Significant Therapeutic Advances in Diabetes Care Over Past 20 Years

**Professional Practice Committee**

Members of the PPC
- Rita R. Kalyani, MD, MHS, FACP (Chair)
- Christopher P. Cannon, MD
- Andrea L. Cherrington, MD, MPH
- Donald R. Covrit, MD
- Ian H. de Boer, MD, MS
- Hope Feldman, CRNP, FNP-BC
- Judith Feinberg, MD
- David Maahs, MD, PhD
- Melinda Marynik, MEd, RD, CDE
- Madha H. Murthy, MD
- Joshua J. Nunnally, PharmD, CDE, FASCP
- Guillermo E. Umpierrez, MD, CDE, FACE, FACP

ADA Staff
- Erika Gebel Berg, PhD
- Matthew P. Peterson
- Sacha Usdin, RDN, CDE
- William T. Cefalu, MD

ACC Designated Representatives (Section 9)
- Sandeep Das, MD, MPH, FACC
- Mikhail Kosiborod, MD, FACC

**Process**

- ADA’s Professional Practice Committee (PPC) conducts annual review & revisions.
- Literature search of human studies related to each diabetes subsection and published since January 1 of the previous year.
- Recommendations are revised based on new evidence, for clarity, or to update the text to match the strength of evidence.

professional.diabetes.org/SOC

**Evidence Grading System**

- **A** - high level of evidence, rigorous study design, minimal or no bias. Commonly found in meta-analyses, RCTs, or systematic reviews of multiple studies.
- **B** - moderate level of evidence, less rigorous study design, and some potential for selection bias. Commonly found in RCTs, well-designed observational studies, or cohort studies.
- **C** - low level of evidence, weak study design, and potential for selection and/or bias. Commonly found in case reports, uncontrolled studies, or case series.
- **D** - very low level of evidence, uncontrolled studies, and potential for bias. Commonly found in case series or expert opinion.

**Trend Toward Higher Level of Evidence**

Trend from 2005 to 2014 in number and proportion of recommendations made each year in the ADA Standards of Care that were based on higher-level evidence vs. lower-level evidence.

*Richard W. Grant, and M. Sue Kirkman*  
_DiaCare_ 2015;38:6

©2015 by American Diabetes Association
Trend Toward Higher Level of Evidence

Trends from 2005 to 2014 in annual proportion of recommendations based on higher-level evidence, stratified into four mutually exclusive categories

![Graph showing trends from 2005 to 2014 in annual proportion of recommendations based on higher-level evidence, stratified into four mutually exclusive categories.]

Standards of Care: Table of Contents

1. Improving Care and Promoting Health in Populations
2. Classification and Diagnosis of Diabetes
3. Comprehensive Medical Evaluation and Assessment of Co-morbidities
4. Lifestyle Management
5. Prevention and Delay of Type 2 Diabetes
6. Glycemic Targets
7. Obesity Management for the Treatment of Type 2 Diabetes
8. Pharmacologic Approaches to Glycemic Treatment
9. Cardiovascular Disease and Risk Management
10. Microvascular Complications and Foot Care
11. Older Adults
12. Children and Adolescents
13. Management of Diabetes in Pregnancy
14. Diabetes Care in the Hospital
15. Diabetes Advocacy

Changes are needed to Improve Care Quality in Diabetes: Type 2 Diabetes Trends in the U.S. 2006-2013

Advances in health technology, drug therapies and policy have NOT translated to improvements in diabetes care quality

Care Delivery Systems

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

Diabetes and Population Health: Recommendations

- Care systems should facilitate team-based care, patient registries, decision support tools, and community involvement to meet patient needs.
- Efforts to assess the quality of diabetes care and create quality improvement strategies should incorporate reliable data metrics, to promote improved processes of care and health outcomes, with simultaneous emphasis on costs.
Health Inequities

- Health inequities related to diabetes and its complications are well documented and are heavily influenced by social determinants of health.

- Social determinants of health are defined as:
  - The economic, environmental, political, and social conditions in which people live.
  - Responsible for a major part of health inequality worldwide.

