American Diabetes Association
Standards of Medical Care in Diabetes 2017:
Focus on Complications

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Rising Cost of Diabetes

• In 2012, the total cost of diabetes was estimated at $245 billion ($176 billion in direct costs and $69 billion in indirect costs)

• The largest components of medical expenditures were:

- **43%**  
  Hospital inpatient care

- **18%**  
  Prescription meds to treat complications of diabetes

- **12%**  
  Diabetes medications and supplies

- **9%**  
  Physician office visits

- **8%**  
  Nursing / residential facility stays
# Targets for Glycemic Control

<table>
<thead>
<tr>
<th>Test</th>
<th>Glycemic control targets</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>ADA</td>
</tr>
<tr>
<td>A1C</td>
<td>&lt;7%</td>
</tr>
<tr>
<td>FPG</td>
<td>80-130 mg/dL (4.4-7.2 mmol/L)</td>
</tr>
<tr>
<td>PPG</td>
<td>&lt;180 mg/dL (&lt;10 mmol/L) (measured within 1 to 2 hours after the start of a meal)</td>
</tr>
</tbody>
</table>

A1C target should be individualized based on numerous factors, including age, life expectancy, comorbid conditions, duration of diabetes, risk of hypoglycemia or adverse consequences from hypoglycemia, patient motivation, and adherence<sup>1,2</sup>

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Antihyperglycemic Therapy in Type 2 Diabetes: General Recommendations

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

**Metformin**

- **EFFICACY**: high
- **HYPO RISK**: low risk
- **WEIGHT**: neutral/loss
- **SIDE EFFECTS**: GI/lactic acidosis
- **COSTS**: low

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

**Metformin**

**Sulfonylurea**

- **EFFICACY**: high
- **HYPO RISK**: moderate risk
- **WEIGHT**: gain
- **SIDE EFFECTS**: hypoglycemia
- **COSTS**: low

**Thiazolidinedione**

- **EFFICACY**: high
- **HYPO RISK**: low risk
- **WEIGHT**: gain
- **SIDE EFFECTS**: edema, HF, fxS
- **COSTS**: low

**DPP-4 Inhibitor**

- **EFFICACY**: intermediate
- **HYPO RISK**: low risk
- **WEIGHT**: neutral
- **SIDE EFFECTS**: none
- **COSTS**: high

**SGLT2 Inhibitor**

- **EFFICACY**: intermediate
- **HYPO RISK**: low risk
- **WEIGHT**: loss
- **SIDE EFFECTS**: increase in urinary tract infection
- **COSTS**: high

**GLP-1 receptor agonist**

- **EFFICACY**: high
- **HYPO RISK**: high risk
- **WEIGHT**: gain
- **SIDE EFFECTS**: nausea
- **COSTS**: high

**Insulin (basal)**

- **EFFICACY**: highest
- **HYPO RISK**: high risk
- **WEIGHT**: gain
- **SIDE EFFECTS**: hypoglycemia
- **COSTS**: high

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

**Metformin**

**Sulfonylurea**

- **TZD** or **DPP-4-I** or **SGLT2-I** or **GLP-1-RA** or **insulin*”

**Thiazolidinedione**

- **SU** or **TZD** or **DPP-4-I** or **SGLT2-I** or **GLP-1-RA** or **insulin*”

**DPP-4 Inhibitor**

- **SU** or **TZD** or **DPP-4-I** or **SGLT2-I** or **GLP-1-RA** or **insulin*”

**SGLT2 Inhibitor**

- **SU** or **TZD** or **DPP-4-I** or **SGLT2-I** or **GLP-1-RA** or **insulin*”

**GLP-1 receptor agonist**

- **SU** or **TZD** or **DPP-4-I** or **SGLT2-I** or **GLP-1-RA** or **insulin*”

**Insulin (basal)**

- **SU** or **TZD** or **DPP-4-I** or **SGLT2-I** or **GLP-1-RA** or **insulin*”

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)

