Case Based Continuous Glucose Monitoring Reports and Interpretation

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Disclosure:

No Conflicts of Interest to Disclose

This presentation is intended for educational purposes only and does not replace independent professional judgment.

I am expressing my own views of evidence medicine based on my reading, analysis and interpretation of the scientific information.

I am a member of SPED and a Federal Government employee, but I am <u>not</u> speaking in representation of or presenting the views of the Veterans Administration,

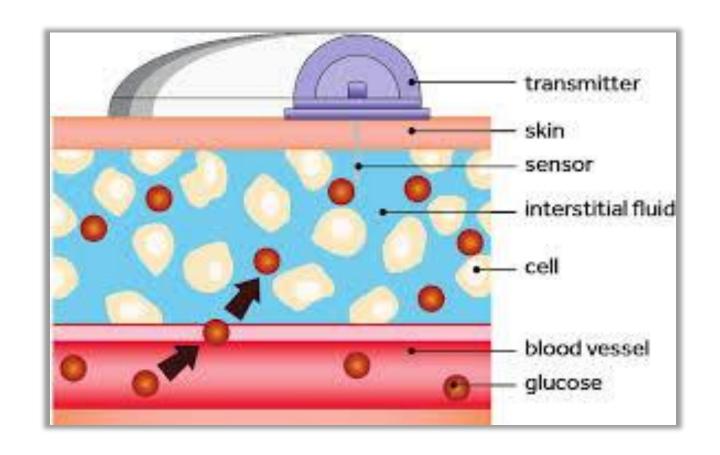
Puerto Rican Society of Endocrinology and Diabetes, State or Federal Government Agency or Department, other Professional Societies, Public or Private Corporation, or Pharmaceutical Company.

Learning Objectives

- At the end of this lecture, participants will be able to:
 - Understand the Continuous Glucose Monitoring (CGM) technology and the difference with the capillary blood glucose monitoring
 - □ Discuss the Continuous Glucose Monitoring systems in the market
 - Outline the Continuous Glucose Monitoring use recommendations.
 - □ Interpret the Ambulatory Glucose Profile (AGP)
 - □ Apply the concepts of CGM to real life cases

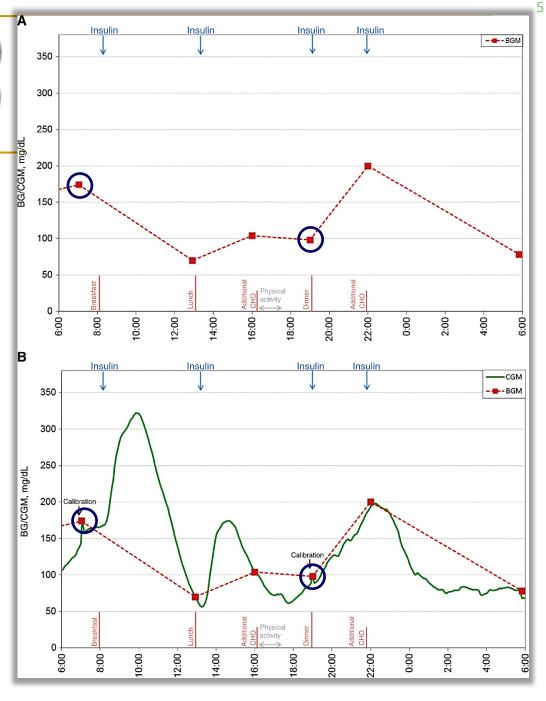
Continuous Glucose Monitoring (CGM)

- System
 - Sensor
 - □ Transmitter
 - □ Reader
 - Smart phones
 - CSII
 - CGM's Reader
- Continuous Glucose Monitoring is measuring interstitial glucose, not blood glucose, which lags behind ~ 15 minutes.



Self-Monitoring of Blood Glucose (SMBG) vs Continuous Glucose Monitoring (CGM)

- Self-monitoring of blood glucose (SMBG) systems have achieved improved accuracy; however, they offer only static information about glucose levels without taking into consideration the dynamic nature of glucose changes.
- Continuous Glucose Monitoring (CGM) technology has enabled patients and clinicians to gain a more comprehensive view of glycemic dynamic trends and patterns.



Continuous Glucose Monitoring (CGM)

- Currently, two different types of CGM systems are available on the market:
 - □ **Real-time continuous glucose monitoring** (rt-CGM) systems
 - System measures the glucose values and automatically display
 - □ **Intermittently scanned continuous glucose monitoring** (isc-CGM, flash glucose monitoring [FGM]) systems
 - Measures glucose levels every minute and stores one value every 15 min
 - System needs to be actively scanned to obtain glucose information and to show it on the device display.
 - The scans must be performed at least every 8 h

Personal Continuous Glucose Monitoring

Freckmann G. *J of Lab Med* 2020;44:71

Kravarusic, J Aleppo, G. *Endocrinol Metab Clin North Am* 2020; 49:37 Aleppo G. *J Diabetes Sci Technol*. 2019;13:664

	Dexcom G6®	Eversense [®] Eversense XL [®]	FreeStyle Libre® FreeStyle Libre 2®	Medtronic Guardian 3® or Enlite 2®
Population	<u>≥</u> 2 yrs	≥ 18 yrs	≥ 18/≥ 4 yrs	≥ 2 Guardian 3®
Sensor Life	10 days	90/180 days	14 days 6d Enlite/7d Guardian	
Application	Abdomen	Implanted Upper arm	Back Upper Arm	
Calibration	N/A Optional Manual	4 after warm-up then every 10-14 h	N/A	2-4 per day
Freq of Readings	5 mins	5 mins	Per scanning: every 1m but stored Q 15 m	
Technology	Enzyme Electrode	Optical Fluorescence	Enzyme Electrode	
Alert/Alarms	Yes	Yes	No/Yes	Yes
	Interoperable		No/Interoperable	
MARD	9	8.8	9.4/9.3	8.7-9.1/13.6
Manufacturer	Dexcom	Senseonics	Abbott	Medtronic

Personal Continuous Glucose Monitoring

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	Dexcom G6 [®]	Eversense [®] Eversense XL [®]	FreeStyle Libre® FreeStyle Libre 2®	Medtronic Guardian 3® or Enlite 2®
Population	<u>≥</u> 2 yrs	≥ 18 yrs	≥ 18/≥ 4 yrs	≥ 2 Guardian 3®
Sensor Life	10 days	90/180 days	14 days	6d Enlite/7d Guardian3
Application	Abdomen	Implanted Upper arm	Back Upper Arm	
Calibration	N/A None Optional Ma	or ESRD patients.		2-4 per day
Freq of Readings	5 mins			
Technology	Enzyme Electrode	Optical Fluorescence	Enzyme Electrode	
Alert/Alarms	Yes	Yes	No/Yes	Yes
	Interoperable		No/Interoperable	
MARD	9	8.8	9.4/9.3	8.7-9.1/13.6
Manufacturer	Dexcom	Senseonics	Abbott	Medtronic

Pregnancy: CONCEPTT Trial CGM therapy is not yet approved for use during pregnancy.

NON-FDA APPROVED

- 215 women with T1DM preconception or less than 14 weeks of gestation in MDI or CSII.
- Randomized to CGM vs SBGM
- CGM patients:
 - □ **↓** in A1c 0.19% (p=0.02)
 - Were 100 min/d in target (70-140)and 72 fewer mins in HyperG

Offspring:

- - HR = 0.51 (CI: 0.28 -0.90)
- □ ↓ admission to neonatal ICU
 - HR = 0.48 (CI: 0.26-0.86)
- → episodes of neonatal hypoglycemia requiring IV dextrose
 - HR = 0.45 (CI: 0.22-0.89)

Professional Continuous Glucose Monitoring

Professional CGM is a way to introduce CGM technology to the patients

	Dexcom G6 Pro®	FreeStyle Libre Pro®	Medtronic Enlite iPro2® Guardian Connect®
Sensor Life	10 days	14 days	6/7 days
Application			
Calibration	No	No	Yes, every 12-hrs
Freq of Readings			
Technology			
Alert/Alarms	Yes, if unblinded	NA	NA/Yes
MARD	9	12.3	13.6
Manufacturer	Dexcom	Abbott	Medtronic

Kravarusic, J Aleppo, G. *Endocrinol Metab Clin North Am* 2020; 49;37 Aleppo G. *J Diabetes Sci Technol*. 2019;13:664

American Diabetes Association Standard of Care

- 7.9/7.10 When used properly, real-time continuous glucose monitors/ intermittently scanned continuous glucose monitors in conjunction with insulin therapy are useful tools to lower A1C levels and/or reduce hypoglycemia in adults with type 1 diabetes who are not meeting glycemic targets, have hypoglycemia unawareness, and/or have episodes of hypoglycemia. A/C
- 7.11 When used properly, real-time and intermittently scanned continuous glucose monitors in conjunction with insulin therapy are useful tools to lower A1C and/or reduce hypoglycemia in adults with <u>type 2 diabetes who are not</u> <u>meeting glycemic targets</u>. B

Continuous Glucose Monitoring

Improves quality of life

Benefits

- Improved glycemic control
- Decreased hypoglycemic events
 - Impaired hypoglycemic awareness
 - Nocturnal hypoglycemia
- Attenuate the fear of hypoglycemia events
 - □ Alarms/Alerts/Share features
- Attenuate diabetes-related stress
- Reduce need for finger sticks
- Shows glucose variability and patterns of hypo- and hyperglycemia

Barriers

- Time required education
- Cognitive restraints
 - □ Initial or during course of treatment
- Dexterity or physical decline
- Anxiety
- Visual/hearing impairments
- Alarm/alert fatigue
- Insurance coverage/Cost
- Clinical practice integration
- Aversion to wear a device
- Signal to others of having DM

Freckmann G. *J of Lab Med* 2020;44:71

Continuous Glucose Monitoring

Therefore, improves quality of life.

