

American Diabetes Association
STANDARDS OF MEDICAL CARE IN
DIABETES-2019

Guidelines Update

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Presenter Financial Relationships Disclosure

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Speaker's Bureau: Sanofi

Key Learning Objectives

At the end of this presentation, the attendee should be able to:

- Identify the recommendations and updates in the 2019 American Diabetes Association's *Standards of Care*
- Discuss available resources and ways to access the *Standards of Care*

Objectives

- The American Diabetes Association's *Standards of Medical Care in Diabetes* is updated and published annually in supplement to the January issue of *Diabetes Care*
 - Includes the most current evidence-based recommendations for diabetes and treating adults and children with all forms of diabetes
- Evidence levels to support recommendations:
 - A: Clear evidence from well-conducted, generalizable randomized control trials that are adequately powered
 - B: Supportive evidence from well-conducted cohort studies
 - C: Supportive evidence from poorly controlled or uncontrolled studies
 - E: Expert consensus or clinical experience

American Diabetes Association. *Diabetes Care*, 2019;42(Supplement 1):S1-S2

Improving Care and Promoting Health in Populations

- New data on the financial costs of diabetes to individuals and society:

In 2017, the cost of diagnosed diabetes was 327 billion, an increase of 26% since 2012

- Because telemedicine is a growing field that may increase access to care for patients with diabetes, discussion was added on its use to facilitate remote delivery of health-related services and clinical information.

Classification and Diagnosis of Diabetes

- Based on new data, the criteria for the diagnosis of diabetes was changed to include two abnormal test results from the same sample (i.e., fasting plasma glucose and A1c from same sample).
- Additional conditions were identified that may affect A1c test accuracy including the postpartum period.

Classification and Diagnosis of Diabetes

Criteria for the Diagnosis of Diabetes

In the absence of unequivocal hyperglycemia, a diagnosis requires two abnormal test results from the same sample or in two separate test samples

FPG ≥ 126 mg/dL (7.0 mmol/L). Fasting is defined as no caloric intake for at least 8 h.

OR

2-h PG ≥ 200 mg/dL (11.1 mmol/L) during OGTT. The test should be performed as described by the WHO, using a glucose load containing the equivalent of 75-g anhydrous glucose dissolved in water.

OR

A1C $\geq 6.5\%$ (48 mmol/mol). The test should be performed in a laboratory using a method that is NGSP certified and standardized to the DCCT assay.

OR

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

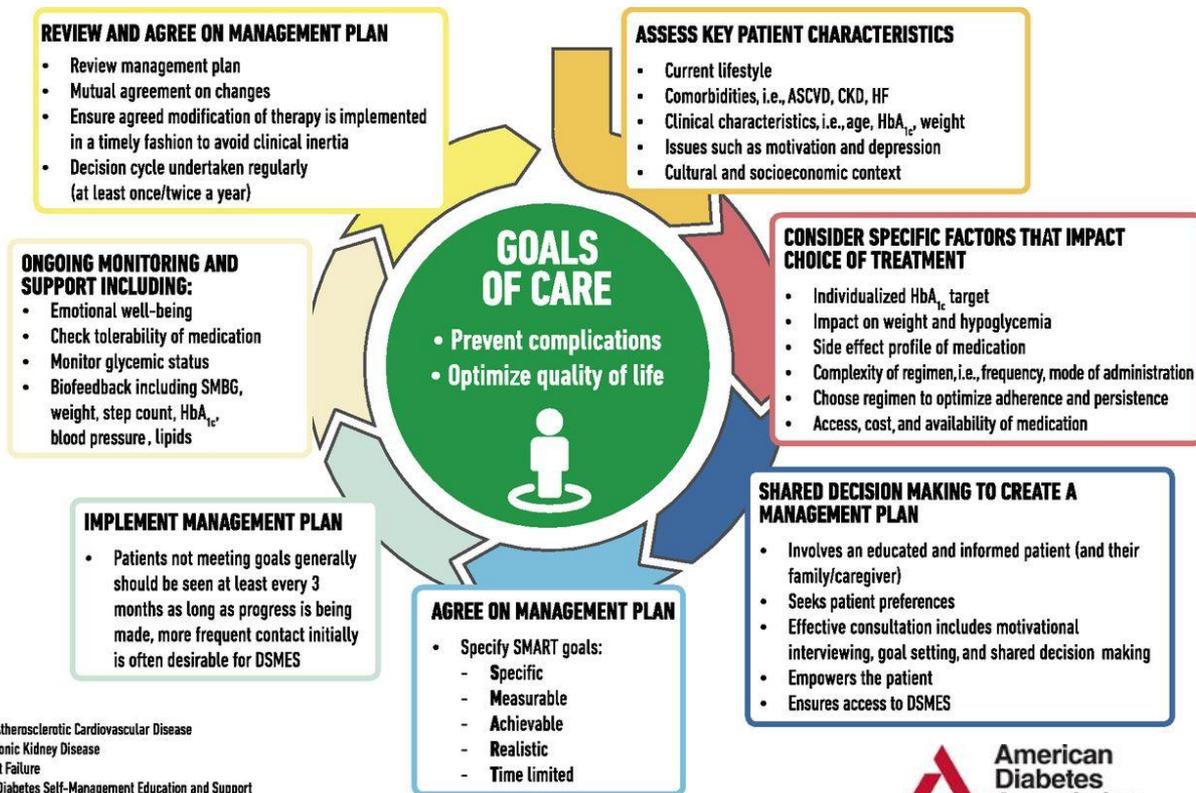
Prevention or Delay of Type 2 Diabetes

- This section was previously Section 5 and is now located before the Lifestyle Management section to better reflect the progression of type 2 diabetes.
- The nutrition section was updated to highlight the importance of weight loss for those at high risk for developing type 2 diabetes, who are overweight, or obese.
- Because smoking may increase the risk of type 2 diabetes, a section on tobacco use and cessation was added.

