



# Introduction

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Diabetes is a complex, chronic illness requiring continuous medical care with multifactorial risk-reduction strategies beyond glycemic control. Ongoing patient self-management education and support are critical to preventing acute complications and reducing the risk of long-term complications. Significant evidence exists that supports a range of interventions to improve diabetes outcomes.

The American Diabetes Association's (ADA's) "Standards of Medical Care in Diabetes" is intended to provide clinicians, patients, researchers, payers, and other interested individuals with the components of diabetes care, general treatment goals, and tools to evaluate the quality of care. The Standards of Care recommendations are not intended to preclude clinical judgment and must be applied in the context of excellent clinical care, with adjustments for individual preferences, comorbidities, and other patient factors. For more detailed information about management of diabetes, please refer to *Medical Management of Type 1 Diabetes* (1) and *Medical Management of Type 2 Diabetes* (2).

The recommendations include screening, diagnostic, and therapeutic actions that are known or believed to favorably affect health outcomes of patients with diabetes. Many of these interventions have also been shown to be cost-effective (3).

The ADA strives to improve and update the Standards of Care to ensure that clinicians, health plans, and policy makers can continue to rely on them as the most authoritative and current guidelines for diabetes care.

## ADA STANDARDS, STATEMENTS, AND REPORTS

The ADA has been actively involved in the development and dissemination of diabetes care standards, guidelines, and related documents for over 20 years. ADA's clinical practice recommendations are viewed as important resources for health care professionals who care for people with diabetes. ADA's "Standards of Medical Care in Diabetes," position statements, and scientific statements undergo a formal review process by ADA's Professional Practice Committee (PPC) and the Executive Committee of the Board of Directors. The Standards and all ADA position statements, scientific statements, and consensus reports are available on the Association's Web site at <http://professional.diabetes.org/adastatements>.

**"Standards of Medical Care in Diabetes" Standards of Care:** *ADA position statement that provides key clinical practice recommendations.* The PPC performs an extensive literature search and updates the Standards annually based on the quality of new evidence.

### ADA Position Statement

*A position statement is an official ADA point of view or belief that contains clinical or research recommendations.* Position statements are issued on scientific or medical issues related to diabetes. They are published in ADA journals and other scientific/medical publications. ADA position statements are typically based on a systematic review or other review of published literature. Position statements undergo a formal review process. They are updated annually or as needed.

### ADA Scientific Statement

*A scientific statement is an official ADA point of view or belief that may or may not contain clinical or research recommendations.* Scientific statements contain scholarly synopsis of a topic related to diabetes. Workgroup reports fall into this category. Scientific statements are published in the ADA journals and other scientific/medical publications, as appropriate. Scientific statements also undergo a formal review process.

### Consensus Report

*A consensus report contains a comprehensive examination by an expert panel (i.e., consensus panel) of a scientific or medical issue related to diabetes.* A consensus report is not an ADA position and represents expert opinion only. The category may also include task force and expert committee reports. The need for a consensus report arises when clinicians or scientists desire guidance on a subject for which the evidence is contradictory or incomplete. A consensus report is typically developed immediately following a consensus conference where the controversial issue is extensively discussed. The report represents the panel's collective analysis, evaluation, and opinion at that point in time based in part on the conference proceedings. A consensus report does not undergo a formal ADA review process.

### GRADING OF SCIENTIFIC EVIDENCE

Since the ADA first began publishing practice guidelines, there has been considerable evolution in the evaluation of scientific evidence and in the development of evidence-based guidelines. In 2002, we developed a classification

"Standards of Medical Care in Diabetes" was originally approved in 1988. Most recent review/revision: October 2014.

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**Table 1—ADA evidence-grading system for “Standards of Medical Care in Diabetes”**

Level of evidence	Description
<b>A</b>	<p>Clear evidence from well-conducted, generalizable randomized controlled trials that are adequately powered, including</p> <ul style="list-style-type: none"> <li>• Evidence from a well-conducted multicenter trial</li> <li>• Evidence from a meta-analysis that incorporated quality ratings in the analysis</li> </ul> <p>Compelling nonexperimental evidence; i.e., “all or none” rule developed by the Centre for Evidence-Based Medicine at the University of Oxford</p> <p>Supportive evidence from well-conducted randomized controlled trials that are adequately powered, including</p> <ul style="list-style-type: none"> <li>• Evidence from a well-conducted trial at one or more institutions</li> <li>• Evidence from a meta-analysis that incorporated quality ratings in the analysis</li> </ul>
<b>B</b>	<p>Supportive evidence from well-conducted cohort studies</p> <ul style="list-style-type: none"> <li>• Evidence from a well-conducted prospective cohort study or registry</li> <li>• Evidence from a well-conducted meta-analysis of cohort studies</li> </ul> <p>Supportive evidence from a well-conducted case-control study</p>
<b>C</b>	<p>Supportive evidence from poorly controlled or uncontrolled studies</p> <ul style="list-style-type: none"> <li>• Evidence from randomized clinical trials with one or more major or three or more minor methodological flaws that could invalidate the results</li> <li>• Evidence from observational studies with high potential for bias (such as case series with comparison with historical controls)</li> <li>• Evidence from case series or case reports</li> </ul> <p>Conflicting evidence with the weight of evidence supporting the recommendation</p>
<b>E</b>	Expert consensus or clinical experience

system to grade the quality of scientific evidence supporting ADA recommendations for all new and revised ADA position statements. A recent analysis of the evidence cited in the Standards of Care found steady improvement in quality over the past 10 years, with last year’s Standards for the first time having the majority of bulleted recommendations supported by **A-** or **B-**level evidence (4). A grading system (**Table 1**) developed by ADA and modeled after existing methods was used to clarify

and codify the evidence that forms the basis for the recommendations.

ADA recommendations are assigned ratings of **A**, **B**, or **C**, depending on the quality of evidence. Expert opinion **E** is a separate category for recommendations in which there is no evidence from clinical trials, in which clinical trials may be impractical, or in which there is conflicting evidence. Recommendations with an **A** rating are based on large well-designed clinical trials or well-done meta-analyses. Generally, these

recommendations have the best chance of improving outcomes when applied to the population to which they are appropriate. Recommendations with lower levels of evidence may be equally important but are not as well supported.

Of course, evidence is only one component of clinical decision making. Clinicians care for patients, not populations; guidelines must always be interpreted with the individual patient in mind. Individual circumstances, such as comorbid and coexisting diseases, age, education, disability, and, above all, patients’ values and preferences, must be considered and may lead to different treatment targets and strategies. Also, conventional evidence hierarchies, such as the one adapted by the ADA, may miss nuances important in diabetes care. For example, although there is excellent evidence from clinical trials supporting the importance of achieving multiple risk factor control, the optimal way to achieve this result is less clear. It is difficult to assess each component of such a complex intervention.

## References

1. Kaufman FR (Ed.). *Medical Management of Type 1 Diabetes*, 6th ed. Alexandria, VA, American Diabetes Association, 2012
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3. Li R, Zhang P, Barker LE, Chowdhury FM, Zhang X. Cost-effectiveness of interventions to prevent and control diabetes mellitus: a systematic review. *Diabetes Care* 2010;33:1872–1894
4. Grant RW, Kirkman MS. Trends in the evidence level for the American Diabetes Association’s “Standards of Medical Care in Diabetes” from 2005 to 2014. *Diabetes Care* 2015;38:6–8