

# Chronic Care Roundtable Meeting

## *Waves of Change: Technology and Type 2 Diabetes Care*

June 3, 2020

*Welcome!*



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# Thank You



Abbott



# Diabetes Technology = A New Frontier for Providers



# **Waves of Change: Technology and Type 2 Diabetes Care**

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## **Structure:**

### **1) Diabetes in numbers 2020**

### **2) Barriers to achieving better glycemic control in T2D**

### **3) Technology: Continuous Glucose Monitoring Overview**

- **CGMs currently available and their main features**
- **new CGM systems coming up**
- **what is the “ideal CGM”?**

### **4) CGM Data**

- **understanding CGM metrics and the AGP**
- **TIR vs HbA1c (are we ready for the change?)**

### **5) Impact of CGM data on diabetes management**

- **TIR and glycemic control**
- **benefits beyond “metrics”**
- **potential impact of CGM in T2D (or even prediabetes?)**

### **6) Expanding CGM use**

- **what do our patients want, how do they feel?**
- **what do healthcare providers want?**
- **what are the barriers to expanding CGM use?**

# 1) Diabetes today, in numbers

## THE STAGGERING COST OF DIABETES

Today, **4,660**  
AMERICANS WILL BE DIAGNOSED  
WITH **DIABETES**

NEARLY **30**  
MILLION AMERICANS  
HAVE DIABETES



**86 million**  
Americans have prediabetes

More than the population of the east coast  
from Connecticut to Georgia



DIABETES AND  
PREDIABETES COST AMERICA  
**\$322 BILLION**  
PER YEAR

**\$ 1 in 5 health care dollars**  
is spent caring for  
people with diabetes

**\$ 1 in 3 Medicare dollars** is spent  
caring for people  
with diabetes

**\$** People with diagnosed  
diabetes have health  
care costs **2.3 times**  
**higher** than if they  
didn't have the disease



Learn how to combat this costly disease at  
**diabetes.org/congress**



- 90-95% of PwD (16.5 million people in the United States) have T2D
- intensive glycemic control (to achieve glycated hemoglobin [A1C] goals <7%) significantly decreased rates of T2D complications:
  - 16% reduction in cardiovascular disease events (combined fatal or nonfatal myocardial infarction and sudden death)
  - 13% reduction in myocardial infarction after 10 years of follow-up
  - 27% reduction in all-cause mortality after 10 years of follow-up
- **31% to 92% of patients with T2D fail to reach recommended glycemic goals**
- **more than 70% of patients are not meeting the recommended A1C goal of less than 7%**
- Only 30% to 50% of US patients with diabetes met the individualized targets for glycemic control, blood pressure, and/or lipid control

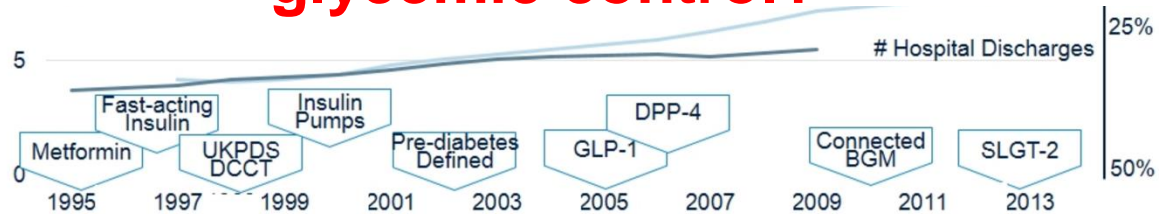


## TYPE 2 DIABETES IS AN EPIDEMIC IN THE UNITED STATES

DEVICE AND DRUG INNOVATIONS HAVE NOT TRANSLATED INTO BETTER HEALTH



**Can technology improve adherence to long term glycemic control?**



## Barriers to achieving glycemic control in Type 2 Diabetes: SMBG

- ~33% of PWT2D adhere to recommended SMBG frequency (Wagner 2005)
- ~63% report of PwT2D skip SMBG because of invasiveness (Wagner 2005)
- of the potentially modifiable diabetes care factors, adherence to insulin, **greater filling of glucose self-testing supplies** and visiting an endocrinologist were strongly associated with improved glycemic control in PwT2D on insulin (TARGIT)
- Higher SMBG frequency clearly associated with improved glycemic control in PwT2D on insulin but not necessarily on OAD

**Monitoring is a major factor in achieving better diabetes control**

## Barriers to achieving glycemic control in Type 2 Diabetes: SMBG

- SMBG is invasive
- Benefits are not immediately palpable (vs hypo avoidance in PwT1D)
- Hyperglycemic surfing much more accepted for PwT2D (if it's below 250mg% it's OK)
- Stigma seriously impairing full patient empowerment (overeating, fat, patient's own fault)
- Healthcare delivery extremely important (yet rarely emphasized)
- PwT2D tend to be older and less tech savvy (which is oftentimes = less interested, but not true)
- Modifiable factors (behavior, OAD) take time to show effects on BGV (no perceived value of RTCGM)

Case from own practice:

44 year old woman

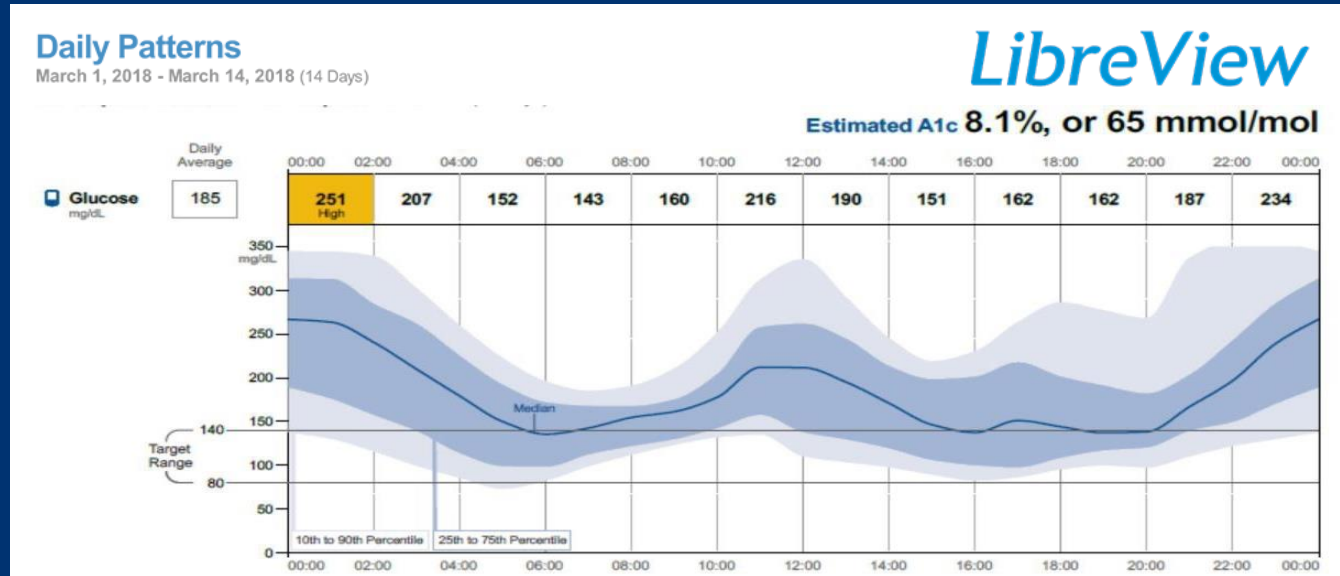
T2D for 12 years (after pregnancy)

On Metformin and Januvia

HbA1c: 8.2%

SMBG: “pretty often” (once weekly on average)

