Standards of Medical Care In Diabetes - 2017

Robert E. Ratner, MD, FACP, FACE
Professor of Medicine
Georgetown University School of Medicine

Disclosed no conflict of interest
Standards of Care
Professional.diabetes.org/SOC
## Clinical Practice Recommendations

### Evidence Grading System

<table>
<thead>
<tr>
<th></th>
<th>Evidence Type</th>
</tr>
</thead>
</table>
| **A** | • Clear evidence from adequately-powered, well-conducted, generalizable randomized, controlled trials (RCTs), including evidence from a multicentre trial or meta-analysis that incorporated quality ratings in the analysis;  
  • Compelling nonexperimental evidence  
  • Supportive evidence from adequately-powered, well-conducted RCTs |
| **B** | • Supportive evidence from well-conducted cohort studies  
  • Supportive evidence from a well-conducted case-control study |

Continued…
### Clinical Practice Recommendations

**Evidence Grading System (cont’d)**

<table>
<thead>
<tr>
<th>Grade</th>
<th>Evidence</th>
</tr>
</thead>
</table>
| **C** | • Supportive evidence from poorly controlled or uncontrolled studies or evidence from observational studies with high potential for bias  
• Evidence from case series or case reports  
• Conflicting evidence with the weight of evidence supporting the recommendation |
| **E** | • Expert consensus or clinical experience |

Care Delivery Systems

- 33–49% of patients still do not meet targets for A1C, blood pressure, or lipids
- 14% meet targets for all A1C, BP, lipids, and nonsmoking status
- Substantial system-level improvements are needed
- Delivery system is fragmented, lacks clinical information capabilities, duplicates services, and is poorly designed

Objective 3: Change the Care System

• Successful practices prioritize providing a high quality of care. Changes that have been shown to increase quality of care include:
  – Basing care on evidence-based guidelines
  – Expanding the role of teams to implement more intensive disease management strategies
  – Redesigning the care process
  – Implementing electronic health record tools
  – Empowering and educating patients

Objective 3: Change the Care System (cont’d)

- Successful practices prioritize providing a high quality of care. Changes that have been shown to increase quality of care include:
  - Removing financial barriers and reducing patient out-of-pocket costs
  - Identifying community resources and public policy that support healthy lifestyles
  - Coordinated primary care, e.g., through Patient-Centered Medical Home
  - Changes to the reimbursement structure

Updated Characterization of Diabetes

- Primarily a beta cell disease
  - Destruction of the beta cell
    - Autoimmune or chemical-induced
  - Dysfunction of the beta cell
    - Unable to compensate for higher levels of glucose

Criteria for the Diagnosis of Diabetes

Fasting plasma glucose (FPG) ≥126 mg/dL (7.0 mmol/L)

OR

2-h plasma glucose ≥200 mg/dL (11.1 mmol/L) during a glucose tolerance test (OGTT)

OR

A1C ≥6.5%

OR

Random plasma glucose (RPG) ≥200 mg/dL (11.1 mmol/L)
# Staging of Type 1 Diabetes

<table>
<thead>
<tr>
<th>Stage</th>
<th>Diagnostic Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Stage 1</strong></td>
<td>Autoimmunity</td>
</tr>
<tr>
<td></td>
<td>- Multiple autoantibodies</td>
</tr>
<tr>
<td></td>
<td>- Normoglycemia</td>
</tr>
<tr>
<td></td>
<td>- Presymptomatic</td>
</tr>
<tr>
<td></td>
<td>No IGT or IFG</td>
</tr>
<tr>
<td></td>
<td><strong>Stage 2</strong></td>
</tr>
<tr>
<td></td>
<td>Autoimmunity</td>
</tr>
<tr>
<td></td>
<td>- Multiple autoantibodies</td>
</tr>
<tr>
<td></td>
<td>- Dysglycemia</td>
</tr>
<tr>
<td></td>
<td>- IFG, IGT, or elevated A1C</td>
</tr>
<tr>
<td></td>
<td>- Presymptomatic</td>
</tr>
<tr>
<td></td>
<td><strong>Stage 3</strong></td>
</tr>
<tr>
<td></td>
<td>New-onset hyperglycemia</td>
</tr>
<tr>
<td></td>
<td>- Clinical symptoms</td>
</tr>
<tr>
<td></td>
<td>- Symptomatic</td>
</tr>
<tr>
<td></td>
<td>- Diabetes by standard criteria</td>
</tr>
</tbody>
</table>

