Optimizing Use of Continuous Glucose Monitoring in Clinical Practice

Diana Isaacs, PharmD, BCPS, BCACP, BC-ADM, CDCES
Clinical Pharmacy Specialist/CGM Program Coordinator
Cleveland Clinic Diabetes Center
Cleveland, OH

Disclosures

- Diana Isaacs, PharmD is a consultant or speaker for the following companies:
  - Dexcom, Abbott, Companion Medical, Insulet, Novo Nordisk, Lilly, Xeris Pharmaceuticals

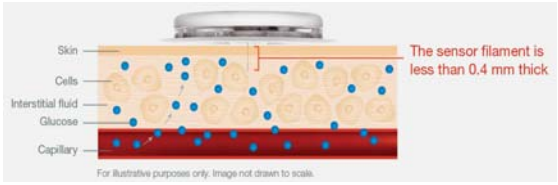
Learning Objectives

At the end of this presentation, participants will be able to:

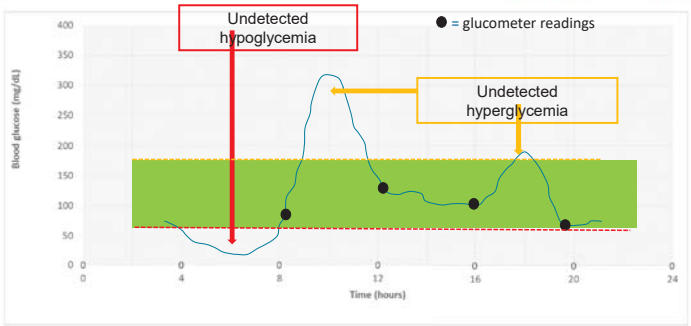
- Summarize the clinical data supporting CGM use in people with diabetes
- Compare and contrast CGM devices available for personal and professional use
- Utilize the ambulatory glucose profile and key metrics to systematically review a CGM report
- Describe how to use retrospective and real time CGM data to engage the PWD in self-management

Introduction to CGM

- Measures glucose from interstitial fluid (ISF) every 1-5 minutes
- Records glucose every 5-15 minutes (up to 288 readings/day)
- 3 components (Sensor, Transmitter, Receiver)



SMBG vs CGM



Poor Technique Can Negatively Affect Accuracy

Skin contaminants reduce meter accuracy 1 hour after peeling fruit

Exposure	Washed Hands	Exposed Finger (No Washing)	1 Alcohol Wipe	5 Alcohol Wipes
Peeling an orange (n=10)	98 mg/dL	171 mg/dL	118 mg/dL	119 mg/dL
Peeling a grape (n=10)	93 mg/dL	360 mg/dL	274 mg/dL	131 mg/dL
Peeling a kiwi (n=10)	90 mg/dL	183 mg/dL	144 mg/dL	106 mg/dL

Hirose T et al. *Diabetes Care*. 2011;34(3):596-597.

Limitations to Hemoglobin A1C

994 Diabetes Care Volume 40, August 2017

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

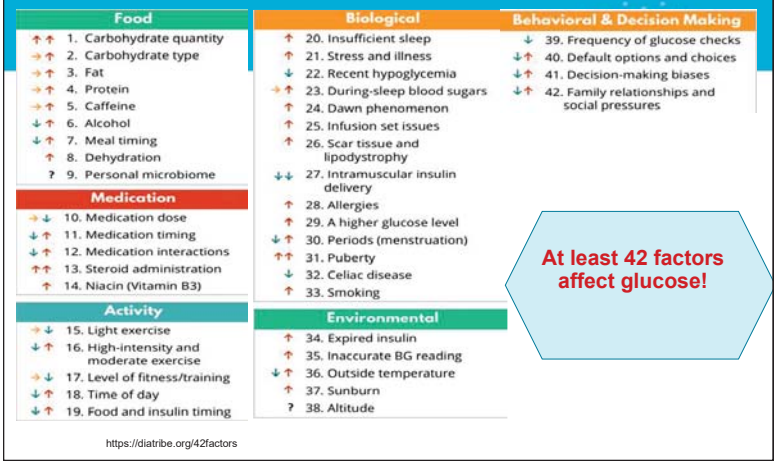
Roy W. Beck,[1] Crystal G. Connor,[1] Deborah M. Mullen,[2] David M. Wesley,[2,3] and Richard M. Bergenstal[2]

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

- It is a surrogate marker
- Based on an average
- Factors that affect red blood cell turnover can make this inaccurate
- Anemia, hemoglobinopathies and other conditions may falsely elevate or decrease

How does exercise affect glucose levels?

