

A HealthTrust Presentation
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Understanding Personal Continuous Glucose Monitoring in the Outpatient Setting



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Disclosures

The presenter and her preceptor have no relevant financial relationships with ineligible companies to disclose.

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Objectives For Pharmacists

01

IDENTIFY

the most appropriate continuous glucose monitoring (CGM) device for a patient

02

RECALL

solutions to overcome barriers to obtaining a CGM for a patient

03

RECOGNIZE

an example of a CGM report to help optimize glycemic control for a patient

Objectives For Technicians

01

RECOGNIZE

the different components of different CGM devices

02

RECALL

common barriers to CGM access for patients

03

IDENTIFY

strategies to use CGM data to counsel patients

01 BACKGROUND



Continuous Glucose Monitors (CGM)



Sources: How do CGM systems work?: The Dexcom G6 CGM. Dexcom.
FreeStyle Libre 2 system: CGM with real-time glucose alarms. Continuous Glucose Monitoring (CGM).
Leelarathna L, et al.; FLASH-UK Trial Study Group. N Engl J Med. 2022 Oct 20;387(16):1477-1487



Continuous Glucose Monitors (CGM)



REAL-TIME

continuous measurements
of interstitial glucose



PATTERNS

of glycemic variability

4x

INCREASED USE

from 7% in 2016
to 30% in 2020

CGMs aggregate important data regarding a patient's glucose control and capture trends to allow patients to intervene when necessary and providers to optimize medication regimens

Personal Or Professional CGMs



Professional CGM

- Distributed by clinic to patients
- Limited supply
 - usually up to 2 weeks
- Option for blinded or unblinded data



Personal CGM

- Device owned by patient
- Supply can be refilled
- Data is always unblinded



Blinded Data

- CGM data only visible to provider and not the patient
- Results may reflect a more realistic day in terms of behaviors and glycemic control



Unblinded Data

- CGM data visible to both provider and patient
- Patient able to track glycemic patterns and modify behaviors accordingly

Components Of All CGM Devices

SENSOR

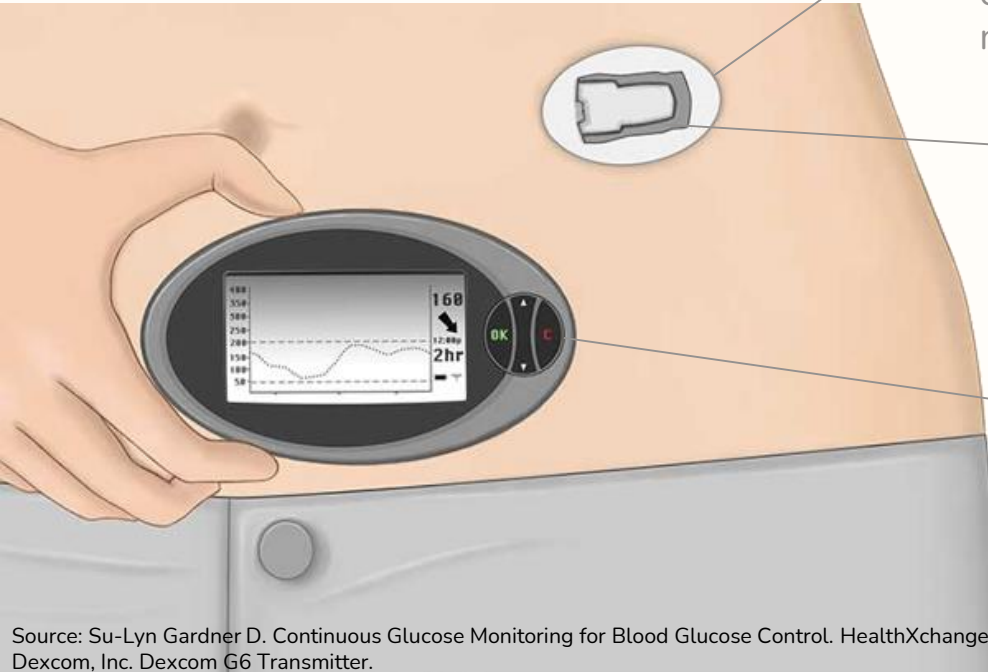
patch-like adhesive which contains a microneedle or filament that is inserted under the skin and measures interstitial glucose levels

TRANSMITTER

sends glucose readings to reader via Bluetooth. May be integrated into the sensor or user may need to manually insert the transmitter into the sensor

READER or RECEIVER

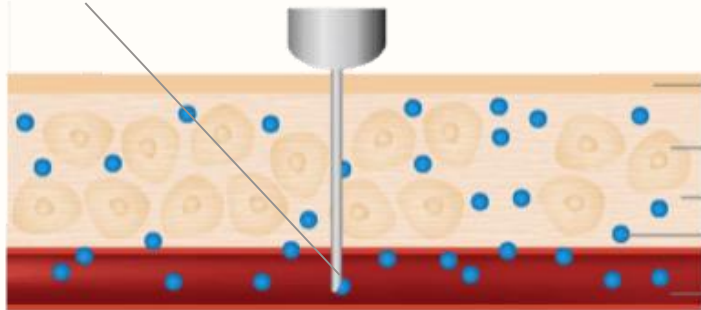
hand-held device that displays glucose levels, patterns, and arrows. May also be a computer or smartphone device



