

Overview and Discussion of the 2017 VA/DoD Clinical Practice Guideline for the Management of Type 2 Diabetes Mellitus in Primary Care

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The 2017 diabetes mellitus guidelines emphasize shared decision making, dietary changes, and HbA_{1c} target range for optimal control of diabetes mellitus.

Diabetes mellitus (DM) is an epidemic in the U.S. More than 30 million people (9.4% of the total population) have DM; type 2 DM (T2DM) accounts for 95% of these cases.¹ The estimated prevalence of DM among individuals aged > 65 years is about 3 times higher at 26%. The prevalence among veterans enrolled in the VA is higher than in the general population; about 25% of VA users have been diagnosed with DM.² As a result, DM is the leading cause of blindness, end stage renal disease, amputations, and a significant contributor to myocardial infarction and stroke. Older adults with DM have an increased risk of mortality compared with individuals without DM.³ In 2012, DM was estimated to cost \$176 billion in direct and indirect medical costs.⁴ These health and cost implications make effective management of DM a priority for health care providers (HCPs), policy makers, and patients nationwide.

The 2017 VA/DoD Clinical Practice Guideline (CPG) for the Management of T2DM in Primary Care provides the primary care team an evidence-based and individual-

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ized approach to holistic care of the patient with T2DM.⁵ Key recommendations were developed based on methods established by the VA/DoD Evidence-Based Practice Working Group (EBPWG) and are aligned with standards for trustworthy guidelines by using the Grading of Recommendations Assessment, Development and Evaluation system to assess the quality of the evidence base and assign a grade for the strength for each recommendation.^{6,7} The EBPWG included a multidisciplinary panel of practicing clinician stakeholders, including primary care physicians, endocrinologists, medical nutritionists, pharmacists, diabetes educators, and nurse practitioners. The CPG development process also included a patient focus group. Important themes from the focus group were shared with the EBPWG to help address the needs and perspectives of patients receiving treatment for DM in the VA and DoD.

In this article, the authors briefly review several of the most pertinent CPG updates for the busy clinician.

SHARED DECISION MAKING

Shared decision making (SDM) is a central component of the approach to patients with DM. Shared decision making involves the patient and care providers together making important decisions about the treatment plan and goals of care, using communication tools and exploring patient preferences.⁸

Using an empathetic and nonjudgmental approach facilitates discussions about a patient's specific health care needs and goals for care. Shared decision making also can provide culturally appropriate treatment and care information to meet the needs of those with limited literacy or numeracy skills, or other learning barriers, such as physical, sensory, or learning disabilities. Family involvement is an important component of SDM when desired by the patient.⁹

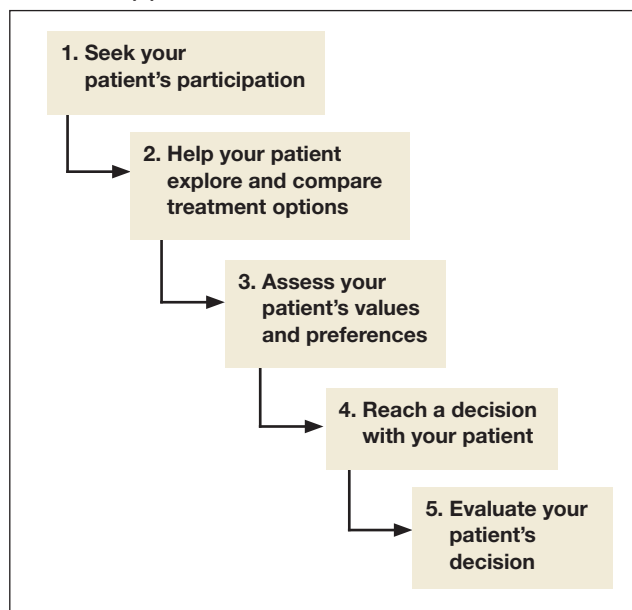
The goals of successful SDM include a decrease in patient anxiety and an increase in trust in the health care team, ideally leading to improvement in adherence and patient outcomes.^{8,10-12} Improved patient-clinician communication conveys openness to discuss any future concerns. Furthermore, SDM does not need to take a significant amount of a clinician's time to create an environment of consideration and goal formation. Training in communication skills may be helpful for those unfamiliar with SDM techniques. Patients are most likely to participate in the SDM process when they are comfortable speaking with clinicians and have some knowledge about their specific disease process.¹³

