Diabetes Education SERVICES

15 years

Pt Centered Meds Update – Special Focus on Inhaled Insulin

Beverly Dyck Thomassian, RN, MPH, BC-ADM, CDE
President, Diabetes Education Services
www.DiabetesEd.net

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Diabetes MiniSeries – Earn 7.5 CEs

Presented Live – Then recorded June 10-July 7

- Session 1 – recorded
  - Overview, Types of DM, diagnoses
- Session 2- recorded
  - Diabetes Prevention, Landmark Studies, Goals of Care
- Session 3 – recorded
  - Insulin basal bolus therapy, pattern management – From hospital to home
- Session 4 – recorded
  - New guidelines for MNT, Lower Extremity Assess
- Session 5 – Live today!
  - Meds update for Type 2, AACE algorithm, Inhaled Insulin

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Objectives – Meds and Diabetes

1. Discuss the ADA and AACE approaches to managing hyperglycemia.
2. State strategies to treat hyperglycemia from lifestyle to medications.
3. Describe insulin therapy and inhaled insulin
4. Discuss how the unique characteristics of patients determine the best approach to hyperglycemic management.
5.

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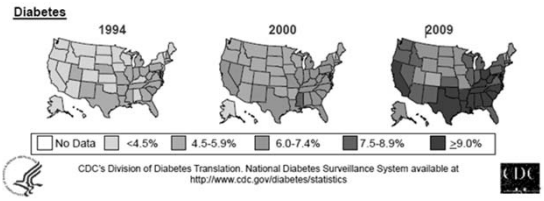
Diabetes in America 2014

- 29 million or > 9.3%
- 27% don't know they have it
- 37% of US adults have pre diabetes



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Management of Hyperglycemia in Type 2 Diabetes

American Diabetes Association. EASD

A Patient-Centered Approach Position Statement of the American Diabetes Association (ADA) and the European Association for the Study of Diabetes (EASD)

Diabetes Care 2012;35:1364–1379
Diabetologia 2012;55:1577–1596

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Type 2 – What is broken?

- **Pathogenesis of T2DM**
  - **Insulin secretory dysfunction**
  - **Insulin resistance (muscle, fat, liver)**
  - **Increased endogenous glucose production**
  - **Deranged adipocyte biology**
  - **Decreased incretin effect**
  - **Increased renal glucose reabsorption**

ADA-EASD Position Statement: Management of Hyperglycemia in T2DM

Diabetes Care **2012;35:1364–1379**
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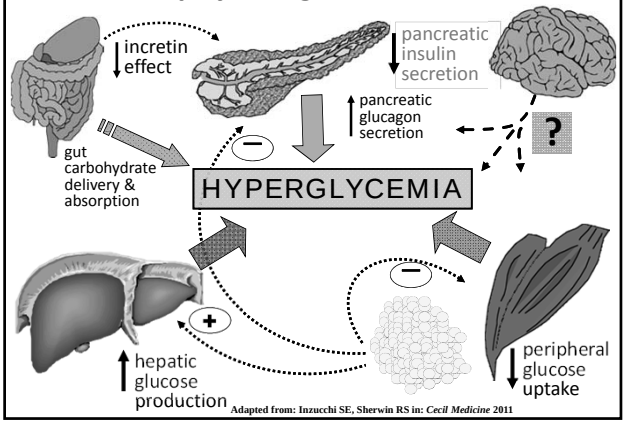
Main Pathophysiological Defects in T2DM



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

Glycemic Targets

- **HbA1c < 7.0%** (mean PG ~150-160 mg/dl [8.3-8.9 mmol/l])
  - Pre-prandial PG <130 mg/dl (7.2 mmol/l)
  - Post-prandial PG <180 mg/dl (10.0 mmol/l)
  - **Individualization** is key:
    - Tighter targets (6.0 - 6.5%) - younger, healthier
    - Looser targets (7.5 - 8.0%+) - older, comorbidities, hypoglycemia prone, etc.
  - Avoidance of hypoglycemia

ADA-EASD Position Statement: Management of Hyperglycemia in T2DM

Diabetes Care **2012;35:1364–1379**
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Patient Centered Approach

"...providing care that is respectful of and responsive to individual patient preferences, needs, and values - ensuring that patient values guide all clinical decisions."