Self-Monitoring Blood Glucose (SMBG)

Glucometer

Measures capillary blood glucose level

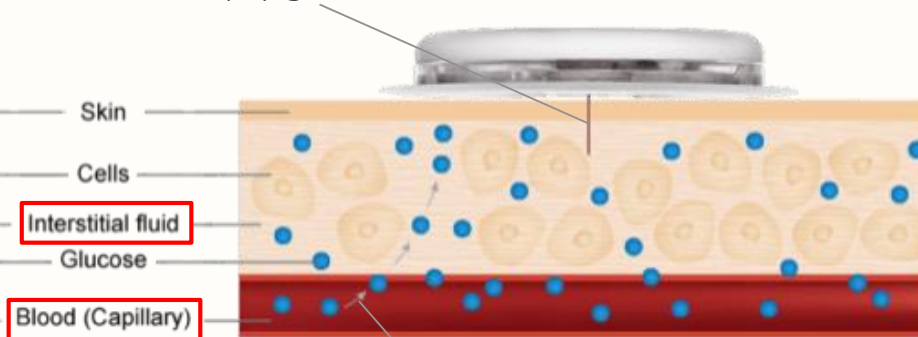


Multiple fingersticks can be inconvenient, painful, and lead to poor adherence

Glucometer testing is the most accurate method of patient-measured BG levels and is recommended with the onset of hypoglycemic symptoms or suspected inaccurate CGM readings

CGM

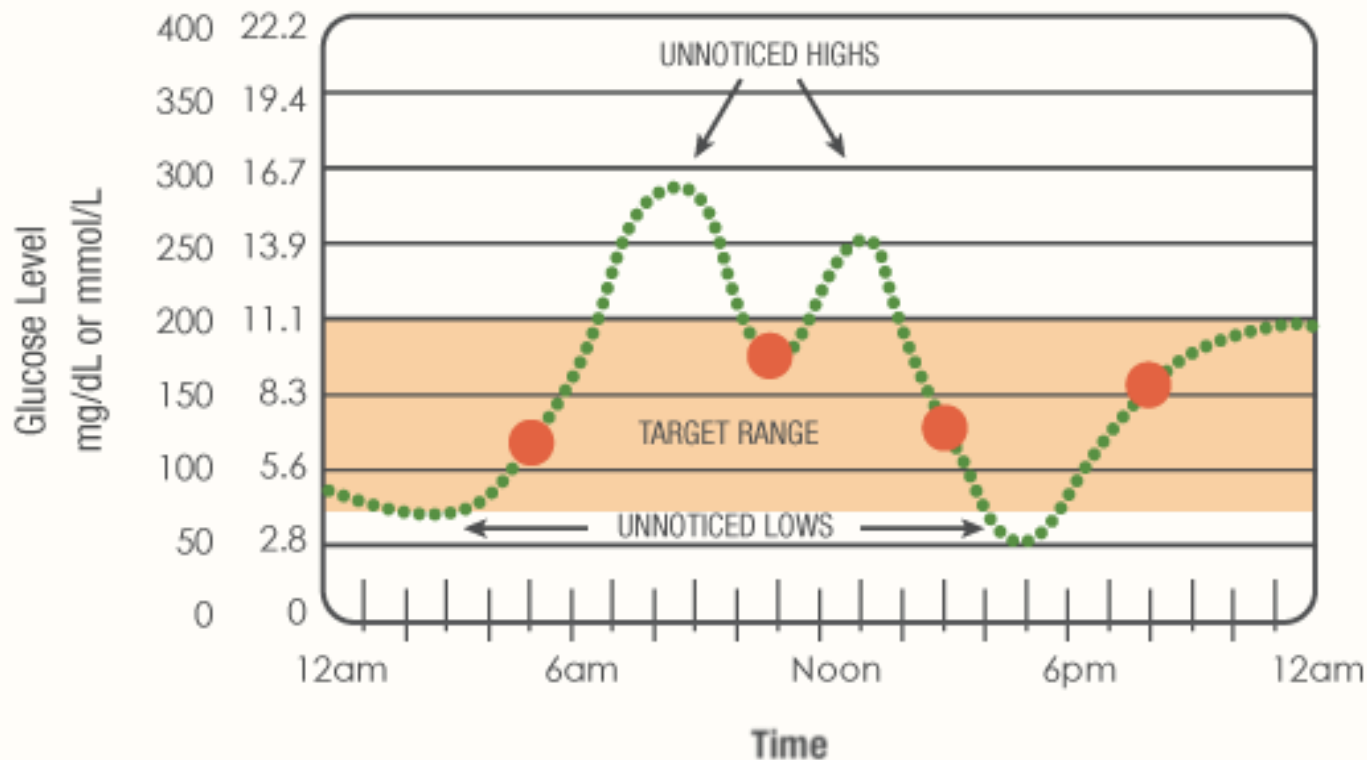
Measures interstitial fluid (IF) glucose level



Glucose diffuses from capillaries into IF

Readings may lag behind BG readings by 15 minutes

Self-Monitoring Blood Glucose (SMBG)



CGM

Allows for continuous measurement and provides trend arrows to predict BG levels over time