Prediabetes*

FPG 100–125 mg/dL (5.6–6.9 mmol/L): IFG

OR

2-h plasma glucose 140–199 mg/dL (7.8–11.0 mmol/L): IGT

OR

A1C 5.7–6.4%

*For all three tests, risk is continuous, extending below the lower limit of a range and becoming disproportionately greater at higher ends of the range.

Recommendations:
Screening for Type 2 Diabetes

• Screening for type 2 diabetes (T2D) with an informal assessment of risk factors or validated tools should be considered in asymptomatic adults B

• Consider testing in asymptomatic adults of any age with BMI ≥25 kg/m² or ≥23 kg/m² in Asian Americans who have one or more additional diabetes mellitus (DM) risk factors B

• For all patients, testing should begin at age 45 years B

• If tests are normal, repeat testing carried out at a minimum of three-year intervals is reasonable C

To test for T2D, fasting plasma glucose, 2-h plasma glucose after 75 g oral glucose tolerance test, and A1C are equally appropriate B

Testing for T2D should be considered in children and adolescents who are overweight or obese and who have two or more additional risk factors for diabetes E
Testing Criteria for T2DM in Children and Adolescents

- Overweight plus any two:
  - Family history of T2D in first or second degree relative
  - Race/ethnicity
  - Signs of insulin resistance or conditions associated with insulin resistance
  - Maternal history of diabetes or gestational diabetes mellitus (GDM)

- Age of initiation: 10 years, or at onset of puberty
- Frequency: every three years
- Screen with A1C

Recommendations: Patient-Centred Collaborative Care

• A patient-centred communication style that:
  – uses active listening
  – elicits patient preferences and beliefs
  – assesses literacy, numeracy, and potential barriers to care

• Should be used to optimize:
  – patient health outcomes
  – health-related quality of life

Recommendations: Comprehensive Medical Evaluation

• A complete medical evaluation should be performed at initial visit to:
  – Detect diabetes complications and potential comorbid conditions E
  – Review previous treatment and risk factor control in patients with established diabetes E
  – Begin patient engagement in the formulation of a care management plan B
  – Develop a plan for continuing care B

Recommendations: Diabetes Self-Management Education and Support

• All people with diabetes should participate in DSME and DSMS both at diagnosis and as needed thereafter B

• Effective self-management, improved clinical outcomes, health status, and quality-of-life are key outcomes of DSME and DSMS and should be measured and monitored as part of care C

• DSME/S should be patient-centred, respectful, and responsive to individual patient preferences, needs, and values, and should guide clinical decisions A

Effectiveness of Nutrition Therapy:

- An individualized MNT program is recommended for all people with T1DM and T2D

- For people with T1DM or those with T2D who are on a flexible insulin program, education on carb counting or in some cases, fat and protein gram estimation

- For patients on a fixed insulin program, having a consistent pattern of carbohydrate intake with respect to time and amount can result in improved glycemic control and a reduced risk of hypoglycemia
Effectiveness of Nutrition Therapy:

• Emphasizing portion control and healthy food choices may be more helpful for people with T2D who are not taking insulin, who have limited health literacy or numeracy, and who are elderly and prone to hypoglycemia. **B**

• Diabetes nutrition therapy can result in cost savings **B** and improved outcomes **A**, MNT should be adequately reimbursed by insurance and other payers. **E**
Recommendations: Physical Activity

- Children with diabetes/prediabetes: at least 60 min/day physical activity C
- Most adults with diabetes: at least 150 min/wk of moderate intensity aerobic activity over at least three days/week with no more than two consecutive days without exercise (T1DM C, T2D B)
- All individuals, including those with diabetes, should reduce sedentary time, particularly by breaking up extended amounts of time (>30 min) spent sitting B
- Adults with T1DM (C) T2D (B) should perform resistance training two to three times/week
- Flexibility training and balance training are recommended two to three times/week for older adults with diabetes C