- **Gauge patient's preferred level of involvement.**
- **Explore, where possible, therapeutic choices.**
- **Utilize decision aids.**
- **<u>Shared</u> decision making – final decisions re: lifestyle choices ultimately lie with the patient.**

ADA-EASD Position Statement: Management of Hyperglycemia in T2DM

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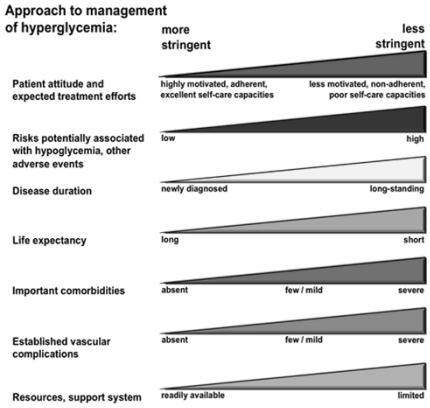

Figure 1

Diabetes Care **2012;35:1364–1379**
Diabetologia **2012;55:1577–1596**
(Adapted with permission from: Ismail-Beigi et al. *Ann Intern Med* 2011;154:554)

AACE COMPREHENSIVE DIABETES MANAGEMENT ALGORITHM 2013

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Goals for Glycemic Control

A1c ≤ 6.5%

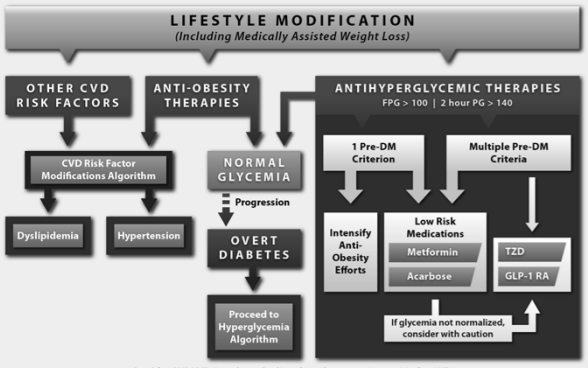
For healthy patients without concurrent illness and at low hypoglycemic risk

A1c > 6.5%

Individualize goals for patients with concurrent illness and at risk for hypoglycemia

Prediabetes Algorithm

IFG (100–125) | IGT (140–199) | METABOLIC SYNDROME (NCEP 2005)



Antihyperglycemic Therapy – 1st Step

- Lifestyle Changes
  - Weight control
  - Healthy eating
  - Activity

ADA-EASD Position Statement: Management of Hyperglycemia in T2DM

Diabetes Care 2012;35:1364–1379
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Special Consideration

- *At diagnosis, a highly motivated patient with a A1c near target (<7.5%) could try lifestyle for 3-6 months before starting metformin therapy.*

ADA-EASD Position Statement: Management of Hyperglycemia in T2DM

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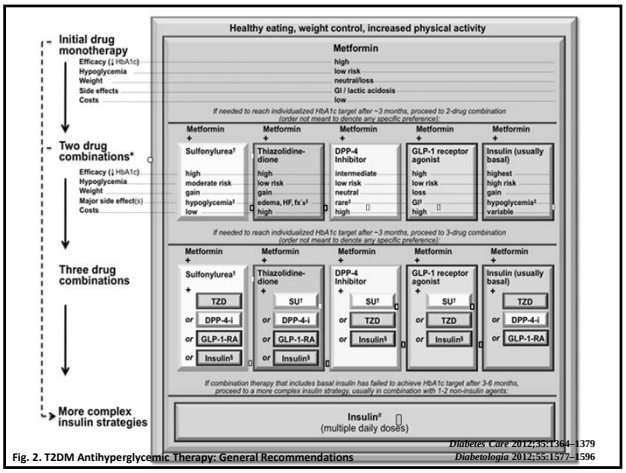

Diabetes Care **2012;35:1364–1379**
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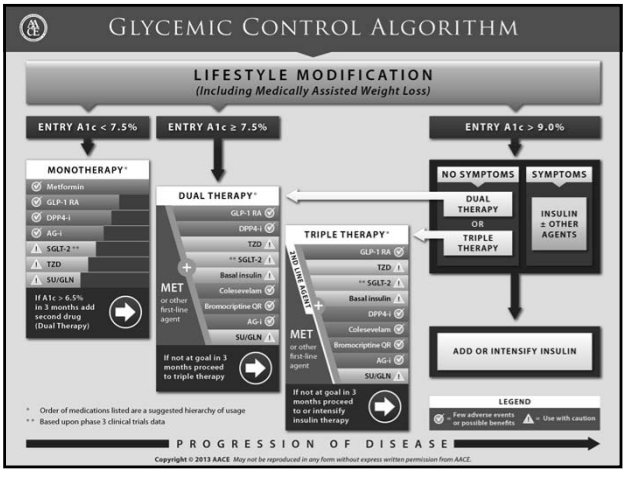
Fig. 2. T2DM Antihyperglycemic Therapy: General Recommendations



