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Park Nicollet® *International Diabetes Center*

Diabetes Management: Latest Guidelines and Emerging Technological Advances

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International Diabetes Center;
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International Diabetes Center...

*Ensuring that every individual with diabetes or
at risk for diabetes receives the best possible care*



Presentation Overview

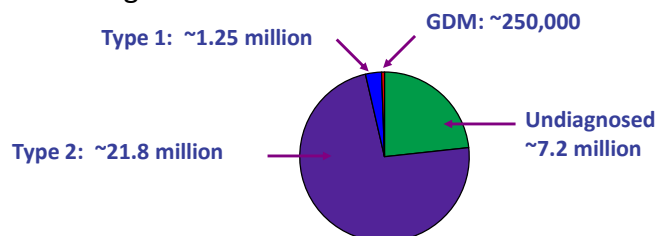
- **Latest ADA Guidelines for Diagnosis and Management**
 - Epidemiology and diagnostic criteria
 - Glycemic targets
 - Type 2 Diabetes Guideline
- **Weight loss and diabetes**
 - Weight loss goals
 - Role of bariatric surgery
- **Emerging Diabetes Technology**
 - Beyond A1C
 - Continuous glucose monitoring



Epidemiology of Diabetes

Based on 2015 Statistics

- 30.3 million people in U.S. have diabetes
 - 9.4% of U.S. population
- 1.5 million new cases diagnosed
- 1 in 4 seniors (65+) has diabetes
- 7th leading cause of death



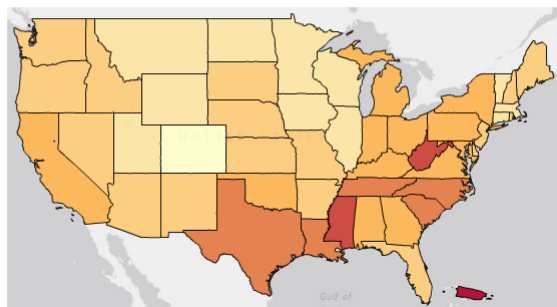
American Diabetes Association Statistics



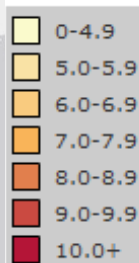
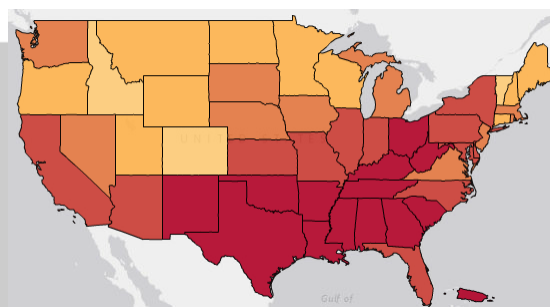
Prevalence of Diabetes by State 2004 to 2014

Percentage of Population

2004



2014

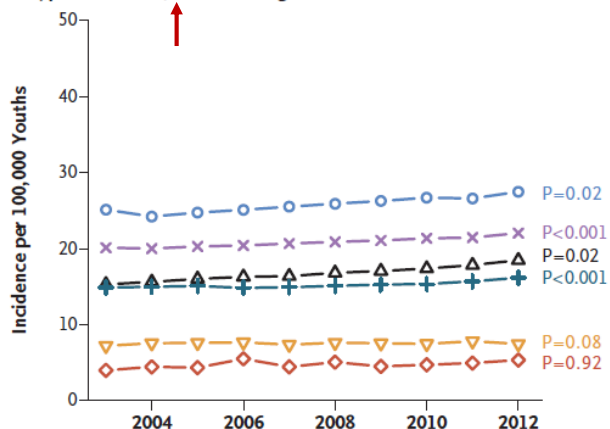


Centers for Disease Control and Prevention

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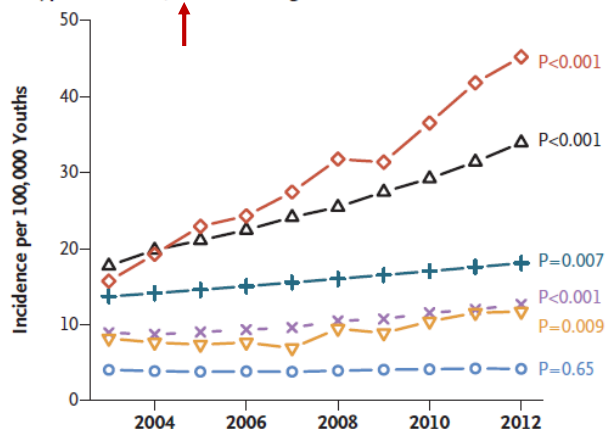
Incidence Trends in Type 1 and Type 2 in Children and Adolescents, 2002-2012

A Type 1 Diabetes, 0-19 Yr of Age



Mayer-Davis et al. *NEJM* 2017; 376:1419-1429.

B Type 2 Diabetes, 10-19 Yr of Age



All
Non-Hispanic White
Non-Hispanic Black
Hispanic
Asian or Pacific Islander
Native American

Screening for Diabetes or Prediabetes in Asymptomatic Youth

- Type 1 Diabetes
 - Clinical testing of asymptomatic, low-risk individuals not recommended
- Type 2 Diabetes/Prediabetes
 - Overweight (BMI >85th percentile for age and gender; weight >120% of ideal for height)**and** one or more of the following risk factors:
 - Maternal history of diabetes or GDM during child's gestation
 - Family history type 2 diabetes in first or second degree relative
 - Race/ethnicity: Native American, African American, Latino, Asian American and Pacific Islander
 - Signs of insulin resistance (Acanthosis Nigricans, PCOS, HTN, Dyslipidemia, small-for-gestational age)