NEW Recommendations: Psychosocial Care

• Psychosocial care should be integrated with a collaborative, patient-centered approach and provided to all people with diabetes A

• Routinely screen for depression, diabetes distress, anxiety, disordered eating and cognitive capacities B

• Adults aged ≥65 years with DM should be considered for evaluation of cognitive impairment and depression B

Recommendations: Glycemic Goals in Adults

• Lowering A1C to <7% has been shown to reduce microvascular complications and, if implemented soon after the diagnosis of diabetes, is associated with long-term reduction in macrovascular disease \textit{B}

• Consider more stringent goals (e.g., <6.5%) for select patients if achievable without significant hypos or other adverse effects \textit{C}

• Consider less stringent goals (e.g., <8%) for patients with a hx of severe hypoglycemia, limited life expectancy, or other conditions that make <7% too difficult to attain \textit{B}

\textit{American Diabetes Association Standards of Medical Care in Diabetes. Glycemic Targets. Diabetes Care 2017; 40(Suppl 1):S48-S56.}
At each patient encounter, BMI should be calculated and documented in the medical record. B

Diet, physical activity, and behavioural therapy designed to achieve >5% weight loss should be prescribed for overweight and obese patients with T2D ready to achieve weight loss. A

Such interventions should be high intensity (≥16 sessions in six months) and focus on diet, physical activity, and behavioural strategies to achieve a 500-750 kcal/day energy deficit. A

Continued…
Recommendations: Obesity Management for the Treatment of Type 2 Diabetes (cont’d)

- Metabolic surgery should be recommended to T2D in appropriate surgical candidates with BMI ≥40 kg/m² (BMI ≥37.5 kg/m² in Asian Americans), regardless of the level of glycemic control or complexity of glucose-lowering regimens, and in patients with BMI 35.0–39.9 kg/m² (32.5–37.4 kg/m² in Asian Americans) when hyperglycemia is inadequately controlled despite lifestyle and optimal medical therapy. 

Recommendations: Pharmacological Therapy for Type 1 Diabetes

• Most people with T1DM should be treated with multiple dose insulin (MDI) injections or continuous subcutaneous insulin infusion (CSII) A

• Most individuals with T1DM should use rapid-acting insulin analogues to reduce hypoglycemia risk A

### Approach to the Management of Hyperglycemia

<table>
<thead>
<tr>
<th>Patient / Disease Features</th>
<th>More stringent</th>
<th>A1C 7%</th>
<th>Less stringent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Risks potentially associated with hypoglycemia and other drug adverse effects</td>
<td>low</td>
<td>A1C 7%</td>
<td>high</td>
</tr>
<tr>
<td>Disease duration</td>
<td>newly diagnosed</td>
<td>A1C 7%</td>
<td>long-standing</td>
</tr>
<tr>
<td>Life expectancy</td>
<td>long</td>
<td>A1C 7%</td>
<td>short</td>
</tr>
<tr>
<td>Relevant comorbidities</td>
<td>absent</td>
<td>A1C 7%</td>
<td>few / mild</td>
</tr>
<tr>
<td>Established vascular complications</td>
<td>absent</td>
<td>A1C 7%</td>
<td>severe</td>
</tr>
<tr>
<td>Patient attitude and expected treatment efforts</td>
<td>highly motivated, adherent, excellent self-care capabilities</td>
<td>A1C 7%</td>
<td>less motivated, nonadherent, poor self-care capabilities</td>
</tr>
<tr>
<td>Resources and support system</td>
<td>readily available</td>
<td>A1C 7%</td>
<td>limited</td>
</tr>
</tbody>
</table>

Antihyperglycemic Therapy in Type 2 Diabetes

Start with Monotherapy unless:
- A1C is greater than or equal to 9%, consider Dual Therapy.
- A1C is greater than or equal to 10%, blood glucose is greater than or equal to 300 mg/dL, or patient is markedly symptomatic, consider Combination Injectable Therapy (See Figure 8.2).

