Less is More:
The Promise of Weekly Insulin in Type 2 Diabetes

This activity is jointly provided by

MLI

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Activity Overview

Target Audience

This activity is intended for PCPs and other members of the healthcare team in the U.S. who care for patients with T2D.

Educational Objectives

After completing this activity, the participant should be better able to:

- Describe the place of novel insulin therapies, including once-weekly basal insulin, in treating type 2 diabetes
- Develop strategies for initiating, dosing, and titrating once-weekly basal insulin for type 2 diabetes
- Examine the consequences of delaying initiation and intensification of basal insulin in eligible patients
- Communicate to your patients the advantages of once-weekly basal insulin, considering patient concerns about weight gain and hypoglycemia

Agenda

- Once-Weekly Insulin: A Game Changer in a Crowded Market
- Practices for Initiating and Dosing Once-Weekly Basal Insulin in T2D
- The Promise of Once-Weekly Insulin

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Once-Weekly Insulin: A Game Changer in a Crowded Market

Treatment Challenges

- Dose administration, timing, multiple injections
- Hypoglycemia
- Frequent dose adjustments
- High number of injections (365/year)
- Poor adherence
- Weight gain/fluid retention
- Only ~5% to 45% of patients achieve desired glycemic goals in the real world

69% to 87% of people with type 2 diabetes (T2D) reported missing basal insulin dose injections

Learning Point!

3.6 to 4.3 missed doses in a month significantly impacted glucose control

5.7 to 6.2 mistimed basal doses in a month significantly impact glycemic control

Rosenstock J, et al. *Endocr Rev*. 2024;45(3):379-413; ADA Professional Practice Committee. *Diabetes Care*. 2024;47;
Robinson S, et al. *Diabetes Technol Ther*. 2021;23(12):844-856.

Opportunities of Weekly Basal Insulins

Advantages:

- Extend the time-action profile to allow for once-weekly administration
- Development of a once-weekly basal insulin with a longer, flatter exposure profile
- More closely mimic endogenous basal insulin distribution profiles
- Controlled tissue distribution properties and attenuated potency at the insulin receptor (IR)
- Reduce variability by controlling fluctuations in glucose levels during the week
- Maintaining an acceptable and manageable hypoglycemia profile

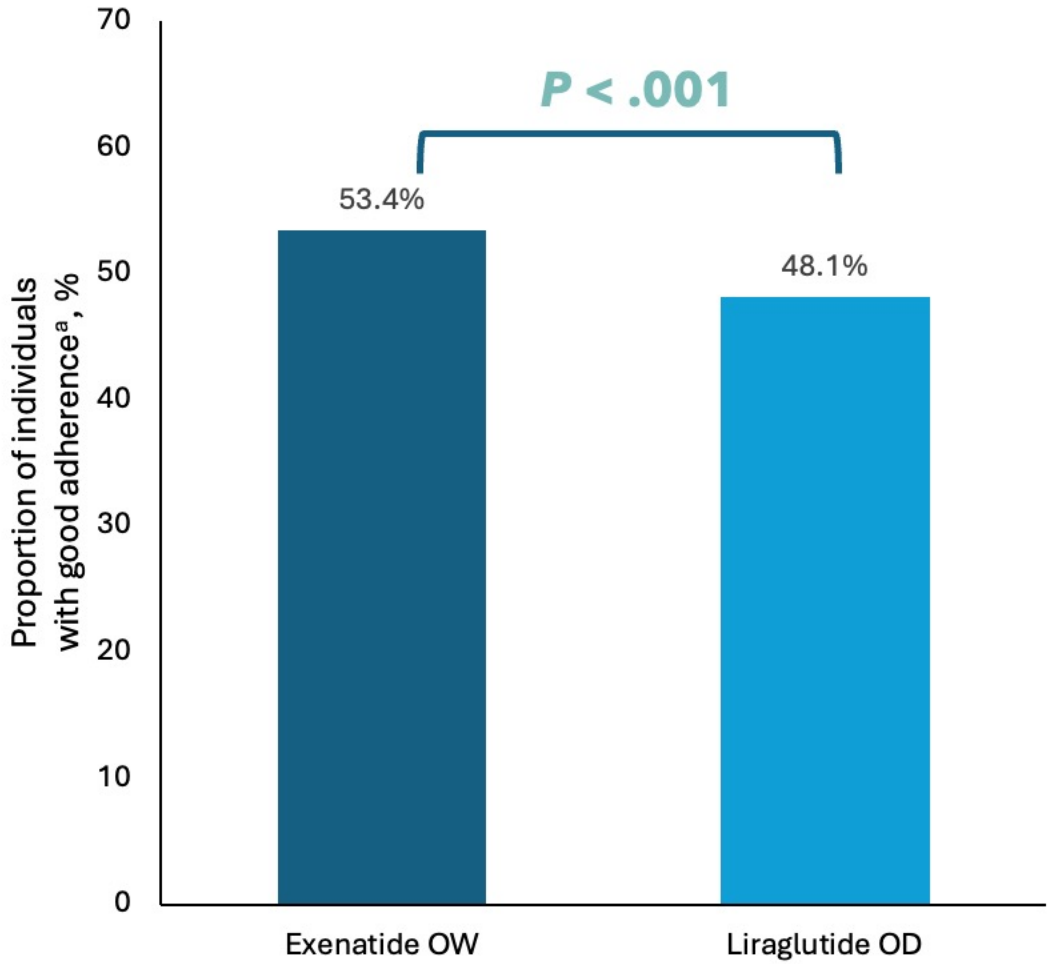
Limitations: inability to rapidly adapt to changes in insulin requirements, which the body achieves with controlled endogenous insulin secretion

However, patient preference for fewer injections may improve acceptance, adherence, and persistence

Once-weekly basal insulin formulations are not currently approved by the FDA.

