WHAT'S NEW & AROUND THE CORNER IN CGM

EDEN MILLER, DO

DIABETES & OBESITY CARE, LLC

BEND, OREGON

DISCLOSURES

- Eden Miller, DO, faculty for this educational event, is on the advisory board and speaker's bureau for Abbott, Bayer, BI/Lilly, Corcept, Novo Nordisk, Embecta, and Insulet. Dr. Miller has also received research funding from Abbott.
- The remaining Faculty, CME Planning Committee, Reviewer and Moderator have no relevant financial relationships with ineligible companies to disclose.
- The OSMA CME Manager has mitigated all information with ineligible companies listed for these individuals and has resolved all conflicts of interest if applicable.

LEARNING OBJECTIVES

Describe	Describe new and emerging technologies in CGM use, including OTC CGM devices and continuous glucose-ketone monitoring.
Interpret	Interpret CGM data such as the AGP accurately to inform changes in diabetes therapy and optimize glucose control.
Initiate	Initiate CGM in patients with diabetes who would benefit from enhanced glucose monitoring and better blood glucose control, including those with insulin delivery devices.
Engage	Engage members of the health care team in collaborating on diabetes management and to help patients receive CGM.

EXISTING MODELS OF CARE ARE NOT ENOUGH

Diabetes is continuous

The majority of diabetes care transpires between visits, outside of clinical encounters.[1]

A1C, glycated hemoglobin or HbA1C; BGM, blood glucose monitoring.

1. Corathers S et al. *Diabetes Spect.* 2020;33(1):22-30. 2. AACE Consensus Guidelines. *Endocr Prac.* 2020;26(1):107-139.
3. Adolfsson P et al. *Eur Endocrinol.* 2018;14(1):24-29.

EXISTING MODELS OF CARE ARE NOT ENOUGH

Diabetes is continuous

The majority of diabetes care transpires between visits, outside of clinical encounters.[1]

A1C alone may not be enough

Using A1C alone may not be very helpful to patients for understanding their diabetes.[2]

A1C, glycated hemoglobin or HbA1C; BGM, blood glucose monitoring.
1. Corathers S et al. *Diabetes Spect.* 2020;33(1):22-30. 2. AACE Consensus Guidelines. *Endocr Prac.* 2020;26(1):107-139.
3. Adolfsson P et al. *Eur Endocrinol.* 2018;14(1):24-29.

EXISTING MODELS OF CARE ARE NOT ENOUGH

Diabetes is continuous

The majority of diabetes care transpires between visits, outside of clinical encounters.[1]

A1C alone may not be enough

Using A1C alone may not be very helpful to patients for understanding their diabetes.[2]

BGM has notable limitations[3]

It only measures blood glucose at a single point in time.

A1C, glycated hemoglobin or HbA1C; BGM, blood glucose monitoring.

1. Corathers S et al. *Diabetes Spect.* 2020;33(1):22-30. 2. AACE Consensus Guidelines. *Endocr Prac.* 2020;26(1):107-139.
3. Adolfsson P et al. *Eur Endocrinol.* 2018;14(1):24-29.

Suboptimal A1C

Only **50%** achieve an A1C <7%[1]

THREE MONTHS TURNS INTO ALMOST THREE YEARS!

Therapeutic Inertia

The failure to initiate or intensify therapy when therapeutic goals are not reached

Suboptimal glucose management for ~2.9 years

due to therapeutic inertia[1-3]

Economic burden

Substantial **clinical** and **economic burden**[4]

A1C, glycated hemoglobin or HbA1C.

1. Fang M et al. *N Engl J Med.* 2021;384:2219-2228. 2. Khunti K et al. *Diabetes Care.* 2013;36(11):3411-3417. 3. Ziemer DC et al. *Diabetes Educ.* 2005;31(4):564-571.
4. Ali SN et al. *Adv Ther.* 2020;37:869-882.

American Diabetes Association. Overcoming Therapeutic Inertia

7

CGM EARLY CAN SUPPORT GLYCEMIC OUTCOMES

Reaching & sustaining A1C targets in the first year of treatment, showed long-term health improvements, even when control waned over time.[1]

A1C, glycated hemoglobin or HbA1C; T2D, type 2 diabetes.
1. Laiteerapon N et al. *Diabetes Care*. 2019;42:416-426.

CGM EARLY CAN SUPPORT GLYCEMIC OUTCOMES

Reaching & sustaining **A1C targets in the first year of treatment**, showed long-term health improvements, even when control waned over time.[1]

Managing glucose levels early in diagnoses **reduces chance of complications.**[1]

A1C, glycated hemoglobin or HbA1C; T2D, type 2 diabetes.
1. Laiteerapon N et al. *Diabetes Care*. 2019;42:416-426.

CGM EARLY CAN SUPPORT GLYCEMIC OUTCOMES

Reaching & sustaining **A1C targets in the first year of treatment**, showed long-term health improvements, even when control waned over time.[1]

Managing glucose levels early in diagnoses **reduces chance of complications.**[1]

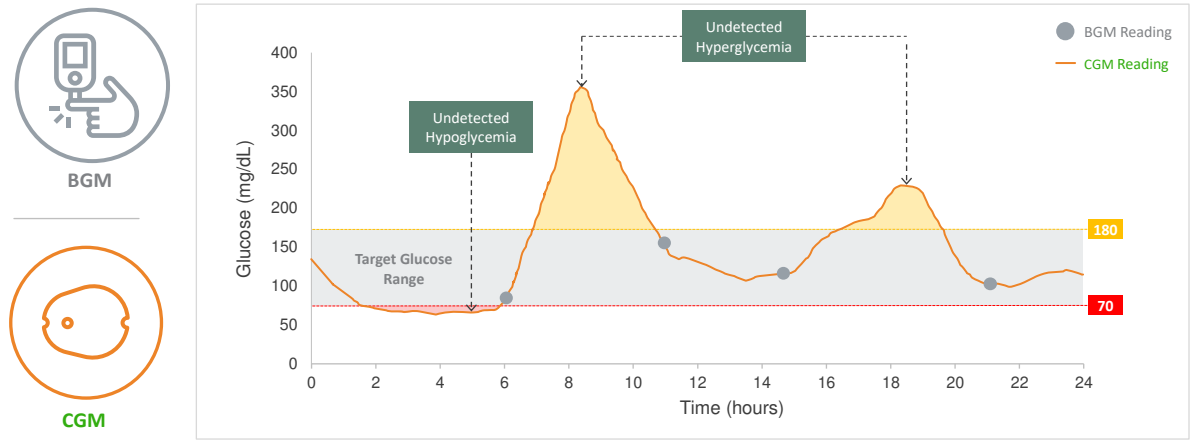
People with T2D that achieve targets soon after diagnosis are more likely to **keep glucose in target range.**[1]

A1C, glycated hemoglobin or HbA1C; T2D, type 2 diabetes.
1. Laiteerapon N et al. *Diabetes Care*. 2019;42:416-426.

LIMITATIONS OF BLOOD GLUCOSE MONITORING

SELF MONITORING OF BLOOD GLUCOSE

GLYCEMIC PATTERNS ARE OFTEN MISSED BY BLOOD GLUCOSE MONITORS (BGM) BUT SEEN WITH CONTINUOUS GLUCOSE MONITORING (CGM)



BGM, blood glucose monitoring; CGM, continuous glucose monitoring.

13

IS A1C STILL THE GOLD STANDARD OF CARE ?

