

# Summary of Revisions: *Standards* of Care in Diabetes—2023

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#### **GENERAL CHANGES**

The field of diabetes care is rapidly changing as new research, technology, and treatments that can improve the health and well-being of people with diabetes continue to emerge. With annual updates since 1989, the American Diabetes Association (ADA) has long been a leader in producing guidelines that capture the most current state of the field.

The 2023 Standards of Care includes revisions to incorporate person-first and inclusive language. Efforts were made to consistently apply terminology that empowers people with diabetes and recognizes the individual at the center of diabetes care.

Although levels of evidence for several recommendations have been updated, these changes are not outlined below where the clinical recommendation has remained the same. That is, changes in evidence level from, for example, **E** to **C** are not noted below. The 2023 Standards of Care contains, in addition to many minor changes that clarify recommendations or reflect new evidence, more substantive revisions detailed below.

#### SECTION CHANGES

# Section 1. Improving Care and Promoting Health in Populations

(https://doi.org/10.2337/dc23-S001)
Recommendation 1.7 was added to address the use of community health workers to support the management of diabetes and cardiovascular risk factors, especially in underserved communities and health care systems.

Additional language and definitions regarding digital health, telehealth, and telemedicine were added, along with the benefits of these modalities of care delivery, including social determinants of health in the telehealth subsection.

The subsection "Access to Care and Quality Improvement" was revised to add language regarding value-based payments to listed quality improvement efforts.

The "Migrant and Seasonal Agricultural Workers" subsection was updated to include more recent data for this population.

More defining terms were added for non-English speakers and diabetes education in the "Language Barriers" subsection.

# Section 2. Classification and Diagnosis of Diabetes

(https://doi.org/10.2337/dc23-S002)

Recommendation 2.1b was added to the "A1C" subsection to address the utility of point-of-care A1C testing for diabetes screening and diagnosis.

# Section 3. Prevention or Delay of Type 2 Diabetes and Associated Comorbidities

(https://doi.org/10.2337/dc23-S003) Recommendation 3.9 was added to address statin use and the risk of type 2 diabetes, including the recommendation to monitor glucose status regularly and enforce diabetes prevention approaches in individuals at high risk of developing type 2 diabetes who were prescribed statin therapy.

Recommendation 3.10 was added to address the use of pioglitazone for reducing the risk of stroke or myocardial infarction in people with history of stroke and evidence of insulin resistance and prediabetes.

Recommendation 3.12 was added to communicate that pharmacotherapy (e.g., weight management, minimizing the progression of hyperglycemia, cardiovascular risk reduction) may be considered to support person-centered care goals for people at high risk of developing diabetes.

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Recommendation 3.13 was added to state that more intensive preventive approaches should be considered for individuals who are at particularly high risk of progression to diabetes.

#### Section 4. Comprehensive Medical Evaluation and Assessment of Comorbidities

(https://doi.org/10.2337/dc23-S004) In Recommendation 4.3, language was modified to include evaluation for overall health status and setting of initial goals.

Considerable changes were made in the immunizations subsection to reflect new indications and guidance, particularly for COVID-19 and pneumococcal pneumonia vaccinations, including agespecific recommendations and the bivalent COVID-19 booster.

**Table 4.1** was modified to include changes throughout Section 4.

The subsection "Nonalcoholic Fatty Liver Disease" (NAFLD) incorporates more detail regarding its diagnosis and risk stratification in primary care and diabetes clinics, such as using the fibrosis-4 index to assess the risk of liver fibrosis, and includes a fibrosis-4 index risk calculator. It expands on the rationale for fibrosis risk stratification in people with diabetes and when to refer to a gastroenterologist or hepatologist for further workup.

Discussion was added about the management of people with type 2 diabetes who have NAFLD, highlighting lifestyle changes that promote weight loss, the use of obesity pharmacotherapy with emphasis on treatment with glucagon-like peptide 1 (GLP-1) receptor agonists, bariatric surgery, and the role of diabetes medications (e.g., pioglitazone and GLP-1 receptor agonists) to treat people with type 2 diabetes and nonalcoholic fatty liver disease (NASH).

Revisions to Section 4, including the addition of Fig. 4.2, are based on the American Gastroenterological Association 2021 "Preparing for the NASH Epidemic: A Call to Action" (reference 64 in this section) and its associated "Clinical Care Pathway for the Risk Stratification and Management of Patients with Nonalcoholic Fatty Liver Disease" (reference 66 in this section), agreed upon by a multidisciplinary task force of experts, including representatives of the ADA. Detailed recommendations from an ADA consensus statement will be published separately in 2023.

