VA/DoD CLINICAL PRACTICE GUIDELINE FOR THE MANAGEMENT OF TYPE 2 DIABETES MELLITUS IN PRIMARY CARE

Department of Veterans Affairs

Department of Defense

Pocket Card

QUALIFYING STATEMENTS

The Department of Veterans Affairs and the Department of Defense guidelines are based upon the best information available at the time of publication. They are designed to provide information and assist decision-making. They are not intended to define a standard of care and should not be construed as one. Neither should they be interpreted as prescribing an exclusive course of management.

This Clinical Practice Guideline is based on a systematic review of both clinical and epidemiological evidence. Developed by a panel of multidisciplinary experts, it provides a clear explanation of the logical relationships between various care options and health outcomes while rating both the quality of the evidence and the strength of the recommendations.

Variations in practice will inevitably and appropriately occur when clinicians take into account the needs of individual patients, available resources, and limitations unique to an institution or type of practice. Every healthcare professional making use of these guidelines is responsible for evaluating the appropriateness of applying them in the setting of any particular clinical situation.

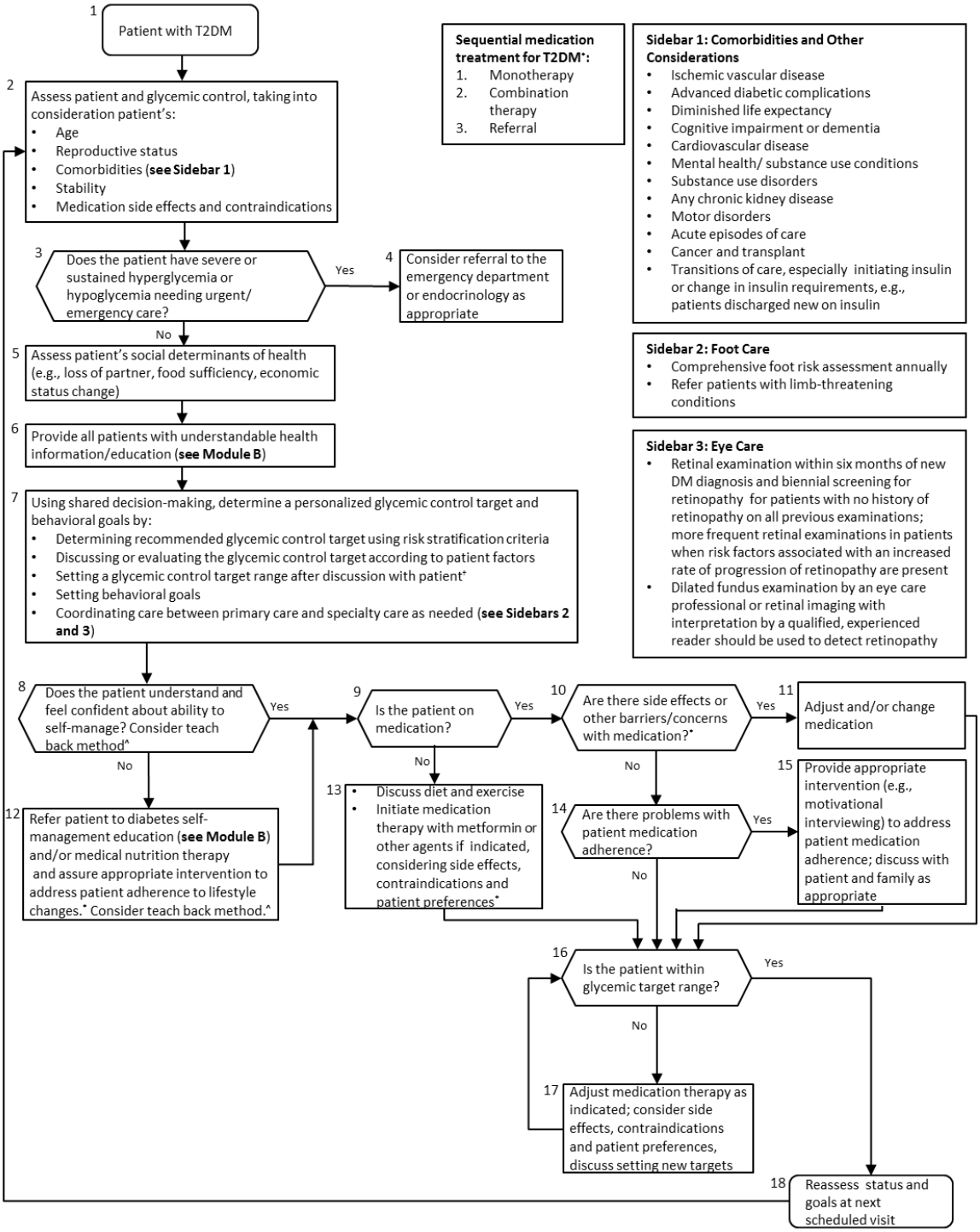
These guidelines are not intended to represent Department of Veterans Affairs or TRICARE policy. Further, inclusion of recommendations for specific testing and/or therapeutic interventions within these guidelines does not guarantee coverage of civilian sector care. Additional information on current TRICARE benefits may be found at www.tricare.mil or by contacting your regional TRICARE Managed Care Support Contractor.

