Continuous Glucose Monitoring (CGM)



Ji Hyun Chun (CJ), PA-C, BC-ADM

Medical Science Liaison, Corcept

Immediate Past President, American Society of Endocrine PAs

OptumCare Medical Group: Endocrinology, Irvine, CA

Objectives

- Acknowledge the unmet need of A1c and finger stick blood glucose monitoring
- Review current state of glucose monitoring technology with CGM
- Review how to interpret and bill for CGM

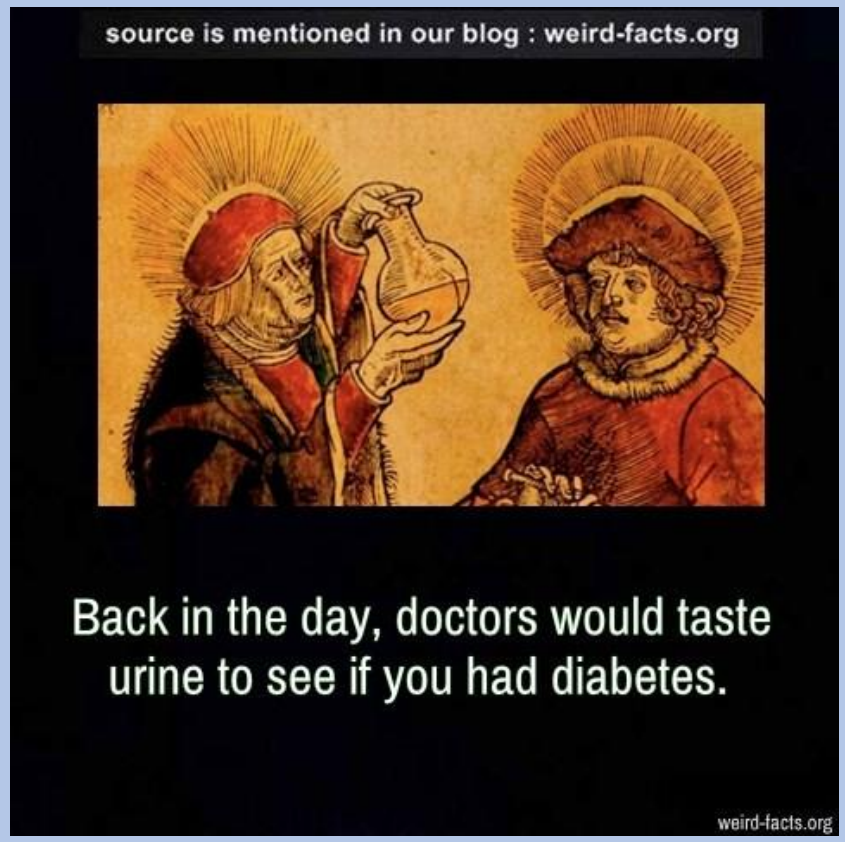
Glucose Monitoring

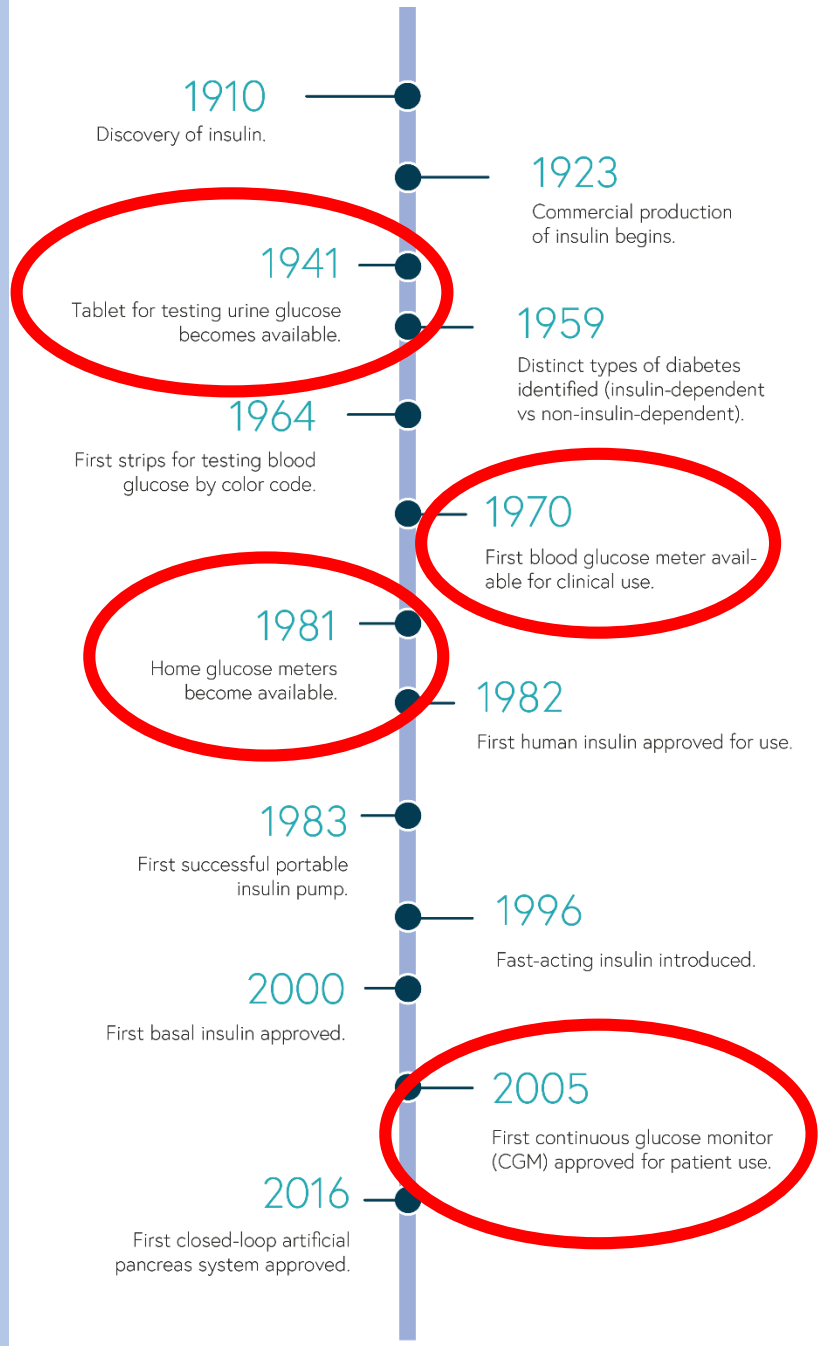
<u>Diabetes Mellitus</u> (from ancient Greek) means

Diabetes -“siphon” and

Mellitus - 'honey sweet flow' from a time in which tasting a patient's urine was still part of the provider's diagnostic repertoire.

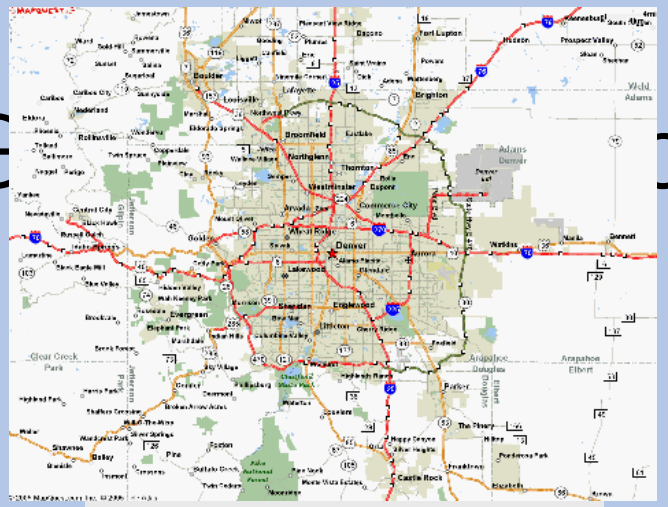





1910
Discovery of insulin.
1923
Commercial production of insulin begins.
1941
Tablet for testing urine glucose becomes available.
1959
Distinct types of diabetes identified (insulin-dependent vs non-insulin-dependent).
1964
First strips for testing blood glucose by color code.
1970
First blood glucose meter available for clinical use.
1981
Home glucose meters become available.
1982
First human insulin approved for use.
1983
First successful portable insulin pump.
1996
Fast-acting insulin introduced.
2000
First basal insulin approved.
2005
First continuous glucose monitor (CGM) approved for patient use.
2016
First closed-loop artificial pancreas system approved.

G ori

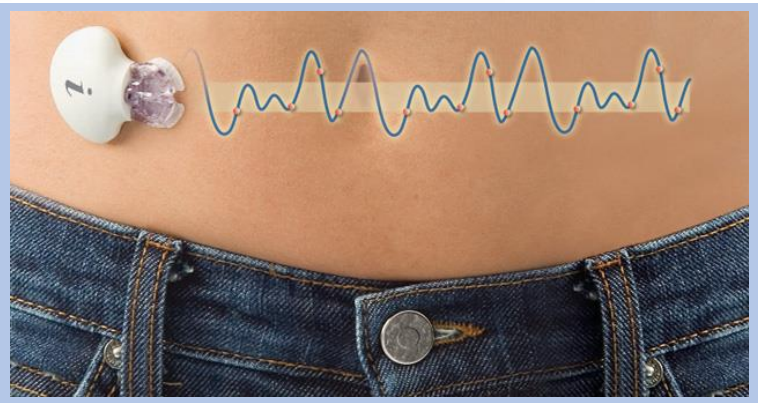












A1c: ↓ ↓

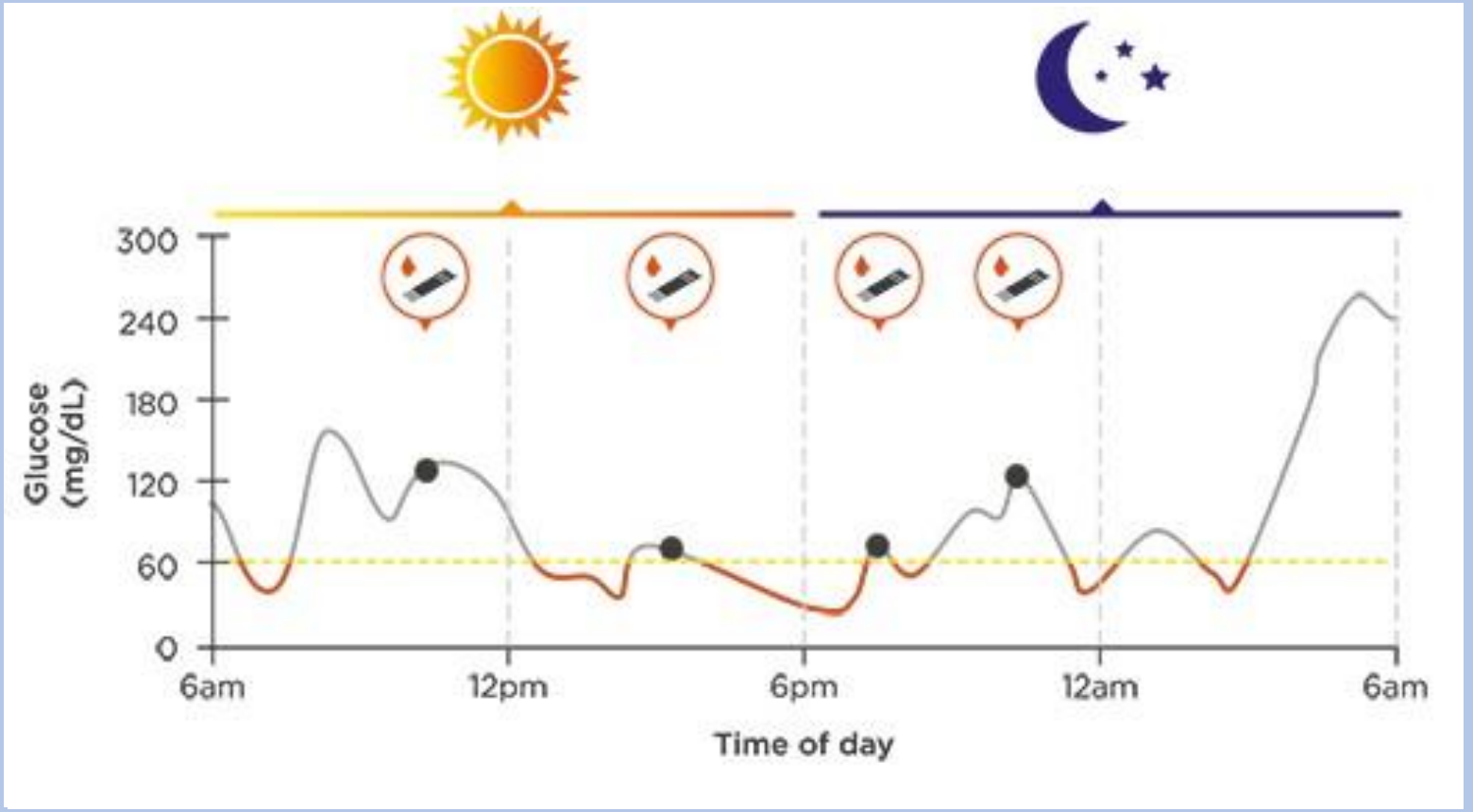
Hypo: ↑ ↓







Continuous Glucose Monitoring (CGM)



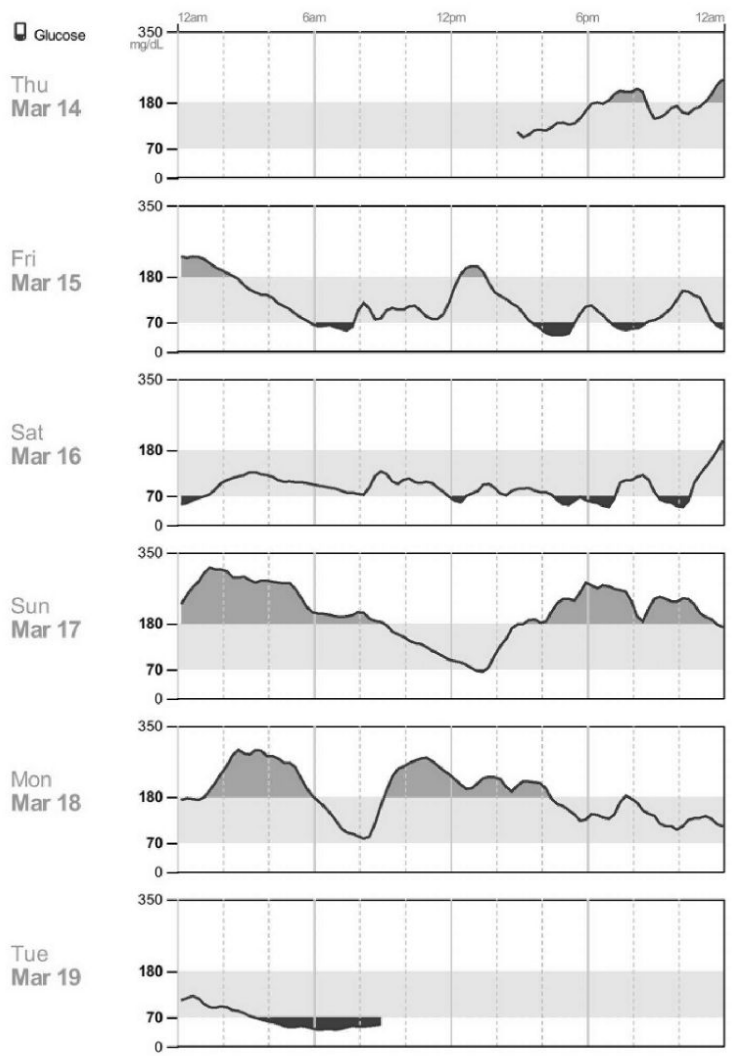
Images from freestylelibre.us. Accessed 4/8/19