Tailoring Treatment for Social Context

Key Recommendations:

- Providers should assess social context, including potential food insecurity, housing stability, and financial barriers, and apply that information to treatment decisions. A
- Refer patients to local community resources when available. B
- Provide patients with self-management support from lay health coaches, navigators, or community health workers when available. A

Classification of Diabetes

1. Type 1 diabetes
   - \( \beta \)-cell destruction

2. Type 2 diabetes
   - Progressive insulin secretory defect

3. Gestational Diabetes Mellitus (GDM)

4. Other specific types of diabetes due to other causes:
   - Monogenic diabetes syndromes
   - Diseases of the exocrine pancreas, e.g., cystic fibrosis
   - Drug- or chemical-induced diabetes

Criteria for the Diagnosis of Diabetes

Table 2.2—Criteria for the diagnosis of diabetes

<table>
<thead>
<tr>
<th>FPG (mg/dL)</th>
<th>126</th>
<th>7.0 mmol/L</th>
</tr>
</thead>
<tbody>
<tr>
<td>OR</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2-h PG (mg/dL)</td>
<td>≥200</td>
<td>≥11.1 mmol/L</td>
</tr>
<tr>
<td>OR</td>
<td></td>
<td></td>
</tr>
<tr>
<td>A1C (%)</td>
<td>≥6.5</td>
<td>48 mmol/mol</td>
</tr>
</tbody>
</table>

In a patient with classic symptoms of hyperglycemia or hyperglycemic crisis, a random plasma glucose of 200 mg/dL (11.1 mmol/L) is diagnostic.

*In the absence of unequivocal hyperglycemia, results should be confirmed by repeat testing.

Categories of Increased Risk for Diabetes (Prediabetes)

Table 2.4—Categories of increased risk for diabetes (prediabetes)*

<table>
<thead>
<tr>
<th>FPG (mg/dL)</th>
<th>≥126</th>
<th>7.0 mmol/L</th>
</tr>
</thead>
<tbody>
<tr>
<td>OR</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2-h PG (mg/dL)</td>
<td>≥140</td>
<td>≥7.8 mmol/L</td>
</tr>
<tr>
<td>OR</td>
<td></td>
<td></td>
</tr>
<tr>
<td>A1C (%)</td>
<td>≥5.7</td>
<td>48 mmol/mol</td>
</tr>
</tbody>
</table>

*For all three tests, risk is continuous, extending below the lower limit of the range and becoming disproportionately greater at the higher end of the range.
A1C: New Recommendations

- To avoid misdiagnosis or missed diagnosis, the A1C test should be performed using a method that is certified by the NGSP and standardized to the Diabetes Control and Complications Trial (DCCT) assay.
- Marked discordance between measured A1C and plasma glucose levels should raise the possibility of A1C assay interference due to hemoglobin variants (i.e., hemoglobinopathies) and consideration of using an assay without interference or plasma blood glucose criteria to diagnose diabetes.
- In conditions associated with increased red blood cell turnover, such as sickle cell disease, pregnancy (second and third trimesters), hemodialysis, recent blood loss or transfusion, or erythropoietin therapy, only plasma blood glucose criteria should be used to diagnose diabetes.

Testing for Diabetes or Prediabetes in Asymptomatic Adults

Table 3.3—Criteria for testing for diabetes or prediabetes in asymptomatic adults

1. Testing should be considered in overweight or obese (BMI ≥ 25 kg/m² or ≥ 23 kg/m² in Asian Americans) adults with risk factors for diabetes or with a history of prediabetes.
2. First-degree relative with diabetes.
3. High-risk minority (e.g., African American, Latin American, Native American, Asian American, Pacific Islander).
4. History of CVD.
5. Hypertension (≥140/90 mmHg or on drug therapy for hypertension).
6. HDL cholesterol level ≤ 35 mg/dL (≤ 40 mg/dL in men) and/or triglycerides level > 250 mg/dL.
7. Women with polycystic ovary syndrome.
8. Physical inactivity.
9. Other clinical conditions associated with insulin resistance (e.g., severe obesity, anorexia nervosa).

- 2. Patients with prediabetes (A1C 5.7%–6.4% also B1C or IFG should be tested yearly.
- 3. Women who were diagnosed with GDM should have lifelong testing at least every 4 years.
- 5. Pregnancy testing should be repeated at least at 9 months.

Patient-Centered Collaborative Care

- A patient-centered communication style that uses person-centered and strength-based language, active listening, elicits patient preferences and beliefs, and assesses literacy, numeracy, and potential barriers to care should be used to optimize patient health outcomes and health-related quality of life.