Only two meals per day

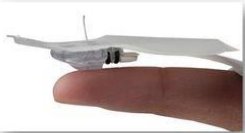


Breakfast: 10-11:00AM: 135-150g CHO

Dinner: 8-9:00PM: 155-185g CHO

Snack: 11:30PM-12:00AM: 15-20g CHO

## Continuous Glucose Monitoring



Subcutaneous sensor reads interstitial fluid glucose every few minutes

Attached transmitter sends values to receiver

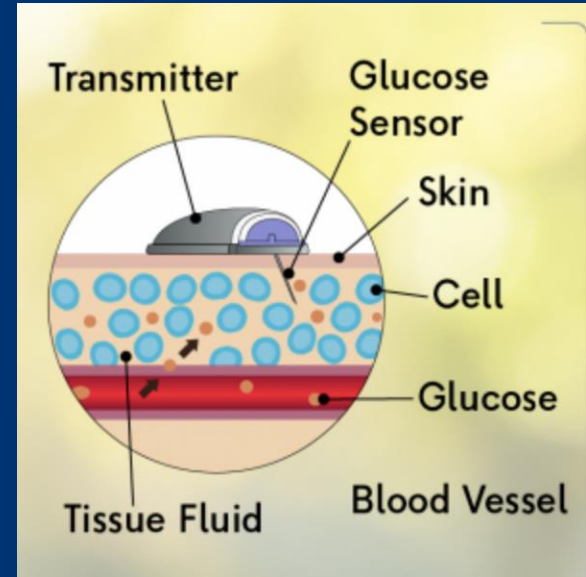


Receiver displays glucose values in real time and provides trend arrows

Trend arrows show how quickly glucose is changing

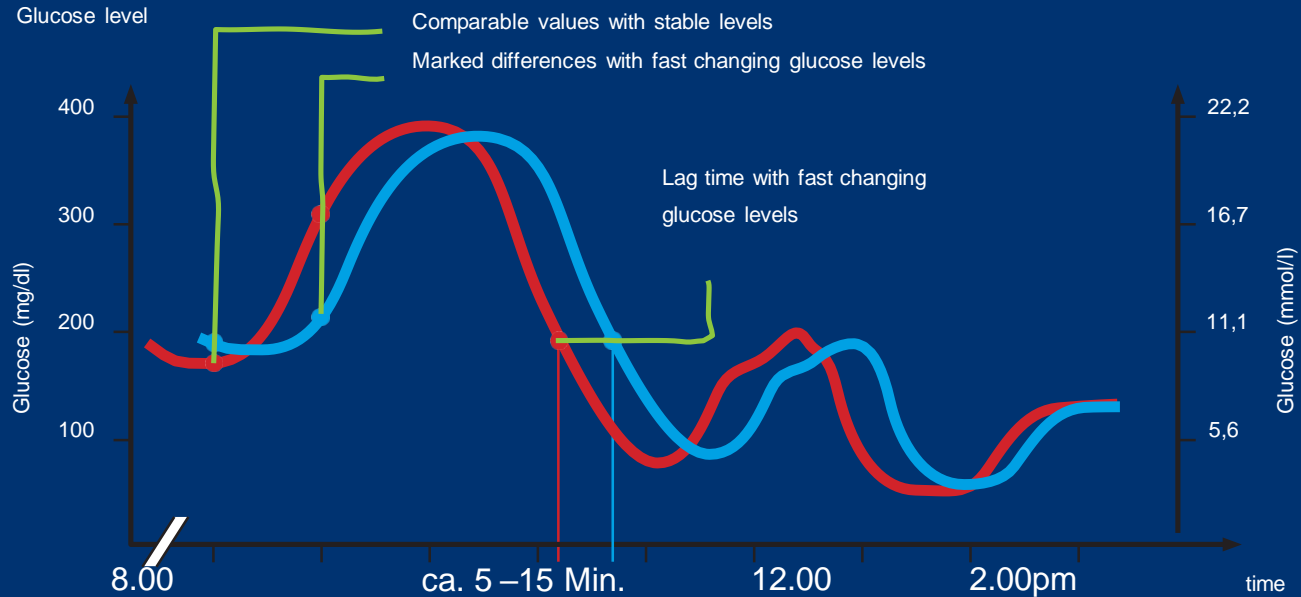


Sensor is changed by patient every 6-7 days



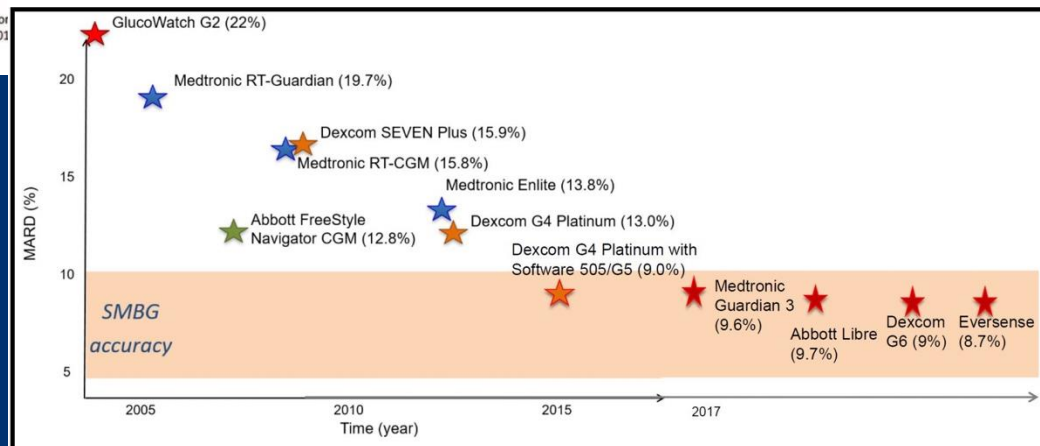
- A device that provides “real-time” glucose readings and data about trends in glucose levels
- Reads the glucose levels under the skin every 1-5 minutes (10-15 minute delay)
- Provides alarms for high and low glucose levels and trend information

# Blood glucose versus tissue glucose levels



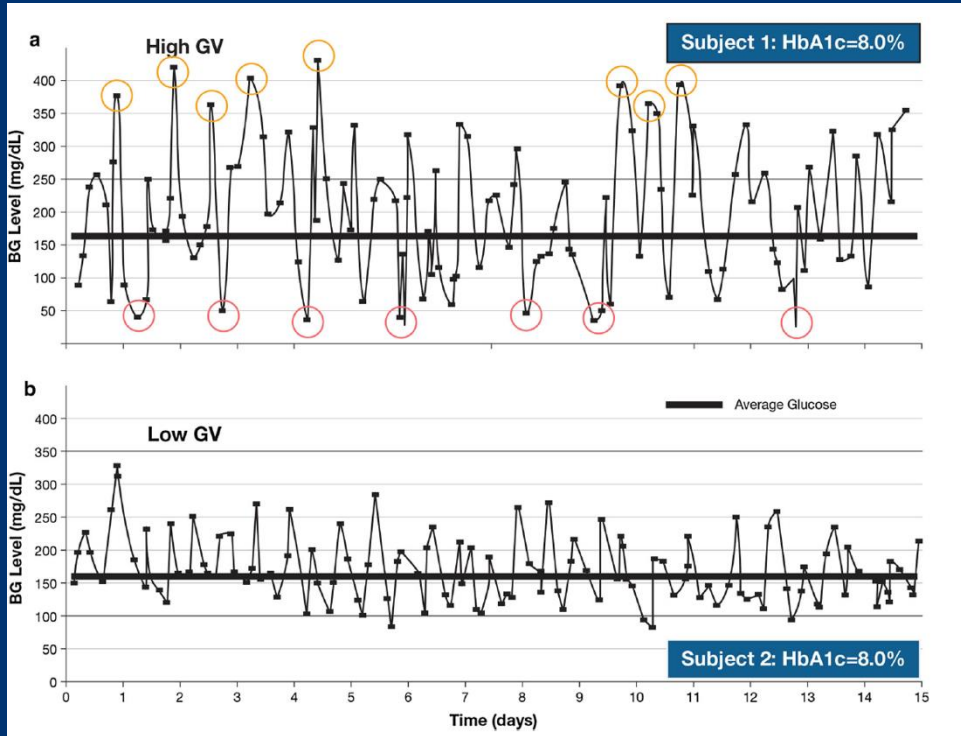
Differences between blood (**red**) and tissue (**blue**) glucose levels occur with fast changing glucose levels (mealtime, exercise)

# Continuous Glucose Monitoring - Timeline



CGM accuracy timeline

# Why is CGM better than SMBG and/or A1C?



HbA1c is 8.0% in both cases: who is doing better?



# CGM Overview 2020

Features common to all CGM systems:

- System includes a subcutaneous sensor and a transmitter (separate or built in).
- Wireless communication between transmitter and receiver.
- Waterproof sensors/transmitters (receiver/display not waterproof).
- Multiple on-screen trend graphs.
- Direction and rate-of-change arrows.
- Mechanical device used to insert sensors.
- Sensor not reusable. Life varies between manufacturers and from person to person.
- Warmup period (with no data) at beginning of sensor session.
- Some lag time between blood glucose (fingerstick) and subcutaneous glucose (sensor) values (as high as 30min with exercise).
- Backlogged data reported to receiver/app when in range.
- Events such as food, insulin or activity can be logged.

# Continuous Glucose Monitoring Overview End 2019

COMPANY/ PRODUCT	TRANSMITTER AND SENSOR SIZE	RECEIVER SIZE	BATTERY	RANGE	WARM-UP TIME	CALIBRATION
<b>STAND-ALONE CONTINUOUS GLUCOSE MONITORS</b>						
<b>ABBOTT</b> FreeStyle Libre 14-Day System 	1.38 in. diameter x 0.2 in.  0.18 oz.	2.36 x 3.74 x 0.63 in.  2.3 oz.	Sensor has 1 silver oxide battery. Reader has 1 rechargeable lithium ion battery.	The reader must be within 1.5 inches of the sensor to scan it.	It takes 1 hour to be ready after inserting the sensor and scanning it with the reader.	No calibration required.
<b>DEXCOM</b> G5 Mobile 	1.52 x 0.88 x 0.47 in.  0.4 oz. with sensor	4 x 1.8 x 0.5 in.  2.4 oz.	Transmitter has integrated battery with a three-month warranty. Rechargeable receiver.	The sensor and transmitter must be within 20 (unobstructed) feet of the receiver or a supported smart device running the Dexcom app.	It takes 2 hours to be ready after inserting the sensor.	Calibrate every 12 hours. Blood glucose levels must be between 40 and 400 mg/dl to calibrate.
<b>DEXCOM</b> G6 CGM System 	1.68 x 0.86 x 0.33 in.  0.42 oz. with sensor	4.02 x 2.44 x 0.46 in.  3.3 oz.	Transmitter has integrated battery with a three-month warranty. Rechargeable receiver.	The sensor and transmitter must be within 20 (unobstructed) feet of the receiver or a supported smart device running the Dexcom app.	It takes 2 hours to be ready after inserting the sensor.	No calibration required.
<b>MEDTRONIC DIABETES</b> Guardian Connect CGM System 	1.41 x 1.13 x 0.38 in.  0.04 oz. with sensor	Receiver not required; sends data to mobile device.	Rechargeable transmitter. Charger uses 1AAA battery.	The transmitter must be within 20 feet of your mobile device.	It takes up to 2 hours to be ready after inserting the sensor.	Calibrate every 12 hours. Blood glucose levels must be between 40 and 400 mg/dl to calibrate.
<b>SENSEONICS</b> Eversense CGM System 	1.48 x 1.89 x 0.35 in.  0.39 oz.	Receiver not required; sends data to mobile device.	Rechargeable lithium polymer battery	The transmitter must be within 25 feet of your mobile device.	It takes 24 hours to be ready after inserting the sensor.	Calibrate every 12 hours. Blood glucose levels must be between 40 and 400 mg/dl to calibrate.

