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Diabetes Medications & Treatments: Clinical Updates

Justin Ortique, PharmD, RPh, CPM

Executive Director - District of Columbia Board of Pharmacy

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Course Overview

- This course provides updates on diabetes medication pharmacology and diabetes management recommendations, as well as the evidence base.
- This module will be a lecture style format with knowledge check questions at the end of the presentation.
- In order to receive completion credit, you must receive a passing score on the knowledge checks and complete the evaluation.
- This module will be approximately 90 minutes in length for viewing and completion of the evaluation.
- This module is approved for CME.

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Conflict of Interest

- The instructor and advisor have no conflicts of interest to declare.

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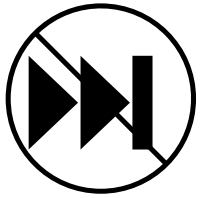

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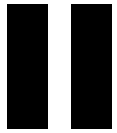

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Learning Objectives

- Describe the pharmacologic mechanisms of medications used for the treatment of diabetes
- Examine the latest evidence on how medications used in diabetes treatment affect the heart, kidneys, and weight management
- Identify clinical pearls and potential side effects of the most commonly used diabetes medications
- Design a therapeutic regimen and monitoring plan for patients based on the updated diabetes treatment algorithm
- Demonstrate how to add non-insulin agents to insulin therapy

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Background

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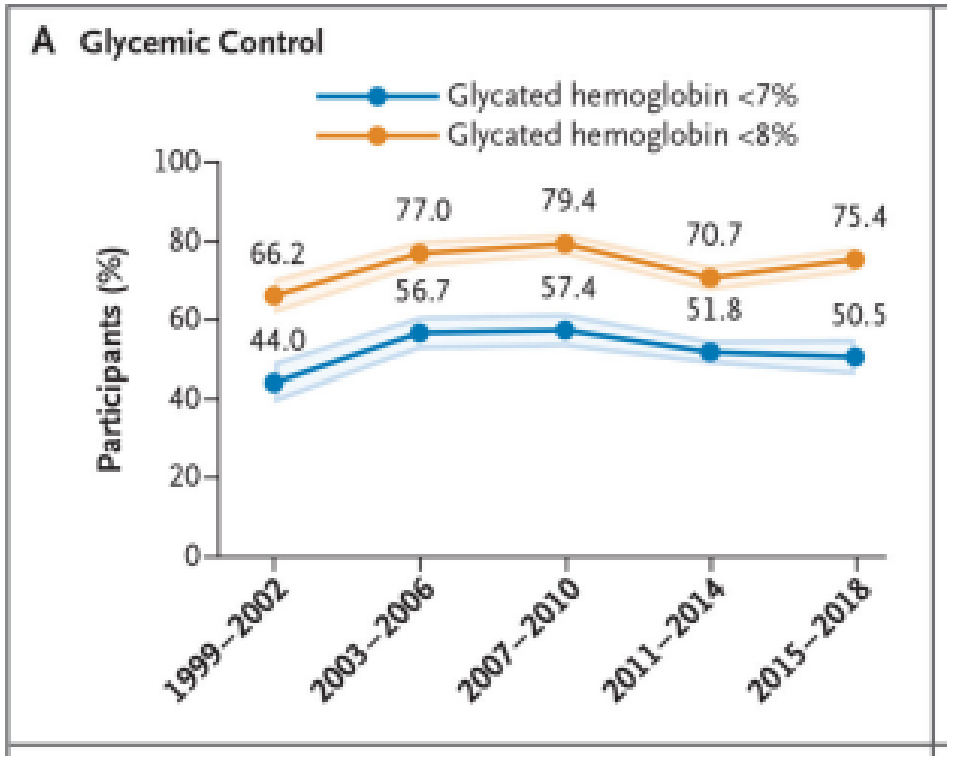
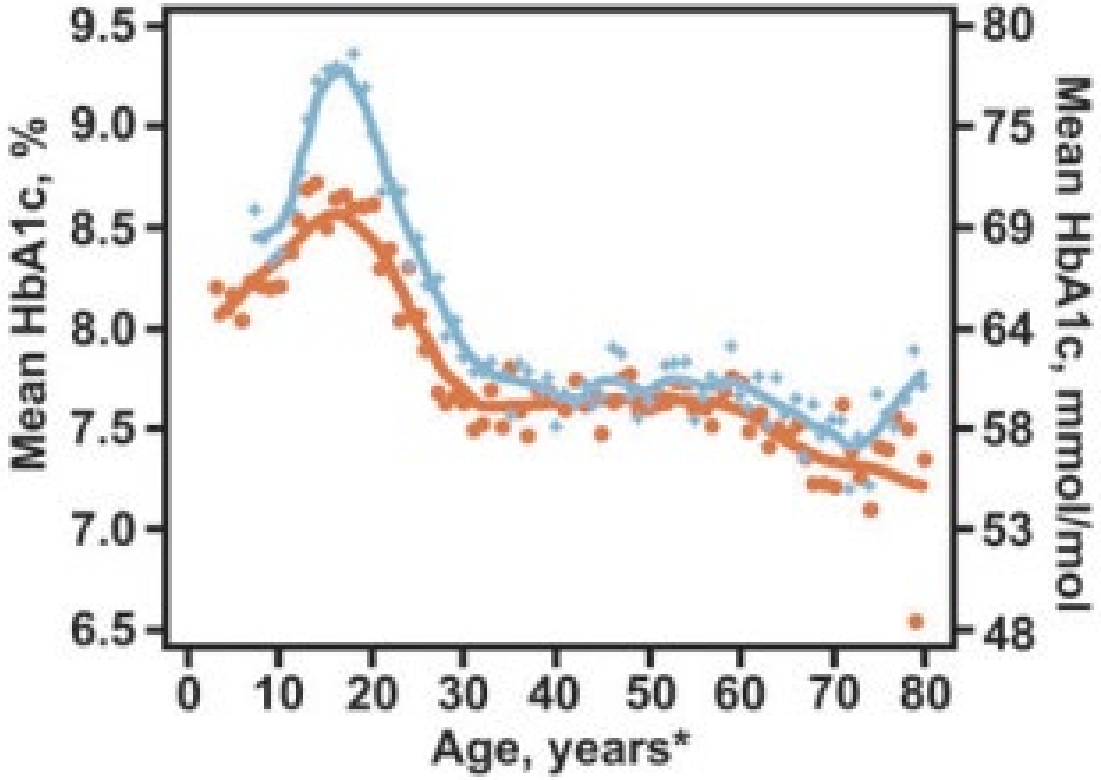
The Current State of Diabetes

37.3 million people have diabetes (11.3% of US population), 38% with prediabetes

NHANES Data



T1D Exchange



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Fang M, et al. N Engl J Med. 2021 June 10; 384(23): 2219–2228. , Foster NC, et al. Diabetes Technol Ther. 2019 Feb;21(2):66-72. National Diabetes Statistics Report | Diabetes | CDC

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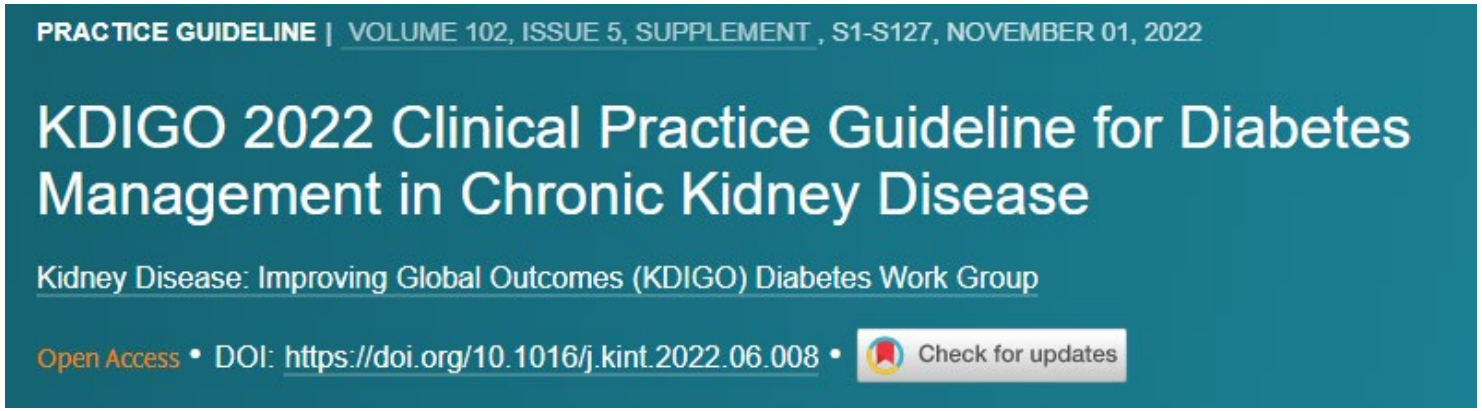
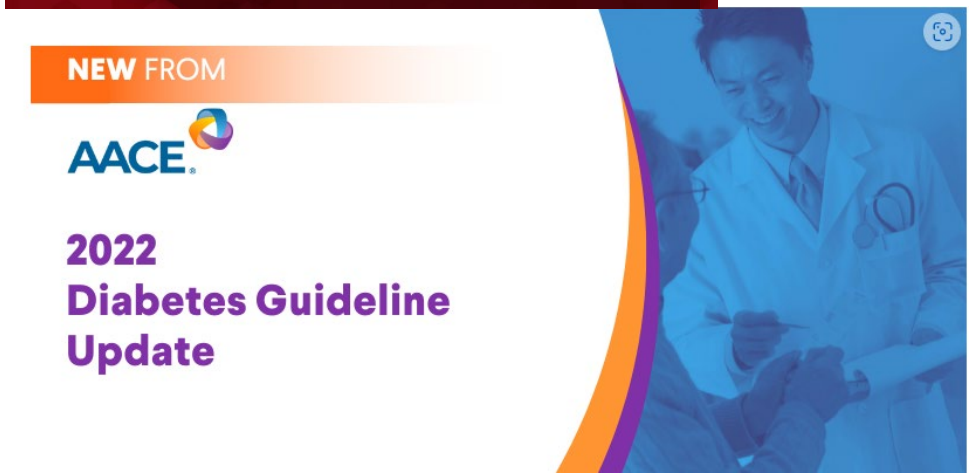
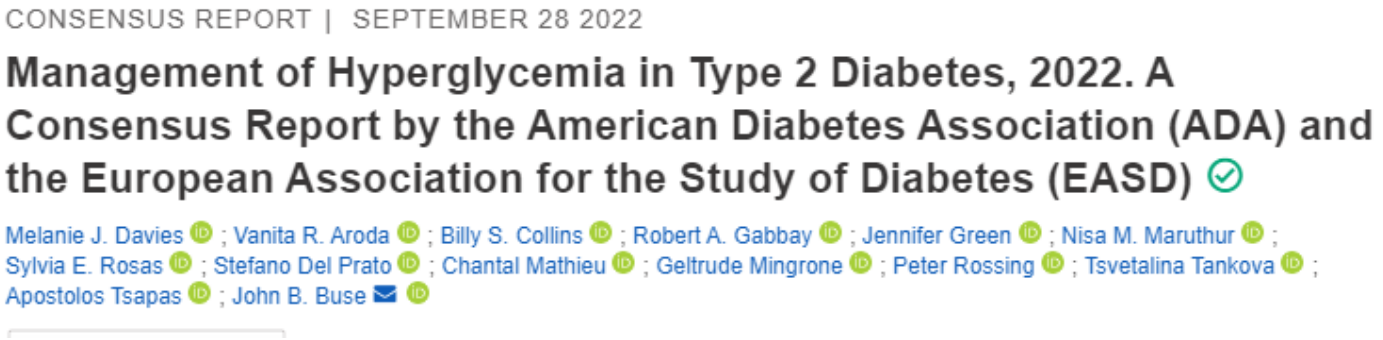
Diabetes Guidelines







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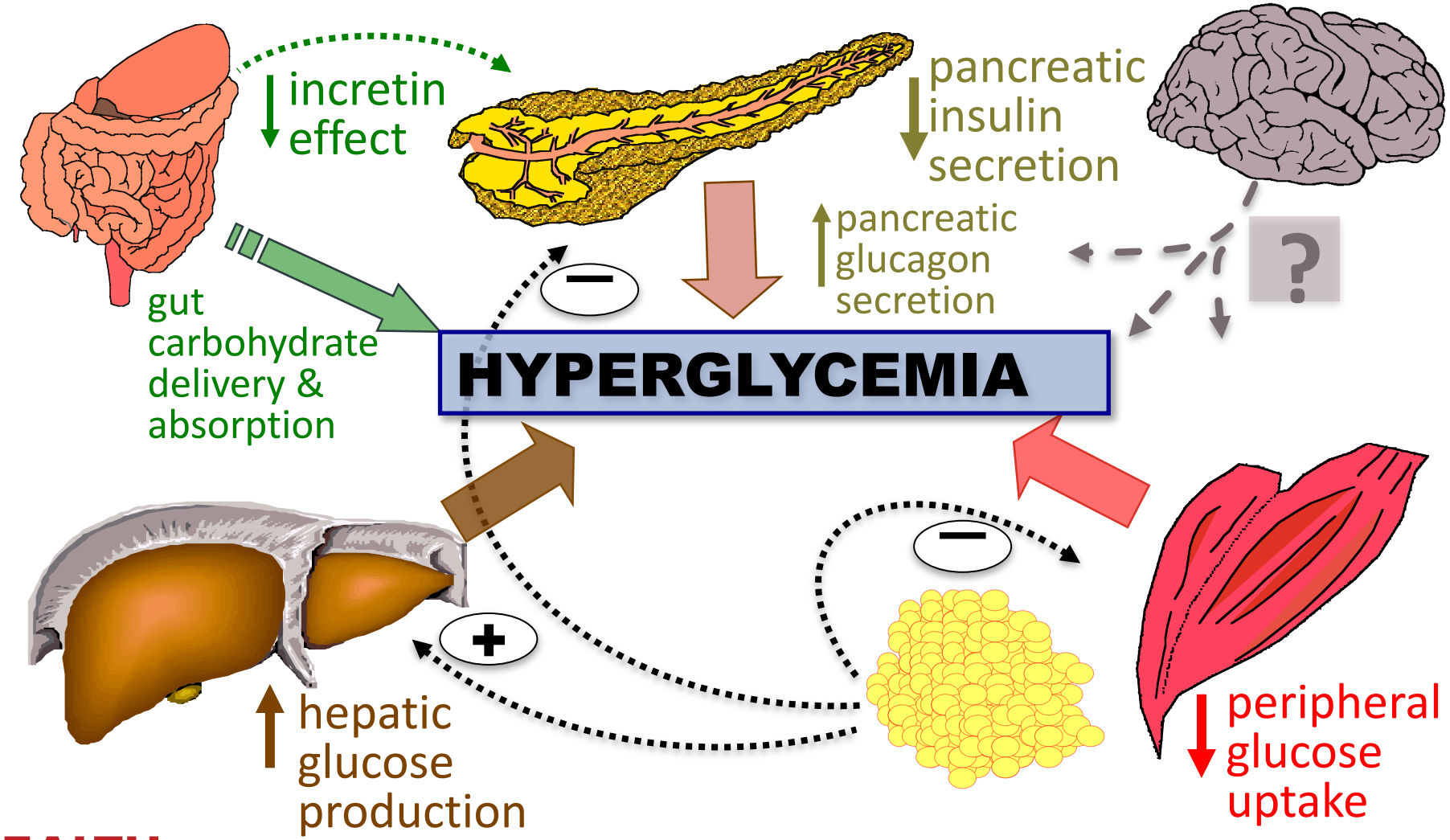
Main Pathophysiological Defects in T2DM



