Clinical Conversations in Diabetes Technology:

Resources and Acceptance

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- Abbott Diabetes Care
- Novo Nordisk
- Medtronic

Disclosures

Faculty	Disclosures
Armand Krikorian, MD, MBA	Doximity Inc: Stock ownership
Jeffrey Unger, MD, FAAFP, FACE, DACT	Abbott Diabetes: Consultant, Speakers bureau Dexcom: Consultant Novo Nordisk: Stock ownership, Speakers bureau
Maria A Mogollon APRN, FNP-BC	No relationships to disclose

Planners	Disclosure
Amy Ogunsunlade	No relationships to disclose
Diane Alberson	No relationships to disclose
Dan O'Sullivan	No relationships to disclose
Alice Kelly	No relationships to disclose

Learning Objectives

Upon completion of this program, you will be able to:

- Examine various approaches to implementing diabetes technologies such as continuous glucose monitors (CGMs) into practice workflows and systems such as team roles, documentation, data interpretation, communication, billing, and coding — even with limited resources.
- Address tactics to overcome and provide alternative options to patient resistance to technology, lack of finances, and tackling multiple comorbidities.
- Identify resources to help patients use their diabetes technology devices allowing them to become more successful at achieving their prescribed metabolic targets.

The Diabetes Epidemic

A sobering reality

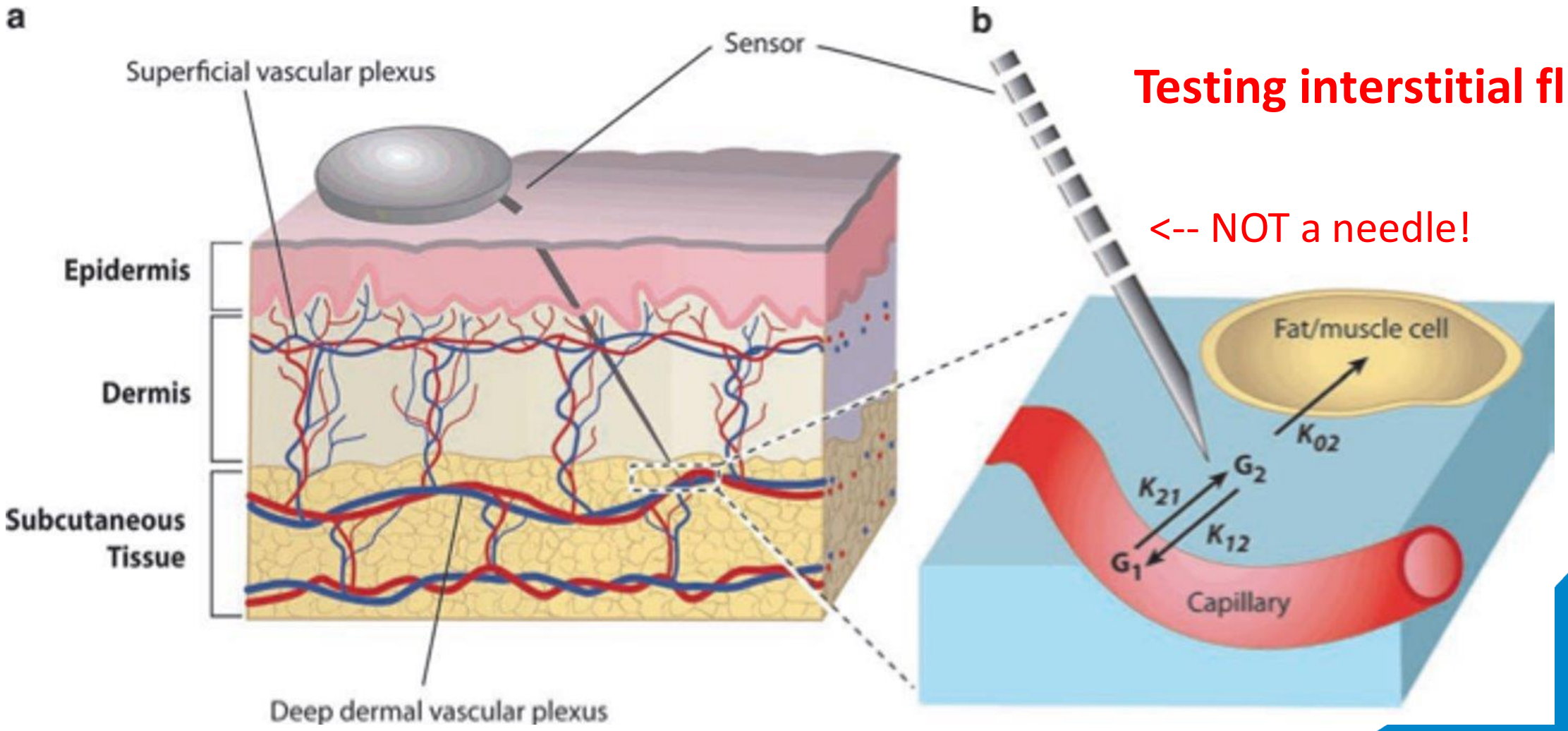
- 1.2M individuals in the U.S. are diagnosed with diabetes mellitus (DM) each year.*
- DM is the eighth-leading cause of death in the U.S.*
- 38.4M individuals in the U.S. have DM.*
- An additional 97.6M individuals in the U.S. have prediabetes.*
- 9 in 10 people with type 2 diabetes are cared for in primary care.**
- 97.6 million Americans in the US have prediabetes ***

* "National Diabetes Statistics Report," CDC

** "Type 2 Diabetes Management in Primary Care: The Role of Retrospective, Professional Continuous Glucose Monitoring," Diabetes Spectrum : A Publication of the American Diabetes Association

***https://www.cdc.gov/diabetes/data/statistics-report/index.html (Accessed 4/13/2024)

Continuous Glucose Monitoring (CGM) vs. Self Blood Glucose Monitoring



Testing interstitial fluid

<-- NOT a needle!

Cengiz E, Tamborlane WV. A tale of two compartments: interstitial versus blood glucose monitoring. Diabetes Technol Ther. 2009 Jun;11 Suppl 1(Suppl 1):S11-6.

Ok, What About The Cost?

- Cost of a single test strip is $1.16
- If patient checks 5 times a day monthly cost is $174

- CGM monitors interstitial glucose values every 1-5 minutes for the life of the sensor (7-10 days)
- 1440 readings a day/20,160 readings in a month
- Cost of a single sensor reading: $.007.
  Cost of a 2 weak wear $32 (Libre)
  - Freestyle libre: $36/2 week wear
  - Dexcom 7: $177/10 day wear

American Diabetes Association. Standards of medical care in diabetes-2022 abridged for primary care providers. Clin Diabetes. 2022;40(1):10-38. doi: 10.2337/cd22-as01

Unger, J. Continuous Glucose Monitoring Overview: Features and Evidence. American Journal of Managed Care. Vol 28, N. 4; S59-S67. 2022

Program Overview

Each case study will include:

- An overview
- General recommendations
- "Curveball" scenario
- Recommendations for curveball scenario

Case Study 1

Clinician has limited resources

Case Study 1: Clinician Has Limited Resources

Overview

- Primary care provider operates a busy rural practice.
- Limited availability of well-trained staff (e.g., MAs, RNs, CDEs).
- About 1 in 10 of his patients have DM.
- Concerned about time and related costs required to review patients' ambulatory glucose profile (AGP) reports.

Case Study 1

General recommendations

- Reviewing AGP reports is billable.
- You can do good for your patients while also being reimbursed.
- Billing code 95251 ($28 reimbursement*) covers CGM data interpretation. 95249 ($45 reimbursement*) covers the cost of onboarding CGM in office. The following rules apply (courtesy American Diabetes Association):
  - Data must be derived from a minimum of 72 hours of CGM wear time.
  - A face-to-face patient encounter is not required.
  - Data can be obtained from the CGM receiver via downloading in the clinic, electronic transfer, or accessing and printing data from a cloud-based platform.
  - Data interpretation services can be billed on the day of the download or at any time analysis is performed before or after a virtual or in-person patient encounter.