FINGER STICKS

Only provides BG data for a specific point in time and does not capture patterns or predict changes in glucose levels

Mean Absolute Relative Difference (MARD)

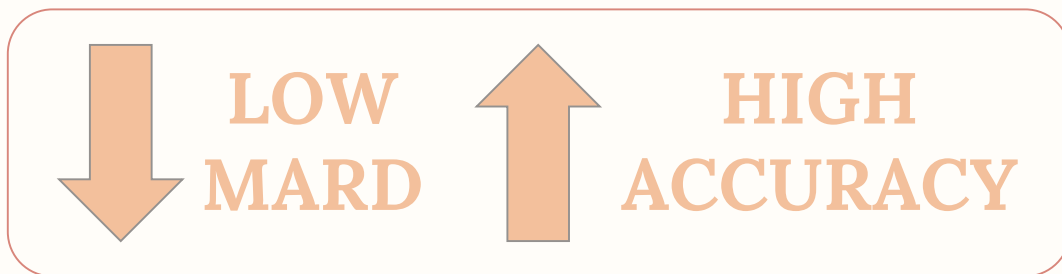
- There is no international standard to define accuracy in the setting of CGM readings
- MARD is widely accepted to estimate CGM accuracy
- Requires SMBG values to be compared to CGM glucose levels at specified time points

MARD 0%

Device has perfect
accuracy and precision

MARD <10%

Marker of adequate
analytical performance



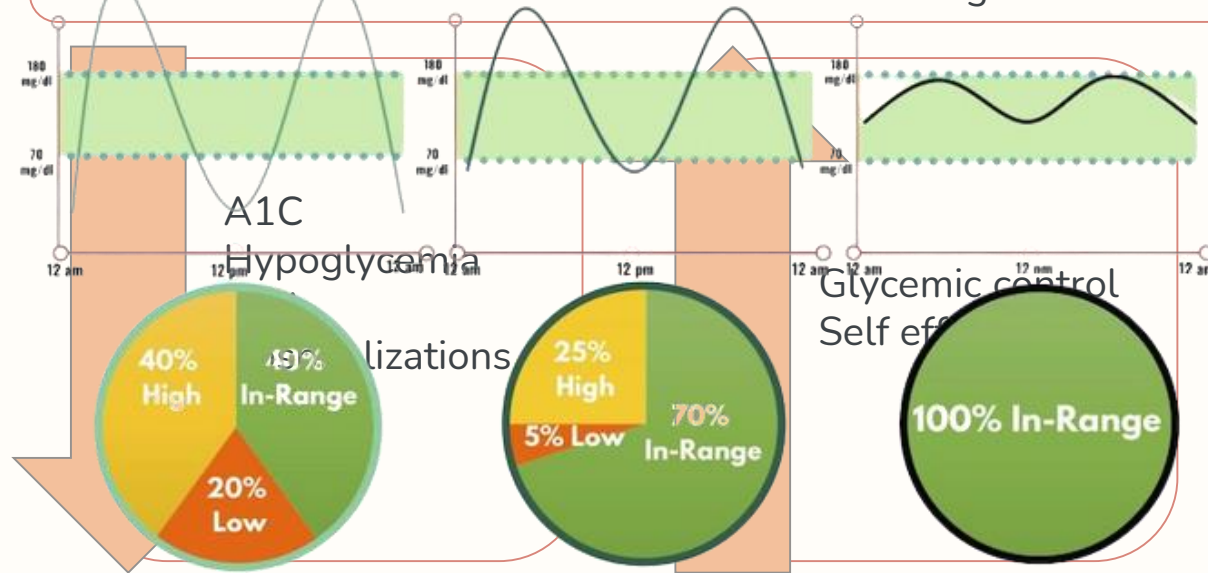
02 CLINICAL BENEFITS OF CGM

2023 American Diabetes Association (ADA) Recommendations

Guideline on Glycemic Targets and Guideline on Diabetes Technology

- Glycemic control is assessed by A1C, CGM measurements of TIR and GMI, and SMBG (and an average blood glucose of 154 mg/dl)
- CGM should be considered from outset of diagnosis of diabetes that requires insulin

THE MANY FACES OF A 7% A1C



Time in Range (TIR)

TIR 70% = A1C of 7%

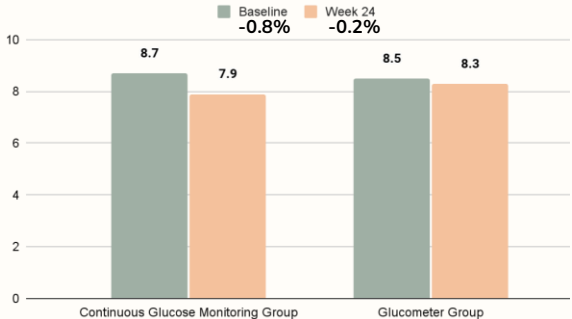
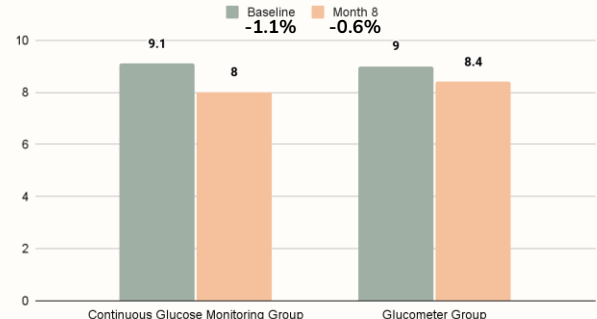
↑ TIR = ↓ complications

