

# The Oasis in the Desert: *Miracle Medications*

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# Case Study: Fred, 61 Years Old With T2D, Obesity, Dyslipidemia, Hypertension, and History of MI



- Physical Examination
  - No apparent distress
  - Height: 5 ft 10 in
  - Weight: 246 lb (BMI: 35.3 kg/m<sup>2</sup>)
  - Blood pressure: 130/88 mm Hg. Pulse 72bpm
  - No edema noted
- Laboratory Findings
  - Fasting blood glucose: 133 mg/dL; A1C: 8.6%; UACR 25 mg/g; eGFR: 70 mL/min/1.73 m<sup>2</sup>
  - All other labs normal
- PMH
  - MI 4 years ago
- Medications
  - Atorvastatin 80 mg daily
  - Lisinopril 40 mg daily
  - Metoprolol tartrate 25 mg twice daily
  - Metformin 1000 mg twice daily
  - Aspirin 81 mg daily
- Allergies/Adverse Drug Events: GI issues when first starting Metformin
- Family Hx: Mother: dyslipidemia, MI age 68. Father HTN, Obesity
- Social
  - Lives alone, retired
  - Has BC/BS insurance

# What are next steps for Fred?



- Change Metformin to XR?
  - Add a GLP1? GLP/GIP?
  - Add an SGLT2?
  - Add an Sulfonylurea?
  - Other?
- 
- Refer to Diabetes Self Management Education and Support?
  - Continuous Glucose Monitoring (CGM)?

# GLUCOSE-CENTRIC ALGORITHM FOR GLYCEMIC CONTROL

## LIFESTYLE INTERVENTION

Start or continue metformin if appropriate<sup>1</sup>

## INDIVIDUALIZE GLYCEMIC TARGET

A1C ≤6.5% for most persons or 7%-8% if high risk for adverse consequences from hypoglycemia and/or limited life expectancy

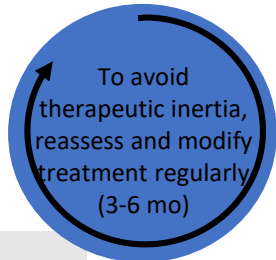
	Overweight or Obesity <sup>2</sup>	Hypoglycemia Risk <sup>3</sup>	Access / Cost	Severe Hyperglycemia <sup>4</sup>	Patients may present with >1 scenario
Preferred	GLP-1 RA or GIP/GLP-1 RA or SGLT2i	GLP-1 RA or GIP/GLP-1 RA or SGLT2i	TZD or SU/GLN	Basal Insulin <sup>5</sup> + Prandial Insulin or + GLP-1 RA   GIP/GLP-1 RA <sup>6</sup>	Order of medications suggests hierarchy for selection <sup>7</sup>
Alternatives	DPP-4i <sup>8</sup> or TZD <sup>9</sup>	DPP-4i <sup>8</sup> or TZD	Insulin or DPP-4i <sup>10</sup>	Basal Insulin + other agent(s)	A1C >7.5% start 2 agents, A1C >9.0% or >1.5% above goal start 2-3 agents
Concerns or Not Preferred	Avoid SU/GLN	Avoid SU/GLN	GLP-1 RA   GIP/GLP-1 RA   SGLT2i   COLSVL   BRC-QR	Other agents likely ineffective in the setting of glucotoxicity <sup>5</sup>	

Titrate to maximum tolerated dose. If not at glycemic target at ≤3 months, add best available agent not in use<sup>7</sup>  
GLP-1 RA | GIP/GLP-1 RA | SGLT2i | TZD | DPP-4i | SU/GLN | COLSVL | BRC-QR | PRAML<sup>11</sup>

IF NOT AT GOAL: CONTINUE TO ALGORITHM FOR ADDING/INTENSIFYING INSULIN

<sup>1</sup>Take with food with dose titration for enhanced tolerance. <sup>2</sup>See also COMPLICATIONS-CENTRIC MODEL FOR THE CARE OF PERSONS WITH OVERWEIGHT/OBESITY and PROFILES OF WEIGHT-LOSS MEDICATIONS table. <sup>3</sup>Evaluate for issues leading to hypoglycemia or hypoglycemia unawareness and manage with patient-centered strategies. <sup>4</sup>If A1C >10% and/or BG ≥300 with symptomatic hyperglycemia, reduce glucose/A1C as promptly and safely as possible. <sup>5</sup>See also ALGORITHM FOR ADDING/INTENSIFYING INSULIN. <sup>6</sup>GLP-1 RA requires titration phase which can delay glycemic control. After glucose toxicity is resolved, consider adding other agents. <sup>7</sup>See also PROFILES OF ANTIHYPERGLYCEMIC MEDICATIONS table. <sup>8</sup>GLP-1 RA and DPP-4i should not be combined. <sup>9</sup>TZD can cause fluid retention but have benefit for NAFLD, CVD prevention, dyslipidemia. <sup>10</sup>Access/Cost are dependent on location of the market. Insulin costs vary widely with devices (e.g., pens versus vials) and formulations (e.g., analogues versus combinations such as 70/30). <sup>11</sup>PRAML is used as an adjunct with prandial insulin.

# Use of Glucose-Lowering Medications in Management of Type 2 Diabetes



HEALTHY LIFESTYLE BEHAVIORS, DIABETES SELF-MANAGEMENT EDUCATION AND SUPPORT, SOCIAL DETERMINANTS OF HEALTH

## Goal: Cardiorenal Risk Reduction in High-Risk Patients With Type 2 Diabetes (in addition to comprehensive CV risk management)

<b>+ ASCVD</b> Defined differently across CVOTs but all included individuals with established CVD (eg, MI, stroke, any revascularization procedure). Variably included conditions such as transient ischemic attack, unstable angina, amputation, symptomatic or asymptomatic coronary artery disease	<b>+ Indicators of High Risk</b> Definitions vary, but most comprise ≥55 yr of age with 2 or more additional risk factors (including obesity, hypertension, smoking, dyslipidemia, or albuminuria)	<b>+ HF</b> Current or prior symptoms of HF with documented HFrEF or HFpEF	<b>+ CKD</b> eGFR <60 mL/min/1.73 m <sup>2</sup> OR albuminuria (ACR ≥3.0 mg/mmol [30 mg/g]) These measurements may vary over time; thus, a repeat measure is required to document CKD
<b>+ ASCVD/Indicators of High Risk</b> GLP-1 RA with proven CVD benefit <b>Either/ or</b> SGLT2i with proven CVD benefit (IF ABOVE GOALS TARGET) For patients receiving GLP-1 RA, consider adding SGLT2i with proven CVD benefit and vice versa TZD		<b>+ HF</b> SGLT2i with proven HF benefit in this population	<b>+ CKD (receiving maximally tolerated dose of ACEi/ARB)</b> <b>PREFERABLY</b> SGLT2i with primary evidence of reducing CKD progression Use SGLT2i in people with eGFR ≥20 mL/min/1.73 m <sup>2</sup> ; once initiated, should be continued until initiation of dialysis or transplantation <b>OR</b> GLP-1 RA with proven CVD benefit if SGLT2i not tolerated or contraindicated receiving SGLT2i, consider incorporating GLP-1 RA or vice versa

Additional Cardiorenal Risk Reduction or Glycemic Lowering Needed

## Goal: Achievement and Maintenance of Glycemic and Weight Management Goals

<b>Glycemic Management:</b> <b>Choose approaches that provide the efficacy to achieve goals</b> Metformin OR agent(s) including COMBINATION therapy that provide adequate EFFICACY to achieve and maintain treatment goals Consider avoidance of hypoglycemia a priority in high-risk individuals	<b>Achievement and Maintenance of Weight Management Goals</b> Set individualized weight management goals <table border="1" style="width: 100%;"> <tr> <td style="background-color: #e6f2ff;">General lifestyle advice: medical nutrition therapy/eating patterns/physical activity</td> <td style="background-color: #e6f2ff;">Intensive evidence-based structured weight management program</td> </tr> <tr> <td style="background-color: #e6f2ff;">Consider medication for weight loss</td> <td style="background-color: #e6f2ff;">Consider metabolic surgery</td> </tr> </table> When Choosing Glucose-Lowering Therapies: Consider regimen with high to very high dual glucose and weight efficacy	General lifestyle advice: medical nutrition therapy/eating patterns/physical activity	Intensive evidence-based structured weight management program	Consider medication for weight loss	Consider metabolic surgery
General lifestyle advice: medical nutrition therapy/eating patterns/physical activity	Intensive evidence-based structured weight management program				
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have greater likelihood of achieving glycemic goals <b>Efficacy for Glucose Lowering</b> VERY HIGH: Dulaglutide (high dose), semaglutide, tirzepatide Insulin Combination oral, combination injectable (GLP-1 RA/insulin) HIGH: GLP-1 RA (not listed above), metformin, SGLT2i, sulfonylurea, TZD INTERMEDIATE: DPP-4i	<b>Efficacy for Weight Loss</b> VERY HIGH: Semaglutide, tirzepatide HIGH: Dulaglutide, liraglutide INTERMEDIATE: GLP-1 RA (not listed above), SGLT2i NEUTRAL: DPP-4i, metformin				

If A1C Above Target

- Identify Barriers to Goals:
- Consider DSMES referral to support self-efficacy in achievement of goals
  - Consider technology (eg, diagnostic CGM) to identify therapeutic gaps and tailor therapy
  - Identify and address SDOH that affect achievement of goals

# Use of Glucose-Lowering Medications in Management of Type 2 Diabetes

To avoid therapeutic inertia, reassess and modify treatment regularly (3-6 mo)

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**+ HF**

Current or prior symptoms of HF with documented HFrEF or HFpEF

**+ CKD**

eGFR <60 mL/min/1.73 m<sup>2</sup> OR albuminuria (ACR ≥3.0 mg/mmol [30 mg/g])  
These measurements may vary over time; thus, a repeat measure is required to document CKD

**+ HF**

SGLT2i with proven HF benefit in this population

**+ CKD (receiving maximally tolerated dose of ACEi/ARB)**

**PREFERABLY**  
SGLT2i with primary evidence of reducing CKD progression  
Use SGLT2i in people with eGFR ≥20 mL/min/1.73 m<sup>2</sup>; once initiated, should be continued until initiation of dialysis or transplantation  
**OR**  
GLP-1 RA with proven CVD benefit if SGLT2i not tolerated or contraindicated

**If A1C above target, for patients receiving SGLT2i, consider incorporating GLP-1 RA or vice versa**

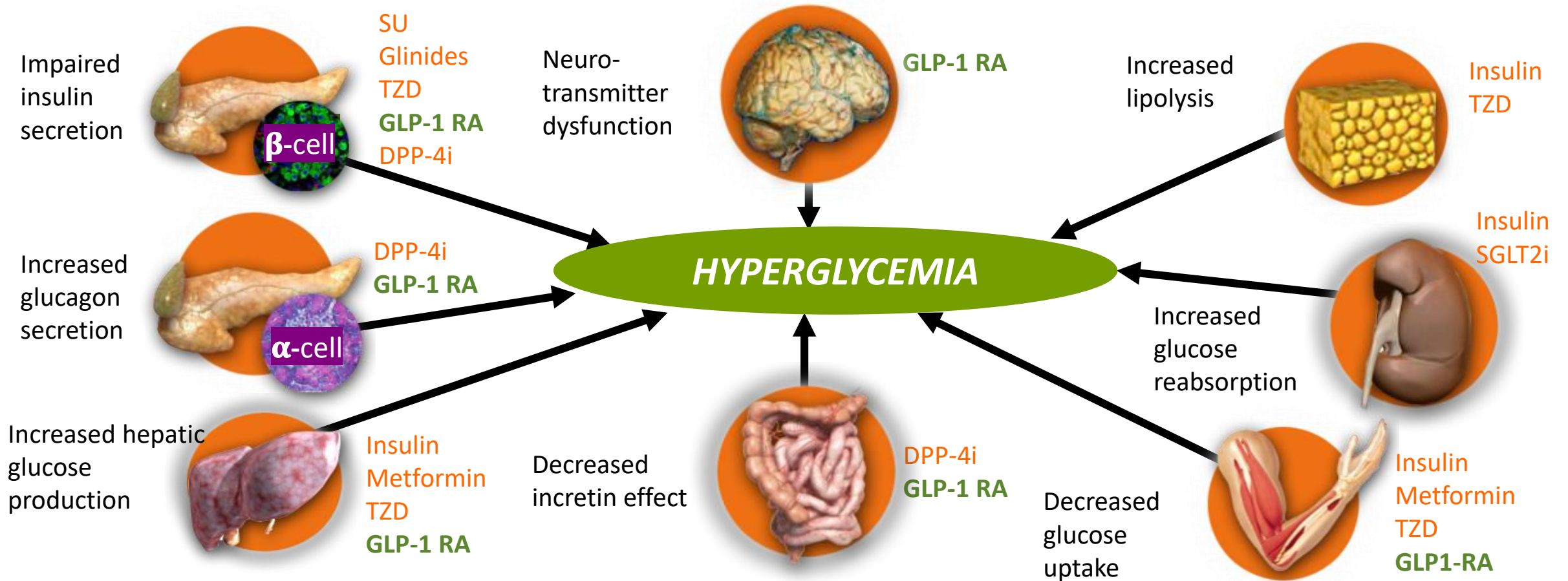
**+ ASCVD/Indicators of High Risk**

GLP-1 RA with proven CVD benefit **Either/or** SGLT2i with proven CVD benefit

- For patients receiving GLP-1 RA, consider adding SGLT2i with proven CVD benefit and vice versa
- TZD

If Additional **Cardiorenal Risk Reduction or Glycemic Lowering Needed**

# The “Ominous Octet”: Multiple, Complex Pathophysiologic Abnormalities in T2D

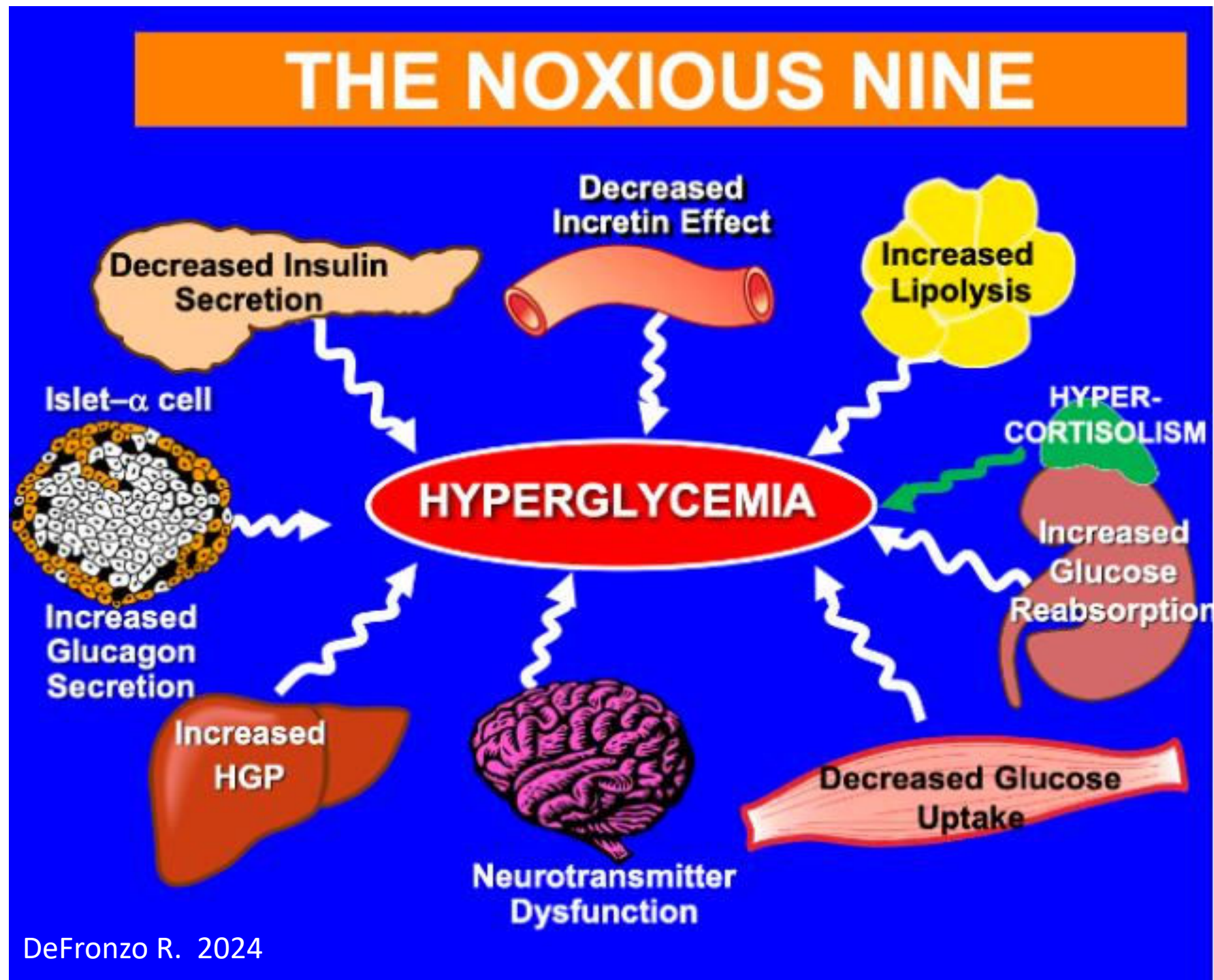


CATALYST trial ADA 2024

-Hypercortisolism in 24% of T2D pts on 2 orals  
-33% of participants had an adrenal adenoma.