Date	Overnight			Early Morning			Late Morning			Early Afternoon			Late Afternoon			Early Evening			Late Evening			Bedtime		
	12 AM - 6 AM			6 AM - 9 AM			9 AM - 11 AM			11 AM - 2 PM			2 PM - 5 PM			5 PM - 7 PM			7 PM - 10 PM			10 PM - 12 AM		
	Gluc.	Med.	CHO	Gluc.	Med.	CHO	Gluc.	Med.	CHO	Gluc.	Med.	CHO	Gluc.	Med.	CHO	Gluc.	Med.	CHO	Gluc.	Med.	CHO	Gluc.	Med.	CHO
3/23/2019	*54* *3:51*												**179** **14:59**											
3/22/2019	140 2:20																		*42* *20:02*					
3/21/2019	**150** **2:00**			**226** **8:21**						*44* *12:55*									101 20:03			84 23:33		
				168 **8:55**																				
3/20/2019				96 7:28															*24* *21:30*			76 22:07		
																			23 *21:31*			110 22:34		
																			24 *21:39*					
																			23 *21:40*					
																			35 *21:46*					
																			41 *21:49*					
3/18/2019	**277** **4:57**																							
3/16/2019				92 8:06																				
3/15/2019				*67* *7:15*									*54* *16:49*											
3/13/2019																						109 22:40		
Avgs.	155			130						44			117						39			95		

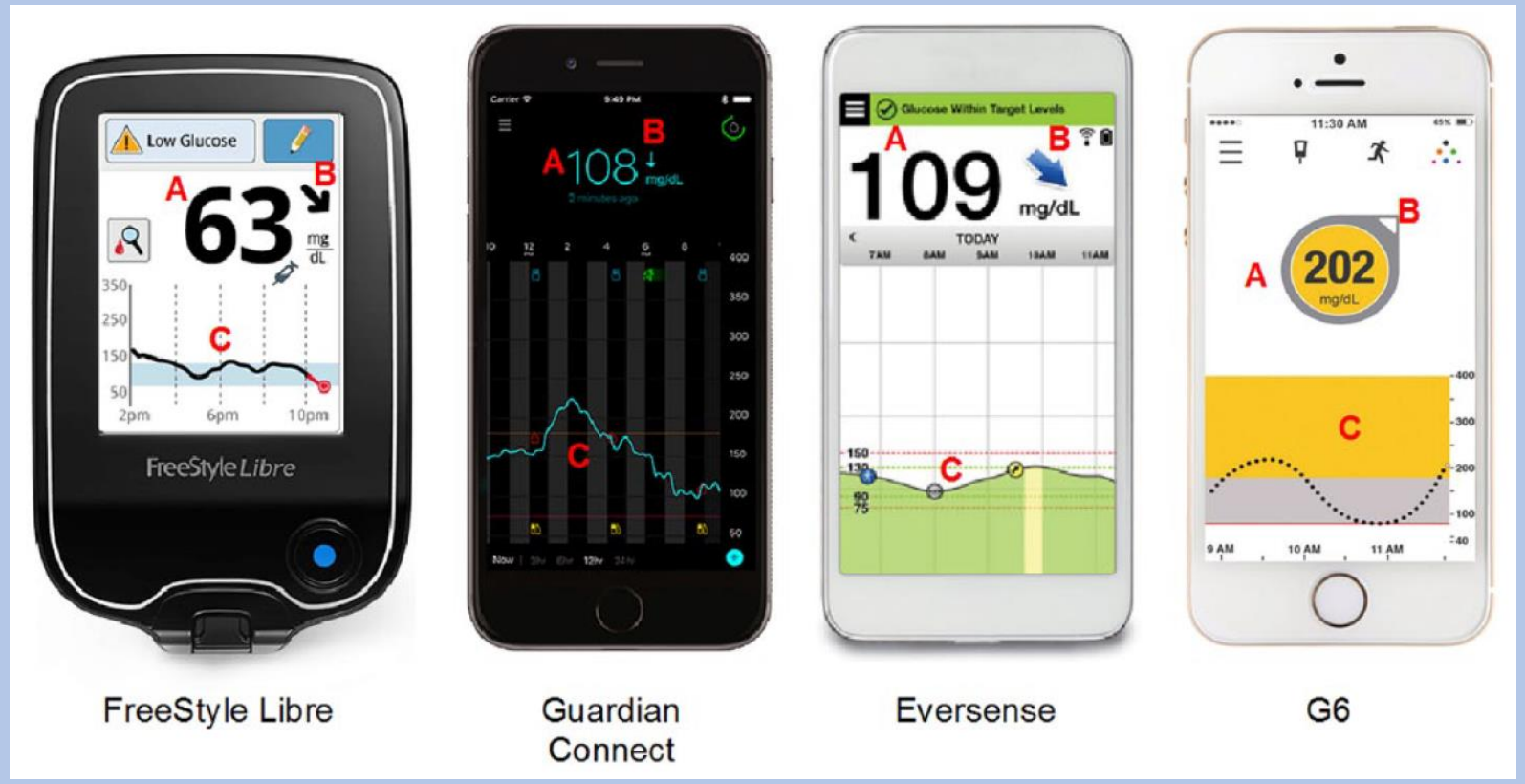
Daily Glucose Summary

March 14, 2019 - March 19, 2019 (6 Days)

LibreView



	Average Glucose	Time In Target	Time Below Target	Time Above Target
Thu Mar 14	161 mg/dL	70 %	0 %	30 %
Fri Mar 15	111 mg/dL	59 %	25 %	16 %
Sat Mar 16	90 mg/dL	73 %	26 %	1 %
Sun Mar 17	208 mg/dL	26 %	2 %	72 %
Mon Mar 18	187 mg/dL	49 %	0 %	51 %
Tue Mar 19	67 mg/dL	36 %	64 %	0 %
March 14, 2019 - March 19, 2019	144 mg/dL	52 %	16 %	32 %



- A: current glucose
- B: trend arrow direction/velocity
- C: historical data

Kruger DF et al. Diabetes Educ. 2019 Feb;45(1_suppl):3S-20S

Trend Arrows: Direction and Velocity

Dexcom G5/G6*		Guardian Connect		FreeStyle Libre		Eversense	
Arrow	Meaning	Arrow	Meaning	Arrow	Meaning	Arrow	Meaning
⇈	**Glucose rapidly rising** >3 mg/dL/min >0.2 mmol/L/min	⇈	**Glucose rapidly rising** >3 mg/dL/min >0.2 mmol/L/min	—	—	—	—
↑	**Glucose rising** 2–3 mg/dL/min 0.1-0.2 mmol/L/min	↑	**Glucose is rising** 2–3 mg/dL/min 0.1-0.2 mmol/L/min	↑	**Glucose rapidly rising** >2 mg/dL/min >0.1 mmol/L/min	↑	**Glucose rapidly rising** >2 mg/dL/min >0.1 mmol/L/min
↗	**Glucose slowly rising** 1–2 mg/dL/min 0.06-0.1 mmol/L/min	↑	**Glucose slowly rising** 1–2 mg/dL/min 0.06-0.1 mmol/L/min	↗	**Glucose rising** 1–2 mg/dL/min 0.06-0.1 mmol/L/min	↗	**Glucose slowly rising** 1–2 mg/dL/min 0.06-0.1 mmol/L/min
→	**Glucose steady** *Increasing/decreasing* <1 mg/dL/min <0.06 mmol/L/min	—	**Glucose steady** Increasing/decreasing <1 mg/dL/min <0.06 mmol/L/min	→	**Glucose steady** *Increasing/decreasing* <1 mg/dL/min <0.06 mmol/L/min	→	**Glucose steady** *Increasing/decreasing* <1 mg/dL/min <0.06 mmol/L/min
↘	**Glucose slowly falling** 1–2 mg/dL/min 0.06-0.1 mmol/L/min	↓	**Glucose slowly falling** 1–2 mg/dL/min 0.06-0.1 mmol/L/min	↘	**Glucose slowly falling** 1–2 mg/dL/min 0.06-0.1 mmol/L/min	↘	**Glucose slowly falling** 1– 2 mg/dL/min 0.06-0.1 mmol/L/min
↓	**Glucose falling** 2–3 mg/dL/min 0.1-0.2 mmol/L/min	↓	**Glucose is falling** 2–3 mg/dL/min 0.1-0.2 mmol/L/min	↓	**Glucose rapidly falling** >2 mg/dL/min >0.1 mmol/L/min	↓	**Glucose rapidly falling** >2 mg/dL/min >0.1 mmol/L/min
⇊	**Glucose rapidly falling** >3 mg/dL/min >0.2 mmol/L/min	⇊	**Glucose rapidly falling** >3 mg/dL/min >0.2 mmol/L/min	—	—	—	—

Kruger DF et al. Diabetes Educ. 2019 Feb;45(1_suppl):3S-20S

Trend Arrows: Direction and Velocity

- Increasing by 2mg/dL/min:
  - ↑ 20 in 10min
  - ↑ 60 in 30min
- Increasing by 3mg/dL/min:
  - ↑ 30 in 10min
  - ↑ 90 in 30min

→ Take action proactively

- Insulin to Carb Ratio: 1unit to 10g
- Insulin Sensitivity (Correction) Factor: 1unit for every 40 over 120

Premeal			Insulin calculation			Post meal
Glucose		CHO	Food	Correction	Total	Glucose
200		60g	6u	2u	8u	60
200		60g	6u	2u	8u	120
200		60g	6u	2u	8u	220

New Approach to Adjusting Insulin Doses Using Trend Arrows in Adults: Pre-meal and Corrections ≥4 Hours Post-meal

Trend Arrows		Correction Factor* (CF)	Insulin Dose Adjustment (U)
Receiver	App		
↑↑		<25	+4.5
		25–<50	+3.5
		50–<75	+2.5
		≥75	+1.5
↑		25–<50	+2.5
		≥75	+1.0
↗		<25	+2.5
		25–<50	+1.5
		50–<75	+1.0
		≥75	+0.5
→		<25	No adjustment
		25–<50	No adjustment
		50–<75	No adjustment
		≥75	No adjustment
↘		<25	-2.5
		25–<50	-1.5
		50–<75	-1.0
		≥75	-0.5
↓		<25	-3.5
		25–<50	-2.5
		50–<75	-1.5
		≥75	-1.0
↓↓		25–<50	-3.5
		≥75	-1.5

Aleppo G et al. Journal of Endocrine Society. Dec 2017. Vol (1), Iss. 12:1-16

- Insulin to Carb Ratio: 1unit to 10g
- Insulin Sensitivity (Correction) Factor: 1unit for every 40 over 120

Premeal			Insulin calculation			Adjusted dose	New dose	Post meal
Glucose	Trend	CHO	Food	Correction	Total	adjust	Total	Glucose
200	↓ ↓	60g	6u	2u	8u	- 3.5u	4.5u	110
200	→	60g	6u	2u	8u	0u	8u	120
200	↑	60g	6u	2u	8u	+ 2.5u	10.5u	125

Postprandial Monitoring and Treatment: Using trend arrows for up to 4 hours

Hypoglycemia Prevention

From 2 to 4 hr Postprandial	Trend Arrow Direction / Recommended Action
Near 150 mg/dL	**Arrow Direction: ↘**
	Action: ▸ Re-check CGM in 30 min.
	Arrow Direction: ↓ or ↓↓
	Action: ▸ Re-check CGM in 15 min.
Near 100 mg/dL	**Arrow Direction: ↘ or ↓**
	Action: ▸ Consider taking 15 g fast-acting carbohydrate. ▸ Re-check CGM in 20 min. If CGM reads <70 mg/dL with arrows still trending down, confirm with fingerstick and take an additional 15 g fast-acting carbohydrate. ▸ If CGM reading continues to drop or CGM level has not begun to rise as expected, confirm with fingerstick and re-check CGM every 15 min.
	Arrow Direction: ↓↓
	Action: ▸ Follow instructions above but take 30 g of fast-acting carbohydrate.

Hyperglycemia Prevention

Avoid correcting hyperglycemia for the first 2 hours following a mealtime bolus to prevent insulin stacking.

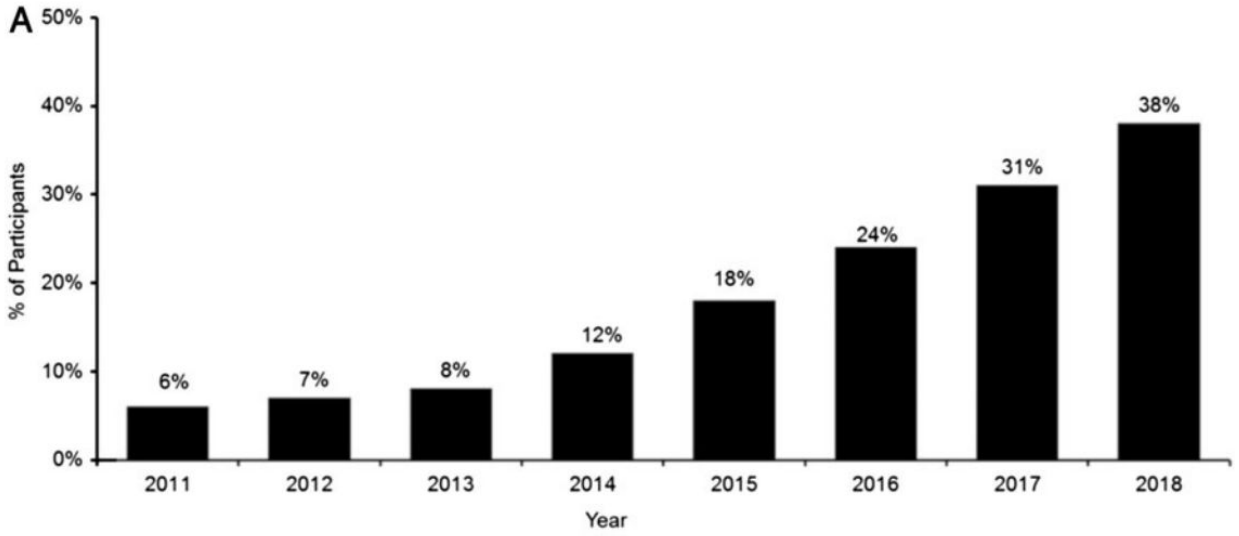
From 2 to 4 hr Postprandial	Trend Arrow Direction / Recommended Action
150–250 mg/dL	**Arrow Direction: ↑ or ↑↑**
	Action: ▸ Consider taking a correction bolus using CF. ▸ Monitor for the next 2 hrs. ▸ Avoid additional correction doses for 2 hrs.
>250 mg/dL	**Arrow Direction: ↑ or ↑↑**
	Action: ▸ Confirm with fingerstick. ▸ Check for ketones if BG is >300 mg/dL. ▸ Take corrective insulin dose by injection (MDI-treated and insulin pump users). ▸ If 2 UP after additional 1 hr: ▷ Confirm with fingerstick. ▷ Take additional corrective insulin. ▷ Change infusion site (if using an insulin pump).

