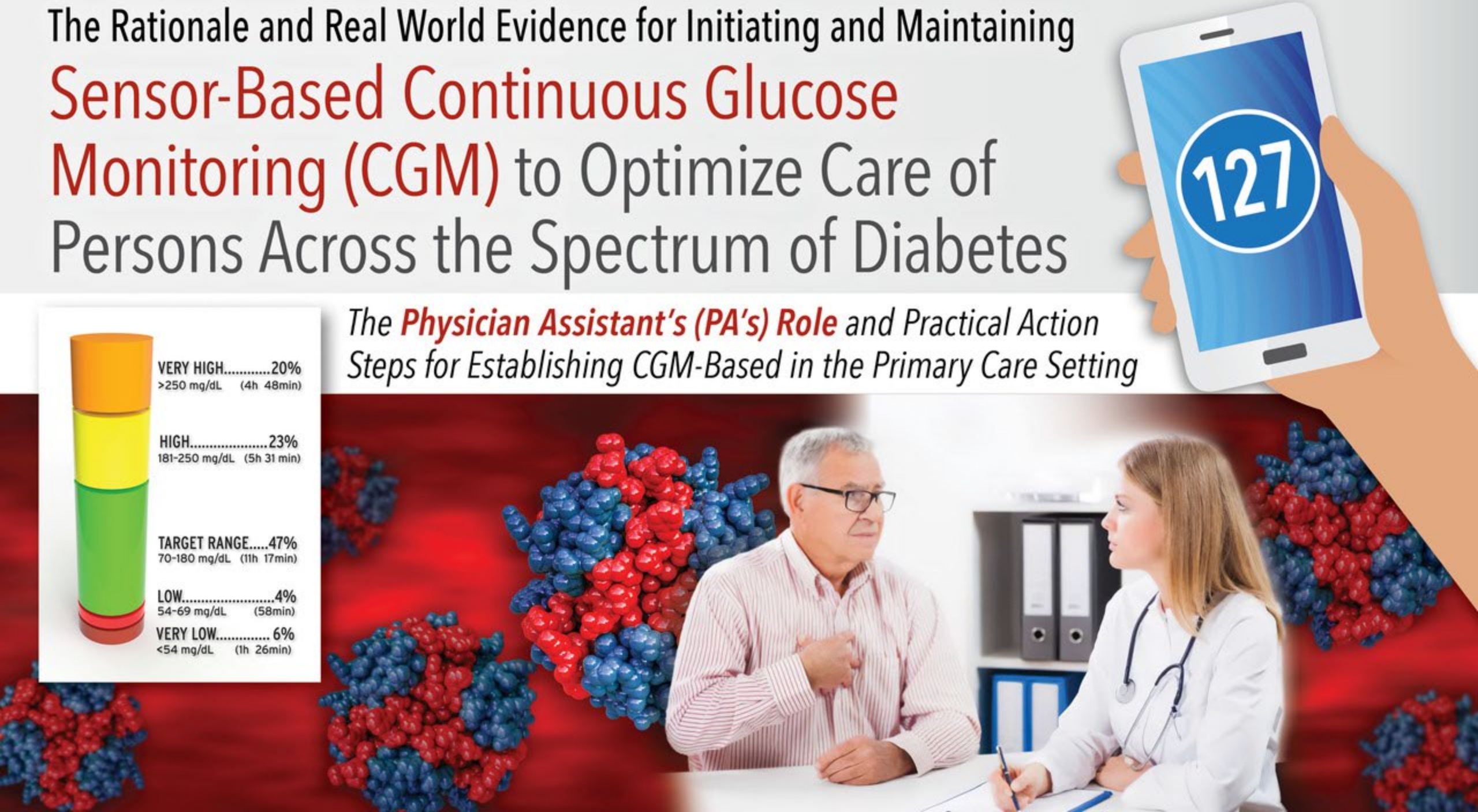
The Rationale and Real World Evidence for Initiating and Maintaining

Sensor-Based Continuous Glucose Monitoring (CGM) to Optimize Care of Persons Across the Spectrum of Diabetes



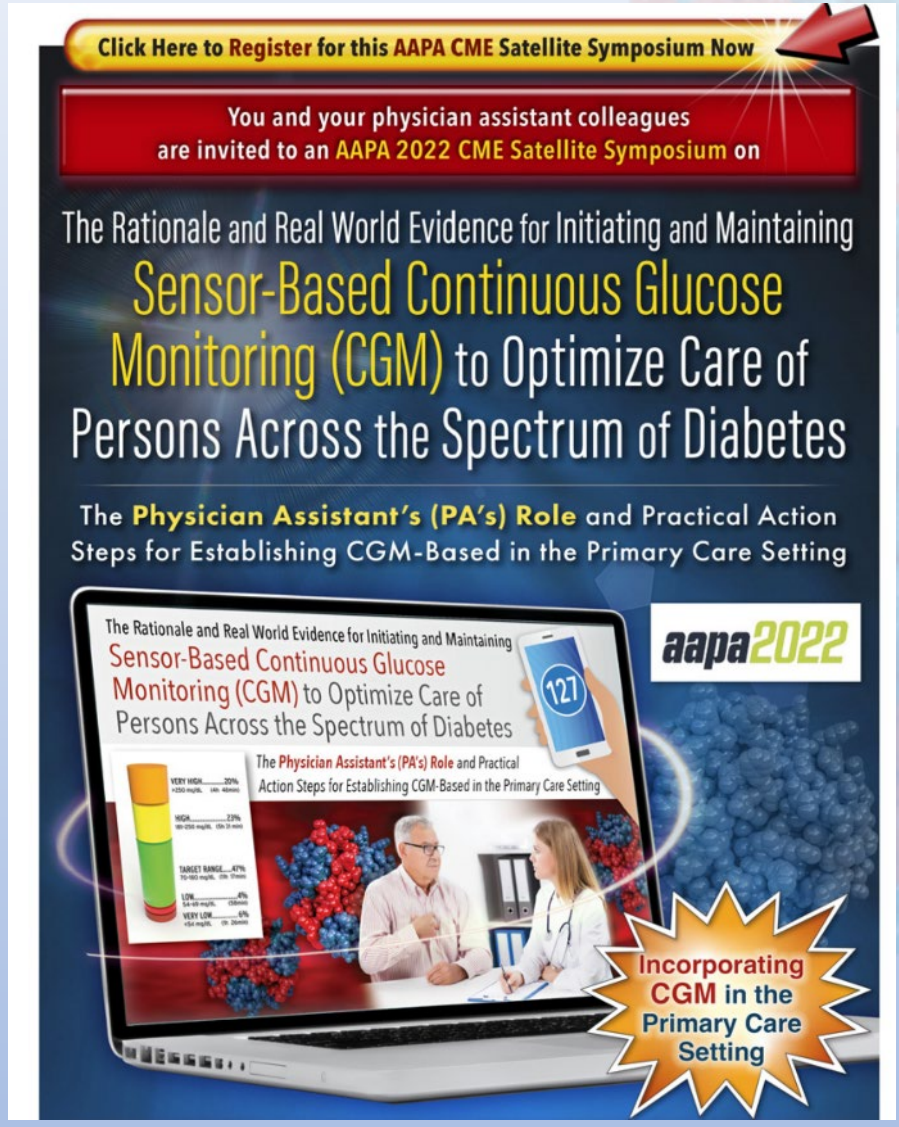
*The **Physician Assistant's (PA's) Role** and Practical Action Steps for Establishing CGM-Based in the Primary Care Setting*

Welcome and Program Overview

CME Certification: This activity has been reviewed by the AAPA Review Panel and is compliant with AAPA CME Criteria. This activity is designated for 1.5 AAPA Category 1 CME credits. PAs should only claim credit commensurate with the extent of their participation. Approval is valid from 5/22/2022 to 5/22/2022. AAPA reference number: CME-206183.

Commercial Support: Supported by an educational grant from Abbott Diabetes Care

PA
AAPA CATEGORY 1 CME



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The Critical Fundamentals of Sensor-Based CGM: A Primary Provider's Perspective

AAPA 2022

Ashlyn Smith, MMS PA-C

Adult Endocrine Physician Assistant, Phoenix, AZ

President, American Society of Endocrine Physician Assistants

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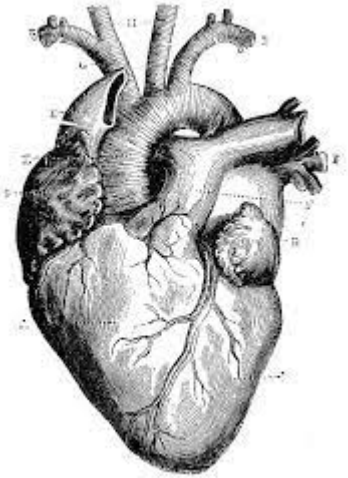
Diabetes Statistics in US

37.3 million

People living with DM

Leading cause of new blindness



2- to 8-fold increased risk of CVD

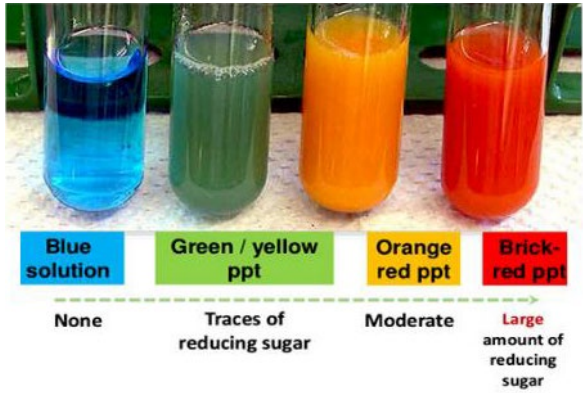
Most common cause of death in DM

Leading cause of ESRD

1. Lind, Marcus MD PhD; et al. “Glycemic Control and Excess Mortality in Type 1 Diabetes.” November 20, 2014. N Engl J Med 2014; 371:1972-1982. DOI: 10.1056/NEJMoa1408214
2. Centers for Disease Control and Prevention. National Diabetes Statistics Report website. https://www.cdc.gov/diabetes/data/statistics-report/index.html. Accessed April 24, 2022 .

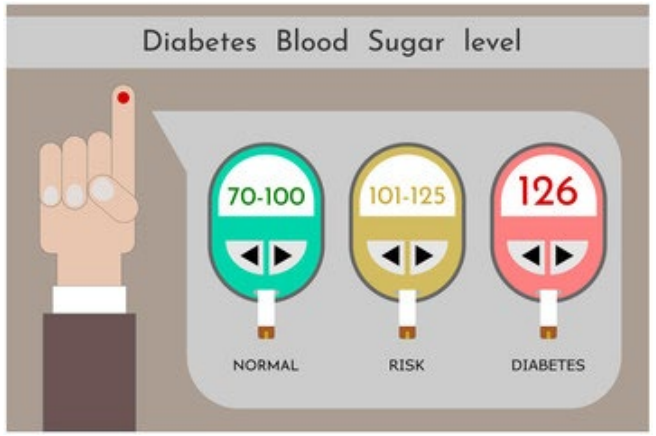
Evolution of Glucose Monitoring

Urine Glucose Test



Blood Glucose Test Strip

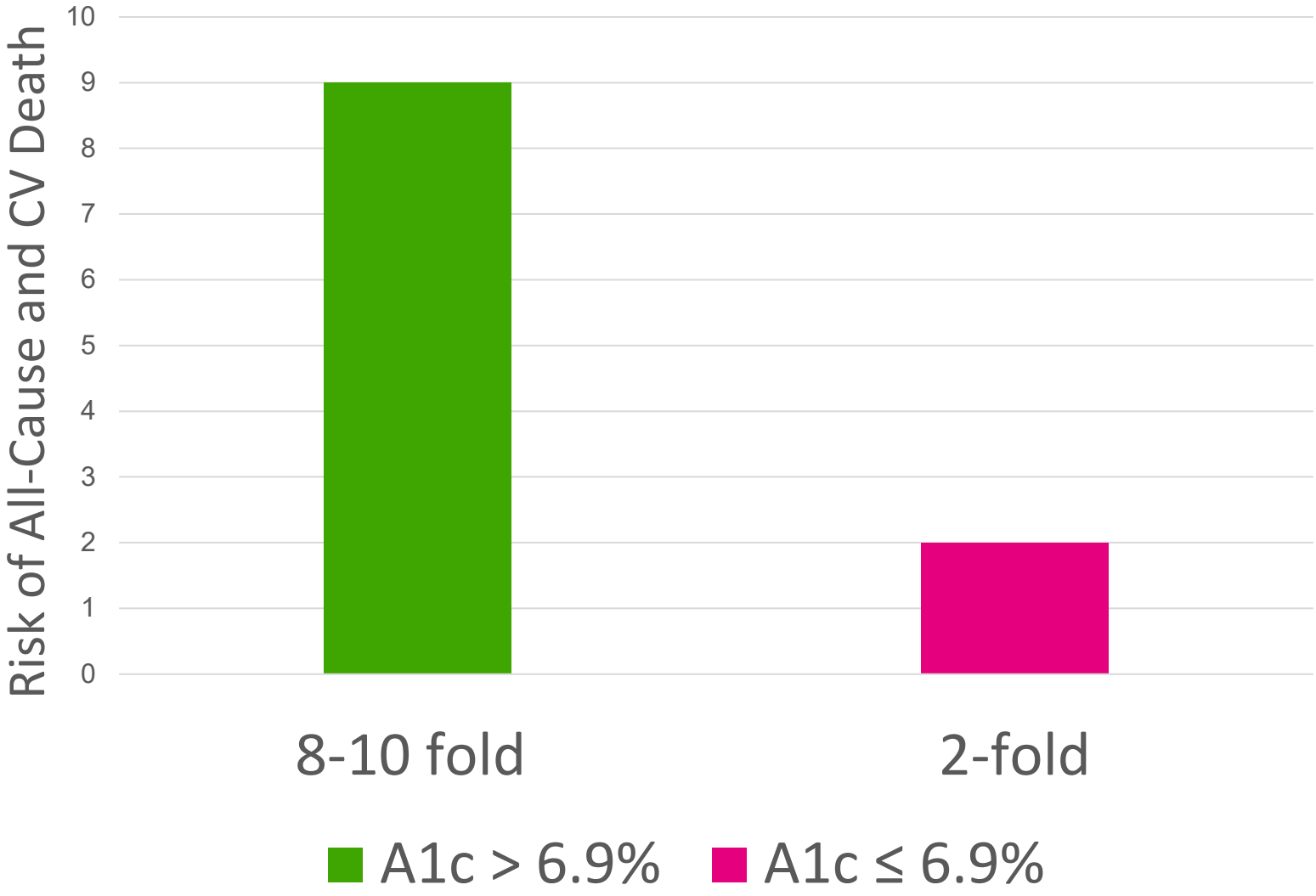
Blood Glucose Meter



Continue Glucose Monitor

1908 → 1964 → 1970s → 1999

Risk of All-Cause Mortality and Cardiovascular Death



Lind, Marcus MD PhD; et al. “Glycemic Control and Excess Mortality in Type 1 Diabetes.” November 20, 2014. N Engl J Med 2014; 371:1972-1982. DOI: 10.1056/NEJMoa1408214

Intensive Intervention vs Standard of Care: Landmark Trials

ACCORD

- Established or high risk for CVD
- Target A1c 6% vs 7%
- **Increased risk of CV death and all-cause mortality**
- Study stopped prematurely due to increased rate of death

ADVANCE

- Hx of a microvascular or macrovascular complication or a risk factor of vascular disease
- Target A1c 6.3% vs 7%
- Reduction in nephropathy
- No difference in death
- **Increased severe hypoglycemia and hospitalizations**

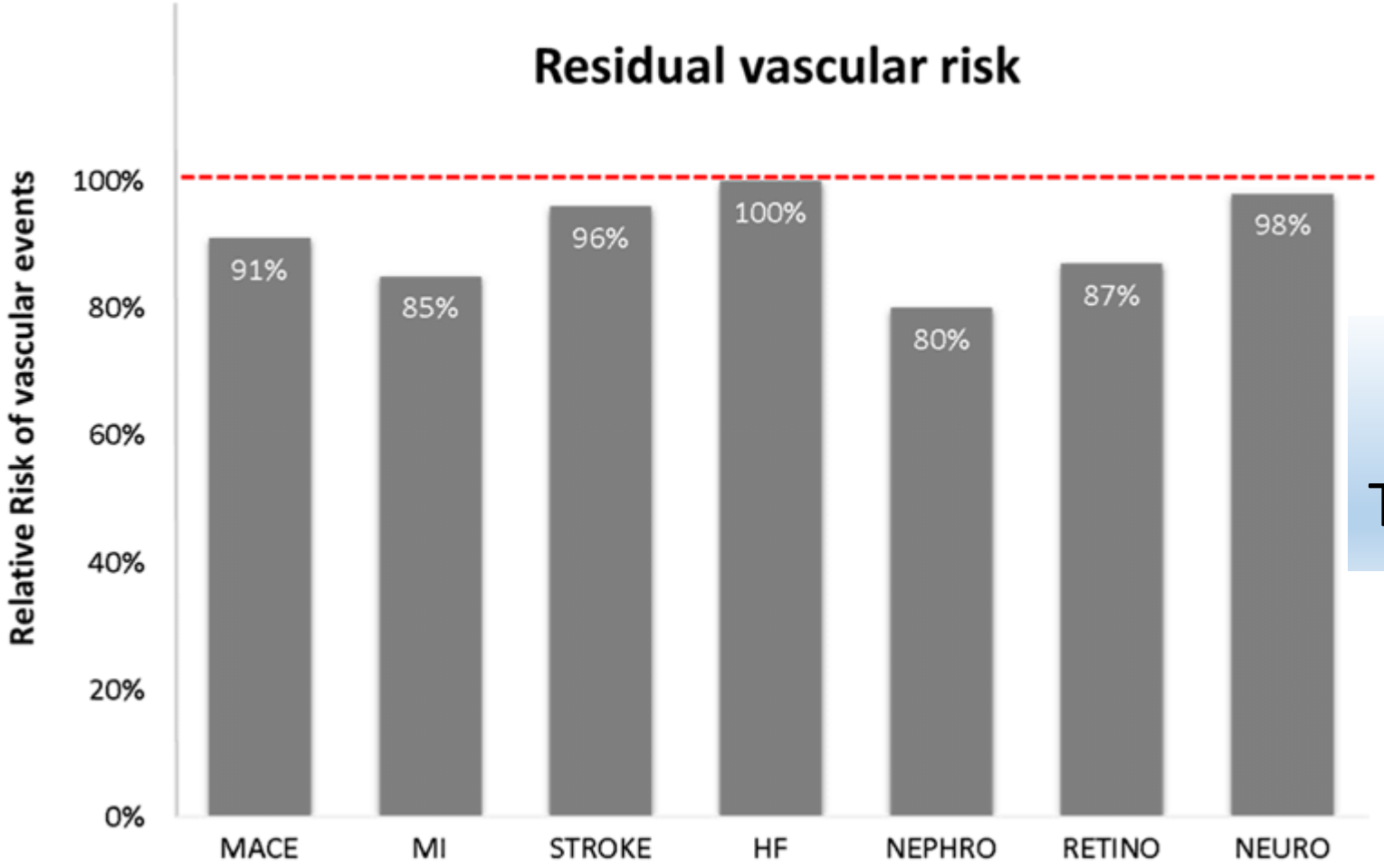
VADT

- Established CVD and no prior CVD
- Target A1c 6% vs 8-9%
- No change in MACE*
- **Increased symptomatic, asymptomatic, and nocturnal hypoglycemia**
- **Increased CV death**

*MACE=major adverse cardiovascular events

1. The Action to Control Cardiovascular Risk in Diabetes Study Group. “Effects of Intensive Glucose Lowering in Type 2 Diabetes.” N Engl J Med 2008; 358:2545-2559.
2. The ADVANCE Collaborative Group. “Intensive Blood Glucose Control and Vascular Outcomes in Patients with Type 2 Diabetes.” N Engl J Med 2008; 358:2560-2572.
3. Veterans Affairs Diabetes Trial – VADT. Duckworth W, Abraira C, Moritz T, et al., on behalf of the VADT Investigators. Glucose control and vascular complications in veterans with type 2 diabetes. N Engl J Med 2009;360:129-39.

Residual Risk After Intensive Intervention



Reduce Residual Risk:
Think Beyond A1c

Giugliano, Dario & Maiorino, Maria & Bellastella, Giuseppe & Esposito, Katherine. (2018). Type 2 diabetes and cardiovascular prevention: the dogmas disputed. Endocrine. 60. 10.1007/s12020-017-1418-y.

Effective T2DM Therapy Requires Balance

Timely, effective and stable glycemic control

- Achievement of HbA1c targets
- Prevention of complications
- Lower healthcare utilization
- Less restrictive regimens to improve adherence and reduce burden

Low risk of hypoglycemia

- Reduce fear of hypoglycemia
- Facilitate medication initiation and titration
- May improve adherence
- Reduced morbidity and healthcare utilization

Only **6 of the top 18** glucose meters met the accuracy standard of 2016 FDA guidance

Klonoff; et al. *Diabetes Care* 2018;41(8):1681–1688

Pogach L & Aron D. JAMA 2010;303:2076–7; Khunti K, et al. Diabetes Obes Metab 2016;18:907–15; Riddle M, et al. Diabetes Technol Ther 2016;18:252–7; Peyrot M, et al. Diabet Med 2012;29:682–9; Russell-Jones D, et al. Diabetes Obes Metab 2018;20:488–96; Davies MJ, et al. Diabet Med 2013;30:512–24; Willis WD, et al. Expert Rev Pharmacoecon Outcomes Res 2013;13:123–30; Ahrén B. Vasc Health Risk Manag 2013;9:155–63

Fundamental Barriers to Treatment Success

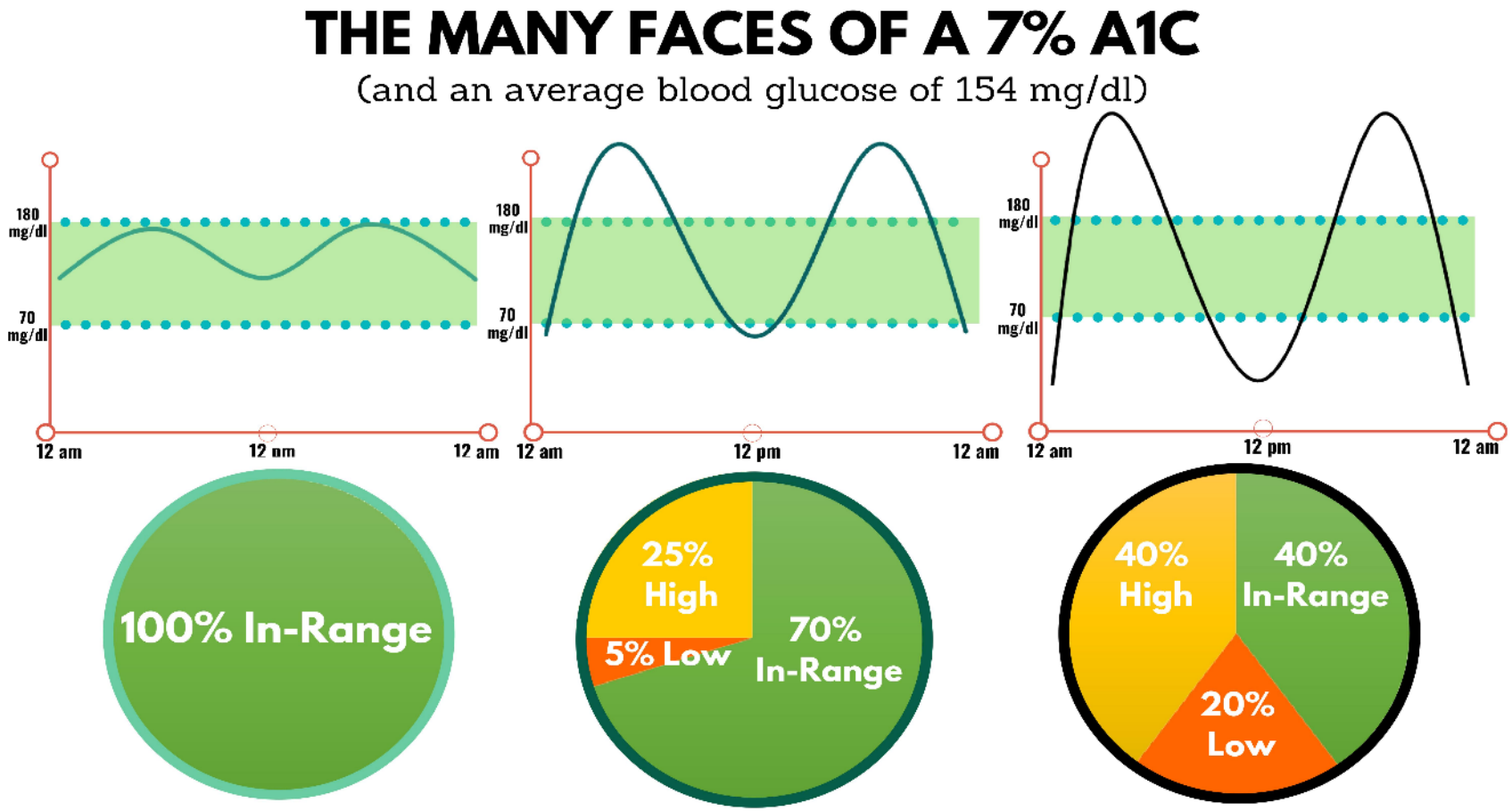
- Not all A1c's are created equal
- Pair A1c with glucose data
- Fingerstick blood glucose testing = snapshot in time
- Glucose variability
  - Drives complications
  - Increases hypoglycemia risk
  - Contributes to non-adherence
  - Prolongs clinical inertia
  - Impacts disease burden

Higher coefficient of variation (CV)[1]:

- Unfavorable metabolic profile
- Increased risk of developing micro- and macrovascular complications and mortality
- Association of CV of glucose was more consistent than A1c in predicting metabolic outcomes and complications

Slieker, Roderick C; et al. "Visit-to-visit variability of glycemia and vascular complications: the Hoorn Diabetes Care System cohort." Cardiovasc Diabetol. 2019 Dec 12;18(1):170. doi: 10.1186/s12933-019-0975-1.