Screening: with an overnight 1 mg dexamethasone suppression test. Specifically, individuals with cortisol >1.8 µg/dL and dexamethasone levels >140 ng/dL in the morning following administration would be diagnosed with hypercortisolism.

Cortisol raises glucose



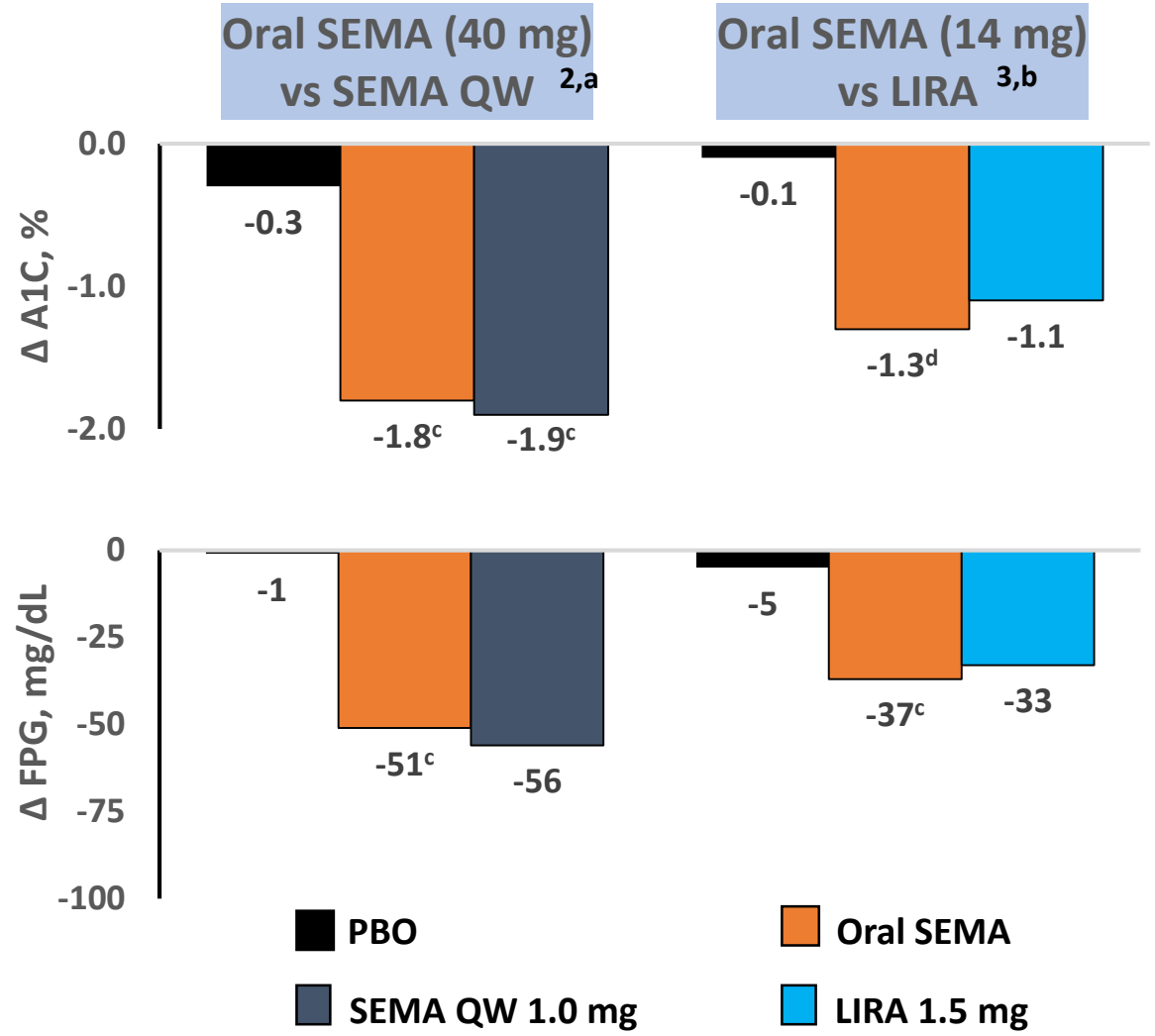
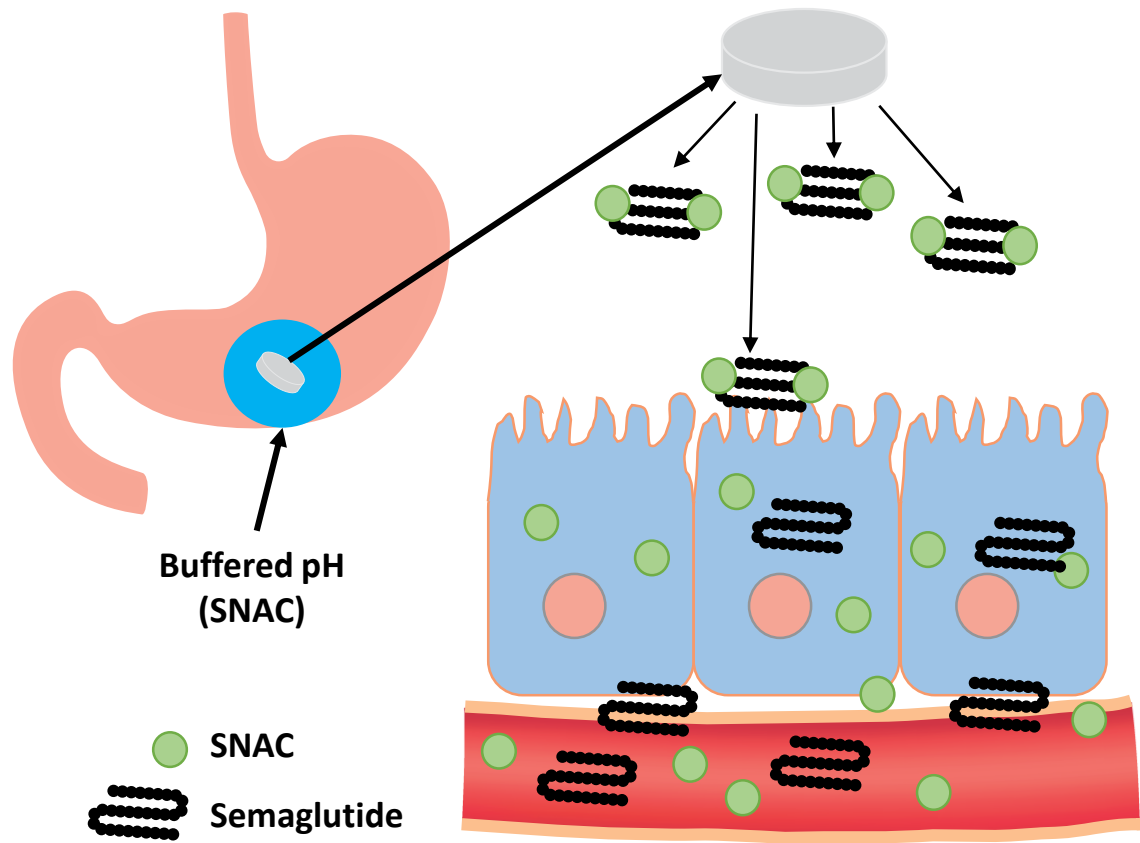


# GLP-1 RA Dosage Guidelines and Benefits in T2D

GLP-1 RA	Dosing			Titration Frequency	Cardiovascular Benefit	Kidney Benefit
	Frequency	Starting Dose	Max Dose			
Exenatide BID	Twice daily	5 mcg	10 mcg	1 month		
Lixisenatide	Once daily	10 mcg	20 mcg	14 days		
Liraglutide	Once daily	0.6 mg	1.8 mg	1 week	Yes	Yes
Semaglutide PO	Once daily	3 mg	14 mg	30 days		
Dulaglutide	Once weekly	0.75 mg	4.5 mg	≥4 weeks	Yes	Yes
Semaglutide SC	Once weekly	0.25 mg	2 mg	4 weeks	Yes	Yes
Exenatide ER	Once weekly	2 mg	2 mg	NA		

# How Does Oral Semaglutide Compare With Other GLP-1 RAs?

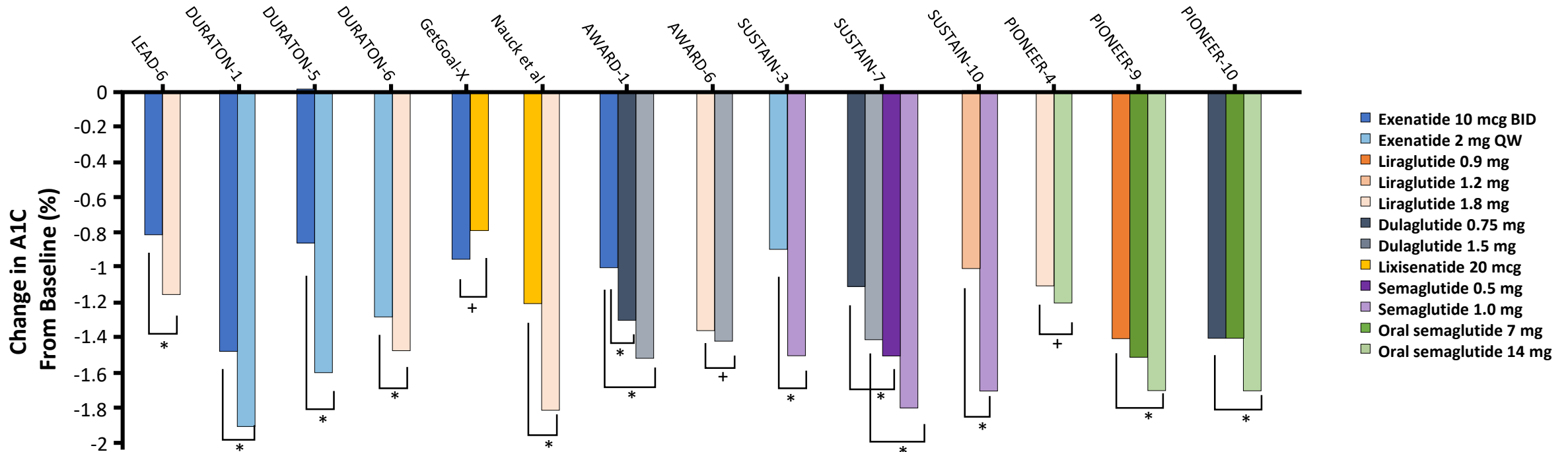
## SEMA Formulation With SNAC: Protection and Absorption<sup>1</sup>



<sup>a</sup> Randomized trial; 26 weeks; N = 632; BL A1C 7.9%.  
<sup>b</sup> Randomized trial; 52 weeks (26-week data, trial product estimand presented); N = 711; BL A1C 8.0%.  
<sup>c</sup> P < .05 vs PBO.  
<sup>d</sup> P < .05 vs PBO and LIRA.

1. Bucheit JD, et al. *Diabetes Technol Ther.* 2019 Oct 1. [Epub ahead of print];  
 2. Davies M, et al. *JAMA.* 2017;318:1460-1470; 3. Pratley R, et al. *Lancet.* 2019;394:39-50.

# GLP-1 RA Comparative Studies: Change in A1C

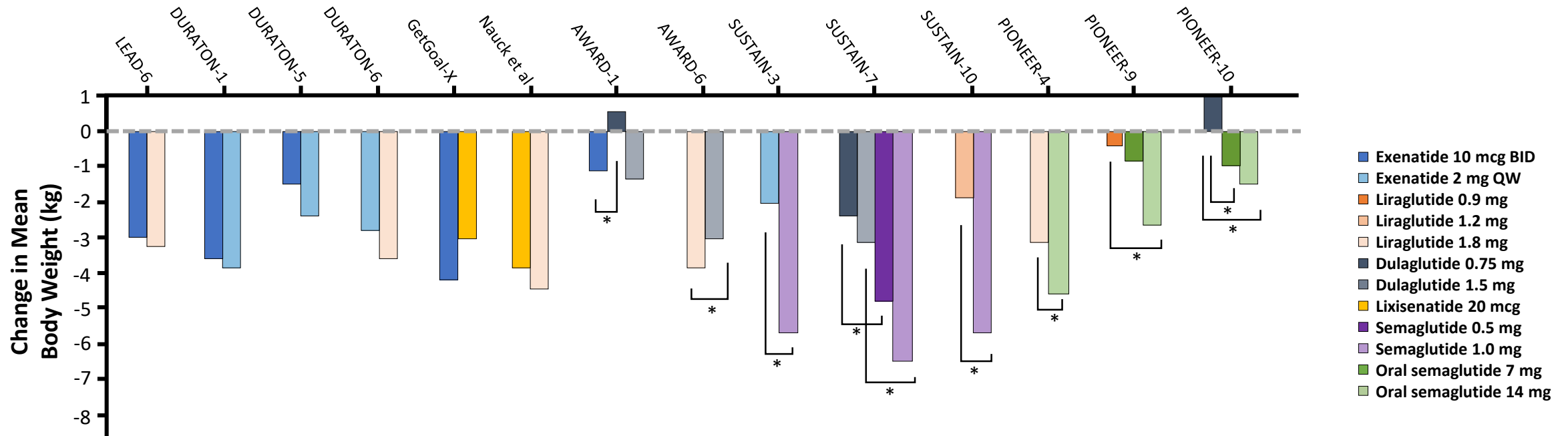


\* $P < 0.05$ . † $P < 0.05$ , meeting predefined noninferiority margin.

Figure adapted from Trujillo. Ther Adv Endocrinol Metab. 2021;12:2042018821997320. Note that direct comparisons between clinical trials cannot be made.

Ahmann. Diabetes Care. 2018;41:258. Blevins. J Clin Endocrinol Metab. 2011;96:1301. Buse. Lancet. 2009;374:39. Buse. Lancet. 2013;381:117. Capehorn. Diabetes Metab. 2020;46:100-109. Drucker. Lancet. 2008;372:1240. Dungan. Lancet. 2014;384:1349. Nauck. Diabetes Care. 2016;39:1501. Pratley. Lancet. 2019;394:39-50. Pratley. Lancet Diabetes Endocrinol. 2018;6:275. Rosenstock. Diabetes Care. 2013;36:2945. Wysham. Diabetes Care. 2014;37:2159. Yabe. Lancet Diabetes Endocrinol. 2020;8:392-406. Yamada. Lancet Diabetes Endocrinol. 2020;8:377-391.