A1C

8.8%

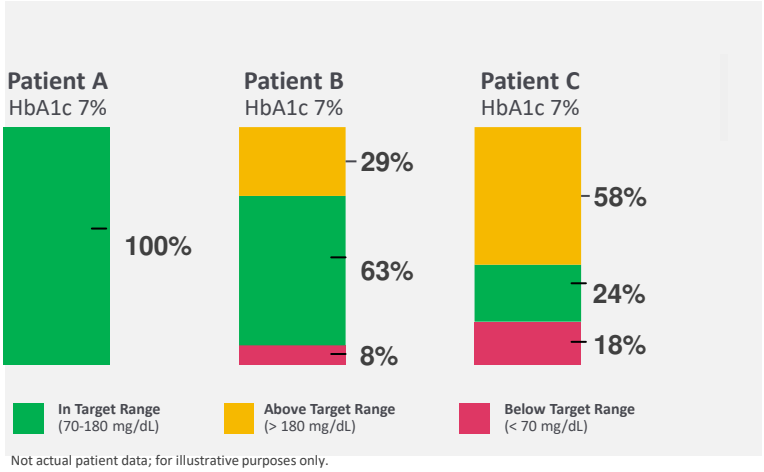
AN INDIVIDUAL'S GLYCEMIC CONTROL AND TREATMENT PLAN SHOULD NOT BE DEFINED BY HBA1C ALONE

- May underestimate or overestimate glucose control (eg, HbA1c of 7% could represent good, fair, or poor control)
- Does not indicate extent or timing of hypoglycemia or hyperglycemia
- Does not reveal glycemic variability
- Limited utility for insulin dosing decisions
- Unreliable in patients with hemolytic anemia, hemoglobinopathies, iron deficiency, or who are pregnant
- Correlation with mean glucose can vary across races

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

- Beck RW, et al. *Diabetes Care*. 2017;40:994-999; Nathan DM, et al. *Diabetes Care*. 2008;31:1473-1478.

EQUAL A1C VALUES DO NOT EQUATE TO EQUAL TIME IN RANGE (TIR)



Not actual patient data; for illustrative purposes only.

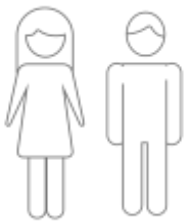
A1C provides only an average of a patient's glucose history.

TIR provides more actionable information than A1C alone and should complement A1C.

Each 5% increase in TIR is clinically beneficial.

Battelino T, Danne T, Bergenstal RM, et al. Clinical targets for continuous glucose monitoring data interpretation: recommendations from the International Consensus on Time in Range. Diabetes Care. 2019;42:1593-1603

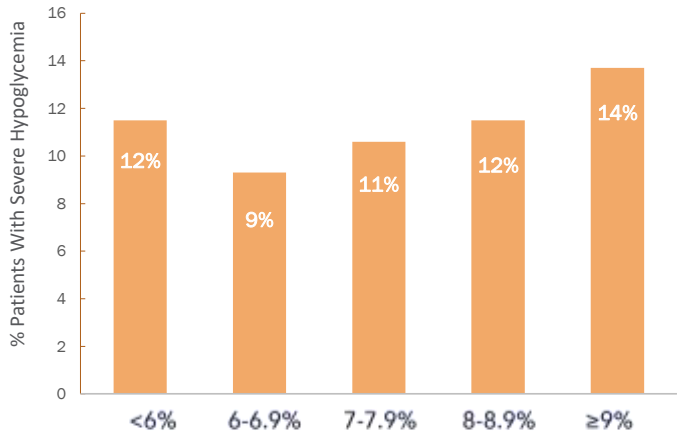
A1C DOES NOT REVEAL GLYCEMIC VARIABILITY OR EXTENT OR TIMING OF HYPOGLYCEMIA[1]



11% of individuals with T2D reported ≥1 severe hypoglycemic event.[2]

9094 persons with Type 2 diabetes (ages 30-77 years) in Kaiser Diabetes Registry on glycemic lowering medication surveyed.

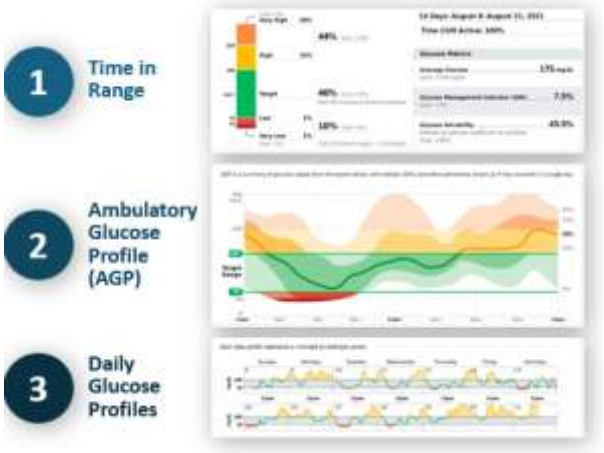
Prevalence of severe hypoglycemia by A1C[3]



1. Nathan DM et al. *Diabetes Care*. 2008;31(8):1473-1478. 2. Lipska KJ et al. *Diabetes Care*. 2013:36(11):3535-3542 3. Hirsch, I.F. et al. *Diabetic Medicine*. 2019;36(12;1637-1642

SEVERE HYPOGLYCEMIA DEFINED AS LOSS OF CONSCIOUSNESS OR REQUIREMENT OF ASSISTANCE FOR TREATMENT

WHAT ABOUT CONTINUOUS GLUCOSE MONITORING ?



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

ADA STANDARDS OF CARE

Diabetes devices should be offered to people with diabetes **(A)***

* Grade A: Clear evidence from well-conducted, generalizable randomized controlled trials that are adequately powered; † Grade B: Supportive evidence from well-conducted cohort studies; ‡ Grade C: Supportive evidence from poorly controlled or uncontrolled studies.
ADA, American Diabetes Association; AID, automated insulin delivery; CGM, continuous glucose monitoring; CSII, continuous subcutaneous insulin infusion; IS-CGM, intermittently scanned continuous glucose monitoring, MDI, multiple daily injection; T1D, type 1 diabetes.

- 1. American Diabetes Association. *Diabetes Care*. 2024;47(Suppl. 1):S1-S4. 2. American Diabetes Association. *Diabetes Care*. 2024;47(Suppl. 1):S126-S144. 3. American Diabetes Association. *Diabetes Care*. 2024;47(Suppl. 1):S111-S125.

ADA STANDARDS OF CARE

- Diabetes devices should be offered to people with diabetes **(A)***
- **Real-time CGM (A)*** or **IS-CGM (B)†** should be offered for diabetes management in adults with diabetes on basal insulin, MDI or CSII

  Use of CGM is beneficial and recommended for individuals at high risk for hypoglycemia. **(A)***

* Grade A: Clear evidence from well-conducted, generalizable randomized controlled trials that are adequately powered; † Grade B: Supportive evidence from well-conducted cohort studies; § Grade C: Supportive evidence from poorly controlled or uncontrolled studies.
ADA, American Diabetes Association; AID, automated insulin delivery; CGM, continuous glucose monitoring; CSII, continuous subcutaneous insulin infusion; IS-CGM, intermittently scanned continuous glucose monitoring, MDI, multiple daily injection; T1D, type 1 diabetes.

- 1. American Diabetes Association. *Diabetes Care*. 2024;47(Suppl. 1):S1-S4. 2. American Diabetes Association. *Diabetes Care*. 2024;47(Suppl. 1):S126-S144. 3. American Diabetes Association. *Diabetes Care*. 2024;47(Suppl. 1):S111-S125.