Components of the Comprehensive Diabetes Evaluation

3. Comprehensive Medical Evaluation and Assessment of Comorbidities

- Components of the Comprehensive Diabetes Evaluation

- Patient-Centered Collaborative Care

- Components of the Comprehensive Diabetes Evaluation:

- Comprehensive Medical Evaluation and Assessment of Comorbidities

- Diabetes Care 2018; 41 (Suppl. 1): S13–S27

- Comprehensive Medical Evaluation and Assessment of Comorbidities

- Diabetes Care 2018; 41 (Suppl. 1): S28–S37
Components of the Comprehensive Diabetes Evaluation

Comprehensive Medical Evaluation and Assessment of Comorbidities: Standards of Medical Care in Diabetes - 2018. Diabetes Care 2018; 41 (Suppl. 1): S28-S37

† May be needed more frequently in patients with known chronic kidney disease or with changes in medications that affect kidney function and serum potassium.

‡ May also need to be checked after initiation or dose changes of medications that affect these laboratory values (i.e., diabetes medications, blood pressure medications, cholesterol medications, or thyroid medications).

˄ In people without dyslipidemia and not on cholesterol-lowering therapy, testing may be less frequent.

4. Lifestyle Management

- Diabetes self-management education and support (DSMES)
- Medical nutrition therapy (MNT)
- Physical activity
- Smoking cessation counseling
- Psychosocial care
Diabetes Self-Management Education and Support

Four critical time points for DSMES delivery:
1. At diagnosis
2. Annually for assessment of education, nutrition, and emotional needs
3. When new complicating factors (health conditions, physical limitations, emotional factors, or basic living needs) arise that influence self-management; and
4. When transitions in care occur

Nutrition: Recommendations

<table>
<thead>
<tr>
<th>Type</th>
<th>Recommendations</th>
<th>Evidence rating</th>
</tr>
</thead>
<tbody>
<tr>
<td>Energy balance</td>
<td>To prevent the development of obesity, achieve weight loss, and maintain weight loss, adults with type 2 diabetes should engage in moderate- or vigorous-intensity aerobic activity at least 3 days per week, 150 minutes or more per week, or the equivalent.</td>
<td>B, C</td>
</tr>
<tr>
<td>Eating patterns and macronutrient distribution</td>
<td>Adults with type 2 diabetes should achieve fiber intake of 25 g or more per day, especially from complex carbohydrates, and should limit intake of saturated and trans fats.</td>
<td>E</td>
</tr>
</tbody>
</table>

Diabetes Food Hub

- Diabetes Food Hub allows users to customize recipes to meet individual needs:
  - adjust the number of servings to make or the portion to eat, and
  - nutrition facts and ingredient lists are recalculated based on the servings and portions chosen.

Diabetes Distress

- Diabetes distress
  - Very common and distinct from other psychological disorders
  - Negative psychological reactions related to emotional burdens of managing a demanding chronic disease
- Recommendation:
  - Routinely monitor people with diabetes for diabetes distress, particularly when treatment targets are not met and/or at the onset of diabetes complications.

Physical Activity: Recommendations

- Children and adolescents with diabetes or prediabetes should engage in 60 min/day or more of moderate- or vigorous-intensity aerobic activity, with vigorous muscle-strengthening and bone-strengthening activities at least 3 days/week.
- Most adults with type 1 and type 2 diabetes should engage in 150 min or more of moderate-to-vigorous intensity aerobic activity per week, spread over at least 5 days/week, with no more than 2 consecutive days without activity. Shorter durations (minimum 75 min/week) of vigorous-intensity or interval training may be sufficient for younger and more physically fit individuals.

Mental Health Provider Diabetes Education Program (MHDEP)

ADA and the American Psychological Association (APA) partnered to create the first ever, diabetes-focused continuing education (CE) program for licensed mental health providers.

Upon successful completion of the program, the provider can:
- Become an ADA member at the Associate level
- Receive 12 CE credits from the APA
- Become eligible for inclusion on the Mental Health Provider Referral Directory
- Access the ADA’s new listserv for behavioral health and psychosocial topics
- Access monthly ‘mentoring’ calls with experts in the field
5. Prevention or Delay of Type 2 Diabetes

Prevention or Delay of T2DM: Recommendations

- Patients with prediabetes should be referred to an intensive behavioral lifestyle intervention program modeled on the Diabetes Prevention Program to achieve and maintain 7% loss of initial body weight and increase moderate-intensity physical activity (such as brisk walking) to at least 150 min/week.