The clinical team can review all prior treatment attempts with the patient to understand the patient's perspective on these interventions. Lastly, patients are involved in prioritizing problems to be addressed and in setting specific goals. A 5-step SDM process prompted by the SHARE acronym can be used:

- Seek your patient's participation;
- Help your patient explore and compare treatment options;
- Assess your patient's values and preferences;
- Reach a decision with your patient; and
- Evaluate your patient's decision (Figure).⁸

The VA/DoD CPG noted that there is high-quality evidence supporting SDM for improving patients' knowledge, satisfaction, and engagement with their treatment plan.¹⁴⁻¹⁶ Specific methodologic approaches to SDM are not well defined for individual patient groups, which represents a significant research gap. Patients diagnosed with T2DM might respond differently to SDM depending on personal goals, life experiences, and coping strategies.¹⁴⁻¹⁶ Shared decision making should be used at every decision point in the treatment process, from the diagnosis of prediabetes to the patient with advanced complications. This includes—at a minimum—at initial diagnosis, when experiencing difficulties in management, and at times of transition or development of complications.¹⁶

Figure. Shared Decision Making: SHARE Approach⁸



Abbreviation: SHARE, seek, help, assess, reach, evaluate.

A shared understanding is critical to the SDM process. Diabetes self-management education and diabetes self-management support provide a framework that involves a collaborative, ongoing, interactive process to help patients gain knowledge, modify behavior, and successfully manage the disease. The goal of DM education in SDM is to ensure that the patient has sufficient knowledge and skills to achieve the treatment goals they set with their health care team. Assessment of patient understanding in the clinic could include use of the “teach-back method.”¹⁷ Health coaching and motivational interviewing strategies also may help clinicians understand patients' perceptions, values, and beliefs regarding their condition, treatment, and self-management options, particularly when patients seem to be reluctant to fully participate in decisions and care.

A challenge for HCPs is to help patients understand how they can successfully manage DM and partner with health care teams to express their goals and preferences to aid in individualized health care decisions. Using SDM tools and ensuring that clinicians can use patient-centered communication skills increase patients' willingness to share in decision making and engage in the treatment plan.

Table 1. Dietary Recommendations in the Mediterranean Diet^a

Food	Goal
Recommended	
Olive oil	≥ 4 tbsp per d
Tree nuts and peanuts	≥ 3 servings per wk
Fresh fruits, including natural fruit juices	≥ 3 servings per d
Vegetables	≥ 2 servings per d
Seafood (primarily fatty fish)	≥ 3 servings per wk
Legumes	≥ 3 servings per wk
Sofrito ^b	≥ 2 servings per wk
White meat	In place of red meat
Wine with meals (optional)	Discuss with provider
Discouraged	
Soda	< 1 drink per d
Commercial baked goods, sweets, pastries ^c	< 3 servings per wk
Spread fats	< 1 serving per d
Red and processed meats	< 1 serving per d

^aAdapted from Estruch R, Ros E, Salas-Salvadó J, et al; PREDIMED Study Investigators. Primary prevention of cardiovascular disease with a Mediterranean diet. *N Engl J Med*. 2013;368(14):1279-1290.

^bSofrito is a sauce made with tomato and onion and often includes garlic, herbs, and olive oil.

^cCommercial bakery goods, sweets, and pastries include cakes, cookies, biscuits, and custard and do not include those that are homemade.

NUTRITION RECOMMENDATIONS

Nutrition therapy is a key component of any successful DM management plan. The EBPWG added 2 strong recommendations for DM nutrition strategies. The first recommendation is to follow a Mediterranean diet, if this resonates with the patient's values and preferences (Table 1). Features commonly used to describe a traditional Mediterranean diet include:

- High intake of vegetables, fruits, nuts, unrefined grains, and olive oil;
- Moderate intake of fish and poultry;
- Low or moderate intake of wine; and
- Low intake of red meat, processed meat, dairy, and sweets.