*as of 2024

How To Onboard a CGM

Discussions with 1st time CGM patients

- How /where to place CGM
- Are the subcutaneous glucose values being streamed to cell phone/reader or acquired by scanning?
- What is the warm-up time for the sensor (30 minutes - 2 hours dependent on the CGM)
- Explain high and low alarms
- What is the duration of CGM wear?
- What are individual goals?
- How to respond to glucose values < 70 and > 240 mg/dL
- How to upload data to share with clinician

Case Study 1

Curveball scenario

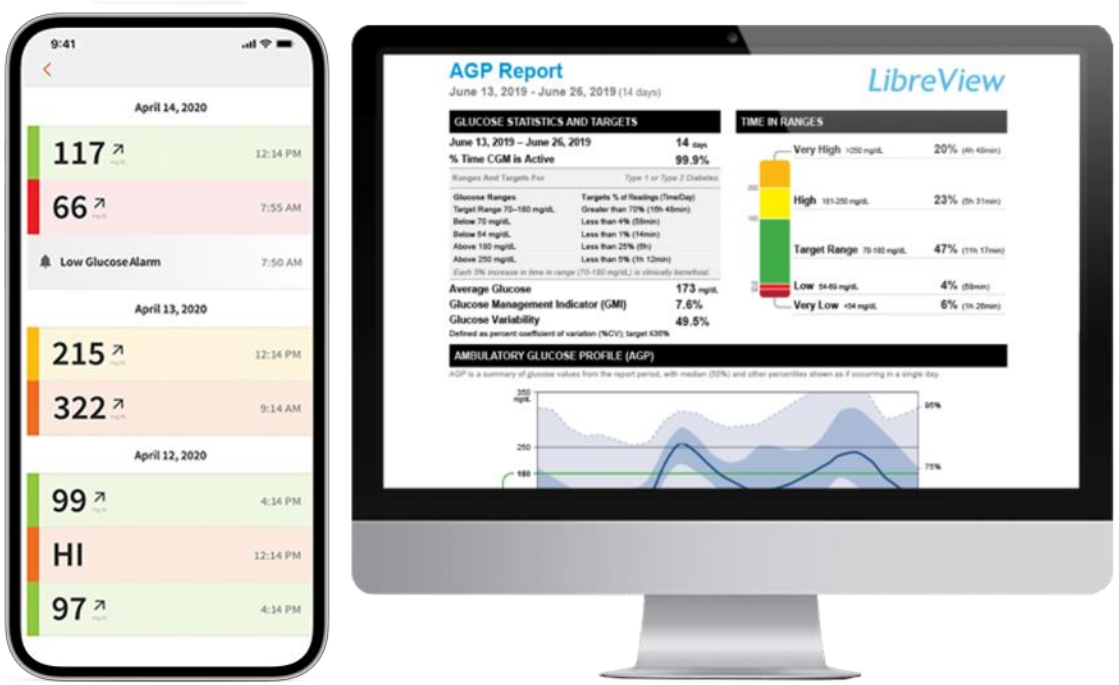
- There are many CGMs on the market today.
- These include the Dexcom Stelo Glucose Biosensor System, the first over-the-counter CGM cleared for marketing by the FDA (March 2024).
- How can you manage all these portals to do the reads?

Dexcom Stelo

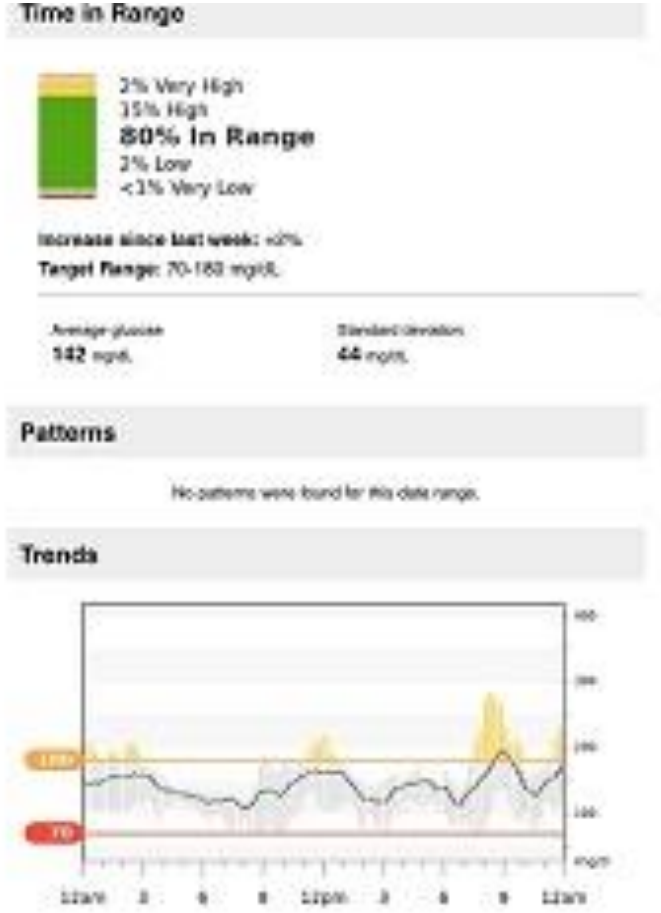
Dexcom 6

Libre-3

CGM Data Can Be Shared With Others



Libre View



Dexcom Clarity

Benefits of CGM

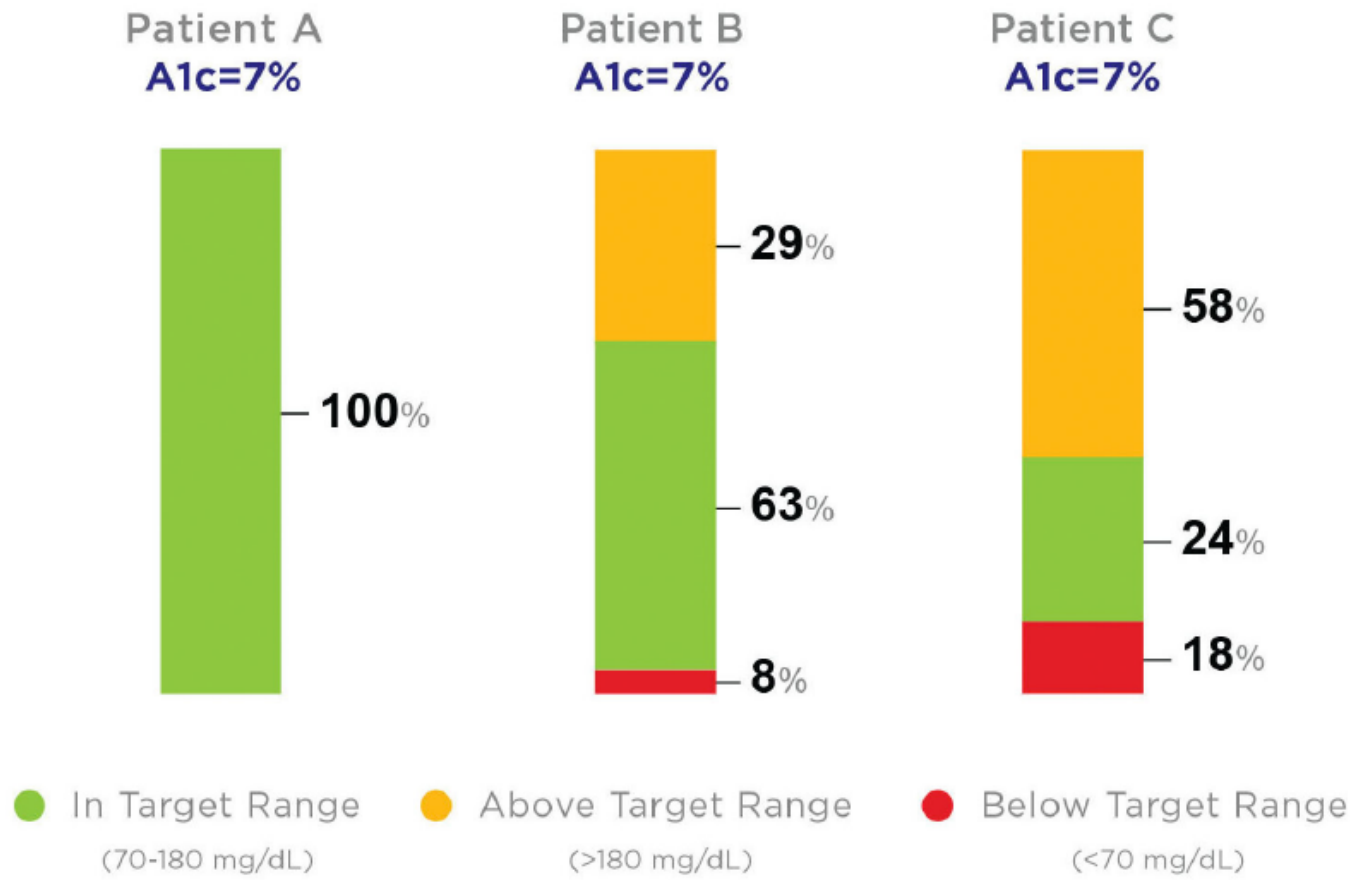
- Insights into effects of food, exercise, illness and medication on real-time diabetes management
- Improved Time in Range (TIR)
- Directional arrows
- Audible alarms for highs and lows
- Approved for children and adults with diabetes
- Connectivity to insulin pumps
  - Predictive alerts for highs and lows can automatically adjust insulin delivery rates
- Connectivity with clinicians and family members
- Data can be easily downloaded to the clinician's office and reviewed during a face to face or virtual visit
- Improved A1C
- Reduced absenteeism from work
- Reduced ED Visits
- Reduction in Hypoglycemia
- Reduction in long and short-term DM related complications

1) ADA 2020 Scientific Sessions. Presented 6/13/20. Abstract 898-P. Grunberger G, Sherr J, Allende M, Blevins T, Bode B, Handelsman Y, Hellman R, Lajara R, Roberts VL, Rodbard D, Stec C, Unger J. AACE Guideline. American Association of Clinical Endocrinology Clinical Practice Guideline: The Use Of Advanced Technology in the management of persons with diabetes Mellitus. Endocrine Practice. 2021. 27. 505-537 2) ADA 2020 Scientific Sessions. Abstract 898-P. 3) 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

AACE®

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

If basal insulin is increased by 20 % which patient is likely to develop treatment emergent hypoglycemia?

