Technology and Diabetes: Advancing Diabetes Management with Technology

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Disclosures:

- Speaker Bureau- Abbott, Novo Nordisk, Xeris
- Advisory Board- Corcept, Xeris

Learning Objectives

- Assess the current CGM therapies that are available for personal and professional use

- Understand how to interpret an AGP report to individualize your patient's management plan

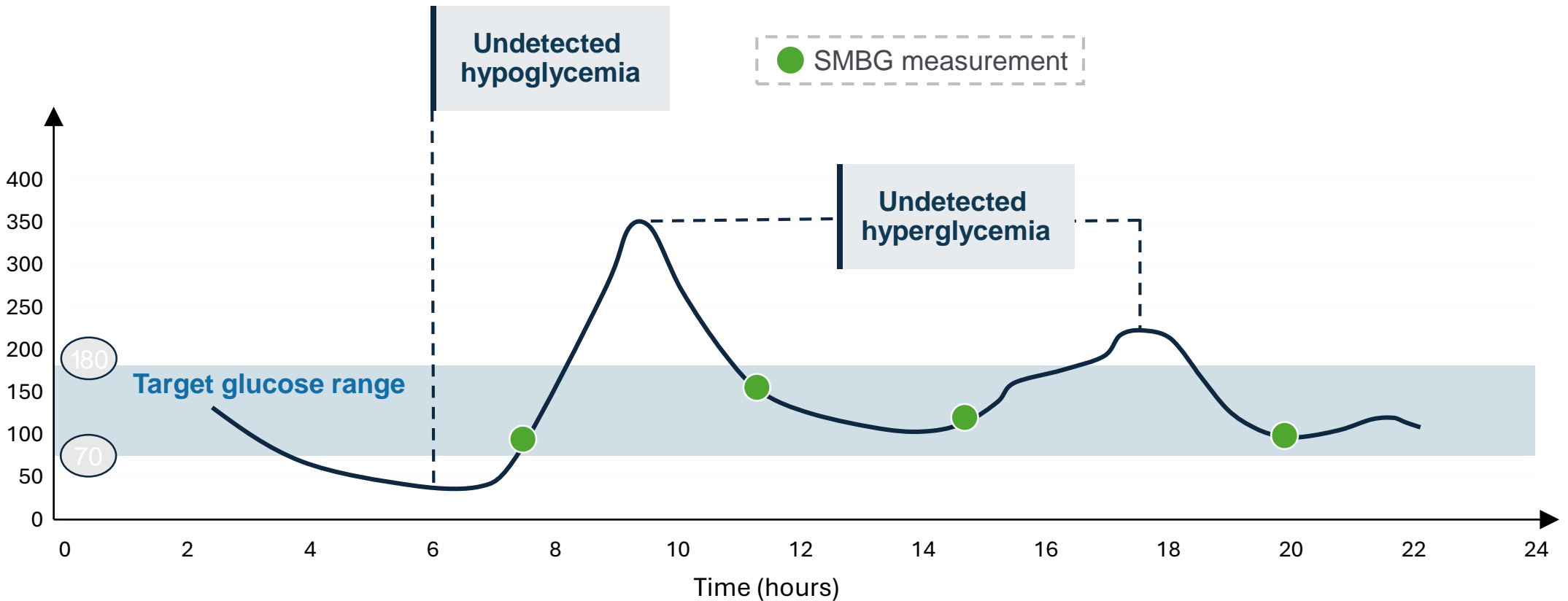- Evaluate the current technology available for insulin delivery devices

3

Glycemic Patterns Are Often Missed by SMBG but Detected With CGM

SMBG

CGM

Undetected hypoglycemia

Undetected hyperglycemia

● SMBG measurement

Glucose (mg/dL)

Target glucose range

400
350
300
250
200
180
150
100
70
50
0

Time (hours)

0 2 4 6 8 10 12 14 16 18 20 22 24

- CGM, continuous glucose monitoring; SMBG, self-monitoring blood glucose.

Poor Testing Technique Can Negatively Affect Accuracy

Skin contaminants reduce meter accuracy 1 hour after peeling fruit

Median blood glucose levels measured by portable analyzer in 10 subjects with normal glucose tolerance

Exposure	Washed Hands	Exposed Finger (No Washing)	One Alcohol Wipe	Five Alcohol Wipes
Peeling an orange (n = 10)	98 mg/dL	171 mg/dL	118 mg/dL	119 mg/dL
Peeling a grape (n = 10)	93 mg/dL	360 mg/dL	274 mg/dL	131 mg/dL
Peeling a kiwi (n = 10)	90 mg/dL	183 mg/dL	144 mg/dL	106 mg/dL

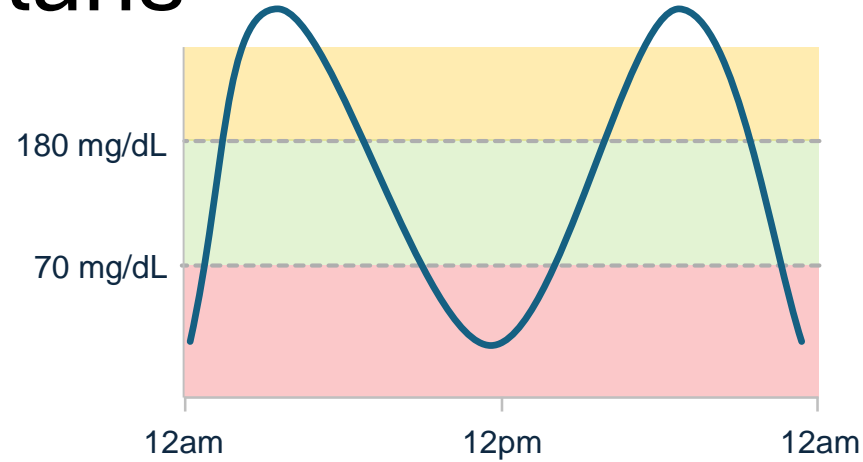- Hirose et al. Diabetes Care. 2011;34(3):596-597.

Glycemic Management and Treatment Plan Should Not Be Defined by HbA1c Alone

HbA1c, %	Glucose, mg/dL	95% CI
5	97	(76, 120)
6	126	(100, 152)
7	**154**	**(123, 185)**
8	183	(147, 217)
9	212	(170, 249)
10	240	(193, 282)
11	269	(217, 314)
12	298	(240, 347)

1. May underestimate or overestimate average glucose *(eg, HbA1c 7% could represent a range between 123 mg/dL and 185 mg/dL)*
2. Does not indicate extent or timing of hypoglycemia or hyperglycemia
3. Does not reveal glycemic variability
4. Limited utility for insulin dosing decisions
5. Unreliable in patients with hemolytic anemia, hemoglobinopathies, or iron deficiency
6. Underestimates in end-stage kidney disease or during pregnancy
7. Correlation with mean glucose can vary among races

- American Diabetes Association. Diabetes Care. 2020;43(Suppl 1):S66-S76; Nathan DM, et al. Diabetes Care. 2008;31:1473-1478.

Same A1C but CGM Patterns Drive Different Treatment Plans

A1C 7%

180 mg/dL
70 mg/dL

12am — 12pm — 12am

High 40%
In-Range 40%
Low 20%

A1C 7%

180 mg/dL
70 mg/dL

12am — 12pm — 12am
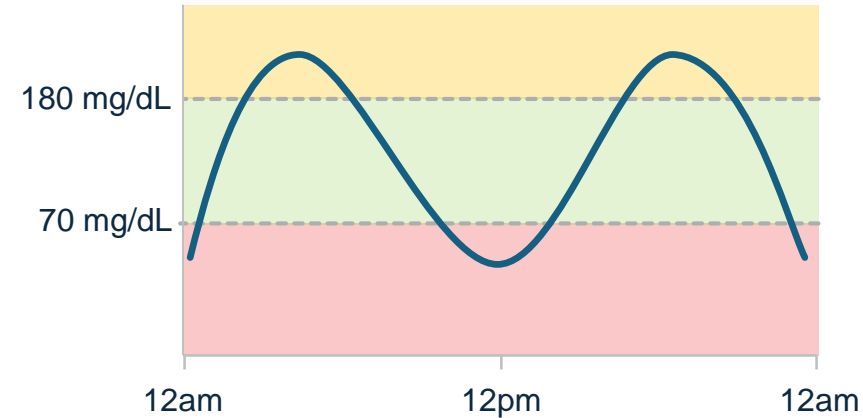
High 25%
In-Range 70%
Low 5%

Professional CGM

Professional CGM

- **Clinic-based devices applied by HCP in the office**

- **Used for patients who are not at glycemic goal and do not want or qualify for a personal CGM device**

- **Can be used blinded or unblinded**

- **Patients can wear it for 7 to 14 d, then return to the office**

- **HCP can download the data, interpret it, and make effective changes to medications**

Professional CGM Devices

	FreeStyle Libre Pro	G6 Pro
Data type	Blinded	Blinded or unblinded
Frequency of glucose readings	Records glucose every 15 min	Glucose readings sent to patient's smart device every 5 min in unblinded mode; data also sent to HCP Sensor/transmitter returned after 10 days and CGM data uploaded for HCP and patient
Approved ages	≥ 18 y	≥ 2 y
Location for placement	Back of upper arm	Abdomen (also buttocks for patients 2 to 17 y)
Sensor life	14 d	10 d
Calibration	No	No
Warm-up time	1 h	2 h
Potential interfering agents	Ascorbic acid Salicylic acid	Hydroxyurea High-dose acetaminophen (> 1 g every 6 h in adults)
Alerts or alarms	No	Yes (unblinded)

2024 ADA Standards of Care in Diabetes - Technology

7.20 Periodic use of rtCGM or isCGM or use of professional CGM can be helpful for diabetes management in circumstances where consistent use of CGM is not desired or available. **C**

• American Diabetes Association Professional Practice Committee. Diabetes Care. 2024;47(Suppl 1):S126-S144.