A. Increase
B. Decrease
C. No effect
D. It depends



https://diatribe.org/42factors

Types of CGM

Professional	Personal
Owned by the clinic	Owned by the patient
Blinded and unblinded (real-time feedback) options	Real-time feedback or scan for feedback (flash device)
Short term use (3-14 days)	Long term use
Alarms for hypo/hyperglycemia in select devices	Alarms for hypo/hyperglycemia in select devices
Insurance coverage for most people with type 1 or type 2 diabetes	Insurance coverage more limited to type 1 diabetes or those on MDI insulin
Not compatible with insulin pumps	Compatible with smartphones and insulin pumps with select devices

Wright L et al. *Diabetes Technology and Therapeutics* 2017; 19:S-16-S-26.

Professional CGM Options

Libre Pro

iPro2

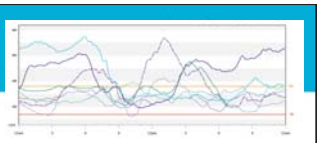
G6 Pro

Professional CGM Comparison

	IPro2	G6 Pro	Freestyle LibrePro
Blinded vs unblinded	Blinded	Both	Blinded
Maximum wear time	6 days	10 days	14 days
Calibration	3-4 per day	None	None
Downloading reports	Carelink	Clarity	LibreView
Care between uses	Clean and disinfect transmitter	Disposable 1 time use	Disposable 1 time use
MARD (accuracy-the lower the better)	11.05%	9%	12.3%
Alarms for high/low alerts	No	Yes	No
Interfering substances	Acetaminophen	Hydroxyurea	Salicylic acid and vitamin C

ADCES Practice Paper. The Diabetes Care and Education Specialist Role in CGM. Available at: https://www.diabeteseducator.org/practice/educator-tools/diabetes-management-tools/self-monitoring-of-blood-glucose.

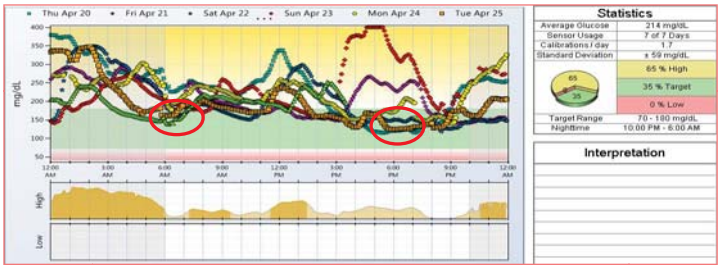
CGM Shared Medical Appointments



- Class time: 60-90 minutes
- 4-6 patients, 2 clinicians, 1 student
- Download devices
- Show report on the screen and interpret with the PWD's food/activity/medication logs
- PWD learn from each other
  - Discuss "bright spots" and "landmines"
- Lifestyle/meal planning recommendations
- Medication adjustments
- Each PWD gets a printed copy of their report and sent to ordering provider

Meet Derek

- 48yoM, type 2 DM x 10 years, maxed out on metformin, GLP-1 agonist, SGLT2 inhibitor, sulfonylurea
- A1C= 9-9.5% for 12 months, FBG and pre-dinner SMBG~150mg/dL
- He agreed to wear a professional CGM for 7 days



Derek was shocked by what happened between breakfast and dinner; he agreed to start insulin.

