doubt about the statistical or clinical significance of effect	Studies 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	Objective data unavailable	Indicate area for future research

Strength of Evidence Elements	Grade I Good/Strong	Grade II Fair	Grade III Limited/Weak	Grade IV Expert Opinion Only	Grade Grade Assigna
Generalizability To population of interest	Studied population, intervention and outcomes are free from serious doubts about generalizability	Minor doubts about generalizability	Serious doubts about generalizability due to narrow or different study population, intervention or outcomes studied	Generalizability limited to scope of experience	NA

This grading system was based on the grading system from: *Greer N, Mosser G, Logan G, Wagstrom Halaas G. A practical approach to evidence grading. Jt Comm. J Qual Improv. 2000; 26:700-712*. In September 2004, The ADA Research Committee modified the grading system to this current version.

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 1: Formulate the question

Specify a question in a defined area of practice; or state a tentative conclusion or recommendation that is being considered. Include the patient type and special needs of the target population involved, the alternatives under consideration, and the outcomes of interest.

Step 2: Gather and classify evidence reports

Conduct a systematic search of the literature 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 3: Critically appraise each report

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

Step 4: Summarize evidence in a narrative and an overview table

Combine findings from all reports in a table that pulls out the important information from the article worksheets. Write a brief narrative that summarizes and synthesizes the information abstracted from the articles that is related to the question asked.

Step 5: Develop a conclusion statement and grade the strength of evidence supporting the conclusion

Develop a concise conclusion statement (the answer to the question), taking into account the synthesis of all relevant studies and reports, their class and their quality ratings. 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

The expert workgroup, which includes practitioners and researchers with a depth of experience in the specific field of interest, develops the disease-specific guideline. The guideline development involves the following steps.

Review Evidence Based Conclusions

The workgroup meets to review the materials resulting from the evidence analysis, which may include review of the conclusion statements, evidence summaries and evidence worksheets.

Formulate Recommendations for the Guideline Integrating Conclusions from Evidence Analysis

The work group uses an expert consensus method to formulate recommendations, taking into account the following:

- Recommendations for what the dietitian should do and why
- Rating of recommendations based on strength of supporting evidence
- Label of Conditional (clearly define a specific situation) or Imperative (broadly applicable to the target population without restraints on the pertinence)
- Risks and Harms of Implementing the Recommendations, including potential risks, harms, or adverse consequences
- Conditions of Application, including organizational barriers or conditions that may limit application
- Potential Costs Associated with Application
- Recommendation Narrative
- Recommendation Strength Rationale, evidence strength and methodological issues
- Minority Opinions, when the expert working group cannot reach consensus on a recommendation
- Supporting Evidence

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Criteria for Recommendation Rating

Statement Rating	Definition	Implication for Practice
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	Practitioners should be flexible in deciding whether to follow a recommendation classified **Consensus**, although they may

Statement Rating	Definition	Implication for Practice
	available scientific evidence did not present consistent results, or controlled trials were lacking.	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.

*Conclusion statements are assigned a grade based on the strength of the evidence. Grade I is good; grade II, fair; grade III, limited; grade IV signifies expert opinion only and grade V indicates that a grade is not assignable because there is no evidence to support or refute the conclusion. The evidence and these grades are considered when assigning a rating (Strong, Fair, Weak, Consensus, Insufficient Evidence - see chart above) to a recommendation.

Adapted by the American Dietetic Association from the American Academy of Pediatrics, Classifying Recommendations for Clinical Practice Guideline, Pediatrics. 2004;114;874-877.

COST ANALYSIS

An analysis was performed of potential costs associated with application of the recommendations in the guideline.

Although costs of medical nutrition therapy (MNT) sessions and reimbursement vary, MNT sessions are essential for improved outcomes. MNT education can be considered cost effective when considering the benefits of nutrition interventions on the onset and progression of comorbidities versus the cost of the intervention. Furthermore, MNT can be considered cost effective as interventions for prevention or delay of type 2 diabetes saves the cost of the intervention.

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 AGREE (Appraisal of Guidelines for Research and Evaluation) 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 (EAL).

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."

