Introduction and Methodology: *Standards of Care in Diabetes—2024*

*American Diabetes Association Professional Practice Committee**

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Diabetes is a complex, chronic condition requiring continuous medical care with multifactorial risk-reduction strategies beyond glycemic management. Ongoing diabetes self-management education and support are critical to empowering people, 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 Care in Diabetes," referred to here as the Standards of Care, is intended to provide clinicians, 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 ADA Professional Practice Committee (PPC) updates the Standards of Care annually and strives to include discussion of emerging clinical considerations in the text, and as evidence evolves, clinical guidance is added to the recommendations in the Standards of Care. 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 or technology approvals, label changes) merit immediate inclusion. More information on the "Living Standards" can be found on the ADA professional website DiabetesPro at professional.diabetes.org/content-page/living-standards. The Standards of Care supersedes all previously published ADA position statements—and the recommendations therein—on clinical topics within the purview of the Standards of Care; while still containing valuable analysis, ADA position statements should not be considered the current position of the ADA. The Standards of Care receives annual review and approval by the ADA Board of Directors and is reviewed by ADA staff and clinical leadership. The Standards of Care also undergoes external peer review annually.

SCOPE OF THE GUIDELINES

The recommendations in the Standards of Care include screening, diagnostic, and therapeutic actions that are known or believed to favorably affect health outcomes of people with diabetes. They also cover the prevention, screening, diagnosis, and management of diabetes-associated complications and comorbidities. The recommendations encompass care throughout the life span for youth (children aged birth to 11 years and adolescents aged 12–17 years), adults (aged 18–64 years), and older adults (aged ≥65 years). The recommendations cover the management of type 1 diabetes, type 2 diabetes, gestational diabetes mellitus, and other types of diabetes and/or hyperglycemic conditions.

The Standards of Care does not provide comprehensive treatment plans for complications associated with diabetes, such as diabetic retinopathy or diabetic foot ulcers, but offers guidance on how and when to screen for diabetes complications, management of complications in the primary care and diabetes care settings, and referral to specialists as appropriate. Similarly, regarding the psychosocial and behavioral health factors often associated with diabetes and that can affect diabetes care, the Standards of Care provides guidance on how and when to screen, management in the primary care and diabetes care settings, and referral but does not provide comprehensive management plans for conditions that require specialized care, such as mental illness.

TARGET AUDIENCE

The target audience for the Standards of Care includes primary care physicians, endocrinologists, nurse practitioners, physician associates/assistants, pharmacists, dietitians, diabetes care and education specialists, and all members of the diabetes care team. The Standards of Care also provides guidance to specialists caring for people with diabetes and its multitude of complications, such as cardiologists, nephrologists, emergency physicians, internists, pediatricians, psychologists, neurologists, ophthalmologists, and podiatrists. Additionally, these recommendations help payers, policy makers, researchers, research funding organizations, and advocacy groups to align their policies and resources and deliver optimal care for people living with diabetes.

The "Standards of Care in Diabetes," formerly called "Standards of Medical Care in Diabetes," was originally approved in 1988. The most recent full review and revision was in December 2023.

**A complete list of members of the American Diabetes Association Professional Practice Committee is provided in this section.*

Duality of interest information for each author is available at https://doi.org/10.2337/dc24-SDIS.

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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. The Standards of Care recommendations are not intended to preclude clinical judgment. They 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).

METHODOLOGY AND PROCEDURE

The Standards of Care includes discussion of evidence and clinical practice recommendations intended to optimize care for people with diabetes by assisting health care professionals and individuals in making shared decisions about diabetes care. The recommendations are informed by a systematic review of evidence and an assessment of the benefits and risks of alternative care options.