Benefits

Barriers

Improved glycem

Decreased hypog

- Impaired hypogly
- Nocturnal hypogly
- Attenuate the fea events
 - □ Alarms/Alerts/Share features
- Attenuate diabete
- Reduce need for

Shows glucose valuability and patterns of hypo- and hyperglycemia

This can be time-consuming and may dissuade the busy provider, but with regular practice, interpretation of ambulatory glucose profiles becomes guite simple and can be effectively streamlined.

Health insurance coverage/Cost

Be careful with device upgrades. Tell the patients to always check compatibility with their equipment PRIOR upgrading!

of treatment

ecline

nents

Clinical practice integration

Freckmann G. *J of Lab Med* 2020;44:71

Toschi E Munshi MN. Endocrinol Metab Clin North Am 2020;49: 57

American Diabetes Association Standard of Care

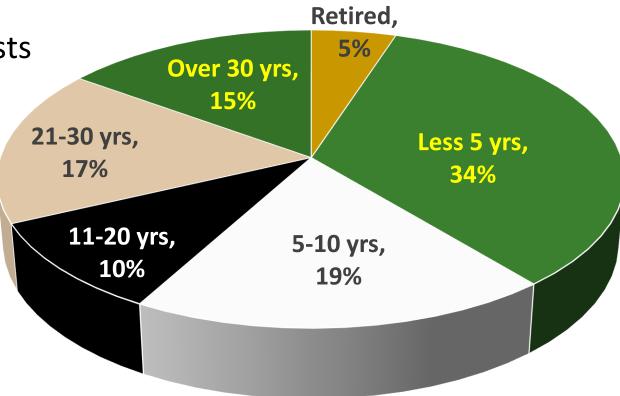
■ 7.8 When prescribing continuous glucose monitoring (CGM) devices, <u>robust</u> <u>diabetes education, training, and support are required</u> for optimal CGM device implementation and ongoing use. People using CGM devices need to have the ability to perform self-monitoring of blood glucose in order to calibrate their monitor and/or verify readings if discordant from their symptoms. E

Survey Thanks to all who replied

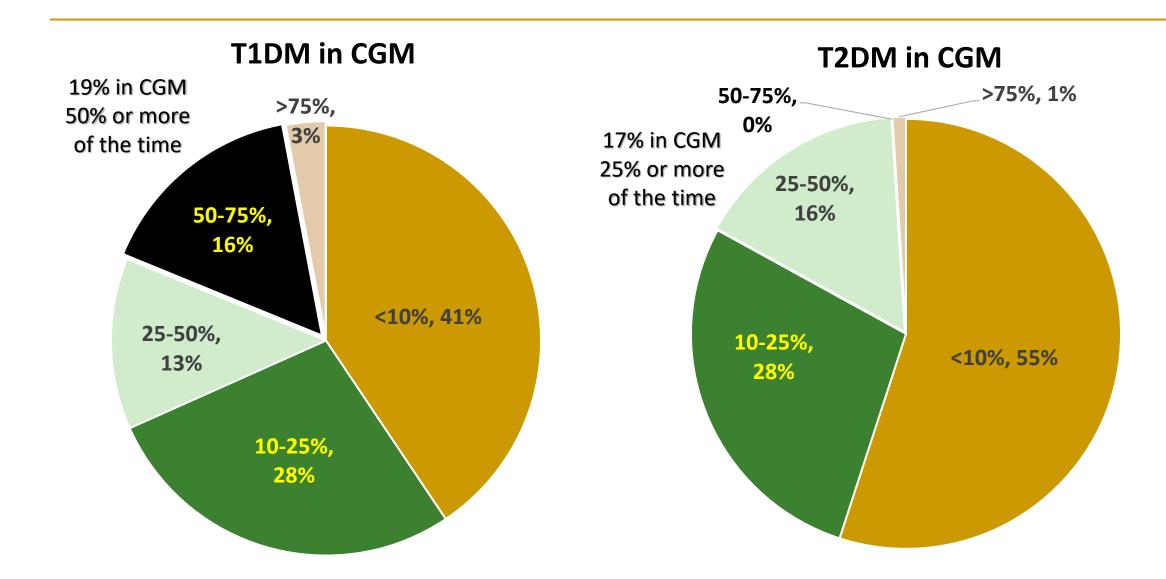
- 79 Replies
 - □ 65% response rate

69 adult endocrinologists

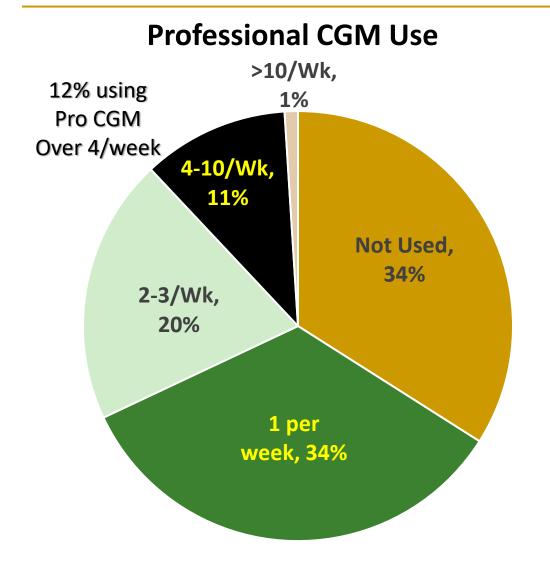
■ 10 pediatric endocrinologists



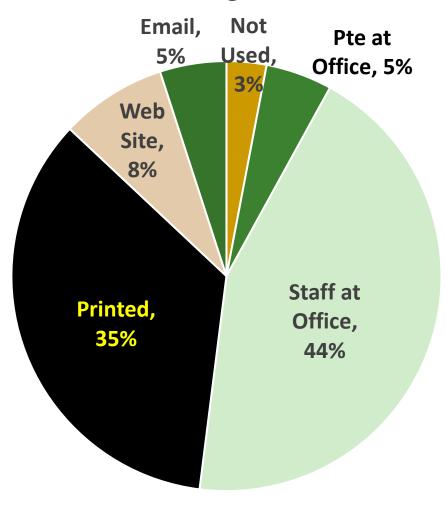
Patient NOT using CSII who are using CGM