Therapeutic Options: Insulin

- **Human Neutral protamine Hagedorn (NPH)**
- **- Human Regular – Injectable or Inhaled**
- **- Basal analogues (glargine, detemir)**
- **- Rapid analogues (lispro, aspart, glulisine)**
- **- Pre-mixed varieties**

ADA-EASD Position Statement: Management of Hyperglycemia in T2DM

Diabetes Care **2012;35:1364–1379**
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Insulin PocketCard™ Diabetes Education SERVICES

Action		Insulin Name	Onset	Peak	Effective Duration	Considerations
Bolus	Rapid Acting Analogs	Aspart (Novolog)	5 - 15 min	30 - 90 min	< 5 hrs	**Bolus** insulin lowers after-meal glucose. Efficacy reflected in post-meal BG. **Basal** insulin controls BG between meals and HS. Efficacy reflected in fasting BG. **Side effects:** hypoglycemia, weight gain. **Typical dosing** range: 0.5–1.0 units/kg body wt/day. Discard opened insulin vials after 28 days.
		Lispro (Humalog)				
		Glulisine (Apidra)				
	Short Acting	Regular	30 - 60 min	2 - 3 hrs	5 - 8 hrs	
Basal	Intermediate	NPH	2 - 4 hrs	4 - 10 hrs	10 - 16 hrs	
	Long Acting	Detemir (Levemir)	3 - 8 hrs	No peak	6 - 24 hrs	
		Glargine (Lantus)	2 - 4 hrs	No peak	20 - 24 hrs	
Bolus + Basal	Intermediate + rapid	Novolog® Mix 70/30 70/30 = 70% NPA + 30% aspart	5 - 15 min	Dual peaks	10 - 16 hrs	
		Humalog® Mix 75/25 = 75% NPL + 25% lispro 50/50 = 50% NPL + 50% lispro				
	Intermediate + short	Combo of NPH + Reg 70/30 = 70% NPH + 30% Reg 50/50 = 50% NPH + 50% Reg	30 - 60 min	Dual peaks	10 - 16 hrs	

Adapted from American Association of Clinical Endocrinologists Guidelines 2007. Because insulin action times can vary with each injection, time periods listed here are general guidelines only; please consult prescribing information for details.

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Bolus Insulins
(½ of total daily dose ÷ meals)

Name	Onset	Peak Action
Lispro (Humalog)	15-30 min	1-1.5 hrs
Aspart (NovoLog)		
Glulisine (Apidra)		
Afrezza (Inhaled)	15 min	1 hr
Regular	30 mins	2-4 hrs

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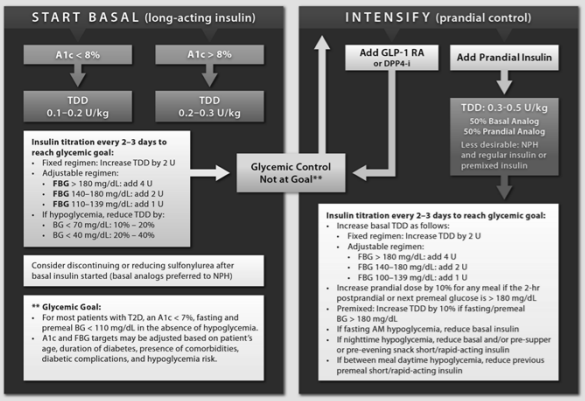
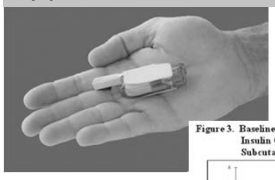
Algorithm for Adding/Intensifying Insulin



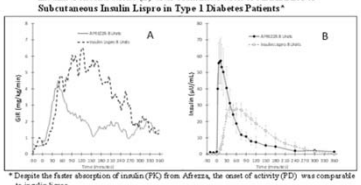
Afrezza – Inhaled Insulin – Approved 2014 – Type 1 or 2



afrezza

Only studied in adults over 18
Not indicated for pregnancy, while breastfeeding

Figure 3. Baseline-Corrected Glucose Infusion Rate (A) and Baseline-Corrected Serum Insulin Concentrations (B) after Administration of AFREZZA or Subcutaneous Insulin Lispro in Type 1 Diabetes Patients*



* Despite the faster absorption of insulin (PK) from Afrezza, the onset of activity (PD) was comparable to insulin lispro.

PocketCard includes Inhaled Insulin

A Diabetes PocketCard™ from Diabetes Education Services | DiabetesEd.Net

Inhaled Insulin

Action	Insulin Name	Dose Range	Onset	Peak	Duration	Considerations
Bolus – Rapid-acting	Afrezza Inhaled regular human insulin	4 and 8 unit cartridges before meals	15 mins	1 hr	3 hrs	Assess lung function before starting. Avoid in chronic lung disease—bronchospasm risk. Side effects: hypoglycemia, cough, throat irritation.