The Mediterranean diet effectively improves glycemic

control, delays the time to first pharmacologic intervention, and reduces cardiovascular risk factors in individuals with diabetes.¹⁸ An additional benefits of this dietary pattern includes significant hemoglobin A_{1c} (HbA_{1c}) reduction.^{19,20} A Mediterranean diet also has been linked to improved cardiovascular outcomes and weight loss. In general, the evidence supporting a Mediterranean diet are robust, but securing and adapting to these types of foods can be challenging for some patients.

The second nutrition recommendation is to reduce the percentage of energy from carbohydrates to between 14% and 45% per day and/or eat foods with lower glycemic index. Patients who do not choose a Mediterranean diet can employ this dietary pattern. A systematic review compared dietary interventions, including lower carbohydrate and low-glycemic index diets, and showed both dietary interventions improved glycemic control.¹⁸ Unfortunately, many studies compare different intervention diets rather than comparing an intervention against a control diet. However, based on the available evidence, the Working Group endorses a Mediterranean diet and carbohydrate reduction and low glycemic index foods as dietary options in which the benefits seem to outweigh harms.

TARGET HEMOGLOBIN A_{1c} RANGE

The EBPWG reviewed several large, intensive glucose control trials to apply recent evidence to ongoing HbA_{1c} treatment targets. The CPG strongly reaffirms that rather than assigning a single glycemic goal for all patients, clinicians should use SDM to develop an HbA_{1c} target range that is risk-stratified (Table 2).

When summarizing evidence regarding the risks and benefits of treatment, the guidelines strongly recommend that absolute risk reduction (ARR) be considered rather than relative risk reduction (RRR).²¹ As an example of the difference between the ARR and RRR, in the United Kingdom Prospective Diabetes Study (UKPDS) there was a 37% RRR for microvascular complications (eg, retinopathy, neuropathy, and nephropathy) with an HbA_{1c} reduction from 7.9% to 7.0%. However, the ARR was about 5.0%, and the number needed to treat for benefit was almost 20.²² In addition, when initial HbA_{1c} is lower, the incremental health benefits by further reducing HbA_{1c} are smaller because of the lower overall incidence of microvascular complications. Therefore, a patient with a lower initial HbA_{1c} is less likely to derive benefit from treatment than are individuals with a higher HbA_{1c} (eg, > 9%).

The ARR of complications must be balanced against the risk of therapy. Several major trials tested the hypothesis that intensive glycemic control (target HbA_{1c}

at least < 7%) improved cardiovascular outcomes in patients with T2DM.²³⁻²⁵ These trials did not demonstrate cardiovascular benefit from intensive control to reach HbA_{1c} < 7%, and the Action to Control Cardiovascular Risk in Diabetes (ACCORD) study revealed possible cardiovascular harm.²⁴

In addition, because these studies enrolled patients with established T2DM, they demonstrated less reduction in microvascular complications than was seen in newly diagnosed patients in UKPDS.²² Systematic reviews comparing intensive and conventional glucose control showed no significant differences in all-cause mortality or death from cardiovascular disease.^{26,27} Therefore, intensive control of T2DM has the greatest impact on microvascular complications and is most successful when initiated early in the disease process.

A target HbA_{1c} range is recommended rather than a threshold value (eg, HbA_{1c} < 8.0%) for several reasons. Most important the clinical trials that provide evidence for improved glycemic control used an HbA_{1c} value recorded over time, not a single value measured at one point in time. Many factors influence HbA_{1c} measurements other than just glycemic control.²⁸ These include anemia, chronic kidney disease, race/ethnicity, and hemoglobinopathies.²⁹⁻³² Patients can have clinically significant variation in HbA_{1c} results between test samples, even when obtained from the same laboratory.³³ For these reasons, the CPG continues to recommend use of fasting glucose ≥ 126 mg/dL to establish a DM diagnosis when the HbA_{1c} is < 7.0%. This limits the likelihood that patients will be incorrectly diagnosed with DM, which can affect insurability, disability, or the trajectory of a military career. For patients with diagnosed T2DM, glycemic control over time remains important, but overreliance on a single HbA_{1c} test could lead to overtreatment and potential adverse outcomes.

