

INITIATING BASAL INSULIN

***Moving
from Hesitancy
to Action***

Supported by an educational grant from Novo Nordisk Inc.

CME
OUTFITTERS





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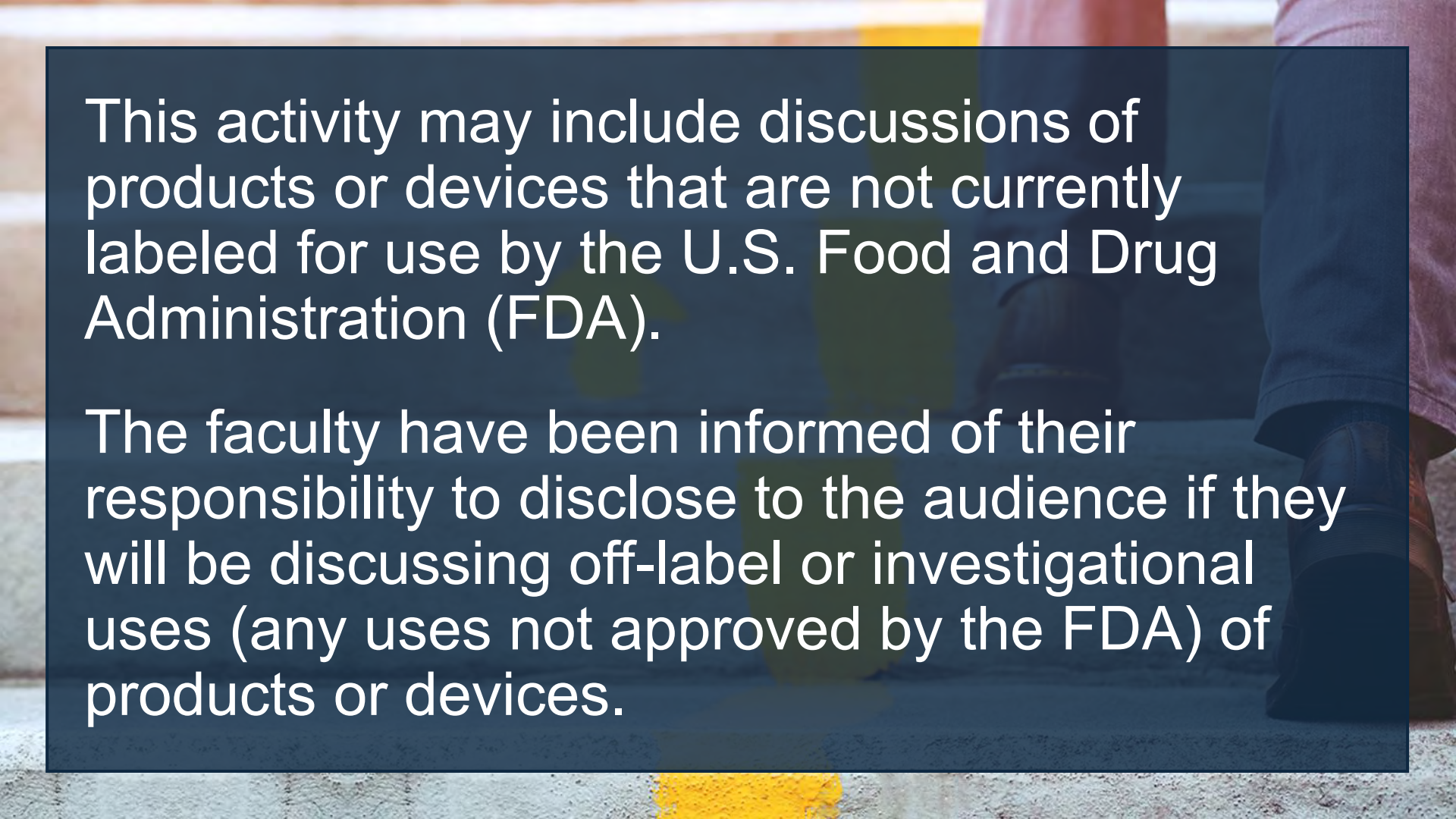
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To Ask a Question

To submit a question, please
use the Slido technology.



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Disclosures

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Advisory board—Abbott; Amgen Inc.; Bayer; Boehringer Ingelheim; Lilly; and Novo Nordisk

Consultant—Amgen Inc.; Bayer; Boehringer Ingelheim; Lilly; and Novo Nordisk

Speakers bureau—Abbott; Amgen Inc.; Bayer; Boehringer Ingelheim; Lilly; and Novo Nordisk

Disclosures

The following individuals have no financial relationships to disclose:

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LEARNING OBJECTIVE

**Identify how
overcoming delays
to insulin initiation
can improve
outcomes in
patients with type 2
diabetes (T2D)**



LEARNING OBJECTIVE

**Differentiate current
and emerging basal
insulin therapies
and their impact on
therapeutic inertia**

Spotting the “Why” of Delays and Moving Past It: Addressing Therapeutic Inertia for Basal Insulin in T2D



Therapeutic Inertia: Causes Are Multifactorial

Therapeutic inertia: Failure to initiate or intensify therapy when treatment goals are not reached¹

Causes of Therapeutic Inertia²



People with
T2D



Clinicians
and HCPs



Healthcare
systems



Payors



Industry

HCP = healthcare professional.

1. American Diabetes Association [ADA]. <https://therapeuticinertia.diabetes.org/about-therapeutic-inertia>; 2. Karam SL, et al. *Diabetes Spectr*. 2020;33(1):8-1.

Glycemic Targets Should Be Individualized

ADA* recommendation for most nonpregnant adults with T2D¹

A1C < 7%

AACE advises a more stringent target²

A1C ≤ 6.5%

Various factors to consider when setting an A1C target^{1,2}:



Duration
of disease



Age/life
expectancy



Comorbidities



CVD risk factors,
micro- and
macrovascular
complications



Risk of
hypoglycemia



Cognitive and
psychological
status

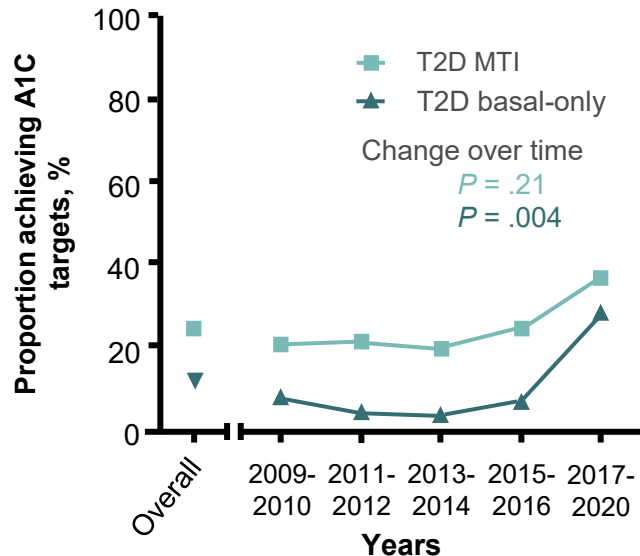
*Target fasting glucose between 80-130mg/dl & peak postprandial glucose of < 180mg/dl.

AACE = American Association of Clinical Endocrinology; ADA = American Diabetes Association; CVD = cardiovascular disease.

1. ADA Professional Practice Committee. *Diabetes Care*. 2024;47(Suppl 1):S111-S125; 2. Samson SL, et al. *Endocr Pract*. 2023;29(9):305-340.