ADA Standards of Medical Care. Diab Care 2018; 41 Supplement 1

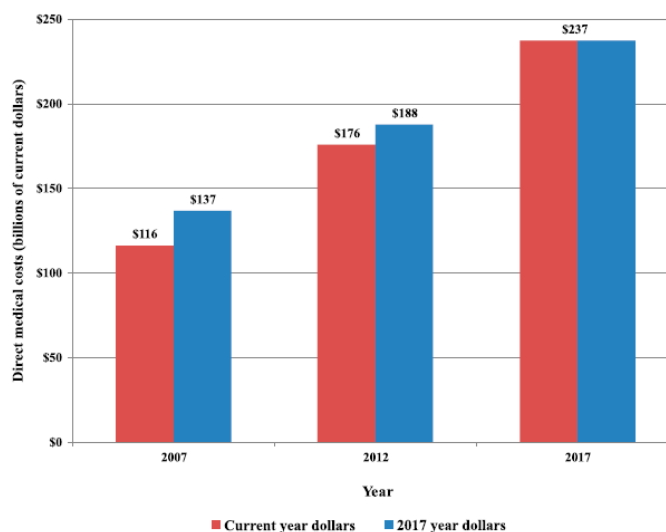


Economic Costs of Diabetes in the U.S. in 2017

American Diabetes Association

Diabetes Care 2018;41:917–928 | <https://doi.org/10.2337/dci18-0007>

- ◆ Direct medical cost \$237 billion
- ◆ 1 in 4 of all U.S. healthcare dollars for people with diabetes
- ◆ Avg. cost \$16,750/year/patient total
 - ◆ \$9,600/year of total for direct diabetes related expenses
- ◆ ~40% direct cost for emergency department and inpatient management



Criteria for Diagnosis of Diabetes

Fasting Plasma Glucose*	≥126 mg/dL (no caloric intake for 8 hrs)
2-hour 75 gram OGTT*	≥200 mg/dL at 2 hours
A1C (lab only)*	≥6.5 %
Random Plasma Glucose	≥200 mg/dL and classic symptoms (polyuria, polydipsia) or hyperglycemic crisis

- *Must be confirmed on subsequent day unless unequivocal symptoms of hyperglycemia
- A1C has less variability, but do not use if abnormal RBC turnover, anemia, hemoglobinopathies

ADA Standards of Medical Care. Diab Care 2018; 41 Supplement 1



Glycemic Targets for Type 2 Diabetes

	ADA and IDC	AACE
A1C	<7%*	≤6.5% (for most)
Fasting and Premeal	80 - 130 mg/dL (ADA) 70 - 130 mg/dL (IDC)	<110 mg/dL
1-2 Hour Postmeal	<180 mg/dL**	<140 mg/dL (2 hr)

* A1C goals should be individualized

** Note: 2 hour postmeal value should be no more than 50 mg/dL above premeal value

ADA Standards of Medical Care. Diab Care 2018; 41 Supplement 1; American Association of Clinical Endocrinologist



Hemoglobin A_{1c} Targets for Glycemic Control With Pharmacologic Therapy for Nonpregnant Adults With Type 2 Diabetes Mellitus: A Guidance Statement Update From the American College of Physicians

Amir Qaseem, MD, PhD, MHA; Timothy J. Wilt, MD, MPH; Devan Kansagara, MD, MCR; Carrie Horwitch, MD, MPH; Michael J. Barry, MD; and Mary Ann Forciea, MD; for the Clinical Guidelines Committee of the American College of Physicians*

Doctors' Group Issues Controversial Advice for Type-2 Diabetes

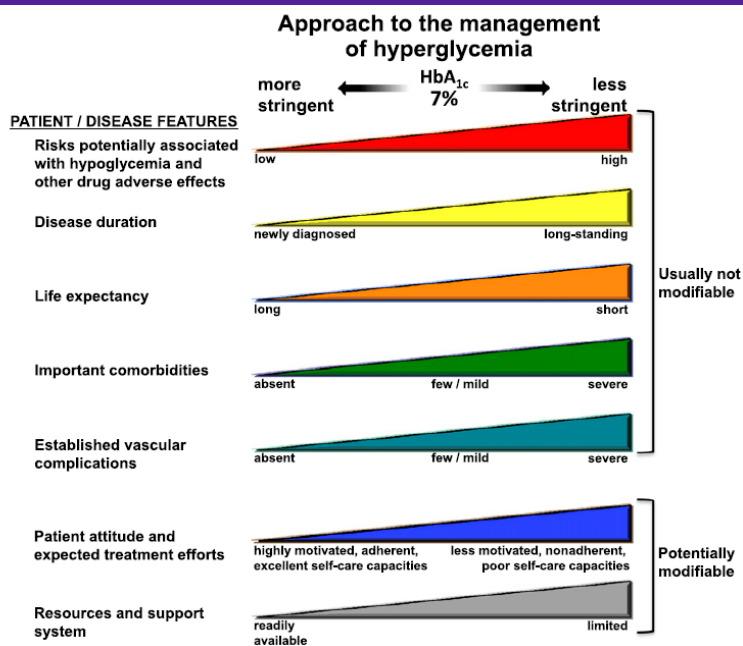
American College of Physicians ups A1c limit to 8%

TREATMENTS

Major Medical Associations Feud Over Diabetes Guidelines

March 5, 2018 · 5:01 PM ET

Ann Intern Med. 6 March 2018



Inzucchi et al. *Diab Care* 2015;38:140-149

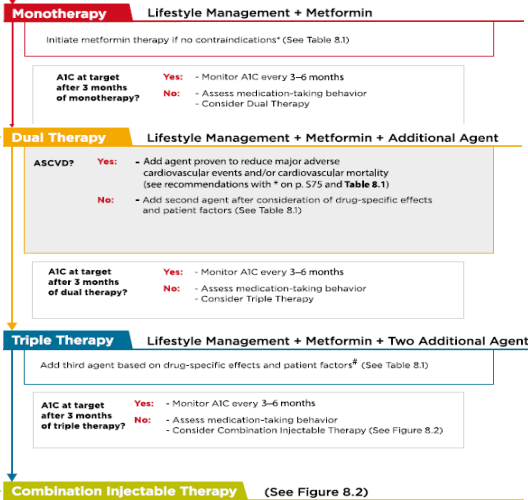
Antihyperglycemic Therapy in Adults with Type 2 Diabetes

At diagnosis, initiate lifestyle management, set A1C target, and initiate pharmacologic therapy based on A1C:

A1C is less than 9%, **consider Monotherapy.**

A1C is greater than or equal to 9%, **consider Dual Therapy.**

A1C is greater than or equal to 10%, blood glucose is greater than or equal to 300 mg/dL, or patient is markedly symptomatic, **consider Combination Injectable Therapy** (See Figure 8.2).



