

Sweet Success:

Expert Tips in Using New & Old Diabetes Medications

There's MORE
new stuff to
know?



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King George , Virginia

Suffering from the conference coma?



My Industry Associations

- **Novo Nordisk** – advisor and speaker (obesity only)
- **Astra Zeneca** – T2DM advisor
- **Medtronic** – Insulin pumps and continuous glucose monitoring (outpatient and inpatient)

Objectives

- Analyze and compare AACE & ADA diabetes guidelines in light of the primary care setting.
- Identify appropriate glycemic target goals of patients.
- Describe appropriate use of the newest oral and injectable anti-hyperglycemic agents.
- Discuss how selected diabetes meds are more safely and effectively used together.

Recent Diabetes Rx Innovations

- Improving incretins
- New class: SGLT2 inhibitors
- New insulin varieties *
- Needleless systems **
- TECHNOLOGY! **

**There she is...she has diabetes,
HLD, HTN, BMI 32 and BG 230,
A1C 8.1...now what?**



So many drug choices...



**So many treatment
algorithms**

LIFESTYLE MODIFICATION

(Including Medically Assisted Weight Loss)

Entry A1c < 7.5%

Entry A1c ≥ 7.5%

Entry A1c > 9.0%

MONOTHERAPY*

- ✓ Metformin
- ✓ GLP-1 RA
- ✓ SGLT-2i
- ✓ DPP-4i
- ✓ AGi
- ⚠ TZD
- ⚠ SU/GLN

If not at goal in 3 months proceed to Double Therapy

DUAL THERAPY*

- ✓ GLP-1 RA
 - ✓ SGLT-2i
 - ✓ DPP-4i
 - ⚠ TZD
 - ⚠ Basal Insulin
 - ✓ Colesevelam
 - ✓ Bromocriptine QR
 - ✓ AGi
 - ⚠ SU/GLN
- MET**
or other 1st-line agent
- +

If not at goal in 3 months proceed to Triple Therapy

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 - ⚠ Basal insulin
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 - ✓ AGi
 - ⚠ SU/GLN
- MET**
or other 1st-line agent + 2nd-line agent
- +

If not at goal in 3 months proceed to or intensify insulin therapy

SYMPTOMS

NO

YES

DUAL Therapy

OR

TRIPLE Therapy

INSULIN ± Other Agents

ADD OR INTENSIFY INSULIN

Refer to Insulin Algorithm

LEGEND

- ✓ Few adverse events or possible benefits
- ⚠ Use with caution

* Order of medications listed represents a suggested hierarchy of usage

PROGRESSION OF DISEASE →

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NO

DUAL Therapy

OR

TRIPLE Therapy

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INSULIN ± Other Agents

ADD OR INTENSIFY INSULIN

Refer to Insulin Algorithm

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PROGRESSION OF DISEASE →

ADA Guidelines

Mono-therapy

Efficacy[†]
Hypo risk
Weight
Side effects
Costs^{*}

Healthy eating, weight control, increased physical activity, and diabetes education

Metformin

high
low risk
neutral / loss
GI / lactic acidosis
low

If A1C target not achieved after ~3 months of monotherapy, proceed to 2-drug combination (order not meant to denote any specific preference—choice dependent on a variety of patient- and disease-specific factors):

Dual therapy[†]

Efficacy[†]
Hypo risk
Weight
Side effects
Costs^{*}

Metformin +	Metformin +	Metformin +	Metformin +	Metformin +	Metformin +
Sulfonylurea	Thiazolidinedione	DPP-4 inhibitor	SGLT2 inhibitor	GLP-1 receptor agonist	Insulin (basal)
high efficacy moderate risk gain weight hypoglycemia low costs	high efficacy low risk gain weight edema, HF, fxs low costs	intermediate efficacy low risk neutral weight rare side effects high costs	intermediate efficacy low risk loss weight GU, dehydration high costs	high efficacy low risk loss weight GI high costs	highest efficacy high risk gain weight hypoglycemia variable costs

If A1C target not achieved after ~3 months of dual therapy, proceed to 3-drug combination (order not meant to denote any specific preference—choice dependent on a variety of patient- and disease-specific factors):

Triple therapy

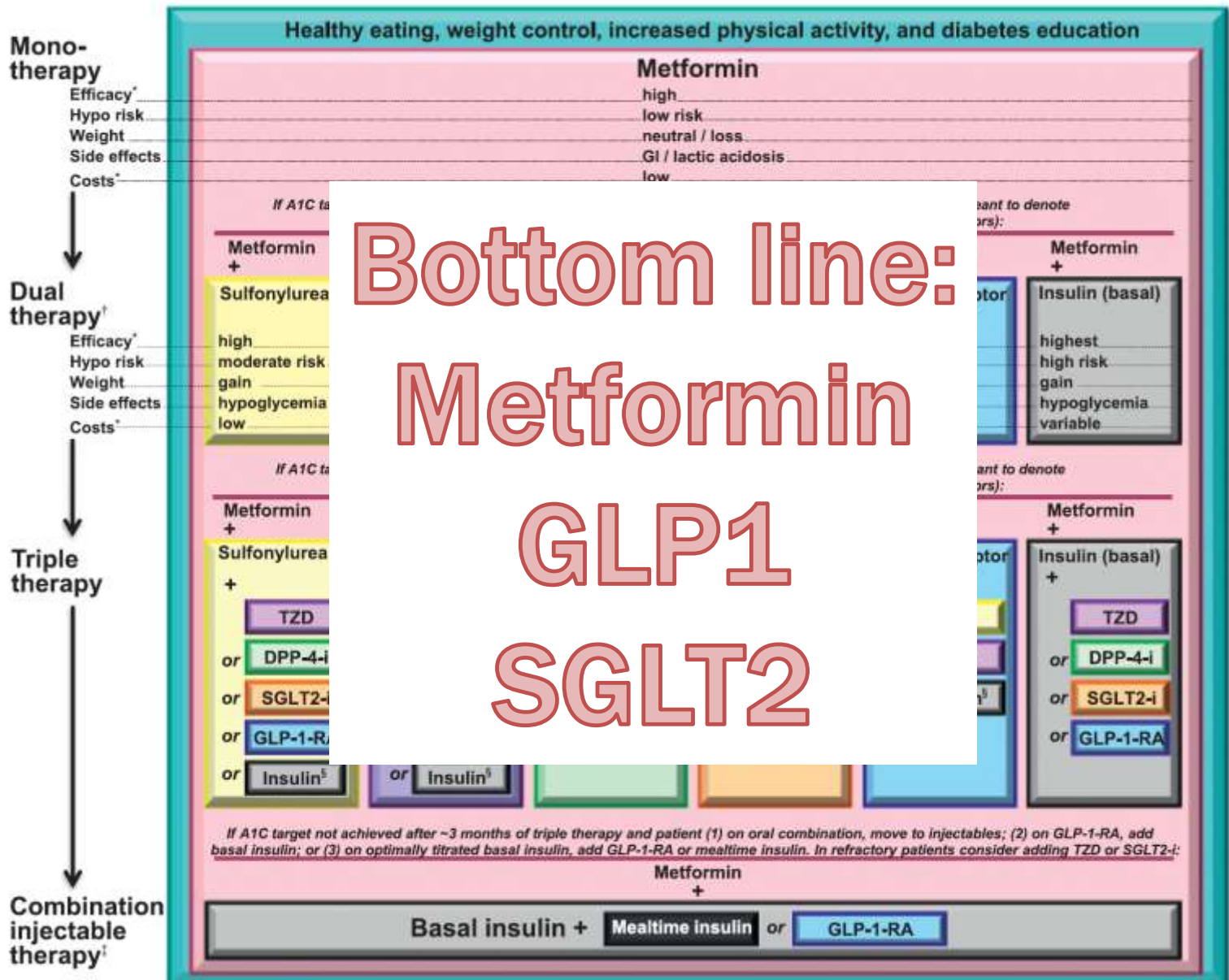
Metformin +	Metformin +	Metformin +	Metformin +	Metformin +	Metformin +
Sulfonylurea + TZD or DPP-4-i or SGLT2-i or GLP-1-RA or Insulin ⁵	Thiazolidinedione + SU or DPP-4-i or SGLT2-i or GLP-1-RA or Insulin ⁵	DPP-4 inhibitor + SU or TZD or SGLT2-i or Insulin ⁵	SGLT2 inhibitor + SU or TZD or DPP-4-i or Insulin ⁵	GLP-1 receptor agonist + SU or TZD or Insulin ⁵	Insulin (basal) + TZD or DPP-4-i or SGLT2-i or GLP-1-RA