# Trials of GLP-1 RAs: Changes in Body Weight



\* $P < 0.05$ .

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# Drug shortages allow FDA to authorize “Compounding”

## FDA alert on “Faux-zempic”

. [FDA warns HCPs and patients of dosing errors with compounded injectable semaglutide](#) - Last Friday, the FDA [issued](#) an alert to HCPs, compounders, and patients about recent reports of dosing errors and **overdoses** with compounded injectable semaglutide. The majority of these reports were **largely due to incorrect dose measurements by patients and miscalculations by HCPs, leading to the administration of five to 20 times more than the intended dose of semaglutide.** Resulting adverse events included severe nausea, vomiting, hypoglycemia, and hospitalization.

To prevent challenges with dosing errors and overdoses, the **FDA encourages** patients to talk to HCPs about **how to measure and administer correct doses and clarify any confusion with units.** The FDA also recommends raising awareness on dosing, especially as most reports indicated that patients were unfamiliar with measuring the intended dose with a syringe.

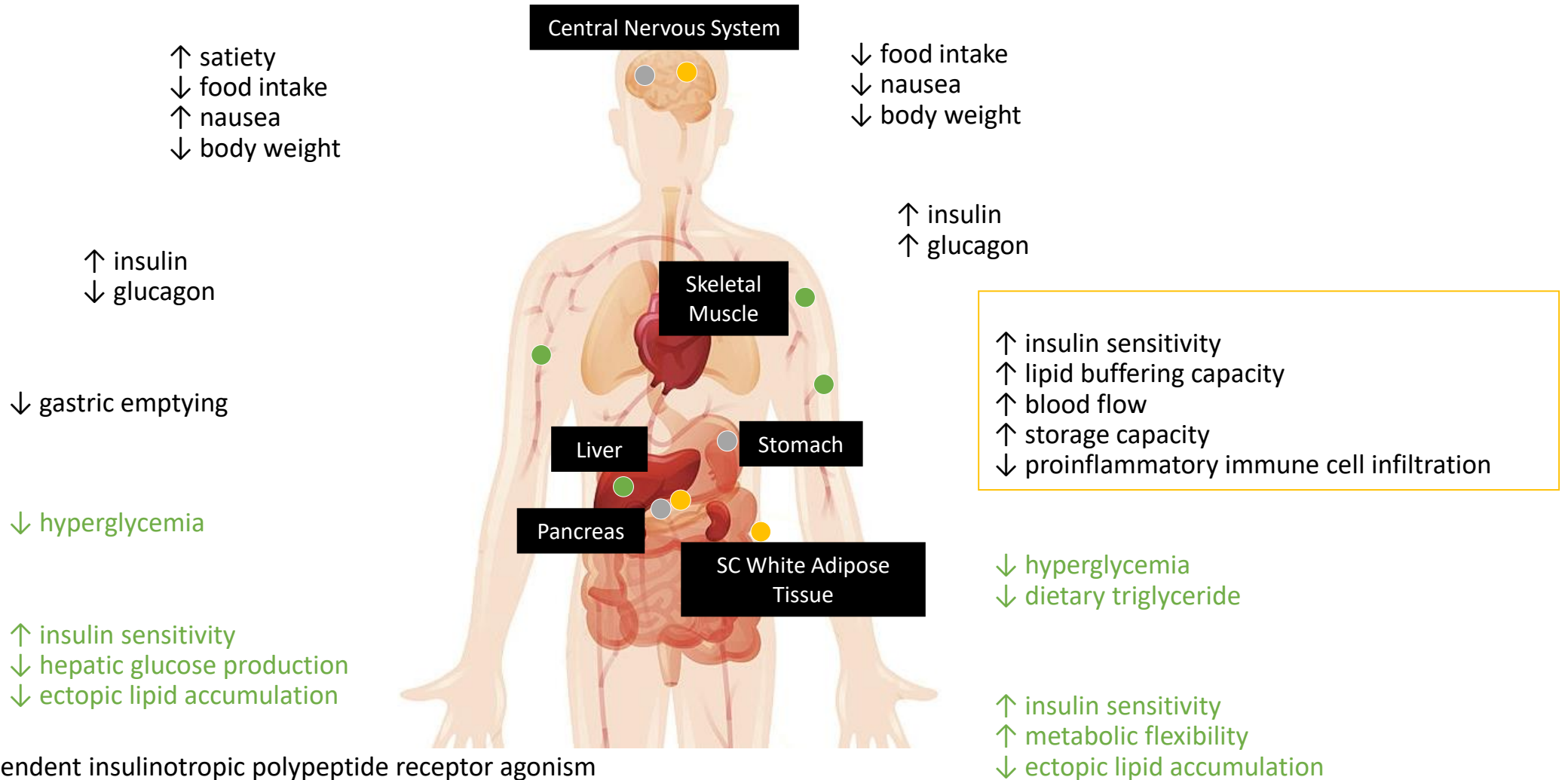
FDA’s warning comes amid challenges with global shortages of GLP-1 RAs, including Novo Nordisk’s Wegovy (semaglutide 2.4 mg) and Ozempic (semaglutide 1.0 mg). While the FDA [acknowledges](#) use of compounded versions may occur when a drug is in shortage, it continues to acknowledge concerns with reports of adverse events.

# GLP-1 RA Cardiovascular Outcomes Trials

Agent	Lixisenatide SC, Daily	Liraglutide SC, Daily	Semaglutide SC, Weekly	Exenatide ER SC, Weekly	Albiglutide SC, Weekly	Dulaglutide SC, Weekly	Semaglutide PO, Daily
Study	ELIXA	LEADER	SUSTAIN-6	EXSCEL	HARMONY	REWIND	PIONEER-6
N	6068	9340	3297	14,752	9463	9901	3183
Trial duration	25 mo	3.8 yr	2.1 yr	3.2 yr	1.5 yr	>5 yr	16 mo
Mean diabetes duration, yr	9.3	12.8	13.9	12	14	10.5	14.9
Mean age, yr	60	64	65	62	64	66	66
Female, %	30	36	39	38	30	47	32
Prior CVD, %	100	72	59	73	100	31	85
Mean BMI, kg/m <sup>2</sup>	30	33	33	32	32	32	32
Mean A1C, %	7.7	8.7	8.7	8.0	8.7	7.3	8.2

## Glucagon-Like Peptide-1 (GLP-1) Receptor Agonism

## Glucose-Dependent Insulinotropic Polypeptide (GIP) Receptor Agonism

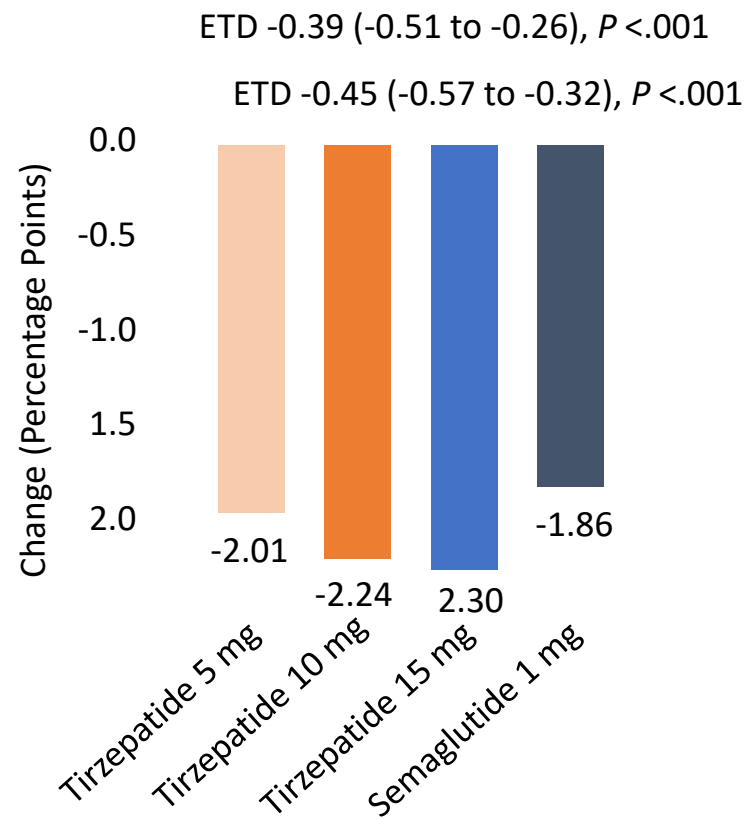


- Glucose-dependent insulinotropic polypeptide receptor agonism
- Glucagon-like peptide-1 receptor agonism
- Indirect action

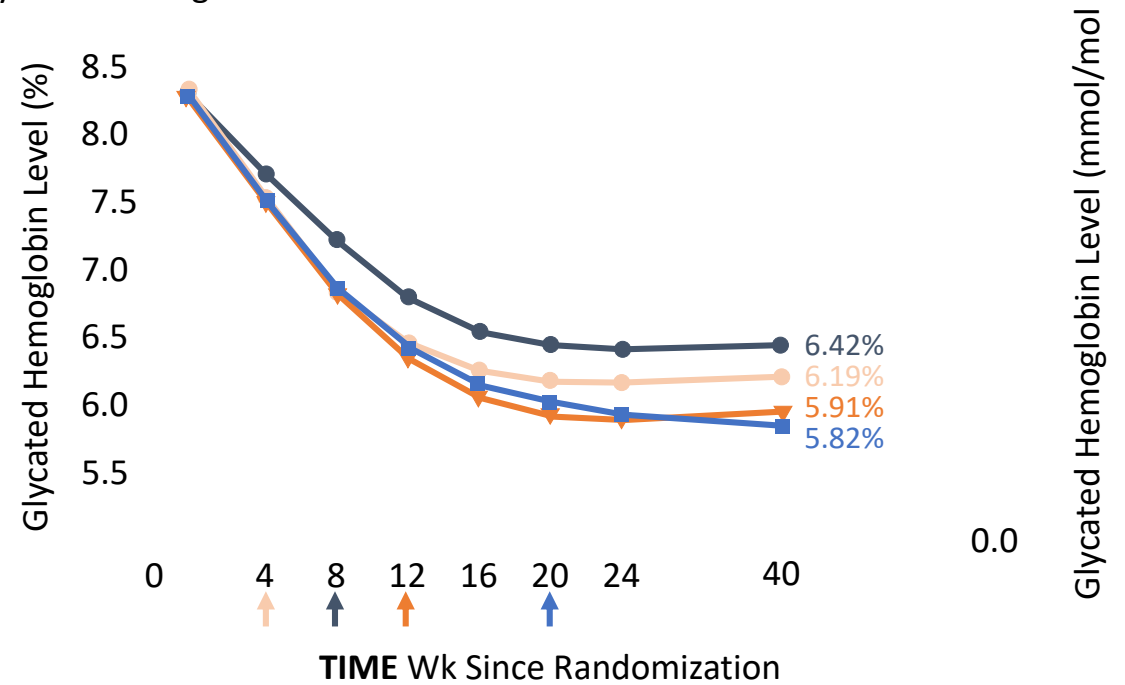
# Tirzepatide vs Semaglutide in T2D: Change in A1C

● ■ Tirzepatide 5 mg   
 ▼ ■ Tirzepatide 10 mg   
 ◆ ■ Tirzepatide 15 mg   
 ● ■ Semaglutide 1 mg