Complications of Diabetes

**Acute Complications**
- Diabetic Ketoacidosis
- Hyperosmolar Hyperglycemic Syndrome
- Hypoglycemia

**Chronic Complications**

**Microvascular**
- Diabetic Nephropathy
- Diabetic Retinopathy
- Diabetic Neuropathy

**Macrovascular**
- Coronary Artery Disease
- Cerebrovascular Disease
- Peripheral Vascular Disease
Hypoglycemia

“Hypoglycemia is the major limiting factor in the glycemic management of type 1 and type 2 diabetes”

“Symptoms of hypoglycemia include, but are not limited to, shakiness, irritability, confusion, tachycardia, and hunger”

“Severe hypoglycemia may be recognized or unrecognized and can progress to loss of consciousness, seizure, coma, or death”

## Classification of Hypoglycemia

<table>
<thead>
<tr>
<th>Level</th>
<th>Glycemic Criteria</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glucose alert value (level 1)</td>
<td>≤70 mg/dL (3.9 mmol/L)</td>
<td>Sufficiently low for treatment with fast-acting carbohydrate and dose adjustment of glucose-lowering therapy</td>
</tr>
<tr>
<td>Clinically significant hypoglycemia (level 2)</td>
<td>&lt;54 mg/dL (3.0 mmol/L)</td>
<td>Sufficiently low to indicate serious, clinically important hypoglycemia</td>
</tr>
<tr>
<td>Severe hypoglycemia (level 3)</td>
<td>No specific glucose threshold</td>
<td>Hypoglycemia associated with severe cognitive impairment requiring external assistance for recovery</td>
</tr>
</tbody>
</table>

Hypoglycemia

• For individuals at risk of hypoglycemia, ask about symptomatic and asymptomatic hypoglycemia at each encounter

• Glucose (15-20 g) is the preferred treatment for conscious individual with hypoglycemia. Re-treat after 15 min if continued hypoglycemia.

• Glucagon should be prescribed for individuals at risk of clinically significant hypoglycemia; Caregivers, school personnel, family members, etc. should know when and how to administer.
Hypoglycemia (cont.)

• Hypoglycemia unawareness or episodes of severe hypoglycemia should trigger reevaluation of the treatment regimen.

• Glycemic targets should be raised for at least several weeks in insulin-treated patients with hypoglycemia unawareness or an episode of severe hypoglycemia.

• Increased vigilance for hypoglycemia should occur in patients with low or declining cognition.
Atherosclerotic Cardiovascular Disease

• ASCVD: Acute coronary syndrome, history of MI, stable or unstable angina, coronary or other arterial revascularization, stroke, TIA, or PVD

• LEADING CAUSE OF MORBITY AND MORALITY FOR PERSONS WITH DIABETES AND LARGEST CONTRIBUTOR TO DIABETES-RELATED COSTS

• ASCVD Risk Factors:
  • Hypertension
  • Dyslipidemia
  • Smoking
  • Presence of albuminuria
  • Family history of premature CAD

• Diabetes itself confers independent risk of ASCVD

• Addressing risk factors simultaneously confers large benefits
Hypertension and Blood Pressure Control

- BP should be measured at every routine visit

- Seated position, feet on floor and arm supported at heart level, after 5 min of rest

- BP GOALS:
  - Most patients: <140/<90 mmHg
  - Lower targets (e.g., 130/80 mm/Hg) in patients at high risk of CVD (if it can be achieved without undue treatment burden)
Hypertension and Blood Pressure Control (cont.)

• Confirmed office-based BP >140/90 mmHg - lifestyle therapy and initiation and titration of pharmacological therapy

• If >160/100 mmHg, two drugs or single combination pill

• Multiple drugs usually required to achieve targets

• Drug classes demonstrated to reduce CV events in people with diabetes should be used: ACE inh., angiotensin receptor blockers (ARBs), thiazide diuretics, or dihydropyridine calcium channel blockers

• Should not combine ACE inh. and ARBs

Hypertension and Blood Pressure Control (cont.)