Glycemic Targets For People With T2D

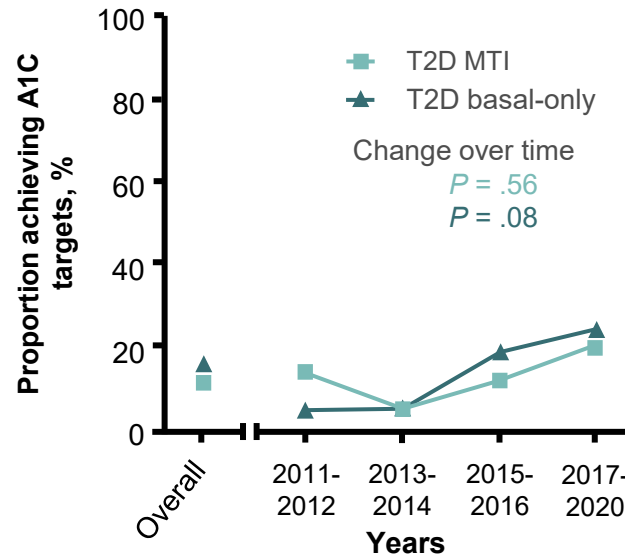
NHANES 2009–2020 prevalence of people with T2D achieving ADA glycemic targets



ADA - A1C target: < 7%

≈ 75%-80% of adults with T2D using basal insulin still did not achieve glycemic targets in 2017-2020

NHANES 2011–2020 prevalence of people with T2D achieving personalized glycemic targets



People with T2D treated with insulin need more support to achieve their glycemic targets

ADA Guidelines: For Basal Insulin

ADA recommends starting basal insulin when:

- Individualized A1C targets are not achieved with noninsulin therapies (including either GLP-1 RA or SGLT2i)
- Individuals present with blood glucose ≥ 300 mg/dL or A1C $> 10\%$
- Individuals have ongoing catabolism, and/or symptoms of glucotoxicity

Treating to Target: Basal Insulin

Basal insulin
Once daily (twice if required)

Biphasic insulin
Twice daily

Prandial insulin
Three times daily

A1C change, %	-0.8	-1.3	-1.4
Median rate of grade 1 hypoglycemia, events per person per year	2.0	5.0	8.0
Median rate of grade 2 or 3 hypoglycemia, events per person per year	0.0	3.9	8.0
Body weight change, kg	+1.9	+4.7	+5.7

Basal insulin is associated with lower rates of hypoglycemia and less weight gain than other forms of insulin therapy

Basal Insulin in T2D

A review of 22 studies conducted over a 10-year period in people with T2D showed that initiation of basal insulin therapy is often delayed¹

- Mean A1C at insulin initiation:
8.7% to 9.8%¹
- Median time to insulin initiation:
5.25 years²
- **71%** of PCPs didn't initiate insulin until elevated A1C levels were confirmed twice³

Early treatment intensification is crucial to improve patient outcomes⁴

2023 study: As little as 25% of patients using basal insulin achieved their glycemic goals⁵

2016 study: 18% of patients discontinued basal insulin within a year of initiation⁶

2016 study: 62% of patients who initiated basal insulin had interrupted therapy⁶

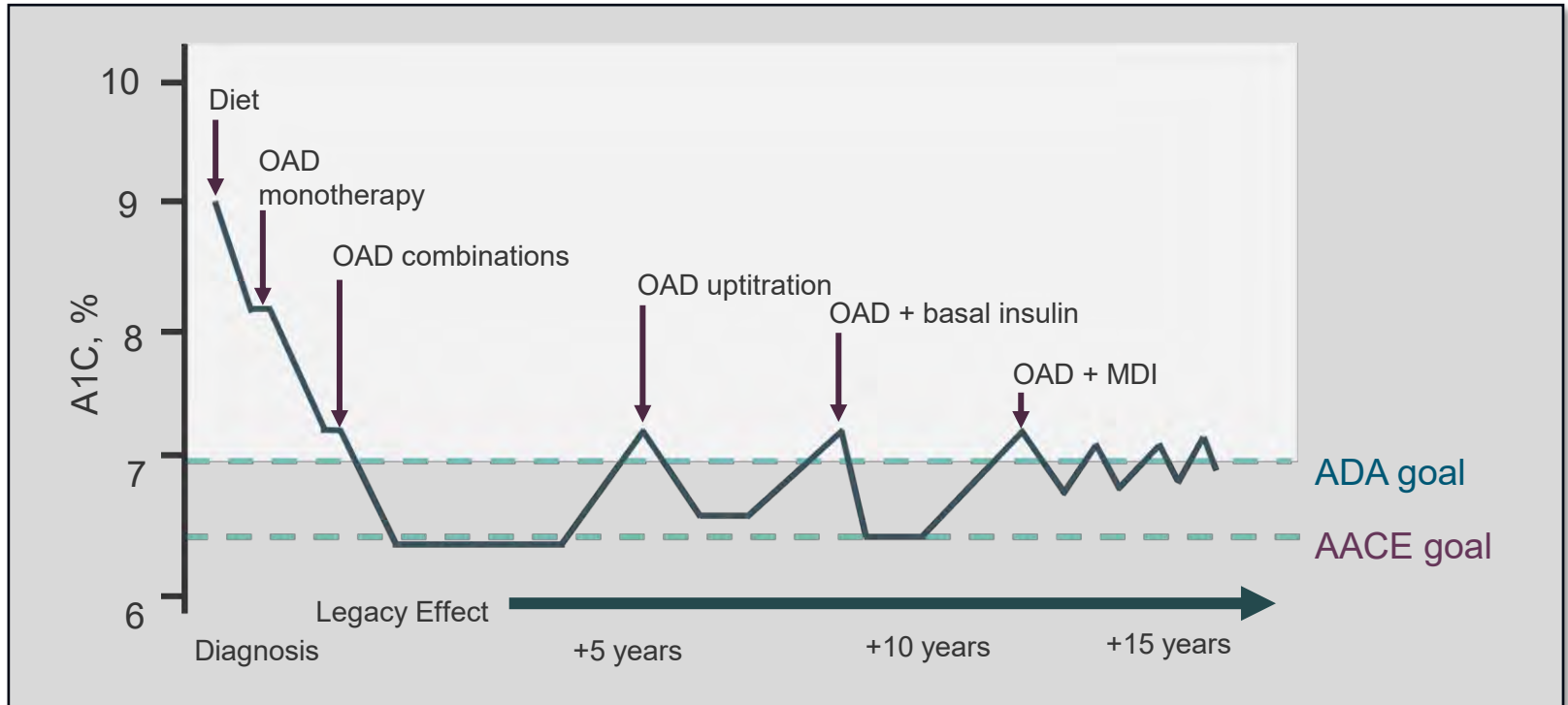
2010 study: 25% of patients prescribed basal insulin never refilled their prescription⁷

Patients have barriers to treatment adherence with basal insulin

PCP = primary care professional.

1. Gavin JR, et al. *Diabetes Spectr.* 2023;36(4):379-384; 2. Kostev K, et al. *J Diabetes Sci Technol.* 2019;13(6):1129-1134; 3. Escalada J, et al. *Diabetes Res Clin Pract.* 2016;122:46-53. 4. Shabnam S, et al. *Diabetes Obes Metab.* 2024;26(2):512-523. 5. Hankosky ER, et al. *Diabetes Ther.* 2023;14(6):967-975; 6. Perez-Nieves M, et al. *Curr Med Res Opin.* 2016;32(4):669-680. 7. Karter AJ, et al. *Diabetes Care.* 2010;33(4):733-735.

Treat-to-Target Approach



AACE = American Association of Clinical Endocrinology; MDI = multiple daily insulin injections; OAD = oral antidiabetic drug.
Del Prato S, et al. *Int J Clin Pract.* 2005;59(11):1345-1355; ADA Professional Practice Committee. *Diabetes Care.* 2024;47(Suppl 1):S111-S125;
Samson SL, et al. *Endocr Pract.* 2023;29(5):305-340.

Barriers to Insulin Initiation in T2D

HCPs

- **Perception^{1,2}**
 - Patient resistance
 - Doubts about adherence
- **Lack of experience²**
 - When to start or intensify therapy
- **Inadequate monitoring¹⁻³**
 - People with T2D must be trained in SMBG
- **Concerns^{1,2,4}**
 - Hypoglycemia
 - Weight gain
- **General therapeutic inertia³**
- **Lack of patient education and training resources¹⁻³**

People with T2D

- **Perception^{1,2}**
 - Insulin as “last resort”
 - Personal failure
- **Concerns¹⁻³**
 - Hypoglycemia
 - Long-term adverse events
 - Weight gain
 - Social stigma
- **Fears¹⁻³**
 - Needles
 - Pain of injecting
- **Convenience^{1,3}**
 - Complexity of delivering insulin
- **Cost²**

SMBG = self-monitoring of blood glucose.