ADA STANDARDS OF CARE

- Diabetes devices should be offered to people with diabetes **(A)***
- **Real-time CGM (A)*** or **IS-CGM (B)†** should be offered for diabetes management in adults with diabetes on basal insulin, MDI or CSII

  Use of CGM is beneficial and recommended for individuals at high risk for hypoglycemia. **(A)***
- Initiation of CGM, CSII, or AID **early, even at diagnosis**, in the treatment of diabetes can be beneficial **(C)§**

  Initiation of CGM should be offered to people with T1D **early** in the disease, even at time of **diagnosis**. **(A)***

* Grade A: Clear evidence from well-conducted, generalizable randomized controlled trials that are adequately powered; † Grade B: Supportive evidence from well-conducted cohort studies; § Grade C: Supportive evidence from poorly controlled or uncontrolled studies.
ADA, American Diabetes Association; AID, automated insulin delivery; CGM, continuous glucose monitoring; CSII, continuous subcutaneous insulin infusion; IS-CGM, intermittently scanned continuous glucose monitoring, MDI, multiple daily injection; T1D, type 1 diabetes.

- 1. American Diabetes Association. *Diabetes Care*. 2024;47(Suppl. 1):S1-S4. 2. American Diabetes Association. *Diabetes Care*. 2024;47(Suppl. 1):S126-S144. 3. American Diabetes Association. *Diabetes Care*. 2024;47(Suppl. 1):S111-S125.

ADA STANDARDS OF CARE: NEW IN 2025

7.16 Consider using rtCGM and isCGM in adults with type 2 diabetes treated with glucose-lowering medications other than insulin to achieve and maintain individualized glycemic goals. The choice of device should be made based on the individual's circumstances, preferences, and needs. **B**

rtCGM = Real Time CGM; isCGM = Intermittently scanned CGM

American Diabetes Association Professional Practice Committee; 7. Diabetes Technology: Standards of Care in Diabetes—2025. *Diabetes Care* 1 January 2025; 48 (Supplement_1): S146–S166. https://doi.org/10.2337/dc25-S007

REMEMBER YOUR KNOWLEDGE QUESTION?

The HBA1c is the gold standard of care and used to guide the Health Care Provider in managing diabetes.

A. **Looking at an HbA1c value advises the clinician when a patient with diabetes is having low blood glucose.**

B. **The HbA1c provides enough data to determine how well a patient's diabetes is controlled.**

C. **The HbA1c provides a 30- to 90-day retrospective average of blood glucose data.**

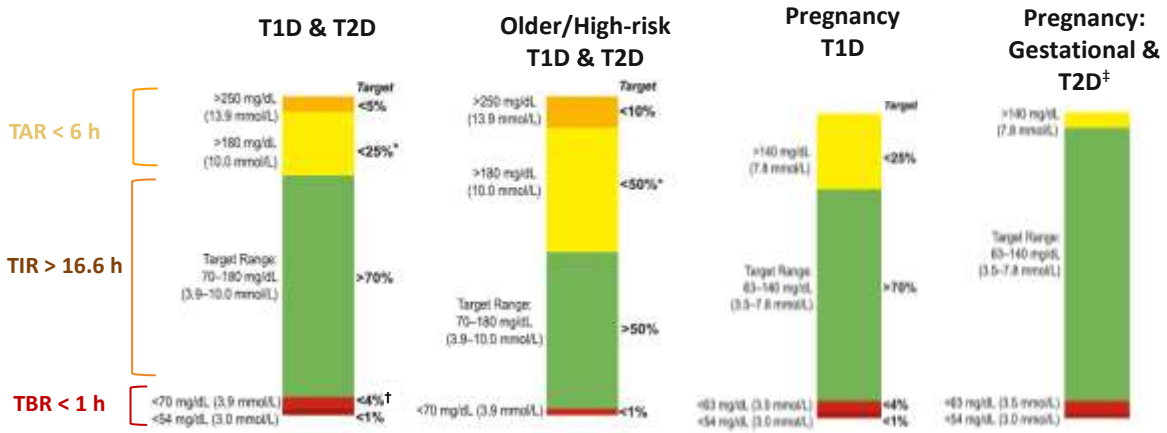
D. **The HbA1c and the glucose management indicator (GMI) are interchangeable.**

INITIATION OF CONTINUOUS GLUCOSE MONITORING IS LINKED TO IMPROVED GLYCEMIC CONTROL AND FEWER CLINICAL EVENTS IN TYPE 1 AND TYPE 2 DIABETES IN THE VETERANS HEALTH ADMINISTRATION

	CGM initiation verses self-monitoring glucose	
	Type 1 diabetes	Type 2 diabetes
12-month change in HbA1c	n = 4,930 vs n = 3,263	n = 15,292 vs n = 28,467
CGM use leads to more reduction in 12-month HbA1c		
B (95% CI):	-0.26 (-0.33, -0.19) ⬇	-0.35 (-0.42, -0.36) ⬇
Clinical events over 12 months	n = 5,015 vs n = 3,815	n = 15,706 vs n = 29,912
I. Hypoglycemia admissions	CGM use leads to reduced hypoglycemia admissions in T1D	
HR (95% CI):	0.69 (0.48, 0.98) ⬇	0.93 (0.74, 1.16)
II. Hyperglycemia admissions	CGM use leads to reduced hyperglycemia admissions in T2D	
HR (95% CI):	0.83 (0.65, 1.06)	0.87 (0.77, 0.99) ⬇
III. All hospitalizations	CGM use leads to reduced hospitalizations	
HR (95% CI):	0.75 (0.63, 0.93) ⬇	0.89 (0.82, 0.87) ⬇

- Reaven PD, et al. Diabetes Care. 2023;46:854-863.

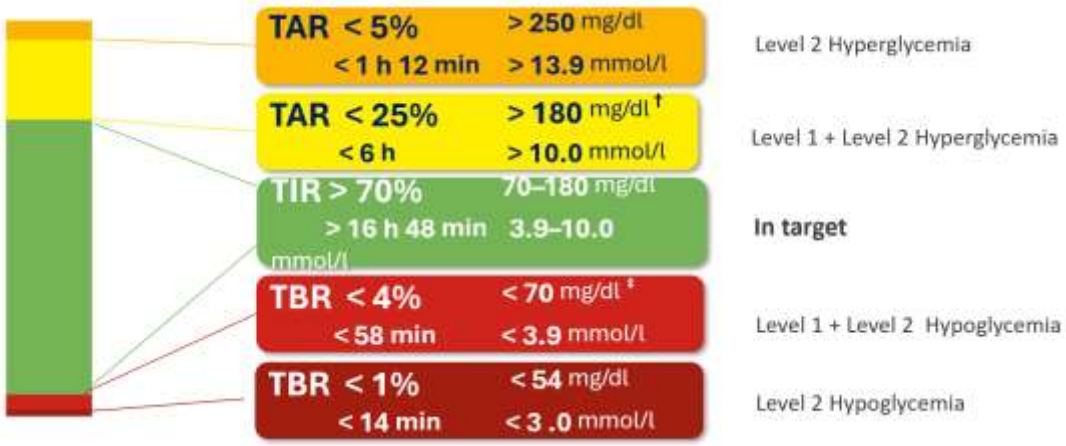
TIME RANGE TARGETS



*Includes percentage of values > 250 mg/dL
†Includes percentage of values < 54 mg/dL
‡Percentages for time in range have not been included because there is limited evidence in this area; more research is needed

Battelino T, et al. *Diabetes Care* 2019;42:1593-1603.