If A1C target not achieved after ~3 months of triple therapy and patient (1) on oral combination, move to injectables; (2) on GLP-1-RA, add basal insulin; or (3) on optimally titrated basal insulin, add GLP-1-RA or mealtime insulin. In refractory patients consider adding TZD or SGLT2-i:

Combination injectable therapy[†]

Metformin +
Basal insulin + Mealtime insulin or GLP-1-RA

ADA Guidelines



Kessler's Diabetes Rx Points

- **Safety first**
 - Safe target, safe drug—*think co-morbidities*
 - Can't treat blind—need pt to give you data
- Timing is everything
- Does it cause weight gain???
- **Always** think....BASAL first then Prandial sugar!!
- All diabetes agents will affect one or both of these

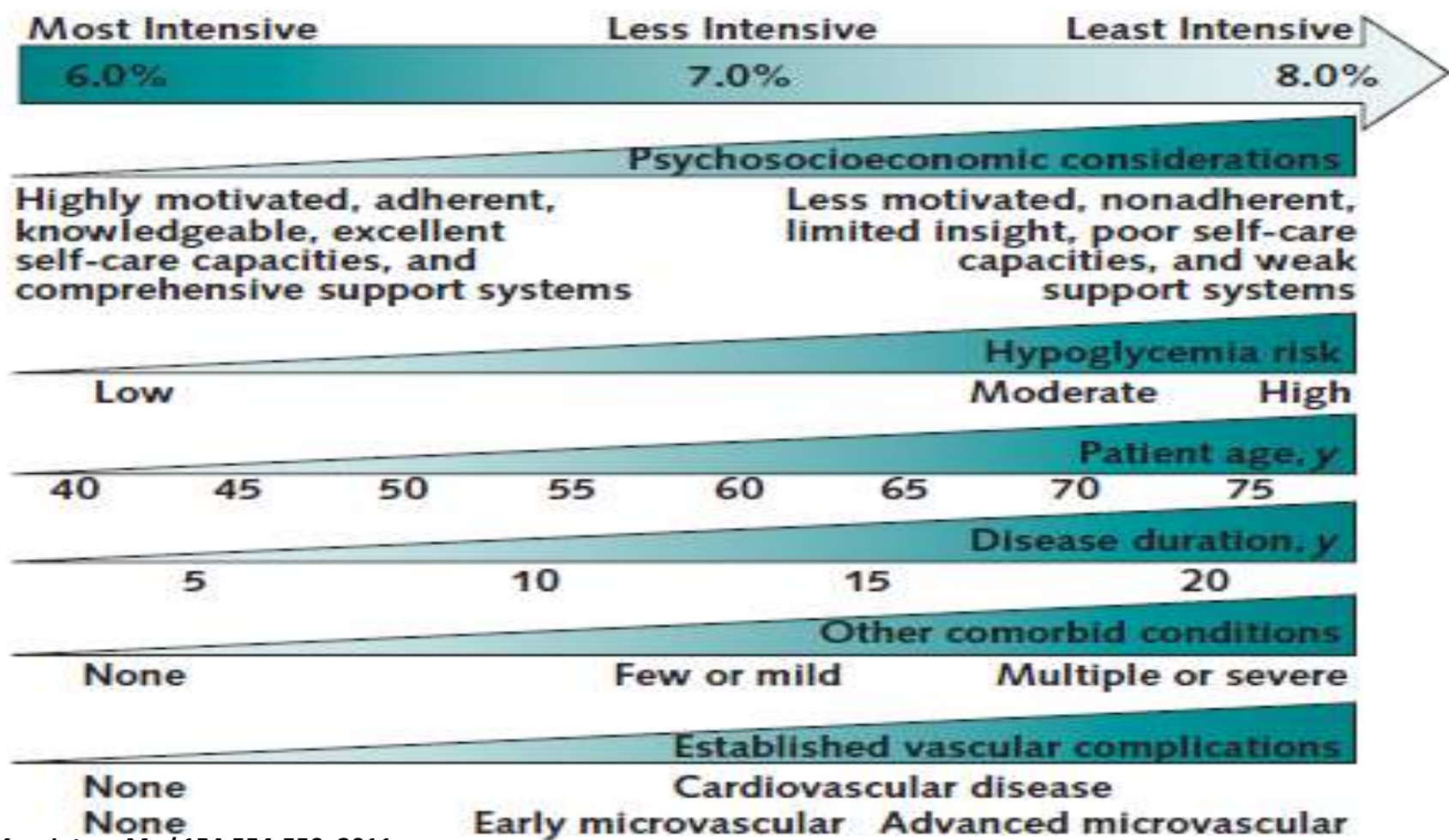


So what blood
A1C levels
should we aim
at?

FLEX that A1C!!!!