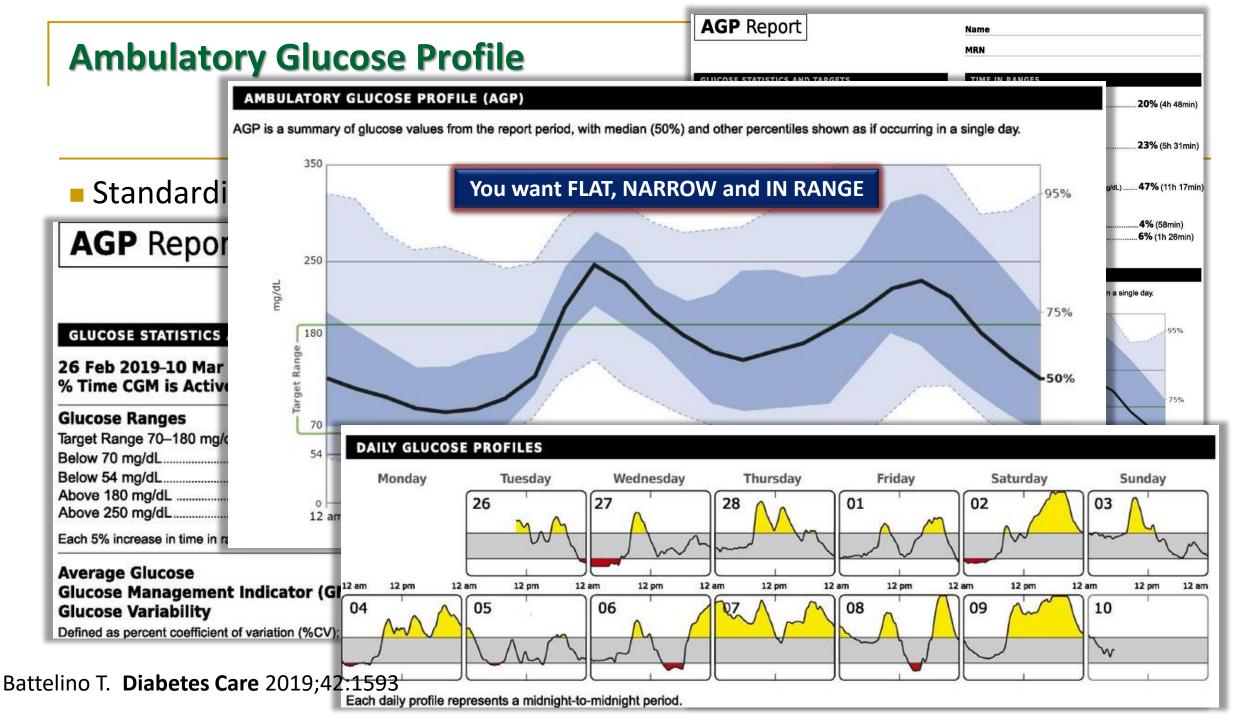


Professional CGM and Patient's Sharing Data

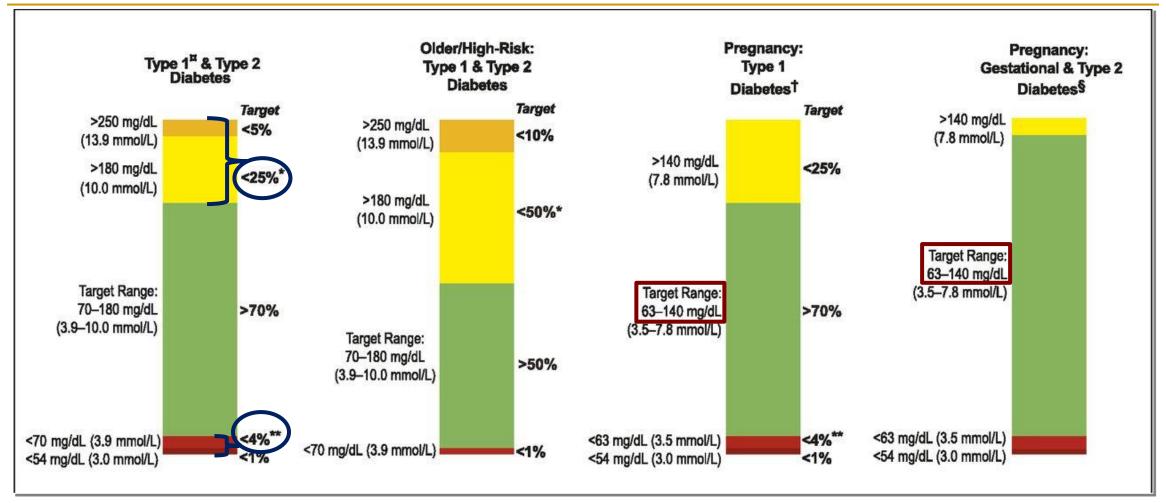


Data Sharing Method



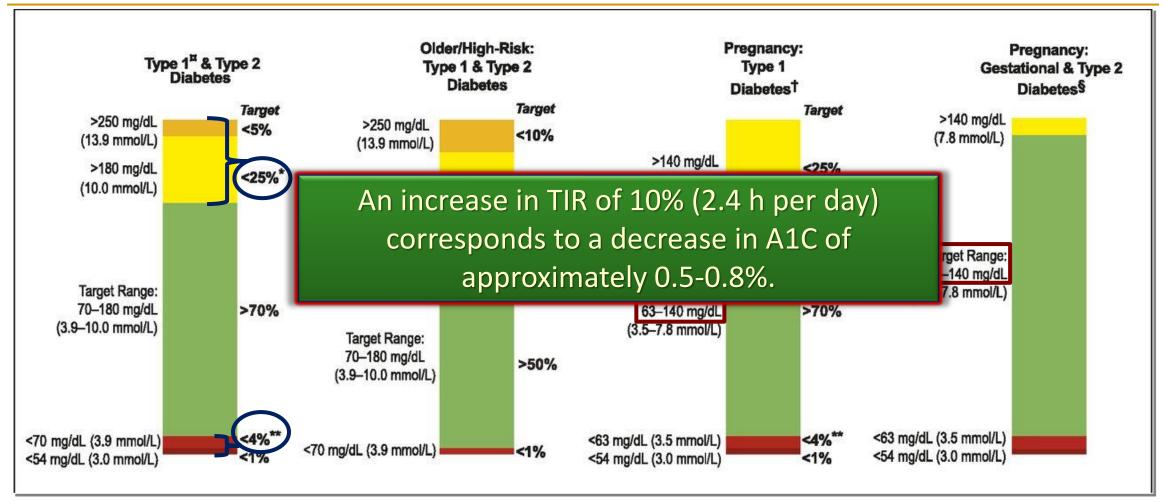


CGM-based targets for different diabetes populations.



Battelino T. **Diabetes Care** 2019;42:1593

CGM-based targets for different diabetes populations.



Battelino T. **Diabetes Care** 2019;42:1593

Suggested Approach to Ambulatory Glucose Profile (AGP)

Johnson ML, *Diabetes Technol Ther* 2019;21 Suppl 2:S217 Aleppo G. *J Diabetes Sci Technol*. 2019;13:664

- Make sure there are adequate data for decision making
- 2. Identify:
 - Waking, breakfast, lunch, dinner and bedtime times
 - Medication and doses used
 - Exercise or snacking time
- 3. Ask the patient to tell you what do they see
- 4. Look for patterns of low glucose readings
 - Isolated or recurrent?
 - Weekends vs. weekdays?
 - Physical activity, missed meal, meal type, alcohol related, insulin & meal alignment?
- 5. Look for patterns of high glucose readings
 - How many times per week a medication may have been forgotten?
 - Is meal-time insulin taken before meals?
 - Check for differences in weekend vs. weekdays
 - □ Be conservative if there is hypoglycemia 12-18 hours later

Suggested Approach to Ambulatory Glucose Profile (AGP) (Cont'd)

- 6. Discuss areas where darker blue (50% of values) or lighter blue (90% of values) shaded areas are very wide (corresponding to high glucose variability).
- 7. Compare current AGP and CGM metrics to those from last visit (or contact), if available, and discuss progress.
- 8. Agree on an action plan consisting of one or two specific recommendations:
 - Treat hypoglycemia first
- 9. Print a copy of the marked-up AGP for the patient and store a PDF of the AGP into the EMR, if possible, or at least copy (snip) and paste the AGP into the EMR progress note.

Ambulatory Glucose Profile (AGP) Interpretation

- To maximize the benefits of CGM sessions in clinical practice, patients should be advised to keep a blood glucose log, as well as medication, food and activity diary.
- CGM data always need to be assessed in context to the patients' carbohydrate intake, insulin dosing and physical activity.
- Documenting events that may contribute to changes in glucose levels such as physical activity, stressors, illness, menses, special events, is also advised.

Frequent Behavior Pitfalls Identified Upon Evaluating the Continuous Glucose Monitoring

- Insulin dosing during or after meals
- Holding or delaying insulin doses for near-normal BG before a meal
- Overreliance on post-meal correction doses
- Multiple small corrective insulin boluses.
- Inaccurate carbohydrate counting
- Neglecting effects of protein and fat intake

Sensors' Problems

- Skin Reactions
 - Skin protection barrier may help
 - Rotate sites to preserve skin integrity