ADA Standards of Medical Care. Diab Care 2018; 41 Supplement 1

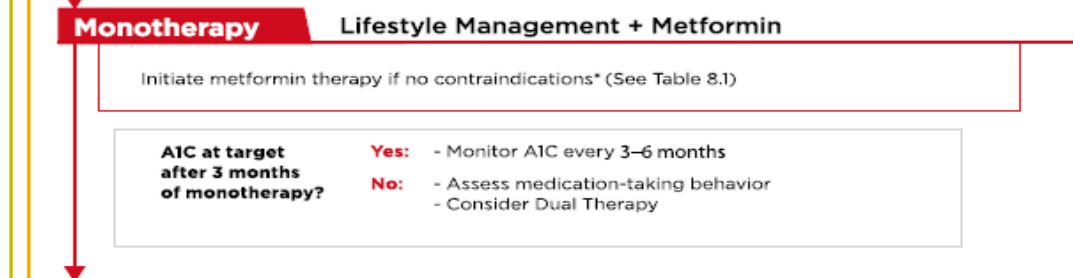
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ADA Standards of Medical Care. Diab Care 2018; 41 Supplement 1

Why should metformin be the first-line therapy for type 2 diabetes?

- Efficacious and durable therapy
- Demonstrated CV event risk reduction (UKPDS)
- Weight neutral, modest improvement in lipids
- Many years of experience
- Lower cost
- Effective in combination therapy
 - Many combo tablet formulations available
- May reduce risk of cancer

Kahn et al., NEJM 2006; 355:2427-2443
 UKPDS Study Group, *The Lancet* 1998; 352:854-865
 Currie et al. *Diabetologia*. 2009;52:1766-1777.

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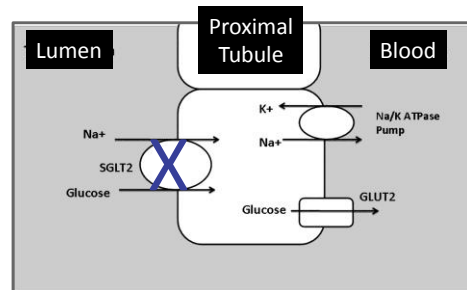


ADA Standards of Medical Care. Diab Care 2018; 41 Supplement 1

Sodium-Glucose Cotransporter-2 (SGLT2) Inhibitor

- Inhibits renal re-absorption through inhibition of SGLT2
 - Selective inhibitor of SGLT2 -- acts in early proximal tubule to block reabsorption of filtered glucose
 - Normally ~180 g glucose filtered/day
- Causes about 70 g (~300 kcal) glucose excretion per day; potential for weight loss

List et al. *Diabetes Care*, 2009; 32:650-657; Neumiller et al. *Drugs*, 2010; 70:377-385
 Nair S. et al. *J Clin Endocrinol Metab* 2010;95:34-42
 Copyright ©2010 The Endocrine Society.



Sodium-Glucose Cotransporter 2 (SGLT2)

Canagliflozin (Invokana), Dapagliflozin (Farxiga), and Empagliflozin (Jardiance), Ertugliflozin (Steglatro)

- **Clinical Indicators**
 - Modest reduction in both FPG and PPG
 - Approved as monotherapy, and in combination with metformin, SU, pioglitazone and/or insulin
 - Modest weight loss, no additional hypoglycemia
- **Precautions and contraindications**
 - Use caution with renal impairment (eGFR <45-60)
 - Symptomatic hypotension especially in elderly, renal impairment, patients treated with loop diuretics, ACE-I, and/or ARBs
 - Genital mycotic infections, especially in women or if history of mycotic infections; urinary tract infections
 - Acute kidney injury, especially with dehydration, history of CKD
 - Diabetic ketoacidosis (DKA)

Package Insert Data

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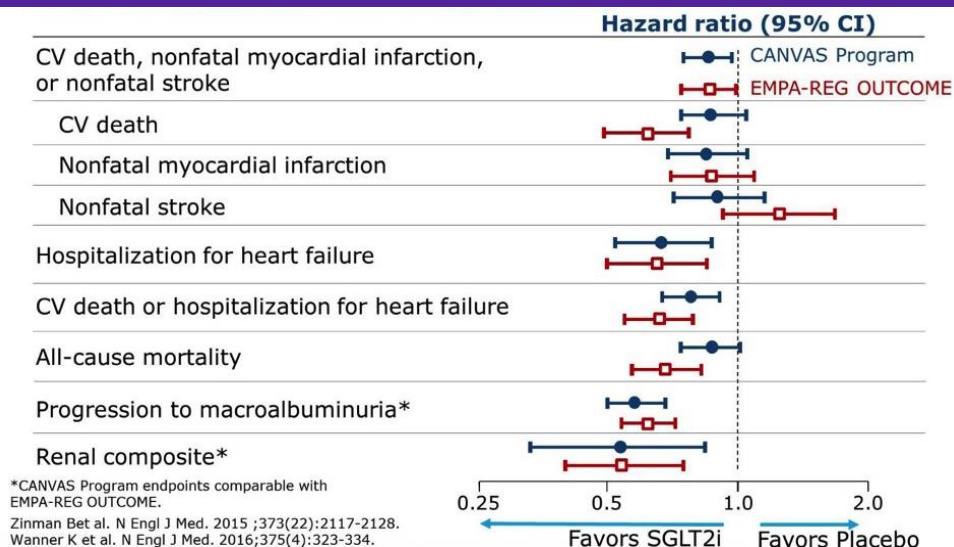
Overview of SGLT2 Inhibitors

Drug	Dose	eGFR cutoff	Comment
Canagliflozin (Invokana)	100/300 mg/day	<45; use 100 mg if eGFR 45-60	Not recommended if severe hepatic impairment; black box warning for amputation
Dapagliflozin (Farxiga)	5/10 mg/day	<60	Avoid if history of bladder cancer
Empagliflozin (Jardiance)	10/25 mg/day	<45	Increased risk of volume depletion in pts. aged 75 yrs and older
Ertugliflozin (Steglatro)	5/15 mg/day	<60	Risk of amputation (toe) may be increased, consider risk factors such as PVD, ulcers, neuropathy