CGM TIR TARGETS FOR MOST INDIVIDUALS WITH T1D AND T2D*

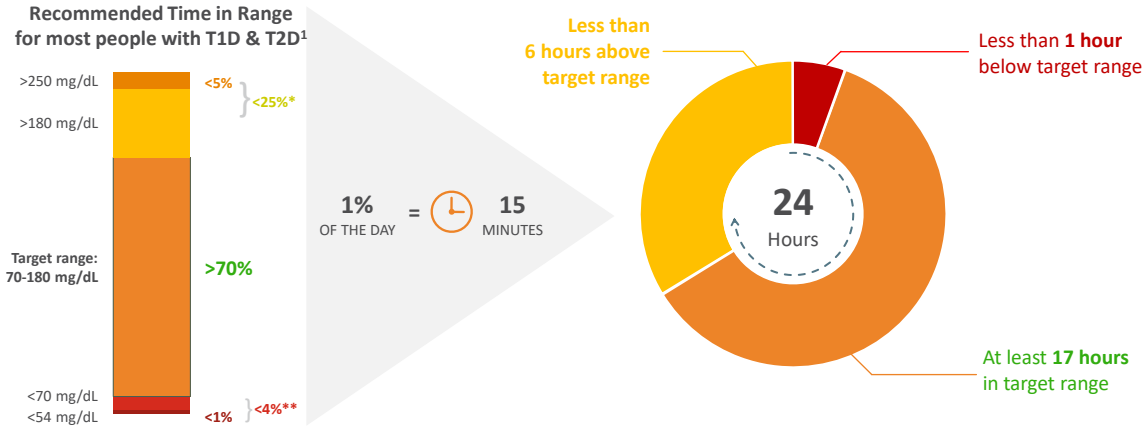


TAR = time above range; TIR = time in range; TBR = time below range.

*High risk individuals have different targets—eg, patients with complications or comorbidities and patients who are pregnant
†Includes percentage of values > 250 mg/dL
‡Includes percentage of values < 54 mg/dL

Battelino T, et al. *Diabetes Care* 2019;42:1593-1603.

TIME IN RANGE (TIR) TARGETS AND HOURS PER DAY[1,2]



*Includes percentage of values >250 mg/dL **Includes percentage of values <54 mg/dL

1. Battelino T et al. *Diabetes Care.* 2019;42(8):1593-1603. 2. American Diabetes Association. *Diabetes Care* 2021;44(Suppl. 1):S73–S84.

THE AGP REPORT

1 Metrics, Values, Goals
Summary of values to help assess the overall quality of glucose management

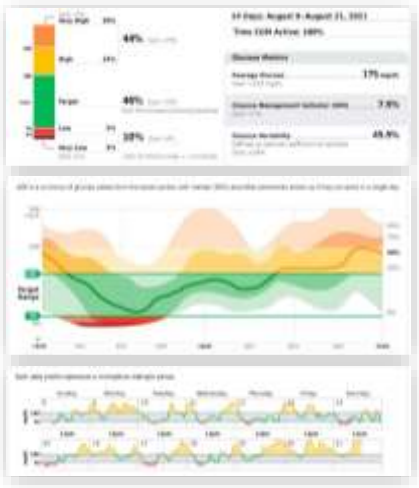
2 AGP Profile
Shows all values as if collected over a single 24-h period. Shows variability in the mean glucose and patterned areas of highs and lows.

3 Daily Views
Shows daily values -- helpful in determining causes of patterns or exceptions to usual patterns.

1 Time in Range

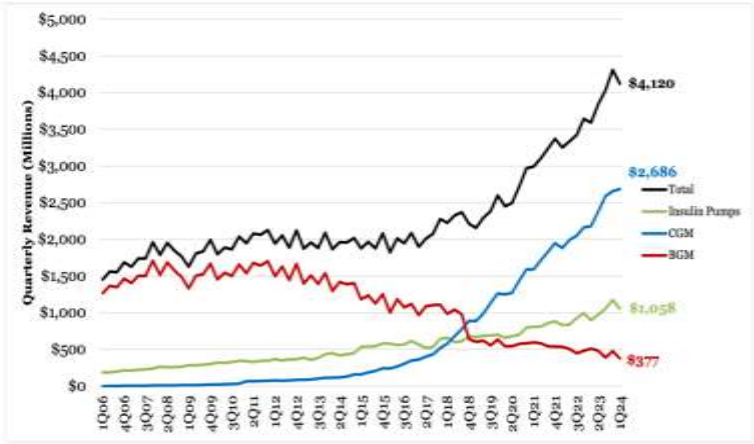
2 Ambulatory Glucose Profile (AGP)

3 Daily Glucose Profiles



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

Overall Diabetes Technology Market (1Q06 – 1Q24)



- Developed by Kelly Close of Close Concerns. Reprinted with Permission July 2024

CGM DEVICES

	FreeStyle Libre 14 day isCGM/ 2 isCGM/3/3plus rtCGM,libre 2 plus/Rio	Dexcom G6 / G7 rtCGM/Stelo	Guardian Sensor 3 & 4 (pump integrated) and Guardian Connect (stand-alone) rtCGM/Simplera	Eversense 90-Day/ E3 rtCGM
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	Replaces fingersticks for treatment decisions; requires ≥ 2 fingerstick calibrations/d
Age	≥ 18 y /2&3 ≥ 4 y /2+&3+ ≥ 2 y 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 Stelo	Guardian 4: ≥ 7 y Guardian 3: ≥ 14 y Connect: ≥ 14 y Simplera _> 7Y	≥ 18 y
Medicare coverage	Yes / Yes / Yes/No	Yes / Yes/No	Sensor 3: Yes / 780 G: Yes / Connect: No	Yes
Wear length	14 d / up to 15 d / up to 15 d/15d	10 d / 10 d + 12 h 15.5 days	7 d/up to 7 d	90 d / 180 d
Warm-up	1 h	2 h / up to 30 min	2 h	24 h after implementation
Alarms	No / Yes / Yes/no	Yes/no	Yes	Yes
Data display/ integration	Reader; Android and iOS Apps 2 / 3: Libre 2 plus for integration with AID systems; 3+ twiist AID	Receiver; Android and iOS Apps; smartwatches Integrated :slim X2 pump, Omnipod 5	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 (lasts 1 year, charge daily) separate from sensor
Accuracy	11.4% / 9.3% / 7.9%	9.0% / 8.2%	9.6% / 9.0% to 11%	8.5% to 9.5%

AID, automated insulin delivery; FDA, US Food and Drug Administration; GDM, gestational diabetes mellitus; T1D, type 1 diabetes; T2D, type 2 diabetes.

MOST RECENTLY FDA-APPROVED CGM DEVICES

	FreeStyle Libre 2 Plus/3 Plus	G7	Guardian™ Connect Simplera™	Eversense® 365
Approved labeling	Replaces fingersticks for treatment decisions; no fingerstick calibration required	Replaces fingersticks for treatment decisions; no fingerstick calibration required;	Replaces fingersticks for treatment decisions; no fingerstick calibration required	Replaces fingersticks for treatment decisions; requires calibration once a week after first 2 weeks
Age	≥ 2 y 2/3 Plus: T1D, T2D, GDM, pregnancy	≥ 2 y G7: T1D, T2D, GDM, pregnancy	Connect: ≥ 14 y T1D, T2D Simplera™: ≥ 7 y	≥ 18 y T1D, T2D
Medicare coverage	Yes / Yes	Yes	780G/Guardian™ 4: Yes Simplera (awaiting Launch/coverage)	Yes
Wear length	14/up to 15 d	10 d + 12 h – 15 d now approved	7 d/up to 7 d	365 d
Warm-up	1 h	Up to 30 min	2 h	24 h after implementation
Alarms	Yes / Yes	Yes	Yes	Yes
Data display/ integration	Reader; Android and iOS Apps Integrated: 2+ + t:slim X2and Omnipod 5 insulin pump; 3+ Beta Bionics insulin pump and twiist AID	Reader; Android and iOS Apps; smartwatches Integrated: G6/7 + t:slim X2 insulin pump and Mobi; G6/G7 + Omnipod 5 and Beta Bionic G6/G7	Android and iOS Apps Guardian™ 4: 780G Simplera: For MDI and connects with Inpen :Use with Smart phone	Android and iOS Apps, smartwatches
Form	Integrated sensor-transmitter	Integrated sensor-transmitter	Transmitter (rechargeable) separate from sensor Integrated sensor-transmitter	Smart transmitter (charge daily) separate from sensor