#### Section 5. Facilitating Positive Health Behaviors and Well-being to Improve Health Outcomes

(https://doi.org/10.2337/dc23-S005)
The title has been changed from "Facilitating Behavior Change and Well-being to Improve Health Outcomes" to be inclusive of strength-based language.

Recommendation 5.8 was added to the "Diabetes Self-Management Education and Support" subsection to address social determinants of health in guiding design and delivery of diabetes self-management education and support (DSMES). Additional information was also added supporting use of telehealth delivery of care and other digital health solutions to deliver DSMES.

Screening for food insecurity by any members of the health care team was added to the nutrition section.

A section on intermittent fasting and time-restricted eating was included in the "Eating Patterns and Meal Planning" subsection.

Emphasis was placed on supporting larger weight losses (up to 15%) based on efficacy and access of newer medications.

Language was added to Recommendation 5.23 about the harms of  $\beta$ -carotene supplementation based on the U.S. Preventative Services Task Force report.

The new subsection "Supporting Positive Health Behaviors" was added, including the addition of Recommendation 5.37, which encourages use of behavioral strategies by members of the diabetes care team, with the goal to support diabetes self-management and engagement in health behaviors to promote optimal diabetes health outcomes.

The "Psychosocial Issues" subsection was renamed "Psychosocial Care" to highlight the recommendations' emphasis on providing appropriate psychosocial support to people with diabetes as part of or in conjunction with standard diabetes care.

The "Psychosocial Care" subsection includes a new Recommendation 5.55 to screen for sleep health in people with diabetes and make referrals to sleep medicine and/or qualified behavioral health professional as indicated.

Other recommendations in this subsection were revised to specify the roles of diabetes care professionals as well as qualified mental/behavioral health professionals to provide psychosocial care, to specify topics for psychosocial screening, treatment, and referrals when indicated, and to include caregivers and family members of people with diabetes. Details were added about resources for developing psychosocial screening protocols and about intervention. Across the specific psychosocial domains (e.g., diabetes distress, anxiety), details were added about data supporting intervention and care approaches to support psychosocial and behavioral outcomes in people with diabetes and their family members.

#### Section 6. Glycemic Targets

(https://doi.org/10.2337/dc23-S006) New language was added to Recommendation 6.5b to outline that for those with frailty or at high risk of hypoglycemia, a target of >50% time in range with <1% time below range is now recommended.

Recommendation 6.9 was added to address the effectiveness of goal setting for glycemic control.

#### Section 7. Diabetes Technology

(https://doi.org/10.2337/dc23-S007)
The importance of "preference" for diabetes devices was added in all

recommendations.

Recommendation 7.12 for the use of continuous glucose monitoring (CGM) in adults with diabetes treated with basal

insulin was reworded to reflect updated

evidence in the literature.

Recommendation 7.15 was modified to state that people with diabetes should have uninterrupted access to their supplies to minimize gaps in CGM

Recommendation 7.19 was added to address CGM interfering substances, with evidence level **C**.

A new paragraph addressing substances and factors affecting CGM accuracy was added to the "Continuous Glucose Monitoring Devices" subsection. **Table 7.4** was added to address interfering substances for CGM.

Information was added on all three integrated CGM devices available, and it was specified that although there is more than one CGM system approved by the U.S. Food and Drug Administration (FDA) for use with automated insulin delivery systems, only one system with integrated CGM designation is FDA approved for

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use with automated insulin delivery systems.

Literature and information was added on benefits on glycemic outcomes of early initiation of real-time CGM in children and adults and the need to continue CGM use to maximize benefits.

The paragraph on connected pens was updated to include smart pen caps.

References were updated for automated insulin delivery systems to include all the approved systems in the U.S. in 2022.

The text was updated to include doit-yourself closed loop systems.

The "Inpatient Care" subsection was updated to include updated evidence and a paragraph on the use of CGM in the inpatient setting during the COVID-19 pandemic.

#### Section 8. Obesity and Weight Management for the Prevention and Treatment of Type 2 Diabetes

(https://doi.org/10.2337/dc23-S008) Language was amended to reinforce that obesity is a chronic disease.

Recommendation 8.5 was added to reinforce that both small and larger weight losses should be considered as treatment goals on a case-by-case basis. Notably, larger (10% or more) weight loss may have disease-modifying effects, including diabetes remission, and may improve long-term cardiovascular outcomes.