Individualizing Glycemic Targets in Type 2 Diabetes Mellitus: Implications of Recent Clinical Trials

Faramarz Ismail-Beigi, MD, PhD; Etie Moghissi, MD; Margaret Tiktin, NP; Irl B. Hirsch, MD; Silvio E. Inzucchi, MD; and Saul Genuth, MD



ADA 2015 Recommended A1C Goals

< 8%

- History of severe hypoglycemia
- Advanced micro- or macrovascular complications
- Extensive comorbid conditions,
- Limited life expectancy, or
- Long-standing diabetes where the general goal is difficult to attain despite active management

American Diabetes Association. *Diabetes Care*. 2015;38:S1-S93.

http://care.diabetesjournals.org/content/suppl/2014/12/23/38.Supplement_1.DC1/January_Supplement_Combined_Final.6-99.pdf. Accessed April/2015.

ADA 2015 Recommended A1C Goals

< 7%

- Most non-pregnant adults

< 6.5%

- Without significant hypoglycemia or other high risk issues
- Short duration of diabetes
- T2DM treated with lifestyle or metformin only
- Long life expectancy
- No significant CVD

American Diabetes Association. *Diabetes Care*. 2015;38:S1-S93.

http://care.diabetesjournals.org/content/suppl/2014/12/23/38.Supplement_1.DC1/January_Supplement_Combined_Final.6-99.pdf. Accessed April/2015.

**Why don't patients attain
their glycemic goals?**

Reality Check



NOTE TO SELF

Take meds

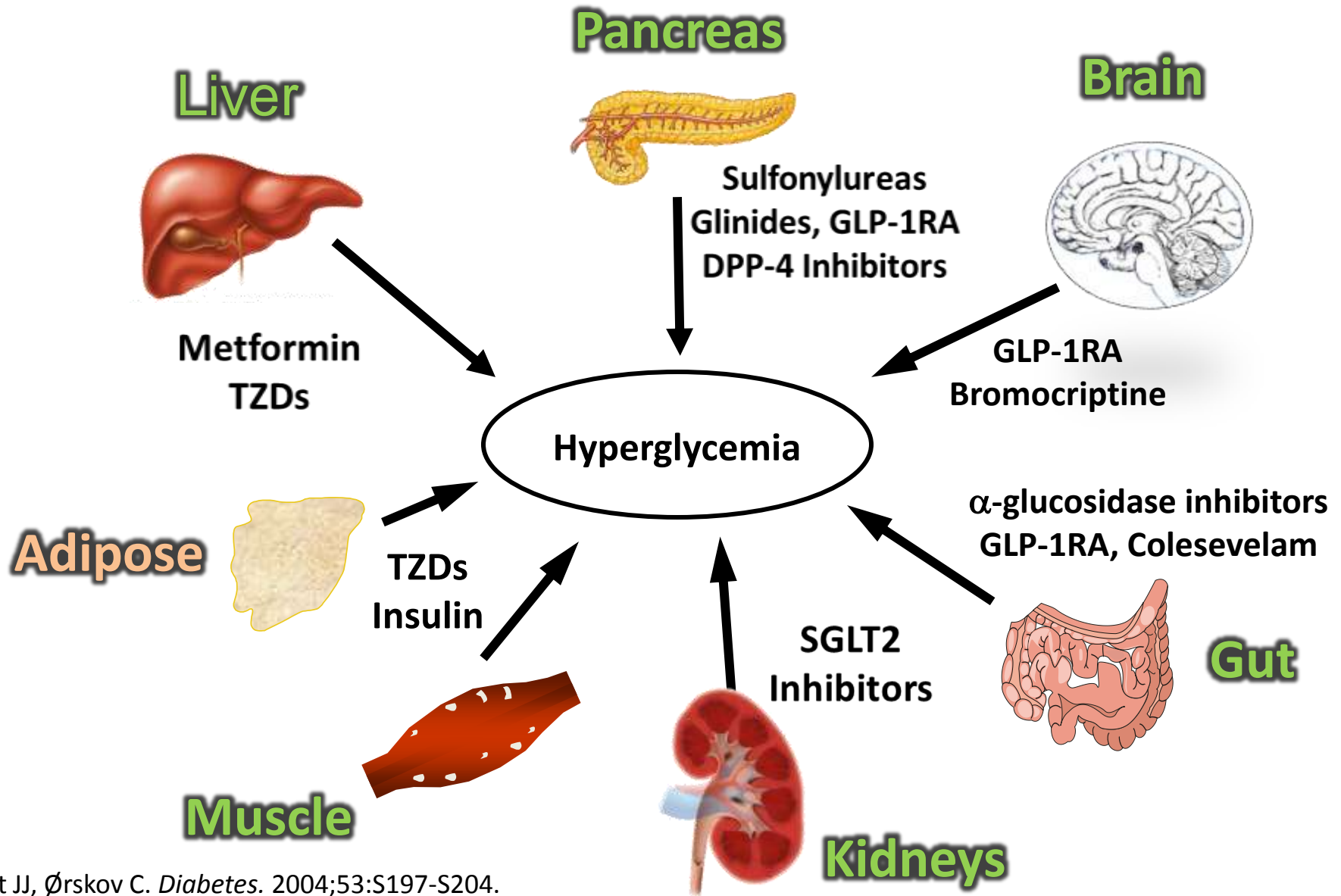
Finding Diabetes Drugs To...

- Increase insulin output
- Decrease insulin resistance
- Decrease hepatic glucose output
- Improve GI glucose metabolism
- Increase glucose excretion

Bennett W et al. Comparative effectiveness and safety of medications for type 2 diabetes: an update including new drugs and 2-drug combinations. *Annals of internal medicine*; 2011 May 3;154(9):602-13.

Qaseem V et al. Oral Pharmacologic Treatment of Type 2 Diabetes Mellitus: A Clinical Practice Guideline From the American College of Physicians. *Annals of internal medicine*; 2012 Feb 7;156(3):218-231.

Organs Involved with Glucose Homeostasis



Holst JJ, Ørskov C. *Diabetes*. 2004;53:S197-S204.

