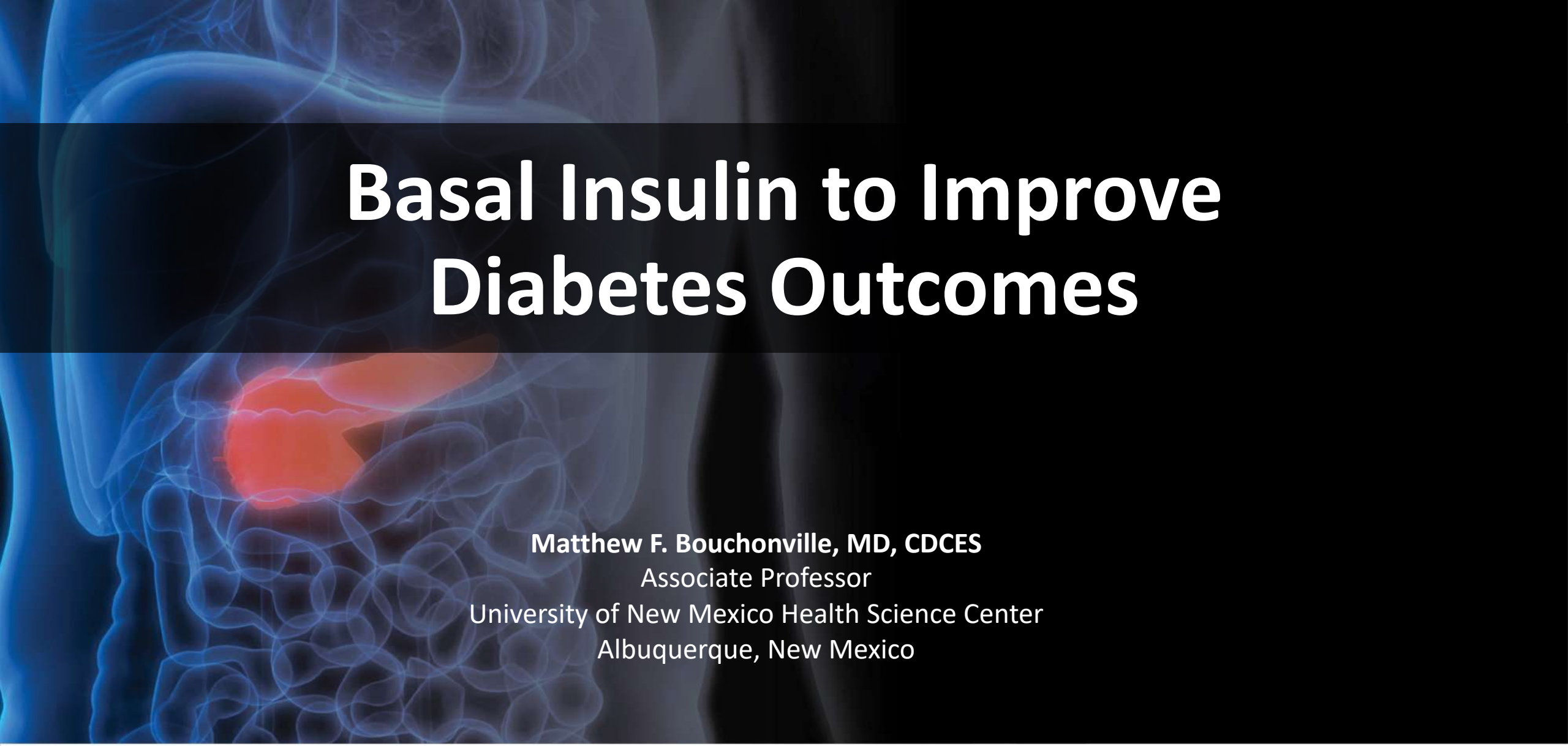

Basal Insulin to Improve Diabetes Outcomes

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Associate Professor
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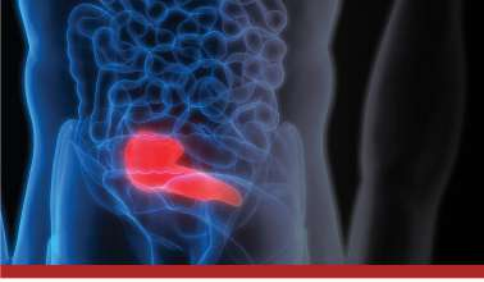
Albuquerque, New Mexico

Provided by academiccme

This activity has been supported by an independent educational grant from Sanofi US.



This activity is supported by an independent grant from Sanofi US.

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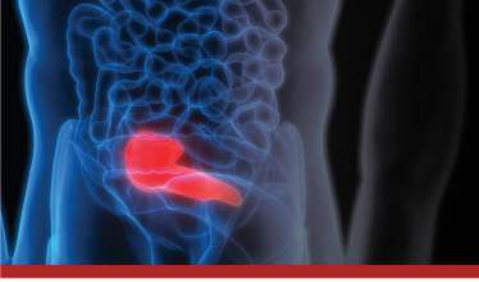
academic CME



CME Credit

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JOINT ACCREDITATION
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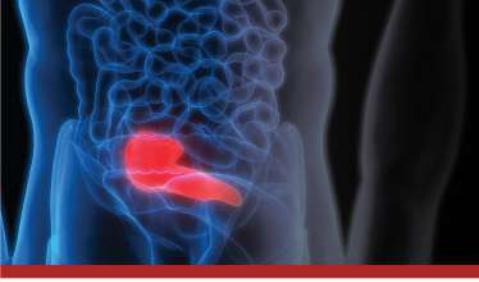
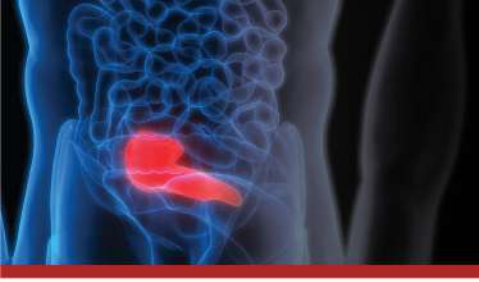


Faculty Disclosures

It is the policy of AcademicCME that all faculty, instructors, and planners disclose real or apparent conflicts of interest relating to the topics of this educational activity.

Matthew F. Bouchonville, MD reported the following financial relationships or relationships to products or devices they or their spouse/life partner have with commercial interests related to the content of this CME activity:

Consultant/Advisor: Nothing to disclose



Learning Objectives

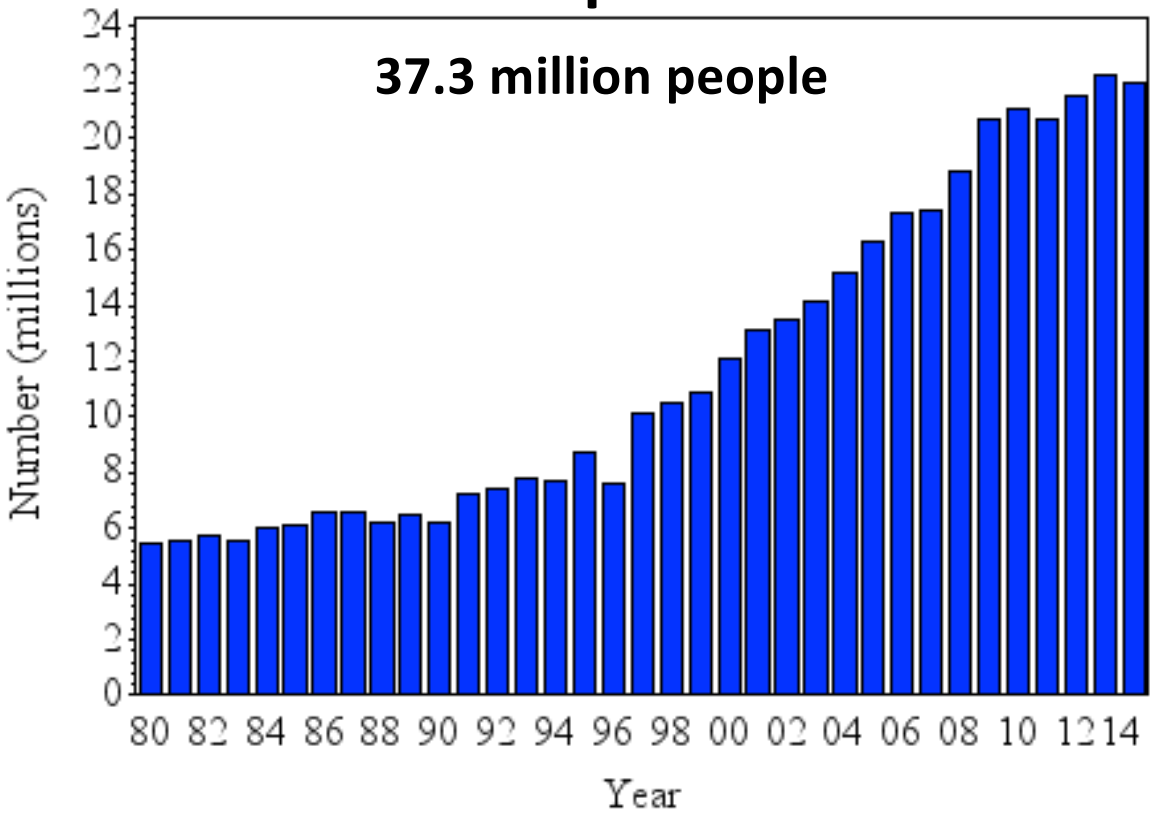
1. Recognize the importance of improving patients' glucose to time-in-range, minimizing glucose variability, and incorporating continuous glucose monitoring in patients with diabetes

2. Distinguish between insulins and incorporate them into practice in patients with diabetes

3. Tailor treatment plans with the interprofessional team and the activated patient with diabetes

Diabetes Prevalence in the United States

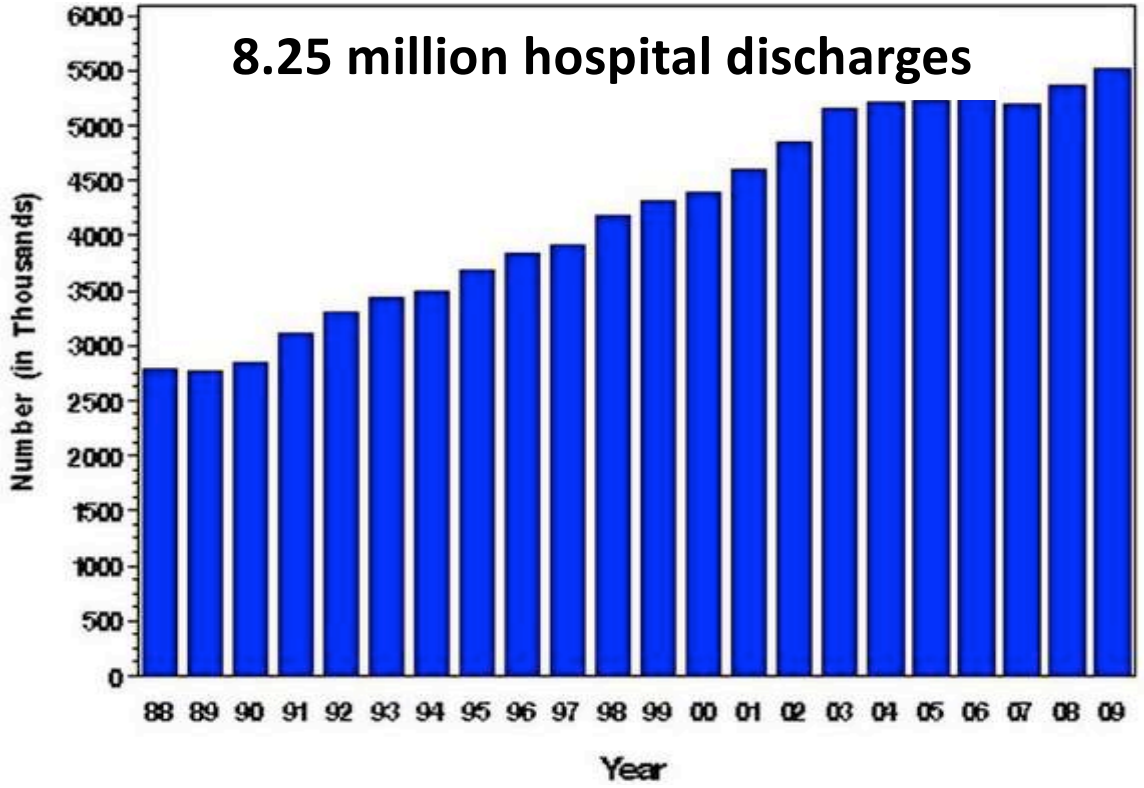
US Population



Prevalence quadrupled from 5.5 million to 21.9 million between 1980 and 2014

- 12.6% (2011-2014) of US population

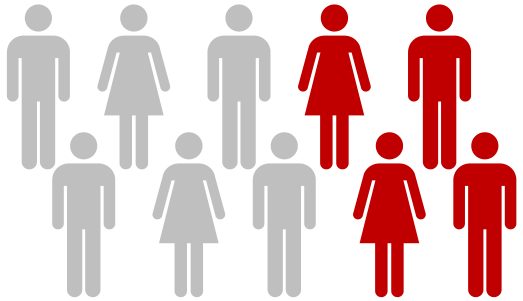
Inpatient Diabetes



- Diabetes listed in 23% of all discharges
- 17 million ED visits/year
- Annual cost: $327 billion (2017) = 30% of total annual cost

CDC. National Diabetes Statistical Report 2020; American Diabetes Association. 2022.