Patient Selection for Professional CGM

Helpful to evaluate when rtCGM or isCGM is not available to patient

Patient's who prefer a shorter experience or blinded data

Those who are not sure they want to wear a device on a regular basis

ElSayed NA et al 7. Diabetes Technology: *Standards of Care in Diabetes—2023. Diabetes Care* 1 January 2023; 46 (Supplement_1): S111–S127.

Personal CGM

Real-Time CGM vs Intermittently Scanned CGM

rtCGM
Measures and displays
BG levels continuously

isCGM

ElSayed NA, et al. Diabetes Care. 2023;46(Suppl 1):S111-S127.
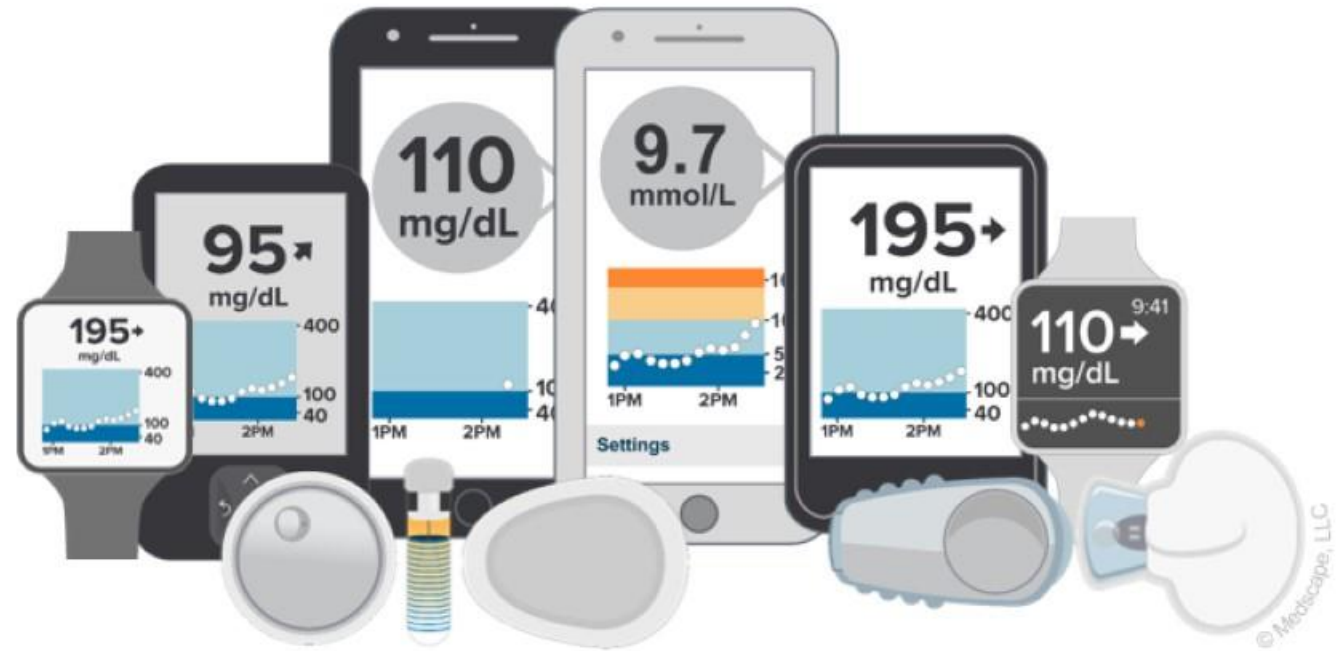
Real-Time CGM vs Intermittently Scanned CGM

rtCGM

isCGM
Measures BG levels continuously but requires scanning for visualization and storage of data

ElSayed NA, et al. Diabetes Care. 2023;46(Suppl 1):S111-S127.

Personal CGM Devices

	FreeStyle Libre 14-Day isCGM/ 2 isCGM/2plus rtCgm/ 3 rtCGM/3 plus rtCGM	G6 / G7 rtCGM	Guardian Sensor 3 & 4 (pump integrated) and Guardian Connect (stand-alone) rtCGM	Eversense 180 day
Approved labeling	Replaces fingersticks for treatment decisions; no fingerstick calibration required	Replaces fingersticks for treatment decisions; no fingerstick calibration required	4: Replaces fingersticks for treatment decisions; no fingerstick calibration required 3: Requires ≥ 2 fingerstick calibrations/d	Two fingerstick blood glucose calibrations per day, approximately 12 hours apart
Age	≥ 18 y / ≥ 4 y / ≥ 4 y/ ≥ 2 y 2plus/3plus 2 / 3: Use during pregnancy by women with T1D, T2D, or GDM	≥ 2 y G 7: Use during pregnancy by women with T1D, T2D, or GDM	Guardian 4: ≥ 7 y Guardian 3: ≥ 14 y Connect: ≥ 14 y	≥ 18 y
Medicare coverage	Yes / Yes / yes	Yes / Yes	Sensor 3: Yes / 780 G: Yes / Connect: No	Yes
Wear length	14 d / up to 15 d / up to 15 d	10 d / 10 d + 12 h	7 d	180 d
Warm-up	1 h	2 h / up to 30 min	2 h	N/A
Alarms	No / Yes / Yes	Yes	Yes	Yes
Data display/integration	14 / 2/3: Reader; Android and iOS Apps 2 / 3: CGM for integration with AID systems	Receiver; Android and iOS Apps; smartwatches t:slim X2 pump, Omnipod 5	Connect: Android and iOS Apps Guardian 3: 630G, 670G, 770G Guardian 4: 780G	Android and iOS Apps, smartwatches
Form	Disposable transmitter integrated with sensor patch	G6: Transmitter (3-mo use) separate from sensor/G7 integrated	Transmitter (rechargeable every 6 days) separate from sensor	Transmitter needs to be charged 10 minutes daily
Accuracy*	11.4% / 9.3% / 7.9%	9.0% / 8.2%	9.6% / 9.0% to 11%	8.5% to 9.5%

- *Accuracy measured by MARD (mean absolute relative difference) relative to venous glucose. Lower numbers are more accurate. Accuracy figures and specifications for each device provided by manufacturers. AID, automated insulin delivery; FDA, US Food and Drug Administration; GDM, gestational diabetes mellitus; T1D, type 1 diabetes; T2D, type 2 diabetes.

2024 ADA Standards of Care in Diabetes - Technology
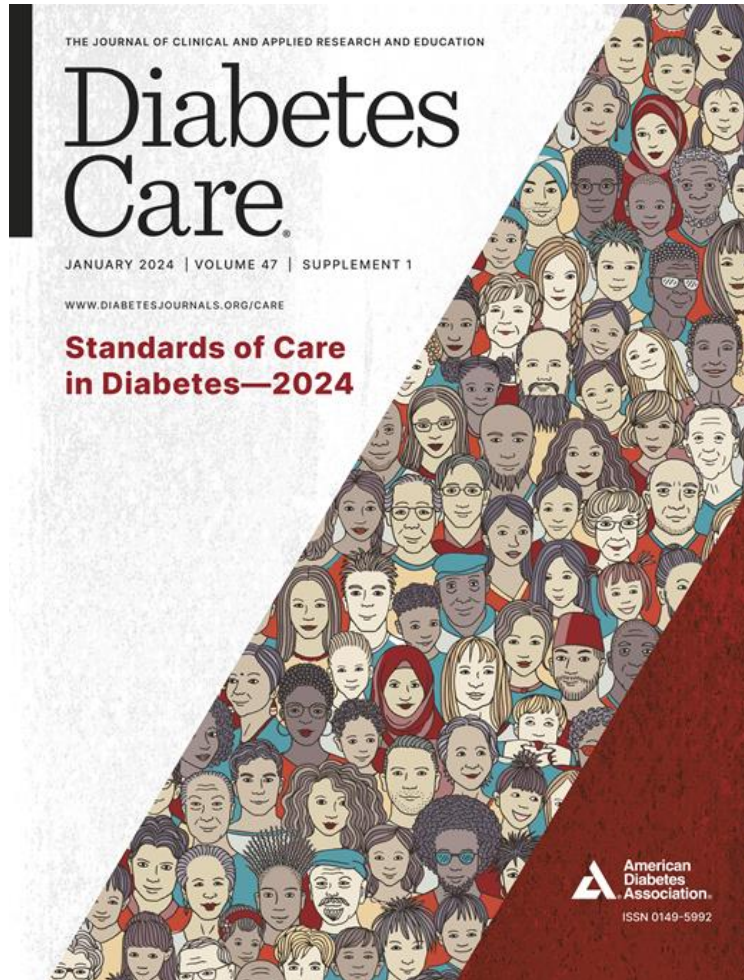
7. Diabetes Technology: *Standards of Care in Diabetes—2024*