Comprehensive Medical Evaluation and Assessment of Comorbidities

- New text was added to guide health care professionals' use of language to communicate with people with diabetes and professional audiences in an informative, empowering, and educational style.
- A diabetes care decision cycle figure from the ADA-EASD consensus report was added to emphasize the need for ongoing assessment & shared decision making to achieve health goals and avoid therapeutic inertia.
- A new recommendation was added to explicitly call out the importance of the diabetes care team and to list the professionals that make up the team.

Decision Cycle for Patient-centered Glycemic Management in Type 2 Diabetes



ASCVD = Atherosclerotic Cardiovascular Disease
CKD = Chronic Kidney Disease
HF = Heart Failure
DSMES = Diabetes Self-Management Education and Support
SMBG = Self-Monitored Blood Glucose

Comprehensive Medical Evaluation and Assessment of Comorbidities

- The table listing the components of a comprehensive medical evaluation was revised, and the section on assessment and planning was used to create a new table.
- A new table was added listing factors that increase risk of treatment associated hypoglycemia.
- A recommendation was added to include an assessment of the 10-year atherosclerotic cardiovascular disease (ASCVD) risk as part of overall risk assessment.
- The fatty liver disease section was revised to include updated text and a new recommendation regarding when to test for liver disease.

Assessment and Treatment Plan

- ASCVD, atherosclerotic cardiovascular disease
- Assessment and treatment planning is an essential component of initial and all follow-up visits

Assess risk of diabetes complications

- ASCVD and heart failure history
- ASCVD risk factors (see Table 10.2) and 10-year ASCVD risk assessment
- Staging of chronic kidney disease (see Table 11.1)
- Hypoglycemia risk (Table 4.3)

Goal setting

- Set A1C/blood glucose target
- If hypertension present, establish blood pressure target
- Diabetes self-management goals (e.g., monitoring frequency)

Therapeutic treatment plan

- Lifestyle management
- Pharmacologic therapy (glucose lowering)
- Pharmacologic therapy (cardiovascular disease risk factors and renal)
- Use of glucose monitoring and insulin delivery devices
- Referral to diabetes education and medical specialists (as needed)



Assessment and Treatment Plan

Assessment of Hypoglycemia Risk

Factors that increase risk of treatment-associated hypoglycemia

- • Use of insulin or insulin secretagogues (i.e., sulfonylureas, meglitinides)
- • Impaired kidney or hepatic function
- • Longer duration of diabetes
- • Frailty and older age
- • Cognitive impairment
- • Impaired counterregulatory response, hypoglycemia unawareness
- • Physical or intellectual disability that may impair behavioral response to hypoglycemia
- • Alcohol use
- • Polypharmacy (especially ACE inhibitors, angiotensin receptor blockers, nonselective β -blockers)

Lifestyle Management

- More discussion was added about the importance of macronutrient distribution based on an individualized assessment of current eating patterns, preferences, and metabolic goals.
- There is not a one-size-fits-all eating pattern for individuals with diabetes and meal planning should be individualized.
- Recommendation was made to encourage people with diabetes to decrease consumption of both sugar sweetened and nonnutritive-sweetened beverages and use other alternatives, with an emphasis on water intake.
- The sodium consumption recommendation was modified to eliminate the further restriction that was potentially indicated for those with both diabetes and hypertension.

Lifestyle Management

- Additional discussion was added to the physical activity section to include the benefit of a variety of leisure-time physical activities and flexibility and balance exercises.
- The discussion about e-cigarettes was expanded to include more on public perception and how their use to aide smoking cessation was not more effective than “usual care”.

Glycemic Targets

- This section now begins with a discussion of A1c tests to highlight the centrality of A1c testing in glycemic management.
- The self-monitoring of blood glucose and continuous glucose monitoring text and recommendations were moved to the new Diabetes Technology section.
- To emphasize that the risks and benefits of glycemic targets can change as diabetes progresses and patients age, a recommendation was added to reevaluate glycemic targets of over time.
- The section was modified to align with the living Standards updates made in April 2018 regarding the consensus definition of hypoglycemia.