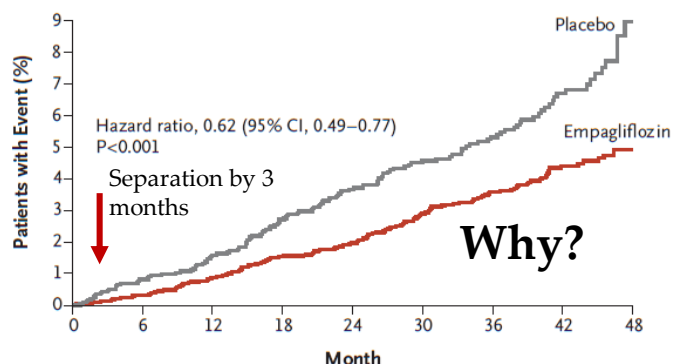
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CANVAS and EMPA-REG Outcomes



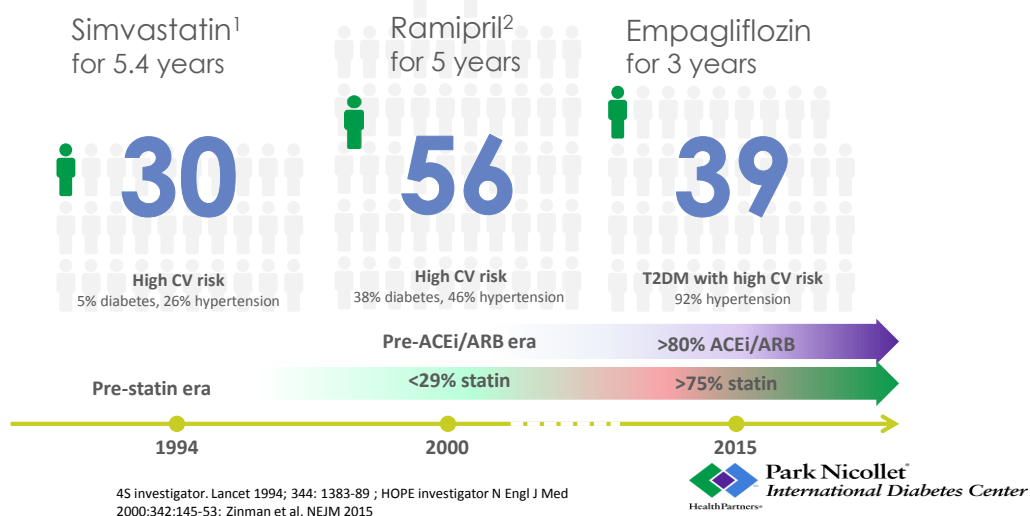
EMPA- REG Outcome: Death From Cardiovascular Causes



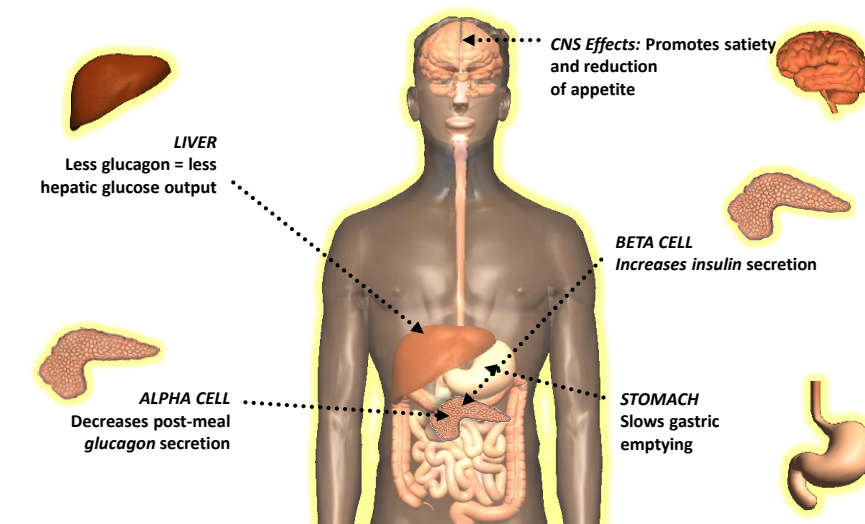
No. at Risk									
Empagliflozin	4687	4651	4608	4556	4128	3079	2617	1722	414
Placebo	2333	2303	2280	2243	2012	1503	1281	825	177

In addition a 35% risk reduction in hospitalization for heart failure

Number Needed to Treat (NNT) to Prevent one Death Across Landmark Trials in Patients with High CV Risk



Glucagon Like Peptide -1 (GLP-1) Action



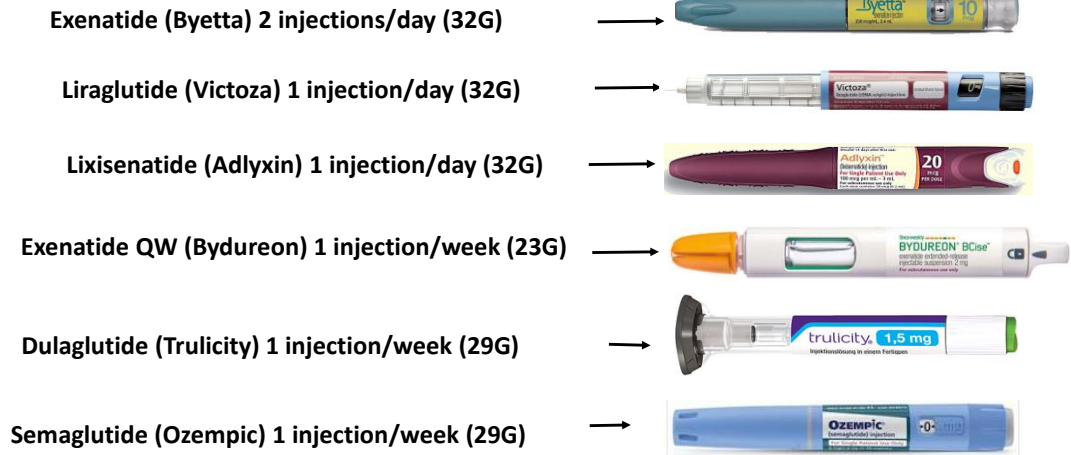
Ahren B Curr Diab Rep 2003; 3:365-372.
Baggio LL and Drucker DJ. Gastroenterology 2007; 132:2131-2157.