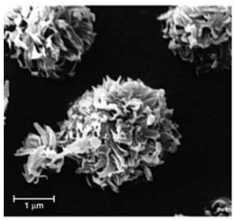
Injectables That Lower Glucose

Class/Main Action	Name	Dose Range	Considerations
GLP-1 Agonist "Incretin Mimetic" • Increases insulin release with food • Slows gastric emptying • Promotes satiety • Suppresses glucagon	exenatide (Byetta)	5 - 10 mcg BID (renally excreted)	**Side effects for all:** Nausea, vomiting, weight loss, injection site reaction. Report signs of acute pancreatitis (severe abdominal pain, vomiting), stop med. **Black box:** liraglutide,exenatide XR, and albiglutide: Thyroid C-cell tumor warning (avoid if family history of medullary thyroid cancer; notify MD of hoarseness, throat lump).
	exenatide (XR) extended release (Bydureon)	2mg 1x a week (renally excreted)	
	liraglutide (Victoza)	0.6 mg daily for 1 wk 1.2 mg daily for 1 wk then 1.8 mg daily (max dose)	
Lowers A1c 0.5 – 1.6%. Wt loss of – 3lbs	albiglutide (Tanzeum)	30 - 50 mg 1x a week pen injector	
Amylin Mimetic • Slows gastric emptying • Supresses glucagon • Promotes satiety • Lowers A1c 0.5 – 1%.	pramlintide (Symlin)	Type 1: 15 - 60 mcg; Type 2: 60 - 120 mcg immediately before major meals	For Type 1 or 2 on insulin. Prevent hypoglycemia, decrease insulin dose when starting pramlintide. **Black box** warning: severe hypoglycemic risk 3 hrs post injection. Side effects: nausea, wt loss.

The information listed here are general guidelines only; please consult prescribing information for details.

Steps, Cost, Terms

- 1st step – FDA approved. Will take time to produce, market and distribute
- Pricing –similar pricing as pens ~ $300 a month
- Afrezza is regular human insulin in powder form using Technosphere technology.
- Referred to as TI in papers – "Technosphere Insulin"



Afrezza Dosing and Considerations

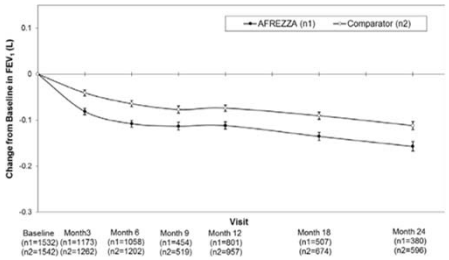
- Bolus regular insulin – inhaled before meals
- Dosing: 4 and 8 unit cartridges
  - Convert with 1:1 ratio to existing insulin dose
- Lung function test before start (FEV1)
  - Not for pts w/ chronic lung issues
    - Asthma, COPD, history of lung cancer, smokers
    - Can cause acute bronchospasm – Black box warning
- Side effects:
  - Hypoglycemia, sore throat, cough
  - Less hypoglycemia than injected insulin

Lung function

- Lung function diminishes over first 3 months and then stabilizes (in 2 yr study)
- Measured by Forced Expiratory Volume (FEV1)
- Measure lung function with Incentive Spirometry at baseline, 6 months and yearly
- If FEV1 declines by more than 20%, consider stopping Afrezza
- Not tested on smokers
- Enhanced absorption for those on albuterol

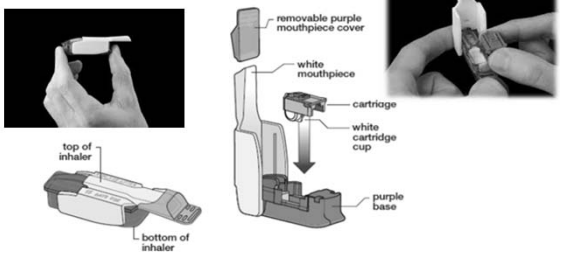
Lung function – Pts on Afrezza compared to pts on oral meds

Figure 2. Mean (+/-SE) Change in FEV_1 (Liters) from Baseline for Type 1 and Type 2 Diabetes Patients



Afrezza Inhaler

Know your AFREZZA® inhaler:



Replace inhaler every 15 days – Do not wash

Afrezza– Storage and Terms

- Storage:
  - Refrigerated - Not in use and sealed – until expires
  - Foil package at room temp – use within 10 days
  - Once strips opened, good for 3 days

