



Complete Summary

GUIDELINE TITLE

Lipid control in the management of type 2 diabetes mellitus: a clinical practice guideline from the American College of Physicians.

BIBLIOGRAPHIC SOURCE(S)

Snow V, Aronson MD, Hornbake ER, Mottur-Pilson C, Weiss KB. Lipid control in the management of type 2 diabetes mellitus: a clinical practice guideline from the American College of Physicians. *Ann Intern Med* 2004 Apr 20;140(8):644-9. [28 references] [PubMed](#)

GUIDELINE STATUS

This is the current release of the guideline.

COMPLETE SUMMARY CONTENT

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SCOPE

DISEASE/CONDITION(S)

Type 2 diabetes mellitus

GUIDELINE CATEGORY

Management
Prevention

CLINICAL SPECIALTY

Endocrinology
Family Practice
Internal Medicine

INTENDED USERS

Advanced Practice Nurses
Allied Health Personnel
Nurses
Physician Assistants
Physicians

GUIDELINE OBJECTIVE(S)

To provide internists and other primary care physicians with recommendations for the management of dyslipidemia, particularly hypercholesterolemia, in people with type 2 diabetes

The guideline also addresses the following questions:

- What are the benefits of tight lipid control for both primary and secondary prevention in type 2 diabetes?
- What is the evidence for treating to certain target levels of low-density lipoprotein (LDL) cholesterol for patients with type 2 diabetes?
- Are certain lipid-lowering agents more effective or beneficial in patients with type 2 diabetes?

TARGET POPULATION

All persons with type 2 diabetes, including those who already have some form of microvascular complication and, of particular importance, premenopausal women.

INTERVENTIONS AND PRACTICES CONSIDERED

Treatment/Prevention

Lipid-lowering pharmacologic agents

1. Atorvastatin
2. Lovastatin
3. Pravastatin
4. Simvastatin
5. Fluvastatin
6. Gemfibrozil
7. Niacin
8. Colestipol
9. Cholestyramine
10. Fenofibrate

MAJOR OUTCOMES CONSIDERED

- All-cause mortality
- Cardiovascular mortality
- Cardiovascular events (e.g., myocardial infarction, stroke, cardiovascular mortality)

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

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

The literature review was limited to randomized, controlled trials of drug therapy that included patients with diabetes. Only studies that measured major clinical end points were included. Major clinical end points were defined as major cardiovascular events (for example, cardiovascular mortality, myocardial infarction, stroke), cardiovascular mortality, and total mortality. Of note, many of the trials reported somewhat different clinical end points in the patients with diabetes. All included cardiovascular mortality and myocardial infarction in their composite end point; some included stroke and revascularization, and one included unstable angina. The developers used the primary reported data directly from the published study in their review. They also subdivided the literature review into 2 categories. The first category evaluated the effects of lipid management in primary prevention (that is, patients without known cardiovascular disease); the second evaluated the effects in secondary prevention.

The developers used several sources to identify the relevant literature. They started with a search of the Cochrane Library. They then performed a MEDLINE search in September 2002. The developers used the keywords *exp diabetes mellitus* and *exp lipids [therapy or prevention and control]* and limited the search to randomized, controlled trials and human studies. The final search produced 919 results. Of these, most were discarded because they did not measure major clinical end points, did not report outcomes for patients with diabetes, were observational in nature, or were reviews or editorials. The developers then updated the search through consultation with experts and through references from the identified articles, meta-analyses, and review articles.

NUMBER OF SOURCE DOCUMENTS

12 lipid lowering studies presented diabetes-specific data and reported clinical outcomes

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Not stated

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Meta-Analysis
Review of Published Meta-Analyses
Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

The primary author extracted data from the primary study reports. Accuracy and quality of the abstraction were confirmed through reabstraction and comparison with the original abstraction. The outcomes were broken into categories as described earlier (see National Guideline Clearinghouse section "Description of Methods Used to Collect/Select the Evidence"), and data on absolute and relative risk reduction and numbers needed to treat for benefit were derived from the primary reports or were calculated in standard fashion.

The results of the studies were then combined by using meta-analytic techniques. We pooled data for both relative and absolute risks. A Mantel-Haenszel test was done to test for heterogeneity. In the analyses of secondary prevention, the data had substantial heterogeneity, so the pooled risk ratios and differences were calculated by using the DerSimonian and Laird method with a random-effects model. Sensitivity analyses were done by excluding studies that appeared to be outliers to ascertain the source of the heterogeneity. All analyses were done by using the statistical package Stata (Stata Corp., College Station, Texas).