Diabetes Technology: An Opportunity to Solve Persistent Problems



Reduce Residual Risk--Beyond A1c

Decrease glycemic variability: A1c + Time in Range

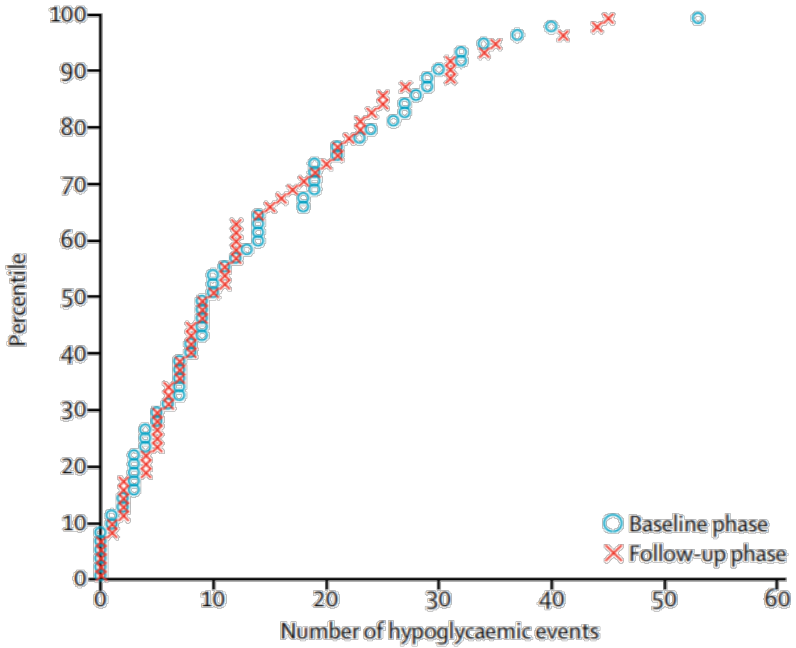
Available CGM Technology

	Medtronic Guardian Sensor 3	DEXCOM G6	Freestyle Libre 2	EversenseE3
MARD (%)	9.6	9	9.3	8.5
Calibrations/day	2-4	None	None	1-2
Non-adjunctive therapy	No	Yes	Yes	Yes

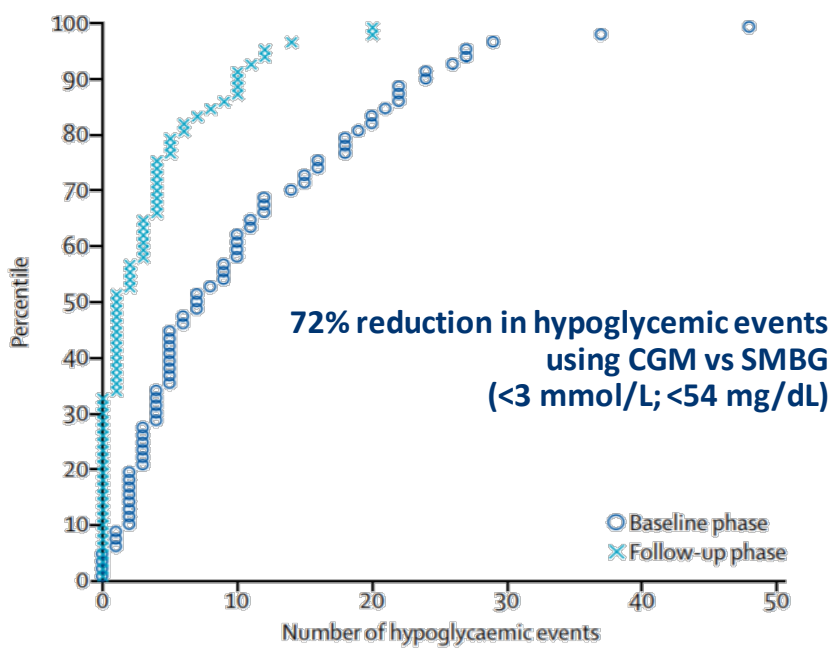
CGM Changes Diabetes Management

The HypoDE Study (baseline vs intervention)

Control group



CGM group



72% reduction in hypoglycemic events using CGM vs SMBG (<3 mmol/L; <54 mg/dL)

- Real-time continuous glucose monitoring (rtCGM) in avoidance of hypoglycemia in T1DM on MDI with impaired hypoglycemia awareness or severe hypoglycemia

Heinemann L, et al. Lancet 2018;391:1367–77.

CGM Changes Diabetes Management

Intermittent rtCGM[1]

- RCT in T2DM on diet/exercise alone or other therapies except prandial insulin
  - **Significant reduction in A1C**
  - "Improvement…occurred **without** a greater **intensification of medication**[2]"
  - **Sustained improvement** over subsequent 40 weeks without rt-CGM

Flash Glucose Monitoring [3]

- Open label RCT in T2DM on insulin
  - **Significant reductions** in the risk of all levels of **hypoglycemia**
  - **Significant improvement in treatment satisfaction** measured by validated questionnaires

1. Vigersky, Robert A, MD; et al.. Diabetes Care 2012;35(1):32–38. https://doi.org/10.2337/dc11-1438
2. American Association of Clinical Endocrinology Clinical Practice Guideline. CLINICAL PRACTICE GUIDELINE| VOLUME 27, ISSUE 6, P505-537, JUNE 01, 2021. *emphasis added*
3. Haak, Thomas; et al. Diabetes Ther. 2017 Feb; 8(1): 55–73. Published online 2016 Dec 20. doi: 10.1007/s13300-016-0223-6

Real World Evidence for CGM in T2DM

TABLE 1. REAL-WORLD STUDIES OF CONTINUOUS GLUCOSE MONITORING USE IN POPULATIONS WITH TYPE 2 DIABETES

Studies	*Design*	*Study population*	*Outcome measures following CGM initiation*	*Findings*
T2D				
Bergenstal[27]	A 12-month, retrospective observational study, pre- and post-CGM acquisition (IBM MarketScan Commercial Claims and Medicare Supplemental databases)	$N=2463$ T2D Age: ≥18 years Short- or rapid-acting insulin	ADEs and ACHs	ADE rates decreased from 0.180 to 0.072 events/patient-year HR: 0.39 [0.30, 0.51]; $P<0.001$) ACH rates decreased from 0.420 to 0.283 events/patient-year (HR: 0.68 [0.59 0.78]; $P<0.001$)
Miller[25]	A 12-month, retrospective observational study, pre- and post-CGM acquisition (IBM MarketScan Commercial Claims and Medicare Supplemental databases)	$N=10,282$ T2D Age: ≥18 years Basal insulin or noninsulin therapy	ADEs and ACHs	ADE rates decreased from 0.076 to 0.052 events/patient-year (HR: 0.68 [0.58 0.80]; $P<0.001$) ACH rates decreased from 0.177 to 0.151 events/patient-year (HR: 0.85 [0.77 0.94]; $P=0.002$)
Wright[26]	A 12-month, retrospective observational study, pre- and post-CGM acquisition (IBM Explorys database)	$N=1034$ T2D Age: ≥18 years Basal insulin or noninsulin therapy	A1C change	Reductions in A1C within the full cohort (from 10.1% ± 1.7% to 8.6% ± 1.8%, $P<0.001$) Greatest reductions in patients with baseline A1C ≥12.0% (−3.7%, $P<0.001$) Reductions in A1C in both treatment groups (basal insulin, −1.1%; and noninsulin −1.6%, both $P<0.001$)
Elliot[30]	A 3- to 6-month, retrospective chart review	$N=91$ T2D Age: ≥18 years Basal insulin	A1C change	Reductions in A1C after ≥3 months of CGM use (−0.8% ± 1.1%, $P<0.0001$) Subgroup analysis by baseline A1C (<9.0% vs. ≥9.0%) showed A1C reductions in both groups (−0.5% ± 0.8% and 1.6% ± 1.3%, $P<0.0001$, respectively)
Carlson[31]	A 12-month, retrospective chart review, pre- and post-CGM acquisition	$N=100$ T2D Age: ≥18 years Basal insulin	A1C change	Reduction in A1C after ≥3 months of CGM use (−1.4% ± 1.3%, $P<0.0001$) Subgroup analysis by baseline A1C (<9.0% vs. ≥9.0%) showed significant A1C reductions in both groups (−0.8% ± 0.7% and 1.7% ± 1.4%, both $P<0.0001$, respectively)
Kröger[21]	A 3- to 6-month, pragmatic, parallel, European, retrospective, noninterventional chart review (Austria, French, and German Registries)	$N=363$ T2D adults	A1C change Subgroup analyses by age (<65 vs. ≥65 years), duration of insulin therapy (<9 vs. ≥9 years), BMI (<30 vs. ≥30 kg/m^2), and gender	Reduction in A1C in all three countries: −0.9% (Austria), −0.8% (France), and −0.9% (Germany), all $P<0.0001$ A1C improvements across all subgroups, with no significant differences between subgroups

ACH=all-cause hospitalization

ADEs= acute diabetes-related adverse events

Gavin, James R, MD; et al. DIABETES TECHNOLOGY & THERAPEUTICS Volume 23, Supplement 3, 2021 Mary Ann Liebert, Inc. DOI: 10.1089/dia.2021.0211

Guideline-Directed Therapy

American Association of Clinical Endocrinology Clinical Practice Guideline:

The Use of Advanced Technology in the Management of Persons With Diabetes Mellitus

Advanced diabetes technology can assist persons with diabetes to safely and effectively achieve glycemic targets, improve quality of life, add greater convenience, potentially reduce burden of care, and offer a personalized approach to self-management.

Furthermore, diabetes technology can improve the efficiency and effectiveness of clinical decision-making.

Includes recommendations for CGM

- Strongly recommend: All persons with diabetes treated with intensive insulin therapy
- Recommend: All individuals with problematic hypoglycemia
- May recommend: Individuals with T2D who are treated with less intensive insulin therapy

Guideline-Directed Therapy

American Diabetes Association:

Standards of Medical Care in Diabetes—2022

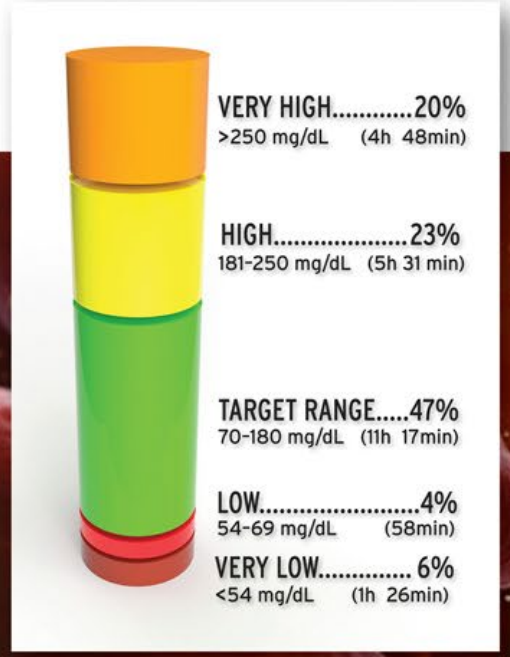
Real-time continuous glucose monitoring or intermittently scanned continuous glucose monitoring

- Should be offered for diabetes management in adults with diabetes on multiple daily injections or continuous subcutaneous insulin infusion who are capable of using devices safely
- Can be used for diabetes management in adults with diabetes on basal insulin who are capable of using devices safely

The Rationale and Real World Evidence for Initiating and Maintaining

Sensor-Based Continuous Glucose Monitoring (CGM) to Optimize Care of Persons Across the Spectrum of Diabetes

*The **Physician Assistant's (PA's) Role** and Practical Action Steps for Establishing CGM-Based in the Primary Care Setting*



The Foundational Importance of CGM/AGP-Based Management of Persons with T2D in the Physician's Assistant Setting

What Do the Studies and Guidelines Teach Us?

Jeff Unger, MD, FAAFP, FACE
Director, Unger Primary Care Concierge Medical Group
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Associate Medical Director Mission Hospice
Director Metabolic Studies Catalina Research Institute, LLC; Montclair CA
Assistant Clinical Professor of Family Medicine, UC Riverside School of Medicine
Medical Director, Akasha Recovery Center, Cardiff By The Sea, CA

Disclosures

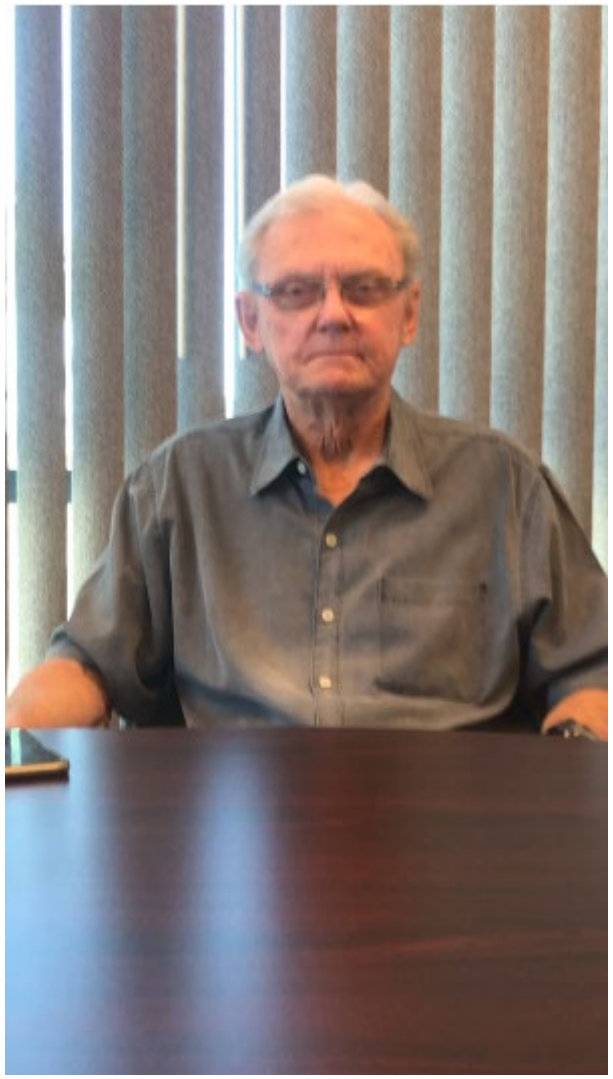
Faculty	Disclosures
Jeffrey Unger, MD, FAAFP, FACE	Abbot Diabetes: Primary Care Advisory Board, Speaker. Dexcom: Primary Care Advisory Board. Medtronic Diabetes: Primary Care Advisory Board.

Learning Objectives

- Review available diabetes technologies to manage patients with diabetes in the physician assistant/primary care setting
- Discuss how CGMs, connected pens, insulin pumps and integrated devices can be applied in the shared clinical-decision making process to better manage patients with diabetes
- Select the appropriate diabetes technologies and devices for each patient
- Incorporate diabetes technologies that are effective in managing patients in special populations

Meet Roy

- 77-year-old man diagnosed with type 1 diabetes at age 15 (in 1961)
- Placed initially on a single injection of pork insulin daily
- Advised to perform urine testing once daily
- Told by his doctor that he would likely die by age 20
- Started on integrated “hybrid” insulin pump and sensor in July 2020



Why Consider Using Continuous Glucose Monitoring (CGM)?

- In 1993 the DCCT established the “A1C” as the gold standard for estimating diabetes complication risk
- Despite the introduction of 18 new therapeutic interventions, only 50% of patients are able to achieve their targeted glycemic goals
- Patients are frustrated by glycemic variability - caused by lack of insulin secretion and excess excretion of glucagon
- The rate limiting step to diabetes management is hypoglycemia
- Identifying interventions which can add value to A1C interpretation and maintain “in-target” glucose values would improve patient adherence and reduce the occurrence of “dysglycemia”

Hirsch IB, Verderese CA. PROFESSIONAL FLASH CONTINUOUS GLUCOSE MONITORING WITH AMBULATORY GLUCOSE PROFILE REPORTING TO SUPPLEMENT A1C: RATIONALE AND PRACTICAL IMPLEMENTATION. Endocr Pract. 2017 Nov;23(11):1333-1344.

Common Sources of Error in A1C Interpretation

Directionality of Effect	Source of Error
Falsely elevated A1C	• Iron deficiency • Anemia • Hemoglobinopathies • Race: African American, Hispanic, Asian
Falsely low A1C	• Hemolysis • Reticulocytosis • Hemoglobinopathies • Post-hemorrhage or post-transfusion • Drugs: Iron, erythropoietin, dapsone • Uremia • Splenomegaly

Rubinow KB, Hirsch IB. Reexamining metrics for glucose control. JAMA. 2011 Mar 16;305(11):1132-3.

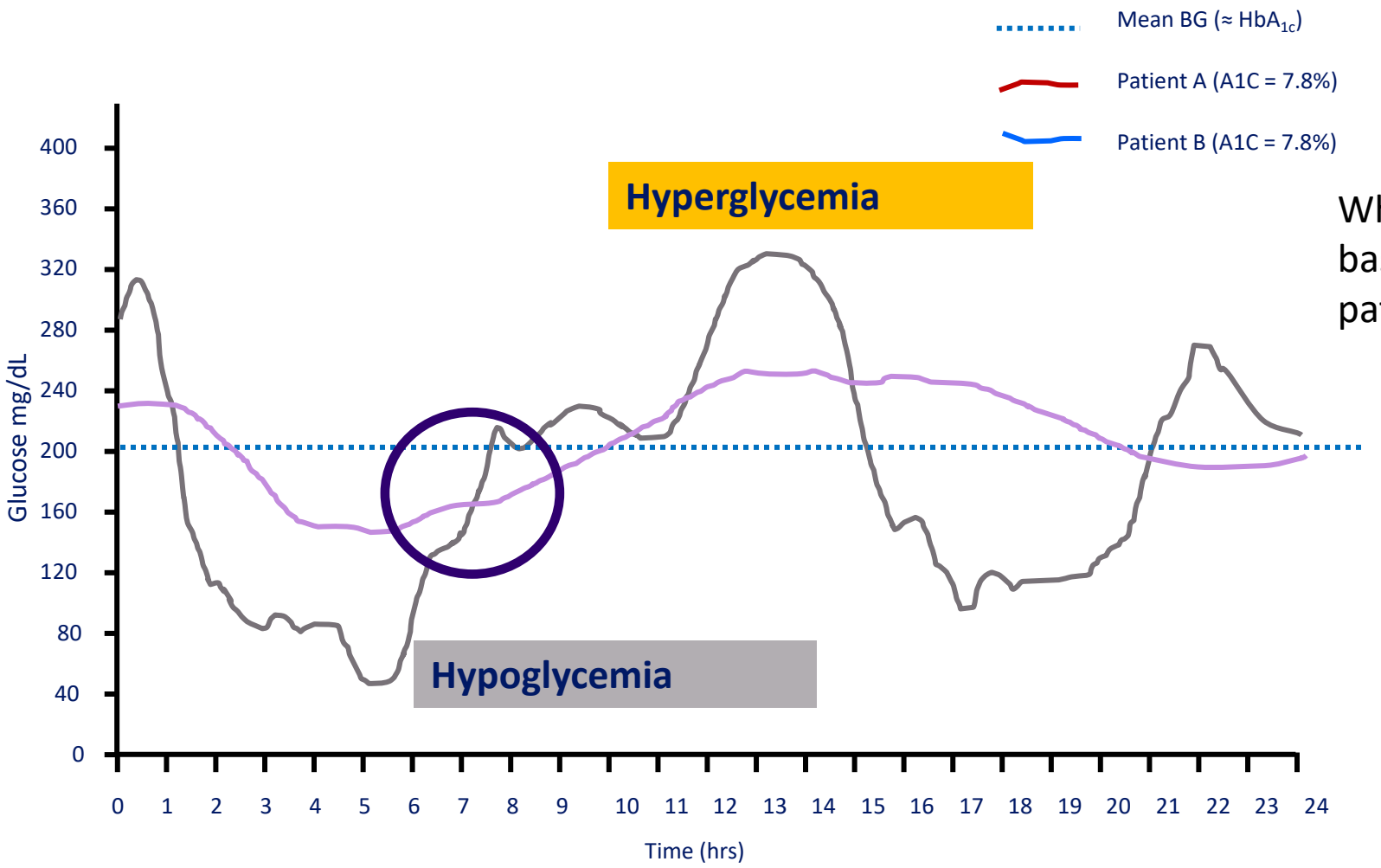
Not All A1cs Are Created Equal

HbA1c only provides a broad look at a patient's glucose history. Time in Range provides more actionable information than A1c alone and should complement A1c.[1]

Not actual patient data; for illustrative purposes only.

1. Battelino T, Danne T, Berganstal RM, et al. Clinical targets for continuous glucose monitoring data interpretation: recommendations from the international consensus on time in range. *Diabetes Care.* 2019;42(8):1593-1603.

Glucose Variability is not Apparent from A1C



What happens if 10 units basal insulin is initiated on patient A?

Image adapted from Penckofer S, Quinn L, et al. Does glycemic variability impact mood and quality of life? Diabetes Technol Ther. 2012 Apr;14(4):303-10.

42-year-old construction worker
T2DM x 5 years
How would you interpret this glucose log?

- A1C 7.6 %
- How would you safely and effectively adjust his medical regimen?
- Meds:
  - Metformin 500 mg BID
  - Insulin degludec + Liraglutide 22 u/d

?

Date	Overnight	Early Morning	Late Morning	E
	12 AM - 6 AM	6 AM - 9 AM	9 AM - 11 AM	
2/6/2018 Tue		**181 6:16 AM**		
2/5/2018 Mon		177 6:17 AM		
2/3/2018 Sat		148 7:29 AM		
2/2/2018 Fri		145 6:16 AM		
2/1/2018 Thu		144 6:19 AM		
1/31/2018 Wed		170 6:29 AM		
1/30/2018 Tue		160 6:20 AM		
1/29/2018 Mon		169 6:17 AM		
1/26/2018 Fri		131 6:21 AM		
1/25/2018 Thu		144 6:18 AM		
1/24/2018 Wed		133 6:15 AM		
1/23/2018 Tue		139 6:13 AM		
1/22/2018 Mon		**184 6:16 AM**		
1/20/2018 Sat		149 8:31 AM		
1/19/2018 Fri		148 6:21 AM		
1/18/2018 Thu		137 6:23 AM		
1/17/2018 Wed		165 6:15 AM		

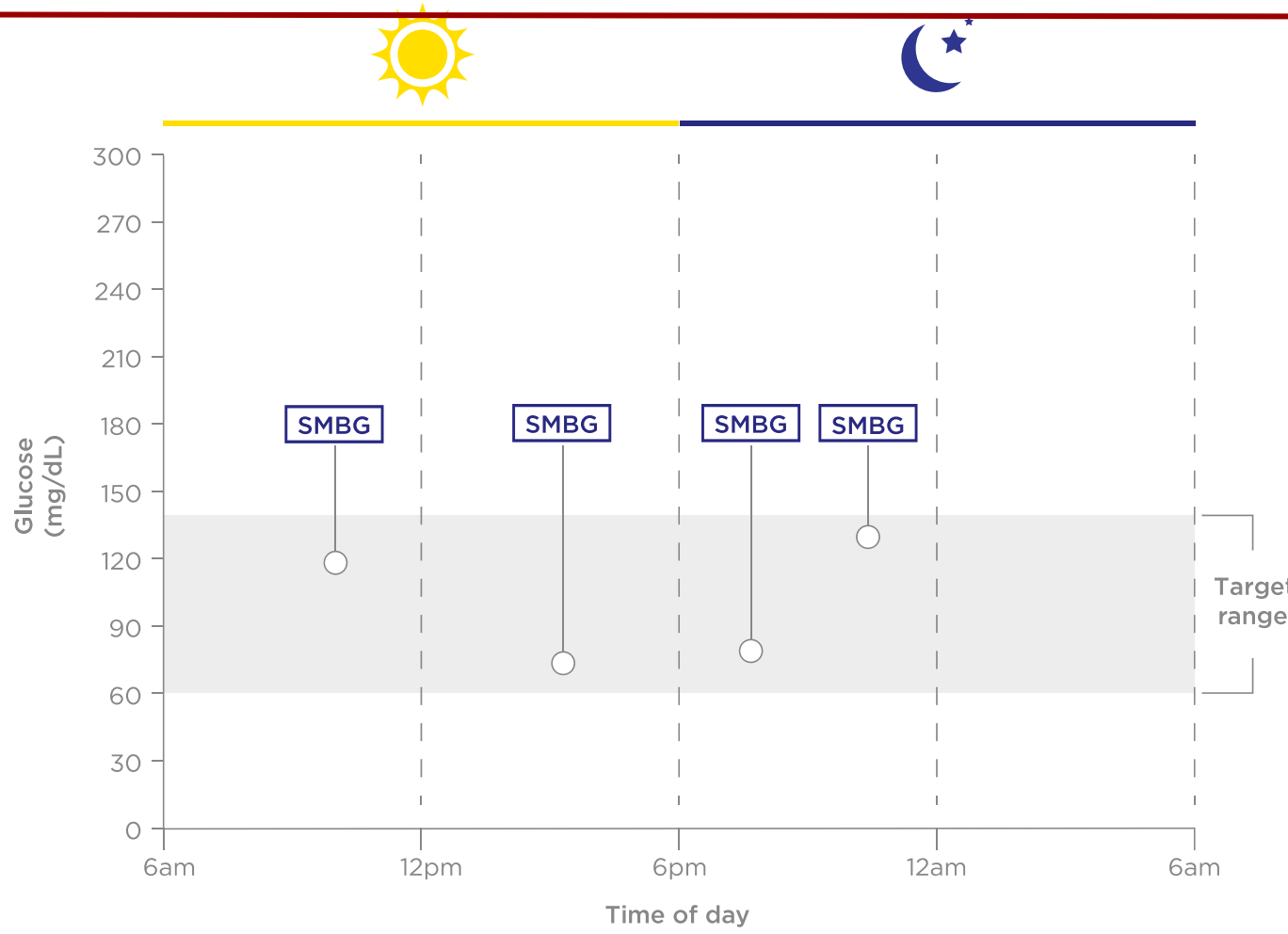
How CGM Can Help Reduce Diabetes Management Challenges

Self-monitoring of blood glucose (SMBG) limitations

Even with multiple daily fingersticks, SMBG can leave highs & lows undetected[1]

Patients using SMBG could be spending significant time outside of range

SMBG only provides readings for a single point in time



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1. Janapala Rajesh Naidu, et al. "Continuous Glucose Monitoring Versus Self-monitoring of Blood Glucose in Type 2 Diabetes Mellitus: A Systematic Review with Meta-analysis." *Cureus* 11, no. 9 (September 2019):e5634.

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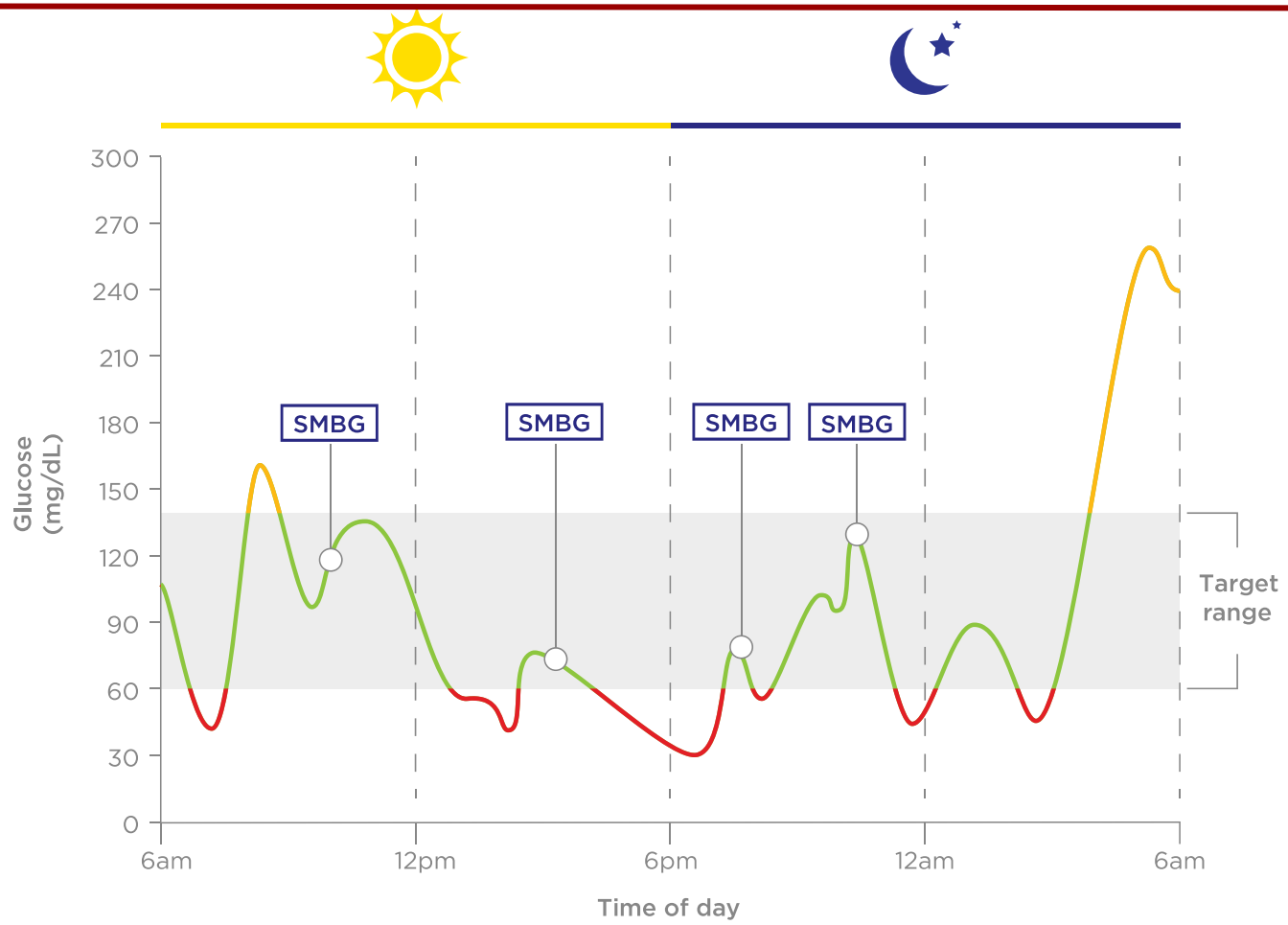

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Value of CGM In Patients With T2DM

- Discover previously unknown hyper and hypoglycemic events
- Measure glycemic control directly rather than via the surrogate metric of A1C
- Observe metrics such as glycemic variability, time spent within, below or above targeted glucose range throughout the day
- Determine the duration and severity of unrecognized hypoglycemia, especially nocturnal
- Provide actionable information derived from the CGM report
- Initiate safe and effective management of patients undergoing hemodialysis
- Analyze glucose effects of targeted pharmacologic interventions (both fasting and post-meal glucose values)
- Determine the individualized duration of action of glucose lowering therapies
- Evaluate the effect of exercise on glycemic control
- Provide behavioral interventions based on real-time glycemic values

Vigersky R, Shrivastav M. Role of continuous glucose monitoring for type 2 in diabetes management and research. J Diabetes Complications. 2017 Jan;31(1):280-287.