Rosenstock J, et al. *Endocr Rev*. 2024;45(3):379-413.

Fewer Injections = Improved Adherence



Once-weekly formulations of GLP-1 RAs are associated with significantly better adherence than once-daily formulations

Similar benefits may be observed with once-weekly basal insulins

Used with permission from Dr. Wysham.

[a] Good adherence, ≥ 80% proportion of days covered.
GLP-1 RA, glucagon-like peptide-1 receptor agonist; OD, once daily; OW, once weekly.

Qiao Q, et al. *Diabetes Metab Syndr Obes*. 2016;9:201-205.

Social Listening: Once-Weekly Insulin Concerns & Importance of Education

I would worry about any weekly medication. If you have a bad reaction to it, you are stuck with it for a week.

~DD

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Social Listening: Once-Weekly Insulin Concerns & Importance of Education

A weekly insulin if they could make it, would be one heck of a HUGE shot too though! Imagine someone who needs 100 units a day, that'd be a 700 unit shot, egads! You'd look like you had a golf ball under your skin lol.

~RH

acofp

Habitual Prescribing?

- Proven efficacy in managing blood glucose
- Guideline-driven prescribing and standard of care
- Patient convenience
- Cost and insurance coverage: biosimilar options and insurance formularies
- Positive impact on comorbidities
- Familiarity to both physicians and patients

Galdon Sanz-Pastor A, et al. *Front Endocrinol (Lausanne)*. 2024;15:1366368; Davies MJ, et al. *Diabetologia*. 2022;65(12):1925-1966; Rushforth B, et al. *Br J Gen Pract*. 2016;66(643):e114-127.

Addressing Hypoglycemia Concerns

How long would an episode of hypoglycemia last?

- Two-period crossover study in patients with T2D on insulin ± oral glucose-lowering meds
- Compared clinical, physiological, and counterregulatory hormone responses to 2× & 3× doses of icodec with insulin glargine U100
- 2× & 3× doses of once-weekly icodec do not lead to increased risk of hypoglycemia
- Time to develop hypoglycemia and recover were comparable

Would the episode recur?

- Continuous glucose monitoring (CGM) data: time spent in hypoglycemia in the weeks following the 2× & 3× doses was low
- Even in pts with clinically significant hypoglycemia (mean ± SD TBR [<54 mg/dL]: 2x dose 0.21 ± .45%; 3x dose 0.56 ± 1.70%)

How are acute episodes managed?

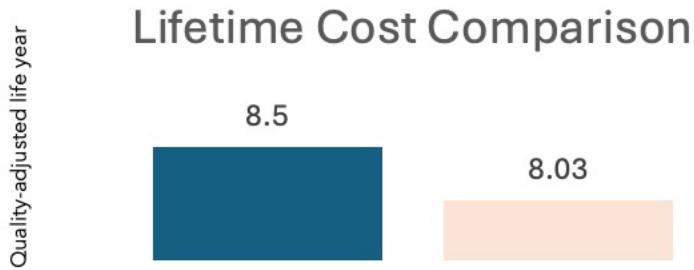
- Fundamentally, no differently than with once-daily basal insulins
- Administer calculated amounts of carbohydrates, monitor response, and repeat as necessary

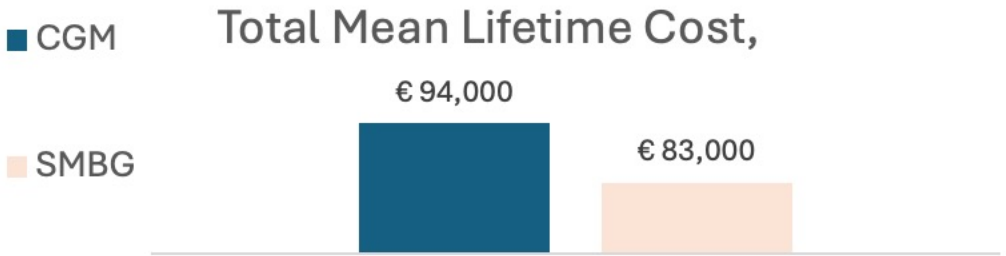
Once-weekly basal insulin formulations are not currently approved by the FDA.

Pieber TR, et al. *Diabetologia*. 2023;66(8):1413-1430.

CGM as Part of the Team

Compared to SMBG, rt-CGM is highly likely to be a cost-effective intervention for patients living with insulin-treated T2D





- The lower the mean patient age, the more cost-effective rt-CGM was likely to be
- CGM should be considered as an alternative to drug therapy for improving blood glucose

In 6-week intervention of of CGM with telemonitoring versus enhanced usual care:

	CGM	Enhanced Usual Care
Mean change HbA_{1C}, %	–0.69	–0.33
Body weight, kg	–2.48	+0.31

rt-CGM, real-time CGM; SMBG, self-measured blood glucose.

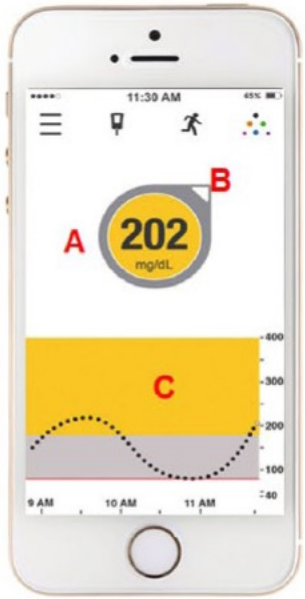
Alshannaq H, et al. *J Comp Eff Res*. 2024;13(3):e230174; Lau D, et al. *Diabetes Res Clin Pract*. 2024;217:111899.

Examples of CGM Devices

FreeStyle Libre

Guardian Connect

Eversense



G6

G7

Adapted with permission from Dr. Shubrook.