Glucose Management Indicator (GMI)

Estimate of A1C

Assessed after days
Unaffected by red blood
cell turnover

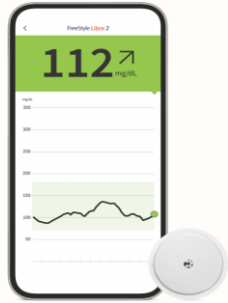
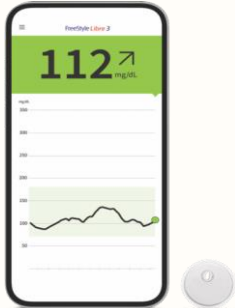


Benefit: A1C Lowering

	Intermittently Scanned Continuous Glucose Monitoring for Type 1 Diabetes	Effect of CGM on Glycemic Control in Type 2 Diabetes Treated with Basal Insulin
Design	Parallel-group, multicenter, randomized controlled trial	
Population	n=156; type 1 diabetes; A1C between 7.5%-11%	n=175; type 2 diabetes treated with basal insulin; baseline mean A1C 9.1%
Methods	1:1 randomization to CGM or glucometer	2:1 randomization to CGM or glucometer
Results	<p>Changes in A1C Over 24 Weeks</p>  <p>p<0.001</p>	<p>Changes in A1C Over 8 Months (34 Weeks)</p>  <p>p=0.02</p>
	Use of a CGM resulted in significantly lower A1C levels than use of a glucometer	





Benefit: Reduced Hypoglycemia

<div>*MDI = multiple daily injections</div>	<div>Hypoglycemic Frequency and Effect of CGM in Type 1 Diabetes Treated With MDI Insulin</div>	<div>Effect of CGM on Glycemic Control in Type 2 Diabetes Treated with Basal Insulin</div>
<div>Design</div>	<div>Parallel-group, multicenter, randomized controlled trial</div>	
<div>Population</div>	<div>n=158; type 1 diabetes treated with MDI insulin; A1C between 7.5%-9.9%</div>	<div>n=175; type 2 diabetes treated with basal insulin; baseline mean A1C 9.1%</div>
<div>Methods</div>	<div>2:1 randomization to CGM or glucometer</div>	<div>2:1 randomization to CGM or glucometer</div>
<div>Results</div>	<div><div><div><div><div><div>Hypoglycemic Event Rate per 24 Hours</div><div><div><div>Baseline</div><div>Week 24</div></div><div><div>-0.07</div><div>-0.01</div></div></div><div><div><div>0.23</div><div>0.16</div></div><div><div>0.31</div><div>0.3</div></div></div><div><div>Continuous Glucose Monitoring Group</div><div>Glucometer Group</div></div></div></div><div><div>p=0.03</div></div></div></div></div>	<div><div><div><div><div><div>Hypoglycemic Event Rate per Week</div><div><div><div>Baseline</div><div>Month 8</div></div><div><div>-0.1</div><div>+0.1</div></div></div><div><div><div>0.1</div><div>0</div></div><div><div>0.1</div><div>0.2</div></div></div><div><div>Continuous Glucose Monitoring Group</div><div>Glucometer Group</div></div></div></div><div><div>p<0.001</div></div></div></div></div>
	<div>Use of a CGM resulted in significantly lower rates of hypoglycemia than use of a glucometer</div>	

03 TYPES OF CGM DEVICES

	Abbott		Dexcom	
Device	FreeStyle Libre 2	FreeStyle Libre 3	G6	G7
				
Components	Reader and sensor	Reader and sensor	Reader, sensor, transmitter	Reader and sensor
Type	isCGM – scan every 8 hours	rtCGM	rtCGM	rtCGM
Calibration	None	None	Only if sensor code not used	Optional
Warm Up	1 hour	1 hour	2 hours	30 minutes
Lifespan	14 days	14 days	10 days	10 days
MARD	9.2%	7.8%	9.0%	8.2%

*Other devices include Eversense's Senseonics E3 and Medtronic's Guardian Sensor 3

	Abbott		Dexcom	
Device	FreeStyle Libre 2	FreeStyle Libre 3	G6	G7
Sensor				
Approval Age	>4 years	>4 years	>2 years	>2 years
Application Site	Back of upper arm	Back of upper arm	Abdomen Back of upper arm (>18 yo) Upper buttocks (2-17 yo)	Back of upper arm Upper buttocks (2-6 yo)
Insulin Pump Compatibility	Not available	Not available	Omnipod 5 Tandem t:slim X2	Not available yet
Interactions	<p><u>Vitamin C</u></p> <ul style="list-style-type: none"> • ↑glucose readings • Do not take ≥500mg per day 		<p><u>Acetaminophen</u></p> <ul style="list-style-type: none"> • ↑glucose readings with high doses • Do not take ≥1g every 6 hours <p><u>Hydroxyurea</u></p> <ul style="list-style-type: none"> • ↑glucose readings • Use alternative CGM device 	

*Other devices include Eversense’s Senseonics E3 and Medtronic’s Guardian Sensor 3