American Diabetes Association Professional Practice Committee*

Diabetes Care 2024;47(Suppl. 1):S126–S144 | https://doi.org/10.2337/dc24-S007

> *"Diabetes devices should be offered to people with diabetes."* A

Broad Application of CGM in T2D On and Off Oral Therapies

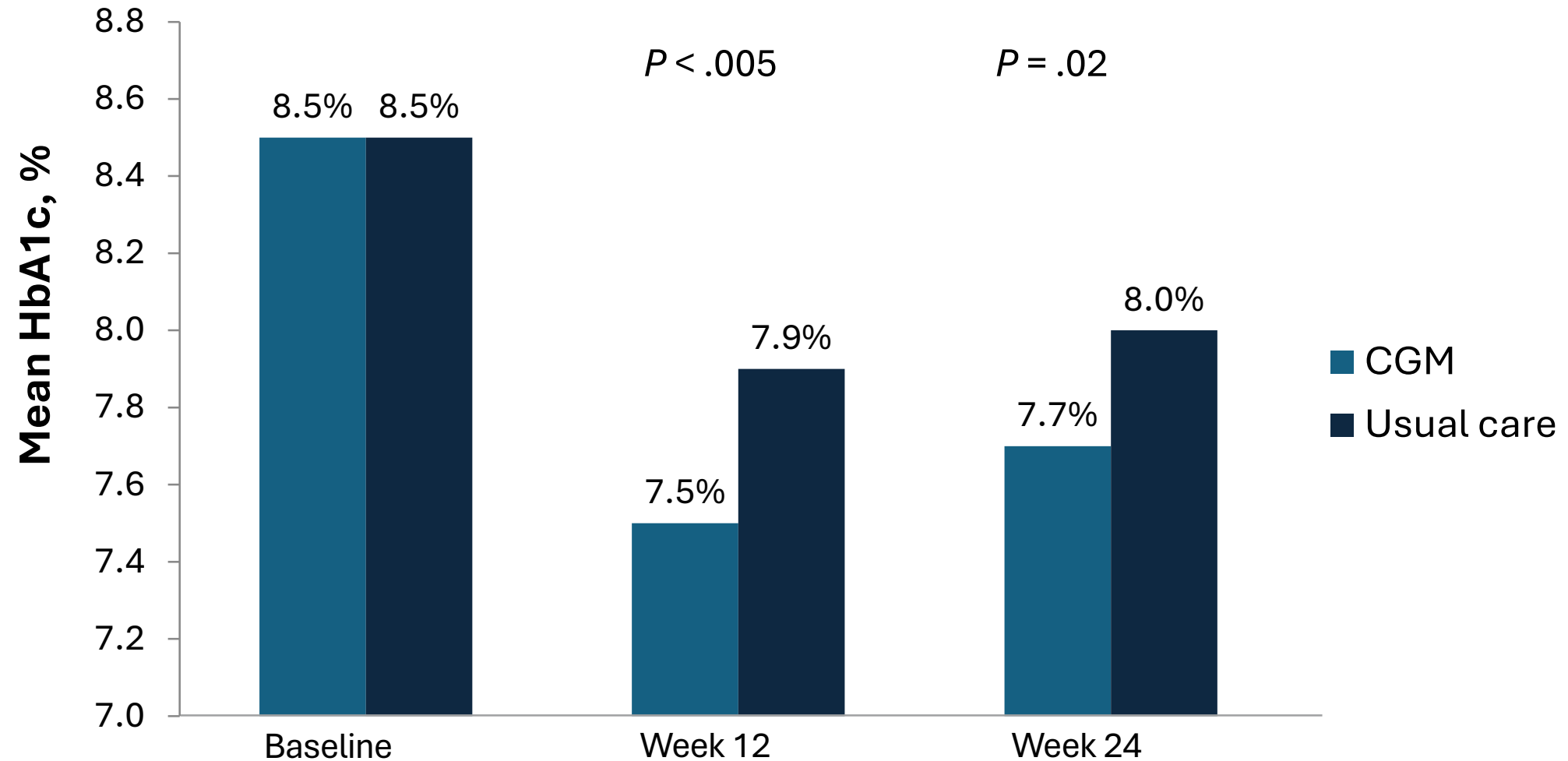| CGM and MDI	CGM and Basal Insulin	BGM and Non-Insulin Therapies
7.14 rtCGM **A** or isCGM **B** should be ==offered for diabetes management in adults with diabetes on MDI or CSII== who are capable of using the devices safely (either by themselves or with a caregiver). The choice of device should be made based on the individual's circumstances, preferences, and needs	**7.15** rtCGM **A** or isCGM **B** should be ==offered for diabetes management in adults with diabetes on basal insulin== who are capable of using the devices safely (either by themselves or with a caregiver). The choice of device should be made based on the individual's circumstances, preferences, and needs.	**7.12** Although BGM in people on noninsulin therapies has not consistently shown clinically significant reductions in A1c levels, it may be helpful when ==altering meal plans, physical activity plans, and/or medications (particularly medications that can cause hypoglycemia)== in conjunction with a treatment adjustment program. **E**

DIAMOND T2D Study

- Randomized Trial of 158 adult MDI users with T2D

- Randomly assigned to G4 or Usual Care
- Mean baseline HbA1c 8.5% in both groups
- Primary outcome HbA1c at 24 weeks: completed by 96%

- Results

- CGM usage in month 6: > 6 days/wk in 93%
- Mean HbA1c decreased 1.0% in CGM Group and 0.6% in Control Group (P = .02)
- CGM increased time-in-range 70-180 mg/dL and reduced hyperglycemia
- Little hypoglycemia in both groups
- CGM Satisfaction Scale scores extremely high

- Beck RW, et al. Ann Intern Med. 2017;167:365-374.

DIAMOND T2D: HbA1c Treatment Group Differences

Mean HbA1c, %

- Baseline: CGM 8.5%, Usual care 8.5%
- Week 12: CGM 7.5%, Usual care 7.9%, $P < .005$
- Week 24: CGM 7.7%, Usual care 8.0%, $P = .02$

Legend: CGM, Usual care

- Beck RW, et al. Ann Intern Med. 2017;167:365-374.

REPLACE Randomized Trial

Randomized Trial of 224 pts with T2D using insulin (95% MDI)

- Randomization 2:1 to Libre CGM or Usual Care
- Mean baseline HbA1c 8.7%

Results

- Libre usage overall 93%
- SMBG tests 0.3 versus 3.8 times/day
- Mean sensor scans per day 8
- HbA1c decreased 0.3% in both groups from baseline to 6 mos (P=0.82)
- Libre reduced time < 70 mg/dL by 28 min/day (P<0.001)
- No severe hypo events
- High treatment satisfaction and quality of life with Libre

CGM in Primary Care

- 176 participants with T2D receiving NIIT followed by primary care clinicians, randomly assigned to G6 and BGM groups and followed for 8 months. CGM initiated/interpreted by diabetes specialists; management by PCPs
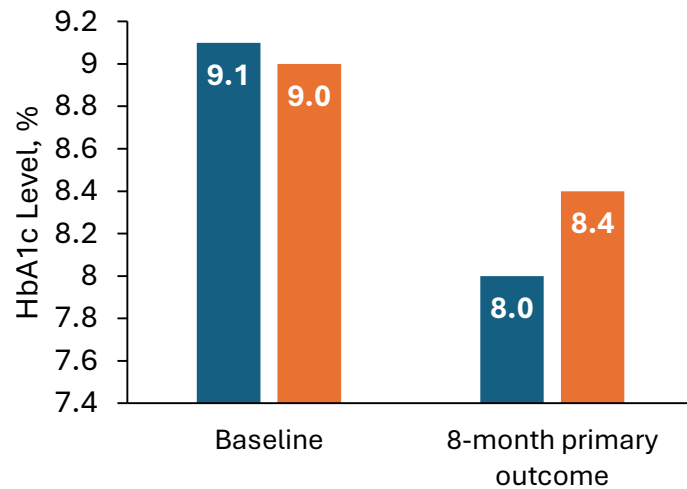
Difference: -0.4%†
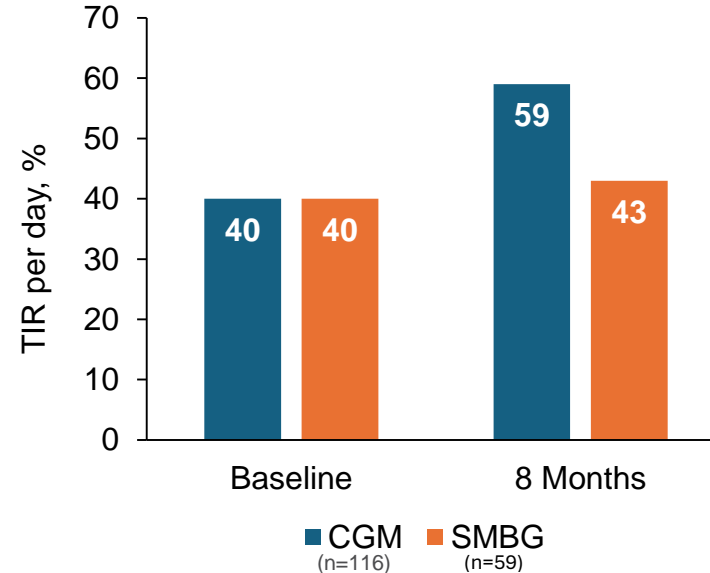
Difference: +15%*
Equivalent to 3.6 h more per day

Difference: -16%*
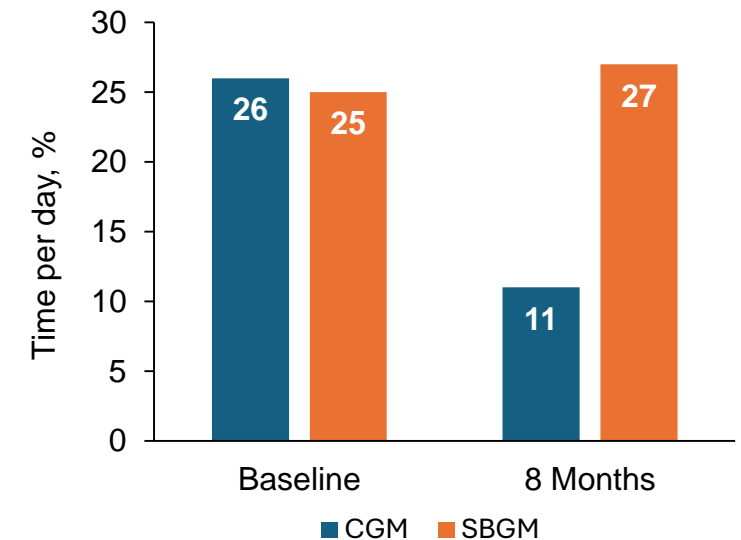**Equivalent to 3.8 h less per day**

HbA1c over 8 months

Mean % TIR of 70-180 mg/dL

Mean % Time > 250 mg/dL

- *P < .001; †P = .02   ■CGM Group   ■BGM Group

- SMBG, self-monitoring of blood glucose; TIR, time in range.