Social Listening: Patient Preference & Convenience

I was really happy that I only had to do an injectable once a week rather than at every meal or once a day. I was just amazed how something could stay in your system for a week and work for the whole week.

-Patient enrolled in ONWARDS-5 (insulin-naïve T2D)

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Polonsky W, et al. *Diabetes Res Clin Pract*. 2024;217:111885.

Key Takeaways

Once-weekly basal insulins are promising options that address many of the barriers associated with once-daily formulations

Incorporating once-weekly basal insulins into T2D treatment plans will require shared decision-making supported by empowering, patient-first communication strategies, addressing individual patient needs/concerns, and detailed education

Once-weekly basal insulin formulations are not currently approved by the FDA.

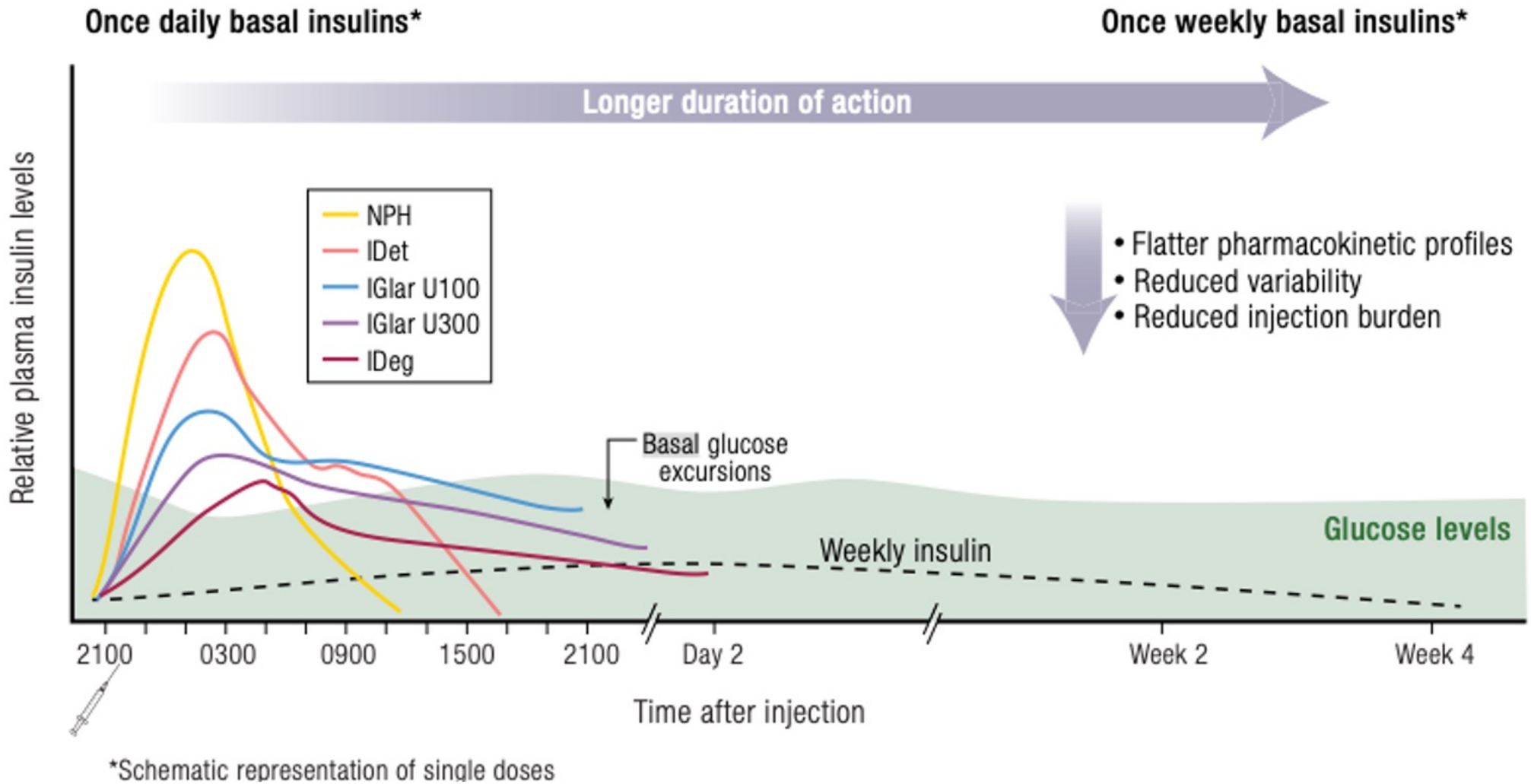
Practices for Initiating and Dosing Basal Insulin in T2D

Implications of Delayed Initiation

- Due to delays in initiation and intensification, only a minority of patients reach glycemic targets
- In the first 3 months, approximately 50% of patients interrupt their basal insulin therapy, and 15% discontinue it
- In patients with a delay in intensification of more than 1 year:
  - Reduced QOL
  - Increased risk of morbidity and mortality, including higher rates of myocardial infarction (67%), heart failure (64%), and stroke (51%)

Blonde L, et al. *Diabetes Spectr*. 2019;32(2):93-103; Blonde L, et al. *Diabetes Ther*. 2018;9(3):1347-1358; Khunti S, et al. *Ther Adv Endocrinol Metab*. 2019;10:2042018819844694; Paul SK, et al. *Cardiovasc Diabetol*. 2015;14:100; Perez-Nieves M, et al. *Curr Med Res Opin*. 2016;32(4):669-680.

Once-Weekly vs Daily Insulin



Once-weekly basal insulin formulations are not currently approved by the FDA.

Rosenstock J, et al. *Endocr Rev*. 2024;45(3):379-413.

Initial Dosing

Learning Point!

