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

<table>
<thead>
<tr>
<th>#</th>
<th>Recommendation</th>
<th>Strength</th>
<th>Category</th>
</tr>
</thead>
<tbody>
<tr>
<td>A. General Approach to T2DM Care</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1.</td>
<td>We recommend shared decision-making to enhance patient knowledge and satisfaction.</td>
<td>Strong for</td>
<td>Reviewed, New-added</td>
</tr>
<tr>
<td>B. Glycemic Control Targets and Monitoring</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4.</td>
<td>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.</td>
<td>Strong for</td>
<td>Reviewed, New-added</td>
</tr>
<tr>
<td>5.</td>
<td>We recommend developing an individualized glycemic management plan, based on the provider’s appraisal of the risk-benefit ratio and patient preferences.</td>
<td>Strong for</td>
<td>Reviewed, Amended</td>
</tr>
<tr>
<td>6.</td>
<td>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.</td>
<td>Strong for</td>
<td>Reviewed, New-added</td>
</tr>
<tr>
<td>7.</td>
<td>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).</td>
<td>Strong for</td>
<td>Reviewed, New-replaced</td>
</tr>
<tr>
<td>C. Non-pharmacological Treatments</td>
<td></td>
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<tr>
<td>12.</td>
<td>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).</td>
<td>Strong for</td>
<td>Not Reviewed, Amended</td>
</tr>
<tr>
<td>13.</td>
<td>We recommend a Mediterranean diet if aligned to patient’s values and preferences.</td>
<td>Strong for</td>
<td>Reviewed, New-added</td>
</tr>
<tr>
<td>14.</td>
<td>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.</td>
<td>Strong for</td>
<td>Reviewed, New-added</td>
</tr>
</tbody>
</table>
Module A: General Care and Treatment

1. Patient with T2DM
   - Assess patient and glycemic control, taking into consideration patient’s:
     - Age
     - Reproductive status
     - Comorbidities (see Sidebar 1)
     - Stability
     - Medication side effects and contraindications
     - Does the patient have severe or sustained hyperglycemia or hypoglycemia needing urgent/emergency care?
       - Yes
         - Consider referral to the emergency department or endocrinology as appropriate
       - No
     - Assess patient’s social determinants of health (e.g., loss of partner, food sufficiency, economic status change)
     - Provide all patients with understandable health information/education (see Module B)
     - Using shared decision-making, determine a personalized glycemic control target and behavioral goals by:
       - Determining recommended glycemic control target using risk stratification criteria
       - Discussing or evaluating the glycemic control target according to patient factors
       - Setting a glycemic control target range after discussion with patient
       - Setting behavioral goals
       - Coordinating care between primary care and specialty care as needed (see Sidbars 2 and 3)
     - Does the patient understand and feel confident about ability to self-manage? Consider teach back method?
       - Yes
         - Is the patient on medication?
           - Yes
             - Are there side effects or other barriers/concerns with medication?
               - Yes
                 - Adjust and/or change medication
               - No
                 - Discuss diet and exercise
                 - Initiating medication therapy with metformin or other agents if indicated, considering side effects, contraindications, and patient preferences
               - No
                 - Are there problems with patient medication adherence?
                   - Yes
                     - Provide appropriate intervention (e.g., motivational interviewing) to address patient medication adherence; discuss with patient and family as appropriate
                   - No
                     - Continue monitoring for medication adherence
                   - No
                     - Is the patient within glycemic target range?
                       - Yes
                         - Adjust medication therapy as indicated; consider side effects, contraindications, and patient preferences, discuss setting new targets
                       - No
                         - Reassess status and goals at next scheduled visit
         - Refer to diabetes self-management education (see Module B) and/or medical nutrition therapy and assure appropriate intervention to address patient adherence to lifestyle changes. Consider teach back method.
       - No
     - Sidebar 1: Comorbidities and Other Considerations
       - Ischemic vascular disease
       - Advanced diabetic complications
       - Diminished life expectancy
       - Cognitive impairment or dementia
       - Cardiovascular disease
       - Mental health/substance use conditions
       - Substance use disorders
       - Any chronic kidney disease
       - Motor disorders
       - Acute episodes of care
       - Cancer and transplant
       - Transitions of care, especially initiating insulin or change in insulin requirements, e.g., patients discharged new on insulin
     - Sidebar 2: Foot Care
       - Comprehensive foot risk assessment annually
       - Refer patients with limb-threatening conditions
     - Sidebar 3: Eye Care
       - Retinal examination within six months of new DM diagnosis and biennial screening for retinopathy for patients with no history of retinopathy on all previous examinations; more frequent retinal examinations in patients when risk factors associated with an increased rate of progression of retinopathy are present
       - Dilated fundus examination by an eye care professional or retinal imaging with interpretation by a qualified, experienced reader should be used to detect retinopathy