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Adapted from: Inzucchi SE, Sherwin RS in: *Cecil Medicine* 2011

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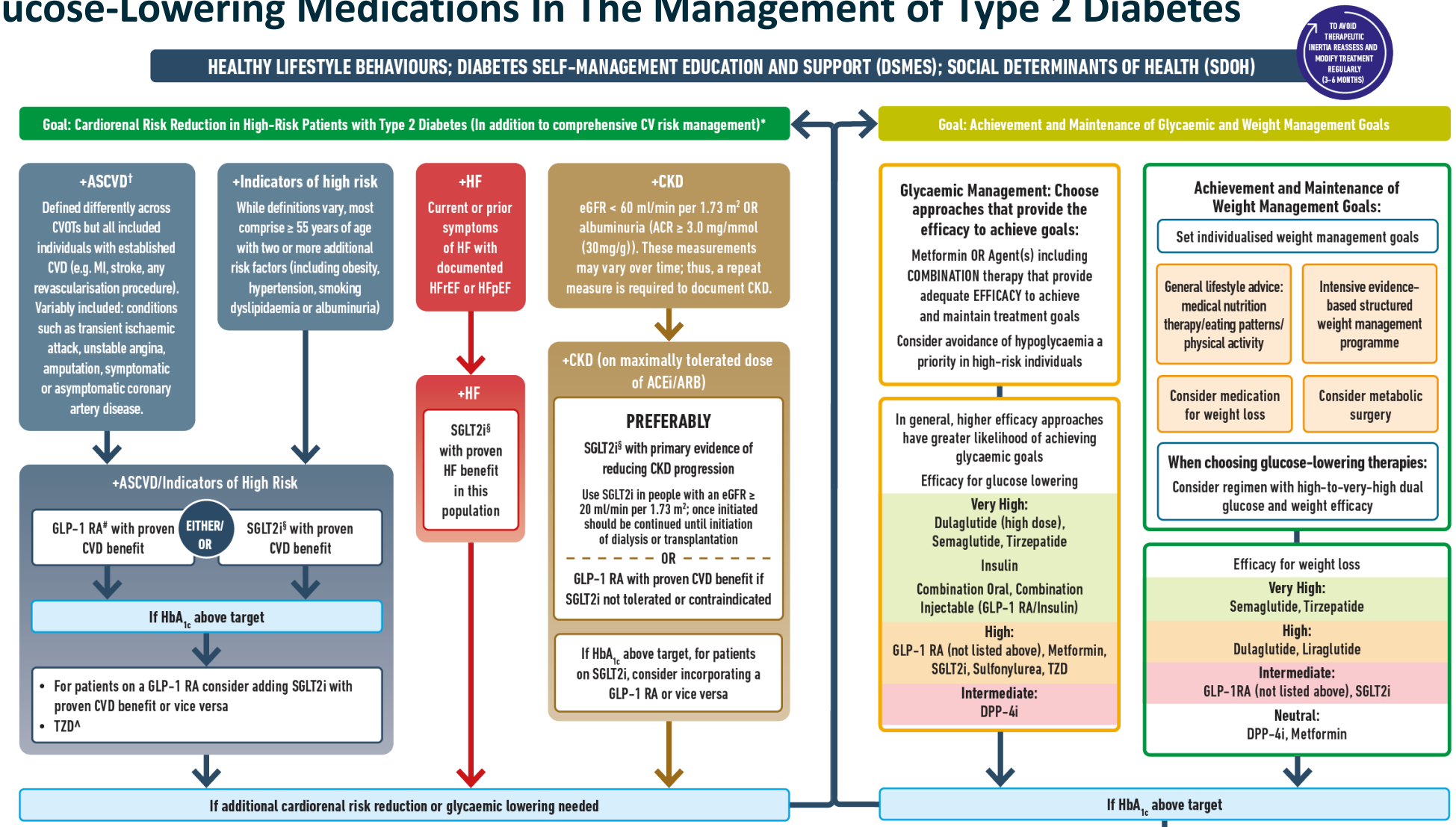
Use of Glucose-Lowering Medications In The Management of Type 2 Diabetes

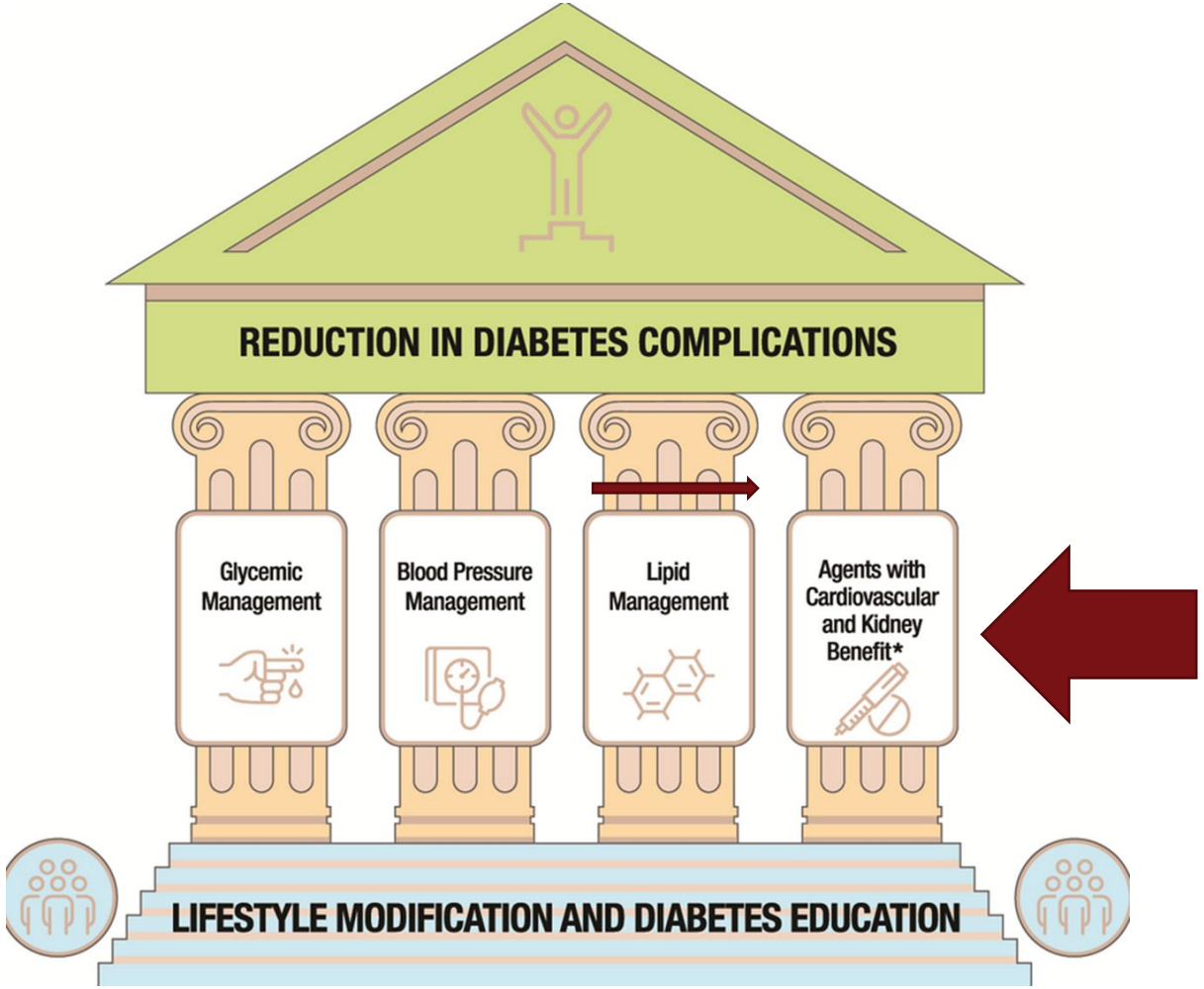


ACEi, Angiotensin-Converting Enzyme Inhibitor; ACR, Albumin/Creatinine Ratio; ARB, Angiotensin Receptor Blocker; ASCVD, Atherosclerotic Cardiovascular Disease; CGM, Continuous Glucose Monitoring; CKD, Chronic Kidney Disease; CV, Cardiovascular; CVD, Cardiovascular Disease; CVOT, Cardiovascular Outcomes Trial; DPP-4i, Dipeptidyl Peptidase-4 Inhibitor; eGFR, Estimated Glomerular Filtration Rate; GLP-1 RA, Glucagon-Like Peptide-1 Receptor Agonist; HF, Heart Failure; HFpEF, Heart Failure with preserved Ejection Fraction; HFrEF, Heart Failure with reduced Ejection Fraction; HHF, Hospitalisation for Heart Failure; MACE, Major Adverse Cardiovascular Events; MI, Myocardial Infarction; SDOH, Social Determinants of Health; SGLT2i, Sodium-Glucose Cotransporter-2 Inhibitor; T2D, Type 2 Diabetes; TZD, Thiazolidinedione.

* In people with HF, CKD, established CVD or multiple risk factors for CVD, the decision to use a GLP-1 RA or SGLT2i with proven benefit should be independent of background use of metformin;† A strong recommendation is warranted for people with CVD and a weaker recommendation for those with indicators of high CV risk. Moreover, a higher absolute risk reduction and thus lower numbers needed to treat are seen at higher levels of baseline risk and should be factored into the shared decision-making process. See text for details; ^ Low-dose TZD may be better tolerated and similarly effective; § For SGLT2i, CV/renal outcomes trials demonstrate their efficacy in reducing the risk of composite MACE, CV death, all-cause mortality, MI, HHF and renal outcomes in individuals with T2D with established/high risk of CVD; # For GLP-1 RA, CVOTs demonstrate their efficacy in reducing composite MACE, CV death, all-cause mortality, MI, stroke and renal endpoints in individuals with T2D with established/high risk of CVD.

Pharmacologic Approaches to Glycemic Management:
Standards of Care in Diabetes - 2023. Diabetes Care 2023;46(Suppl. 1):S140-S157

Cardiovascular Disease and Risk Management



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Diabetes Care 20231;46(Suppl 1):S158-S190

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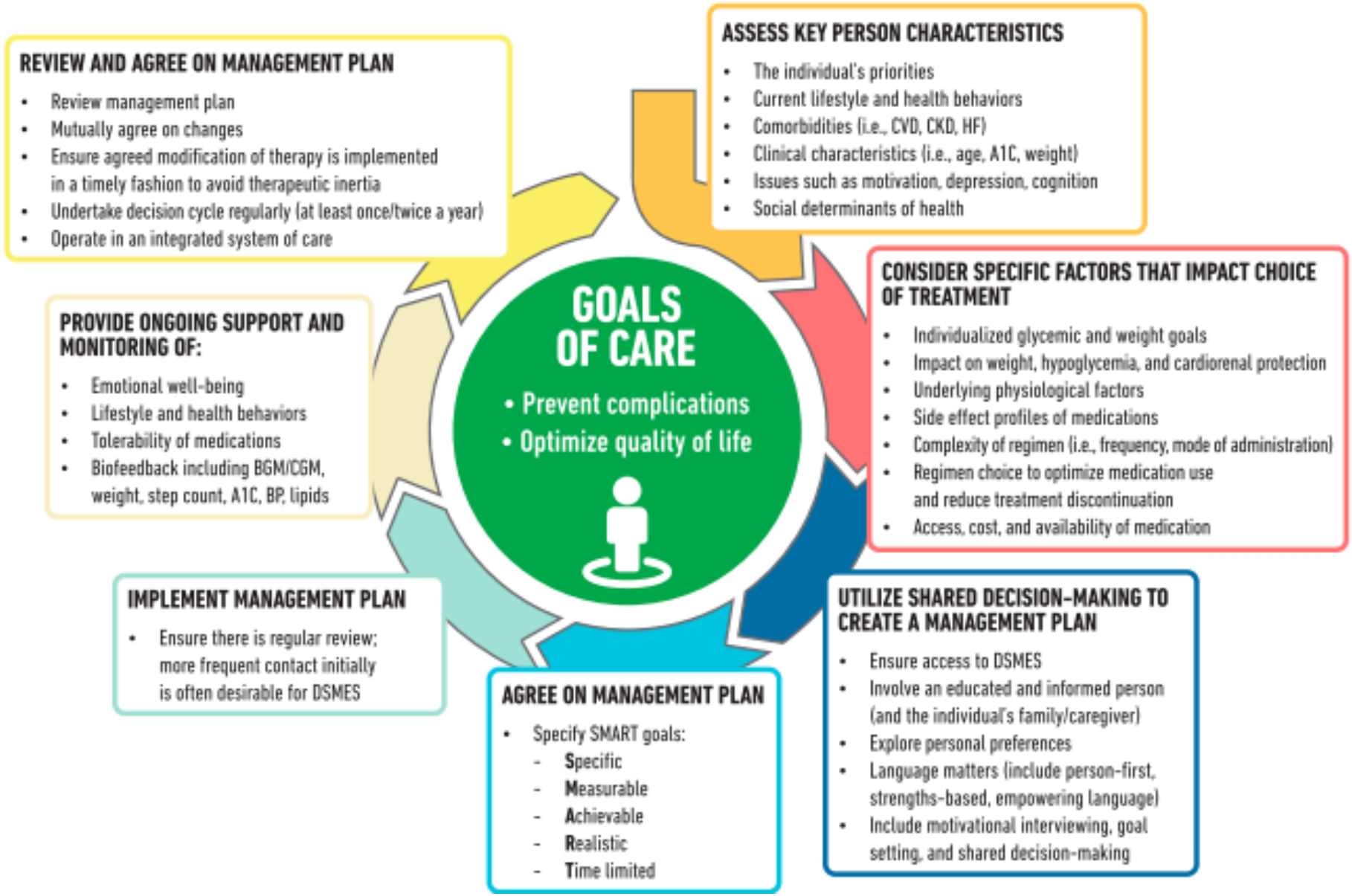
DECISION CYCLE FOR PERSON-CENTERED GLYCEMIC MANAGEMENT IN TYPE 2 DIABETES



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Diabetes Care 2023;46(suppl 1)S49-S67