Estimated starting basal insulin dose = <u>10 units/day</u> OR <u>0.1 to 0.2 units/kg body weight/day</u>
(depending on the degree of hyperglycemia)

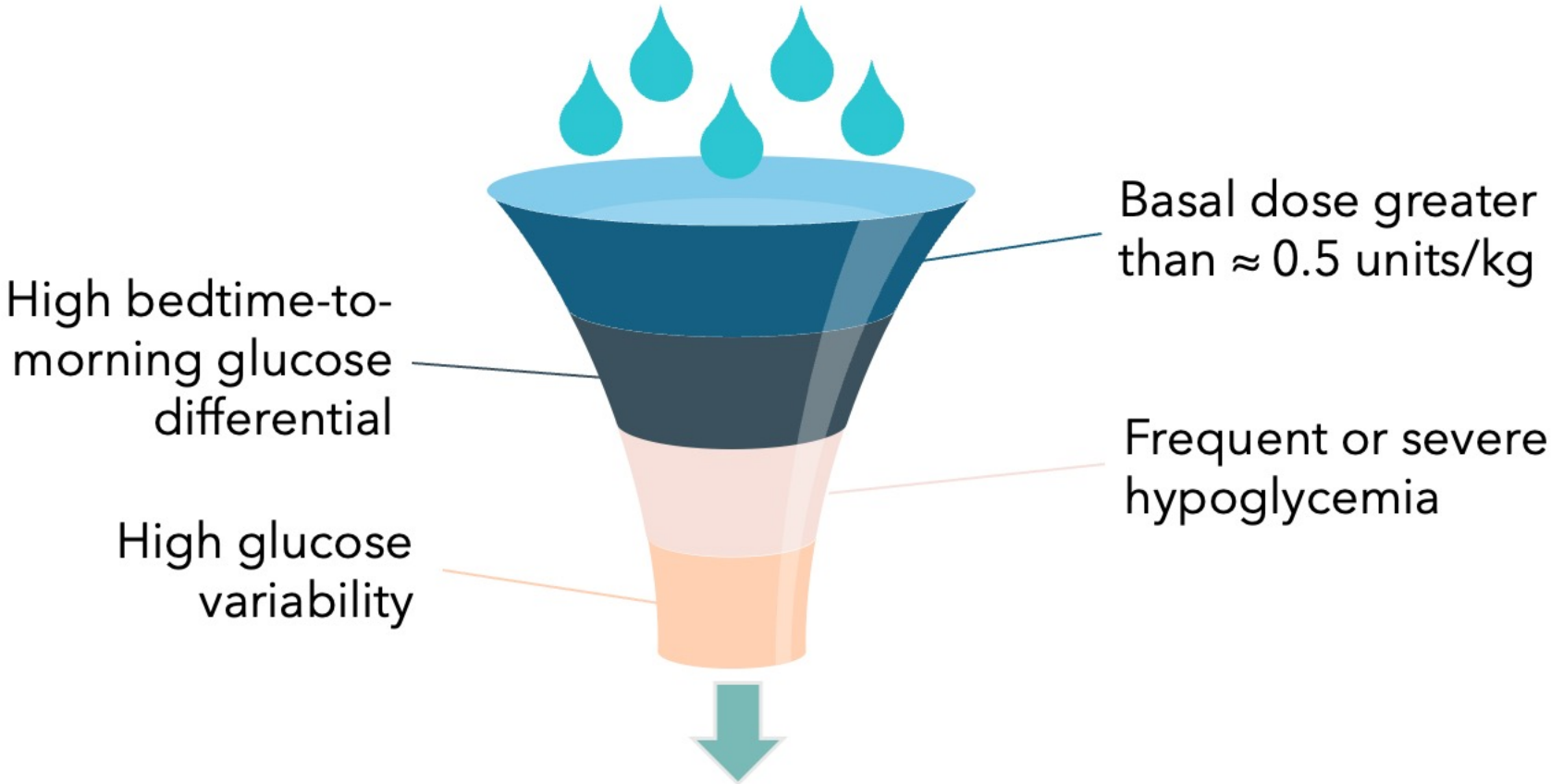
Doses should be individualized and titrated over following days and weeks as needed

Fasting Plasma Glucose (FPG)	2 or more values of < 70 mg/dL	71 to 130 mg/dL	No values of < 70 mg/dL and 3 or more values > 130 mg/dL	No values of < 70 mg/dL and 3 or more values > 180 mg/dL
Insulin dose	Subtract 4 units	Maintain dose	Add 2 units	Add 4 units
Dose should be up/down titrated 1 to 2 times per week				

Used with permission from Dr. Wysham.

ADA Professional Practice Committee. *Diabetes Care*. 2024;47(Suppl 1):S158-S178; Kuritzky L, et al. *Clin Diabetes*. 2019;37(4):368-376; Johnson ML, et al. *Clin Diabetes*. 2022;40(4):489-497.

Clinical Signals That May Indicate Overbasalization



Used with permission from Dr. Wysham.

ADA Professional Practice Committee. *Diabetes Care*. 2024;47(Suppl 1):S158-S178.