- Martens T, et al. JAMA. 2021;325:2262-2272.

Benefits of Using FreeStyle Libre with GLP-1 Therapy

Overview

- Conducted a large, real-world study to evaluate whether adding FreeStyle Libre to GLP-1 therapy further improves HbA1c
- Study included patients with T2D who were already using a GLP-1 and had an elevated HbA1c level (≥ 8%) at the time they first started using FreeStyle Libre

Conclusions

- Patients who were already using a GLP-1 had a significant improvement in HbA1c after adding FreeStyle Libre
- Average HbA1c improvement of 1.5 points
- Improvement in HbA1c seen:
  - Regardless of the time gap between starting GLP-1 therapy and adding FreeStyle Libre
  - Across all GLP-1 products
  - In insulin and non-insulin users

- Miller E, et al. Diabetes Technol Ther. 2024:26:A252. Presented during the Advanced Technologies & Treatments for Diabetes (ATTD) Conference. March 6-9, 2024, Florence, Italy. E-poster #1311.

Study Design and Results

Study Design

Data Source

- Optum's de-identified Market Clarity Data, a linked EHR-claims database

Inclusion Criteria

- Adults ≥ 18 yo
- T2D diagnosis between 2018-2022
- Elevated HbA1c (≥ 8%) at time of starting to use FreeStyle Libre
- Active user of GLP-therapy, defined by having ≥ 1 GLP-1 prescription filled within 6 months of first using FreeStyle Libre

Measurement

- Change in HbA1c from the time of first using FreeStyle Libre to 6 months later

Overall Results

Patients who were already using a GLP-1 saw a significant ($P < .001$) improvement in HbA1c after adding FreeStyle Libre
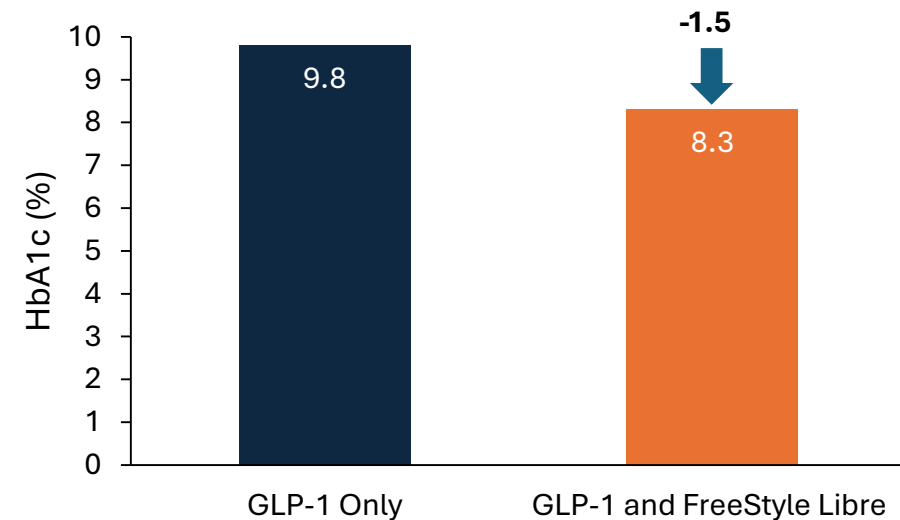
N = 1781
Gray bar represents baseline HbA1c measurement just before adding FreeStyle Libre
Blue bar represents follow-up measurement 6 months after adding FreeStyle Libre

- Miller E, et al. Diabetes Technol Ther. 2024:26:A252. Presented during the Advanced Technologies & Treatments for Diabetes (ATTD) Conference. March 6-9, 2024, Florence, Italy. E-poster #1311.
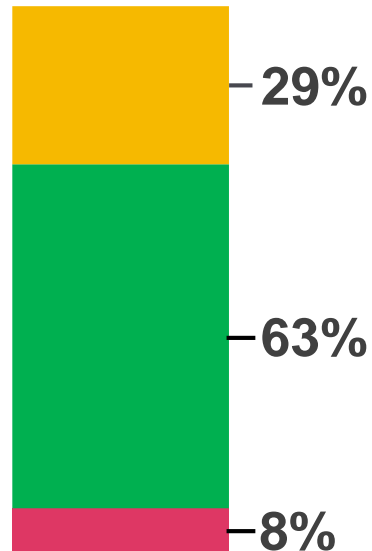
Interpreting Data and AGP Reports

Equal HbA1c Values Do Not Equal TIR

Patient A
HbA1c 7%
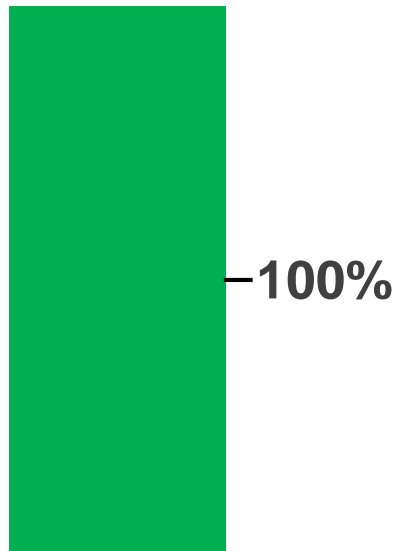
Patient B
HbA1c 7%

Patient C
HbA1c 7%

—100%

—29%

—63%

—8%

—58%

—24%

—18%
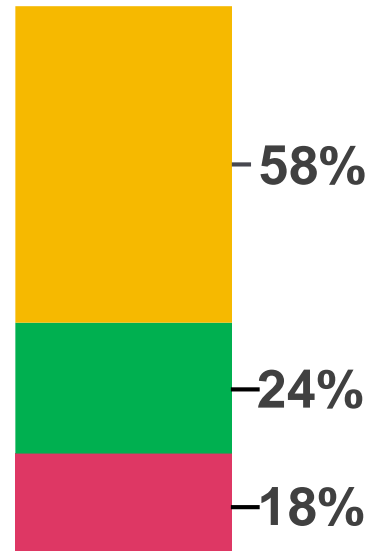
In Target Range (70-180 mg/dL)

Above Target Range (> 180 mg/dL)

Below Target Range (< 70 mg/dL)

HbA1c provides only an average of a patient's glucose history

TIR provides more actionable information than HbA1c alone and should complement HbA1c

Each 5% increase in TIR is clinically beneficial

- Not actual patient data; for illustrative purposes only.
  Battelino T, et al. Diabetes Care. 2019;42:1593-1603.

Time in Range (TIR) Targets for CGM Data Interpretation

Patients With T1D and T2D

Target (%)

Older, High-Risk Patients With T1D and T2D

Target (%)

TAR < 6 h
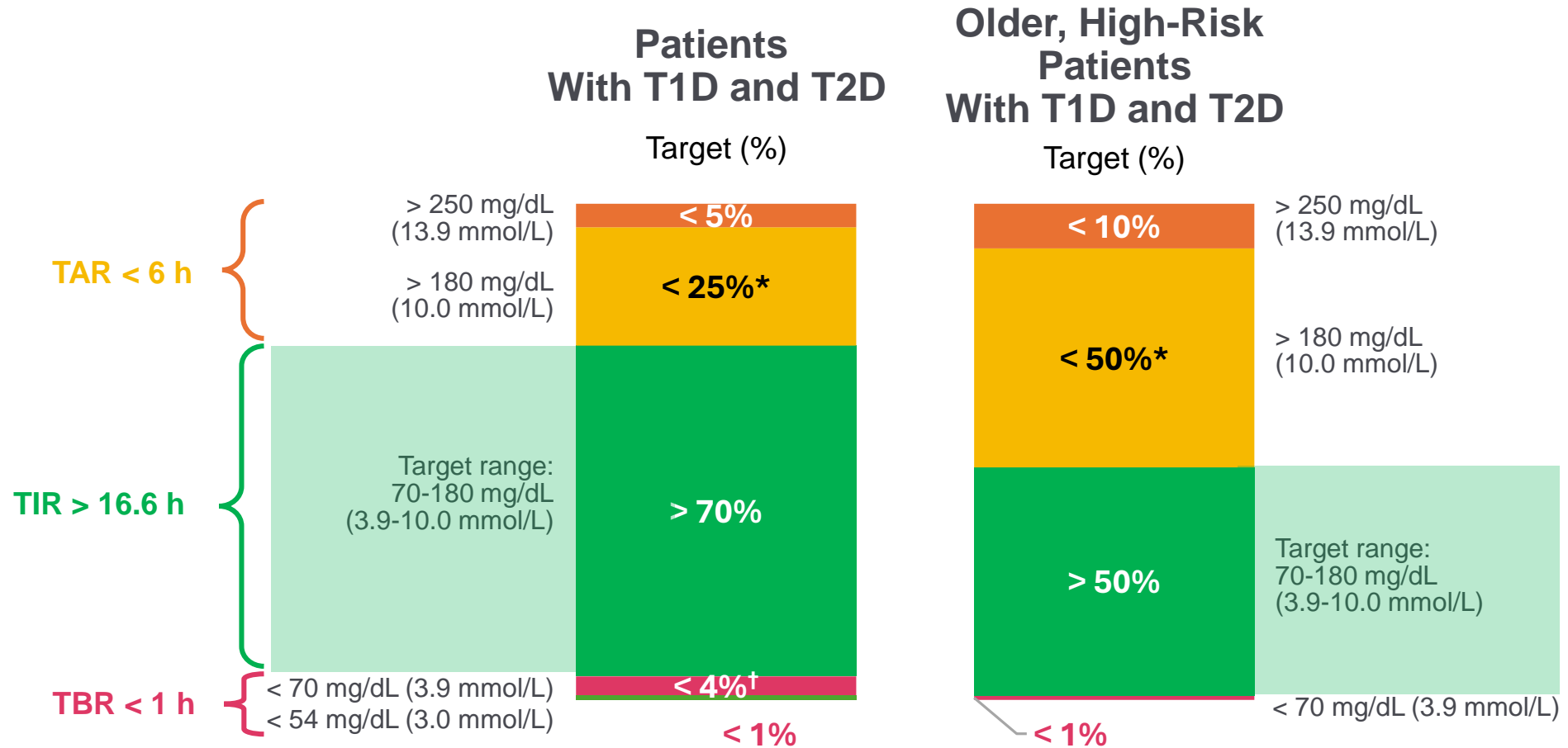- > 250 mg/dL (13.9 mmol/L) — < 5%
- > 180 mg/dL (10.0 mmol/L) — < 25%*