Diabetes Mellitus (DM): Medical Nutrition Therapy (MNT)

DM: MNT and Number/Length of Initial Series of Encounters

MNT provided by a registered dietitian (RD) is recommended for individuals with type 1 and type 2 diabetes. An initial series of three to four encounters each lasting from 45 to 90 minutes is recommended. This series, beginning at diagnosis of diabetes or at first referral to an RD for MNT for diabetes, should be completed within three to six months. The RD should determine if additional MNT encounters are needed after the initial series based on the nutrition assessment of learning needs and progress towards desired outcomes. Studies based on a range in the number (1 to 5 individual sessions or a series of 6 to 12 group sessions) and length (45 to 90 minutes) report sustained positive outcomes at one year and longer. Studies implementing a variety of nutrition interventions report a reduction in A1C levels, and some studies also report improved lipid profiles, improved weight management, adjustments in medications, and reduction in the risk for onset and progression of comorbidities.

Strong, Imperative

DM: MNT Long-Term Follow-up Encounters

At least one follow-up encounter is recommended annually to reinforce lifestyle changes and to evaluate and monitor outcomes that impact the need for changes in MNT or medication. The RD should determine if additional MNT encounters are needed. Studies involving regular lifestyle intervention sessions (up to 1 per month) report sustained positive outcomes at one year and longer.

Strong, Imperative

Recommendations Strength Rationale

- **Conclusion statement was Grade I**

DM: Assessment and Diabetes

DM: Nutrition Assessment

The RD should assess food intake (focusing on carbohydrate), medication, metabolic control (glycemia, lipids, and blood pressure), anthropometric measurements and physical activity to serve as the basis for implementation of the nutrition prescription, goals and intervention. Individuals who have diabetes should receive MNT tailored by the RD.

Strong, Imperative

Recommendations Strength Rationale

- **Conclusion statement was Grade I**

DM: Assessment of Glycemic Control

Assessment of Glycemic Control

The RD should assess glycemic control and focus medical nutrition therapy to achieve and maintain blood glucose levels in the target range (target glucose levels noted in the American Diabetes Association Standards of Medical Care in Diabetes). Studies evaluating the effectiveness of diabetes MNT at three to six months reported reductions in A1C ranging from 0.25% to 2.9%.

Strong, Imperative

Recommendation Strength Rationale

- **Conclusion statement was Grade I**

DM: Assess Relative Importance of Weight Management

Assess Relative Importance of Weight Management

The RD should assess the relative importance of weight management for persons with diabetes who are overweight or obese. While modest weight loss has been shown to improve insulin resistance in overweight and obese insulin-resistant individuals, research on sustained weight loss interventions lasting 1 year or longer reported inconsistent effects on A1C.

Strong, Conditional

Recommendation Strength Rationale

- **Conclusion statement was Grade II**

DM: Intervention Options

Intervention Options

The RD should implement MNT selecting from a variety of interventions (reduced energy and fat intake, carbohydrate counting, simplified meal plans, healthy food

choices, individualized meal planning strategies, exchange lists, insulin-to-carbohydrate ratios, physical activity and behavioral strategies). Nutrition education and counseling should be sensitive to the personal needs, willingness to change, and ability to make changes of the individual with diabetes. Studies reporting on effectiveness of MNT report a variety in the number and type of MNT sessions that lead to improved outcomes.

Strong, Imperative

Recommendation Strength Rationale

- **Conclusion statement was Grade I**

DM: Macronutrients

Macronutrient Percentages

The RD should encourage consumption of macronutrients based on the Dietary Reference Intakes (DRI) for healthy adults. Research does not support any ideal percentage of energy from macronutrients for persons with diabetes.

Strong, Imperative

Recommendation Strength Rationale

- **Conclusion statement for Carbohydrate was Grade I**
- **Conclusion statement for Protein was Grade II**

DM: Carbohydrate

DM: Carbohydrate Intake Consistency

In persons on either MNT alone, glucose-lowering medications or fixed insulin doses, meal and snack carbohydrate intake should be kept consistent on a day-to-day basis. Consistency in carbohydrate intake results in improved glycemic control.

Strong, Conditional

Carbohydrate Intake and Insulin Dose Adjustment

In persons with type 1 or type 2 diabetes who adjust their mealtime insulin doses or who are on insulin pump therapy, insulin doses should be adjusted to match carbohydrate intake (insulin-to-carbohydrate ratio). This can be accomplished by comprehensive nutrition education and counseling on interpretation of blood glucose patterns, nutrition-related medication management and collaboration with the healthcare team. Adjusting insulin dose based on planned carbohydrate intake improves glycemic control and quality of life without any adverse effects.

