



American Diabetes Association

# 1. Improving Care and Promoting Health in Populations: *Standards of Medical Care in Diabetes—2021*

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The American Diabetes Association (ADA) “Standards of Medical Care in Diabetes” includes the ADA’s current clinical practice recommendations and is intended to provide the components of diabetes care, general treatment goals and guidelines, and tools to evaluate quality of care. Members of the ADA Professional Practice Committee, a multidisciplinary expert committee (<https://doi.org/10.2337/dc21-SPPC>), are responsible for updating the Standards of Care annually, or more frequently as warranted. For a detailed description of ADA standards, statements, and reports, as well as the evidence-grading system for ADA’s clinical practice recommendations, please refer to the Standards of Care Introduction (<https://doi.org/10.2337/dc21-SINT>). Readers who wish to comment on the Standards of Care are invited to do so at [professional.diabetes.org/SOC](http://professional.diabetes.org/SOC).

## DIABETES AND POPULATION HEALTH

### Recommendations

- 1.1 Ensure treatment decisions are timely, rely on evidence-based guidelines, and are made collaboratively with patients based on individual preferences, prognoses, and comorbidities. **B**
- 1.2 Align approaches to diabetes management with the Chronic Care Model. This model emphasizes person-centered team care, integrated long-term treatment approaches to diabetes and comorbidities, and ongoing collaborative communication and goal setting between all team members. **A**
- 1.3 Care systems should facilitate team-based care and utilization of patient registries, decision support tools, and community involvement to meet patient needs. **B**
- 1.4 Assess diabetes health care maintenance (see **Table 4.1**) using reliable and relevant data metrics to improve processes of care and health outcomes, with attention to care costs. **B**

Population health is defined as “the health outcomes of a group of individuals, including the distribution of health outcomes within the group”; these outcomes can be measured in terms of health outcomes (mortality, morbidity, health, and functional status), disease burden (incidence and prevalence), and behavioral and metabolic factors (exercise, diet, A1C, etc.) (1). Clinical practice recommendations for health care providers are tools that can ultimately improve health across populations; however, for optimal outcomes, diabetes care must also be individualized for each patient. Thus, efforts to improve population health will require a combination of policy-level, system-level, and patient-level approaches. With such an integrated approach in

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mind, the American Diabetes Association (ADA) highlights the importance of *patient-centered care*, defined as care that considers individual patient comorbidities and prognoses; is respectful of and responsive to patient preferences, needs, and values; and ensures that patient values guide all clinical decisions (2). Further, social determinants of health (SDOH)—often out of direct control of the individual and potentially representing lifelong risk—contribute to medical and psychosocial outcomes and must be addressed to improve all health outcomes (3). Clinical practice recommendations, whether based on evidence or expert opinion, are intended to guide an overall approach to care. The science and art of medicine come together when the clinician is faced with making treatment recommendations for a patient who may not meet the eligibility criteria used in the studies on which guidelines are based. Recognizing that one size does not fit all, the standards presented here provide guidance for when and how to adapt recommendations for an individual.

### Care Delivery Systems

The proportion of patients with diabetes who achieve recommended A1C, blood pressure, and LDL cholesterol levels has fluctuated in recent years (4). Glycemic control and control of cholesterol through dietary intake remain challenging. In 2013–2016, 64% of adults with diagnosed diabetes met individualized A1C target levels, 70% achieved recommended blood pressure control, 57% met the LDL cholesterol target level, and 85% were nonsmokers (4). Only 23% met targets for glycemic, blood pressure, and LDL cholesterol measures while also avoiding smoking (4). The mean A1C nationally among people with diabetes increased slightly from 7.3% in 2005–2008 to 7.5% in 2013–2016 based on the National Health and Nutrition Examination Survey (NHANES), with younger adults, women, and non-Hispanic Black individuals less likely to meet treatment targets (4). Certain segments of the population, such as young adults and patients with complex comorbidities, financial or other social hardships, and/or limited English proficiency, face particular challenges to goal-based care (5–7). Even after adjusting for these patient factors, the persistent variability in the quality of diabetes care across providers and practice settings indicates that substantial system-level improvements are still needed.

Diabetes poses a significant financial burden to individuals and society. It is estimated that the annual cost of diagnosed diabetes in 2017 was \$327 billion, including \$237 billion in direct medical costs and \$90 billion in reduced productivity. After adjusting for inflation, economic costs of diabetes increased by 26% from 2012 to 2017 (8). This is attributed to the increased prevalence of diabetes and the increased cost per person with diabetes. Ongoing population health strategies are needed in order to reduce costs and provide optimized care.