Diabetes Forecast

CGM Brand	Dexcom G5	Dexcom G6	Medtronic Guardian	Freestyle Libre Flash	Eversense
Calibration required?	Yes	No	Yes	No	Yes
How often should you calibrate?	Every 12 hours	None	Every 12 hours, accuracy improves if 4 times daily	None	Every 10-14 hours
Can you dose insulin off of the sensor reading?	Yes	Yes	No	Yes	Yes
Can you take Tylenol?	No	Yes	No	Yes	Yes, but you can't take tetracycline.
How often should the sensor be changed?	Every 7 days	Every 10 days	Every 7 days	Every 14 days (depending on shipping date)	Every 90 days
How long is the warm- up period?	2 hours	2 hours	2 hours	1 hour	24 hours
Easy to insert?	No	Yes	No	Yes	Requires medical procedure
Alarms and alerts?	Yes	Yes	Yes	No	Yes
Predicts lows?	No	Yes	Yes	No	Yes

## Pros

- No calibration needed
- Calibration **available** to improve accuracy
- Approved Sensor life 10 days
- Customizable alerts for different times and days
- Single button push insertion
- Vibrate & audio alerts (receiver)
- Interoperability to Tandem X2 pump
- Sends data to phone app (and apple watch), receiver, or pump.
- Real time alerts for high, low, rate of change, predictive urgent low
- “Always sound” feature can sound alerts when phone is on silent.
- Not impacted by acetaminophen use
- Real-time sharable data

## Dexcom G6



Receiver: \$355/y  
Transmitter:  
\$475/6mt  
Sensors: \$350/mt

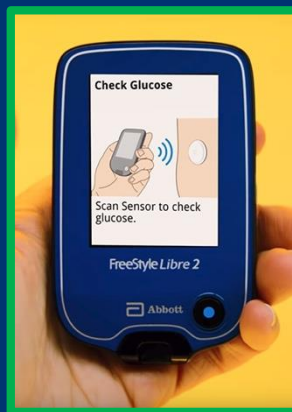
## CONS

- Transmitter must be replaced every 3 months
- **Lots of medical waste with sensor inserters**
  - Occasional delays receiving orders and technical support
  - Re-use of sensors involves a difficult process
- **Costly sensors and transmitters**
- **Phone needed for Apple watch connection**

# Freestyle Libre

## Pros

- No calibration needed
- Sensor life 14 days
- Single button press insertion
- Low profile transmitter
- Lowest cost
- 1-hour warm up (shortest)
- Glucometer built into reader
- Reading updated every 60 seconds, recorded to memory every 15 minutes,
- Sensor stores up to 8 hours of data if not read.
- Reader accepts notes or events
- Medicare approved



Receiver: \$85-100  
Sensors: \$120/mt

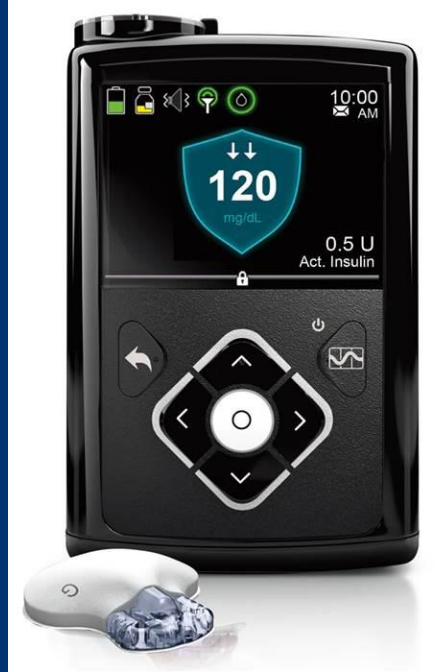
## CONS

- No realtime high/low alerts
- Need to carry reader and scan sensor to get data
- No “sharing” feature
- Calibration not available to improve accuracy.
- Widest inaccuracy at low glucose
- Reader requires up to 3h charge every 7 days
- Freestyle software uploading can be confusing
- May be impacted by Vitamin C and aspirin
- Events must be entered at time of event (cannot back-enter)
- Transmitter adhesive may not last 14 days

## Pros

- **Available with 670G** integration or Guardian Connect app (but not both)
- Approved Sensor life 7 days (sensor life may be extended via hack)
- Customizable alerts for different times and days
- Single-button insertion
- Vibrate & audio alerts only limited by phone's options (Guardian Connect only)
- Real time alerts for high, low, rate of change, or predictive low/high
- **Real-time sharable data** (Guardian Connect only)
- **Sugar IQ companion app** generates reports, indicates patterns/trends (Guardian Connect only)

## Medtronic Guardian



Transmitter: \$775/2y  
Sensors: \$535/mt

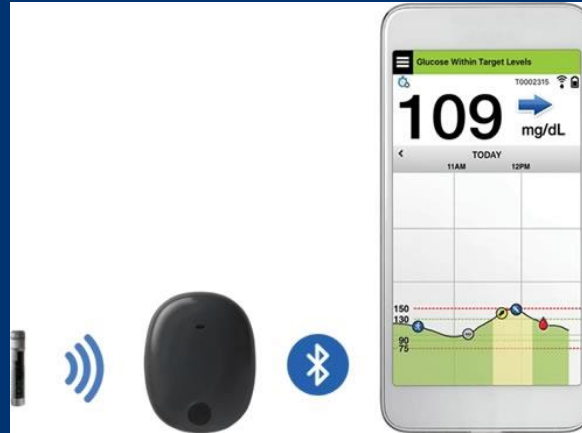
## CONS

- 2 hour warm up time
- **Complicated taping procedure**
- **Multiple tapes can cause skin skin issues**
- Requires at least once calibration every 12 hours
- Stops generating data if not calibrated
- Transmitter requires 10-20 minute charge every 7 days
  - **Only compatible with Medtronic pumps, apps Guardian Connect App only for iOS (Android Summer 20)**
- Impacted by acetaminophen
- Fair accuracy

## Pros

- Approved Sensor life 90 days (EU: 180 days)
- Variety of vibrate & audio alerts via phone app
- **Transmitter vibrates** when out of range
- Data back fills when away from phone/receiver
- Real time alerts for high, low, rate of change, or predictive low
- Not impacted by acetaminophen use (but tetracycline)
- Real-time sharable data
- Transmitter can be removed and replaced without sensor change
- (Least medical waste)
- Medicare (pre)approved?

## Senseonics Eversense



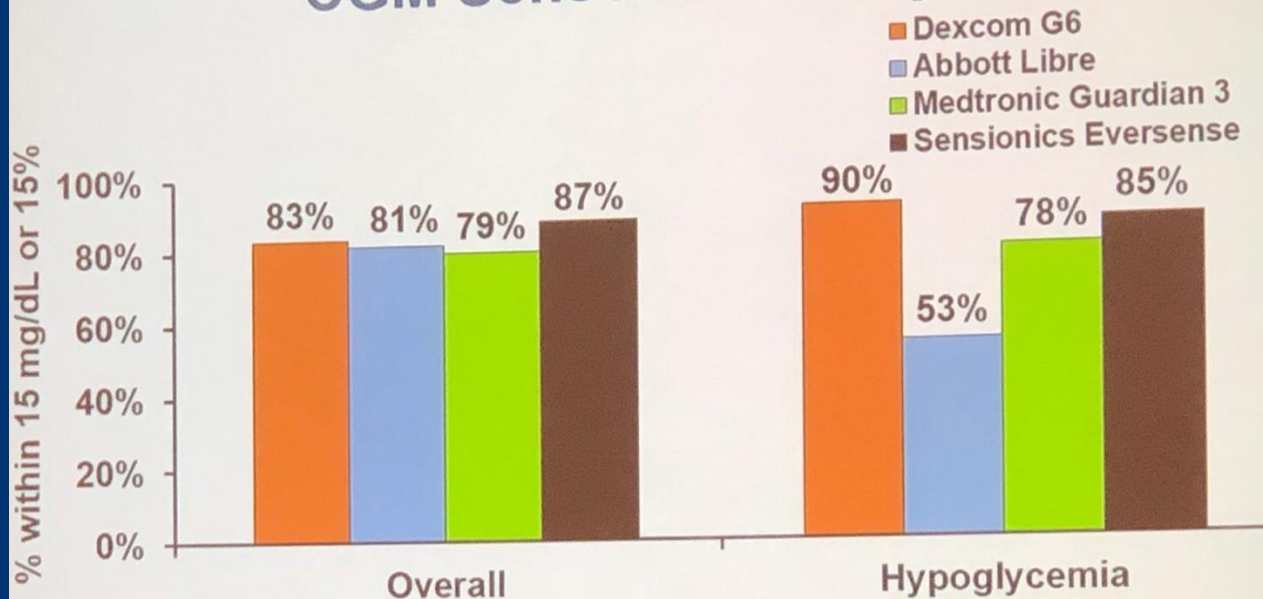
Insertion: \$250/3mt  
Sensors: \$99 for first 2