04 CGM DATA INTERPRETATION

Ambulatory Glucose Report Metrics

Glycemic Metric	Definition	ADA 2023 Target
Percentage of time CGM is active	The percent of time the CGM is worn	≥70%
Time Above Range (TAR)	<div> <div> <div>Very High: >250 mg/dL</div> <div>High: >180 mg/dL</div> </div> <div> <div><5%</div> <div><25%</div> </div> </div>	
Time in Range (TIR)	<div> <div>Target 80-130 mg/dL</div> <div>>70%</div> </div>	
Time Below Range (TBR)	<div> <div>Low: <70 mg/dL</div> <div>Very Low: <54 mg/dL</div> <div><4%</div> <div><1%</div> </div>	
Mean Glucose	Average daily glucose values during time CGM is worn	<154 mg/dL
Glucose Management Indicator	Estimate of A1C level	<7%
Glucose Variability	Degree of fluctuation and frequency of variations in glucose readings	≤36%

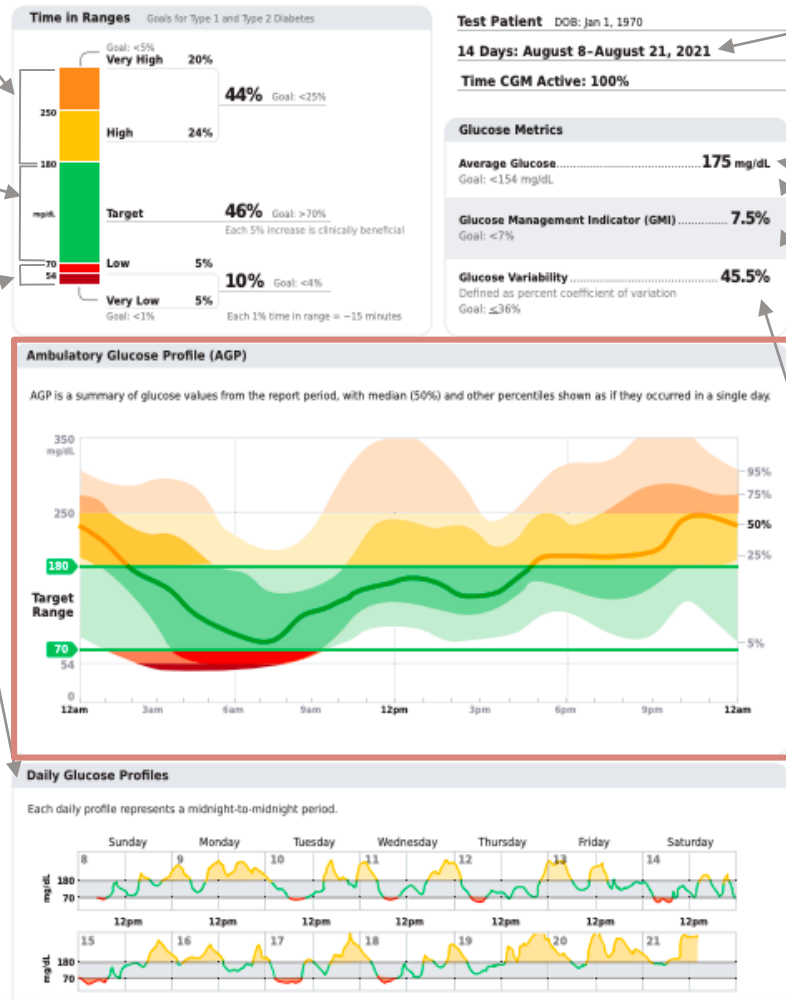
AGP Report: Continuous Glucose Monitoring

Time Above Range (TAR)

Time in Range (TIR)

Time Below Range (TBR)

- refer to daily glucose profile reports to assess daily patterns of hypoglycemia



Number of Days
CGM is Worn

Percentage of
Time CGM is Active

Mean Glucose

Glucose Management
Indicator (GMI)