Version 5.0 – 2017

Table 1: Selected Recommendations

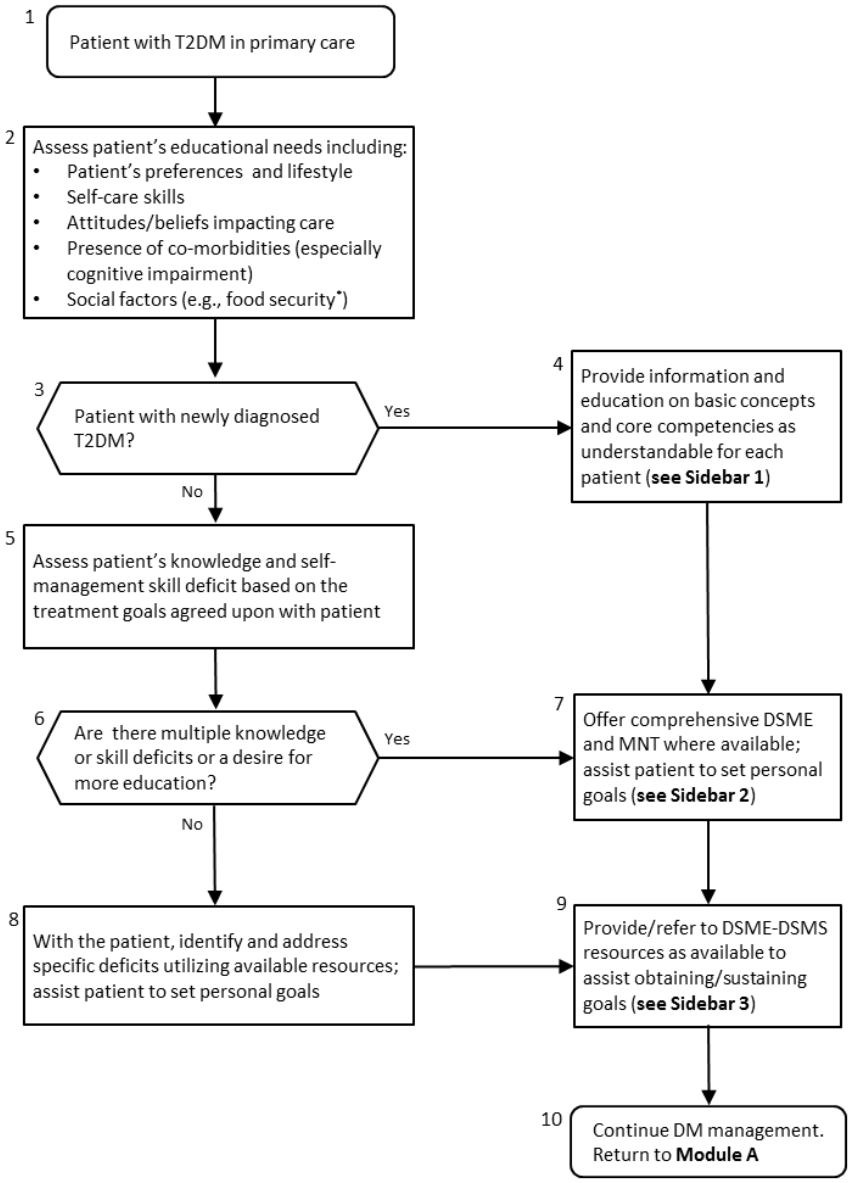
#	Recommendation	Strength	Category
A. General Approach to T2DM Care			
1.	We recommend shared decision-making to enhance patient knowledge and satisfaction.	Strong for	Reviewed, New-added
B. Glycemic Control Targets and Monitoring			
4.	We recommend setting an HbA1c target range based on absolute risk reduction of significant microvascular complications, life expectancy, patient preferences and social determinants of health.	Strong for	Reviewed, New-added
5.	We recommend developing an individualized glycemic management plan, based on the provider's appraisal of the risk-benefit ratio and patient preferences.	Strong for	Reviewed, Amended
6.	We recommend assessing patient characteristics such as race, ethnicity, chronic kidney disease, and non-glycemic factors (e.g., laboratory methodology and assay variability) when interpreting HbA1c, fructosamine and other glycemic biomarker results.	Strong for	Reviewed, New-added
7.	We recommend an individualized target range for HbA1c taking into account individual preferences, presence or absence of microvascular complications, and presence or severity of comorbid conditions (See Table 3).	Strong for	Reviewed, New-replaced
C. Non-pharmacological Treatments			
12.	We recommend offering therapeutic lifestyle changes counseling that includes nutrition, physical activity, cessation of smoking and excessive use of alcohol, and weight control to patients with diabetes (See VA/DoD CPGs for obesity, substance use disorders, and tobacco use cessation).	Strong for	Not Reviewed, Amended
13.	We recommend a Mediterranean diet if aligned to patient's values and preferences.	Strong for	Reviewed, New-added
14.	We recommend a nutrition intervention strategy reducing percent of energy from carbohydrate to 14-45% per day and/or foods with lower glycemic index in patients with type 2 diabetes who do not choose the Mediterranean diet.	Strong for	Reviewed, New-added