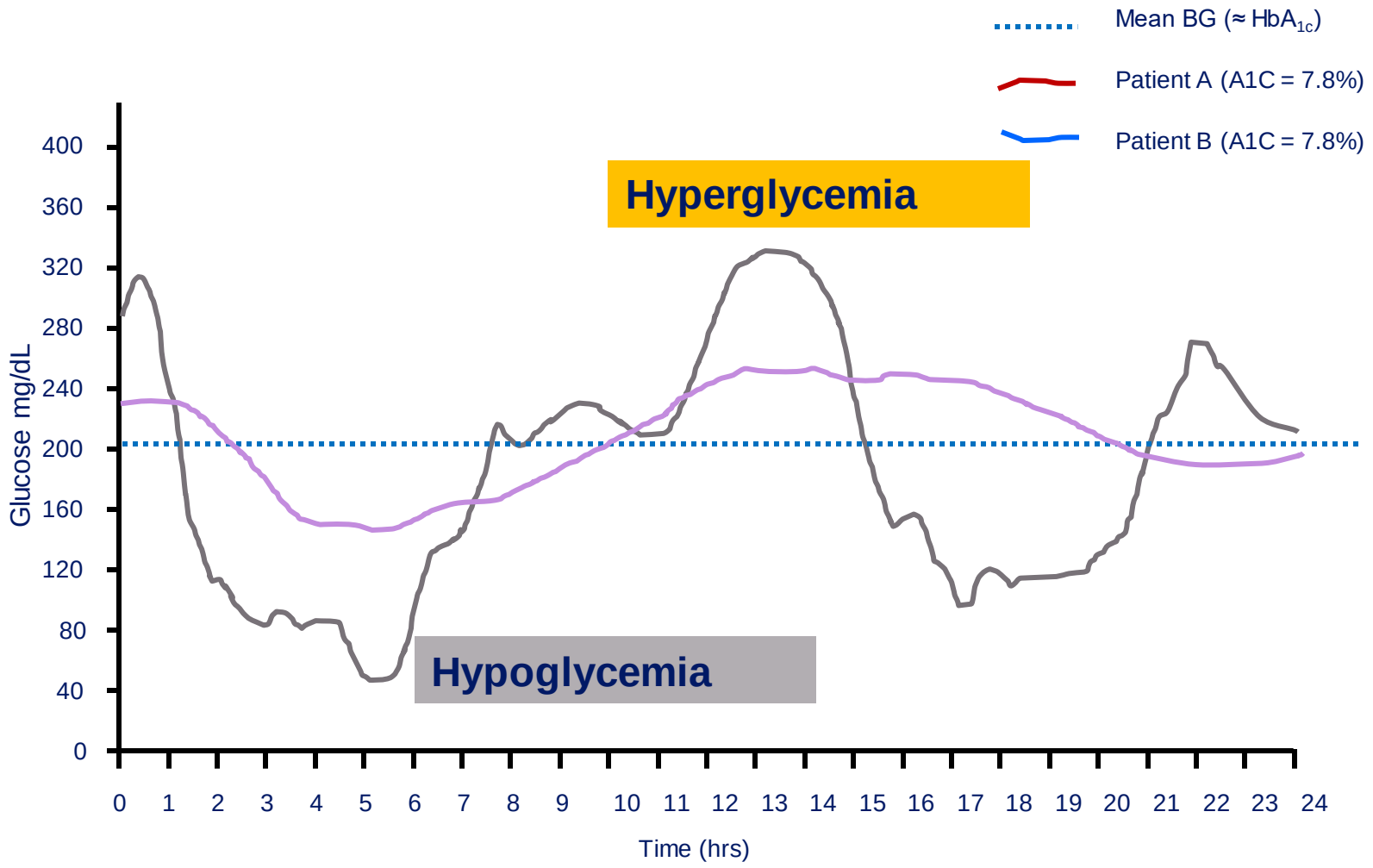


Image adapted from Penckofer S, Quinn L, et al. Does glycemic variability impact mood and quality of life? Diabetes Technol Ther. 2012 Apr;14(4):303-10.

AACE®

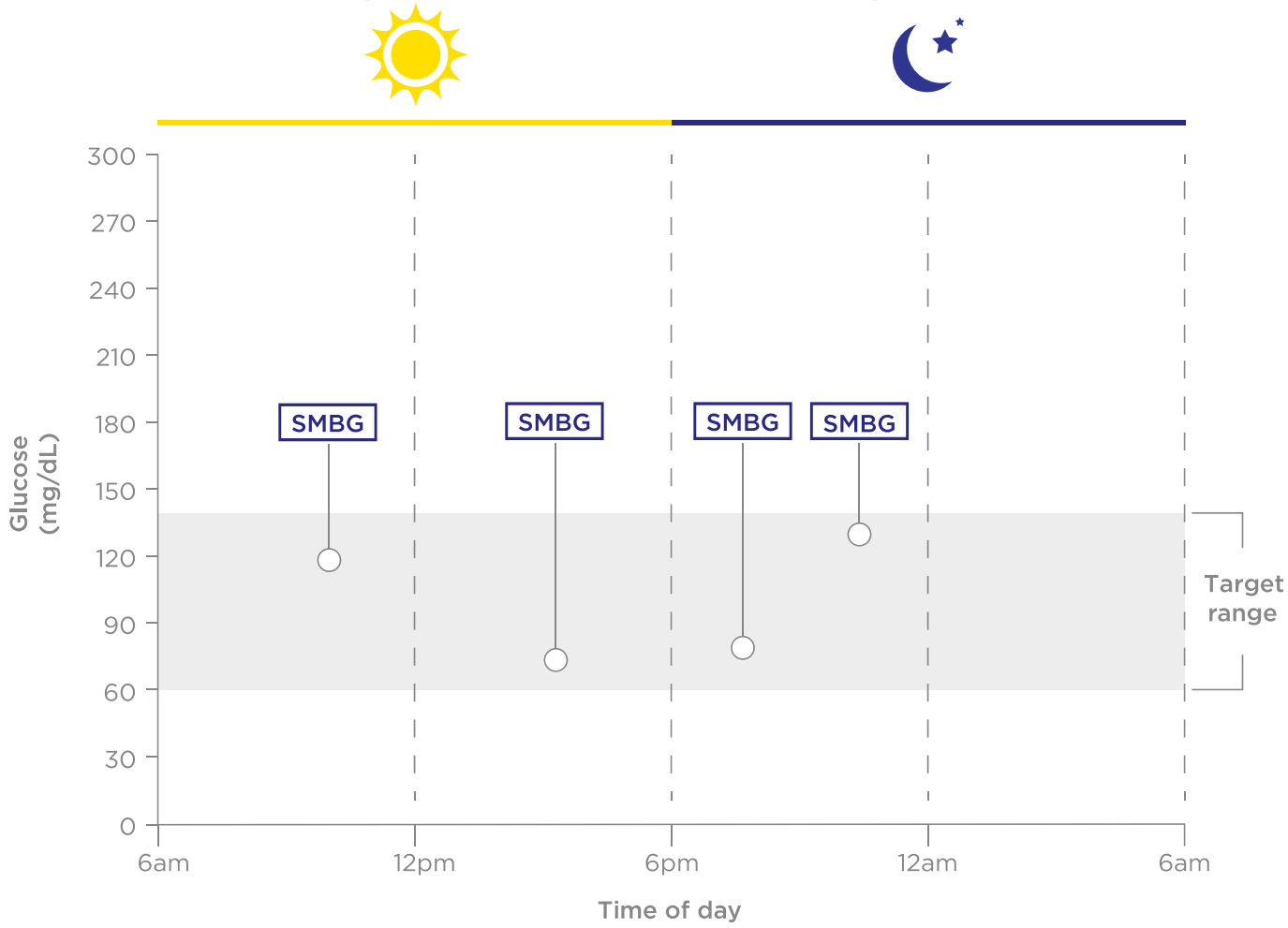
How CGM Can Help Reduce Diabetes Management Challenges

- 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



Not actual patient data; for illustrative purposes only.