1. Perreault L, et al. *J Am Board Fam Med*. 2019;32(3):431-447; 2. Brod M, et al. *Patient*. 2014;7(4):437-450;

3. Ng CJ, et al. *Int J Clin Pract*. 2015;69(10):1050-1070; 4. Berard L, et al. *Diabetes Obes Metab*. 2018;20:301-308.

Obstacles to Insulin Therapy in T2D Impacting Adherence

Concern	Newly prescribed insulin	
	Not started (n = 69)	Started (n = 100)
Ability to make dose adjustments	41%	12%
Impact on social life	38%	18%
Impact on work	33%	8%
Pain associated with injections	30%	15%
Side effects	44%	12%
Hypoglycemia	43%	16%
Risks and benefits not well explained by HCP	55%	39%
Inadequate health literacy	51%	30%

People starting insulin as prescribed were less likely to report concerns ($P < .05$)

Addressing Barriers to Insulin Initiation: Communication and Collaboration

- ✓ 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

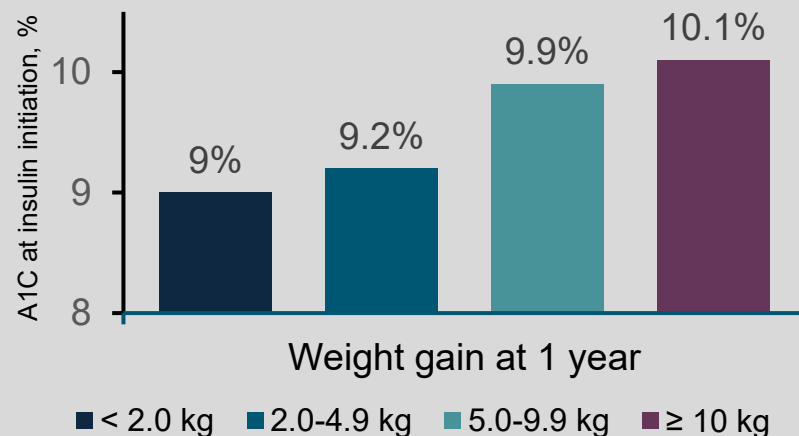
Insulin Initiation, A1C and Weight

75% of participants with baseline A1C < 8% attained A1C ≤ 7%, when basal insulin was added to oral therapy

Data from 12 RCTs (N = 2,312) ²	< 8.0%*	8.0 to < 8.5%	8.5 to < 9.0%	9.0 to < 9.5%	≥ 9.5%
Average A1C change from baseline to week 24, %	-0.9	-1.4	-1.6	-2.0	-2.6
Proportion of individuals with A1C ≤ 7.0% at week 24	75.4%	62.8%	55.8%	46.8%	34.2%

*hypoglycemia was higher in the lower baseline A1c, severe hypoglycemia was not frequent at all baseline HbA1c levels.

Analysis of factors predicting weight gain at 1 year in people starting any insulin (N = 2179)¹



RCTs = randomized controlled trials.

Balkau B, et al. *Diabetes Care*. 2014;37(8):2108-2113; Riddle MC, et al. *Diabetes Obes Metab*. 2013;15(9):819-825.

Patient Case



Mr. J.D. is a 58-year-old male with a 12-year history of Type 2 Diabetes Mellitus (T2D), along with **coronary heart disease (CHD), hypertension, and hyperlipidemia.**

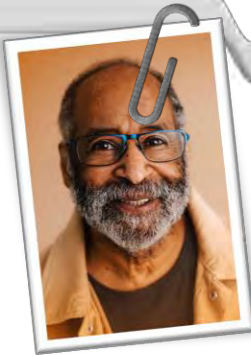


Patient medications:

- Losartan 100 mg daily
- Rosuvastatin 10 mg daily
- Metformin 1000 mg BID for over a decade
- Dapagliflozin 10 mg daily x 2 years
- Started semaglutide 1 mg weekly six months ago when his **HbA1C was 10.4%.**



At today's follow up, his **HbA1C is 8.1%**, fasting blood glucose (FBG) is 190 mg/dL, and postprandial glucose levels are consistently above 220 mg/dL. His BMI is 35.1 kg/m² (Obese Class II), and his eGFR remains stable at 75 mL/min/1.73m². He has lost 20 pounds since his last visit 6 months ago. He reports checking his blood glucose twice daily most days.



Audience Response



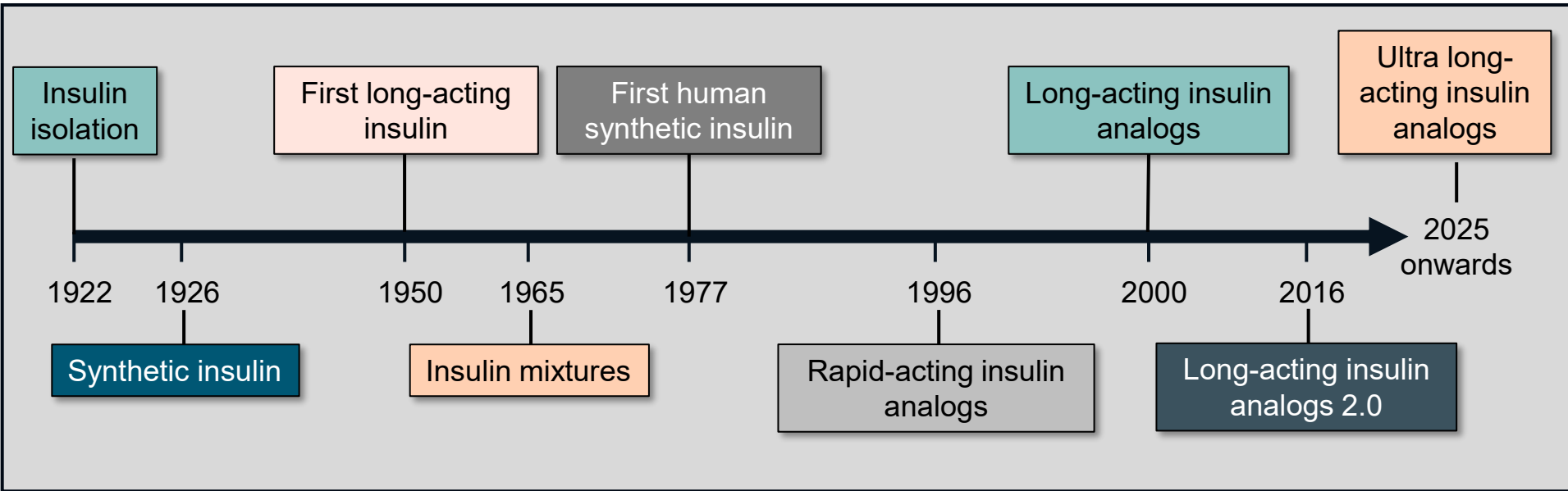
During the visit, you engage in a shared-decision making conversation with Mr. J.D. What is the next appropriate topic to discuss to improve overall glycemic control in this patient?

- A. Scheduling a 3 month follow up to check HbA1C again
- B. The importance of exercise and consistently monitoring blood glucose
- C. Discuss the benefit of basal insulin initiation with structured hypoglycemia education
- D. The benefit of basal-bolus insulin when post-prandial readings are elevated above goal