TIR > 16.6 h
- Target range: 70-180 mg/dL (3.9-10.0 mmol/L) — > 70%

TBR < 1 h
- < 70 mg/dL (3.9 mmol/L) / < 54 mg/dL (3.0 mmol/L) — < 4%† / < 1%

Older, High-Risk:
- > 250 mg/dL (13.9 mmol/L) — < 10%
- > 180 mg/dL (10.0 mmol/L) — < 50%*
- Target range: 70-180 mg/dL (3.9-10.0 mmol/L) — > 50%
- < 70 mg/dL (3.9 mmol/L) — < 1%

- *Includes percentage of values > 250 mg/dL. †Includes percentage of values < 54 mg/dL.
Battelino T, et al. Diabetes Care. 2019;42:1593-1603.

Standardized CGM metrics for clinical care in nonpregnant individuals with type 1 or type 2 diabetes

Metric	Interpretation	Goals
1. Number of days CGM device is worn		14-day wear for pattern management
2. Percentage of time CGM device is active		70% of data from 14 days
3. Mean glucose	Simple average of glucose values	*
4. Glucose management indicator	Calculated value approximating A1C (not always equivalent)	*
5. Glycemic variability (%CV) target	Spread of glucose values	≤36%†
6. TAR: % of readings and time >250 mg/dL (>13.9 mmol/L)	Level 2 hyperglycemia	<5% (most adults); <10% (older adults)
7. TAR: % of readings and time 181–250 mg/dL (10.1–13.9 mmol/L)	Level 1 hyperglycemia	<25% (most adults);<50% (older adults)‡
8. TIR: % of readings and time 70–180 mg/dL (3.9–10.0 mmol/L)	In range	>70% (most adults);>50% (older adults)
9. TBR: % of readings and time 54–69 mg/dL (3.0–3.8 mmol/L)	Level 1 hypoglycemia	<4% (most adults);<1% (older adults)§
10. TBR: % of readings and time <54 mg/dL (<3.0 mmol/L)	Level 2 hypoglycemia	

The Ambulatory Glucose (AGP) Report Summarizes CGM Data

A single-page, standardized report for interpreting a patient's daily glucose and insulin patterns

Allows "big picture" view of diabetes management

Easily shared with patients and parents/caregivers

Facilitates communication with the diabetes care team

- AGP, ambulatory glucose profile.

- Johnson ML, et al. Diabetes Technol Ther. 2019;21(suppl):S2-17–S2-25.

3 Sections of the AGP Report

1 **Metrics, Values, Goals**

Summary of values to help assess the overall quality of glucose management
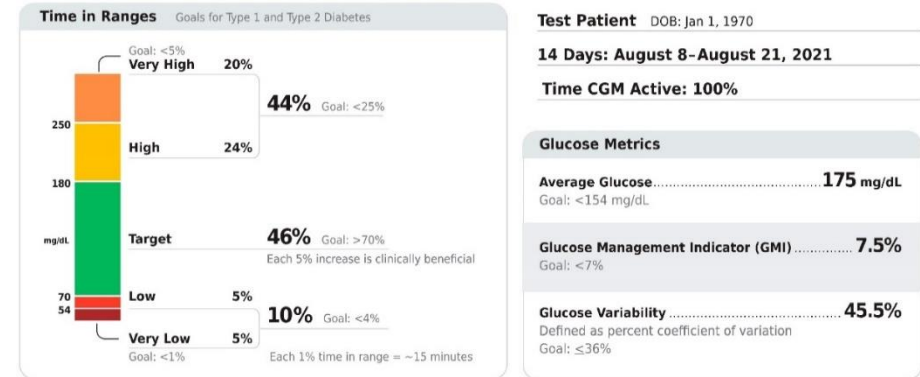
2 **AGP Profile**

Shows all values as if collected over a single 24-h period. Shows variability in the mean glucose and patterned areas of highs and lows
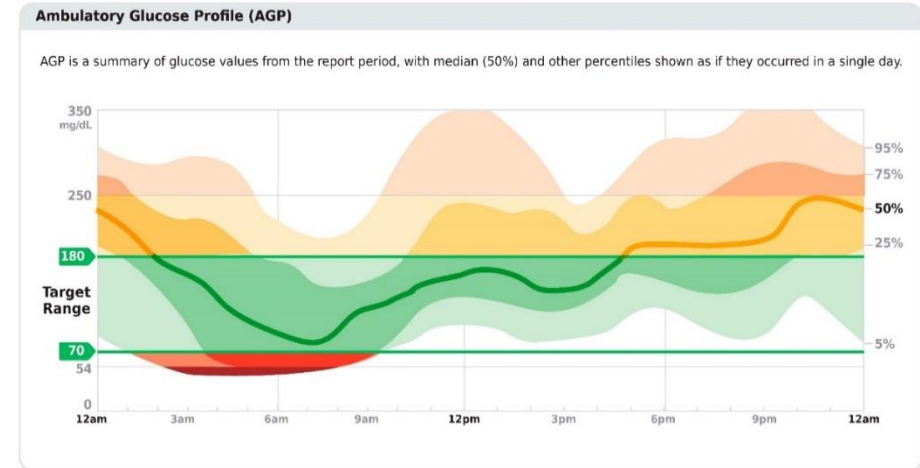
3 **Daily Views**

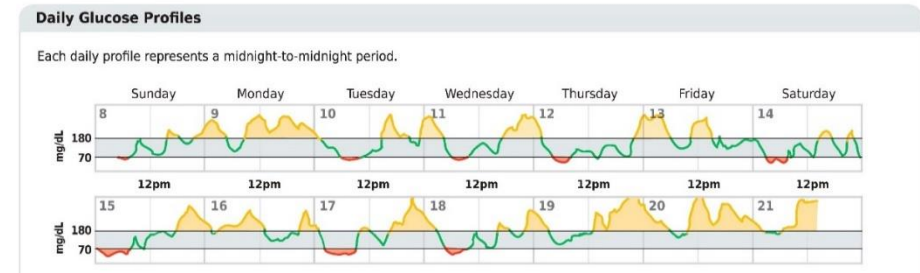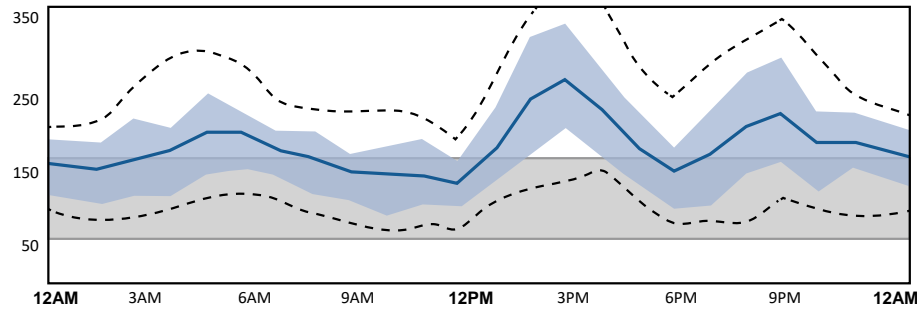Shows daily values -- helpful in determining causes of patterns or exceptions to usual patterns

- ElSayed NA, et al. Diabetes Care. 2023;46(suppl):S97-S110.

What to Strive for in Ambulatory Glucose Profile (AGP)?