Change in Glycated Hemoglobin Levels From Baseline of 8.3%

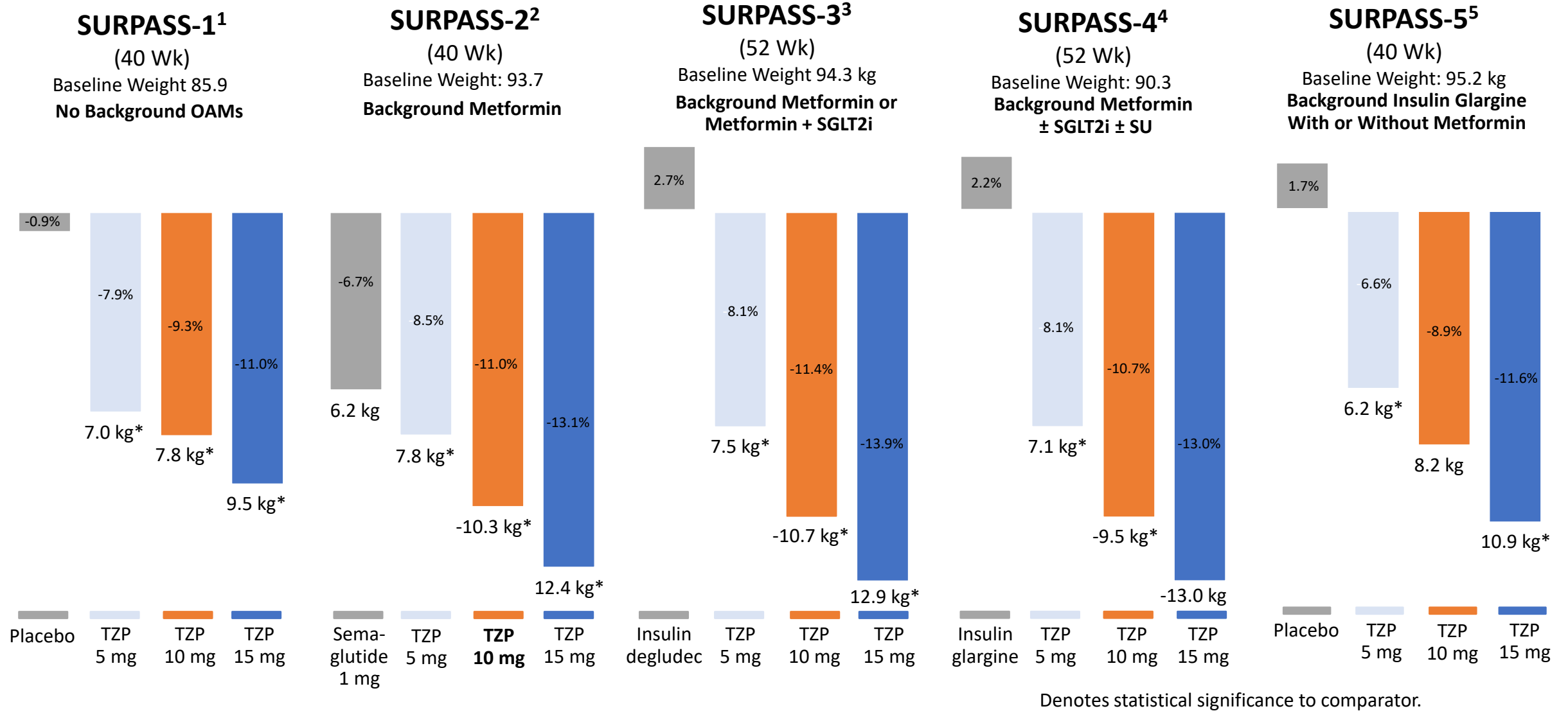


Overall mean baseline glycated hemoglobin: 8.28%





# SURPASS: Weight Loss With Tirzepatide in T2D



1. Rosenstock. Lancet. 2021;398:143. 2. Frias. NEJM. 2021;385:503. 3. Giorgino. ADA 2021. Abstr 78-LB.

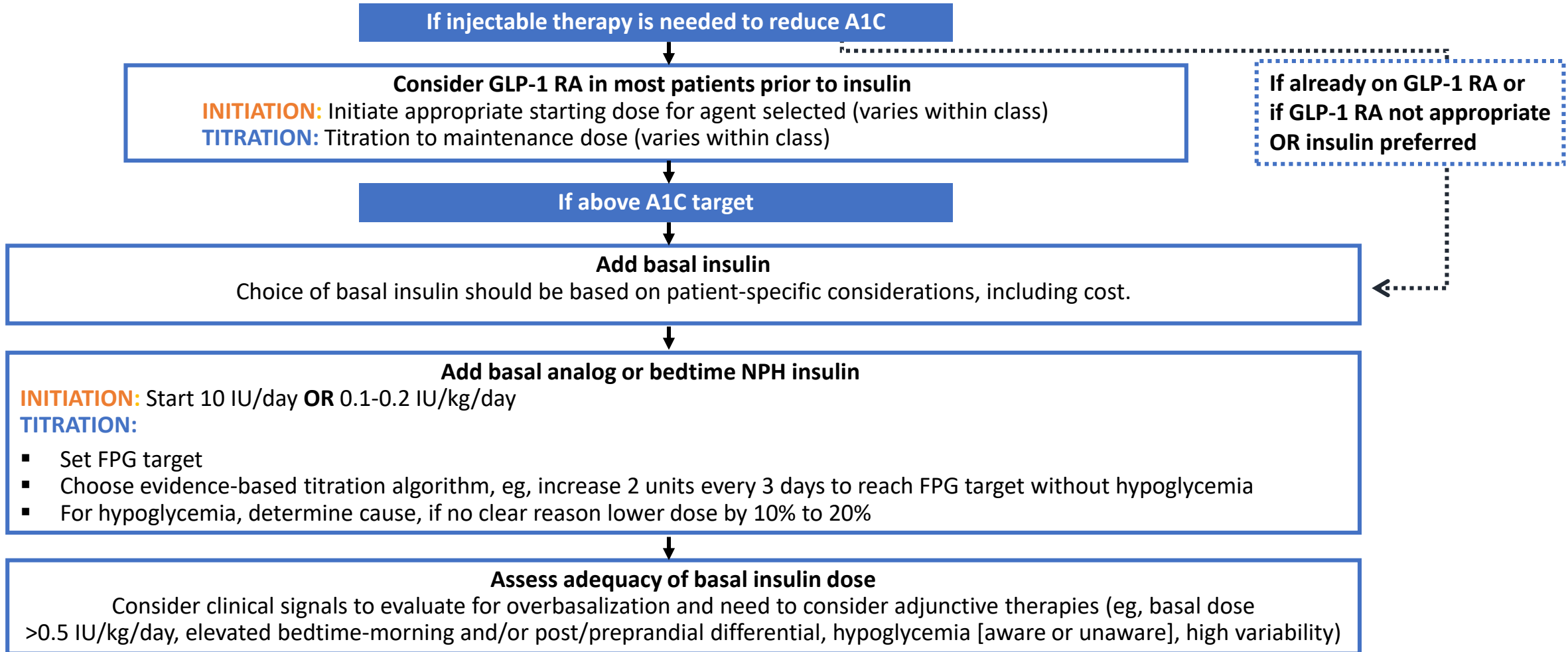
4. Del Prato. Lancet. 2021;398:1811. 5. Dahl. ADA 2021. Abstr 80-LB.

# Terzepatide/(Mounjaro)

- Once a week auto injector
- 2.5mg/5/mg/7.5mg/10mg/12.5mg/15mg per 0.5 mL
- Works on fasting and post meal glucose
- Helps you feel full, can contribute to weight loss (13-25lb)
- Potential Side effects: Nausea/Vomiting/↓ Appetite /Diarrhea or Constipation
  - Acute kidney diseases can occur if you get dehydrated
- Contraindicated: personal or family history of medullary thyroid carcinoma (MTC), or in patients with Multiple Endocrine neoplasia syndrome type 2 (MEN2),
- Risk of Thyroid c-cell tumors, acute pancreatitis, hypoglycemia if used with SU or Insulin (dose needs to be adjusted).
- A1c reduction 1.8% to 2.
- Cost: \$\$\$, co-pay card



# Choose GLP-1 RA Before Insulin Nearly Always



# Starting Therapies in Patients With T2D

## Coverage Search App



Apple App Store

<https://apps.apple.com/us/app/coverage-search/id834992816>

Google Play Store

[https://play.google.com/store/apps/details?id=testformularysearch.mmit.com.formulary&hl=en\\_US&gl=US&pli=1](https://play.google.com/store/apps/details?id=testformularysearch.mmit.com.formulary&hl=en_US&gl=US&pli=1)

1. Use *Coverage Search* or another formulary search resource
  - Requires the drug, state, and insurance category to determine coverage
2. Review the mechanism of action and benefits of the drug (eg, A1C reductions, weight reductions, CV or renal protection)
3. Review the side effects and how to mitigate
  - For GLP-1 RA GI adverse effects: snack for the first few days, eat about one-half of what you usually eat, stop eating when full, follow or slow the titration schedule
  - For SGLT2i adverse effects: good genital hygiene (clean and dry), drink extra water
4. Show patients how to inject with demo pen or sample and supervise self injection
5. Call (or have an MA call) the pharmacy to verify prescription was received, run the prescription, and determine out-of-pocket cost
6. Print (or have an MA print) co-pay card for patients with commercial insurance

# Case → Fred



- Fred followed your advice and
  - started semaglutide at 0.25mg.
  - He was queasy, so week 2 decreased to 10 clicks. Week 3: 0.25mg, and week 4: 0.5mg
  - Weeks 5-8 and 9-12 he took 0.5mg/weekly injection
  - Weeks 13-20 he increased to 1mg/week
  - His early nausea abated with “click” titration, and after 4 months, he was able to increase to 1 mg weekly.
  - 2 months later, he was taking 2mg weekly with no further side effects
- Since originally starting a GLP-1, he has lost a total of 25 lb. He states he has more energy, and has started walking daily
- Physical Examination
  - Height: 5 ft 10 in
  - Weight: 221 lb (BMI: 31.7kg/m<sup>2</sup>)
  - Blood pressure: 128/80 mm Hg
  - Pulse: 70 beats/min
- Laboratory Findings
  - Fasting blood glucose: 108 mg/dl; A1C: 7.2%
  - All other repeat labs normal

**IS THIS ENOUGH?**

# Case Study: Fred, 61 Years Old With T2D, Obesity, Dyslipidemia, Hypertension, and History of MI



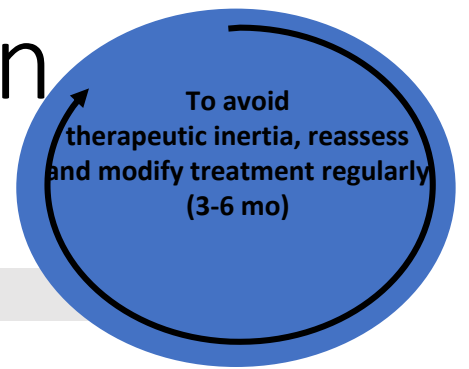
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- Allergies/Adverse Drug Events: GI issues when first starting Metformin
- Family Hx: Mother: dyslipidemia, MI age 68. Father HTN, Obesity
- Social
  - Lives alone, retired
  - Has MCare with BC/BS supplement

# So what do we do next for Fred?



- SGLT2
- Basal Insulin
- Upgrade to GLP/GIP
- Add Pioglitazone
- Refer for bariatric surgery

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Either/  
or

SGLT2i with proven CVD benefit

IF A1C ABOVE TARGET

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- TZD

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SGLT2i with proven HF benefit in this population

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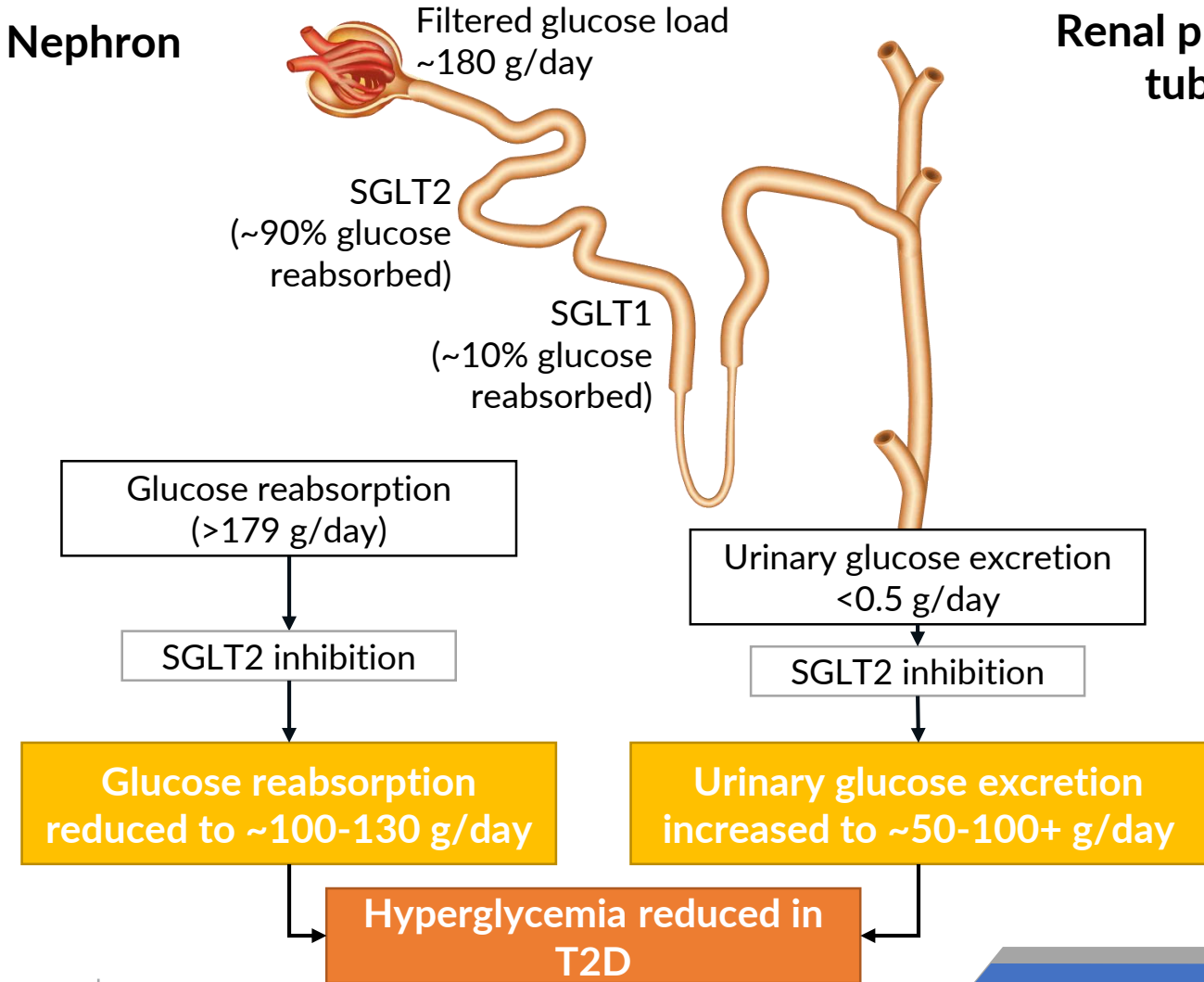
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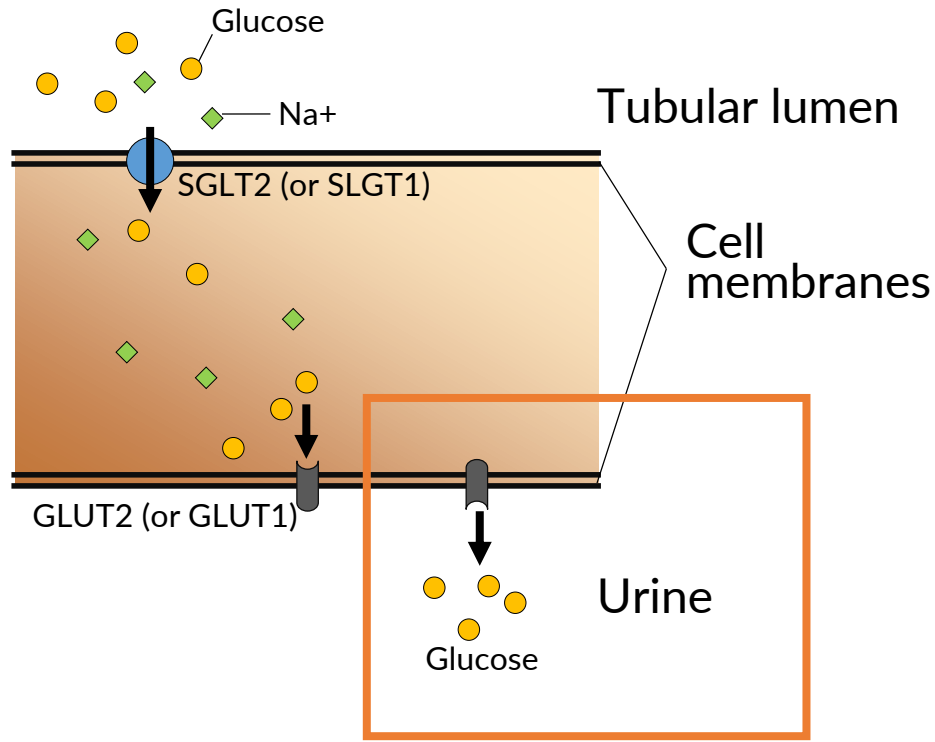
Cardiorenal Risk Reduction or Glycemic Lowering Needed



# Role of SGLT2 Inhibitors



## Renal proximal tubule cell



# SGLT2 Inhibitor Summary

SGLT2 inhibitor	FDA Approval for Risk Reduction			A1C Reduction	Dose	Renal dosing
	CVD	HF	CKD			
<b>Brenzavvy®</b> (bexagliflozin)	No indication	No indication	No indication	-0.5%	20 mg/day	<ul style="list-style-type: none"> <li>&lt;30 mL/min/1.73 m<sup>2</sup>: not recommended</li> </ul>
<b>Invokana®</b> (canagliflozin)	✓	No indication	✓	-0.77% to -1.03%	100-300 mg/day	<ul style="list-style-type: none"> <li>30-59 mL/min/1.73 m<sup>2</sup>: 100 mg</li> <li>&lt;30 mL/min/1.73 m<sup>2</sup>: not recommended</li> </ul>
<b>Farxiga®</b> (dapagliflozin)	✓	✓ (HFrEF only)	✓	-0.6% to -0.8%	5-10 mg/day	<ul style="list-style-type: none"> <li>25-&lt;45 mL/min/1.73 m<sup>2</sup>: 10 mg</li> <li>&lt;30 mL/min/1.73 m<sup>2</sup>: not recommended</li> </ul>
<b>Jardiance®</b> (empagliflozin)	✓	✓	Under FDA review	-0.7% to -0.8%	10-25 mg/day	<ul style="list-style-type: none"> <li>&lt;30 mL/min/1.73 m<sup>2</sup>: not recommended</li> </ul>
<b>Steglatro®</b> (ertugliflozin)	No indication	No indication	No indication	-0.7% to -0.9%	5-15 mg/day	<ul style="list-style-type: none"> <li>&lt;45 mL/min/1.73 m<sup>2</sup>: not recommended</li> </ul>

**Brenzavvy: No PA, No Insurance required: ~ \$47/mo**

# Case Summary: Fred



- Fred followed your advice and
  - started empagliflozin 10mg
  - No adverse events reported
  - No hypoglycemia
- Laboratory Findings after 3 months
  - Fasting blood glucose: 104 mg/dL; A1C: 6.8%
  - All other repeat labs normal

AND he attended diabetes education classes!

# Meet Sarah, 46 y/0 F Uncontrolled DM ~ 9 years: T2, T1 or LADA?

---

## DX:

- peripheral neuropathy,
- hyperlipidemia,
- iron deficiency anemia
- persistently elevated A1C
- BMI 30.78 (wt 185, ht 65 inches)

## MEDS:

- 54 units of Glargine (lantus) at bed time,
- 1.8mg Liraglutide (Victoza) injection daily,
- Metformin 1000mg twice a day and
- Dapagliflozin (Farxiga) 10mg daily.

## PMH:

- She has a strong family history of diabetes
- hx of gestational diabetes when she was pregnant some ago.