Patient selection for CGM Therapy

International Consensus[1]	AACE [2]	American Diabetes Association[3]
• All patients with T1D • T2D on multiple daily injections (MDI) not meeting goals • Problematic hypoglycemia	• CGM is strongly recommended for all persons with diabetes treated with intensive insulin therapy **A** • Problematic hypoglycemia • Pregnancy/GDM on insulin therapy **A***	• Real-time CGM (rtCGM) **A** or intermittently scanned CGM (isCGM) **B** for adults with diabetes on multiple daily injections (MDI) or CSII • rtCGM **A** or isCGM **C** can be used for diabetes management in adults with diabetes on basal insulin • Adjunct to pre/post BGM in pregnancy **B**

Who Benefits From Routine Use Of Continuous CGM?

- ALL patients treated with intensive insulin therap (MDI or insulin pumps)
- ALL patients with "problematic hypoglycemia" (Frequent, nocturnal, hypoglycemia unawareness)
- Children and adolescents with T1DM
- Pregnant women with either T1DM or T2DM (treated with insulin)
- Patients with gestational diabetes treated with insulin
- Consider CGM for patients with T2DM who are treated with less intensive therapy

"Everyone!"

Grunberger G, Sherr J, Allende M, Blevins T, et al. American Association of Clinical Endocrinology Clinical Practice Guideline: The Use of Advanced Technology in the Management of Persons With Diabetes Mellitus. Endocr Pract. 2021 Jun;27(6):505-537.

Three Types of CGM Systems

- Real-time CGM
  - Continuous sensor glucose values, trends and alarms to a CGM receiver or smartphone
- Intermittent scanned CGM (Flash)
  - Glucose values and trends after scanning the CGM sensor with a reader or smartphone
- Professional CGM
  - No real-time glucose data or alarms, only retrospective review of sensor glucose data (blinded sensor)

Professional vs Personal CGM

PROFESSIONAL CGM[a]

- Use in the office
- The CGM device is put on the patient
- Patient comes back later
- Download the information
- Professional CGM is useful for improving glycemic control in a low socioeconomic population with limited access to current technology
  - Can lower A1C 0.8 % with intermittent use
  - Can encourage lifestyle changes and medication adherence

PERSONAL CGM[a]

- What the patient uses
- Patient uses the information to make decisions on their insulin, when to eat, etc
- Provides alarms for lows and highs
- Can increase engagement in diabetes self-management

CGM technology can be extremely important in lowering HbA_{1c} and minimizing hypoglycemia in patients on MDI with T1D[b,c]

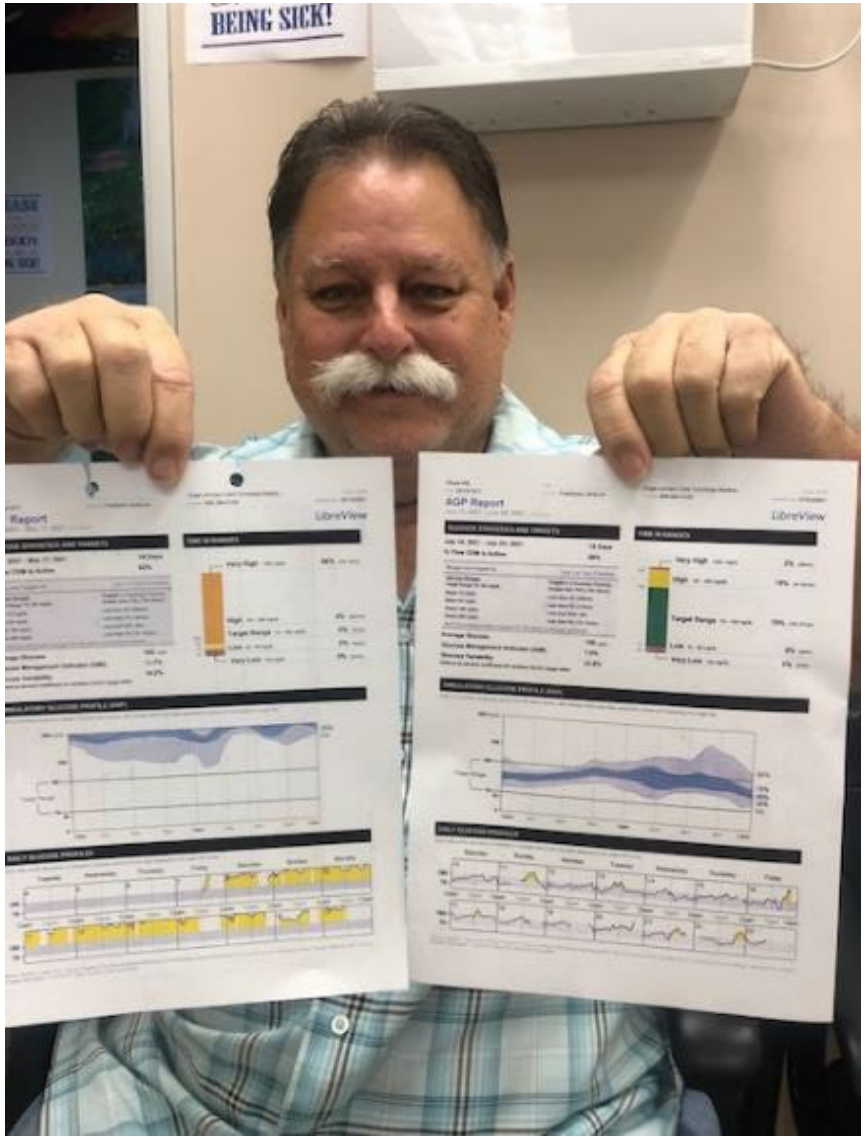
a. Blevins TC. Professional continuous glucose monitoring in clinical practice 2010. J Diabetes Sci Technol. 2010 Mar 1;4(2):440-56.
b. Beck RW, Riddlesworth T, et al. Effect of Continuous Glucose Monitoring on Glycemic Control in Adults With Type 1 Diabetes Using Insulin Injections: The DIAMOND Randomized Clinical Trial. JAMA. 2017 Jan 24;317(4):371-378.
b. Sulman H, et al. Diabetes 2018 Jul; 67(Supplement 1)
c. Lind M, Polonsky W, Hirsch IB, et al. Continuous Glucose Monitoring vs Conventional Therapy for Glycemic Control in Adults With Type 1 Diabetes Treated With Multiple Daily Insulin Injections: The GOLD Randomized Clinical Trial. JAMA. 2017 Jan 24;317(4):379-387.

What About “Chuck”

- 62-year-old man with T1DM x 20 years.
- Prescribed insulin regimen: NPH 70 u BID and Reg Insulin 70 u BID (280 u/day). Syringes and vials. Never trained on appropriate timing or administration of insulin.
- Non STEMI MI x 2 years with stenting
- Does not do SBGM (“no one looks at the logs anyway”)
- In past 2 months, patient admitted to 4 hospitals 10 times due to “confusion, difficulty walking, weakness and chest pain”
- Fortunately, all 12 of his brain MRIs are “normal”
- Would he benefit from CGM?

Chuck Before and After 67 Days Of Using CGM

Medications:



May 15, 2021

- 0 % in target
- Average BG 320
- GMI: 11.7 %

July 23, 2021

- 79 % in range. No hypos
- Average BG 165
- GMI 7 %

Continuous Glucose Monitors

- Interstitial glucose sensor (size of an eyelash) is inserted manually
- Data from the interstitial sensor is <u>transmitted</u> to a "reader", insulin pump or app and displayed to the user
- CGM Available Data:
  - Current glucose level
  - Glucose trends related to meals, exercise, medication, sleep, travel
  - Glucose directional trends
  - Alarms for glucose levels < 70 or > 240 mg/dL

Dexcom 6 Transmitter (battery)

Dexcom 6 Sensor

Abbott Freestyle Libre Sensor

Guardian Medtronic pump and sensor

Unger J, Kushner P, Anderson JE. Practical guidance for using the Freestyle Libre Flash continuous glucose monitoring in primary care. Postgraduate Medicine.

Available Glucose Sensors

			
Type of CGM	Sensor (Abbott Freestyle Libre14 day Abbott Freestyle Libre-2 (Intermittent-Flash CGM)	Medtronic Enlite Guardian Sensor 3 iPro2 (Real time CGM)	Dexcom 6 (Real time CGM)
Calibration necessary?	No	Yes	No
Sensor duration	14 days	7 days	10 days
Audible alerts for high and low glucose	FSL 2 only	Yes	Yes
Trend arrow displayed?	Yes	Yes	Yes
Connectivity to insulin pump	No	Yes	Tandem Complete
Start-up cost of system	$360 (3 sensors, 1 reader)	$567 (5 sensors)	$790 (Receiver, transmitter and 4 sensors)

How CGM Can Help Reduce Diabetes Management Challenges

Moving beyond A1c

Using a combination of metrics allows for a more complete picture of glucose profile[1]

A1c + AGP (Ambulatory Glucose Profile)

Combining each patient's A1c with their ambulatory glucose profile (AGP) uncovers critical daily patterns

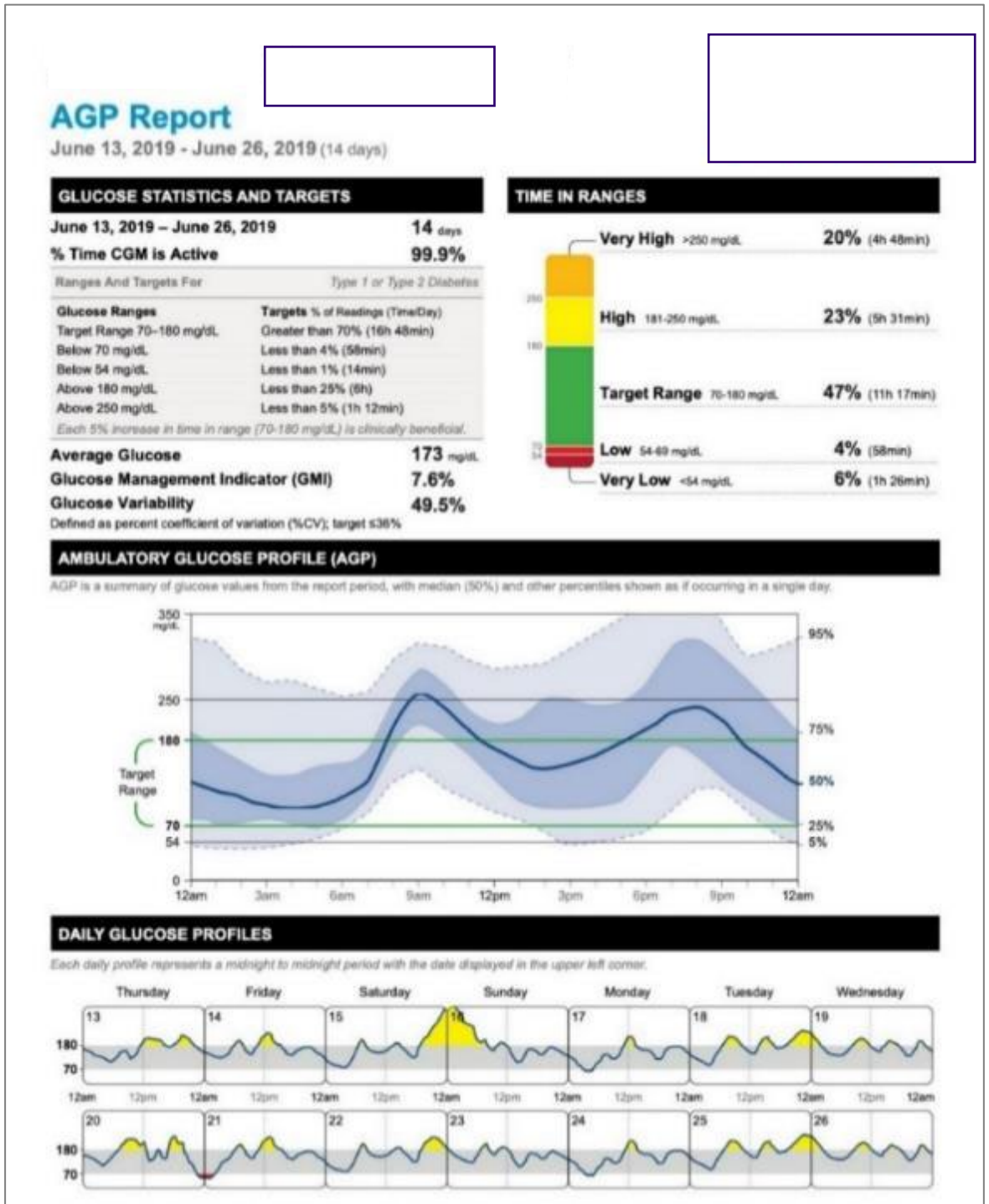
TIR (Time in Range) + TBR (Time below range)

Monitoring TIR and TBR glucose variability helps show how closely readings of an individual patient fall within target range, or below, in hypoglycemia

Glucose data

Additional access to acute, daily, and long-term (90 days) data allows for more informed treatment decisions

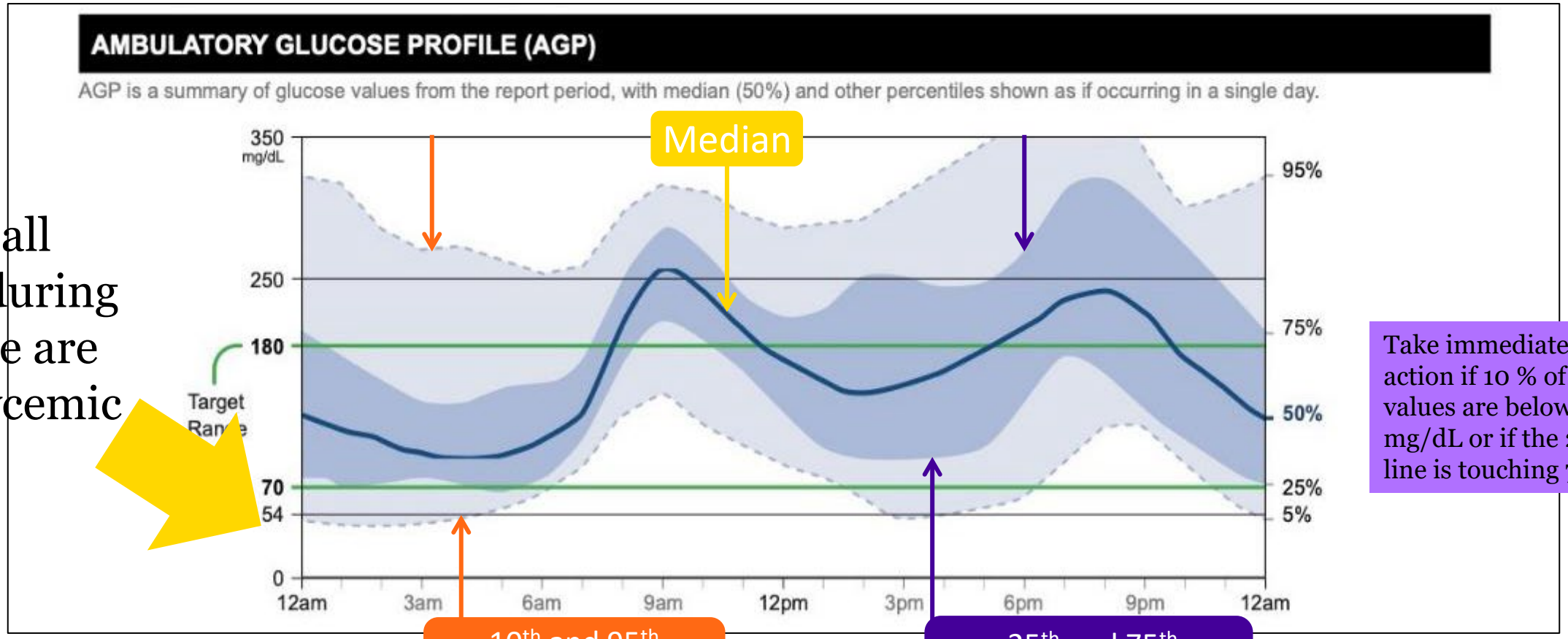
AGP provides a standardized visualization that condenses glucose data generated from GGM over several days or weeks into a single, 24-hour window.



1. Battelino T, Danne T, et al. Clinical Targets for Continuous Glucose Monitoring Data Interpretation: Recommendations From the International Consensus on Time in Range. Diabetes Care. 2019 Aug;42(8):1593-1603.

Ambulatory Glucose Profile (AGP)

Illustrates trends, patterns and glycemic variability



10 % of all values during this time are hypoglycemic

Take immediate action if 10 % of the values are below 54 mg/dL or if the 25 % line is touching 70.

Not based on real patient data. Illustrative only.

10th and 95th Percentile Curves

90% of all values

25th and 75th Percentile Curves

50 % of all values fall within the interquartile range

Note: Other reports will still have 10% - 90% percentiles for the AGP graphs until a later release.

AGP – Clinical Analysis

ARE THE READINGS IN TARGET?

70-180 mg/dL should = 70 % +

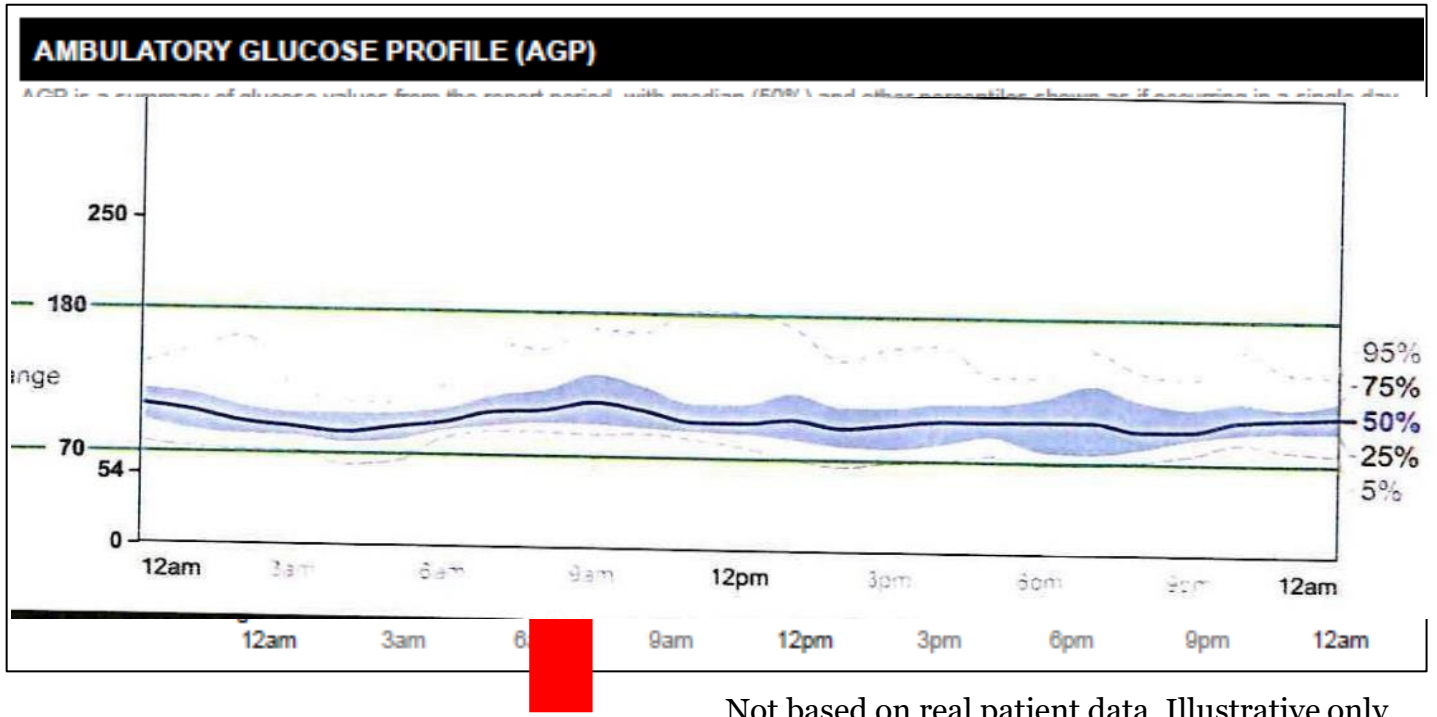
WHAT ARE THE PATTERNS OF HYPOGLYCEMIA?

< 4 % if CGM readings should be < 70 mg/dL

WHAT IS THE SHAPE OF THE MEDIAN CURVE?

Flatten the median curve by reducing glycemic variability

PRESCRIBE TREATMENT STRATEGIES WHICH REDUCE LOWS, MINIMIZE POST MEAL SPIKES AND FLATTEN THE MEDIAN CURVE



Not based on real patient data. Illustrative only.

FLAT IS GOOD!

Unger J, Kushner P, Anderson JE. Practical guidance for using the Freestyle Libre Flash continuous glucose monitoring in primary care. Postgraduate Medicine. https://doi.org/10.1080/00325481.2020.1744393 . March 30, 2020

Dexcom Clarity Report

Time in Range

2% Very High
15% High
80% In Range
2% Low
<1% Very Low

Increase since last week: +2%
Target Range: 70-180 mg/dL

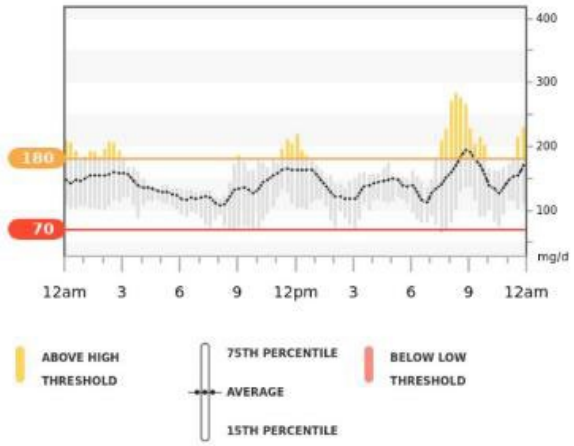
Average glucose
142 mg/dL

Standard deviation
44 mg/dL

Patterns

No patterns were found for this date range.

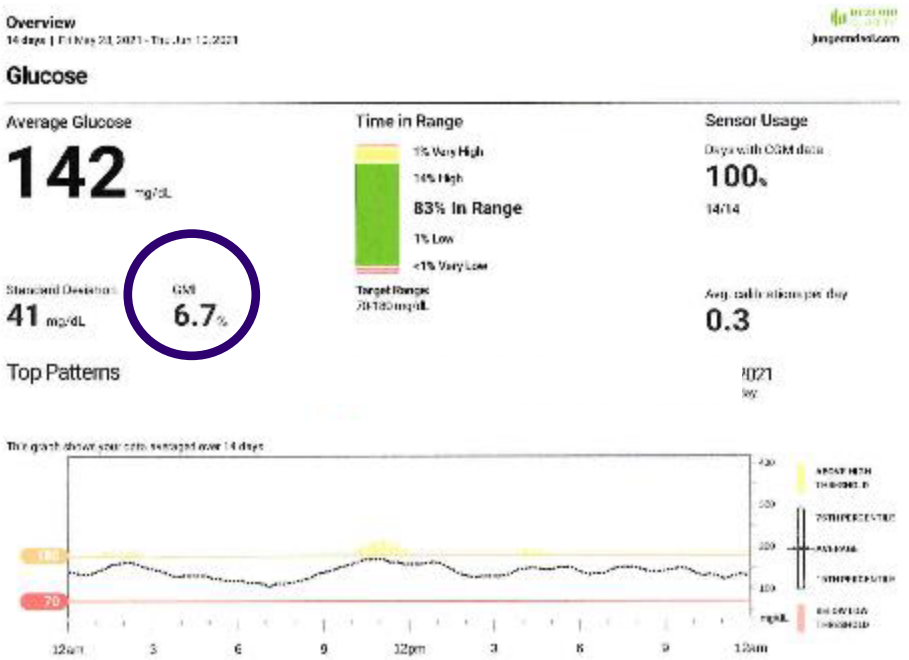
Trends



Visit Dexcom CLARITY on the web for all y

You signed up for this Dexcom CLARITY W
app. Unsubscribe

AGP and Weekly Clarity Report



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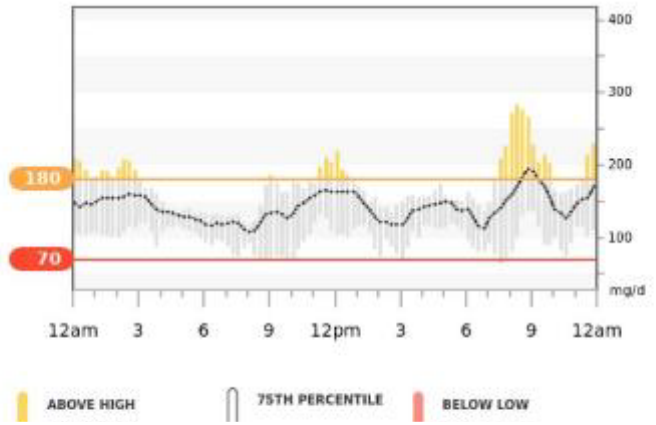


AACE Recommendations For Interpreting AGP Data

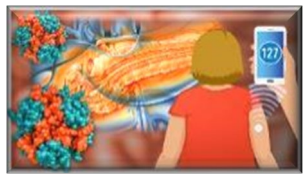
Use a systematic approach

- Review overall glycemic status (GMI-glucose management indicator, average glucose)
- Check Time In Range (TIR), Time below range (TBR) and Time above range (TAR)
  - TBR should be < 4 %
  - TIR should be > 70 %
- Review 24-hour glucose profile to ID problematic times as well as the magnitude of the problem (hypos and hyperglycemic events)
- Review treatment regimen and adjust as needed

Grunberger G, Sherr J, Allende M, et al. American Association of Clinical Endocrinology Clinical Practice Guideline: The Use of Advanced Technology in the Management of Persons With Diabetes Mellitus. Endocr Pract. 2021 Jun;27(6):505-537.