### Chronic Care Model

Numerous interventions to improve adherence to the recommended standards have been implemented. However, a major barrier to optimal care is a delivery system that is often fragmented, lacks clinical information capabilities, duplicates services, and is poorly designed for the coordinated delivery of chronic care. The Chronic Care Model (CCM) takes these factors into consideration and is an effective framework for improving the quality of diabetes care (9).

**Six Core Elements.** The CCM includes six core elements to optimize the care of patients with chronic disease:

1. Delivery system design (moving from a *reactive* to a *proactive* care delivery system where planned visits are coordinated through a team-based approach)
2. Self-management support
3. Decision support (basing care on evidence-based, effective care guidelines)
4. Clinical information systems (using registries that can provide patient-specific and population-based support to the care team)
5. Community resources and policies (identifying or developing resources to support healthy lifestyles)
6. Health systems (to create a quality-oriented culture)

A 5-year effectiveness study of the CCM in 53,436 primary care patients with type 2 diabetes suggested that the use of this model of care delivery reduced the cumulative incidence of diabetes-related complications and all-cause mortality (10). Patients who were enrolled in the CCM experienced a reduction in cardiovascular disease (CVD) risk by 56.6%, microvascular complications by 11.9%,

and mortality by 66.1% (10). The same study suggested that health care utilization was lower in the CCM group, which resulted in health care savings of \$7,294 per individual over the study period (11).

Redefining the roles of the health care delivery team and empowering patient self-management are fundamental to the successful implementation of the CCM (12). Collaborative, multidisciplinary teams are best suited to provide care for people with chronic conditions such as diabetes and to facilitate patients' self-management (13–15). There are references to guide the implementation of the CCM into diabetes care delivery, including opportunities and challenges (16).

### Strategies for System-Level Improvement

Optimal diabetes management requires an organized, systematic approach and the involvement of a coordinated team of dedicated health care professionals working in an environment where patient-centered, high-quality care is a priority (7,17,18). While many diabetes processes of care have improved nationally in the past decade, the overall quality of care for patients with diabetes remains suboptimal (4). Efforts to increase the quality of diabetes care include providing care that is concordant with evidence-based guidelines (19); expanding the role of teams to implement more intensive disease management strategies (7,20,21); tracking medication-taking behavior at a systems level (22); redesigning the organization of the care process (23); implementing electronic health record tools (24,25); empowering and educating patients (26,27); removing financial barriers and reducing patient out-of-pocket costs for diabetes education, eye exams, diabetes technology, and necessary medications (7); assessing and addressing psychosocial issues (28,29); and identifying, developing, and engaging community resources and public policies that support healthy lifestyles (30). The National Diabetes Education Program maintains an online resource ([www.cdc.gov/diabetes/ndep/training-tech-assistance/index.html](http://www.cdc.gov/diabetes/ndep/training-tech-assistance/index.html)) to help health care professionals design and implement more effective health care delivery systems for those with diabetes. Given the pluralistic needs of patients with diabetes and how the constant challenges they experience vary over the course of disease management (complex

insulin regimens, new technology, etc.), a diverse team with complementary expertise is consistently recommended (31).

#### **Care Teams**

The care team, which centers around the patient, should avoid therapeutic inertia and prioritize timely and appropriate intensification of lifestyle and/or pharmacologic therapy for patients who have not achieved the recommended metabolic targets (32–34). Strategies shown to improve care team behavior and thereby catalyze reductions in A1C, blood pressure, and/or LDL cholesterol include engaging in explicit and collaborative goal setting with patients (35,36); identifying and addressing language, numeracy, or cultural barriers to care (37–39); integrating evidence-based guidelines and clinical information tools into the process of care (19,40,41); soliciting performance feedback, setting reminders, and providing structured care (e.g., guidelines, formal case management, and patient education resources) (7); and incorporating care management teams including nurses, dietitians, pharmacists, and other providers (20,42). Initiatives such as the Patient-Centered Medical Home show promise for improving health outcomes by fostering comprehensive primary care and offering new opportunities for team-based chronic disease management (43).