Types of Personal CGM

Real-Time CGM (rtCGM)

- Sensor data transmitted continuously to a receiver or display device, which allows for alerts and alarms to be provided to the wearer without any action

Intermittently Scanned CGM (isCGM)

- Results are available only when the sensor is scanned with a reading device; optional real time alerts
- Full 24-h data can be captured and downloaded if the sensor is scanned at least every 8 hours

Petrie JR et al. *Diabetes Care*. 2017;40(12):1614-1621.

Personal CGM Options

Libre 2

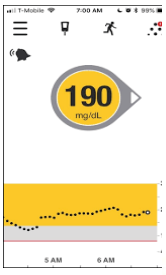
Medtronic Guardian Connect or Guardian 3

Freestyle Libre Flash

Dexcom G6

Senseonics Eversense

CGM: Real Time Data



Personal CGM Comparison

	Dexcom G6	Freestyle Libre 14 Day	Freestyle Libre 2	Guardian Connect or Guardian 3	Eversense
Insulin pump integration	T:Slim X2	No	No	Medtronic 670G, 770G, 630G (Guardian 3)	No
Receiver	iPhone, Android or receiver	iPhone, Android, or reader	Reader	iPhone or Android (Guardian Connect)	iPhone, Android
Maximum wear time	10 days	14 days	14 days	7 days	90 days
Warm-up time	2 hours	1 hour	1 hour	Up to 2 hours	24 hours
Calibrations required/day	0	0	0	2-4	2
Downloading reports	Clarity, Glooko, Tidepool	Libreview, Tidepool	Libreview, Tidepool	Carelink, Tidepool	Eversense data management system, Glooko
FDA Approved for dosing	Yes	Yes	Yes	No	Yes
Drug Interactions	Hydroxyurea	Salicylic acid, vitamin C	Vitamin C	Acetaminophen	Tetracycline
MARD	9%	9.4%	9.2%	9.64%	8.5%
Alarms for high/low	Yes	No	Yes	Yes	Yes

ADCES Practice Paper. The Diabetes Care and Education Specialist Role in CGM. Available at: https://www.diabeteseducator.org/practice/educator-tools/diabetes-management-tools/self-monitoring-of-blood-glucose. Accessed 11/1/20

CGM Integration

t:slim Basal IQ

t:slim Control IQ

InPen smart pen

Medtronic 770G

Medtronic 670G

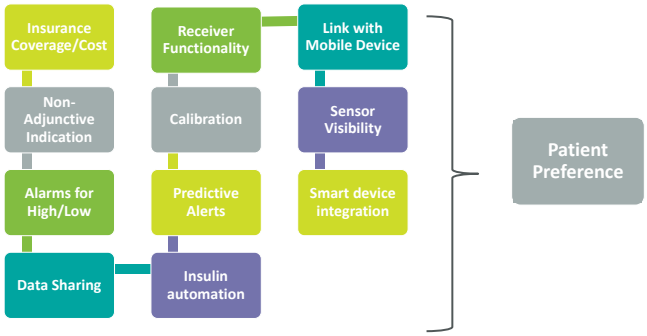
All people with diabetes should wear CGM

True or False?

Give PWD a Choice!

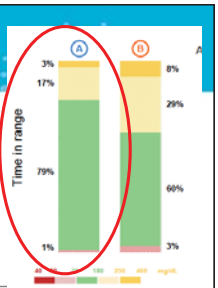
There is no “one-size-fits-all” approach to technology use in people with diabetes

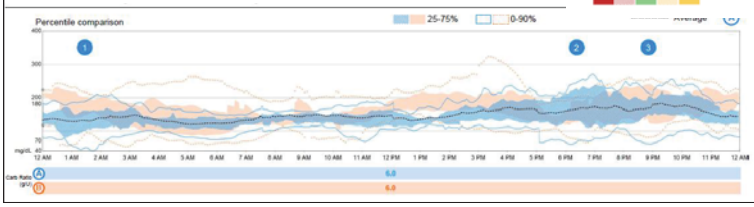
Patient Factors and Preferences Are Key in Individualizing CGM Device Selection