• If proteinuria or microalbuminuria, an ACE inh. or ARB at maximal tolerated dose indicated for HTN should be first line therapy

• Monitor serum Cr / eGFR and potassium

• For patients with BP >120/80 mmHg: Weight loss if overweight or obese, DASH diet, moderate ETOH, and physical activity
Polling Question #1

True or False, an individual with diabetes and known ASCVD should be on high-intensity statin therapy irrespective of their age?

a) True
b) False
Statin and Combination Therapy in Diabetes

<table>
<thead>
<tr>
<th>Age</th>
<th>Risk Factors</th>
<th>Recommended 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>
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<tr>
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*In addition to lifestyle therapy. **ASCVD risk factors include LDL cholesterol ≥100 mg/dL (2.6 mmol/L), high blood pressure, smoking, chronic kidney disease, albuminuria, and family history of premature ASCVD.
## High-intensity and Moderate-intensity Statin Therapy

<table>
<thead>
<tr>
<th>High-intensity statin therapy (lowers LDL cholesterol by ≥50%)</th>
<th>Moderate-intensity statin therapy (lowers LDL cholesterol by 30% to &lt;50%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Atorvastatin 40-80 mg</td>
<td>Atorvastatin 10-20 mg</td>
</tr>
<tr>
<td>Rosuvastatin 20-40 mg</td>
<td>Rosuvastatin 5-10 mg</td>
</tr>
<tr>
<td></td>
<td>Simvastatin 20-40 mg</td>
</tr>
<tr>
<td></td>
<td>Pravastatin 40-80 mg</td>
</tr>
<tr>
<td></td>
<td>Lovastatin 40 mg</td>
</tr>
<tr>
<td></td>
<td>Fluvastatin XL 80 mg</td>
</tr>
<tr>
<td></td>
<td>Pitavastatin 2-4 mg</td>
</tr>
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*Once-daily dosing. XL, extended release.

- PCSK9 inhibitors (e.g., evolocumab and alirocumab) may be considered as adjunctive therapy for people with diabetes at high risk for ASCVD who require additional LDL-C lowering or who are intolerant to high-intensity statin therapy.
Lipid Management

• Obtain lipid panel at time of diagnosis and every 5 years thereafter (more frequent if indicated)

• Obtain lipid panel at initiation of statin therapy and periodically thereafter

• Lifestyle modification (focus on weight loss, if indicated, and MNT)

• For elevated triglycerides (≥150 mg/dL) and/or low HDL-C (<40 mg/dL men; <50 mg/dL women) - Lifestyle therapy and optimal glycemic control

• Triglycerides ≥500 mg/dL - Evaluate for secondary causes and consider medical therapy
Lipid Management (cont.)

• Statin therapy based on age and presence of ASCVD or risk factors:

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

- Combination therapy (statin+ezetimibe, statin+fenofibrate)
- Statin+niacin not generally recommended (may increase risk of stroke)
- Statins contraindicated in pregnancy
Polling Question #2

Which of the following people with type 2 diabetes is a good candidate for aspirin monotherapy?

a) A 65-yo woman with a history of multiple myocardial infarctions and with an aspirin allergy.

b) A 45-yo man with no additional CV risk factors and no history of CV disease.

c) A 56-yo obese woman with HTN, dyslipidemia and a strong family history or early CAD. She has severe non-proliferative diabetic retinopathy.

d) A 45-yo man with a history of acute myocardial infarction 2 months ago.
• Aspirin therapy as **secondary prevention strategy** in individuals with diabetes and a history of ASCVD (75-162 mg daily)

• If aspirin allergy, use clopidogrel 75 mg daily

• Dual antiplatelet therapy is reasonable for up to 1 year after an acute coronary syndrome (may have benefits beyond this period)
Aspirin therapy as **primary prevention strategy** for individuals with high CV risk (and not at increased risk of bleeding)

- Most men and women ≥50 yo and at least one additional major risk factor
- 75-162 mg daily
- Not recommended for individuals at low atherosclerotic risk (adverse effects offset the potential benefits)
Antihyperglycemic Therapies and CV Outcomes: Empagliflozin (EMPA-REG OUTCOME)

- Randomized, double-blind, PBO-controlled CV outcomes trial assessing empagliflozin (SGLT-2 inhibitor) vs. placebo on CV outcomes in patients with T2DM and existing CVD

- Over a median follow-up of 3.1 years, treatment reduced the composite outcome of MI, stroke, and CV death by 14% (absolute rate 10.5% vs. 12.1%) and CV death by 38% (absolute rate 3.7% vs. 5.9%).