Aleppo G et al. Journal of Endocrine Society. Dec 2017. Vol (1), Iss. 12:1-16

Continuous Glucose Monitoring

- Why the need?
  - Improve overall glycemic control
  - Reduce glycemic variability (going beyond A1c)
  - Enhance patient/family confidence in DM self-care or family management
  - Reduce fear of hypo/hyperglycemia
- Who would benefit?
  - ANY patients on intensive insulin therapy
  - Frequent hypoglycemia / Hypoglycemic unawareness
  - Varying schedule / intensive activities
  - Desires to improve glycemic control
- Benefits of Realtime CGM
  - Realtime CGM (measures glucose every 5min) → proactive decision making
  - Alerts (highs and lows and predictive)

Uptake in use of CGM



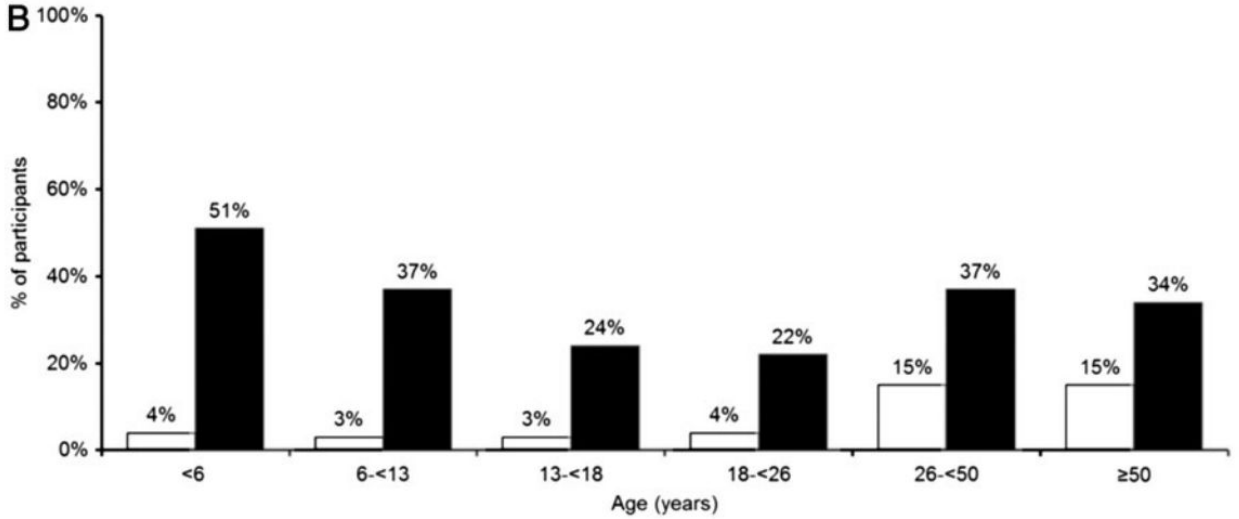


FIG. 1. **(A)** CGM use over time. **(B)** CGM use in 2010–2012 versus 2016–2018. Solid white represents 2010–2012 (7% use of CGM overall). Solid black represents 2016–2018 (30% use of CGM overall). CGM, continuous glucose monitoring.

Foster NC et al. T1D Exchange 2016-2018. Diabetes Technology&Therapeutics. Vol 21, Number 2, 2019

MDI only vs Pump only vs MDI&CGM vs Pump&CGM

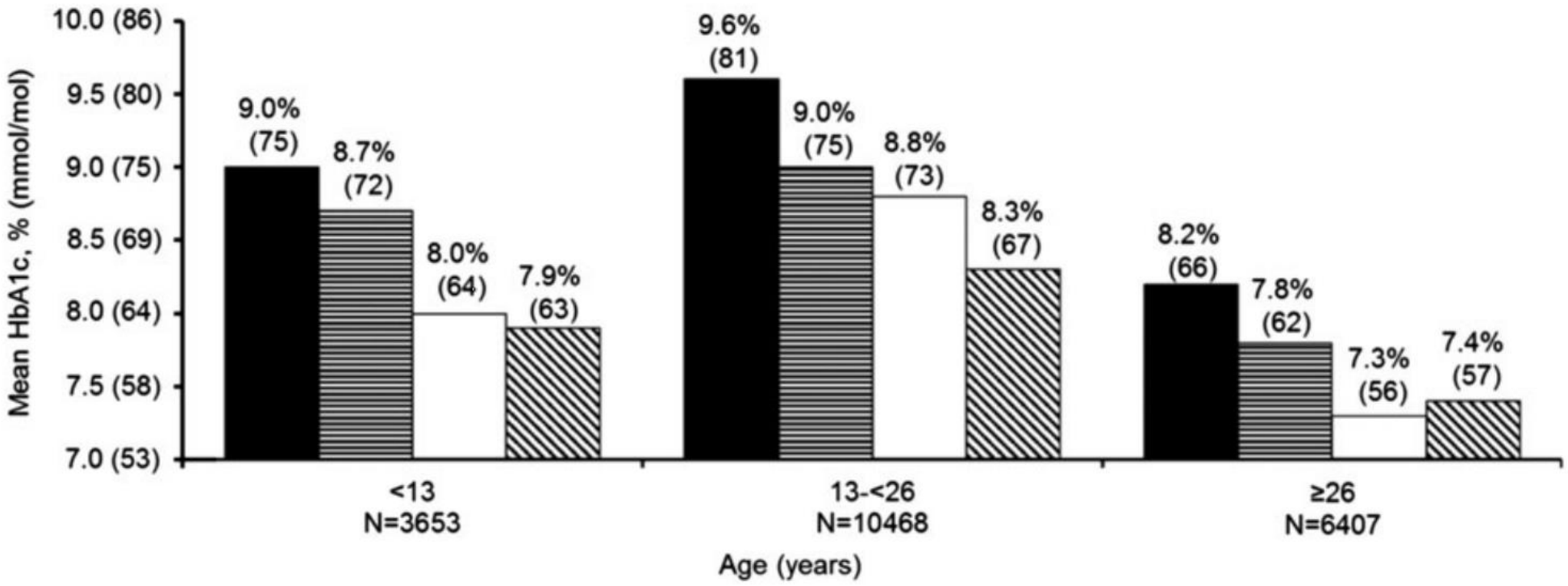


FIG. 3. Mean HbA1c by technology use in 2016–2018. Solid black represents injection only. Horizontal stripes represent pump only. Solid white represents injection+CGM. Diagonal stripes represent pump+CGM.

Foster NC et al. T1D Exchange 2016-2018. Diabetes Technology&Therapeutics. Vol 21, Number 2, 2019

Shift in thinking: Moving “Beyond A1c”

How Does Diabetes Affect Daily Life? A Beyond-A1C Perspective on Unmet Needs

Divya Gopisetty,[1] Brian Levine,[1] Nancy Liu,[2] Phin Younge,[3] Adam Brown,[1,2] Kelly L. Close,[1,2] and Richard Wood[3]

Clinical Diabetes Online Ahead of Print, published online January 10, 2018

Diabetes Care Volume 40, August 2017

The Fallacy of Average: How Using HbA_{1c} Alone to Assess Glycemic Control Can Be Misleading

Roy W. Beck,[1] Crystal G. Connor,[1] Deborah M. Mullen,[2] David M. Wesley,[2,3] and Richard M. Bergenstal[2]

Diabetes Care 2017;40:994–999 | https://doi.org/10.2337/dc17-0636

Glucose Management Indicator (GMI): A New Term for Estimating A1C From Continuous Glucose Monitoring

Richard M. Bergenstal,[1] Roy W. Beck,[2] Kelly L. Close,[3] George Grunberger,[4] David B. Sacks,[5] Aaron Kowalski,[6] Adam S. Brown,[7] Lutz Heinemann,[8] Grazia Aleppo,[9] Donna B. Ryan,[10] Tonya D. Riddlesworth,[2] and William T. Cefalu[11]

https://doi.org/10.2337/dc18-1581

Same A1c (average), same control?

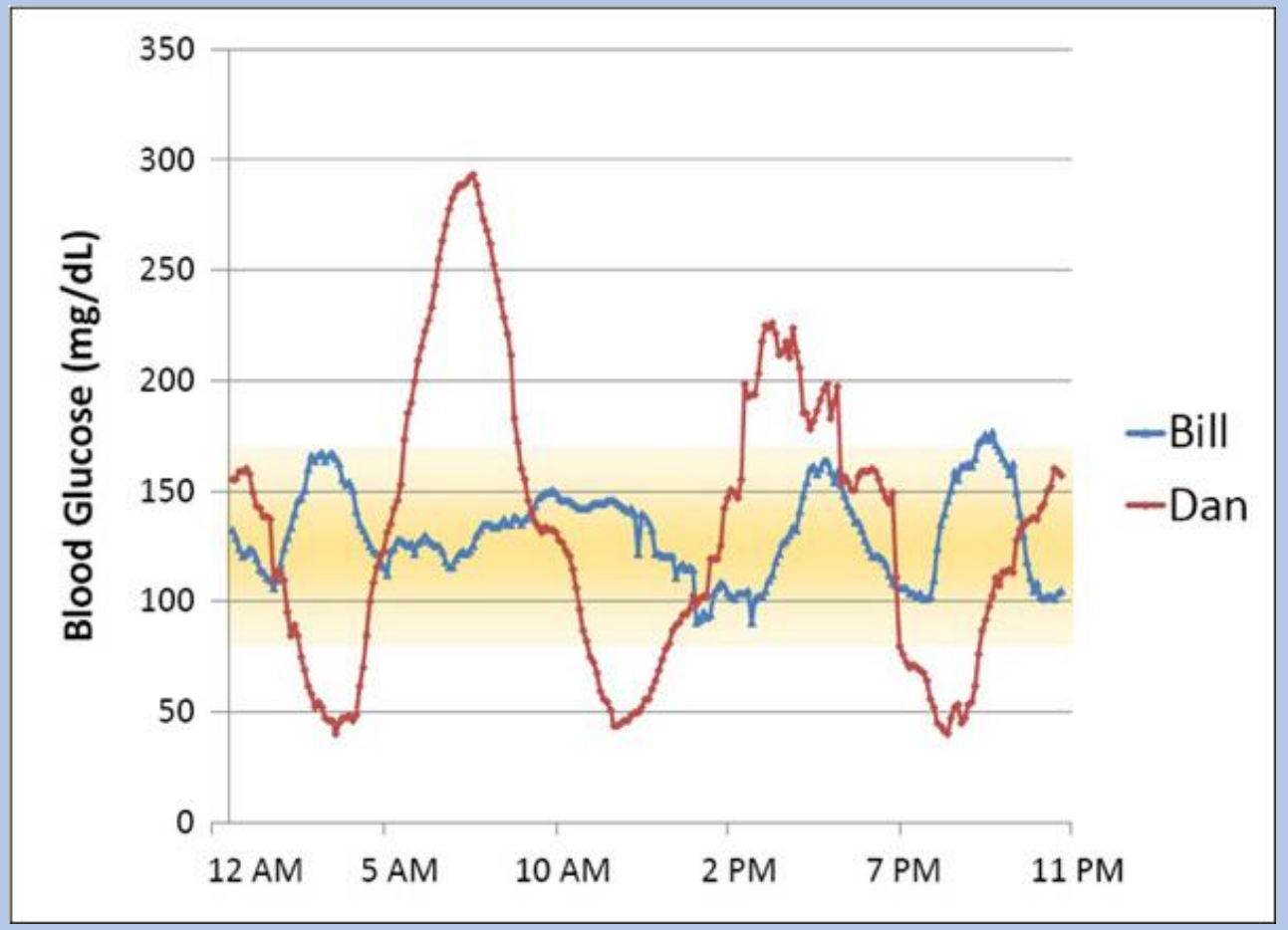


Table 2. Conditions Associated with Falsely Elevated or Lowered A1c

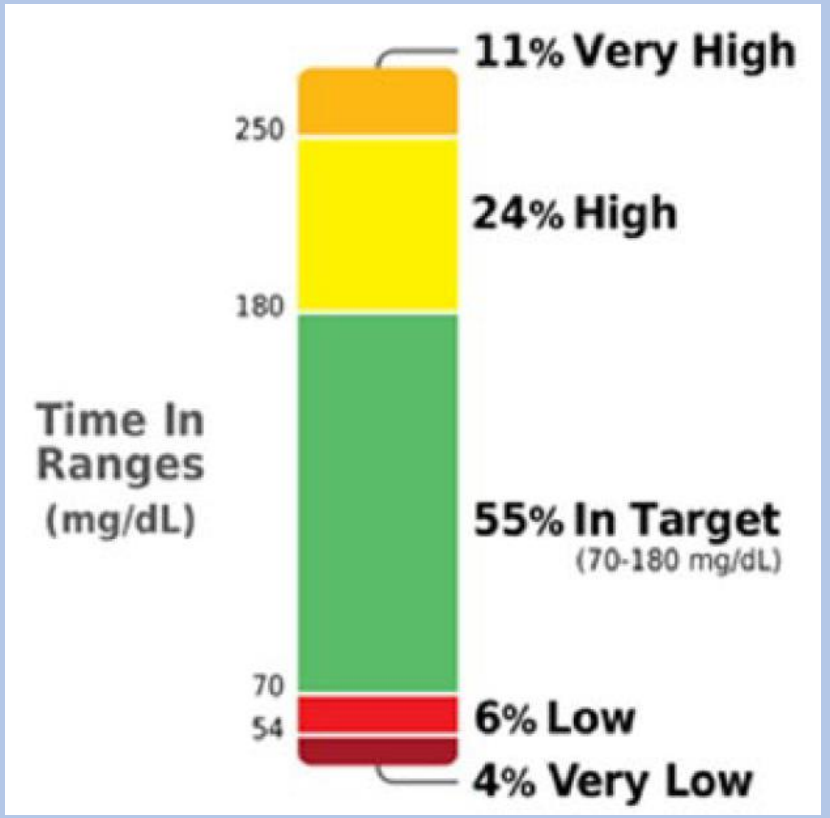
Condition	Effect on A1c	Comments
Anemias associated with decreased red cell turnover	False Increase	I.e., iron deficiency, vitamin B-12, folate deficiency anemias
Asplenia	False Increase	Increased erythrocyte lifespan
Uremia	False Increase	Formation and detection of carbamyl-hemoglobin
Severe hypertriglyceridemia	False Increase	When level >1,750 mg/dL
Severe hyperbilirubinemia	False Increase	When level >20 mg/dL
Chronic alcohol consumption	False Increase	Formation of acetaldehyde-HbA1 compound
Chronic salicylate ingestion	False Increase	Mechanism uncertain, may interfere with assay
Chronic opioid ingestion	False Increase	Mechanism uncertain
Lead poisoning	False Increase	Mechanism uncertain
Anemia from acute or chronic blood loss	False Decrease	Includes hemolytic anemia
Splenomegaly	False Decrease	Decreased erythrocyte lifespan
Pregnancy*	False Decrease	Decreased erythrocyte lifespan
Vitamin E ingestion	False Decrease	Reduced glycation
Ribavirin and interferon-alpha	False Decrease	Possibly due to hemolytic anemia
Red blood cell transfusion†	False Increase or False Decrease	High glucose concentration in storage medium (False Increase) Dilutional effect (False Decrease)
Hemoglobin variants	False Increase or False Decrease	Depends on method and assay used A1c generally reliable for heterozygous variants, but not homozygous variants (See Table 3)
Vitamin C ingestion	False Increase or False Decrease	May increase A1c when measured by electrophoresis May decrease levels when measured by chromatography due to competitive inhibition of glycosylation