All data in this table has been taken from the manufacturer's product websites Accessed September 13, 2024.
AID, automated insulin delivery; CGM, continuous glucose monitoring; FDA, US Food and Drug Administration; GDM, gestational diabetes mellitus; T1D, type 1 diabetes;

CGM DEVICE INTEGRATION

AID	Sensor	Partner
Ilet Bionic Pancreas AID	Dexcom G6 and G7 Libre 3 Plus	Dexcom Abbott
Inpen Smart Insulin Pen	Simplera	Medtronic
780G Insulin Pump	Guardian 4	Medtronic
Omnipod 5 Insulin Pump	G6 and G7 Libre 2 Plus	Dexcom Abbott
Tslim x2	Dexcom G6 and G7 Libre 2 Plus	Dexcom Abbott
MOBI AID*	G6 and G7	Dexcom
Twiist AID	Libre 3 Plus	Abbott

Presented in order of integration
Produce information current as of March 2025.
*FDA-cleare4d for use in adults with T2Dnm..

OVER-THE-COUNTER CGM FOR USE IN NON-INSULIN REQUIRING TYPE 2 DIABETES

	Stelo	FS Rio
Wear Period	15.5 Days	15 Days
Warm Up	30 Min	1 Hour
Reading Interval	15 Min *	1 Min
Glucose Range	70-250	40-400
Alarms	No	No
Finger sticks	None	None
Placement	Back of arm	Back of arm
Insurance Coverage	No	No
Reader	No	No

*Looks at data every minute, reports every 5 Min

OVER-THE-COUNTER CGM FOR PEOPLE WITHOUT DIABETES: LINGO

- Designed to track blood glucose levels for those without diabetes
- Provides insights to help users understand how the body reacts to food, exercise, stress
- Worn on the back of the arm for up to 14 days
- Sends data to a smart phone app, which provides personalized coaching and insights, glucose graph, food and activity logs
- Over-the-counter, no prescription needed, not covered by insurance
- Available in two-week, four-week, or three-month plans

NEW PARTNERSHIP

- Abbott is building a new CGM to be integrated exclusively in the Medtronic insulin pump.
- Stay tuned for updates.

WHAT IS PROFESSIONAL CGM?

- New to practice and no CGM
- Does not qualify for Personal CGM
- Wear 10/14 days
- Blinded and unblinded
- Clinic owns the sensor, must have compatible phone for unblinded only

Reimbursement

- 95250—Professional CGM
  - Ambulatory CGM of interstitial tissue fluid via a subcutaneous sensor for a minimum of 72 hours
  - Physician or other qualified health care professional (office) provided equipment, sensor placement, hook-up, calibration of monitor, patient training, removal of sensor, printout of recording
  - *Do not bill more than once per month*
- 95251—CGM Interpretation
  - Ambulatory CGM of interstitial tissue fluid via a subcutaneous sensor for a minimum of 72 hours; analysis, interpretation, report
  - *Do not bill more than once per month*

Libre Professional CGM no longer available after December 31st 2024

WHAT TO LEARN FROM PROFESSIONAL CGM RESULTS

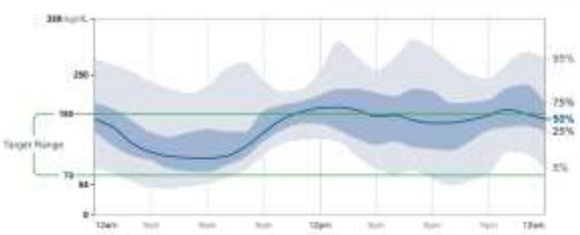
INTERPRETING CGM DATA

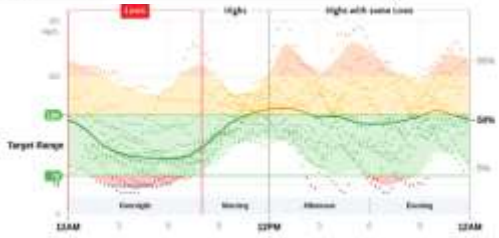
WHAT WOULD YOU DO WITH THIS DATA?

- A1C: 7.5% - was 8%
- Metformin twice daily
- SU twice daily
- Weekly GLP1-RA (2 months ago)
- Feels well, no complaints
- Denies hypoglycemia
- SMBG when feels badly

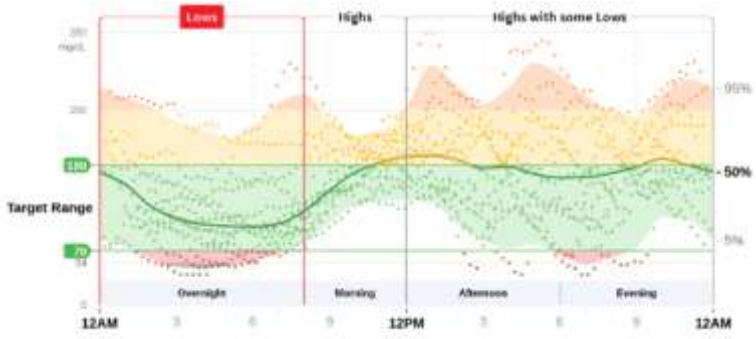
WHAT WOULD YOU DO BASED ON *THIS* INFORMATION?

- A1C: 7.5% - was 8%
- Metformin twice daily
- SU twice daily
- Weekly GLP1-RA (2 months ago)
- Feels well, no complaints
- Denies hypoglycemia
- SMBG when feels badly