Glucagon-Like Peptide-1 (GLP-1) Receptor Agonists

Dulaglutide, Exenatide, Exenatide QW, Liraglutide, Lixisenatide, and Semaglutide

- **Action**
 - Enhances glucose-dependent insulin secretion and glucagon suppression
 - Slows gastric emptying
 - Induce satiety and reduce food intake
- **Clinical Indicators**
 - Elevated postmeal BG (exenatide), elevated postmeal and fasting BG (all others)
 - In combination with metformin, sulfonylurea, thiazolidinedione or insulin
- **Side effects**
 - Transient nausea (up to 40% patients) vomiting (~10%) and diarrhea (~10%)
 - Low risk of hypoglycemia unless used in combination with SU or insulin
 - Modest weight loss in >85% of patients
- **Precautions and Contraindications**
 - Kidney Disease (no exenatide if eGFR <30 ml/min) others use with caution
 - Gastrointestinal disease, pancreatitis (rare)
 - Pregnancy (Category C)

Examples of GLP-1 Agonists

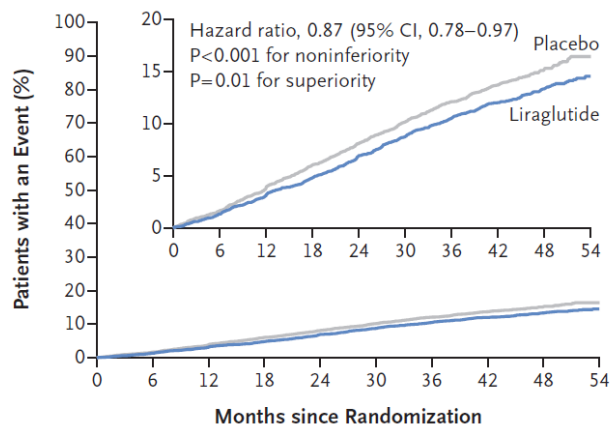


LEADER Trial Results

Liraglutide vs. Placebo in Patients with CVD or at Very High Risk

Primary Outcome = Non Fatal MI, Nonfatal Stroke, Death due to CV Cause

NNT to prevent one event in 3 years = 66



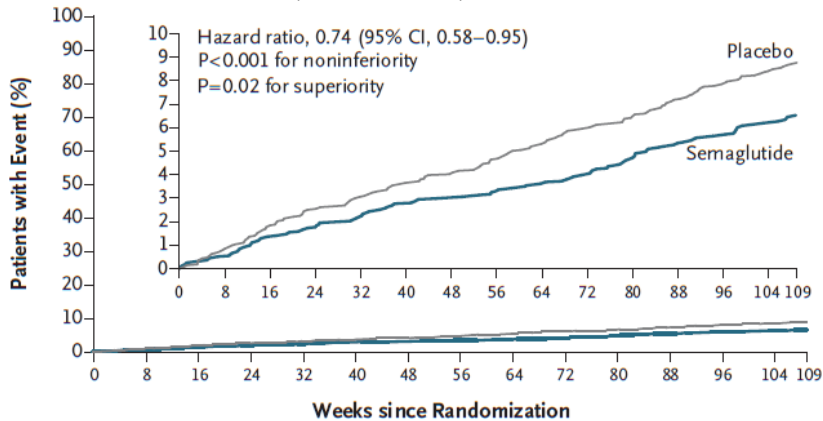
No. at Risk

Liraglutide	4668	4593	4496	4400	4280	4172	4072	3982	1562	424
Placebo	4672	4588	4473	4352	4237	4123	4010	3914	1543	407

SUSTAIN-6 Trial Results

Semaglutide vs. Placebo in Patients with CVD or at Very High Risk

A Primary Outcome = Non Fatal MI, Nonfatal Stroke, Death due to CV Cause



No. at Risk

Placebo	1649	1616	1586	1567	1534	1508	1479
Semaglutide	1648	1619	1601	1584	1568	1543	1524

Cost of Noninsulin Therapies

Medication	AWP/Month* Monthly Max Dose)
Metformin IR and 500 mg ER	~\$90 (\$1,000 for 1000 mg ER)
Sulfonylureas	~\$50-\$90
Pioglitazone	\$348
DPP-4 Inhibitors	~\$450
SGLT-2 Inhibitors	~\$515
Exenatide/Exenatide XR	\$802/\$747
Liraglutide	\$968
Dulaglutide	\$811

* Do not account for discounts, rebates, or other price adjustments

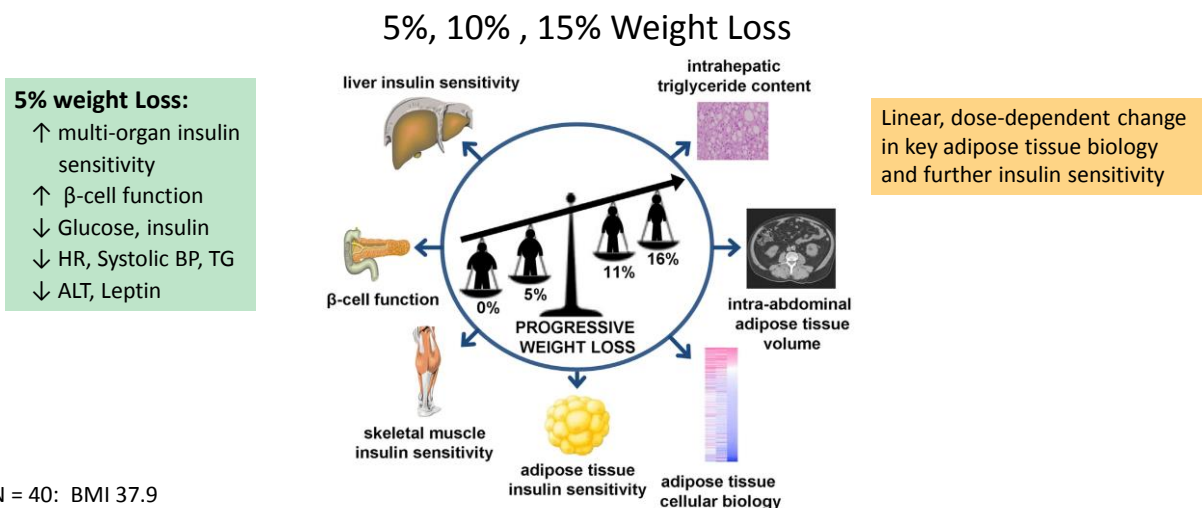
ADA Standards of Medical Care 2018. *Diab Care* 41:Suppl 1