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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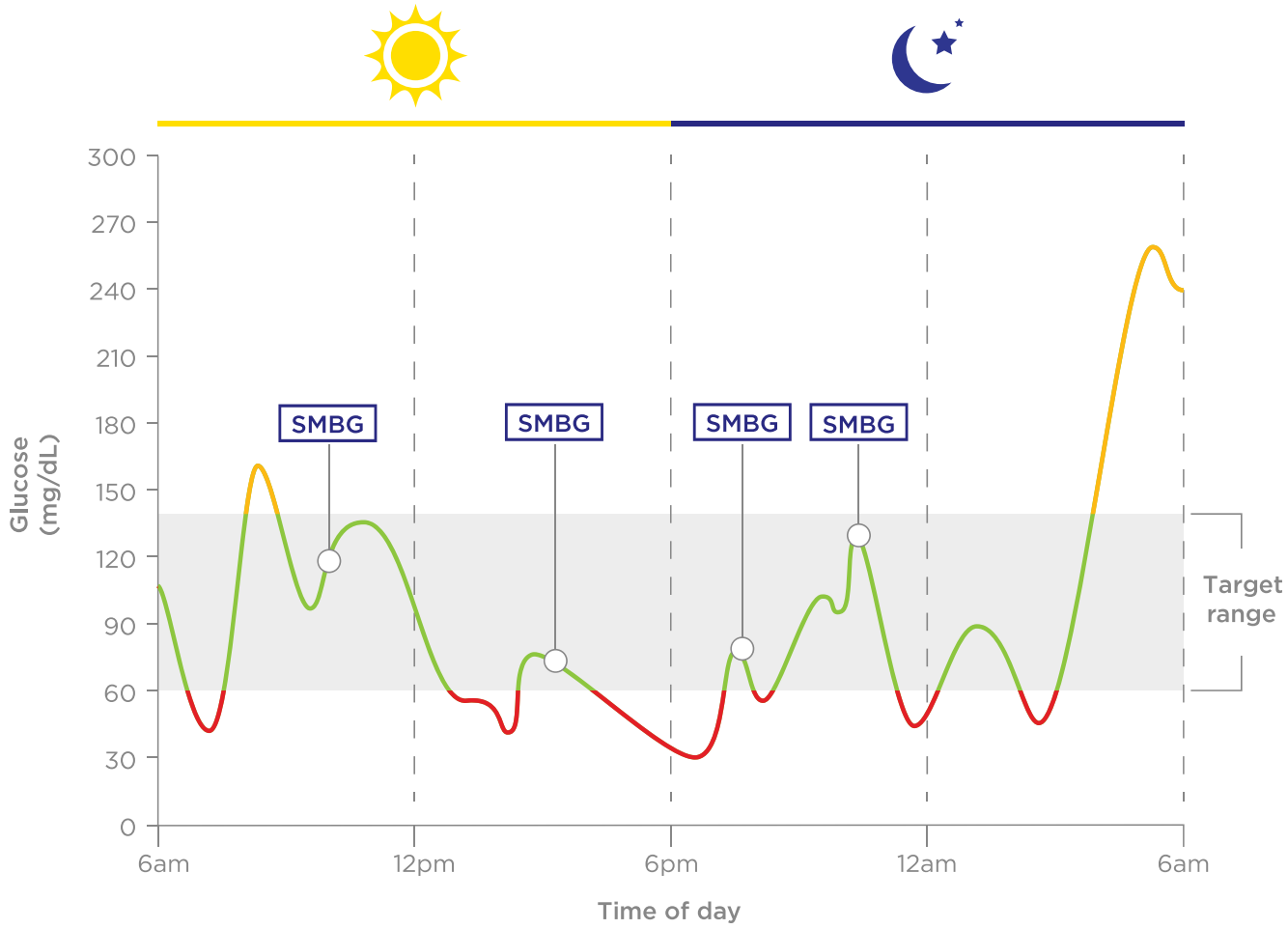

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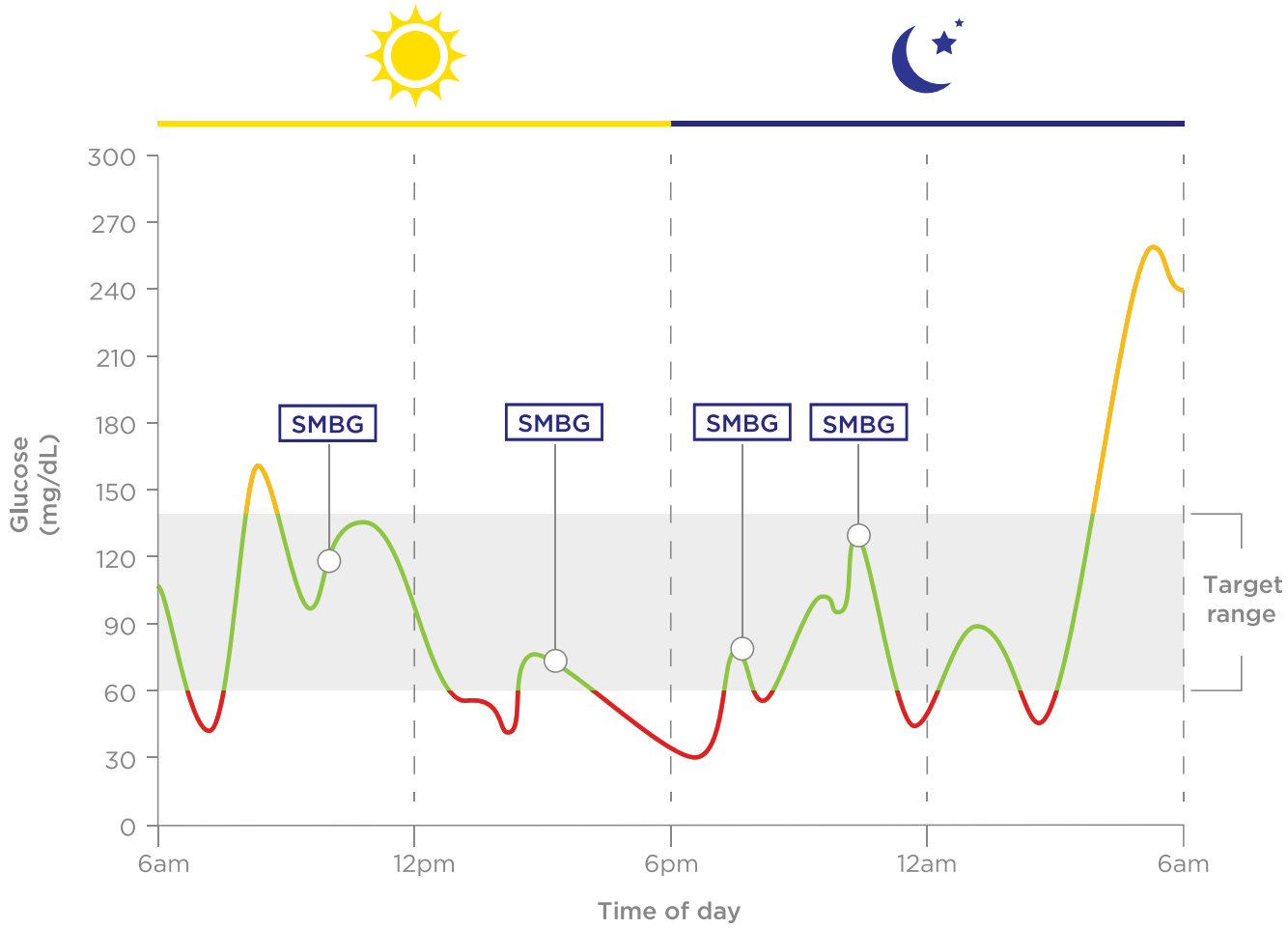