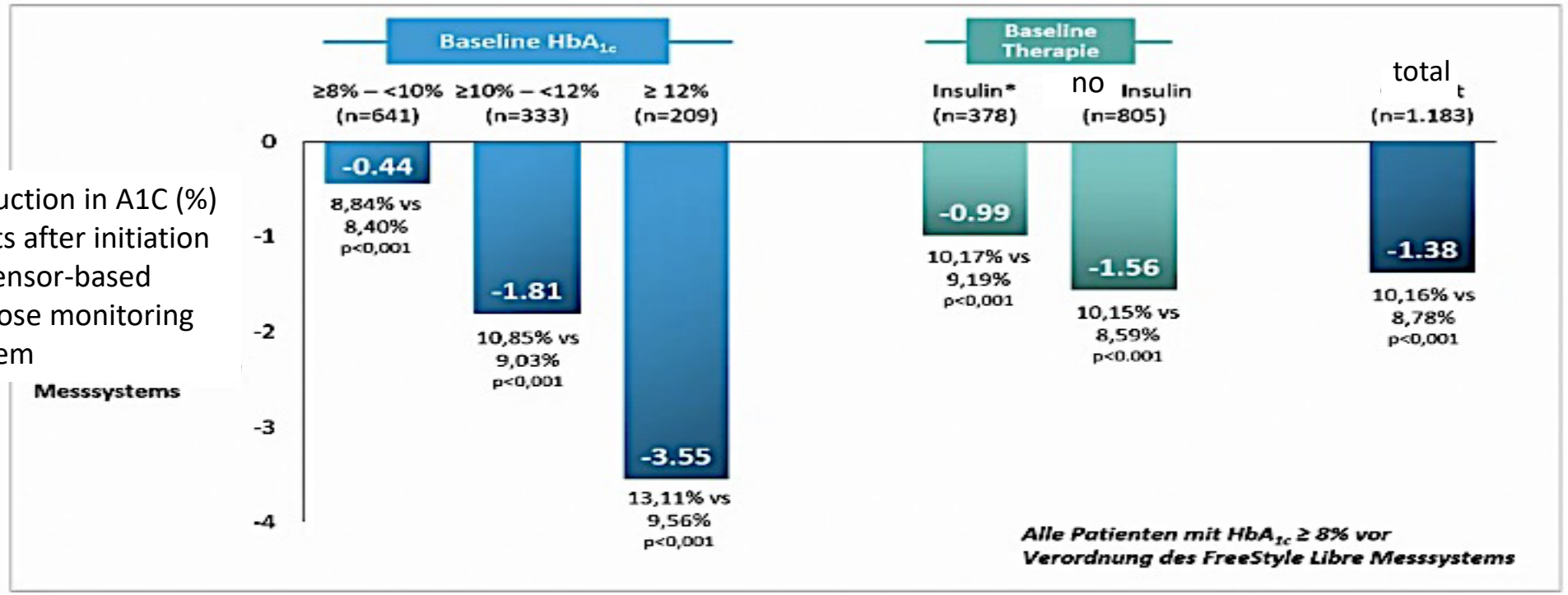
Clinical and economic benefits of CGM

"I sometimes wonder if you hear one word I say!"



RWE: A1C Reduction Using Sensor-Based Glucose Monitoring System in Type 2 Diabetes Patients with Basal A1C ≥ 8 %

Reduction in A1C (%) 6 mts after initiation of sensor-based glucose monitoring system



*Basal, NPH, or mixed insulin; NPH = neutral protamine Hagedorn; T2DM = Typ 2 Diabetes mellitus; US = United States

Wright et al. A1c reduction associated with FreeStyle Libre system in people with type 2 diabetes not on bolus insulin therapy. Poster presented at: American Diabetes Association 80th Scientific Session; June 12-16, 2020; Virtual.

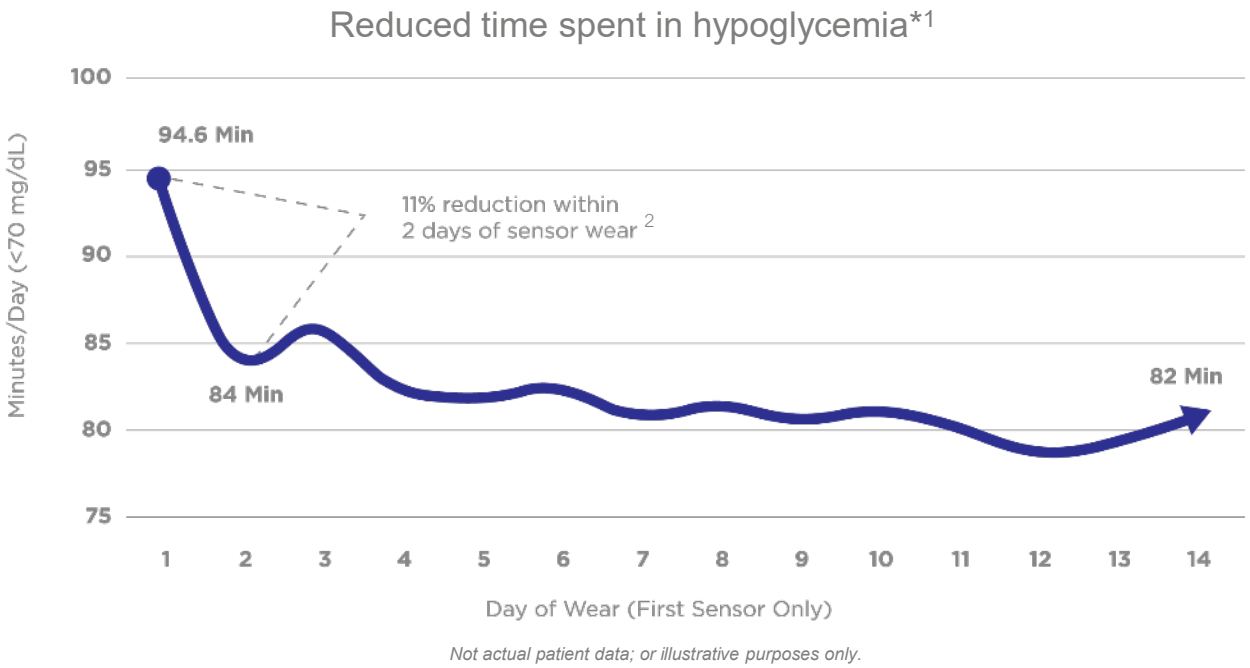
Reduced Time in Hypoglycemia

Frequent glucose level checks with sensor-based CGM resulted in reduction in time in hypoglycemia*[1]

On average, patients scanned glucose 16 times a day

- 50,831 readers
- 86.4 million hours of readings

Patients were able to make improvements quickly on their own: 74% of reduced time in hypoglycemia was achieved in 2 days[1]



Not actual patient data; or illustrative purposes only.

1. Dunn, Timothy C., Yongjin Xu, Gary Hayter, and Ramzi A. Ajjan. "Real-World Flash Glucose Monitoring Patterns and Associations Between Self-Monitoring Frequency and Glycaemic Measures: A European Analysis of Over 60 Million Glucose Tests." *Diabetes Research and Clinical Practice* 137 (March 2018): 37-46. https://doi.org/10.1016/j.diabres.2017.12.015. **2.** Data on file. Abbott Diabetes Care.

Increased Time in Range (TIR)

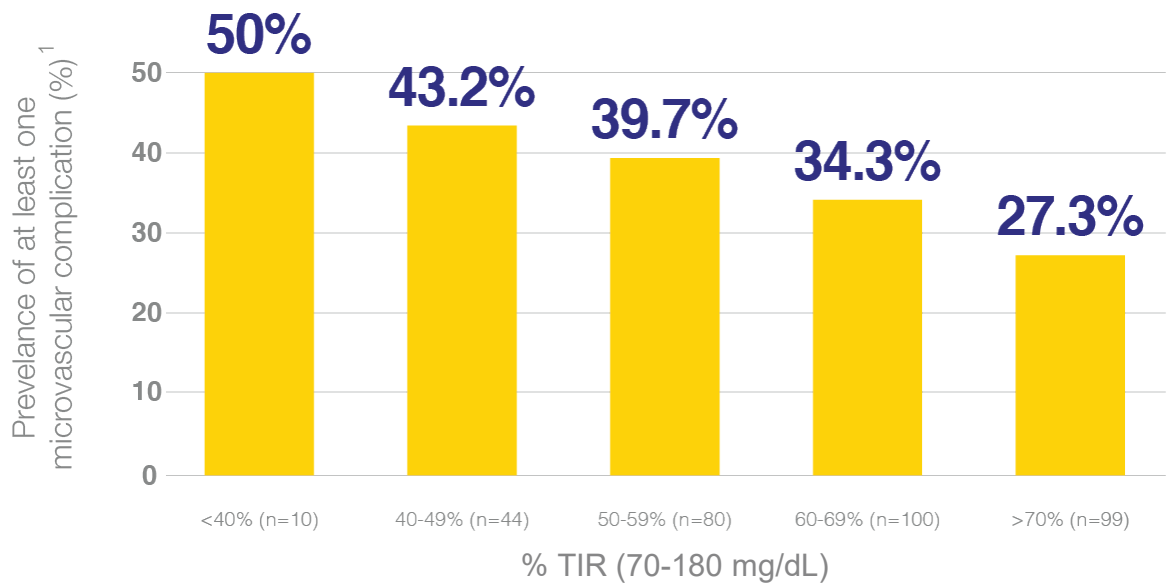
By improving TIR, sensor-based CGM may deter from microvascular and macrovascular complications[1,2]

Microvascular complications*[1]

Patients who spend less TIR are more likely to experience complications such as retinopathy, nephropathy, and neuropathy.

Macrovascular complications†[2]

Patients who spend more TIR are more likely to experience a lower rate of first major adverse cardiac events (MACE).



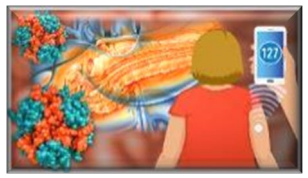
*Results from a study of 515 adults with T1D using real-time CGM. †Results from a study of 7637 patients with T2D with cardiovascular disease or at high risk.

1. El Malahi, Anass, et al. "Chronic Complications Versus Glycaemic Variability, Time in Range and HbA1c in People with Type 1 Diabetes: Sub Study of the RESCUE-trial." European Association for the Study of Diabetes 56th Congress, Vienna, Austria, September 22, 2020. DOI: https://doi.org/10.1530/endoabs.71.012. **2.** Berganstal Richard M, Elise Hachman-Nielsen, Kajsa Kvist, John B. Buse. "Derived Time-in-range is Associated with MACE in T2D: Data From the DEVOTE Trial." *Diabetes* 69 (suppl 1) (June 2020). DOI: https://doi.org/10.2337/db20-21-LB.

Benefits Of Improving Time In Range (TIR) Using CGM

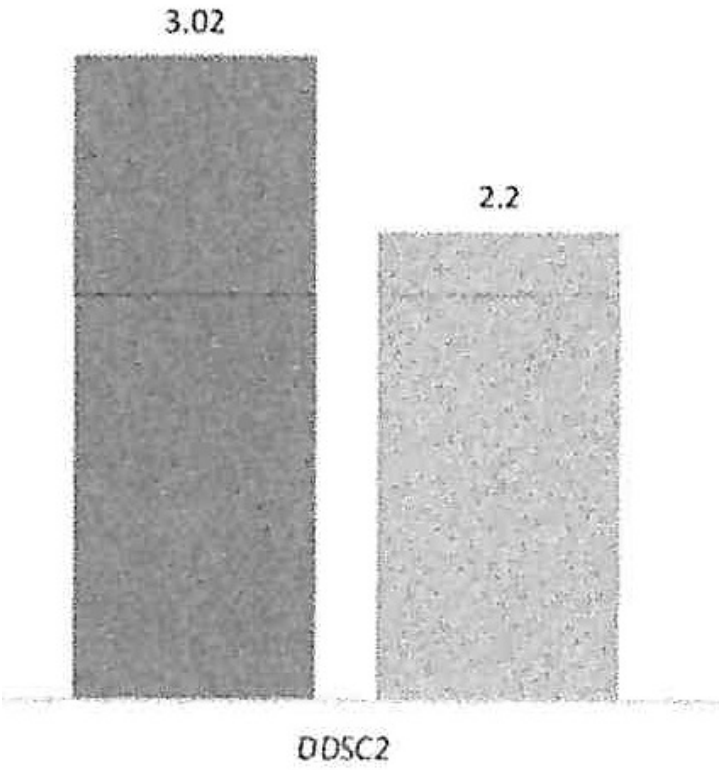
Population	Outcome	Results
3262 T2DM Patients	Retinopathy	Each 10 % increase in TIR from baseline reduces risk by 8 %
2215 T2DM Patients	Carotid intima media thickness (CVD)	Each 10 % increase in TIR improves CIMT thickness by 6.4 %
866 T2DM Patients	Albuminuria	Each 10 % increase in TIR reduces risk of albuminuria by 6 %
26 T1DM Patients	Albuminuria	Each 10 % increase in TIR reduces albuminuria risk by 19 %
364 Patients with Diabetic	Painful Neuropathy	TIR is correlated with painful neuropathy independent of A1C Glucose variability metrics and risk factors in patients with DM

Yang J, Yang X, Zhao D, Wang X, Wei W, Yuan H. Association of time in range, as assessed by continuous glucose monitoring, with painful diabetic polyneuropathy. *J Diabetes Investig*. 2021;12(5):828-836. doi:10.1111/jdi.13394



Improvement Of Diabetes Distress Syndrome In Patients Using Flash Glucose Monitoring

28 % improvement in DSS scores

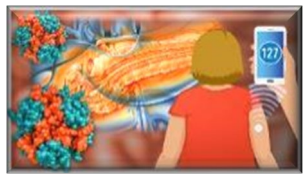


10,370 patients (97 % T1DM)-British Study- 12 months

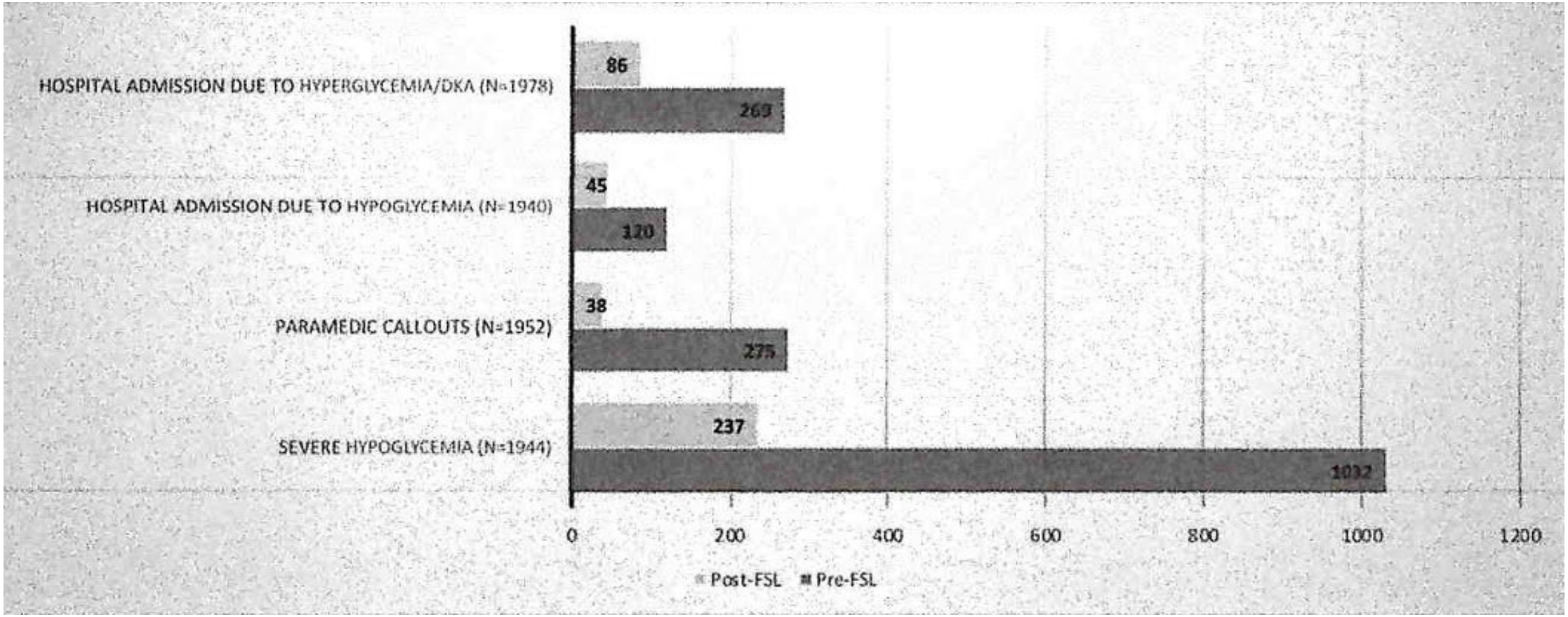
DDSC2 Questions:

- Do you feel overwhelmed by the demands of living with diabetes?
- Do you feel that you are often failing with your diabetes regimen

Deshmukh H,et al. Diabetes Care 2020;43:2153-2160



Why CGM? A 1 year Prospective Study Pre and Post CGM Initiation (N= 10,370 patients)



Deshmukh H,et al. Diabetes Care 2020;43:2153-2160

Costs Savings of CGM Vs SBGM

Real-time CGM is associated with a mean reduction in spending per-person-per-month of $424.

In the year prior to initiating real-time CGM therapy, the mean per-person-per-month cost associated with diabetes management was $1680 compared to $1256 after starting real-time CGM.

Pts with severe hypoglycemia reduced their annual costs $1887 after switching from SBGM to Flash Glucose Monitoring

Pts using CGM had a 90 % decrease in the need for SBGM as well as reduced costs for ED and hospital visits

The cost of 1 SBGM (One Touch Ultra)= $1.16.

4 Strips/day= $139.20/month

2 strips/day= $2.32/day; $69.60/month

Dexcom: 288 interstitial tests/day or 2880 per 10 day wear (2 cents per data point or $5.76 per day of wear)

FSL-2: 1440 test/day or 20,160/14 day wear (.0018 cents per data point or $2.59/day)

ADA 81st Scientific Sessions, June 2021. Amazon.com costs (3/20/22)

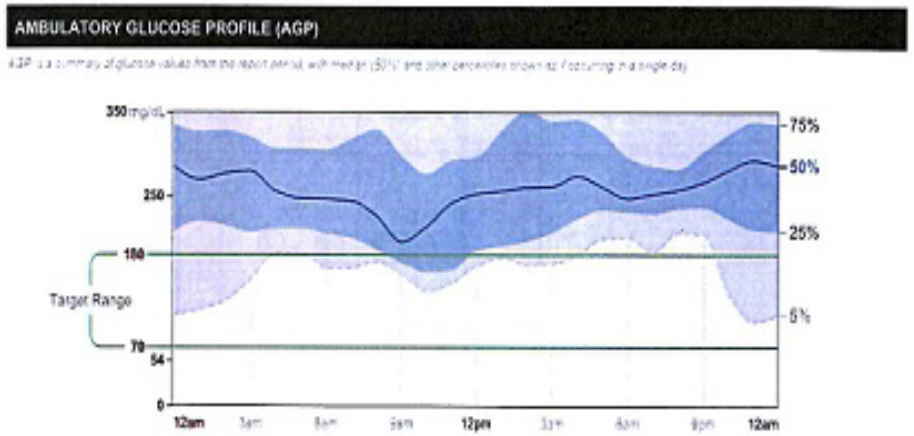
Meet Lee

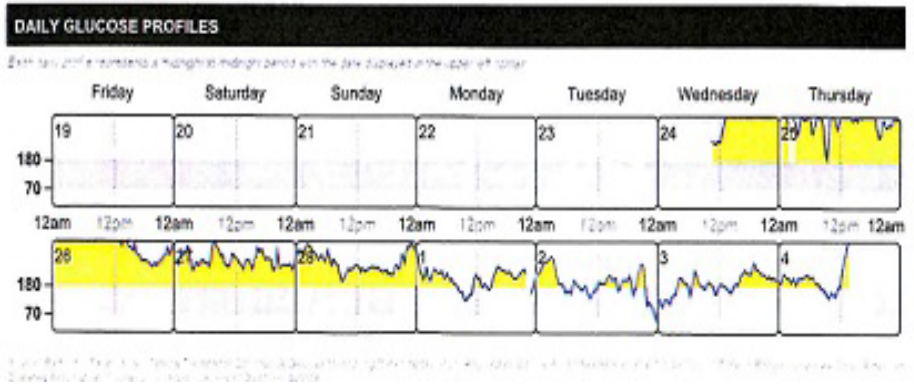
48-year-old man with multiple medical concerns:

- Anticardiolipin antibody syndrome with complete occlusion of his IVC
- Opioid use dependency
- Portal hypertension
- Fatty liver
- And…newly diagnosed diabetes with a baseline A1C of 10.2 %

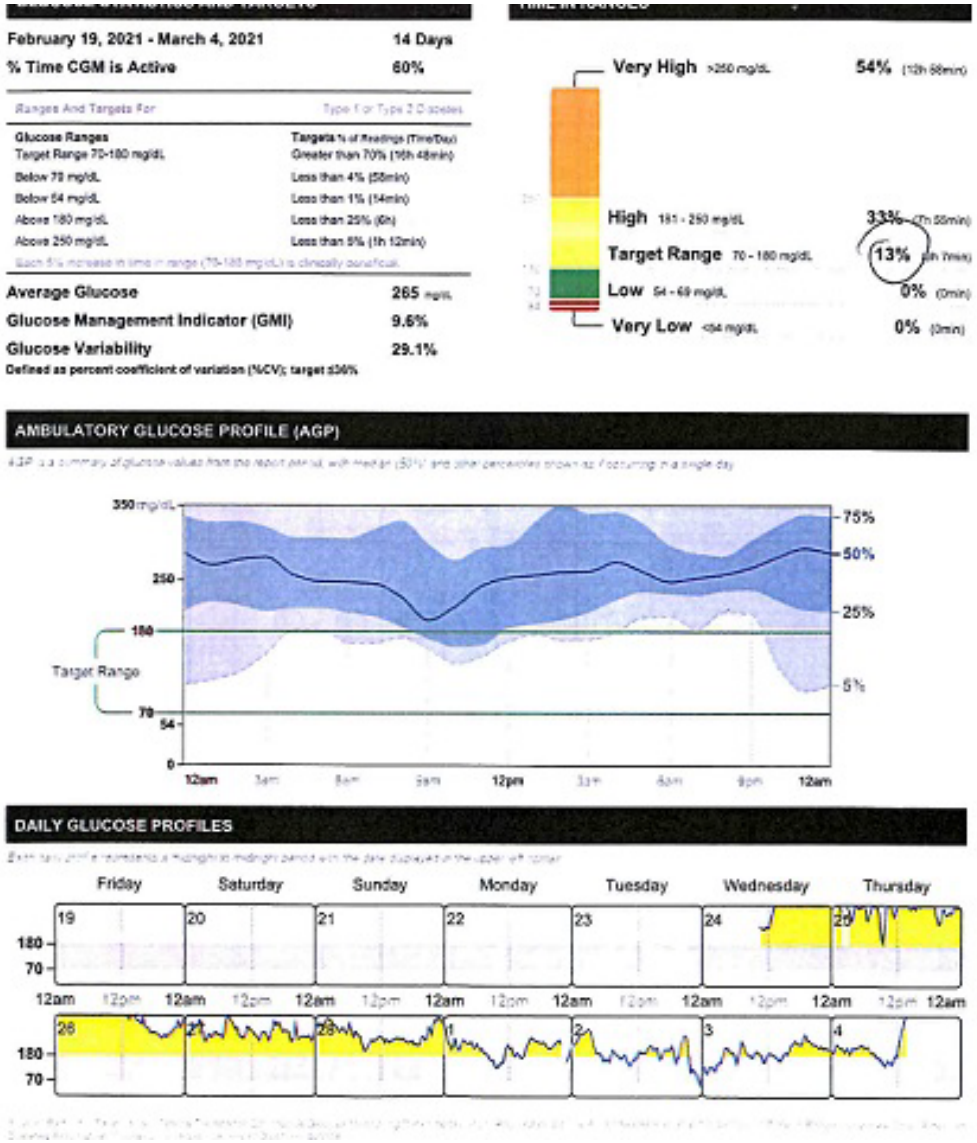
Note: Lee is a managed within primary care with specialty referrals as needed

Initial CGM (2/19-2/28/21)





Meet Lee (2)



February 19, 2021 - March 4, 2021	14 Days
% Time CGM is Active	60%

Glucose Ranges	Targets % of Readings (Time/Day)
Target Range 70-180 mg/dL	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)

Average Glucose	265 mg/dL
Glucose Management Indicator (GMI)	9.6%
Glucose Variability	29.1%

Defined as percent coefficient of variation (%CV); target ≤36%

AMBULATORY GLUCOSE PROFILE (AGP)

DAILY GLUCOSE PROFILES

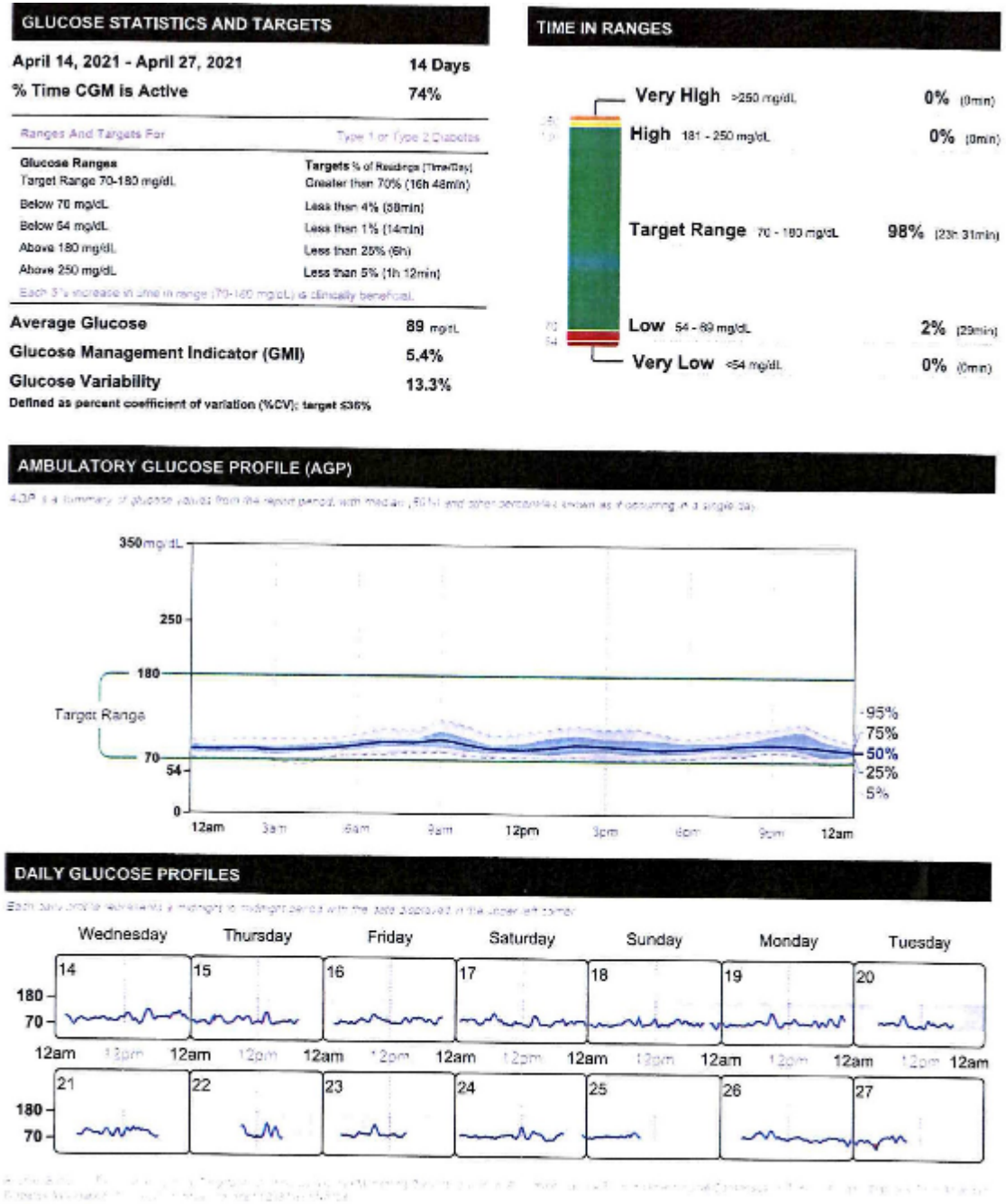
Questions?

- How often is Lee achieving the prescribed in range target (70-180 mg/dL)
- How do the GMI (9.6%) and A1C (10.2 %) correlate with each other?
- What treatments will you recommend?