Glycemic Targets

Glycemic Recommendations (for many non-pregnant adults with diabetes)

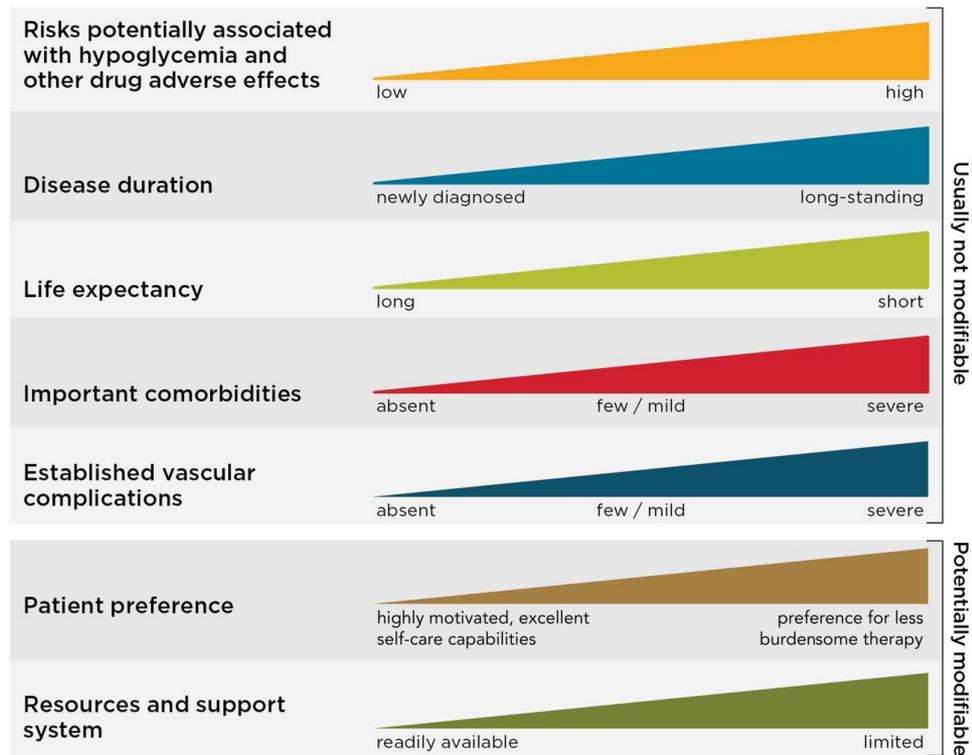
- More or less stringent glycemic goals may be appropriate for individual patients
- Goals should be individualized based on duration of diabetes, age/life expectancy, comorbid conditions, known CVD or advanced microvascular complications, hypoglycemia unawareness, and individual patient considerations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

A1C	<7.0% (53 mmol/mol)
Preprandial capillary plasma glucose	80–130 mg/dL (4.4–7.2 mmol/L)
Peak postprandial capillary plasma glucose	<180 mg/dL (10.0 mmol/L)

Glycemic Targets

Approach to Individualization of Glycemic Targets

Patient / Disease Features More stringent ← A1C 7% → Less stringent



Glycemic Targets

Classification of Hypoglycemia

Level	Glycemic criteria/description
Level 1	Glucose <70 mg/dL (3.9 mmol/L) and glucose \geq 54 mg/dL (3.0 mmol/L)
Level 2	Glucose <54 mg/dL (3.0 mmol/L)
Level 3	A severe event characterized by altered mental and/or physical status requiring assistance

Diabetes Technology

- This new section includes new recommendations, the self-monitoring of blood glucose section formerly included in the “Glycemic Targets” section, and a discussion of insulin delivery devices(syringes, pens, and insulin pumps), blood glucose meters, continuous glucose monitors (real-time and intermittently scanned), and automated insulin delivery devices.
- The recommendation to use self-monitoring of blood glucose in people who are not using insulin was changed to acknowledge that routine glucose monitoring is of limited additional clinical benefit in this population.

Meter Accuracy

Comparison of ISO 15197 and FDA Blood Glucose Meter Accuracy Standards

- BG, blood glucose
- To convert mg/dL to mmol/L, see <http://www.endmemo.com/medical/unitconvert/Glucose.php>
- The range of BG values for which the meter has been proven accurate and will provide readings (other than low, high, or error)
- Values outside of the “clinically acceptable” A and B regions are considered “outlier” readings and may be dangerous to use for therapeutic decisions

Setting	FDA ¹²⁵⁻¹²⁶	ISO 15197-2013 ¹²⁷
Home use	95% within 15% for all BG in the usable BG range [‡]	<ul style="list-style-type: none"> • 95% within 15% for BG ≥100 mg/dL • 95% within 15 mg/dL for BG <100 mg/dL • 99% in A or B region of Consensus Error Grid[‡]
	99% within 20% for all BG in the usable BG range [‡]	
Hospital use	95% within 12% for BG ≥75 mg/dL	
	95% within 12 mg/dL for BG <75 mg/dL	
	98% within 15% for BG ≥75 mg/dL	
	98% within 15 mg/dL for BG <75 mg/dL	

Interfering Substances

Glucose oxidase monitors

Uric acid

Galactose

Xylose

Acetaminophen

L-dopa

Ascorbic acid

Glucose dehydrogenase monitors

Icodextrin (used in peritoneal dialysis)

Obesity Management for the Treatment of Type 2 Diabetes

- Recommendation was modified to acknowledge the benefits of tracking weight, activity, etc., in the context of achieving and maintaining a healthy weight.
- A brief section was added on medical devices for weight loss, which are not currently recommended due to limited data in people with diabetes.
- The recommendations for metabolic surgery were modified to align with recent guidelines citing the importance of considering comorbidities beyond diabetes when contemplating the appropriateness of metabolic surgery.