Early Detachment

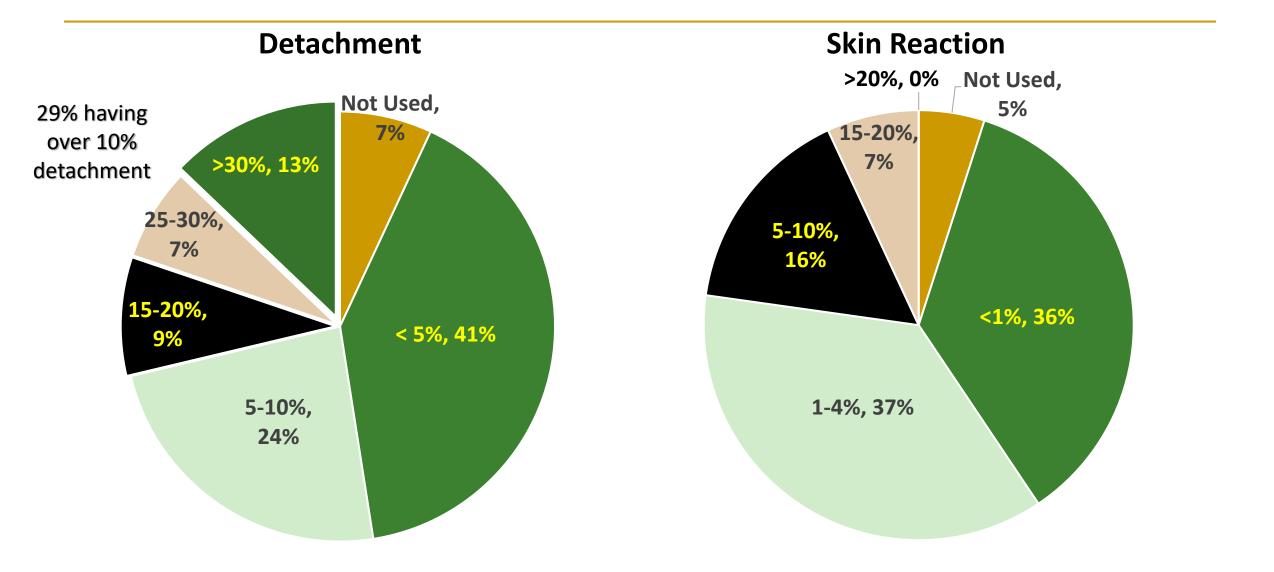








Sensor Detachment and Skin Reactions



VCR

VCR Oct 2019

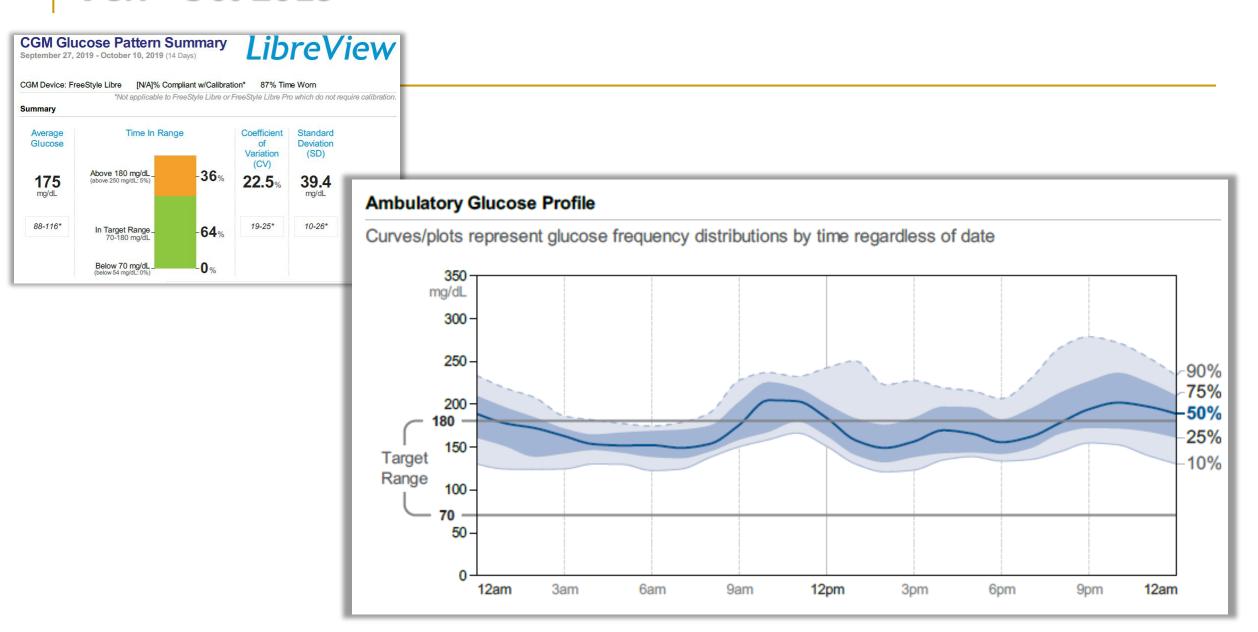
- 74-year-old male patient with T2DM Dx in 2008 using:
 - Glargine 60 units bedtime
- Intolerant to metformin
- Monitors CBG once or twice a week
- A1c progressively increasing from 7.0% to 8.2% to 9.0% during last year
- He refuses to add pre-prandial insulin or to monitor more frequently
- Agreed to try FreeStyle Libre 14 days. No covered by his health insurance.

VCR - Oct 2019

LibreView **CGM Glucose Pattern Summary** September 27, 2019 - October 10, 2019 (14 Days) CGM Device: FreeStyle Libre [N/A]% Compliant w/Calibration* 87% Time Worn *Not applicable to FreeStyle Libre or FreeStyle Libre Pro which do not require calibration. Summary Time In Range Coefficient Standard Average Glucose of Deviation Variation (SD) (CV) Above 180 mg/dL_ 36% 22.5% 175 39.4 (above 250 mg/dL: 5%) mg/dL mg/dL 19-25* 88-116* 10-26* 64% In Target Range_ 70-180 mg/dL Below 70 mg/dL _ (below 54 mg/dL: 0%) 0%

VCR - Oct 2019

Glargine 60 units bedtime



VCR - Oct 2019

SAT Oct 5

Glucose mg/dL

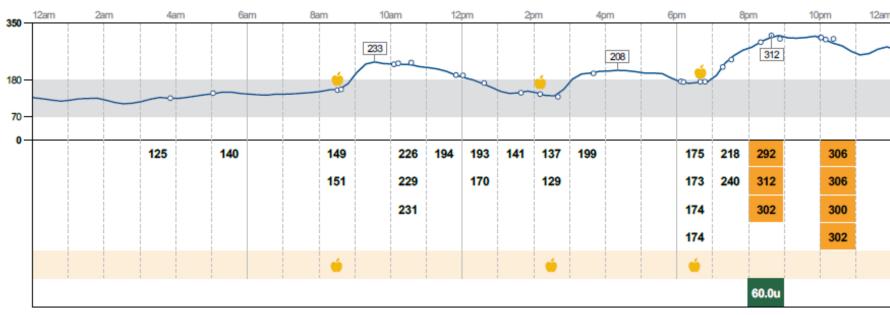
Carbs grams

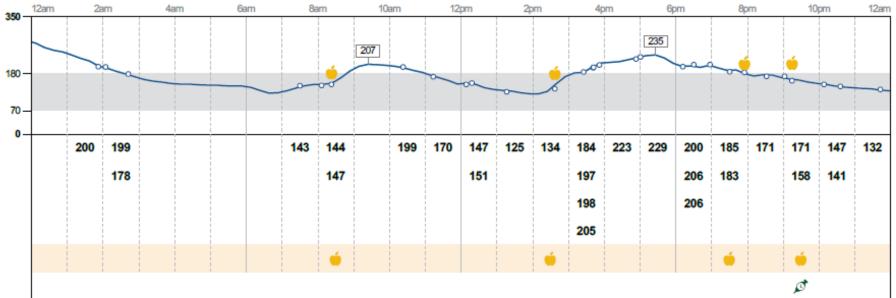
SUN Oct 6

Glucose mg/dL

Carbs grams

C Long-Acting Insulin





VCR - Jan 2020

CGM Glucose Pattern Summary

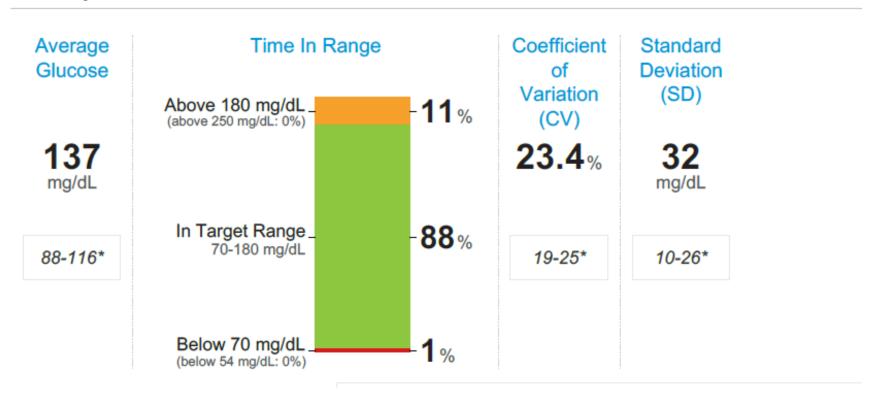
January 8, 2020 - January 21, 2020 (14 Days)