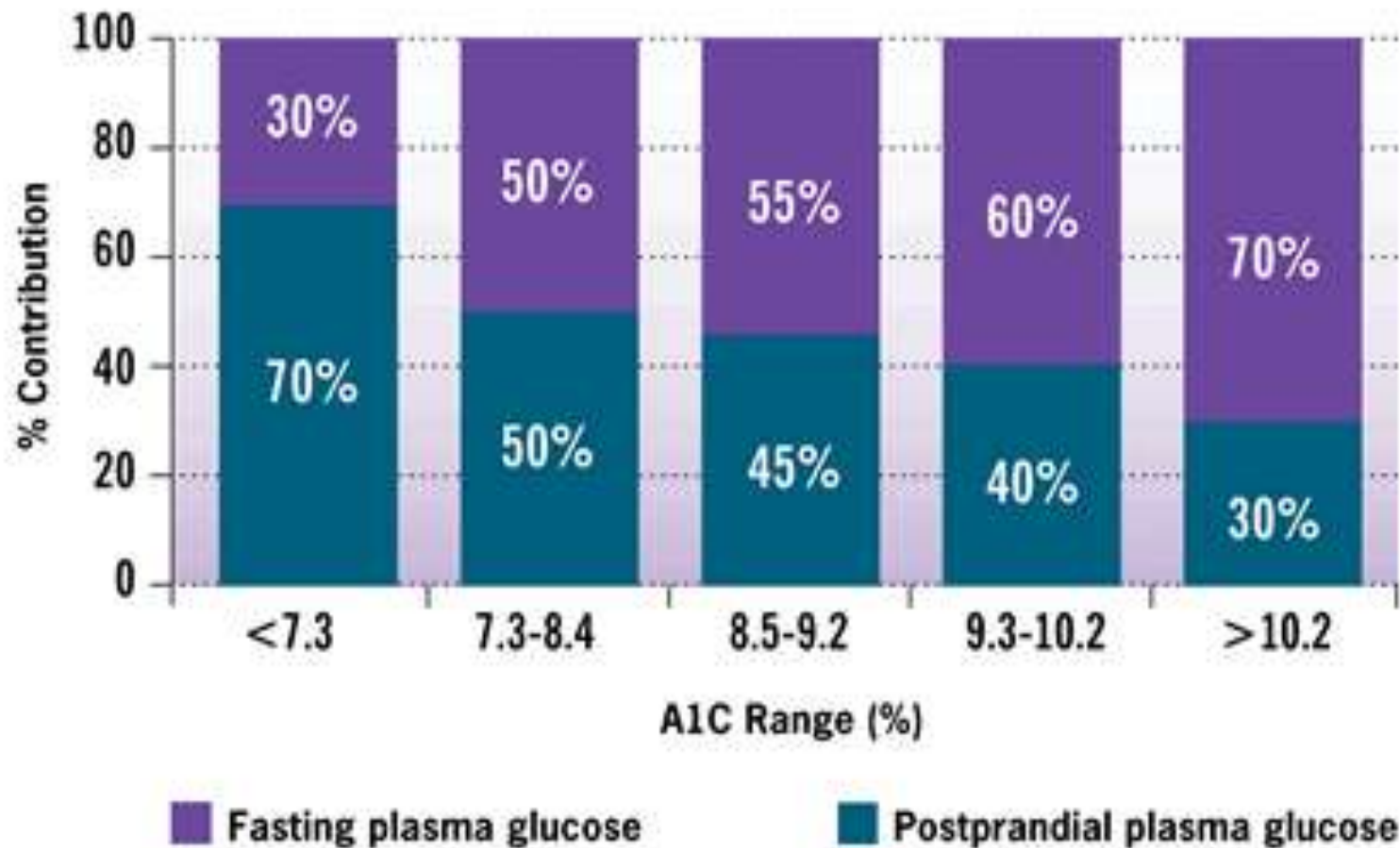
Lebovitz HE. *Diabetes Rev*. 1999;7:139-153.

Courtesy: Lucia Novak NP

What Sugars Do We Attack?

- Basal sugars
(hepatic/fasting)
- Prandial sugar (prandial)

POSTPRANDIAL AND FASTING GLUCOSE CONTRIBUTION TO A1C



Post-prandial sugars are a big target!

So What Do We Have?

- Insulin sensitizers

- Biguanides

- Metformin (short & long form)

- Thiazolidinediones (TZDs)

- Pioglitazone (Actos)
 - Rosiglitazone (Avandia)

Endogenous Hearing aids!

Metformin

- Renal clearance—risk of lactic acidosis in CKD
- Reduction of GI problems with XR version
- *Can be used in low doses in patients with GFR 30-60 ml/min*
 - Avoid if GFR < 30 ml/min
 - But should we avoid if serum creatinine...?
 - >1.5 in men
 - >1.3 in women
 - Hmmmm....maybe not

More benefits?

So many combos!!

Thiazolidinediones (TZDs)

- Bad raps?
 - Rosiglitazone - CV risk
 - Pioglitazone – bladder cancer
- Fine to use in CKD—no dose adjustment needed
- Associated with weight gain
- Associated with fluid retention (worry re: CHF)
- *Concern about increased bone fractures*
- *May potentiate CKD-related bone disease?*
- **Can give 15 mg tri weekly only**

So What Do We Have?

- Secretagogues— *release insulin*
 - **Sulfonylureas**
 - Glyburide (Glynase), glipizide (Glucotrol), glimeperide (Amaryl)*
 - Basal and prandial support
 - **Meglitinide analogues** (*fast release*)
 - Repaglinide (Prandin)*, nateglinide (Starlix)
 - Prandial support

Insulin Secretagogues

Cheap

- **Sulfonylureas**
 - Vary in metabolism & elimination
 - Tips for use in CKD & ischemic heart disease
 - Hypoglycemia risk!! **Must feed!**
(*prandial/basal*)
 - Avoid glyburide in ischemic heart & CKD
 - Decrease glimeperide to 1 mg in CKD 3-5
 - Less dose adjusting with glipizide
- **Combos (with metformin and pioglitazone)**

Insulin Secretagogues

- Meglitinides (pancreas *pops*)
 - Hypoglycemia risk
 - Rapaglinide (Prandin) best in CKD
- Tips for use
- HELPS PRANDIAL

So What Do We Have?

- Glucosidase inhibitors —starch blockers
 - Acarbose, miglitol
- Difficult to treat hypoglycemia PO
- Avoid if SCr > 2 mg/dl