## LABS:

- Her sugars range from 70-400mg/dl and she complains of daily nausea and dyspepsia.
- GAD 65 (results +) and other labs ordered to evaluate for type 1
- eGFR 52
-

# Questions about Sarah's case....

---

1. Does she have late onset T1 diabetes?
2. Since GAD65 was positive, do we need to test other antibodies? What are they?
3. If LADA, should she continue other meds or just insulin?
  1. Dapagliflozin? Other renal protection?
  2. Continue Metformin? Switch to GLP?
  3. Insulin? Adjust current 54u glargine (basal)?
    1. How do you switch to Multiple daily insulin (MDI)? How to titrate basal/bolus
4. When should she do Blood glucose testing? What about a CGM? Insulin Pump?
5. What other auto immune issues should be checked?
6. Other?

# Goals of Basal Insulin Therapy

## Goals of Basal Insulin Therapy in Patients With T2D

- Supplement normal physiologic insulin production, providing steady insulin levels throughout the day
- Improve glycemic control after noninsulin therapies prove insufficient
- Control fasting blood glucose (FBG) levels

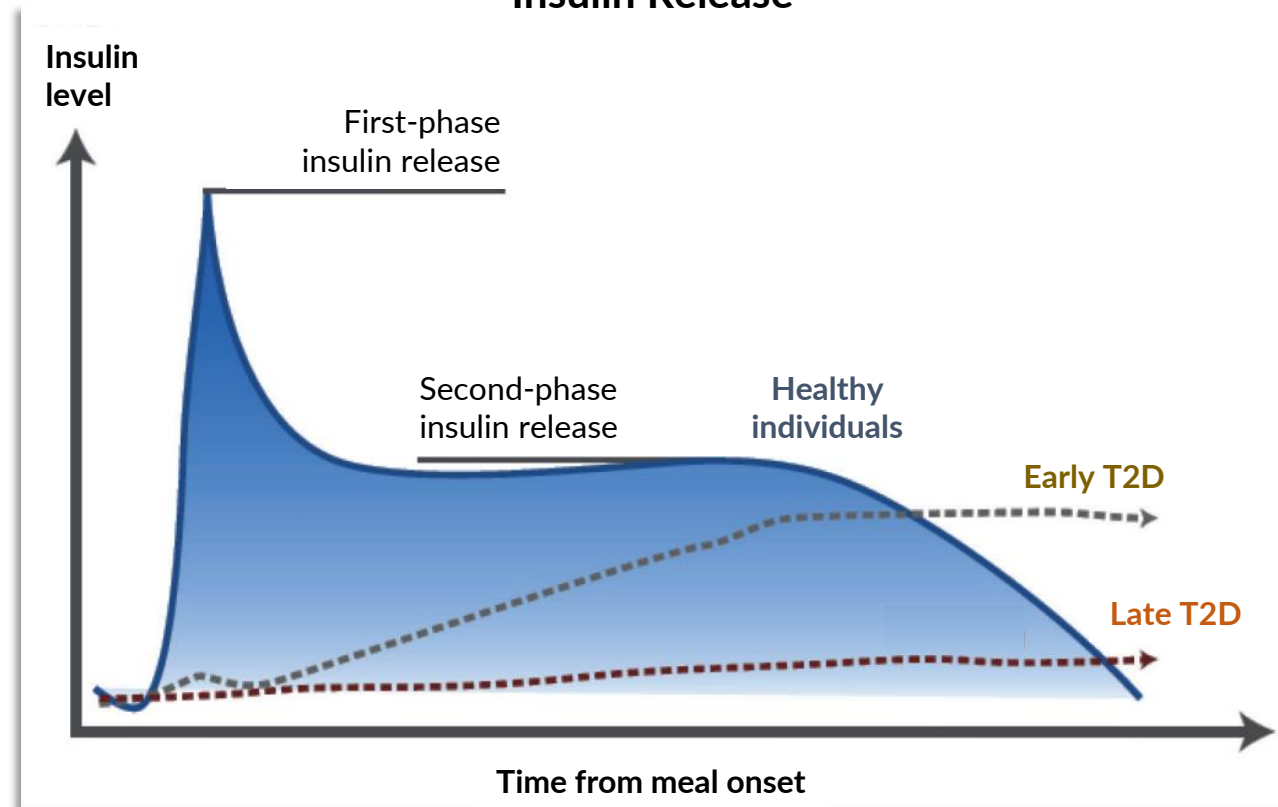
**NOTE:** Basal insulin therapy assumes sufficient beta-cell function for prandial insulin secretion and has minimal effects on postprandial glucose (PPG) levels.

Vargas-Uricoechea H. *J Clin Med Res.* 2022;14(1):8-21.

Meece J. *Diabetes Ther.* 2018;9(3):877-890.

Vargas-Uricoechea H. *J Clin Med Res.* 2022;14(1):8-21.

## Effects of Insulin Resistance on Postprandial Insulin Release



# 5 Steps to Freedom

Insulin titration schedule for		
Change date (when new doses start)	Units of pre-meal rapid-acting analog c lispro (Humalog) c aspart (Novolog) c glulisine (Apidra)	Units of peakless insulin glargine (Lantus) c Before breakfast c Before bedtime
	8	24
	10	24
	10	30
	12	30
	12	36
	14	36
	14	42
	16	42
	16	48
	18	48
	18	54
	20	54
	20	60
	22	60
	22	66
	24	66
	24	72
	26	72
	26	78
	28	78
	28	84
	30	84
	30	90
	32	90
	32	96
	34	96

While we are trying to discover the amount of insulin that you need, please eat \_\_\_\_\_ (c gm) (c servings) of carbohydrate at every meal. The instruction to eat the same amount at each meal is a temporary restriction. Our goal is to discover the amount of insulin that is needed to get good results for a certain amount of carbohydrate. Then, once we discover the matching rule, you will be free to change the amount that you eat from meal to meal.

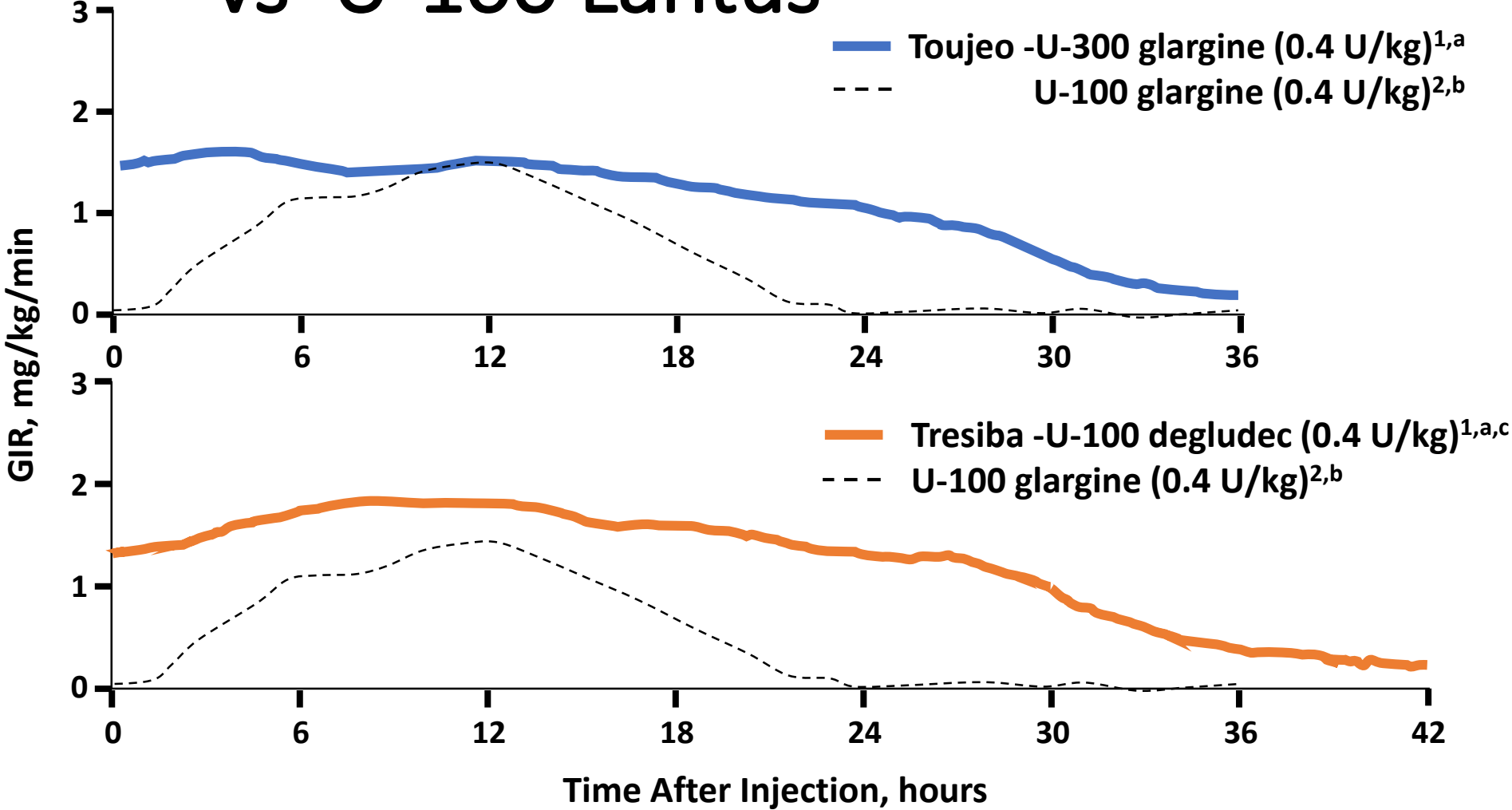
Call me if you begin to show any readings under 80 or if you have symptoms of hypoglycemia. If you begin to show some blood glucose readings before meals that are in the target range of \_\_\_\_\_ to \_\_\_\_\_ mg/dL, please hold with the dose you are taking, make no further changes of insulin dose, and come in to visit me to review your logbook. Be sure to carry in your meter and one week of log-

# Time Action of Insulins

<b>Insulin</b>	<b><i>Starts</i></b> <b>(m-hr)</b>	<b><i>Peak</i></b> <b>(hr)</b>	<b><i>Duration</i></b> (hrs)
<b>Aspart, Lispro, Gulisine</b> Novolog, Humalog, Apidra	<b>10-15m</b>	<b>1-1.5</b>	<b>3-4</b>
<b>Lyumjev, FiAsp Ultra fast</b>	<b>1-5 m</b>	<b>30-90m</b>	<b>3</b>
<b>Afrezza (inhaled rapid)</b>	<b>12-15</b>	<b>53min</b>	<b>180min</b>
<b>Regular</b>	<b>30+m</b>	<b>2-3</b>	<b>4-6</b>
<b>NPH (Walmart \$25 no Rx)</b>	<b>2-4h</b>	<b>6-8</b>	<b>10-12</b>
<b>Glargine (Lantus) u-100</b>	<b>2+h</b>	<b>~Flat</b>	<b>24+/-</b>
<b>(Toujeo) - U300</b>		<b>VERY flat</b>	<b>32 hr</b>
<b>Detemir (Levemir)</b>	<b>2+h</b>	<b>6+/-</b>	<b>20-24</b>
<b>Degludec (Tresiba)</b>	<b>2+ hr</b>	<b>VERY flat</b>	<b>42 hr</b>



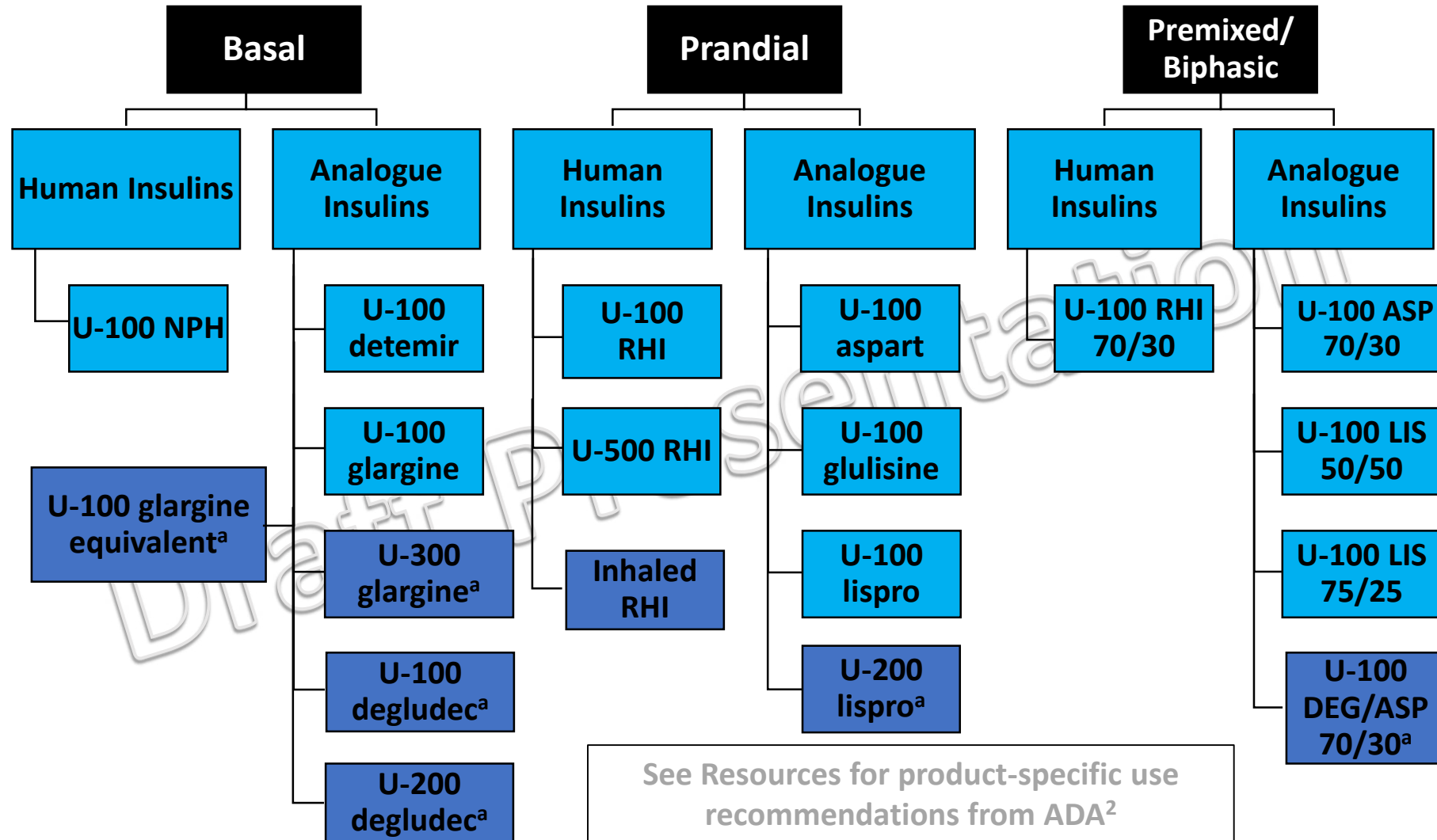
# Time Action of Ultralong-Acting Insulins vs U-100 Lantus



<sup>a</sup> Results shown for individuals with T1DM; <sup>b</sup> Individuals with and without T1DM; <sup>c</sup> U-200 degludec curve is similar.<sup>3</sup>

1. Drugs@FDA. <http://www.accessdata.fda.gov/scripts/cder/daf/>.  
 2. Google Patents. <http://www.google.com/patents/US20120122774>.  
 3. Heise T, et al. *Diabetes*. 2012;61(suppl 1):A91 [abstract 349-OR].

# Approved Insulins: United States



<sup>a</sup> Available only in prefilled pens.