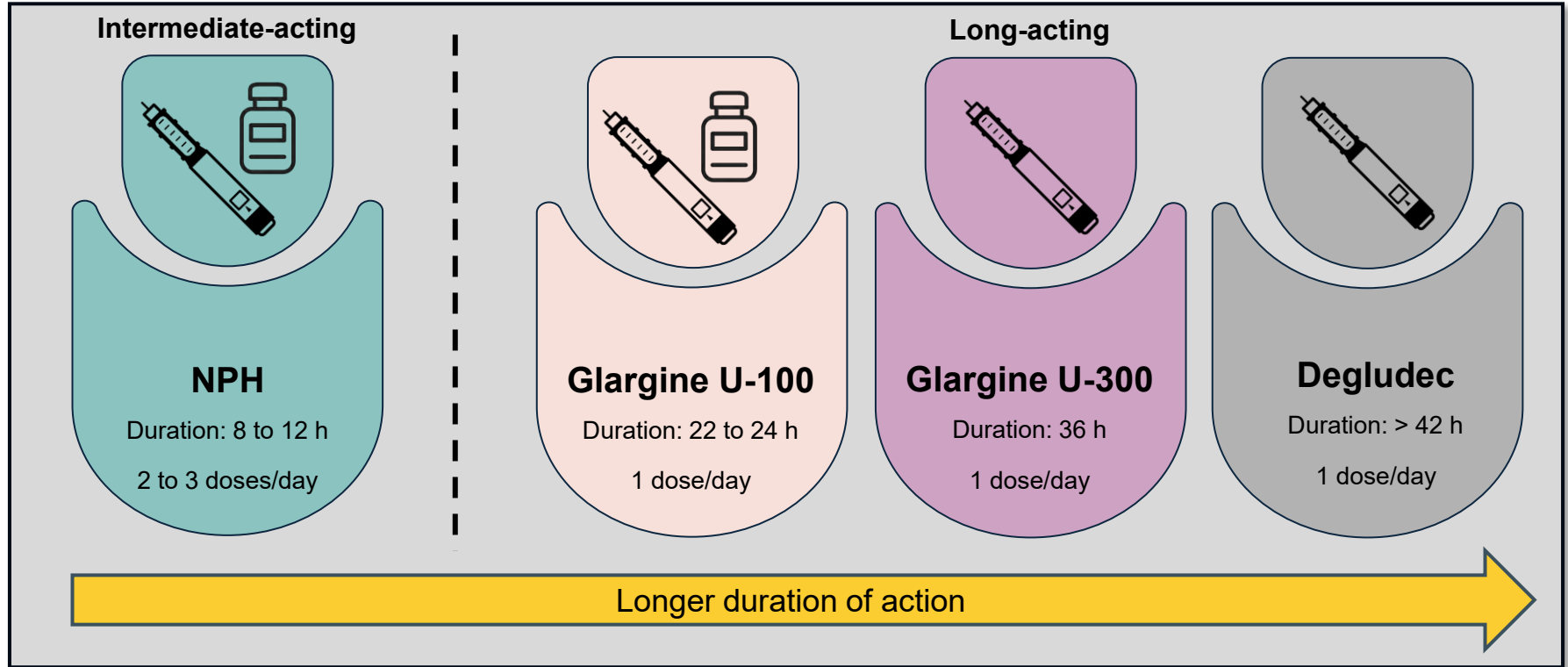
What Are the Clinically Meaningful Differences Among Available and Next-Generation Basal Insulin?



Insulin Therapy Has Developed Significantly Over the Past 100 Years



Multiple Options for Basal Insulin Therapy Are Currently Available



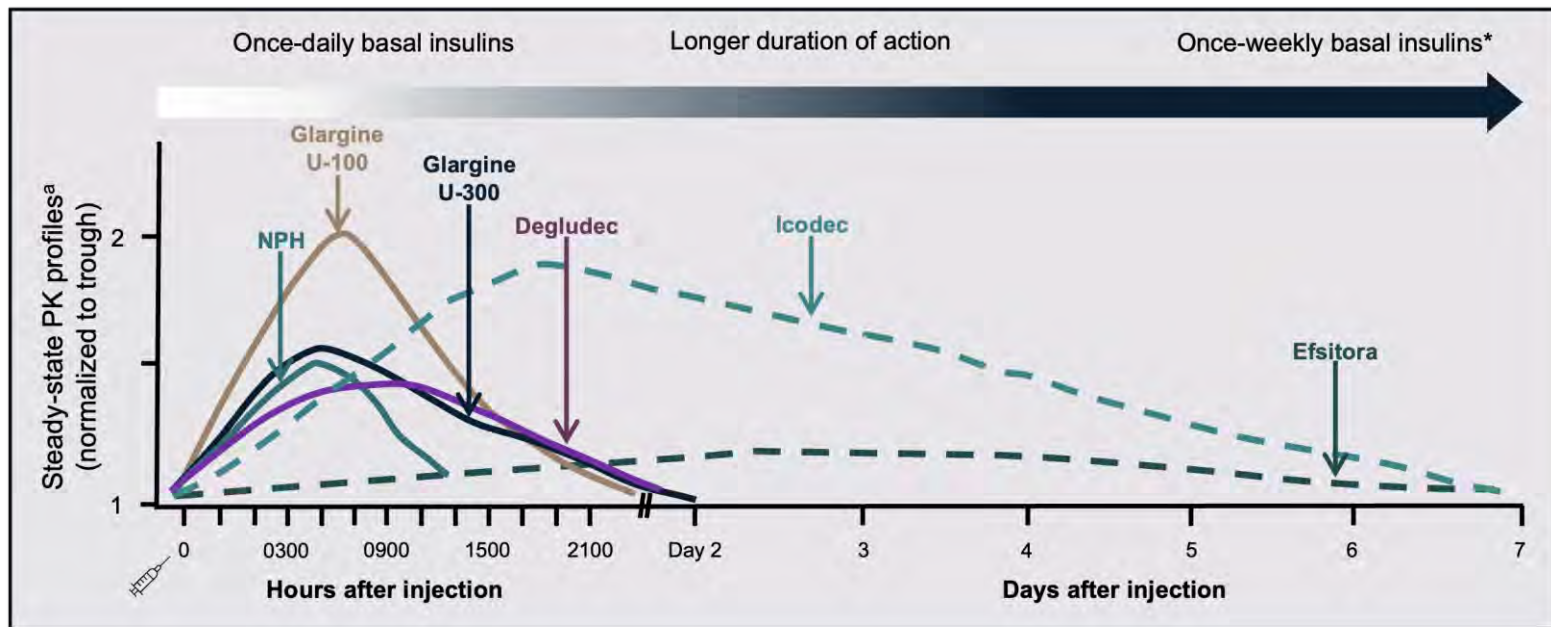
Weekly Basal Insulin Analogs in Late-Stage Development

INSULIN ICODEC

Novel basal insulin analog that strongly, but reversibly, binds to albumin

INSULIN EFSITORA ALFA

Fusion protein that combines a single-chain variant of insulin with a human IgG Fc domain



*Icodec and efsitora are not currently approved by the FDA.

^aInsulin profiles were normalized to trough levels at time 0 to facilitate comparison of P/T ratios across the basal insulins. Schematic representations.

Fc = fragment crystallizable; IgG = immunoglobulin G; NPH = neutral protamine Hagedorn; PK = pharmacokinetic; P/T = peak-to-trough.

Pieber TR, et al. *Endocr Pract.* 2024;30:863-869.

Potential Benefits of Weekly Vs. Daily Basal Insulins

Reduced burden
of insulin
injections

Reduced
pharmacodynamic
variability

Longer half-life

Comparable
hypoglycemia risk

Greater
convenience for
patients

Potential to
overcome clinical
inertia

Possible fixed-
ratio combination
with once-weekly
GLP-1 RA

Once-weekly basal insulin formulations are not currently approved by the FDA.
FDA = US Food and Drug Administration; GLP-1 RA = glucagon-like peptide-1 receptor agonist.
Rosenstock J, Del Prato S. *Metabolism*. 2022;126:154924.

Insulin Stacking Effect

- **Insulin Stacking**
 - Occurs with repeated doses of rapid-acting insulin before prior doses are cleared
 - Results in overlapping insulin action and increased hypoglycemia risk
- Basal insulins with long half-lives **do not stack** when titrated appropriately
- Lower peak-to-trough variability leads to **stable glucose control** and **reduced risk of hypoglycemia**

New Generation Ultra-Long Acting Basal Insulin

4
Trials

Efsitora

QWINT Trias: 2 of 4 Phase 3 trials,
and phase 2 results

8
Trials

Icodec

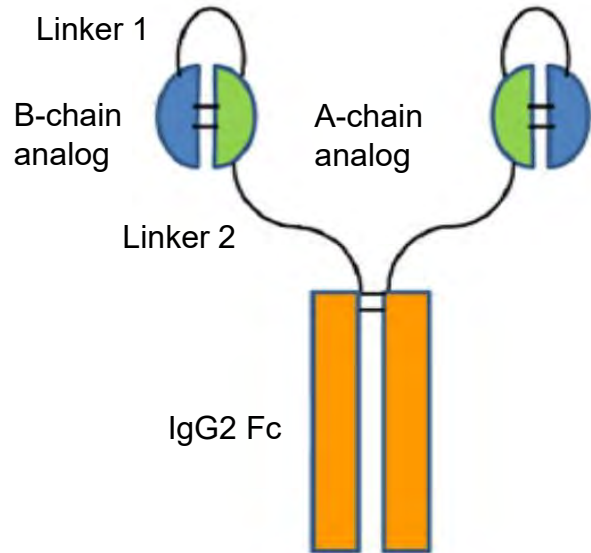
ONWARDS Trials:
Results of 6 phase 3 trials and phase 2
results