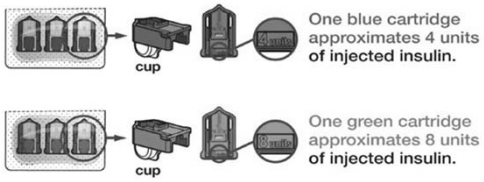
1 foil package

2 blister cards per package (5 strips per blister card)

3 cartridges per strip

Afrezza – Foil Packages Contain 30 cartridges – Use w/in 10 days

There are two strengths of AFREZZA® cartridges:

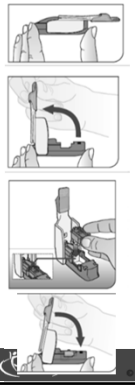


One blue cartridge approximates 4 units of injected insulin.

One green cartridge approximates 8 units of injected insulin.

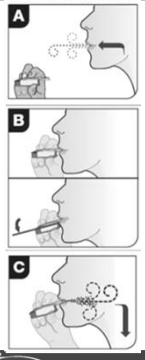
Let insulin cartridges and inhaler sit at room temp for 10 minutes before using

Afrezza – Loading Cartridge into device



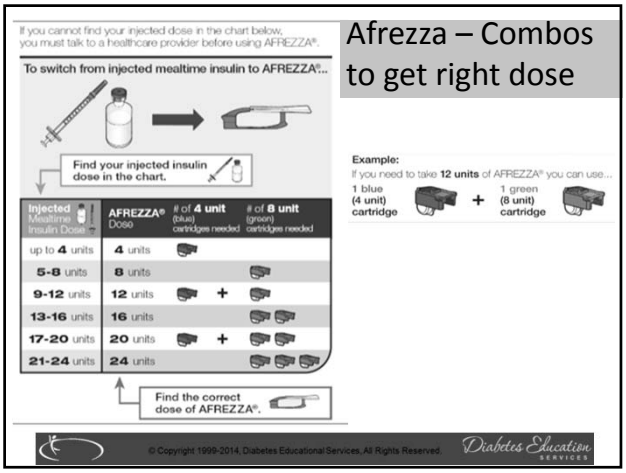
- Hold inhaler level
- Open inhaler by lifting white mouthpiece
- Hold insulin cartridge with cup facing down.
- Place cartridge inside and close lid. Keep level.
- Make sure cartridge has been at room temp for 10 minutes

Afrezza – Proper Inhale Technique



- Exhale
- Position inhaler in mouth (take off cover)
- Tilt inhaler down toward chin, keep head level
- Inhale deeply and hold breath for as long as comfortable
- Remove cartridge
- Replace cover

Afrezza – Combos to get right dose



Sample situations - Pt on….

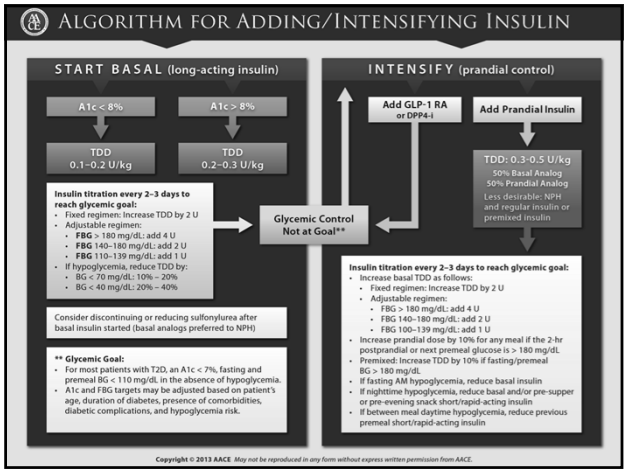
- 7 units Humalog at meals, 20 u Lantus at hs
- 5 units regular break, dinner, 10 units detemir
- 10 units apart at meals, 30 Lantus
- Carb counts – 1:15 .. Had 75 gms
  - Type 1
  - Type 2
  - BG before meal 67
  - BG before meal 170

Case Study

- 70 yr old, weighs 100kg
- History of CABG, tobacco
- A1c – 11.3%, BG 400-500 for past weeks
- Insulin – 100+ units Lantus at hs (solostar)
- Oral Meds: Metformin, Invokana
- What is a better insulin dosing strategy?
- Pt can't afford insulin pen – what other option
- Diabetes Meds on a Budget - 2014 - provides practical and affordable strategies to manage hyperglycemia

Cost Per Vial in Northern CA

Per vial cost	Walmart	Walgreens	Costco
Regular Insulin	$25*	$92	$99
NPH	$25*	$92	$99
70/30	$25*	$92	$101
Humalog	$200	$220	$178
Novolog	$197	$217	$178
Apidra	$180	$246	$178
Levemir	$300	$300	$300
Lantus	$226	$221	$206



