



# Introduction: *Standards of Medical Care in Diabetes—2021*

*Diabetes Care* 2020;44(Suppl. 1):S1–S2 | <https://doi.org/10.2337/dc21-S1NT>

Diabetes is a complex, chronic illness requiring continuous medical care with multifactorial risk-reduction strategies beyond glycemic control. Ongoing diabetes 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 (ADA) “Standards of Medical Care in Diabetes,” referred to as the Standards of Care, is intended to provide clinicians, patients, researchers, policy makers, 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 the management of diabetes, please refer to *Medical Management of Type 1 Diabetes* (1) and *Medical Management of Type 2 Diabetes* (2).

The recommendations in the Standards of Care 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 (3,4).

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 it as the most authoritative source for current guidelines for diabetes care.

## ADA STANDARDS, STATEMENTS, REPORTS, and REVIEWS

The ADA has been actively involved in the development and dissemination of diabetes care clinical practice recommendations and related documents for more than 30 years. The ADA’s Standards of Medical Care is viewed as an important resource for health care professionals who care for people with diabetes.

### Standards of Care

***The annual Standards of Care supplement to Diabetes Care contains official ADA position, is authored by the ADA, and provides all of the ADA’s current clinical practice recommendations.***

To update the Standards of Care, the ADA’s Professional Practice Committee (PPC) performs an extensive clinical diabetes literature search, supplemented with input from ADA staff and the medical community at large. The PPC updates the Standards of Care annually. However, the Standards of Care is a “living” document, where important updates are published online should the PPC determine that new evidence or regulatory changes (e.g., drug approvals, label changes) merit

immediate inclusion. More information on the “living Standards” can be found on the ADA’s professional website DiabetesPro at [professional.diabetes.org/content-page/living-standards](http://professional.diabetes.org/content-page/living-standards). The Standards of Care supersedes all previous ADA position statements—and the recommendations therein—on clinical topics within the purview of the Standards of Care; ADA position statements, while still containing valuable analysis, should not be considered the ADA’s current position. The Standards of Care receives annual review and approval by the ADA’s Board of Directors.

### ADA Statement

***An ADA statement is an official ADA point of view or belief that does not contain clinical practice recommendations and may be issued on advocacy, policy, economic, or medical issues related to diabetes.***

ADA statements undergo a formal review process, including a review by the appropriate ADA national committee, ADA science and medicine staff, and the ADA’s Board of Directors.

### Consensus Report

***A consensus report of a particular topic contains a comprehensive examination and is authored by an expert panel (i.e., consensus panel) and represents the panel’s collective analysis, evaluation, and opinion.***

The need for a consensus report arises when clinicians, scientists, regulators,

The “Standards of Medical Care in Diabetes” was originally approved in 1988. Most recent review/revision: December 2020.

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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

and/or policy makers desire guidance and/or clarity on a medical or scientific issue related to diabetes for which the evidence is contradictory, emerging, or incomplete. Consensus reports may also highlight gaps in evidence and propose areas of future research to address these gaps. A consensus report is not an ADA position but represents expert opinion only and is produced under the auspices of the ADA by invited experts. A consensus report may be developed after an ADA Clinical Conference or Research Symposium.

### Scientific Review

**A scientific review is a balanced review and analysis of the literature on a scientific or medical topic related to diabetes.**

A scientific review is not an ADA position and does not contain clinical practice recommendations but is produced under the auspices of the ADA by invited experts. The scientific review may provide a scientific rationale for clinical practice recommendations in the Standards of Care. The category may also include task force and expert committee reports.

### GRADING OF SCIENTIFIC EVIDENCE

Since the ADA first began publishing clinical practice guidelines, there has been considerable evolution in the evaluation of scientific evidence and in the development of evidence-based guidelines. In 2002, the ADA developed a classification system to grade the quality of scientific evidence supporting ADA recommendations. A 2015 analysis of the evidence cited in the Standards of Care found steady improvement in quality over the previous 10 years, with the 2014 Standards of Care for the first time having the majority of bulleted recommendations supported by **A** level or **B** level evidence (5). A grading system (Table 1) developed by the 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 the evidence in support of the recommendation. Expert opinion **E** is a separate category for recommendations in which there is no evidence from clinical trials, clinical trials may be impractical, or there

is conflicting evidence. Recommendations with **A** level evidence 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 for which they are appropriate. Recommendations with lower levels of evidence may be equally important but are not as well supported.

Of course, published 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. Furthermore, 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

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