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

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

METHOD OF GUIDELINE VALIDATION

Internal Peer Review
Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

This paper was developed by the Clinical Efficacy Assessment Subcommittee of the American College of Physicians (ACP). It was approved by the ACP Board of Regents in July 2003.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Recommendation 1: Lipid-lowering therapy should be used for secondary prevention of cardiovascular mortality and morbidity for all patients (both men and women) with known coronary artery disease and type 2 diabetes.

Recommendation 2: Statins should be used for primary prevention against macrovascular complications in patients (both men and women) with type 2 diabetes and other cardiovascular risk factors.

Recommendation 3: Once lipid-lowering therapy is initiated, patients with type 2 diabetes mellitus should be taking at least moderate doses of a statin.

Recommendation 4: For those patients with type 2 diabetes who are taking statins, routine monitoring of liver function tests or muscle enzymes is not recommended except in specific circumstances.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The recommendations are supported by data from randomized controlled trials that included patients with diabetes. See related background article: Vijan S, Hayward RA; American College of Physicians. Pharmacologic lipid-lowering therapy in type 2 diabetes mellitus: background paper for the American College of Physicians. *Ann Intern Med.* 2004 Apr 20;140(8):650-8.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Appropriate lipid management in patients with type 2 diabetes and decreased risk of cardiovascular morbidity and mortality.

POTENTIAL HARMS

Not stated

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

- No studies of lipid-lowering therapy have been conducted solely in patients with diabetes. Moreover, many trials excluded patients with diabetes. The sample sizes of participants with diabetes were often small, and many studies reported results only for the combined groups. Thus, the reports included in this review are of the subgroup analyses for studies that included patients with diabetes.
- Clinical practice guidelines are "guides" only and may not apply to all patients and all clinical situations. Thus, they are not intended to override clinicians' judgment.
- All American College of Physicians (ACP) clinical practice guidelines are considered automatically withdrawn or invalid 5 years after publication or once an update has been issued.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

IMPLEMENTATION TOOLS

Patient Resources

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
Staying Healthy

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Snow V, Aronson MD, Hornbake ER, Mottur-Pilson C, Weiss KB. Lipid control in the management of type 2 diabetes mellitus: a clinical practice guideline from the

American College of Physicians. Ann Intern Med 2004 Apr 20;140(8):644-9. [28 references] [PubMed](#)

ADAPTATION

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

DATE RELEASED

2004 Apr 20

GUIDELINE DEVELOPER(S)

American College of Physicians - Medical Specialty Society

SOURCE(S) OF FUNDING

American College of Physicians

GUIDELINE COMMITTEE

Clinical Efficacy Assessment Subcommittee (CEAS)

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

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Clinical Efficacy Assessment Subcommittee Members: Kevin Weiss, MD (Chair); Mark Aronson, MD; Patricia Barry, MD; Virginia Collier, MD; J. Thomas Cross Jr., MD; Nick Fitterman, MD; E. Rodney Hornbake, MD; Douglas K. Owens, MD; Katherine D. Sherif, MD

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Financial support for this guideline comes exclusively from the American College of Physicians operating budget.

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available from the American College of Physicians (ACP) Web site:

- [HTML Format](#)
- [Portable Document Format \(PDF\)](#)

Print copies: Available from the American College of Physicians (ACP), 190 N. Independence Mall West, Philadelphia PA 19106-1572.

AVAILABILITY OF COMPANION DOCUMENTS

The following is available:

- Vijan S, Hayward RA; American College of Physicians. Pharmacologic lipid-lowering therapy in type 2 diabetes mellitus: background paper for the American College of Physicians. *Ann Intern Med.* 2004 Apr 20;140(8):650-8.

Electronic copies: Available from the American College of Physicians (ACP) Web site:

- [HTML Format](#)
- [Portable Document Format \(PDF\)](#)

Print copies: Available from the American College of Physicians (ACP), 190 N. Independence Mall West, Philadelphia PA 19106-1572.

PATIENT RESOURCES

The following is available:

- Summaries for patients. Control of lipids in patients with Type 2 Diabetes: recommendations from the American College of Physicians. *Ann Intern Med* 2004 Apr 20; 140 (8): I-85

Electronic copies: Available from the American College of Physicians (ACP) Web site:

- [HTML Format](#)
- [Portable Document Format \(PDF\)](#)

Print copies: Available from the American College of Physicians (ACP), 190 N. Independence Mall West, Philadelphia PA 19106-1572.

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NGC STATUS

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Date Modified: 9/15/2008