New “Old” Drugs

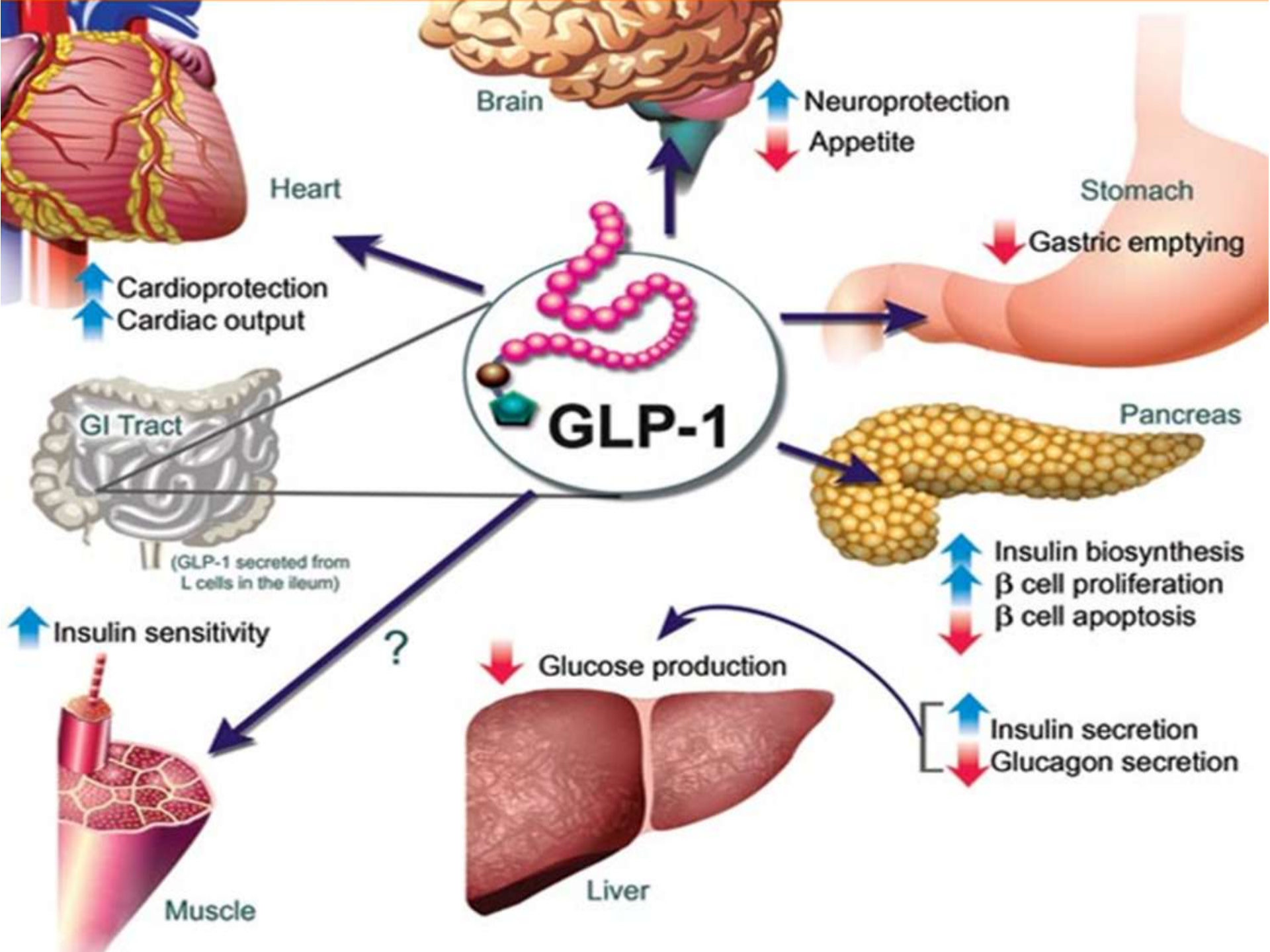
- Bile-acid sequestrants
(colesevelam, Welchol)
- Dopamine Agonists
(bromocriptine, Cycloset)

What About These DM Meds?

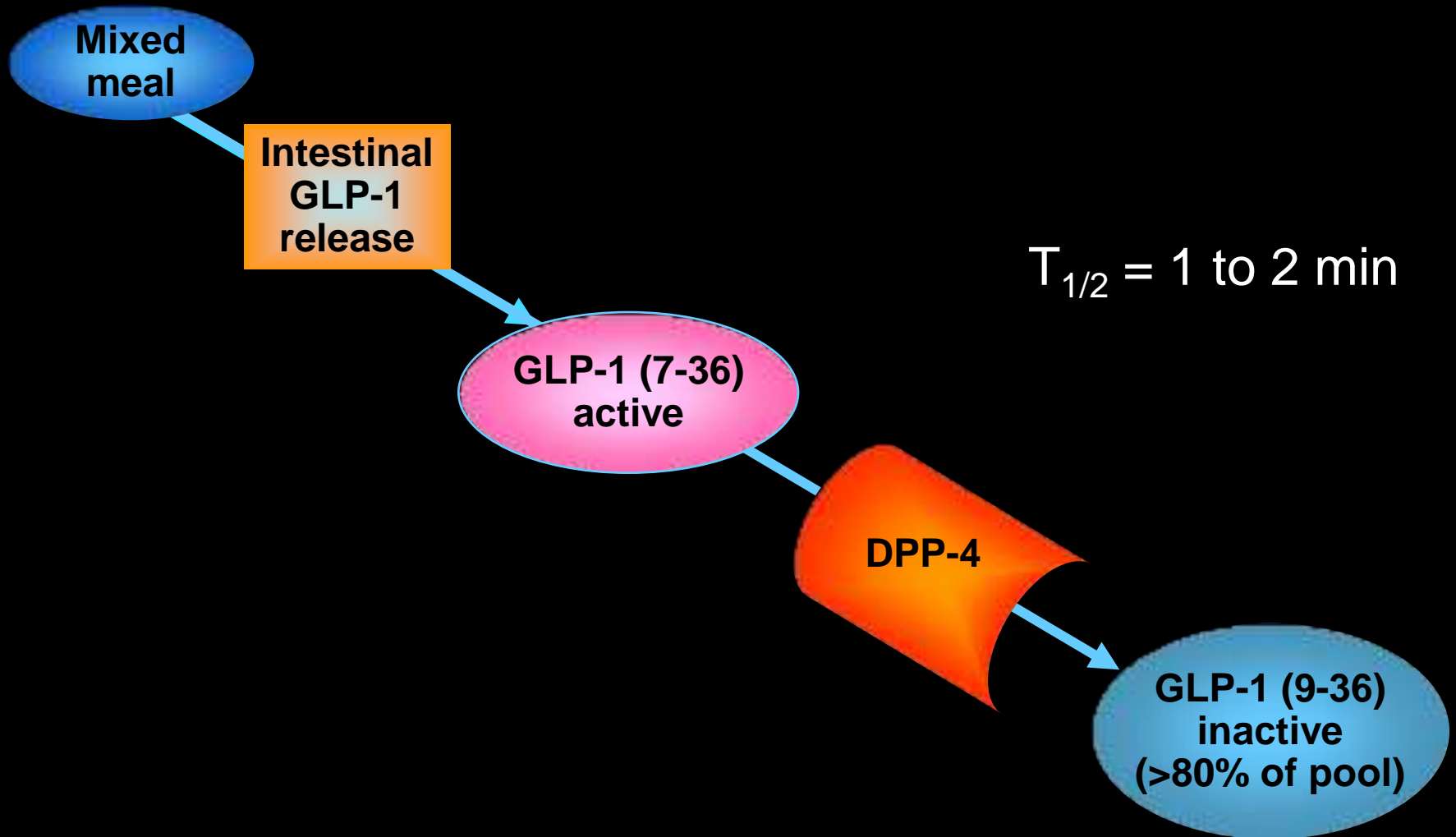
- Incretins
 - Glucagon-like peptide-1 (GLP-1)
 - DPP-4 antagonists

Works on the prandial glucose

- SGLT2 antagonists
- **Works on basal & prandial sugars**



GLP-1 Secretion and Inactivation



What Are Our Incretins?