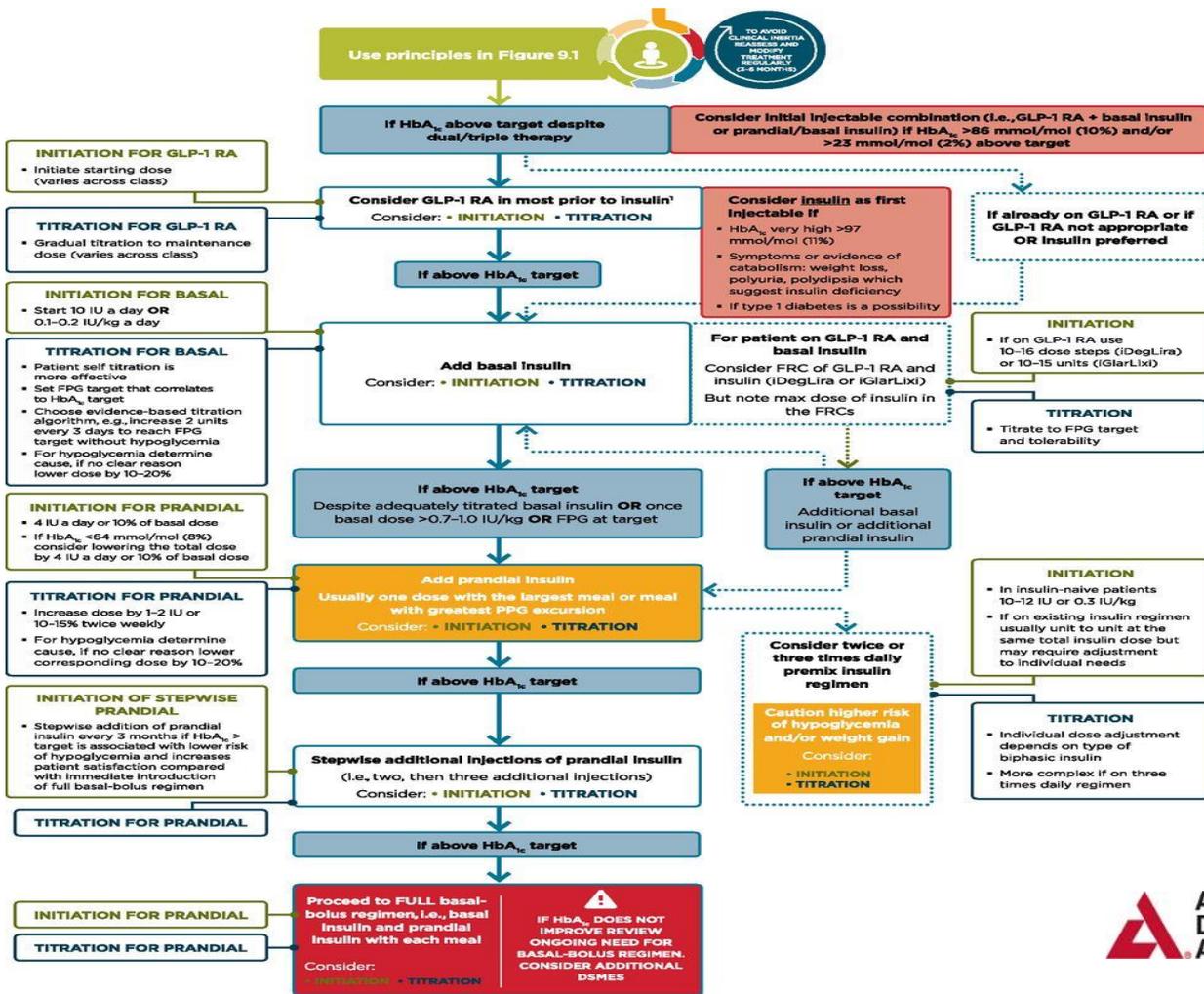
Pharmacologic Approaches to Glycemic Management

- The section on the pharmacologic treatment of type 2 diabetes was significantly changed to align, as per the living Standards update in October 2018, with the ADA-EASD consensus report on this topic (summarized in the following figures).
- Includes consideration of key patient factors: a) important comorbidities such as ASCVD, chronic kidney disease, and heart failure, b) hypoglycemia risk, c) effects on body weight, d) side effects, e) costs, and f) patient preferences.

Pharmacologic Approaches to Glycemic Management

- The approach to injectable medication therapy was revised to align with the ADA-EASD consensus report.
- The recommendation that for most patients who need the greater efficacy of an injectable medication, a glucagon-like peptide 1 receptor agonist should be the first choice, ahead of insulin.

ASCVD-Risk-Estimator-Plus



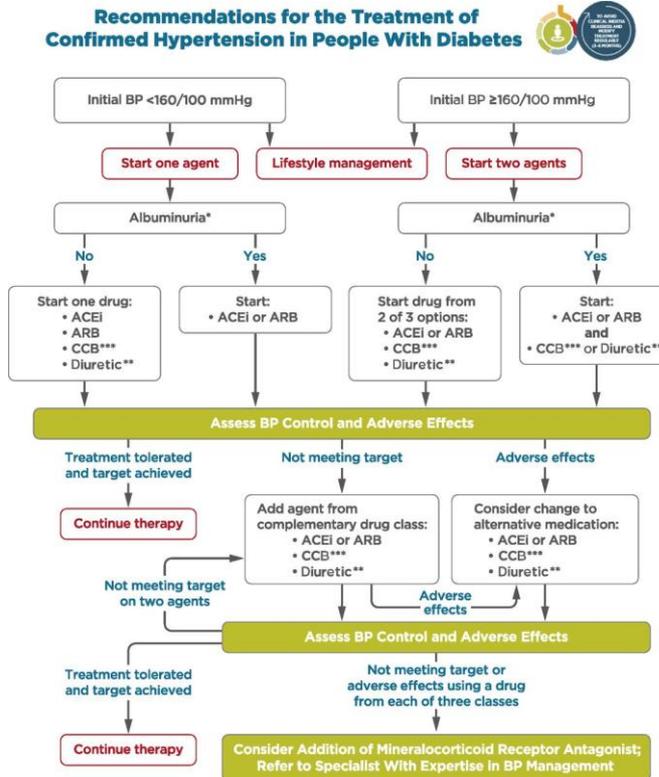
Pharmacologic Approaches to Glycemic Management

