Complete Summary

GUIDELINE TITLE

American Association of Clinical Endocrinologists medical guidelines for clinical practice for the management of diabetes mellitus. Lipid management.

BIBLIOGRAPHIC SOURCE(S)

AACE Diabetes Mellitus Clinical Practice Guidelines Task Force. AACE diabetes mellitus guidelines. Lipid management. Endocr Pract 2007 May-Jun;13(Suppl 1):40-7. [71 references]

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previously published version: American Association of Clinical Endocrinologists, American College of Endocrinology. Medical guidelines for the management of diabetes mellitus: the AACE system of intensive diabetes self-management--2002 update. Endocr Pract 2002 Jan-Feb;8(Suppl 1):40-82.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Diabetes mellitus, including:

- Type 1 diabetes
- Type 2 diabetes
- Gestational diabetes

GUIDELINE CATEGORY

Management
Prevention
Treatment

CLINICAL SPECIALTY

Cardiology
Endocrinology
Family Practice
Internal Medicine
Nursing
Nutrition
Obstetrics and Gynecology
Preventive Medicine

INTENDED USERS

Advanced Practice Nurses
Dietitians
Nurses
Physician Assistants
Physicians

GUIDELINE OBJECTIVE(S)

To provide clinicians with clear and accessible guidelines to care for patients with diabetes mellitus

TARGET POPULATION

Children, adolescents, and adults with or at risk of developing diabetes mellitus

INTERVENTIONS AND PRACTICES CONSIDERED

1. Lifestyle modifications
2. Statins
3. Ezetimibe
4. Fibrates
5. Niacin
6. Combination therapy
    - Statins plus fibrate
    - Statins plus niacin
    - Statins plus ezetimibe
    - Statins plus bile acid sequestrant
    - Statins plus omega-3 fatty acids
7. Low-dose aspirin prophylaxis

MAJOR OUTCOMES CONSIDERED

- Blood lipid levels (low density lipoprotein-C, high density lipoprotein-C, triglycerides
- Cardiovascular morbidity and mortality
- Adverse effects of therapy

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

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Searches of Unpublished Data

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

References were obtained by performing a computerized search of the literature using PubMed and other search engines; scanning incoming journals in the medical library; and reviewing references in publications relevant to diabetes including review articles, leading textbooks, and syllabi from national and international meetings.

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

Levels of Substantiation in Evidence-Based Medicine[a]

Level-of-Evidence Category[b]	Study Design or Information Type	Comments
1	Randomized controlled trials Multicenter trials Large meta-analyses with quality ratings	Well-conducted, well-controlled trials at 1 or more medical centers Data derived from a substantial number of trials with adequate power; substantial number of subjects and outcome data Consistent pattern of findings in the population for which the recommendation is made – generalizable results Compelling nonexperimental, clinically obvious

Level-of-Evidence Category[b]	Study Design or Information Type	Comments
		evidence (e.g., use of insulin in diabetic ketoacidosis); "all or none" evidence
2	Randomized controlled trials Prospective cohort studies Meta-analyses of cohort studies Case-control studies	Limited number of trials, small number of subjects Well-conducted studies Inconsistent findings or results not representative for the target population
3	Methodologically flawed randomized controlled trials Nonrandomized controlled trials Observational studies Case series or case reports	Trials with 1 or more major or 3 or more minor methodologic flaws Uncontrolled or poorly controlled trials Retrospective or observational data Conflicting data with weight of evidence unable to support a final recommendation
4	Expert consensus Expert opinion based on experience Theory-driven conclusions Unproven claims Experience-based information	Inadequate data for inclusion in level-of-evidence categories 1, 2, or 3; data necessitates an expert panel's synthesis of the literature and a consensus

[a]Adapted from the American Association of Clinical Endocrinologists Protocol for the Standardized Production of Clinical Practice Guidelines.

[b]Level-of-evidence categories 1 through 3 indicate scientific substantiation or proof; level-of-evidence category 4 indicates unproven claims.

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

The American Association of Clinical Endocrinologists (AACE) Task force members reviewed selected reports and studies and rated the clinical evidence from these sources.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

When possible, clinical recommendations put forth in the clinical practice guideline have been assigned a letter grade (A-D) based on the level of scientific substantiation (see "Rating Scheme for the Strength of the Recommendations"). However, when task force members determined that clinical judgment regarding a recommendation outweighed study findings or a recommendation lacked supporting studies, they assigned the final grade based on their extensive clinical experience and expertise in diabetes management. An A grade is the strongest recommendation, and a D grade is the weakest recommendation. These recommendations include subjective components such as: (a) judgment regarding whether results from a particular study are conclusive; (b) the relative weighing of positive and negative conclusive study results; (c) assignment of evidence rating when certain study methodologies are controversial; (d) the impact of risk-benefit analysis; (e) the impact of cost-effectiveness; (f) assessment of geographical differences in practice standards and availability of certain technologies; (g) assessment of ethnic, racial, and genetic differences in pathophysiology; (h) incorporation of patient preferences; and (i) incorporation of physician preferences.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Recommendation Grades in Evidence-Based Medicine[a]