- **Exenatide (Byetta)**
 - meal timed....bid SC
 - 5 mcg bid daily for 1 month then 10 mcg Bid
- **Bydureon** once a week SC
 - 2 mg single syringe
- **Liraglutide (Victoza) Daily*****
 - Weekly up-titrate: 0.6 mg-1.2 mg- 1.8 mg SC
- **Albiglutide (Tanzeum)** Once a week 30 mg—50 mg
- **Dulaglutide (Trulicity)** Once a week 0.75 mg-1.5 mg

GLP-1 Receptor Agonist Drugs

	Short-Acting	Long-Acting
FDA Approved Drugs	Exenatide (Byetta)	Liraglutide (Victoza) Exenatide-LAR (Bydureon) Albiglutide (Tanzeum) Dulaglutide (Trulicity)
Half-life	2–5 h	12 h–several days
Fasting BG	Modest reduction	Strong reduction
A1C	Modest reduction	Strong reduction
Postprandial hyperglycemia	Strong reduction	Modest reduction
Gastric emptying rate	Deceleration	No effect
Blood pressure	Reduction	Reduction
Body weight reduction	1–5 kg	2–5 kg

Meier JJ. *Nat Rev Endocrinol.* 2012;8(12):728-742.

Lund A, et al. *Eur J Intern Med.* 2014;25(5):407-414.

GLP-1 Products



What patients take

User Tips on GLP-1 agonists

- Weight (also think inches vs pounds)
- Caution in renal insufficiency (not use if GFR <30)
- Delayed gastric emptying issues... "pukey"
- Will need with basal drug if A1C > 9
- Pancreatitis a concern...?
- Thyroid medullary cancer: BLACK BOX
- 15% will not have good responses

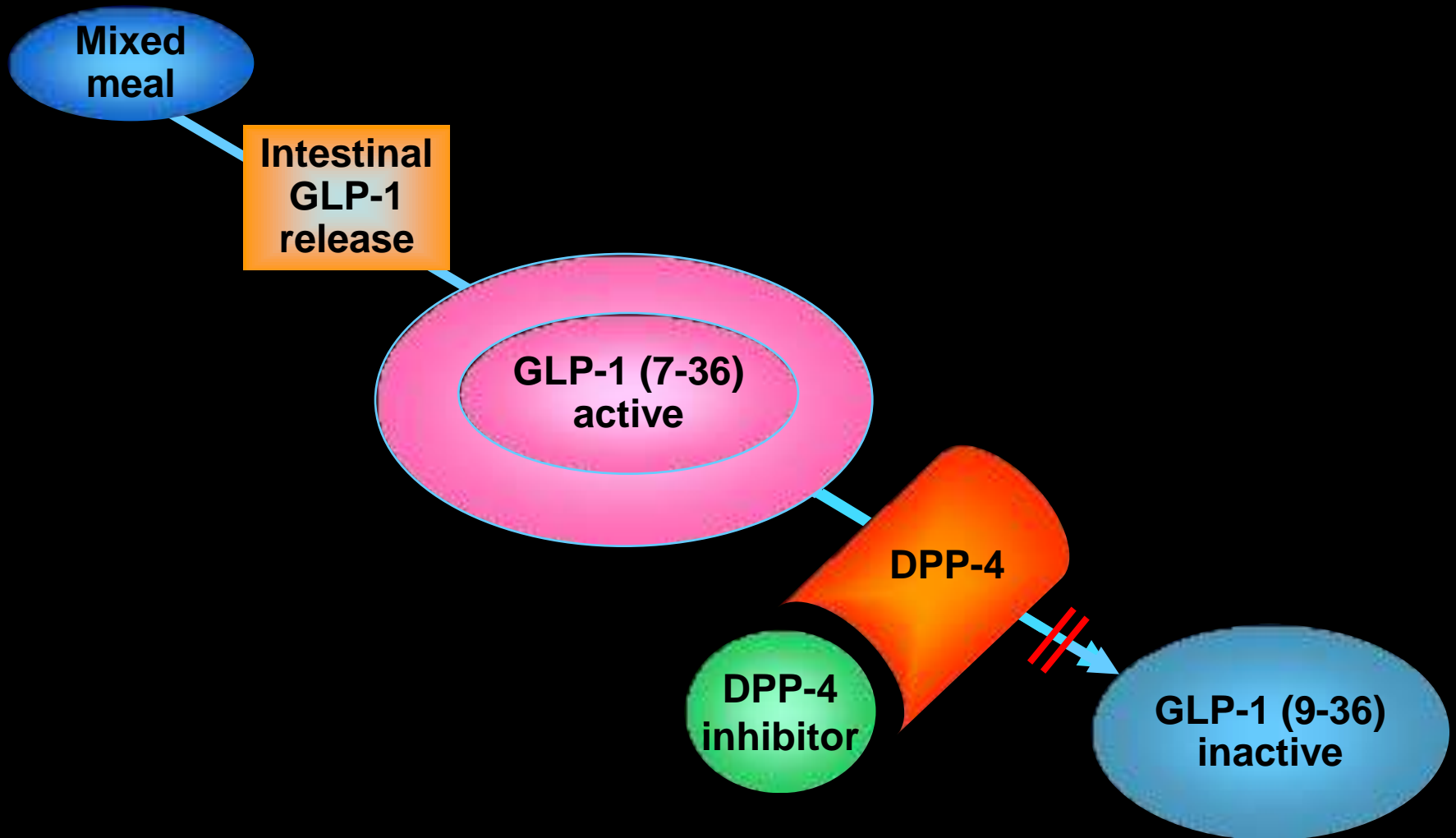
More Tips

- Can use with basal insulin, and other oral diabetes meds
- Caution with secretagogues (cut their dose at least 50%)
- Timing
- New basal insulin/GLP-1 combo approved in Europe:

More Incretins

- DPP-4 antagonists
 - Sitagliptin (Januvia, Janumet)
 - Saxagliptin (Onglyza, Kombiglyze)
 - Linagliptin (Trajenta, Jentadueto)
 - Alogliptin (Nesina)
 - Vidalgliptin (Galvus)

Inhibition of DPP-4 Increases Active GLP-1



Adapted from Rothenberg P, et al. *Diabetes*. 2000;49(suppl 1):A39.

DPP-4 Inhibitor

- Blocks enzyme that down regulates GLP-1
- *Prandial support—great in elderly*
- Sitagliptin (Januvia)
 - Renal based dosing 25, 50, 100 mg
- Saxagliptin (Onglyza)
 - 2.5 or 5 mg (P450)
- Linagliptin (Tradjenta)
 - 5 mg
- Concerns: severe rhinitis, chronic inflammatory skin issues, pancreatitis? Others?