Epidemiology of Common Comorbidities in T2DM



Up to 40% of patients with T2DM develop CKD[1]

2–4 FOLD

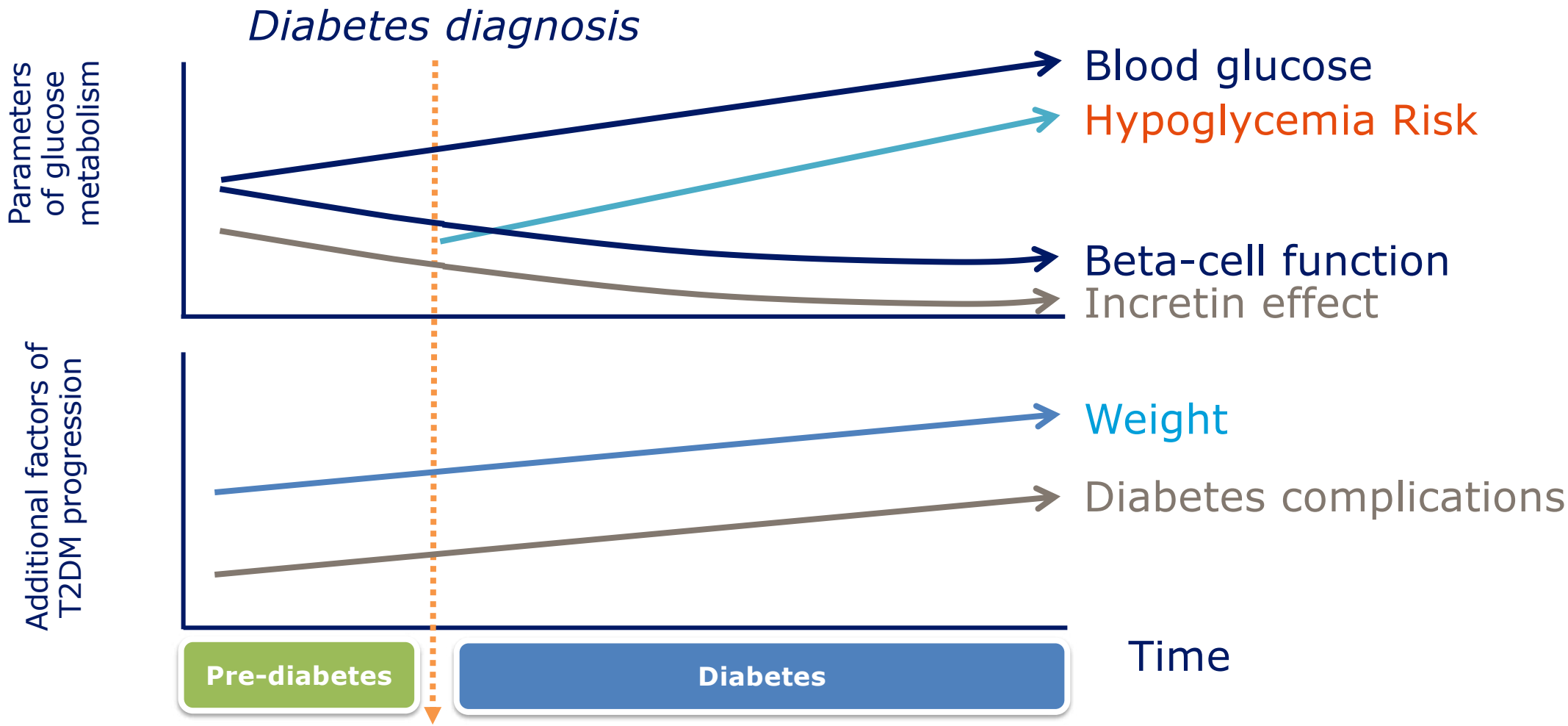
increased risk of CVD in T2DM vs general population[2]

2–5 FOLD

increased risk of HF in T2DM vs general population[3]

1. Gheith O, et al. *J Nephropharmacol.* 2016;5(1):49-56; 2. King RJ, Grant PJ. *Herz*. 2016;41(3):184-192; 3. Rosano GM, et al. *Card Fail Rev*. 2017;3(1):52-55.

Type 2 Diabetes is a Progressive Disease

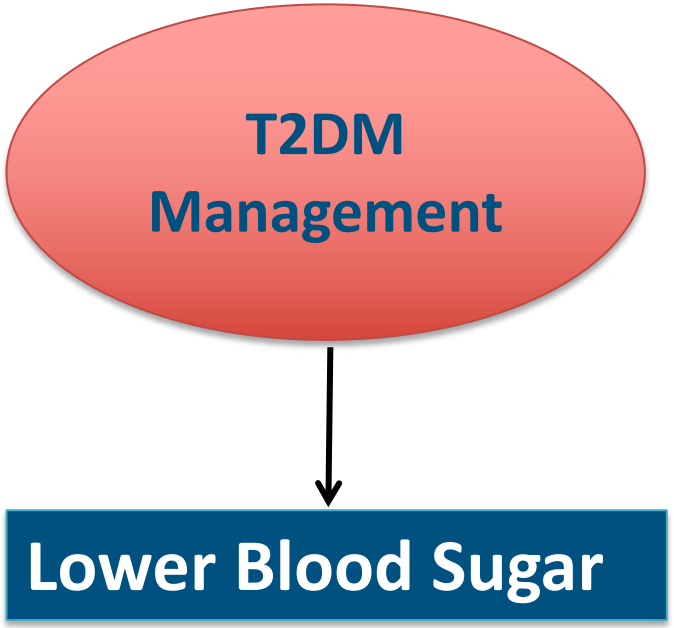


1. UK Hypoglycaemia Study Group: Diabetologia 2007; 50: 1140-1147; 2. UKPDS 16. *Diabetes*. 1995;44:1249–58;
3. Fonseca VA. *Diabetes Care*. 2009; 32(2):S151-S156; 4. Knop, et al. *Diabetes.* 2007; 56(8):1951-1959

The Evolving Role of Primary Care in T2DM Management

- PCPs deliver clinical care to **>90%** of individuals with T2DM
- This will likely increase over time with the growth of the aging population
- T2DM management has become increasingly complex:

The Old Role



Shrivastav, et al. *Diabetes Spectr.* 2018 ;31(3):279-287.

The Evolving Role of Primary Care in T2DM Management

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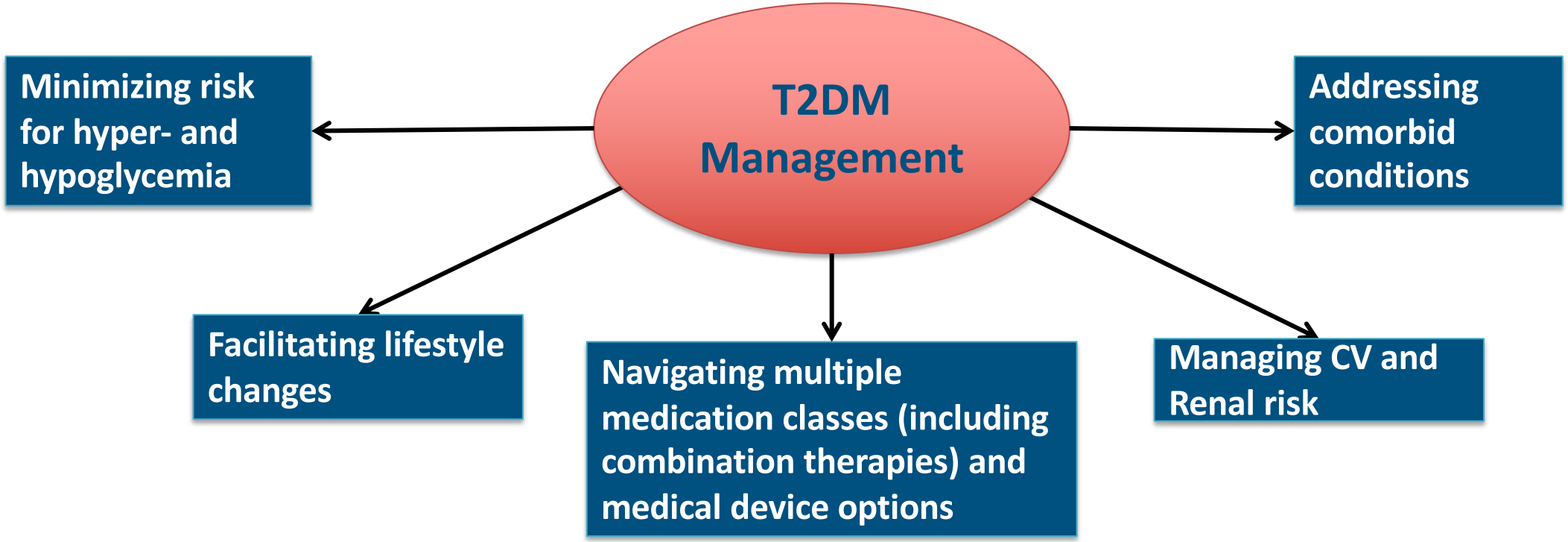
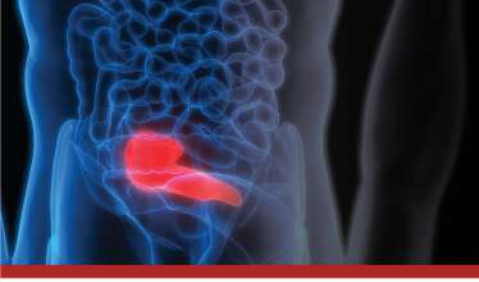


Shrivastav, et al. *Diabetes Spectr.* 2018 ;31(3):279-287.

ADA Standards of Medical Care in Diabetes - 2023

American Diabetes Association.
Connected for Life

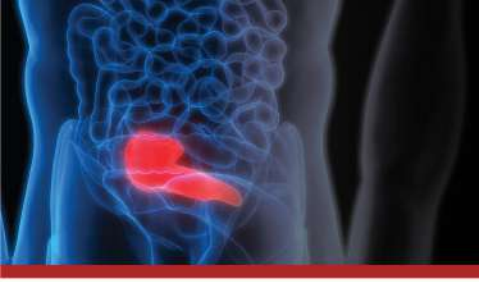


Glycemic Goals

- A1C goal for many nonpregnant adults of <7% without significant hypoglycemia is appropriate.
  - Closer to normal (<6.5%) in younger individuals without co-morbidities
  - Less stringent A1C goals (such as <8%) may be appropriate for older individuals with multiple comorbidities

Glycemic Targets
Standards of Medical Care in Diabetes - 2022. *Diabetes Care* 2022;45(Suppl. 1)

American Diabetes Association.
Connected for Life



Glycemic Assessment

- For patients patients who are meeting treatment goals (and who have stable glycemic control) - A1C or other glycemic measurement *at least* two times a year

- In patients whose therapy has recently changed and/or who are not meeting glycemic goals - ssess glycemic status at least quarterly, and as needed

Glycemic Targets
Standards of Medical Care in Diabetes - 2022. *Diabetes Care* 2022;45(Suppl. 1)

American Diabetes Association.
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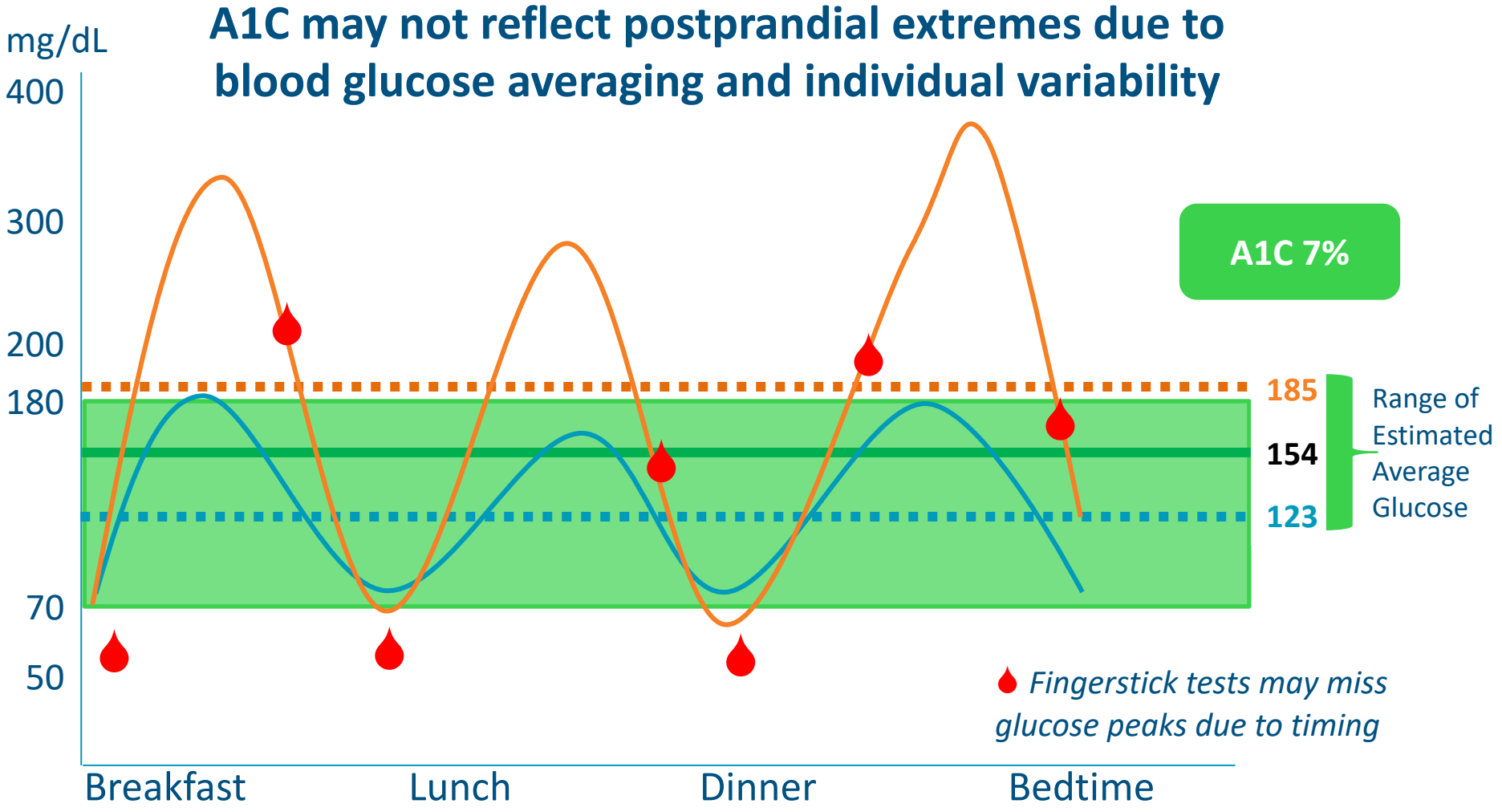
Looking Beyond a "Good" A1C of 7%



D Nathan, et al. Translating the A1C Assay into Average Glucose Values, *Diabetes Care.* Vol. 31, No. 8, Aug 2008.