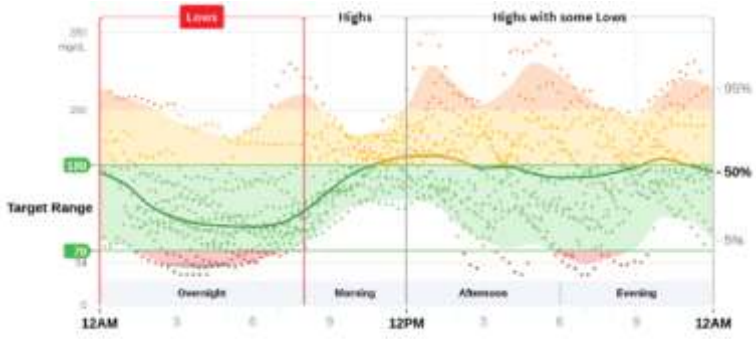


STEPS TO QUICKLY REVIEW AND INTERPRET DATA



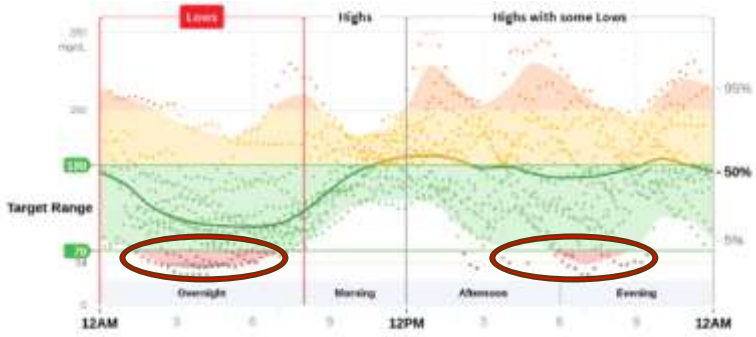
STEPS TO QUICKLY REVIEW AND INTERPRET DATA

1) Riding the Waves
   a) Have patient explain what they see



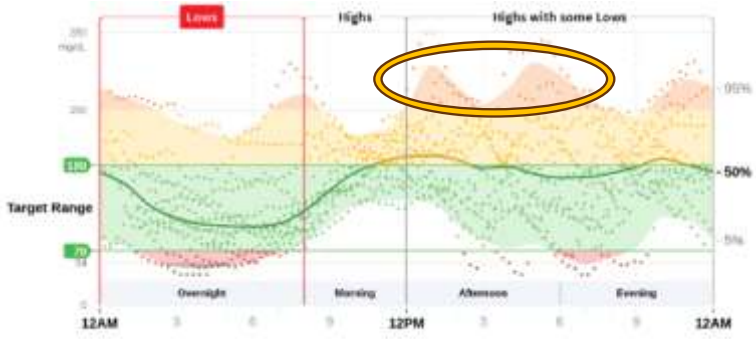
STEPS TO QUICKLY REVIEW AND INTERPRET DATA

1) Riding the Waves
   a) Have patient explain what they see
   b) Identify hypoglycemia



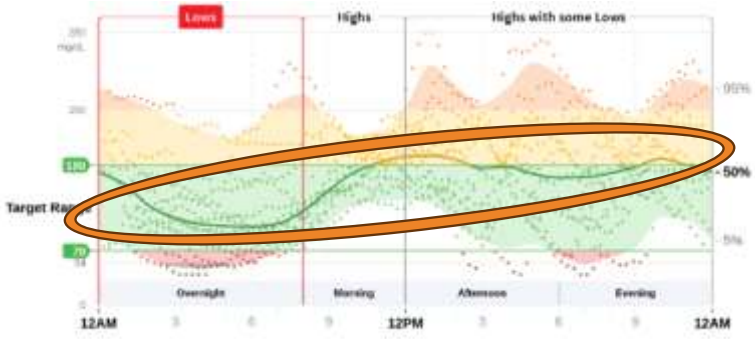
STEPS TO QUICKLY REVIEW AND INTERPRET DATA

1) Riding the Waves
   a) Have patient explain what they see
   b) Identify hypoglycemia
   c) Identify hyperglycemia



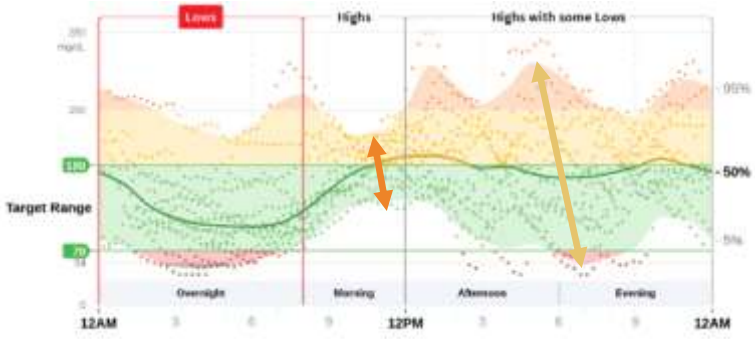
STEPS TO QUICKLY REVIEW AND INTERPRET DATA

1) Riding the Waves
   a) Have patient explain what they see
   b) Identify hypoglycemia
   c) Identify hyperglycemia
   d) Patterns?



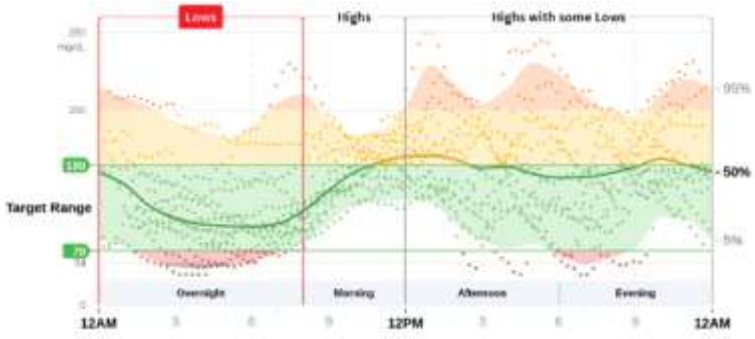
STEPS TO QUICKLY REVIEW AND INTERPRET DATA

1) Riding the Waves
   a) Have patient explain what they see
   b) Identify hypoglycemia
   c) Identify hyperglycemia
   d) Patterns?
2) Peaks and Valleys
   a) Variability



STEPS TO QUICKLY REVIEW AND INTERPRET DATA

1) Riding the Waves
   a) Have patient explain what they see
   b) Identify hypoglycemia
   c) Identify hyperglycemia
   d) Patterns?
2) Peaks and Valleys
   a) Variability
3) Compare with previous



TYPE 2 DIABETES

- 62-year-old male
- Glargine 30 units twice daily
- Aspart 12 units three times daily before meals
- 6ft 252 lbs., BMI 34.2
- A1c 8.0%
- Started on 2.5 MG of Tirzepatide
- Insulin lowered 30%
- Using Personal CGM

4 WEEKS LATER

- Patient requests increase in Tirzepatide

Present Insulin Program

Lantus 20 units BID

Aspart 8 units twice daily

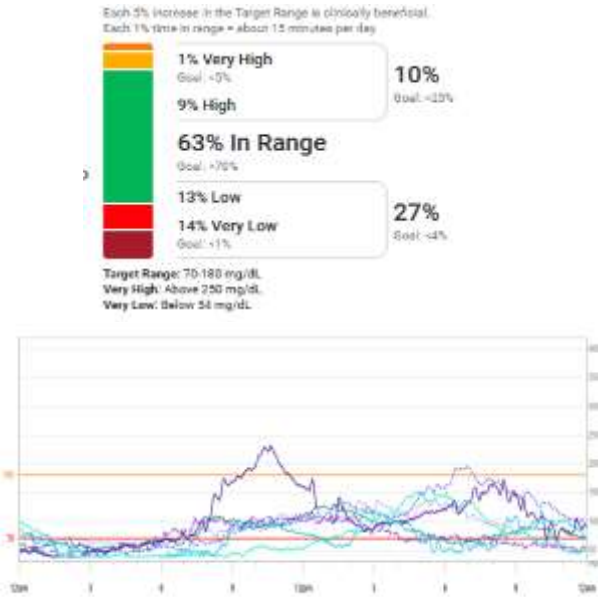
Tirzepatide 2.5 mg

A1c 8.0

CGM DATA IS REVIEWED:

What do you see ?

What are next steps ?