The EBPWG considered the target HbA_{1c} and outcomes in UKPDS, ACCORD, Veterans Affairs Diabetes Trial (VADT), and the Action in Diabetes and Vascular Disease: Preterax and Diamicron MR Controlled Evaluation (ADVANCE) when considering HbA_{1c} target ranges.^{23,25,34,35} Indeed, target HbA_{1c} ranges, with both lower and upper bounds, were considered a better way to balance the potential risks and benefits of therapy. For example, a target HbA_{1c} range of 6% to 7% might be appropriate in patients with a life expectancy more than 10 to 15 years with no significant microvascular disease and no other socioeconomic limitations to therapy. For patients with established microvascular disease or a life expectancy < 10 years, target ranges from 7% to 9% might be appropriate depending on patient-specific

Table 2. Determination of Average Target Hemoglobin A_{1c} Level Over Time^{a,b}

Major Comorbidity or Physiologic Age ^c	Microvascular Complications		
	Absent or Mild ^d	Moderate ^e	Advanced ^f
Absent ^g > 10 years of life expectancy	6.0-7.0% ^h	7.0-8.0%	7.5-8.5% ^k
Present ^h 5-10 years of life expectancy	7.0-8.0% ^h	7.5-8.5%	7.5-8.5% ^k
Marked ⁱ < 5 years of life expectancy	8.0-9.0% ^k	8.0-9.0% ^k	8.0-9.0% ^k

^aUsing hemoglobin A_{1c} in management decisions:

- Based upon the NGSP reference standard. Clinicians need to obtain information regarding the coefficient of variation (CV) from the methodology used at their site; for example, an hemoglobin A_{1c} of 8% from a laboratory with a CV of 3% could be within 7.76-8.24%;
- The hemoglobin A_{1c} range reflects an average goal over time; intensification or relaxation of therapy should be undertaken based upon individual clinical circumstances and treatment options;
- A medication change in response to a single hemoglobin A_{1c} test that encompasses the goal is discouraged, especially if it is discordant with self-monitoring of blood glucose results; and
- African Americans, on average, have higher hemoglobin A_{1c} levels than do whites, and this difference cannot be explained by measured differences in glycemia; caution is recommended changing medication therapy based upon hemoglobin A_{1c} results, especially for patients on insulin therapy, without correlation with self-monitoring of blood glucose (SMBG) results.
- For all the above reasons, the VA/DoD diabetes mellitus clinical practice guidelines does not recommend the use of estimated average glucose.

^bSocial determinants of health, including social support, ability to self-monitor on insulin, food insufficiency, and cognitive impairment need to be considered. Additionally, side effects of medications, and patient preferences need to be considered in a process of shared decision making.

^cMajor comorbidity includes, but is not limited to, any or several of the following active conditions: significant cardiovascular disease, severe chronic kidney disease, severe chronic obstructive pulmonary disease, severe chronic liver disease, recent stroke, and life-threatening malignancy.

^dMild microvascular disease is defined by early background retinopathy, and/or microalbuminuria, and/or mild neuropathy.

^eModerate microvascular disease is defined by pre-proliferative (without severe hemorrhage, intra-retinal microvascular anomalies [IRMA], or venous bleeding) retinopathy or persistent, fixed proteinuria (macroalbuminuria), and/or demonstrable peripheral neuropathy (sensory loss).

^fAdvanced microvascular disease is defined by severe non-proliferative (with severe hemorrhage, IRMA, or venous bleeding), or proliferative retinopathy and/or renal insufficiency (serum creatinine level > 2.0 mg/dL), and/or insensate extremities or autonomic neuropathy (eg, gastroparesis, impaired sweating, or orthostatic hypotension).

^gProgression to major complications of diabetes is likely to occur in individuals with longer than 15-20 y of life expectancy; therefore, goal ranges are more beneficial early in disease in younger individuals with a longer life expectancy.

^hMajor comorbidity is present, but is not end-stage and management achievable.

ⁱMajor comorbidity is present and is either end-stage or management is significantly challenging; this can include mental health conditions and substance/opioid use.