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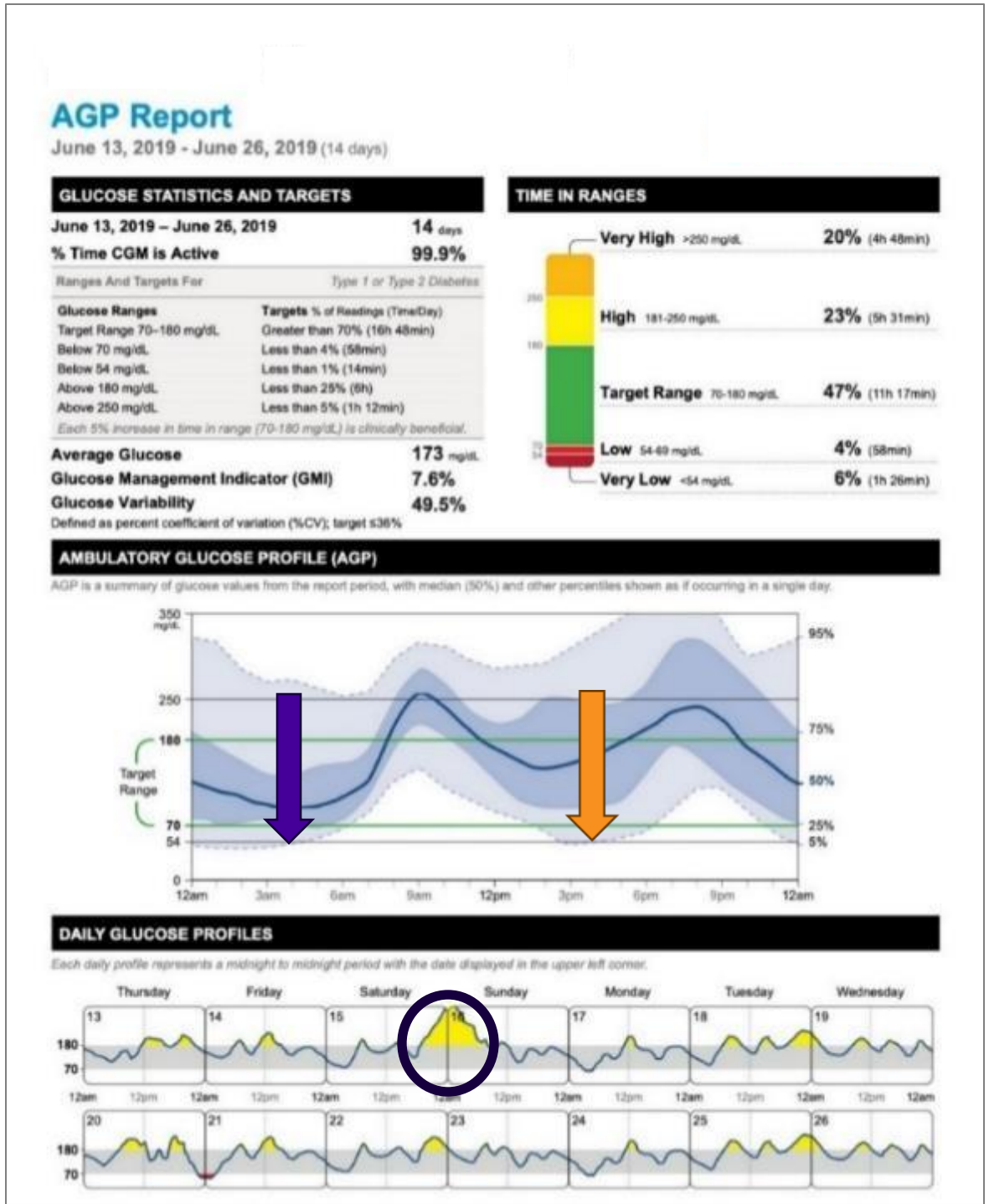
Interpretation of Ambulatory Glucose Profile

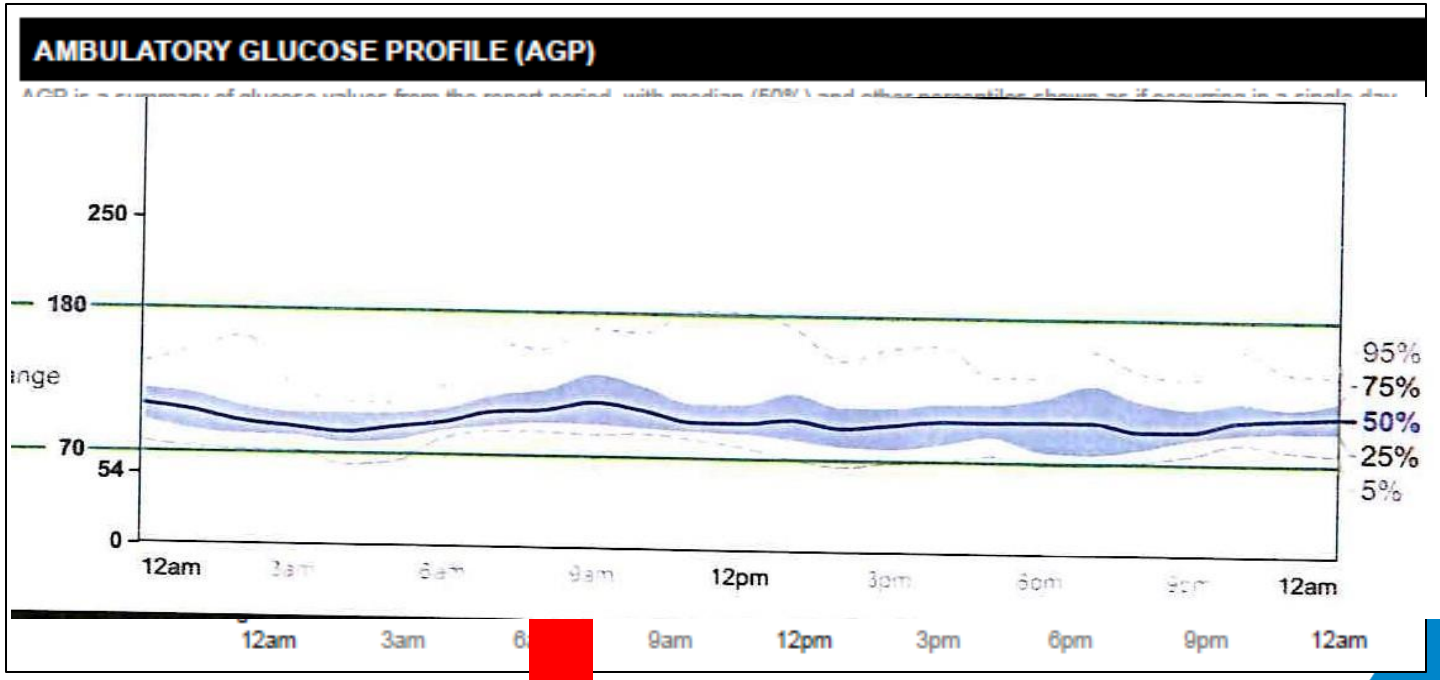
- Systematic Approach
- Time in Range (70-180 mg/dL 70 % of the time
- Hypoglycemia (< 70 mg/dL)should be ≤ 4 % or ≤ 2 % in at risk patients who are over age 65 with a hx of ASCVD
- Achieve a GMI ≤ 7 %
- Glycemic variability ≤ 33 mg/dL



Grunberger G, Sherr J, Allende M, Blevins T, Bode B, Handelsman Y, Hellman R, Lajara R, Roberts VL, Rodbard D, Stec C, Unger J. AACE Guideline. American Association of Clinical Endocrinology Clinical Practice Guideline: The Use Of Advanced Technology in the management of persons with diabetes Mellitus. Endocrine Practice. 2021. 27. 505-537

AGP – Targeted Goals

- Step 1: Fix the lows
- Step 2: Fix the PPG spikes
- Step 3: Flatten the 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

Case Study 2

Patient has insurance coverage issues

Case Study 2: Patient Has Insurance Coverage Issues

Meet Chuck

- Patient, a 62-year-old male, diagnosed with T2D at age 41.
- On Insulin therapy + self-blood glucose monitoring (does not bring logs to visits because “no one looks at them anyway”)
- Has HMO insurance health insurance
- Has multiple co-existing medical issues

Case Study 2

General recommendations

- Understand that patients with commercial insurance get CGMs from pharmacy.
- Patients with Medicare or Medicaid get CGMs from third-party vendors, including:
  - Abbott Diabetes Care
  - Byram Healthcare
  - US MED
- CGMs covered by Medicare include:
  - Dexcom G6
  - Eversense
  - Freestyle Libre
  - Medtronic Guardian

Case Study 2

Curveball scenario

- New commercial insurer denies coverage for particular CGM that patient uses.
- What can PCP do to help?