4 MORE WEEKS LATER

Before increasing tirzepatide, work with patient to eliminate low BG

<u>Present Diabetes Program:</u>

Insulin

Lantus 8 units BID

Aspart 4 units twice daily

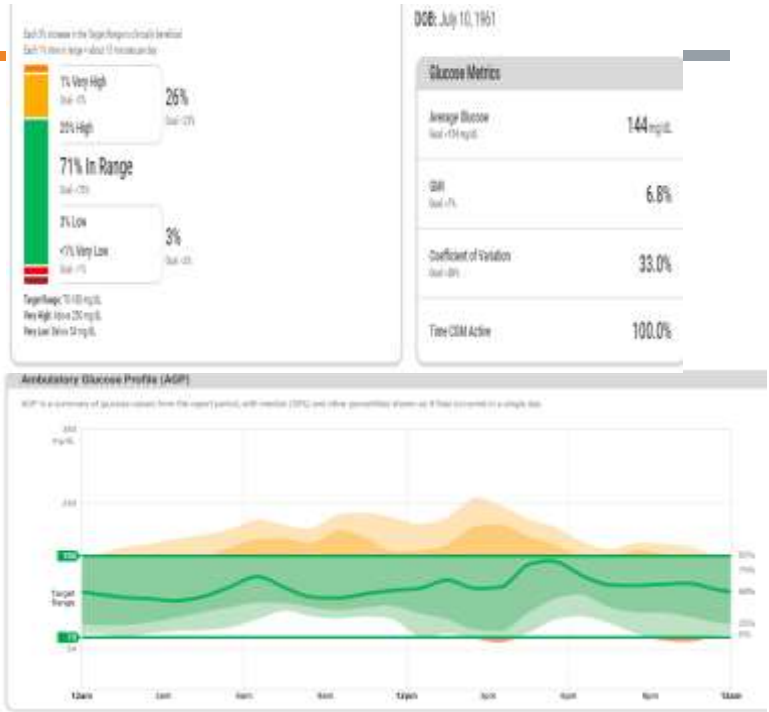
Tirzepatide 2.5 mg

GMI 6.8

Based On CGM Data and GMI:

Insulin stopped:

Tirzepatide increased to 5.0 mg



CMS EXPANDED CGM COVERAGE IN 2024

2023 changes effective April 16, 2023[1]

Meet at least one of the following criteria:

- Treated with **insulin**

OR

- 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

OR

  - A history of one level 3 hypoglycemic event (glucose <54 mg/dL)
    - Requiring third-party assistance for treatment of hypoglycemia

As long as the beneficiary uses any insulin, the beneficiary is eligible for CGM coverage

CGM, continuous glucose monitoring;
CMS, Centers for Medicare & Medicaid Services.

1. Centers for Medicare & Medicaid Services. Accessed March 2, 2023. https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=33822.

CODING FOR REIMBURSEMENT

CGM Devices

- 95249—Personal CGM Start-up and Training
  - Ambulatory CGM of interstitial tissue fluid via a subcutaneous sensor for a minimum of 72 hours
  - Patient provided equipment, sensor placement, hook-up, calibration of monitor, patient training, printout of recording
  - *Bill only once while the patient owns the device*
- 95250—Professional CGM
  - Ambulatory CGM of interstitial tissue fluid via a subcutaneous sensor for a minimum of 72 hours
  - Physician or other qualified health care professional (office) provided equipment, sensor placement, hook-up, calibration of monitor, patient training, removal of sensor, printout of recording
  - *Do not bill more than once per month*
- 95251—CGM Interpretation
  - Ambulatory CGM of interstitial tissue fluid via a subcutaneous sensor for a minimum of 72 hours; analysis, interpretation, report
  - *Do not bill more than once per month*

Evaluation and Management

- 99212–99215
  - For an established patient in a non-facility or health setting; appropriate code to be determined by office
  - Note: Bill E/M codes if office visit services were performed in addition to procedure codes

American Association of Clinical Endocrinologists. CPT Codes 94259, 94250, and 95251. https://www.aace.com/practice-management/cpt-codes-95249-95250-and-95251.
USDHHS. CMS. Physician Fee Schedule Search. https://www.cms.gov/apps/physician-fee-schedule/search/search-criteria.aspx.
Waller TA. *Fam Pract Manag.* 2007 Jan;14(1):21-25.

WHAT IS YOUR BEST TOOL FOR YOUR PRACTICE?

This?

WHAT IS YOUR BEST TOOL FOR YOUR PRACTICE?

This?

Or this?

A1C

8.8%

WHAT IS YOUR BEST TOOL FOR YOUR PRACTICE?

This?

Or this?

A1C

8.8%

How about CGM?

55

WHAT IS DIABETIC KETOACIDOSIS (DKA)?

- Diabetic ketoacidosis is a serious complication of diabetes.
- The condition develops when the body can't produce enough insulin. Insulin plays a key role in helping sugar — a major source of energy for muscles and other tissues — enter cells in the body.
- Without enough insulin, the body begins to break down fat as fuel. This causes a buildup of acids in the bloodstream called ketones. If it's left untreated, the buildup can lead to diabetic ketoacidosis.
- Type 1 Diabetes: DKA occurs in 30-40% at diagnosis and 6-8% of those with established Diabetes annually
- Type 2 Diabetes: Less common but risk increases with age and highest in those aged 60-90.
- Increased risk for those on SGLT2 inhibitors

Diabetic ketoacidosis - Symptoms & causes - Mayo Clinic. Mayo Clinic. https://www.mayoclinic.org/diseases-conditions/diabetic-ketoacidosis/symptoms-causes/syc-20371551. Published October 6, 2022.

SYMPTOMS OF DKA

Diabetic ketoacidosis symptoms often come on quickly, sometimes within 24 hours. For some, these symptoms may be the first sign of having diabetes. Symptoms might include:

- Being very thirsty
- Urinating often
- Feeling a need to throw up and throwing up
- Having stomach pain
- Being weak or tired
- Being short of breath
- Having fruity-scented breath
- Being confused

More-certain signs of diabetic ketoacidosis — which can show up in home blood and urine test kits — include:

- High blood sugar level
- High ketone levels in urine

Diabetic ketoacidosis - Symptoms & causes - Mayo Clinic. Mayo Clinic. https://www.mayoclinic.org/diseases-conditions/diabetic-ketoacidosis/symptoms-causes/syc-20371551. Published October 6, 2022.

WHAT IS AVAILABLE TODAY TO DETERMINE KETOSIS/RISK OF DKA AT HOME?

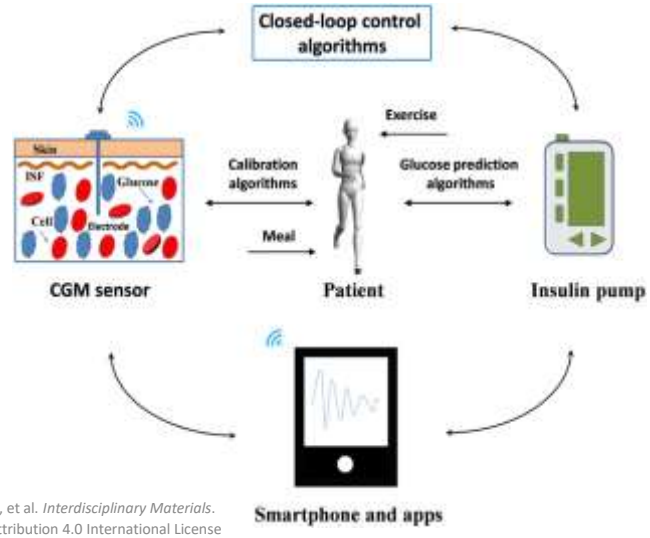
- Urine Ketone Strips
- Blood Ketone strips/meter