Glycemic Variability Increases Risk for Microvascular Complications

Diabetes Care Volume 40, June 2017

Association of Glycemic Variability in Type 1 Diabetes With Progression of Microvascular Outcomes in the Diabetes Control and Complications Trial

*John M. Lachin,[1] Ionut Bebu,[1] Richard M. Bergenstal,[2] Rodica Pop-Busui,[3] F. John Service,[4] Bernard Zinman,[5] and David M. Nathan,[6] for the DCCT/EDIC Research Group**

Diabetes Care 2017;40:777–783 | https://doi.org/10.2337/dc16-2426

Glycemic Variability Increases Risk for Macrovascular Complications

Open access Original research

BMJ Open Diabetes Research & Care

Long-term variability of glycemic markers and risk of all-cause mortality in type 2 diabetes: the Look AHEAD study

Arnaud D Kaze ,[1] Prasanna Santhanam,[2] Sebhat Erqou,[3] Rexford S Ahima,[2] Justin Basile Echouffo-Tcheugui [2]

To cite: Kaze AD, Santhanam P, Erqou S, *et al*. Long-term variability of glycemic markers and risk of all-cause mortality in type 2 diabetes: the Look AHEAD study. *BMJ Open Diab Res Care* 2020;**8**:e001753. doi:10.1136/bmjdrc-2020-001753

► Supplemental material is published online only. To view, please visit the journal online (http://dx.doi.org/10.1136/bmjdrc-2020-001753).

Received 3 July 2020

ABSTRACT

Introduction Glycemic variability may predict poor outcomes in type 2 diabetes. We evaluated the associations of long-term variability in glycosylated hemoglobin (HbA_{1C}) and fasting plasma glucose (FPG) with cardiovascular disease (CVD) and death among individuals with type 2 diabetes.

Research design and methods We conducted a secondary, prospective cohort analysis of the Look AHEAD (Action for Health in Diabetes) data, including 3560 participants who attended four visits (baseline, 12 months, 24 months, and 36 months) at the outset. Variability of HbA_{1C} and FPG was assessed using four indices across measurements from four study visits. Participants without CVD during the first 36 months were followed for incident outcomes including a CVD composite (myocardial infarction, stroke, hospitalization for angina, and CVD-

Significance of this study

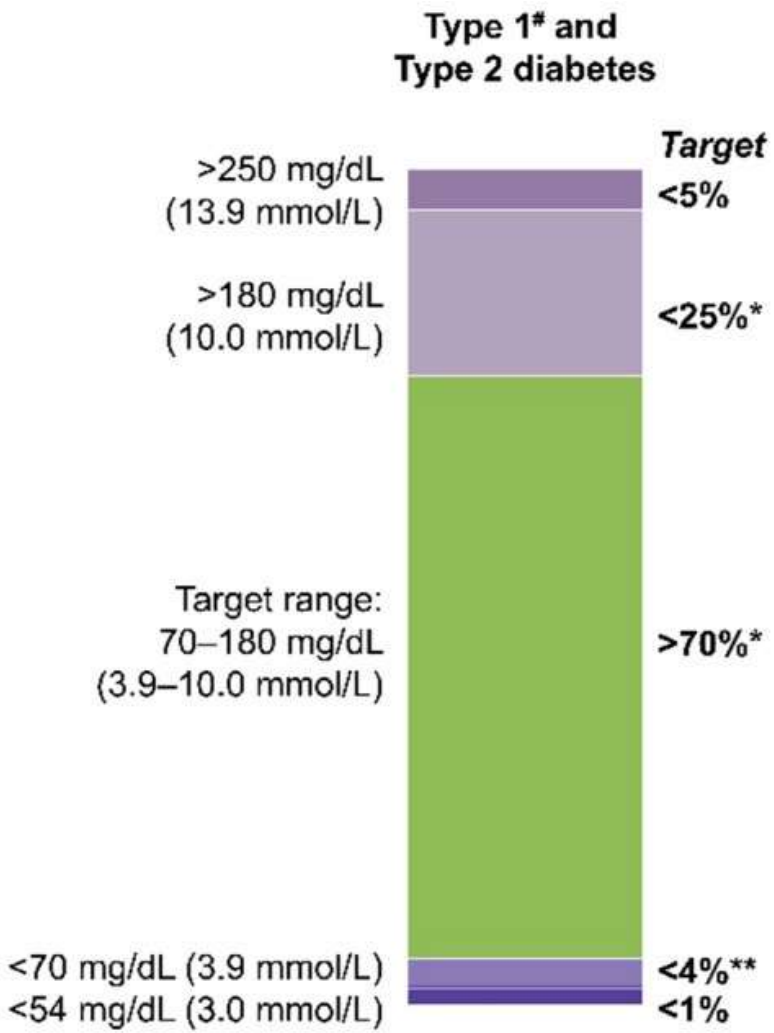
What is already known about this subject?

- Glycemic variability may predict poor outcomes in type 2 diabetes.
- In assessing the adverse effects of long-term variability of glycemic measures in type 2 diabetes, previous studies have only focused on a single glycemic marker and have seldom evaluated several glycemic measures concomitantly.

What are the new findings?

- Participants in the highest quartile of SD of glycosylated hemoglobin (HbA_{1C}) had a 2.10-fold higher risk of all-cause mortality compared with those in the lowest quartile.

Glycemic Monitoring Targets in Diabetes



#For patients aged <25 years, if 7.5% HbA_{1c} is desired, then time-in–range should be set around 60%.
*Includes percentage of values >250 mg/dL.
**Includes percentage of values <54 mg/dL.

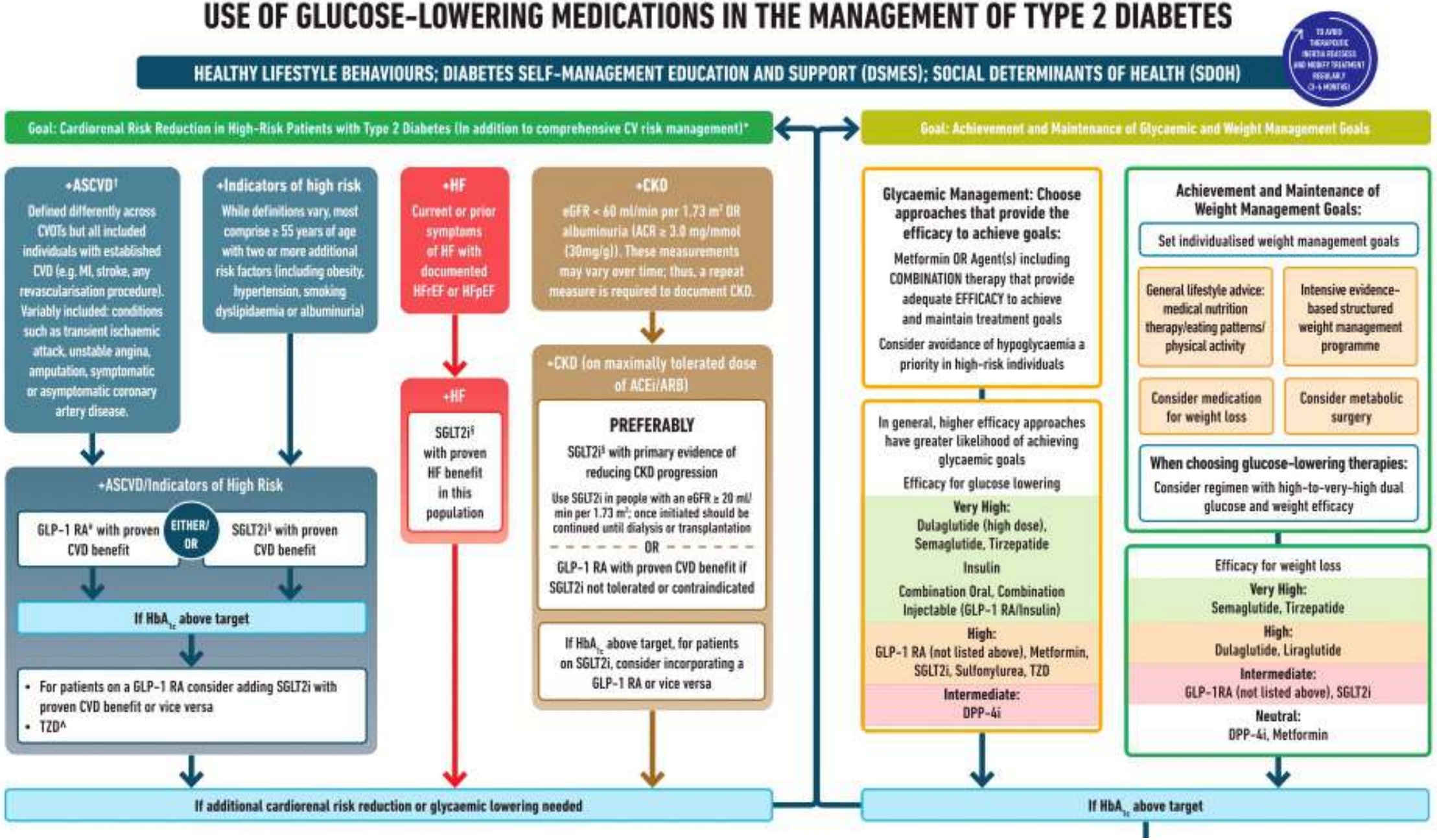
Adapted from: Battelino *et al.*, 2019.

		Type 1 / Type 2	Older/high-risk Type 1 / Type 2
Time above range (TAR)	Above target range	> 180 mg/dL > 10.0 mmol/L	
	% of time/d	< 25% < 6 h	
	Above target range	> 250 mg/dL > 13.9 mmol/L	> 250 mg/dL > 13.9 mmol/L
	% of time/d	< 5% < 1 h, 12 min	< 10% < 2 h, 24 min
Time in range (TIR)	Target range	70–180 mg/dL 3.9–10.0 mmol/L	70–180 mg/dL 3.9–10.0 mmol/L
	% of time/d	> 70% > 16 h, 48 min	> 50% > 12 h
Time below range (TBR)	Below target range	< 70 mg/dL < 3.9 mmol/L	< 70 mg/dL < 3.9 mmol/L
	% of time/d	< 4% < 1 h	< 1% < 5 min
	Below target range	< 54 mg/dL < 3.0 mmol/L	
	% of time/d	< 1% < 15 min	

Each incremental 5% increase towards time in range (TIR) targets is associated with clinically significant benefits for Type 1 / Type 2. Adapted from: Battelino T, *et al.* Clinical targets for continuous glucose monitoring data interpretation: recommendations from the International Consensus on Time in Range (58).

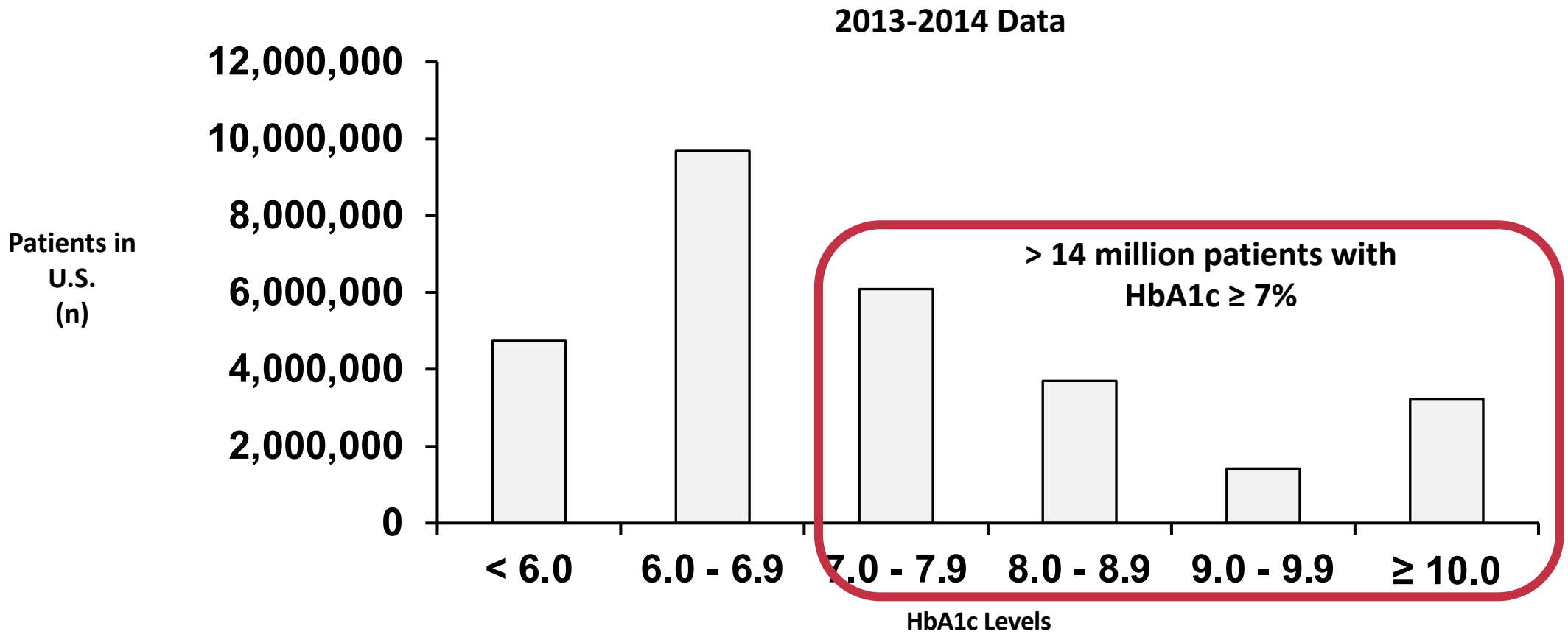
Glycemic Management

USE OF GLUCOSE-LOWERING MEDICATIONS IN THE MANAGEMENT OF TYPE 2 DIABETES

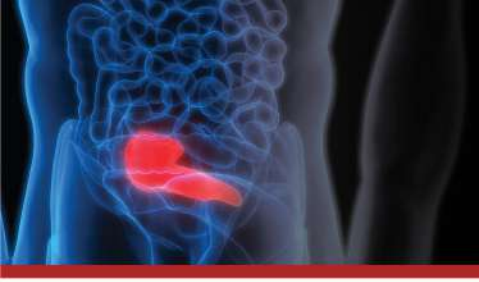


Pharmacologic Approaches to Glycemic Management:
Standards of Medical Care in Diabetes - 2021. *Diabetes Care.* 2021;44(Suppl. 1):S111-S124.

NHANES:
Half of Patients Have HbA1c Greater than Treatment Goal of 7%



Derived from Hoerger, et al. *Diabetes Care*. 2008 Jan; 31(1): 81-86 and CDC, Questionnaires, Datasets, and Related Documentation, https://gis.cdc.gov/grasp/diabetes/DiabetesAtlas.html; US Census Data.



Therapeutic Inertia

The delay in intensifying therapy when a therapeutic goal is not reached.