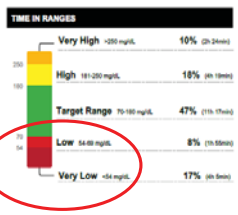
Technology Access

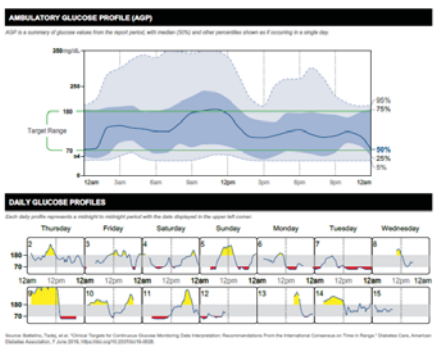
- Meet Abby who is feeling great on her hybrid-close loop insulin pump
- She wears the sensor that is designed for her pump
- She became 65 and went on Medicare
- Medicare doesn’t pay for her sensor





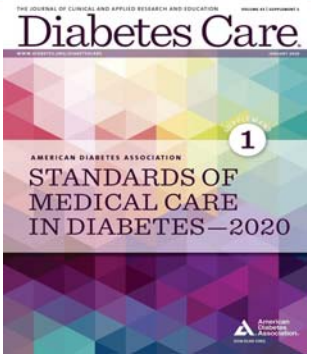
Abby Is Forced to Switch her Technology





What is the Evidence for CGM?

Guideline Updates



- Technology section added in 2019
- Ambulatory glucose profile (AGP) and time in range discussed as glycemic targets (in addition to A1C)
- Real-time CGM (rtCGM) and intermittently scanned CGM (isCGM) are useful to lower A1C and/or reduce hypoglycemia in adults who are not meeting glycemic targets, have hypoglycemia episodes, and/or unawareness
- There is no "one-size-fits-all" approach to technology use in people with diabetes
- CGM use requires robust and ongoing diabetes education, training, and support

Increased BG Monitoring Leads to Lower A1C in T1DM

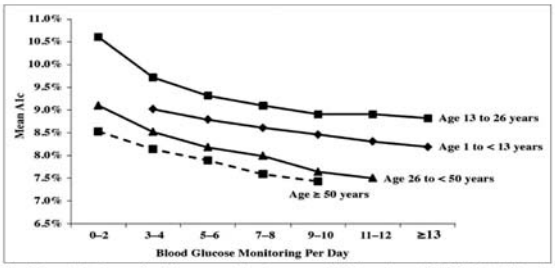
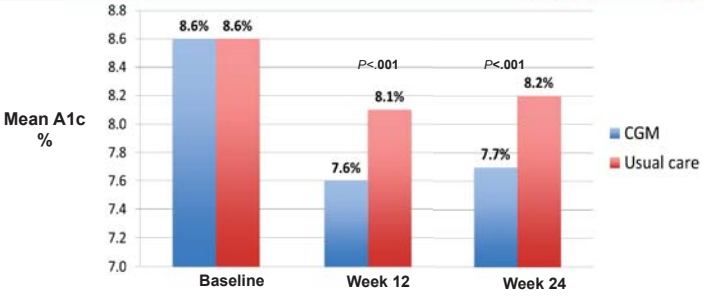


Fig. 2. Association between blood glucose monitoring frequency and A1C in patients with T1DM (70). *AIC* = glycated hemoglobin; *TIDM* = type 1 diabetes mellitus.

Type1 DM Exchange N=20,555

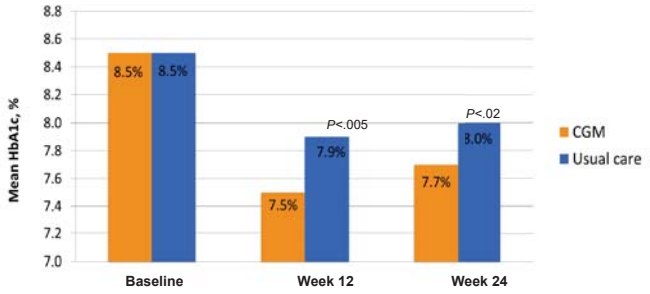
DIAMOND Trial: T1DM MDI A1C Treatment Group Differences



A1C: 0.6% difference at 24 weeks (N=158)

Beck RW et al., *JAMA*. 2017;317(4):371-378.