DPP4-antagonist Considerations

- Cost
- Safety
- Half-life
- Renal/liver issues

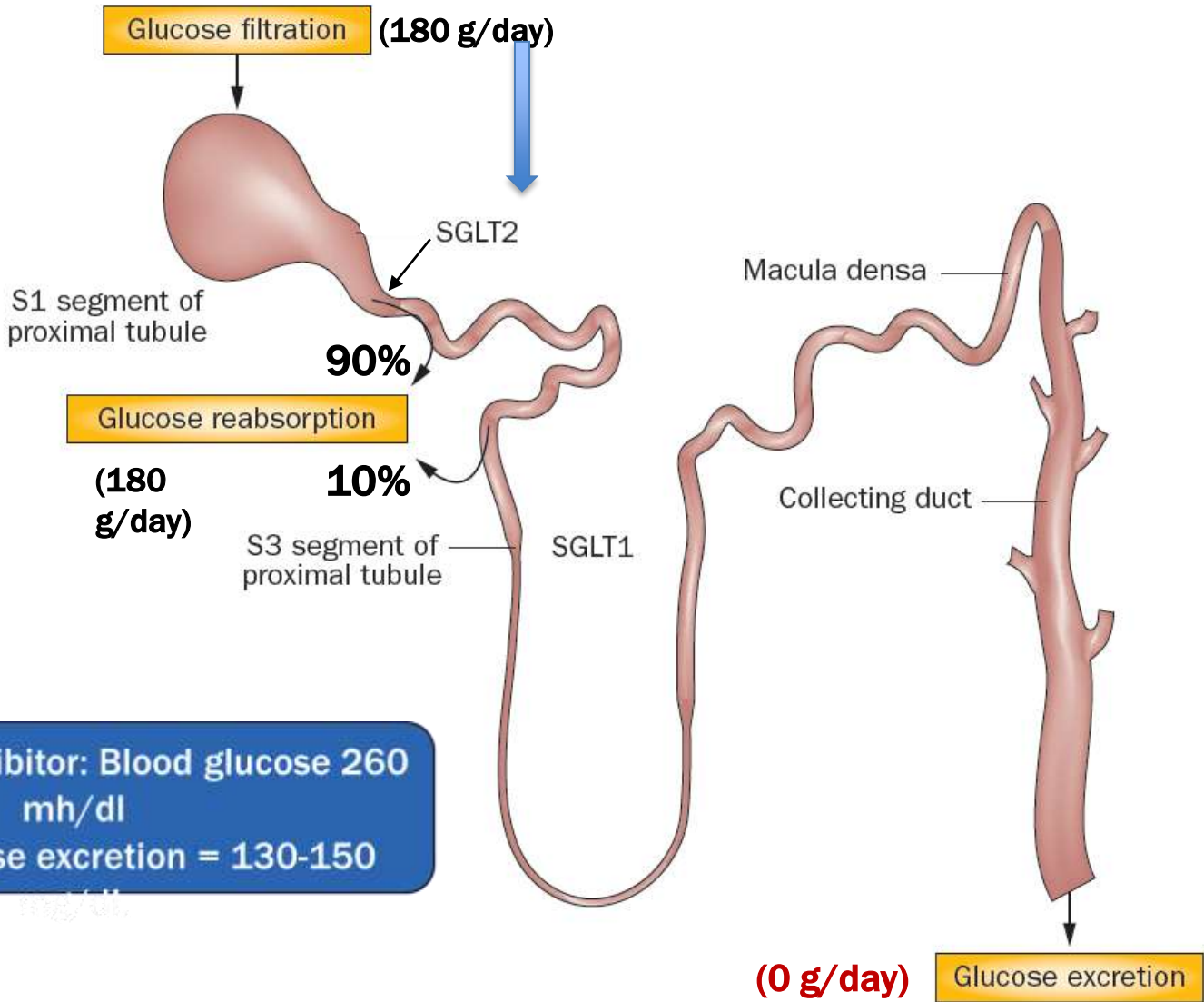


DPP-4 Antagonist Combos

- Januvia-metformin
 - Janumet
 - 50/500 or 50/1000 b.i.d. regular and XR
 - tips
- Linagliptin-metformin
 - Jentadueto
 - 2.5/500 and 2.5/1000 b.i.d
 - Wait and see—no head to head
 - Combo reportedly can drop a1c 1.5-1.7%

New combos with SGLT2 inhibitors

Glucose: From Blood to Urine



With SGLT2 Inhibitor: Blood glucose 260 mg/dl
Urinary glucose excretion = 130-150 mg/dl.

Adapted from Ferrannini E, Solini A. *Nat Rev Endocrinol.* 2012;8:495-502.

SGLT2 Inhibitors (Gliflozins)

- What do we have?
- Canagliflozin (Invokana) (Invokamet)
- Dapagliflozin (Forxiga) (Xigduo)
- Empagliflozin (Jordiance)
- *Use as add on med for type 2 DM (2nd or 3rd)*
- Promotes glucosuria & and secondary weight loss
- Low incidence of hypoglycemia
- A1C reduction of 0.5-1.5%
- Seen in combo **Basal & prandial sugars**

SGLT2 Inhibitors: Points to Consider

- Not as effective with GFR < 45
- Average 3 Kg weight loss

Adverse reactions:

- Increased genital mycotic infection
- Bacterial urinary tract infections
 - Infections were manageable (Prevention?....*Kessler tips*)
- Rare elevations in potassium
- FDA warns that SGLT2 inhibitors may lead to diabetic ketoacidosis....rare but should be alert to this...especially in T1DM

<http://www.fda.gov/Drugs/DrugSafety/ucm446845.htm>.

Ferrannini E, et al. *Diabetes Obes Metab*. 2013;15(8):721-728.

Fonseca V, et al. *J Diabetes Complications*. 2013;27:268-273.

Nauck MA, et al. *Diabetes Care*. 2011;34:2015-2022.

Stenlöf K, et al. *Diabetes Obes Metab*. 2013;15:372-382.

Wilding JPH, et al. *Diabetes Obes Metab*. 2013;15:403-409.

What about Empagliflozin?

- Similar to others
- FDA closely reviewed cardiovascular data- helps heart failure
- Pediatric trials on going ...