4
Trials

IcoSema

COMBINE Trials:
Results of 1 of 4 phase 3

Efsitora: Once-Weekly Insulin Analog



Key Attributes

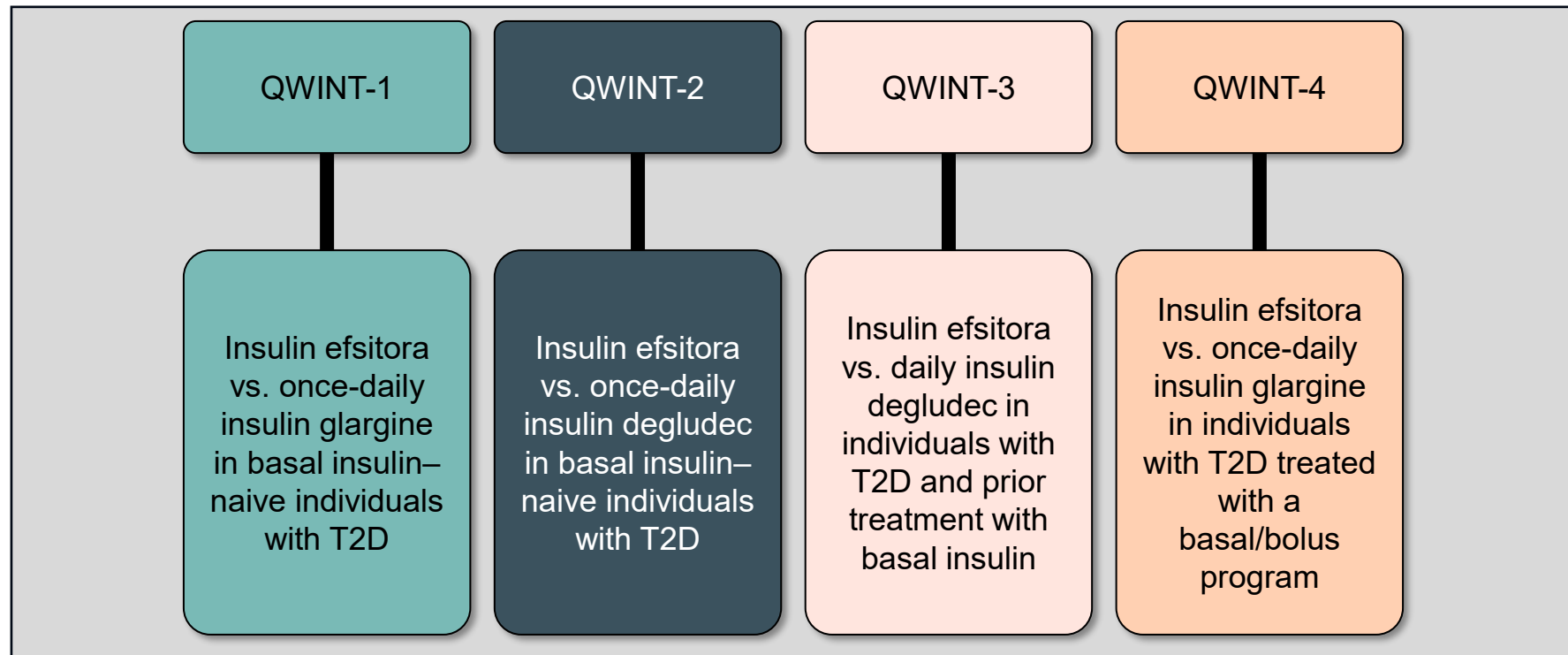
- Selective insulin receptor agonist (vs. IGF-1R)
- Homodimer with molecular weight of 64.1 kDa
- Half-life of 17 days, allowing once-weekly dosing
- Prolonged half-life due to slow absorption from SC space, Fc-Rn-mediated recycling, reduced renal clearance, and reduced IR affinity (↓ receptor-mediated endocytosis)
- Low mitogenicity potential

Efsitora is not currently approved for T2D by the FDA.

Fc-Rn = neonatal fragment crystallizable; IR = insulin receptor; SC = subcutaneous.

Moyers JS, et al. *Pharmacol Exp Ther.* 2022;382:346-355; Figure reproduced from Moyers JS, et al. *Pharmacol Exp Ther.* 2022;382:346-355.

Efsitora - The QWINT Phase 3 Clinical Trials in T2D



Efsitora is not currently approved for T2D by the FDA.
QWINT-5 assesses safety and efficacy in people with type 1 diabetes.
Bergenstal RM, et al. *Diabetes Obes Metab*. 2024;26(8):3020-3030.

QWINT-2 - Efsitora Vs. Degludec: Reduction in A1C

QWINT-2

Efsitora vs once-daily insulin degludec in basal insulin-naïve individuals with T2D

	Efsitora	Degludec
Change in A1C from baseline to week 52, %	-1.26	-1.17
Estimated treatment difference (95% CI)	-0.09 (-0.22 to 0.04) ^a	
Rates of combined level 2 or 3 hypoglycemia, events per person-year	0.58	0.45
Estimated rate ratio (95% CI)	1.30 (0.94 to 1.78)	

Efsitora is not currently approved for T2D by the FDA.

^aEfsitora demonstrated noninferiority to degludec, but superiority was not shown (P = .19).

CI = confidence interval.

Wysham C, et al. *N Engl J Med*. 2024;391(23):2201-2211.

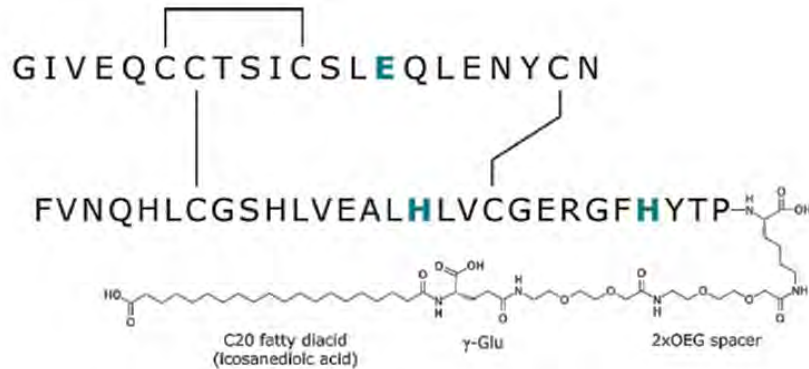
QWINT-2 - Efsitora Vs. Degludec: Safety

Rates of serious AEs: 8.8% with efsitora, 8.2% with degludec

Rates of injection site reactions (all mild): 2.4% with efsitora, 1.7% with degludec

