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Standards of Care in Diabetes 2016-- What's New?

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Terminology

- No longer using the term “diabetic.”
- Diabetes does not define people.
- People with diabetes are individuals with diabetes, not “diabetics.”
- “Diabetic” will continue to be used related to complications, e.g., “diabetic retinopathy.”



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Section 1. Strategies for Improving Care

- ❖ Therapy must be tailored for patients with:
 - ❖ Food insecurity-lack of funds to afford appropriate food
 - ❖ Cognitive dysfunction-special consideration
 - ❖ HIV- screen for DM prior to starting therapy and annually





- Intensive glucose control is not advised for the improvement of poor cognitive function in hyperglycemic individuals with T2DM.
- In individuals with poor cognitive function or severe hypoglycemia, glycemic therapy should be tailored to avoid significant hypoglycemia.



Cognitive Dysfunction

- In individuals with diabetes at high CVD risk, the cardiovascular benefits of statin therapy outweigh the risk of cognitive dysfunction.
- If a second-generation antipsychotic medication is prescribed, changes in weight, glycemic control, and cholesterol levels, should be carefully monitored and the treatment regimen reassessed.



Section 2. Classification and Diagnosis of Diabetes

- ❖ None of the test used for diagnosis are preferred over the other.
- ❖ All persons over age of 45 should be tested regardless of weight.
- ❖ Adults who are obese with one or more risk factors should be tested regardless of age.



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

OR

**2-h plasma glucose ≥ 200 mg/dL
(11.1 mmol/L) during an OGTT**

OR

A1C $\geq 6.5\%$

OR

**Random plasma glucose
 ≥ 200 mg/dL (11.1 mmol/L)**



- Performed in a laboratory using a method that is NGSP certified and standardized to the DCCT assay –
www.ngsp.org
- POC testing not recommended
- Greater convenience, preanalytical stability, and less day-to-day perturbations than FPG and OGTT
- Consider cost, age, race/ethnicity, anemia, etc.



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Foundations of Care

1. Self Management Education
2. Nutrition
3. Counseling
4. Physical Activity
5. Smoking Cessation
6. Immunizations
7. Psychosocial Care
8. Medications



Recommendations: Physical Activity

- Children with diabetes/pre-diabetes: at least 60 min/day physical activity
- Adults with diabetes: at least 150 min/wk of moderate-intensity aerobic activity over at least 3 days/week with no more than 2 consecutive days without exercise
- All individuals, including those with diabetes, should reduce sedentary time, particularly by breaking up extended amounts of time (>90 min) spent sitting.
- Adults with type 2 diabetes should perform resistance training at least twice weekly



Section 4. Prevention or Delay of Type 2 Diabetes

- Refer those with pre-diabetes to intensive diet and physical activity behavioral counseling program (lose 7% weight and increase moderate-intensity PA to at least 150 min/week)
- Follow up counseling and maintenance programs long term
- Diabetes prevention programs should be covered by third party payers
- Metformin therapy for prevention should be considered in those with pre-diabetes, especially those with BMI greater 35 kg/m², those less than 60 years and women with prior gestational diabetes mellitus



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Table 6.1—Treatment for overweight and obesity in type 2 diabetes

| Treatment | BMI category (kg/m ²) | | | | |
|--|-----------------------------------|---------------|---------------|---------------|-----|
| | 23.0* or 25.0–26.9 | 27.0– 29.9 | 30.0– 34.9 | 35.0– 39.9 | 40+ |
| Diet, physical activity, and behavioral therapy | + | + | + | + | + |
| Pharmacotherapy | | + | + | + | + |
| Bariatric surgery | | | | + | + |



Section 4. Prevention or Delay of Type 2 Diabetes

- Annual monitoring for development of diabetes
- Screening for and treatment of modifiable risk factors for CVD
- DSME programs are appropriate venues for those with prediabetes to receive education and support
- NEW – technology assisted tools including internet based social networks, distance learning, DVD-based content, and mobile applications can be useful for lifestyle modification to prevent diabetes