Nearly half of patients with diabetes have a glycated hemoglobin (HbA1c) above target

30% of primary care physicians "never or rarely" intensify insulin

1. Skolnik, N, Jaffa, F, Kiriakov, Y. *Journal of Family Practice*. 2017.
2. Diabetes Ther. 2018; 9:501–519.

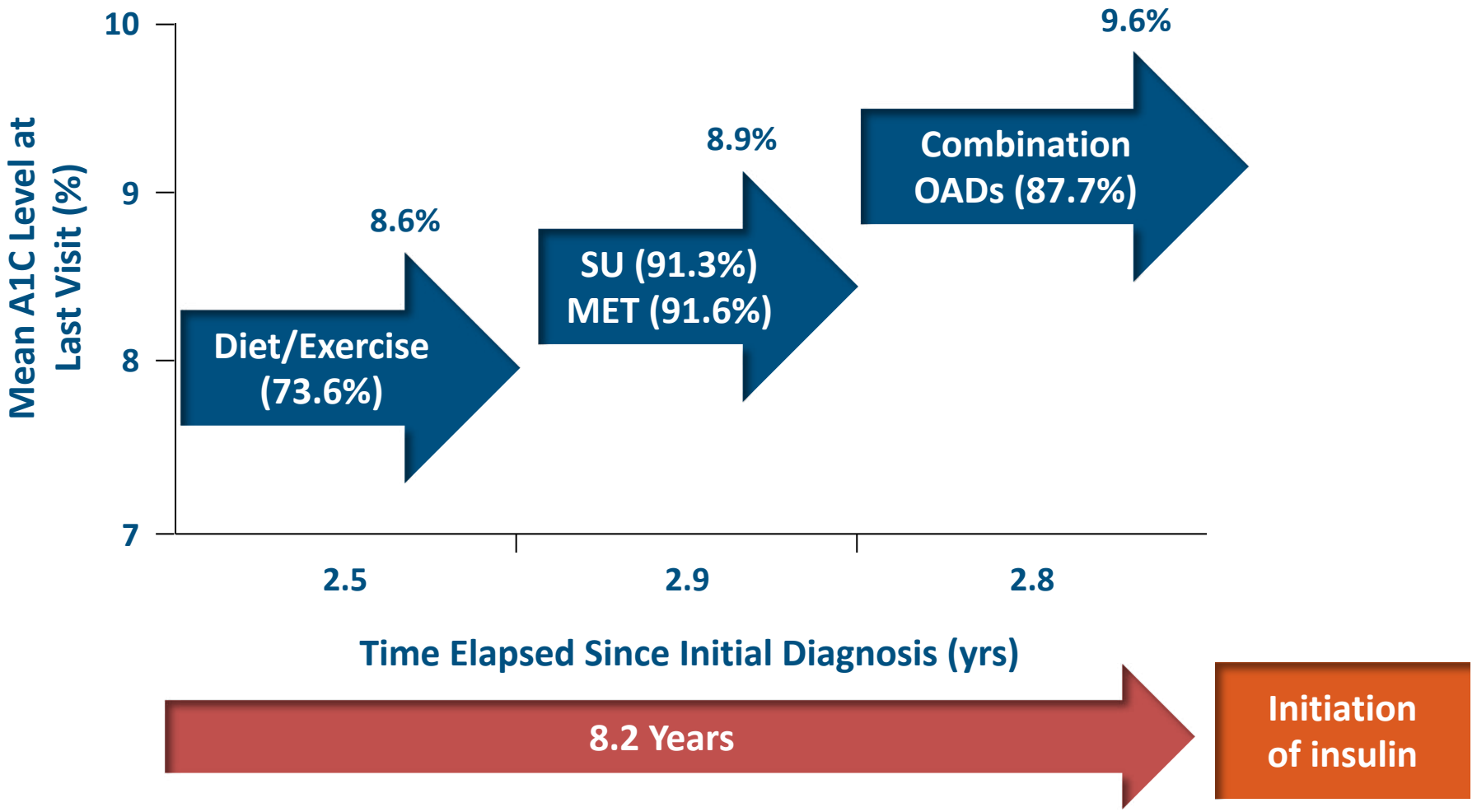
Clinical Inertia in People With Type 2 Diabetes

- Retrospective cohort study based on 81,573 people with type 2 diabetes in the U.K.
- Median time from above HbA1c cutoff to intensification of Therapy

Baseline Regimen	A1c>7.0	A1c>7.5	A1c>8.0
One Oral Agent	2.9 years	1.9 years	1.6 years
Two Oral Agents	7.2 years	7.2 years	6.9 years
Time to Insulin (base one, two or three oral agents)	7.1 years	6.1 years	6.0 years

Khunti K, et al. *Diabetes Care*. 2013;36(11):3411-3417.

Most Patients Have 8–10 Years of Poor Glucose Control Before Insulin Is Started



MET = metformin; OADs = oral antidiabetes drugs; SU = sulfonylurea.

Brown JB, et al. *Diabetes Care*. 2004;27:1535–1540.

Time to Achievement of Control After Starting Medication

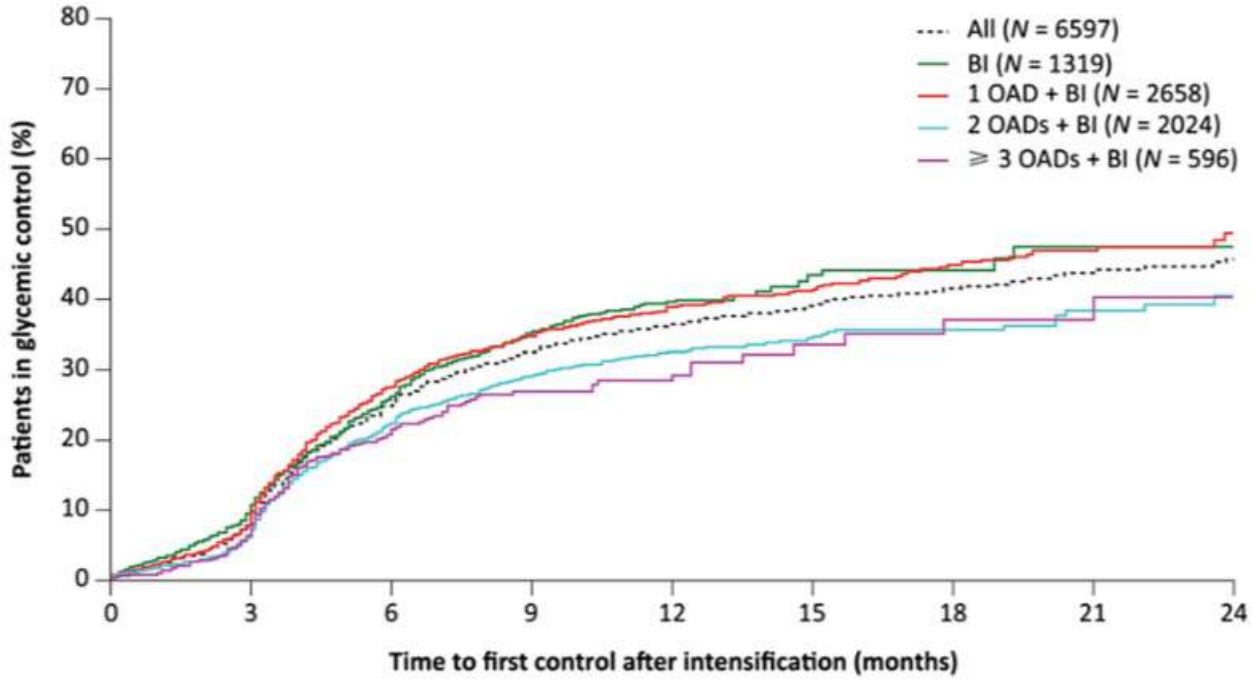
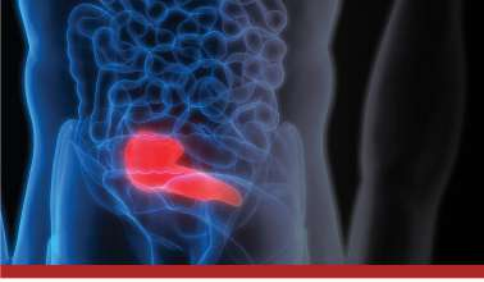


Fig. 3 Kaplan–Meier curves for time to reach glycemic control (HbA1c < 7%) for the overall study cohort and the four subcohorts. *BI* basal insulin, *HbA1c* glycated hemoglobin, *OAD* oral antidiabetic

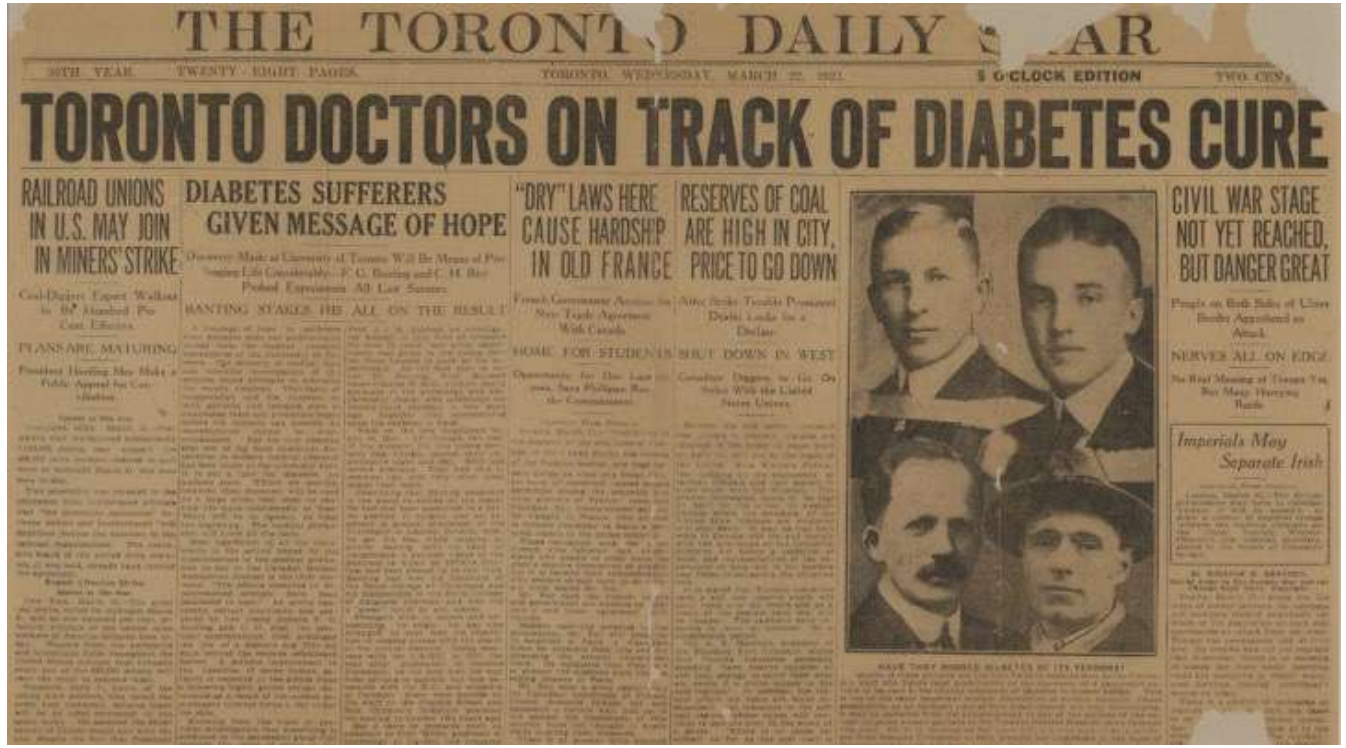
Blonde L, *et al. Diabetes Ther.* 2018;9:1347–58.



Keep Moving Forward

If selected medication dose does not achieve or maintain the A1C target **after 3 months – DO SOMETHING**.

Insulin – 100 Years



THE TORONTO DAILY STAR

TORONTO DOCTORS ON TRACK OF DIABETES CURE

RAILROAD UNIONS IN U.S. MAY JOIN IN MINERS' STRIKE

DIABETES SUFFERERS GIVEN MESSAGE OF HOPE

"DRY" LAWS HERE CAUSE HARDSHIP IN OLD FRANCE

RESERVES OF COAL ARE HIGH IN CITY, PRICE TO GO DOWN

CIVIL WAR STAGE NOT YET REACHED, BUT DANGER GREAT

Imperials May Separate Irish

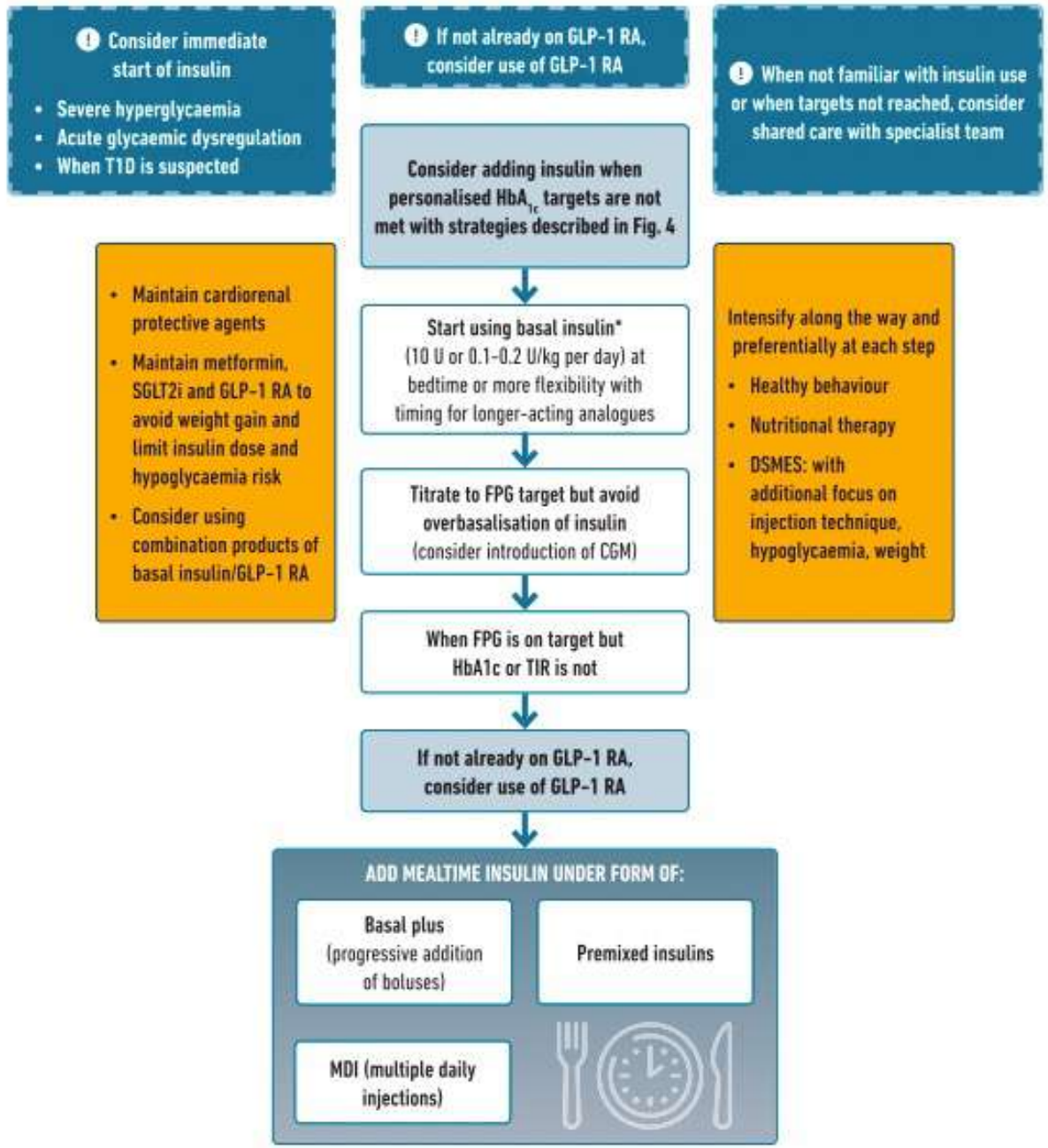
Injectable Therapy (Insulin and GLP-1 RA)

GLP-1 RA preferred over insulin as first injectable in most situations.