Average change in bodyweight: +3.6 kg with efsitora, +3.5 kg with degludec

Icodec: An Insulin Analog Designed for Once-Weekly Administration

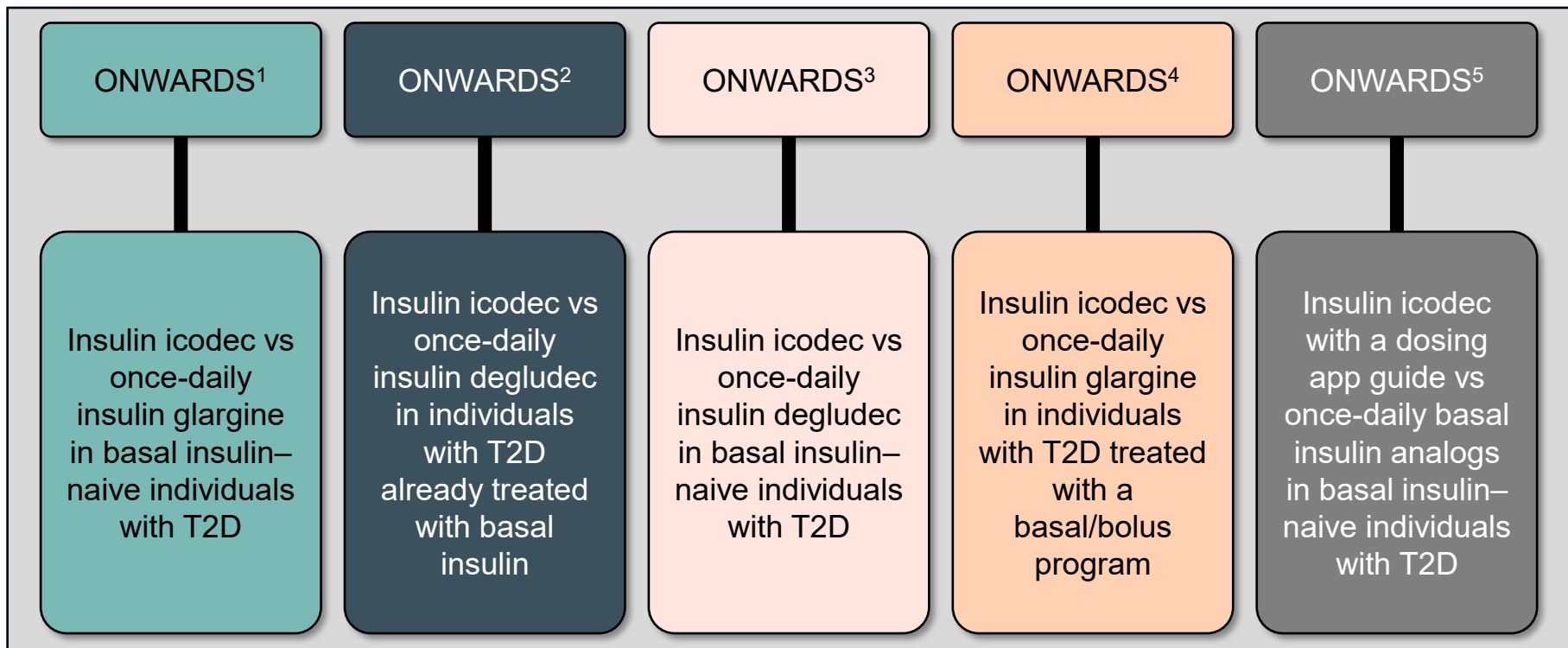


Key Attributes

- Novel ultralong-acting insulin analog
- Half-life of 196 h, allowing once-weekly dosing
- Prolonged half-life due to strong, reversible albumin binding and reduced IR affinity (slowing receptor-mediated clearance)
- Formation of an essentially inactive albumin-bound depot (slow continuous insulin action)
- Selective agonist of the hIR (vs IGF-1R)
- Low mitogenicity potential

Icodec is not currently approved for T2D by the FDA.
hIR = human insulin receptor; IGF-1R = insulin-like growth factor-1 receptor.
Nishimura E, et al. *BMJ Open Diabetes Res Care*. 2021;9:e002301.

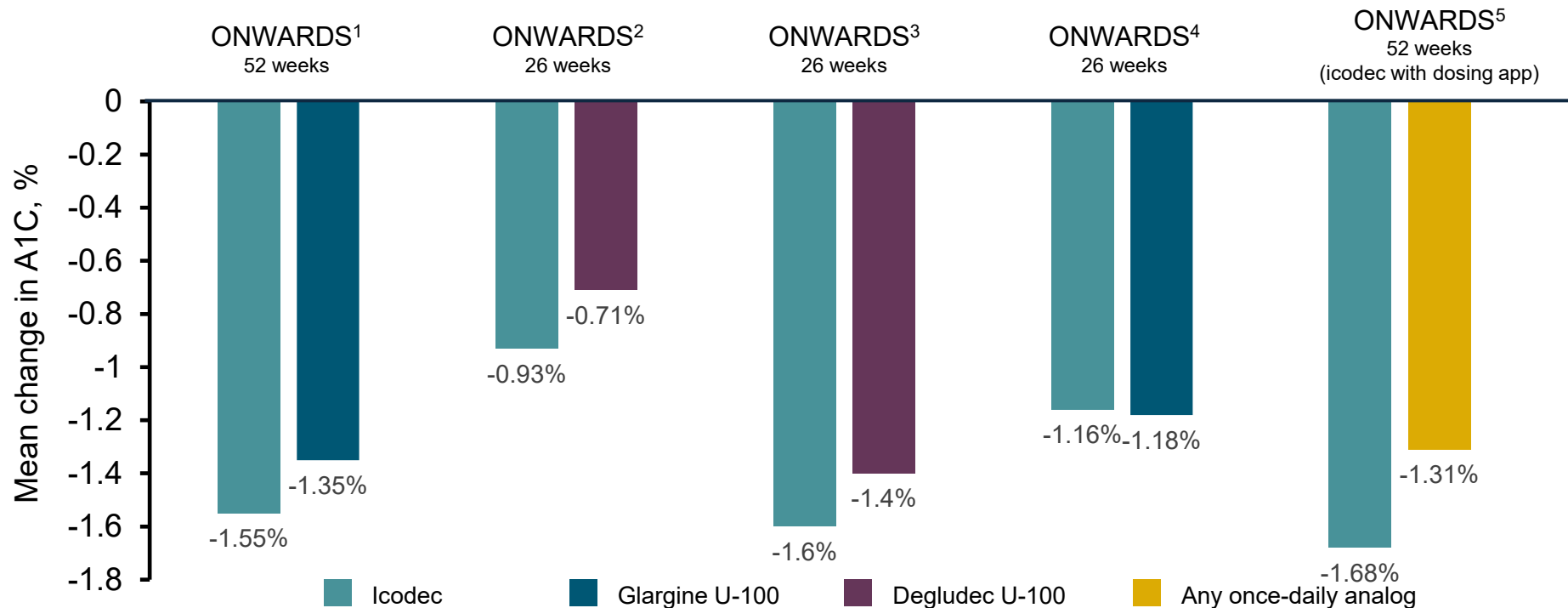
Icodec - The ONWARDS Phase 3 Clinical Trials



Icodec is not currently approved for T2D by the FDA. T2D = type 2 diabetes.

1. Rosenstock J, et al. *N Engl J Med*. 2023;389(4):297-308; 2. Philis-Tsimikas A, et al. *Lancet Diabetes Endocrinol*. 2023;11(6):414-425; 3. Lingvay I, et al. *JAMA*. 2023;330(3):228-237; 4. Mathieu C, et al. *Lancet*. 2023;401(10392):1929-1940; 5. Bajaj HS, et al. *Ann Intern Med*. 2023;176(11):1476-1485.

Icodec - Change in A1C Across the ONWARDS Phase 3 Clinical Trials

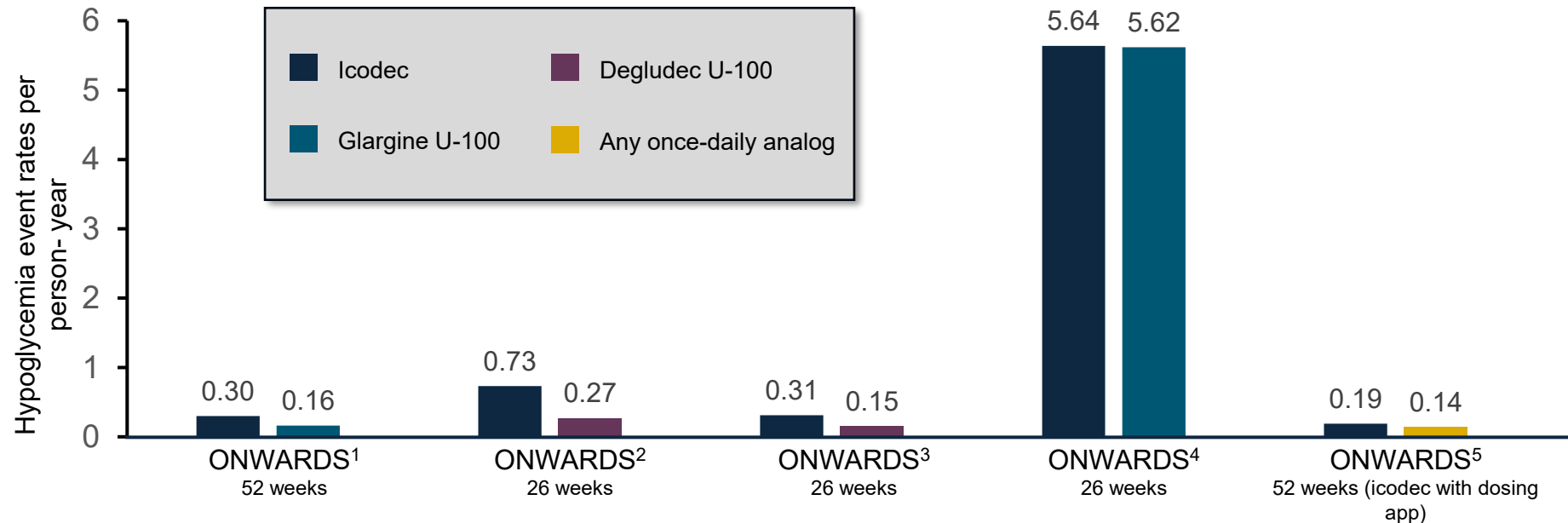


Icodec is not currently approved for T2D by the FDA.