Module A: General Care and Treatment



Abbreviations: T2DM: Type 2 diabetes mellitus
*For sequential treatment of DM, see Figure 5
†Target range incorporates the known variation in the HbA1c test from the laboratory used by the patient
^Use the Teach-Back Method: Tool #5. Content last reviewed February 2015. Agency for Healthcare Research and Quality, Rockville, MD. http://www.ahrq.gov/professionals/quality-patient-safety/quality-resources/tools/literacy-toolkit/healthlittoolkit2-tool5.html

Module B: Diabetes Self-Management Education



Sidebar 1: Basic Education/Core Competencies (Survival Skills)

- Prescribed medication information
- How to recognize and treat hypoglycemia/hyperglycemia
- Basic nutrition
- Sick day/ when to call the provider

Sidebar 2: Comprehensive DSME

- Diabetes disease process/ treatment options
- Nutrition/eating healthy
- Physical activity
- Medications in diabetes
- Self-monitoring blood glucose
- Prevention/treatment of hypoglycemia/hyperglycemia
- Prevention/screening of acute and chronic complications (eye/heart/nerve/kidney/dental)
  - Lab tests
  - Foot care/foot exam
  - Smoking cessation
  - Immunizations
- Psychosocial issues/concerns
- Tools/strategies to identify/incorporate patient's goals/preferences

Sidebar 3: DSMS

- Ongoing support
  - Assess personal goal status, knowledge, skills; re-educate as necessary
  - Resources: community, primary care follow-up
- Offer "refresher" education when:
  - Change of regimen
  - Life event
  - Change in health/cognitive/social status

Abbreviations: DSME: Diabetes self-management education; DSMS: Diabetes self-management support; MNT: Medical nutrition therapy; T2DM: Type 2 diabetes mellitus

*Food security: "In the past month, was there any day when you or anyone in your family went hungry because you did not have enough money for food?" (Reference: Kleinman RE, Murphy JM, Wieneke KM, et al. "Use of a single-question screening tool to detect hunger in families attending a neighborhood health center." Ambul Pediatr. 7.4 (2007): 278-84)

Figure 1: Shared Decision-making: SHARE Approach [1]