- A new section was added on insulin injection technique, emphasizing the importance of technique for appropriate insulin dosing and the avoidance of complications (lipodystrophy, etc.).
- The section on noninsulin pharmacologic treatments for type 1 diabetes was abbreviated, as these are not generally recommended.

Cardiovascular Disease and Risk Management

- For the first time this section is endorsed by the American College of Cardiology.
- Additional text was added to acknowledge heart failure as an important type of cardiovascular disease in people with diabetes for consideration when determining optimal diabetes care.
- The blood pressure recommendations were modified to emphasize the importance of individualization of targets based on cardiovascular risk.
- A discussion of the appropriate use of the ASCVD risk calculator was included, and recommendations were modified to include assessment of 10-year ASCVD risk as part of the overall risk assessment and in determining optimal treatment approaches.

Recommendations for the treatment of confirmed hypertension in people with diabetes. *An ACE inhibitor (ACEi) or angiotensin receptor blocker (ARB) is suggested to treat hypertension for patients with urine albumin-to-creatinine ratio 30–299 mg/g creatinine and strongly recommended for patients with urine albumin-to-creatinine ratio ≥ 300 mg/g creatinine. **Thiazide-like diuretic; long-acting agents shown to reduce cardiovascular events, such as chlorthalidone and indapamide, are preferred. ***Dihydropyridine calcium channel blocker (CCB).

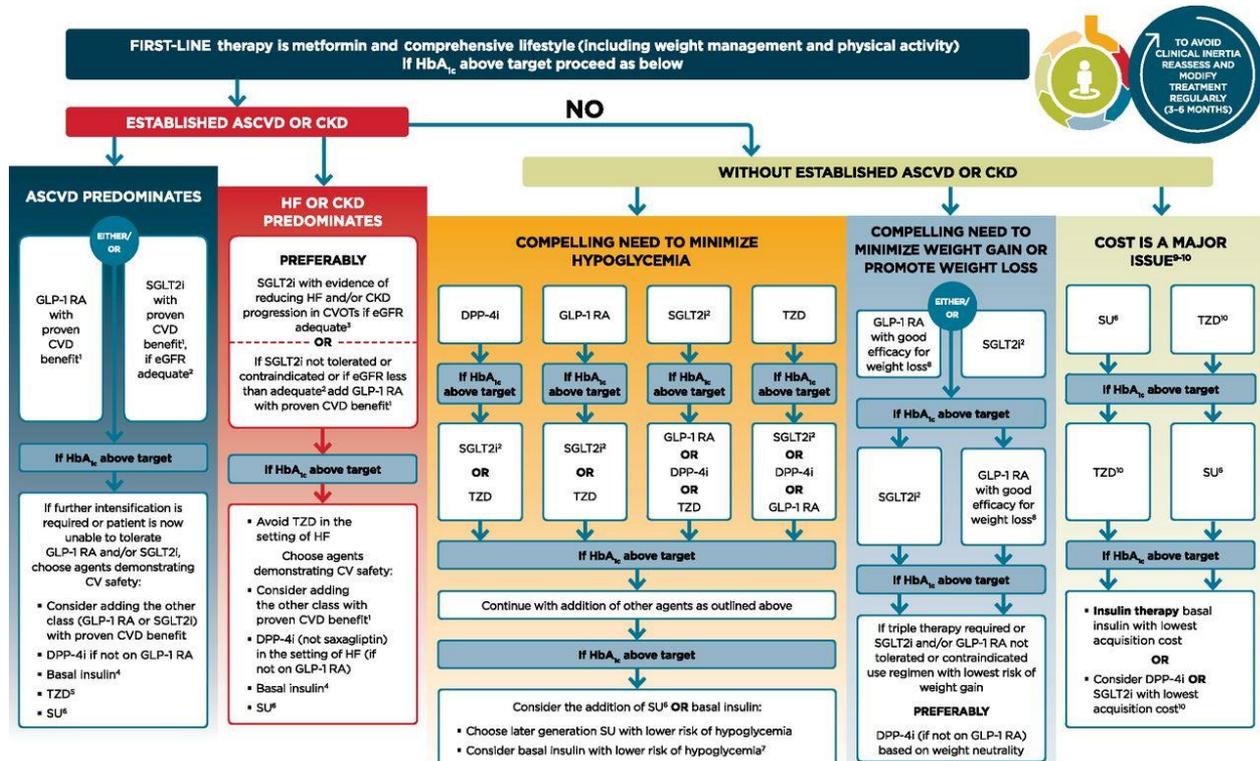


American Diabetes Association Dia Care 2019;42:S103-S123

Cardiovascular Disease and Risk Management

- The recommendation and text regarding the use of aspirin in primary prevention was updated with new data.
- For alignment with the ADA-EASD consensus report, two recommendations were added for the use of medications that have proven cardiovascular benefit in people with ASCVD, with and without heart failure.