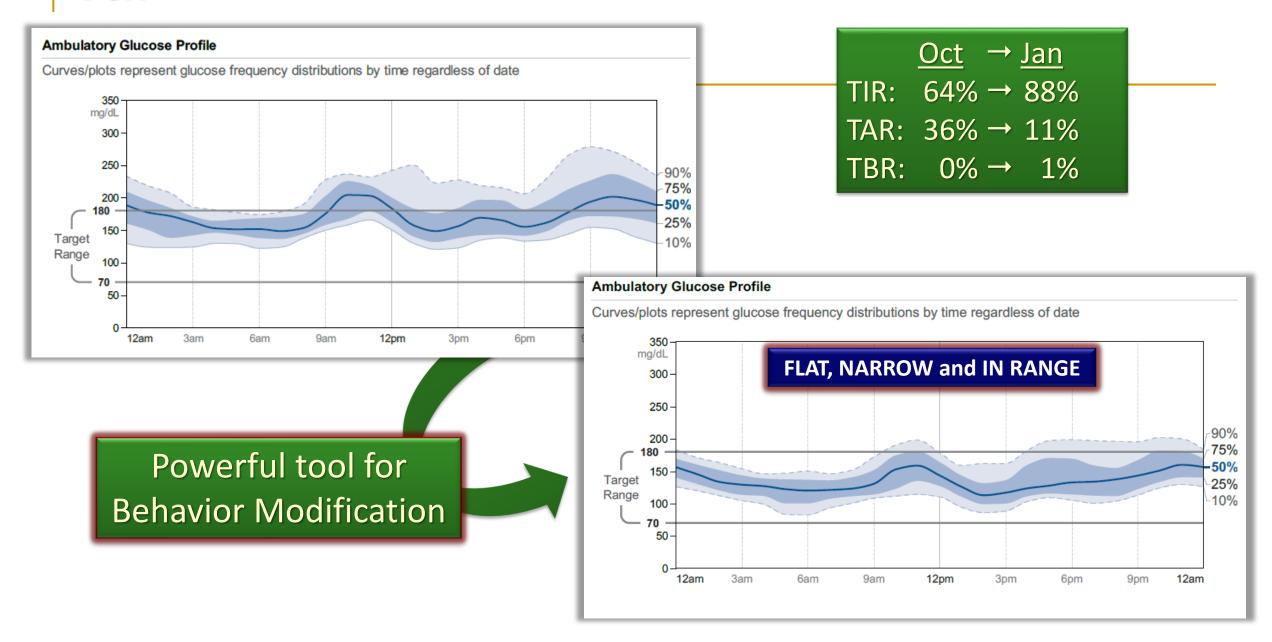
CGM Device: FreeStyle Libre [N/A]% Compliant w/Calibration* 91% Time Worn

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

Summary



VCR



Case JOV

Pte JOV Case Consult for Professional CGM

74-year-old male patient with T2DM using:

□ Glargine 300 unit/ml: 110 units AM

□ Aspart25 units prior breakfast

□ Aspart 25 units prior lunch

□ Aspart 30 units prior dinner

□ Empagliflozin 12.5mg AM

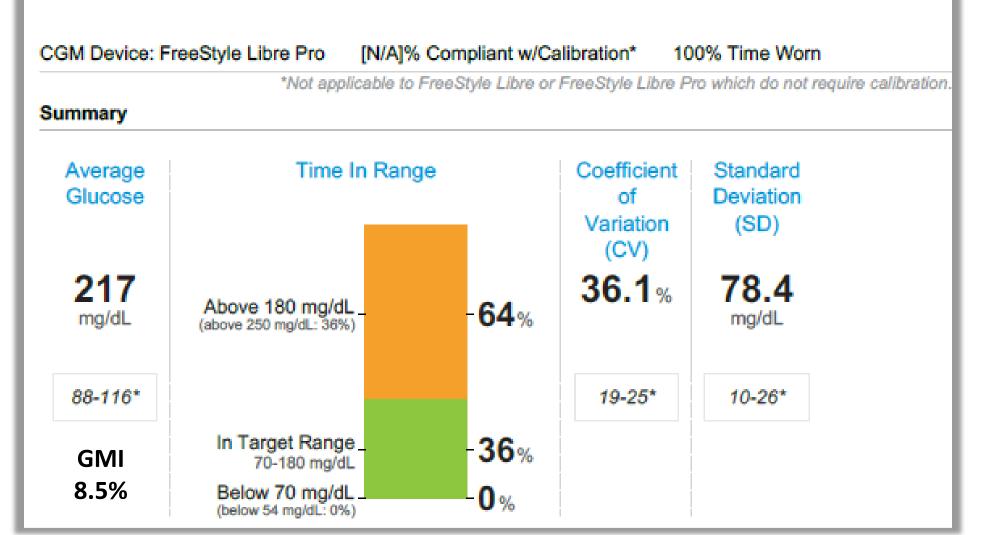
- Monitoring capillary blood glucose (CBG) once daily AM with values 99-240mg/dL with a median and average of 176 mg/dL.
- A1c at 9.1%, estimated average glucose of 214mg/dL

Pte JOV

CGM Glucose Pattern Summary

January 17, 2020 - January 31, 2020 (15 Days)





Pte JOV

Glargine 110 units AM

Aspart 25 units prior breakfast

Aspart 25 units prior lunch

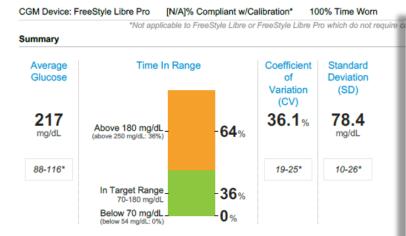
Aspart 30 units prior dinner

Empagliflozin 12.5mg AM

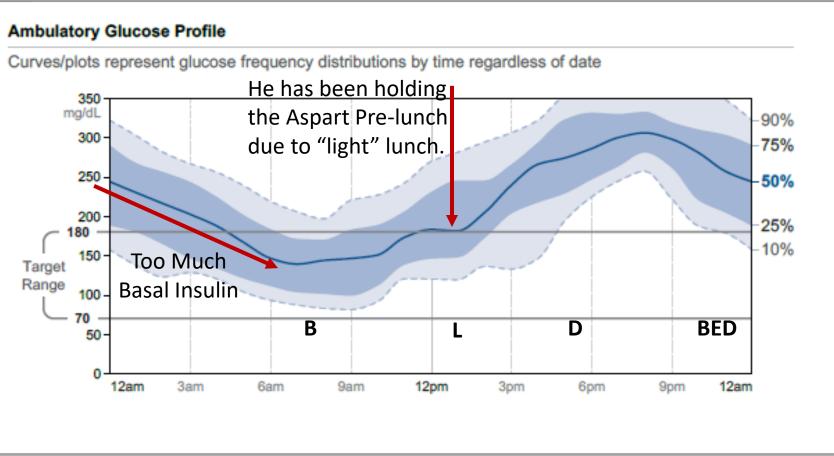
CGM Glucose Pattern Summary

January 17, 2020 - January 31, 2020 (15 Days)

LibreView



- His lunch and dinner are very similar
- 7:30 PM corn flakes with milk



Pte JOV

The provider was advised to either:

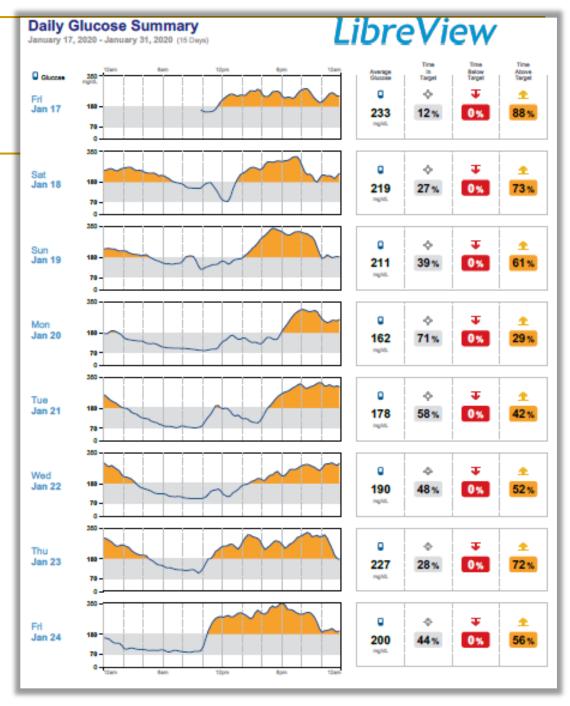
- Switch the aspart and glargine insulin to Concentrated U-500 insulin:
 - □ 110 units PRIOR breakfast
 - 50 units PRIOR PM dinner

OR

 Add Semaglutide weekly titrate according to glycemia up to maximal dosage and reduce glargine

OR

Add aspart pre-lunch ~25 and reduce
 Glargine by the same amount



Patient FSC

Patient FSC - Jan 2020

- 66 year old male patient with T2DM (Dx 1997) for 23 years. s/p kidney (2012) and liver (2006) transplants. He denied hypoglycemic events
- Patient Rx with glargine 33 units ~9PM and aspart prior each meal 10-6-16, adjusted according to CBG.
- Monitor CBG twice daily.