Blood Glucose Monitoring

People who take insulin should be encouraged to check their blood glucose levels

SMBG is essential for:

- Monitoring safety and efficacy of current treatment plan/dosing
- Hypoglycemia prevention and prompt treatment

Assessing FPG with SMBG to inform dose adjustments results in lower A1C levels

Increasingly, people with T2D have access to CGM and FGM, which encourages better awareness of blood glucose levels

Used with permission from Dr Wysham

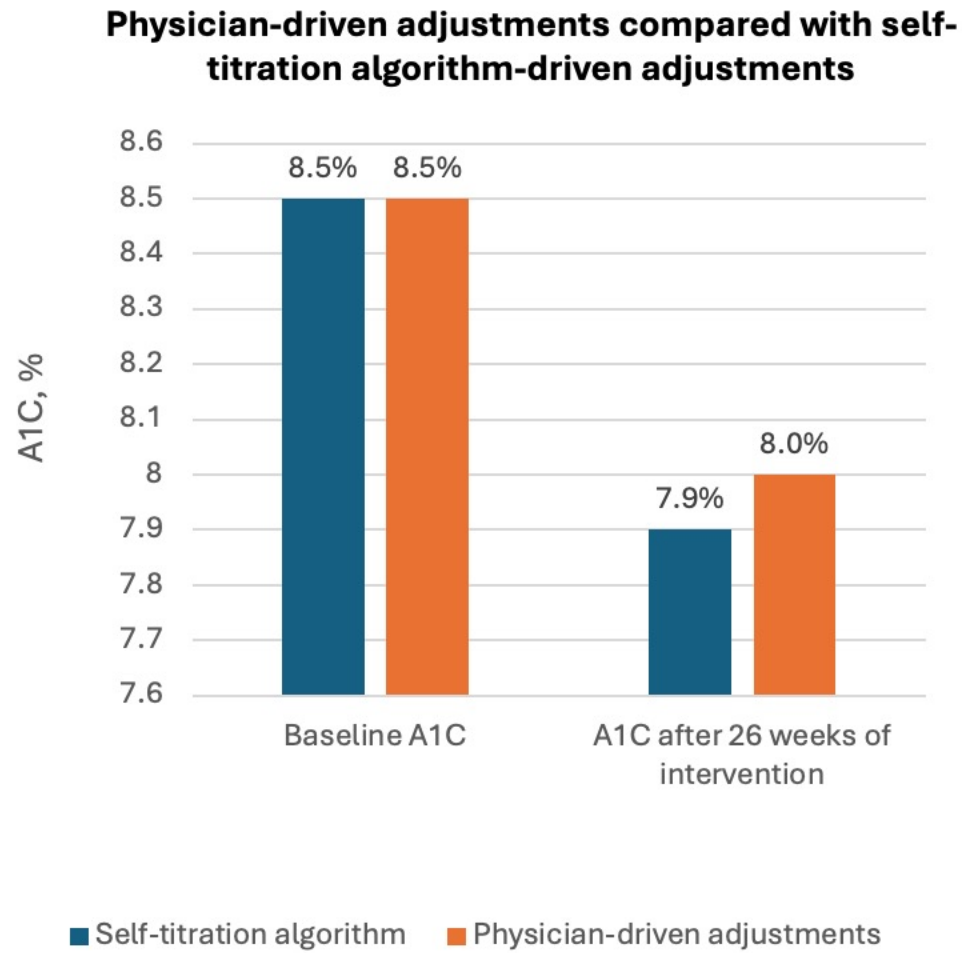
A1C, glycated hemoglobin; FGM, flash glucose monitoring.

ADA Professional Practice Committee. *Diabetes Care*. 2025;48(Supplement_1):S146-S166; Ajjan RA, et al. *Nat Rev Endocrinol*. 2024;20(7):426-440.

Physician-Driven vs Self-Titration

The self-titration algorithm instructed participants to adjust their basal insulin dose every 3 days based on the mean of 3 adjusted FPG values

<80 mg/dL	80 to 110 mg/dL	>110 mg/dL
Reduce by 3 units	No change	Increase by 3 units



Used with permission from Dr. Wysham.

Meneghini L, et al. *Diabetes Obes Metab*. 2007;9(6):902-913.

The Promise of Once-Weekly Insulin

Once-weekly basal insulin formulations are not currently approved by the FDA.

Advantages of Once-Weekly Insulin

Clinical	Molecular
Improved or similar glycemic control with low hypoglycemia risk	Long half-life
Reduced treatment burden	More stable pharmacokinetics/ pharmacodynamics, with less inter-patient and intra-patient variability
Easier to overcome therapeutic inertia	Slower clearance

Better treatment acceptance and adherence

Once-weekly basal insulin formulations are not currently approved by the FDA.

Karakasis P, et al. *Diabetes Obes Metab*. 2023;25(12):3648-3661.

In Development: Weekly Basal Insulin

Efsitora	**QWINT Trial Program**: Topline Results of Phase III Trials
Icodec	**ONWARDS Trial Program:** Results of 6 Phase III Trials

Once-weekly basal insulin formulations are not currently approved by the FDA.

Insulin Efsitora: Efficacy and Safety of the Phase III QWINT Program

	QWINT 1	QWINT 2	QWINT 3	QWINT 4	QWINT 5
	BASAL INITIATION	BASAL INITIATION	BASAL SWITCH	BASAL SWITCH	BASAL/BOLUS SWITCH
Trial duration (weeks)	52	52	78	26	52
Baseline HbA_{1c} (%)		8.22%			
Non-inferiority confirmed	✓	✓	✓	✓	✓
Superiority confirmed		No			
Estimated change from baseline in HbA_{1c} (%)	-1.31 vs -1.27; 2	-1.26 vs -1.17; 3	-0.86 vs -0.75; 5	-1.07 vs -1.07; 6	-0.53 vs -0.59; 7
Hypoglycemia event rates[1]	0.50 vs 0.88	0.58 vs 0.45; 4	0.84 vs 0.74	6.6 vs 5.9	14.03 vs 11.59
	Insulin-naïve T2D	Insulin-naïve T2D	Insulin-treated T2D	Insulin-treated T2D	Insulin-treated T1D