Dual GLP-1/glucose-dependent insulinotropic polypeptide (GIP) receptor agonist (tirzepatide) was added as a glucoselowering option with the potential for weight loss.

#### Section 9. Pharmacologic Approaches to Glycemic Treatment

(https://doi.org/10.2337/dc23-S009)
Section 9 was updated to align with the latest consensus report on management of hyperglycemia in type 2 diabetes by the American Diabetes Association (ADA) and the European Association for the Study of Diabetes (EASD). Recommendation 9.4a was added to state that healthy lifestyle behaviors, DSMES, avoidance of clinical inertia, and social determinants of health (SDOH) should be considered in the glucose-lowering management of type 2 diabetes.

Recommendation 9.4b was added to indicate that in adults with type 2 diabetes and established/high risk of atherosclerotic cardiovascular disease, heart failure,

and/or chronic kidney disease, the treatment plan should include agents that reduce cardiorenal risk.

Recommendation 9.4c was added to address the consideration of pharmacologic approaches that provide the efficacy to achieve treatment goals.

Recommendation 9.4d was added to address weight management as an impactful component of glucose-lowering management in type 2 diabetes.

Information was added to address considerations for a GLP-1 receptor agonist prior to prandial insulin to further address prandial control and to minimize the risks of hypoglycemia and weight gain associated with insulin therapy.

Information was added to address alternative insulin routes.

**Table 9.2** and **Fig. 9.3** were updated based on the latest consensus report on management of hyperglycemia in type 2 diabetes by the ADA and the EASD.

# Section 10. Cardiovascular Disease and Risk Management

(https://doi.org/10.2337/dc23-S010) Recommendation 10.1 was revised with updated definitions of hypertension. These recommendations align with the current definition of hypertension according to the American College of Cardiology and American Heart Association.

Recommendation 10.4 on blood pressure treatment goals in individuals with diabetes was revised to target a blood pressure of <130/80 mmHg. The discussion of the evidence to support this recommendation was extensively revised. In addition, the recently reported results of the STEP (Strategy of Blood Pressure Intervention in the Elderly Hypertensive Patients) trial were added. Recommendation 10.7 was updated to consider pharmacological treatment in people with diabetes and a confirmed blood pressure ≥130/80. Table 10.1 and Fig. 10.2 were updated accordingly.

In the subsection "Pregnancy and Antihypertensive Medications," the results of the CHAP (Chronic Hypertension and Pregnancy) trial were included to further support the current treatment goal recommendations in pregnant individuals with diabetes.

Recommendation 10.20 was revised to recommend the use of high-intensity statin therapy in individuals with diabetes aged 40–75 years at higher risk, including those with one or more

atherosclerotic cardiovascular disease risk factors, to reduce the LDL cholesterol by ≥50% of baseline and to target an LDL cholesterol goal of <70 mg/dL.

Recommendation 10.21 was added to consider adding treatment with ezetimibe or a PCSK9 inhibitor to maximum tolerated statin therapy in these individuals.

Recommendations 10.22 and 10.23 were added to recommend continuing statin therapy in adults with diabetes aged >75 years currently receiving statin therapy and to recommend that it may be reasonable to initiate moderate-intensity statin therapy in adults with diabetes aged >75 years, respectively.

Recommendation 10.26 was updated to recommend treatment with high-intensity statin therapy in individuals with diabetes and established atherosclerotic cardiovascular disease to target an LDL cholesterol reduction of ≥50% from baseline and an LDL cholesterol goal of <55 mg/dL. If this goal is not achieved on maximum tolerated statin therapy, the addition of ezetimibe or a PCSK9 inhibitor is now recommended.

Language regarding evidence in the section "Statin Treatment" was revised to consider the evidence supporting lower LDL cholesterol goals in people with diabetes with and without established cardiovascular disease.

In the subsection "Combination Therapy for LDL Cholesterol Lowering" a paragraph was added to include inclisiran, an siRNA directed against PCSK9, as a new FDAapproved cholesterol-lowering therapy.

Recommendation 10.42b was added to recommend treatment with a so-dium-glucose cotransporter 2 inhibitor in individuals with type 2 diabetes and established heart failure with either preserved or reduced ejection fraction to improve symptoms, physical limitations, and quality of life. The discussion of evidence to support this new recommendation was included in the last paragraph of the section "Glucose-Lowering Therapies and Heart Failure."