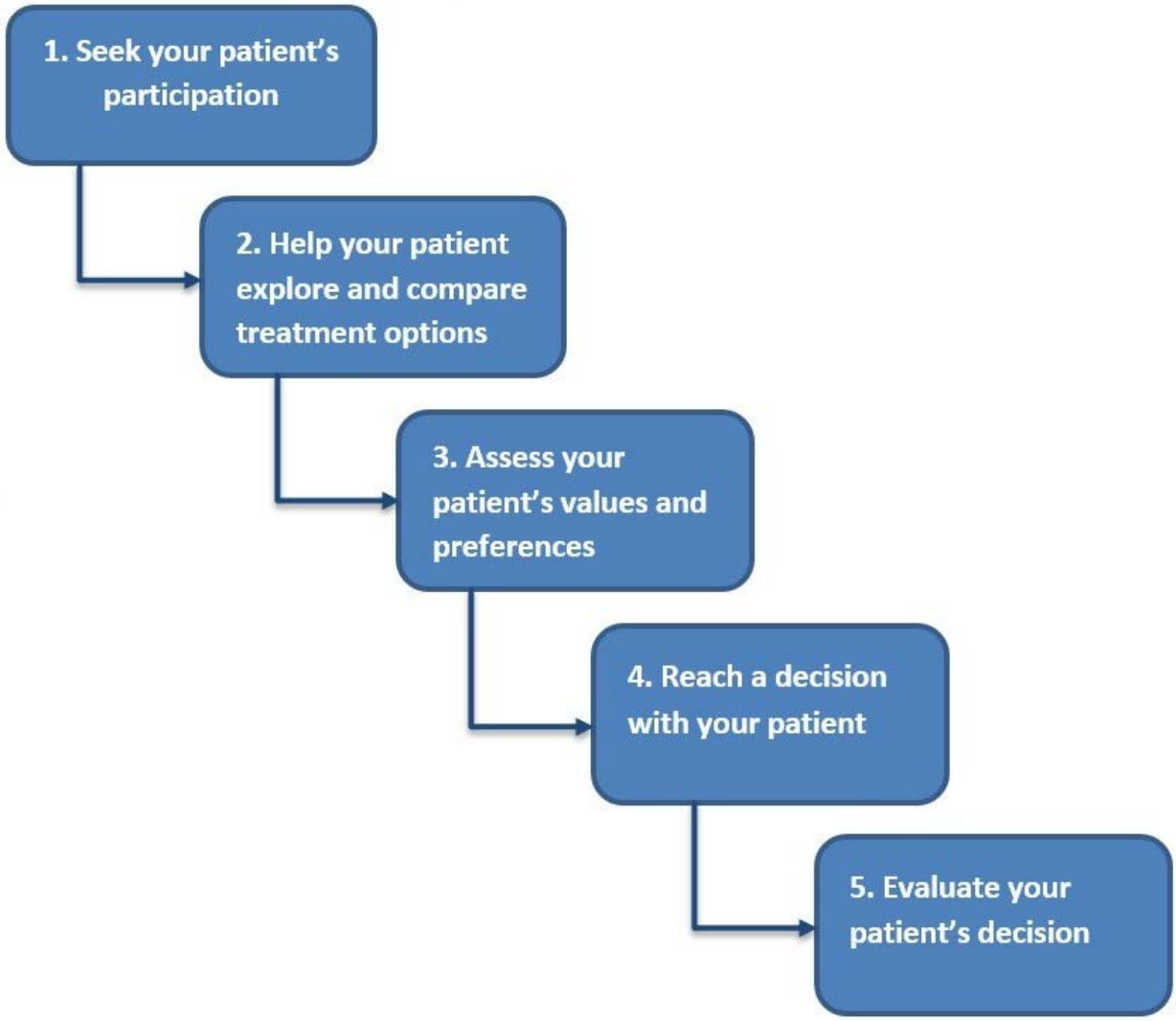
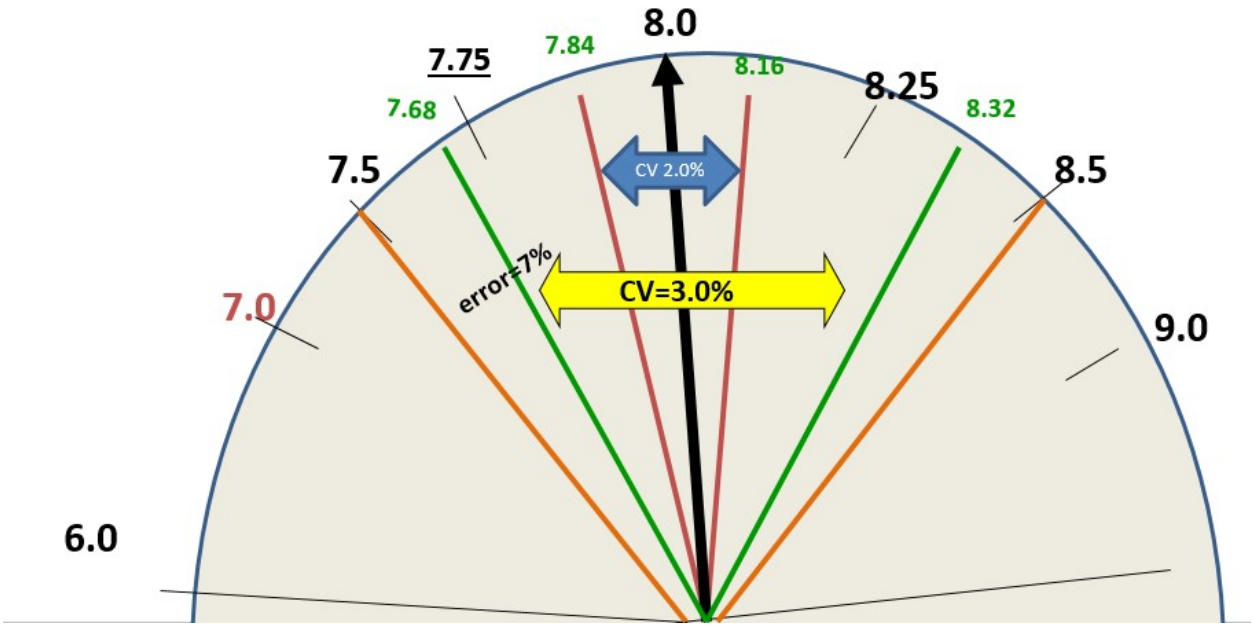