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
Module B: Diabetes Self-Management Education

1. Patient with T2DM in primary care

2. Assess patient’s educational needs including:
   - Patient’s preferences and lifestyle
   - Self-care skills
   - Attitudes/beliefs impacting care
   - Presence of co-morbidities (especially cognitive impairment)
   - Social factors (e.g., food security)

3. Patient with newly diagnosed T2DM?
   - Yes
   - Provide information and education on basic concepts and core competencies as understandable for each patient (see Sidebar 1)
   - No

4. Assess patient’s knowledge and self-management skill deficit based on the treatment goals agreed upon with patient

5. Are there multiple knowledge or skill deficits or a desire for more education?
   - Yes
   - Offer comprehensive DSME and MNT where available; assist patient to set personal goals (see Sidebar 2)
   - No

6. With the patient, identify and address specific deficits utilizing available resources; assist patient to set personal goals

7. Provide/refer to DSME-DSMS resources as available to assist obtaining/sustaining goals (see Sidebar 3)

8. Continue DM management. Return to Module A

Sidebar 1: Basic Education/Core Competencies (Survival Skills)
- Prescribed medication information
- How to recognize and treat hypoglycemia/hyperglycemia
- Basic nutrition
- Sick day/w hen 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, Wienieke 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]

1. Seek your patient’s participation
2. Help your patient explore and compare treatment options
3. Assess your patient’s values and preferences
4. Reach a decision with your patient
5. Evaluate your patient’s decision
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]

<table>
<thead>
<tr>
<th>Status</th>
<th>Fasting Plasma Glucose(^1,2) or Hemoglobin A1c (^3)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diabetes Mellitus</td>
<td>FPG (\geq 126) mg/dL (7.0 mmol/L) on two occasions</td>
</tr>
<tr>
<td></td>
<td>OR</td>
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<tr>
<td></td>
<td>HbA1c (\geq 6.5)% with a confirmatory FPG (\geq 126) mg/dL (7.0 mmol/L)</td>
</tr>
<tr>
<td></td>
<td>OR</td>
</tr>
<tr>
<td></td>
<td>HbA1c (\geq 7.0)% on two occasions</td>
</tr>
<tr>
<td>Prediabetes</td>
<td>FPG (\geq 100) mg/dL and (&lt; 126) mg/dL on two occasions</td>
</tr>
<tr>
<td></td>
<td>OR</td>
</tr>
<tr>
<td></td>
<td>HbA1c (\geq 5.7)% and FPG (\geq 100) mg/dL and (&lt; 126) mg/dL (7.0 mmol/L)</td>
</tr>
<tr>
<td></td>
<td>OR</td>
</tr>
<tr>
<td>Normal</td>
<td>2-hr plasma glucose 140-199 mg/dL (7.8-11.0 mmol/L) (IGT)</td>
</tr>
<tr>
<td></td>
<td>FPG (&lt; 100) mg/dL</td>
</tr>
<tr>
<td></td>
<td>HbA1c (&lt; 5.7)%</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Major Comorbidity6 or Physiologic Age</th>
<th>Microvascular Complications</th>
</tr>
</thead>
<tbody>
<tr>
<td>Absent* &gt; 10-15 years of life expectancy</td>
<td>Absent or Mild 7</td>
</tr>
<tr>
<td></td>
<td>6.0-7.0%1</td>
</tr>
<tr>
<td>Present 10 5-10 years of life expectancy</td>
<td>7.0-8.0%1</td>
</tr>
<tr>
<td>Marked 11 &lt;5 years of life expectancy</td>
<td>8.0-9.0%1</td>
</tr>
</tbody>
</table>

*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).
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***

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

*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*

**Establish HbA1c goal and urgency of treatment**

**Non-pharmacological therapy**
- Nutrition
- Exercise
- DSME

**First-line agent**
- Metformin†

**Second-line agents‡**
- α-glucosidase inhibitors
- DPP-4 inhibitors
- GLP-1 receptor agonists
- Meglitinides
- SGLT2 inhibitors
- Sulfonylureas
- Thiazolidinediones

**Insulin and non-pharmacological therapy**

Marked symptoms, ketosis, type 1 diabetes, severe hyperglycemia

Oral agent not tolerable or HbA1c >2% above target

Glycemic goals not achieved

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

‡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:


