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Using Continuous Glucose Monitoring (CGM) System Data to Assess and Improve Glucose Control

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- Notice of Requirements For Successful Completion
 - Please refer to learning goals and objectives
 - Learners must attend the full activity and complete the evaluation in order to claim continuing education credit/hours
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Objective

- Compare and contrast blood glucose meter and continuous glucose monitoring (CGM) data
- Describe the differences between CGM systems
- Identify best candidates for CGM use
- Discuss the correlation between CGM results and A1C values
- Utilize the trend arrow to adjust insulin dose
- Identify Medicare eligibility requirements for reimbursement

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Mary



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Mary

Mary is 77 year-old female with history of type 2 diabetes for the past 30 years. She is referred to your clinic for diabetes education and therapy management. She is a retired nurse and lives with her husband.

Insurance: Medicare A&B and secondary United Health Care

Labs:

HgbA1C: 12%

GFR: 46 ml/min

Microalb/Creat ratio: 57 mcg/mg

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Medications

- glargine-lixisenatide injection
34 units daily
- Aspart insulin 5 units with lunch and dinner also 1 unit with snacks that contain high carbohydrate such as cookies, cakes, ice-creams.

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Mary

- Does not like to check her blood glucose (BG) because "it hurts"
- She would like to obtain **Freestyle Libre** advertised on TV
- Her goal is to lose 20 lbs and to get her BG under control
- Reports she has "sweet tooth" and eats candy frequently at home
- She would like to see a dietician to get consult on how to lose weight.
- Exercises with her trainer everyday for 1 hour at the gym from 9-11am

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Is CGM a suitable device for this person with diabetes?



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Fingerstick Measurement



Measured by blood glucose meter

Interstitial Fluid Glucose Measurement



Measured by Continuous Glucose Monitor

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Available CGM Systems

Professional CGM Systems	Personal CGM Systems
<ul style="list-style-type: none"> • Abbott Freestyle Libre Pro system • Medtronic iPro2 Enlite sensor and recorder 	<ul style="list-style-type: none"> • Abbott FreeStyle Libre sensor and reader • Dexcom Platinum G4/Dexcom Mobile G5 sensor and G4 or G5 transmitter • Dexcom G6 sensor and transmitter • Medtronic Enlite sensor and MiniLink or Guardian Link transmitter • Medtronic Guardian Sensor 3 and Guardian Link 3 transmitter • Eversense implantable sensor and transmitter

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<p>Eversense</p> 	<p>FreeStyle Libre</p> 	
<p>Dexcom G6</p> 	<p>Dexcom G5</p> 	<p>Guardian Link</p> 

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CGM Comparison

Real time vs Intermittent Scan /Flash CGM

CGM	Duration of sensor wear (days)	Start up time (minute)	Calibration requirement	Trend arrows	Alarm and Alerts	iCloud Sharing	Smart phone use
Realtime CGM	7-10	60-120	Some devices Yes	Yes	Yes	Yes	Yes
Flash CGM	14	60	No	Yes	No	No	Yes (iPhone 7 or Android 5 or higher)

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Best Candidates for CGM

Preferred (rt)CGM

- T1D
- Nocturnal hypoglycemia or unawareness
- On CSII (insulin pump)
- Persons with diabetes who have severe fear of hypoglycemia
- Visually impaired or have dexterity problem
- Pregnant women with diabetes

rtCGM or (is)CGM

- T2D on insulin
- Any individual who has elevated A1C and are not adherent to medications or insulin and do not monitor blood glucose

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Pros and Cons of Glucose meters vs. Intermittent Scan Continuous Glucose Monitor

Glucose meter

- Requires to perform fingerstick
- The fingerstick can negatively influence individual adherence
- SMBG may not be feasible at work or school
- It is susceptible to poor testing technique, inadequate blood sample or contaminations
- It only measures glucose at a single point in time and does not give any direction at which the blood glucose change is projected
- Cannot detect impending hypoglycemia
- Nocturnal and asymptomatic hypoglycemia can go undetected
- Accurate measure of blood glucose at a point in time