**Expect falsely low A1c values through the 2nd trimester, but may rise during the 3rd trimester*
†Typically reported to falsely elevate A1c, but may also result in false decrease

Radin MS. JGIM 2014. 29(2):388-94

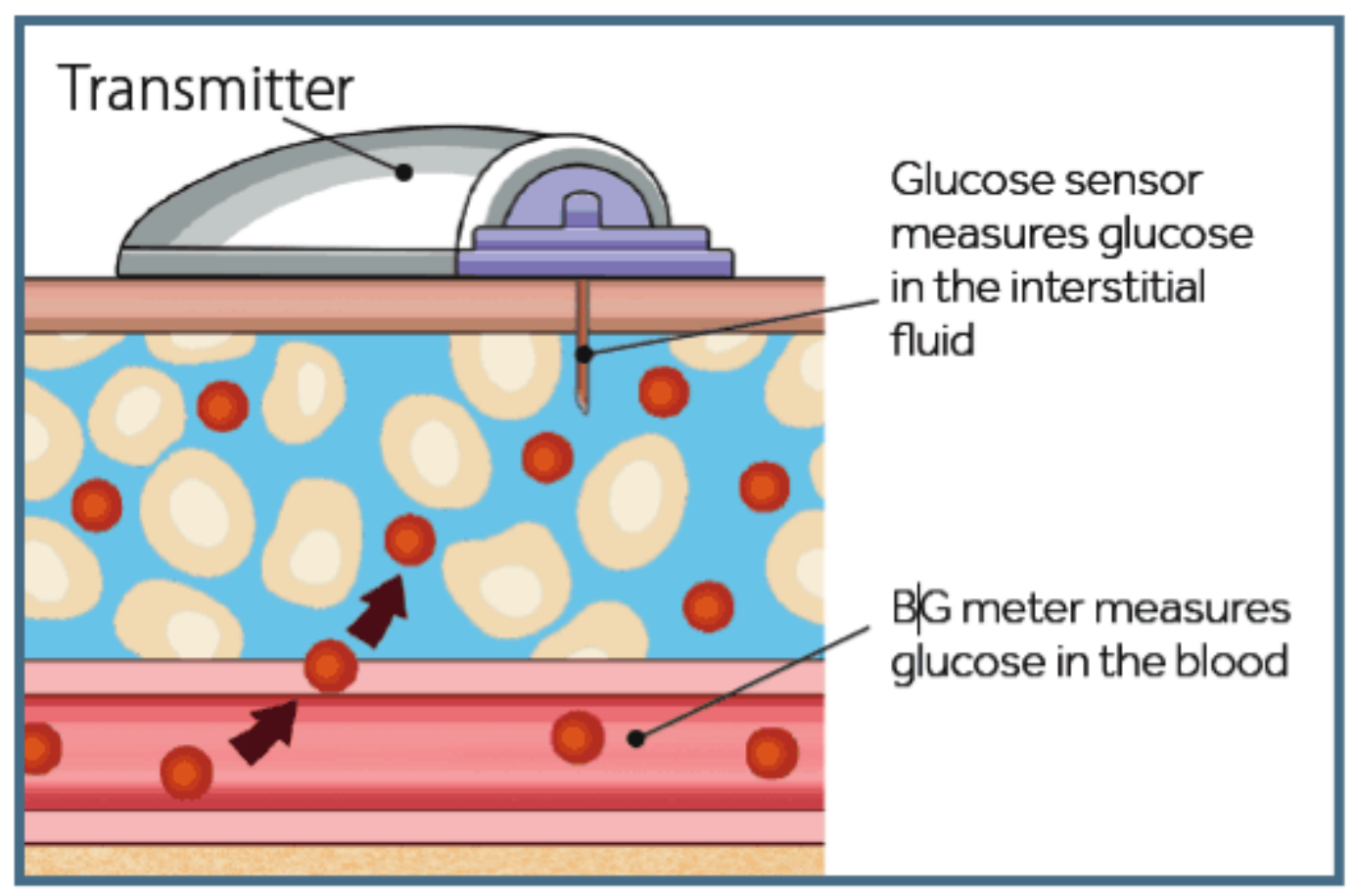
Change in concept of Glycemic control "beyond A1c"

- Time in Range (%time in "safe" range: 70-180)
- Hypoglycemia
  - Level 1 - %time spent < 70
  - Level 2 - %time spent < 54
- Hyperglycemia
  - Level 1 - %time spent > 180
  - Level 2 - %time spent > 250