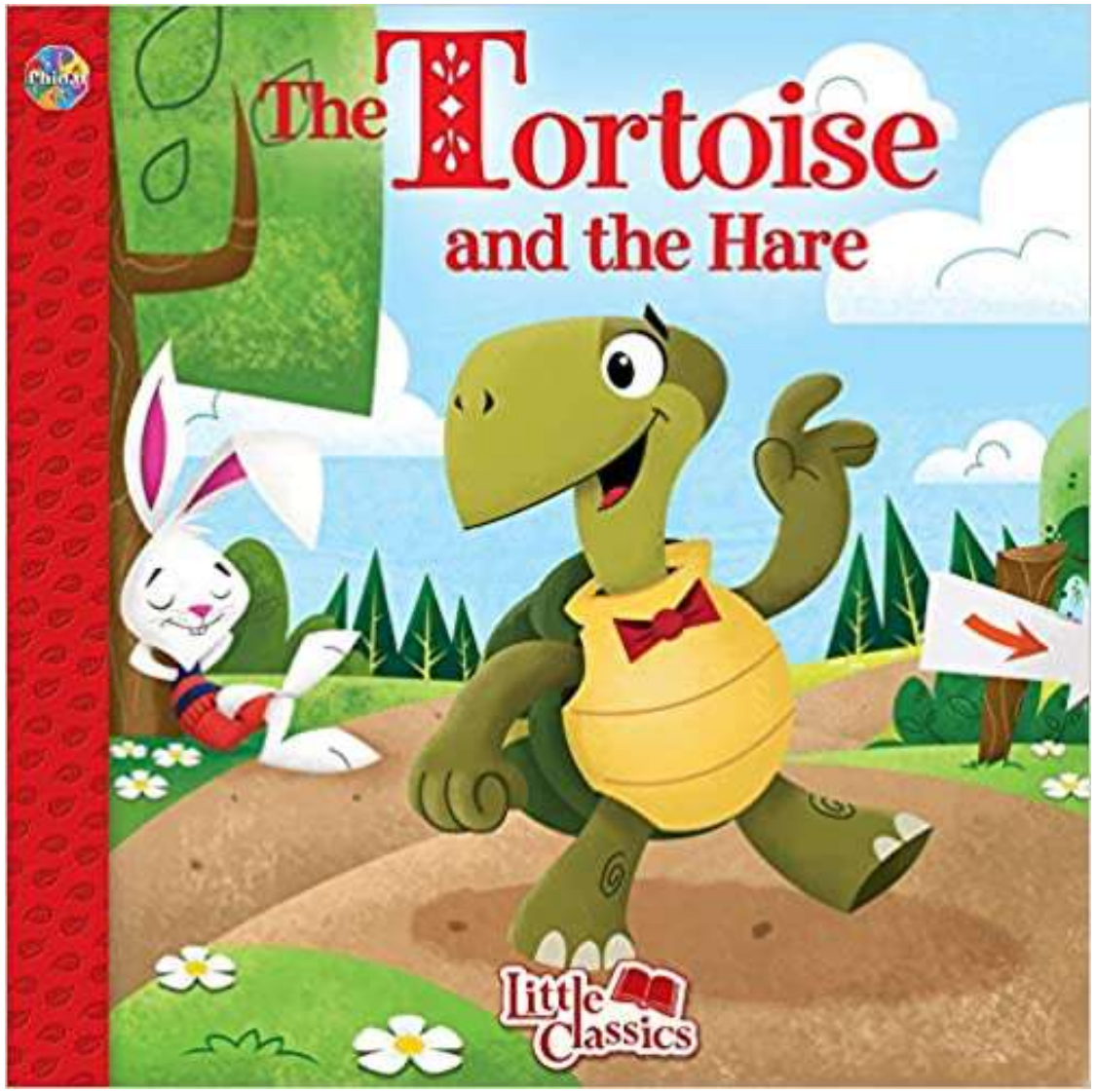
- Evidence from trials comparing GLP-1 receptor agonists and insulin (basal, pre- mixed, or basal-bolus) shows similar or even better efficacy in HbA1c reduction
- GLP-1 receptor agonists have a lower risk of hypoglycemia and are associated with reductions in body weight compared with weight gain with insulin
- Exception is when A1c is very high, and patient is symptomatic.

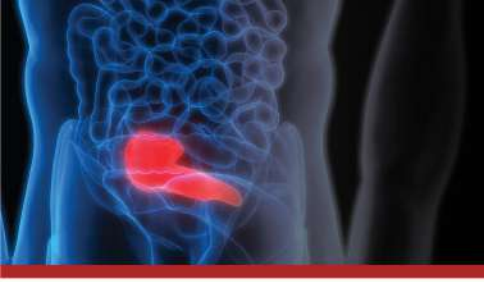
If insulin is used, combination therapy with a GLP-1 RA is recommended for greater efficacy and durability of treatment effect.

PLACE OF INSULIN[1]



Practical Insulin Management: Starting and Titrating Insulin

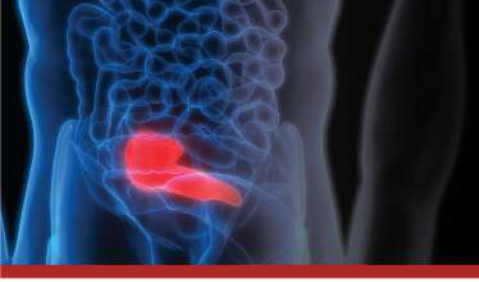




Indications for Insulin

- A1c not controlled on other medicines
- Catabolic (weight loss)
- Very high A1c (>10%)

Diabetes Care – Standards of Care 2022



Barriers to Insulin Initiation

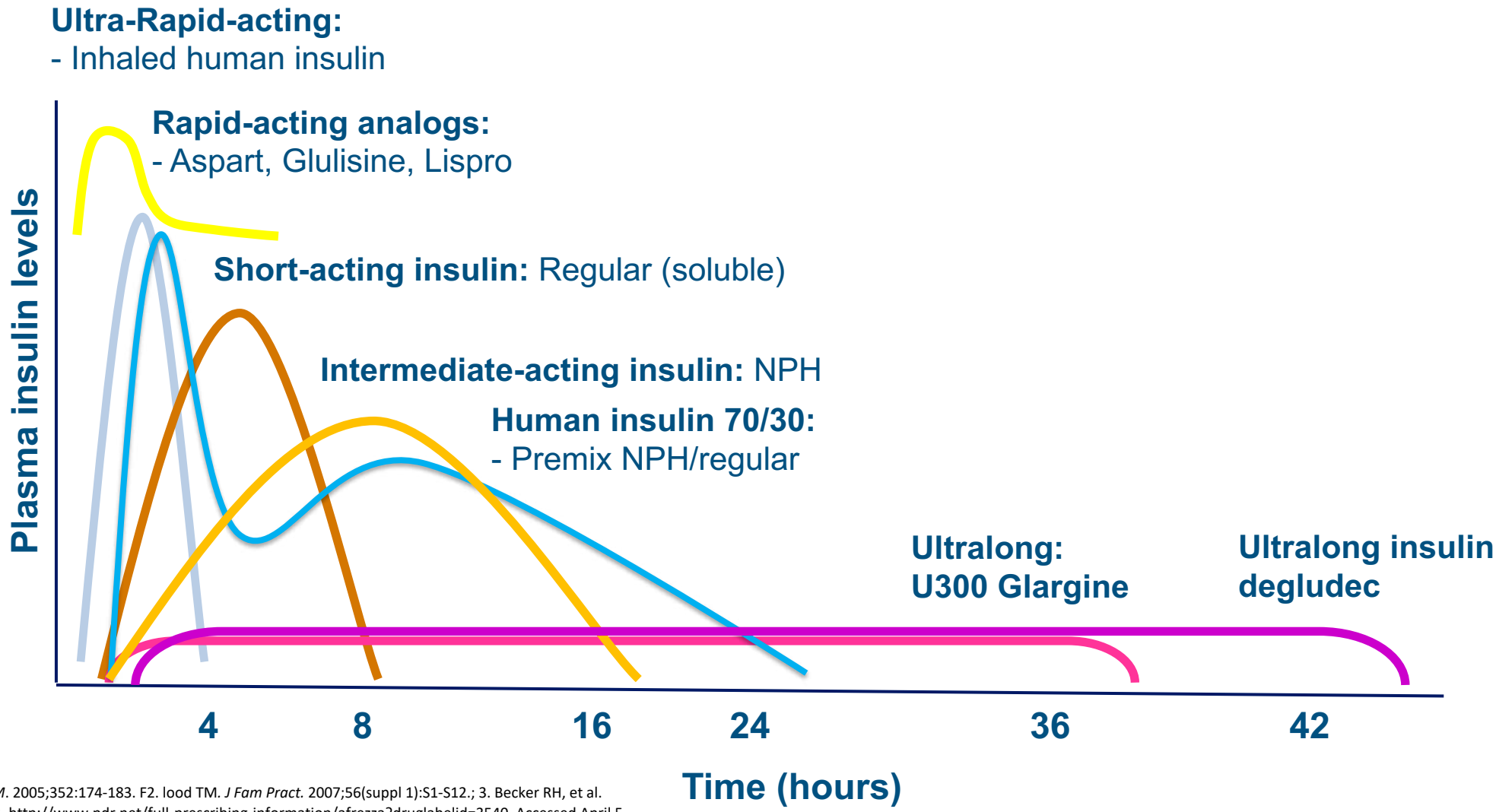
Patient Barriers

- Fear of injections
- Fear of hypoglycemia
- Weight gain
- False Beliefs – insulin leads to complications
- Personal sense of failure
- Cost

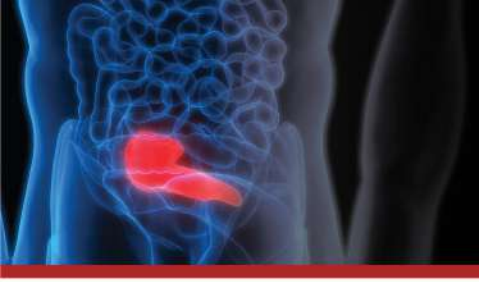
Clinician Barriers

- Therapeutic Inertia
- Fear of hypoglycemia
- Weight gain
- Logistic challenges
- Lack of Comfort

Types of Insulin



1. Adapted from Hirsch IB. *NEJM*. 2005;352:174-183. F2. lood TM. *J Fam Pract.* 2007;56(suppl 1):S1-S12.; 3. Becker RH, et al. *Diabetes Care.* 2015;38:637-643. http://www.pdr.net/full-prescribing-information/afrezza?druglabelid=3540. Accessed April 5, 2015. 4. Hompesch M, et al. *Clin Ther*. 2014;36(4):507-15.



Basal Insulins

Basal Insulin Type		Onset	Peak	Duration of Action (h)	Variability
Intermediate-acting	Human NPH	1-2 h	4-12 h	10-24 h	Greater
Long-acting analogs	Insulin glargine (U-100)	1.1-2 h	No pronounced peak	7.6 to >24	Less
	Insulin detemir	1.1 h	No pronounced peak	6 to >24	Less
Ultra-long-acting analogs	Insulin glargine U-300	6 h	Nearly peakless	>36 h	Minimal
	Insulin degludec (U-100/U-200)	30-90 min	Nearly peakless	>42	Minimal

Less variability = Less hypoglycemia

PL Detail-Document, Comparison of Insulins and Injectable Diabetes Meds. *Pharmacist's Letter/Prescriber's Letter*. March 2015; PDR.net. http://www.pdr.net/full-prescribing-information/toujeo?druglabelid=3688. Accessed Jan 26, 2018; PDR.net. http://www.pdr.net/drug-summary/lantus?druglabelid=520.
Accessed Jan 26, 2018; Tresiba package insert. http://www.novo-pi.com/tresiba.pdf. Accessed Jan 3, 2018. Fiasp package insert. http://www.novo-pi.com/fiasp.pdf. Accessed Jan 26, 2018; Monami M, et al. *Diabetes Res Clin Pract*. 2008;81(2):184-189; Marso SP et al. *N Engl J Med* 2017;377:723-732.

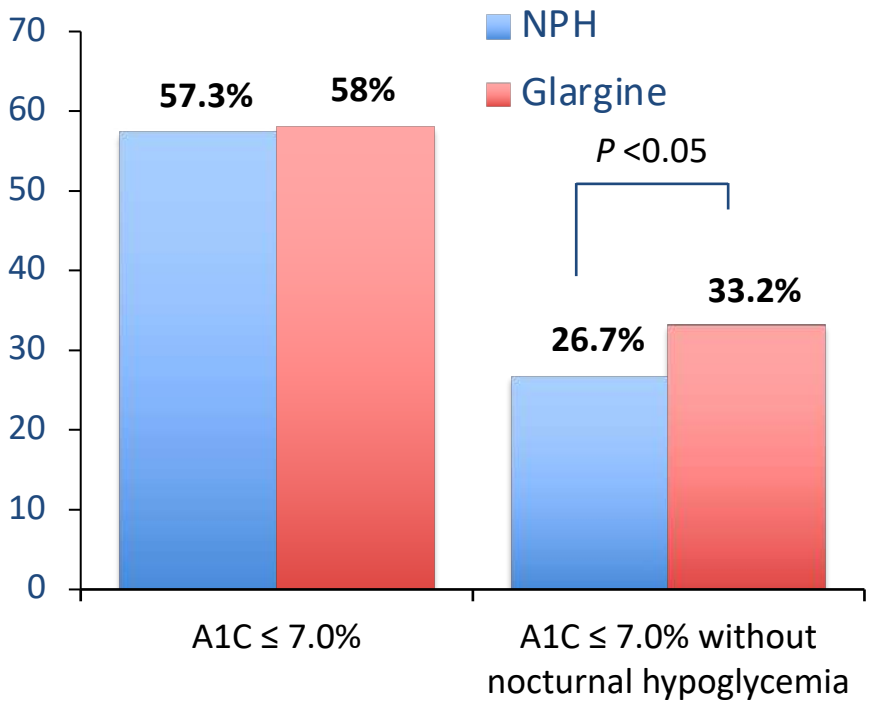
Treat-to-Target: Insulin Glargine vs NPH Added to Oral Therapy

No Difference in A1C Level But Lower Rate of Hypoglycemia

Study

- N = 756
- Currently on stable doses of OADs
- A1C level >7.5%
- Randomized to insulin glargine or NPH at bedtime added to existing oral therapy × 24 weeks
- Weekly titration of insulin to target FPG ≤100 mg/dL

Results



Riddle, MC et al. *Diabetes Care.* 2003;26(11):3080–3086.