Case Study 2

Recommendations for curveball scenario

- Write letter to commercial insurer appealing the denial.
- Cite latest AACE guidelines, which support use of CGMs in *all* individuals with DM.
- Reference eligibility criteria. For instance, Blue Cross/Blue Shield:
  - BCBS coverage is subject to the specific terms of the member's benefit plan.
  - A CGM system may be considered medically necessary when ONE of the following criteria is met:
    - Individual has type 1 diabetes and is receiving insulin therapy.
    - Individual has type 2 diabetes and is receiving insulin therapy.
    - Individual has gestational diabetes or is pregnant, and a CGM is recommended by the provider.
    - Individual has an insulin pump.
    - **Patient has a history of hypoglycemia/hypoglycemia unawareness**

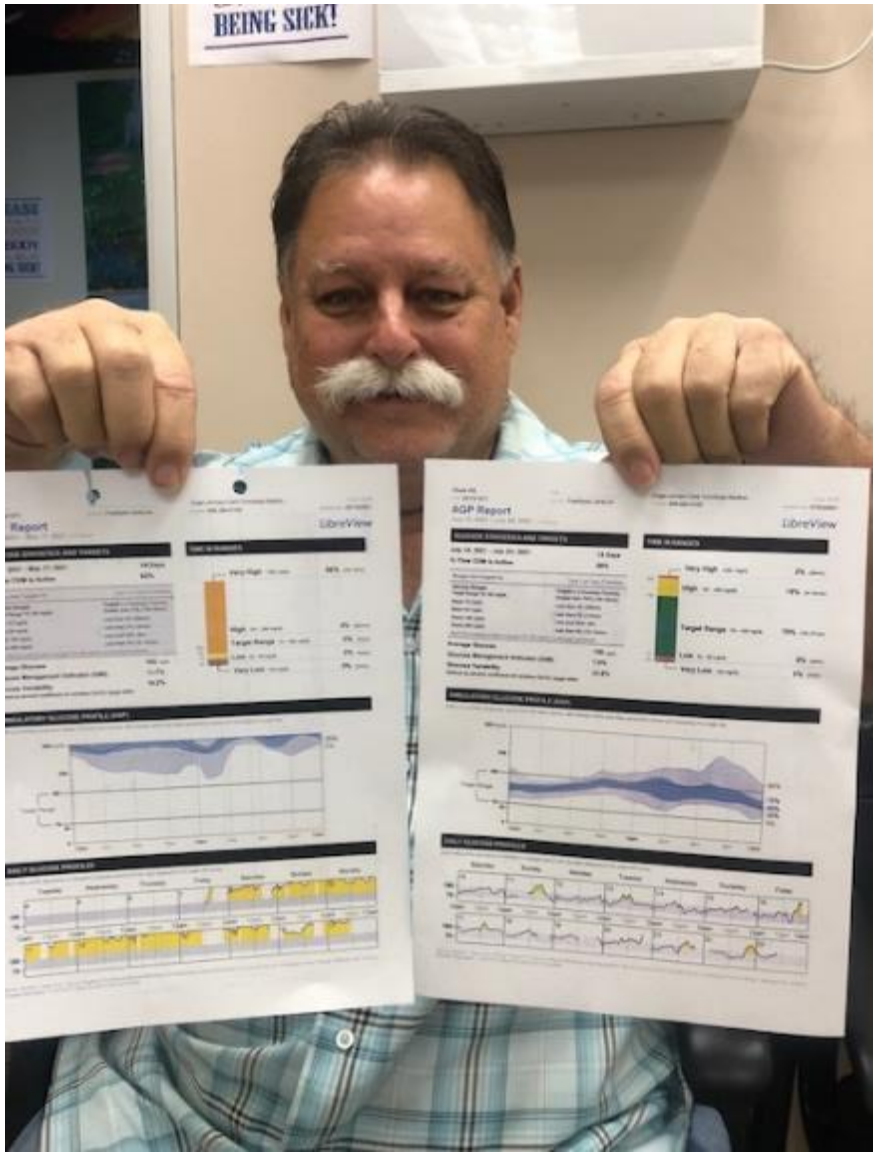
Chuck

- 62-year-old man with T2DM 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 Baseline:
Changed from NPH/Reg to: Degludec 10 u + semaglutide 0.25 mg/week

May 15, 2021
- 0 % in target
- Average BG 320
- GMI: 11.7 %



Medications at 8 Weeks:
Degludec 20 u + semaglutide 0.5 mg/week

July 23, 2021
- 79 % in range. No hypos
- Average BG 165
- GMI 7 %

Who Benefits From Routine Use Of Continuous CGM?

- ALL patients treated with intensive insulin therapy (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

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.

Case Study 2

Recommendations for curveball scenario

- FYI, according to Medicare/Medicaid, patients must meet at least one of following criteria:
  - **A. Insulin-treated:** If you are treated with insulin (any type and any amount)
  - **B. History of problematic hypoglycemia:**
    - Recurrent (more than one) **level 2 hypoglycemic events** (glucose <54 mg/dL or 3.0 mmol/L) that persist despite multiple attempts to adjust medication or modify the diabetes treatment plan
    - **OR** A history of **one level 3 hypoglycemic event** (glucose <54 mg/dL or 3.0 mmol/L) characterized by altered mental and/or physical state requiring third-party assistance for treatment of hypoglycemia

Case Study 3

Patient has accessibility issues

Case Study 3: Patient Has Accessibility Issues

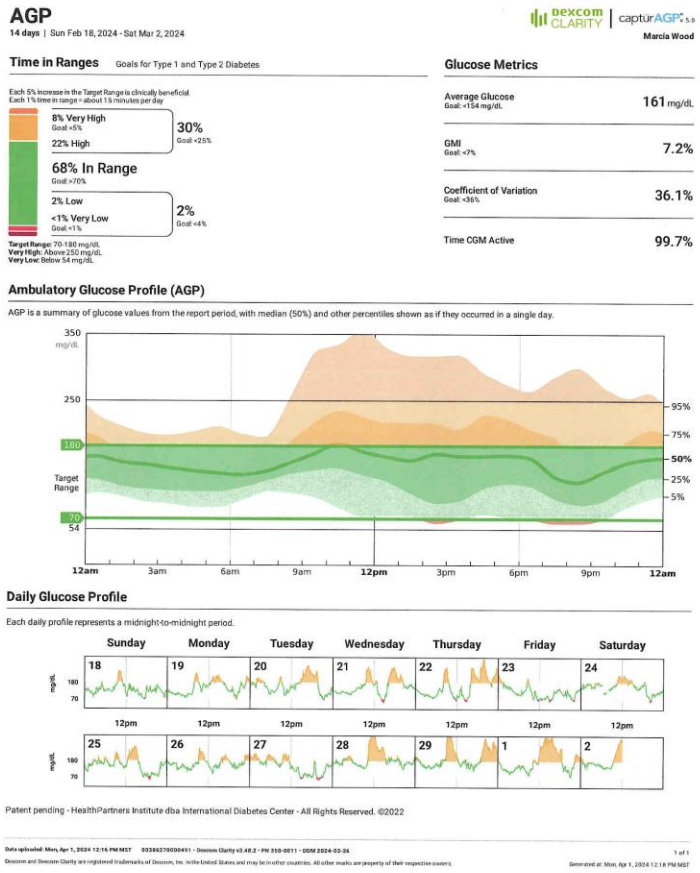
Overview

- Patient, a 75-year-old male, diagnosed with T2D at age 55.
- Retired farmer who lives on a ranch far from medical facilities.
- Son is responsible for taking him to medical appointments.
- Patient uses intermittent CGM with smart phone app that shares data with his PCP.
- PCP has been adjusting patient's DM medications, (semaglutide, insulin + metformin) and patient has been experiencing hypoglycemia events.

Case Study 3

General recommendations

- Make greater use of telemedicine appointments.
- Review and analyze CGM data and go over it with patient.
- Change prescription from intermittent CGM to real-time CGM.
- Adjust insulin remotely based on glucose trends and patterns from CGM report.



AGP

14 days | Sun Feb 18, 2024 - Sat Mar 2, 2024

Marcia Wood

Time in Ranges Goals for Type 1 and Type 2 Diabetes

Each 5% increase in the Target Range is clinically beneficial.
Each 1% time in range = about 15 minutes per day

8% Very High	Goal: <5%	30% Goal: <25%
22% High		
68% In Range	Goal: >70%	
2% Low		2% Goal: <4%
<1% Very Low	Goal: <1%	

Target Range: 70-180 mg/dL
Very High: Above 250 mg/dL
Very Low: Below 54 mg/dL

Glucose Metrics

Average Glucose (Goal: <154 mg/dL)	161 mg/dL
GMI (Goal: <7%)	7.2%
Coefficient of Variation (Goal: <36%)	36.1%
Time CGM Active	99.7%

Ambulatory Glucose Profile (AGP)

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

Daily Glucose Profile

Each daily profile represents a midnight-to-midnight period.

Case Study 3

Curveball scenario

- Patient comes for in-person appointment with son, who says patient is forgetting to inject insulin/take his medications sometimes because of early-stage cognitive impairment.
- Son unable to track how many times father injects insulin, or the amount.
- What can PCP do to help?

Case Study 3

Recommendations for curveball scenario

- Switch from standard insulin pen to connected pen integrated with CGM.
- Sensors in connected pen monitor dose administration and share insulin data with patient and son.