# Basal Insulin Time Actions

Concentration	Insulin	Duration of Action	Classification	Mixing Needed?
U-100	NPH	Variable, up to 24 h	Intermediate	Yes
U-100	Detemir	7.6 to > 24 h	Long	No
U-100	Glargine <sup>a</sup>	10.8 to > 24 h	Long	No
U-100	Degludec	> 42 h	Longer	No

Concentration	Insulin	Duration of Action	Classification	Mixing Needed?
U-200	Degludec	> 42 h	Longer	No
U-300	Glargine	16 to > 36 h	Longer	No
U-500	Human regular <sup>b</sup>	13 to 24 h	Intermediate	No



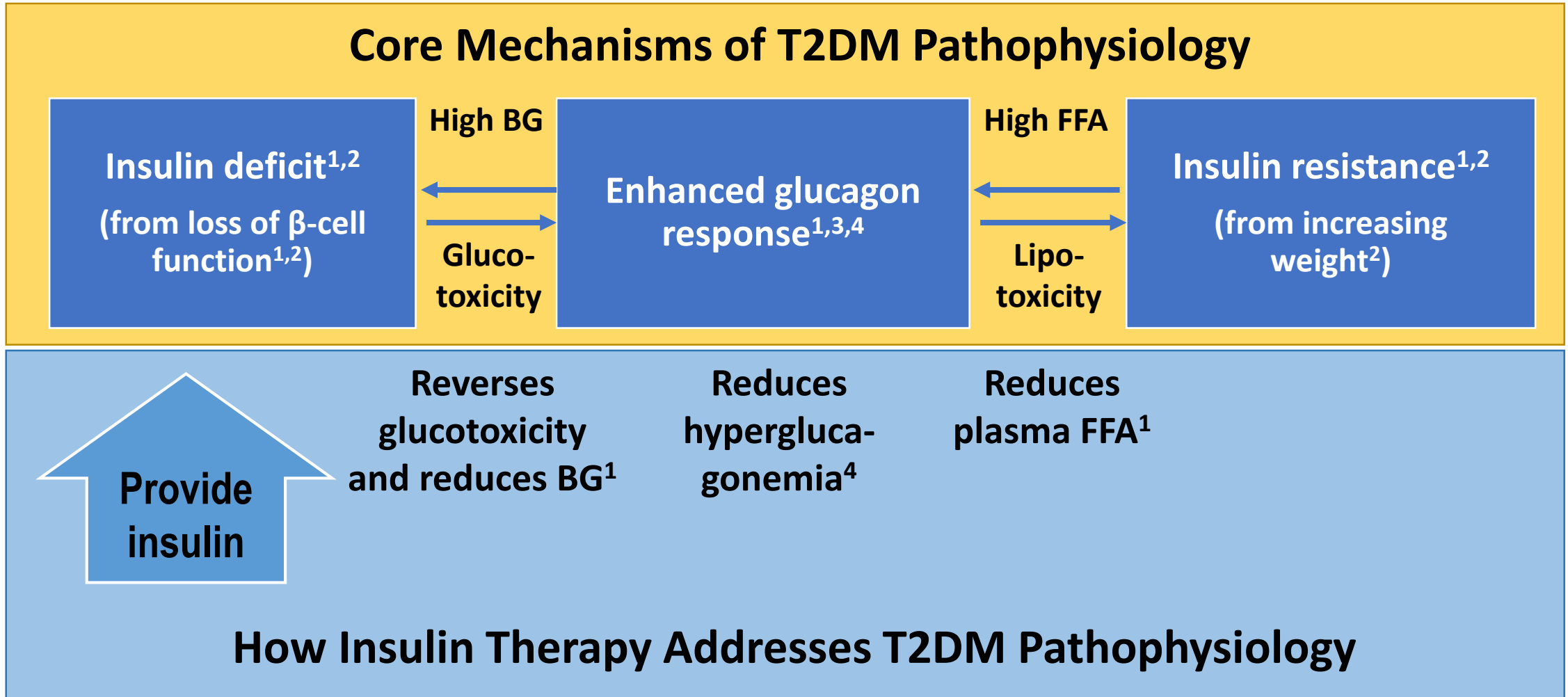
- The number after “U” represents the concentration in terms of units of insulin per 1 mL
- 
- Concentrated insulins may have different time-action profiles than their U-100 versions

Pro

<sup>a</sup> Includes equivalent and follow-on formulations; <sup>b</sup> Has both basal and prandial action at U-500 concentration.

1. Drugs@FDA. <https://www.accessdata.fda.gov/scripts/cder/daf/>;  
2. ADA. *Diabetes Care*. 2018;41(suppl 1):S1-S159.

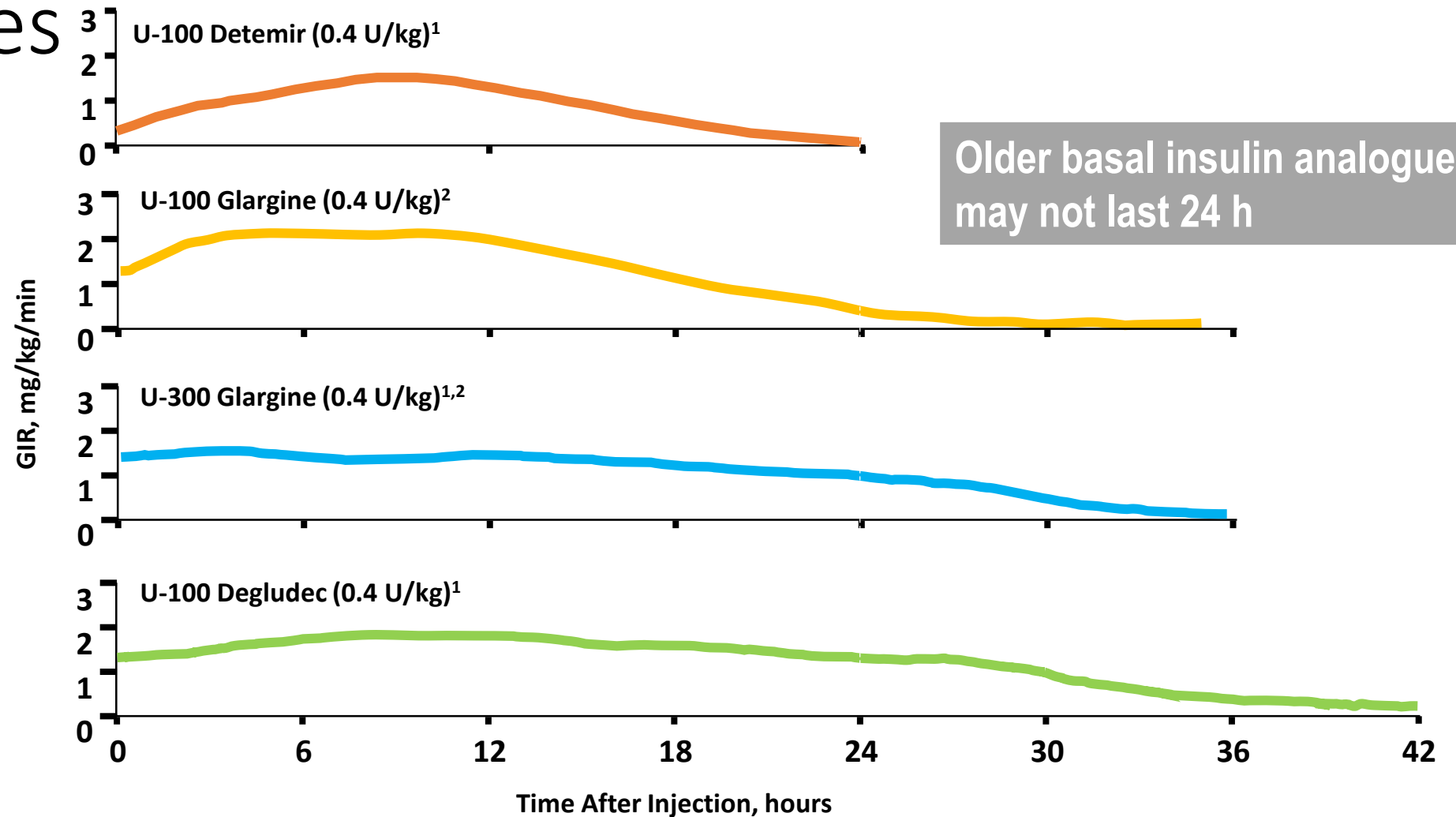
# Role of Basal Insulin Therapy in T2DM



1. Hanefeld M, et al. *Diabetes Ther.* 2016;7:187-201; 2. Kahn SE. *Diabetologia.* 2003;46:3-19; 3. Mitrakou A, et al. *N Engl J Med.* 1992;326:22-29; 4. Kramer CK, et al. *J Clin Endocrinol Metab.* 2015;100:2987-2995.

# Clamp Study Results: Current Basal Insulin Analogues

Graphs depict the adjustments needed to a glucose infusion to keep blood glucose levels as flat as possible



1. Drugs@FDA. <http://www.accessdata.fda.gov/Scripts/cder/DrugsatFDA>.

2. Becker RH, et al. *Diabetes Care*. 2015;38:637-643.

# Initiating Ultra long Basal Insulins in Patients With T2DM: Guidelines and Evidence

## General Guidelines for Any Basal Insulin

**AACE Guidelines<sup>1</sup>**

---

0.1-0.2 U/kg/d  
if A1C < 8%

0.2-0.3 U/kg/d  
if A1C > 8%

**ADA Guidelines<sup>2</sup>**

---

0.1-0.2 U/kg/d

*or*

10 U/d

## Specific Guidelines for Newer Insulins

**U-300 Glargine<sup>3</sup>**

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0.2 U/kg/d

**U-100 or U-200 Degludec<sup>3</sup>**

---

10 U/d

**Smallest dose increment:**

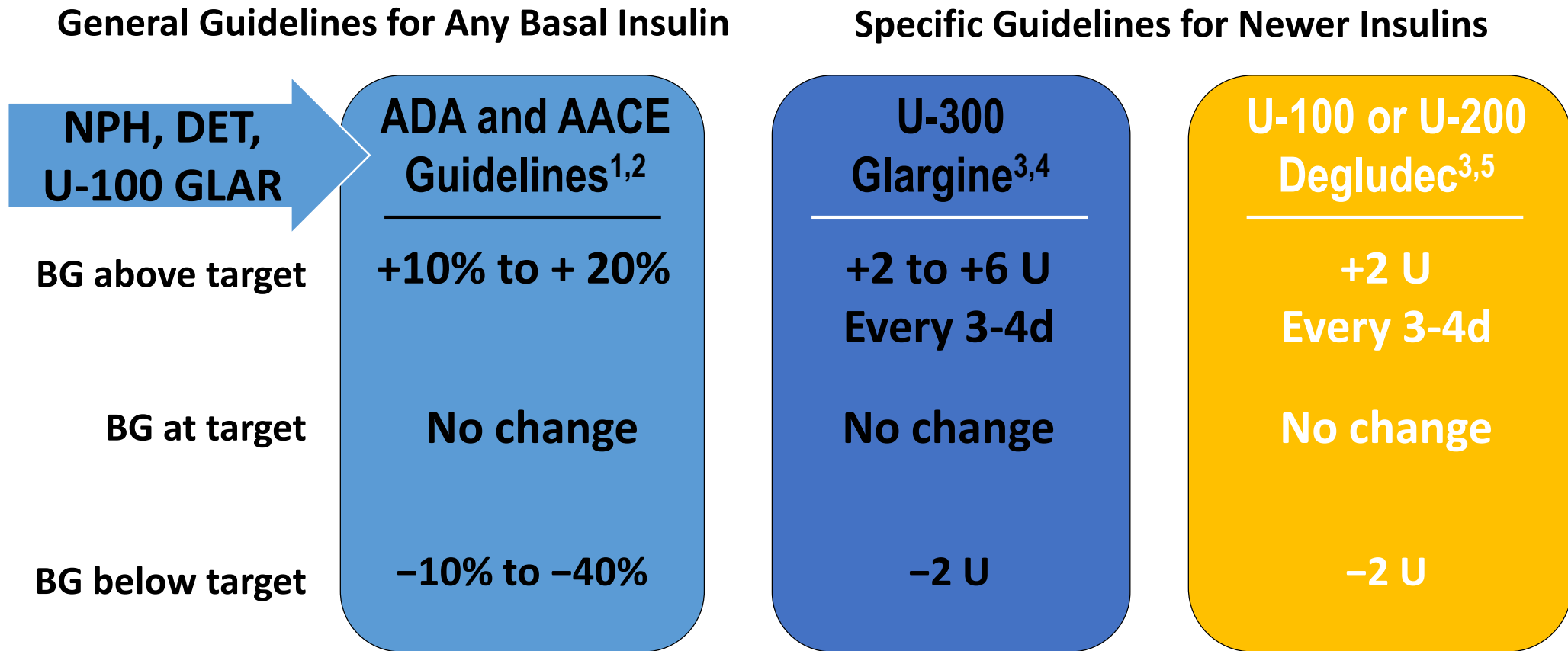
450 U pen: 1 U  
900 U pen: 2 U

U-100: 1 U  
U-200: 2 U

**\*\*Short Cut: Weight in lbsX10%. Ex 220 lbs=22u basal {on formulary}** 1. dhinnen clinical practice.

1. Garber AJ, et al. *Endocr Pract.* 2018;24:91-120;  
2. ADA. *Diabetes Care.* 2018;41(suppl 1):S1-S159;

# Titration Basal Insulins: Guidelines and Evidence



- Compute average FBG from 2-3 (or median of 3) previous measurements<sup>4-6</sup>

1. Garber AJ, et al. *Endocr Pract.* 2018;24:91-120; 2. ADA. *Diabetes Care.* 2018;41(suppl 1):S1-S159;  
4. Rosenstock J, et al. *Diabetes Care.* 2018 Aug  
13. [Epub ahead of print]; 5. Vora J, et al. *Diabetes Res Clin Pract.* 2015;109:19-31.

# Considerations for Using Ultralong-Acting Basal Insulins in Patients With Renal Impairment

## U-100 and U-200 Degludec

- No differences in PK activity in patients with mild to severe CKD<sup>1</sup>
- Steady-state half-life is  $\approx$  25 hours in individuals with T2DM and normal renal function<sup>2</sup>
- < 10% of participants in clinical trials had eGFR < 60<sup>3</sup>

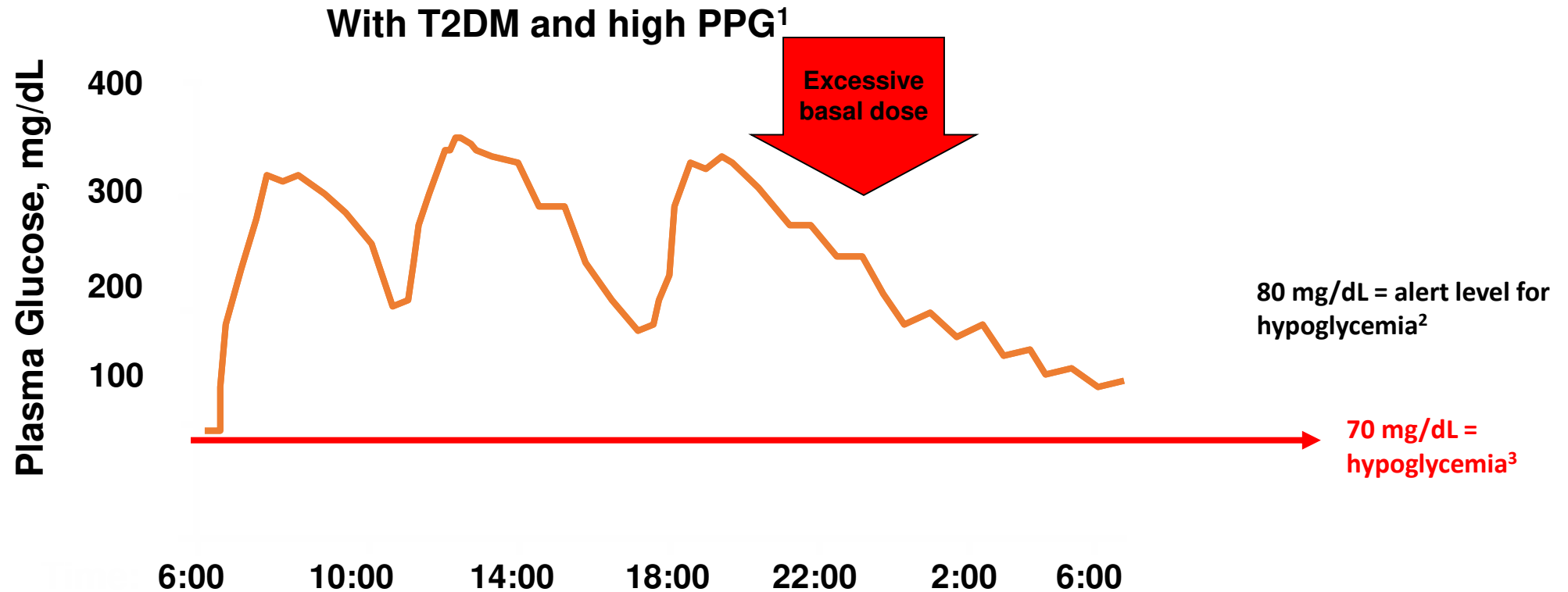
## U-300 Glargine

- U-100 and U-300 GLAR have equivalent efficacy if eGFR  $\geq$  30<sup>4</sup>
- Less nocturnal hypoglycemia with U-300 if eGFR  $\geq$  30<sup>4</sup>
- Less overall hypoglycemia with U-300 if eGFR  $\geq$  30 and < 90<sup>4</sup>

• eGFR stated in mL/min/1.73 m<sup>2</sup>. 1. Kiss I, et al. *Clin Pharmacokinet*. 2014;53:175-183; 2. Heise T, et al. *Diabetes Obes Metab*. 2012;14:944-950; 3. Drugs@FDA. <http://www.accessdata.fda.gov/Scripts/cder/DrugsatFDA>; 4. Escalada J, et al. *Diabetes*. 2016;65(suppl 1):A18 [69-OR].