Pharmacologic Approaches to Glycemic Treatment



1. Proven CVD benefit means it has label indication of reducing CVD events. For GLP-1 RA strongest evidence for liraglutide > semaglutide > exenatide extended release. For SGLT2i evidence modestly stronger for empagliflozin > canagliflozin.
2. Be aware that SGLT2i vary by region and individual agent with regard to indicated level of eGFR for initiation and continued use.
3. Both empagliflozin and canagliflozin have shown reduction in HF and reduction in CKD progression in CVOTs.
4. Degludec or U100 glargine have demonstrated CVD safety.
5. Low dose may be better tolerated though less well studied for CVD effects.

6. Choose later generation SU with lower risk of hypoglycemia
7. Degludec / glargine U300 < glargine U100 / detemir < NPH Insulin
8. Semaglutide > liraglutide > dulaglutide > exenatide > lixisenatide
9. If no specific comorbidities (i.e., no established CVD, low risk of hypoglycemia, and lower priority to avoid weight gain or no weight-related comorbidities)
10. Consider country- and region-specific cost of drugs. In some countries TZDs relatively more expensive and DPP-4i relatively cheaper

Microvascular Complications and Foot Care

- To align with the ADA-EASD consensus report, a recommendation was added for people with type 2 diabetes and chronic kidney disease to consider agents with proven benefit with regard to renal outcomes.
- The recommendation on the use of telemedicine in retinal screening was modified to acknowledge the utility of this approach, so long as appropriate referrals are made for a comprehensive eye examination.
- Gabapentin was added to the list of agents to be considered for the treatment of neuropathic pain in people with diabetes based on data on efficacy and the potential for cost savings.

	Efficacy	Hypoglycemia	Weight change	CV effects		Cost	Oral/SQ	Renal effects		Additional considerations
				ASCVD	CHF			Progression of DKD	Dosing/use considerations*	
Metformin	High	No	Neutral (potential for modest loss)	Potential benefit	Neutral	Low	Oral	Neutral	<ul style="list-style-type: none"> Contraindicated with eGFR <30 	<ul style="list-style-type: none"> Gastrointestinal side effects common (diarrhea, nausea) Potential for B12 deficiency
SGLT-2 inhibitors	Intermediate	No	Loss	Benefit: empagliflozin, canagliflozin	Benefit: empagliflozin, canagliflozin	High	Oral	Benefit: canagliflozin, empagliflozin	<ul style="list-style-type: none"> Renal dose adjustment required (canagliflozin, dapagliflozin, empagliflozin, ertugliflozin) 	<ul style="list-style-type: none"> FDA Black Box: Risk of amputation (canagliflozin) Risk of bone fractures (canagliflozin) DKA risk (all agents, rare in T2DM) Genitourinary infections Risk of volume depletion, hypotension ↑LDL cholesterol Risk of Fournier's gangrene
GLP-1 RAs	High	No	Loss	Neutral: lixisenatide Benefit: liraglutide > semaglutide > exenatide extended release	Neutral	High	SQ	Benefit: liraglutide	<ul style="list-style-type: none"> Renal dose adjustment required (exenatide, lixisenatide) Caution when initiating or increasing dose due to potential risk of acute kidney injury 	<ul style="list-style-type: none"> FDA Black Box: Risk of thyroid C-cell tumors (liraglutide, albiglutide, dulaglutide, exenatide extended release) Gastrointestinal side effects common (nausea, vomiting, diarrhea) Injection site reactions ↑Acute pancreatitis risk
DPP-4 inhibitors	Intermediate	No	Neutral	Neutral	Potential risk: saxagliptin, alogliptin	High	Oral	Neutral	<ul style="list-style-type: none"> Renal dose adjustment required (sitagliptin, saxagliptin, alogliptin); can be used in renal impairment No dose adjustment required for linagliptin 	<ul style="list-style-type: none"> Potential risk of acute pancreatitis Joint pain
Thiazolidinediones	High	No	Gain	Potential benefit: pioglitazone	Increased risk	Low	Oral	Neutral	<ul style="list-style-type: none"> No dose adjustment required Generally not recommended in renal impairment due to potential for fluid retention 	<ul style="list-style-type: none"> FDA Black Box: Congestive heart failure (pioglitazone, rosiglitazone) Fluid retention (edema; heart failure) Benefit in NASH Risk of bone fractures Bladder cancer (pioglitazone) ↑LDL cholesterol (rosiglitazone)
Sulfonylureas (2nd generation)	High	Yes	Gain	Neutral	Neutral	Low	Oral	Neutral	<ul style="list-style-type: none"> Glyburide: not recommended Glipizide and glimepiride: initiate conservatively to avoid hypoglycemia 	<ul style="list-style-type: none"> FDA Special Warning on increased risk of cardiovascular mortality based on studies of an older sulfonylurea (tolbutamide)
Insulin	Human insulin	Yes	Gain	Neutral	Neutral	Low	SQ	Neutral	<ul style="list-style-type: none"> Lower insulin doses required with a decrease in eGFR; titrate per clinical response 	<ul style="list-style-type: none"> Injection site reactions Higher risk of hypoglycemia with human insulin (NPH or premixed formulations) vs. analogs
	Analog					High	SQ			