- Metformin therapy for prevention of type 2 diabetes should be considered in those with prediabetes, especially for those with BMI ≥35 kg/m², those aged <60 years, and women with prior GDM.

6. Glycemic Targets

Summary of Glycemic Recommendations

Table 6.2—Summary of glycemic recommendations for many nonpregnant adults with diabetes

- A1C: <7.0% (53 mmol/mol)*
- Preprandial capillary plasma glucose: 80–130 mg/dL (4.4–7.3 mmol/L)
- Peak postprandial capillary plasma glucose*: <180 mg/dL (10.0 mmol/L)

*More or less stringent glycemic goals may be appropriate for individual patients. Goals should be individualized based on duration of diabetes, age, life expectancy, comorbid conditions, known CVD or advanced microvascular complications, hypoglycemia unawareness, and individual patient considerations. Postprandial glucose may be targeted if A1C goals are not met despite reaching preprandial glucose goals. Postprandial glucose measurements should be made 1–2 h after the beginning of the meal, generally peak levels in patients with diabetes.

7. Obesity Management for the Treatment of Type 2 Diabetes

Treatment of Type 2 Diabetes

Published new algorithm for the treatment of T2D, as recommended by DSS-II voting delegates.
Algorithm for the Treatment of T2D

Overweight/Obesity Treatment Options in T2DM

<table>
<thead>
<tr>
<th>Body Mass Index (BMI) Category (kg/m²)</th>
<th>Treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>≤25.0 - 25.9 (or 23.0 - 25.9)</td>
<td>Diet, physical activity &amp; behavioral therapy</td>
</tr>
<tr>
<td>26.0 - 29.9</td>
<td>Diet, physical activity &amp; behavioral therapy, Pharmacotherapy</td>
</tr>
<tr>
<td>≥30.0 - 34.9 (or 27.5 - 32.4)</td>
<td>Diet, physical activity &amp; behavioral therapy, Pharmacotherapy, Metabolic surgery</td>
</tr>
<tr>
<td>≥35.0 - 39.9 (or 32.5 - 37.4)</td>
<td>Diet, physical activity &amp; behavioral therapy, Pharmacotherapy, Metabolic surgery</td>
</tr>
<tr>
<td>≥40</td>
<td>Diet, physical activity &amp; behavioral therapy, Pharmacotherapy, Metabolic surgery</td>
</tr>
</tbody>
</table>

* Cutoff points for Asian-American individuals.
+ Treatment may be indicated for selected, motivated patients.

Pharmacologic Therapy For Type 1 Diabetes: Recommendations

- Most people with T1DM should be treated with multiple daily injections of prandial insulin and basal insulin or continuous subcutaneous insulin infusion (CSII).
- Most individuals with T1DM should use rapid-acting insulin analogs to reduce hypoglycemia risk.

Management Approach for Hyperglycemia

Mortality and Cardiovascular Disease in Type 1 and Type 2 Diabetes

"Data from 1999 to 2014 showed marked reductions in mortality and in the incidence of cardiovascular complications among adults with either type 1 diabetes or type 2 diabetes."

"Residual Risk"

"There remains a substantial excess of mortality and of all outcomes analyzed among persons with either type 1 diabetes or type 2 diabetes as compared with the general population."
• In patients with T2DM and established ASCVD, antihyperglycemic therapy should begin with lifestyle management and metformin and subsequently incorporate an agent proven to reduce major adverse CV events and CV mortality (currently empagliflozin and liraglutide), after considering drug-specific and patient factors (Table 8.1). A

• In patients with T2DM and established ASCVD, after lifestyle management and metformin, the antihyperglycemic agent canagliflozin may be considered to reduce major adverse CV events, based on drug-specific and patient factors (Table 8.1). C
Doctors prescribe medicine of which they know little, to cure diseases of which they know less, in human beings of which they know nothing.