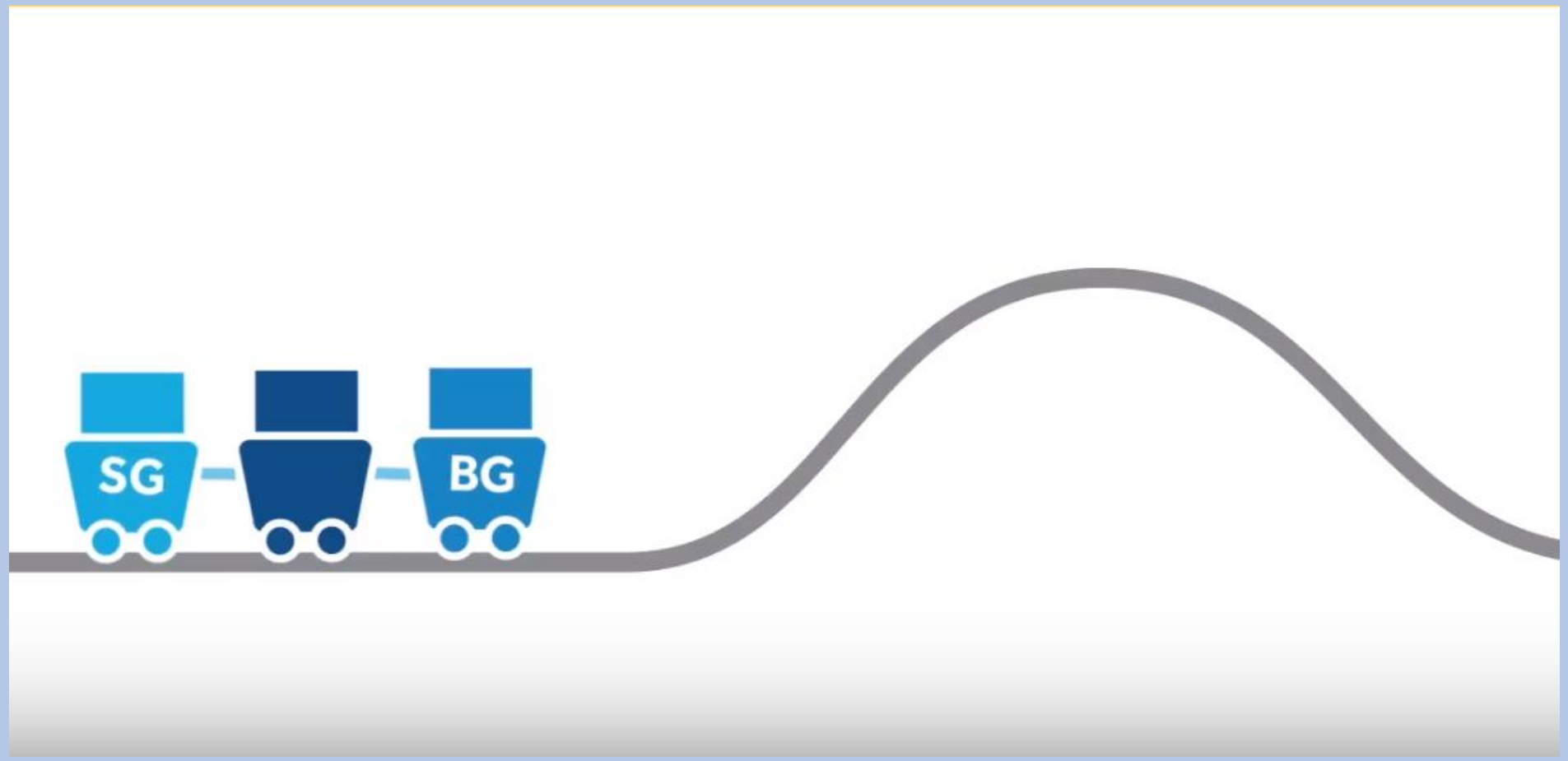


Consensus Report on Use of CGM. Diabetes Care 2017 Dec; 40 (12): 1622-1630

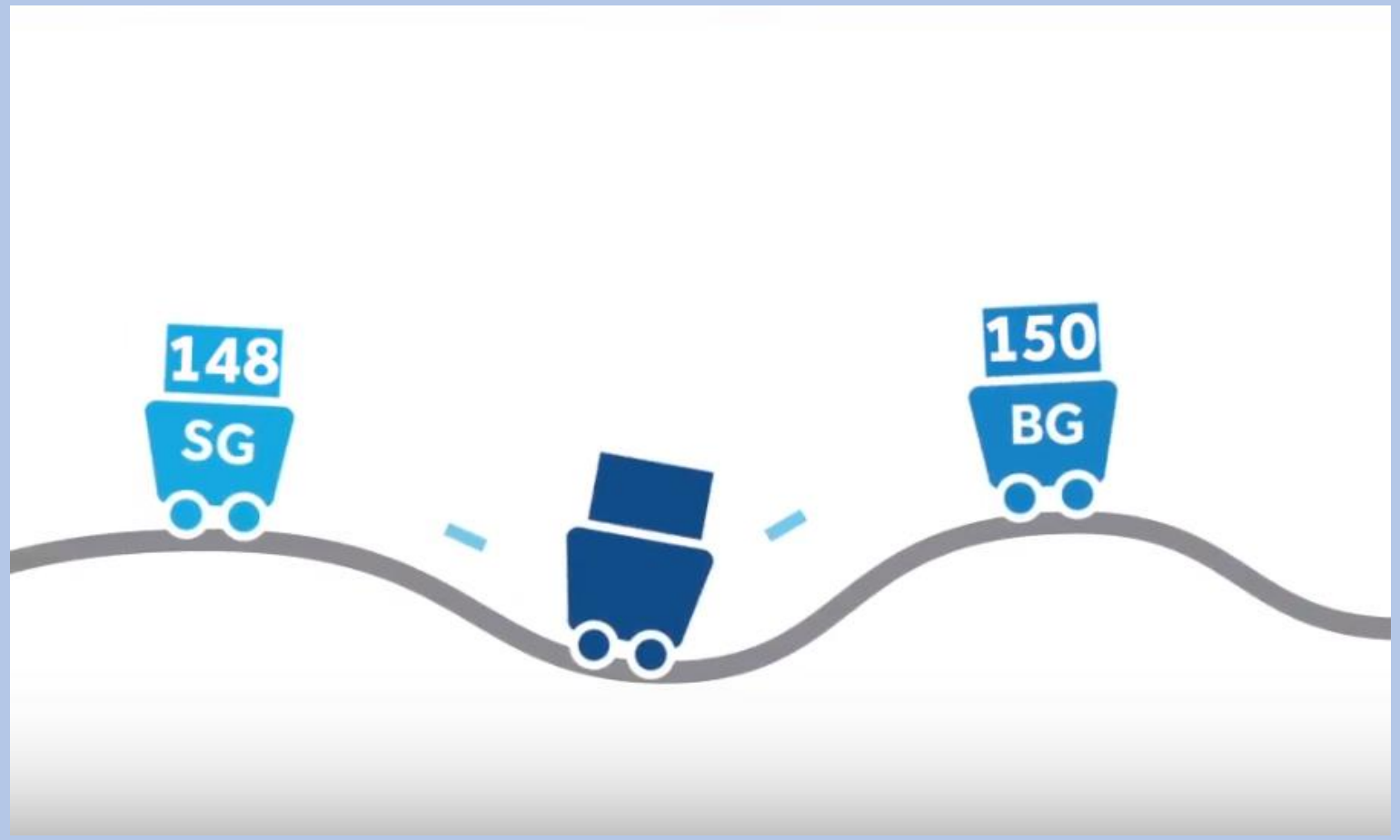
Sensor glucose vs meter glucose



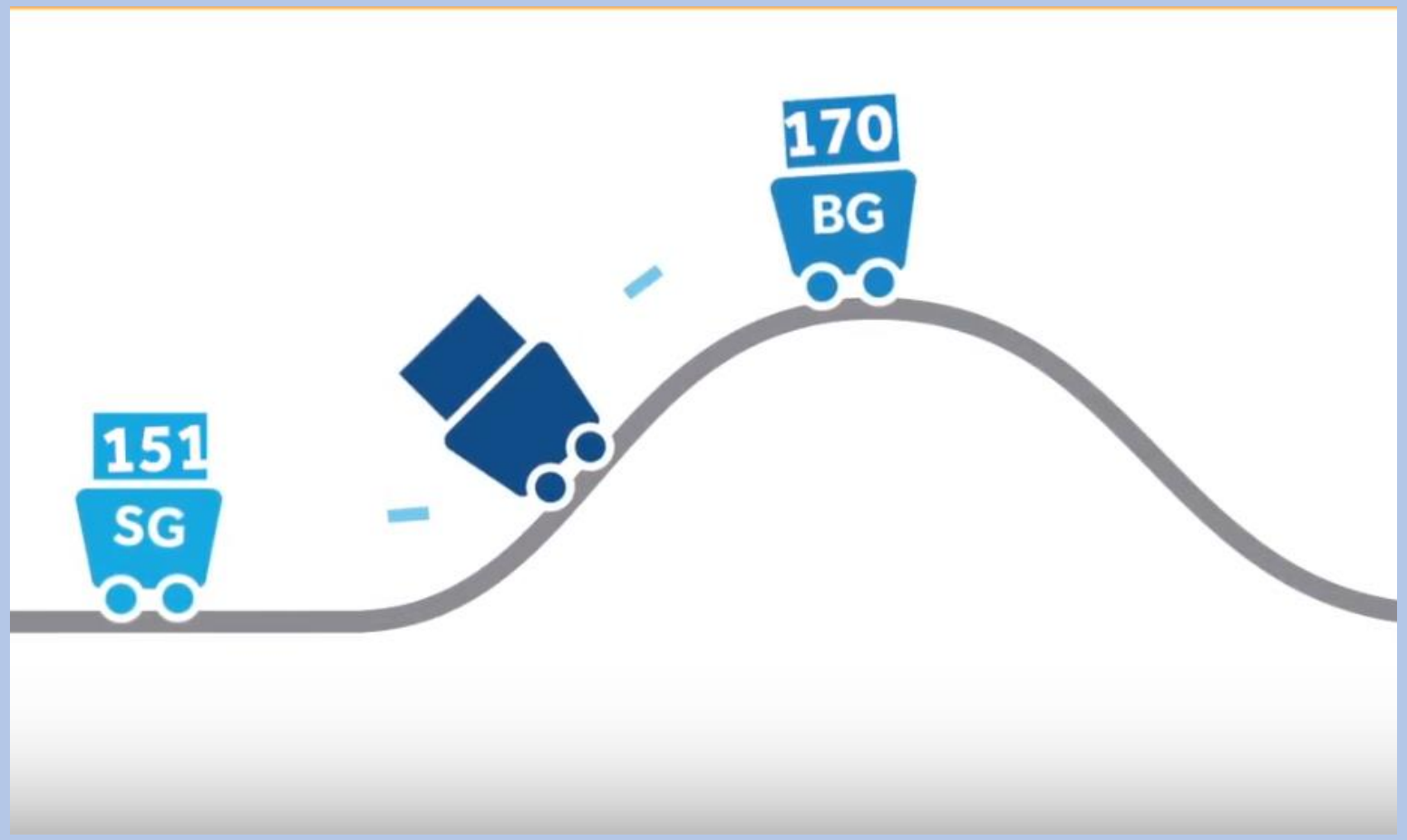
Sensor glucose vs meter glucose



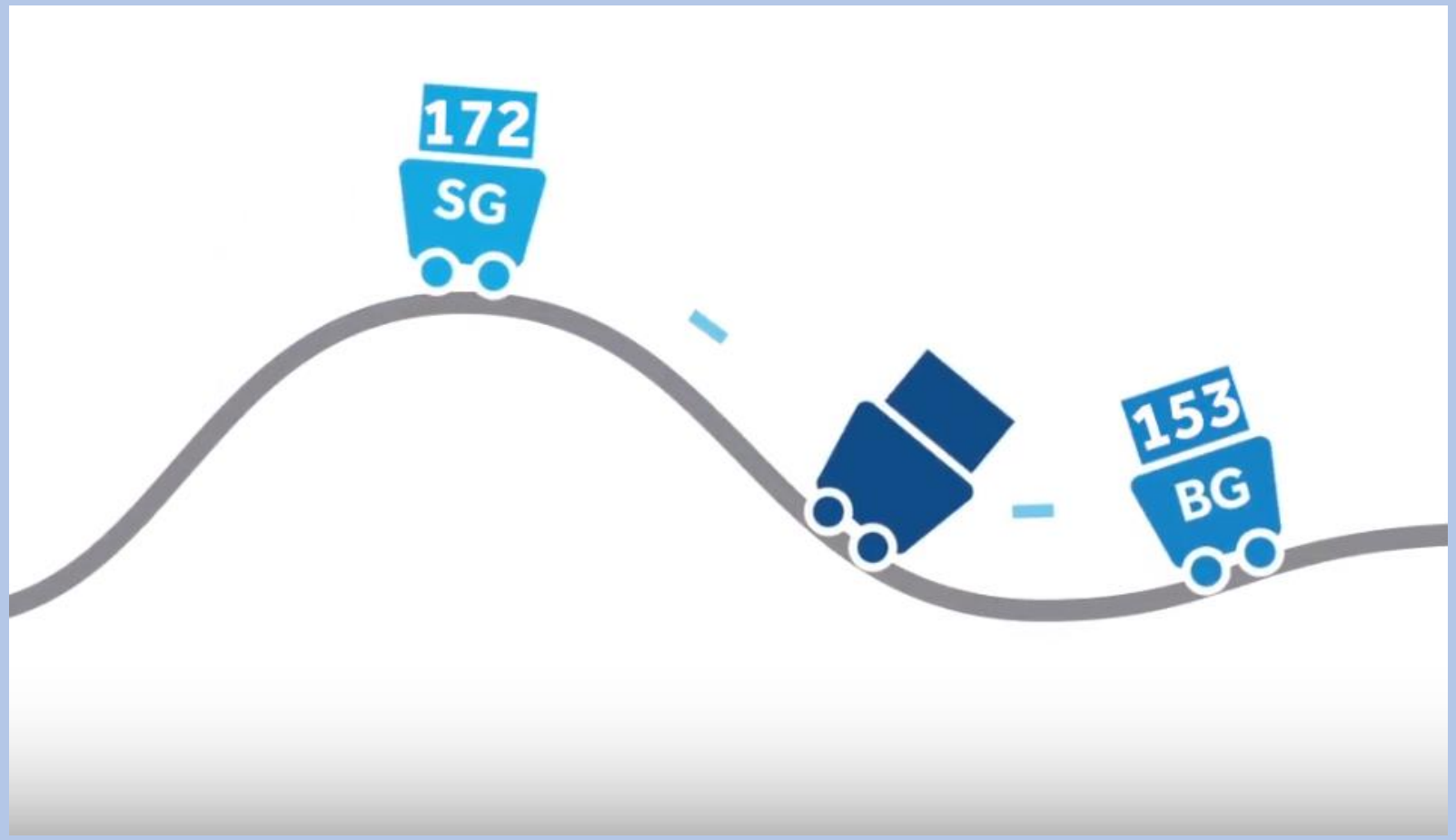
Sensor glucose vs meter glucose



Sensor glucose vs meter glucose



Sensor glucose vs meter glucose



Types of CGM

Personal CGM	Professional CGM
Dexcom G6	Dexcom Pro
Medtronic Guardian 3	Medtronic iPro 2
Freestyle Libre 2	Freestyle Libre Pro
Eversense	

- Personal CGM: patient owns the device and get the data real time (and react to it - proactive)
- Professional CGM: Provider owned device and blinded to patient (retrospective analysis)

Which one to pick?

- Patient factors (always first!)
  - Main goal (lower A1c, prevent hypo, convenience, etc)
  - Convenience (ease of use, need for calibration, duration, etc)
  - Need for alarm?
  - Integration with pump?
  - Cost/insurance coverage
- Clinician/Clinic factor
  - Familiarity
  - Established infrastructure
  - Cost/profit

	MARD	Nonadjunctive	Alarm	Data share	Age	Length	Receiver	Note
Dexcom G6	9%	O	O	O	≥ 2	10-d	Receiver/iOS/Android	
Freestyle Libre 2	9.3%	O	O	O	≥ 18	14-d	Receiver/iOS/Android	intermittent scanning
Guardian 3	10.6%		O	O	≥ 7	7-d	No receiver/iOS only	Tylenol interference
Eversense	8.8%	O	O	Text only	≥ 18	90-d	No Receiver / iOS/Android	implantable



Dexcom G6



Guardian 3

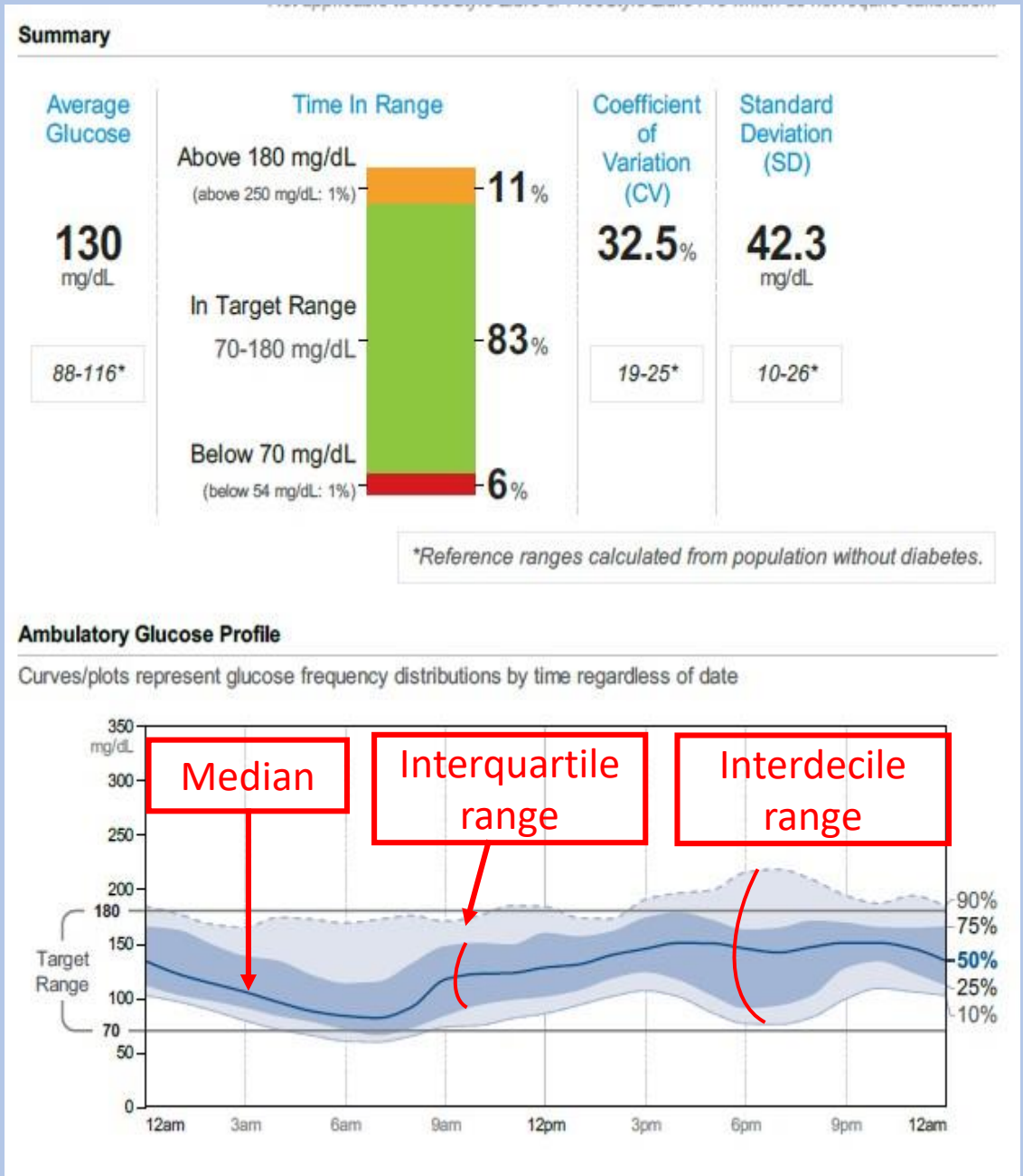


Eversense



Freestyle libre 2

Modified from Kruger DF et al. Diabetes Educ. 2019 Feb;45(1_suppl):3S-20S



Time in Range (TIR)

Goal: >70% in target, <3% in low

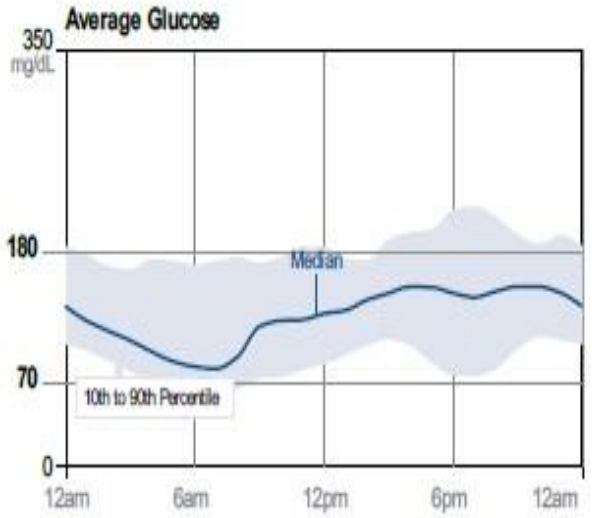
Markers for glucose variability

- Standard Deviation
  - Goal: < 1/3 of average glucose
- Coefficient of Variation (CV)
  - Goal < 33%

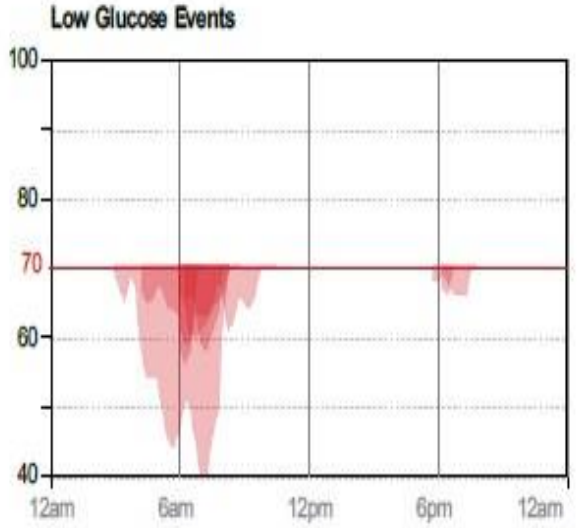
Ambulatory Glucose Profile (AGP): Standardized report showing all glucose data collapsed and displayed into a modal view