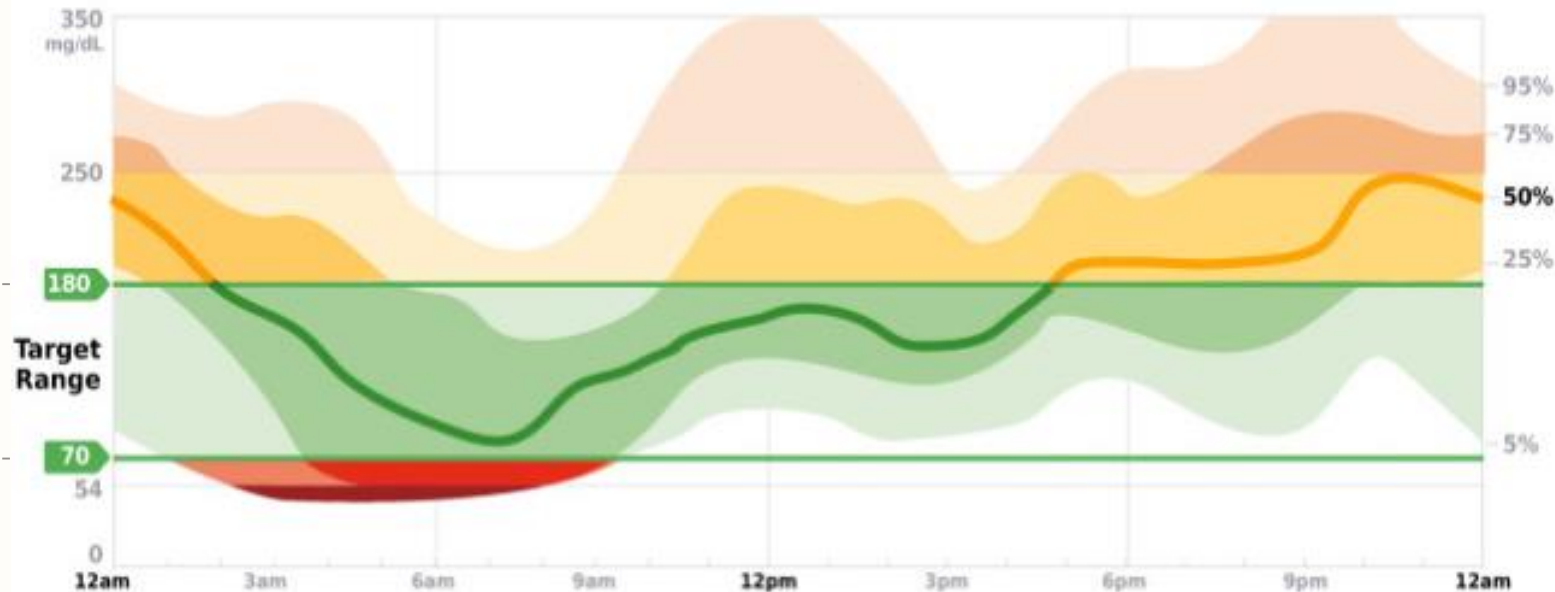
Glycemic Variability

Ambulatory Glucose Profile (AGP)

AGP is a summary of glucose values from the report period, with median (50%) and other percentiles shown as if they occurred in a single day.

TAR

- Medication adherence or adjustments
- Diet and exercise
- Snacks



TBR

- Medication timing or adjustments
- Skipping meals
- Excessive exercise

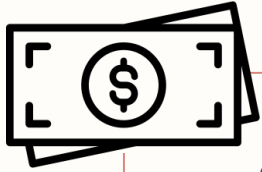
ADA recommends use of AGPs to make glycemic metrics more actionable

Other Counseling Points

	Counseling Points
Sensor Application	
Sensor Wear	
Sensor Removal	

04 BARRIERS

Barriers



Financial Burden

- Assess formulary coverage
- Eligibility for manufacturer coupon or free trials



Wear Discomfort

- Rotate placement of sensor
- Consider smaller devices
- Suggest adhesive patches or bandages



Technological Literacy

- Provide initial and ongoing support and education
- Consider CGM with more user-friendly features



Inaccurate Readings

- Discuss pros and cons of CGMs
- Counsel patient on when SMBG may be needed

05 FINANCIAL COVERAGE

Medicare and Medicaid Coverage

All the following eligibility criteria must be met:

A

Diagnosis of diabetes

B

Treatment with multiple (≥ 3) daily administrations of insulin or a continuous subcutaneous insulin infusion pump

C

Insulin regimen requires frequent adjustments on the basis of BG monitoring results

D

In-person doctor's visit for diabetes management 6 months prior to CGM initiation

E

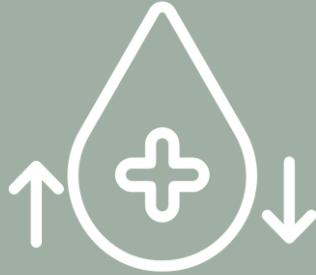
In-person follow-up visits every 6 months after CGM initiation to assess diabetes management

Patients Who Would Benefit from a CGM



Insulin

- Multiple daily injections



Glucose Variability

- Hypoglycemia
- Hyperglycemia



Type 1 Diabetes

- Frequent variability
- Insulin treated



Highly Motivated

- Eager to take an active role in their care

06 ASSESSMENT QUESTIONS

Question 1 – Pharmacists

A patient asks for your help in choosing a CGM device. He would prefer a device that (1) does not require scanning and (2) does not need to be replaced for 14 days. Which CGM device best matches the patient's preferences?

- a. FreeStyle Libre 2
- b. FreeStyle Libre 3
- c. Dexcom G6
- d. Dexcom G7

Question 1 – Answer

A patient asks for your help in choosing a CGM device. He would prefer a device that (1) does not require scanning and (2) does not need to be replaced for 14 days. Which CGM device best matches the patient's preferences?

- a. FreeStyle Libre 2
- b. FreeStyle Libre 3**
- c. Dexcom G6
- d. Dexcom G7

Question 2 – Pharmacists

The following patients are interested in obtaining a CGM device but are concerned about a potential financial barrier. Identify the patient who is eligible for coverage of a personal CGM device through their CMS-based insurance?

- a. Patient A who takes metformin and empagliflozin
- b. Patient B who injects semaglutide once weekly
- c. Patient C who injects Lantus nightly and Humalog three times daily with meals
- d. Patient D who takes pioglitazone and glipizide and checks his blood glucose via a fingerstick four times daily

Question 2 – Answer

The following patients are interested in obtaining a CGM device but are concerned about a potential financial barrier. Identify the patient who is eligible for coverage of a personal CGM device through their CMS-based insurance?