### Monotherapy

<table>
<thead>
<tr>
<th>Medication</th>
<th>Efficacy*</th>
<th>Hypo Risk</th>
<th>Weight</th>
<th>Side Effects</th>
<th>Costs*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Metformin</td>
<td>High</td>
<td>Low risk</td>
<td>Neutral</td>
<td>GI/lactic acidosis</td>
<td>Low</td>
</tr>
</tbody>
</table>

If A1C target not achieved after approximately 3 months of monotherapy, proceed to 2-drug combination (order not meant to denote any specific preference — choice dependent on a variety of patient- & disease-specific factors):

### Dual Therapy

<table>
<thead>
<tr>
<th>Combination</th>
<th>Efficacy*</th>
<th>Hypo Risk</th>
<th>Weight</th>
<th>Side Effects</th>
<th>Costs*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sulfonluries + Thiazolidinedione</td>
<td>High</td>
<td>Moderate risk</td>
<td>Gain</td>
<td>Hypoglycemia</td>
<td>Low</td>
</tr>
<tr>
<td>DPP-4 Inhibitor</td>
<td>Intermediate</td>
<td>Low Risk</td>
<td>Neutral</td>
<td>Edema, HF, fx</td>
<td>High</td>
</tr>
<tr>
<td>SGLT2 Inhibitor</td>
<td>Intermediate</td>
<td>Low Risk</td>
<td>Loss</td>
<td>Dehydration, fx</td>
<td>High</td>
</tr>
<tr>
<td>GLP-1 Receptor agonist</td>
<td>High</td>
<td>Low Risk</td>
<td>High</td>
<td>GI</td>
<td>High</td>
</tr>
<tr>
<td>Insulin (basal)</td>
<td>Highest</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

If A1C target not achieved after approximately 3 months of dual therapy, proceed to 3-drug combination (order not meant to denote any specific preference — choice dependent on a variety of patient- & disease-specific factors):

### Triple Therapy

<table>
<thead>
<tr>
<th>Combination</th>
<th>Efficacy*</th>
<th>Hypo Risk</th>
<th>Weight</th>
<th>Side Effects</th>
<th>Costs*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sulfonluries + Thiazolidinedione + DPP-4 Inhibitor</td>
<td>High</td>
<td>Moderate risk</td>
<td>Low</td>
<td>Hypoglycemia</td>
<td>Low</td>
</tr>
<tr>
<td>SGLT2 Inhibitor</td>
<td>Intermediate</td>
<td>Low Risk</td>
<td>Gain</td>
<td>Edema, HF, fx</td>
<td>High</td>
</tr>
<tr>
<td>GLP-1 Receptor agonist</td>
<td>Intermediate</td>
<td>Low Risk</td>
<td>Loss</td>
<td>Dehydration, fx</td>
<td>High</td>
</tr>
<tr>
<td>Insulin (basal)</td>
<td>High</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

If A1C target not achieved after approximately 3 months of triple therapy and patient (1) on oral combination, move to basal insulin or GLP-1 RA, (2) on GLP-1 RA, add basal insulin, or (3) on optimally titrated basal insulin, add GLP-1 RA or mealtime insulin. Metformin therapy should be maintained, while other oral agents may be discontinued on an individual basis to avoid unnecessarily complex or costly regimens (i.e., adding a fourth antihyperglycemic agent).

### Combination Injectable Therapy

(See Figure 8.2)
Combination Injectable Therapy for Type 2 Diabetes

Initiate Basal Insulin
Usually with metformin +/- other noninsulin agent

- **Start:** 10 U/day or 0.1–0.2 U/kg/day
- **Adjust:** 10–15% or 2–4 units once or twice weekly to reach FBG target
- **For hypo:** Determine & address cause; if no clear reason for hypo, ↓ dose by 4 units or 10–20%