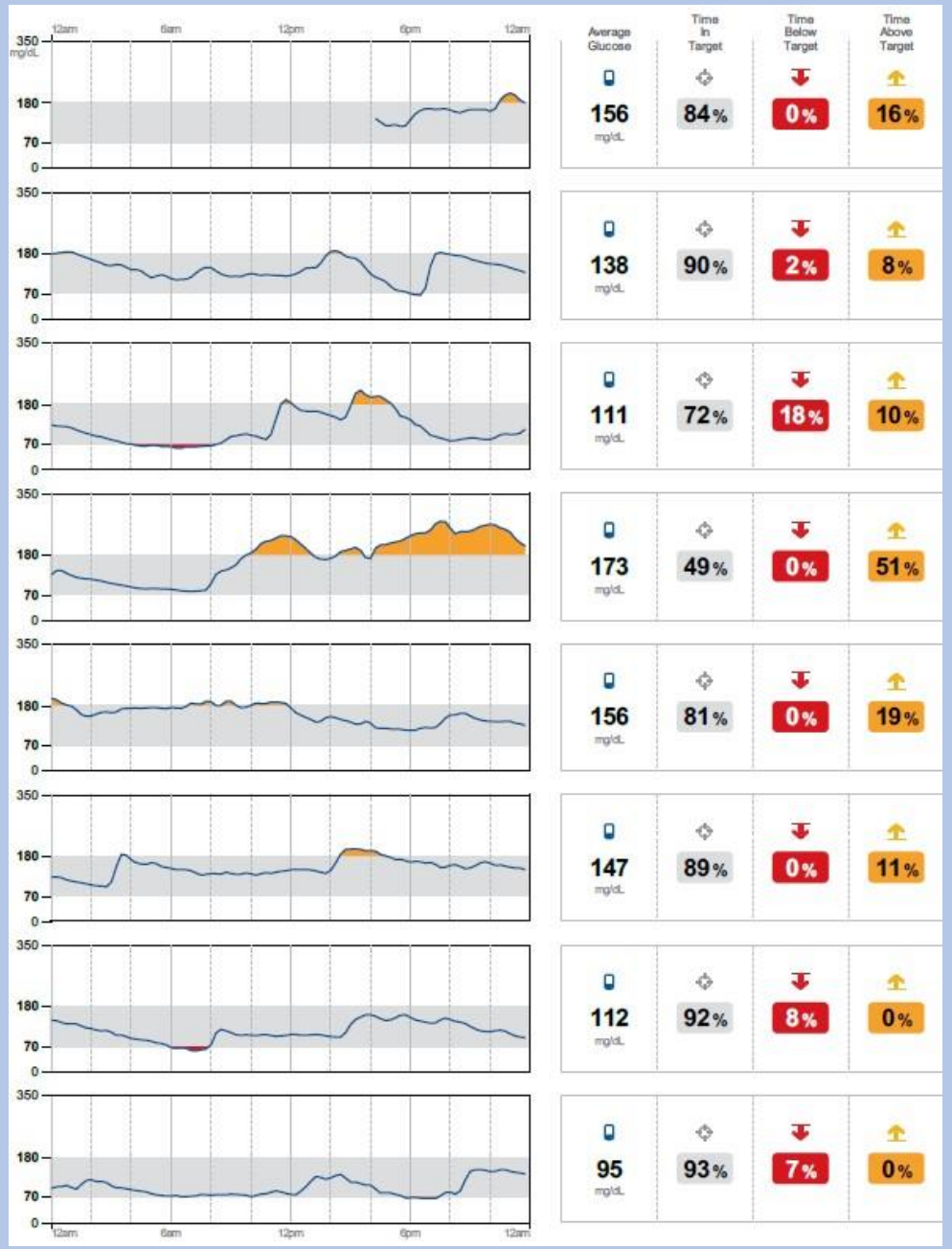
Glucose

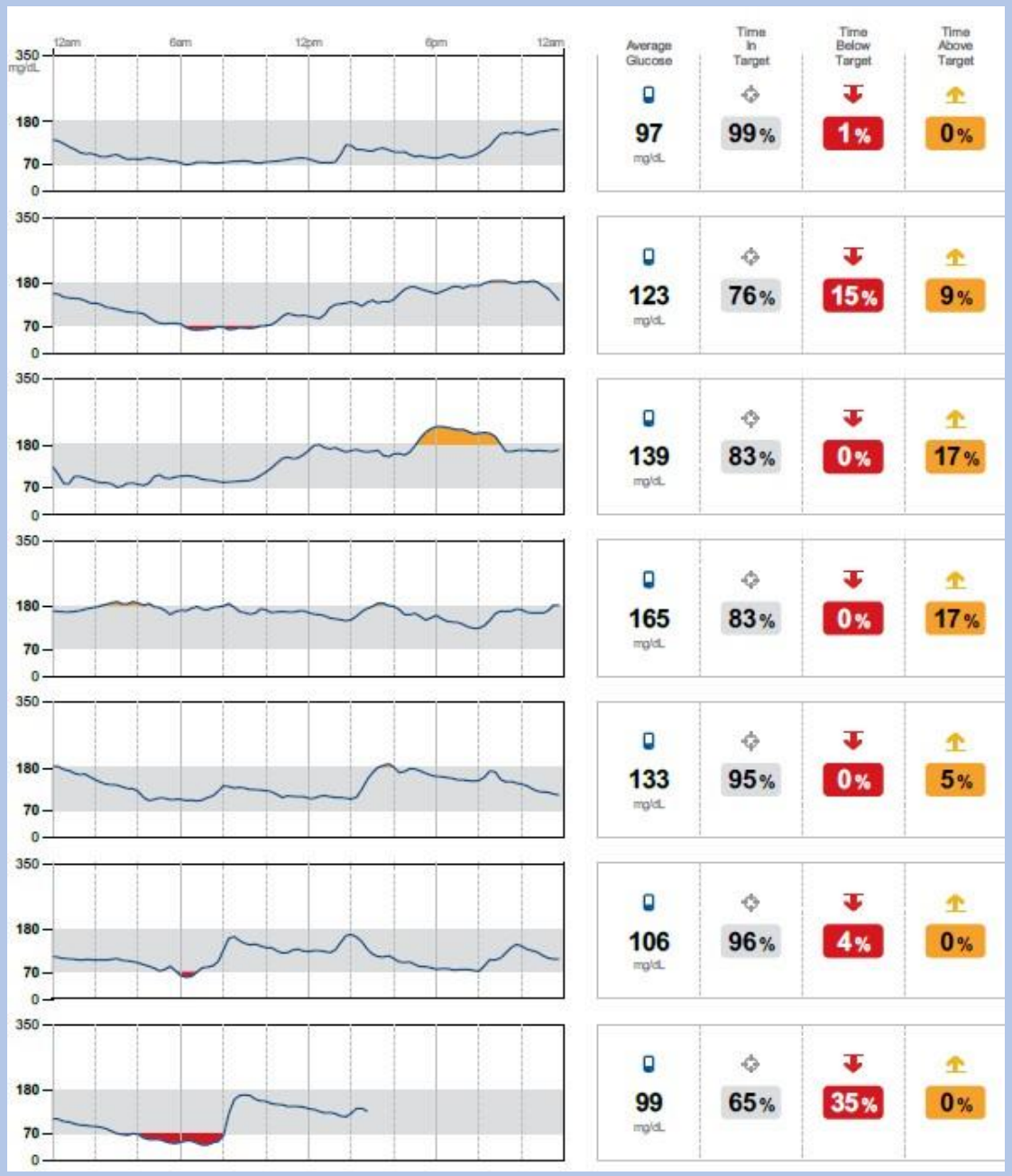
AVERAGE GLUCOSE	**130** mg/dL
% above target	**11** %
% in target	**83** %
% below target	**6** %



LOW GLUCOSE EVENTS	**7**
Average duration	**169** Min

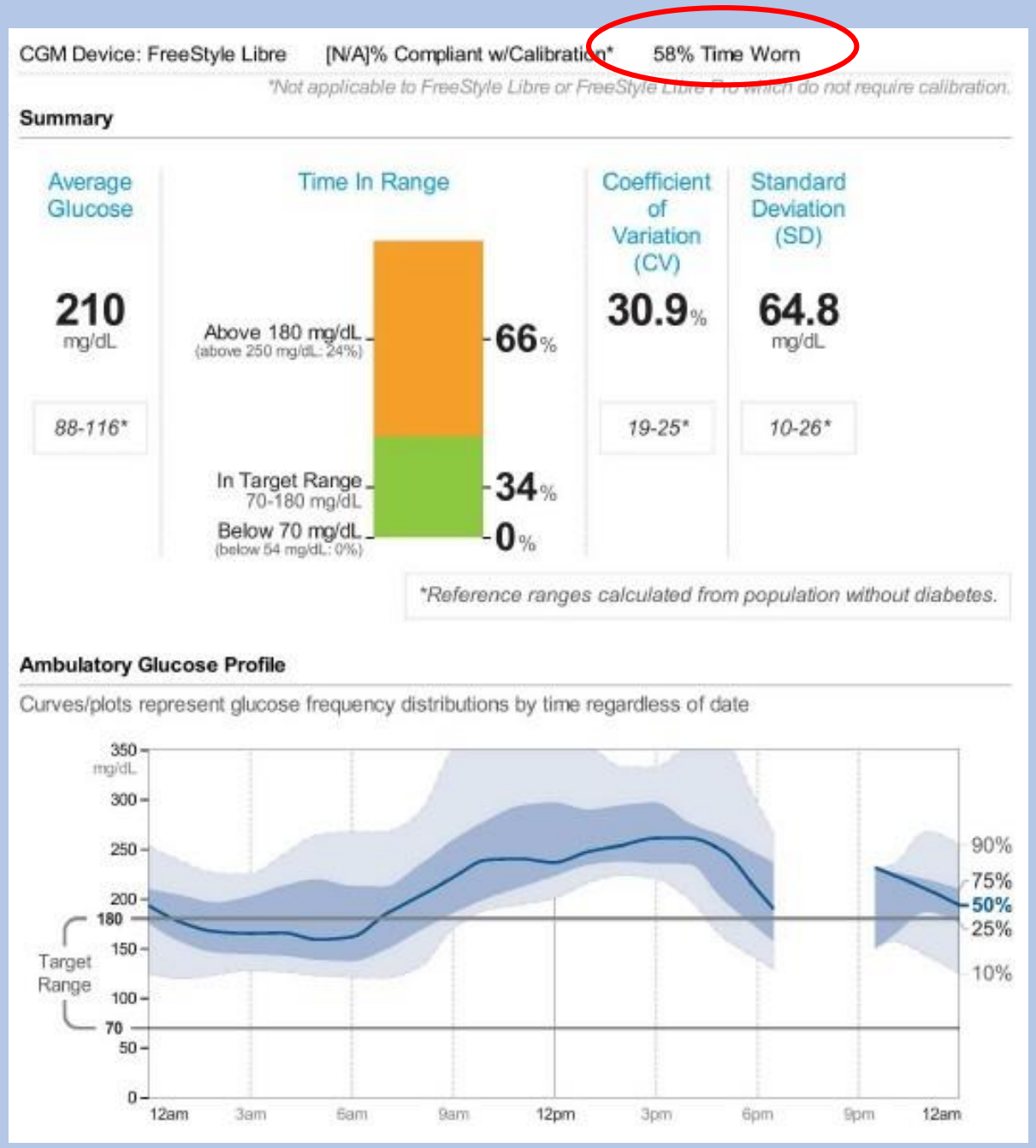



12am
6am
12pm
6pm
12am
350
mg/dL
180
70
0
Average Glucose
Time In Target
Time Below Target
Time Above Target
156 mg/dL
84%
0%
16%
138 mg/dL
90%
2%
8%
111 mg/dL
72%
18%
10%
173 mg/dL
49%
0%
51%
156 mg/dL
81%
0%
19%
147 mg/dL
89%
0%
11%
112 mg/dL
92%
8%
0%
95 mg/dL
93%
7%
0%

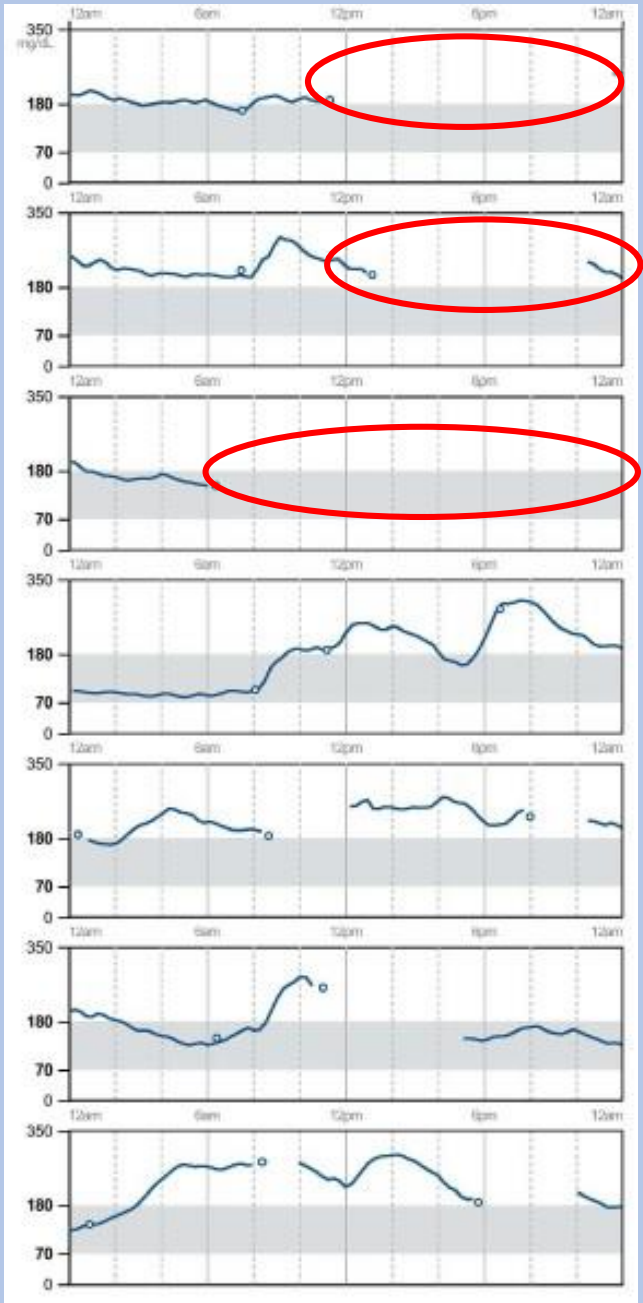

12am
6am
12pm
6pm
12am
350
mg/dL
180
70
0
Average Glucose
Time In Target
Time Below Target
Time Above Target
97 mg/dL
99%
1%
0%
123 mg/dL
76%
15%
9%
139 mg/dL
83%
0%
17%
165 mg/dL
83%
0%
17%
133 mg/dL
95%
0%
5%
106 mg/dL
96%
4%
0%
99 mg/dL
65%
35%
0%