Lee (3)

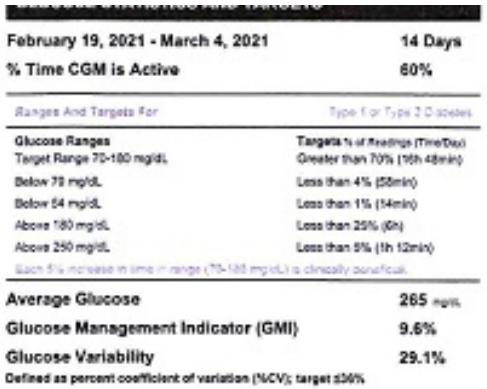
Medications:

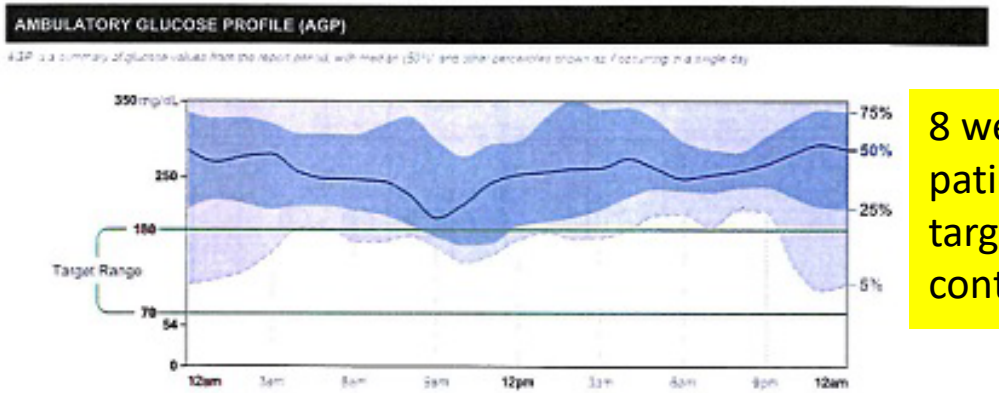
- Liraglutide - 1.2 mg/d
- Insulin degludec- 10 units at 9 PM daily

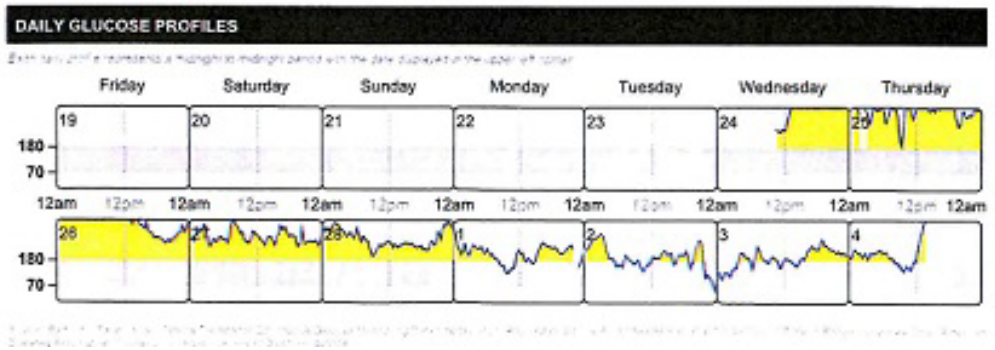


Download 3 weeks after initiating pharmacotherapy

Lee (4) Before and After

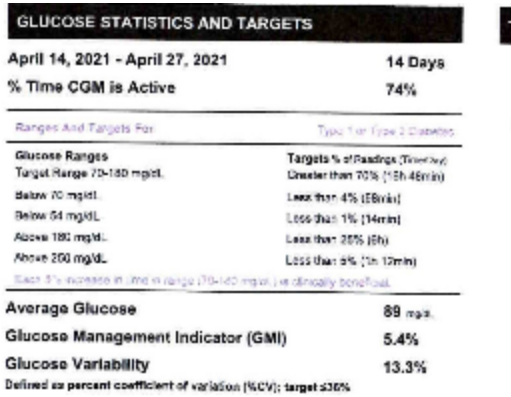


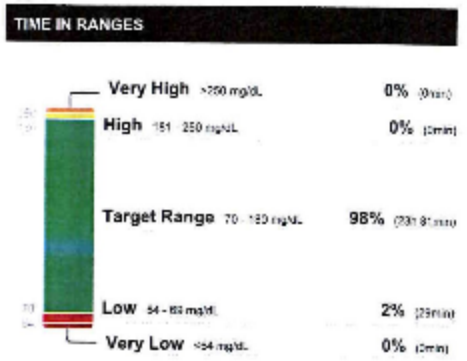


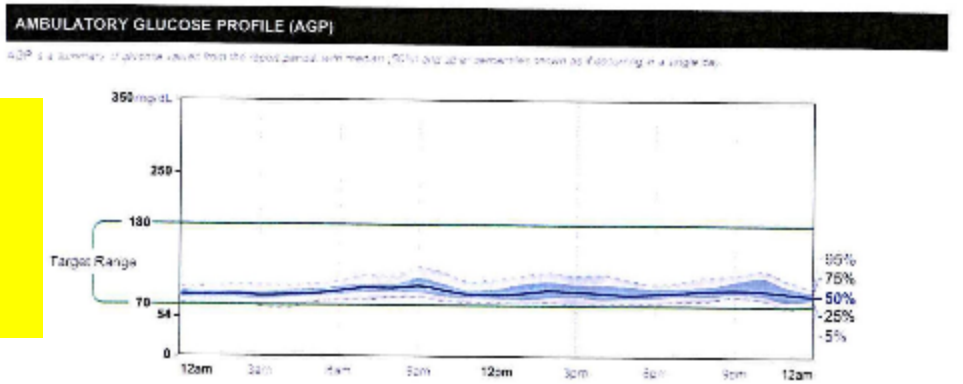


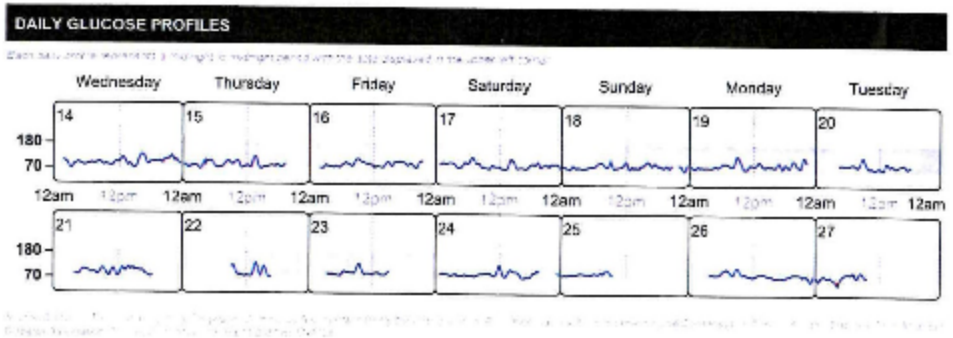
No pharmacotherapy 3/4/21

8 weeks until patient achieved target glycemic control!









4/29/21: Liraglutide 1.2 mg/d + insulin degludec 10 units/d

Addressing Problematic Glycemic Patterns

Hypoglycemia (> 4 %)

- Review potential meal skips
- Stop or reduce SUs
- Consider use of meds which do not increase likelihood of hypoglycemia
- Reduce basal or premeal insulin dose
- Modify exercise timing related to insulin dosing
- Reduce or stop alcohol consumption
- Mismatch of prandial insulin dose and carbohydrate intake

Time in Range < 70 %

- Discuss med adherence
- Add basal insulin, GLP-1RA, SGLT2, or prandial insulin
- Discuss carb counting (identification) or meal size as related to prescribed insulin dosing

Unger J, Kushner P, Anderson JE. Practical guidance for using the FreeStyle Libre flash continuous glucose monitoring in primary care. Postgrad Med. 2020 May;132(4):305-313.

Tricks to Successful Initiation of CGM In Primary Care

Role of the Clinician

- Make it simple!
- Put the first sensor on in the office for the patient. Subsequent sensors can be placed by the patient with guidance from MA
- Explain how the CGM may benefit patients' diabetes control
  - More time in prescribed range
  - Reduced incidence of hypoglycemia
  - Improved glycemic variability
  - Access to data while sleeping
  - Improve A1C
  - Reduce risk of hospitalizations
  - Improved rates of work absenteeism

Role of the Patient

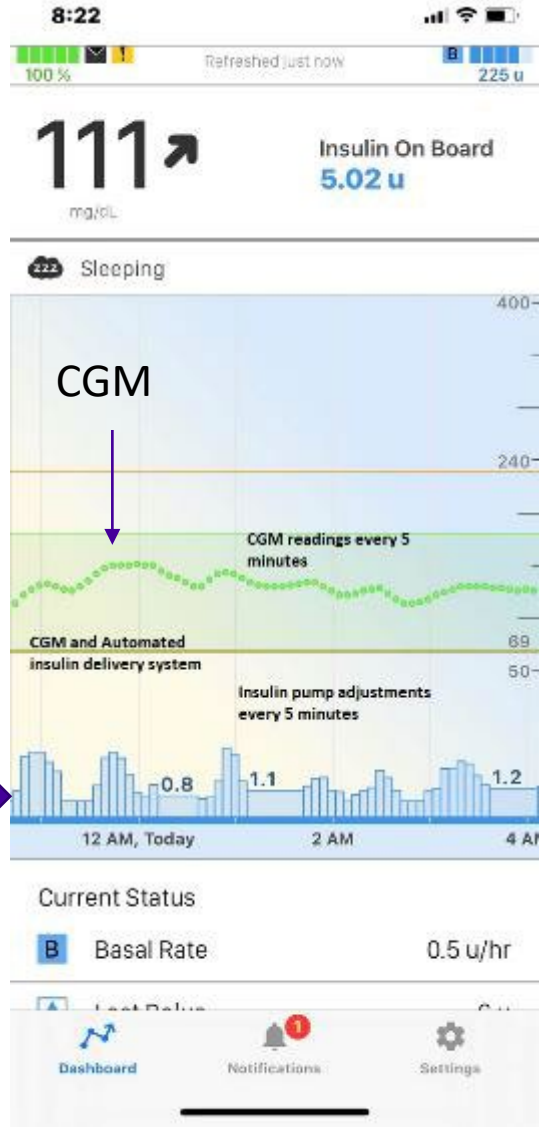
- Confidence in applying the sensor appropriately
- Scan frequently
- Minimize gaps in sensor wear
- Contact Customer Service if sensors fail or fall off
- Bring data to each visit
- Understand glycemic patterns related to food, sleep, exercise, travel, etc.

Connecting the Insulin Pump and CGM

Tandem Complete IQ with Dexcom 6 CGM

Medtronic 670 G plus Guardian CGM

Connected CGM and Insulin Pumps. Why Consider Such An Option?



Insulin Deliver Via pump

- Note that glucose values change every 5 minutes.
- Using automated insulin delivery connected to CGM, insulin dosing can be adjusted every 5 minutes as well
- Higher glucose results in insulin correction
- Lower glucose reduces or stops insulin delivery

CPT Codes For Professional Reimbursement

CPT Codes Can Be Billed:

- 95250 - Covers initial sensor placement and patient training. Can bill once only

- 95251 - Interpretation and report of CGM for a minimum of 72 hours. Can bill monthly

Summary

- Advanced diabetes technology holds the promise to be beneficial for all patients with diabetes
- Technologies provide insight in targeting a rational, safe and comprehensive approach to glycemic management
- Patients using advanced technology have been able to improve their time in range, reduce risk of and time spent within hypoglycemia, improve quality of life

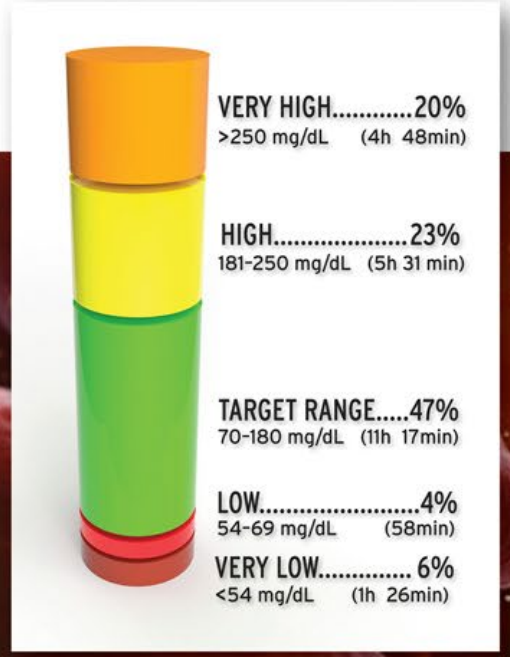
This is how you treat patients with a chronic disease SUCCESSFULLY!

Questions?

The Rationale and Real World Evidence for Initiating and Maintaining

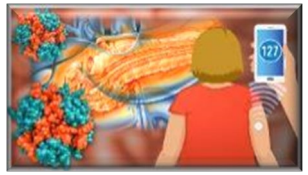
Sensor-Based Continuous Glucose Monitoring (CGM) to Optimize Care of Persons Across the Spectrum of Diabetes

*The **Physician Assistant's (PA's) Role** and Practical Action Steps for Establishing CGM-Based in the Primary Care Setting*



Strategies for Incorporating CGM into Practice

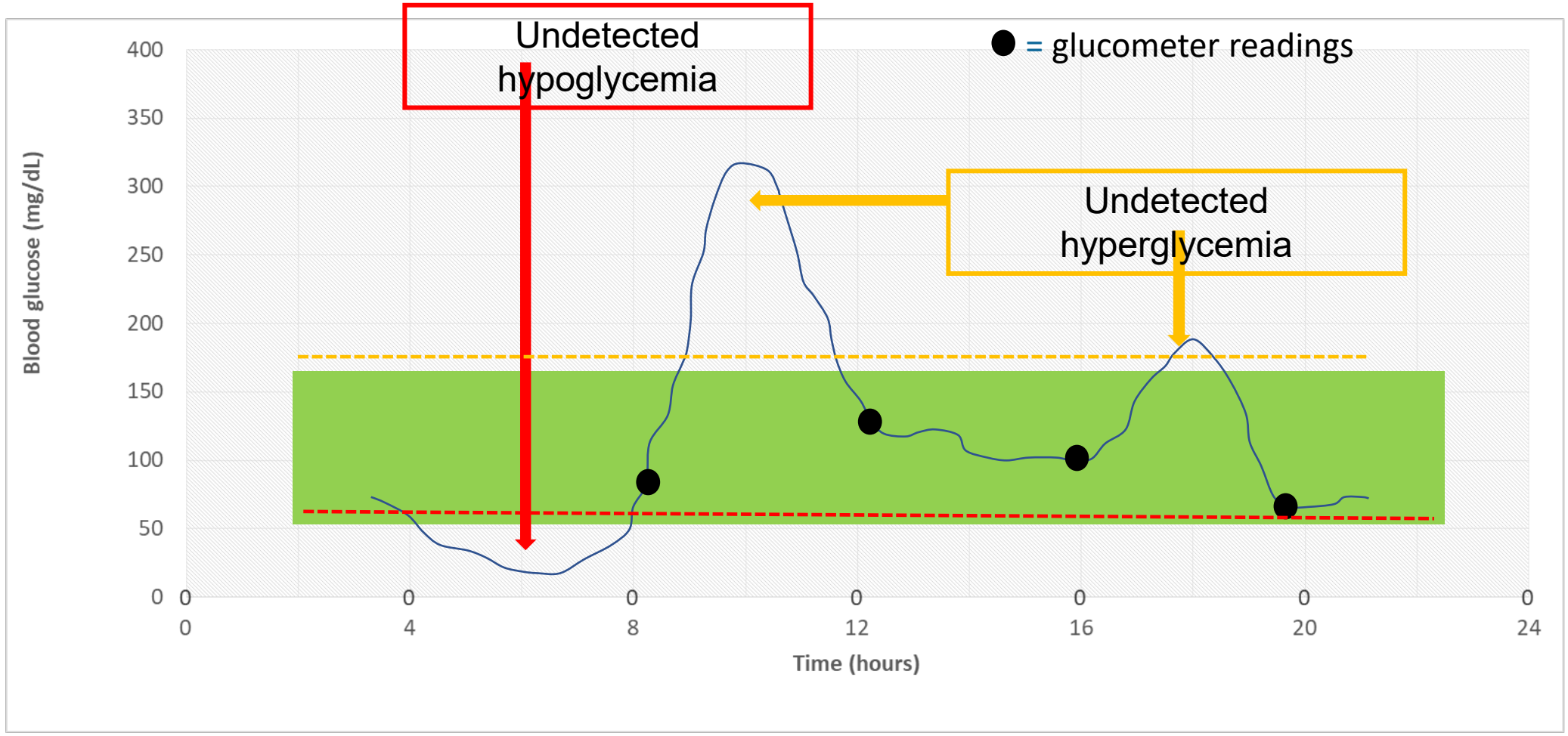
Diana Isaacs, PharmD, BCPS, BCACP, CDCES, BC-ADM, FADCES, FCCP
Endocrine Clinical Pharmacy Specialist
CGM and Remote Monitoring Program Coordinator
Cleveland Clinic Endocrinology and Metabolist Institute



Learning Objectives

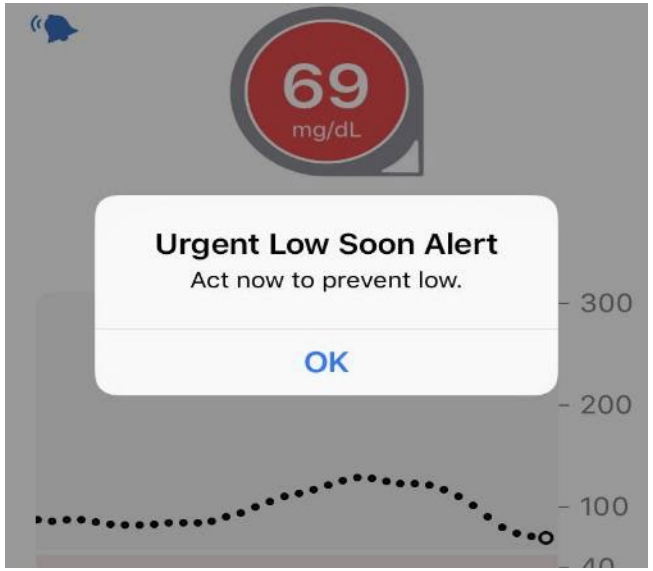
- Describe barriers to incorporating CGM into practice
- Discuss real world strategies to overcome barriers to CGM use in practice
- Outline how the identify, configure, collaborate framework can be used to address many common barriers

BGM vs CGM: Experience the Difference



CGM: Real-Time Data

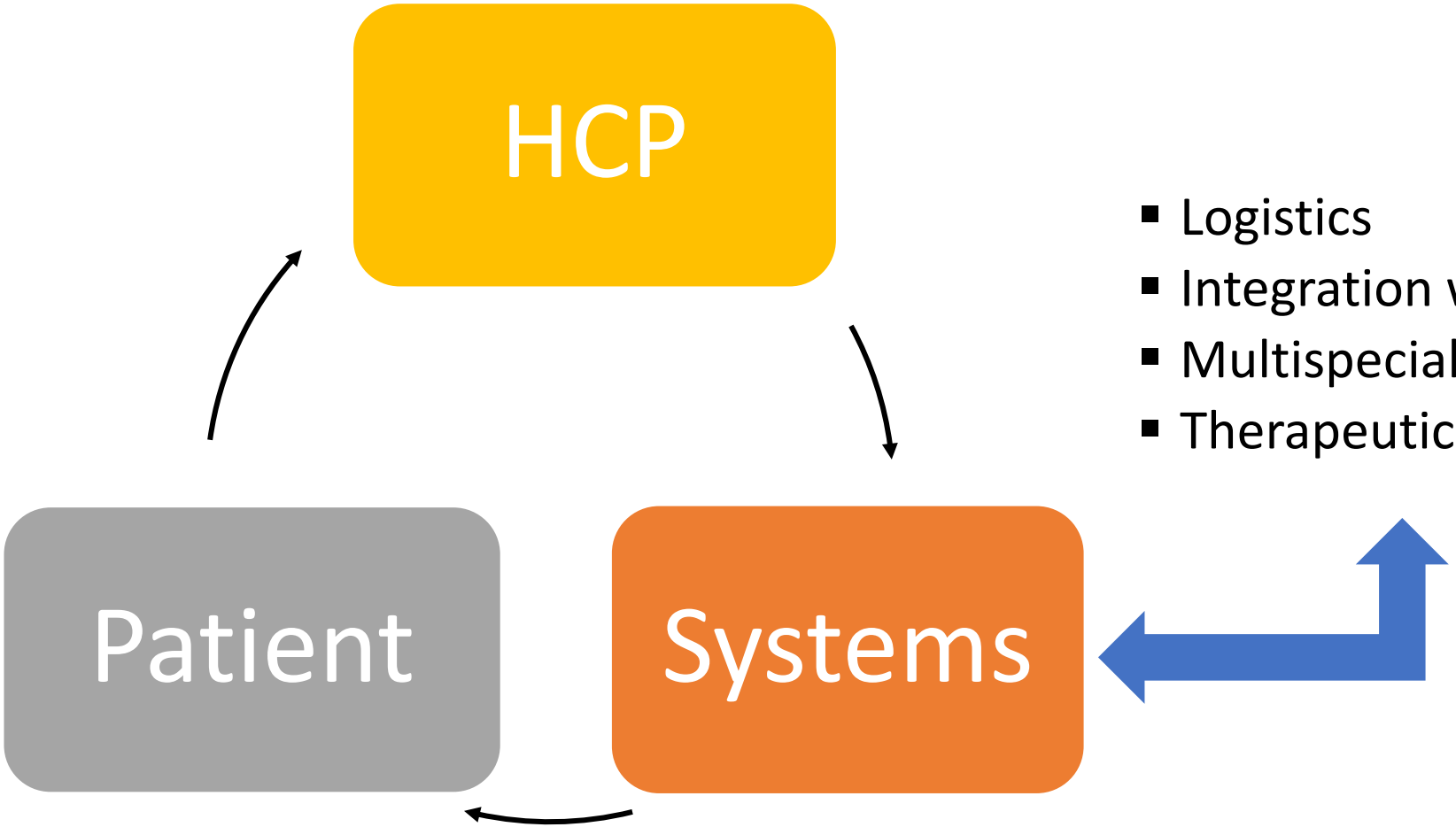
Take action: treat before going low, recognize before going too high



CGM Outcomes:

- Reduce episodes of severe hypoglycemia and hyperglycemia and associated ED and hospital visits
- Increase time in range
- Reduce A1C levels

What are Barriers to CGM Use?



- Logistics
- Integration with EMR
- Multispecialty team
- Therapeutic inertia

EMR, electronic medical record; HCP, healthcare professional.

HCP and Patient Barriers

HCP

- Tech aversions- “It can be scary learning something new”
- How to communicate benefits to patients
- Process for prescribing, education, and training
- Data interpretation

Patient

- Tech aversions, “I don’t want to constantly wear my diabetes”
- Cost/access
- Education/training
- Understanding what all the data means

Overcoming Disparities in CGM Use

- 65% of Black and Hispanic compared with 79% of White beneficiaries knew that Medicare helps pay for diabetes testing supplies and self-management education.
- A retrospective chart review showed that 30.5% of Black and 32.5% of Hispanic patients initiated CGM, compared with 54.3% of White patients
- Among Medicare beneficiaries who acquired a CGM device between July-Dec, 2020 (*n* = 3022), there was a significantly lower proportion of CGM use by Black and Hispanic beneficiaries (0.5% and 2.9%) compared with White (91.0%) and other (5.6%) beneficiaries

Power MA et al. Diabetes Care 2020;43:1636–1649. Lai CS et al. Diabetes Care 2021;44:255–257. Isaacs D et al. Diabetes Technol Ther. 2021 Sep;23(S3):S81

Identify, Configure, Collaborate

A framework to overcome barriers to technology use and therapeutic inertia

Leveraging Technology to Achieve Diabetes and Cardiometabolic Outcomes

Identify	Configure	Collaborate
▪ Right technology ▪ Right person ▪ Right time	▪ User preferences ▪ Treatment plan ▪ Ongoing support	▪ Data driven conversations ▪ Shared decision making ▪ Care team integration

Greenwood. The Diabetes educator. 2020;46:315.

Considerations When Choosing A Glucose Monitoring Device

Frequency of sensor change

Cost

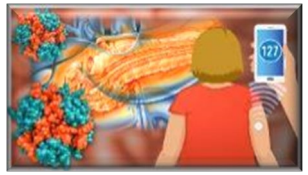
Compatibility with other devices

Size of the sensor

Accuracy of the sensor

Real time/ predictive alerts

MacLeod. ADCES In Practice. 2020;8:48.



Identifying the “Right” Technology

How do I prefer to check my glucose?

“I don’t want to have something attached to me.”

“If I could see more information, I think I’d feel motivated to take my meds and eat healthier.”

Configuring the Technology

Based on a person's unique needs and preferences

Examples

- CGM high/low alerts
- Rise/fall rates
- Frequency of reminders
- Time of day settings
- Sharing data

Alert Settings for Device

General

Low	On	70 mg/dL	Low	On	70 mg/dL
Low Repeat	On	15 min	Low Repeat	On	15 min
High	Off	200 mg/dL	High	On	250 mg/dL
High Repeat	Off	30 min	High Repeat	On	60 min
Fall Rate	On	3 mg/dL/min	Fall Rate	On	3 mg/dL/min
Rise Rate	On	3 mg/dL/min	Rise Rate	On	3 mg/dL/min
Urgent Low	On	55 mg/dL	Urgent Low	On	55 mg/dL
Urgent Low Repeat	On	30 min	Urgent Low Repeat	On	30 min
Urgent Low Soon	On	55 mg/dL	Urgent Low Soon	On	55 mg/dL
Urgent Low Soon Repeat	On	30 min	Urgent Low Soon Repeat	On	30 min
Signal Loss	Off	20 min	Signal Loss	Off	20 min

Scheduled - Bedtime

Status: On
Sun, Mon, Tue, Wed, Thu, Fri, Sat
10:30 PM - 7:00 AM

Configuring Examples

Sharing Data

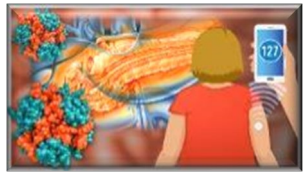
“I want my wife and kids to see if I’m having a high or low blood sugar, so they can help me if I need it, especially when I am out of town on business.”

Alarms

“Sleep is really important to me. I heard CGM buzzes/beeps at night. I don’t want anything beeping at me during my sleep. I have always been able to feel my lows.”

Reminders

“I get so wrapped up in what I am doing that I forget to check my glucose or take insulin. I could really use the reminders.”



Collaboration: The Importance of Education and Training

“No device used in diabetes management works optimally without education, training, and follow-up.”

ADA. Diabetes Care. 2022;45:S1.

"Simply wearing the devices may not automatically translate to health benefits."

Camille was given a CGM but not educated on her glucose targets. She has been wearing it for 3 months!

GLUCOSE STATISTICS AND TARGETS

February 27, 2021 - March 12, 2021	14 Days
% Time CGM is Active	74%

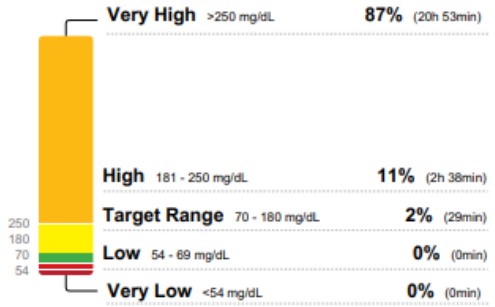
Ranges And Targets For	Type 1 or Type 2 Diabetes
Glucose Ranges	**Targets** % of Readings (Time/Day)
Target Range 70-180 mg/dL	Greater than 70% (16h 48min)
Below 70 mg/dL	Less than 4% (58min)
Below 54 mg/dL	Less than 1% (14min)
Above 180 mg/dL	Less than 25% (6h)
Above 250 mg/dL	Less than 5% (1h 12min)

Each 5% increase in time in range (70-180 mg/dL) is clinically beneficial.