Recommendation 10.43 was added to recommend the addition of finerenone in the treatment of individuals with type 2 diabetes and chronic kidney disease with albuminuria treated with maximum tolerated doses of ACE inhibitor or angiotensin receptor blocker.

This section is endorsed for the fifth consecutive year by the American College of Cardiology.

# Section 11. Chronic Kidney Disease and Risk Management

(https://doi.org/10.2337/dc23-S011)

The recommendation order was rearranged to reflect the appropriate order for clinical interventions aimed at preventing and slowing progression of chronic kidney disease.

In Recommendation 11.5a, the levels at which a sodium–glucose cotransporter 2 inhibitor could be initiated were changed. The new levels for initiation are an estimated glomerular filtration rate  $\geq$ 20 mL/min/1.73 m<sup>2</sup> and urinary albumin  $\geq$ 200 mg/g creatinine.

Recommendation 11.5b also recommends that sodium–glucose cotransporter 2 inhibitor might also be effective in people with urinary albumin of normal to ≥200 mg/g creatinine, but this is **B** level at this time, as the study reporting this has not been published.

Mineralocorticoid receptor antagonists are now recommended along with other medications for cardiovascular and kidney protection rather than as alternatives when other treatments have not been effective.

Recommendation 11.8 addressing referral to a nephrologist was expanded to include referrals for continuously increasing urine albumin-to-creatinine ratio and/or for continuously decreasing estimated glomerular filtration rate.

# Section 12. Retinopathy, Neuropathy, and Foot Care

(https://doi.org/10.2337/dc23-S012) Language regarding pregnancy as a risk factor for retinopathy in people with preexisting type 1 or type 2 diabetes was revised and updated.

Screening details about autonomic neuropathy were added to Recommendation 12.17.

Language was added to the neuropathy screening subsection to clarify that treatments of other modifiable risk factors (including lipids and blood pressure) can aid in prevention of diabetic peripheral neuropathy progression in type 2 diabetes and may reduce disease progression in type 1 diabetes.

Information was added to the "Diabetic Autonomic Neuropathy" subsection to include criteria for screening for symptoms of autonomic neuropathy.

Additional references were added to support Recommendation 12.18.

Recommendation 12.20 was revised to reflect that gabapentinoids, serotonin-norepinephrine reuptake inhibitors, tricy-clic antidepressants, and sodium channel blockers are recommended as initial pharmacologic treatments for neuropathic pain in diabetes and that health care professionals should refer to a neurologist or pain specialist when pain control is not achieved within the scope of practice of the treating physician.

New information was added in the "Neuropathy" subsection, under "Treatment," to address lipid control and blood pressure control.

The "Neuropathic Pain" subsection includes an expanded discussion of treating neuropathic pain in people with diabetes.

Recommendation 12.25 was added to address screening for peripheral arterial disease.

Recommendation 12.26 was revised to include peripheral arterial disease.

Recommendation 12.27 was edited to signify that not all people who smoke are referred to foot care specialists but that a referral is now recommended for people who smoke and also have other risk factors or symptoms.

Recommendation 12.29 was edited to reflect a change from "severe neuropathy" to "loss of protective sensation," which is consistent with other recommendations.

Recommendation 12.30 was edited to reflect that topical oxygen therapy is not equivalent to hyperbaric oxygen therapy.

#### Section 13. Older Adults

(https://doi.org/10.2337/dc23-S013)

The language in Recommendation 13.5 was strengthened for older adults with type 1 diabetes to recommend continuous glucose monitoring to reduce hypoglycemia with an evidence grade of A based on a 6-month extension of the Wireless Innovation in Seniors with Diabetes Mellitus (WISDM) trial and observational data from the Diabetes Control and Complications Trial/Epidemiology of Diabetes Interventions and Complications (DCCT/EDIC) study.

Recommendation 13.6 was added to communicate that for older adults with type 2 diabetes on multiple daily doses of insulin, continuous glucose monitoring should be considered to improve glycemic outcomes and decrease glucose variability, with an evidence grade of **B** based on results of the DIAMOND (Multiple Daily

Injections and Continuous Glucose Monitoring in Diabetes) trial.

A new Recommendation 13.7 was added: for older adults with type 1 diabetes, consider the use of automated insulin delivery systems (evidence grade B) and other advanced insulin delivery devices such as connected pens (evidence grade E) should be considered to reduce risk of hypoglycemia, based on individual ability. The addition of this recommendation was based on the results of two small randomized controlled trials (RCTs) in older adults, which demonstrated that hybrid closed-loop advanced insulin delivery improved glucose metrics relative to sensor-augmented pump therapy.