AROUND THE CORNER: A BIOWEARABLE: ONE SENSOR FOR GLUCOSE, KETONES

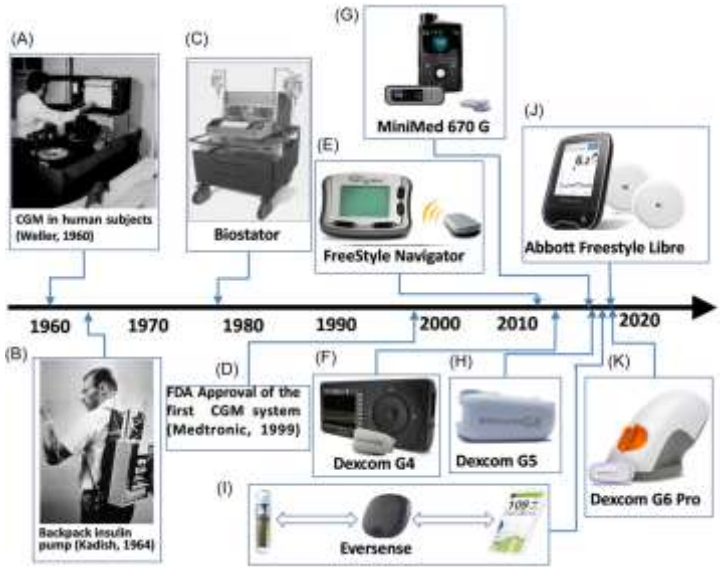
- **A first-of-its-kind dual monitoring system that will enable people with diabetes to continuously monitor glucose and ketone levels in one sensor is under development.**
- **The goal is early detection of diabetic ketoacidosis, a potentially fatal condition.**
- **This technology, currently in development, received breakthrough device designation from the U.S. Food and Drug Administration. This designation is designed to expedite the review of innovative technologies.**

ARTIFICIAL INTELLIGENCE BIOSENSORS FOR CGM

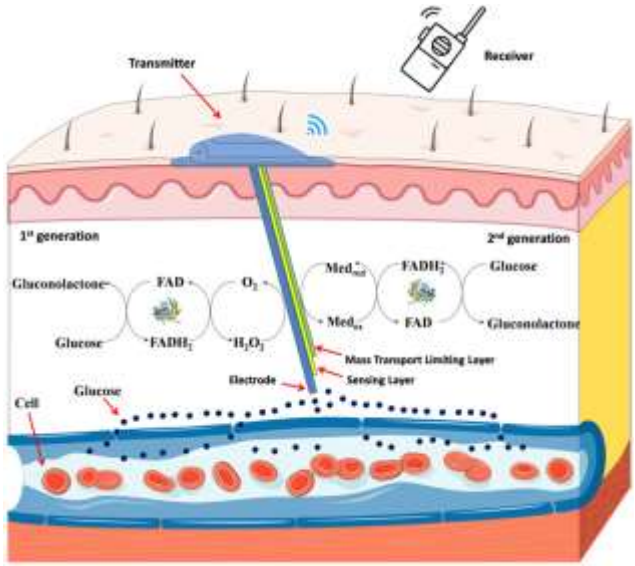
Artificial intelligence biosensors for continuous glucose monitoring: Closed-loop Control Algorithms



Artificial intelligence biosensors for continuous glucose monitoring : History

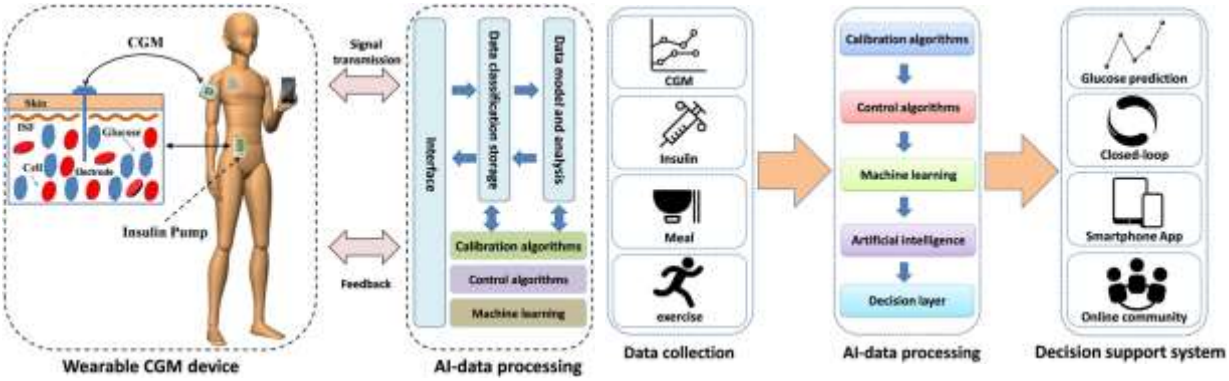


Artificial intelligence biosensors for continuous glucose monitoring



AI TECHNOLOGIES FOR CGM BIOSENSORS

Schematic Representation of AI in Diabetes Management: CGM



SUMMARY AI

- Three main applications:
  - Closed loop control algorithms
  - Glucose predications based on CGM biosensors
  - AI Algorithms and Calibration of the CGM biosensor based on AI algorithms
- CGM Sensors can be worn up to 15 days, a calibration algorithm is required for the insulin pump after sensor change
- It is necessary for insulin pumps to take closed-loop decisions and to learn from data adaptation
- Closed-loop therapy technology is perfect embodiment of CGM and AI providing numerous clinical opportunities and technical advancements

AND A CONTINUING ISSUE

Primary Care > Diabetes

CGM Uptake Very Low for Vulnerable Diabetes Populations

— But how to achieve equitable use remains "complicated," says expert

by Kristen Monaco, Senior Staff Writer, MedPage Today

CGM uptake very low for vulnerable diabetes populations. *MedPage Today*. https://www.medpagetoday.com/primarycare/diabetes/113079. Published November 22, 2024.

HEALTH DISPARITIES...

- LOCATION
- SOCIOECONOMIC STATUS
- RACIAL/ETHNIC DISPARITIES
- INSURANCE COVERAGE
- TECHNOLOGICAL CHALLENGES
- HEALTH LITERACY

ALL CAN IMPACT THE ACCESS AND USE OF CGM BY YOUR PATIENTS.

TELEHEALTH AND DIABETES EDUCATORS CAN HELP!

ALEPPO G, ET AL. JAMA NETW OPEN. 2023;6:E2336876; VRANY EA, ET AL. FRONT ENDOCRINOL (LAUSANNE). 2023;14:1083145; SHEON AR, ET AL. JMIR DIABETES. 2017;2:E16. GAL RL, ET AL. DIABETES. 2023;72(SUPPL 1): POSTER 149-LB; AGARWAL S, ET AL. CURR DIAB REP. 2022;22:275-281; AMERICAN DIABETES ASSOCIATION PROFESSIONAL PRACTICE COMMITTEE. DIABETES CARE. 2024;47(SUPPL 1):S77-S110.

SUMMARY

- A1c alone is not an appropriate actionable marker when making therapeutic changes.
- SMBG has significant limitations as well.
- Lack of symptoms does not mean patients are not experiencing dysglycemia.
- Goal of therapy is to reduce hyperglycemia without causing hypoglycemia.
- The AGP allows for visualization of patterns for HCPs, PWD, caregivers.
  - Suitable for all reading levels
  - Reduced language barrier
  - Numeracy not required
- How do you want to practice?

RESOURCE TOOLKIT:
HTTPS://WWW.PCMG-US.ORG/TOOLKIT/NEWCGM

Links to pages devoted to the individual devices, both professional and personal, including insertion videos

Links to references used in this presentation

Links to download the deck and review the presentation

Extensive cost and use data

A list of helpful resources from the ADA, diaTribe, AAFP, the Association of Diabetes Care & Education Specialists, and more

WHAT'S NEW & AROUND THE CORNER IN CGM

EDEN MILLER, DO

DIABETES & OBESITY CARE, LLC

BEND, OREGON