Average Glucose	**368** mg/dL
Glucose Management Indicator (GMI)	**12.1%**
Glucose Variability	**25.3%**

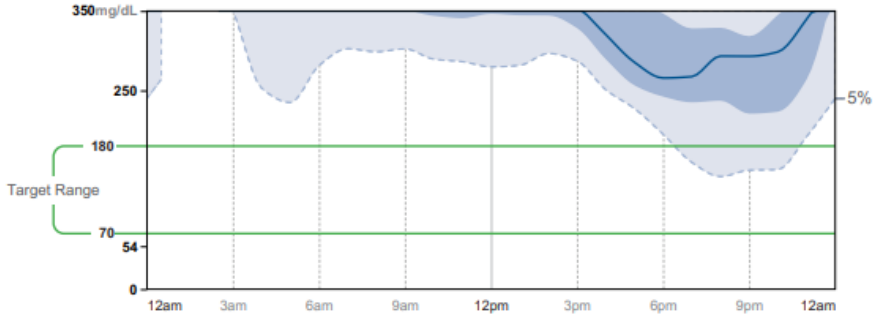
Defined as percent coefficient of variation (%CV); target ≤36%

TIME IN RANGES



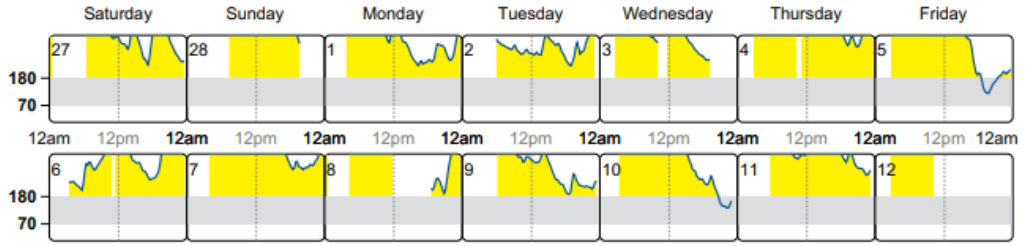
AMBULATORY GLUCOSE PROFILE (AGP)

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



DAILY GLUCOSE PROFILES

Each daily profile represents a midnight to midnight period with the date displayed in the upper left corner.



Source: Battelino, Tadej, et al. "Clinical Targets for Continuous Glucose Monitoring Data Interpretation: Recommendations From the International Consensus on Time in Range." Diabetes Care, American Diabetes Association, 7 June 2019, https://doi.org/10.2337/dci19-0028.

At Least 42 Factors Affect Glucose!

Food | **Medication** | **Activity** | **Biological** | **Environmental** | **Behavioral and decision making**

1. ↑↑ Carbohydrate quantity
2. →↑Carbohydrate type
3. →↑ Fat
4. →↑ Protein
5. →↑ Caffeine
6. ↓↑Alcohol
7. ↓↑ Meal timing
8. ↑Dehydration
9. **?** Personal microbiome

10. →↓Dose
11. ↓↑ Timing
12. ↓↑ Interactions
13. ↑↑ Steroid administration
14. ↑ Niacin (vitamin B3)

15. →↓ Light exercise
16. ↓↑ High/ moderate exercise
17. →↓ Level of fitness/training
18. ↓↑ Time of day
19. ↓↑ Food and insulin timing

20. ↑ Insufficient sleep
21. ↑ Stress and illness
22. ↓ Recent hypoglycemia
23. →↑ During-sleep blood sugars
24. ↑ Dawn phenomenon
25. ↑ Infusion set issues
26. ↑ Scar tissue and lipodystrophy
27. ↓↓ Intramuscular insulin delivery
28. ↑ Allergies
29. ↑ A higher glucose level
30. ↓↑ Menstruation
31. ↑↑ Puberty
32. ↓ Celiac disease
33. ↑ Smoking

34. ↑ Expired insulin
35. ↑ Inaccurate BG reading
36. ↓↑ Outside temperature
37. ↑ Sunburn
38. **?** Altitude

39. ↓ Frequency of glucose checks
40. ↓↑ Default options and choices
41. ↓↑ Decision-making biases
42. ↓↑ Family relationships and social pressures

http://diatribe.org/42factors.

CGM Leading to Timely Titration and Care Plan Assessment

Optimal Therapy Plan?

Escalate or de-escalate therapy as needed

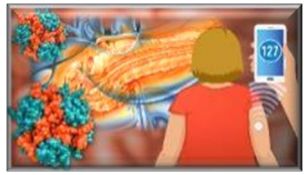
Following the Therapy Plan?

Address barriers as needed

TECHNOLOGY ALONE FIXES NOTHING

Ongoing collaborative use of the data leading to **persistent, incremental adjustments** in the diabetes care plan and **addressing barriers to using the technology and following the care plan** can change everything.

Who in the patient's care team will review and respond to the data?

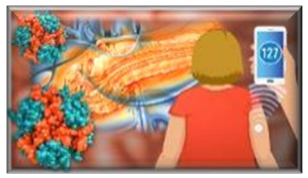


Team Based Care

Who on the care team will help with

- Identify
- Configure
- Collaborate

Team based, person-centered, data-driven care



Review of Continuous Glucose Monitoring (CGM) - DATAA

D — Download Data
- Key metrics, AGP, day by day or spaghetti graph
- Start with global overview; what AGP, key metrics mean, ask what the person learned/what is going well with self-management

A — Assess Safety
- Hypoglycemia - identify times below range, % time in hypoglycemia, # events
- Interactive discussion: possible causes and solutions

T — Time in Range
- Focus on the positive - identify days or times where time in range is highest
- Interactive discussion: how to replicate what is working well

A — Areas to Improve
- Hyperglycemia - Identify times above range, % time in hyperglycemia, # events
- Interactive discussion: possible causes, solutions, and adjustments to self-management

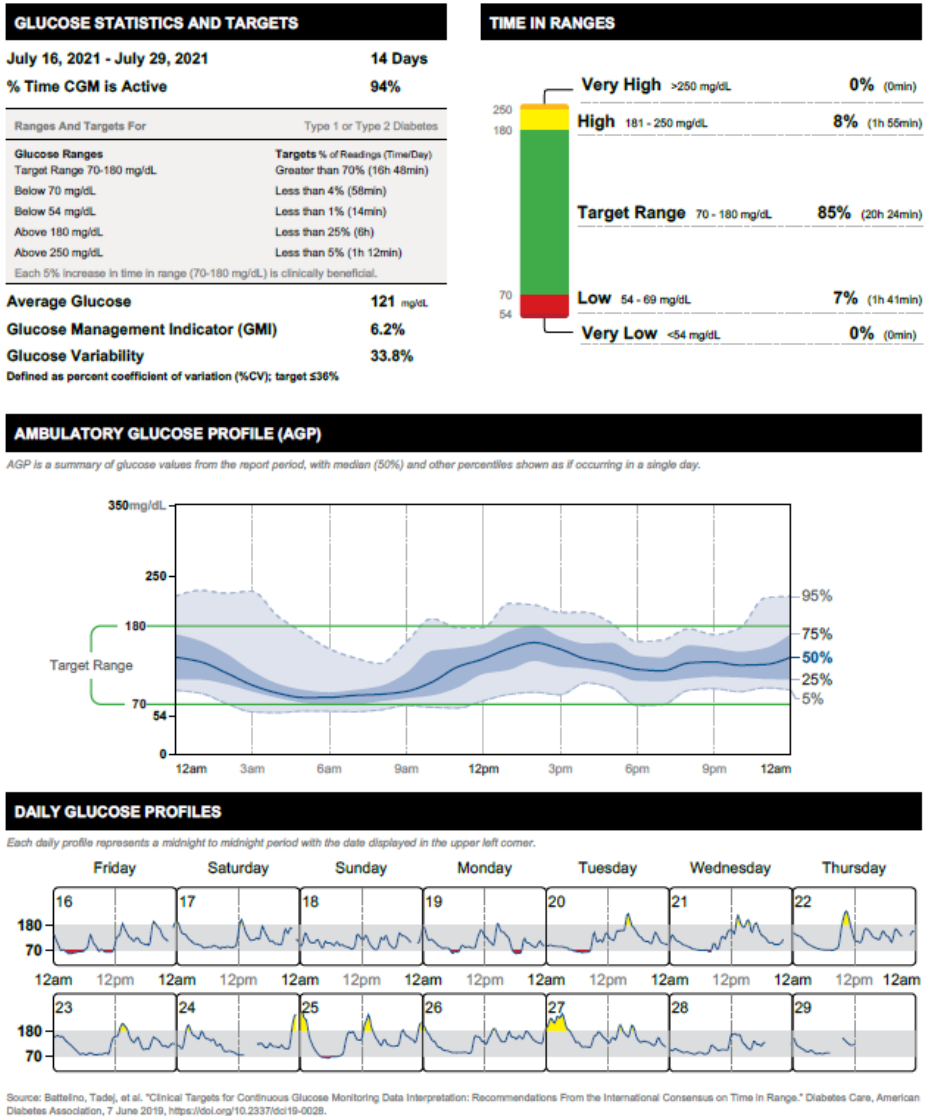
A — Action Plan
- Develop collaboratively with the person with diabetes

At each step, express that this is information, not good or bad

Isaacs D, et al. The Diabetes Educator. 2020;46(4):323-334.

Collaboration: Using Data to Optimize Treatment

Initial CGM Report



GLUCOSE STATISTICS AND TARGETS

July 16, 2021 - July 29, 2021	14 Days
% Time CGM is Active	94%

Ranges And Targets For	Type 1 or Type 2 Diabetes
Glucose Ranges	**Targets** % of Readings (Time/Day)
Target Range 70-180 mg/dL	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	121 mg/dL
Glucose Management Indicator (GMI)	6.2%
Glucose Variability	33.8%

Defined as percent coefficient of variation (%CV); target ≤36%

TIME IN RANGES

Very High	>250 mg/dL	0% (0min)
High	181 - 250 mg/dL	8% (1h 55min)
Target Range	70 - 180 mg/dL	85% (20h 24min)
Low	54 - 69 mg/dL	7% (1h 41min)
Very Low	<54 mg/dL	0% (0min)

AMBULATORY GLUCOSE PROFILE (AGP)

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

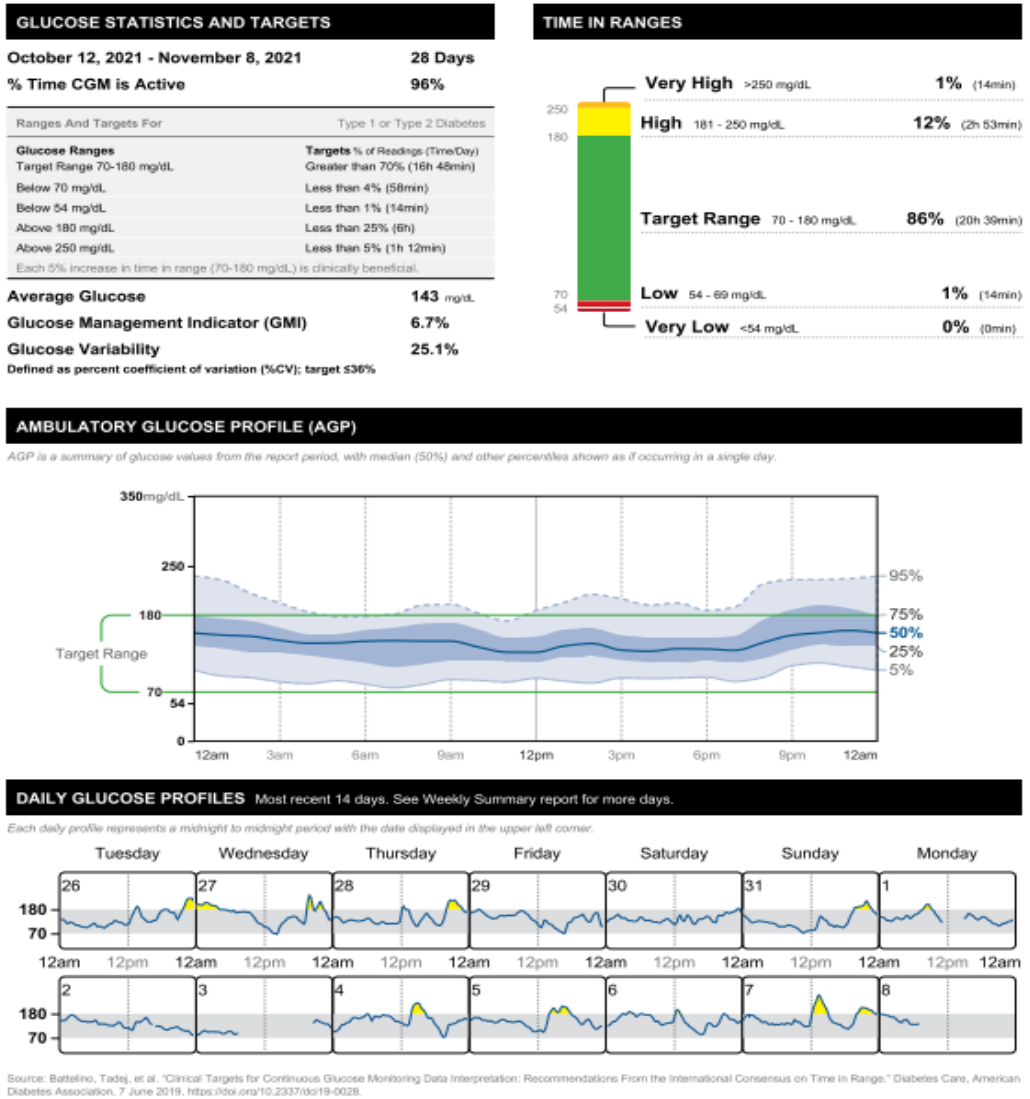
DAILY GLUCOSE PROFILES

Each daily profile represents a midnight to midnight period with the date displayed in the upper left corner.

Source: Battelino, Tadej, et al. "Clinical Targets for Continuous Glucose Monitoring Data Interpretation: Recommendations From the International Consensus on Time in Range." Diabetes Care, American Diabetes Association, 7 June 2019, https://doi.org/10.2337/dci19-0028.

Collaboration: Using Data to Optimize Treatment

Follow-up CGM Report after medication adjustments and lifestyle changes



GLUCOSE STATISTICS AND TARGETS

October 12, 2021 - November 8, 2021	28 Days
% Time CGM is Active	96%

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	143 mg/dL
Glucose Management Indicator (GMI)	6.7%
Glucose Variability	25.1%

Defined as percent coefficient of variation (%CV); target ≤36%

TIME IN RANGES

Very High	>250 mg/dL	1% (14min)
High	181 - 250 mg/dL	12% (2h 53min)
Target Range	70 - 180 mg/dL	86% (20h 39min)
Low	54 - 69 mg/dL	1% (14min)
Very Low	<54 mg/dL	0% (0min)

AMBULATORY GLUCOSE PROFILE (AGP)

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

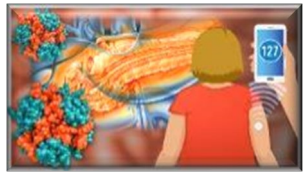
DAILY GLUCOSE PROFILES Most recent 14 days. See Weekly Summary report for more days.

Each daily profile represents a midnight to midnight period with the date displayed in the upper left corner.

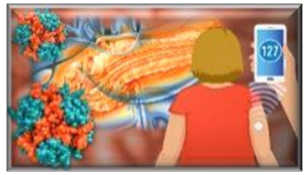
Source: Battelino, Tadej, et al. "Clinical Targets for Continuous Glucose Monitoring Data Interpretation: Recommendations From the International Consensus on Time in Range." Diabetes Care, American Diabetes Association, 7 June 2019, https://doi.org/10.2337/dci19-0028.

An Opportunity: Using CGM Data for Remote Monitoring and Population Health

Last Available Data	Average Glucose (mg/dL)	Average Scans/Views per Day	% In Target	LibreView User Status	% Below Target	Coefficient of Variation	% Time Sensor is Active
Today	167	2	58	Connected	4	39.9	49
Today	206	2	41	Connected	1	37.8	43
Today	168	3	63	Connected	1	23.7	47
Today	166	3	56	Connected	3	29.5	76
Today	137	6	88	Connected	0	27.7	87
Today	158	5	68	Connected	1	35.1	72
Today	148	8	89	Connected	0	20.1	87
Today	179	4	43	Connected	14	55.7	83
Today	108	3	94	Connected	3	27.7	74
Today	173	9	55	Connected	1	30.5	94
Today	218	8	33	Connected	1	36.3	90
Today	185	6	46	Connected	1	26.2	84
Today	174	3	60	Connected	0	29.4	65
Today	165	3	75	Connected	0	24.0	66



Additional Barriers & Solutions



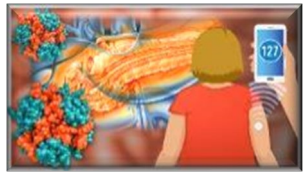
Patient Says, “My Sensor Fell Off Early”

Advise to call the companies directly for replacements

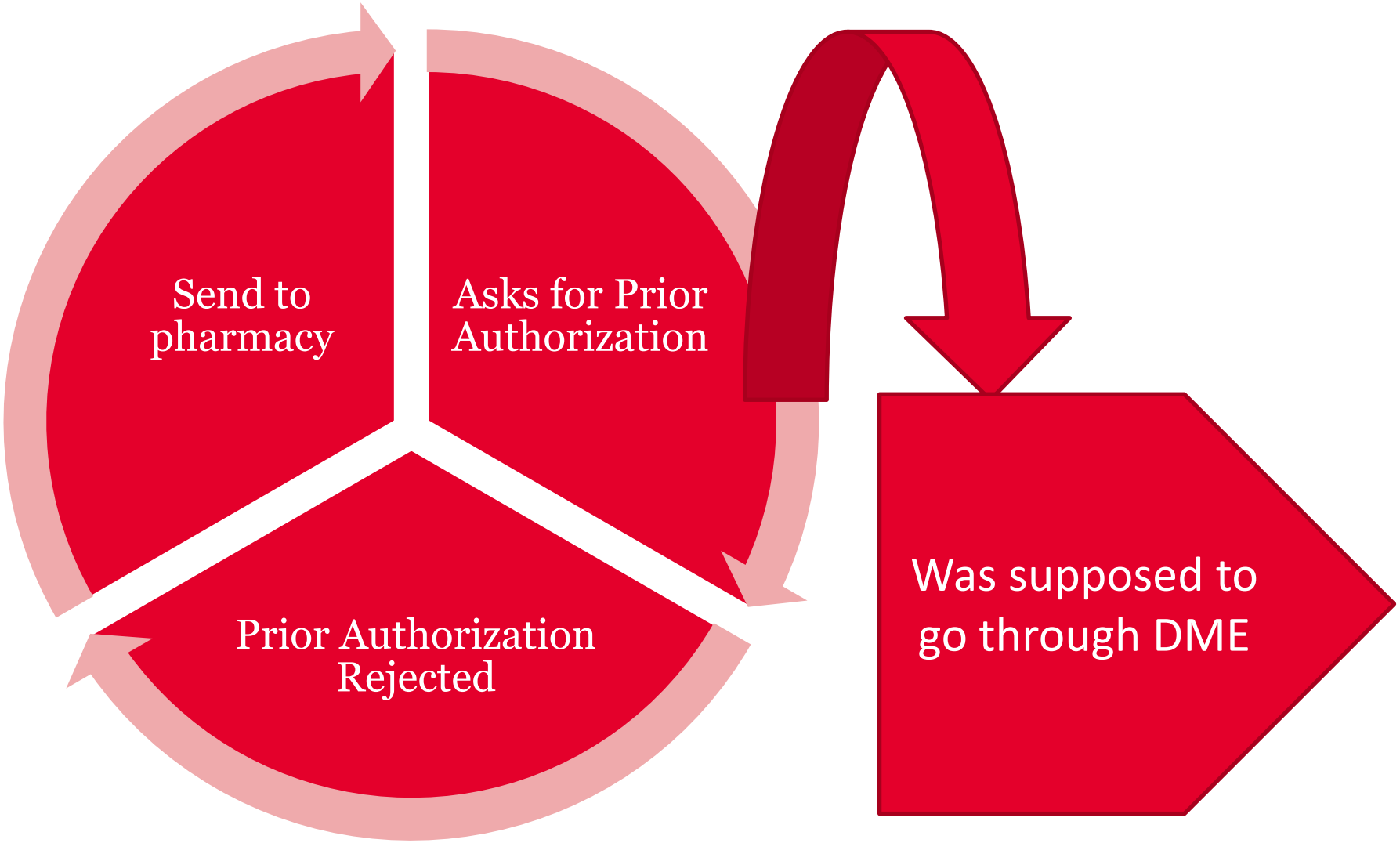
Options to tape over the sensor

Options to help it stick better

Messer. Diabet Med. 2018;35:409.



CGM Coverage: Pharmacy vs. DME



When to Check BGM?

- A calibration or blood glucose symbol appears on the device
- Symptoms or expectations do not match CGM readings
- CGM readings are suspected to be inaccurate or used for an off- label indication like pregnancy
- Determining an insulin dose if the device is only approved as adjunctive therapy (ex. Guardian sensors)
- If taking an interfering substance (ex. vitamin C, acetaminophen hydroxyurea)

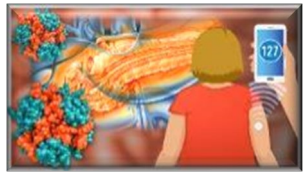
Per ADA, every person using CGM should have access to a meter and test strips

ADCES Practice Paper. The Diabetes Care and Education Specialist's Role in Continuous Glucose Monitoring. Updated March 2021

ADA Standards of Care 2022.

Summary

- Continuous glucose monitoring has demonstrated many improved outcomes, to experience maximum benefit, people with diabetes need education and training on the devices and the healthcare team needs to be trained on how to use the data
- The Identify, Configure, Collaborate (ICC) framework is a tool that can address many of the barriers to CGM use
- There are many ways that the care team can help with CGM access, initiation, education and collaboration of data to ensure optimal use and maximum benefit



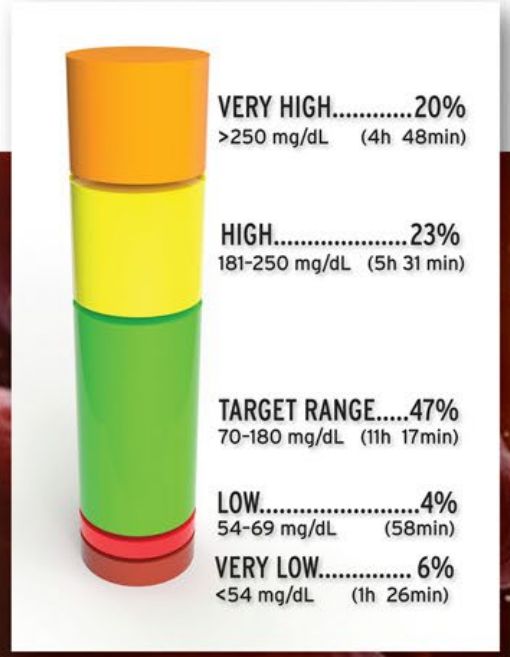
Additional Resources

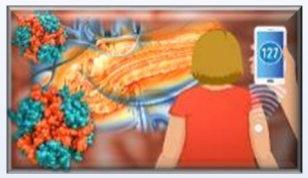
- Diabetes Technology Device Selection
  - For patients: Diabeteswise.org
  - For HCPs: Home — DiabetesWise for Health Providers
- AACE Guide to CGM
  - AACE Guide to Continuous Glucose Monitoring (CGM) | American Association of Clinical Endocrinology
- ADCES CGM resources
  - Glucose Monitoring Resources (diabeteseducator.org)
- ADA Time in Range
  - Time in Range | American Diabetes Association

The Rationale and Real World Evidence for Initiating and Maintaining

Sensor-Based Continuous Glucose Monitoring (CGM) to Optimize Care of Persons Across the Spectrum of Diabetes

*The **Physician Assistant's (PA's) Role** and Practical Action Steps for Establishing CGM-Based in the Primary Care Setting*



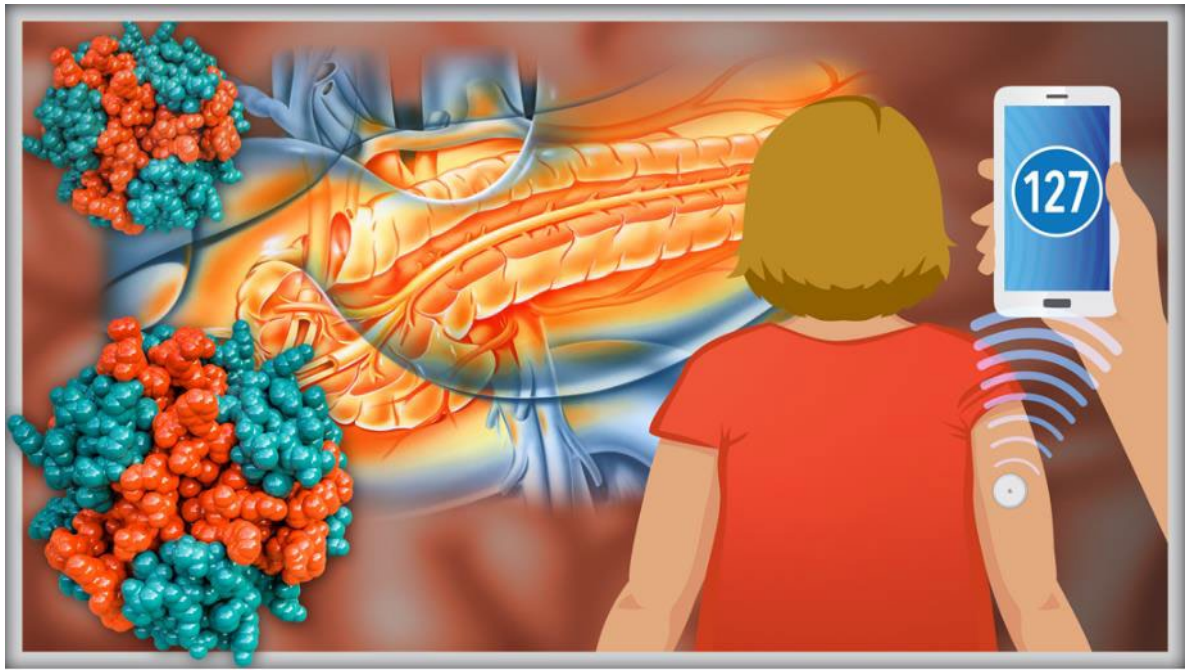


Using CGM-Based Glycemic Management and AGP Readouts to Improve Diabetes Management and Outcomes for Persons with T2D Cared for in the Physician Assistant Setting

Real-World Case Management Sessions

AAPA 2022
Ashlyn Smith, MMS PA-C
Adult Endocrine Physician Assistant, Phoenix, AZ
President, American Society of Endocrine Physician Assistants
Adjunct Assistant Professor, Midwestern University

Clinical Case #1



Case Studies/AGP Reports Provided Courtesy of

Eden Miller, DO

Executive Director and Co-Founder | Diabetes Nation

High Lakes Health Care | St. Charles Hospital | Bend, Oregon

Clinical Case #1
Patient Presentation

- 66-year-old male with T2DM
- Renal impairment
- On sulfonylurea
- A1c discrepant with glucose tests

AGP Report
May 4, 2021 - May 17, 2021 (14 Days)

LibreView

GLUCOSE STATISTICS AND TARGETS

May 4, 2021 - May 17, 2021	**14 Days**
% Time CGM is Active	**97%**

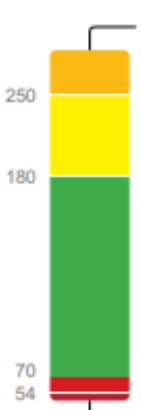
Ranges And Targets For	Type 1 or Type 2 Diabetes
Glucose Ranges	**Targets** % of Readings (Time/Day)
Target Range 70-180 mg/dL	Greater than 70% (16h 48min)
Below 70 mg/dL	Less than 4% (58min)
Below 54 mg/dL	Less than 1% (14min)
Above 180 mg/dL	Less than 25% (6h)
Above 250 mg/dL	Less than 5% (1h 12min)

Each 5% increase in time in range (70-180 mg/dL) is clinically beneficial.