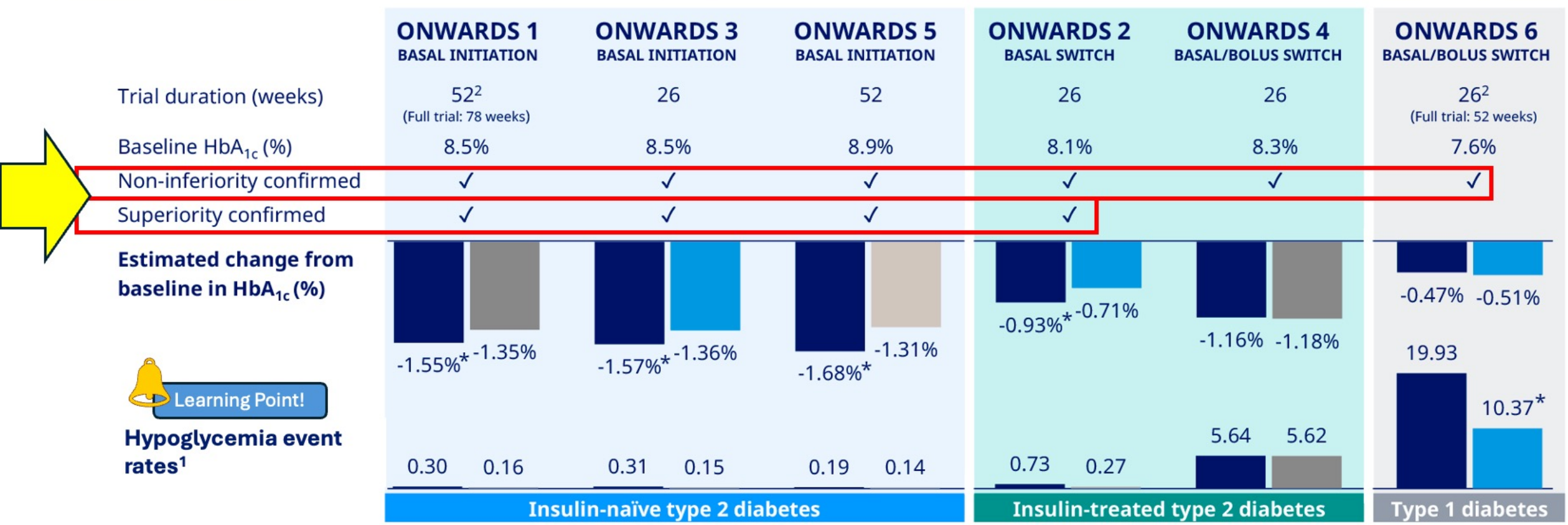
Learning Point!

Once-weekly insulin efsitora alfa | Once-daily insulin degludec | Once-daily insulin glargine

1. Events per participant-year of exposure; 2. 95% CI, -0.22 to 0.04; 3. 95% CI, 0.94 to 1.78; 4. 95% CI, -0.22 to 0.061; 5. 95% CI, -0.19 to 0.12; 6. 95% CI, -0.22 to 0; 7. 95% CI, -0.075% to 0.19%.

QWINT 1. https://www.clinicaltrials.gov/ct2/show/NCT05662332; QWINT 2. https://www.clinicaltrials.gov/ct2/show/NCT05362058; QWINT 3. https://www.clinicaltrials.gov/ct2/show/NCT05275400; QWINT 4. https://www.clinicaltrials.gov/ct2/show/NCT05462756; Eli Lilly and Company. With Once-a-Week Dosing, Insulin Efsitora Alfa Delivers A1C Reduction and Safety Profile Consistent with Daily Insulin. May 16, 2024; Eli Lilly and Company. In a first-of-its-kind fixed dose study, once weekly insulin efsitora alfa leads to A1C reduction similar to daily insulin. September 5, 2024; Bergenstal RM, et al. *Lancet.* 2024;404(10458):1132-1142; Wysham C, et al. *N Engl J Med.* 2024;391(23):2201-2211.

Insulin Icodec: Efficacy and Safety of the Phase III ONWARDS Program



In people with type 2 diabetes: *No statistical difference in estimated hypoglycaemia events*

*P<0.001 (noninferiority); P=0.02 (superiority)

Once-weekly insulin icodec | Once-daily insulin glargine U100 | Once-daily insulin degludec | Once-daily basal insulins

*Statistically significant. 1 Severe or clinically significant hypoglycaemia events (blood glucose <3 mmol/L) per patient year, included for end of trial/end main phase in-trial. 2 Duration refers to trial main phase.
ONWARDS 1: QW insulin icodec vs QD insulin glargine U100 both with non-insulin anti-diabetic treatment in insulin-naïve people with T2D; ONWARDS 2: QW insulin icodec vs QD insulin degludec in people with T2D switching from a QD insulin; ONWARDS 3: QW insulin icodec vs QD insulin degludec in insulin-naïve people with T2D; ONWARDS 4: QW insulin icodec vs QD insulin degludec both with mealtime insulin in people with T2D treated with basal and bolus insulin; ONWARDS 5: QW insulin icodec vs QD basal insulin with an app providing dosing recommendation in insulin-naïve people with T2D; ONWARDS 6: QW insulin icodec vs QD insulin degludec both with mealtime insulin in people with T1D
T1D: Type 1 diabetes; T2D: Type 2 diabetes. Note: Overview refer to primary end-points in main phases of trials

Bajaj HS, Goldenberg RM. *touchREV Endocrinol*. 2023;19(1):4-6.

In Brief...

- Insulin efsitora demonstrated non-inferior glycemic control compared with daily insulins
- Insulin efsitora demonstrated a favorable safety profile in phase II clinical trials and topline results from the QWINT-2 and -4 phase III trials
- Insulin icodec demonstrated superior glycemic control compared to daily insulins in 4/6 phase III ONWARDS clinical trials and non-inferiority in the other 2
- Insulin icodec showed a favorable safety profile with no increased risk of hypoglycemia in patients with T2D
- Once-weekly insulins offer a safe, effective option with a convenient dosing regimen, potentially reducing the burden of insulin therapy for persons with T2D
- **Reminder: Prework Activity & Clinical Data**

Once-weekly basal insulin formulations are not currently approved by the FDA.