Figure 2: The HbA1c test result and its dependence upon the assay

An HbA1c Test Result is Within a Range Dependent Upon the Assay

The variation in the HbA1c test result is dependent upon the assay characteristics. Therefore, this supports the recommendations of a target glycemic range for patients instead of an absolute HbA1c number. A result of 8.0% is within a 7.84% to 8.16% range from a high quality laboratory (intra-assay coefficient of variation [CV]=2.0%) and between 7.68% and 8.32% if the CV is 3.0%). A CV of 2% will produce a 95% probability that a difference of about 0.5% HbA1c between successive patient samples is a true difference 95 out of 100 times for an HbA1c value of 7.0%.



HbA1c results should be correlated with laboratory and home blood glucose testing to ensure individualized and safe glycemic control. People of African American, Hispanic, Asian and American Indian descent may have higher HbA1c values than Whites for measures of glycemic control. Persons with risk factors (ethnicity, family history) for sickle cell anemia or a thalassemia trait may also have HbA1c results that do not correlate with glycemic control.

Table 2: Criteria for the diagnosis of diabetes mellitus and prediabetes [2]

Status	Fasting Plasma Glucose [1,2] or Hemoglobin A1c [3]
Diabetes Mellitus	FPG ≥ 126 mg/dL (7.0 mmol/L) on two occasions
	OR
	HbA1c ≥ 6.5% with a confirmatory FPG ≥ 126 mg/dL (7.0 mmol/L)
	OR
	HbA1c ≥ 7.0% on two occasions
Prediabetes	FPG ≥ 100 mg/dL **and** < 126 mg/dL on two occasions
	OR
	HbA1c ≥ 5.7% **and** FPG ≥ 100 mg/dL and < 126 mg/dL (7.0 mmol/L)
	OR
	2-hr plasma glucose 140-199 mg/dL (7.8-11.0 mmol/L) (IGT)
Normal	FPG < 100 mg/dL HbA1c < 5.7%

Abbreviations: dL: deciliter; FPG: fasting plasma glucose; HbA1c: hemoglobin A1c; hr: hour; IGT: impaired glucose tolerance; L: liter; mg: milligram; mmol: millimole

[1] Fasting is defined as no caloric intake for at least eight hours.

[2] FPG is the preferred test for diagnosis, but either of the two listed is acceptable. In the absence of unequivocal hyperglycemia with acute metabolic decompensation, one of these two tests should be done on different days.

[3] Using a clinical laboratory (not a point-of-care) methodology standardized to the National Glycohemoglobin Standardization Program (NGSP)

Racial differences were reported among participants in the Diabetes Prevention Program. Despite having comparable measures of glycemia, African Americans had significantly higher HbA1c levels (6.2%) than Whites (5.8%).[2]

Table 3: Determination of average target HbA1c level over time [1,2,3,4,5,12]

Major Comorbidity[6] or Physiologic Age	Microvascular Complications		
	Absent or Mild [7]	Moderate [8]	Advanced [9]
Absent[*] > 10-15 years of life expectancy	6.0-7.0%[†]	7.0-8.0%	7.5-8.5%[‡]
Present [10] 5-10 years of life expectancy	7.0-8.0%[†]	7.5-8.5%	7.5-8.5%[‡]
Marked [11] <5 years of life expectancy	8.0-9.0%[‡]	8.0-9.0%[‡]	8.0-9.0%[‡]

[*]Progression to major complications of diabetes is likely to occur in individuals with longer than 15-20 years of life expectancy. Therefore, goal ranges are more beneficial early in disease in younger individuals, or healthier older adults with a longer life expectancy.

[†]Without significant side effects, including but not limited to hypoglycemia.

[‡]Further reductions may be appropriate, balancing safety and tolerability of therapy.

HbA1c laboratory considerations:

[1] Based upon the NGSP reference standard. Clinicians need to obtain information regarding the coefficient of variation (CV) from the methodology used at their site. As an example, an HbA1c of 8.0% from a laboratory with a CV of 3% would be within a 7.76-8.24% range 13 out of 20 times (1 standard deviation), and would be between a 7.53-8.47% range 19 out of 20 times (2 standard deviations).