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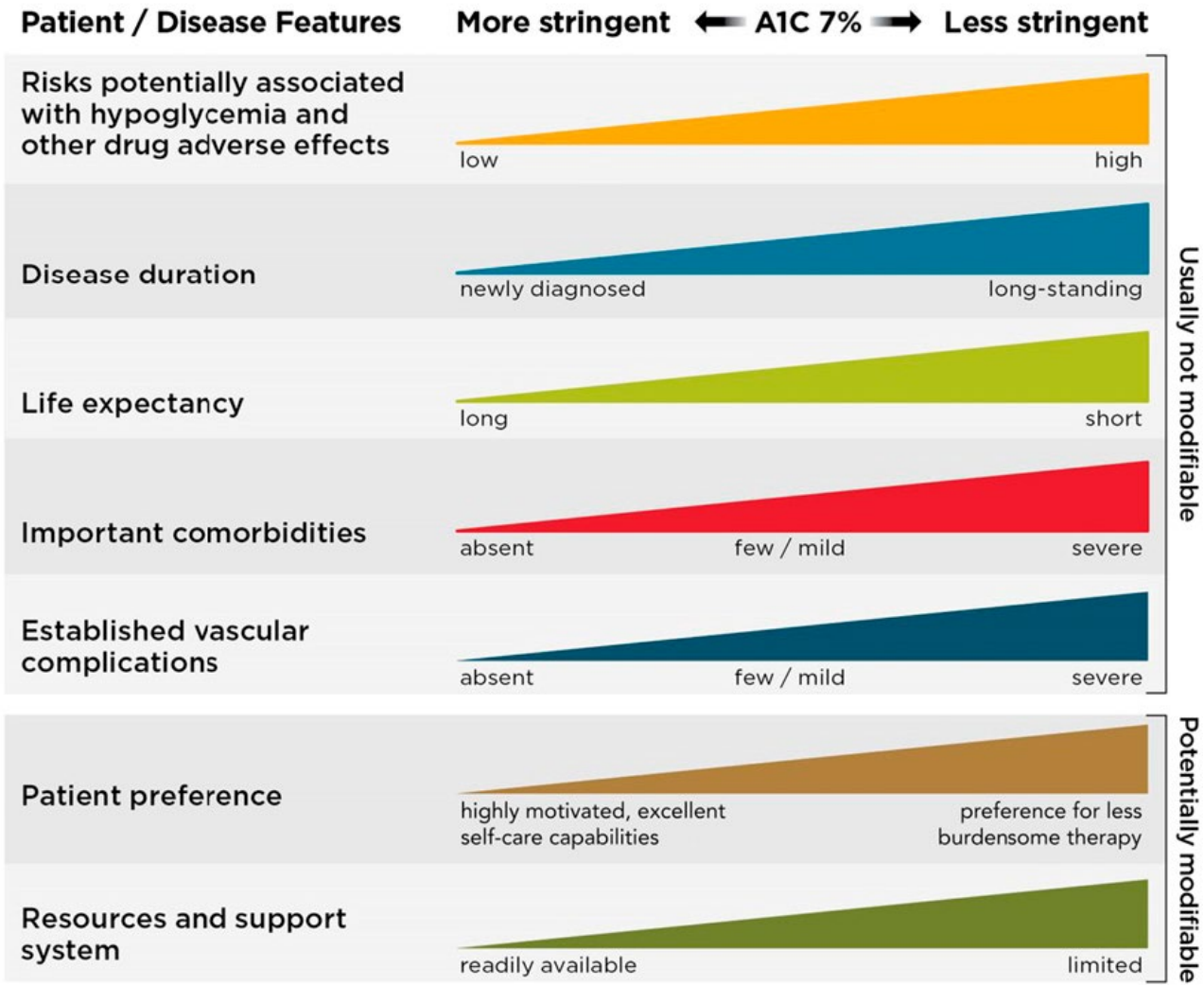
Individualize Glycemic Targets



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Glucose Targets

- Pre-meal: 80-130mg/dL, 2 hr post-meal: <180mg/dL
- Time in Range (TIR)
  - Target 70-180mg/dL (>70% of time)
  - Target time *below* goal
    - Less than 70 (< 4% of time) and Less than 54 (< 1% of time)
  - Target time *above* goal
    - Above 180 (< 25% of time) and Above 250 (<5% of time)
- For those with frailty or at high risk of hypoglycemia recommend
  - Target > 50% time in range
  - Less than 70 (< 1% of time)

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Diabetes Care 2023;46 (supple 1)S97-S110

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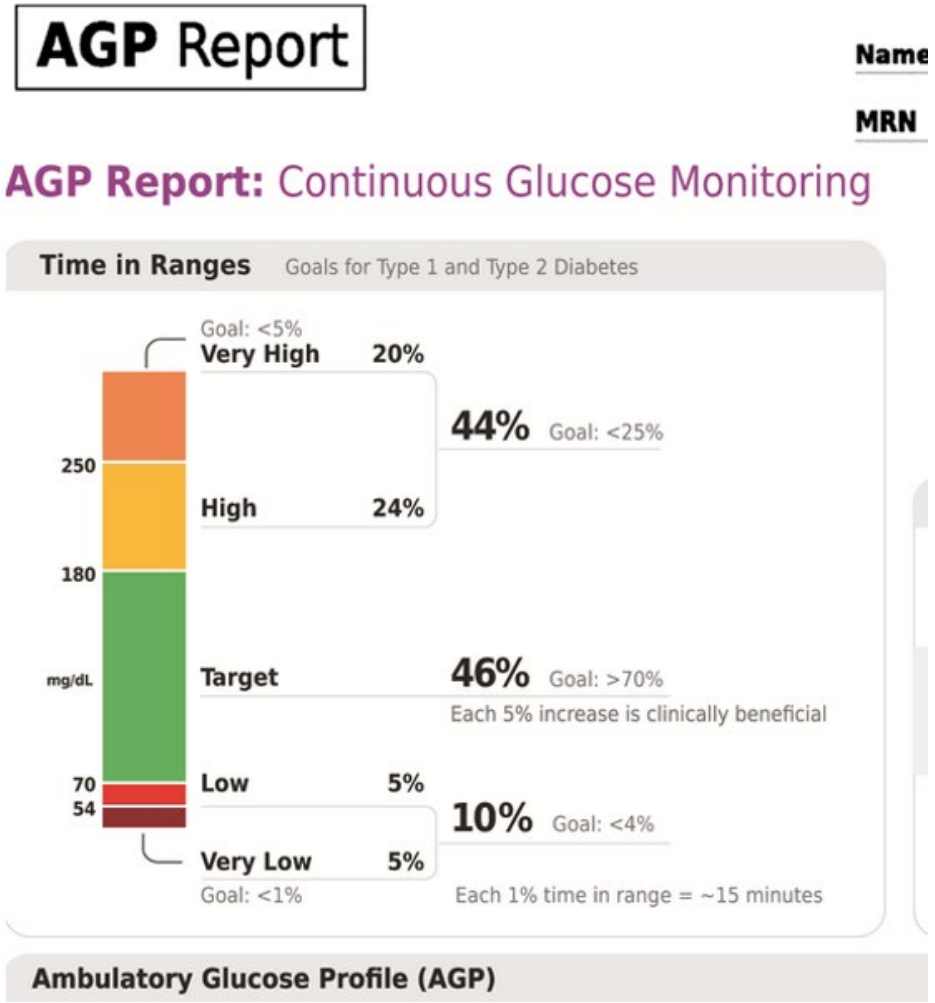
Ambulatory Glucose Profile (AGP)

- Standardized report with visual cues for those on continuous glucose monitoring (CGM) devices



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6. Glycemic Targets: *Standards of Care in Diabetes—2023* FREE

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Diabetes Drug Classes

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Many Drug Classes for Diabetes

- Sodium-glucose cotransporter-2 (SGLT2) inhibitors
- Bile acid sequestrant
- Dopamine-2 agonists
- Amylin mimetic
- Alpha-glucosidase inhibitors
- Insulin
- Glucagon
- Biguanide
- Sulfonylureas
- Meglitinides
- Thiazolidinediones (TZD's)
- Dipeptidyl peptidase-4 (DPP-4) inhibitors
- Glucagon-like-peptide-1 (GLP-1) receptor agonists
- GLP/GIP receptor agonists

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Metformin is "Usually" 1st Line for Type 2 Diabetes without Complications

- Longstanding evidence for efficacy and safety, inexpensive
- If ASCVD, HF or CKD or high ASCVD risk, use SGLT2i or GLP-1 RA +/- metformin
- Mechanism of action: decreases hepatic glucose production
  - Usual dose 1000 mg twice daily, max dose: 2550 mg/day
  - Data suggest metformin may be safely continued with eGFR of 30-45 mL/min/1.73m^2 with dose reductions (i.e., 1000 mg/day)
  - Do not initiate when eGFR < 45
- Expected A1C lowering: 1-2%
- Monitor vitamin B12 levels and renal function, very rare lactic acidosis
- Gastrointestinal (GI) issues: nausea, vomiting, diarrhea
  - Consider long-acting formulation, dose reduction

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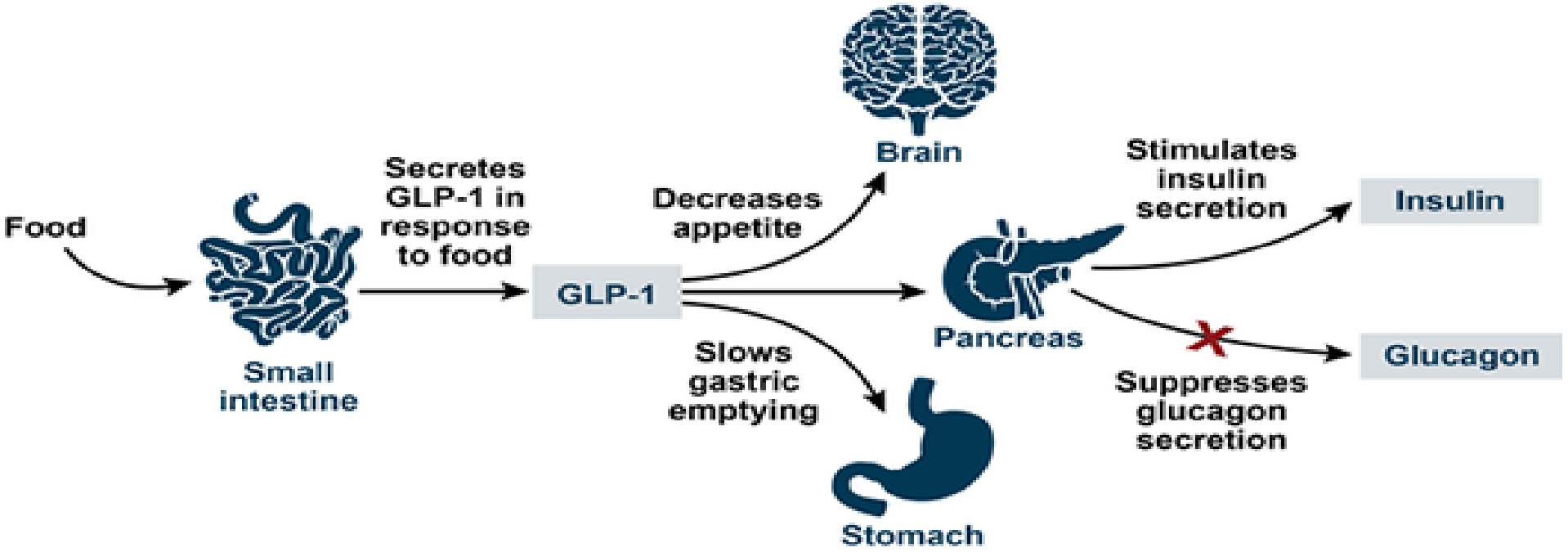
GLP-1 Receptor Agonist Mechanism



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Meier JJ. Nat Rev Endocrinol. 2012;8:728-742.

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GLP-1 & GIP Receptor Agonists

Class/Main Action	Name	Dose Range
GLP-1 Receptor Agonist (GLP-1 RA) **"Incretin Mimetic"** • Increases insulin release with food • Slows gastric emptying • Promotes satiety • Suppresses glucagon	exenatide (Byetta) exenatide XR (Bydureon)	5 and 10 mcg BID 2 mg 1x a week Pen injector – Bydureon BCise
	liraglutide (Victoza)	0.6, 1.2 and 1.8 mg daily
	dulaglutide (Trulicity)	0.75, 1.5, 3.0 and 4.5 mg 1x a week pen injector
	lixisenatide (Adlyxin)	10 mcg 1x a day for 14 days 20 mcg 1x a day starting day 15
	semaglutide (Ozempic) (Rybelsus) Oral tablet	0.25, 0.5, 1.0 and 2.0 mg 1x a week pen injector 3, 7, and 14 mg daily in a.m. Take on empty stomach w/H20 sip
Dual Incretin Agonist Combines both GLP-1 and GIP Incretins. Same action profile as GLP-1 RA, with more intensive action profile.	Tirzepatide (Mounjaro)	2.5, 5.0, 7.5, 10, 12.5 and 15 mg 1x a week prefilled single dose pen Increase dose by 2.5 mg once monthly to reach targets.

- All injectables except Rybelsus
- May inject in abdomen, legs, arms
- Expected A1C lowering
  - GLP-1 RA: 0.5-1.6%
  - Dual incretin: 1.8-2.4%

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Oral Semaglutide (Rybelsus)

- Barriers to GLP-1 oral absorption:
  - Degradation by gastrointestinal enzymes
  - pH induced conformational changes
  - Limited protein permeability of the intestinal membrane
- Semaglutide co-formulated with sodium N-(8-[2-hydroxybenzoyl] amino) caprylate (SNAC), an absorption enhancer
- Absorbed in stomach where SNAC causes a localized increase in pH, leading to higher solubility and protection against proteolytic degradation
- Take daily at least 30 mins before first food, beverage, or other oral meds
- Take with no more than 4 ounces of plain water
- Swallow tablets whole (don't cut or crush)

Rybelsus package insert

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GIP/GLP-1 Receptor Agonist Tirzepatide (Mounjaro)

Dual action

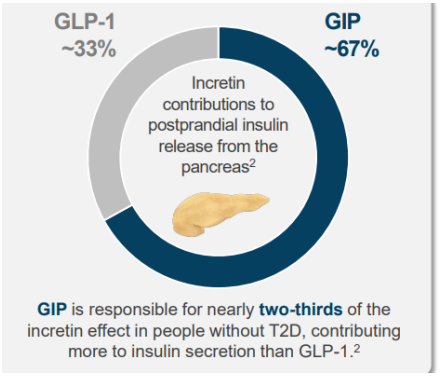
- GIP: glucose-dependent insulinotropic polypeptide and GLP-1 agonist
- Studied in the SURPASS clinical program (T2DM) and SURMOUNT clinical program (Obesity)

In Healthy Patients

1. **GIP and GLP-1 drive the incretin effect**, which leads to insulin release and postprandial glucose clearance[3]
2. **GIP is responsible for nearly two-thirds of the incretin effect** in healthy humans, contributing more to insulin secretion than GLP-1[4]

In Preclinical Studies

1. **Unlike GLP-1, GIP receptors are located in adipose tissue** and may promote proper lipid storage and fat regulation[5]
2. GLP-1 is known to regulate body weight via its actions in the CNS. Preclinical studies have also shown **GIP receptors are located in appetite control centers**. Activity on these receptors has been shown to be associated with reduced caloric intake.[5-7]
3. While GLP-1 can increase insulin sensitivity, it is likely an indirect action through weight regulation. **But GIP has displayed direct effects on insulin sensitivity** in preclinical studies.[5, 8-10]



CNS=central nervous system.