#### **Telemedicine**

Telemedicine is a growing field that may increase access to care for patients with diabetes. The American Telemedicine Association defines telemedicine as the use of medical information exchanged from one site to another via electronic communications to improve a patient's clinical health status. Telemedicine includes a growing variety of applications and services using two-way video, smartphones, wireless tools, and other forms of telecommunications technology (44). Increasingly, evidence suggests that various telemedicine modalities may be effective at reducing A1C in patients with type 2 diabetes compared with usual care or in addition to usual care (45). For rural populations or those with limited physical access to health care, telemedicine has a growing body of evidence for its effectiveness, particularly with regard to glycemic control as measured by A1C (46–48). Interactive strategies that facilitate communication between providers and

patients, including the use of web-based portals or text messaging and those that incorporate medication adjustment, appear more effective. Telemedicine and other virtual environments can also be used to offer diabetes self-management education and clinical support and remove geographic and transportation barriers for patients living in underresourced areas or with disabilities (49). There is limited data available on the cost-effectiveness of these strategies.

#### **Behaviors and Well-being**

Successful diabetes care also requires a systematic approach to supporting patients' behavior-change efforts. High-quality diabetes self-management education and support (DSMES) has been shown to improve patient self-management, satisfaction, and glucose outcomes. National DSMES standards call for an integrated approach that includes clinical content and skills, behavioral strategies (goal setting, problem solving), and engagement with psychosocial concerns (29). For more information on DSMES, see Section 5 "Facilitating Behavior Change and Well-being to Improve Health Outcomes" (<https://doi.org/10.2337/dc21-S005>).

#### **Cost Considerations**

The cost of diabetes medications, particularly insulin, is an ongoing barrier to achieving glycemic goals. Up to 25% of patients who are prescribed insulin report cost-related insulin underuse (50). Insulin underuse due to cost has also been termed cost-related medication nonadherence (CRN). The cost of insulin has continued to increase in recent years for reasons that are not entirely clear. There are recommendations from the ADA Insulin Access and Affordability Working Group for approaches to this issue from a systems level (51). Recommendations including concepts such as cost-sharing for insured people with diabetes should be based on the lowest price available, list price for insulins that closely reflect net price, and health plans that ensure that people with diabetes can access insulin without undue administrative burden or excessive cost (51). Reduction in CRN is associated with better biologic and psychologic outcomes, including quality of life.

#### **Access to Care and Quality Improvement**

The Affordable Care Act and Medicaid expansion have resulted in increased

access to care for many individuals with diabetes with an emphasis on the protection of people with preexisting conditions, health promotion, and disease prevention (52). In fact, health insurance coverage increased from 84.7% in 2009 to 90.1% in 2016 for adults with diabetes aged 18–64 years. Coverage for those  $\geq 65$  years remained nearly universal (53). Patients who have either private or public insurance coverage are more likely to meet quality indicators for diabetes care (54). As mandated by the Affordable Care Act, the Agency for Healthcare Research and Quality developed a National Quality Strategy based on the triple aims that include improving the health of a population, overall quality and patient experience of care, and per capita cost (55,56). As health care systems and practices adapt to the changing landscape of health care, it will be important to integrate traditional disease-specific metrics with measures of patient experience, as well as cost, in assessing the quality of diabetes care (57,58). Information and guidance specific to quality improvement and practice transformation for diabetes care is available from the National Institute of Diabetes and Digestive and Kidney Diseases guidance on diabetes care and quality (59). Using patient registries and electronic health records, health systems can evaluate the quality of diabetes care being delivered and perform intervention cycles as part of quality improvement strategies (60). Improvement of health literacy and numeracy is also a necessary component to improve care (61,62). Critical to these efforts is provider adherence to clinical practice recommendations (see **Table 4.1**) and the use of accurate, reliable data metrics that include sociodemographic variables to examine health equity within and across populations (63).

In addition to quality improvement efforts, other strategies that simultaneously improve the quality of care and potentially reduce costs are gaining momentum and include reimbursement structures that, in contrast to visit-based billing, reward the provision of appropriate and high-quality care to achieve metabolic goals (64) and incentives that accommodate personalized care goals (7,65). (Also see **COST CONSIDERATIONS** above regarding CRN reduction.)