February 02, 2015

**U.S. FDA approves first-in-class Glyxambi®
(empagliflozin/linagliptin) tablets for adults with
type 2 diabetes**

Comparative Considerations

Drug	Availability	~A1c Reduction	Cost/30 d Varies	Hypoglycemia Risk	Weight Change
SFU/glinides	Generic*	~1.5%	\$/-\$-\$\$\$	Yes	GAIN
Metformin	Generic	1.0 – 1.5%	\$	No	Neutral
TZD	Generic	1.0 – 1.5%	\$\$	No	GAIN
AGI	Generic*	0.5 – 1.0%	\$\$	No	Neutral
DPP4-Is	Brand	0.5 – 0.8%	\$\$\$\$	No	Neutral
GLP-1 RAs	Brand	0.4 – 1.5%	\$\$\$\$	No	LOSS
Colesevelam	Brand	0.5%	\$\$\$	No	Neutral
SGLT2 inhibitors	Brand	0.5 – 1.0%	\$\$\$\$	No	LOSS



PROFILES OF ANTIDIABETIC MEDICATIONS



	MET	GLP-1 RA	SGLT-2i	DPP-4i	AGI	TZD	SU GLN	COLSVL	BCR-QR	INSULIN	PRAML
HYPO	Neutral	Neutral	Neutral	Neutral	Neutral	Neutral	Moderate/ Severe Mild	Neutral	Neutral	Moderate to Severe	Neutral
WEIGHT	Slight Loss	Loss	Loss	Neutral	Neutral	Gain	Gain	Neutral	Neutral	Gain	Loss
RENAL/ GU	Contra- indicated CKD Stage 3B,4,5	Exenatide Contra- indicated CrCl < 30	Genital Mycotic Infections	Dose Adjustment May be Necessary (Except Linagliptin)	Neutral	May Worsen Fluid Retention	More Hypo Risk	Neutral	Neutral	More Hypo Risk & Fluid Retention	Neutral
GI Sx	Moderate	Moderate	Neutral	Neutral	Moderate	Neutral	Neutral	Mild	Moderate	Neutral	Moderate
CHF	Neutral	Neutral	Neutral	Neutral	Neutral	Moderate	Neutral	Neutral	Neutral	Neutral	Neutral
CVD	Benefit	Neutral	Increased LDL	Neutral	Neutral	Neutral	?	Neutral	Safe	Neutral	Neutral
BONE	Neutral	Neutral	Neutral	Neutral	Neutral	Moderate Bone Loss	Neutral	Neutral	Neutral	Neutral	Neutral

■ Few adverse events or possible benefits
 ■ Use with caution
 ■ Likelihood of adverse effects

Then there is insulin





ALGORITHM FOR ADDING/INTENSIFYING INSULIN

START BASAL (long-acting insulin)

A1c < 8%

TDD
0.1–0.2 U/kg

A1c > 8%

TDD
0.2–0.3 U/kg

Insulin titration every 2–3 days to reach glycemic goal:

- Fixed regimen: Increase TDD by 2 U
- Adjustable regimen:
 - FBG > 180 mg/dL: add 4 U
 - FBG 140–180 mg/dL: add 2 U
 - FBG 110–139 mg/dL: add 1 U
- If hypoglycemia, reduce TDD by:
 - BG < 70 mg/dL: 10% – 20%
 - BG < 40 mg/dL: 20% – 40%

Consider discontinuing or reducing sulfonylurea after basal insulin started (basal analogs preferred to NPH)

** Glycemic Goal:

- For most patients with T2D, an A1c < 7%, fasting and premeal BG < 110 mg/dL in the absence of hypoglycemia.
- A1c and FBG targets may be adjusted based on patient's age, duration of diabetes, presence of comorbidities, diabetic complications, and hypoglycemia risk.

Glycemic Control
Not at Goal**

INTENSIFY (prandial control)

Add GLP-1 RA
or DPP4-i

Add Prandial Insulin

TDD: 0.3–0.5 U/kg
50% Basal Analog
50% Prandial Analog
Less desirable: NPH
and regular insulin or
premixed insulin

Insulin titration every 2–3 days to reach glycemic goal:

- Increase basal TDD as follows:
 - Fixed regimen: Increase TDD by 2 U
 - Adjustable regimen:
 - FBG > 180 mg/dL: add 4 U
 - FBG 140–180 mg/dL: add 2 U
 - FBG 100–139 mg/dL: add 1 U
- Increase prandial dose by 10% for any meal if the 2-hr postprandial or next premeal glucose is > 180 mg/dL
- Premixed: Increase TDD by 10% if fasting/premeal BG > 180 mg/dL
- If fasting AM hypoglycemia, reduce basal insulin
- If nighttime hypoglycemia, reduce basal and/or pre-supper or pre-evening snack short/rapid-acting insulin
- If between meal daytime hypoglycemia, reduce previous premeal short/rapid-acting insulin

FYI: New Insulin

- Long-acting Basal
 - **U-300 Glargine (Trujeo)**
 - **Degludec (Tresiba)**
 - Up to 42 hr duration –take daily
 - » (OR 2-3- x week in some T2DM)
 - APPROVED September 2015
 - **Ryzodeg 70/30** (insulin degludec/insulin aspart injection)
- It will also come in combo with liraglutide (DegLira)

What would you do for these
SWEET patients?

Josh

- 49 y/o male with known DM x 3 years refusing meds—now ready to talk to you.
- Sugar 300 mg/dl in office; no ketones
- A1C 10.2, Fructosamine 423; up urinating at night.
- BMI 29; HLD (stable), HTN (stable),
- Rx: atorvastatin, HCTZ, lisinopril, ASA
- Strong family Hx of DM
- What should you consider about this pt?

What Med(s) Would You Choose?

- Metformin
- TZD
- Sulfonylurea
- Glinide
- GLP-1 agonist
- DDP-4 antagonist
- SGLT2 inhibitor
- Basal insulin

Sam

- 60 y/o with DM x 8 years
- A1C 9; BG 220; c/o fatigue, weight gain & great hunger
- Hx: HTN, HLD, BPH, gout, hypothyroidism,
- Rx: metformin 2000 mg/d, glipizide XL 10 bid, allopurinol; levothyroxine; ceruvastatin, ASA, Lisinopril, metoprolol
- BMI 35; renal & liver function normal
- *What do you do next?*

What Med(s) Would You Choose?

- TZD
- Glinide
- GLP-1 agonist
- DDP-4 antagonist
- SGLT2 inhibitor
- Basal insulin
- *What would you do with the metformin and SU?*

Minnie

- 56 y/o AA woman new onset DM
- A1C 11.2, BG in office 410mg/dl; 10 lb wgt loss past 3 months
- BMI: 38; HLD, HTN, fibromyalgia, carpal tunnel; CKD 3A (GFR 34); IBS
- On statin, HCTZ, ACEi, ASA
- What should you consider about this pt?

What Med(s) Would You Choose?

- Metformin
- TZD
- Sulfonylurea
- Glinide
- GLP-1 agonist
- DDP-4 antagonist
- SGLT2 inhibitor
- Basal insulin

How our patients live..



If you're crazy and you know it, shake
your meds!



ROTTENCARDS

Had enough?

Death by PowerPoint