Average Glucose	**167** mg/dL
Glucose Management Indicator (GMI)	**7.3%**
Glucose Variability	**39.1%**

Defined as percent coefficient of variation (%CV); target ≤36%

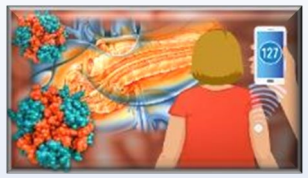
TIME IN RANGES



Very High	>250 mg/dL	**12%** (2h 53min)
High	181 - 250 mg/dL	**23%** (5h 31min)
Target Range	70 - 180 mg/dL	**63%** (15h 7min)
Low	54 - 69 mg/dL	**2%** (29min)
Very Low	<54 mg/dL	**0%** (0min)

Clinical Case #1
Problems in This Clinical Scenario

- Common scenario
  - Sulfonylurea used in renal patients who cannot take metformin
  - Metabolized in the kidney
  - CKD=Changed pharmacokinetics
  - Sulfonylurea + CKD = high risk of hypoglycemia
- Yet high glucose at times—A1c becomes unreliable
- Concern about other complications
  - CKD increases risk of CAD



Clinical Case #1
Ambulatory Glucose Profile (AGP) Report

AGP Report

May 4, 2021 - May 17, 2021 (14 Days)

LibreView

GLUCOSE STATISTICS AND TARGETS

May 4, 2021 - May 17, 2021	**14 Days**
% Time CGM is Active	**97%**

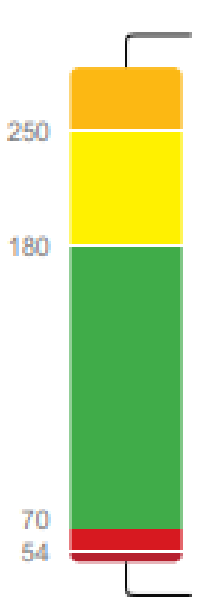
Ranges And Targets For	Type 1 or Type 2 Diabetes
Glucose Ranges	**Targets** % of Readings (Time/Day)
Target Range 70-180 mg/dL	Greater than 70% (16h 48min)
Below 70 mg/dL	Less than 4% (58min)
Below 54 mg/dL	Less than 1% (14min)
Above 180 mg/dL	Less than 25% (6h)
Above 250 mg/dL	Less than 5% (1h 12min)

Each 5% increase in time in range (70-180 mg/dL) is clinically beneficial.

Average Glucose	**167** mg/dL
Glucose Management Indicator (GMI)	**7.3%**
Glucose Variability	**39.1%**

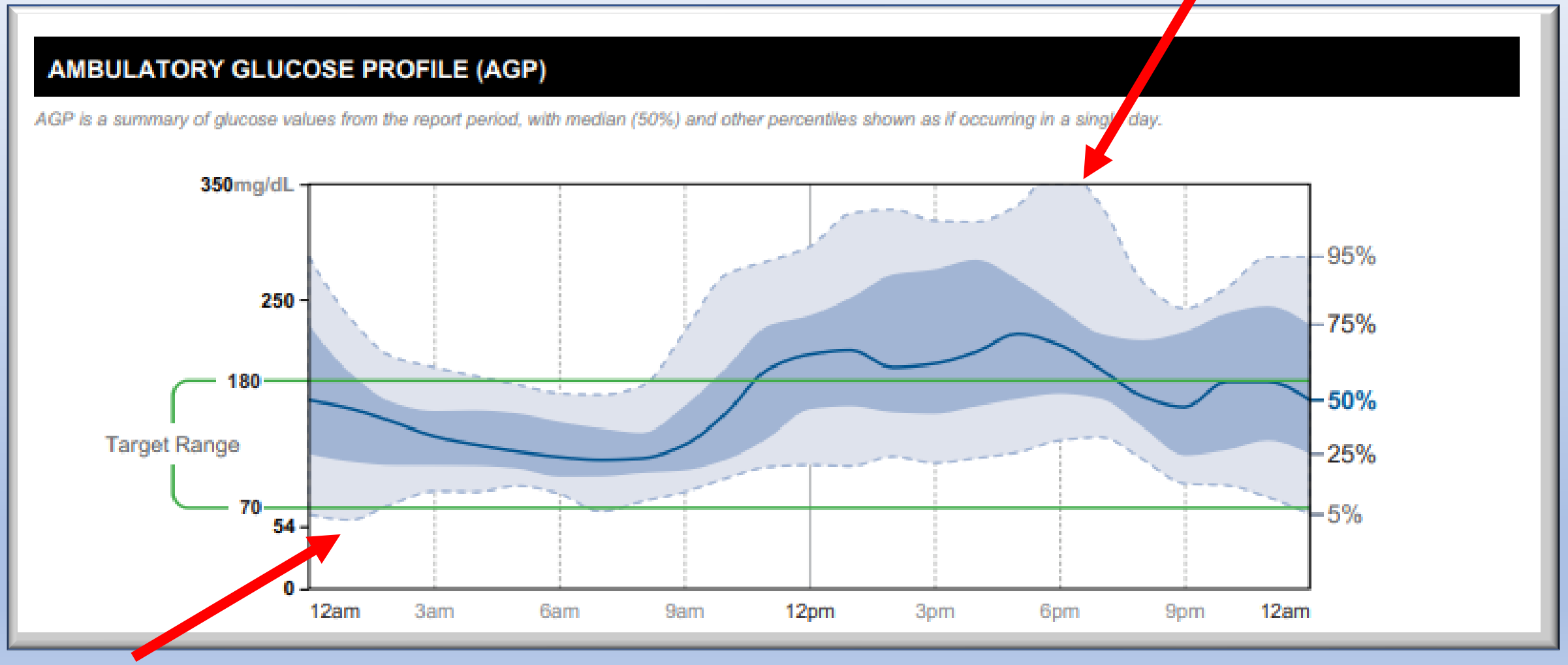
Defined as percent coefficient of variation (%CV); target ≤36%

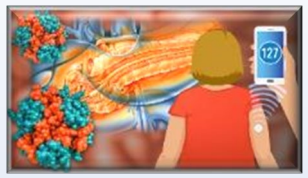
TIME IN RANGES



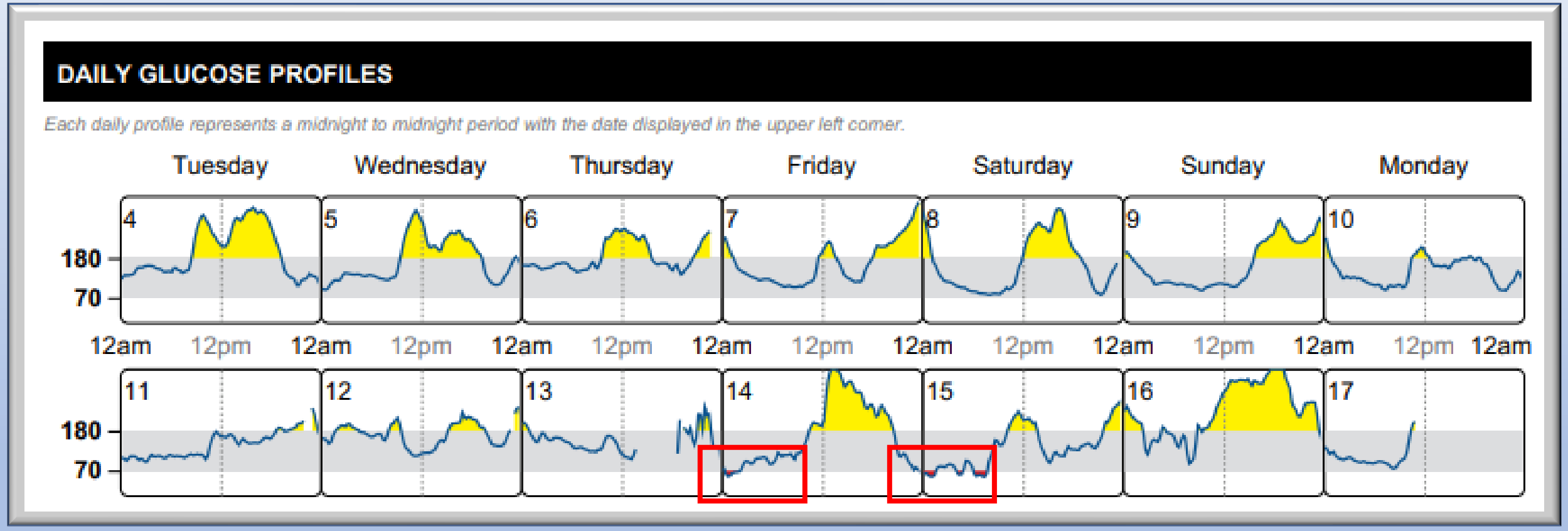
Very High	>250 mg/dL	**12%**	(2h 53min)
High	181 - 250 mg/dL	**23%**	(5h 31min)
Target Range	70 - 180 mg/dL	**63%**	(15h 7min)
Low	54 - 69 mg/dL	**2%**	(29min)
Very Low	<54 mg/dL	**0%**	(0min)

Clinical Case #1
AGP

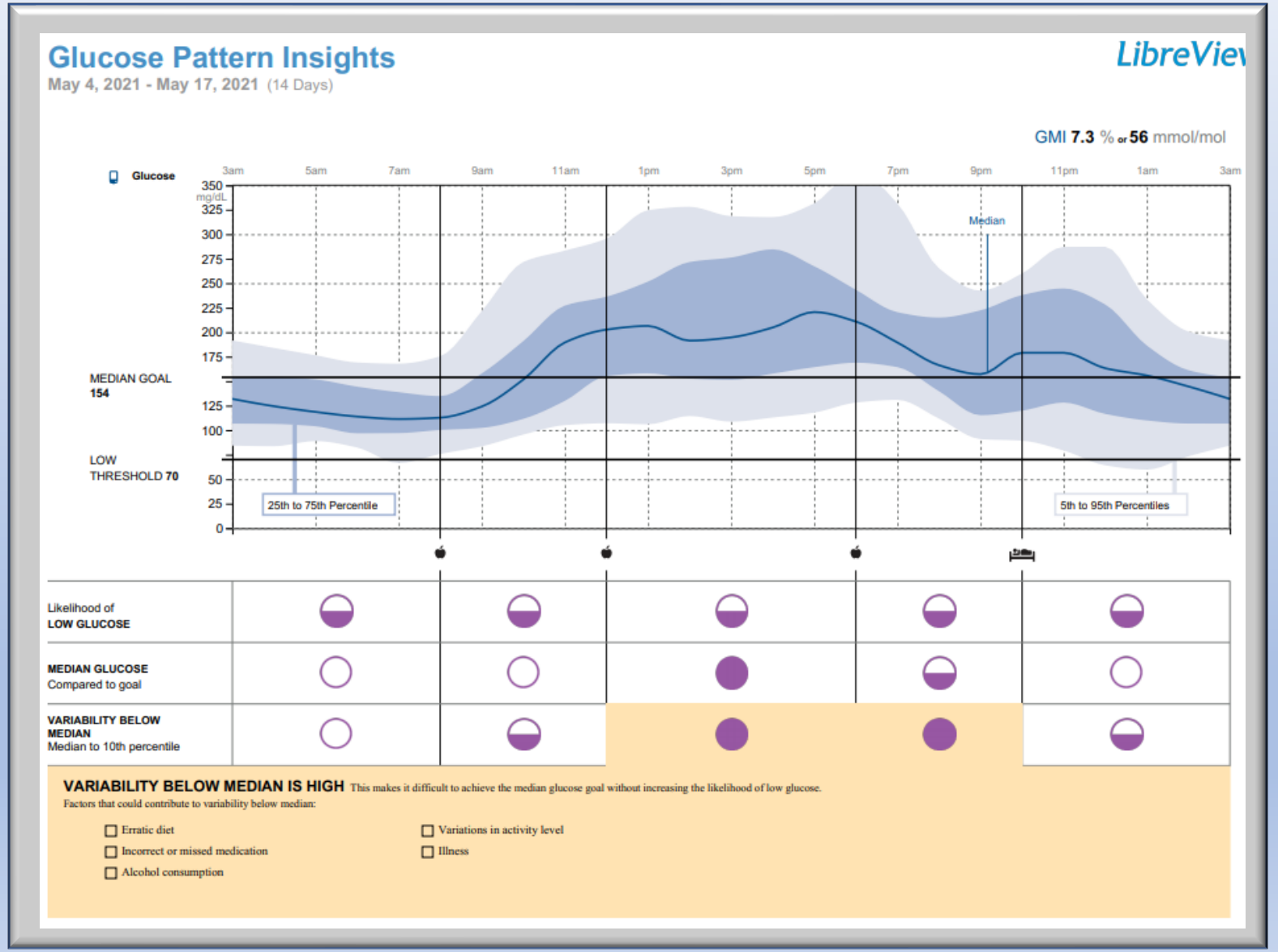


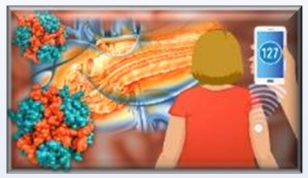


Clinical Case #1
Daily Glucose Profiles



Clinical Case #1
Glucose Pattern Insights





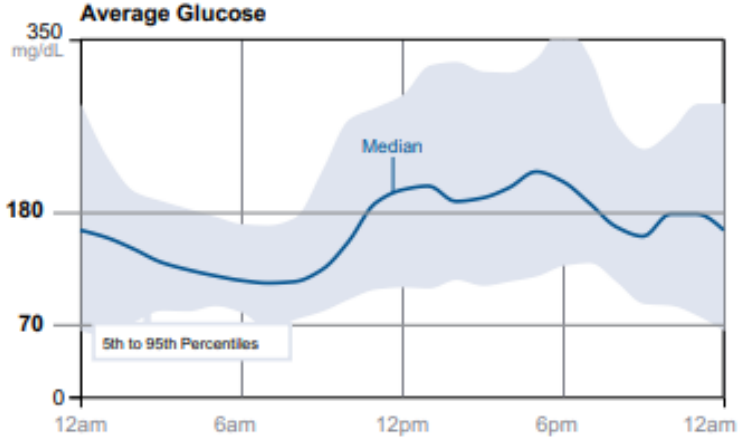
Clinical Case #1
Snapshot

Glucose

GMI **7.3** % or **56** mmol/mol

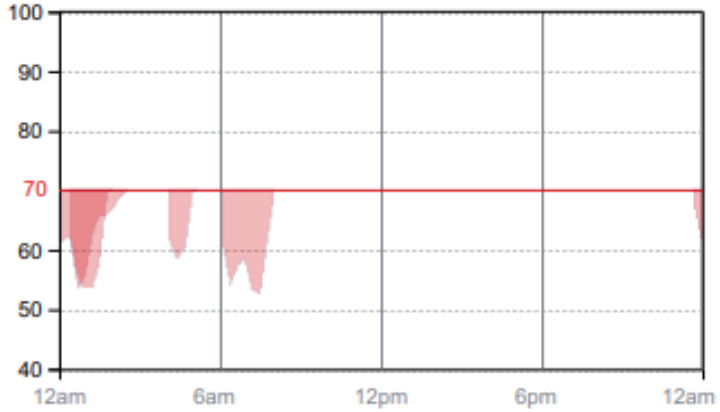
AVERAGE GLUCOSE	**167**	mg/dL
% above target	**35**	%
% in target	**63**	%
% below target	**2**	%

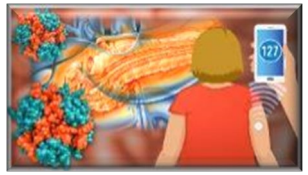
Average Glucose



LOW GLUCOSE EVENTS	**4**	
Average duration	**105**	Min

Low Glucose Events

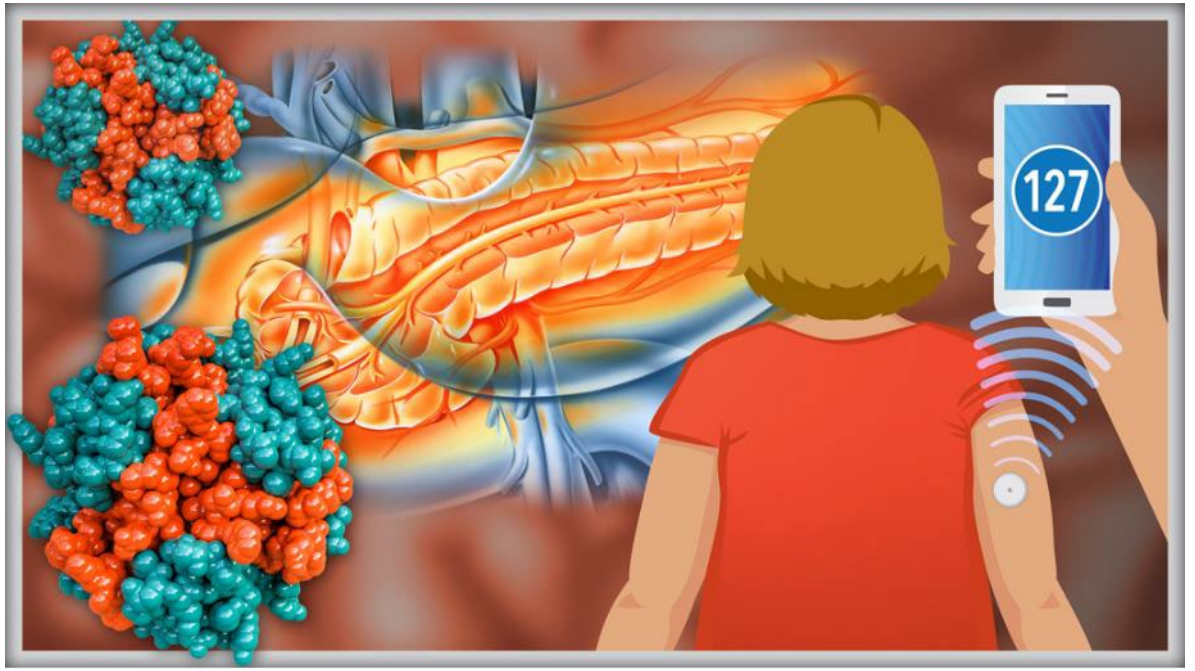


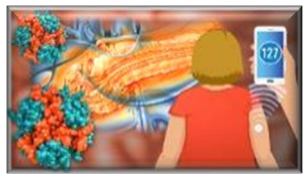


Clinical Case #1
What are the clinical issues and solutions?

ISSUES	SOLUTIONS
▶ Considerable variability – intraday and interday • Unrecognized hypoglycemia, particularly at night • Poor post prandial control ▶ Sulfonylurea alone = problematic • CKD and hypoglycemia	▶ Reduction in sulfonylurea dose, particularly at night • Bedtime snack? ▶ Consider alternatives • Long acting GLP-1 RA if tolerated would reduce PPG excursions • Cardiorenal favorable

Clinical Case #2





Clinical Case #2
Patient Presentation

- 49-year old female with T2DM
- Ketosis prone
- On basal insulin, small bolus
- High Glucose, A1c 8%

AGP Report
May 7, 2021 - May 14, 2021 (14 Days)

LibreView

GLUCOSE STATISTICS AND TARGETS

May 7, 2021 - May 20, 2021	14 Days
% Time CGM is Active	89%

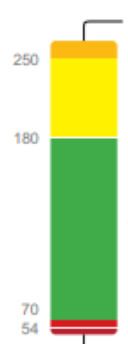
Ranges And Targets For	Type 1 or Type 2 Diabetes
Glucose Ranges	**Targets** % of Readings (Time/Day)
Target Range 70-180 mg/dL	Greater than 70% (16h 48min)
Below 70 mg/dL	Less than 4% (58min)
Below 54 mg/dL	Less than 1% (14min)
Above 180 mg/dL	Less than 25% (6h)
Above 250 mg/dL	Less than 5% (1h 12min)

Each 5% increase in time in range (70-180 mg/dL) is clinically beneficial.

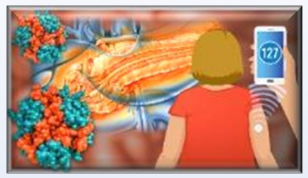
Average Glucose	162 mg/dL
Glucose Management Indicator (GMI)	7.2%
Glucose Variability	27.3%

Defined as percent coefficient of variation (%CV); target ≤36%

TIME IN RANGES



Very High	>250 mg/dL	4% (58min)
High	181 - 250 mg/dL	28% (6h 43min)
Target Range	70 - 180 mg/dL	68% (16h 19min)
Low	54 - 69 mg/dL	0% (0min)
Very Low	<54 mg/dL	0% (0min)



Clinical Case #2
AGP Report

AGP Report

May 7, 2021 - May 20, 2021 (14 Days)

LibreView

GLUCOSE STATISTICS AND TARGETS

May 7, 2021 - May 20, 2021	**14 Days**
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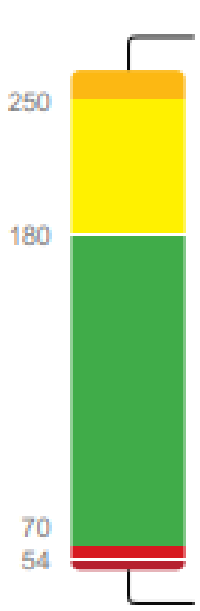
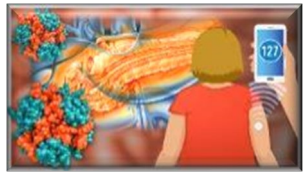


Very High	>250 mg/dL	**4%**	(58min)
High	181 - 250 mg/dL	**28%**	(6h 43min)
Target Range	70 - 180 mg/dL	**68%**	(16h 19min)
Low	54 - 69 mg/dL	**0%**	(0min)
Very Low	<54 mg/dL	**0%**	(0min)



Clinical Case #2
Problems in this scenario

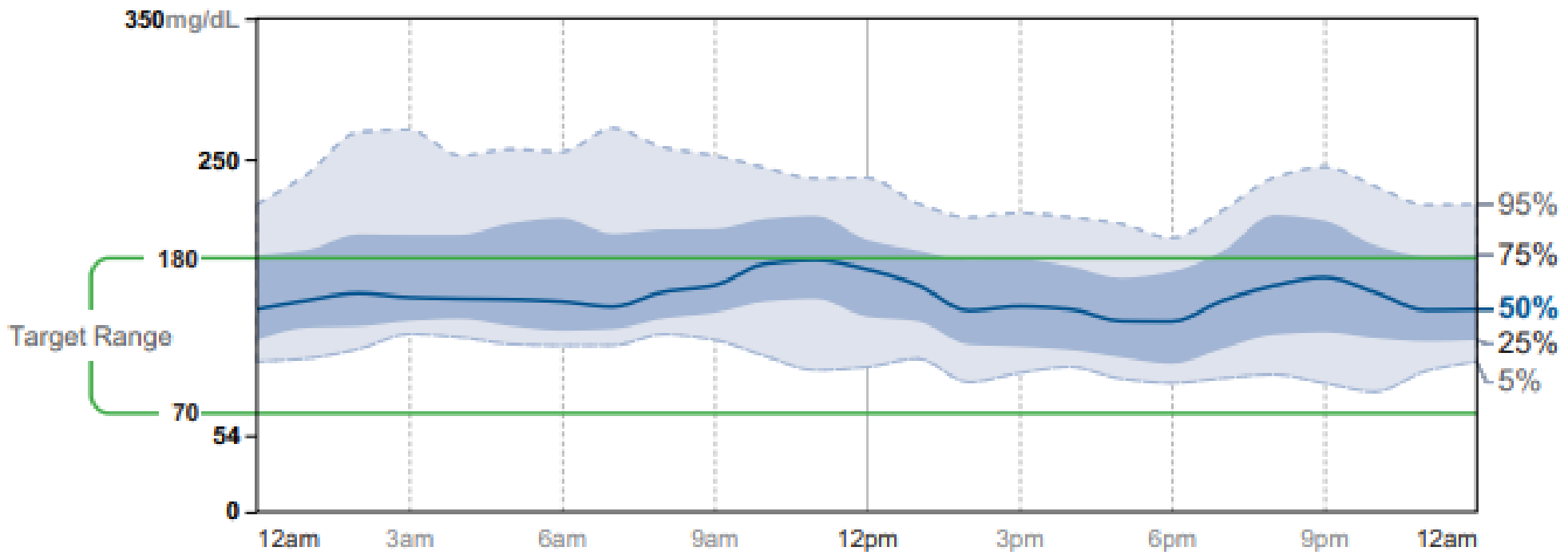
- Is this Type 1 Diabetes? – 1/3 of adults >30 dx as “type 2” are actually “type 1”[1]
- GMI does not reflect glucose peaks
- Glucose is high most of the time
- Fortunately, no hypoglycemia!
- Little overall variation
  - Overnight/early morning variability

Nicholas J. Thomas, Anita L. Lynam, Anita V. Hill, Michael N. Weedon, Beverley M. Shields, Richard A. Oram, Timothy J. McDonald, Andrew T. Hattersley, Angus G. Jones. Type 1 diabetes defined by severe insulin deficiency occurs after 30 years of age and is commonly treated as type 2 diabetes. Diabetologia, 2019; DOI: 10.1007/s00125-019-4863-8

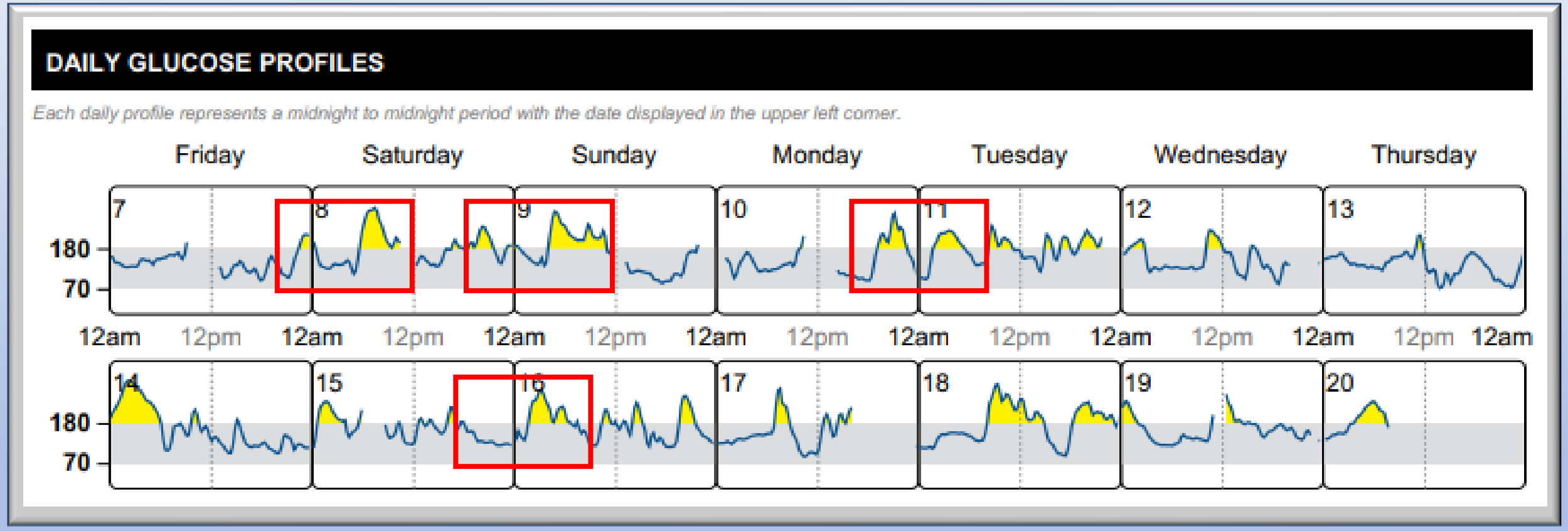
Clinical Case #2
AGP

AMBULATORY GLUCOSE PROFILE (AGP)