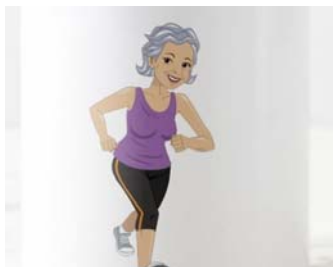
Intermittent Scan Continuous Glucose Monitor (isCGM)

- Does not require fingerstick
- Requires scanning the reader over the sensor
- Does not alert of hypo or hyperglycemia unless it is scanned
- Contains blood glucose trend arrow allowing to accurately determine the direction and rate of blood glucose
- Can give an overview of the pattern of the blood glucose throughout the day
- Can be worn up to 14 days
- Requires 2 hours of warming up period after applying new sensor
- Does not need calibration
- iPhone 7 or more can be used as a reader after downloading LibreLink app
- Not as accurate as actual blood glucose reading

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Mary has started on Flash CGM



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CGM Data interpretation

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CGM Data Interpretation

- Wearing a CGM alone will not improve blood glucose
- Engaging users in interpreting their CGM data empowers them to respond appropriately to extreme glycemic excursions and effectively manage their diabetes
- Clinicians should understand how to interpret the retrospective CGM data to effectively guide persons with diabetes in their diabetes management journey
- Diabetes Educators should assist individuals with appropriate CGM selection, initiation and education on advanced pattern management skills and also provide an on going support to keep individuals engage on their diabetes management

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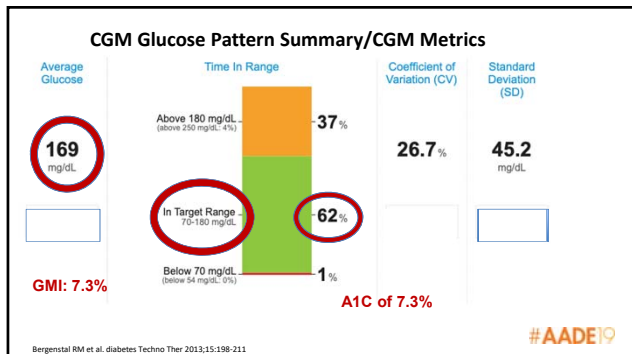
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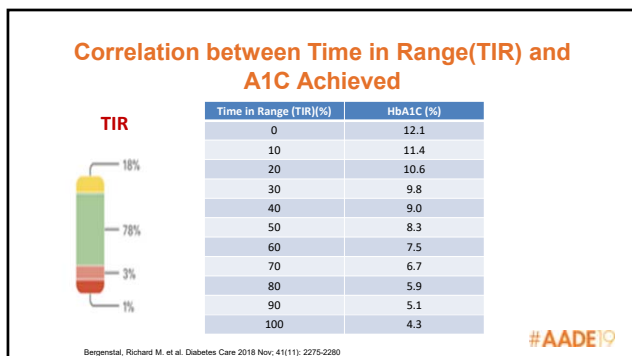
Glucose management Indicator (GMI)

CGM-Derived mean glucose mg/dL (mmol/L)	GMI % (mmol/mol)
100 (5)	5.7 (36.2)
125 (6)	6.3 (40.9)
150 (7)	6.9 (45.7)
175 (8)	7.5 (50.4)
200 (9)	8.1 (55.1)
225 (10)	8.7 (59.8)
250 (12)	9.3 (69.2)
275 (14)	9.9 (78.6)
300 (16)	10.5 (88.0)
350 (18)	11.7 (97.4)

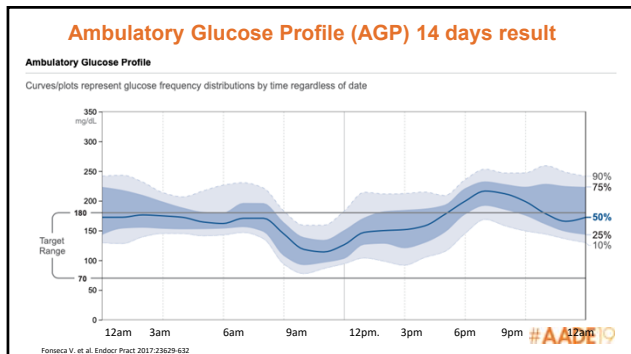
Bergental, Richard M. et al. Diabetes Care 2018 Nov; 41(11): 2275-2280

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Take Home Message for AGP Interpretation

- A minimum of 10-14 days is needed for adequate decision making
- Good goal for hypoglycemia:
 - $\leq 3\text{-}5\%$ of the day at $<70\text{mg/dL}$ ($<3.9\text{mmol/L}$)
 - $\leq 1\%$ of the day at $<54\text{mg/dL}$ ($<3.0\text{mmol/L}$)
- Coefficient variation (CV) is a metric that determines the level of glycemic variability. This indicator is important as it correlates with future diabetes complications, such as nephropathy and CVD
 - The stable glycemic variability is $<36\%$
- Glucose management indicator (GMI): new terminology replacing A1C
 - It is from CGM derived mean glucose to an estimated current A1C

Kovatchev B, et al. *Diabetes Care* 2016;39:502-510;Bergenstal R, et al. *DiabetesCare* 2018;41:2275-2280

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Factors Affecting A1C values

Factors Affect HgbA1c	Effect
Pregnancy	Decrease
hemodialysis	Decrease
Fatty liver	Decrease
Alcohol	Decrease
Medications	Decrease or Increase

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Factors Affecting A1C values

Factors Affect HgbA1c	Effect
Uremia with CKD	Decrease
Iron deficiency anemia	Increase
Hemoglobinopathies	Decrease

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A1C and GMI Differences and Action Plan

Laboratory A1C	GMI	Results	Reasons	Plan
8.0%	7.8%	A1C similar to GMI	Average CGM blood glucose is what would be predicted from measured A1C	Plan the management as needed to patient's fasting goal
8.0%	7.2%	A1C > GMI	During the short periods of much lower values of glucose reading (Starting a much lower CHO reduced diet, an intensive exercise, starting a new diabetes agents that is very effective in reducing BG)	Plan a higher A1C goal for individual as there maybe excessive hypoglycemic episodes during the day or week -Goal <3% in 70 mg/dL -Goal <1% in 54 mg/dL
7.2%	8.0%	A1C < GMI	During short periods of acute hyperglycemia (DKA, steroid administration, illness)	No to set high A1C goal for patient.

Bergenstal, Richard M. et al. Diabetes Care 2018 Nov, 41(11): 2275-2280

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Mary's CGM Glucose overview

CGM Device: FreeStyle Libre [N/A]% Compliant w/Calibration* **79% Time Worn**

*Not applicable for FreeStyle Libre or FreeStyle Libre Pro which do not require calibration

Summary

Average Glucose

146

mg/dL

88-116*

Time In Range

Above 180 mg/dL <small>(above 200 mg/dL: 7%)</small>	23%
In Target Range 70-180 mg/dL	74%
Below 70 mg/dL <small>(below 54 mg/dL: 0%)</small>	3%

Coefficient of Variation (CV)

37.5%

19-25*

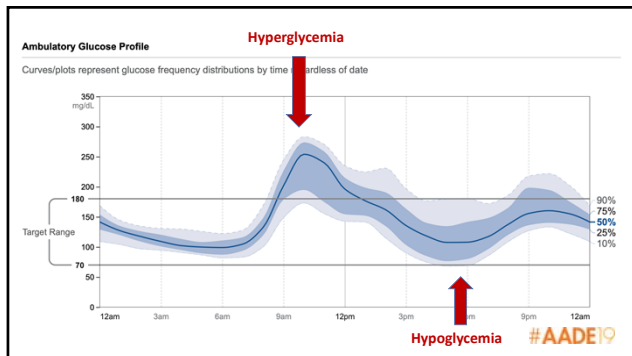
Standard Deviation (SD)