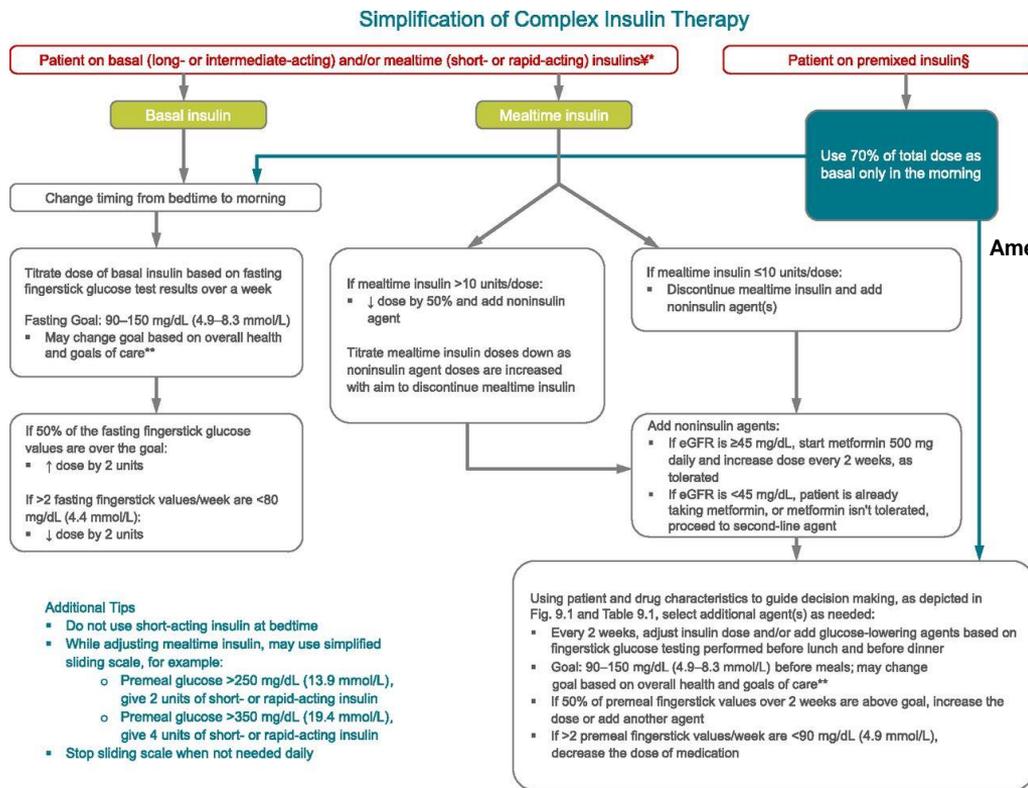
Microvascular Complications and Foot Care

- The gastroparesis section includes a discussion of a few additional treatment modalities.
- The recommendation for patients with diabetes to have their feet inspected at every visit was modified to only include those at high risk for ulceration.
- Annual examinations remain recommended for everyone.

Older Adults

- A new section and recommendation on lifestyle management was added to address the unique nutritional and physical activity needs and considerations for older adults.
- Within the pharmacologic therapy discussion, de-intensification of insulin regimens was introduced to help simplify insulin regimen to match individuals, self-management abilities.
- A new figure was added that provides a path for simplification
- A new table was added to help guide providers considering medication regimen simplification and de-intensification/de-prescribing in older adults with diabetes.

Algorithm to simplify insulin regimen for older patients with type 2 diabetes. eGFR, estimated glomerular filtration rate. Basal insulins: glargine U-100 and U-300, detemir, degludec, and human NPH. Mealtime insulins: short-acting (regular human insulin) or rapid-acting (lispro, aspart, and glulisine). Premixed insulins: 70/30, 75/25, and 50/50 products.



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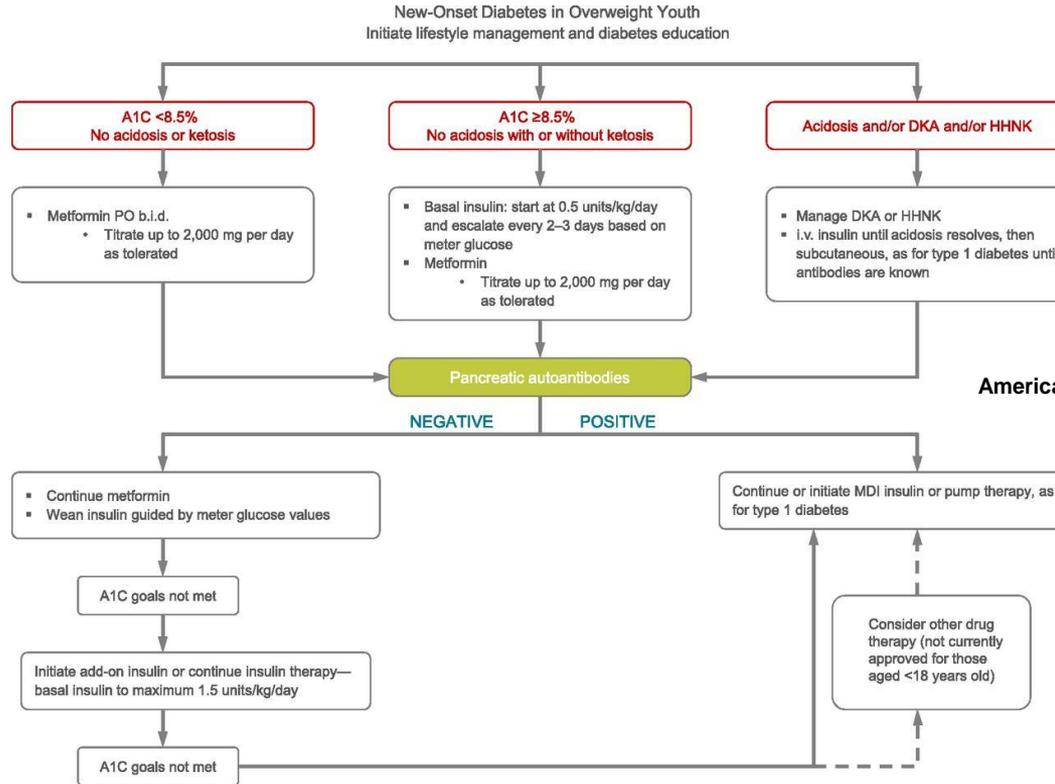
Children and Adolescents