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Question 3 – Technicians



Which of the following CGM components is highlighted in the red box above?

- a. Receiver
- b. Sensor
- b. Transmitter
- d. Lancing device

Question 3 – Answer



Which of the following CGM components is highlighted in the red box above?

- a. **Receiver**
- b. Transmitter
- b. Sensor
- d. Lancing device

Question 4 – Technicians

Which of the following is not a common barrier to CGM use?

- a. Having difficulty utilizing the reader or app on a smartphone device to see glucose readings
- b. Needing to remove and replace the sensor after every shower
- c. Concern about sensor being visible to others
- d. CGM derived readings may be inaccurate during periods of hypoglycemia

Question 4 – Answer

Which of the following is not a common barrier to CGM use?

- a. Having difficulty utilizing the reader or app on a smartphone device to see glucose readings
- b. Needing to remove and replace the sensor after every shower**
- c. Concern about sensor being visible to others
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Question 5 – Pharmacists

JY is a 42-year-old male who was diagnosed with type 2 diabetes 15 years ago and has been working towards an A1C goal of 7%.

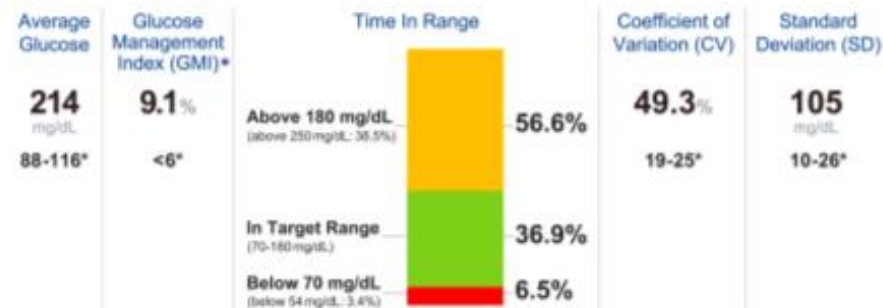
Current Medications:

- Metformin 1000 mg po BID
- Empagliflozin 10 mg po daily
- Insulin glargine 30 units sc nightly
- Insulin lispro 6 units sc TID with meals

Based on JY's AGP report, during which time of day is he experiencing hyperglycemia?

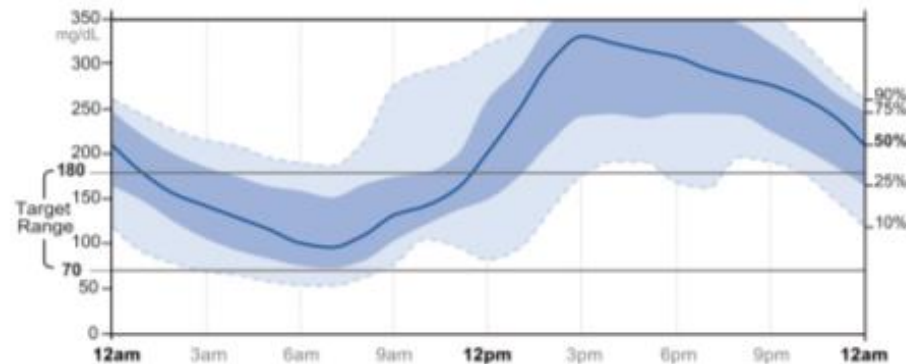
- Between 3am to 6 am
- Between 6 am to 9 am
- Between 9 am to 12pm
- Between 3pm to 6 pm

Summary



Ambulatory Glucose Profile

Curves/plots represent glucose frequency distributions by time regardless of date



Question 5 – Answer

JY is a 42-year-old male who was diagnosed with type 2 diabetes 15 years ago and has been working towards an A1C goal of 7%.

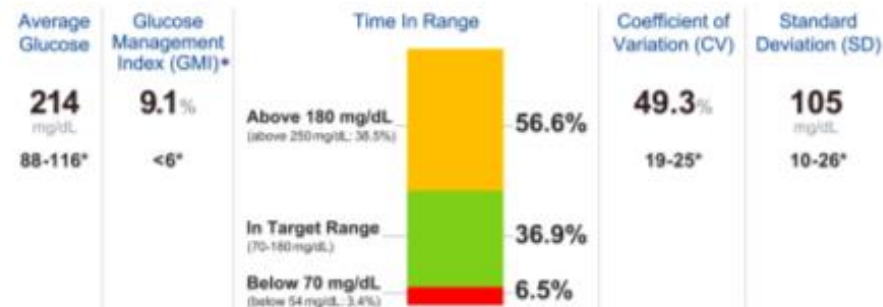
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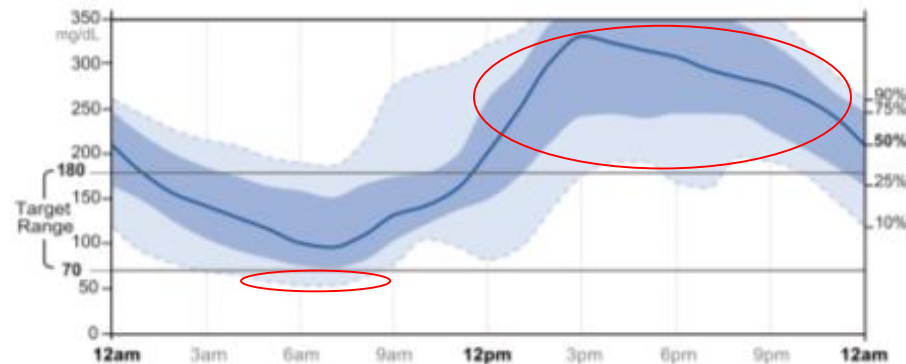
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Question 6 – Technicians