## CONS

- Sensor insertion (and removal) requires small surgery
- 24 hour warm up period
- Requires twice-daily calibration
- Transmitter requires daily or bi-daily charging
- Data upload not compatible with third party software
- Data not collected if transmitter not worn (but not lost)
- No full integration with Apple watch

**Covid19:**  
**No sensors for new patients in the US**

## CGM Sensor Accuracy\*



\* within 15 mg/dL for <100 mg/dL and 15% for  $\geq$ 100 mg/dL

## What are professional CGM systems?

- CGM sensors w/o receiver
- Insertion in medical office
- 14d collection of q5min data
- Patient writes diet and activity log
- Extremely valuable data source



Features	Abbott Freestyle Libre Pro	Dexcom G4 Platinum	Medtronic iPro2
Blinded or Unblinded	Blinded	Either	Blinded
Wear Time	14 days	7 days	6 days
Calibration Required?	0	Twice Daily	3-4 times daily
Components	Disposable wired sensor/transmitter  Separate touchscreen reader device that does not go home with the person with diabetes	Disposable wired sensor  Data transmitter attached to the sensor  Receiver for data display/storage	Disposable wired sensor  Data transmitter attached to the sensor
Care Between Use	Disposable sensor/ transmitter	Transmitter and receiver must be cleaned and disinfected	Transmitter must be cleaned and disinfected
Insertion	Single step process with auto-inserter	Two-step process which inserting sensor and attaching transmitter	Multi-step process which includes inserting and taping both the sensor and transmitter
Site	Upper Arm	Abdomen	Abdomen
Downloading/ Data Reports	LibreView	Clarity Studio	Carelink



## Anticipated Diabetes Management Products for 2020-2021

- Abbott
  - Libre
  - Libre with LibreLink
  - *Libre2*
- DexCom
  - G6
  - G7
  - *G6 program for Type 2*
  - *Pro Q*
- Medtronic
  - Guardian Connect
  - Multiple options
- Senseonics
  - Eversense
  - *Eversense XL*
  - *Eversense 365*

**Covid19:  
Major delays**

## A brief glance into the (near) future (from ATTD Madrid 2020)

### Sensor enabled CGM

- Ascensia's relaunch of PocTech
- Agamatrix's Waveform Cascade (Bayer)
- Aidex from GlucoRX
- Infinovo's Glunovo i3 (low cost CGM)

### Less invasive Microneedle CGM

- KTH Sweden

### Non invasive patch CGM

- Nemauro's Sugarbeat

# Indication for CGM use

ADA [8]	AACE/ACE [66]	Endocrine Society [105]	International consensus [47]
<p>CGM in conjunction with intensive insulin regimens is a useful tool to lower HbA1c in adults with T1D who are not meeting glycemic targets</p> <p>CGM may be a useful tool in those with hypoglycemia unawareness and/or frequent hypoglycemia episodes</p>	<p>CGM is recommended for adult and pediatric patients with T1D (particularly for those with history of severe hypoglycemia and hypoglycemia unawareness) and to assist in the correction of hyperglycemia in patients not at goal</p> <p>No recommendations in patients with T2D because of limited data</p>	<p>RT-CGM is recommended for adults with T1D (with HbA1c levels above target or with well-controlled glycemia) who are willing and able to use these devices on a nearly daily basis</p> <p>Short-term, intermittent use of RT-CGM is suggested for adult patients with T2D (not on prandial insulin) who have HbA<sub>1c</sub> levels <math>\geq</math> 7% and are willing and able to use the device</p>	<p>CGM should be considered in conjunction with HbA1c monitoring for glycemic status assessment and therapy adjustment in all patients with T1D or T2D receiving intensive insulin therapy who are not attaining glucose targets, especially if the patient is experiencing problematic hypoglycemia</p>

# All Adult and Pediatric Patients with T1D and All Adult and Pediatric Patients with T2D in IIT Almost unethical to have patients on intense insulin therapy w/o CGM!

Any patient treated by intensive insulin therapy

Experiencing frequent hypoglycemia

Hypoglycemia unawareness

Excessive glucose variability

Varying and/or intensive activity

Desire to improve glycemic control

Willing and able to use CGM on a nearly daily basis

Willing and able to learn how to use device and receive ongoing education

Aleppo G, Laffel LM, et al. *J Endocr Soc.* 2017 Nov 20;1(12):1445-1460.

Laffel LM, Aleppo G, et al. *J Endocr Soc.* 2017 Nov 20;1(12):1461-1476.

Peters AL, et al. *J Clin Endocrinol Metab.* 2016 Nov;101(11):3922-3937.

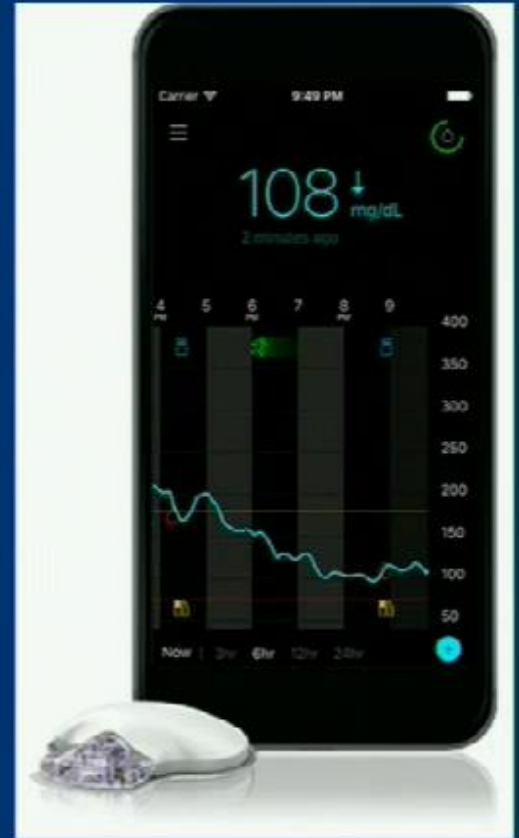
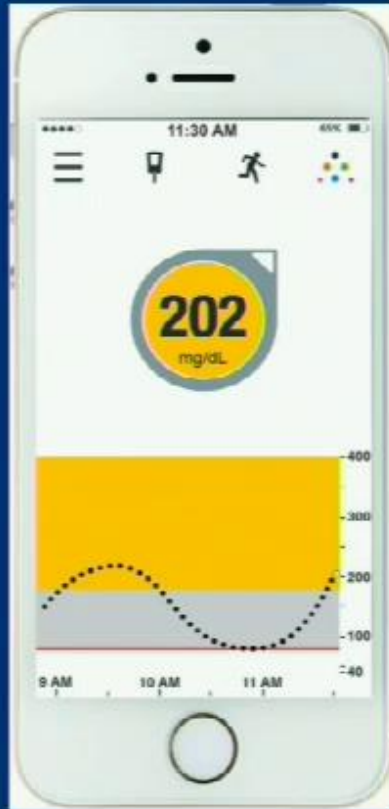
## Continuous Glucose Monitoring – Medicare Criteria

- A diagnosis of T1D or T2D and a requirement for therapeutic CGM
- ~~Frequent (4 or more per day) SMBG testing~~
- ~~Three or more injections of insulin per day or use of an insulin pump~~
- An insulin regimen that requires frequent adjustments on the basis of the CGM data, which requires that the CGM be classified as a “therapeutic” device
- ~~An in-person visit with treating practitioner within 6 months of ordering the CGM to evaluate their diabetes control and determine if the above criteria are met~~
- ~~An in-person meeting with the treating practitioner every 6 months to assess adherence to their CGM regimen and diabetes treatment plan~~
- Use of a receiver classified as durable medical equipment to display glucose data, alone or in conjunction with a compatible smart device








COVID19 CMS changes

[Dexcom.com/medicare-coverage](https://www.dexcom.com/medicare-coverage)