If A1C not controlled, consider combination injectable therapy

Add 1 rapid-acting insulin injection before largest meal

- **Start:** 4 units, 0.1 U/kg, or 10% basal dose. If A1C <8%, consider ↑ basal by same amount
- **Adjust:** ↑ dose by 1–2 units or 10–15% once or twice weekly until SMBG target reached
- **For hypo:** Determine and address cause; if no clear reason for hypo, ↓ corresponding dose by 2–4 units or 10–20%

If A1C not controlled, advance to basal-bolus

Add ≥2 rapid-acting insulin injections before meals (‘basal-bolus’)

- **Start:** 4 units, 0.1 U/kg, or 10% basal dose/meal. If A1C <8%, consider ↓ basal by same amount
- **Adjust:** ↓ dose(s) by 1–2 units or 10–15% once or twice weekly to achieve SMBG target
- **For hypo:** Determine and address cause; if no clear reason for hypo, ↓ corresponding dose by 2–4 units or 10–20%

Add GLP-1 RA

- **Start:** Divide current basal dose into ½ AM, ½ PM or ½ AM, ½ PM
- **Adjust:** ↑ dose by 1–2 units or 10–15% once or twice weekly until SMBG target reached
- **For hypo:** Determine and address cause; if no clear reason for hypo, ↓ corresponding dose by 2–4 units or 10–20%

If goal(s) not met, consider changing to alternative insulin regimen

Change to premixed insulin twice daily (before breakfast and supper)

- **Start:** Add additional injection before lunch
- **Adjust:** ↑ doses by 1–2 units or 10–15% once or twice weekly to achieve SMBG target
- **For hypo:** Determine and address cause; if no clear reason for hypo, ↓ corresponding dose by 2–4 units or 10–20%

If A1C not controlled, advance to 3rd injection

Cardiovascular Disease

- CVD is the leading cause of morbidity and mortality for those with diabetes
- Largest contributor to direct/indirect costs
- Common conditions coexisting with T2D (e.g., hypertension, dyslipidemia) are clear risk factors for ASCVD
- Diabetes itself confers independent risk
- Control individual cardiovascular risk factors to prevent/slow CVD in people with diabetes
- Systematically assess all patients with diabetes for cardiovascular risk factors

Recommendations: Hypertension/Blood Pressure Control

Systolic Targets:

- People with diabetes and hypertension should be treated to a systolic blood pressure goal of <140 mmHg. A
- Lower systolic targets, such as <130 mmHg, may be appropriate for individuals at high risk of CVD, if they can be achieved without undue treatment burden. C
- In pregnant women with diabetes and chronic hypertension, targets of 120–160 mmHg are suggested to optimize long-term maternal health and minimize impaired fetal growth. E

Recommendations: Hypertension/Blood Pressure Control (cont’d)

Diastolic Targets:
• Patients with diabetes should be treated to a diastolic blood pressure <90 mmHg A
• Lower diastolic targets, such as <80 mmHg, may be appropriate for individuals at high risk of CVD, if they can be achieved without undue treatment burden C
• In pregnant women with diabetes and chronic hypertension, targets of 80–105 mmHg are suggested to optimize long-term maternal health and minimize impaired fetal growth E

# Recommendations for Statin Treatment in People with Diabetes

<table>
<thead>
<tr>
<th>Age</th>
<th>Risk Factors</th>
<th>Statin Intensity*</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;40 years</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td></td>
<td>ASCVD risk factor(s)**</td>
<td>Moderate or high</td>
</tr>
<tr>
<td></td>
<td>ASCVD</td>
<td>High</td>
</tr>
<tr>
<td>40–75 years</td>
<td>None</td>
<td>Moderate</td>
</tr>
<tr>
<td></td>
<td>ASCVD risk factors</td>
<td>High</td>
</tr>
<tr>
<td></td>
<td>ASCVD</td>
<td>High</td>
</tr>
<tr>
<td></td>
<td>ACS &amp; LDL &gt;50 who can’t tolerate high-dose statins</td>
<td>Moderate + ezetimibe</td>
</tr>
<tr>
<td>&gt;75 years</td>
<td>None</td>
<td>Moderate</td>
</tr>
<tr>
<td></td>
<td>ASCVD risk factors</td>
<td>Moderate or high</td>
</tr>
<tr>
<td></td>
<td>ASCVD</td>
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<td></td>
<td>ACS &amp; LDL &gt;50 who can’t tolerate high-dose statins</td>
<td>Moderate + ezetimibe</td>
</tr>
</tbody>
</table>

*In addition to lifestyle therapy. **ASCVD risk factors include LDL cholesterol $100 \text{mg/dL}$ (2.6 mmol/L), high blood pressure, smoking, chronic kidney disease, albuminuria, and family history of premature ASCVD.