Some supportive apps

- Myfitnesspal – more specific to calorie counting
 - American Diabetes Association Standards of Care
 - Medtronic –Carb Counting with Lenny
 - AADE Diabetes Goal Tracker
-
- Some are free and others range from \$2.99 - \$9.99



Section 5. Glycemic Targets

❖ Methods for assessing glycemic control

❖ SMBG

❖ A1c

*CGM could be useful addition



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Mean Glucose Levels for Specified A1C Levels

| Mean Glucose | | | | | | |
|--------------|----------------------|--------|--|---------|----------|---------|
| | Mean Plasma Glucose* | | Fasting | Premeal | Postmeal | Bedtime |
| A1C% | mg/dL | mmol/L | mg/dL | mg/dL | mg/dL | mg/dL |
| 6 | 126 | 7.0 | | | | |
| <6.5 | | | 122 | 118 | 144 | 136 |
| 6.5-6.99 | | | 142 | 139 | 164 | 153 |
| 7 | 154 | 8.6 | | | | |
| 7.0-7.49 | | | 152 | 152 | 176 | 177 |
| 7.5-7.99 | | | 167 | 155 | 189 | 175 |
| 8 | 183 | 10.2 | | | | |
| 8-8.5 | | | 178 | 179 | 206 | 222 |
| 9 | 212 | 11.8 | professional.diabetes.org/eAG | | | |
| 10 | 240 | 13.4 | | | | |
| 11 | 269 | 14.9 | | | | |
| 12 | 298 | 16.5 | | | | |



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Approach to the Management of Hyperglycemia

Patient/Disease Features

Risks associated with hypoglycemia
& other drug adverse effects

Disease Duration

Life expectancy

Important comorbidities

Established vascular complications

Patient attitude & expected treatment
efforts

Resources & support system

more stringent ← A1C 7% → less stringent

low high

newly diagnosed long-standing

long short

absent Few/mild severe

absent Few/mild severe

Usually not
modifiable

highly motivated, adherent,
excellent self-care capabilities less motivated, nonadherent,
poor self-care capabilities

readily available limited

Potentially
modifiable





Glycemic Recommendations for Nonpregnant Adults 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) |

Postprandial glucose measurements should be made 1–2 hours after the beginning of the meal.



Recommendations: Hypoglycemia

- Individuals at risk for hypoglycemia should be asked about symptomatic and asymptomatic hypoglycemia at each encounter.
- Glucose (15–20 g) preferred treatment for conscious individual with hypoglycemia.
- Prescribe glucagon for all patients at significant risk of severe hypoglycemia. Instruct caregivers in administration.
- Hypoglycemia unawareness or one or more episodes of severe hypoglycemia should trigger treatment re-evaluation.



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Section 6. Obesity Management for Treatment of Type 2 Diabetes.

- New section that includes previous recommendations about bariatric surgery
- Now incorporates comprehensive assessment of weight in diabetes, including approved medications.

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- Strong evidence that reducing obesity can delay the progression from pre-diabetes to type 2 diabetes.
- Modest and sustained weight loss improves glycemic control and need for medications.
- Weight loss most effective early in the course of diabetes to maintain beta cell function and insulin secretion. Weight loss also improves mobility, physical function, intimacy, and health related quality of life.



Current Recommendations

- At each patient encounter, BMI should be calculated and documented in medical record. Assess the patient's readiness to lose weight
- Diet, PA, and behavioral therapy should be included to support a 5% weight loss
- High interventions of at least 16 sessions in 6 months (2-3 visits/month) to support a 500-750 calorie/day energy deficit (independent of protein, carb, fat distribution)



- Maintenance programs should be offered for at least 1 year with monthly contact
- Very low calorie diets (less than 800 kcal/day) used along with trained practitioners with close monitoring
- When choosing glucose lowering medications, consider their effect on weight and minimize those associated with weight gain



- Discontinue medications if after 3 months there is less than 5% of weight loss achieved
- Bariatric surgery may be considered for adults with a BMI greater than 35 kg/m² and diabetes
- Livelong support necessary for those who have undergone surgery



- Insufficient evidence to recommend surgery to those with a BMI less than or equal to 35 kg/m².
- Higher remission rates in those who are younger, have shorter duration of type 2 diabetes, lower A1c, higher serum insulin levels, and non-use of insulin
 - Remission means normal blood glucose levels without need for medications.