Importance of Adherence in T2D

Impact on glucose control:

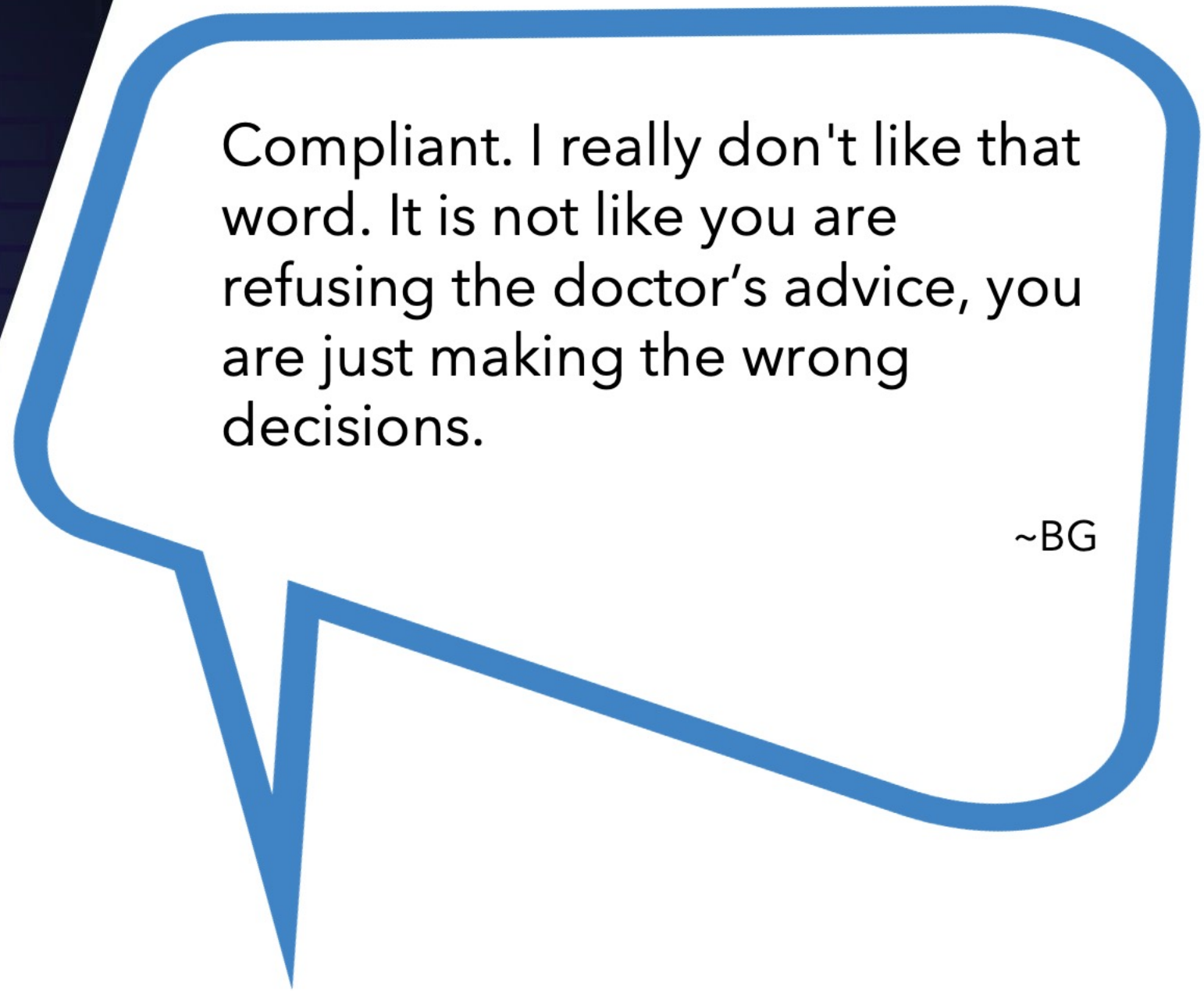
- 3.6 to 4.3 **missed** doses in a month significantly impacts glucose control
- 5.7 to 6.2 **mistimed** doses in a month significantly impacts glycemic control

Of people with T2D who reported missing basal insulin dose injections:

- 3× more likely to develop cardiovascular disease
- 10× more likely to develop kidney disease than people without diabetes
- 1/3 of people with diabetes will develop some form of vision loss during their lifetime
- In the USA, more than 100 000 people with diabetes have limbs amputated each year

The Lancet Diabetes Endocrinology. *Lancet Diabetes Endocrinol*. 2024;12(9):601.

Social Listening: Patient-First Language



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Social Listening: Non-Judgmental

Don’t tell me I am a bad patient. You don’t have diabetes. You don’t know how hard it is. I try my best to manage what I didn’t ask for.

~ EO

acofp

Preferences for Once-Weekly Basal Insulin

Patients are most concerned about:

- Avoiding 10-pound weight change
- Achieving longest time-in-range

Gelsey FT, et al. *Diabetes Ther*. 2024;15(11):2367-2379.

Patient and Provider Preferences

Evaluating Patient and Provider Preferences for a Once-Weekly Basal Insulin in Adults with Type 2 Diabetes

A US survey-based study that included a discrete choice experiment among patients with T2D (insulin naïve and current insulin users) and HCPs who treat patients with T2D to assess preferences regarding a hypothetical once-weekly basal insulin in comparison to current basal insulin options.