54.8

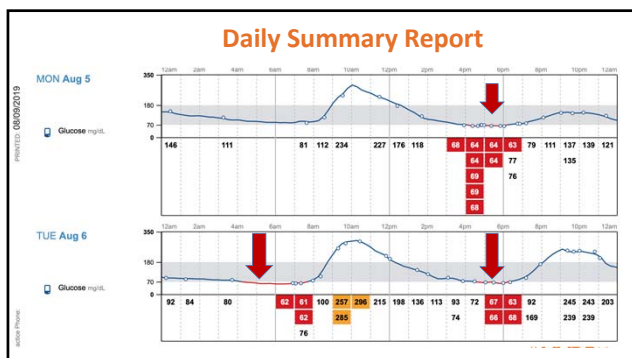
mg/dL

10-26*

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Glucose management Indicator (GMI)

CGM-Derived mean glucose mg/dL (mmol/L)	GMI % (mmol/mol)
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Bergensdal, Richard M. et al. Diabetes Care 2018 Nov; 41(11): 2275-2280

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Action Plan for Mary

- First Pattern of hypoglycemia
- Second Pattern of hyperglycemia
- Third Glucose Variability

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What Do Trend Arrows Mean and How can we use them?

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Trend Arrow Usage

- Allows the user to determine the direction of blood glucose
- Trend arrows correspond to different rate of glucose change depending on the brand of CGM system.
- It can be used to adjust insulin dosage
- Flash CGMs BG trends has a large margin of error for glucose below 70mg/dl and above 250 mg/dl hence fingerstick BG should be obtained for the accuracy BG reading.
- For individuals on bolus insulin, the rise of trend arrow, allows the patient to be proactive in correcting BG rise.
- The use of trend arrows before exercise allow the user to be proactive to prevent hypoglycemia by consuming a small snack before the activity.

- ↑ Rising quickly
- ↗ Rising
- Changing slowly
- ↘ Falling
- ↓ Falling quickly

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FreeStyle Libre Trend Arrow Insulin Dose Adjustment

Trend Arrow	Freestyle Trend Definition	Correction Factor (mg/dl)	Insulin Dose Adjustment (units)
↑	Glucose is rising quickly (>2 mg/dL per min)	<25 25-50 50-75 >75	+4 +3 +2 +1
↗	Glucose is rising (1-2 mg/dL per min)	<25 25-50 50-75 >75	+3 +2 +1 No change
→	Glucose is changing slowly (<1 mg/dL per min)	<25 25-50 50-75 >75	No change for all
↘	Glucose is falling (1-2 mg/dL per min)	<25 25-50 50-75 >75	-4 -3 -2 -1 No change
↓	Glucose is falling quickly (>2 mg/dL per min)	<25 25-50 50-75 >75	-4 -3 -2 -1 No change

Kudva YC, et al. Jendocr Soc. Doi:10.1210/ps.2018-00294 #AADE19


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- ### Key Variables to Consider When Using Trend Arrows
- Variability of insulin onset, peak action, and duration
 - Impact of meal composition and portion size
 - Prior and anticipated exercise taking into account the duration and intensity
 - Medications that raise the glucose values
 - Stress level
 - Illness
- Jeremy Pettus and Steven Edelman, 2017 Journal of Diabetes Science and Technology Vol.11(1)138-147 #AADE19

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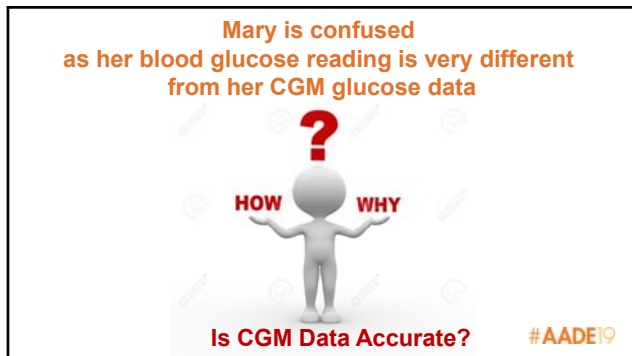
How do we Adjust Mary's bolus insulin dose based on her CGM reading before dinner?