# What the patient is seeing

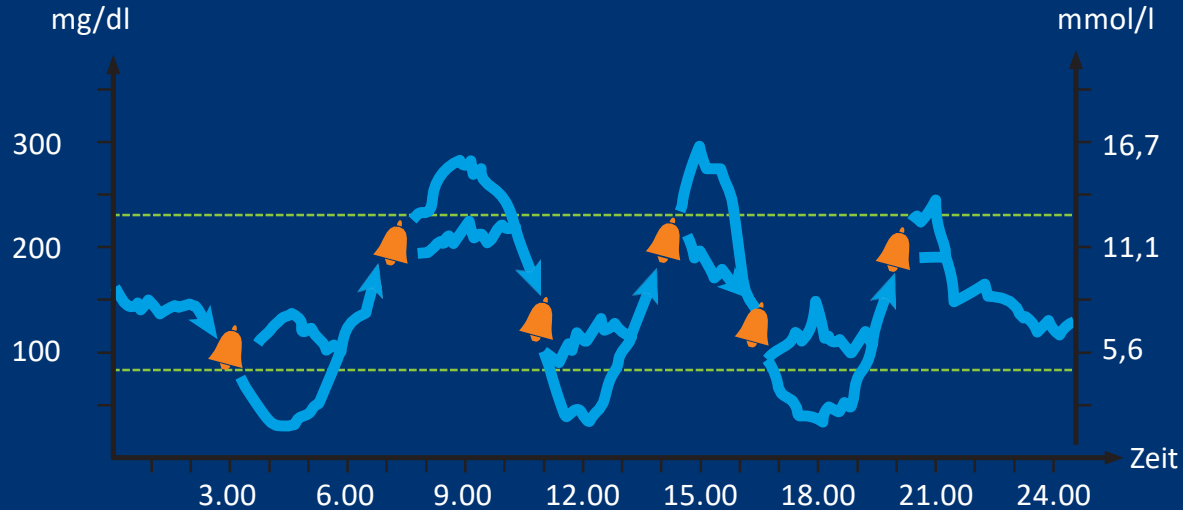


# Trend Arrows Inform Rate of Change

Dexcom G5 Trend Arrows			Change in Glucose
Receiver	App	Glucose Direction	
↑↑		Increasing	<b>Glucose is rapidly rising</b> Increasing >3 mg/dL/min or >90 mg/dL in 30 minutes
↑		Increasing	<b>Glucose is rising</b> Increasing 2-3 mg/dL/min or 60-90 mg/dL in 30 minutes
↗		Increasing	<b>Glucose is slowly rising</b> Increasing 1-2 mg/dL/min or 30-60 mg/dL in 30 minutes
→		Increasing or Decreasing	<b>Glucose is steady</b> Not increasing/decreasing >1 mg/dL/min
↘		Decreasing	<b>Glucose is slowly falling</b> Decreasing 1-2 mg/dL/min or 30-60 mg/dL in 30 minutes
↓		Decreasing	<b>Glucose is falling</b> Decreasing 2-3 mg/dL/min or 60-90 mg/dL in 30 minutes
↓↓		Decreasing	<b>Glucose is rapidly falling</b> Decreasing >3 mg/dL/min or >90 mg/dL in 30 minutes

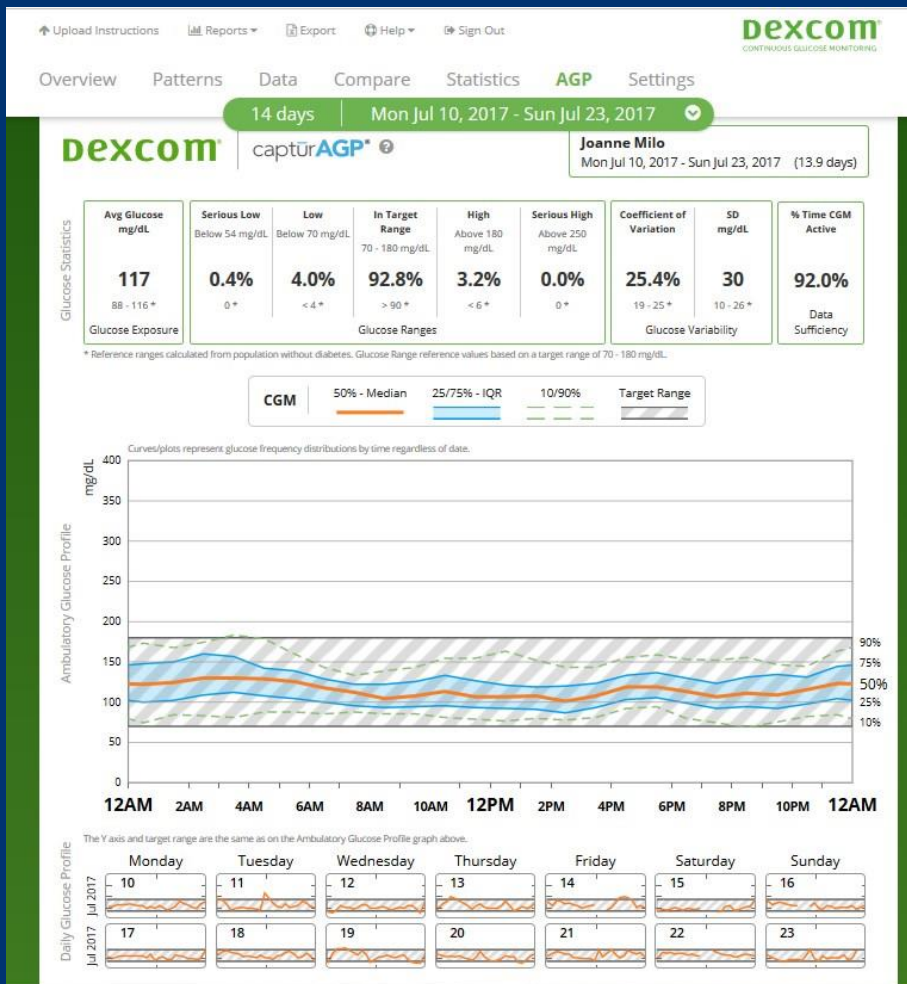


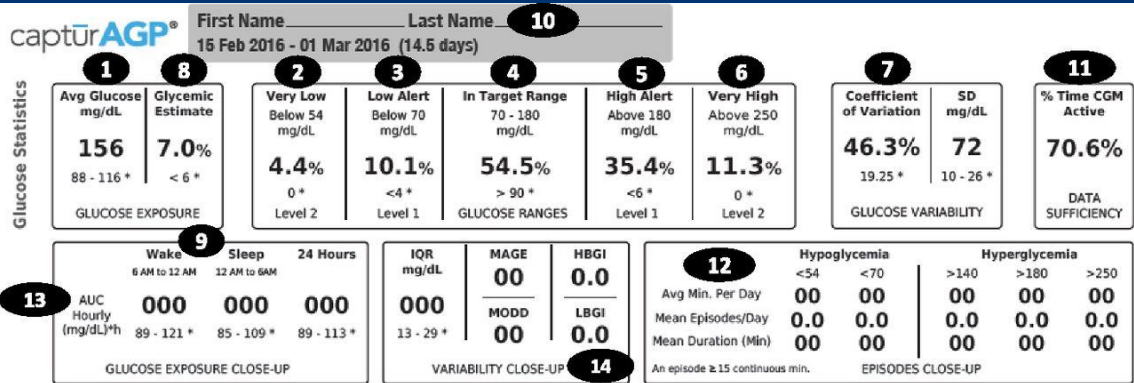
## Trend Arrows



- Alarm: when predicted that glucose levels will trigger a low” or “high” alarm within a certain period of time if trend continues
- Facilitates earlier intervention

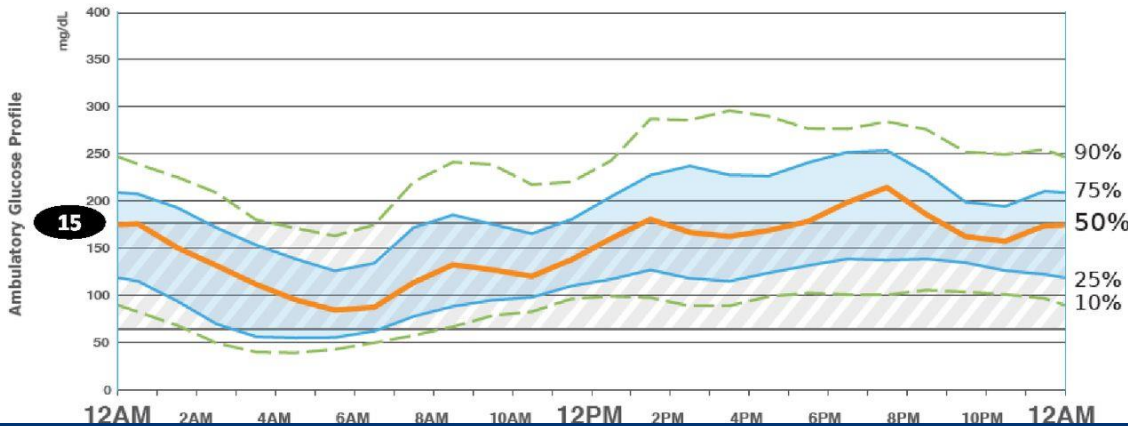
# What the doctor is seeing: CGM metrics





\* Reference ranges calculated from population without diabetes.  
Level 1=Needs attention. Level 2=Immediate action.

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



The electronic AGP report visualizes the key CGM metrics:

- 1) mean glucose,
- 2) hypoglycemia: clinically significant/very low/immediate action required,
- 3) hypoglycemia: alert/low/monitor,
- 4) target range,
- 5) hyperglycemia: alert/elevated/monitor,
- 6) hyperglycemia: clinically significant/very elevated/immediate action required,
- 7) glycemic variability,
- 8) eA1C,
- 9) time blocks,
- 10) collection period,
- 11) percentage of expected readings,
- 12) hypoglycemia/hyperglycemia episodes,
- 13) area under the curve, 1
- 14) hypoglycemia/hyperglycemia risk, and
- 15) standardized rtCGM/iCGM visualization.