[2] The HbA1c range reflects an "HbA1c average goal" over time. Intensification or relaxation of therapy should be undertaken based upon individual clinical circumstances and treatment options.

[3] A medication change in response to a single HbA1c test that encompasses the "goal" is discouraged, especially if it is discordant with self-monitoring of blood glucose (SMBG) results.

[4] African Americans, on average, have higher HbA1c levels than Whites and this difference cannot be explained by measured differences in glycemia. Caution is recommended in changing medication therapy based upon HbA1c results, especially for patients on insulin therapy, without correlation with SMBG results.

[5] For all of the above reasons, the VA/DoD DM CPG does not recommend the use of estimated average glucose.

Comorbid illness considerations:

[6] Major comorbidity includes, but is not limited to, any or several of the following active conditions: significant CVD, severe CKD, severe COPD, severe chronic liver disease, recent stroke, and life-threatening malignancy.

[7] Mild microvascular disease is defined by early background retinopathy, and/or microalbuminuria, and/or mild neuropathy.

[8] Moderate 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).

[9] Advanced 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 (e.g., gastroparesis, impaired sweating, orthostatic hypotension).

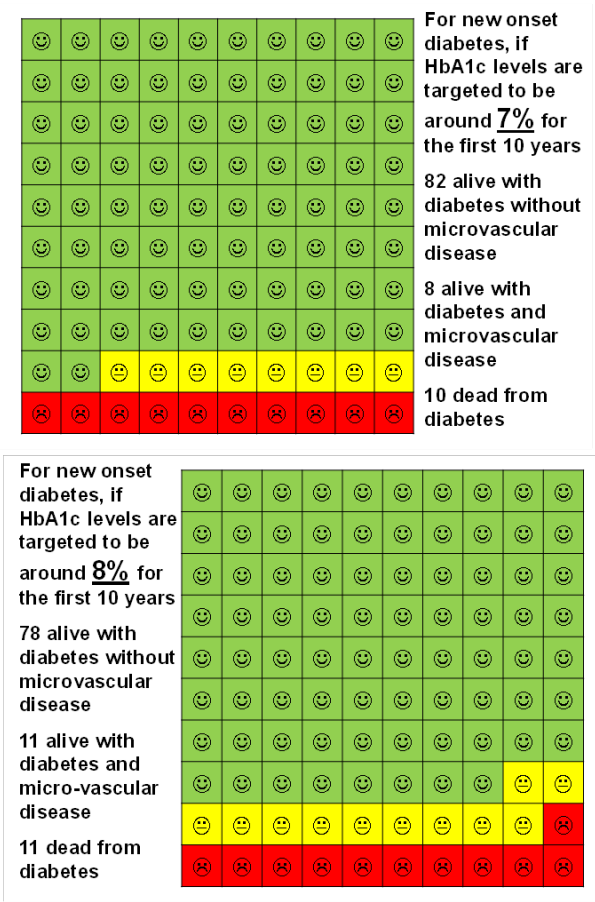
[10] Major comorbidity is present, but is not end-stage and management is achievable.

[11] Major comorbidity is present and is either end-stage or management is significantly challenging. This can include mental health conditions and substance/opioid use.

Social determinant considerations:

[12] Social 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.