Strong, Conditional

Recommendation Strength Rationale

- **Conclusion statement was Grade I**

DM: Sucrose and Diabetes

DM: Sucrose Intake

If persons with diabetes choose to eat foods containing sucrose, the sucrose-containing foods should be substituted for other carbohydrate foods. Sucrose intakes of 10 to 35 percent of total energy intake do not have a negative effect on glycemic or lipid responses when substituted for isocaloric amounts of starch.

Strong, Conditional

Recommendation Strength Rationale

- **Conclusion statement was Grade I**

DM: Non-nutritive Sweeteners and Diabetes

DM: Non-nutritive Sweeteners

If persons with diabetes choose to consume products containing U.S. Food and Drug Administration (FDA)-approved non-nutritive sweeteners, at levels that do not exceed the acceptable daily intakes (ADIs), the RD should advise that some of these products may contain energy and carbohydrate from other sources that needs to be accounted for. Research on non-nutritive sweeteners reports no effect on changes in glycemic response.

Fair, Conditional

Recommendation Strength Rationale

- **Conclusion statements were Grade III**

DM: Glycemic Index and Diabetes

DM: Glycemic Index

If the use of glycemic index (GI) is proposed as a method of meal planning, the RD should advise on the conflicting evidence of effectiveness of this strategy. Studies comparing high versus low GI diets report mixed effects on A1C.

Fair, Conditional

Recommendation Strength Rationale

- **Conclusion statement was Grade II**

DM: Fiber and Diabetes

DM: Fiber Intake and Glycemia

Recommendations for fiber intake for people with diabetes are similar to the recommendations for the general public (daily reference intake [DRI]: 14 grams per 1000 kilocalories [kcal]). While diets containing 44 to 50 grams of fiber daily are reported to improve glycemia, more usual fiber intakes (up to 24 grams daily) have not shown beneficial effects on glycemia. It is unknown if free-living individuals can daily consume the amount of fiber needed to improve glycemia.

Strong, Imperative

DM: Fiber Intake and Cholesterol

Include foods containing 25 to 30 grams of fiber per day, with special emphasis on soluble fiber sources (7 to 13 grams). Diets high in total and soluble fiber, as part of cardioprotective nutrition therapy, can further reduce total cholesterol by 2% to 3% and low-density lipoprotein (LDL) cholesterol up to 7%.

Strong, Imperative

Recommendation Strength Rationale

- **Conclusion statement for Fiber and Diabetes was Grade I**
- **Conclusion statement for Fiber and Coronary Heart Disease (CHD) were Grades I, II, and III**

DM: Protein and Diabetes

DM: Protein Intake and Normal Renal Function

In persons with type 1 or type 2 diabetes with normal renal function, the RD should advise that usual protein intake of approximately 15% to 20% of daily energy intake does not need to be changed. Although protein has an acute effect on insulin secretion, usual protein intake in long-term studies has minimal effects on glucose, lipids, and insulin concentrations.

Fair, Conditional

Protein Intake and Nephropathy

In persons with diabetic nephropathy, a protein intake of one gram or less per kg body weight per day is recommended. Diets with less than one gram protein per kg body weight per day have been shown to improve albuminuria in persons with nephropathy; however, they have not been shown to have significant effects on glomerular filtration rates (GFR).

Fair, Conditional

DM: Protein Intake and Late Stage Nephropathy

For persons with late stage diabetic nephropathy (Chronic Kidney Disease [CKD] Stages 3-5), hypoalbuminemia (an indicator of malnutrition) and energy intake must be monitored and changes in protein and energy intake made to correct deficits. A protein intake of approximately 0.7 grams per kg body weight per day has been associated with hypoalbuminemia, whereas a protein intake of approximately 0.9 grams per kg body weight per day has not.