Abbreviations: HCPs, healthcare providers; T2D, Type 2 diabetes; US, United States

Would choose a once-weekly basal insulin product over another type of basal insulin

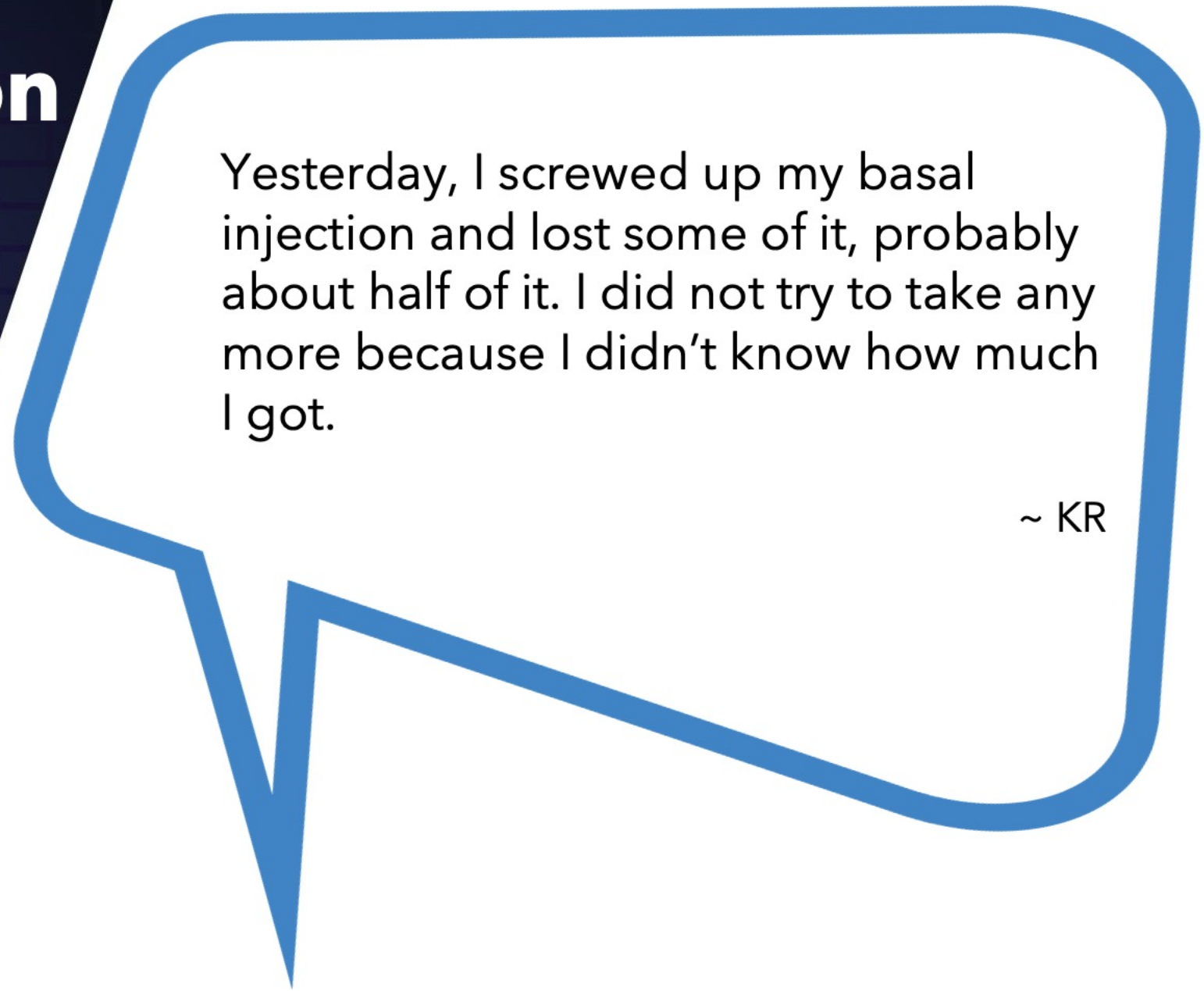
Insulin experienced patients with T2D were more confident that a once-weekly insulin would help with goals for blood glucose levels compared to their current basal insulin.

Insulin-experienced patients with T2D likely to inquire about once-weekly basal insulin

HCPs willing to educate patients on management of their T2D using a once-weekly basal insulin

Kerr D, et al. *Patient Prefer Adherence*. 2024;18:411-424.

Social Listening: Dosing & Injection Challenges



Social Listening: Weight Concerns

I've recently been put on insulin (Nov) and put on 28 lbs! It's making me more miserable than diabetes does – any advice on shifting insulin weight?

~KA

acofp

Communication and Collaboration

Learning Point!

- Upon diagnosis and whenever A1C is at or above goal: Discuss the **progressive nature** of T2D and the need to **frequently review and adjust treatments** in a timely manner
- **Discuss** people's concerns about **side effects and injections**
- Anticipate feelings of **guilt**
- Help people **anchor their treatment** to a daily activity
- Teach **self-titration** and provide **written instructions**; arrange **frequent contact** to ensure people are titrating
- Provide **feedback** based upon **glucose testing results**
  - Breaks a major link in the chain of clinical inertia
  - Promotes self-management

Used with permission from Dr. Wysham.

Polonsky WH, et al. *Int J Clin Pract*. 2017;71(8):e12973.

Talking Points and Top Tips

- Insulin is the most "natural" therapy, replacing what is missing (use thyroid hormone analogy)
- Insulin has no drug interactions
- It prevents complications
- It can be successfully used in most people with minimal weight gain and hypoglycemia (especially when given early)

Learning Point!

- Suggest people try insulin for 1 month and that they can stop if they do not feel it is helping
- If the clinic has a Diabetes Care & Education Specialist, can be used to demonstrate "dry shot" while learning glucose monitoring

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In Brief...

- Once-weekly basal insulin provides an opportunity for achieving patients' glycemic targets, reducing long-term complications of T2D, and improving patient adherence

- Communication and collaboration can alleviate patient concerns about side effects and assist with patient education and long-term adherence

Once-weekly basal insulin formulations are not currently approved by the FDA.