## TAILORING TREATMENT FOR SOCIAL CONTEXT

### Recommendations

- 1.5 Assess food insecurity, housing insecurity/homelessness, financial barriers, and social capital/social community support and apply that information to treatment decisions. **A**
- 1.6 Refer patients to local community resources when available. **B**
- 1.7 Provide patients with self-management support from lay health coaches, navigators, or community health workers when available. **A**

Health inequities related to diabetes and its complications are well documented, heavily influenced by SDOH, and have been associated with greater risk for diabetes, higher population prevalence, and poorer diabetes outcomes (66–70). SDOH are defined as the economic, environmental, political, and social conditions in which people live and are responsible for a major part of health inequality worldwide (71). Greater exposure to adverse SDOH over the life-course results in worse health (72). The ADA recognizes the association between social and environmental factors and the prevention and treatment of diabetes and has issued a call for research that seeks to better understand how these social determinants influence behaviors and how the relationships between these variables might be modified for the prevention and management of diabetes (73,74). While a comprehensive strategy to reduce diabetes-related health inequities in populations has not been formally studied, general recommendations from other chronic disease management and prevention models can be drawn upon to inform systems-level strategies in diabetes (75). For example, the National Academy of Medicine has published a framework for educating health care professionals on the importance of SDOH (76). Furthermore, there are resources available for the inclusion of standardized sociodemographic variables in electronic medical records to facilitate the measurement of health inequities as well as the impact of interventions designed to reduce those inequities (76–78).

SDOH are not always recognized and often go undiscussed in the clinical encounter (69). A study by Piette et al. (79) found that among patients with chronic illnesses, two-thirds of those who reported not taking medications as prescribed due to CRN never shared this with their physician. In a study using data from the National Health Interview Survey (NHIS), Patel et al. (69) found that one-half of adults with diabetes reported financial stress and one-fifth reported food insecurity. One population in which such issues must be considered is older adults, where social difficulties may impair the quality of life and increase the risk of functional dependency (80) (see Section 12 “Older Adults,” <https://doi.org/10.2337/dc21-S012>, for a detailed discussion of social considerations in older adults). Creating systems-level mechanisms to screen for SDOH may help overcome structural barriers and communication gaps between patients and providers (69,81). In addition, brief, validated screening tools for some SDOH exist and could facilitate discussion around factors that significantly impact treatment during the clinical encounter. Below is a discussion of assessment and treatment considerations in the context of food insecurity, homelessness, limited English proficiency, limited health literacy, and low literacy.

### Food Insecurity

Food insecurity is the unreliable availability of nutritious food and the inability to consistently obtain food without resorting to socially unacceptable practices. Over 18% of the U.S. population reported food insecurity between 2005 and 2014 (82). The rate is higher in some racial/ethnic minority groups, including African American and Latino populations, low-income households, and homes headed by a single mother. The rate of food insecurity in individuals with diabetes may be up to 20% (83). Additionally, the risk for type 2 diabetes is increased twofold in those with food insecurity (73) and has been associated with low adherence to taking medications appropriately and recommended self-care behaviors, depression, diabetes distress, and worse glycemic control when compared with individuals who are food secure (84,85). Older adults with food insecurity are more likely to have emergency department visits and

hospitalizations compared with older adults who do not report food insecurity (86). Risk for food insecurity can be assessed with a validated two-item screening tool (87) that includes the statements: 1) “Within the past 12 months we worried whether our food would run out before we got money to buy more” and 2) “Within the past 12 months the food we bought just didn’t last and we didn’t have money to get more.” An affirmative response to either statement had a sensitivity of 97% and specificity of 83%. Interventions such as food prescription programs are considered promising practices to address food insecurity by integrating community resources into primary care settings and directly deal with food deserts in underserved communities (88,89).

### Treatment Considerations

In those with diabetes and food insecurity, the priority is mitigating the increased risk for uncontrolled hyperglycemia and severe hypoglycemia. Reasons for the increased risk of hyperglycemia include the steady consumption of inexpensive carbohydrate-rich processed foods, binge eating, financial constraints to filling diabetes medication prescriptions, and anxiety/depression leading to poor diabetes self-care behaviors. Hypoglycemia can occur as a result of inadequate or erratic carbohydrate consumption following the administration of sulfonylureas or insulin. See **Table 9.1** for drug-specific and patient factors, including cost and risk of hypoglycemia, which may be important considerations for adults with food insecurity and type 2 diabetes. Providers should consider these factors when making treatment decisions in people with food insecurity and seek local resources that might help patients with diabetes and their family members to more regularly obtain nutritious food (90).

### Homelessness and Housing Insecurity

Homelessness/housing insecurity often accompanies many additional barriers to diabetes self-management, including food insecurity, literacy and numeracy deficiencies, lack of insurance, cognitive dysfunction, and mental health issues (91). The prevalence of diabetes in the homeless population is estimated to be around 8% (92). Additionally, patients with diabetes who are homeless need secure places to keep their diabetes supplies, as well as refrigerator access to properly store their

insulin and take it on a regular schedule. Risk for homelessness can be ascertained using a brief risk assessment tool developed and validated for use among veterans (93). Housing insecurity has also been shown to be directly associated with a person's ability to maintain their diabetes self-management (94). Given the potential challenges, providers who care for either homeless or housing-insecure individuals should be familiar with resources or have access to social workers that can facilitate stable housing for their patients as a way to improve diabetes care (95).