- The FDA recently added a new indication for empagliflozin, to reduce the risk of CV death in adults with T2DM and CVD

**Primary Composite Endpoint**

**Death from CV Cause**
Antihyperglycemic Therapies and CV Outcomes: Liraglutide (LEADER)

- Randomized, double-blind, PBO-controlled CV outcomes trial assessing the effect of liraglutide (GLP-1 RA) vs. placebo on CV outcomes in patients with T2DM at high risk for CVD or with existing CVD
- Over a median follow-up of 3.8 years, treatment reduced the composite outcome of MI, stroke, and CV death by 13% (absolute rate 13.0% vs. 14.9%) and CV death by 22% (absolute rate 4.7% vs. 6.0%).

Primary Composite Endpoint

Death from CV Cause
Microvascular Complications

• Diabetes-specific complications
• Due primarily to hyperglycemia
• Diabetic Nephropathy (leading cause of ESRD)
• Diabetic Retinopathy (leading cause of blindness in adults)
• Diabetic Neuropathy (Leading cause of non-traumatic lower extremity amputations)
• Significant human and economic cost
• Development and progression can be prevented or delayed
Polling Question #3

True or False, screening for diabetic nephropathy, retinopathy and neuropathy is recommended at the time of diagnosis for both individuals with type 1 diabetes and type 2 diabetes?

a) True

b) False
Diabetic Nephropathy: Screening

• Spot urine albumin-to-creatinine ratio (UACR) and eGFR (serum Cr) in patients with type 1 diabetes with duration of diabetes \( \geq 5 \) years, in all patients with type 2 diabetes, and in all patients with comorbid HTN

• Important to note that several factors can elevate (UACR) independent of kidney damage:
  • Exercise within 24h
  • Infection
  • Fever
  • Congestive heart failure
  • Marked hyperglycemia and/or HTN
  • Menstruation
Diabetic Nephropathy: Treatment

• Optimize glycemic and blood pressure control

• Protein intake approx. 0.8 g/kg per day (non-dialysis dependent patients)

• If DM and HTN, ACE inh. or ARB (monitor serum Cr and potassium periodically)

• Assess response by periodically monitoring UACR

• ACE inh. or ARB not recommended as primary prevention in patients with normal BP, normal UACR and normal eGFR.

• If eGFR <30 mL/min/1.73 m2, refer for evaluation for renal replacement therapy

Stages and Management of CKD in Diabetes

**Stages of CKD:**

<table>
<thead>
<tr>
<th>Stage</th>
<th>Description</th>
<th>eGFR (mL/min/1.73 m²)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Kidney damage* with normal or increased eGFR</td>
<td>≥90</td>
</tr>
<tr>
<td>2</td>
<td>Kidney damage* with mildly decreased eGFR</td>
<td>60-89</td>
</tr>
<tr>
<td>3</td>
<td>Moderately decreased eGFR</td>
<td>30-59</td>
</tr>
<tr>
<td>4</td>
<td>Severely decreased eGFR</td>
<td>15-29</td>
</tr>
<tr>
<td>5</td>
<td>Kidney failure</td>
<td>&lt;15 or dialysis</td>
</tr>
</tbody>
</table>

* Kidney damage is defined as UACR persistently ≥30 mg/g Cr or other abnormalities on pathological, urine, blood, or imaging tests. Adapted from Levey et al. (4).