Presentation Overview

- Latest ADA Guidelines for Diagnosis and Management
 - Epidemiology and diagnostic criteria
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- **Weight loss and diabetes**
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Weight loss and Metabolic/Adipose Changes



N = 40: BMI 37.9

N = 20 (14 completed) weight maintenance group

N = 20 (19 completed): 5% wt loss group, N= 9 continued to 11% and 16% wt loss

Magkos et al. Cell Metabolism 23, 1-11, Apr 2016



Obesity Management: Diabetes Standard of Care

- Routine BMI at each patient encounter
 - Discuss results with patients
 - Advise overweight patients of increased CVD/all-cause mortality
- Assess weight loss readiness
- Jointly determine weight loss goal/strategies
 - 5% weight loss good, $\geq 7\%$ optimal
 - Aim for lifestyle energy deficit of 500-750 kcals/day
 - Intensive management (≥ 16 sessions in 6 months)
- Comprehensive weight maintenance program
 - At least monthly contact
 - Frequent weight checks (weekly +)
 - Reduced kcals, increased activity (200-300 min/week)



Diab Care 41 (supp 1) , 2018

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Weight Loss Goals

- n = 60 women, Mean BMI 36.3, initial weight 99.1 kg (218 lbs)
- 15 years education, 45% married
- Hx of 4.4 ± 2.6 diets with 11.5 ± 4.8 kg loss per diet (25 lbs)

Self-Selected 4 Weight Goals

	<u>Kg</u>	<u>Lbs</u>	
Dream	61.4	135	↓ 83 lb
Happy	68.0	150	
Acceptable	74.2	158	
Disappointed	81.9	180	↓ 38 lb

**TAKE-AWAY:
HELP SET REALISTIC GOALS**

which is 1.5 times more than previous attempts

Weight goals:

- Reinforce health benefits of even 10-15 lbs weight loss
- Consider 2 tiered goal, 10-15 lbs short term and negotiated long term

J Consult Clin Psych 65: 79, 1997

Why Weight Loss Is Difficult

- Genetics - ~50% of variance genetics and 50% environment
- **Weight tightly regulated by hormonal metabolic and neural metabolic factors**
 - Hormonal adaptations (\downarrow leptin, peptide YY, cholecystokinin, insulin, and \uparrow ghrelin, GLP-1, gastric inhibitory polypeptide, pancreatic polypeptide) promote weight gain after diet-induced weight loss; remain at least 1-yr after initial weight reduction
 - Weight loss results in adaptive thermogenesis (\downarrow resting metabolic rate) maintained up to 1-yr
 - Neural factors (dopamine) signal \uparrow desire for fatty foods after weight loss
- Psychosocial issues

Ochner et al. *Physiol Behav* 2013;120:106; Camps et al. *Am J Cl Nutr* 2013;97:990

Weight Loss: Is One Diet Better?



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Comparison of Named Diet Programs

Type Diet	Branded Diets*	Carb % kcal	Protein % Kcal	Fat % kcal
Low Carb	Atkins, South Beach, Zone	≤ 40	~30	30-55
Moderate Macronutrient	Biggest Loser, Jenny Craig, Nutrisystem, Volumetrics, Weight Watchers	~55-60	~15	21-≤30
Low Fat	Ornish, Rosemary Conley	~60	~10-15	≤20

- 48 RCT, 7286 individuals, mean diet duration 24 weeks (16-52)

- Significant weight ↓ observed with any low-carb/low-fat diet

- **Weight loss differences between diets minimal**

TAKE-AWAY:

“This supports the practice of recommending any diet that a patient will adhere to in order to lose weight”

BC Johnston et al JAMA 312(9) 2014
ADA Position Statement: Diab Care S21, Jan 2015

Review of a current popular diet: Ketogenic Diet

- ≤ 5-10% calories from carbohydrate
 - Non-starchy vegetables, berries
- 15% calories from protein
 - Moderate portions, may be higher or lower fat
- 75-80% calories from fat
 - Majority of calories are from higher fat food sources – nuts, cheese, avocado, coconut

Keto diet

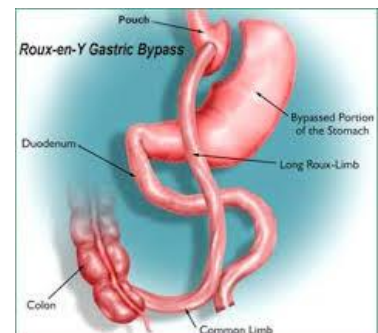
- Body uses different energy pathways – body burns fat for energy
- Long term medical consequences not well researched
 - Difficult to ascertain if glycemic benefits are related to weight loss or the diet
 - Side effects include constipation, headaches
- Requires cutting out many healthy foods (whole grains, fruits, veggies)
- Difficult to meet micronutrient needs (sodium, potassium, vitamin C)
- Likely hard to maintain long term
- Evidence says not necessary to manage diabetes



Bariatric Surgery and Diabetes

- BMI ≥ 40 kg/m² no matter level of glycemic control or level of complexity of glucose-lowering regimen
- BMI ≥ 35 kg/m² when hyperglycemia is inadequately controlled despite lifestyle and optimal medical therapy
- Consider with BMI 30.0–34.9 kg/m² if hyperglycemia is inadequately controlled despite optimal medical therapy
- Patients with Type 2 DM and bariatric surgery need lifelong lifestyle support