Grade	Description
A	Homogeneous evidence from multiple well-designed randomized controlled trials with sufficient statistical power Homogeneous evidence from multiple well-designed cohort controlled trials with sufficient statistical power ≥1 conclusive level of evidence category 1 publications demonstrating benefit >> outweighs risk
B	Evidence from at least one large well-designed clinical trial, cohort or case-controlled analytic study, or meta-analysis No conclusive level of evidence category 1 publication; ≥1 conclusive level of evidence category 2 publications demonstrating benefit >> risk
C	Evidence based on clinical experience, descriptive studies, or expert consensus opinion No conclusive level 1 or 2 publication; ≥1 conclusive level of evidence

Grade	Description
	category 3 publications demonstrating benefit >> risk No conclusive risk at all and no conclusive benefit demonstrated by evidence
D	Not rated No conclusive level of evidence category 1, 2, or 3 publication demonstrating benefit >> risk Conclusive level of evidence category 1, 2, or 3 publication demonstrating risk >> benefit

[a]Adapted from the American Association of Clinical Endocrinologists Protocol for the Standardized Production of Clinical Practice Guidelines.

COST ANALYSIS

Published cost analyses were reviewed.

METHOD OF GUIDELINE VALIDATION

Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

A separate panel composed of American Association of Clinical Endocrinologists (AACE) members with expertise in diabetes reviewed the compiled report. Final recommendations included in this clinical practice guideline represent a consensus among the task force members and have been approved by reviewers, the AACE Publications and Executive Committees, and the AACE Board of Directors.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Definitions of the classes (1-4) and levels of evidence (A-D) are provided at the end of the "Major Recommendations" field.

Lipid Management

- Aggressive management of dyslipidemia in patients with diabetes mellitus is critical; treat patients to achieve the following goals (***grade A***):
  - LDL-C <100 mg/dL (<70 mg/dL is recommended for patients with diabetes mellitus and coronary artery disease.)
  - HDL-C >40 mg/dL in men and >50 mg/dL in women
  - Triglycerides <150 mg/dL.
- Lifestyle modifications are essential (***grade D***).
- Statins are the pharmacologic treatment of choice (***grade A***).
- Use ezetimibe in patients who are intolerant of statins or in combination with statin therapy and other lipid-modifying agents (***grade B***).

- Combination therapy is indicated in patients who have not achieved the desired goals with monotherapy (***grade C***).
- Multiple options are available for combination therapy including statin plus fibrate, statin plus niacin, statin plus ezetimibe, statin plus bile-acid sequestrant, and statin plus omega-3 fatty acids (***grade C***).
- Use fibrates as primary therapy for patients with triglyceride levels greater than 400 mg/dL (***grade C***).
- Use fibrates cautiously in combination with statins because of the risk of rhabdomyolysis; this risk is markedly lower for fenofibrate than for gemfibrozil (***grade C***).
- Niacin may be a useful adjuvant when the primary abnormality is a low HDL-C level (***grade D***).
- Use low-dose aspirin prophylaxis routinely unless a specific contraindication is present; note that benefits may differ between women and men (***grade A***).

Definitions:

Levels of Substantiation in Evidence-Based Medicine[a]

Level-of-Evidence Category[b]	Study Design or Information Type	Comments
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Level-of-Evidence Category[b]	Study Design or Information Type	Comments
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Recommendation Grades in Evidence-Based Medicine[a]

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C	Evidence based on clinical experience, descriptive studies, or expert consensus opinion No conclusive level 1 or 2 publication; ≥1 conclusive level of evidence category 3 publications demonstrating benefit >> risk No conclusive risk at all and no conclusive benefit demonstrated by evidence
D	Not rated

Grade	Description
	No conclusive level of evidence category 1, 2, or 3 publication demonstrating benefit >> risk Conclusive level of evidence category 1, 2, or 3 publication demonstrating risk >> benefit

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CLINICAL ALGORITHM(S)

None provided

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").

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Intensive treatment of diabetes mellitus and conditions known to be risk factors can significantly decrease the development and/or progression of chronic complications.