^jFurther reductions may be appropriate, balancing safety and tolerability of therapy.

^kWithout significant side effects, including but not limited to hypoglycemia.

factors. A patient with advanced disease or limited life expectancy is less likely to derive benefit from intensive control, yet they would be exposed to the adverse effects from intensive therapy. For these patients, consider a less-intensive HbA_{1c} target range. Although life expectancy can be difficult to estimate, this framework can be helpful to reach a target range using SDM with the patient.

An important issue in current DM management is potential overtreatment, which sits at the intersection of overuse of low value practices and medication safety. Up to 65% of older veterans with DM taking hypoglycemic agents might be overtreated based on the presence of DM complications, medical comorbidities, and decreased life expectancy that confer more risk than benefit from lower HbA_{1c} levels.³⁶ Harms from intensive glycemic control, such as increased risk of death from cardiovascular events and severe hypoglycemia must be considered.²⁴ Patient-specific factors that could increase risk of hypoglycemia include the use of specific drugs (insulin and sulfonylureas), advanced age (> 75 years), cognitive impairment, chronic renal insufficiency, and food insufficiency.³⁷⁻³⁹

The CPG did not address specific pharmacologic treatment options because these can change rapidly as the literature evolves. Instead, the CPG refers clinicians to current criteria issued by the VA and DoD, which are updated frequently. In line with recent reviews, the CPG continues to recommend metformin as a first-line therapy for most patients with T2DM.⁴⁰ An important consideration in the future will be the potential for cardiovascular risk reduction from specific medications or classes of medication independent of HbA_{1c} reduction. As ongoing clinical trials are completed, SDM, ARR, and potential harm from therapy will remain important considerations.

CONCLUSION

The VA/DoD Diabetes Clinical Practice Guideline for the Management of Type 2 Diabetes Mellitus in Primary Care strongly recommend SDM in setting management and treatment goals, lifestyle changes that favor a Mediterranean or reduced carbohydrate diet, and targeting HbA_{1c} levels to a range that balances benefits and harms for an individual patient.

This CPG represents a significant step forward in improving the treatment and management of patients with DM in the VA and DoD. This document represents a synthesis of the best available evidence regarding DM care as of March 2016. It is the authors' hope that such recommendations are implemented at the individual

practice level. The CPG can help HCPs, but use of such recommendations should be placed in the context of clinical judgment, the patient's values and preferences, and other available evidence as scientific knowledge and technology advance and treatment patterns evolve.

Application of these CPG recommendations will help VA and DoD clinicians deliver high-quality DM care in a personalized, proactive, and patient-driven manner, that inspires patients to achieve a state of health and well-being that is tailored to their unique characteristics and goals of care. ●

Acknowledgments

The Diabetes Guideline Working Group wishes to thank several VA and DoD participants: David C. Aron, MD, MS; Mercedes Falciglia, MD; Chester B. Good, MD, MPH; Mary M. Julius, RDN, CDE; Deborah Khachikian, PharmD; Rose Mary Pries, DrPH; Elizabeth Rees Atayde, RN, MSN, FNP, CCM, CPHM; Amy M. Lugo, PharmD, BCPS, BC-ADM, FAPhA; Susan McReynolds, RD, CDE; MAJ Tracy L. Snyder, MS, RD; Evan N. Steil, MD, MBA, MHA; Elaine P. Stuffle, RN, BSN, MHA; COL Gwendolyn H. Thompson, PharmD; Nina A. Watson, MSN, RN, CDE.

We also recognize Eric Rodgers, PhD, RNP-BC, director of the Evidence-Based Practice Program in the VA Office of Quality, Safety and Value; Corinne K.B. Devlin, MSN, RN, FNP-BC, director of the Office of Evidence Based Practice U.S. Army Medical Command; the CPG peer reviewers; and the patients involved in the patient focus group.

Author disclosures

The authors report no actual or potential conflicts of interest with regard to this article.

Disclaimer

The opinions expressed herein are those of the authors and do not necessarily reflect those of Federal Practitioner, Frontline Medical Communications Inc., the U.S. Government, or any of its agencies.

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