**Management of CKD in Diabetes:**

- **All patients**
  - Yearly measurement of UACR, serum Cr, potassium
- **45-60**
  - Referral to a nephrologist if possibility for nondiabetic kidney disease exists (duration of type 1 diabetes < 10 years, persistent albuminuria, abnormal findings on renal ultrasound, resistant hypertension, rapid fall in eGFR, or active urinary sediment on urine microscopic examination)
  - Consider the need for dose adjustment of medications
  - Monitor eGFR every 6 months
  - Monitor electrolytes, bicarbonate, hemoglobin, calcium, phosphorus, and parathyroid hormone at least yearly
  - Assure vitamin D sufficiency
  - Vaccinate against Hep B virus
  - Referral for dietary counseling
- **30-44**
  - Monitor eGFR every 3 months
  - Monitor electrolytes, bicarbonate, calcium, phosphorus, parathyroid hormone, hemoglobin, albumin, and weight every 3-6 months
  - Consider the need for dose adjustment of medications
- **<30**
  - Referral to a nephrologist

CKD = Chronic Kidney Disease
Diabetic Retinopathy: Screening

• Initial dilated and comprehensive eye exam in patients with type 1 diabetes within 5 years of diagnosis and in patients with type 2 diabetes at time of diagnosis

• Annual eye exams (ophthalmologist or optometrist)

• If good glucose control and normal exam for one or more annual exams, then consider exams every 2 years

• Woman who are planning pregnancy or are pregnant, should be counseled about risk of development or progression of retinopathy. They should have a pre-pregnancy exam (or in 1st trimester) then every trimester and for 1 year postpartum as indicated by the degree of retinopathy.
Diabetic Retinopathy: Treatment

• Glycemic and BP control

• Prompt referral to ophthalmologist (macular edema, severe non-proliferative or proliferative retinopathy)

• Laser photocoagulation for high-risk proliferative and in some cases, severe non-proliferative retinopathy

• Intravitreal injections of anti-vascular endothelial growth factor for central-involved diabetic macular edema

• Retinopathy is not a contraindication to aspirin therapy for cardioprotection. Aspirin does not increase the risk of retinal hemorrhage.

Diabetic Neuropathy

- Heterogeneous group of disorders with diverse clinical manifestations

- Diagnosis of exclusion

- Numerous treatment options exist for symptomatic diabetic neuropathy

- Up to 50% of diabetic peripheral neuropathy is asymptomatic. If not recognized and preventive foot care not implemented, risk for injury to insensate feet.

- Recognition and treatment of autonomic neuropathy may improve symptoms and improve quality of life

Diabetic Neuropathy

- Assess for diabetic peripheral neuropathy at diagnosis of type 2 diabetes and 5 years after the diagnosis of type 1 diabetes, and at least annually thereafter

- Assessment for distal symmetric polyneuropathy should include:
  - Careful history
  - Assessment of either temperature or pinprick sensation and vibration sensation using a 128-Hz tuning form
  - All patients should have annual 10-g monofilament testing to identify feet at risk for ulceration or amputation

- Autonomic neuropathy should be assessing in patients with microvascular and neuropathic complications

- Optimize glycemic control

- Treatment of pain related to peripheral neuropathy and symptoms of autonomic neuropathy improved quality of life

- Either pregabalin or duloxetine for initial treatment of neuropathic pain

Immunizations

• Routine vaccinations according to age-related recommendations

• Annual influenza vaccine for all persons with diabetes ≥6 months old

• Vaccination against pneumonia is for all people with diabetes 2-64 yo with pneumococcal polysaccharide vaccine (PPSV23). At age ≥65 years, pneumococcal conjugate vaccine (PCV13) at least 1 year after vaccination with PPSV23, followed by another dose of vaccine PPSV23 at least 1 year after PCV13 and at least 5 years after the last dose of PPSV23.

• 3-dose series of hepatitis B vaccine to unvaccinated adults with diabetes 19–59 yo and consider in unvaccinated adults ≥60 yo
Summary

• Diabetes complications are very costly, both from a human and economic perspective.

• Development and progression of complications (acute and chronic) can be prevented and/or delayed.

• Screening for evidence of diabetes complications is critically important.

• Achieving individualized glycemic targets is a key factor in preventing and delaying progression of complications.

• Hypoglycemia - an acute complication of some diabetes therapies - is a major limiting factor to achieving glycemic targets.

• Other CV risk factors that commonly co-exist with diabetes must be treated simultaneously.
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