DIAMOND Trial-T2DM MDI A1c Treatment Group Differences



A1C: 0.3% difference at 24 weeks (N=158)

Beck RW et al. Ann Intern Med. 2017 Sep 19;167(6):365-37

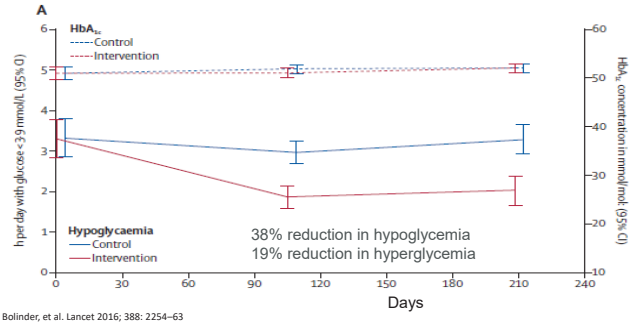
DIAMOND Trial-T2DM MDI Greater Benefit with Higher Baseline A1C

Baseline HbA1c	Change in HbA1c From Baseline		Difference	P value
	CGM Group	Usual Care Group		
≥ 7.5%	-0.9% (n=79)	-0.5% (n=79)	0.4%	0.02
≥ 8.0%	-0.9% (n=63)	-0.6% (n=57)	0.3%	0.05
≥8.5%	-1.1% (n=39)	-0.7% (n=39)	0.4%	0.02
≥ 9.0%	-1.4% (n=17)	-0.7% (n=21)	0.7%	0.04

Beck RW et al. Ann Intern Med. 2017 Sep 19;167(6):365-37

Flash CGM in T1DM

- Prospective, randomized controlled trial
- 241 participants with type 1 diabetes and A1C<7.5%, mean A1C=6.7%



Bolinder, et al. Lancet 2016; 388: 2254–63

FLARE-NL 4 Study

- The FLAsh monitor Registry in the Netherlands (FLARE-NL)
- Prospective, observational nationwide registry
  - 95 internal medicine and diabetes center N=1365, 16% T2DM
- Overall average A1c reduction of 0.4% (p<0.001)
  - Baseline A1c >8.5%, reduction of 0.8% (p<0.001)
- At 12 months decrease in diabetes related hospitalizations from 13.7% to 4.7% (p<0.05), 66% reduction
- 37% of subjects reported they increased their exercise/physical activity
- 95% reported a better understanding of their glucose fluctuations
- 59% reduction in work absenteeism

Fokkert M. et al. BMJ Open Diabetes Research and Care 7, no. 1 (2019).

The Role of the DCES in Technology

Technology Integration

The Role of the Diabetes Care and Education Specialist in Practice

- Diabetes technology is associated with improved outcomes, that is enhanced when the person using is knowledgeable and actively engaged
- Simply wearing the device may not automatically translate into health benefits
- The DCES has the central role in defining and establishing a technology-enabled practice setting that is efficient and sustainable
- The DCES can serve as the technology champion in their respective practices and work to reduce therapeutic inertia while improving health outcomes

Isaacs D et al. Diabetes Educ. August 2020.

Greenwood DA et al. A. Diabetes Educ. August, 2020.