Fair, Conditional

Recommendation Strength Rationale

- **Conclusion statement is Grade II**

DM: Glucose Monitoring

DM: Blood Glucose Monitoring

For individuals on nutrition therapy alone or nutrition therapy in combination with glucose-lowering medications, self-monitoring of blood glucose (SMBG) is recommended. Frequency and timing is dependent on diabetes management goals and therapies (i.e., MNT, diabetes medications and physical activity). When SMBG is incorporated into diabetes education programs and the information from SMBG is used to make changes in diabetes management, SMBG is associated with improved glycemic control.

Fair, Conditional

DM: Frequency of Blood Glucose Monitoring

For persons with type 1 or type 2 diabetes on insulin therapy, at least three to eight blood glucose tests per day are recommended to determine the adequacy of the insulin dose(s) and guide adjustments in insulin dose(s), food intake and physical activity. Some insulin regimens require more testing to establish the best integrated therapy (insulin, food, and activity). Once established, some insulin regimens will require less frequent self-monitoring of blood glucose (SMBG). Intervention studies that include self-management training and adjustment of insulin doses based on SMBG result in improved glycemic control.

Strong, Conditional

DM: Possible Need for Continuous Glucose Monitoring or More Frequent SMBG

Persons experiencing unexplained elevations in A1C or unexplained hypoglycemia and hyperglycemia may benefit from use of continuous glucose monitoring (CGM) or more frequent SMBG. It is essential that persons with diabetes receive education as to how to calibrate CGM and how to interpret CGM results. Studies have proven the accuracy of CGM and most show that using the trend/pattern data from CGM can result in less glucose variability and improved glucose control.

Fair, Conditional

Recommendation Strength Rationale

- **Conclusion statements were Grades I and II**

DM: Prevention and Treatment of CVD

DM: CVD and Cardioprotective Nutrition Therapy

Cardioprotective nutrition interventions for the prevention and treatment of CVD should be implemented in the initial series of encounters. Diabetes is associated with an increased risk for CVD and glycemic control may improve the lipid profile.

Strong, Imperative

CVD and Cardioprotective Nutrition Interventions

Cardioprotective nutrition interventions for prevention and treatment of CVD include reduction in saturated and trans fats and dietary cholesterol, and interventions to improve blood pressure. Studies in persons with diabetes utilizing these interventions report a reduction in cardiovascular risk and improved cardiovascular outcomes.

Strong, Imperative

Recommendation Strength Rationale

- **Conclusion statement was Grade I**

DM: Weight Management

DM: Diabetes and Weight Management

The RD should advise that glycemic control is the primary focus for diabetes management. While decreasing energy intake may improve glycemic control, it is unclear whether weight loss alone will improve glycemic control. Sustained weight loss interventions lasting 1 year or longer reported inconsistent effects on hemoglobin A1C.

Fair, Conditional

Recommendation Strength Rationale

- **Conclusion statement was Grade II**

DM: Physical Activity

DM: Type 2 Diabetes and Physical Activity

In persons with type 2 diabetes, 90 to 150 minutes of accumulated moderate-intensity aerobic physical activity per week as well as resistance/strength training three times per week is recommended. Both aerobic and resistance training improve glycemic control, independent of weight loss. Physical activity also improves insulin sensitivity and decreases risk for cardiovascular disease and all-cause mortality.

Strong, Conditional

DM: Type 1 Diabetes and Physical Activity

Individuals with type 1 diabetes should be encouraged to engage in regular physical activity. Although exercise is not reported to improve glycemic control in persons with type 1 diabetes, individuals may receive the same benefits from exercise as the general public—decreased risk for cardiovascular disease and improved sense of well-being.

Fair, Conditional

DM: Physical Activity and Insulin/Insulin Secretagogue Use

The RD should instruct individuals on insulin or insulin secretagogues on the safety guidelines to prevent hypoglycemia (frequent blood glucose monitoring and possible adjustment in insulin dose or carbohydrate intake). Research indicates that the incidence of hypoglycemia during exercise may depend on baseline glucose levels.

Fair, Conditional

Recommendation Strength Rationale

- **Conclusion statements were Grades I and II**

DM: Coordination of Care and Diabetes

DM: Coordination of Care

The RD should implement MNT and coordinate care with an interdisciplinary team. An interdisciplinary team approach is necessary to integrate MNT for patients with diabetes into overall management.