# AGP Report

February 12, 2020 - February 25, 2020 (14 Days)

LibreView

## GLUCOSE STATISTICS AND TARGETS

February 12, 2020 - February 25, 2020 **14 Days**  
**% Time CGM is Active 95%**

Ranges And Targets For Type 1 or Type 2 Diabetes

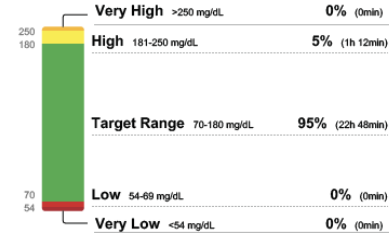
Glucose Ranges	Targets % of Readings (Time/Day)
Target Range 70-180 mg/dL	Greater than 70% (16h 48min)
Below 70 mg/dL	Less than 4% (58min)
Below 54 mg/dL	Less than 1% (14min)
Above 180 mg/dL	Less than 25% (6h)
Above 250 mg/dL	Less than 5% (1h 12min)

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

**Average Glucose 136 mg/dL**  
**Glucose Management Indicator (GMI) 6.6 %**  
**Glucose Variability 17.8%**

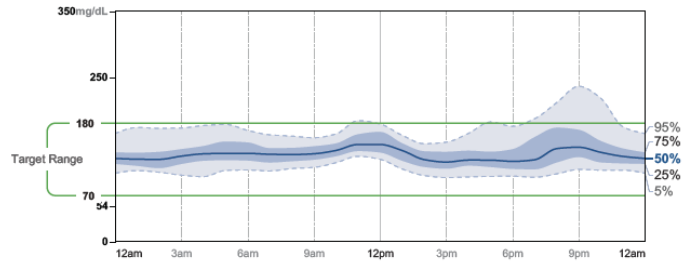
Defined as percent coefficient of variation (%CV); target ≤36%

## TIME IN RANGES



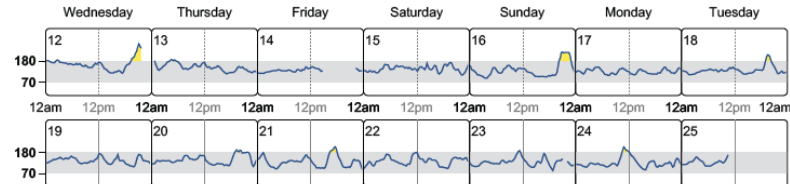
## AMBULATORY GLUCOSE PROFILE (AGP)

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.

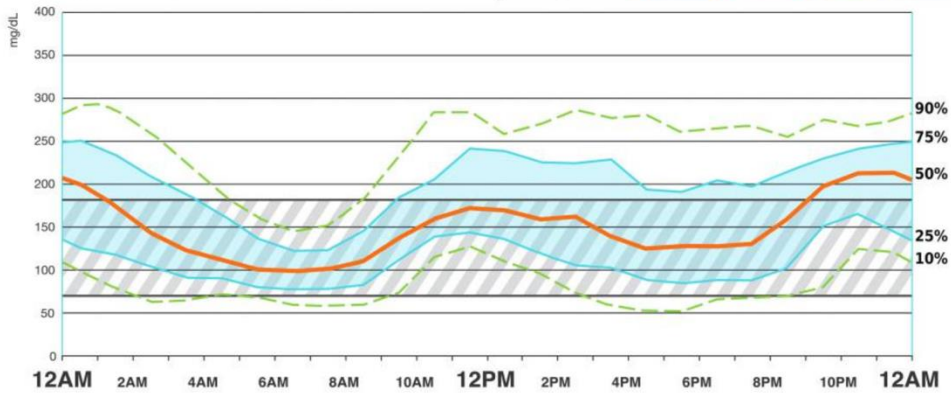


# capturAGP® Patient 3 (14.0 days)

<b>Avg Glucose</b> mg/dL <b>156</b> 88 - 116 *	<b>Estimated HbA1c</b> <b>7.0%</b> < 6 *	<b>Serious Low</b> Below 54 mg/dL <b>4.4%</b> 0 *	<b>Low</b> Below 70 mg/dL <b>10.1%</b> < 4 *	<b>In Target Range</b> 70 - 180 mg/dL <b>54.5%</b> > 90 *	<b>High</b> Above 180 mg/dL <b>35.4%</b> < 6 *	<b>Serious High</b> Above 250 mg/dL <b>11.3%</b> 0 *	<b>SD</b> mg/dL <b>72</b> 10 - 26 *	<b>Coefficient of Variation</b> <b>46.3%</b> 19.25 *	<b>% Time CGM Active</b> <b>70.6%</b>
GLUCOSE EXPOSURE		GLUCOSE RANGES		GLUCOSE VARIABILITY		GLUCOSE VARIABILITY		DATA SUFFICIENCY	

\* Reference ranges calculated from population without diabetes.  
Curves/plots represent glucose frequency distributions by time regardless of date.

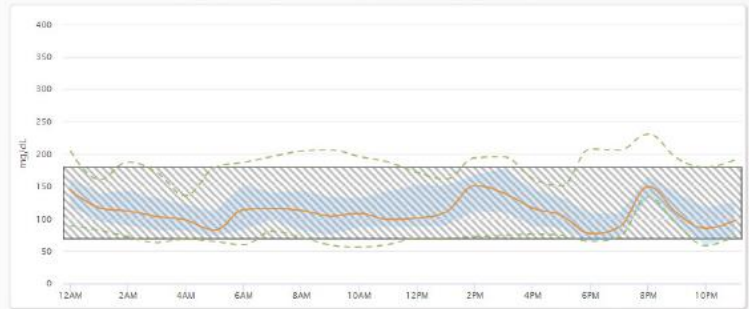
CGM  Data Point  50%-Median  25/75%-IQR  10/90%  Target Range



# eversense | capturAGP™

<b>Avg Glucose</b> mg/dL <b>124</b> 88 - 116 *	<b>Estimated HbA1c</b> <b>5.95%</b> < 6 *	<b>Serious Low</b> Below 54 mg/dL <b>3.7%</b> 0 *	<b>Low</b> Below 70 mg/dL <b>9.24%</b> < 4 *	<b>In Target Range</b> 70 - 180 mg/dL <b>70.84%</b> > 90 *	<b>High</b> Above 180 mg/dL <b>16.07%</b> < 6 *	<b>Serious High</b> Above 250 mg/dL <b>1.13%</b> 0 *	<b>Coefficient of Variation</b> <b>39.52%</b> 19.25 *	<b>SD</b> mg/dL <b>49</b> 10 - 26 *
GLUCOSE EXPOSURE		GLUCOSE RANGES		GLUCOSE RANGES		GLUCOSE VARIABILITY		GLUCOSE VARIABILITY

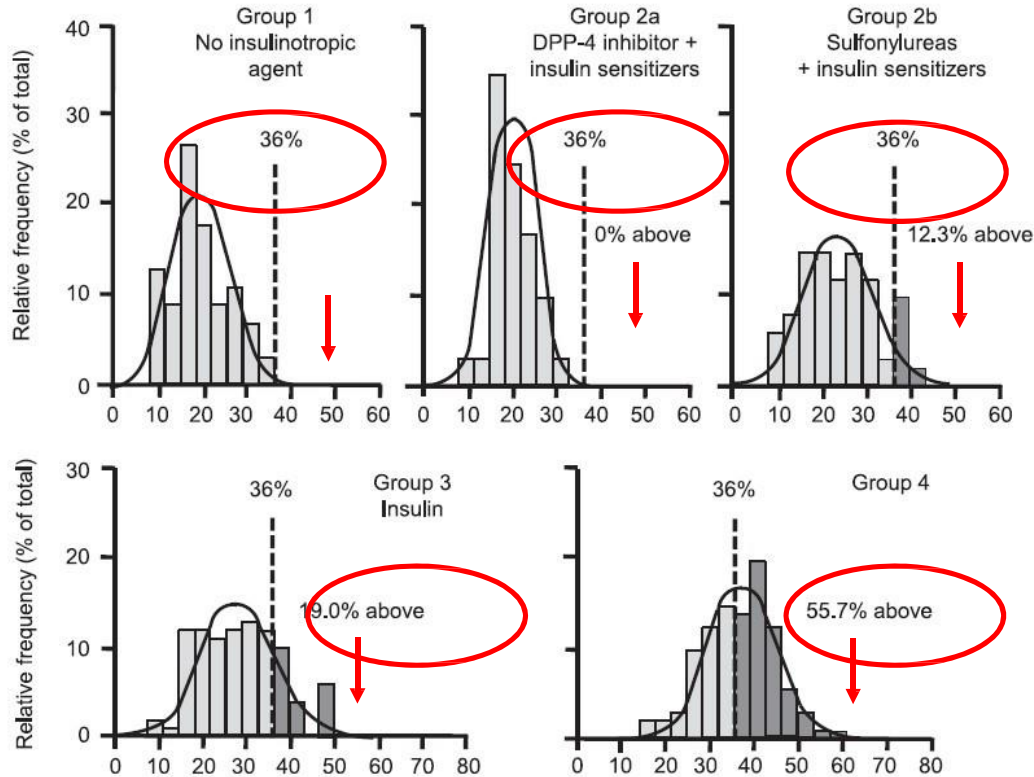
\* Reference ranges calculated from population without diabetes.  
Curves/plots represent glucose frequency distribution by time regardless of date.