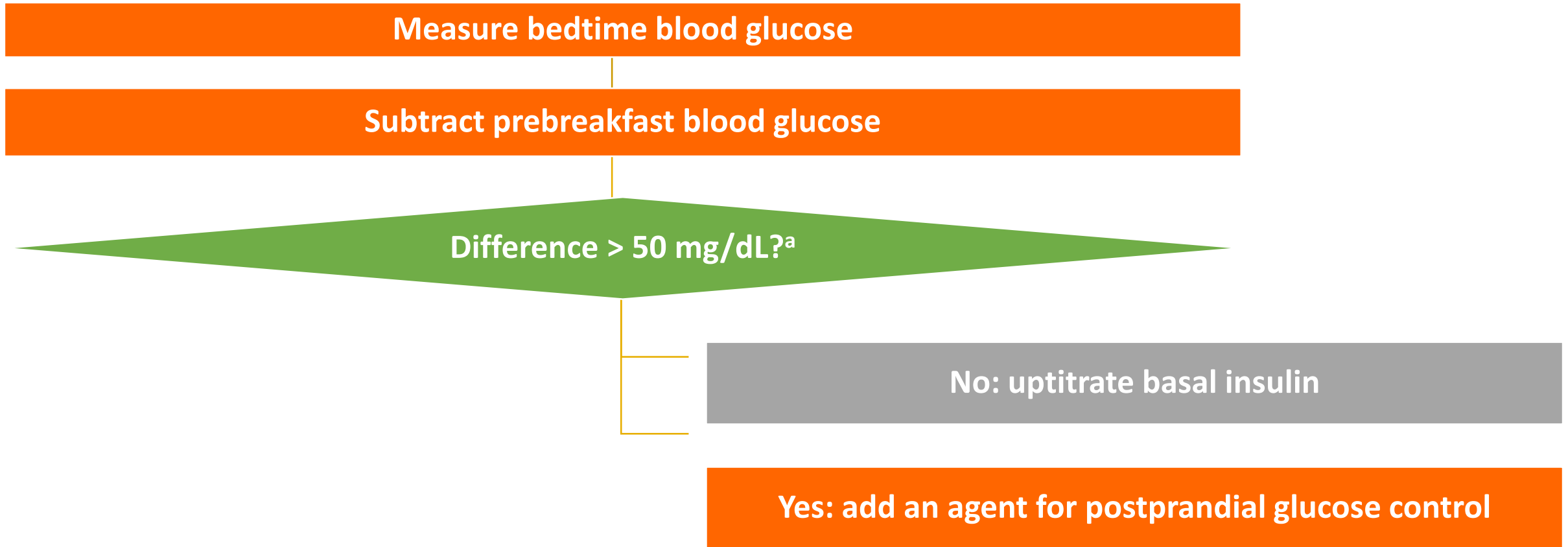


# Overly Aggressive Basal Insulin Titration (Overbasalization) is also Dangerous



1. Polonsky KS, et al. *N Engl J Med*. 1988;318:1231-1239; 2. Seaquist ER, et al. *J Clin Endocrinol Metab*. 2013;98:1845-1859.; 3. Cryer PE. In: *Hypoglycemia in Diabetes: Pathophysiology, Prevalence, and Prevention*. Alexandria, VA: ADA;2009:17-44.

# Avoiding Overbasalization in T2DM



- **Overly aggressive basal insulin dosing increases the risk of severe hypoglycemia without reducing A1C—do not overbasalize to address PPG excursions!<sup>1,2</sup>**

<sup>a</sup> Retrospective analysis used > 50 mg/dL as a cutoff value, but the study authors suggest that values of 45-55 mg/dL merit consideration for additional intervention.

1. Zisman A, et al. *BMJ Open Diabetes Res Care*. 2016;4:e000171.  
2. Tanenberg RJ, et al. *Diabetes*. 2006;55(suppl 1):A135 [abstract 567-P].

# Calculating the Number of Pens to Prescribe

Parameter	U-300 Glargine	U-100 Degludec	U-200 Degludec
Minimum dose increment	1	1	2
Insulin units/pen <sup>a</sup>	450	300	600
<b>Doing the math (with sample calculations for 50 units/day):</b> Daily dose × 30 d/mo = monthly dose      50 units/d × 30 d = 1500 units/mo			
<u>Pens needed</u> = cartons needed* Pens/carton	U-300 glargine: $4/5 = 0.8 \rightarrow 1$ carton U-100 degludec: $5/5 = 1$ carton U-200 degludec: $3/3 = 1$ carton		

**\* Remember to round *up* if there is a fraction so your patient has enough insulin!**

<sup>a</sup> Calculated from dosage form information given in the prescribing information: units/mL × mL/pen.

# Comparing and Contrasting Long-Acting and Ultralong-Acting Basal Insulins

## What Stays the Same

- Basal insulin is administered once a day (except Detemir)
- 1 unit of insulin is still the same, no matter what *concentration* you are using.
- “Start low and go slow” when titrating to minimize hypoglycemia
- No need to refrigerate after opening

## What’s Different

- Ultra long acting insulins are available in pens (Deg U200 also in vial)
- Ultra long insulins have a duration >24 hrs
- Do not titrate ultra long basals more often than every 3-4 days
- Ultralong-acting insulins have more flexible dosing than older insulins
  - $24 \pm 3$  hours for U-300 glargine
  - $24 \pm 16$  hours for degludec
- Flatter profile, less nocturnal hypoglycemia

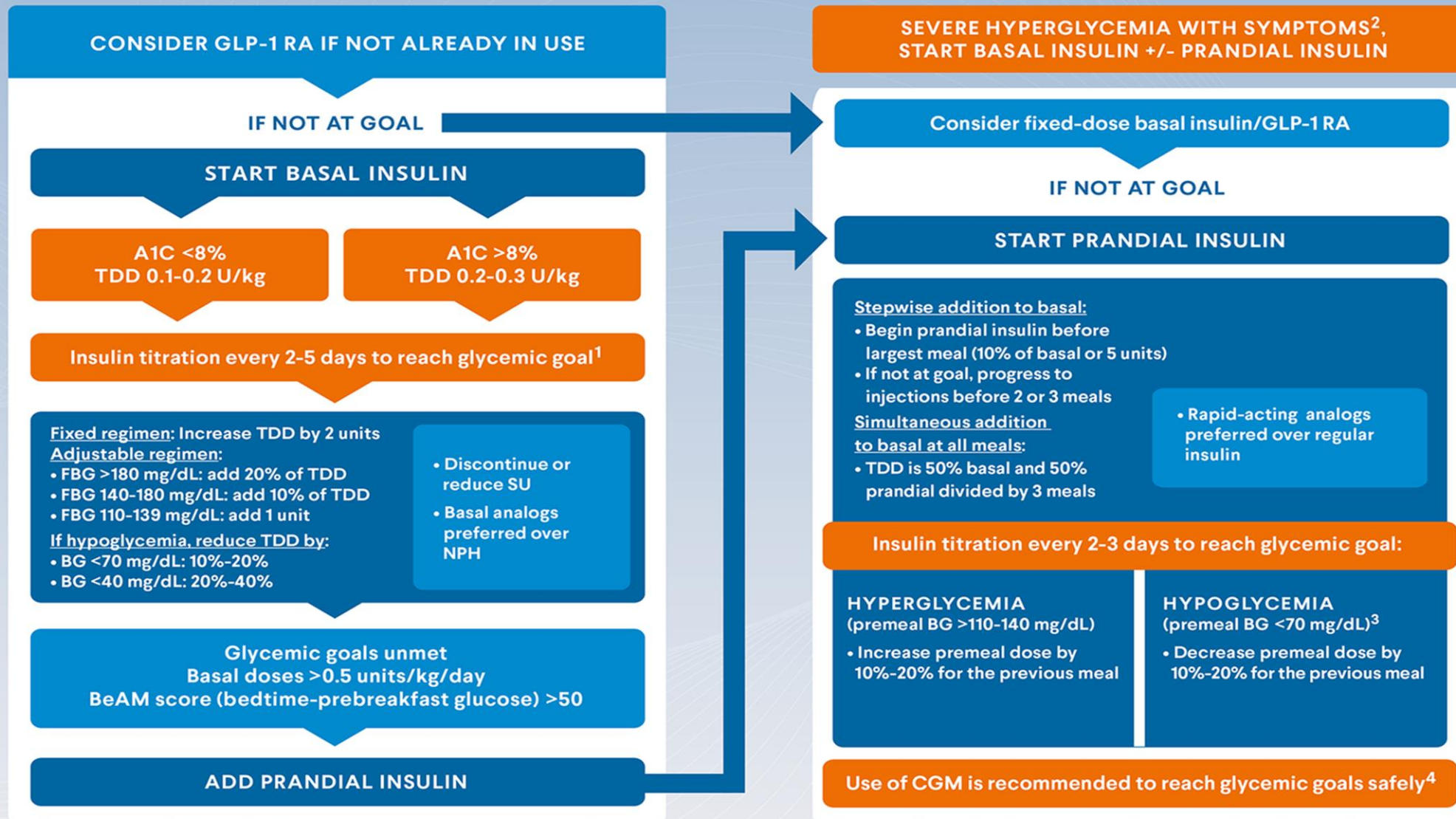
# Current Basal Insulins vs U-100 Glargine: Clinical Characteristics in T2DM

	U-100 NPH <sup>1</sup>	U-100 Detemir <sup>1</sup>	U-100 Glargine Equivalent <sup>2</sup>	U-300 Glargine <sup>3</sup>	U-100 Degludec <sup>4,5</sup>
$\Delta$ A1C	=	=	=	=	=
Overall hypoglycemia	=	=	=	↓ 14%	↓ 26% <sup>a</sup>
Nocturnal hypoglycemia	↑ 37%	=	=	↓ 31%	↓ 29%
Severe hypoglycemia	=	=	=	=	↓ 30%-40%

Newer basal insulin analogues are associated with less hypoglycemia than older basal insulins

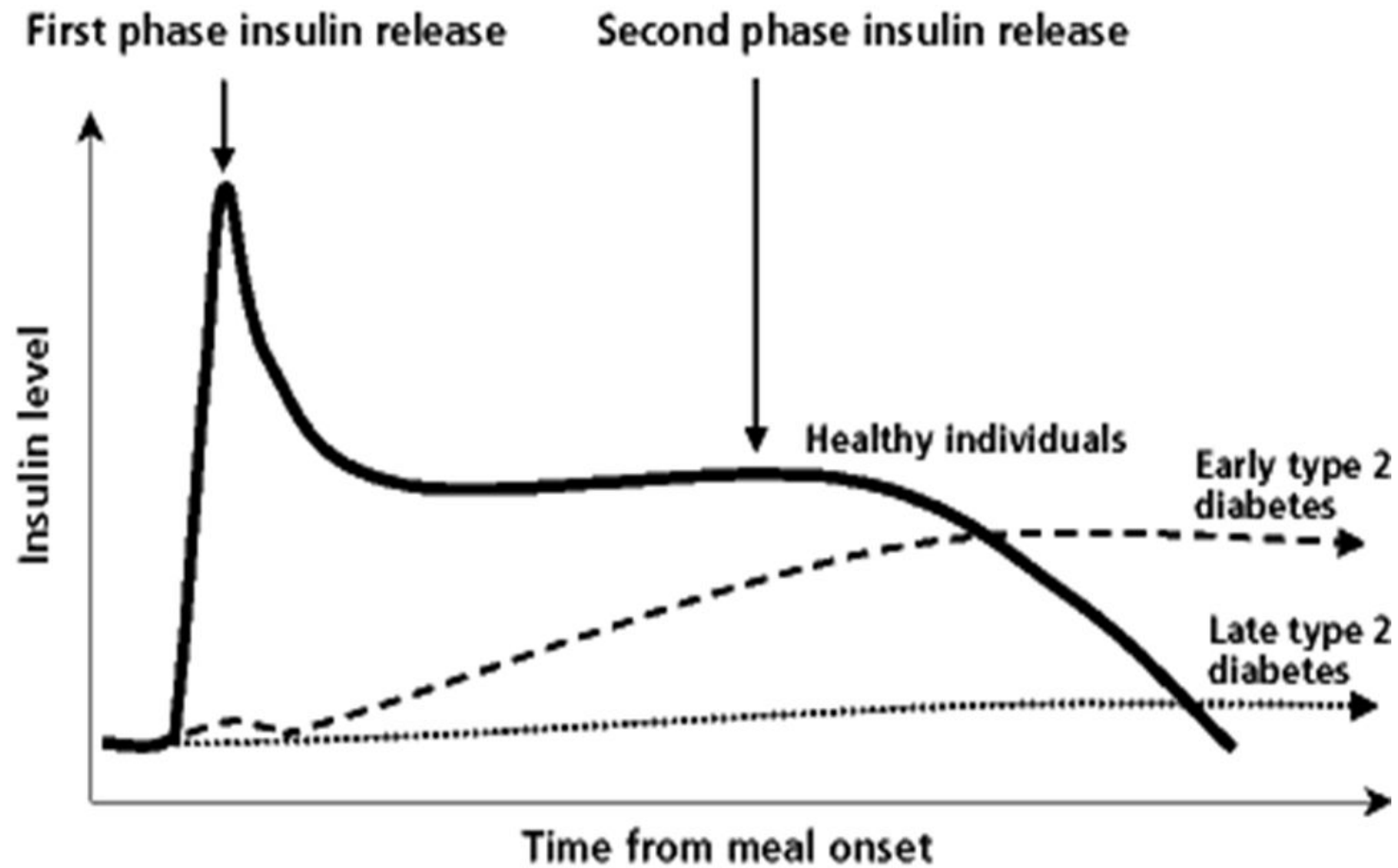
Arrows indicate statistically significant differences at  $P < .05$  or better.  
<sup>a</sup> All confirmed hypoglycemia during maintenance period, in meta-analysis.

1. Rys P, et al. *Acta Diabetol.* 2015;52:649-662; 2. Rosenstock J, et al. *Diabetes Obes Metab.* 2015;17:734-741; 3. Ritzel R, et al. *Diabetes Obes Metab.* 2015;17:859-867; 4. Zhang XW, et al. *Acta Diabetol.* 2018;55:429-441; 5. Marso SP, et al. *N Engl J Med.* 2017;377:723-732.