Professional Practice Committee

The PPC of the ADA is responsible for the Standards of Care. The PPC is an interprofessional expert committee comprising physicians, nurse practitioners, pharmacists, diabetes care and education specialists, registered dietitian nutritionists, behavioral health scientists, and others who have expertise in a range of areas including but not limited to adult and pediatric endocrinology, epidemiology, public health, behavioral health, cardiovascular risk management, microvascular complications, nephrology, neurology, ophthalmology, podiatry, clinical pharmacology, preconception and pregnancy care, weight management and diabetes prevention, and use of technology in diabetes management. Appointment to the PPC is based on excellence in clinical practice and research, with attention to appropriate representation of members based on considerations including but not limited to demographic, geographic, work setting, or identity characteristics (e.g., gender, ethnicity, ability level). A PPC chairperson is appointed by the ADA (currently N.A.E.) and oversees the committee. For the 2024 Standards of Care, as in previous years, two representatives from the American College of Cardiology (ACC) acted as experts and participated in the development of Section 10, "Cardiovascular Disease and Risk Management." ACC reviewed and approved the section. In addition, and new to the 2024 Standards of Care, one representative from the American Society for Bone and Mineral Research (ASBMR) and one representative from The Obesity Society (TOS) acted as external experts for the "Bone Health" subsection in Section 4, "Comprehensive Medical Evaluation and Assessment of Comorbidities," and Section 8, "Obesity and Weight Management for the Prevention and Treatment of Type 2 Diabetes," respectively. Both societies reviewed and approved the section or subsection in which they were involved.

Each section of the Standards of Care is reviewed annually and updated with the latest evidence-based recommendations by a PPC member designated as the section lead as well as subcommittee members. The subcommittees perform systematic literature reviews and identify and summarize the scientific evidence. An information specialist with knowledge and experience in literature searching (a librarian) is consulted as necessary. A guideline methodologist (R.R.B. for the 2024 Standards of Care) with expertise and training in evidence-based medicine and guideline development methodology oversees all methodological aspects of the development of the Standards of Care and serves as a statistical analyst.

Disclosure and Duality of Interest Management

All members of the expert panel (the PPC members and subject matter experts) and ADA staff are required to comply with the ADA policy on duality of interest, which requires disclosure of any financial, intellectual, or other interests that might be construed as constituting an actual, potential, or apparent conflict, regardless of relevancy to the guideline topic. For transparency, ADA requires full disclosure of all relationships. Full disclosure statements from all committee members are solicited and reviewed during the appointment process. Disclosures are then updated throughout the guideline development process (specifically before the start of every meeting), and disclosure statements are submitted by every Standards of Care author upon submission of the revised Standards of Care section. Members are required to disclose for a time frame that includes 1 year prior to initiation of the committee appointment process until publication of that year's Standards of Care. Potential dualities of interest are evaluated by a designated review group and, if necessary, the Legal Affairs Division of the ADA. The duality of interest assessment is based on the relative weight of the financial relationship (i.e., the monetary amount) and the relevance of the relationship (i.e., the degree to which an independent observer might reasonably interpret an association as related to the topic or recommendation of consideration). In addition, the ADA adheres to section 7 of the Council of Medical Specialty Societies "Code for Interactions with Companies" (3). The duality of interest review group also ensures the majority of the PPC and the PPC chair are without potential conflict relevant to the subject area. Furthermore, the PPC chair is required to remain unconflicted for 1 year after the publication of the Standards of Care. Members of the committee who disclose a potential duality of interest pertinent to any specific recommendation are prohibited from participating in discussions related to those recommendations. No expert panel members were employees of any pharmaceutical or medical device company during the development of the 2024 Standards of Care. Members of the PPC, their employers, and their disclosed potential dualities of interest are listed in the section "Disclosures: *Standards of Care in Diabetes—2024*." The ADA funds the development of the Standards of Care from general revenue and does not use industry support for this purpose.

Evidence Review

The Standards of Care subcommittee for each section creates an initial list of relevant clinical questions that is reviewed and discussed by the expert panel. In consultation with a systematic review expert, each subcommittee devises and executes systematic literature searches. For the 2024 Standards of Care, PubMed, Medline, and EMBASE were searched for the time periods of 1 June 2022 to 21 July 2023. Searches are limited to studies published in English. Subcommittee members also manually search journals, reference lists of conference proceedings, and regulatory agency websites. All potentially relevant

citations are then subjected to a full-text review. In consultation with the methodologist, the subcommittees prepare the evidence summaries and grading for each section of the Standards of Care. All PPC members discuss and review the evidence summaries and make revisions as appropriate. The final evidence summaries are then deliberated on by the PPC, and the recommendations that will appear in the Standards of Care are drafted.