## Daily Glucose Profile



# Metrics explained: CV and glycemic variability

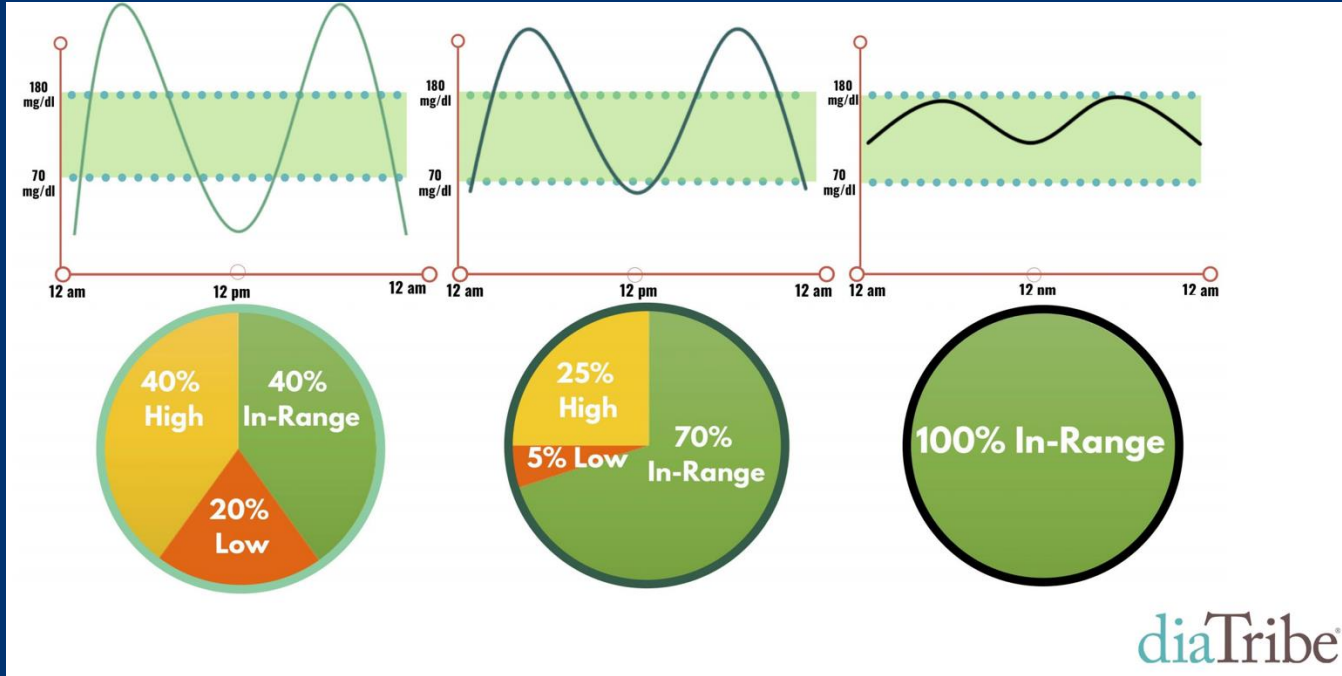


GV may be a better predictor for microvascular complications in T2D: ARIC study: high GV were 11 times more likely to have retinopathy 2x increased risk of incident chronic kidney disease compared with low GV.

A %CV of 36% appears to be a suitable threshold to distinguish between stable and unstable glycemia in diabetes because beyond this limit, the frequency of hypoglycemia is significantly increased, especially in insulin-treated subjects.

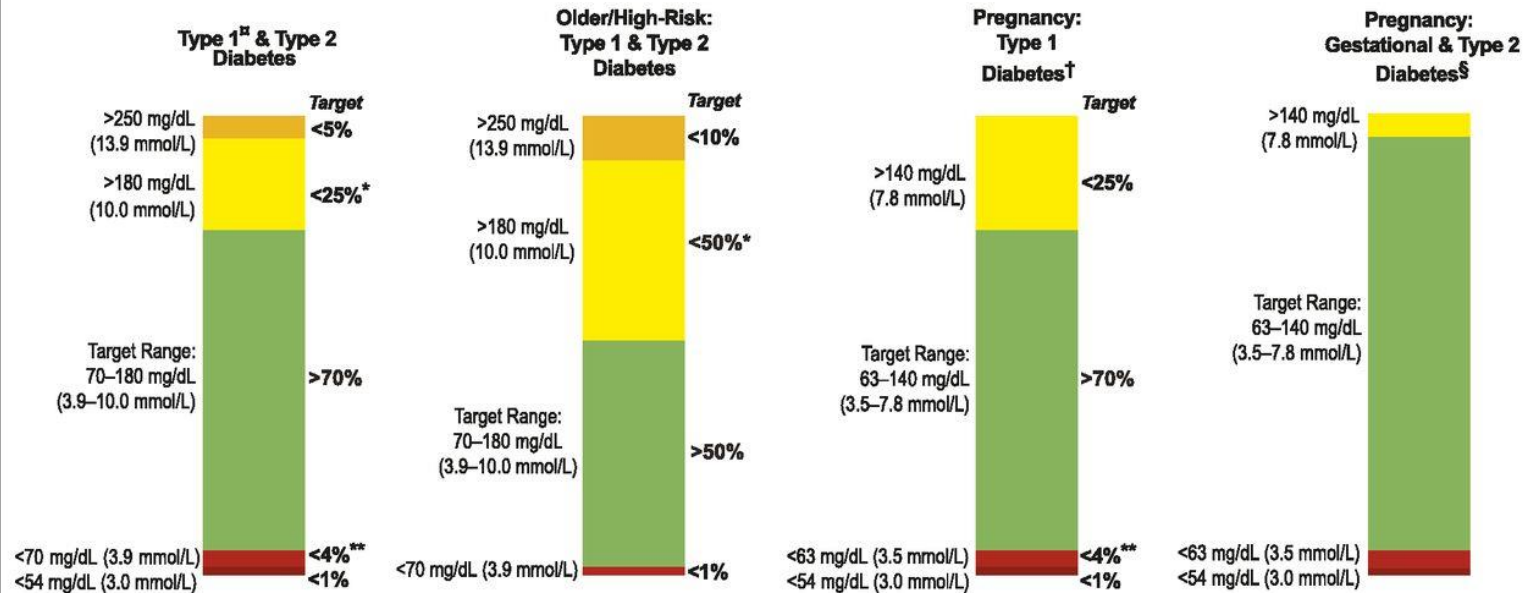
Diabetes Care 2017

# Metrics explained: Time in Range (A1c: 7.5%)





## CGM-based targets for different diabetes populations.



‡ For age <25 yr., if the A1C goal is 7.5%, then set TIR target to approximately 60%. (See *Clinical Applications of Time in Ranges* section in the text for additional information regarding target goal setting in pediatric management.)

† Percentages of time in ranges are based on limited evidence. More research is needed.

§ Percentages of time in ranges have not been included because there is very limited evidence in this area. More research is needed. Please see *Pregnancy* section in text for more considerations on targets for these groups.

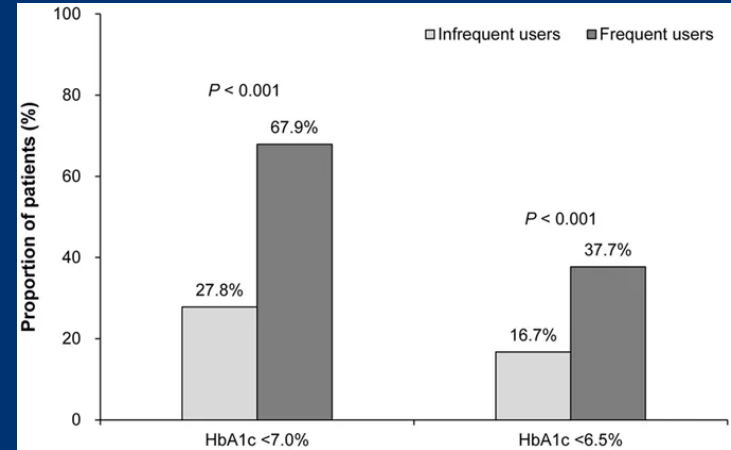
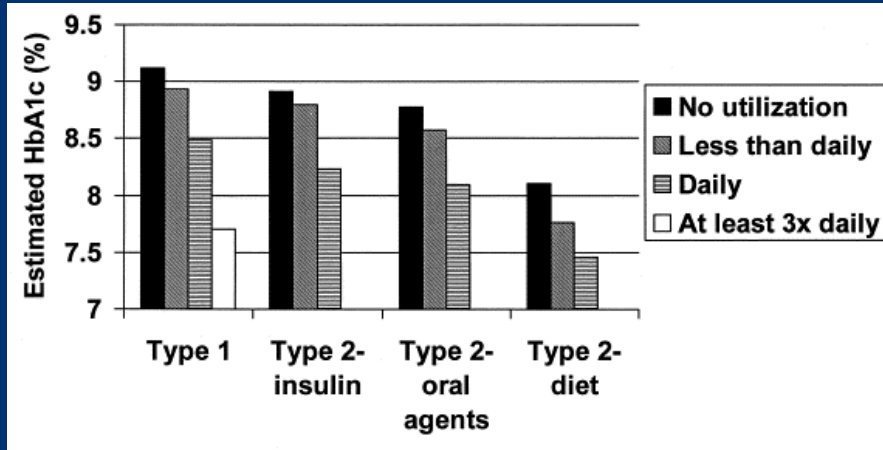
\* Includes percentage of values >250 mg/dL (13.9 mmol/L).