Avg. glucose mg/dl	Serious low <54 mg/dl	In target range	Serious high >250 mg/dl	Coefficient of variation	SD mg/dl
184.6	**0.3%**	**51%**	**19.1%**	**43%**	**79**

Not flat, not narrow, not in range

Avg. glucose mg/dl	Serious low <54 mg/dl	In target range	Serious high >250 mg/dl	Coefficient of variation	SD mg/dl
168.5	**1.4%**	**56.7%**	**14.1%**	**43%**	**70**
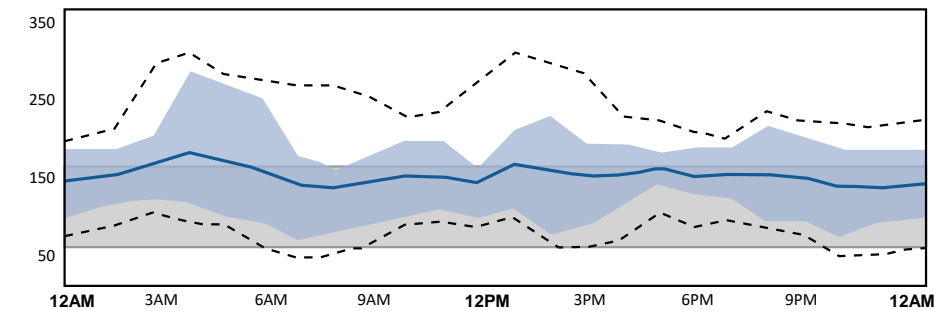
Flat, **not narrow, not in range**

Avg. glucose mg/dl	Serious low <54 mg/dl	In target range	Serious high >250 mg/dl	Coefficient of variation	SD mg/dl
140.7	**0%**	**51.8%**	**6.6%**	**28%**	**49**

Flat, narrow, not in range

Avg. glucose mg/dl	Serious low <54 mg/dl	In target range	Serious high >250 mg/dl	Coefficient of variation	SD mg/dl
140.7	**0%**	**87.7%**	**1.8%**	**29%**	**39**

Flat, Narrow and In

- Courtesy of Richard Bergenstal, MD.
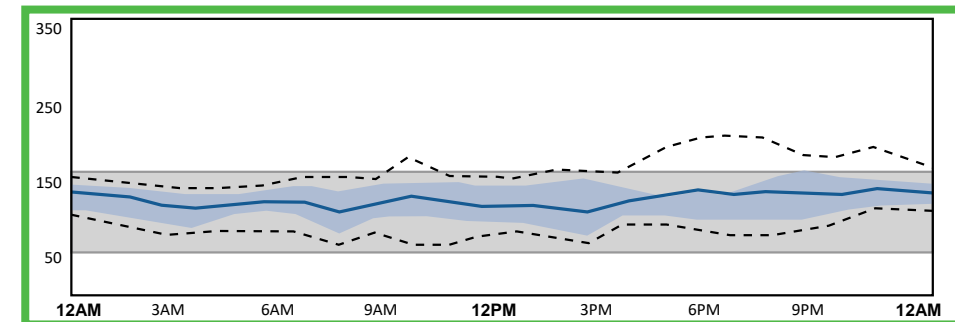
9 Steps in Interpreting an AGP Report

1   **Make sure there are adequate data for decision-making**

2   **"Mark up" the AGP report:**

3   **Ask the patient to briefly describe and explain what he or she sees and why**

4   **Look for patterns of low glucose readings**

5   **Look for patterns of high glucose values**

- Type and duration of diabetes, age, weight (kg), and, if on insulin, daily dose (units/kg)

- Usual times for waking (W), breakfast (B), lunch (L), dinner (D), and bedtime (BT)

- Medication time and doses directly under the curve at the time usually taken (this is a good time to emphasize how critical it is to take bolus insulin before meals)

- If there is a consistent time of exercise or snacking (which should also be marked below the curve)

•   Kruger DF, et al. Diabetes Educ. 2019;45(1_suppl):3S-20S; Johnson ML, et al. Diabetes Technol Ther. 2019;21:S2-17–S2-25.

9 Steps in Interpreting an AGP Report

6 **Discuss areas where dark blue (50% of values) or light blue (80% of values) shaded areas are very wide (corresponding to high GV)**

7 **Compare current AGP and CGM metrics to those from last visit if available and discuss progress**

8 **Agree on an action plan consisting of 1 or 2 recommendations (SMART goals):**
- Always treat hypoglycemia first

9 **Print a copy of the marked-up AGP for the patient and enter it into the EMR system**

- Can the patient do anything to reduce GV by adjusting the timing or amount of food intake, carbohydrate counting, timing of medications, exercise times or amounts, and/or stress?
- Match food and exercise log or electronic data, if available, with AGP

EMR, electronic medical record; GV, glucose variability; SMART, specific, measurable, achievable, relevant, time-bound.

- Kruger DF, et al. Diabetes Educ. 2019;45(1_suppl):3S-20S; Johnson ML, et al. Diabetes Technol Ther. 2019;21:S2-17–S2-25.

CMS Expanded CGM Coverage in 2023

Effective April 16, 2023

CMS CENTERS FOR MEDICARE & MEDICAID SERVICES

2023 Changes

Meet *at least* <u>1</u> of the following criteria:

- Treated with **insulin**; <u>or</u>
- Documented **history of problematic hypoglycemia**
- Recurrent level 2 hypoglycemic events (glucose < 54 mg/dL) despite 2 or more attempts to adjust medication or modify treatment plan; ***<u>or</u>***
- A history of **one level 3 hypoglycemic event** (glucose < 54 mg/dL) requiring third-party assistance

- **As long as the beneficiary uses <u>any insulin</u>, the beneficiary is eligible for CGM coverage**

- CMS, Centers for Medicare & Medicaid Services.
- Centers for Medicare & Medicaid Services. Accessed May 3, 2023. https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=33822

Basics of Billing for CGM

Who owns the equipment?

- Patient or provider: unique codes for each

- Service occurs over > 1 day

- Minimum of 72 hours of wear

- Download of receiver occurs in office, cloud-based printout, or electronic transfer

- Service can be charged at the day of download or time of analysis

Interpretation of data

- Minimum of 72 hours of wear time

- Face to face is not required, CPT standalone or with E&M Code

- Limitations of who can bill: physician, NP, PA (those who can prescribe)

- CPT, current procedural terminology; E&M, evaluation & management; NP, nurse practitioner.

Reimbursement Codes and Descriptions for Clinicians

95249

Personal CGM - Startup/Training: Ambulatory continuous glucose monitoring of interstitial tissue fluid via a subcutaneous sensor for a minimum of 72 h; patient-provided equipment, sensor placement, hook-up, calibration of monitor, patient training and printout of recording. (Do not report more than once while patient owns device)

95250

Professional CGM - Ambulatory continuous glucose monitoring of interstitial fluid via a subcutaneous sensor for a minimum of 72 h; clinician-provided equipment, sensor placement, hook-up, calibration of monitor, patient training removal of sensor, and printout of recording. (Do not report more than once per mo)

95251

Ambulatory CGM of interstitial tissue fluid via a subcutaneous sensor for a minimum of 72 h; interpretation and report. (Do not report more than once per mo)

Evaluation and Management Codes 99212-99215

Established patient visit or G0463. (Medicare outpatient clinic visits)

Eversense Only Codes

0446T (creation of subcutaneous pocket with insertion of implantable sensor, including system activation and patient education), 0447T (removal of implantable sensor from subcutaneous pocket via incision), 0448T(removal of sensor with creation of new pocket for new sensor at a different location, including system activation)

- Miller EM. Clin Diabetes. 2020;38:429-438.

Educating your patients about technology

- Educate patient
    - Blood glucose values are changing constantly
    - A fingerstick is only a snapshot of a 24-hour period
    - CGM provides continuous information to help us with decisions (often show them an example of the AGP and discuss Time in Range)

- Explain to them that CGMs are beneficial if they are having a difficult time reaching or maintaining their glycemic target or A1C. It helps them to understand how certain foods or activities effect their personal glucose journey

- Show them the CGM options that are available on the market and how they differ. Give them choice and empower them to make the right decision for them personally

- Discuss hypoglycemia anxiety and its effects on them and their family members personally. Discuss how it can prevent us from improving our A1Cs and glycemic control

- Explain how the CGM download or ambulatory glucose profile helps us recognize hyperglycemia and hypoglycemia patterns. This will allow the patient and myself to discuss medication and lifestyle choices to develop a treatment plan in a shared-decision approach . "Opens up the conversation"

How to Initiate CGM?

- Shared decision-making to identify the most appropriate device

- Download the mobile app for the smart device or arrange for a compatible reader

- Educate staff (RN or MA) on how to apply glucose sensor and transmitter if applicable

- Trainer to educate staff on application and warm-up time of sensor

- Set low and high alarms based on individualized target glycemic range

- Consider linking to the device's cloud-based system (depending on local data-sharing guidelines) so that data can be shared from the person's own account to the HCP's clinic account to allow for remote review/consultations

- Ensure the person understands when the data will be reviewed

- Arrange for timely review/follow-up

- MA, medical assistant.

- Milne N. Diabetes & Primary Care. 2022; 24:139-141.