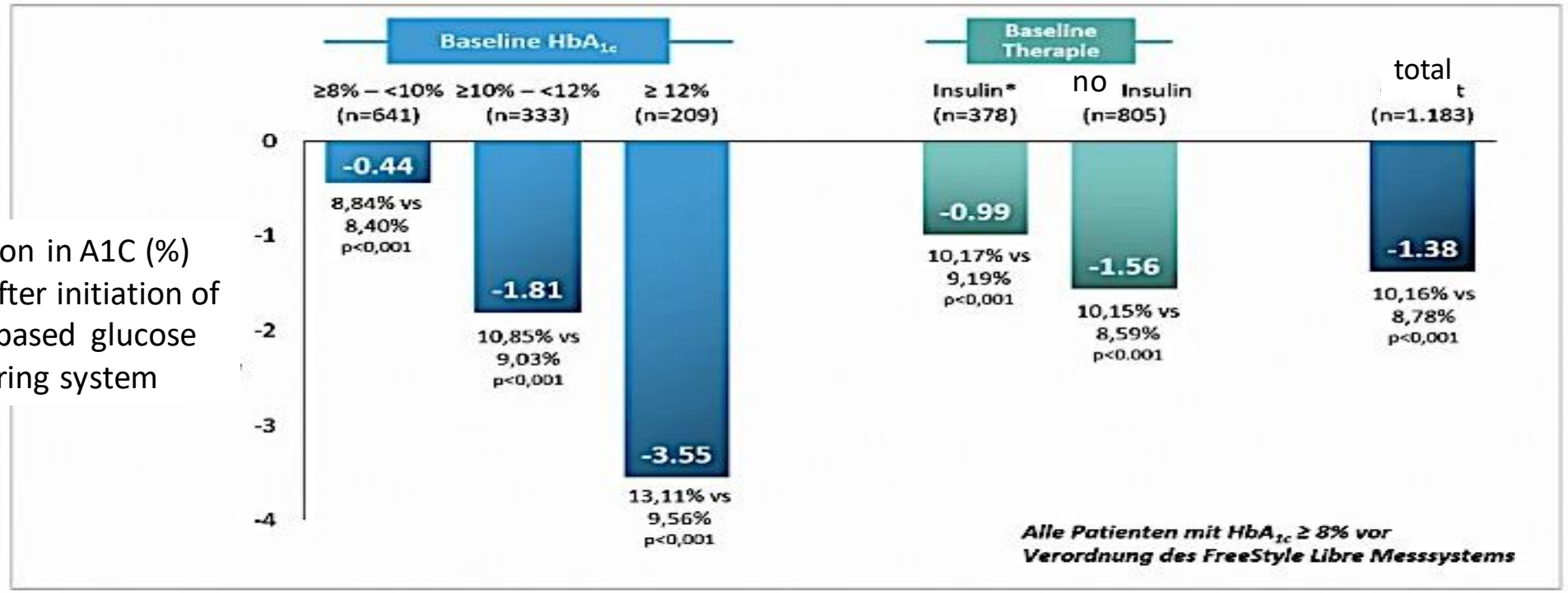
Smart Insulin Pens

- Calculate dose of basal or prandial insulin based on current BG levels, CHO intake, meal size, active (on board) insulin
- Minimize skipped doses
- Calculate appropriate prandial insulin dose with a correction factor
- Transmit diabetes data to HCP
- Work with smart phone and other diabetes tracking platforms

Medtronic Inpen

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.

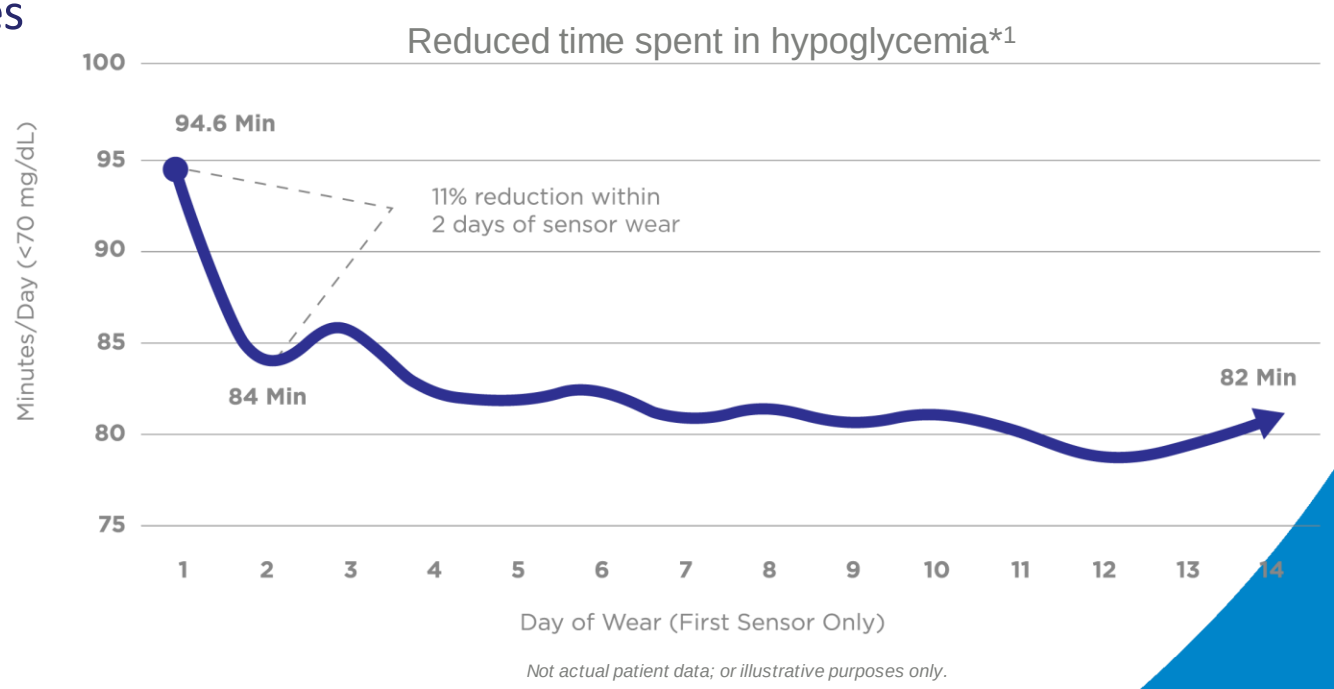
Reduced time in hypoglycemia (continued)

Frequent glucose level checks with FreeStyle Libre sensor 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]



*Data from this study was collected with the outside US version of FreeStyle Libre 14 day system. FreeStyle Libre 2 has the same features as FreeStyle Libre 14 day system with optional, real-time glucose alarms. Therefore, the study data is applicable to both products.

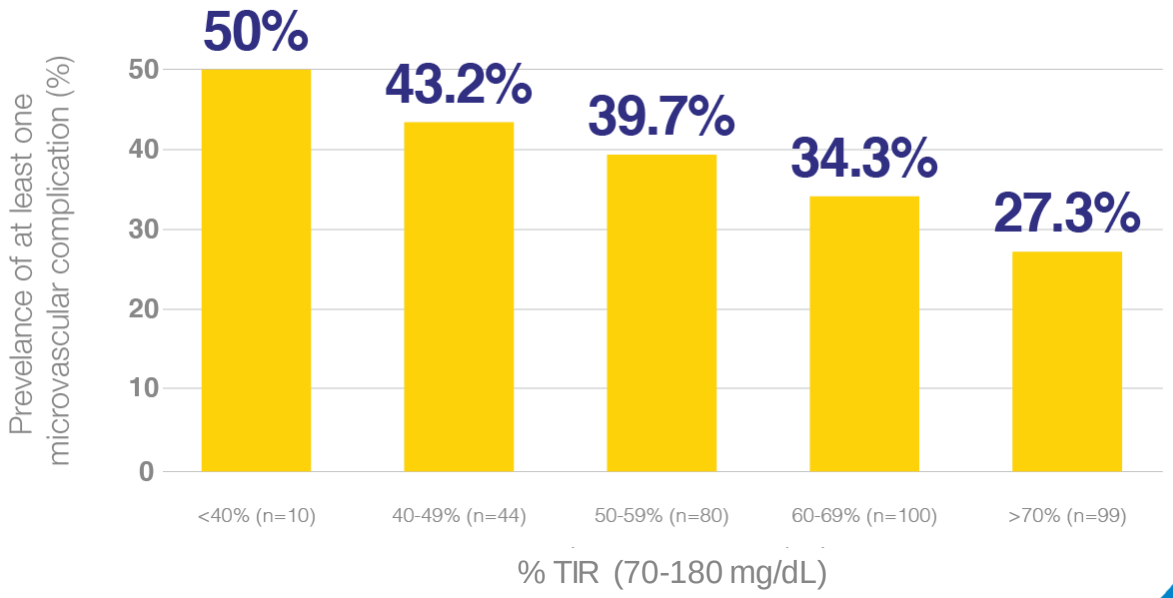
1. Dunn, Timothy C., Yongjin Xu, Gary Hayter, and Ramzi A. Ajjan. "Real-World Flash Glucose Monitoring Patterns and Associations Between Self-Monitoring Frequency and Glycaemic Measures: A European Analysis of Over 60 Million Glucose Tests." *Diabetes Research and Clinical Practice* 137 (March 2018): 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, FreeStyle Libre 2 system 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).lar



*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.