- Introductory language was added to the beginning of this section reminding the reader that epidemiology, pathophysiology, developmental considerations, and response to therapy in pediatric onset diabetes are different from adult diabetes, and that there are also differences in recommended care for children and adolescents with type 1 as opposed to type 2 diabetes.
- A recommendation was added to emphasize the need for disordered eating screening in youth with type 1 diabetes beginning at 10-12 years of age.
- Based on new evidence, a recommendation was added discouraging e-cigarette use in youth.

Children and Adolescents

- The discussion of type 2 diabetes in children and adolescents was significantly expanded, with new recommendations in a number of areas, including screening and diagnosis, lifestyle management, pharmacologic management, and transition of care to adult providers.
- New sections and/or recommendations for type 2 diabetes in children and adolescents were added for glycemic targets, metabolic surgery, nephropathy, neuropathy, retinopathy, non-alcoholic fatty liver disease, obstructive sleep apnea, polycystic ovary syndrome, cardiovascular disease, dyslipidemia, cardiac function testing, and psychosocial factors.
- A figure was added to provide guidance on the management of diabetes in overweight youth.

Management of new-onset diabetes in overweight youth (2).



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Management of Diabetes in Pregnancy

- Women with preexisting diabetes are now recommended to have their care managed in a multidisciplinary clinic to improve diabetes and pregnancy outcomes.
- Greater emphasis as been placed on the use of insulin as the preferred medication for treating hyperglycemia in gestational diabetes mellitus as it does not cross the placenta to a measurable extent and how metformin and glyburide should not be used as first-line agents as both cross the placenta to the fetus.

Diabetes Care in the Hospital

- Because of their ability to improve hospital readmission rates and cost of care, a new recommendation was added calling for providers to consider consulting with a specialized diabetes or glucose management team where possible when caring for hospitalized patients with diabetes.

Diabetes Advocacy

- The “Insulin Access and Affordability Working Group: Conclusions and Recommendations” ADA statement was added to this section.
- Published in 2018, this statement compiled public information and convened a series of meetings with stakeholders throughout the insulin supply chain to learn how each entity affects the cost of insulin for the consumer, an important topic for the ADA and people living with diabetes.

References

- American College of Cardiologists. (2019). ASCVD Risk Estimator Plus (Version 4.0) [Mobile Application Software]. Retrieved from <http://tools.acc.org/ASCVD-Risk-Estimator-Plus/#!/content/about/>
- American Diabetes Association. (2019). ADA Standards of Care (Version 3.1) [Mobile Application Software]. Retrieved from <https://cpms.bbinfotech.com/ada-web-app/home/>
- American Diabetes Association. (2019). Standards of Medical Care in Diabetes—2019 Evidence Table [PDF file]. Retrieved from <https://professional.diabetes.org/content-page/practice-guidelines-resources>
- Davies, M. J., D'Alessio, D. A., Fradkin, J., Kernan, W. N., Mathieu, C., Mingrone, G., . . . Buse, J. B. (2018). Management of hyperglycaemia in type 2 diabetes, 2018. A consensus report by the American Diabetes Association (ADA) and the European Association for the Study of Diabetes (EASD). *Diabetologia*, 61(12), 2461-2498. doi:10.1007/s00125-018-4729-5
- Garber, A. J., Abrahamson, M. J., Barzilay, J. I., Blonde L., Bloomgarden, Z. T., Bush, M. A., ... Umpierrez, G. E. (2018). Consensus Statement By The American Association of Clinical Endocrinologists and American College of Endocrinology on the Comprehensive Type 2 Diabetes Management Algorithm – 2019 Executive Summary. *Endocrine Practice*: January 2019, Vol. 25, No. 1, pp. 69-100. <https://doi.org/10.4158/CS-2018-0535>
- Highlights from the American Diabetes Association Standards of Medical Care in Diabetes—2019. (2019, Winter). *Diabetes Pro Quarterly*. <https://professional.diabetes.org/>
- Standards of Medical Care in Diabetes—2019. (2019, January). *Diabetes Care*, 42 (Suppl.1)
- Standards of Medical Care in Diabetes—2019 Abridged for Primary Care Providers. (2019). *Clinical Diabetes*, 37(1), 1-24. doi:10.2337/cd18-0105
- Summary of Revisions: Standards of Medical Care in Diabetes—2019. (2019, January). *Diabetes Care*, 42 (Suppl. 1), 54-56.