Table 6.2—Medications approved by the FDA for the long-term treatment of obesity

| Generic drug name, (proprietary name[s]) and dosage strength and form | Adult dosing frequency | Average wholesale price (per month) ¹ | 1-Year weight change status ²⁻⁵ | | Adverse effects ^{2,6-12} | |
|---|--|---|---|---|---|---|
| | | | Average weight loss relative to placebo | % Patients with ≥5% loss of baseline weight | | |
| | | | | | Common ⁷ | Serious ⁷ |
| Lipase inhibitor | | | | | | |
| Orlistat (Alli) 60 mg caps or orlistat (Xenical) 120 mg caps | 60 mg or 120 mg t.i.d. (during or up to 1 h after a low-fat meal) | \$41–82 (60 mg) \$615 (120 mg) | 2.5 kg (60 mg) 3.4 kg (120 mg) | 35–73% | Abdominal pain/discomfort, oily spotting/stool, fecal urgency, malabsorption of fat-soluble vitamins (A, D, E, K) and medications (e.g., cyclosporine, thyroid hormone replacement, or anticonvulsants), potentiation of the effects of warfarin | Liver failure and oxalate nephropathy |
| Selective serotonin (5-HT) _{2C} receptor agonist | | | | | | |
| Lorcaserin (Belviq) 10 mg tabs | 10 mg b.i.d. | \$263 | 3.2 kg | 38–48% | Hypoglycemia, headache, fatigue | Serotonin syndrome or NMS-like reactions, heart valve disorder (, 2.4%), bradycardia |
| Sympathomimetic amine anorectic/antiepileptic combination | | | | | | |
| Phentermine/topiramate ER (Qsymia) 3.75 mg/23 mg caps, 7.5 mg/46 mg caps, 11.25 mg/69 mg caps, 15 mg/92 mg caps | Recommended dose: 3.75 mg/23 mg q.d. for 14 days, then increase to 7.5 mg/46 mg q.d. Maximum dose: 15 mg/92 mg q.d. | \$239 (maximum dose using the highest strength) | 6.7 kg (7.5 mg/46 mg) 8.9 kg (15 mg/92 mg) | 45–70% | Paresthesia, xerostomia, constipation, headache | Topiramate is teratogenic and has been associated with cleft lip/palate |
| Opioid antagonist/aminoketone antidepressant combination | | | | | | |
| Naltrexone/bupropion (Contrave) 8 mg/90 mg tabs | Maximum dose: two tablets of Contrave b.i.d. for a total daily dosage of naltrexone 32 mg/bupropion 360 mg | \$239 (maximum dose) | 2.0–4.1 kg (32 mg/360 mg) | 36–57% | Nausea, constipation, headache, vomiting | Depression, precipitation of mania |
| Acyliated human glucagon-like peptide 1 receptor agonist | | | | | | |
| Liraglutide (Saxenda) 6 mg/mL prefilled pen | Maintenance dose: 3 mg s.c. q.d. | \$1,282 | 5.8–5.9 kg | 51–73% | Hypoglycemia, nausea, vomiting, diarrhea, constipation, headache | Pancreatitis, thyroid C-cell tumors in rodents, contraindicated in patients with personal/family history of MTC or MEN2, acute renal failure |

All medications are FDA pregnancy category X; these medications are contraindicated in women who are or may become pregnant. Women in their reproductive years must be cautioned to use a reliable method of contraception. Caps, capsules; ER, extended release; MEN2, multiple endocrine neoplasia type 2; MTC, medullary thyroid carcinoma; NMS, neuroleptic malignant syndrome; s.c., subcutaneous; tabs, tablets.

¹RED BOOK Online. Micromedex 2.0 (electronic version). Truven Health Analytics, Greenwood Village, CO.

²Physicians' Desk Reference. PDR Network, LLC (electronic version). Truven Health Analytics, Greenwood Village, CO.