	90 Days	30 Days	1A	M	PM
■ Average	183	211	12	23	226

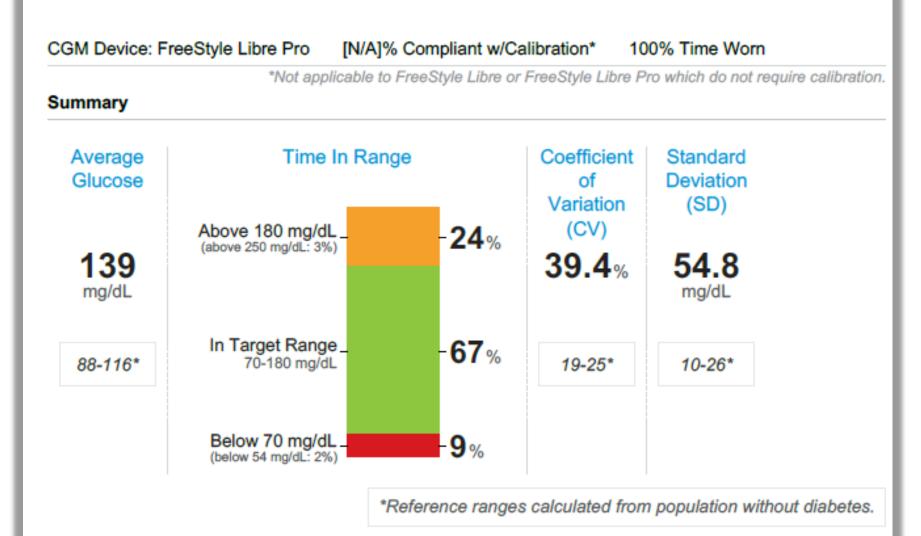
- His eGFR has been ~ 45ml/min
- A1c has been 6.9 to 7.4%; eAG: 151 to 166 mg/dL
- Fructosamine 344 to 395 μmol/L (RR: 205-285)

Patient FSC - Jan 2020

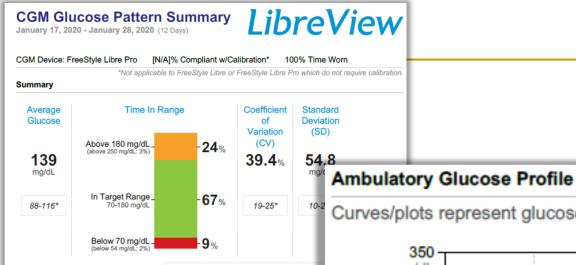
CGM Glucose Pattern Summary

January 17, 2020 - January 28, 2020 (12 Days)



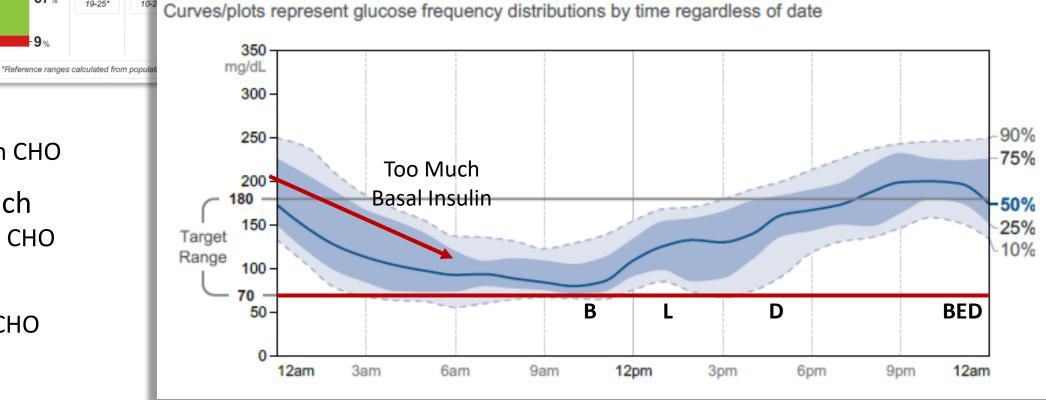


Patient FSC - Jan 2020



Glargine 33 units ~9PM Aspart prior each meal 10-6-16

- Breakfast
 - □ 50-70 gm CHO
- "light" lunch
 - □ 54-74gm CHO
- Dinner
 - □ 100 gm CHO



Patient FSC Nov 2020

■ The glargine was reduced from 33 to 28 units bedtime, which he did not do it.

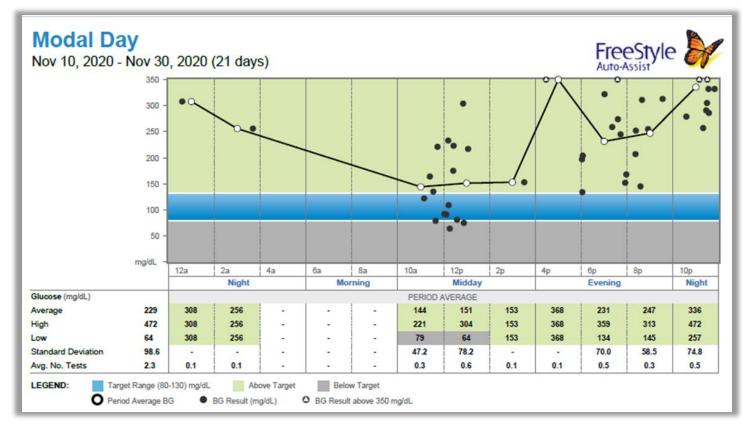
The aspart was left unchanged because he

was holding aspart frequently:

- □ AM dosage because of CBG ~ 120mg/dL
- Lunch because it was light
- □ He decided to modify it to CBG/20 after breakfast and supper.
- Capillary Blood Glucose

	<u>30 days</u>	<u>90 days</u>
Avg	231	214
Test/Day	2.2	2.2

Denied reported hypoglycemia



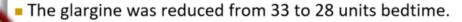
Patient FSC

Patient Rx with glargine 33 units ~9PM and aspart prior each meal 10-6-16, adjusted according to CBG.

Monitor CBG twice daily.

90 Days 30 Days AM PM

□ Average 183 211 123 226



The aspart was left unchanged but he decided to modify it to CBG/20 afte breakfast and supper.

Capillary Blood Glucose

	<u>30 days</u>	<u>90 days</u>
Avg	231	214
Test/Day	2.2	2.2

AGP Report

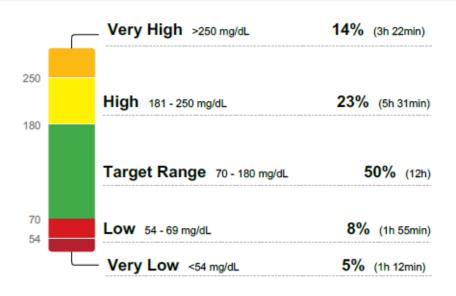
November 17, 2020 - November 30, 2020 (14 Days)

GLUCOSE STATISTICS AND TARGETS

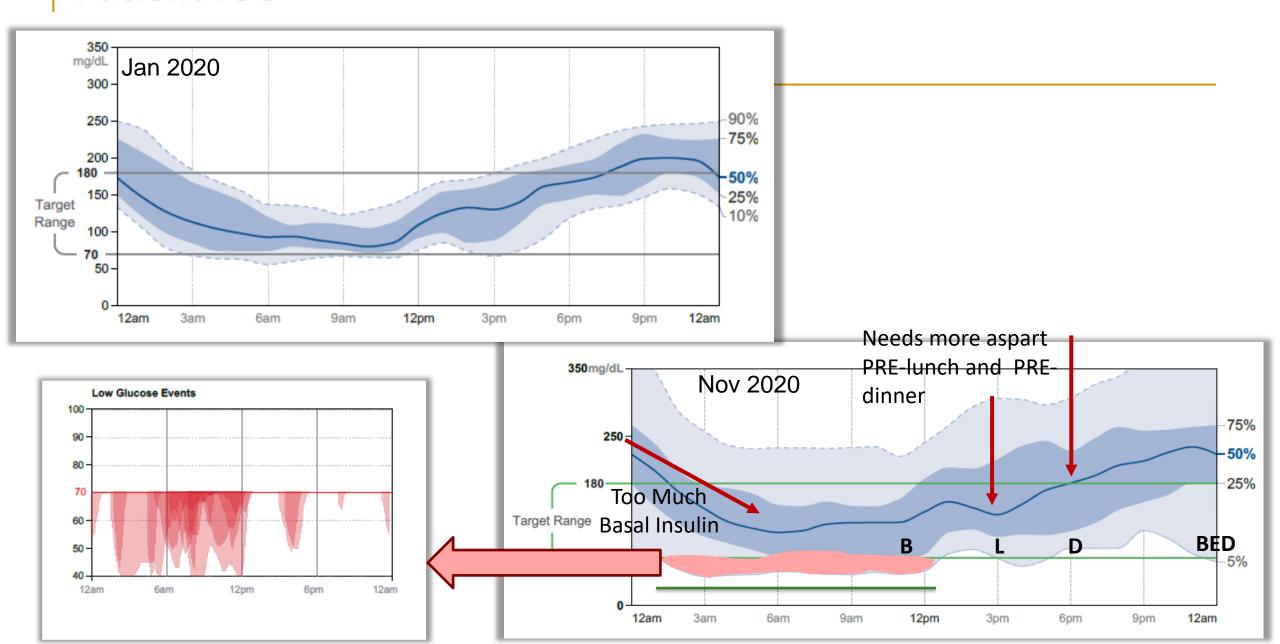
November 17, 2020 - November 30, 2020 14 Days % Time CGM is Active 100%