Francois-Marie Voltaire, 250 years ago
10. Microvascular Complications and Foot Care

**Diabetic Retinopathy: Recommendations**

**Treatment:**
- The traditional standard treatment, panretinal laser photocoagulation therapy, is indicated to reduce the risk of vision loss in patients with high-risk PDR and, in some cases, severe NPDR. **A**
- Intravitreal injections of anti-vascular endothelial growth factor ranibizumab are not inferior to traditional panretinal laser photocoagulation and are also indicated to reduce the risk of vision loss in patients with PDR. **A**

11. Older Adults

**Older Adults: Recommendations**

**Pharmacologic Therapy:**
- In older adults at increased risk of hypoglycemia, medication classes with low risk of hypoglycemia are preferred. **B**
- Overtreatment of diabetes is common in older adults and should be avoided. **B**
- Deintensification (or simplification) of complex regimens is recommended to reduce the risk of hypoglycemia, if it can be achieved within the individualized A1C target. **B**
Framework for Considering Treatment Goals in Older Adults with Diabetes

<table>
<thead>
<tr>
<th>Framework for Considering Treatment Goals in</th>
<th>Older Adults with Diabetes</th>
</tr>
</thead>
</table>

| Standards of Medical Care in Diabetes - 2018. Diabetes Care 2018; 41 (Suppl. 1): S119 - S125 |

<table>
<thead>
<tr>
<th>12. Children and Adolescents</th>
</tr>
</thead>
</table>

Type 2 Diabetes in Youth

- T2DM in youth has increased over the past 20 years
  - ~5,000 new cases per year in the U.S.
- T2DM in youth is different from both T1DM in youth and T2DM in adults
- Disproportionately impacts youth of ethnic and racial minorities
- Additional risk factors include:
  - Adiposity, family history of diabetes, female sex, and low socioeconomic status

<table>
<thead>
<tr>
<th>Risk-Based Screening in Asymptomatic Children and Adolescents</th>
</tr>
</thead>
</table>


SOC Overview

- SOC Overview
  - Provide new, effective resources for health care professionals and offer those resources when, where and how they are needed

- Strategies: ADA will enhance the Standards of Care and aggressively implement innovative approaches to reach critical audiences and expand the integration of the standards into clinical practice, particularly primary care providers.

- Standards of Care:
  - "Living" event-driven SOC updates
  - Timely incorporation of new evidence as it becomes available throughout the year
  - Increasing reach and adoption of clinical recommendations through user-friendly tools:
    - Specialty-focused, executive summaries published in main journals (FCP, Cardiology, JAMA, etc.) (MOU with American College of Cardiology to provide reviewers)
    - Mobile App
    - Micromodules
    - Diabetes is Primary

Living Standards of Care

- Provides all of ADA’s current clinical practice recommendations
  - The Standards supersedes all previous position statements on clinical topics within the purview of the Standards

- Annual review process remains the same, but mid-year updates become ‘Event-Driven’
  - Option to update the Standards mid-year should the PPC determine that new evidence or regulatory changes merit immediate incorporation
  - Updates may be suggested by PPC members, ADA staff, or members of the diabetes community
  - Updates must be reviewed and approved by the PPC
General Process Changes

- SOC are now the sole source of ADA's clinical practice recommendations.
- The PPC will continue to update the Standards annually, and now has the option to update throughout the year, online, if the PPC determines that new evidence or regulatory changes merit immediate updates or inclusion.
- ADA will begin taking proposals from the community for statements, consensus reports, scientific reviews, and clinical/research conferences.

Examples of Evidence-Based Updates:

- FDA makes a decision to approve metformin for prevention in people with prediabetes.
- Approval, clinical use and new indications of technology and devices.
- New drug approval or new indication: etruliflozin and semaglutide.

Living Standards of Care

Taxonomy of ADA Documents & Conferences

- ADA Statements: represent the official ADA position and are in line to with the Standards of Care.
- The following do not represent the official ADA position and are not tied to the SOC:
  - Expert Consensus Reports
  - Scientific Reviews
  - Evolving Clinical Concepts Conferences
  - Research Symposia
  - Conference Proceedings

Standards of Care Scope and Impact

2018 Standards of Care: Resources

- Full version available
- Abridged version for PCPs
- Free app (launching Spring 2018)
- Pocket cards with key figures
- Free webcast for continuing education credit
Professional Education

- Live programs
- Online self-assessment programs
- Online webcasts

professional.diabetes.org/CE

Diabetes Self-Management Education

- Find a recognized Diabetes Self-Management program
- Become a recognized DSME program
- Tools and resources for DSME programs
- Online education documentation tools

professional.diabetes.org/ERP

Professional Membership

- Journals
- Meeting, book and journal discounts
- Career center
- Quarterly member newsletter

professional.diabetes.org/Membership

Thank you.