CGM Data Interpretation

Data Management Tools

System	Website	Associated Mobile Apps	What it Downloads
Glooko	glooko.com	Glooko	Insulin pumps (Omnipod, Tandem), Dexcom, Eversense, many glucose meters, InPen
Clarity	clarity.dexcom.com	Dexcom G6, Clarity, Dexcom Follow	Dexcom, InPen
LibreView	libreview.com	LibreLink, LibreLinkUp	FreeStyle Libre
Carelink	carelink.medtronic.com	Guardian Connect, Carelink, Sugar IQ Diabetes Assistant	Medtronic insulin pump and Medtronic CGM
Tidepool	tidepool.org	Tidepool Mobile	Insulin pumps (Medtronic, Tandem, Omnipod), FreeStyle Libre, Dexcom, Guardian Connect, many glucose meters, InPen
Eversense Data Management System	eversensedms.com	Eversense	Eversense
InPen Insights Report	NA	InPen	InPen, Dexcom

Standardized CGM Metrics for Clinical Care

Key Metrics

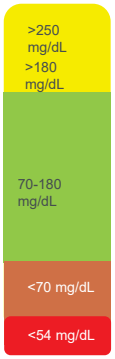
Number of Days CGM is worn
14+ days recommended

Percentage of Time CGM Is Active
>70% of data recommended

Mean Glucose

Glucose Management Indicator (GMI)
CGM-derived estimate of current A1C level

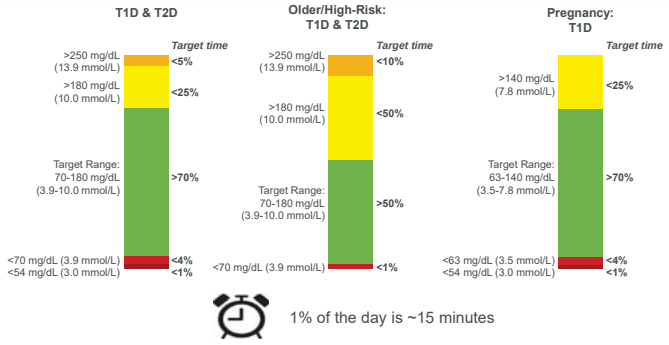
Coefficient of Variation (CV)
Measure of glycemic variability
(st. dev/mean)
CV ≤36% is considered acceptable



Level 2 Hyperglycemia
Level 1 Hyperglycemia
Time above range (TAR)
In target range
Time in range (TIR)
Level 1 Hypoglycemia
Level 2 Hypoglycemia
Time below range (TBR)

Battelino T et al. *Diabetes Care*. 2019;42(8):1593-1603.

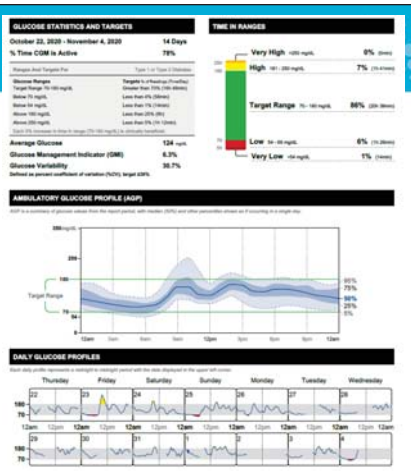
CGM-Based Targets for Different Populations



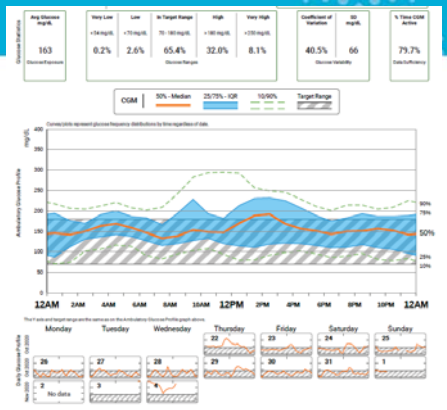
1% of the day is ~15 minutes

CGM = continuous glucose monitoring; T1D = type 1 diabetes; T2D = type 2 diabetes.
Battelino T et al. *Diabetes Care*. 2019;42(8):1593-1603.