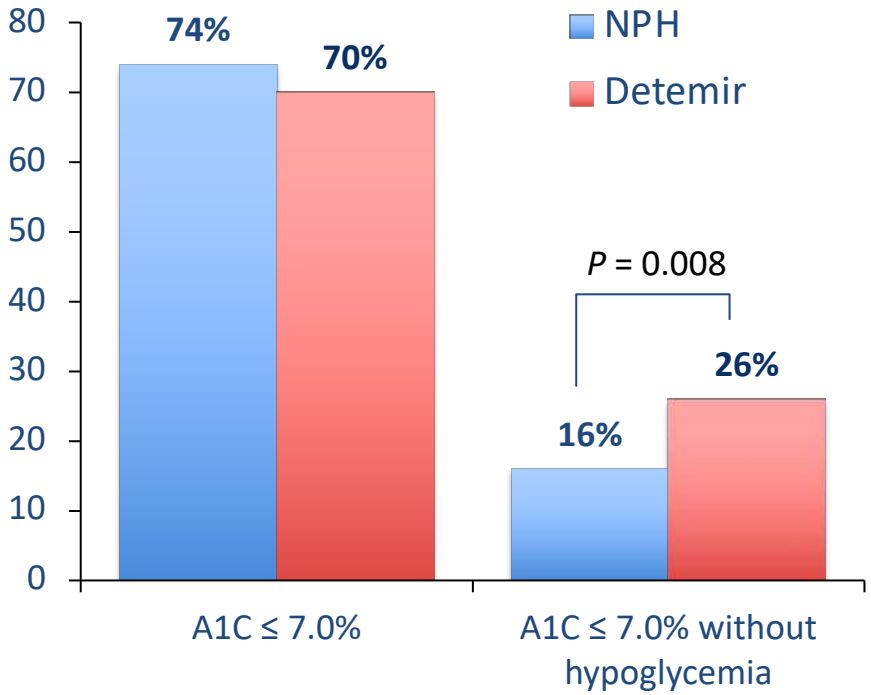
Treat-to-Target: Insulin Detemir vs NPH Added to Oral Therapy

No Difference in A1C Level But Lower Rate of Hypoglycemia

Study

- N = 476
- Currently on 1 or 2 oral agents for at least 4 months
- A1C level = 7.5%–10.0%
- Randomized to twice-daily insulin detemir or twice-daily NPH added to existing oral therapy × 26 weeks
- Titration of insulin to target pre-breakfast/pre-dinner PG ≤108 mg/dL

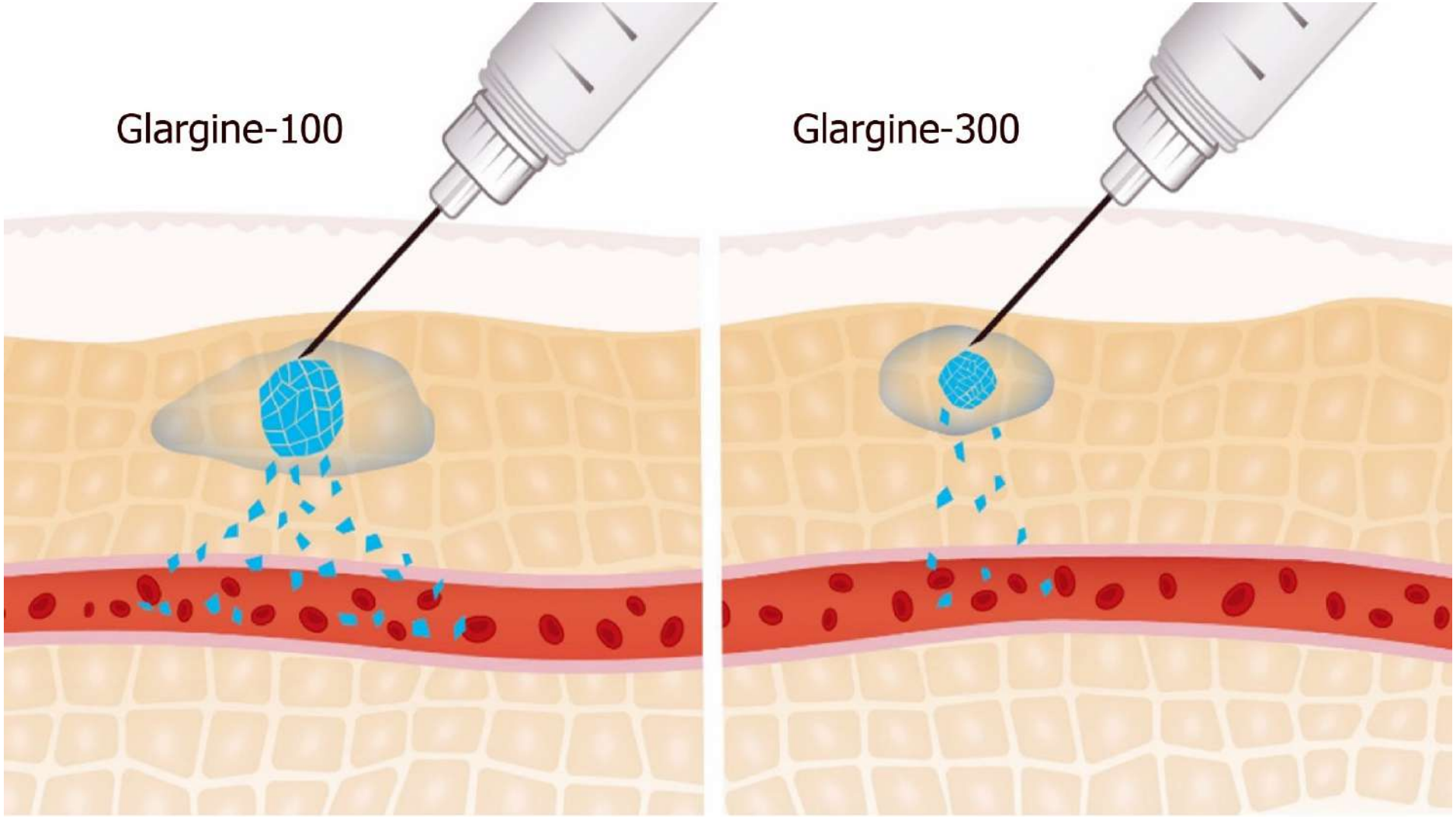
Results



PG = plasma glucose.

Hermansen K, et al. *Diabetes Care.* 2006;29(6):1269–1274.

Glargine U-100 vs U-300

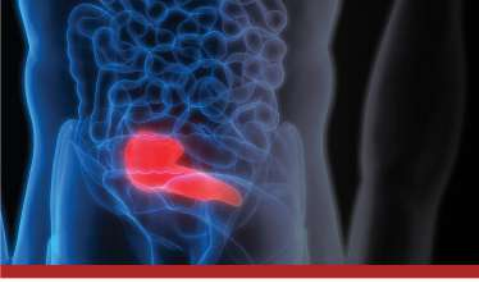


World J Diabetes. Apr 15, 2020; 11(4): 100-114.

Basal Insulin Analog - Glargine U300 (300 U/mL)

- Contains the same molecule as glargine U100, but in a lower volume
- Smaller depot surface area leading to a reduced rate of absorption
- Steady state is 4 days
- Duration of action ≤36 hours
- For patients currently on twice-daily long or intermediate-acting insulin, start U-300 at 80% of the total daily NPH or insulin detemir twice-daily dosage.

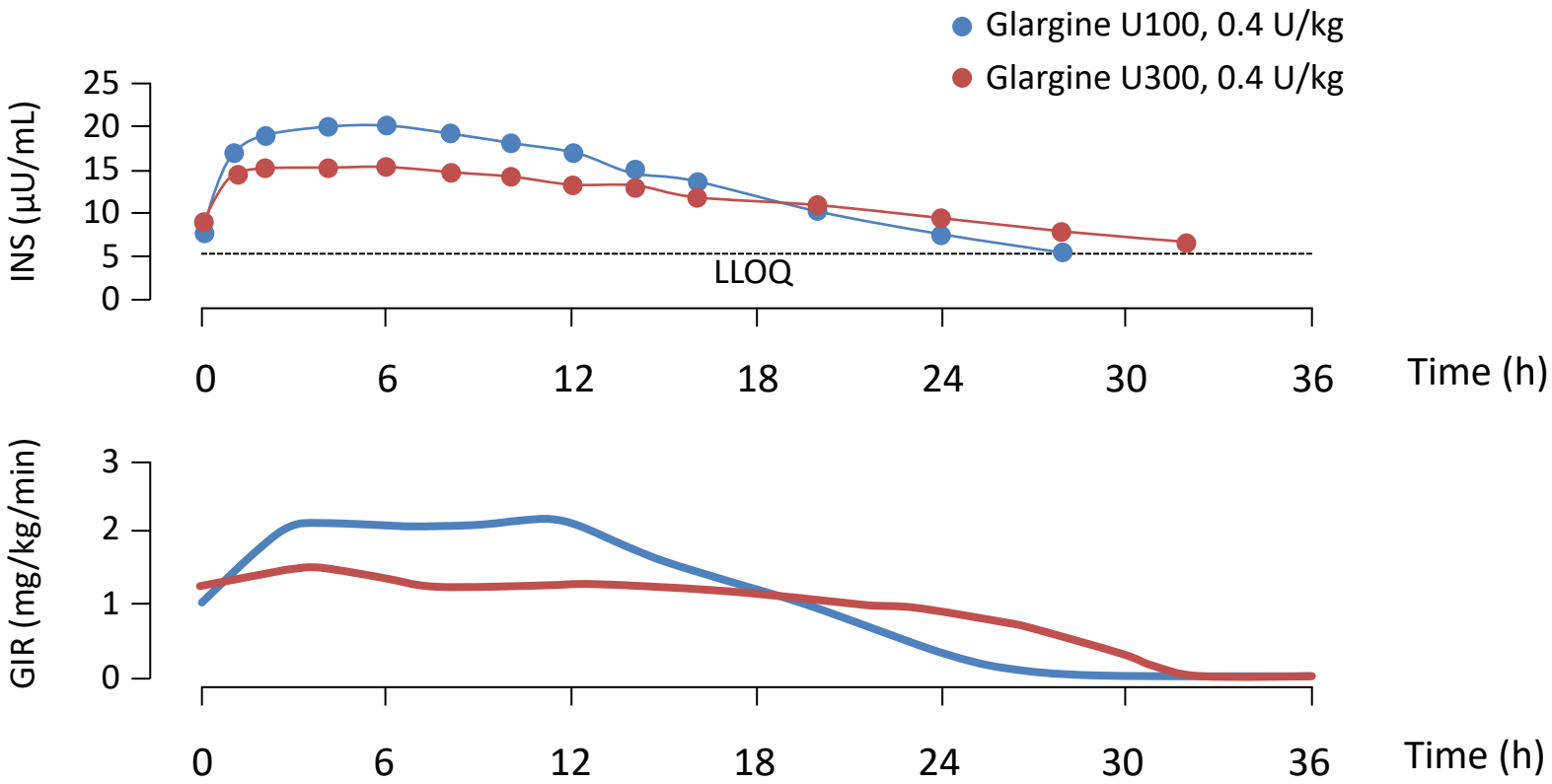
Garber AJ, et al. *Diabetes Obes Metab*. 2014;16:483–491l; https://products.sanofi.us/toujeo/toujeo.pdf.