³Yanovski SZ, Yanovski JA. Long-term drug treatment for obesity: a systematic and clinical review. JAMA 2014;311:74–86.

⁴Astrup A, Carraro R, Finer N, et al.; NN8022-1807 Investigators. Safety, tolerability and sustained weight loss over 2 years with the once-daily human GLP-1 analog, liraglutide. Int J Obes (Lond) 2012;36:843–854.

⁵Wadden TA, Hollander P, Klein S, et al.; NN8022-1923 Investigators. Weight maintenance and additional weight loss with liraglutide after low-calorie-diet-induced weight loss: the SCALE Maintenance randomized study. Int J Obes (Lond) 2013;37:1443–1451.

⁶DrugPoints System (electronic version). Truven Health Analytics, Greenwood Village, CO.

⁷Selective common (defined as an incidence of ≥ 5%) and serious adverse effects are noted. Refer to the medication package inserts for full information about adverse effects, cautions, and contraindications.

⁸Data of common adverse effects for Xenical were derived from seven double-blind, placebo-controlled clinical trials in mixed-type study populations (i.e., patients with or without type 2 diabetes), but the percentage of patients with type 2 diabetes was not reported. In clinical trials in obese patients with diabetes, hypoglycemia and abdominal distension were also observed.

⁹Data of common adverse effects for Belviq were derived from placebo-controlled clinical trials in patients with type 2 diabetes.

¹⁰Data of common adverse effects for Qsymia were derived from four clinical trials in mixed-type study populations (i.e., patients with or without type 2 diabetes); 13% had type 2 diabetes.

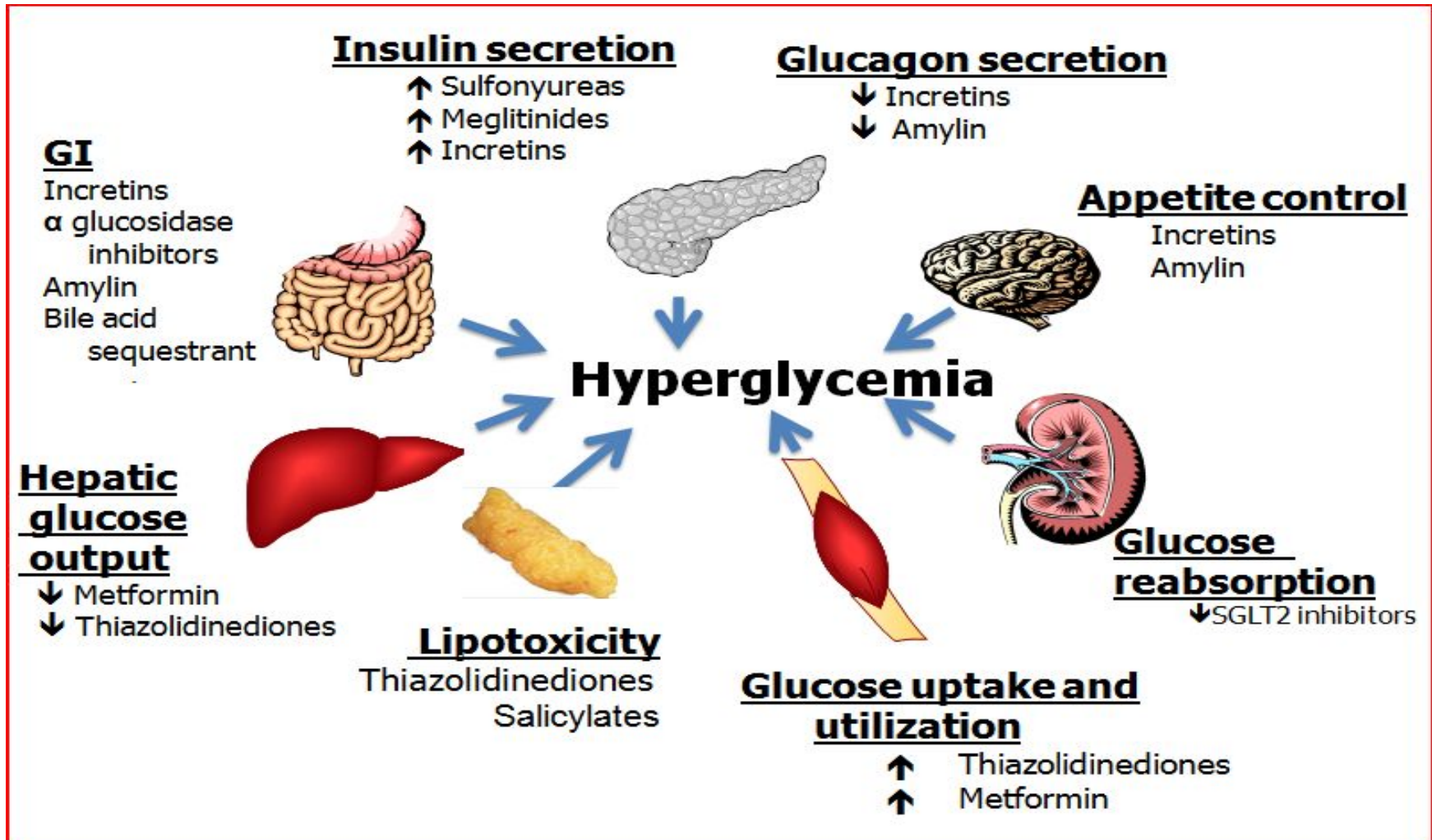
¹²Data of common adverse effects for Saxenda were derived from clinical trials in mixed-type study populations (i.e., patients with or without type 2 diabetes). Percentage of patients with type 2 diabetes was not reported.