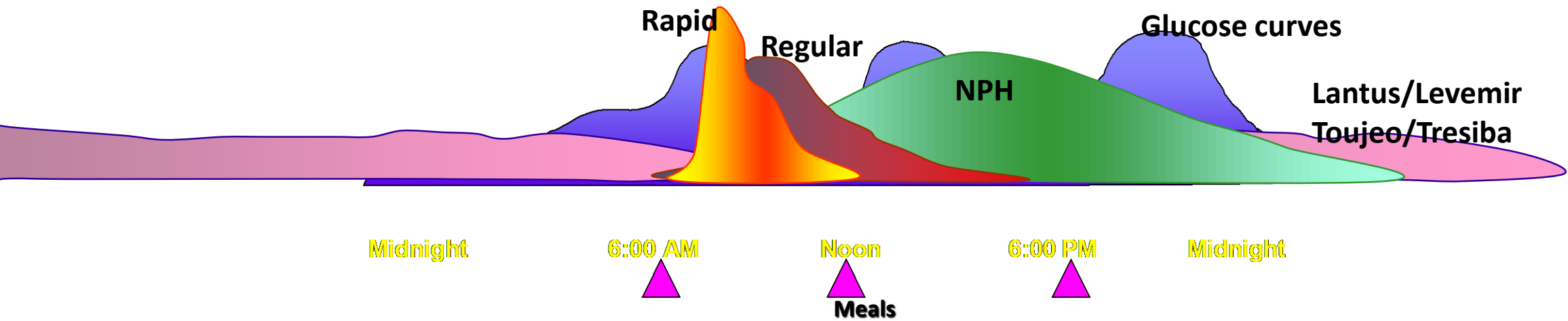


<sup>1</sup>Glycemic goals: A1C ≤6.5%-7% without hypoglycemia, fasting and premeal glucose <110 mg/dL, A1C should be individualized in people with comorbidities and at high adverse consequences of hypoglycemia and/or limited life expectancy. Longer-acting basal insulins (e.g., glargine U300, degludec U100 or U200) require slower titration ≥3 days because of a longer time to steady state. <sup>2</sup>For symptomatic hyperglycemia with A1C >10% and/or BG ≥300 mg/dL, reduce glucose/A1C as promptly and safely as possible. Consider testing for autoimmune diabetes. GLP-1 RA requires titration phase which can delay glycemic control. <sup>3</sup>Oral administration of rapidly absorbed source of glucose (tablet, fruit juice) if person can safely swallow. If unresponsive or unable to swallow, subcutaneous/intramuscular/intranasal glucagon or glucagon analogue can be given by a trained member of the household. <sup>4</sup>See also American Association of Clinical Endocrinology Clinical Practice Guideline: The Use of Advanced Technology in the Management of Persons with Diabetes Mellitus.

# *Impaired Insulin Secretion*

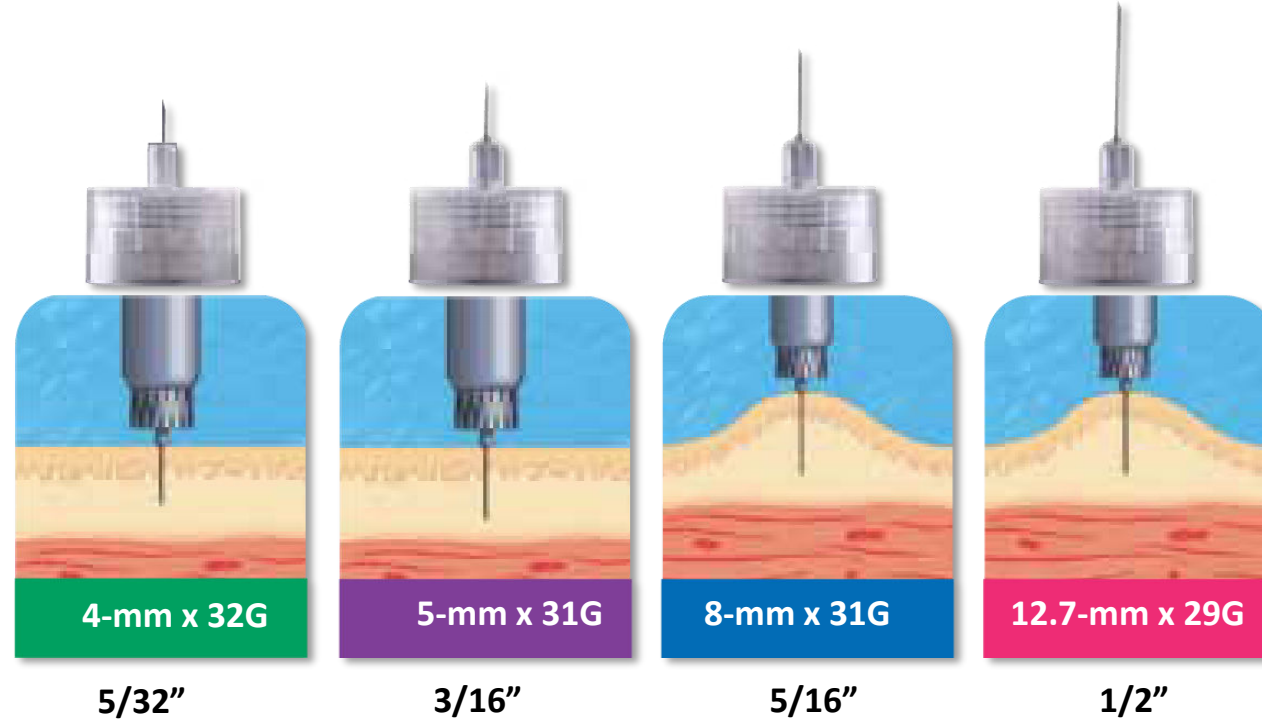


# ***A Variety of Insulins are Available, Including Insulin Analogs***





# Overcoming Patient Fears of Injection



- Use the shortest needle possible
- Demonstrate and administer first injection in the office
- Ensure injection into subcutaneous tissue, not intramuscularly
- Penetrate skin quickly, but inject slowly
- Use a new needle with every injection

Becton Dickinson Diabetes. *Step by step injection guide*. 2012; [www.bd.com/us/diabetes](http://www.bd.com/us/diabetes).

Becton Dickinson Diabetes. BD pen needles fit these pens.

<http://www.bd.com/us/diabetes/hcp/main.aspx?cat=3067&id=3156>

King L, et al. *Nurs Stand*. 2003;17:45-52;Frid A, et al. *Diabetes Metab*. 2010; 36 (suppl 1):S3-S18.

# Not Everything that happens is a Miracle:

## Other Non-Insulin Therapies

- Old clinical management:
  - Metformin (for years)
  - Sulfonylurea (for years)
  - Insulin

# Sulfonylureas/Secretagogues:

Glipizide, Glyburide, Glimiperide  
Prandin and Starlix

- Formulations:
  - Glimepiride (Amaryl) 1, 2, 4mg (max: 8mg) 30 min before meals. 1-2x/d
  - Glyburide (Glynase) 1.5mg,3,6mg (max 12mg) 30 min before meals. 1-2x/d
  - Glipizide (Glucator XL) :5,10mg (max: 20mg) 30 min before meals. 1-2/d
  - Repaglinide (Prandin) 0.5, 1, 2mg (max 16mg)5-30 min before meals. 3x/d
  - Nateglinide (Starlix) 60, 120mg (Max 360mg) 5-30 min before meals 3x/d
- AE: Hypoglycemia. Weight gain after treating hypoglycemia
- Pt Ed: Squeezes insulin out of pancreas. Glipizide/glyburide have similar time actions to NPH. When taking before breakfast, DON'T miss lunch. If dose before dinner, BedTime snack with protein.
- Amaryl is more renal friendly and flatter time action
- dc or cut dose in half when starting GLP, GLP/GIP
- Sulfonylureas increase risk of all cause mortality by 26% and CV mortality by 46%. Crest study. [Clinicalendocrinologynews.com](http://Clinicalendocrinologynews.com) 10(11) 2015

# DPP4s

- Formulations: Oral. Distant cousin to the GLP's
  - Sitagliptin (Januvia) 100mg (renal dose 50mg, GFR<50 )
  - Alogliptin (Nesina) 12.5, 25mg half
  - Saxagliptin (Onglyza) 5mg half
  - \*\*Linagliptin (Tradjenta) 5mg No renal dosing required. Excreted in bile and feces
- MOA: glucose activated, nudges the pancreas
- AE: low risk of hypoglycemia
- Why Not? Not generic \$\$\$, only average about 0.5 % A1C drop

Some things still have benefit....

# Metformin

- Formulations: XR=Extended Release: 500mg (on the \$4 list), 750, 1000mg  
(IR Immediate Release= GAS/DIARRHEA: 500mg, 850mg, 1000mg)
- Clinically Therapeutic Dose: 2000mg (Max dose 2,550mg – no additional benefit)
- Titrate 500mg XR weekly until Fasting Glucose in target and tolerability
- Approved in kids >10yrs
- MOA: Inhibits hepatic gluconeogenesis, decreases intestinal absorption and improves peripheral glucose uptake. **For Pts:** Stops the “Leaky Liver”
- AE’s: Gas, Cramps, Diarrhea.
- Monitor B12 annually. Renal fn if GFR dropping
- Contraindications: GFR<30, hx lactic acidosis, severe hepatic disease, alcohol abuse
- Hold for IV contract or acute dehydration
- Guidelines don’t require this as first Rx started. Insurance does sometimes though.

# Thiazolidones TZDs: Pioglitazone (Actos)

- Pio: **15mg**, 30mg, 45mg. Pro Tip: Weight GAIN >15mg
- Rosiglitazone (Avandia):4mg, 8mg (Controversial = Cardiac AE/s)
- MOA: Works intracellularly to improve signaling: adipose, muscle, liver
  - Very effective to improve insulin resistance (Even Pio 7.5mg –R. DeFronzo)
- AE's: Weight gain, edems (esp if subclinical CHF)
- Do not use if CHF
- Monitor LFT;s prior and following initiation, sx of HF, wt gain, bladder CA
- Takes 2-3 months for therapeutic benefit
- Anti-inflammatory, Reduces visceral fat – NASH/NAFLD, improved heart fn BP and A-Fib

# Glucose-Lowering Agents: T2DM Overview

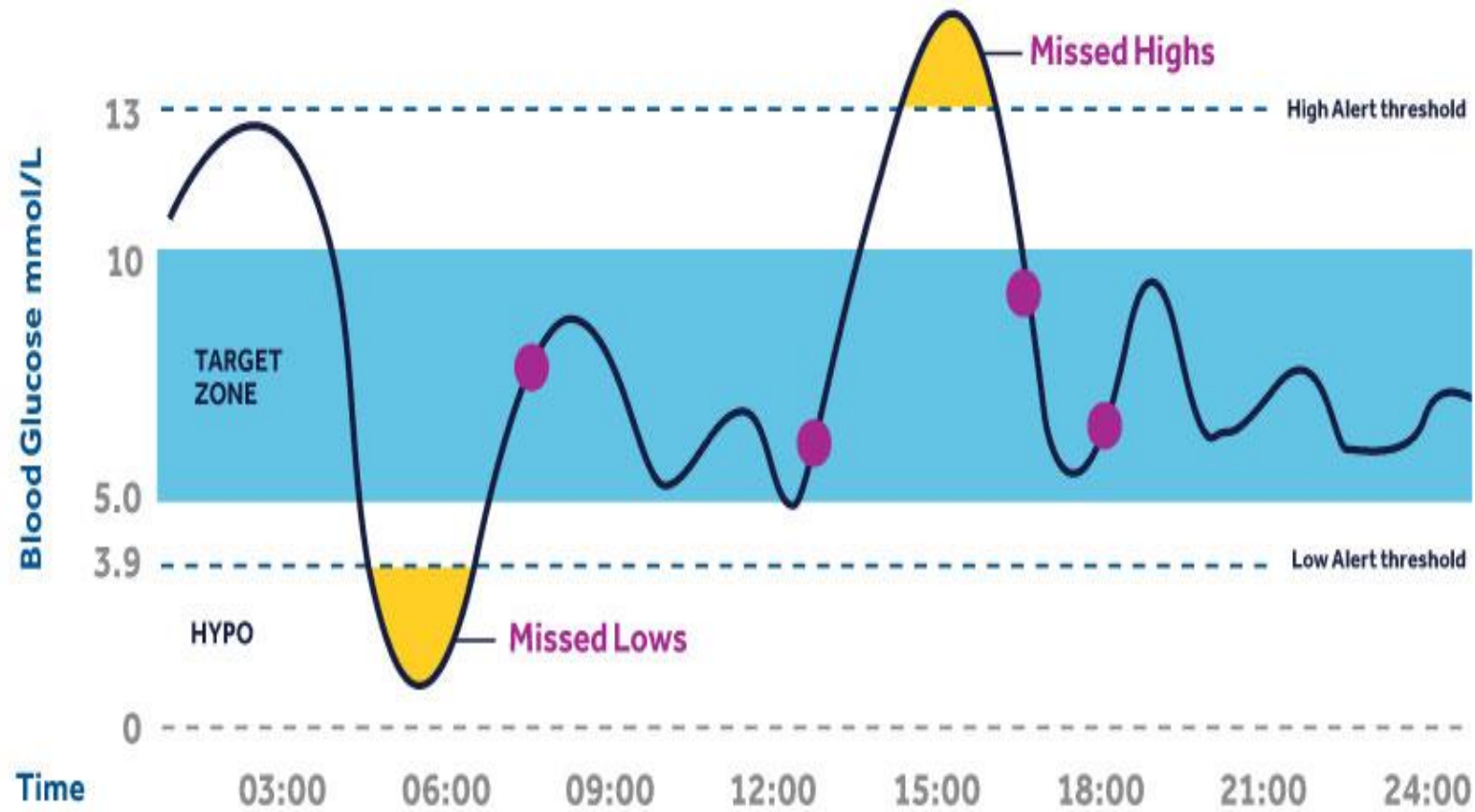
		Metformin	DPP-4 inhibitors	GLP-1 receptor agonists	SGLT2 inhibitors	SUs (second generation)	TZDs	Insulin
<b>Glucose-lowering efficacy</b>		High	Intermediate	High	Intermediate	High	High	Highest
<b>Hypoglycemia</b>						Yes		Yes
<b>Weight</b>		Neutral (potential for modest weight loss)	Neutral	Loss	Loss	Gain	Gain	Gain
<b>CV effect</b>	<b>ASCVD</b>	Potential benefit	Neutral	Benefit/neutral <sup>a</sup>	Benefit <sup>a</sup>	Neutral	Potential benefit <sup>a</sup>	Neutral
	<b>HF</b>	Neutral	Potential risk <sup>a</sup>	Neutral -benefit	Benefit <sup>a</sup>	Neutral	Increased risk	Neutral
<b>Adverse events</b>		GI effects, potential B12 deficiency	Joint pain, potential acute pancreatitis	GI effects, potential acute pancreatitis, thyroid C-cell tumors	Genitourinary infection, volume depletion,	GI effects, increased risk of CV mortality	Congestive HF, fluid retention, fractures	Injection site reactions

<sup>a</sup> Depending upon specific agent; always check the product label.  
 ASCVD, atherosclerotic cardiovascular disease; DKA, diabetic ketoacidosis; HF, heart failure.



# CGM DATA VERSUS

# FINGERPRICKS



# Pumps *PLUS* CGM *automated insulin delivery*



# Summary

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- You can now *Treat Diabetes*, not just *Chase Glucose*
- SGLT2s and GLP's; GLP/GIPs offer simplicity in treatment, Glucose improvement with additional weight loss and very low hypoglycemia risk
- SGLT2s and GLP's also offer Renal, Cardiac, and Stroke protection. (The big uglies if diabetes is out of control long term)
- Help your PWD get the best they can afford: Check the formulary, other resources. It might require a PA
- New technology is empowering. CGMs, Pumps, communication back and forth...
- Ultra long acting insulins are like I-70 through W Ks.
- Plus: Less hypoglycemia, intra patient, intra day variability
- **You Can Do It!**