Ranges And Targets For	Type 1 or Type 2 Diabetes	
Glucose Ranges Target Range 70-180 mg/dL	Targets % of Readings (Time/Day) Greater than 70% (16h 48min)	
Below 70 mg/dL	Less than 4% (58min)	
Below 54 mg/dL	Less than 1% (14min)	
Above 180 mg/dL	Less than 25% (6h)	
Above 250 mg/dL	Less than 5% (1h 12min)	
Each 5% increase in time in range (70-180 mg/dL) is clinically beneficial.		

Average Glucose	163 mg/dL
Glucose Management Indicator (GMI)	7.2%
Glucose Variability	49.5%
Defined as percent coefficient of variation (%CV); target ≤36%	



Patient FSC



Glucose Management Indicator (GMI)

If the GMI is considerably different than the laboratory HbA1c, it may be important to take this difference into account when setting an HbA1c goal.

A1C (0/)	Mean plasma	
A1C (%)	glucose (mg/dL)	
6 %	126 (100–152)	
7 %	154 (123–185)	
8 %	183 (147–217)	
9 %	212 (170–249)	

- Ex: The GMI estimates the HbA1c to be 7.4% and the laboratory HbA1c is 8%
 - □ The actual glucose levels are lower than one would typically associate with the laboratory HbA1c of 8%.
 Therefore, should be very carefully in trying to reach lower A1c and probably the goal should be 8%

- 64 years old male patient diagnosed with Type 1 DM in Mar 2018 when he presented with DKA and positive Anti GAD-65 antibodies.
- He was trained in Dexcom G6 in Dec 2019 but did not start using it until the end of January due to detachment of the sensors and then problems with the reader that required the company to change the reader.

	Prior CGM	While in CGM
Basal	Glargine 16 at 9PM	Glargine 16 at 9PM
Pre-Prandial Aspart	~ 8 units pre meal	~ 8 units pre meal
	Adjust per table for CBG Adjust if overeating	Adjust per table for CBG Adjust if overeating