Consensus, Imperative

Recommendation Strength Rationale

- **Conclusion statement was Grade I**

DM: Monitor & Evaluate and Diabetes

DM: Monitoring and Evaluation

The RD should monitor and evaluate food intake, medication, metabolic control (glycemia, lipids, and blood pressure), anthropometric measurements and physical activity. Research reports sustained improvements in A1C at 12 months and longer with long-term follow-up encounters with an RD.

Strong, Imperative

DM: Evaluation of Glycemic Control

The RD should primarily use blood glucose monitoring results in evaluating the achievement of goals and effectiveness of MNT. Glucose monitoring results can be used to determine whether adjustments in foods and meals will be sufficient to achieve blood glucose goals or if medication additions or adjustments need to be combined with MNT.

Consensus, Imperative

Recommendation Strength Rationale

- **Conclusion statement for MNT was Grade I**

Definitions:

Conditional versus Imperative Recommendations

Recommendations can be worded as ***conditional*** or ***imperative*** statements. Conditional statements clearly define a specific situation, while imperative statements are broadly applicable to the target population without restraints on their pertinence. More specifically, a conditional recommendation can be stated in if/then terminology (e.g., If an individual does not eat food sources of omega-3 fatty acids, then 1g of EPA and DHA omega-3 fatty acid supplements *may* be recommended for secondary prevention).

In contrast, imperative recommendations "require," or "must," or "should achieve certain goals," but do not contain conditional text that would limit their applicability to specified circumstances. (e.g., Portion control should be included as part of a comprehensive weight management program. Portion control at meals and snacks results in reduced energy intake and weight loss).

Levels of Evidence

Strength of Evidence Elements	**Grade I** **Good/Strong**	**Grade II** **Fair**	**Grade III** **Limited/Weak**	**Grade IV** **Expert Opinion Only**	**Grade** **Grade Assigna**
Quality • Scientific rigor/validity	Studies of strong design for question	Studies of strong design for question with minor	Studies of weak design for answering the question	No studies available Conclusion	No evidence that pertains

Strength of Evidence Elements	Grade I Good/Strong	Grade II Fair	Grade III Limited/Weak	Grade IV Expert Opinion Only	Grade Grade Assigna
• Considers design and execution	Free from design flaws, bias and execution problems	methodological concerns OR Only studies of weaker study design for question	 OR Inconclusive findings due to design flaws, bias or execution problems	based on usual practice, expert consensus, clinical experience, opinion, or extrapolation from basic research	question being address
Consistency Of findings across studies	Findings generally consistent in direction and size of effect or degree of association, and statistical significance with minor exceptions at most	Inconsistency among results of studies with strong design OR Consistency with minor exceptions across studies of weaker designs	Unexplained inconsistency among results from different studies OR Single study unconfirmed by other studies	Conclusion supported solely by statements of informed nutrition or medical commentators	NA
Quantity • Number of studies • Number of subjects in studies	One to several good quality studies Large number of subjects studies Studies with negative results having sufficiently large sample size for adequate statistical power	Several studies by independent investigators Doubts about adequacy of sample size to avoid Type I and Type II error	Limited number of studies Low number of subjects studies and/or inadequate sample size within studies	Unsubstantiated by published studies	Relevan studies have no been do
Clinical Impact • Importance of studies outcomes	Studied outcome relates directly to the question	Some doubt about the statistical or clinical significance of	Studies outcome is an intermediate outcome or surrogate for	Objective data unavailable	Indicate area for future research

Strength of Evidence Elements	Grade I Good/Strong	Grade II Fair	Grade III Limited/Weak	Grade IV Expert Opinion Only	Grade Grade Assigna
• Magnitude of effect	Size of effect is clinically meaningful Significant (statistical) difference is large	effect	the true outcome of interest OR Size of effect is small or lacks statistical and/or clinical significance		
Generalizability To population of interest	Studied population, intervention and outcomes are free from serious doubts about generalizability	Minor doubts about generalizability	Serious doubts about generalizability due to narrow or different study population, intervention or outcomes studied	Generalizability limited to scope of experience	NA

This grading system was based on the grading system from: *Greer N, Mosser G, Logan G, Wagstrom Halaas G. A practical approach to evidence grading. Jt Comm. J Qual Improv. 2000; 26:700-712*. In September 2004, The ADA Research Committee modified the grading system to this current version.