1. Nauck MA, et al. *Lancet Diabetes Endocrinol*. 2016;4(6):525-536. 2. Saxena R, et al. *Nat Genet*. 2010;42(2):142-148. 3. Nauck MA, et al. *Diabetes Obes Metab*. 2018;20(suppl 1):5-21. 4. Nauck MA, et al. *Diabetes*. 2019;68(5):897-900. 5. Samms RJ, et al. *Trends Endocrinol Metab*. 2020;31(6):410-421. 6. Adriaenssens AE, et al. *Cell Metab*. 2019;30(5):987-996.e6. 7. van Bloemendaal L, et al. *J Endocrinol*. 2014;221(1):T1-T16. 8. Mohammad S, et al. *J Biol Chem*. 2011;286(50):43062-43070. 9. Drucker DJ. *Cell Metab*. 2018;27(4):740-756. 10. Samms RJ, et al. *J Clin Invest*. 2021;131(12):e146353.

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De Block C. Diabetes Obes Metab. 2023 Jan;25(1):3-17

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Tirzepatide & GLP-1 RA Safety Profile

- Gastrointestinal (GI) side effects: nausea, appetite loss, diarrhea, constipation, dyspepsia, abdominal pain
- Pancreatitis
- Hypoglycemia with concomitant use of insulin or secretagogues
- Hypersensitivity reactions
- Acute kidney injury: related to nausea/vomiting/dehydration
- Thyroid C-Cell tumors: black box warning
- Acute gallbladder disease
- Worsening retinopathy

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Counseling Points: GLP-1 RA & GLP-1/GIP

- Avoid if personal or family history of medullary thyroid cancer
- Start at lower dose and titrate
- Eat smaller *nourishing* meals to reduce nausea
- Avoid high fat meals
- Reconsider nausea as feeling full
- Store extra pens in fridge/review injection technique
- Avoid in combo with DPP-4 inhibitors
- Report any sudden abdominal pain or pancreatitis symptoms
- Back-up birth control when starting or increasing dose of tirzepatide
- Ask about recent eye exam

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Razavi M, et al. . Mil Med Res. 2022 Aug 20;9(1):45.

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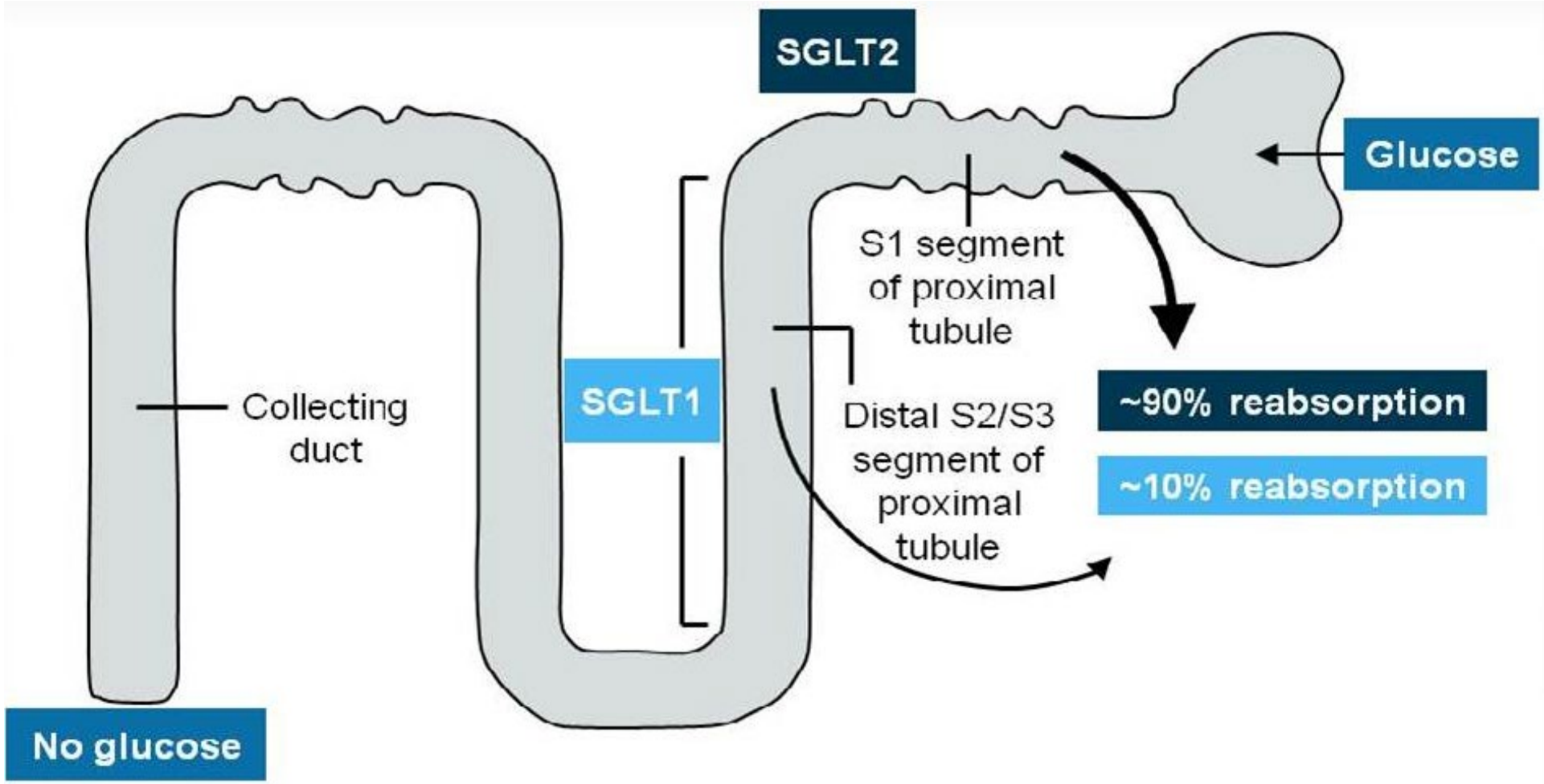
SGLT and the Kidney



https://www.diabetesincontrol.com/sglt2-inhibitors-a-new-class-of-diabetes-medications/

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SGLT2 Inhibitors

- Mechanism of action: decreases renal reabsorption of glucose proximal tubule of kidneys (reset renal threshold)
- **Preferred** diabetes treatment for people with heart and kidney failure
- Lower A1C 0.6-1.5%
- Once an SGLT2i is initiated, it is reasonable to continue an SGLT2i even if the eGFR falls below 20 mL/min/1.73m^2, unless it is not tolerated or kidney replacement therapy is initiated

Package inserts, dailymed.nlm.nih.gov

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SGLT2 Inhibitor Dosing & Indication

Drug	Dose	Renal Adjustment	FDA Approved Indications
Ertugliflozin (Steglatro)	5-15 mg daily	Not recommended for eGFR <45	As an adjunct to diet and exercise to improve glycemic control in adults with T2DM (All)
Dapagliflozin (Farxiga)	5-10 mg daily	Not recommended for eGFR <45 (glycemic control) or <25: avoid initiation, may continue for CV, CKD benefits	• To reduce the risk of hospitalization for HF in adults with T2DM and established CVD or multiple CV risk factors. • To reduce the risk of CV death and hospitalization for HF in adults with NYHA class II-IV with reduced ejection fraction. • To reduce the risk of sustained eGFR decline, ESKD, CV death, and hospitalization for HF in adults with CKD at risk of progression.
Empagliflozin (Jardiance)	10-25 mg daily	Not recommended for eGFR <30mL/min (glycemic control) or <20: avoid initiation, may continue for CV, CKD benefits	• To reduce the risk of CV death in adults with T2DM and established CVD. • To reduce the risk of CV death and hospitalization for HF in adults with HF.
Canagliflozin (Invokana)	100-300 mg daily	eGFR 30 to <60: 100 mg once daily eGFR <30: avoid initiation, may continue 100mg daily until ESRD	• To reduce MACE in adults with T2DM and established CVD. • To reduce the risk of ESKD, doubling of serum creatinine, CV death, and hospitalization for HF in adults with T2DM and diabetic nephropathy with albuminuria >300 mg/day.
Bexagliflozin (Brenzavvy)	20 mg daily	Not recommended for eGFR <30	As an adjunct to diet and exercise to improve glycemic control in adults with T2DM

Package inserts, dailymed.nlm.nih.gov

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Benefits of SGLT2 Inhibitors

A1C lowering	Weight loss	Cardiovascular
Renal	Heart failure	Blood pressure lowering

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Side Effects of SGLT2 Inhibitors

Genitourinary infections	Volume depletion	Increased urination
Hypotension	Urinary tract infection (UTI)	Euglycemic diabetes ketoacidosis (DKA)

Amputation risk? Fournier's gangrene?

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SGLT2i: Managing Adverse Effects

- Maintain good hygiene to reduce risk of genital mycotic infections
  - Higher risk with higher glucose
- Ensure adequate hydration
  - Monitor renal function/potassium
- DKA risk
  - Use caution with reducing insulin dose
  - Discontinue before scheduled surgery (3-4 days), during critical illness or prolonged fasting
- Monitor blood pressure
  - May need to reduce antihypertensive meds or adjust diuretic dose
- Urinary tract infection (UTI) risk greater with hyperglycemia
- Amputations observed with canagliflozin
  - Good foot care, check feet daily

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Case Study: Meet Rick

Rick is a 51yoM diagnosed with type 2 diabetes 5 years ago.

He takes metformin 1000 mg twice daily and semaglutide 1 mg weekly. His A1C=7.3%.

In the last 3 months, he was diagnosed with kidney disease. He has albuminuria and eGFR=56.

Weight: 205lbs, 5”7, BMI=32kg/m^2.

He lost 20lbs in the last year.

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Case Study (*continued*):

What is the best drug to add to Rick's regimen?

A. Glipizide
B. Dapagliflozin (Farxiga)
C. Pioglitazone (Actos)
D. Linagliptin (Tradjenta)
E. More than 1 correct answer

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Sulfonylureas

- Second generation: glipizide, glimepiride, glyburide
- Dosed 1-2x daily before meals
- Mechanism of action: stimulate beta cells in the pancreas to release insulin
- Adverse effects: hypoglycemia, weight gain
- Beta cell burnout? - Decreased longevity
- Low cost, effective A1C lowering
- Recommend to use shorter acting (ex. glipizide) in older adults or CKD

Sulfonylureas • Stimulates sustained insulin release	glyburide: (Diabeta) (Glynase PresTabs)	 1.25 – 20 mg 0.75 – 12 mg	Can take once or twice daily before meals. Low cost generic. **Side effects**: hypoglycemia and weight gain. Eliminated via kidney. **Caution**: Glyburide most likely to cause hypoglycemia. Lowers A1C 1.0% - 2.0%.
	glipizide: (Glucotrol) (Glucotrol XL)	2.5 – 40 mg 2.5 – 20 mg	
	glimepiride (Amaryl)	1.0 – 8 mg	

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Dipeptidyl Peptidase-4 (DPP-4) Inhibitors

- Mechanism of action
  - Prevents the breakdown of GLP-1 and GIP, resulting in 2-3X increased endogenous incretin levels
- Efficacy
  - Hemoglobin A1C reduction by **0.6%–0.8%**
  - Primarily lowers postprandial glucose levels
  - Not as efficacious as GLP-1 agonists
  - CV neutral, increased HF hospitalization with alogliptin/saxagliptin
- Adverse effects
  - Generally well tolerated, dosed once daily
  - Avoid in combo with GLP-1 agonist
  - Caution with h/o pancreatitis
  - Potential joint pain

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DPP-4 Inhibitor Dosing

Drug	Dose	Renal Adjustment
Sitagliptin	100 mg daily	50 mg/day eGFR 30–45 mL/min/1.73m^2 25 mg/day eGFR <30 mL/min/1.73m^2
Linagliptin	5 mg daily	None necessary
Saxagliptin	5 mg daily	2.5 mg/day eGFR < 45 mL/min/1.73m^2
Alogliptin	25 mg daily	12.5 mg/day eGFR 30–59 mL/min/1.73m^2 6.25 mg/day for eGFR <30 mL/min/1.73m^2

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Meglitinides

- Mechanism of action
  - Directly stimulate insulin release from pancreatic beta cells
  - Shorter acting vs. sulfonylureas
- Efficacy
  - A1C reduction of **0.5% – 1%** as monotherapy or add-on therapy
  - A1C reduction of **1.5% – 1.8%** in combination with metformin or thiazolidinedione
  - Reduces postprandial blood glucose
  - Mealtime **(e.g., 3 times/day)** dosing may reduce adherence
- Dose
  - Repaglinide (Prandin): 0.5 – 1 mg, 1 – 15 minutes before meals; max daily dose 16 mg
  - Nateglinide (Starlix): 60 – 120 mg before meals
- Adverse effects
  - Hypoglycemia (< sulfonylurea)
  - Modest weight gain (< sulfonylurea)

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Thiazolidendiones (TZD's)

- TZD's include pioglitazone, rosiglitazone
- Dosed once daily without regard to food
- Mechanism: activates the nuclear transcription factor PPAR-gamma, increases peripheral insulin sensitivity
- Adverse effects: bone fractures, edema/fluid retention, weight gain
- Avoid in heart failure
- Association with bladder cancer (pioglitazone)
- 12 weeks to full effect

Thiazolidinediones "TZDs" • Increases insulin sensitivity	pioglitazone (Actos) rosiglitazone (Avandia)	15 – 45 mg daily 4 – 8 mg daily	Black Box Warning: TZDs may cause or worsen CHF. Monitor for edema and weight gain. Increased peripheral fracture risk. Actos may increase risk of bladder cancer. Lowers A1c 0.5% – 1.0%

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Drug Specific Factors

Class	Efficacy	Hypoglycemia	Weight Change	Effect on MACE	Heart Failure	Renal	Cost
Metformin	High	No	Neutral/ Loss	Potential benefit	Neutral	Neutral	Low
SGLT2 Inhibitors	Intermediate to High	No	Loss, intermediate	Benefit	Benefit	Benefit	High
GLP-1 RA	High to Very High	No	Loss, intermediate to high	Benefit	Neutral	Benefit	High
GIP and GLP-1 RA	High to Very High	No	Loss, very high	Under investigation	Under investigation	Under investigation	High
DPP-4 Inhibitors	Intermediate	No	Neutral	Neutral	Risk: saxa/alogliptin	Neutral	High
TZD	High	No	Gain	Potential benefit: Pio	Risk	Neutral	Low
Sulfonylurea	High	Yes	Gain	Neutral	Neutral	Neutral	Low

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Less Commonly Used Agents

Class	Advantages	Disadvantages	A1C Effect
α-Glucosidase Inhibitor	No hypoglycemia, ↓PPG, non-systemic	Less impact on A1C, GI side effects, frequent dosing	0.5-1%
Acarbose (Precose), miglitol (Glyset)			
Bile Acid Sequestrants	No hypoglycemia, ↓ LDL	Less impact on A1C, constipation, ↑TG, drug interactions	0.5-1%
Colesevelam (Welchol)			
Dopamine Agonist	No hypoglycemia	Dizziness/syncope, nausea, high cost	0.5-1%
Bromocriptine (Cycloset)			
Amylin Mimetic	No hypoglycemia, weight loss	GI side effects, injectable	0.36%
Pramlintide (Symylin)			

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Clinical Resource, Drugs for Type 2 Diabetes. Pharmacist's Letter/Prescriber's Letter.