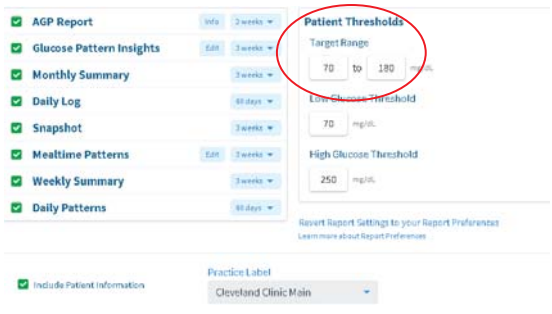
AGP Report



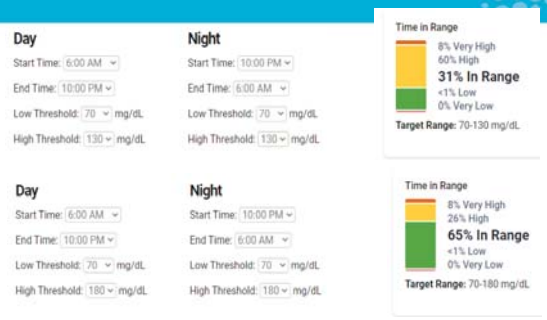
AGP Report



Customizing Reports



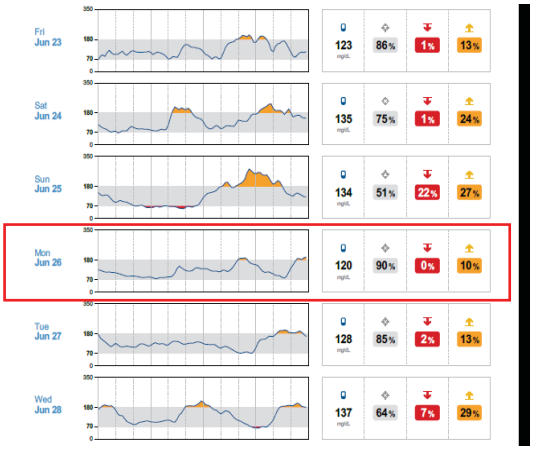
Time in Range Settings



- Target range refers to 70 – 180 mg/dL, except for patients who are pregnant
- Otherwise, interpreting time-in-range and other key metrics is difficult

Snapshot: Hypoglycemia

Comparing Different Days



CGM Data Review- DATAA

Numbers are not Good or Bad

- Thank the person for wearing CGM
- Express that **this is information, not good or bad**
- Ask permission to explore the highs
- If the person wants to stop at any point, develop an action plan until next visit

Action Plan in collaboration with the PWD

Case Study: Meet Janet

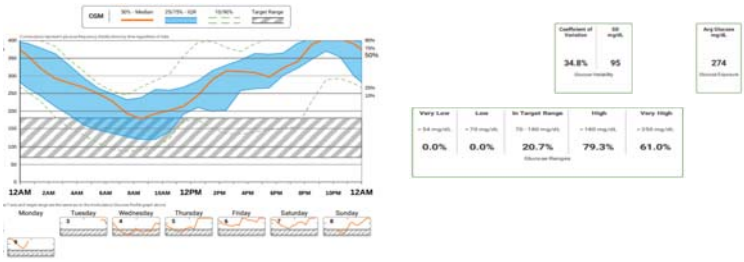
- 70-years old female
- Diagnosed with type 2 diabetes 18 years ago
- Retired
- Married, 3 children, 2 grandchildren
- A1C 10.5%
- Has arthritis, hoping to get a knee replacement, but needs to bring down A1C
- BMI=34kg/m^2
- Meds
  - Metformin 1000 mg BID
  - Insulin glargine 60 units daily
  - Insulin lispro 10-20 units TID at each meal

What is Janet's time in range goal?

A. >50%
B. >70%
C. >80%
D. >100%

Janet Wears Professional CGM

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

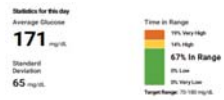


DATAA Discussion

No hypoglycemia, however, glucose falls overnight, Janet feels symptoms
Rarely taking lispro, never misses glargine