Criteria for Recommendation Rating

Statement Rating	Definition	Implication for Practice
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	Practitioners should follow a **Strong** recommendation unless a clear and compelling rationale for an alternative approach is present.

Statement Rating	Definition	Implication for Practice
	benefits strongly outweigh the harms.	
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 **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.

*Conclusion statements are assigned a grade based on the strength of the evidence. Grade I is good; grade II, fair; grade III, limited; grade IV signifies expert opinion only and grade V indicates that a grade is not assignable because there is no evidence to support or refute the conclusion. The evidence

and these grades are considered when assigning a rating (Strong, Fair, Weak, Consensus, Insufficient Evidence - see chart above) to a recommendation.

Adapted by the American Dietetic Association from the American Academy of Pediatrics, Classifying Recommendations for Clinical Practice Guideline, Pediatrics. 2004;114;874-877.

CLINICAL ALGORITHM(S)

Algorithms are provided in the original guideline document for:

- Diabetes type 1 and 2 evidence-based nutrition practice guideline for adults
- Diabetes nutrition assessment
- Diabetes nutrition diagnosis
- Diabetes nutrition intervention: nutrition prescription
- Diabetes nutrition monitoring and evaluation

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence 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 (randomized controlled trials (RCTs), clinical studies, observational studies, cohort and case-control studies) pertaining to the conclusion statement and provide the study details.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

A primary goal of implementing these recommendations includes improving an adult's ability to achieve optimal nutrition through healthful food choices and a physically active lifestyle. Medical nutrition therapy employing either a series of individual or group sessions and employing a variety of nutrition interventions also report improvements in glycemia, lipid profiles and blood pressure, improved weight management, decreased need for medications, and reduction in the risk for onset and progression of comorbidities.

POTENTIAL HARMS

Overall Risk/Harm Considerations

When using these recommendations:

- Review the patient's age, socioeconomic status, cultural issues, and other health conditions.

- Consider a referral to a behavioral specialist if psychosocial issues are a concern.
- Consider a referral to social services to assist patients with financial arrangements if economic issues are a concern.
- Use clinical judgment when evaluating patients with long-standing diabetes and comorbid conditions.

Recommendation Specific Risks/Harms

Macronutrients

Carbohydrate

- Although total carbohydrate content of meals and snacks is the first priority, macronutrient content and total energy intake cannot be ignored as excessive energy intake may lead to weight gain, even if glycemic control is maintained.
- Diets too low in carbohydrates eliminate many foods that are important sources of vitamins, minerals, fiber, and energy.

Sucrose

- Excessive substitution of sucrose for starches could potentially contribute to inadequate intake of foods contributing other essential nutrients. If sucrose-containing foods are habitually added to usual intake, excessive energy intake is a concern.

Protein

- Diets too low in protein and energy intake can lead to hypoalbuminemia (malnutrition) and unintentional weight loss. This needs to be monitored in persons with diabetic neuropathy who are restricting protein intake and may have a diminished appetite.

Self-Monitoring of Blood Glucose

- Frequent glucose self-monitoring may cause pain and discomfort
- Individuals should know of proper disposal of hazardous waste.

Physical Activity

- Before beginning a program of physical activity more vigorous than brisk walking, people with diabetes should be assessed for conditions that might be associated with an increased risk of cardiovascular disease. Of concern are uncontrolled hypertension, severe autonomic or peripheral neuropathy, and preproliferative or proliferative retinopathy or macular edema.
- In previously sedentary individuals whose 10-year risk of a coronary event is likely to be equal to or greater than 10%, a graded exercise test with electrocardiogram monitoring is recommended.
- In individuals taking insulin or insulin secretagogues, physical activity can cause hypoglycemia if medication dose or carbohydrate intake is not

adjusted. Carbohydrate should be ingested if pre-exercise levels are less than 100 mg/dL.

CONTRAINDICATIONS

CONTRAINDICATIONS

Clinical judgment is crucial in application of these guidelines. Careful consideration should be given to the application of these guidelines for patients with significant medical comorbidities.