All comparisons showed noninferiority for icodec versus comparator. A1C, glycated hemoglobin.

1. Rosenstock J, et al. *N Engl J Med*. 2023;389(4):297-308; 2. Philis-Tsimikas A, et al. *Lancet Diabetes Endocrinol*. 2023;11(6):414-425; 3. Lingvay I, et al. *JAMA*. 2023;330(3):228-237; 4. Mathieu C, et al. *Lancet*. 2023;401(10392):1929-1940; 5. Bajaj HS, et al. *Ann Intern Med*. 2023;176(11):1476-1485.

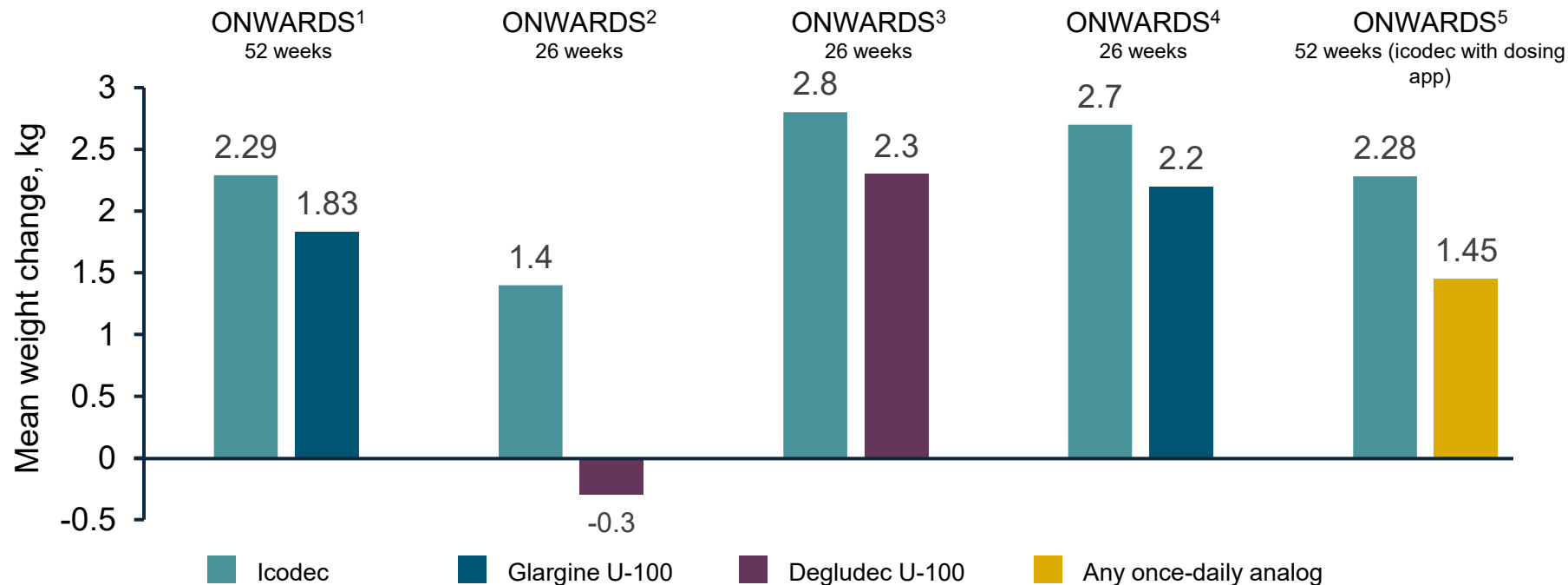
Icodec - Incidence of Clinically Significant or Severe Hypoglycemia Across the ONWARDS Phase 3 Clinical Trials



Icodec is not currently approved for T2D by the FDA.

1. Rosenstock J, et al. *N Engl J Med*. 2023;389(4):297-308; 2. Philis-Tsimikas A, et al. *Lancet Diabetes Endocrinol*. 2023;11(6):414-425; 3. Lingvay I, et al. *JAMA*. 2023;330(3):228-237; 4. Mathieu C, et al. *Lancet*. 2023;401(10392):1929-1940; 5. Bajaj HS, et al. *Ann Intern Med*. 2023;176(11):1476-1485.

Icodec - Body Weight Changes Across the ONWARDS Phase 3 Clinical Trials



Icodec is not currently approved for T2D by the FDA.

1. Rosenstock J, et al. *N Engl J Med*. 2023;389(4):297-308; 2. Philis-Tsimikas A, et al. *Lancet Diabetes Endocrinol*. 2023;11(6):414-425; 3. Lingvay I, et al. *JAMA*. 2023;330(3):228-237; 4. Mathieu C, et al. *Lancet*. 2023;401(10392):1929-1940; 5. Bajaj HS, et al. *Ann Intern Med*. 2023;176(11):1476-1485.

Potential Dosing Considerations for Once-Weekly Basal Insulins

Based on published studies, if approved, once-weekly basal insulins may have specific dosing and titration considerations¹

Loading doses may be necessary¹:

- Rapid glucose lowering not expected with initial doses; steady state takes ≈ 3-4 weeks of dosing
- Loading doses used in icodec ONWARDS 2 and 4 trials (additional 50% dose for first injection)^{2,3} and efsitora QWINT 2, 3, and 4 trials (3x usual weekly dose)⁴

Titration:

- Simple, evidence-based titration regimens are needed¹
- Icodec ONWARDS 5 trial supports use of a dosing-guidance app to improve titration in clinical practice⁵

Switching from daily insulin:

- Trial data suggest switching is generally well tolerated⁶

Once-weekly basal insulin formulations are not currently approved for T2D by the FDA.

1. Rosenstock J, Del Prato S. *Metabolism*. 2022;126:154924; 2. Mathieu C, et al. *Lancet*. 2023;401(10392):1929-1940;

3. Philis-Tsimikas A, et al. *Lancet Diabetes Endocrinol*. 2023;11(6):414-425; 3. 4. Bergenstal RM, et al. *Diabetes Obes Metab*. 2024;26(8):3020-3030;

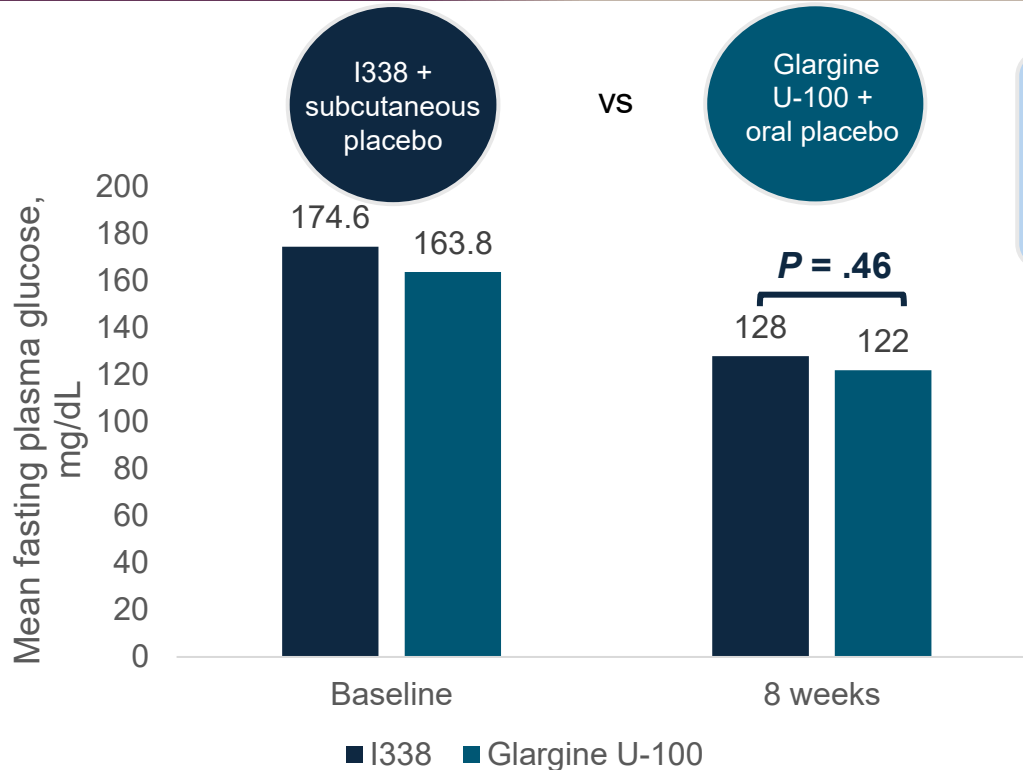
5. Bajaj HS, et al. *Ann Intern Med*. 2023;176(11):1476-1485; 6. Bajaj HS, et al. *Diabetes Care*. 2021;44(7):1586-1594.