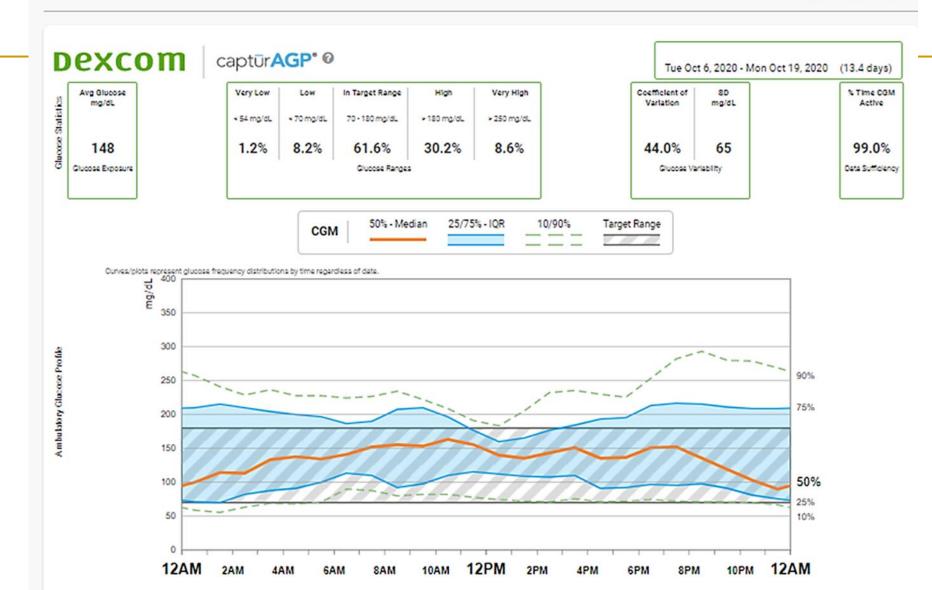
AGP

14 Days Tue Oct 6, 2020 - Mon Oct 19, 2020 🖍

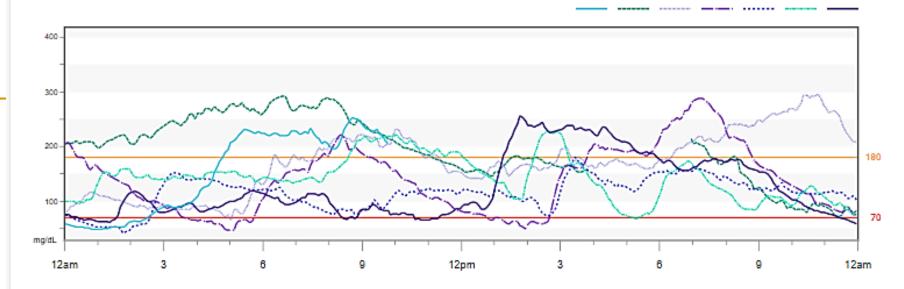




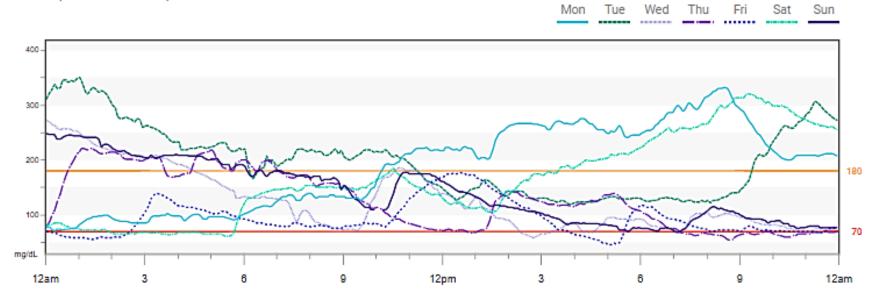


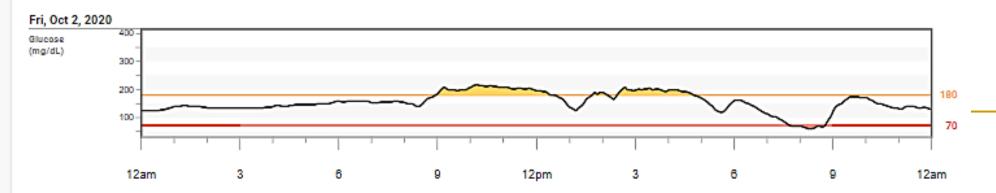


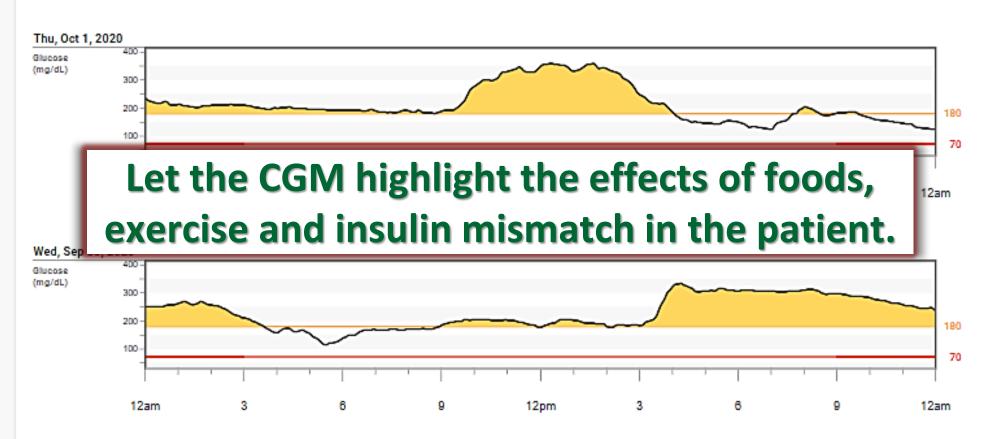


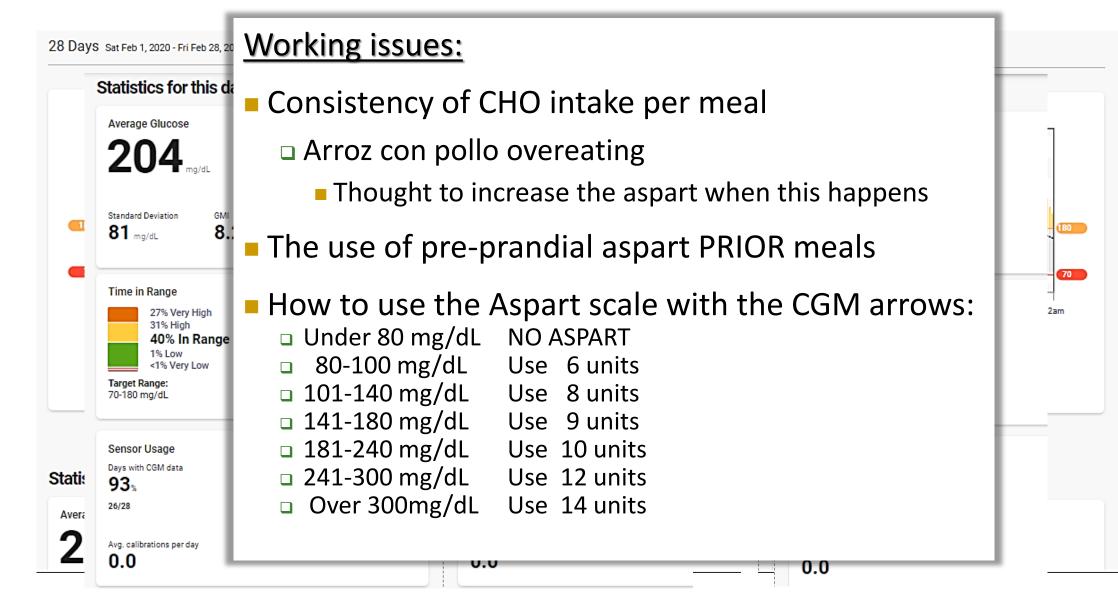


Week 1 Tue Oct 6, 2020 - Mon Oct 12, 2020









Rate of Change Trend Arrows

	Medtronic Guardian 3 or Connect	Dexcom G6	FreeStyle Libre 14 FreeStyle Libre 2	Sensonic Eversense
† † †	≥3mg/dL/min	N/A	N/A	N/A
† †	<pre>>2 but <3mg/dL/min</pre>	>3mg/dL/min	N/A	N/A
†	≥1 but <2mg/dL/min	>2 but <3mg/dL/min	>2mg/dL/min	>2mg/dL/min
7	N/A	1 to 2 mg/dL/min	1 to 2mg/dL/min	1 to 2mg/dL/min
→	N/A	< 1mg/dL/min	< 1mg/dL/min	≤ 1mg/dL/min
`\	N/A	1 to 2 mg/dL/min	1 to 2mg/dL/min	1 to 2mg/dL/min
\	≥1 but <2mg/dL/min	>2 but <3mg/dL/min	>2mg/dL/min	>2mg/dL/min
++	<pre>>2 but <3mg/dL/min</pre>	>3mg/dL/min	N/A	N/A
+++	≥3mg/dL/min	N/A	N/A	N/A

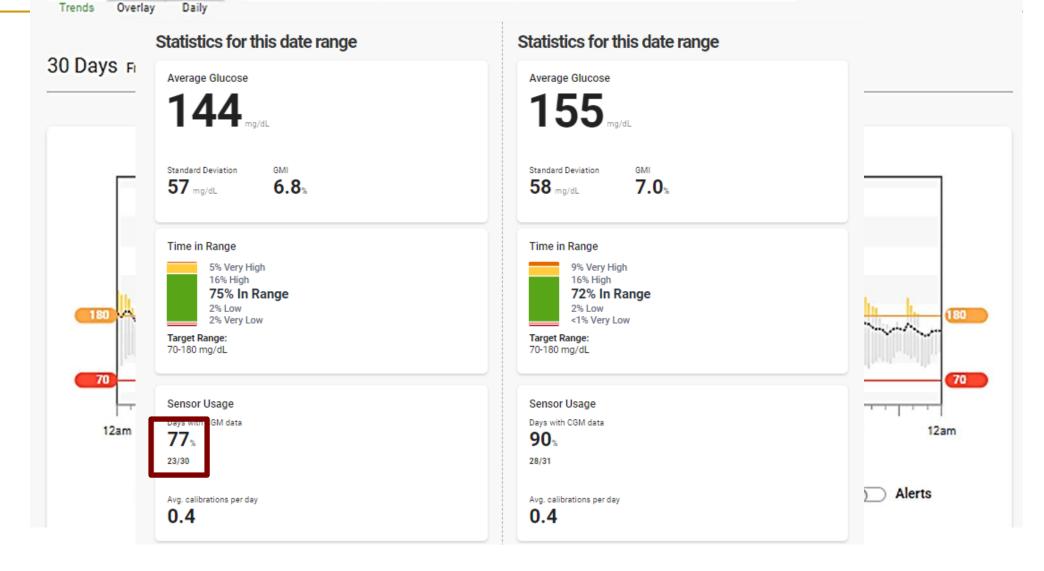
Comparison Feature of Dexcom with Clarity Software

55

AAP Compare

to compare side-by-side.

DAYS • TIME OF DAY **EVENTS** USAGE



Cost & Coverage

Local Cost

□ FreeStyle Libre 14 days: \sim \$60/14 days = \$4.30/day

□ Dexcom G6: $^{\$}118/10 \text{ day} + ^{\$}230-500/90 \text{ days} = $15 - $17/day$

Medicare Coverage

- If using insulin and requiring frequent adjustments to the insulin regimen/dosage, including the need to:
 - Frequently check your blood sugar (four or more times a day)

AND

□ Either use an insulin pump or receive three or more insulin injections per day

Reimbursement

CMS 2020 Fee Schedule

\$56.00

\$153.84

\$36.87

95249* (Personal)

- Startup & Training
- Patient provides equipment
- Patient education
- Sensor placement
- Requires a minimum of72 hours of data
- Once during the time period that patient owns de device

95250* (Professional)

- Patient education
- Sensor placement
- Sensor removal
- Data download
- Generate reports
- Requires a minimum of72 hours of data
- Once monthly per patient.

95251*

- Healthcare provider interprets and reports, either personal or professional.
- Requires a minimum of72 hours of data
- Once monthly per patient.

^{*}Medicare does not reimburse for a CGM system if a smart device is used to display glucose data.

^{*}E/M codes can be used with modifier "-25_ if significant and separately identifiable services took place above and beyond the services associated with CGM

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95251*

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□ Patient provides <u>Medicare Advantage</u>

- Inconsistent coverage
- Fee for professional is ~ \$ 110 to 158

■ Requires a minin Commercial Insurances

- Some of the plan reimburse at a lower rate.
- Most plan may not cover them at all.
- Fee for professional is ~ \$ 50-60
 - Not cost effective
- 95251 reimbursed at \$ 25-30

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lucose data.

^{*}E/M codes can be used with modifier "-25_ if significant and separately identifiable services took place above and beyond the services associated with CGM

Summary/Conclusions

- Continuous Glucose Monitoring (CGM) improves the glycemic control and quality of life of the patients with diabetes mellitus
- CGM requires continuous education to derive its maximal benefit.
- The Ambulatory Glucose Profile provides a standardized quick summary of that is going on with the patient.
- Cases:
 - □ The role of CGM in behavior modification
 - □ Examples of too much basal insulin
 - Postprandial hyperglycemia due to:
 - CHO underestimate
 - Lack or misaligned rapid/short acting insulin administration related to meal intake
 - Hypoglycemia unawareness
 - □ Skin reactions and sensors detachment

Post-Test

■ The black line in the graph of the Ambulatory Glucose Profile (AGP), represents the:

- A. Average glucose
- B. Linear regression
- C. Standard Deviation
- D. Standard Error
- E. Median glucose

Post-Test

■ An Increase in Time in Range of 10% corresponds to a decrease in A1c of approximately:

- A. 0.00% to 0.49%
- B. 0.50% to 0.74%
- C. 0.75% to 0.99%
- D. 1.00% to 1.49%
- E. Over 1.49%

Post-Test

- Although Continuous Glucose Monitoring has NOT been approved by the FDA to be used during pregnancy, if used, the recommended target range is:
 - A. 60-120 mg/dL
 - B. 63-140 mg/dL
 - C. 70-130 mg/dL
 - D. 74-140 mg/dL
 - E. 80-120 mg/dL

COMMENT? CONCERN?