Recommendations: Antiplatelet Agents

- Consider aspirin therapy (75–162 mg/day) C
- As a primary prevention strategy in those with T1DM or T2DM at increased cardiovascular risk (10-year risk >10%)
- Includes most men or women with diabetes age ≥50 years who have at least one additional major risk factor, including:
  - family history of premature ASCVD
  - hypertension
  - smoking
  - dyslipidemia
  - albuminuria

Recommendations: Coronary Artery Disease

Screening:

- In asymptomatic patients, routine screening for CAD isn’t recommended and doesn’t improve outcomes, provided ASCVD risk factors are treated. A
- Consider investigations for CAD with:
  - Atypical cardiac symptoms (e.g., unexplained dyspnea, chest discomfort)
  - Signs or symptoms of associated vascular disease including carotid bruits, transient ischemic attack, stroke, claudication or PAD
  - EKG abnormalities (e.g., Q waves) E

Recommendations:
Diabetic Kidney Disease

Treatment:

• Optimize glucose control to reduce risk or slow progression of diabetic kidney disease A

• Optimize blood pressure control to reduce risk or slow progression of diabetic kidney disease A
Recommendations: Diabetic Retinopathy

Screening:

• Initial dilated and comprehensive eye examination by an ophthalmologist or optometrist:
  – Adults with T1DM, within five years of diabetes onset B
  – Patients with T2D at the time of diabetes diagnosis B

• Women with preexisting T1DM or T2DM who are planning pregnancy or who are pregnant should be counselled on the risk of development and/or progression of diabetic retinopathy B

Treatment:

- Promptly refer patients with macular edema, severe NPDR, or any PDR to an ophthalmologist knowledgeable and experienced in the management and treatment of diabetic retinopathy.

- Laser photocoagulation therapy is indicated to reduce the risk of vision loss in patients with high-risk PDR and, in some cases, severe NPDR.
Recommendations: Neuropathy

Screening:

• Assess all patients for DPN at dx for T2DM, five years after dx for T1DM, and at least annually thereafter B

• Assessment should include history and either temperature or pinprick sensation (for small-fibre function) and vibration sensation using a 128-Hz tuning fork (for large-fibre function). All patients should have an annual 10 g monofilament testing to identify feet at risk for ulceration and amputation B

• Symptoms of autonomic neuropathy should be assessed in patients with microvascular and neuropathic complications E

Recommendations: Neuropathy (cont’d)

Treatment:

• Optimize glucose control to prevent or delay the development of neuropathy in patients with T1DM A and to slow progression in patients with T2D B

• Assess and treat patients to reduce pain related to DPN B and symptoms of autonomic neuropathy and to improve quality of life E

• Either pregabalin or duloxetine are recommended as initial pharmacologic treatments for neuropathic pain in diabetes A

Recommendations: Foot Care

- Perform a comprehensive foot evaluation annually to identify risk factors for ulcers and amputations B
- History should contain prior hx of ulceration, amputation, Charcot foot, angioplasty or vascular surgery, cigarette smoking, retinopathy and renal disease; and should assess current symptoms of neuropathy and vascular disease B

Recommendations: Older Adults

• Annual screening for early detection of mild cognitive impairment or dementia is indicated for adults ≥ 65 years of age B

• Older adults (≥ 65 years of age) with diabetes should be considered a high priority population for depression screening and treatment B

• Hypoglycemia should be avoided in older adults with diabetes; it should be assessed and managed by adjusting glycemic targets and pharmacologic interventions B