IcoSema: Fixed Dose Combination of Insulin Icodec & Semaglutide

COMBINE 2 Trial: Once weekly IcoSema vs. semaglutide in T2D

- Phase 3, 52-week randomized; in adults with T2D uncontrolled on GLP-1 RA therapy
- IcoSema more effective at lowering HbA1c and fasting plasma glucose, compared to semaglutide, with similar safety profiles
- Decreased risk for hypoglycemia (due to increased first and second phase insulin secretion)
- Semaglutide showed significant weight loss

Oral Insulin 338 (I338): Long-Acting Basal Insulin in Phase 2 Clinical Development



Tablet formulation with the absorption-enhancer, sodium caprate

Oral administration would overcome several barriers to insulin initiation

I338 improved fasting plasma glucose levels, with a comparable efficacy to insulin glargine U-100

Audience Response



At Mr. J.D.'s next visit after starting basal insulin, his fasting glucose was 106 and his A1C improved but remains above goal at **7.4%. What is your next recommendation to Mr. J.D. in your shared-decision conversation?**

- A. Transition to a hybrid closed-loop insulin pump system
- B. Continue therapy intensification to reach goals
- C. To test blood sugar once daily rather than twice daily
- D. Prescribe acarbose to blunt postprandial glucose rises

Audience Response



After additional therapy intensification, Mr. J.D. calls the office to ask about his frequent, unpredictable glycemic fluctuations. Which advanced technology would provide real-time data to help fine-tune his diabetes management?

- A. A hybrid closed-loop insulin pump system
- B. A bio-wearable that continuously monitors both glucose and ketone levels
- C. A continuous glucose monitor (CGM) with trend analysis
- D. A traditional ketone meter for periodic testing

Novel Technologies in Glucose Monitoring



Benefits of Novel Technologies

- **Insulin Pumps:**
 - Suitable for people who have different work shifts, illnesses, stress, participation in sports, menstrual periods, etc.
 - Allows establishing up to six personal profiles with different basal insulin rates, insulin-to-carbohydrates ratios (ICR) and correction factors (CF).
 - Different profiles help make the algorithm more or less aggressive according to the patient or the situation.
- **Continuous Glucose Monitoring (CGM)**
 - Provides insights into glucose trends and variability (Over-the-counter option)
- **Potential Benefits of Novel Technologies on T2D Outcomes**
 - Better long-term health outcomes
 - Reduced complications
 - Improved quality of life
 - Lower healthcare costs

Software to Support Enhanced Automatic Insulin Delivery

- iLet Bionic Pancreas (FDA cleared)
- Uses an adaptive closed-loop algorithm that is initialized only with a user's body weight and requires no additional insulin dosing parameters
- Users can estimate the amount of carbs in their meal as small, medium or large and the algorithm learns over time to respond to users' individual insulin needs (so no more carb counting!)

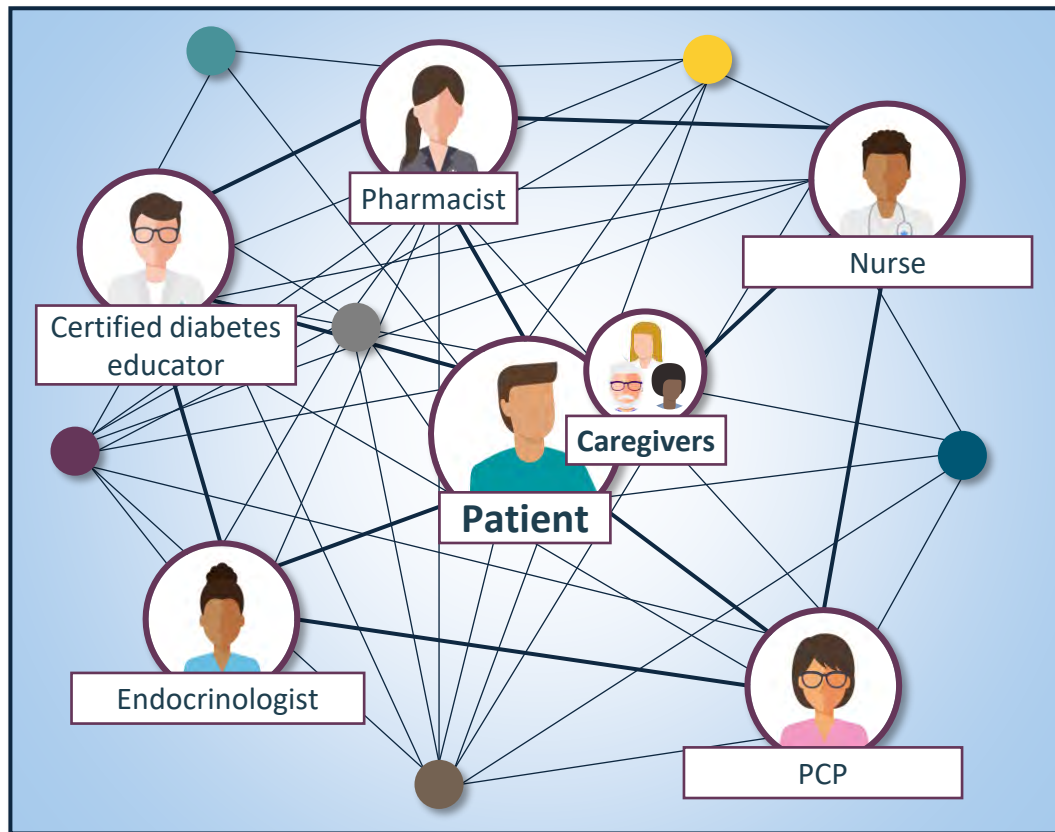
Artificial Intelligence in Future Diabetes Management

- AI algorithms to predict glucose levels and recommend interventions
- Machine learning for personalized treatment plans
- Automated insulin dosing systems
- AI-driven retinal imaging
 - **Function:** Analyzes retinal images to detect early signs of diabetic retinopathy
 - **Benefit:** Enables early intervention and prevents vision loss

Wearable Devices

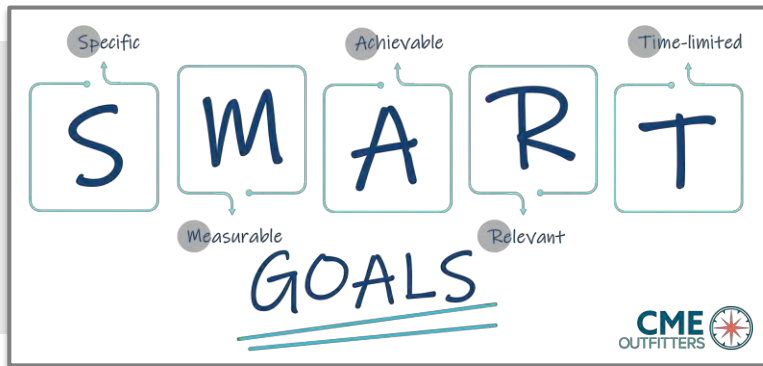
- **Function:** Smart glucose monitors (measures glucose levels in sweat) and socks (via temperature monitoring) that detect foot infections.
- **Benefit:** Helps patients monitor their condition and prevent complications at home
- **Limitations:**
 - AI can be incorrect
 - AI is still experimental
 - Biases in data exist
 - AI sometimes 'hallucinates'

Team-based Approach for the Management of T2D



Multidisciplinary team approach

- Collaboration for comprehensive care
- Shared decision-making
- Improves treatment adherence
- Better A1C levels
- Addresses key barriers



Put information into action!

Takeaways from this program can be implemented into your practice to improve patient care.

- Address therapeutic inertia by reducing delays in insulin therapy that lead to improved glycemic control and better long-term patient outcomes
- Implement latest evidence-based guidelines into clinical practice and educate patients on long-term benefits of early initiation of basal insulin
- Distinguish between current and emerging basal insulin therapies to individualize treatment strategies and overcome therapeutic inertia
- Integrate novel technologies for glucose monitoring that may help improve patient engagement and treatment outcomes

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- In approximately 3 months, complete the follow-up survey from CME Outfitters



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INITIATING BASAL INSULIN

***Moving
from Hesitancy
to Action***

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