U100 and U200 Insulin Degludec

- Dihexamers form soluble multihexamers after injection
- Multihexamers (> 5000 kDa) disassemble slowly
- Monomers released rapidly after hexamers disassemble
- Exposure and activity similar for U100 vs U200 degludec
- Be aware of the ultra-long duration of action when titrating - The recommended days between dose increases are 3 to 4 days
- Adults with T2DM – may start at same unit dose as the total daily long or intermediate-acting insulin unit dose

Glargine U300 vs. Glargine U100: PK and PD:

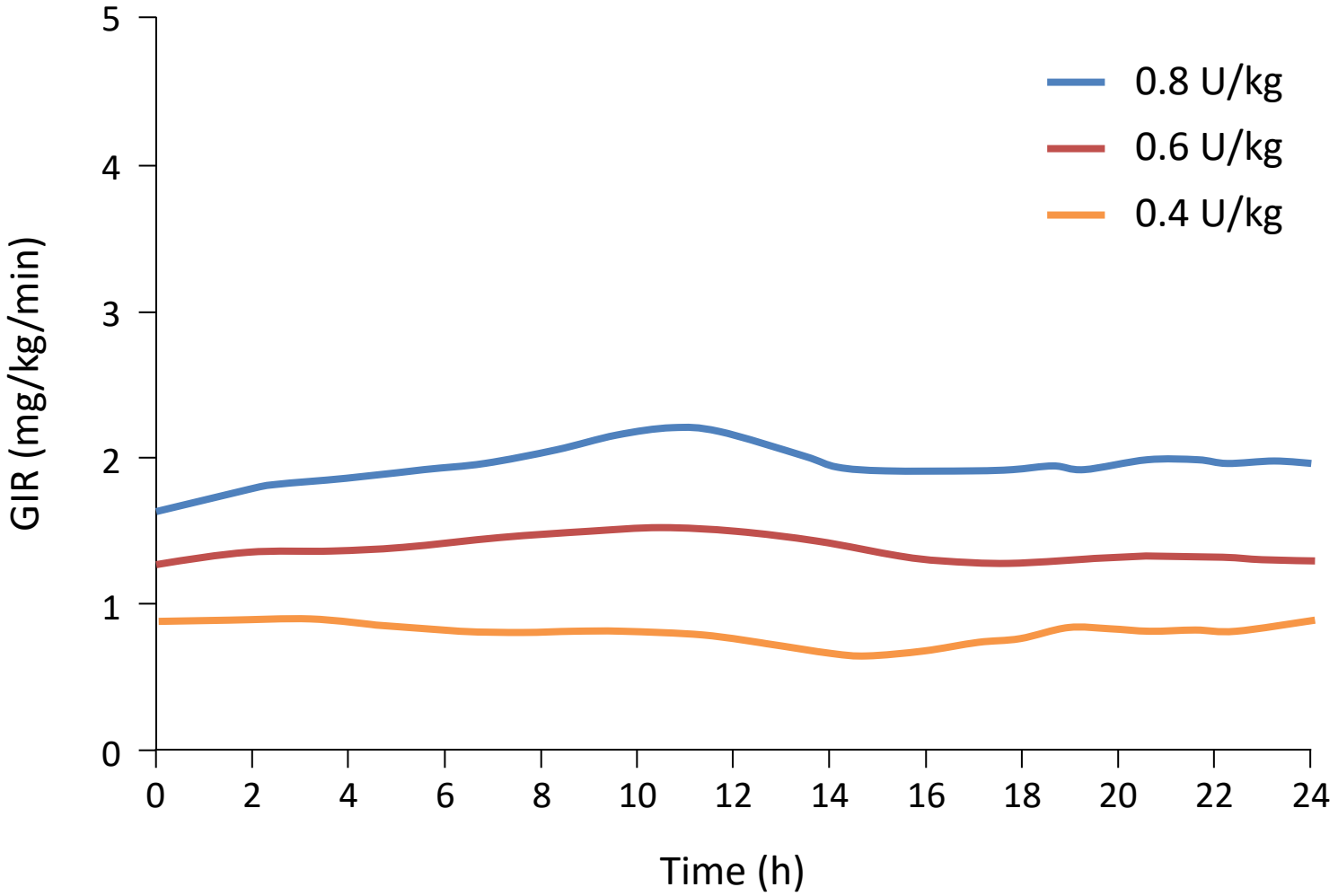


Glargine U300 displays a more even and prolonged PK/PD profile compared with glargine U100, offering BG control beyond 24 hours.

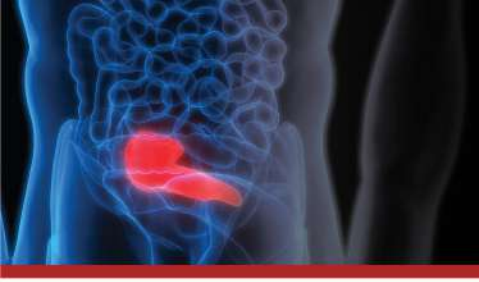
GIR = glucose infusion rate; INS = insulin concentration; LLOQ = lower limit of quantification; PD = pharmacodynamic; PK = pharmacokinetic.

Becker RH, et al. *Diabetes Care*. 2015;38(4):637–643.

Pharmacodynamic Profile of Insulin Degludec in T2DM



Heise T, et al. *Diabetes Obes Metab*. 2012;14(10):944–950.



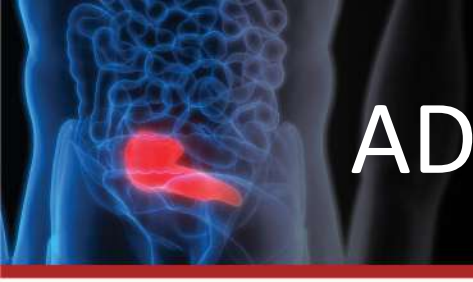
Glycemic Control With Basal Insulin

- Meta-analysis of 22 studies
- Subjects: T2DM receiving insulin glargine or detemir
  - Baseline A1C levels: 8.1% to 9.8% (glargine) and 8.6% to 9.1% (detemir)
  - Mean change in A1c – 1.4%

A1C = glycated hemoglobin.

Dailey G, et al. *Diabetes Technol Ther*. 2010;12(12):1019–1027.


Insulin Initiation



ADA Standard of Care – Titration Algorithm

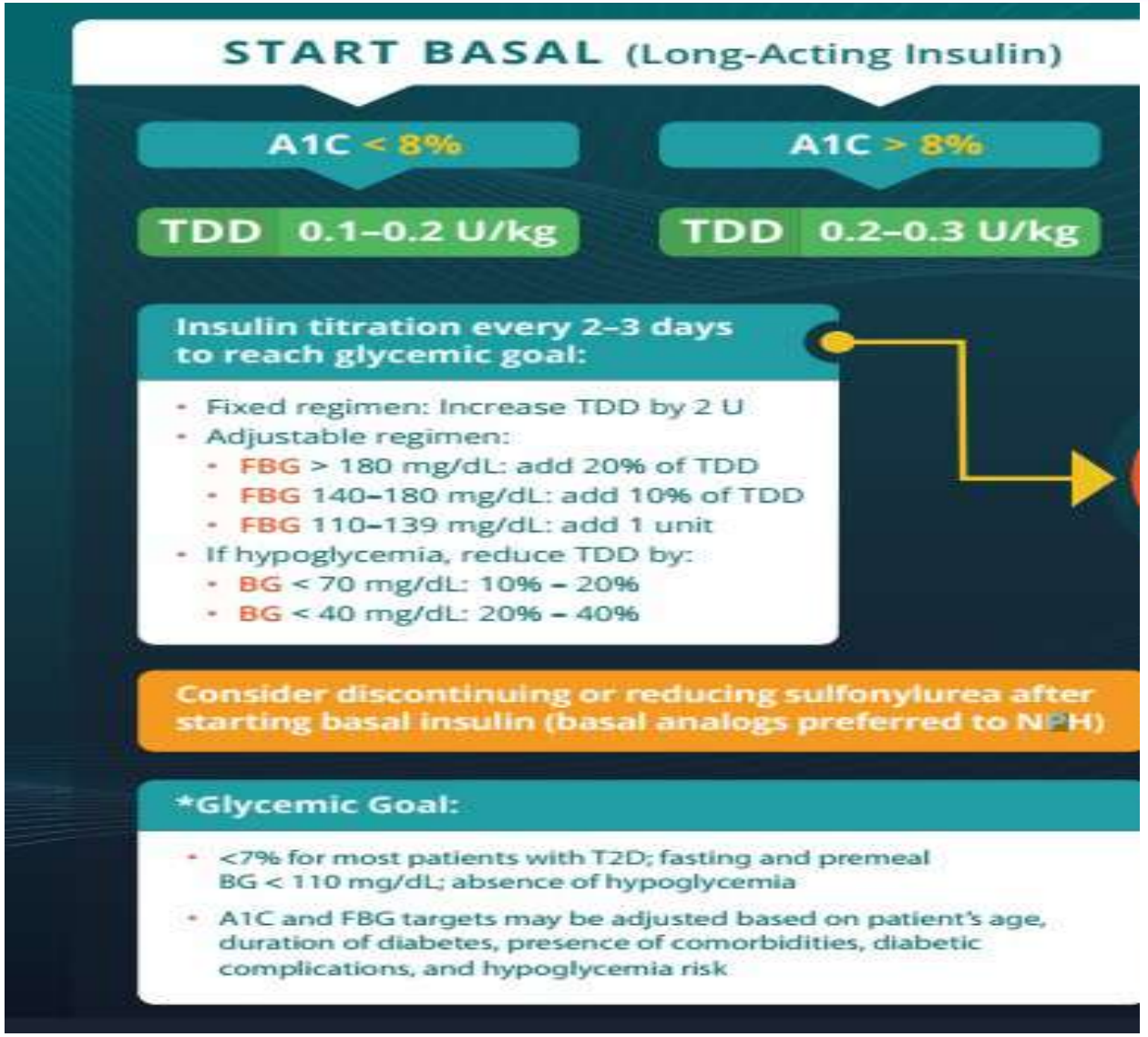
Add basal analog or bedtime NPH insulin

INITIATION: Start 10 units per day **OR** 0.1-0.2 units/kg per day

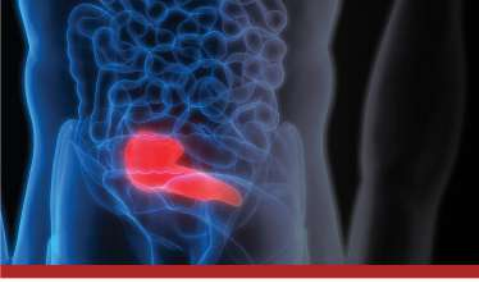
TITRATION:

- Set FPG target (see Section 6: Glycemic Targets)
- Choose evidence-based titration algorithm, e.g., increase 2 units every 3 days to reach FPG target without hypoglycemia
- For hypoglycemia determine cause, if no clear reason lower dose by 10-20%

AACE – Titration Algorithm



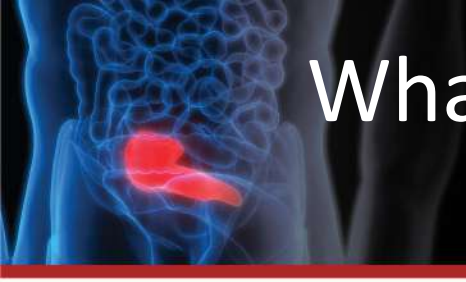
AACE/ACE COMPREHENSIVE TYPE 2 DIABETES MANAGEMENT ALGORITHM. AACE/ACE. Garber AJ, et al. *Endocr Pract*. 2018;24(1):91-120.



Canadian Insulin Titration Algorithm

- Start: 10 u basal insulin once daily
  - Adjust dose by 1 unit once daily when fasting blood glucose is > target (100 - 130mg/dl) (for NPH/detemir/Glargine-100/Glargine-300)
  - Adjust dose by 2 units every 3-7 days when fasting blood glucose is > target (100 - 130mg/dl) (applicable to all)
  - Clinician contact recommended when FBG reaches 130mg/dl

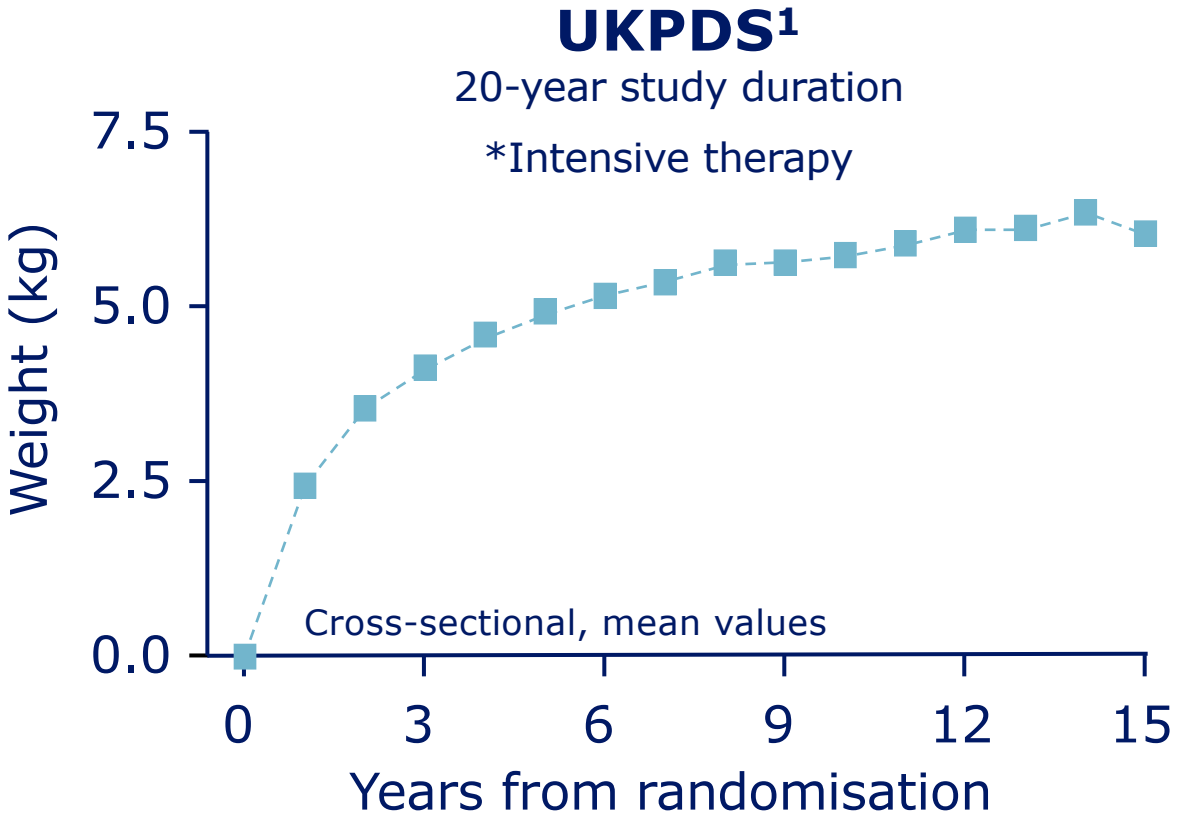
Diabetes Ther. 2018; 9:501–519.