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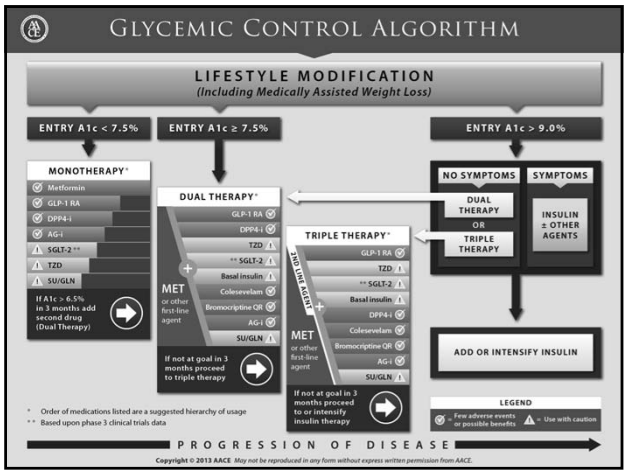

Oral Diabetes Medications

Diabetes Education Services — 15 years

Class/Main Action	Name(s)	Daily Dose Range	Considerations
Biguanides *Decrease hepatic glucose output. American Diabetes Association recommends start at diagnosis of type 2.*	metformin (Glucophage)	500–2500 mg *(usually BID w/meal)*	Take caution if creat>1.4 women, >1.5 men, CHF on meds, >80 yrs, binge drinker, liver disease, during IV dye study, illness. Eliminated via kidney. Side effects include nausea, B12 deficiency, bloating, diarrhea. Take w/ meals. Lowers A1c 1.0% – 2.0%.
	Extended Release-XR (Glucophage XR) (Glumetza) (Fortamet)	*(1x daily w/dinner)* 500–2000 mg 500–2000 mg 500–2500 mg	
Sulfonylureas *Stimulates sustained insulin release.*	glyburide: (Micronase, Diabeta) (Glymase)	1.25–20 mg 0.75–12 mg	Can take once or twice daily. Side effects include hypoglycemia and weight gain. Eliminated via kidney.
	glipizide: (Glucotrol*) (Glucotrol XL)	2.5–40 mg 2.5–20 mg	*Take Glucotrol on an empty stomach. Take Glucotrol XL with first meal.
	glimepiride (Amaryl)	1.0–8 mg	Lowers A1c 1.0%–2.0%.
DPP – 4 Inhibitors *"Incretin Enhancers" Prolongs action of gut hormones = increased insulin secretion, delayed gastric emptying.*	sitagliptin (Januvia)	100 mg daily *(eliminated via kidney*)*	*If creatinine elevated, see pkg insert for dosing info. No wt gain or hypoglycemia. Side effects include nasopharyngitis, headache and upper-respiratory tract infection. Report signs of pancreatitis (abdominal pain, nausea, vomiting). Lowers A1c 0.6%–0.8%.
	saxagliptin (Onglyza)	Up to 5 mg daily *(eliminated via kidney*, feces)*	
	linagliptin (Tradjenta)	5 mg daily *(eliminated via feces)*	
	alogliptin (Nesina)	25 mg once daily *(eliminated via kidney)*	

More medications on back. Note: These meds are for people with Type 2 diabetes and should not be used during pregnancy. Content is for educational purposes only; please consult prescribing information for details.

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A Diabetes PocketCard® from Diabetes Education Services

Class/Main Action	Name(s)	Daily Dose Range	Considerations
SGLT2 Inhibitors *Decrease glucose reabsorption in kidneys "glucoretic."*	Canagliflozin (Invokana)	100–300 mg once daily before first meal	For both, monitor B/P, K• and renal function. If GFR<60, stop Farxiga. If GFR<45, stop Invokana. Side effects: hypotension, UTIs, increased urination, genital infections. Avoid Farxiga in pts w/bladder cancer. Lowers A1c 0.7%–1.5%, lowers wt 1-3 lbs.
	Dapagliflozin (Farxiga)	5-10mg once daily	
Thiazolidinediones "TZDs" *Increase 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%.
Dopamine Receptor Agonists *Resets circadian rhythm.*	bromocriptine mesylate— Quick Release "QR" (Cycloset)	1.6 to 4.8 mg a day (each tab 0.8 mg)	Take within 2 hrs of waking. Start at one tab daily, increase 0.8 mg each wk as tolerated. Side effects: nausea, headache, fatigue, hypotension, syncope, somnolence. Lowers A1c 0.6%–0.9%.
Glucosidase Inhibitors *Delay carb absorption.*	acarbose (Precose) miglitol (Glyset)	25–100 mg w/meals; 300 mg max daily dose	Start with low dose, increase at 4-8 wk intervals to decrease GI effects. Caution with liver or kidney problems. Lowers A1c 0.5%–1.0%.
Meglitinides *Stimulates rapid insulin "burst."*	repaglinide (Prandin)	0.5–4 mg w/meals (metabolized in liver)	Take before meals. Side effects may include hypoglycemia and weight gain. Lowers A1c 1.0%–2.0%.
	natoglinide (Starlix)	60–120 mg w/meals (eliminated via kidney)	