POTENTIAL HARMS

- There is a risk of rhabdomyolysis when fibrates are used in combination with statins; this risk is markedly lower for fenofibrate than for gemfibrozil.
- Statins are associated with a low incidence of myopathy and elevation of liver enzymes.
- Adverse effects from fibrates may include dyspepsia, gallstones, and myopathy.
- Adverse effects of niacin therapy include flushing, mild hyperglycemia, hyperuricemia, upper-gastrointestinal distress, and hepatotoxicity.
- Fibrates and niacin can be used with caution in combination therapy

CONTRAINDICATIONS

CONTRAINDICATIONS

- Concomitant use of statins and certain drugs are contraindicated (e.g., cyclosporins, erythromycin) because of increased risk of myopathy.
- Bile-acid sequestrants are contraindicated in patients with hypertriglyceridemia

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

- Criticism that purely evidence-based clinical practice guidelines do not reflect real life because subjective input is stifled or precluded is addressed to some extent by the American Association of Clinical Endocrinologists (AACE) methodology for developing the guidelines. When the task force members judged that subjective factors influenced the grade of a recommendation to an extent that outweighed the available best evidence, this logic was explicitly described in the detailed discussion that follows each topic section's executive summary. Thus, the process of developing evidence-based recommendations and the incorporation of subjective components are transparent to the reader.
- These methods, nevertheless, have the following shortcomings: (a) reliance on some subjective measures, which compromises reproducibility; (b) dependence on the best available evidence, even if only one study is used to formulate a recommendation grade; and (c) dependence on task force primary authors to perform a comprehensive literature search. Multiple levels of review by both AACE-credentialed and non–AACE-credentialed experts from academia and clinical practice backgrounds serve to address these predicted shortcomings.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Living with Illness
Staying Healthy

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

AACE Diabetes Mellitus Clinical Practice Guidelines Task Force. AACE diabetes mellitus guidelines. Lipid management. Endocr Pract 2007 May-Jun;13(Suppl 1):40-7. [71 references]

ADAPTATION

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

DATE RELEASED

2000 Jan (revised 2007)

GUIDELINE DEVELOPER(S)

American Association of Clinical Endocrinologists - Medical Specialty Society
American College of Endocrinology - Medical Specialty Society

SOURCE(S) OF FUNDING

American Association of Clinical Endocrinologists (AACE)

GUIDELINE COMMITTEE

American Association of Clinical Endocrinologists (AACE) Diabetes Mellitus Clinical Practice Guidelines Task Force

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Task Force Members: Helena W. Rodbard, MD, FACP, MACE (*Chairperson*) Medical Director, Endocrine and Metabolic Consultants Past President, American Association of Clinical Endocrinologists Past President, American College of Endocrinology, Rockville, Maryland; Lawrence Blonde, MD, FACP, FACE, Director, Ochsner Diabetes Clinical Research Unit; Section on Endocrinology, Diabetes, and Metabolic Diseases Associate Residency Program Director, Department of Internal Medicine, New Orleans, Louisiana; Susan S. Braithwaite, MD, FACP, FACE, Clinical Professor of Medicine, University of North Carolina, Division of Endocrinology, Chapel Hill, NC; Elise M. Brett, MD, FACE, Assistant Clinical Professor of Medicine; Division of Endocrinology, Diabetes, and Bone Disease; Mount Sinai School of Medicine, New York, New York; Rhoda H. Cobin, MD, MACE, Clinical Professor of Medicine; Division of Endocrinology, Diabetes, and Bone Disease; Mount Sinai School of Medicine, Immediate Past President, American College of Endocrinology, Past President, American Association of Clinical Endocrinologists, New York, New York; Yehuda Handelsman, MD, FACP, FACE, Medical Director, Metabolic Institute of America, Senior Scientific Consultant, Metabolic Endocrine Education Foundation, Tarzana, California; Richard Hellman, MD, FACP, FACE, Clinical Professor of Medicine, University of Missouri-Kansas City School of Medicine, President, American Association of Clinical Endocrinologists, North Kansas City, Missouri; Paul S. Jellinger, MD, MACE, Professor of Medicine and Voluntary Faculty, University of Miami School of Medicine, Past President, American College of Endocrinology Past President, American Association of Clinical Endocrinologists, Hollywood, Florida; Lois G. Jovanovic, MD, FACE, CEO & Chief Scientific Officer, Sansum Diabetes Research Institute, Adjunct Professor Biomolecular Science and Engineering, University of California-Santa Barbara, Clinical Professor of Medicine, University of Southern California, Keck School of Medicine, Santa Barbara, CA; Philip Levy, MD, FACE, Clinical Professor of Medicine, University of Arizona College

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Dr. Lawrence Blonde reports that he has received grant/research support from Amylin Pharmaceuticals, Inc.; AstraZeneca LP; Bristol-Myers Squibb Company; Eli Lilly and Company; MannKind Corporation; Merck & Co., Inc.; Novo Nordisk Inc.; Novartis Corporation; Pfizer Inc.; and sanofi-aventis U.S. He has received speaker and consultant honoraria from Abbott Laboratories; Amylin Pharmaceuticals, Inc.; Eli Lilly and Company; GlaxoSmithKline; LifeScan, Inc.; Merck & Co., Inc.; Novartis, Novo Nordisk Inc.; Pfizer Inc.; and sanofi-aventis U.S. He has received consultant honoraria from Kos Pharmaceuticals, Inc. and U.S. Surgical. Dr. Blonde has also disclosed that his spouse is a stock shareholder of Amylin Pharmaceuticals, Inc. and Pfizer Inc., in an account that is not part of their community property.