QUALIFYING STATEMENTS

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- This American Dietetic Association Evidence-Based 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.
- While the guideline represents a statement of best practice based on the latest available evidence at the time of publishing, they are not intended to overrule professional judgment. Rather, they may be viewed as a relative constraint on individual clinician discretion in a particular clinical circumstance.
- This guideline recognizes the role of patient preferences for possible outcomes of care, when the appropriateness of a clinical intervention involves a substantial element of personal choice or values.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

The 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 diabetes to all dietetics practitioners engaged in, teaching about, or researching diabetes as quickly as possible. National implementation workshops at various sites around the country and during the ADA Food Nutrition Conference Expo (FNCE) are planned. Additionally, there are recommended dissemination and adoption strategies for local use of the *ADA Diabetes Type 1 and 2 Evidence-Based Nutrition Practice Guideline for Adults*.

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 Diabetes Type 1 and 2 guideline will be achieved by announcement at professional events, presentations and training. Some strategies include:

- **National and Local Events** – State dietetic association meetings 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** – Some of the tools that will be developed to help implement the guideline include specially designed resources such as clinical algorithms, slide presentations, training and toolkits.

Specific distribution strategies include:

Publication in Full – The guideline is available electronically at the ADA Evidence Analysis Library website (www.adaevidencelibrary.com) and has been announced to all the ADA dietetic practice groups. The ADA Evidence Analysis Library will also provide downloadable supporting information and links to relevant position papers.

IMPLEMENTATION TOOLS

Clinical Algorithm

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

Living with Illness

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

American Dietetic Association (ADA). Diabetes type 1 and 2 evidence-based nutrition practice guideline for adults. Chicago (IL): American Dietetic Association (ADA); 2008. Various p. [21 references]

ADAPTATION

The levels of evidence was based on the grading system from: *Greer N, Mosser G, Logan G, Wagstrom Halaas G. A practical approach to evidence grading. Jt Comm. J Qual Improv. 2000; 26:700-712*. In September 2004, The American Dietetic Association (ADA) Research Committee modified the grading system to this current version.

The grades of recommendation were adapted by the American Dietetic Association (ADA) from the American Academy of Pediatrics, Classifying Recommendations for Clinical Practice Guideline, Pediatrics. 2004;114;874-877.

DATE RELEASED

2001 Dec (revised 2008 Mar)

GUIDELINE DEVELOPER(S)

American Dietetic Association - Professional Association

SOURCE(S) OF FUNDING

American Dietetic Association

GUIDELINE COMMITTEE

Diabetes Type 1 and 2 Evidence-Based Guideline Workgroup

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Workgroup Members: Carolyn J. Leontos, MS, RD CDE, *Chair*; Marion J. Franz, MS, RD, CDE; Lea Ann Holzmeister, RD, CDE; Karmeen Kulkarni, MS, RD, CDE; Arlene M. Monk, RD, LD, CDE; Margaret A. Powers, MS. RD; Naomi Wedel, MS, RD

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

In the interest of full disclosure, American Dietetic Association (ADA) has adopted the policy of revealing relationships workgroup members have with companies that sell products or services that are relevant to this topic. Workgroup members are required to disclose potential conflicts of interest by completing the ADA Conflict of Interest Form. It should not be assumed that these financial interests will have an adverse impact on the content, but they are noted here to fully

inform readers. Users of the evidence analysis library may assume that only work group members listed below have potential conflicts of interest to disclose.

Carolyn Leontos: Received honorariums from Takeda, Roche Diagnostics, Aventis, Novartis; shareholder in Johnson & Johnson and Abbott Laboratories, Inc. stock.

Marion Franz: Employed with Nutrition Concept by Franz, Inc., consulted for General Mills and Nestle and has received honorariums for General Mills, Nestle and Kraft.

Karmeen Kulkarni: Employed by Abbott Diabetes care.

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: American Dietetic Association. Nutrition practice guidelines for type 1 and type 2 diabetes mellitus. Chicago (IL): American Dietetic Association; 2001 Dec. Various p.

The guideline will undergo a complete revision every three to five years.

GUIDELINE AVAILABILITY

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

AVAILABILITY OF COMPANION DOCUMENTS

The following is available:

- Executive summary of recommendations. Chicago (IL): American Dietetic Association; March, 2008. Available from the American Dietetic Association Web site.

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI on April 29, 2003. The information was verified by the guideline developer on August 6, 2003. This summary was updated by ECRI Institute on November 5, 2008. The updated information was verified by the guideline developer on December 9, 2008.

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