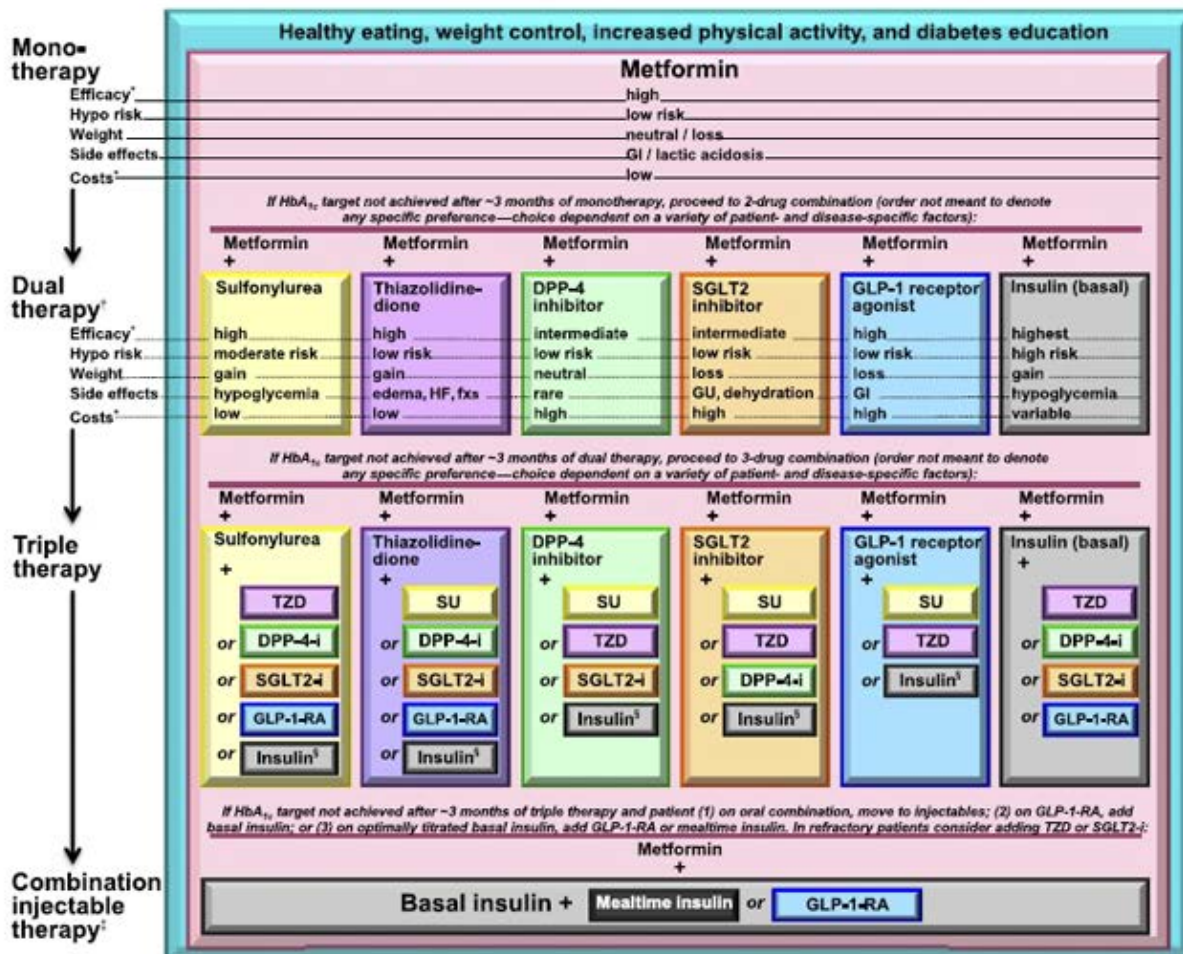
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Section 7.