Dr. Susan S. Braithwaite reports that she does not have any financial relationships with any commercial interests.

Dr. Elise M. Brett reports that her spouse is an employee of Novo Nordisk Inc.

Dr. Rhoda H. Cobin reports that she has received speaker honoraria from GlaxoSmithKline; Pfizer Inc.; sanofi-aventis U.S.; and Novartis and consultant honoraria from Abbott Laboratories.

Dr. Yehuda Handelsman reports that he has received speaker honoraria from Abbott Laboratories; Amylin Pharmaceuticals, Inc.; AstraZeneca LP; Bristol-Myers Squibb Company; GlaxoSmithKline; Merck & Co., Inc.; Novartis; and sanofi-aventis U.S. and consultant honoraria from Abbott Laboratories; Daiichi Sankyo, Inc.; Novartis; and sanofi-aventis U.S.

Dr. Richard Hellman reports that he has received speaker honoraria from Daiichi Sankyo, Inc. and Pfizer Inc. and research grants for his role as an independent contractor from Abbott Laboratories; Pfizer Inc.; and Medtronic, Inc.

Dr. Paul S. Jellinger reports that he has received speaker honoraria from Eli Lilly and Company; Merck & Co., Inc.; Novartis; Novo Nordisk Inc.; and Takeda Pharmaceuticals North America, Inc.

Dr. Lois G. Jovanovic reports that she has received research grants for her role as investigator from Eli Lilly and Company; DexCom Inc.; LifeScan, Inc.; Novo Nordisk Inc.; Pfizer Inc.; Roche Pharmaceuticals; sanofi-aventis U.S.; and Sensys Medical, Inc.

Dr. Philip Levy reports that he has received speaker honoraria from Abbott Laboratories; Amylin Pharmaceuticals, Inc.; GlaxoSmithKline; Eli Lilly and Company; Merck & Co., Inc.; Novo Nordisk Inc.; Novartis; Pfizer Inc.; and sanofi-aventis U.S. and research grants from Amylin Pharmaceuticals, Inc.; MannKind Corporation; Novo Nordisk Inc.; Pfizer Inc.; and sanofi-aventis U.S.

Dr. Jeffrey I. Mechanick reports that he does not have any financial relationships with any commercial interests.

Dr. Helena W. Rodbard reports that she has received consultant honoraria from Ortho-McNeil, Inc.; Pfizer Inc.; sanofi-aventis U.S.; and Takeda Pharmaceuticals North America, Inc.; speaker honoraria from Abbott; GlaxoSmithKline; Merck & Co., Inc.; Novo Nordisk; Pfizer Inc.; and sanofi-aventis U.S. and research support from Biodel, Inc. and sanofi-aventis U. S.

Dr. Farhad Zangeneh reports that he has received speaker honoraria from Eli Lilly and Company; GlaxoSmithKline; Novartis; Novo Nordisk Inc.; Pfizer Inc.; Roche Pharmaceuticals; sanofi-aventis U.S.; and Takeda Pharmaceuticals North America, Inc.

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previously published version: American Association of Clinical Endocrinologists, American College of Endocrinology. Medical guidelines for the management of diabetes mellitus: the AACE system of intensive diabetes self-management--2002 update. Endocr Pract 2002 Jan-Feb;8(Suppl 1):40-82.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from the American Association of Clinical Endocrinologists (AACE) Web site.

Print copies: Available from the American Association of Clinical Endocrinologists (AACE), 1000 Riverside Avenue, Suite 205, Jacksonville, FL 32204.

AVAILABILITY OF COMPANION DOCUMENTS

The following is available:

- American Association of Clinical Endocrinologists protocol for standardized production of clinical practice guidelines. Endocrine Pract 2004 Jul-Aug; 10(4):353-61.

Electronic copies: Available in Portable Document Format (PDF) from the American Association of Clinical Endocrinologists (AACE) Web site.

Print copies: Available from the American Association of Clinical Endocrinologists (AACE), 1000 Riverside Avenue, Suite 205, Jacksonville, FL 32204.

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI on March 1, 2000. The summary was verified by the guideline developer as of March 8, 2000. This summary was updated on April 16, 2002. The information was verified by the guideline developer on November 11, 2002. This summary was updated by ECRI Institute on September 27, 2007. The updated information was verified by the guideline developer on November 12, 2007.

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