Grading of Evidence and Recommendation Development

A grading system (**Table 1**) developed by the ADA and modeled after existing methods is used to clarify and codify the evidence that forms the basis for the recommendations in the Standards of Care. All of the recommendations in the Standards of Care are critical to comprehensive care regardless of rating. 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 assigned an **E** level of evidence are informed by key opinion leaders in the field of diabetes (members of the PPC) and cover important elements of clinical care. All Standards of Care recommendations receive a rating for the strength of the evidence and not for the strength of the recommendation. Recommendations with **A**-level evidence are based on large, well-designed randomized controlled trials or well-done meta-analyses of randomized controlled trials. 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 people, not populations; guidelines must always be interpreted with the individual person in mind. Individual circumstances, such as comorbid and coexisting diseases, age, education, disability, and, above all, the values and preferences of the person with diabetes, must be considered and may lead to different treatment goals 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.

Table 1—ADA evidence-grading system for "Standards of Care in Diabetes"

Level of evidence	Description
A	Clear evidence from well-conducted, generalizable randomized controlled trials that are adequately powered, including: • Evidence from a well-conducted multicenter trial • Evidence from a meta-analysis that incorporated quality ratings in the analysis Supportive evidence from well-conducted randomized controlled trials that are adequately powered, including: • Evidence from a well-conducted trial at one or more institutions • Evidence from a meta-analysis that incorporated quality ratings in the analysis
B	Supportive evidence from well-conducted cohort studies, including: • Evidence from a well-conducted prospective cohort study or registry • Evidence from a well-conducted meta-analysis of cohort studies Supportive evidence from a well-conducted case-control study
C	Supportive evidence from poorly controlled or uncontrolled studies, including: • Evidence from randomized clinical trials with one or more major or three or more minor methodological flaws that could invalidate the results • Evidence from observational studies with high potential for bias (such as case series with comparison with historical controls) • Evidence from case series or case reports Conflicting evidence with the weight of evidence supporting the recommendation
E	Expert consensus or clinical experience

Evidence to Recommendations

All accumulated evidence was reviewed and discussed by all PPC members during virtual meetings and a 2-day in-person meeting in Arlington, Virginia, in July 2023. Standards of Care recommendations were updated based on the newly acquired evidence, and all recommendations were voted on by the PPC, with 80% consensus required for any recommendation to be approved.

Revision Process

Public comment is particularly important in the development of clinical practice recommendations; it promotes transparency and provides key stake holders the opportunity to identify and address gaps in care. The ADA holds a year-long public comment period requesting feedback on the Standards of Care. The PPC reviews compiled feedback from the public in preparation for the annual update but considers more pressing updates throughout the year, which may be published as "living" Standards updates. Feedback from the larger clinical community and general public was invaluable for the revision of the 2023 Standards of Care. Readers who wish to comment on the 2024 Standards of Care are invited to do so at professional.diabetes.org/SOC.

Feedback for the Standards of Care is also obtained from external peer reviewers. The Standards of Care is reviewed by ADA clinical leadership and scientific and medical staff and is approved by the ADA Board of Directors, which includes health care professionals, scientists, and lay people. The ACC performs an independent external peer review and the ACC Board of Directors provides endorsement of Section 10, "Cardiovascular Disease and Risk Management." In addition, the ASBMR Board of Directors provides endorsement for the "Bone Health" subsection of Section 4, "Comprehensive Medical Evaluation and Assessment of Comorbidities," and the TOS Board of Directors provides endorsement for Section 8, "Obesity and Weight Management for the Prevention and Treatment of Type 2 Diabetes." The ADA adheres to the Council of Medical Specialty Societies revised "CMSS Principles for the Development of Specialty Society Clinical Guidelines" (4).

ADA STANDARDS, STATEMENTS, REPORTS, AND REVIEWS

The ADA has been actively involved in developing and disseminating diabetes care

clinical practice recommendations and related documents for more than 30 years. The ADA Standards of Care is an essential resource for health care professionals caring for people with diabetes. ADA Statements, Consensus Reports, and Scientific Reviews support the recommendations included in the Standards of Care.

Standards of Care

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

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 external peer review and review by the appropriate ADA national committee, ADA clinical leadership, science and health care staff, and, as warranted, the ADA Board of Directors.

Consensus Report

A consensus report on a particular topic contains a comprehensive examination, 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, 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 evidence gaps and propose future research areas 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. Consensus reports undergo a formal review process, including external peer review and review by the appropriate ADA national committee, ADA clinical leadership, and the science and health care staff.

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.

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