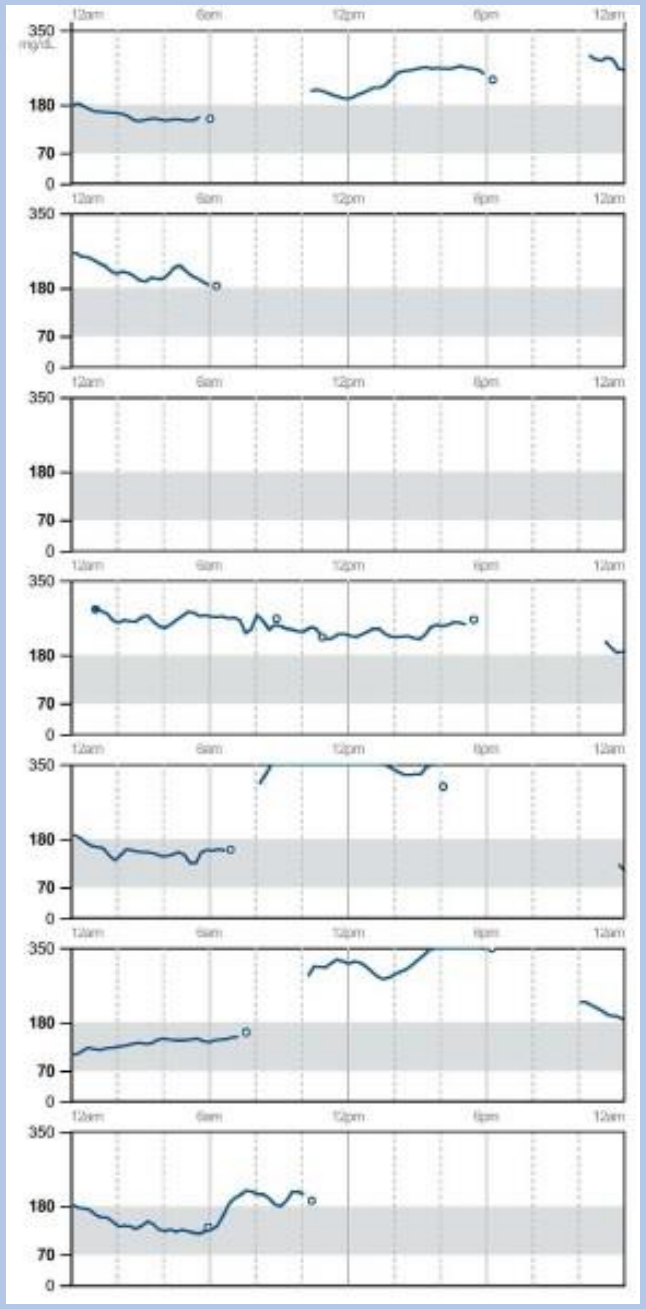
Interpretation

- Systemic Approach
  1. confirm adequate data is available (personal CGM: >70% of 2 weeks)
  2. review the summary (ave, time in range, variability)
  3. inquire patient about their daily routine and mark on the AGP
  4. Ask the patient what they see and inquire their insight (listen!)
  5. look at problematic areas (priority)
     A. hypoglycemia
     B. hyperglycemia
     C. wide glycemic variability
     *From big picture (AGP) to details (daily views)
  6. Collaborate with patient on problem solving and agree on action plan



Step 1: Assessing data quality





Step 1: Assessing data quality

CGM Device: FreeStyle Libre [N/A]% Compliant w/Calibration* 92% Time Worn

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

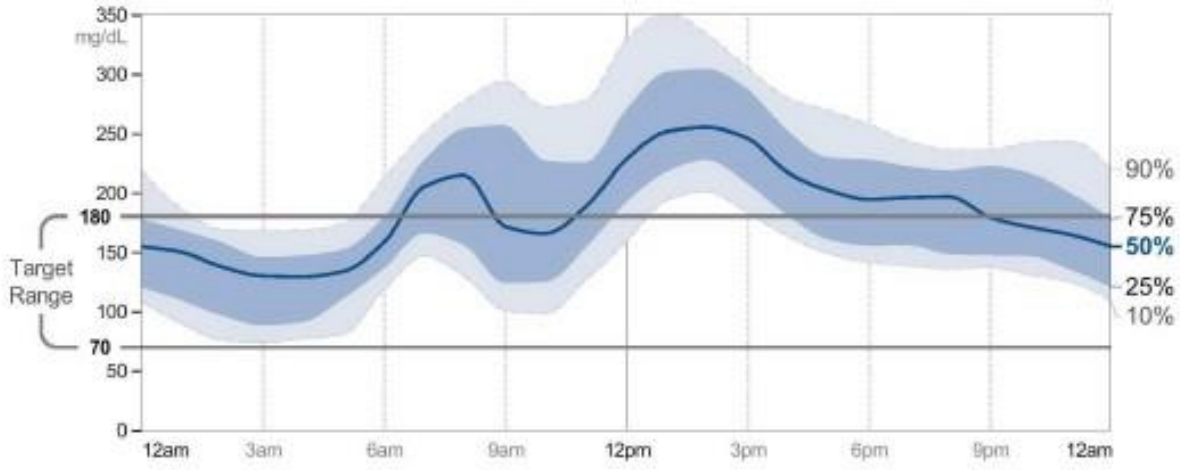
Summary

Average Glucose	Time In Range	Coefficient of Variation (CV)	Standard Deviation (SD)
186 mg/dL	Above 180 mg/dL (above 250 mg/dL: 16%) **47%**	**36.9%**	**68.7** mg/dL
*88-116**	In Target Range 70-180 mg/dL **51%**	*19-25**	*10-26**
	Below 70 mg/dL (below 54 mg/dL: 0%) **2%**		

*Reference ranges calculated from population without diabetes.

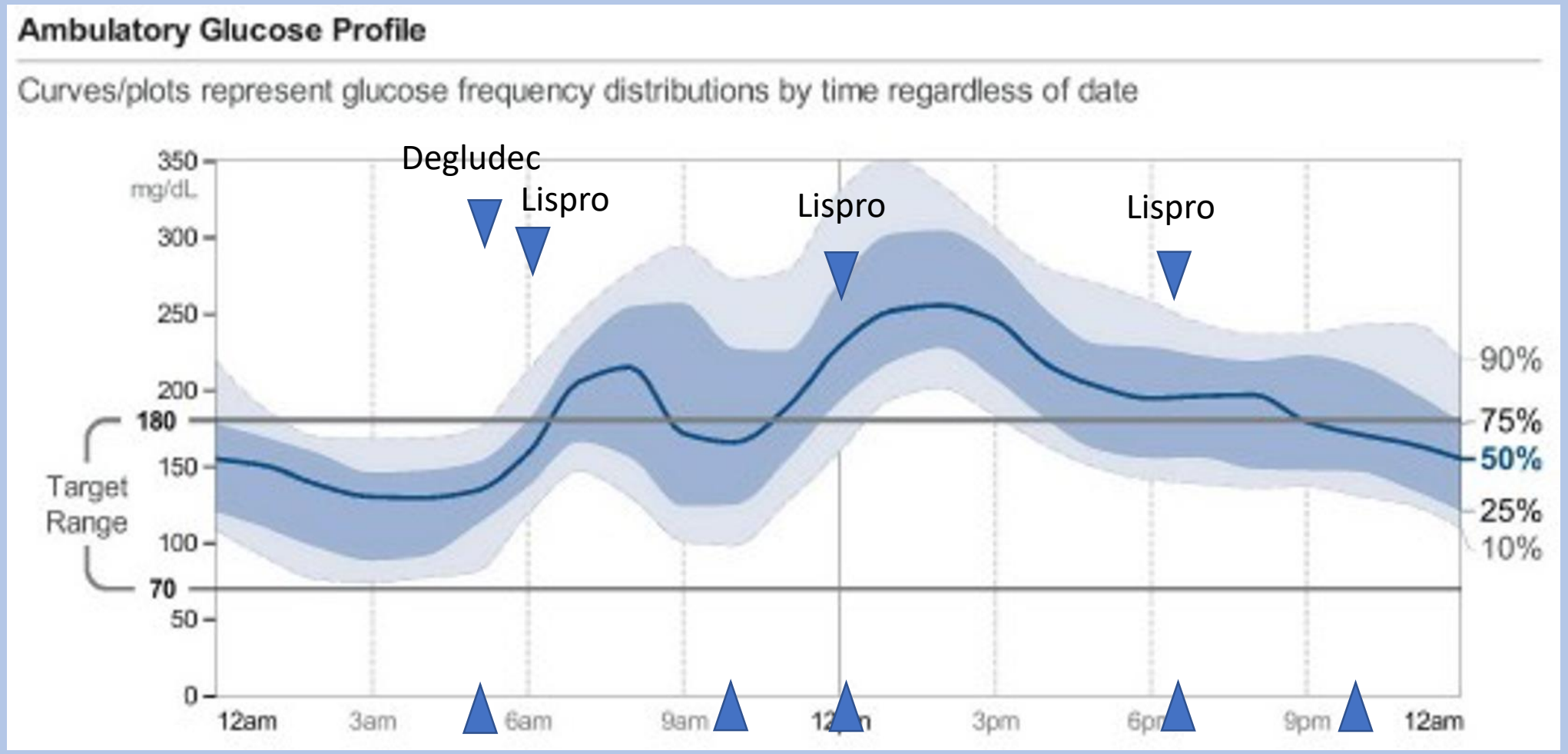
Ambulatory Glucose Profile

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

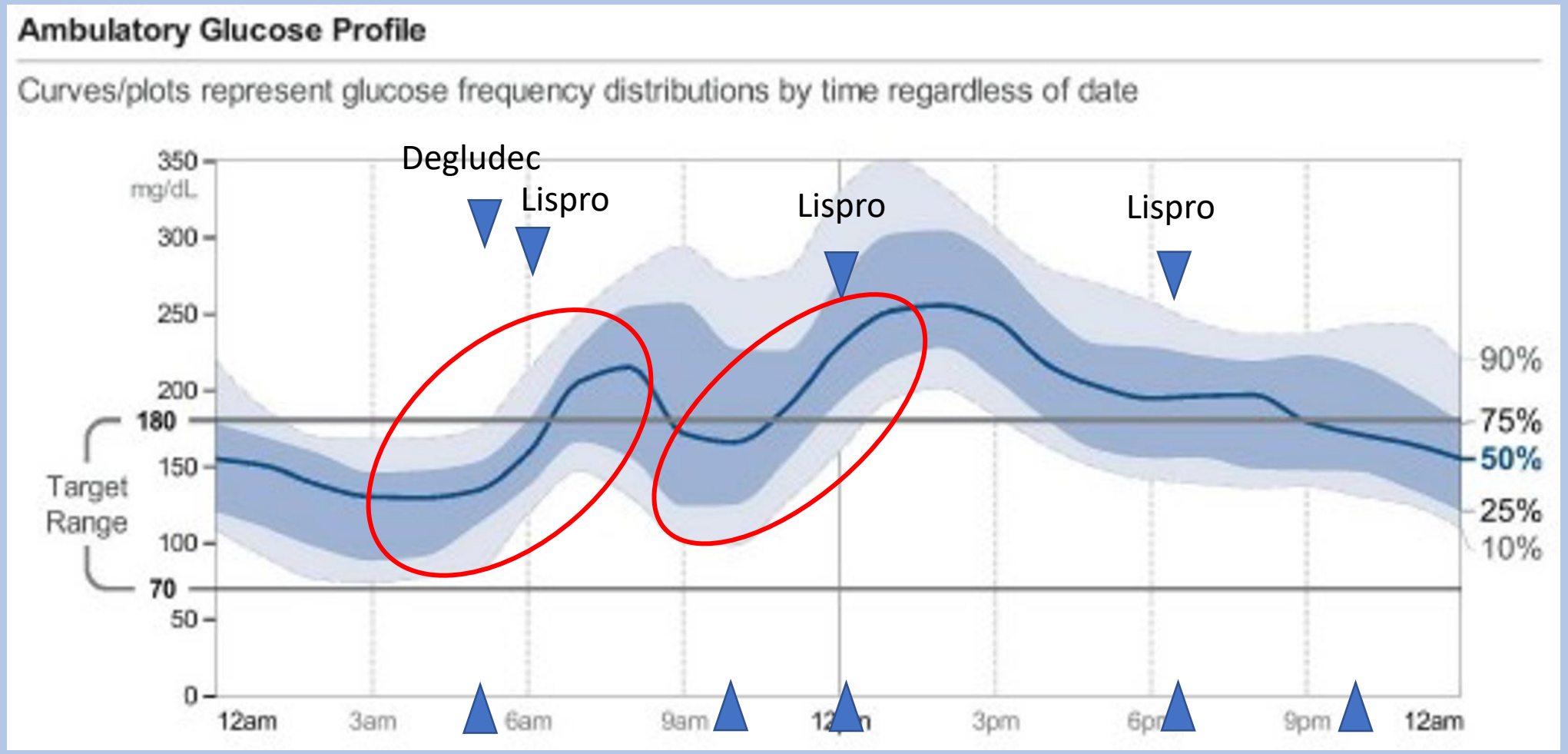


Step 2: review summary

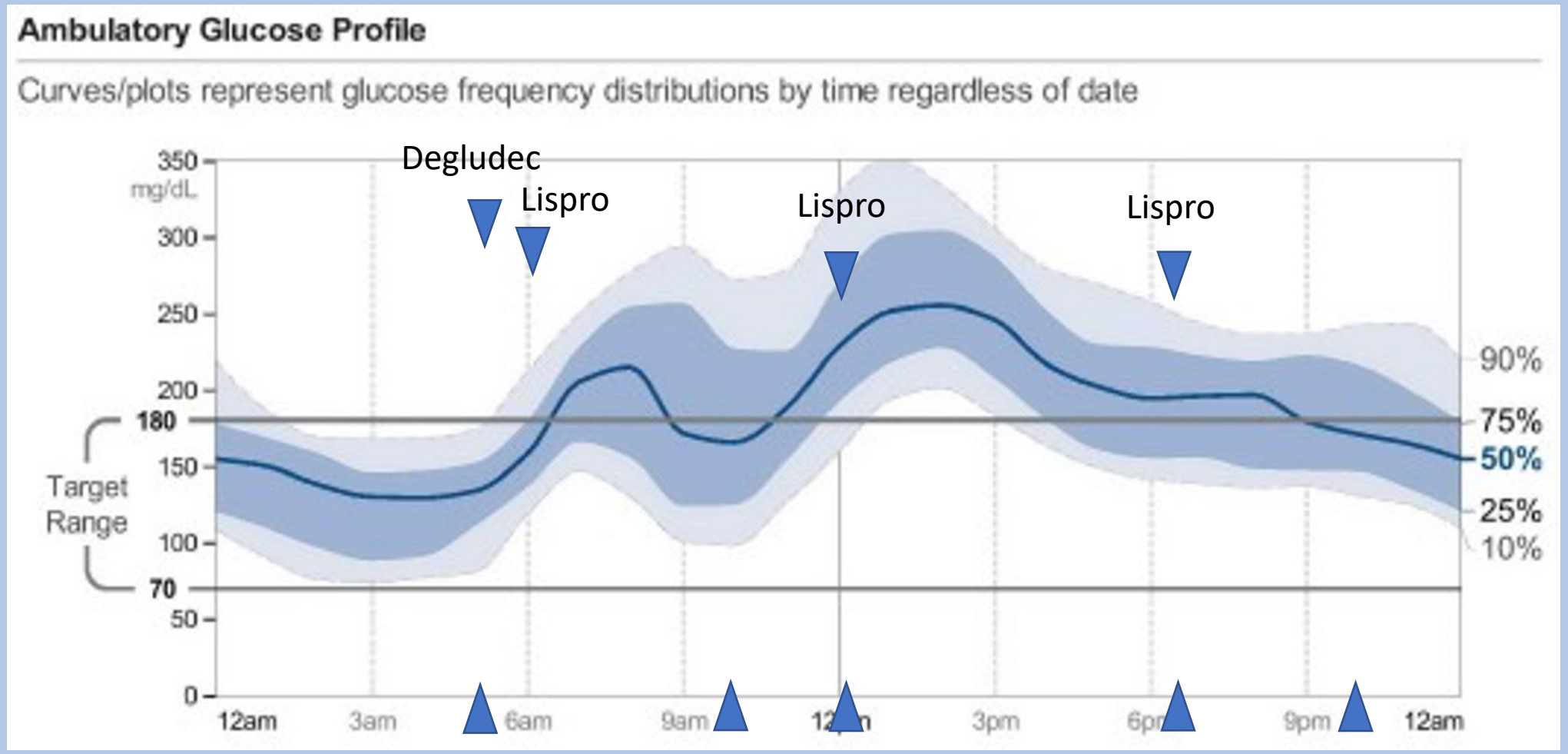
Step 3: mark patient's daily routine on AGP
Med list: Degludec 18units qam, Lispro 4-6u qac