### Migrant and Seasonal Agricultural Workers

Migrant and seasonal agricultural workers may have a higher risk of type 2 diabetes than the overall population. While migrant farmworker-specific data are lacking, most agricultural workers in the U.S. are Latino, a population with a high rate of type 2 diabetes. Living in severe poverty brings with it food insecurity, high chronic stress, and increased risk of diabetes; there is also an association between the use of certain pesticides and the incidence of diabetes (96).

Data from the Department of Labor indicates that there are 2.5–3 million agricultural workers in the U.S., and these agricultural workers travel throughout the country serving as the backbone for a multibillion-dollar agricultural industry. According to 2018 health center data, 174 health centers across the U.S. reported that they provided health care services to 579,806 adult agricultural patients, and 78,332 had encounters for diabetes (13.5%) (97).

Migrant farmworkers encounter numerous and overlapping barriers to receiving care. Migration, which may occur as frequently as every few weeks for farmworkers, disrupts care. Cultural and linguistic barriers, lack of transportation and money, lack of available work hours, unfamiliarity with new communities, lack of access to resources, and other barriers prevent migrant farmworkers from accessing health care. Without regular care, those with diabetes may suffer severe and often expensive complications that affect quality of life.

Health care providers should be attuned to the working and living conditions of all patients. If a migrant farmworker with diabetes presents for care, appropriate referrals should be initiated to

social workers and community resources, as available, to assist with removing barriers to care.

### Language Barriers

Providers who care for non-English speakers should develop or offer educational programs and materials in multiple languages with the specific goals of preventing diabetes and building diabetes awareness in people who cannot easily read or write in English. The National Standards for Culturally and Linguistically Appropriate Services in Health and Health Care (National CLAS Standards) provide guidance on how health care providers can reduce language barriers by improving their cultural competency, addressing health literacy, and ensuring communication with language assistance (98). The National CLAS Standards website (<https://thinkculturalhealth.hhs.gov>) offers a number of resources and materials that can be used to improve the quality of care delivery to non-English-speaking patients (98).

### Health Literacy

Health literacy is defined as the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate decisions (61). Health literacy is strongly associated with patients being able to engage in complex disease management and self-care (99). Approximately 80 million adults in the U.S. are estimated to have limited or low health literacy (62). Clinicians and diabetes care and education specialists should ensure they provide easy-to-understand information and reduce unnecessary complexity when developing care plans with patients. Interventions addressing low health literacy in populations with diabetes seem effective in improving diabetes outcomes, including ones focusing primarily on patient education, self-care training, or disease management. Combining easily adapted materials with formal diabetes education demonstrates effectiveness on clinical and behavioral outcomes in populations with low literacy (100). However, evidence supporting these strategies is largely limited to observational studies, and more research is needed to investigate the most effective strategies for enhancing both acquisition and retention of diabetes knowledge, as well as to examine different

media and strategies for delivering interventions to patients (37).

### Social Capital/Community Support

Social capital, which comprises community and personal network instrumental support, promotes better health, whereas lack of social support is associated with poorer health outcomes in individuals with diabetes (74). Of particular concern are the SDOH of racism and discrimination, which are likely to be lifelong (101). These factors are rarely addressed in routine treatment or disease management but may drive underlying causes of nonadherence to regimen behaviors. Identification or development of community resources to support healthy lifestyles is a core element of the CCM (9) with particular need to incorporate relevant social support networks. There is currently a paucity of evidence regarding enhancement of these resources for those most likely to benefit from such intervention strategies.

Health care community linkages are receiving increasing attention from the American Medical Association, the Agency for Healthcare Research and Quality, and others as a means of promoting translation of clinical recommendations for lifestyle modification in real-world settings (102). Community health workers (CHWs) (103), peer supporters (104–106), and lay leaders (107) may assist in the delivery of DSMES services (76,108), particularly in underserved communities. A CHW is defined by the American Public Health Association as a “frontline public health worker who is a trusted member of and/or has an unusually close understanding of the community served” (109). CHWs can be part of a cost-effective, evidence-based strategy to improve the management of diabetes and cardiovascular risk factors in underserved communities and health care systems (110).

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