Approaches to Glycemic Treatment



Evans, J.L & Rushakoff, R.J, 2010, Endotext.org





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Recommendations: Pharmacological Therapy For Type 1 Diabetes

- Most people with T1DM should be treated with multiple dose insulin (MDI) injections (3–4 injections /day of basal & prandial insulin) or continuous subcutaneous insulin infusion (CSII).
- Individuals who have been successfully using CSII should have continued access after they turn 65 years old.





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Recommendations: Pharmacological Therapy For T2DM (2)

- If noninsulin monotherapy at maximal tolerated dose does not achieve or maintain the A1C target over 3 months, add a second oral agent, a GLP-1 receptor agonist, or insulin.
- Use a patient-centered approach to treatment.
- Don't delay insulin initiation in patients not achieving glycemic goals.





Section 10. Older Adults

- Glycemic goals for some older adults might be relaxed but hyperglycemia leading to symptoms or risk of acute hyperglycemic complications should be avoided in all patients.
- Hypoglycemia should be avoided in older adults with diabetes. It should be screened for and managed by adjusting glycemic targets and pharmacologic interventions.



Section 11. Children & Adolescents

- Distinguishing between type 1 and type 2 can be challenging.
- Excessive weight is common in type 1.
- Diabetes-associated autoantibodies and ketosis may be present in patients with features of type 2 such as obesity and AN).
- Accurate diagnosis is critical.



Section 12. Gestational Diabetes Mellitus (GDM)

- Lifestyle change is an essential part GDM mgmt. and may suffice for many women. Add medications if needed to achieve glycemic targets.
- Preferred medications in GDM are insulin and metformin; glyburide may be used but may have higher rate of neonatal hypoglycemia & macrosomia than insulin or metformin. Other agents have not been adequately studied. Most oral agents cross the placenta and all lack long-term safety data.



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Glycemic Targets in Pregnancy (Preexisting Type 1 or Type 2)

The American College of Obstetricians and Gynecologists (ACOG) recommends the following targets for women with pregestational type 1 or type 2 diabetes:

- Fasting ≤ 90 mg/dL (5.0 mmol/L)
- One-hour postprandial ≤ 130 – 140 mg/dL (7.2–7.8 mmol/L)
- Two-hour postprandial ≤ 120 mg/dL (6.7 mmol/L)





Section 13.

Diabetes Care in the Hospital

- Consider getting an A1C on all patients with diabetes or hyperglycemia admitted to the hospital if not performed in the prior 3 months.
-
- Start insulin therapy for persistent hyperglycemia starting at a threshold ≥ 180 mg/dL (10 mmol/L). Then a target glucose of 140–180 mg/dL (7.8–10 mmol/L) is recommended for the majority of critically ill and noncritically ill patients.



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<http://main.diabetes.org/site/R?i=CcKLVT2ni5UsLHCbVf1bmw>



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