PPG: Post-prandial glucose

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Cardiorenal Therapies

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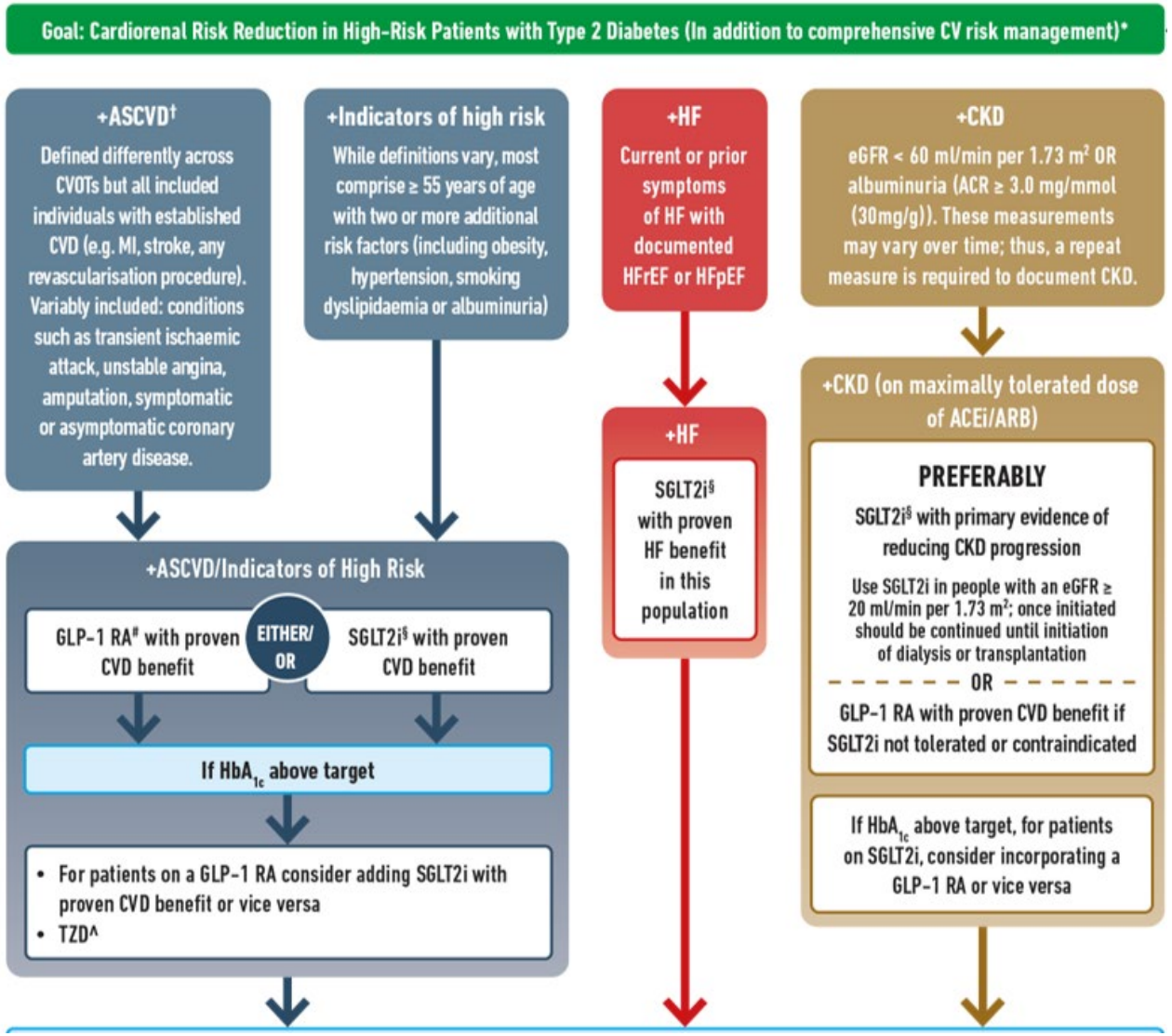
High Risk or Establish CVD, CKD, HF



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Pharmacologic Approaches to Glycemic Management:
Standards of Care in Diabetes - 2023. *Diabetes Care* 2023;46(Suppl. 1):S140-S157

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GLP-1 Analog CVOT Data Summary

Trial Name	GLP-1 Agent/ Comparator	Outcomes (Primary Bolded)	FDA Indication
LEADER	**Liraglutide**/placebo	81% Prior CVD**, 3 point MACE** 0.87 (0.78-0.97) N=9340, Median follow-up 3.8 years Worsening nephropathy 0.78 (0.67-0.92)	As an adjunct to diet and exercise to improve glycemic control in patients **10 years and older** with type 2 DM To reduce the risk of **major adverse CV events** in adults with type 2 DM and **established CVD**
ELIXA	**Lixesenatide**/placebo	100% Prior CVD, **4 point MACE** 1.02 (0.89-1.17) N=6068, Median follow-up 2.1 years	As an adjunct to diet and exercise to improve glycemic control in adults with type 2 DM
SUSTAIN-6	**Semaglutide inj**/ placebo	60% Prior CVD, **3 point MACE** 0.74 (0.58-0.95) N=3297, Median follow-up 2.1 years Worsening nephropathy 0.64 (0.46-0.88)	As an adjunct to diet and exercise to improve glycemic control in adults with type 2 DM To reduce the risk of **major adverse CV events** in adults with type 2 DM and **established CVD**
PIONEER-6	**Semaglutide oral**/ placebo	84.7% Prior CVD, **3 point MACE** 0.79 (0.57-1.11) N=3183, Median follow-up 1.3 years	As an adjunct to diet and exercise to improve glycemic control in adults with type 2 DM
EXSCEL	**Exenatide** –(weekly)/ placebo	73.1% Prior CVD, **3 point MACE** 0.91 (0.83-1.00) N=14752, Median follow-up 3.2 years	As an adjunct to diet and exercise to improve glycemic control in patients **10 years and older** with type 2 DM
REWIND	**Dulaglutide**/placebo	32% Prior CVD, **3 point MACE** 0.88 (0.79-0.99) N=9901, Median follow up 5. 4 years Worsening nephropathy 0.85 (0.77-0.93)	As an adjunct to diet and exercise to improve glycemic control in adults with type 2 DM To reduce the risk of **major adverse CV events** in adults with type 2 DM and **established CVD** or **multiple CVD risk factors**

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American Diabetes Association. 10. Cardiovascular disease and risk management: Standards of Care in Diabetes—2023. Diabetes Care 2023;46(Suppl. 1):S158–S190

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GLP-1 RA Outcomes: CV, HF, Renal

Drug/ Size	Trial	Major Adverse Cardiovascular Events (MACE-stroke, nonfatal MI, CV death)	MACE Benefit	Hospitalization for Heart Failure (HHF)	HHF Benefit	Renal Outcomes	Renal Benefit
Lixisenatide N=6,068	ELIXA	1.02 (0.89-1.17)*^	N	0.96 (0.75-1.23)	N	NA	NA
Liraglutide N=9,340	LEADER	0.87 (0.78-0.97)*	Y	0.87 (0.73-1.05)	N	0.78 (0.67-0.92)	Y
Semaglutide N=3,297	SUSTAIN-6	0.76 (0.78-0.97)*	Y	0.82 (0.47-1.44)	N	0.64 (0.46-0.88)	Y
Semaglutide oral N=3,183	PIONEER-6	0.78 (0.57-1.11)*	N	0.86 (0.48-1.55)	N	NA	NA
Exenatide N=14,752	EXSCEL	0.91 (0.83-1.0)*	N	1.05 (0.74-1.50)	N	NA	NA
Dulaglutide N=9,901	REWIND	0.88 (0.79-0.99)*	Y	0.93 (0.77-1.12)	N	0.85 (0.77-0.93)	Y

MACE refers to 3-point MACE (stroke, nonfatal MI, CV death) except lixisenatide (4-point MACE included hospitalization for unstable angina).
*: primary outcome, renal outcomes refer to worsening nephropathy; Y-yes, N-no. HHF: hospitalizations for heart failure
Confidence interval <1 means that the drug was beneficial compared to placebo

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American Diabetes Association. 10. Cardiovascular disease and risk management: Standards of Care in Diabetes—2023. Diabetes Care 2023;46(Suppl. 1):S158–S190

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SGLT2 Inhibitor HF/ASCVD Evidence Summary

Trial Name	SGLT2 Inhibitor vs. Placebo	Outcomes (Primary Bolded)
EMPA-REG Outcome	Empagliflozin	N=7020, Median follow-up 3.1 years, Prior CVD 99% **3 Point MACE**: 0.86 (0.74-0.99), CV death: 0.62 (0.49-0.77)
EMPEROR Reduced	Empagliflozin	N=3730, 1856 with diabetes, Median follow-up 1.3 years, 100% HF with reduced EF **CV death or HF hospitalization** 0.75 (0.65-0.86)
EMPEROR Preserved	Empagliflozin	N=5988, 2938 with diabetes, Median follow-up 2.2 years, 100% HF with EF > 40% **CV death or HF hospitalization** 0.79 (0.69-0.90)
CANVAS Program	Canagliflozin	N=10142, Median follow-up 3.6 years, Prior CVD 65.6% **3 point MACE**: 0.86 (0.75-0.97), Worsening nephropathy 0.60 (0.47-0.77)
DECLARE-TIMI 58	Dapagliflozin	N=17160, Median follow-up 4.2 years, Prior CVD 40% **3 point MACE**: 0.93 (0.84-1.03), CV death or HF hospitalization: 0.83 (0.73-0.95)
DAPA-HF	Dapagliflozin	N=4744 (1983 with diabetes), Median follow-up 1.5 years, 100% HF **Worsening HF or CV death** 0.74 (0.65-0.85)
DELIVER	Dapagliflozin	N=6263, 2807 with diabetes, Median follow-up 2.3 years, 100% with HF with EF > 40% **Worsening HF or CV death** 0.82 (0.73-0.92)
VERTIS-CV	Ertugliflozin	N=8246, Median follow-up 3.5 years, Prior CVD 99.9% **3 point MACE** 0.97 (0.85-1.11), HF hospitalization 0.70 (0.54-0.90)

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American Diabetes Association. 10. Cardiovascular disease and risk management: Standards of Care in Diabetes—2023. Diabetes Care 2023;46(Suppl. 1):S158–S190

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SGLT2 Inhibitor CKD Evidence Summary

Trial Name	SGLT2 Inhibitor vs Placebo	Outcomes (Primary Bolded)
CREDENCE	Canagliflozin	N=4401, Median follow-up 2.6 years, Prior CVD 50.4% **ESRD, doubling of creatinine or death from renal or CV cause** : 0.70 (0.59-0.82), 3 point MACE 0.80 (0.67-0.95)
DAPA-CKD	Dapagliflozin	N=4304, 2906 with diabetes, Median follow-up 2.4 years, Prior CVD 37.4% **≥50% decline in eGFR, ESKD or renal/CV death** : 0.61 (0.51-0.72)
EMPA-Kidney	Empagliflozin	N=6609, Median follow-up 2.0 years, Prior CVD 27%, 46% with DM **ESKD, >40% decline in eGFR from baseline, or renal/CV death** : 0.72 (0.64-0.82), stopped early due to positive benefit

Perkovic V, Jardine MJ, Neal B, et al. Canagliflozin and renal outcomes in type 2 diabetes and nephropathy. N Engl J Med. 2019;380:2295–2306.
Heerspink HJL, Stefansson BV, Correa-Rotter R, et al. Dapagliflozin in patients with chronic kidney disease. N Engl J Med. 2020;383:1436–1446.
EMPA-KIDNEY Collaborative Group, Herrington WG, Staplin N, Wanner C, et al. Empagliflozin in Patients with Chronic Kidney Disease. N Engl J Med. 2022 Nov 4. doi: 10.1056/NEJMoa2204233. Epub ahead of print. PMID: 36331190.

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SGLT2 Inhibitor Indications

Drug	FDA Approved Indications
Ertugliflozin (Steglatro)	As an adjunct to diet and exercise to improve glycemic control in adults with T2DM (All).
Dapagliflozin (Farxiga)	• To reduce the risk of hospitalization for HF in adults with T2DM and established CVD or multiple CV risk factors. • To reduce the risk of CV death and hospitalization for HF in adults with NYHA class II-IV with reduced ejection fraction. • To reduce the risk of sustained eGFR decline, ESKD, CV death, and hospitalization for HF in adults with CKD at risk of progression.
Empagliflozin (Jardiance)	• To reduce the risk of CV death in adults with T2DM and established CVD. • To reduce the risk of CV death and hospitalization for HF in adults with HF.
Canagliflozin (Invokana)	• To reduce MACE in adults with T2DM and established CVD. • To reduce the risk of ESKD, doubling of serum creatinine, CV death, and hospitalization for HF in adults with T2DM and diabetic nephropathy with albuminuria >300 mg/day.
Bexagliflozin (Brenzavvy)	As an adjunct to diet and exercise to improve glycemic control in adults with T2DM.