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



Clinical Case #2
Daily Glucose Profiles



Clinical Case #2

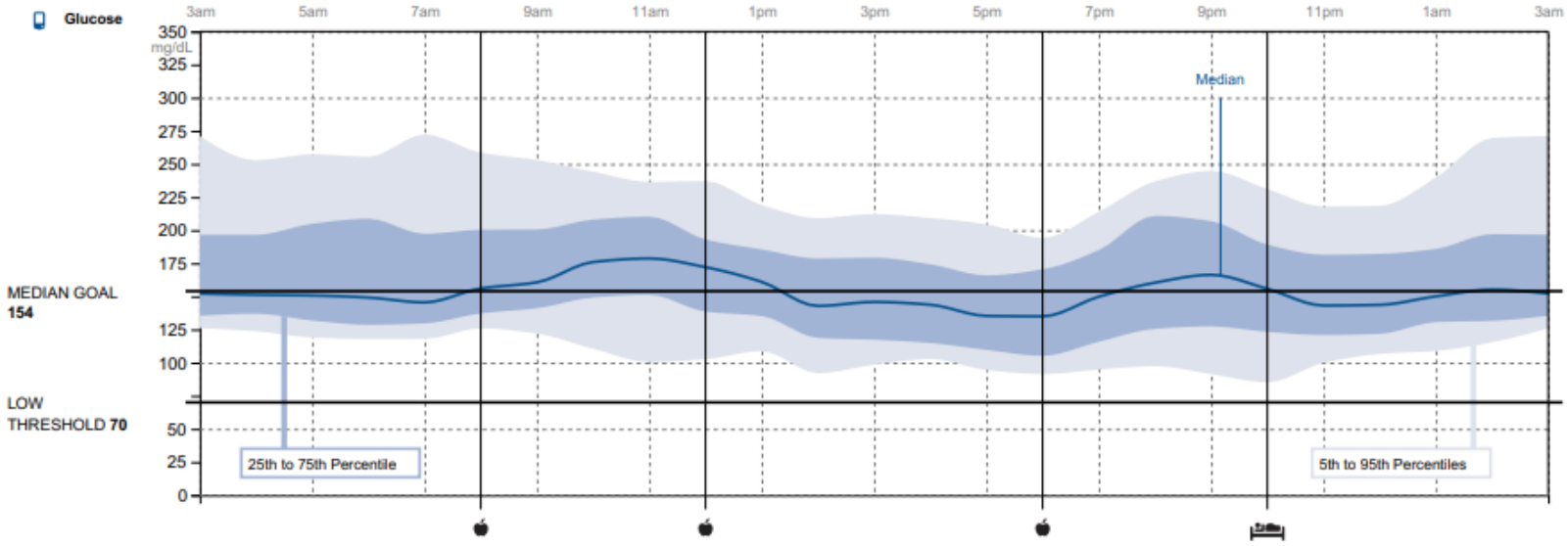
Glucose Pattern Insights

Glucose Pattern Insights

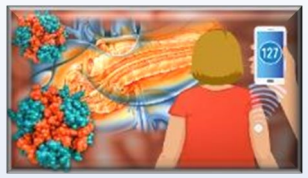
LibreView

May 7, 2021 - May 20, 2021 (14 Days)

GMI **7.2** % or **55** mmol/mol



Likelihood of **LOW GLUCOSE**	○	○	○	◒	○
MEDIAN GLUCOSE Compared to goal	○	◒	○	◒	○
VARIABILITY BELOW MEDIAN Median to 10th percentile	○	◒	◒	◒	◒



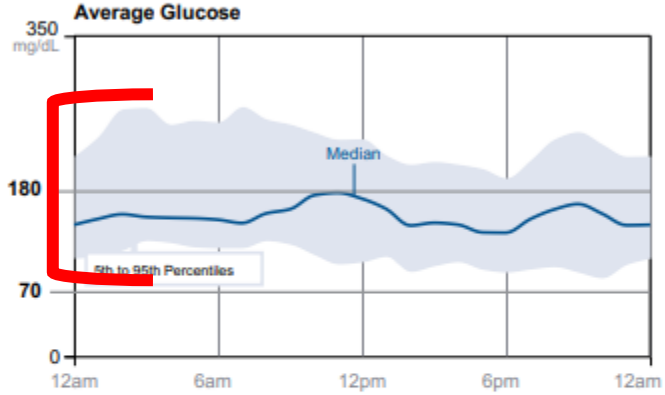
Clinical Case #2
Snapshot

Snapshot
May 7, 2021 - May 20, 2021 (14 Days)

Glucose GMI **7.2** % or **55** mmol/mol

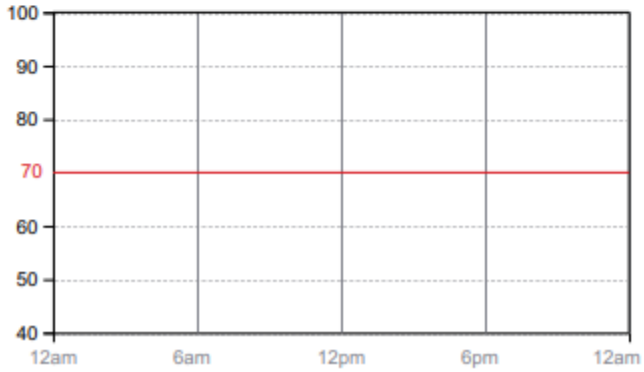
AVERAGE GLUCOSE	**162** mg/dL
% above target	**31** %
% in target	**69** %
% below target	**0** %

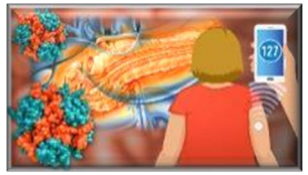
Average Glucose



LOW GLUCOSE EVENTS	**0**
Average duration	**0** Min

Low Glucose Events

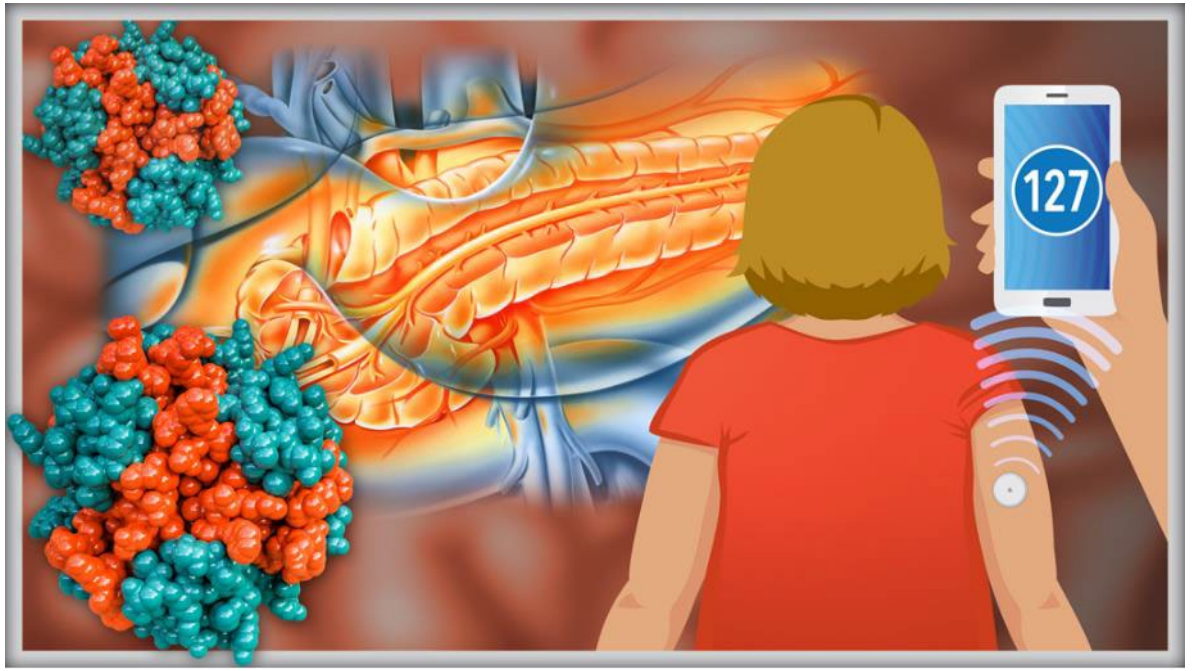




Clinical Case #1
What are the clinical issues and solutions?

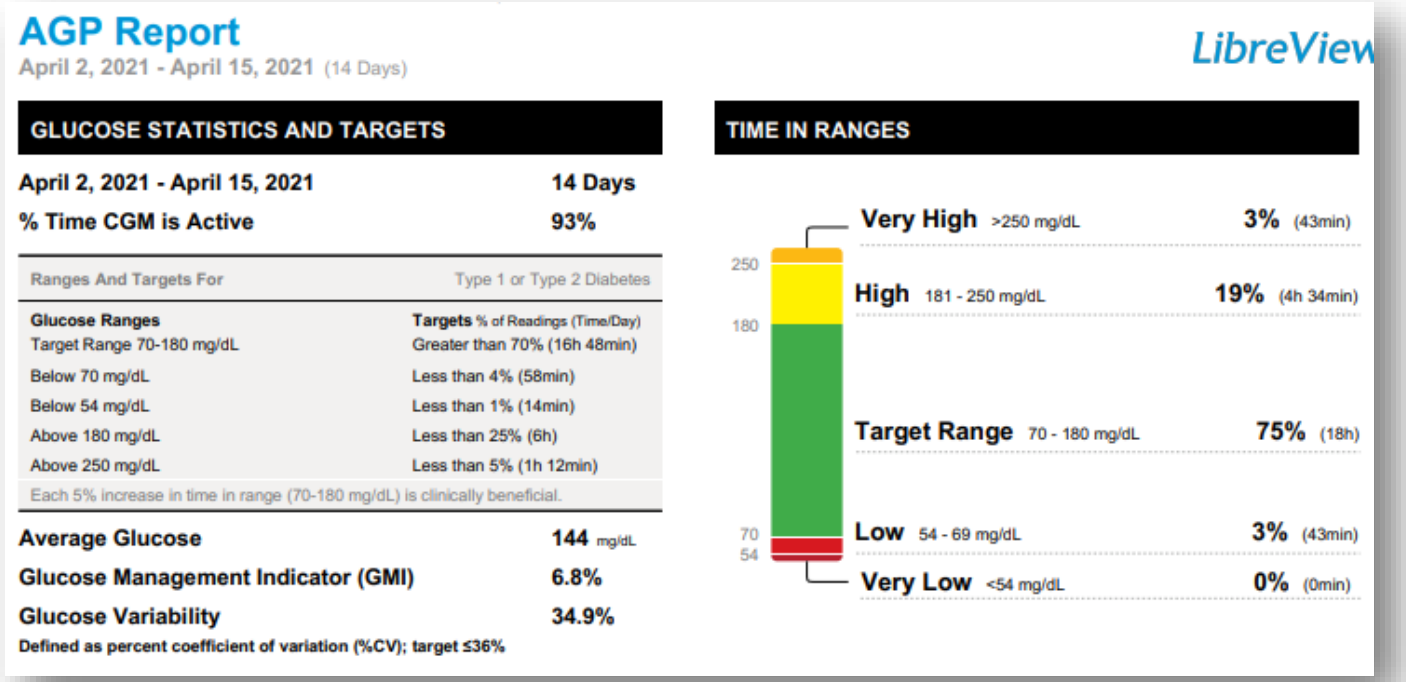
ISSUES	SOLUTIONS
▶ Does this patient have T1DM? • However, enough glucose secretory capacity to avoid postprandial excursions ▶ Some erratic peaks on weekends ▶ High all the time--Inadequate basal insulin	▶ Order T1DM abs • C-Peptide? ▶ Discuss diet, particularly high CHO on weekends • Keep food journal to review with GCM ▶ Augment regimen: • Increase basal insulin? – consider BID • Add GLP-1 RA • Add SGLT2i? Risk of DKA • Basal – Bolus therapy?

Clinical Case #3



Clinical Case #3
Patient Presentation

- 59-year old male with T2DM for 10 years
- Treatment: Basal-bolus
- A1c 7.3% but has some hypoglycemia at night



AGP Report
April 2, 2021 - April 15, 2021 (14 Days)

LibreView

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Each 5% increase in time in range (70-180 mg/dL) is clinically beneficial.

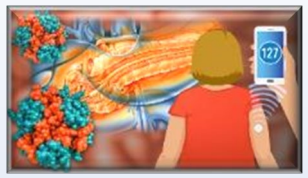
Average Glucose	144 mg/dL
Glucose Management Indicator (GMI)	6.8%
Glucose Variability	34.9%

Defined as percent coefficient of variation (%CV); target ≤36%

TIME IN RANGES

250
180
70
54

Very High	>250 mg/dL	3% (43min)
High	181 - 250 mg/dL	19% (4h 34min)
Target Range	70 - 180 mg/dL	75% (18h)
Low	54 - 69 mg/dL	3% (43min)
Very Low	<54 mg/dL	0% (0min)



Clinical Case #3
AGP Report

AGP Report

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LibreView

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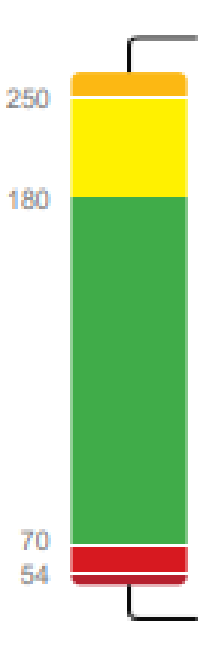
TIME IN RANGES



Very High	>250 mg/dL	**3%**	(43min)
High	181 - 250 mg/dL	**19%**	(4h 34min)
Target Range	70 - 180 mg/dL	**75%**	(18h)
Low	54 - 69 mg/dL	**3%**	(43min)
Very Low	<54 mg/dL	**0%**	(0min)

Clinical Case #3
AGP

AMBULATORY GLUCOSE PROFILE (AGP)

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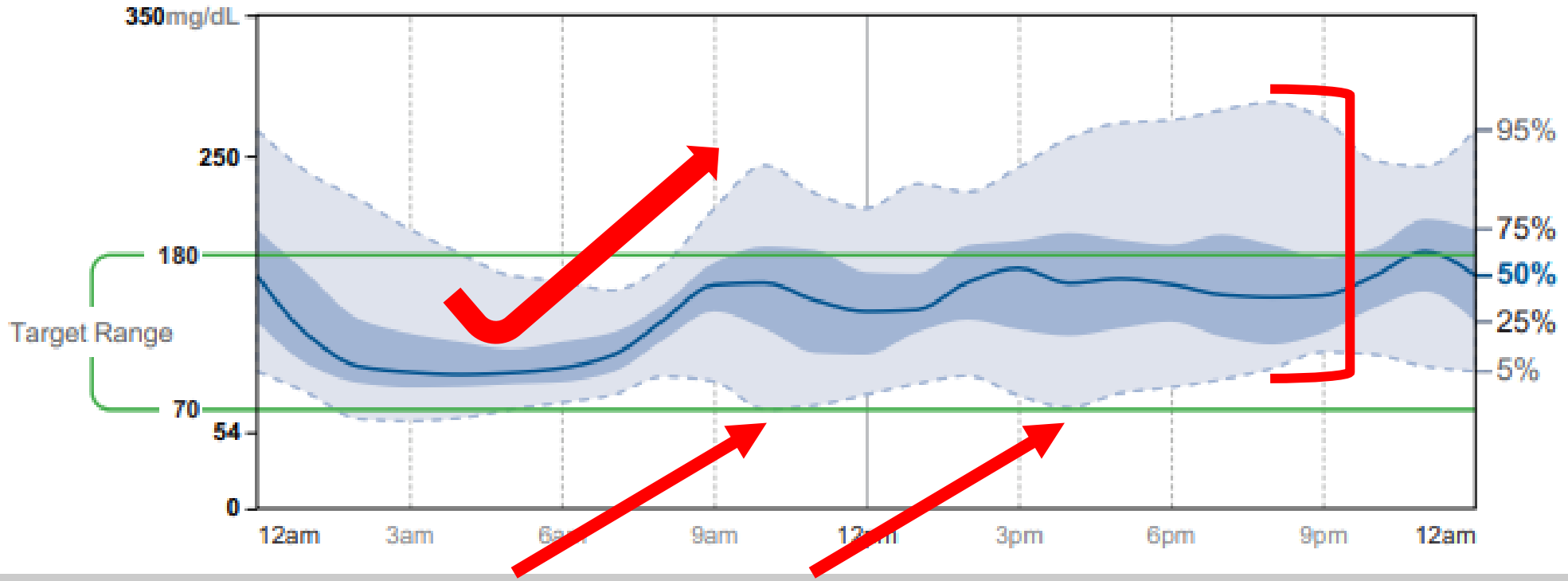
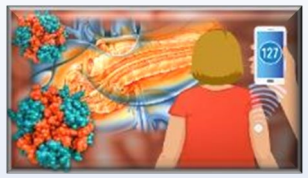
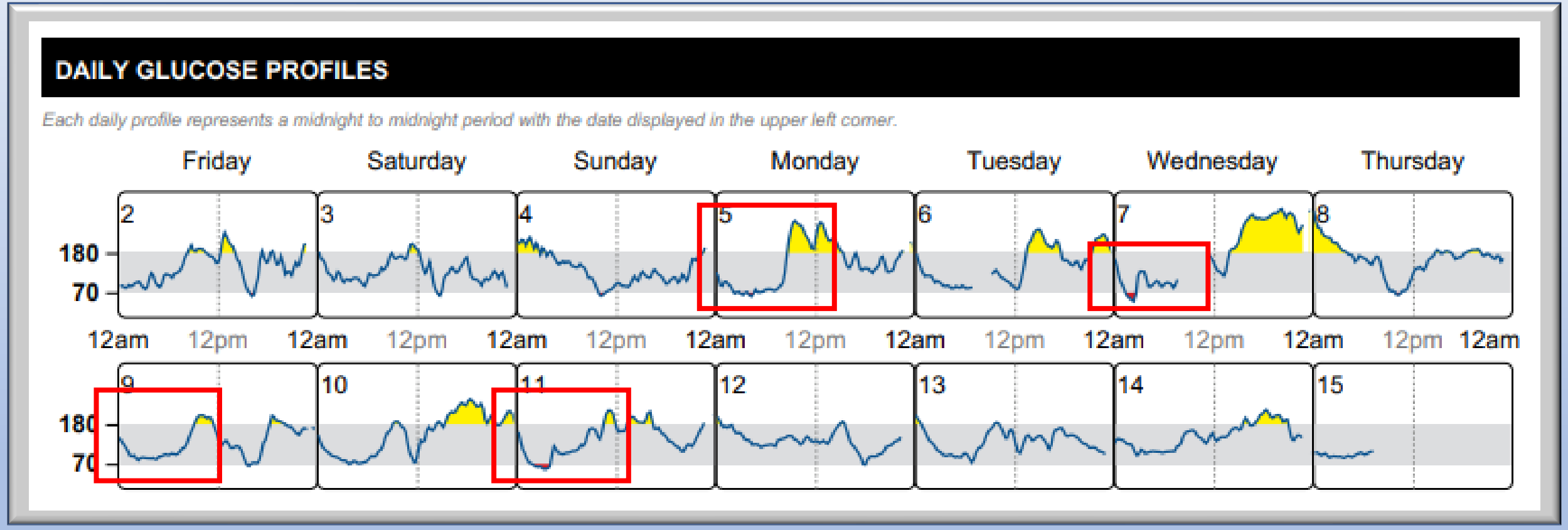




Clinical Case #3

Daily Glucose Profiles



Clinical Case #3

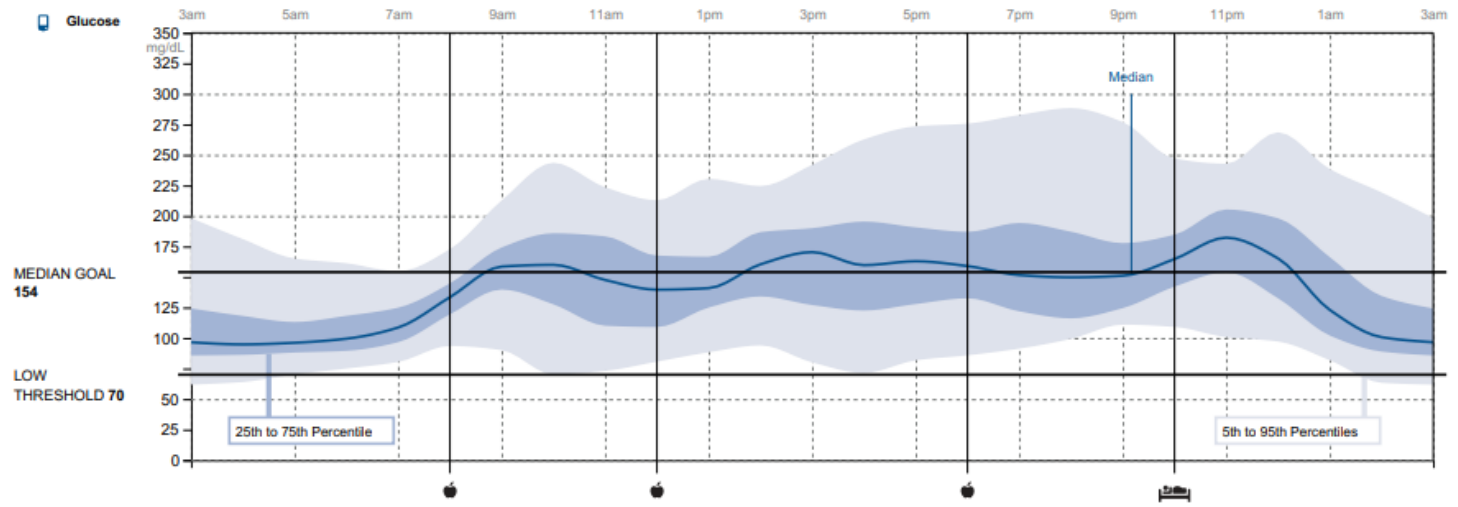
Glucose Pattern Insights

Glucose Pattern Insights

LibreView

April 2, 2021 - April 15, 2021 (14 Days)

GMI **6.8** % or **50** mmol/mol

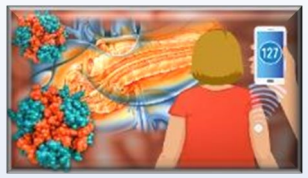


Likelihood of **LOW GLUCOSE**	◒	●	◒	○	◒
MEDIAN GLUCOSE Compared to goal	○	◒	◒	○	○
VARIABILITY BELOW MEDIAN Median to 10th percentile	○	●	◒	◒	◒

VARIABILITY BELOW MEDIAN IS HIGH This makes it difficult to achieve the median glucose goal without increasing the likelihood of low glucose.

Factors that could contribute to variability below median:

- ☐ Erratic diet
- ☐ Incorrect or missed medication
- ☐ Alcohol consumption
- ☐ Variations in activity level
- ☐ Illness

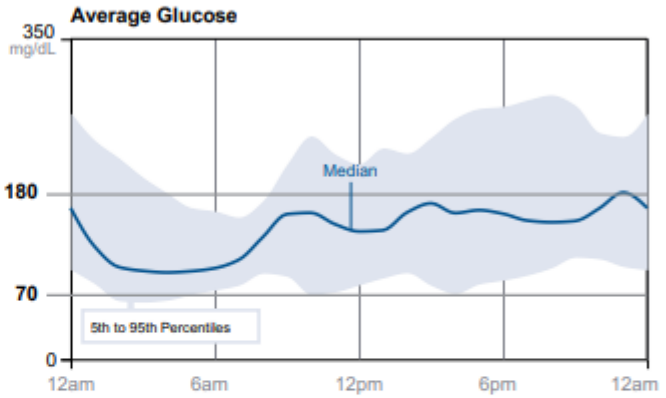


Clinical Case #3
Snapshot

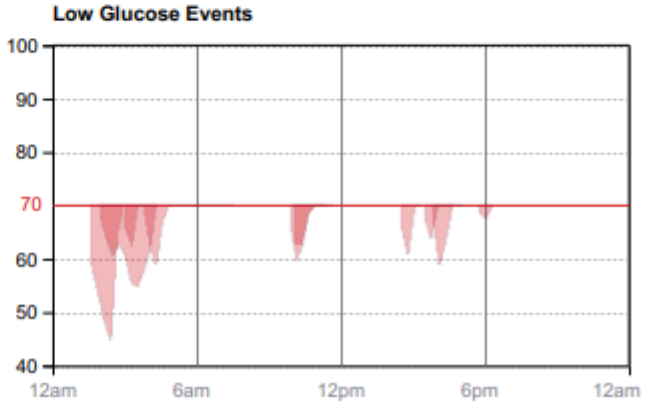
Snapshot
April 2, 2021 - April 15, 2021 (14 Days)

Glucose GMI **6.8** % or **50** mmol/mol

AVERAGE GLUCOSE	**144** mg/dL
% above target	**23** %
% in target	**74** %
% below target	**3** %



LOW GLUCOSE EVENTS	**9**
Average duration	**97** Min



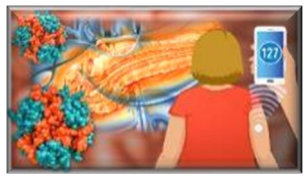
Clinical Case #1
What are the clinical issues and solutions?

ISSUES

- Considerable variability – intraday and interday
- Unrecognized hypoglycemia, particularly at night and afternoons
- High at bedtime with drop at night
  - Too much basal insulin?
- Poor post prandial control on some but not all days

SOLUTIONS

- Identify reasons for variability:
  - Diet, incorrect CHO counting, overcorrection with insulin, delayed meals, stress, exercise
  - Diary would be helpful
- Reduce/split basal dose
  - Bedtime snack?
- Consider adding long acting GLP-1 RA or SGLT2i
  - Reduce postprandial excursions

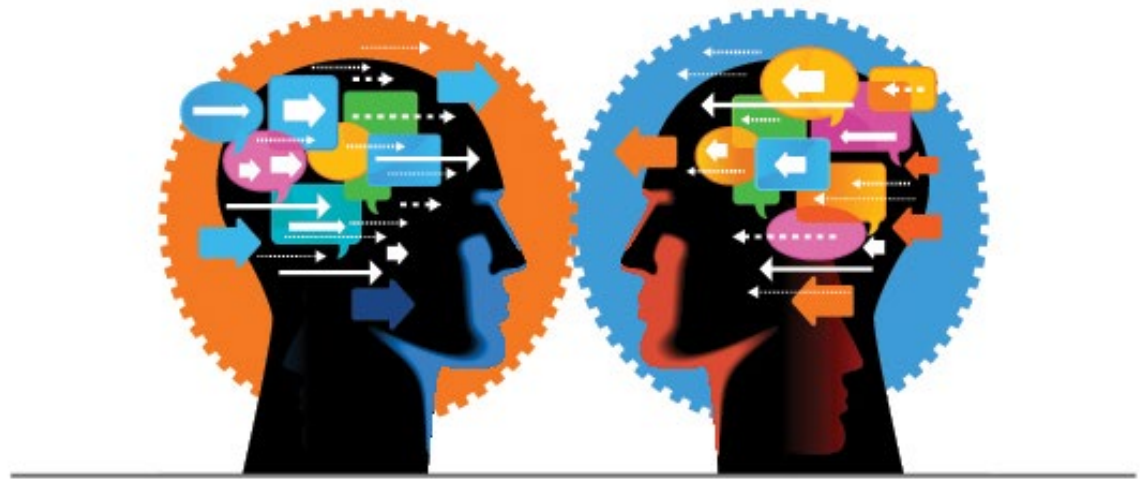


What Do These Cases and CGM Teach Us About Type 2 Diabetes?

- Considerable **heterogeneity** in the disease
  - Intra-person and inter-person variability
  - Many variables can have a **considerable impact** on glucose patterns
  - Diet, stress, activity, medication doses, medication timing, comorbidities
- Glycemic patterns vary: **insights into the disease process** in each patient
  - Identify patterns of glycemic variability
  - Combat barriers to treatment success
    - Decrease risk of complications and hypoglycemia
    - Improve adherence and disease burden
    - Prolongs clinical inertia

CGM may help devise a **safe, effective and personalized treatment strategy**

"INTERACTIVE DIALOGUE SESSION"



Your Questions, Perspectives, and Discussion Points