What to do with Other Hypoglycemic Medications when Starting Insulin

- **Metformin** – may continue metformin – less weight gain than with insulin alone
- **SU** – Increased risk of hypoglycemia when used with insulin. May continue at beginning of starting insulin and then stop as insulin is titrated
- **TZD** – reduce dose or stop to avoid edema and weight gain, though may help in using less insulin in some patients
- **Incretin Mimetics (DPP4, GLP1)** – Helpful in decreasing weight gain and lowering final insulin dose; renal and CV benefits in appropriate populations
- **SGLT2i** – may continue; renal and CV benefits in appropriate populations

Weight Gain Increases Over Time With Therapy Intensification



ACCORD[2]

7-year study duration

- **28%** of patients who gained weight, gained **>10 kg**

VADT[3]

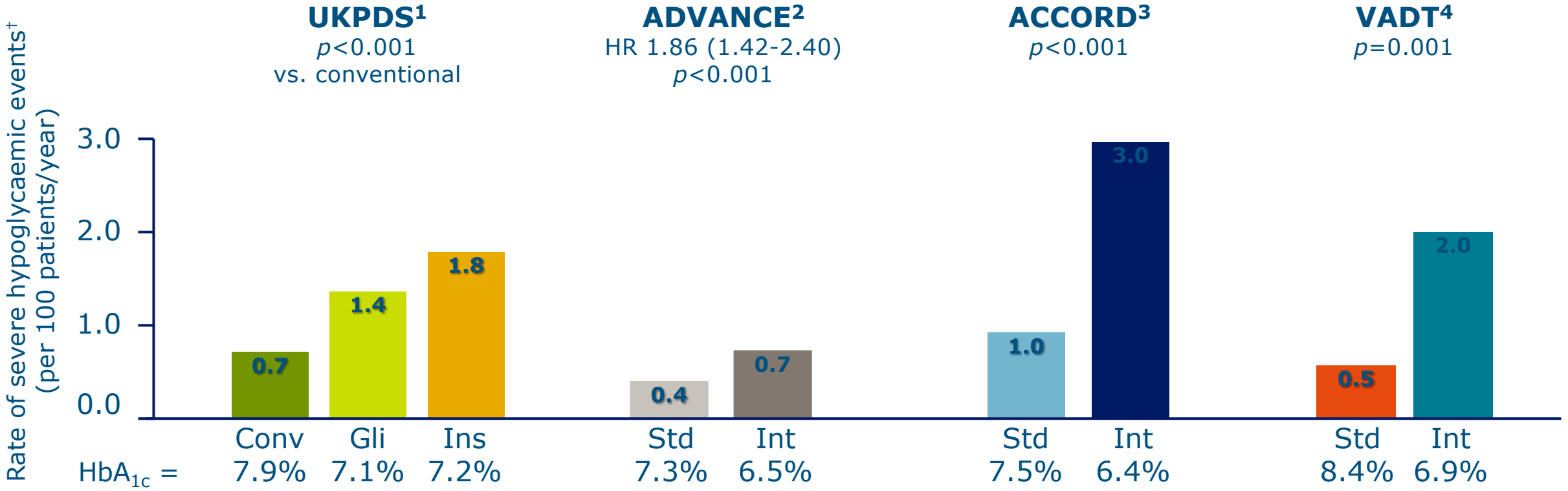
8-year study duration

- Mean of **8.2 kg increase**

*Aim for intensive group (treated with either SU or insulin): FPG<6 mmol/L. Aim for conventional group: best achievable FPG with diet alone, drugs added only if there were hyperglycaemic symptoms or FPG>15 mmol/L.

[1] Adapted from UKPDS 33. *Lancet.* 1998;13:837–53; [2] ACCORD Study Group. *NEJM.* 2008;358(24): 2545-2559;
[3] Duckworth *et al. NEJM.* 2009;360:129-39.

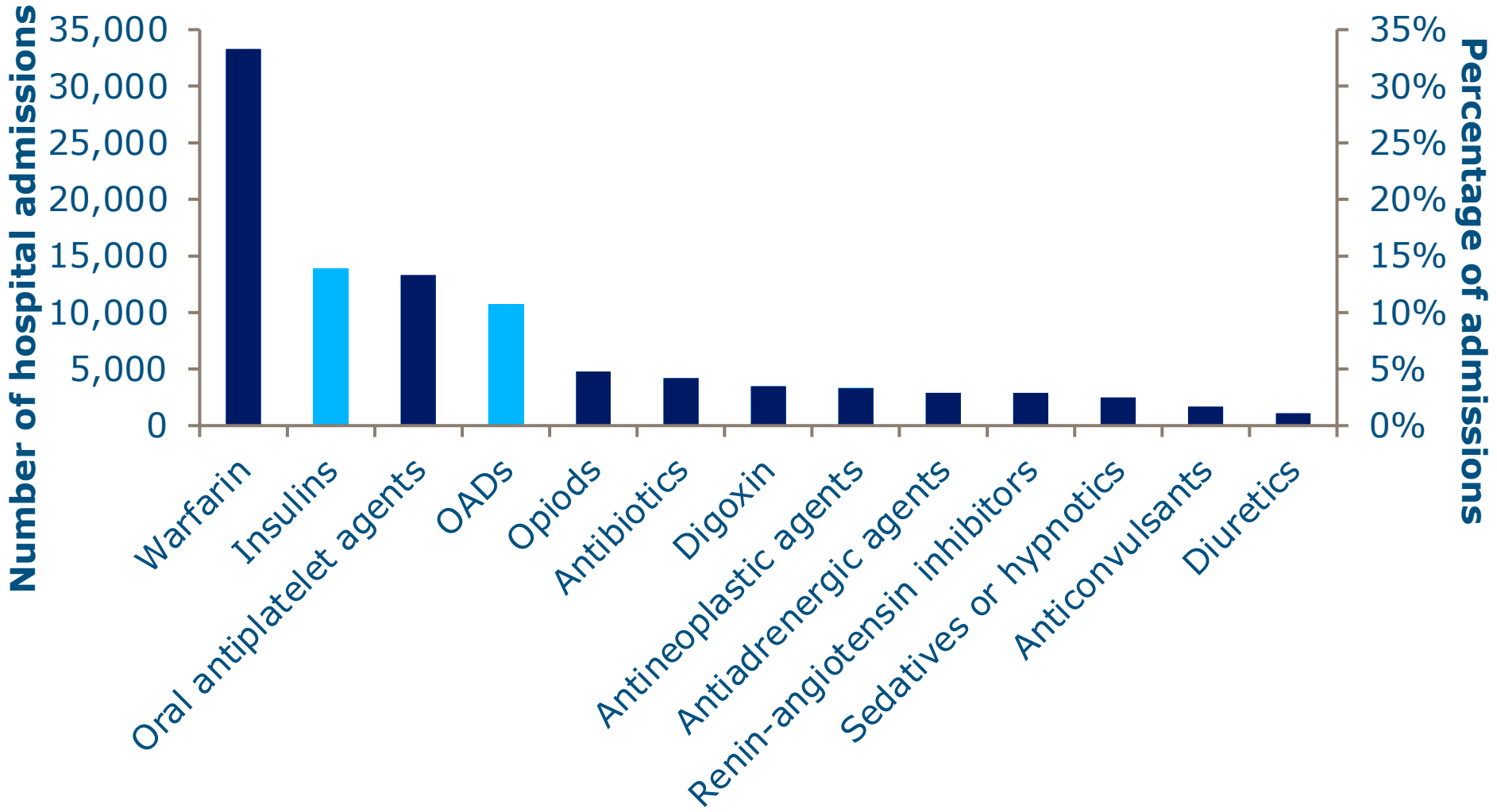
Risk of Severe Hypoglycemia Increases as Therapy Intensifies*



*Intensive glycaemic control was defined differently in these trials
†Hypoglycaemia requiring any assistance in glucose-lowering trials
Conv, conventional therapy; gli, glibenclamide; HR, hazard ratio; ins, insulin; int, intensive therapy; std, standard therapy

[1] UKPDS Group. *Lancet* 1998;352:837–53; [2] Patel *et al;* ADVANCE Collaborative Group. *NEJM* 2008;358:2560–72;
[3] Gerstein *et al*; ACCORD Group. *NEJM* 2008;358:2545–59; [4] Duckworth *et al. NEJM* 2009;360:129–39

Medications Most Commonly Associated with Emergency Admissions in Patients >65



Budnitz, et al. *N Engl J Med*. 2011;365:21.

When to Stop Titrating Basal Insulin and do Something Else – Avoid Overbasalization

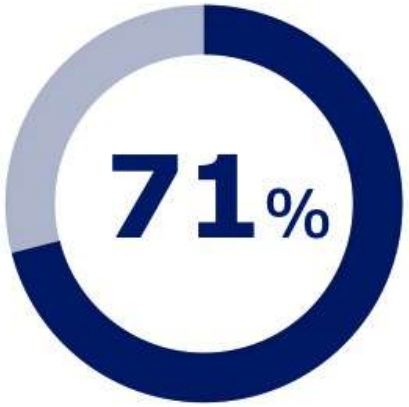
- After 3-6 months of titration, A1c greater than goal
- Fasting glucose at target or low, and A1c greater than goal – this is an indication of post-prandial glucose excursion
- Overnight hypoglycemia
- The need for prandial insulin becomes more likely as the daily insulin dose exceeds 0.5u/kg/d

Glycemic Control Matters but Basal Insulin Intensification is Often Delayed

Many patients do not achieve glycaemic target

Patients with HbA_{1c} ≥7% 2 years following basal insulin initiation in US[1]

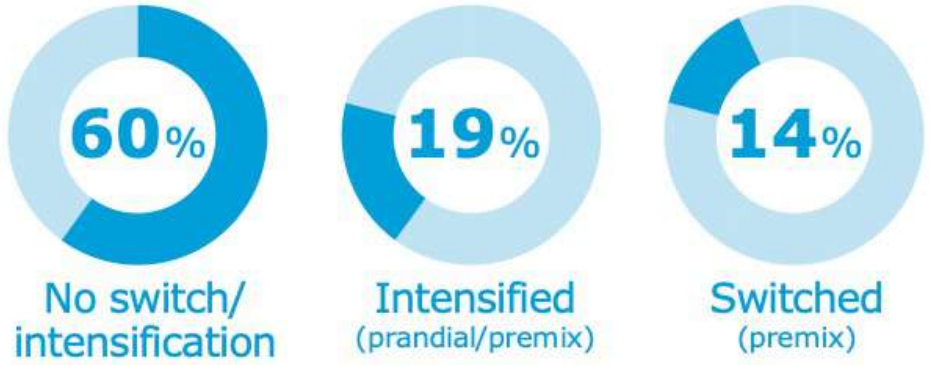
Baseline HbA_{1c} 8.6%



Intensification of basal insulin is often delayed

Change in insulin regimen over 3 years in UK[2,]*

Baseline HbA_{1c} 8.6%



	No switch/ intensification	Intensified (prandial/premix)	Switched (premix)
HbA_{1c} at change	N/A	9.2/9.3%	9.5%
Year 3 HbA_{1c}	8.1%	8.6/8.7%	8.5%

*7% discontinued; N/A, not applicable

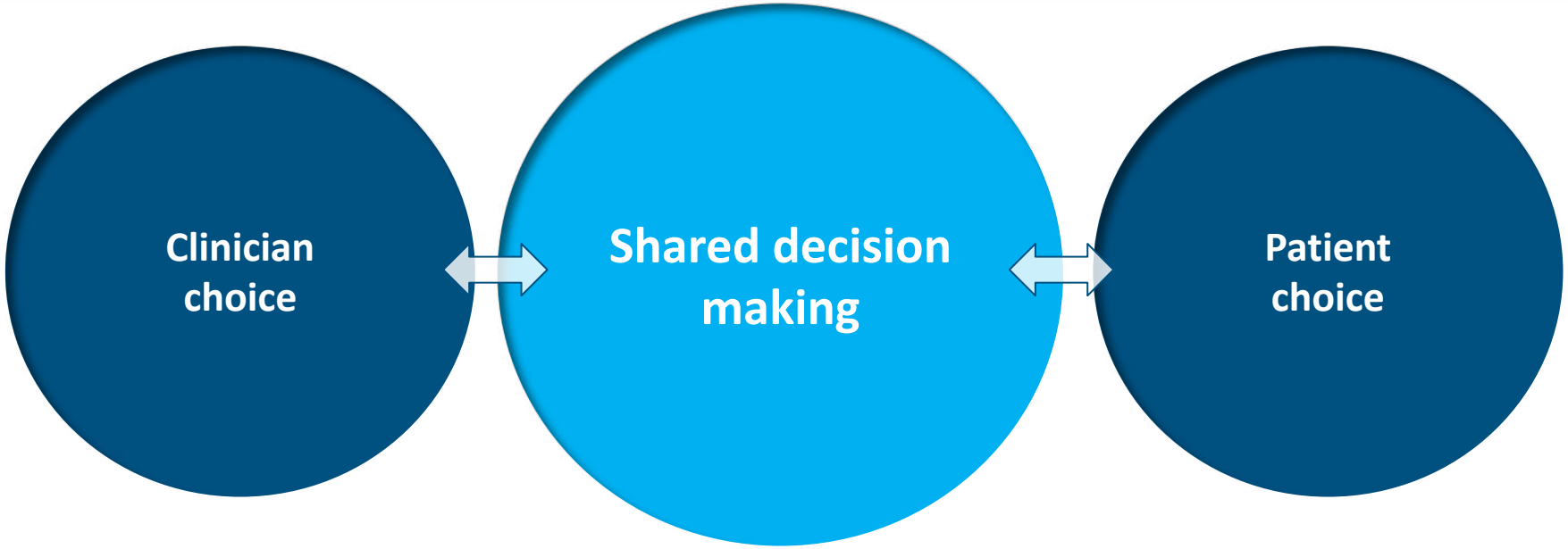
1. Curtis & Lage. *J Med Econ* 2014;17:21–31; 2. Blak, *et al. Diabet Med* 2012;29:e13–20; 4):6–10.

Keys To Insulin Initiation In Primary Care

- Allow patients to self-titrate.
- ***Customize*** insulin care plan for each patient and provide written instructions on protocol.
- Use insulin pens for accurate insulin adjustment and delivery.
- Teach patients how to utilize and interpret results of self-blood glucose monitoring values. Consider “structured glucose testing” rather than random glucose testing for all patients.
- Prepare patients to recognize and treat hypoglycemia.

1. Unger J. *Diabetes, Metabolic Syndrome and Obesity: Targets and Therapy*. 2011;4:253-261.
2. Zisman A, et al. ADA Scientific Sessions. San Diego, CA. 2011. 1121-P.

Shared Decision Making When Initiating Basal Insulin

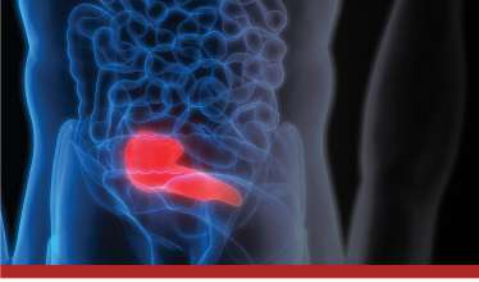


Partnership

Tips for Shared Decision Making

- Invite patients to participate
- Present options
- Provide information on benefits and risks
- Assist patients in evaluating options based on their goals and concerns
- Facilitate deliberation and decision making
- Assist patients to follow through on their decision

National Learning Consortium. https://www.healthit.gov/sites/default/files/nlc_shared_decision_making_fact_sheet.pdf. Accessed February 25, 2015.



Summary

- Continuous glucose monitoring provides additional metrics to guide therapy including time in range, time below range and glycemic variability
- Appropriate and early treatment of hyperglycemia reduces the risk for micro- and macrovascular complications
- Many T2DM patients will require insulin for glycemic control
- Insulin is a core treatment strategy to achieve glycemic control in patients with T2DM
  - It is not a “treatment of last resort”
- Multiple basal insulin agents are available, including newer basal insulins with a longer half-life and less variability and risk for hypoglycemia
- The ADA and Canadian Algorithm provide sample algorithms to help guide insulin initiation
- Insulin works!