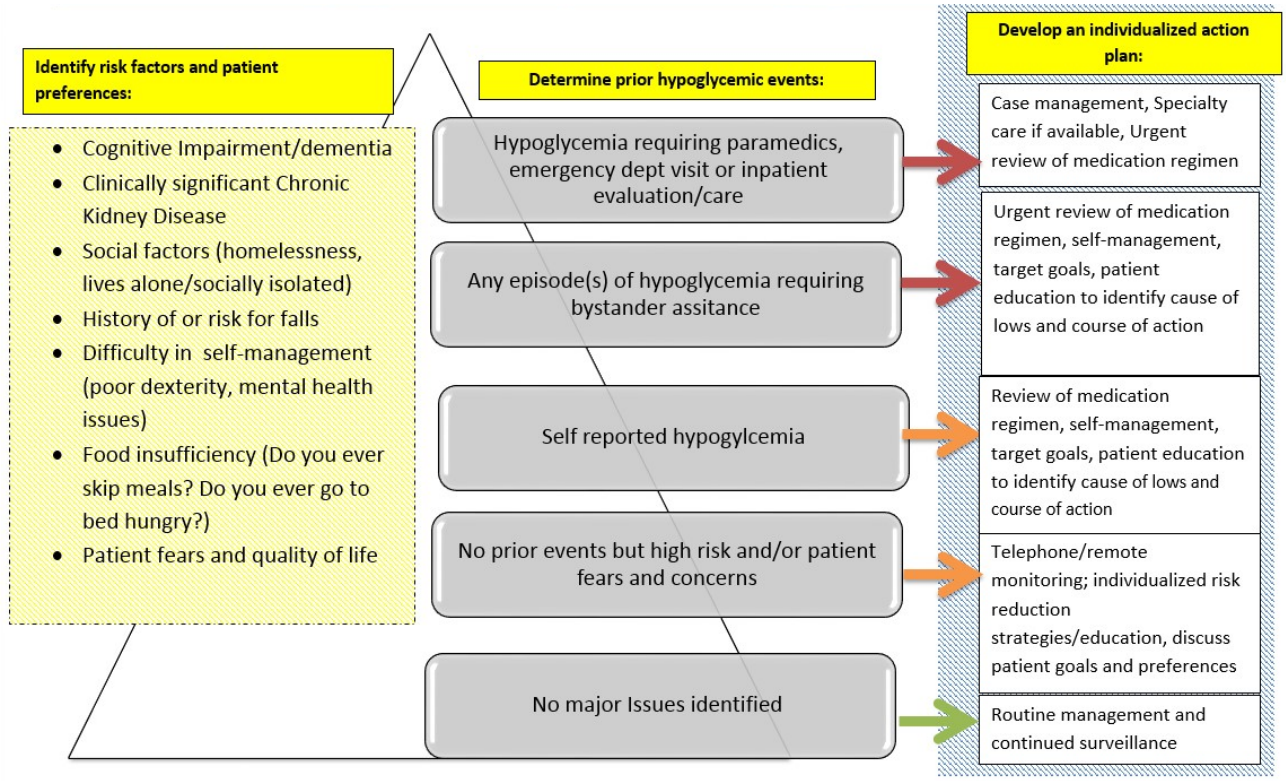
Figure 3: Cates Plot: Pictorial example of the concept of absolute risk reduction from glycemic control [3]



The United Kingdom Prospective Diabetes Study (UKPDS), conducted from the mid-1980s to late 1990s with patients whose average HbA1c was 9% at time of diagnosis, **provides the primary evidence base for tight control of type 2 diabetes from onset of disease for individuals with a life expectancy of around 10 years -** UKPDS 33 (sulfonylurea/insulin therapy compared to conventional therapy - Lancet 1998); Use of metformin may confer additional benefit; UKPDS 34 (metformin versus conventional therapy - Lancet 1988).

☺	**Person alive with diabetes and no microvascular complications**
😐	**Person alive with diabetes and with microvascular complications**
☹	**Person dead from diabetes**
	Microvascular complications include retinopathy, nephropathy, and neuropathy

Figure 4: Risk stratification tool for hypoglycemia and action steps



This tool will assist clinicians to assess and address patients' risk for hypoglycemic events of any severity while using oral hypoglycemic prone medications or insulin. Use this tool to increase your awareness of hypoglycemia as a common and important, yet potentially preventable, complication of therapy. It should not be used as a clinical guideline.