BMI ≥ 35	<u>lbs</u>
5'	≥ 179
5' 4"	≥ 204
5' 9"	≥ 236
6'	≥ 258

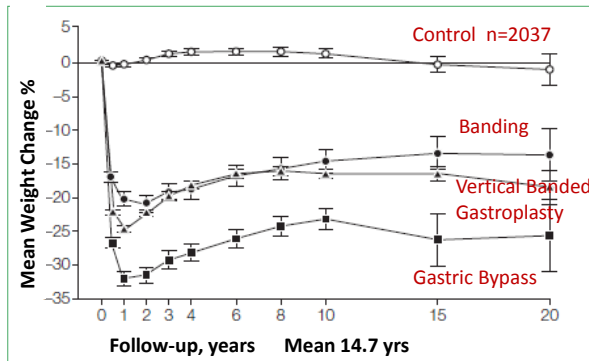


ADA Standards of Care Diab Care 41, Supp 1 Jan 2018
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Swedish Obesity Study

- 3900 patients bariatric procedures, 13% gastric bypass



Diabetes Incidence	Surgical	Control
2 yrs	1%	8%
10 yrs	7%	24%

Buchwald et al. JAMA 292:1724, 2004

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Bariatric Surgery and Diabetes Remission

N- 4,434 RYGB; Retrospective study, 3 sites

- Within 5 yrs complete remission rate = 68.2%.
- Within next 5 years, 35.1% experienced relapse
- More likely to experience relapse if:

Older
On insulin
A1C \geq 6.5%
Longer diabetes duration

DE Arterburn et al. Obesity Surgery Nov 18,2012 Online

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Diabetes Surgery Study

RYGB vs Intensive Lifestyle-Medical Management

- Intensive Lifestyle-Medical Management vs RYGB
- Unblinded, randomized trial, n= 120 (60 per group)
- Subjects: Type 2 at least 6 months, BMI 30-39.9, A1C 8%
- Primary outcomes, A1C < 7, SBP < 130, LDL < 100

End Points	No. (%) of Patients		OR (95% CI) ^a
	Lifestyle and Medical Management	Roux-en-Y Gastric Bypass	
Meets primary outcome triple end point	11 (19)	28 (49)	4.8 (1.9-11.7)
HbA _{1c} <7.0%	18 (32)	43 (75)	6.0 (2.6 to 13.9)
LDL cholesterol <100 mg/dL	38 (70)	45 (79)	1.6 (0.7 to 3.8)
Systolic blood pressure <130 mm Hg	44 (79)	48 (84)	1.7 (0.6 to 4.6)

Ikramuddin et al JAMA 309(21):2240, 2013



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Limitations of A1C

1. Using A1C alone to guide improvement in A1C is not working
 - *52% of A1C's <7% overall*
 - *30% A1C <7% on insulin*
2. No broad agreement on A1C targets
 - *AACE ≤ 6.5%, ADA <7%, ACP <8%*
3. A1C only tells part of the story of glucose control/management
 - CGM may help uncover the rest of the diabetes care story



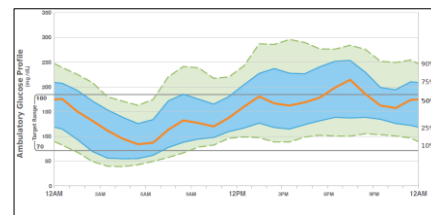
THE LANCET

Comment

Continuous glucose monitoring: transforming diabetes management step by step

Richard M Bergenstal
International Diabetes Center at Park Nicollet

Published online February 16, 2018



Who benefits from CGM: Current Status

AACE/ACE Consensus Statement

AACE/ ACE Consensus Statement 2016

“Evidence supports the benefits of CGM in type 1 diabetes and that these benefits are likely to apply whenever intensive insulin therapy is used, regardless of diabetes type.”

CONTINUOUS GLUCOSE MONITORING: A CONSENSUS CONFERENCE OF THE AMERICAN ASSOCIATION OF CLINICAL ENDOCRINOLOGISTS AND AMERICAN COLLEGE OF ENDOCRINOLOGY

Vivian A. Fonseca, MD, FACE, Co-Chair¹; George Grunberger, MD, FACP, FACE, Co-Chair²;
Henry Anhalt, DO, FACE³; Timothy S. Bailey, MD, FACE, FACP, CPT⁴;
Thomas Blevins, MD, FACE, FNLA, ECNUF⁵; Satish K. Garg, MD⁶;
Yehuda Handelsman, MD, FACP, FNLA, FACE⁷; Irl B. Hirsch, MD⁸;
Eric A. Orzech, MD, FACP, FACE⁹; Victor Lawrence Roberts, MD, MBA, FACP, FACE¹⁰;
William Tamborlane, MD¹¹, on behalf of the Consensus Conference Writing Committee

<https://www.aace.com/files/guidelines/PrePrintContinuousGlucoseMonitoring.pdf>



What's the role in T2DM?

Clinical Care/Education/Nutrition/Psychosocial Research

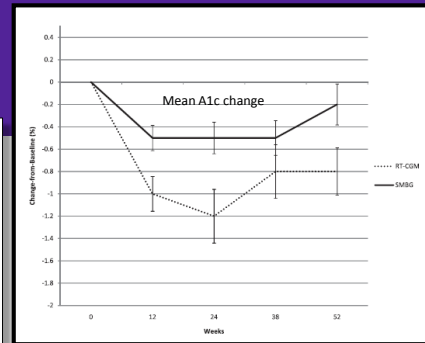
ORIGINAL ARTICLE

Short- and Long-Term Effects of Real-Time Continuous Glucose Monitoring in Patients With Type 2 Diabetes

ROBERT A. VIGERSKY, MD¹
STEPHANIE J. FONDA, PhD¹
MARY CHELLAPPA, MD¹

M. SUSAN WALKER, PhD¹
NICOLE M. EHRLHARDT, MD²

Diabetes Care 35:32–38, 2012



T2D not on prandial insulin

- RCT- effect of RT-CGM on glycemic control (A1C)
- 50 SMBG: 50 RT-CGM for 12 wks
- Diabetes care continued with regular provider
- Followed for an additional 40 weeks (52 wks total)