Insulin Delivery Devices

Insulin Delivery Options Available

Syringes	Insulin pens	Inhaled insulin	Disposable patch pump
Smart pens	Insulin pumps	Sensor-augmented pumps	Automated Insulin Delivery (AID) systems

40

Individual Insulin Delivery Considerations
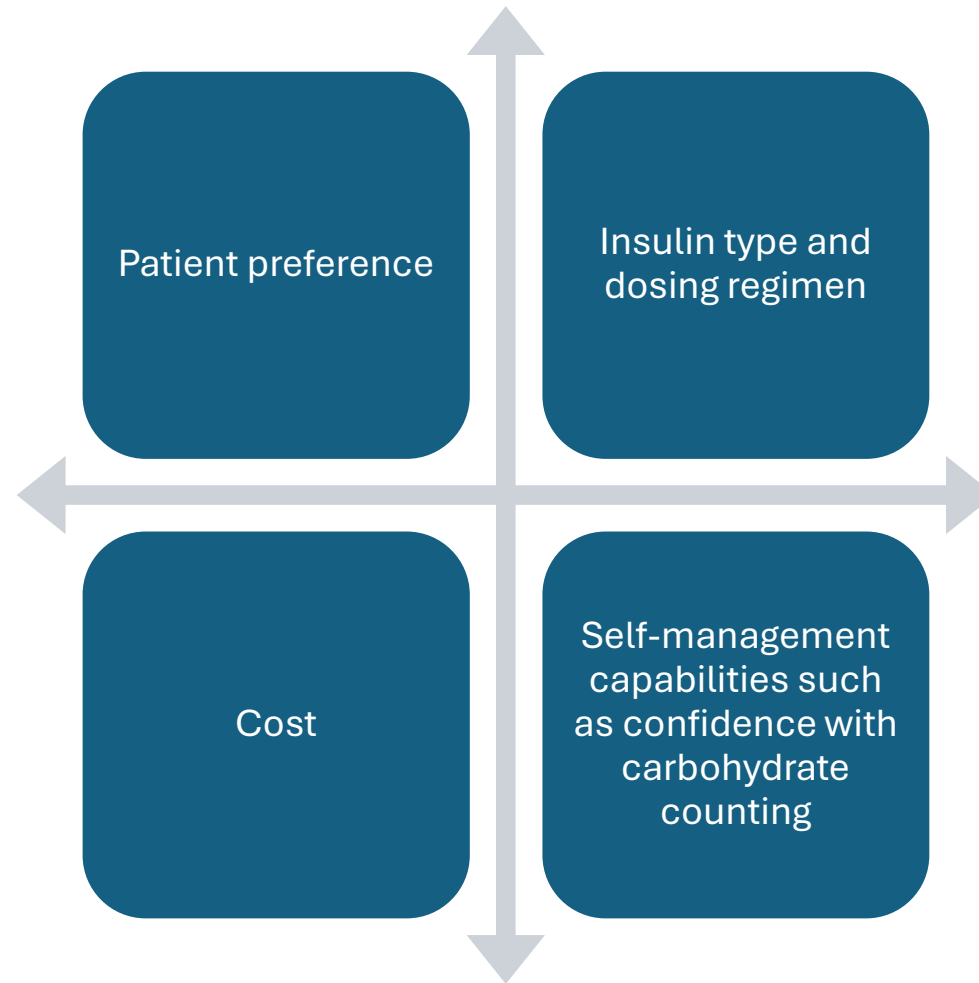
ElSayed NA et al 7. Diabetes Technology: *Standards of Care in Diabetes—2023. Diabetes Care* 1 January 2023; 46 (Supplement_1): S111–S127.

Traditional Insulin Delivery Options

Syringes

Traditional Insulin Pens

Challenges with Traditional Insulin Injections

- Missed or delayed insulin doses

- Remembering to take the dose

- Intentional skipping of doses

- Difficulty calculating the meal time dose

- Insulin stacking (unable to calculate insulin on board)

- Lack of record keeping

- Less capable to manage and analyze the data

Afrezza Inhaled Insulin

4-units   8-units   12-units

Rapid acting inhaled human insulin indicated to improve glycemic control in adult patients with diabetes mellitus

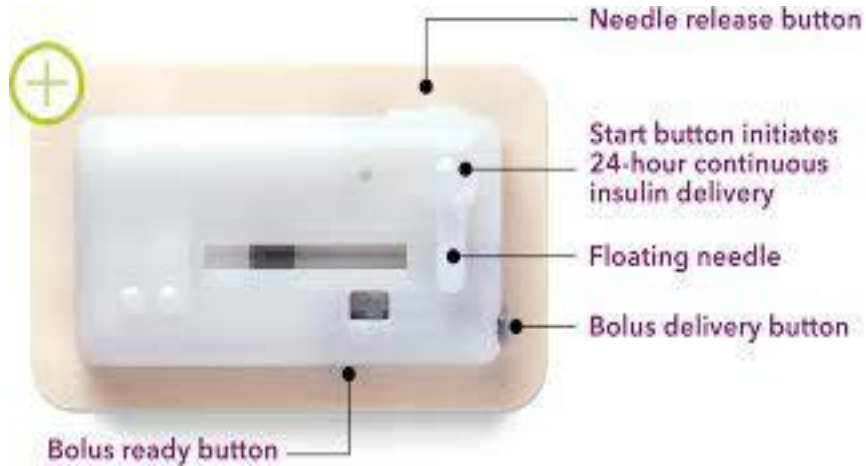Not recommended to be used in patients who smoke or recently stopped smoking

Contraindicated in chronic lung disease such as asthma or COPD

Perform FEV1 spirometry before initiating, 6 months after therapy, and annually thereafter. Discontinue if greater than or equal to 20% decline in FEV1

Administer at the beginning of the meal

Doses available 4 units, 8 units, and 12 units

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Disposable Insulin Patch Pumps

Needle release button

Start button initiates 24-hour continuous insulin delivery

Floating needle

Bolus delivery button

Bolus ready button

V-Go

- Indicated for adults requiring insulin
- Basal/bolus delivery using rapid acting analog
- Basal available in 20, 30, or 40 units
- Bolus in 2 unit increments for a maximum bolus of 36 units for the day
- 1 day wear

CeQur Simplicity

- Indicated for adults over age of 21 requiring insulin
- Delivers mealtime, snack, or correction insulin for hypergylcemia
- Uses rapid acting analog
- Bolus in 2 unit increments
- Holds 200 units of insulin
- Up to 3 day wear

Smart Pens

Roadmap to Smart Insulin Pens

Legacy Insulin Delivery	Tracking Insulin Pen (TIP)			Smart Insulin Pen (SIP)	
STAGE 0	**STAGE 1**	**STAGE 2**	**STAGE 3**	**STAGE 4**	**STAGE 5**
Vial / Syringe Traditional Insulin Pen No tracking or decision support	Tracking Insulin Pen Retrospective, accurate dose data	Real-Time Tracking Insulin Pen Real-Time dose data with IOB and reminders with cloud connectivity	Integrated Tracking Insulin Pen Integrated diabetes management reports including insulin doses, carbohydrates, glucose	Smart Insulin Pen, with Dose Calculator Insulin dose calculator with auto prime detection and individualized settings (e.g. ICR, ISF, Target BG, DIA)	Smart Insulin Pen, with Advanced Decision Support Features may include weight based setup, basal titration, clinical variable learning, education modules, coaching

InPen Smart Pen

- Indications: type 1 or type 2 diabetes on meal-time insulin

- Dose calculator by carb counting, meal estimation, or fixed dose to recommend dose

- Customize insulin setting:
  - Duration of insulin action
  - Insulin sensitivity Factor
  - Insulin to carb ratio or meal size
  - Time of day settings

- Compatible with U-100 Lispro and Aspart insulin cartridges

- Up to 30 units of insulin per dose

- ½ unit increments is available

Smart Pens (cont)

- Non-rechargeable battery that lasts 1 year

- 1 year warranty

- Temperature indicator for insulin

- Records glucose reading and amount of insulin delivered

- InPen app for patients

- Integrates with Medtronic Guardian Connect, DexCom G6, and DexCom G7 for iOS only through Apple Health Kit, and several glucometers

- Insights reports can be visible on Carelink Portal

Tempo Smart Pen/Button & Platform

- Indicated for patients 18 years and older who have type 1 or type 2 diabetes

- Assist in self-management of diabetes

- Allows for shared-decision making with healthcare provider

- Track insulin dose

- TempoSmart Button needs replaced every 8 months. One button can be used for both basal and bolus insulin

Tempo Smart Pen/Button & Platform

- Tempo Pen- Available as Humalog, Lyumjev, & Basaglar

- Tempo Smart Button- Attaches to Tempo Pen and uses Bluetooth technology to send insulin dose-related data to the app

- Tempo Blood Glucose Meter and or DexCom CGM- Transfers glucose readings directly to your smartphone when paired with TempoSmart App

- TempoSmart App- Collects insulin dose-related data and glucose data from paired devices

- Tempo Insights- Healthcare provider's web-based program for reports and remote monitoring

Insulin Pump Therapy in Type 2 Diabetes

- **Traditional Insulin Pumps** - continuous subcutaneous insulin infusion (CSII) that delivers basal insulin and bolus insulin (insulin pump)
- **Sensor Augmented Insulin Pumps** - CSII integrated with a CGM for patients to see glucose levels and trends. May have suspend insulin feature if glucose is low or predicted to be low (insulin pump and CGM)
- **Automated Insulin Delivery (AID) Insulin Pumps** - CSII that increases and decreases insulin delivery based on sensor-derived glucose level (insulin pump, CGM, & algorithm that determines insulin delivery)

CARES Framework for Advanced Diabetes Devices

➕	**C – Calculate**	How does the algorithm calculate insulin delivery?
💉	**A- Adjust**	How can insulin delivery be adjusted?
⚙️	**R- Revert**	When will the system default to no automation?
📚	**E- Educate**	What are the critical education points?
📹	**S- Sensor/Share**	What are the key aspects of the systems' sensor and sharing capabilities?