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



Ate eggs for breakfast, Sandwich for lunch and she injected lispro

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

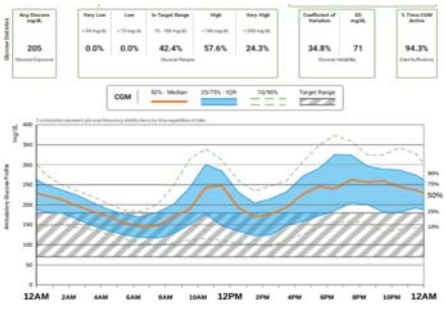
Didn't eat all day Thu and then "went off the wagon"
Ate cookies, ice cream

A Action Plan
- Develop collaboratively with the person with diabetes

- Janet liked seeing the data
- She learned the direct effects of food on her blood sugars
- She realized that she would benefit from taking lispro with her food during the day
- Janet gets a prescription for personal rtCGM
- Follow-up with the diabetes care and education specialist

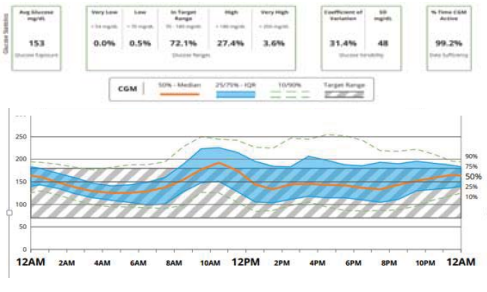
1 Month Later

- Time in range improved!
- Janet is more consistent with lispro (2 injections/day) but asks if there are any other medications that can help with weight and blood sugars
- GLP-1 agonist is added



3 Months Later

- Time in range improved, >70%!
- A1C is now 7.1%
- Janet is eating smaller meals, allows herself 1 treat/day, taking lispro consistently at 2 main meals, continues on glargine and GLP-1 agonist (rarely misses doses)
- She lost 12 lbs, feels great!
- She is scheduled for her surgery



CGM Revenue Opportunities

CGM Services	Medicare Fee Schedule	Private Payer
CPT 95249 (Personal CGM - Startup/Training)		
Ambulatory CGM of interstitial tissue fluid via a subcutaneous sensor for a minimum of 72 hours; patient-provided equipment, sensor placement, hook-up, calibration of monitor, patient training, and printout of recording. *Bill only once during the time period that the patient owns the device.*	$55.58	$127
CPT 95250 (Professional CGM)		
Ambulatory CGM of interstitial tissue fluid via a subcutaneous sensor for a minimum of 72 hours; physician or other qualified health care professional (office) provided equipment, sensor placement, hook-up, calibration of monitor, patient training, removal of sensor, and printout of recording. *Do not bill more than 1x/month.*	$152.66	$303304
CPT 95251 (CGM Interpretation)		
Ambulatory CGM of interstitial tissue fluid via a subcutaneous sensor for a minimum of 72 hours; analysis, interpretation and report. *Do not bill more than 1x/month*	$36.81	$96

*Non-facility is defined as office space. †Medicare outpatient clinic visits.
CGM = continuous glucose monitoring.
Dexcom. 2020 CGM Coding Reference. https://dexcompdf.s3-us-west-2.amazonaws.com/HCP_Website/Telehealth+Resources/CodingReimbursement+Updates-2020-4.pdf accessed 9/24/20

In Summary

- Clinical data and guidelines support use of CGM in many different types of people with diabetes (PWD)
- There are multiple CGM options and connected devices; one size does not fit all
- Retrospective and real time CGM data can engage the PWD in self-management
- Review CGM in 5 steps:
  - Download, assess safety, time in range, areas to improve, action plan

Resources

- Diabetes Advanced Network Access (DANAtech)
  - https://www.danatech.org/
- Association of Diabetes Care & Education Specialists (ADCES) Glucose monitoring resources
  - https://www.diabeteseducator.org/practice/educator-tools/diabetes-management-tools/self-monitoring-of-blood-glucose
- DiaTribe: https://diatribe.org/
- Eversense: https://eversensediabetes.com
- Medtronic Guardian Connect: https://hcp.medtronic-diabetes.com.au/guardian-connect
- Dexcom G6: https://www.dexcom.com/g6-cgm-system
- Freestyle Libre: https://www.freestylelibre.us/

THANK YOU