Table 4: Summary of Dietary Recommendations in the Mediterranean Diet*

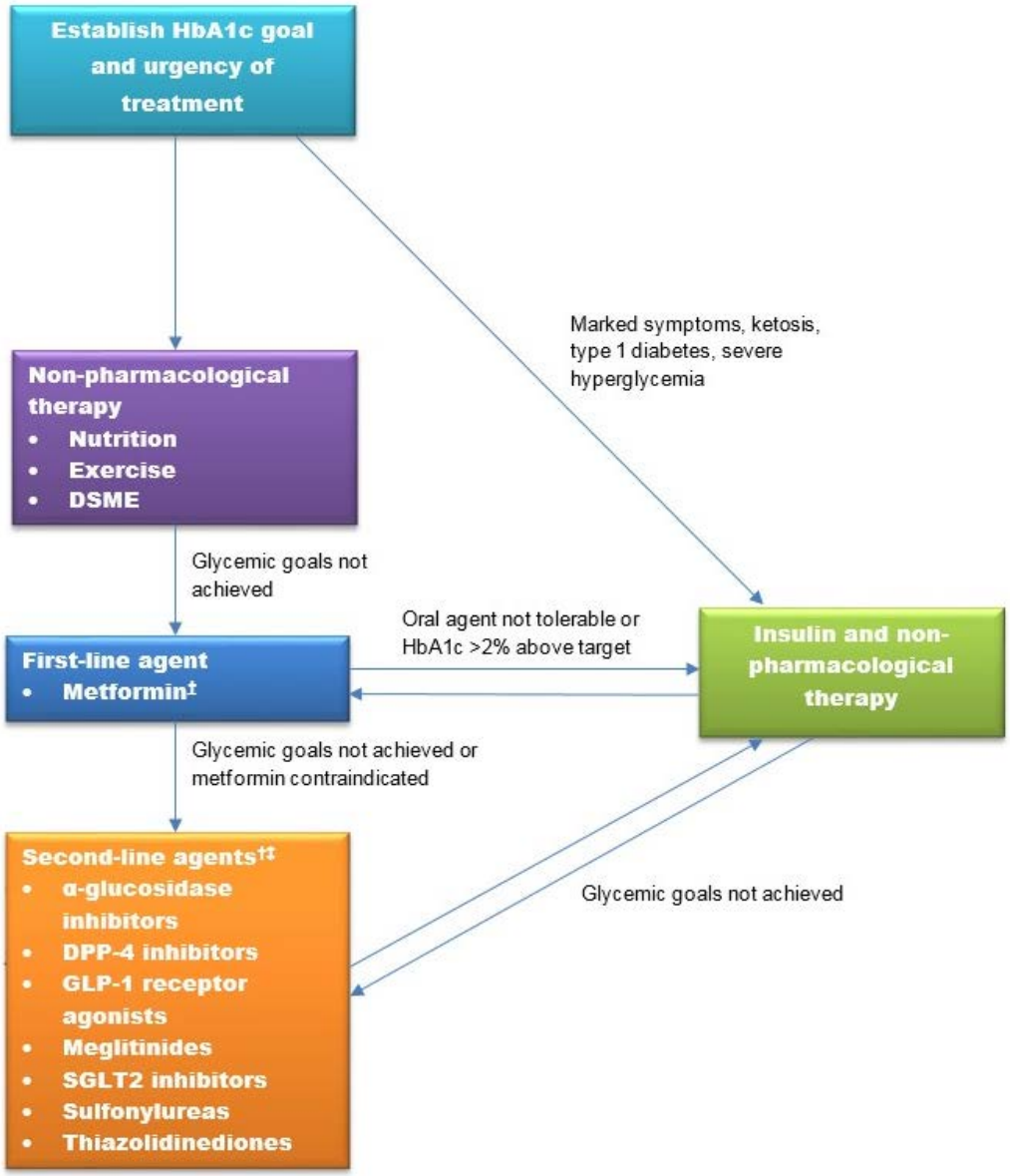
Food	Goal
Recommended	
Olive Oil	≥ 4 tbsp. per day
Tree nuts and peanuts	≥ 3 servings per week
Fresh fruits including natural fruit juices	≥ 3 servings per day
Vegetables	≥ 2 servings per day
Seafood (primarily fatty fish)	≥ 3 servings per week
Legumes	≥ 3 servings per week
Sofrito†	≥ 2 servings per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

*Adapted from Estruch, et al. (2013) [4]

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

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

Figure 5: Sequential Treatment of Type 2 Diabetes*



Abbreviations: DPP-4: dipeptidyl peptidase-4; DSME: diabetes self-management and education; GLP-1: glucagon-like peptide-1; SGLT2: sodium glucose co-transporter 2

*Bile acid sequestrants, bromocriptine quick release, and pramlintide are uncommonly used agents in the management of diabetes and are not included in this guideline.

‡Consider a trial of metformin extended-release in those with persistent adverse gastrointestinal effects from metformin immediate-release

†Second-line agents listed alphabetically; not in order of preference

‡If applicable, refer to VA (http://www.pbm.va.gov/) or DoD (http://www.health.mil/PandT) guidance/criteria for further recommendations on use of these agents

References:

1. Agency for Healthcare Research and Quality. *The SHARE approach*. 2017; https://www.ahrq.gov/professionals/education/curriculum-tools/shareddecisionmaking/index.html. Accessed March 17, 2017.
2. Herman WH, Ma Y, Uwaifo G, et al. Differences in A1C by race and ethnicity among patients with impaired glucose tolerance in the Diabetes Prevention Program. *Diabetes Care.* 2007;30(10):2453-2457.
3. National Prescribing Centre. *Patient decision aid: Type 2 diabetes - tight control of blood glucose using sulphonylurea drugs or insulin*. 2009; https://www.eclipsesolutions.org/UploadedFiles/120_pda_type2_diabetes_su_insulin..pdf. Accessed April 3, 2017.
4. Estruch R, Ros E, Salas-Salvadó J, et al. Primary prevention of cardiovascular disease with a Mediterranean diet. *N Engl J Med.* 2013;368(14):1279-1290.