Package inserts, dailymed.nlm.nih.gov

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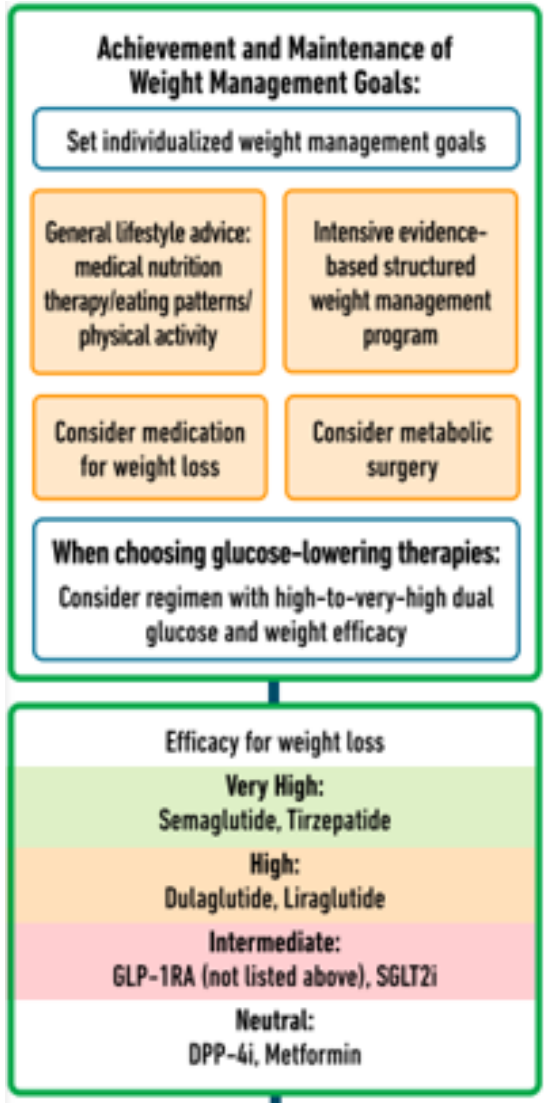
Weight Management

- Meds associated with weight loss
  - GLP-1 Agonists
  - SGLT2 Inhibitors
- Meds are weight neutral
  - Metformin
  - DPP-4 Inhibitors
  - Alpha Glucosidase Inhibitors



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Diabetes Care 2023;46(Suppl. 1):S125-S143.

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Utilizing Insulin Therapy

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Injectable Therapy for Type 2 DM

- GLP-1 RA preferred as 1st injectable unless A1C >10%
- Basal insulin started as 10 units or 0.1 to 0.2 units/kg day
  - Titrate up 2 units every 3 days, until FBG at goal
  - If hypoglycemic, decrease insulin 20% or 4 units
- If basal insulin is >0.5 unit/kg day, add bolus insulin (avoid overbasalization, BeAM score>50mg/dL)
- When insulin is initiated, **continue organ protective glucose lowering medications and metformin**

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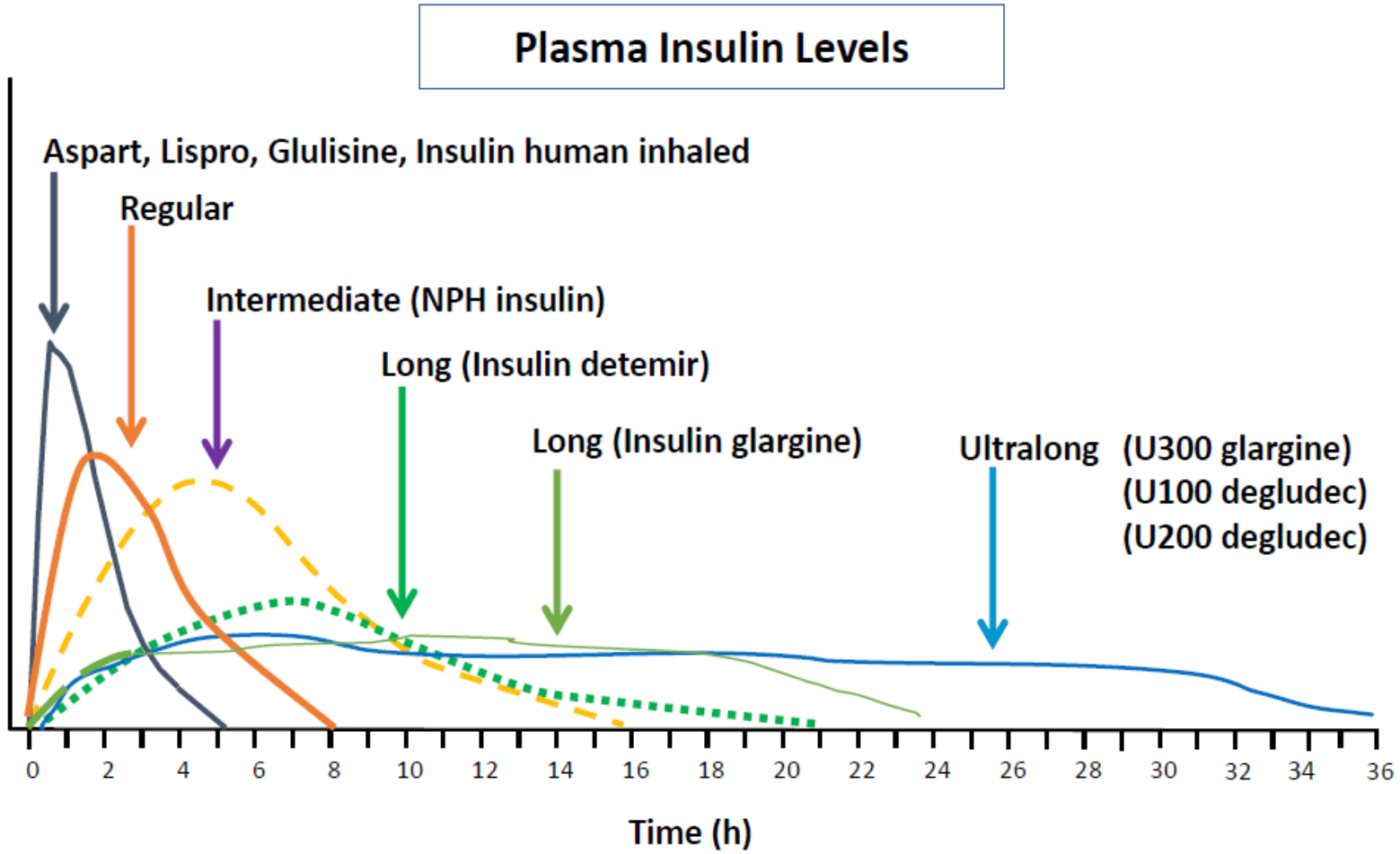
Insulin Profiles



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Hirsch IB. NEJM 2005;352:174-183.
Lexicomp Online, Lexi-Drugs Online, Hudson, Ohio: UpToDate, Inc; 2021; November 2021

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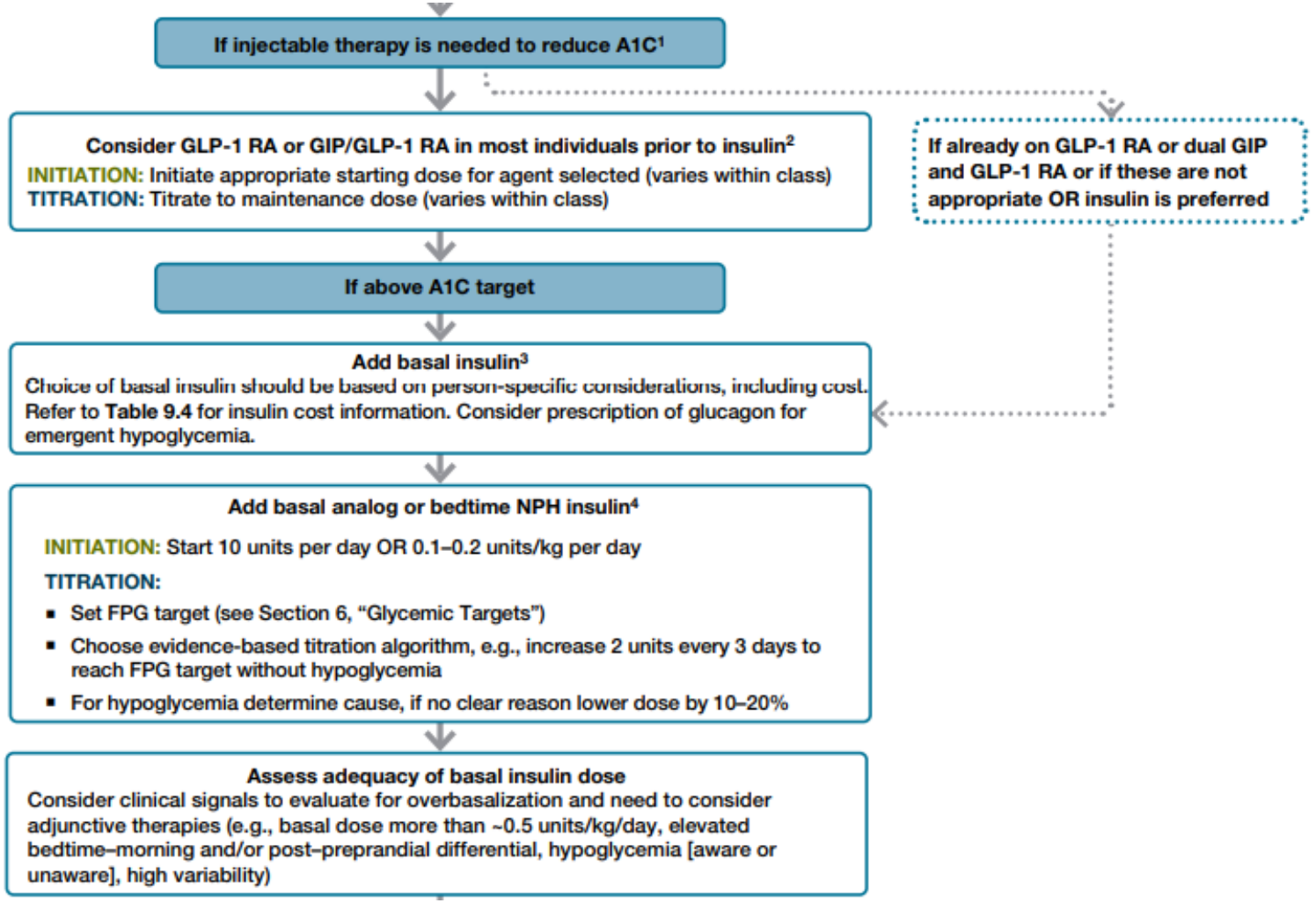
Intensifying to Injectable Therapies (1 of 2)



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Pharmacologic Approaches to Glycemic Treatment: Standards of Care in Diabetes—2023 Diabetes Care 2023;46(Suppl. 1):S140–S157

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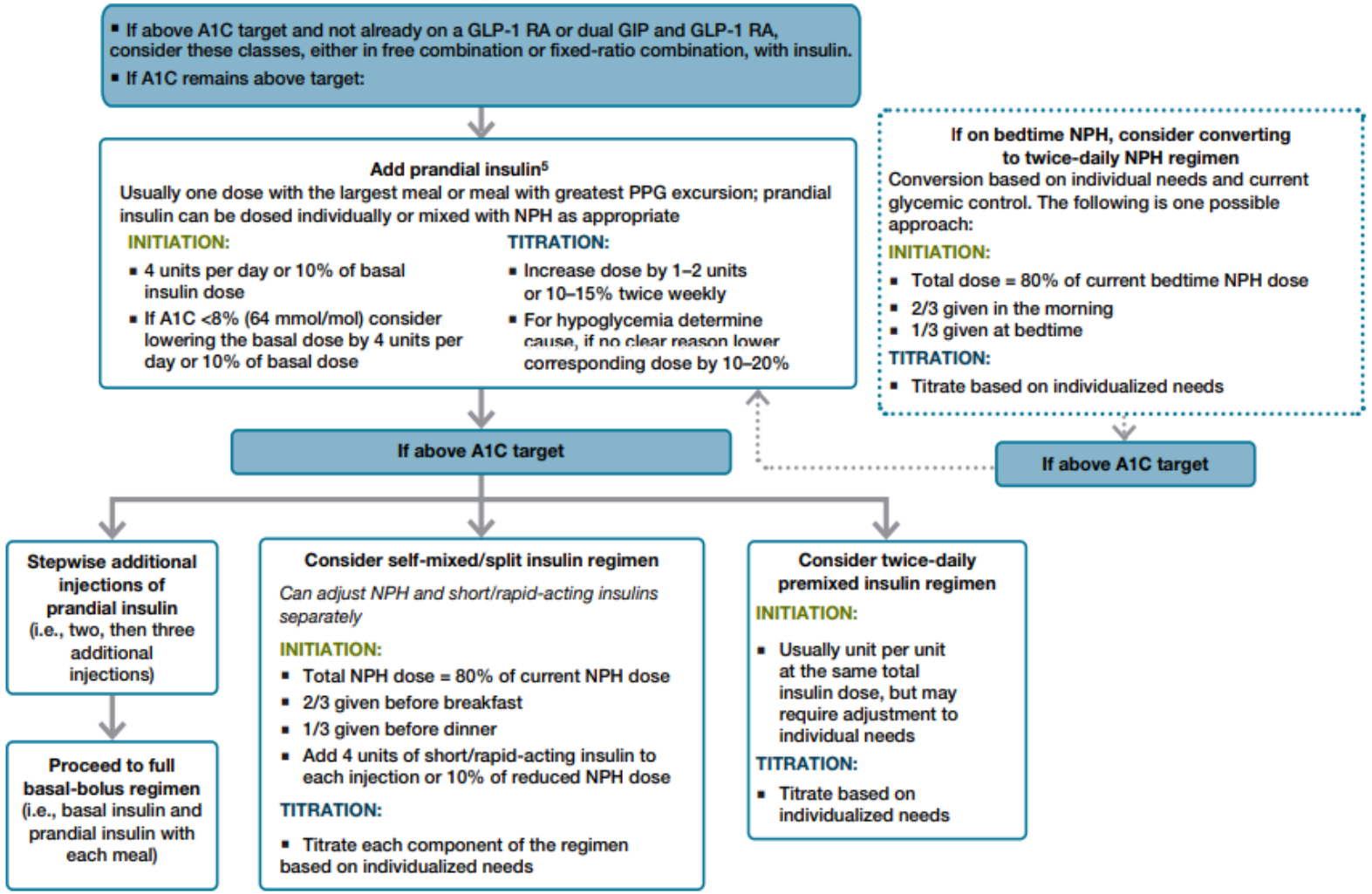
Intensifying to Injectable Therapies (2 of 2)



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Pharmacologic Approaches to Glycemic Treatment: Standards of Care in Diabetes—2023
Diabetes Care 2023;46(Suppl. 1):S140–S157

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Summary of Insulin Options

Action		Insulin Name	Effective Onset	Peak	Duration	Considerations
Bolus	Very Rapid Acting Analogs	Aspart (Fiasp)	16 - 20 min	1 - 3 hrs	5 - 7 hrs	Bolus insulin lowers after-meal glucose. Post meal BG reflects efficacy.
		Lispro-aabc (Lyumjev)	15 - 17 min	2 - 3 hrs	5 - 7 hrs	
	Rapid Acting Analogs	Aspart (Novolog)	20 - 30 min	1 - 3 hrs	3 - 7 hrs	
		Lispro (Humalog*/ Admelog)	30 min	2 - 3 hrs	5 - 7 hrs	Basal insulin controls BG between meals and nighttime. Fasting BG reflects efficacy.
		Glulisine (Apidra)	15 - 30 min	1 - 3 hrs	3 - 4 hrs	
	Short Acting	Regular*	30 - 60 min	2 - 4 hrs	5 - 8 hrs	Side effects: hypoglycemia, weight gain.
Basal	Intermediate	NPH	2 - 4 hrs	4 - 10 hrs	10 - 16 hrs	
	Long Acting	Detemir (Levemir)	3 - 8 hrs	No peak	6 - 24 hrs	Typical dosing range: 0.5-1.0 units/ kg body wt/day.
		Glargine (Lantus*/Basaglar/Semglee/Rezvoglar)	2 - 4 hrs		20 - 24 hrs	
		Degludec (Tresiba)*	~ 1 hr		< 42 hrs	Discard most open vials after 28 days. For pen storage guidelines, see package insert.