Blood pressure treatment goals in **Table 13.1** were lowered to align with evidence from multiple recent trials.

Recommendation 13.15 was split into two recommendations (now 13.17 and 13.18) to acknowledge the conceptual differences between deintensification of goals (13.17) and simplification of complex regimens (13.18).

In recommendation 13.17, deintensification of treatment goals is now recommended to reduce the risk of hypoglycemia if it can be achieved within the individualized A1C target.

In a new recommendation 13.18, simplification of complex treatment plans (especially insulin) is now recommended to reduce the risk of hypoglycemia and polypharmacy and decrease the burden of the disease if it can be achieved within the individualized A1C target.

Recommendation 13.22 was added to consider use of CGM to assess risk for hypoglycemia in older adults treated with sulfonylureas or insulin, despite the lack of evidence.

# Section 14. Children and Adolescents (https://doi.org/10.2337/dc23-S014)

In Recommendations 14.14, 14.106, and 14.107, the language was changed from "assess" to "screen" for consistency with Section 5.

In Recommendations 14.14 and 14.17, text was added for referral to a qualified mental health professional for further assessment and treatment.

More details were added to Recommendation 14.50 on foot examinations for neuropathy.

In Recommendations 14.97 and 14.98, "girls" was changed to "female individuals"

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for more consistency in the Standards of Care.

In Recommendation 14.110, "patients" was changed to "adolescents and young adults" for clarity.

In Recommendation 14.111, "pediatric diabetes provider" was changed to "pediatric diabetes care teams" to reflect the teambased nature of diabetes care.

In Recommendation 14.113, "patient" was changed to "young adult" for clarity.

# Section 15. Management of Diabetes in Pregnancy

(https://doi.org/10.2337/dc23-S015)
Recommendation 15.13 was added to endorse nutrition counseling to improve the quality of carbohydrates and promote a balance of macronutrients including nutrient-dense fruits, vegetables, legumes, whole grains, and healthy fats with n-3 fatty acids that include nuts and seeds and fish in the eating pattern.

Evidence for preconception counseling was strengthened.

A new study demonstrates that the cost of CGM in pregnancies complicated by type 1 diabetes is offset by improved maternal and neonatal outcomes and provides further support for the use CGM.

Recommendation 15.20 is now a composite recommendation based on two different multicentered RCTs with

different methodologies and different outcomes. Both RCTs support stricter blood pressure targets in pregnancy to improve outcomes. This modification is based on new data from the Chronic Hypertension and Pregnancy (CHAP) trial, which included individuals with preexisting diabetes.

The new Recommendation 15.27 supports breastfeeding to reduce the risk of maternal type 2 diabetes. The benefit of breastfeeding should be considered when choosing whether to breastfeed or formula feed.

New language was added to the text regarding the role of weight/BMI after gestational diabetes mellitus (GDM). Systematic reviews and meta-analyses demonstrate each of the following: weight loss reduces the risk of developing GDM in the subsequent pregnancy, the risk of type 2 diabetes increases by 18% per unit of BMI above the prepregnancy BMI at follow-up, and post-delivery lifestyle interventions are effective in reducing risk of type 2 diabetes. These studies highlight the importance of effective weight management after GDM.

### Section 16. Diabetes Care in the Hospital

(https://doi.org/10.2337/dc23-S016) In Recommendation 16.2, additional information was added to support the use of computerized prescriber order entry (CPOE) to facilitate glycemic management as well as insulin dosing algorithms using machine learning in the future to inform these algorithms.

In Recommendation 16.5, the need for individualization of targets was expanded to include a target range of 100–180 mg/dL (5.6–10.0 mmol/L) for noncritically ill patients with "new" hyperglycemia as well as patients with known diabetes prior to admission.

Recommendation 16.7 was revised to reflect that an insulin regimen with basal, prandial, and correction components is the preferred treatment for most non-critically ill hospitalized patients with adequate nutritional intake.

Use of personal CGM and automated insulin delivery devices that can automatically deliver correction insulin doses and change basal insulin delivery rates in real time should be supported during hospitalization when independent self-management is feasible and proper management supervision is available.

#### Section 17. Diabetes Advocacy

(https://doi.org/10.2337/dc23-S017)

The Diabetes Care and Detention Facilities advocacy statement has been removed from this section pending future updates.