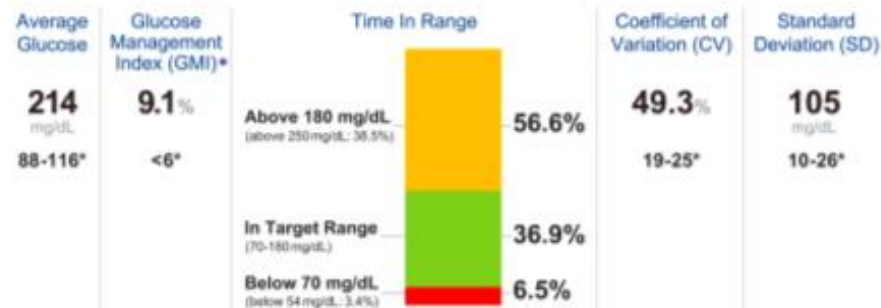
JY is a 42-year-old male who was diagnosed with type 2 diabetes 15 years ago and has been working towards an A1C goal of 7%.

JY states that his next A1C check is scheduled for 2 months from today. He is wondering if an A1C can be estimated from the data collected through his CGM.

Which of the following metrics from his AGP report would you tell JY could be used to estimate an A1C?

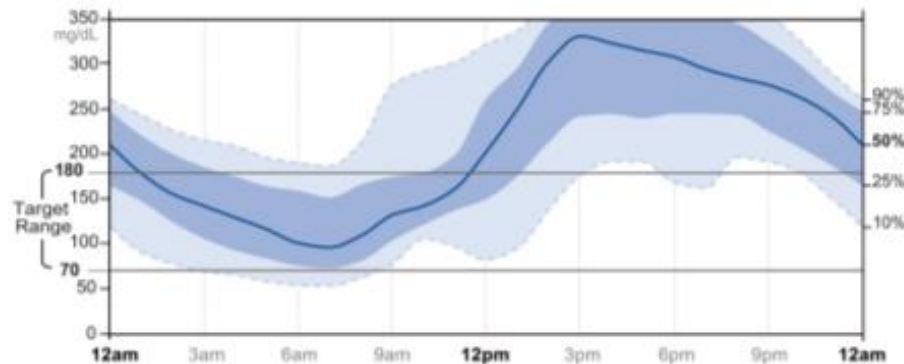
- a. Coefficient of variation
- b. Time above range
- c. Glucose management index
- d. Average glucose

Summary



Ambulatory Glucose Profile

Curves/plots represent glucose frequency distributions by time regardless of date



Question 6 – Answer

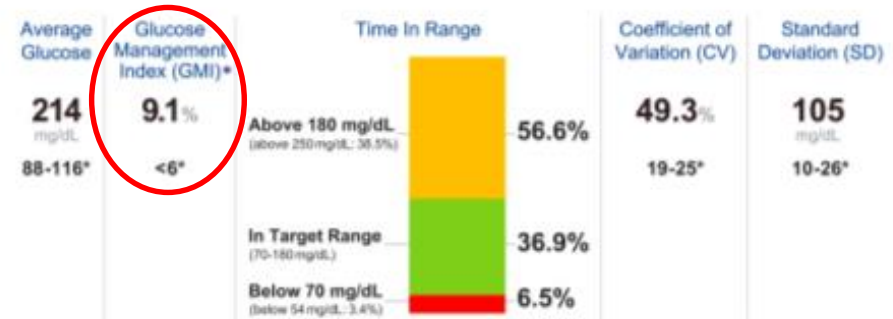
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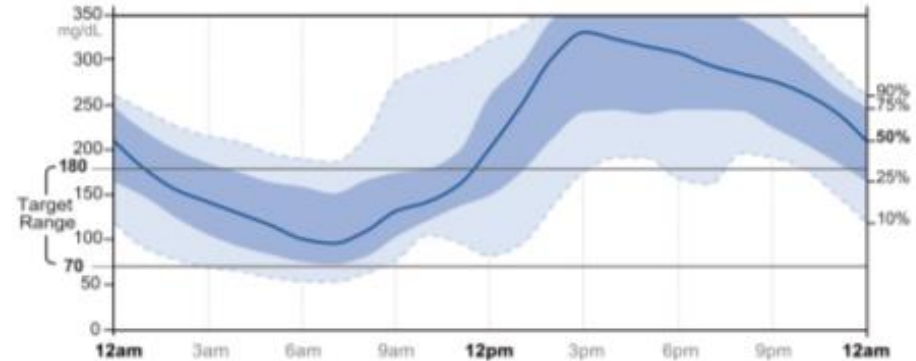
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Summary



Ambulatory Glucose Profile

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References

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Thank you!

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