Mary's target fasting is 150mg/dL
 Correction factor (CF) is 1:50, means for every 1 unit of insulin she reduces her blood sugar by 50 points.
 Based on the correction factor and rising of arrow, patient needs 2 extra units in addition to her correction factor dose.
Calculation:
 Goal: 150
 Before lunch 250
 $250-150=100$ so CF is 1:50= 2 units
 2 units +2 units= 4 total units before dinner.



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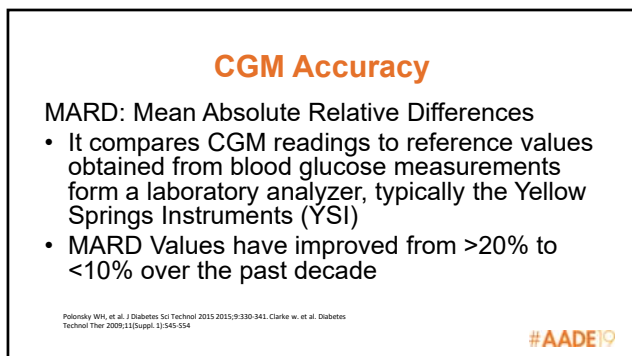
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MARD% Accuracy Comparison Among CGMs

CGM Systems	MARD, %
Abbott FreeStyle Libre Pro sensor	12.3
Medtronic iPro2 Enlite sensor	13.6
Abbott FreeStyle Libre sensor	9.7
Dexcom Platinum G4/G5 sensor	9.0
Dexcom G6 sensor	9.0
	with most current Dexcom software
	with no calibrations
Medtronic Enlite sensor	13.6
Medtronic Guardian Sensor 3 sensor	9.6 with 3-4 calibrations per day; 10.6 with 2 calibrations per day
Eversense implantable sensor	8.5

Rubab Z. et al. Diabetes 2018 Jul; 67 (Supplement)

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Flash CGM Accuracy

- Need Finger stick if:
 - BG reading <70 mg/dL
 - BG Reading >250 mg/dL

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Coverage for Data Analysis

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Current CPT code for Reimbursement

Code	Description	Who can perform and bill for service	Medicare Physician Fee Schedule	Medicare Outpatient Diabetes Center	Private Payer (2018)
95249	Initiation of person's own CGM	RN, PharmD/RPh, RD, CDE or MA	\$56.15	\$55.96	\$132
95250	Initiation of CGM; clinician owned equipment	RN, PharmD/RPh, RD, CDE or MA	\$156.58	\$113.69	\$300
95251	Interpretation of CGM data	Only MD/DO, NP, PA	\$36.72	Paid under the physician fee schedule	\$89

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- Encounter Documentation for Reimbursements**
- Documented glycemic control problem
 - Patient treatment plan
 - Patient's adherence to plan
 - Physician progress notes
 - Evaluations and consultations related to the diagnosis
- <https://provider.myfreestyle.com/pdf> #AADE19

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- Encounter Documentation for Reimbursement**
- Laboratory reports, including HbA1c
 - Blood glucose logs
 - Physician report with interpretation and findings based on information obtained during monitoring
- <https://provider.myfreestyle.com/pdf> #AADE19

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What Does the Person with Diabetes Needs to Know?

- How to apply and start their CGMs
- Importance of consistent wear of the device
- For FreeStyle Libre, frequent scanning of the sensor
- Accuracy of the CGMs in compare to actual Blood Glucose measurements
- Educating individuals on how to interpret their results once downloaded
- How the trend arrow works and how to use them to adjust insulin dosage

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Role of Diabetes Educator

- Identify the most suitable CGMs for individuals with diabetes
- Educate individuals on the features of the device
- Educate individuals on how to apply and use the device
- Discuss the accuracy of the data obtained by the device and the importance of fingerstick BG when needed

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