Action	Insulin Name	Dose Range	Onset	Peak	Duration	Considerations
Bolus – Rapid-acting	Afrezza Inhaled regular human insulin	4, 8, and 12 unit cartridges before meals	~ 12 min	35 - 45 mins	1.5 - 3 hrs	Assess lung function. Avoid in lung disease — bronchospasm risk. Side effects: hypo, cough, throat irritation.

Beverly Thomassien Insulin Pocket Card. Available at: diabetesed.net

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Concentrated & Inhaled Insulins

Name/Concentration	Insulin/Action	Considerations
Humulin Regular U-500 • 500 units insulin/mL • KwikPen or Vial	Regular Bolus / Basal	Indicated for those taking 200+ units daily. 3 mL pen holds 1,500 units. Max dose 300 units. Once opened, good for 28 days. 20 mL vial holds 10,000 units. Max dose 250 units using U-500 syringe. Once opened, good for 40 days.
Humalog KwikPen U-200 200 units insulin/mL.	Lispro (Humalog) Bolus	3 mL pen holds 600 units. Max dose 60 units. Once opened good for 28 days.
Lyumjev KwikPen U-200 200 units insulin/mL.	Lispro (Lyumjev)	3 mL pen holds 600 units. Max dose 60 units. Once opened good for 28 days.
Toujeo Solostar U-300 Pen 300 units insulin/mL.	Glargine (Lantus) Basal	1.5 mL pen holds 450 units. Max dose 80 units. 3 mL Max Solostar pen holds 900 units. Max dose 160 units. Once opened good for 56 days.
Tresiba FlexTouch U-200 Pen 200 units insulin/mL.	Degludec (Tresiba) Ultra basal	3 mL pen holds 600 units. Max dose 160 units. Once opened good for 56 days.
All concentrated insulin pens and the U-500 syringe automatically deliver correct dose (in less volume). No conversion, calculation or adjustments required. For example, if order reads 30 units, dial the concentrated pen to 30 units or draw up 30 units on the U-500 syringe. **Important – never withdraw concentrated insulin from the pen using a syringe.**		

- Advantages of Tresiba U200 and Toujeo U300 is that the pens go up to 160 units/injection
- Humalog and Lyumjev U200 have less volume per injection and more units in pen (600 vs. 300)

Beverly Thomassien Insulin Pocket Card. Available at: diabetesed.net

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Diabetes Technology

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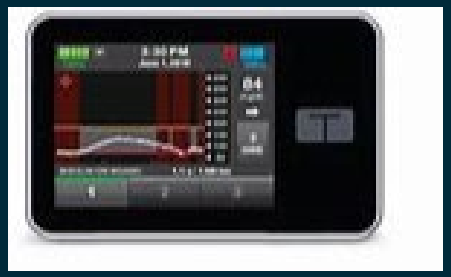
Technology is Here

CONTINUOUS GLUCOSE MONITORS (CGM)



INSULIN PUMPS

CONNECTED PENS AND CAPS

MOBILE APPS

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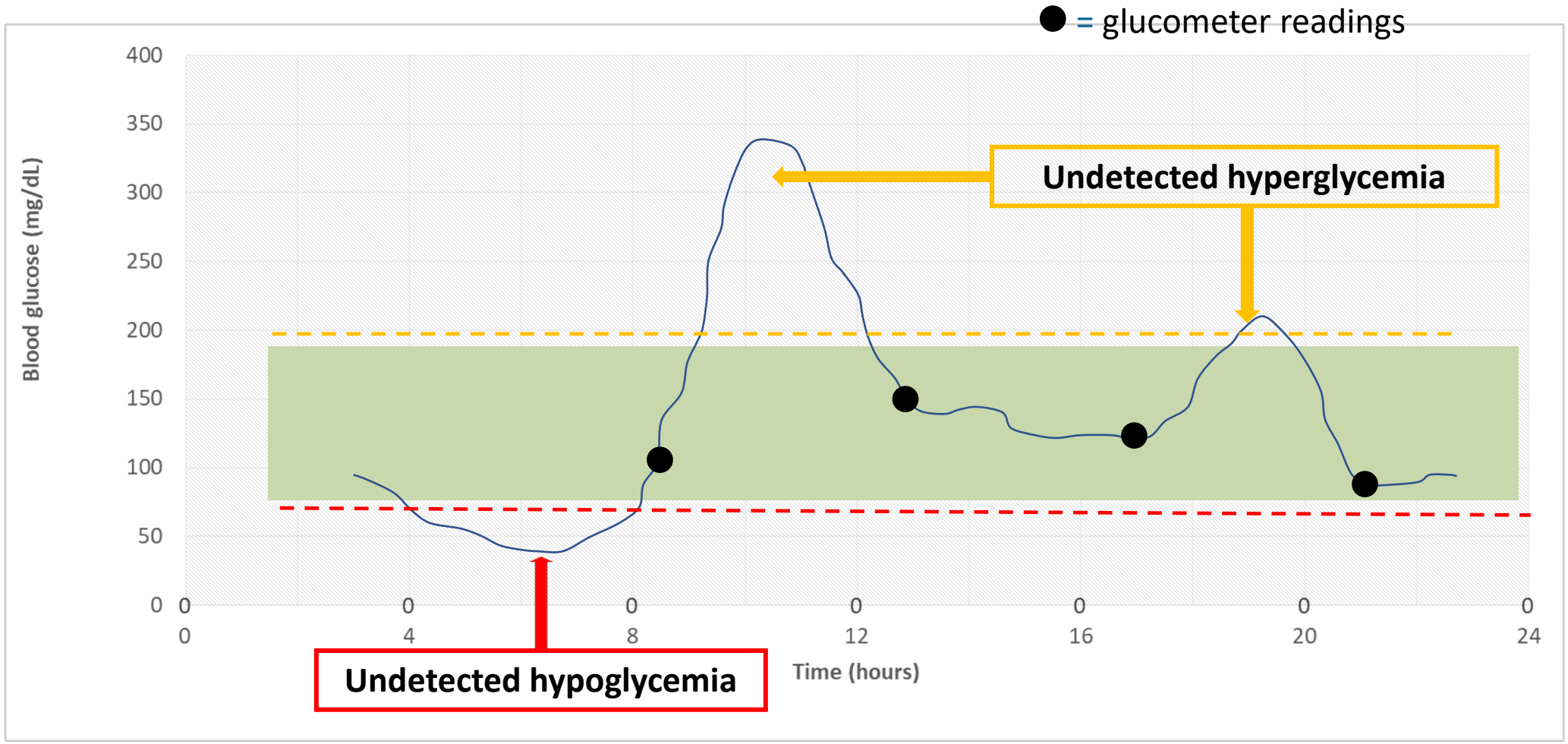
BGM vs CGM



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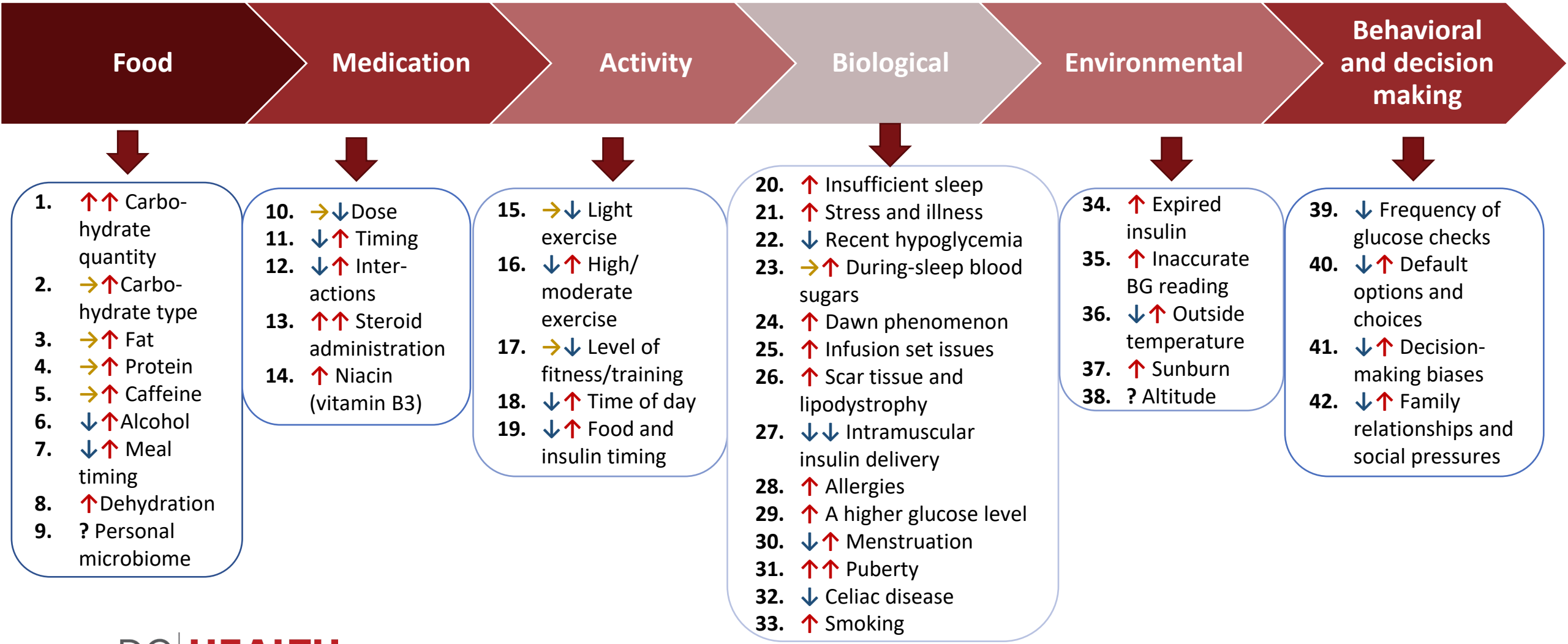
At Least 42 Factors Affect Glucose!



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Adapted from Brown A. DiaTribe Learn: Making sense of diabetes... diatribe.org/42factors

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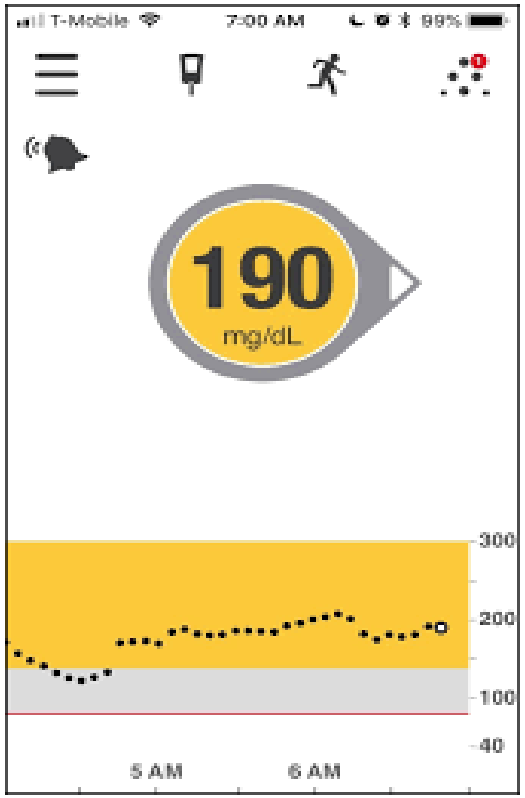
CGM: Real Time Data



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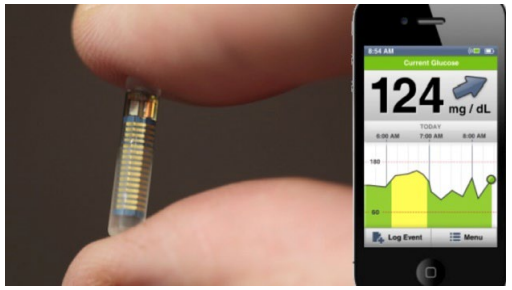
Personal CGM Options

- Owned by the person with diabetes
- Typically used long term
- Device options include real-time glucose monitoring (rtCGM) or intermittent scanning (isCGM)
- Some options can be integrated with insulin pumps or connected insulin pens

Libre 2

Libre 3



Eversense

Guardian

G6

G7

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Personal CGM Comparison

	G6	G7	Libre 2	Libre 3	Guardian	Eversense
Integration	T:Slim X2, Omnipod 5, InPen	No	Bigfoot Unity	No	770G, InPen	No
Display device	Smartphone or receiver		Smartphone or reader	Smartphone or reader	Smartphone or insulin pump	Smartphone only
Maximum wear time	10 days	10.5 days	14 days	14 days	7 days	180 days
Warm-up time	2 hours	30 min	1 hour	1 hour	Up to 2 hours	24 hours
Calibrations required	0	0	0	0	At least 2/day	2/day for 21 days, then 1/day

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Product user guides: Dexcom G6, Dexcom G7, Libre 2, Libre 3, Medtronic Guardian Connect, Guardian 3, Eversense

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Personal CGM Comparison (Continued)

	G6	G7	Libre 2	Libre 3	Guardian	Eversense
FDA approved sites	Abdomen (ages 2+) Upper buttocks (ages 2-17)	Upper arm (ages 7+) Upper buttocks (ages 2-6)	Upper arm	Upper arm	Upper arm, abdomen Upper buttocks (ages 7-13)	Upper arm
FDA approved for dosing	Yes	Yes	Yes	Yes	No	Yes
FDA approved ages (years)	≥2	≥2	≥4	≥4	≥2 Guardian 3 ≥14 Guardian Connect	≥18
Drug Interactions	Hydroxyurea	Hydroxyurea	Vitamin C	Vitamin C	Acetaminophen, Hydroxyurea	Tetracycline antibiotics, mannitol
MARD	9%	8.2%	9.2%	7.9%	9.64%	8.5%
Alarms	High, Low, Predictive Low		High, Low	High, Low	High, Low, Predictive	High, Low, Predictive

Product user guides: Dexcom G6, Dexcom G7, Libre 2, Libre 3, Medtronic Guardian Connect, Guardian 3, Eversense

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Clinical Pearl: When to Check BGM?

- A calibration or blood glucose symbol appears on the device
- Symptoms or expectations do not match CGM readings
- CGM readings are suspected to be inaccurate or used for an off- label indication like in dialysis
- Determining an insulin dose if the device is only approved as adjunctive therapy (ex. Guardian sensors)
- If taking an interfering substance (ex. vitamin C, acetaminophen hydroxyurea)
- Counsel patients about “lag time”

Per ADA, every person using CGM should have access to a meter and test strips

ADCES Practice Paper. The Diabetes Care and Education Specialist’s Role in Continuous Glucose Monitoring. Updated March 2021

ADA Standards of Care 2023.