- RT-CGM 1.2% improvement, then stabilized at 0.8% over 52 weeks, after 12 weeks of CGM
- Significantly better than SMBG group, who also improved



Continuous Glucose Monitoring (CGM)

Personal

- Patient owns device
- Can use 100% of the time
- Variable insurance /Medicare coverage
- Worn for 7-14 days
- With or without alarms

Professional

- Clinic owns device
- Used episodically, e.g. 3 to 14 days
- Can be blinded or un-blinded



Dexcom G6

- 10-day sensor
- No calibrations
- Acetaminophen blocker
- Upload to DexCom Share (up to 5 others)
- Age 2 and older



Medtronic Guardian Connect

- 7-day sensor
- Calibrate every 12hrs
- Predictive alerts (up to 60 minutes)
- Direct to phone app
- Sugar IQ app, IBM Watson compatible
- Data sharing to family/friends
- Age 14-75



Freestyle Libre

- 10-14 day sensor
- Factory calibrated (no fingersticks)
- No alarms
- Worn on back of arm
- Wireless transmission of data from transmitter to receiver
- Inexpensive



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Eversense

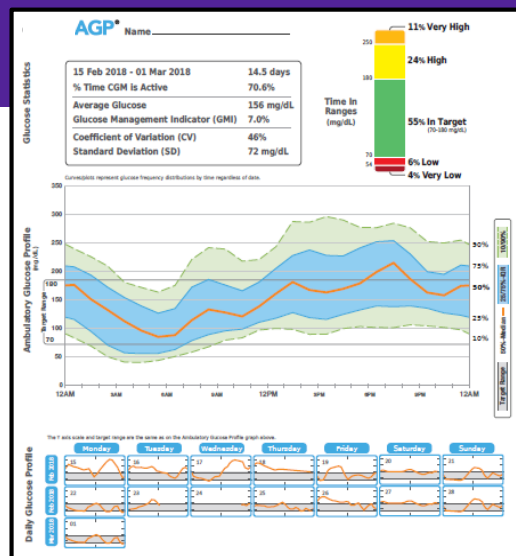
- Eversense (Senseonics)
- Sensor is implanted under skin in upper arm, lasts 90 days
- Transmitter then can be changed easily
 - No warm up time
 - With less sensor trauma, may be less variable/less error prone
- Data sent to smartphone



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Kropff J, DeVries H, Diab Tech Ther, 2016

CGM Ambulatory Glucose Profile (AGP)



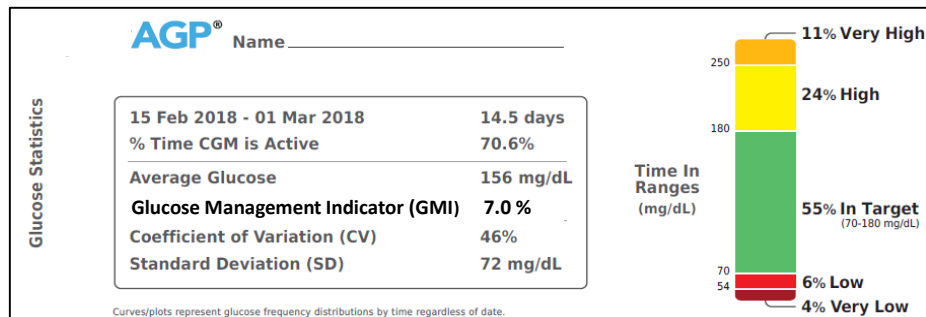
← CGM
Metrics

← CGM
Profile

← CGM
Daily View

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Metrics



Diabetes Care



Glucose Management Indicator (GMI): A New Term for Estimating A1C From Continuous Glucose Monitoring

<https://doi.org/10.2337/dc18-1581> Diabetes Care Publish Ahead of Print, published online September 17, 2018

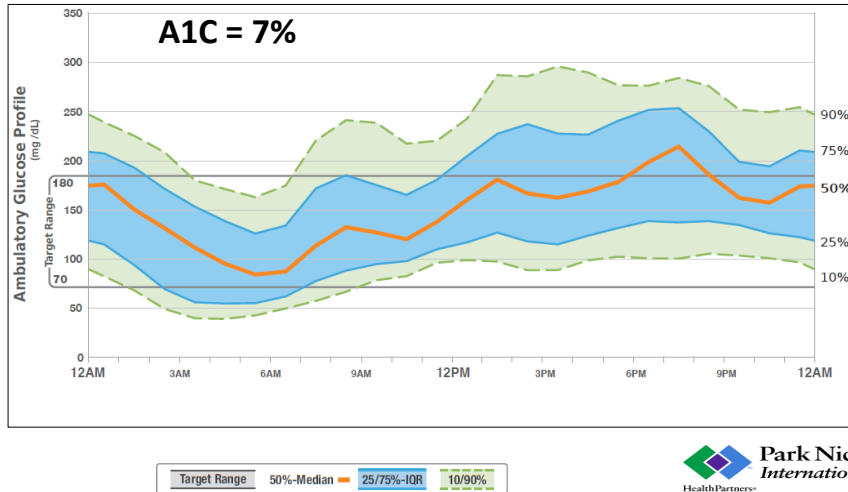
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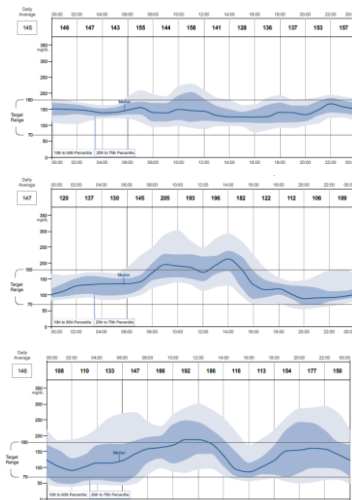
PERSPECTIVES IN CARE



CGM Profile



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A1C %	CV %	% Time Hypo	% TIR 70-180	Therapy
6.7	26	1	83	Artificial Pancreas
6.7	42	6	69	Pump
6.7	53	9	51	MDI

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Questions?