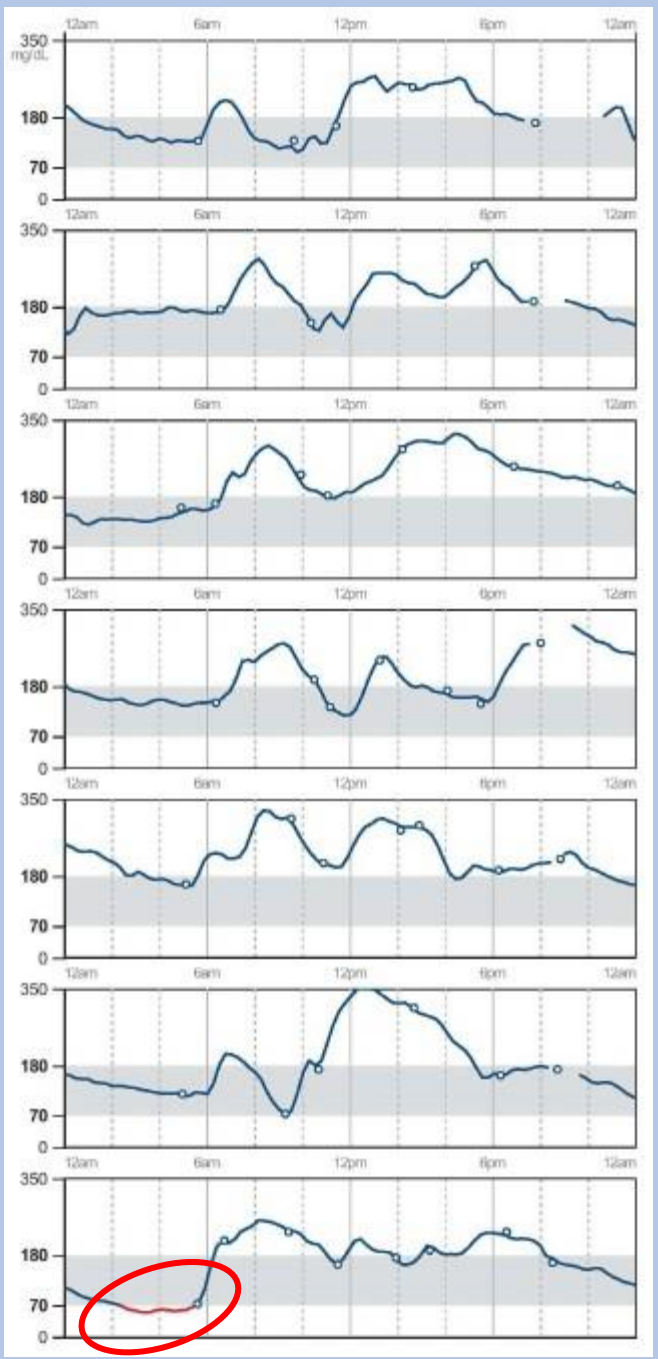


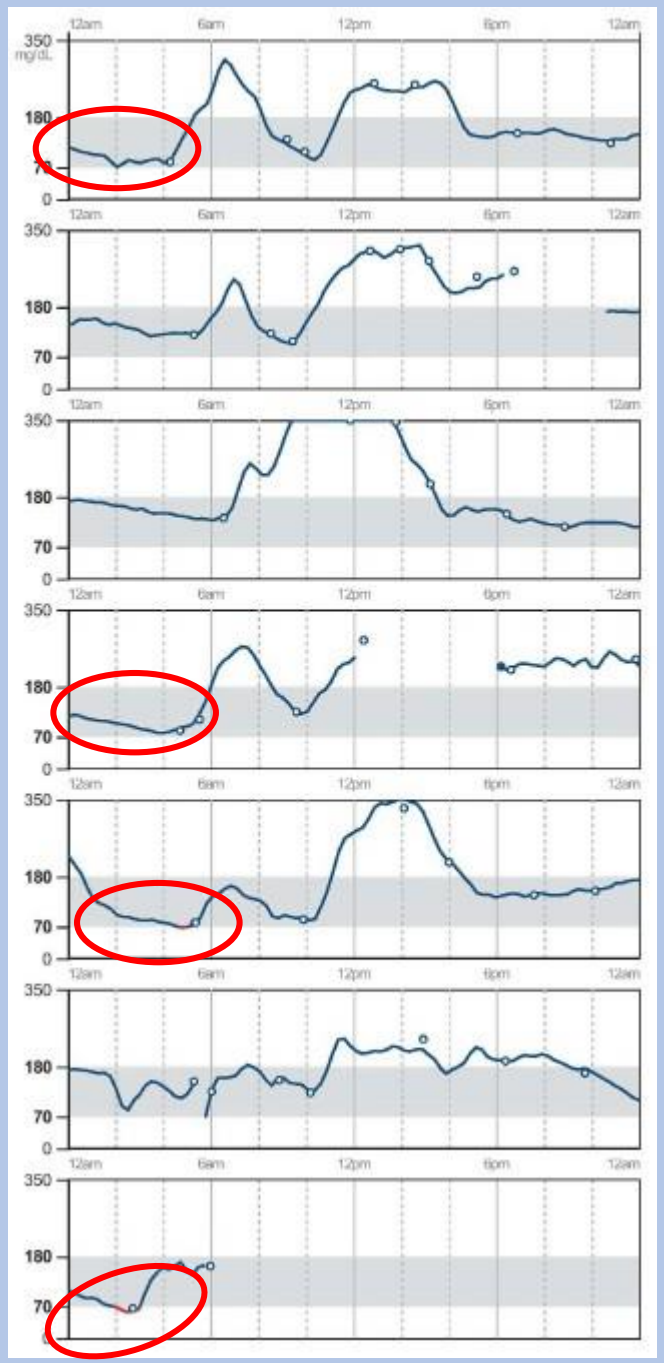
Step 4: Ask patient what they see (listen!)



Step 5: Look at problematic area (hypo-hyper-variability)







Step 5-1: verify with daily review

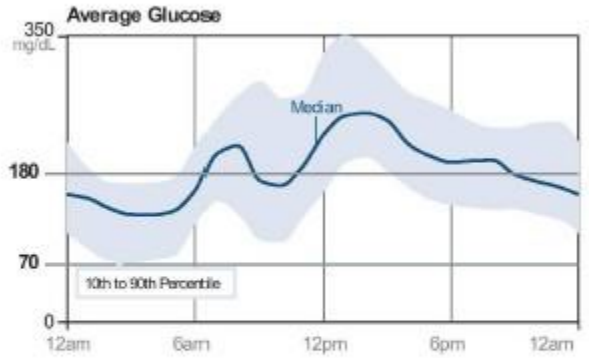
- Nocturnal hypoglycemia

→ after night time correction dose (lispro 4-5u)

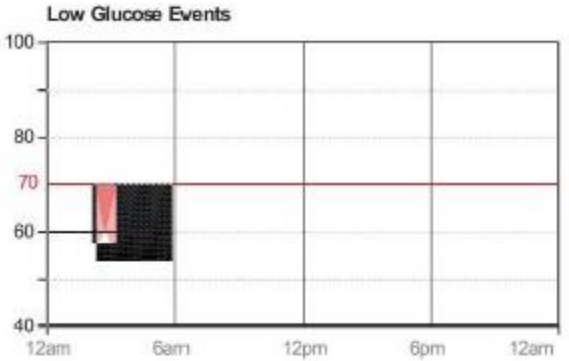
- Otherwise matching AGP

Glucose

AVERAGE GLUCOSE	186 mg/dL
% above target	47 %
% in target	51 %
% below target	2 %



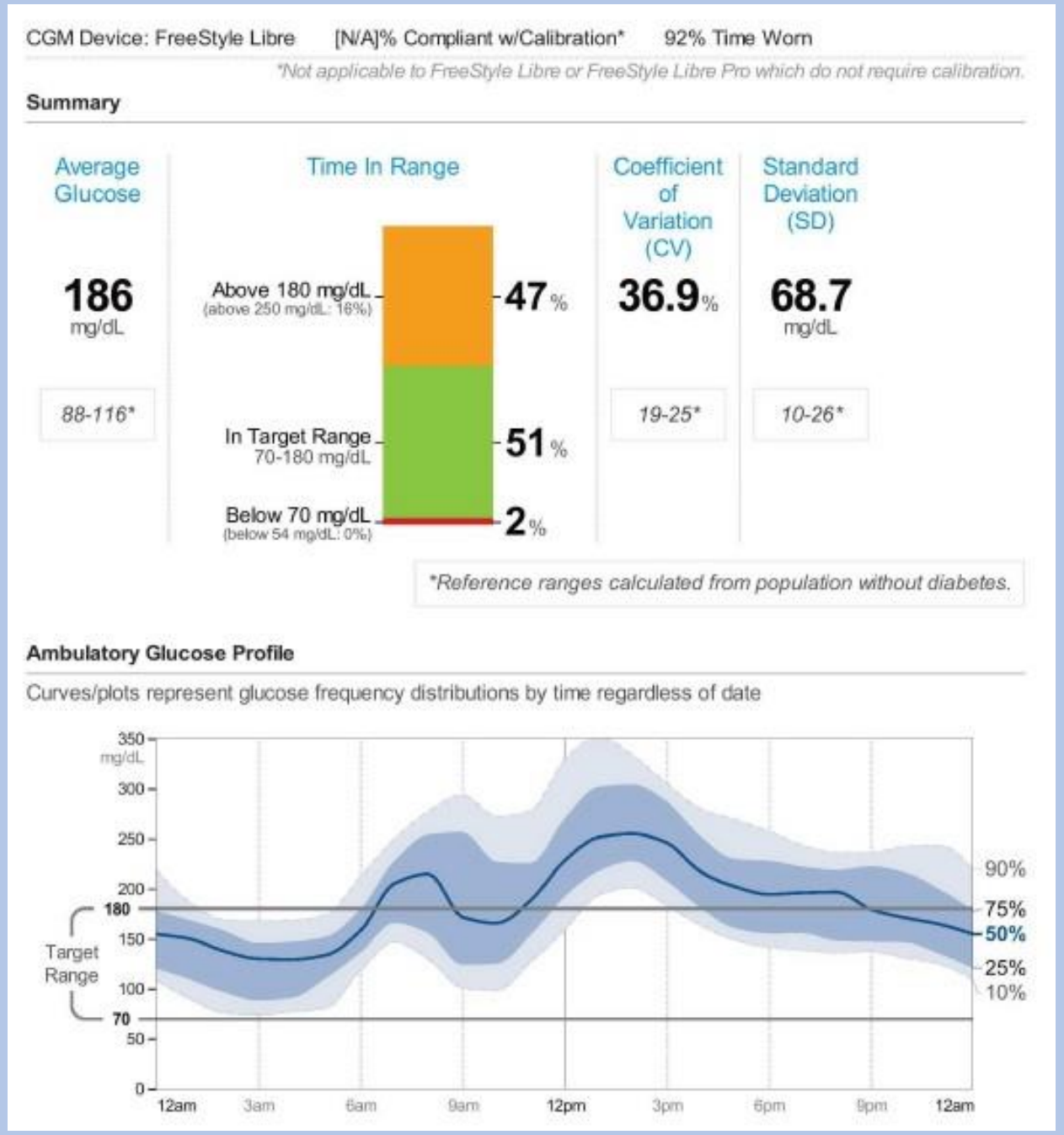
LOW GLUCOSE EVENTS	2
Average duration	136 Min



Sensor Usage

SENSOR DATA CAPTURED	92 %
Daily scans	6





Step 6: Collaborate with patient on problem solving

1. Nocturnal hypoglycemia

→ Conservative approach

2. Breakfast spike

→ Premeal bolusing (at least partial. Pump?)

→ lower CHO breakfast

3. Snack spike

→ Alternative snacking (low carb)

→ presnack bolusing

Coverage Guideline (Medicare)

- Patient has DM (either type 1 or 2)
- Require ≥ 3 insulin administrations per day or on insulin pump
- ~~require frequent glucose checks (≥ 4x/d)~~ to make treatment decisions*

as of 7/18/2021

*covers non-adjunctive/therapeutic CGMs: Dexcom, Freestyle Libre

CMS. Future local coverage determination: Glucose monitors. Available at: https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?lcdid=33822&ver=31&fbclid=IwAR3Y6kzpk9AVnWZePeMHT4-nAAzQpgTLJPqbT9PZJWxVzp8-K-IatjEHIA4. Accessed July 23, 2021

Billing

- Sensor placement: **95249** (personal), **95250** (professional)
- Billed at the time of data retrieval (≥72hrs of data is captured and printed) – not at the time of placement.
- Can only be billed by physician/PA/APRN but can be performed by RN/PharmD/RPh/CDE or MA (if within scope of practice).
- If a separate and significant E/M service is performed on same date, add a modifier 25 to E/M code (i.e., 99213)
- 99249 can only be billed one time while patient owns that receiver (sensor removal not required)
- 99250 can only be billed once a month (requires sensor removal)

Billing

- Data analysis/interpretation: 95251 (for both personal and professional)
- Minimum of 72hrs of data
- No face-to-face encounter required.
- Separate from E/M service (can be billed separately with modifier 25 to E/M code if significant E/M service was done)
- Can only be performed/billed by physician/PA/APRN

Charges

Codes	wRVU (2019)	Medicare (2019)	Commercial
95249 Personal CGM placement	0	$56.22	~$130
95250 Prof. CGM placement	0	$153.53	~$300
95251 Interpretation	0.70	~$36.40	~$90
E/M 99213 With modifier -25	0.97	~$75.32	

cms.gov/apps/physician-fee-schedule/search. Accessed 4/2/19

Kruger DF et al. Diabetes Educ. 2019 Feb;45(1_suppl):3S-20S

Questions

- cjcmedicine@gmail.com