Case Study 4

Patient is resistant to technology adherence

Case Study 4: Patient is Resistant to Technology Adherence

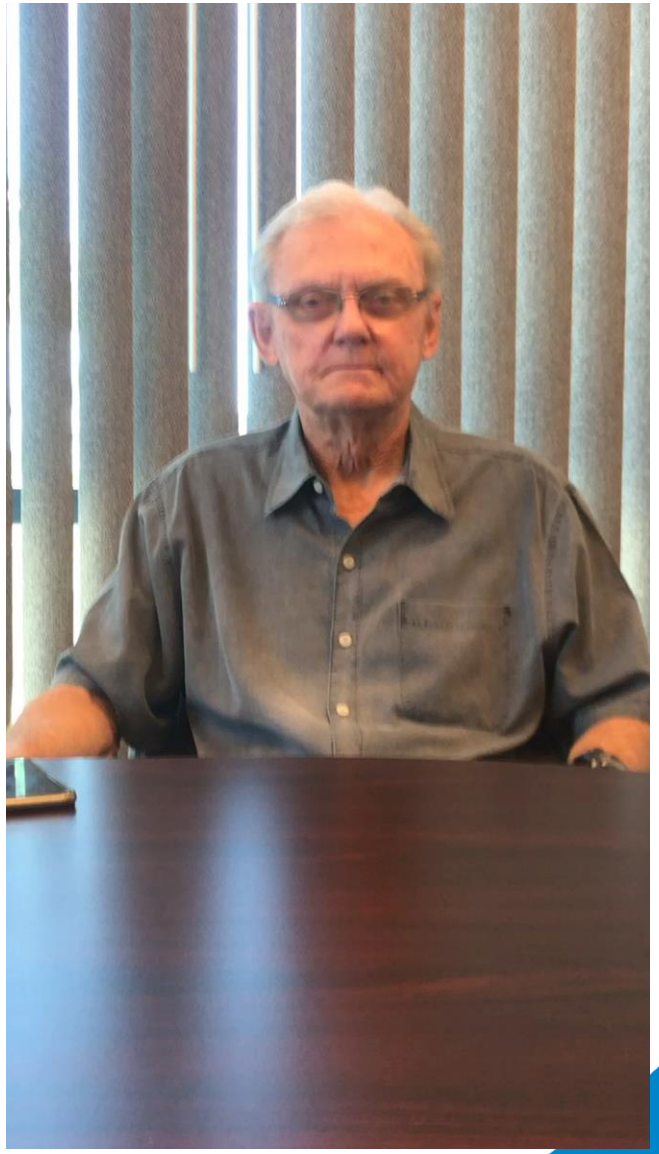
Overview

- Patient, a 19-year-old female, diagnosed with T1D at age 10. HbA1c is 9.2 %
- Used insulin pump for several years and glucose was in good control but decided to stop using it because no longer wants device attached to her body.
- Currently using insulin pens with multiple daily injections.
- Checks glucose with fingersticks/glucometer but only in morning and before bed because busy with college, on volleyball team, etc.
- PCP concerned about patient's glucose fluctuations, risk of hypoglycemia and risk of developing long-term complications.
- Has had two ER visits in past year due to acute complications (DKA and severe hypoglycemia).

- What can she learn from Roy?

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



Case Study 4

General recommendations

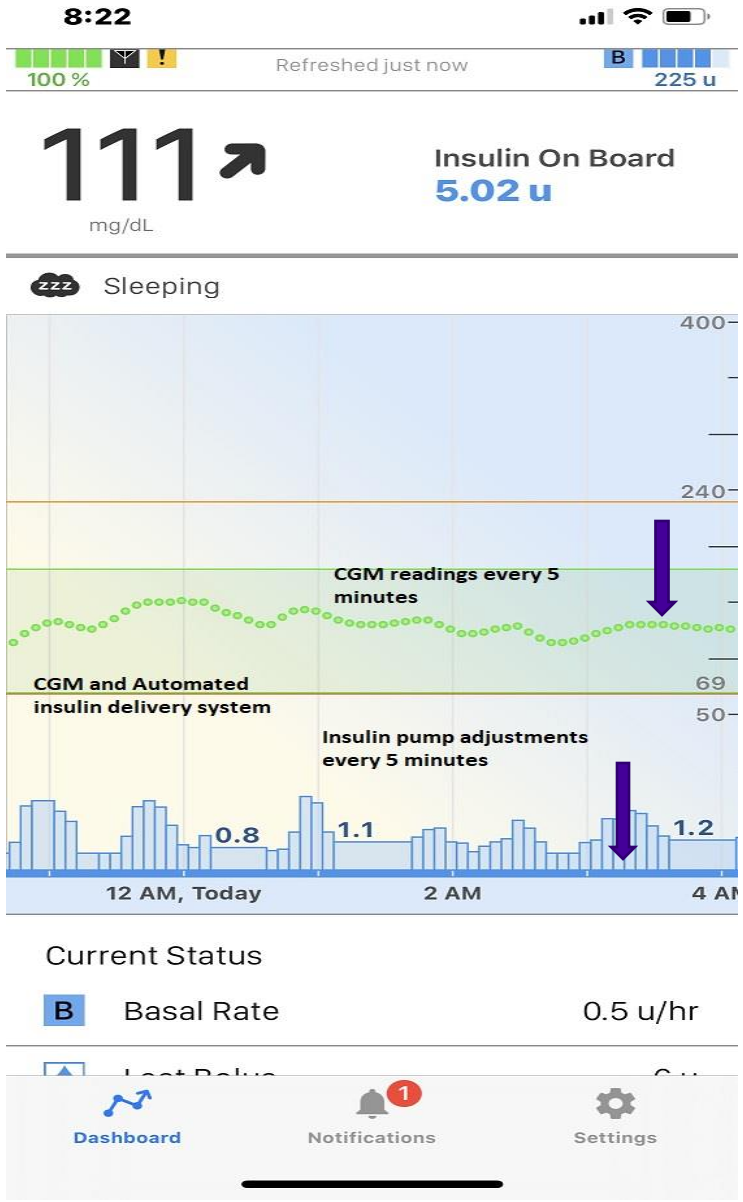
- Suggest using integrated CGM and Sensor
- Doing so would allow her to have pump adjust insulin delivery every 5 minutes
- This would minimize her risk of hypoglycemia
- CGM alarms when glucose levels rise > 240 or begin to fall rapidly below 140 mg/dL

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?



- 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

Case Study 4

Curveball scenario

- After meeting with diabetes educator and talking with other patients her age, patient reports feeling a little less resistant to diabetes technology and would be open to wearing a device.
- However, she is willing to use only one device — not several at a time.
- What can PCP do to help?

Case Study 4

Recommendations for curveball scenario

- Suggest real-time CGM, which would give her information throughout the day that would help her make informed decisions about eating, activity, etc., and help her learn to spot trends and avoid diabetes emergencies.
- Over time, as she becomes accustomed to using real-time CGM, talk with patient about adding insulin pump.

Case Study 5

Patient's environment is constantly changing

Case Study 5: Patient's Environment is Constantly Changing

Overview

- Patient, a 28-year-old male, recently diagnosed with T1D.
- Uses CGM to help maintain optimal glycemic control.
- Does not use an insulin pump.
- Travels frequently in his role as salesperson.

Case Study 5

General recommendations

- Confirm patient has enabled CGM to share data with PCP and selected family members as a means of protection in case he doesn't wake up to a low-glucose alarm at night.
- Stress need to carry diabetes care kit at all times. CDC recommends packing enough supplies to last one to two weeks, including:
  - Bring extra basal and prandial insulin. Carry in purse or backpack, not in luggage
  - Extra pump supplies and sensors
  - Blood sugar (glucose) meter (necessary to have in case of extreme blood glucose values)
  - Extra batteries for blood sugar meter and insulin pump
  - Lancets and lancing devices
  - Hypoglycemia emergency kits: glucagon, glucose tabs, liquid glucose (glucose shots)

Case Study 5

Curveball scenario

- On first day of seven-day business trip to Japan, patient leaves diabetes care kit in back seat of taxi.
- What can PCP do to help?

Case Study 5

Recommendations for curveball scenario

- Let patient know that new CGM in Japan (or any other foreign country) is not an option, as software on new device will be incompatible with software used in U.S.
- Patient should purchase lancets, alcohol wipes, and all other supplies required for fingerstick testing, which he'll need to do for length of trip.
- Patient should also order new CGM and any related supplies that he'll need once he returns home.

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!

The Number One Complications Associated With Well Controlled Diabetes Is…

Nothing

Resources

For additional resources please visit
https://pro.aace.com/cgm/toolkit/cgm-device-comparison.