Messer LH, Berget C, Forlenza GP. A Clinical Guide to Advanced Diabetes Devices and Closed-Loop Systems Using the CARES Paradigm. Diabetes Technol Ther. 2019 Aug;21(8):462-469. doi: 10.1089/dia.2019.0105. Epub 2019 May 29. PMID: 31140878; PMCID: PMC6653788. And manufacturer literature and Panther Tool Kit/DanaTech

Hybrid Closed Loop AIDS in the US

Medtronic 780 G

Tandem Control IQ

Omnipod 5

iLet Bionic Pancreas

- Indicated for Type 1 Diabetes 6 years and older

- Use with DexCom G6 CGM

- Compatible with U100 Aspart or Lispro insulin PWD will fill cartridge
- Fiasp prefilled cartridge has been approved

- Dosing Decision Software autonomously commands an increase, decrease, maintenance or suspension of insulin therapy

- Closed loop functionality

- Initiated by body weight no previous insulin intake required

- No carb counting. Enter "usual meal" or "less than or greater than"

- "Microbolusing" versus set basal rates

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Case Study

- 40 year old male, married with family of 3, works as a Pastor for a local church
- Type 2 diabetes x 11 years
- CVA at 31 years of age
- metformin 1000 mg twice daily, glimepiride 4 mg one daily, and sitagliptin 100 mg daily
- Has taken insulin in past and glucose had improved slightly
- History of taking dapagliflozin and dulaglutide but discontinued due to "side effects" and not improving glucose
- Fasting glucose in 200s and post prandial glucose in 500s
- Symptomatic excessive thirst, excessive urination, weight loss, lethargy
- A1C 11.1%

- Management Plan:
    - Start patient on glargine 15 units nightly
    - Order Type 1 antibody testing and c-peptide level
    - Discussed the possible need to intensify insulin therapy
    - Refer to DSMES
    - Return to the office in two weeks

2 Week Follow Up

- GAD Ab- < 5.0, IA-2 Ab- <5.4, C-peptide- 1.5
- FBS- 100 to 300 mg/dl. Has not checked post prandial
- Has tried to make dietary changes including reducing carbohydrates and fruits

- Management plan:
1. Increase Glargine to 20 units at bedtime
2. Discontinue the Sitagliptin
3. Discussed GLP1-RA use for glycemic and ASCVD benefit due to CVA history. Discussed gastrointestinal side effects and strategies to help with these side effects
4. Trial Semaglutide 0.25 mg weekly x 4 weeks then increase 0.5 mg weekly
5. Start CGM therapy. Patient was hesitant but after discussing benefits he agreed

Initial CGM Report

October 12, 2022 – **October 25, 2022**

FreeStyle Libre 2
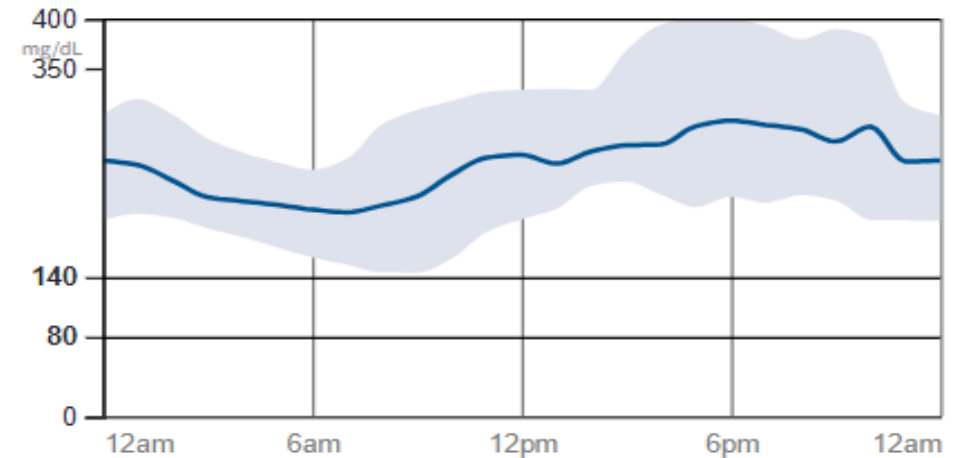SN: 7973f59d-5bf4-4c62-a38c-161e3d148760

251
mg/dL
Average Glucose

100%
Days of Data

0
Hypo Events

Patient did not begin semaglutide due to cost concerns. Patient reports concern with insulin cost as well. Patient is discouraged with results and feels a level of "hopelessness" with his diabetes

Management plan:
1. Educated patient on the range of basal insulin on his body weight is 20 to 50 units daily
2. Target fasting glucose is 130 mg/dl or less. Titrate 2 units every 3 days until fasting glucose is 130 mg/dl
3. Manufacturer coupons given for both insulin and semaglutide to reduce cost
4. Will start Semaglutide sample 0.25 mg weekly x 4 weeks an increase to 0.5 mg weekly

Follow up visit

March 1, 2023 – **March 14, 2023**

FreeStyle Libre 2
SN: 7973f59d-5bf4-4c62-a38c-161e3d148760
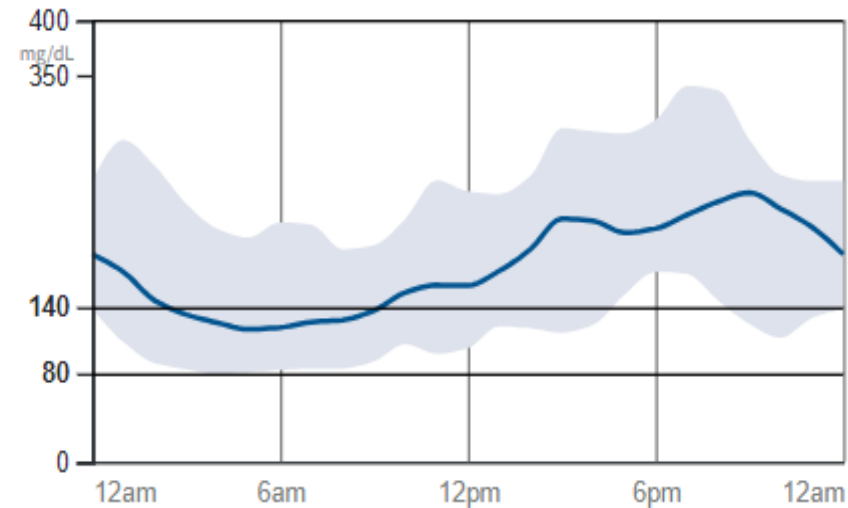
171
mg/dL
Average Glucose

100%
Days of Data

0
Hypo Events

Feels nutritional classes were helpful. Reports semaglutide 0.5 mg helped to suppressed his appetite at first but is not feeling it as much lately. Currently at 30 units of Glargine. Continues on metformin 1000 mg twice daily and glimepiride 4 mg one daily. A1C 8.2%

Management Plan:
1. Increase Semaglutide to 1 mg weekly
2. Remain on Glargine 30 units daily
3. Continue metformin and glimepiride as prescribed

Follow up visit

August 2, 2023 – **August 15, 2023**

FreeStyle Libre 2
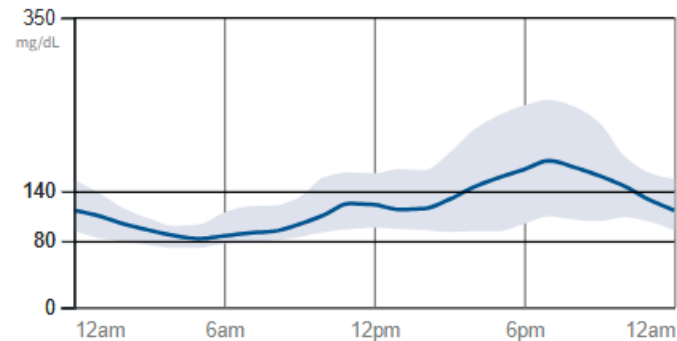SN: 7973f59d-5bf4-4c62-a38c-161e3d148760

124
mg/dL
Average Glucose

100%
Days of Data

0
Hypo Events

Doing well. Feels significantly better. He feels that he is controlling his diabetes and the diabetes is not controlling him. A1C 7.3%
Tracking of Time in Range from beginning reveals below:
Time in Range 6% to 54% to 59%
High 40% to 26% to 23%
Very High 54% to 20% to 18%

Management Plan:
1. Increase Semaglutide 2 mg weekly
2. Remain on Glargine 30 units, metformin and glimepiride

Success!!!

March 14, 2024 – **March 27, 2024**

FreeStyle Libre 2
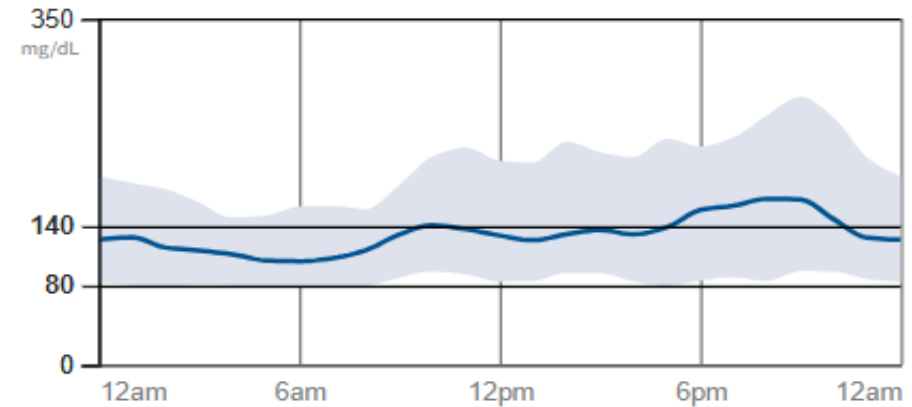SN: 7973f59d-5bf4-4c62-a38c-161e3d148760

135
mg/dL
Average Glucose

100%
Days of Data

0
Hypo Events

Time in Range 6% to 54% to 59% to 86%
High 40% to 26% to 23% to 13%
Very High 54% to 20% to 18% to 1%
Low 0%
Very Low 0%

A1C 6.9%

Summary

- Technology for monitoring and insulin delivery is now available to improve the control & lives of people living with diabetes

- A Person-centered approach & shared decision making should be used when choosing diabetes management tools

- Guidelines & improved coverage promote increased use of CGM and insulin delivery devices to those living with diabetes