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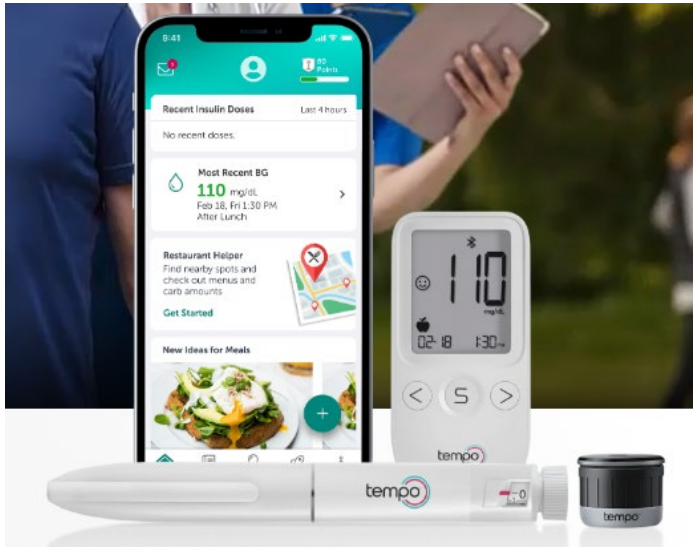
Connected Pens

InPen with Guardian or G6/G7

Bigfoot Unity with Libre 2



Tempo with G6/G7

Mallaya

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Insulin Pump Options

Omnipod DASH
(Insulet)
Omnipod 5 with G6
CGM (Insulet/Dexcom)

t:slim X2 with G6 CGM
(Tandem/Dexcom)
Basal IQ
Control IQ

770G with Guardian 3
(Medtronic)

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Using CGM Data for Remote Monitoring and Population Health

Last Available Data	Average Glucose (mg/dL)	Average Scans/Views per Day	% In Target	LibreView User Status	% Below Target	Coefficient of Variation	% Time Sensor is Active
Today	167	2	58	Connected	4	39.9	49
Today	206	2	41	Connected	1	37.8	43
Today	168	3	63	Connected	1	23.7	47
Today	166	3	56	Connected	3	29.5	76
Today	137	6	88	Connected	0	27.7	87
Today	158	5	68	Connected	1	35.1	72
Today	148	8	89	Connected	0	20.1	87
Today	179	4	43	Connected	14	55.7	83
Today	108	3	94	Connected	3	27.7	74
Today	173	9	55	Connected	1	30.5	94
Today	218	8	33	Connected	1	36.3	90
Today	185	6	46	Connected	1	26.2	84
Today	174	3	60	Connected	0	29.4	65
Today	165	3	75	Connected	0	24.0	66

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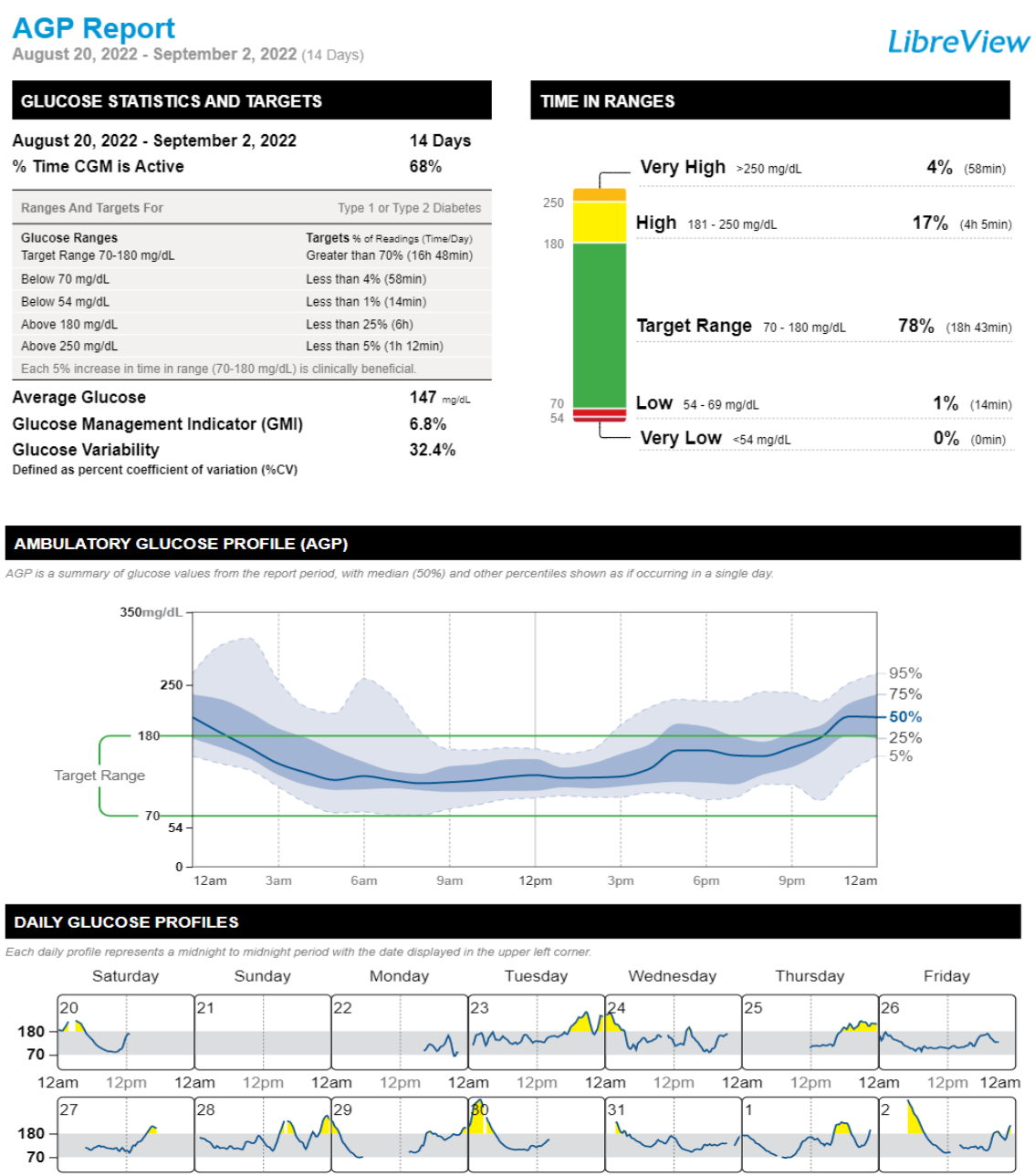
Case Study: Meet Larry

- 73yoM, T2D, CAD s/p stents, CKD, 288lbs, BMI=56
- A1C=7.5%, SCr=1.38, eGFR=40
- Tried SGLT2i, experienced UTIs
- Glargine 18 units daily
- Lispro 5 units TID



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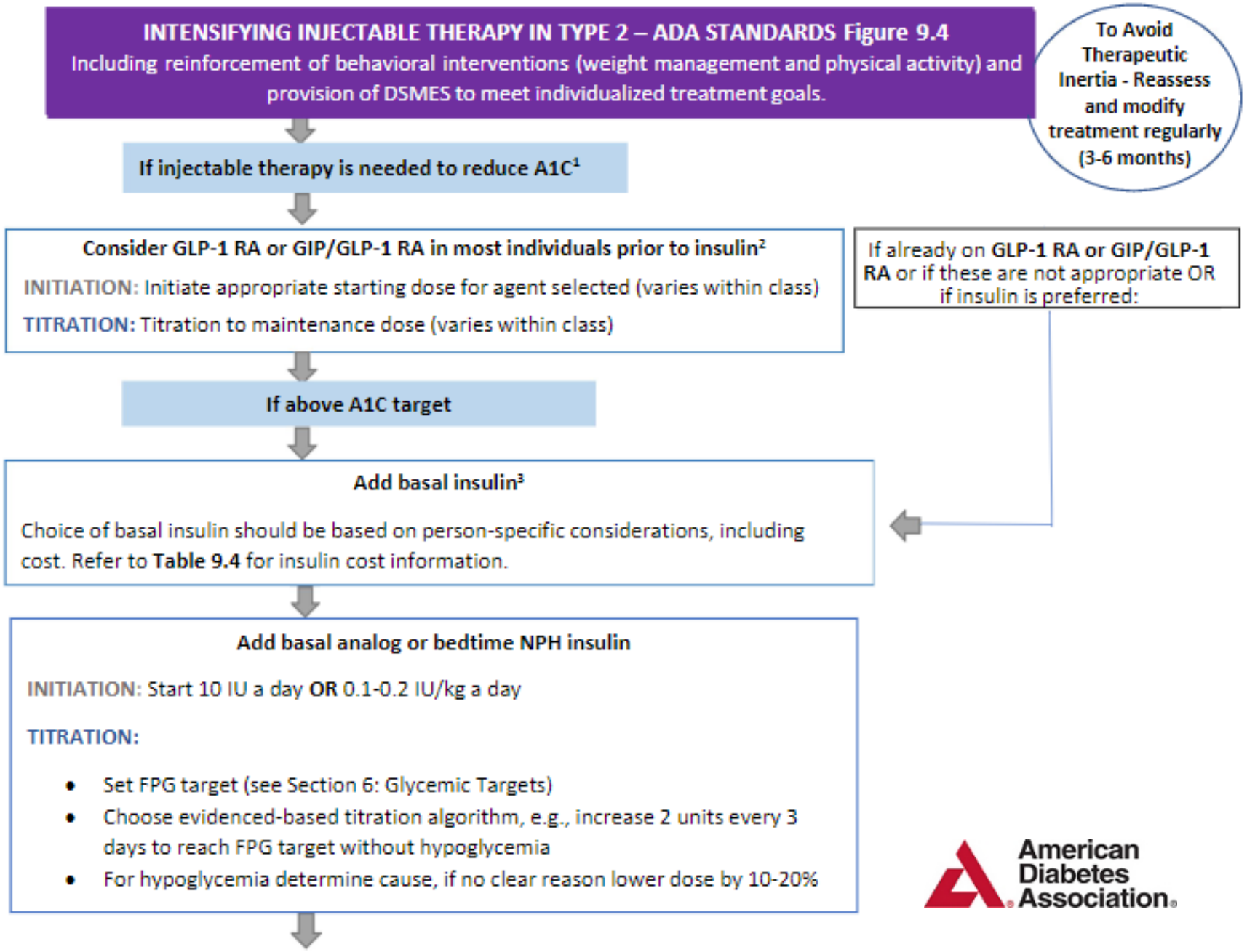

American Diabetes Association.

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Diabetes Care December 2022, Vol.46, S140-S157. doi:https://doi.org/10.2337/dc23-S009

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4 Months Later

- Semaglutide 2mg weekly
- Off insulin
- Lost 15lbs

GLUCOSE STATISTICS AND TARGETS

November 12, 2022 - November 25, 2022	14 Days
% Time CGM is Active	78%

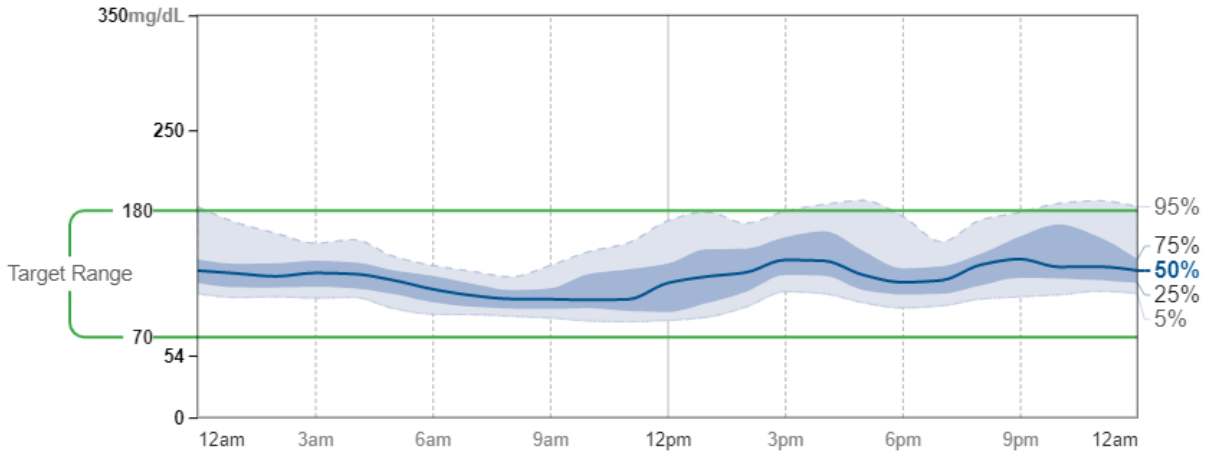
Ranges And Targets For	Type 1 or Type 2 Diabetes
Glucose Ranges	**Targets** % of Readings (Time/Day)
Target Range 70-180 mg/dL	Greater than 70% (16h 48min)
Below 70 mg/dL	Less than 4% (58min)
Below 54 mg/dL	Less than 1% (14min)
Above 180 mg/dL	Less than 25% (6h)
Above 250 mg/dL	Less than 5% (1h 12min)
Each 5% increase in time in range (70-180 mg/dL) is clinically beneficial.	

Average Glucose	**123** mg/dL
Glucose Management Indicator (GMI)	**6.3%**
Glucose Variability	**20.5%**
Defined as percent coefficient of variation (%CV)	

TIME IN RANGES

AMBULATORY GLUCOSE PROFILE (AGP)

AGP is a summary of glucose values from the report period, with median (50%) and other percentiles shown as if occurring in a single day.



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Summary

- Many drugs used for diabetes with different pharmacologic and side effect profiles
- Choose therapies for diabetes based on cardiovascular and renal benefits, efficacy and weight loss
- Education can help prevent or reduce medication side effects
- When adding non-insulin agents to insulin therapy, be cautious about hypoglycemia and proactive reduce insulin doses

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Knowledge Checks

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When adding a GLP-1 agonist like semaglutide 0.25 mg weekly to a basal/bolus regimen in someone like Larry who is meeting glycemic targets, how much should the insulin initially be reduced?

A. Continue current dosing until GLP-1 RA is titrated up
B. Reduce total daily insulin by 10-20%
C. Reduce total daily insulin by 20-30%
D. Reduce total daily insulin by 40-50%

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What is the goal time in range 70-180 mg/dL for most people with diabetes?

A. >50%

B. >70%

C. >80%

D. >90%

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Which drug would be most preferred in a person with type 2 diabetes and heart failure?

A. Saxagliptin
B. Empagliflozin
C. Dulaglutide
D. Glipizide

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Which of the following is an important educational component of SGLT2 inhibitors?

A. Ask about recent eye exam
B. Advise that they may cause nausea and vomiting
C. Advise to stop 3-4 days before surgery
D. Advise that may increase blood pressure

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What is one of the mechanisms of how semaglutide works?

A. Increases glucagon secretion
B. Increases insulin secretion
C. Increases gastric emptying
D. Inhibits absorption of carbohydrates

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