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Beverly Dyck Thomassian
RN, MPH, BC-ADM, CDE

SGLT2 Inhibitors-

- **Action**: "Glucoretic" decreases renal reabsorption in the proximal tubule of the kidneys (reset renal threshold and increase glucosuria)

Decreases Glucose Reabsorption

- **Names**:
  - Canagliflozin (Invokana)
  - Dosing: 100 – 300 mg once daily ac first meal
    - If eGFR 45-60: do not exceed 100mg a day
    - If eGFR <45, do not use
  - Dapagliflozin (Farxiga)
  - Dosing: 5 – 10 mg once daily ac first meal
    - If eGFR <60, do not use
    - Don't use if pt has bladder cancer and report blood in urine
- **Efficacy:**
  - Weight loss of 1-3 lbs
  - Reduce A1C ~0.7-1.5%

Considerations

- Monitor B/P, K+ & renal function.
- Side effects: hypotension, UTI, increased urination, genital yeast infections.
- Initial decrease in GFR, monitor renal fx
- Improves beta cell function?
  - Reverses glucoses toxicity by increasing GLUT4 transport in muscle
  - Increase liver sensitivity to insulin and decreases gluconeogenesis.

Injectables That Lower Glucose

A Diabetes PocketCard® from Diabetes Education Services

Class/Main Action	Name	Dose Range	Considerations
Incretin Mimetic – *Stimulates glucose dependent insulin release, slows gastric emptying, suppresses glucagon, promotes satiety, leading to wt loss over time. For Type 2s only. Lowers A1c 0.5 – 1.6%.*	exenatide (Byetta)	5 - 10 mcg BID (renally excreted)	**Exenatide:** SQ injection given within 60 minutes before breakfast and dinner. **Exenatide XR:** SQ injection once/week. **Liraglutide:** SQ injection once/day. **Side effects for all:** Nausea, vomiting, weight loss. Reports signs of acute pancreatitis (severe abdominal pain, vomiting), stop med. **Black box liraglutide/exenatide XR:** thyroid C-cell tumor warning (avoid if family history of medullary thyroid cancer, notify MD of hoarseness, throat lump).
	exenatide (XR) extended release (Bydureon)	2mg Once a week (renally excreted)	
	liraglutide (Victoza)	0.6 mg daily for 1 wk 1.2 mg daily for 1 wk then 1.8 mg daily (max dose)	
Amylin Mimetic *Slows gastric emptying, supresses glucagon release, promotes satiety. Lowers A1c 0.5 – 1%.*	pramlintide (Symlin)	Type 1: 15 - 60 mcg; Type 2: 60 - 120 mcg immediately before major meals	For Type 1 or 2 on insulin. Prevent hypoglycemia, decrease insulin dose when starting pramlintide. **Black box** warning: severe hypoglycemic risk 3 hrs post injection. Side effects: nausea, wt loss.

The information listed here are general guidelines only; please consult prescribing information for details.

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Diabetes Education Services
(530) 893-8635
Beverly Dyck Thomassian
RN, MPH, BC-ADM, CDE
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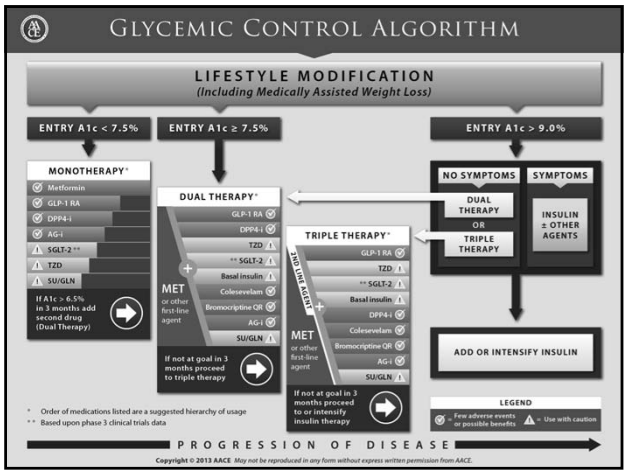
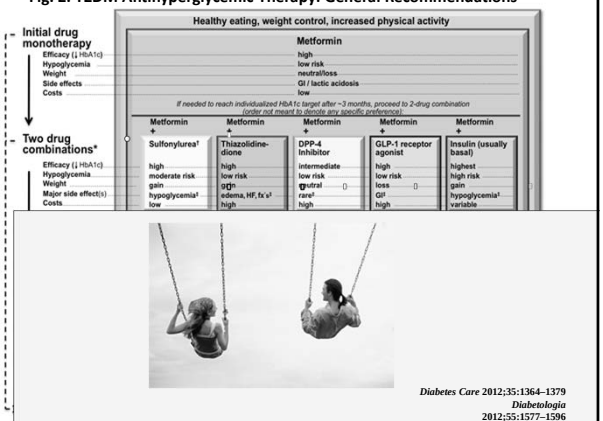


Fig. 2. T2DM Antihyperglycemic Therapy: General Recommendations



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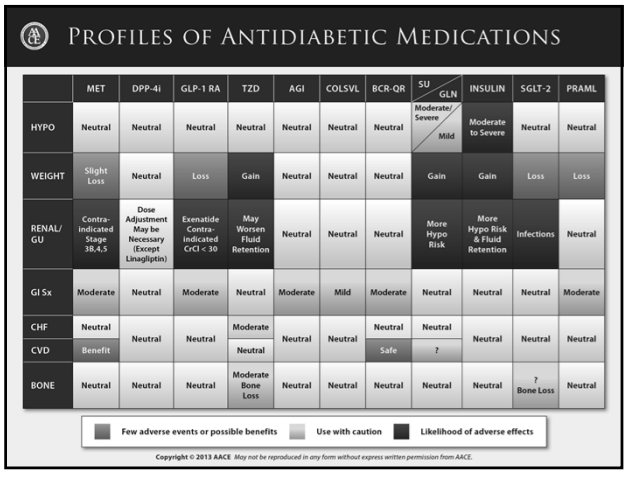

Other Considerations

- Cost
- Hypoglycemia
- Age
- Weight
- Comorbidities
  - Kidney disease
  - Heart disease – CHF, CAD
  - Liver dysfunction

ADA-EASD Position Statement: Management of Hyperglycemia in T2DM

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When goal is to minimize cost

- Go generic. Metformin and Sulfonylureas
- Walmart offers 3 month supply of following meds for ~ $10
  - Metformin and Metformin XR
  - Glipizide, Glyburide, Glimepiride
- Other generics include
  - Actos and Avandia
  - Acarbose
  - They can still cost up to $100 a month
- Meds on a Budget Article

Diabetes Education Services

When goal is to avoid Hypoglycemia

- Avoid sulfonylureas
- Careful insulin dosing
- May need to up adjust glucose goals
- Monitor kidney function
- Reinforce for patients on insulin to "TIE"
  - Test
  - Inject
  - Eat

Diabetes Education Services

When goal is to avoid weight gain

- These meds are weight neutral
  - Metformin
  - DPP-IV Janvia, Onglyza, Tradjenta, Nesina
  - Acarbose
- These meds promote wt loss
  - GLP-1 agonists (Byetta, Bydureon, Victoza)
  - SGLT-2 Inhibitors (Canagliflozin, Dapagliflozin)
  - Symlin (Pramlintide)

Older Adults - Considerations

- Reduced life expectancy
- Higher CVD burden
- Reduced GFR
- At risk for adverse events from polypharmacy
- More likely to be compromised from hypoglycemia

✓**Less ambitious targets**
✓**A1c <7.5–8.0%**
✓**Focus on drug safety**

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Weight Considerations

- Majority of T2DM patients overweight / obese
- Intensive lifestyle program
- Metformin
- GLP-1 receptor agonists
- ? Bariatric surgery
- Consider LADA in lean patients

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ADA-EASD Position Statement: Management of Hyperglycemia in T2DM

Bariatric Surgery

- Consider on diabetes pts w/ BMI >35, esp with comorbidities
- Remission (BG normalized)
  - rates range from 40 – 95%
  - Better results with newer diabetes (more beta cell mass)
  - Due to increase incretins (gut hormones)
- Still researching long term benefits, cost effectiveness and risk

Critical Points

- Individualize Glycemic targets & BG-lowering
- Diet, exercise, & education: foundation T2DM therapy
- Metformin = optimal 1st-line drug.
- After metformin, data limited. Combo therapy reasonable
- Ultimately, many T2 patients will require insulin therap
- All treatment decisions should be made in conjunction with the patient (focus on preferences, needs & values.)
- CV risk reduction - a major focus of therapy.

ADA-EASD Position Statement: Management of Hyperglycemia in T2DM

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