\*\* Includes percentage of values <54 mg/dL (3.0 mmol/L).



# What are the benefits of CGM?

## 1. High monitoring frequency



ADA Criteria 2017: 6-10 x daily SMBG → 67% of PWD do not adhere

**CGM measure glucose levels every 5 minutes**

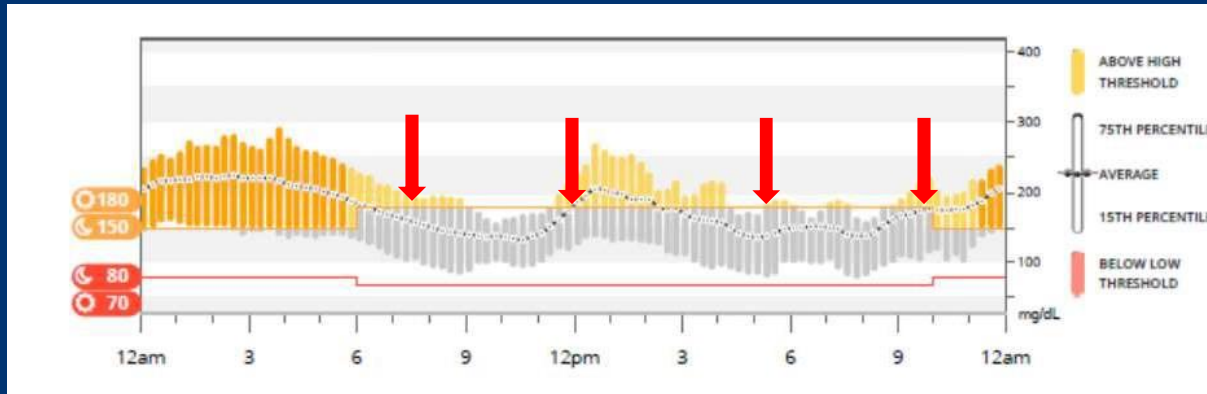
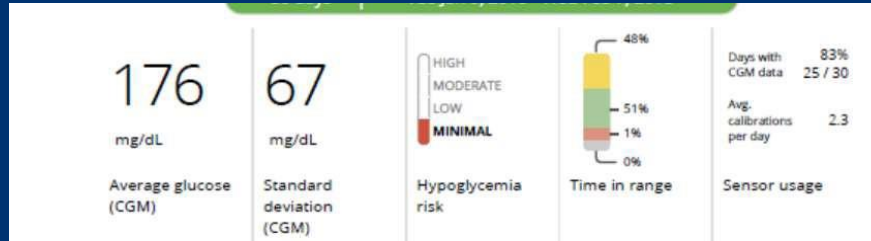
# What are the benefits of CGM?

## 2. See what's going on

68yoM

T2D on M + GLP1

A1c: 8.2%



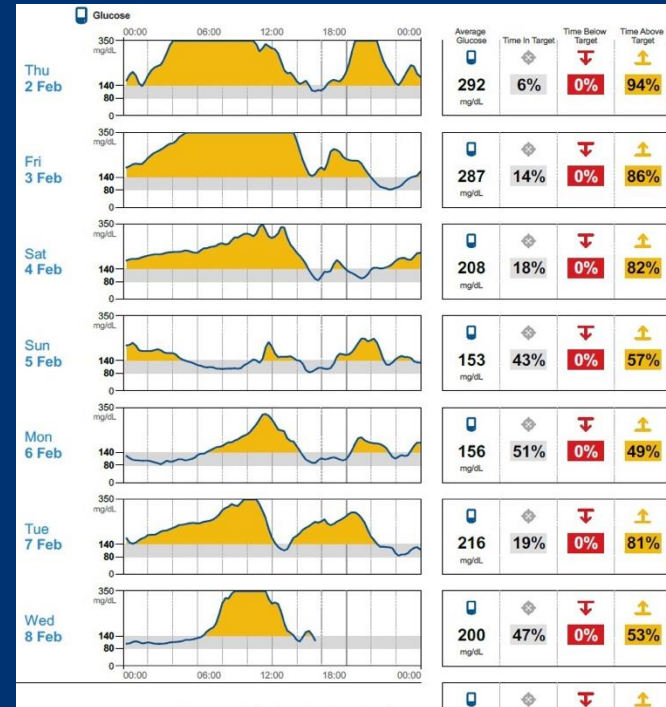
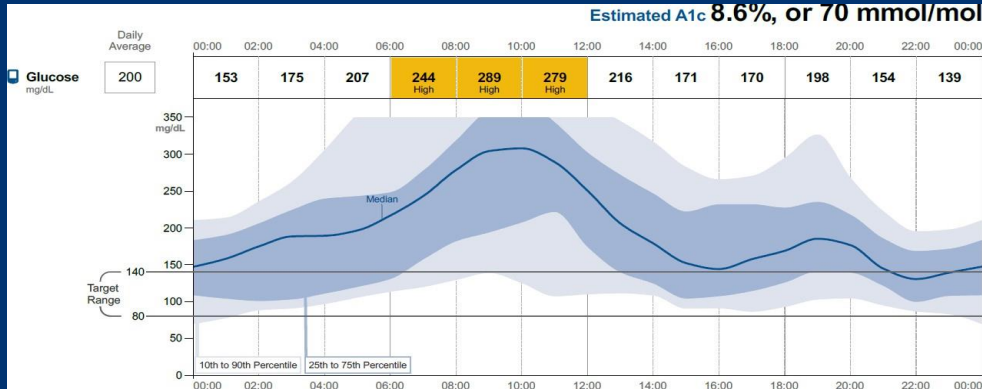
# What are the benefits of CGM?

## 3. Behavioral changes: understand and change

52yoM

T2D on Lantus, Metformin, GLP1a

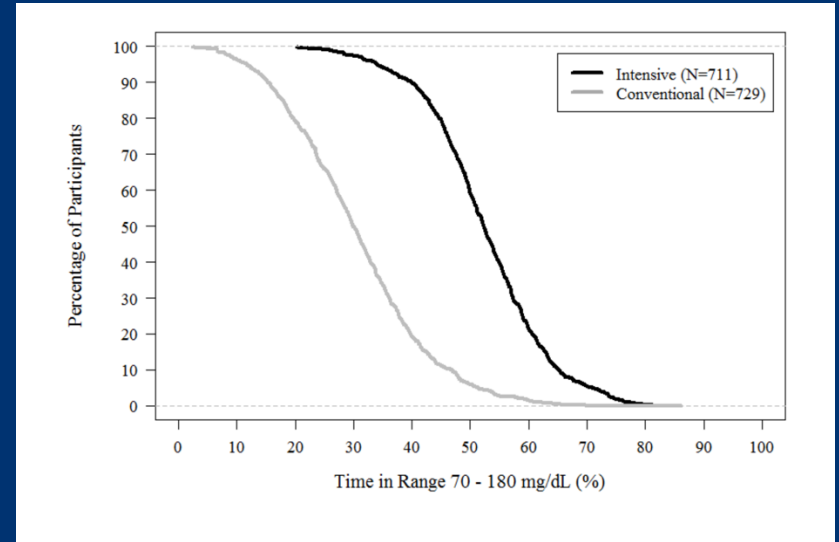
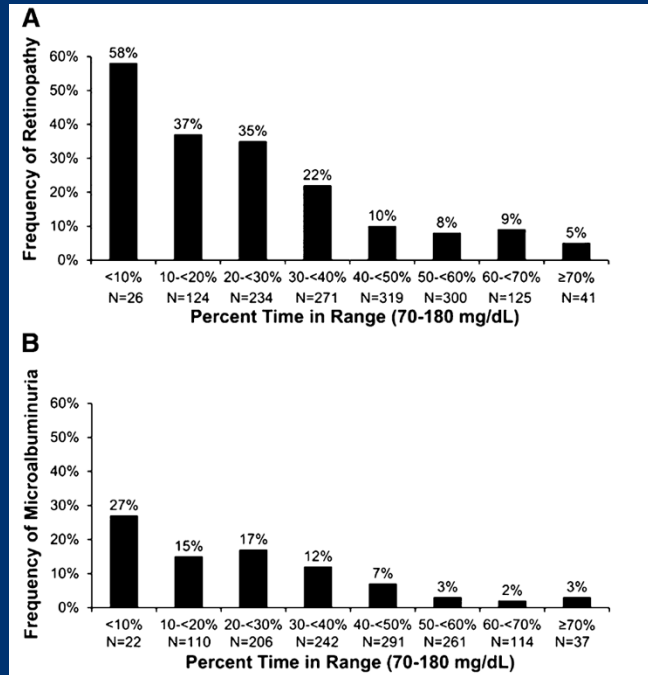
A1c: 8.8%



# What are the benefits of CGM?

4. Improved glycemic control (less hypo, hyper, variability)

→ Less complications



Extrapolated data from the DCCT. Beck RW, Diab Care2018

# Current Evidence Supports a Moderate Independent Effect of CGM on A1c Reduction

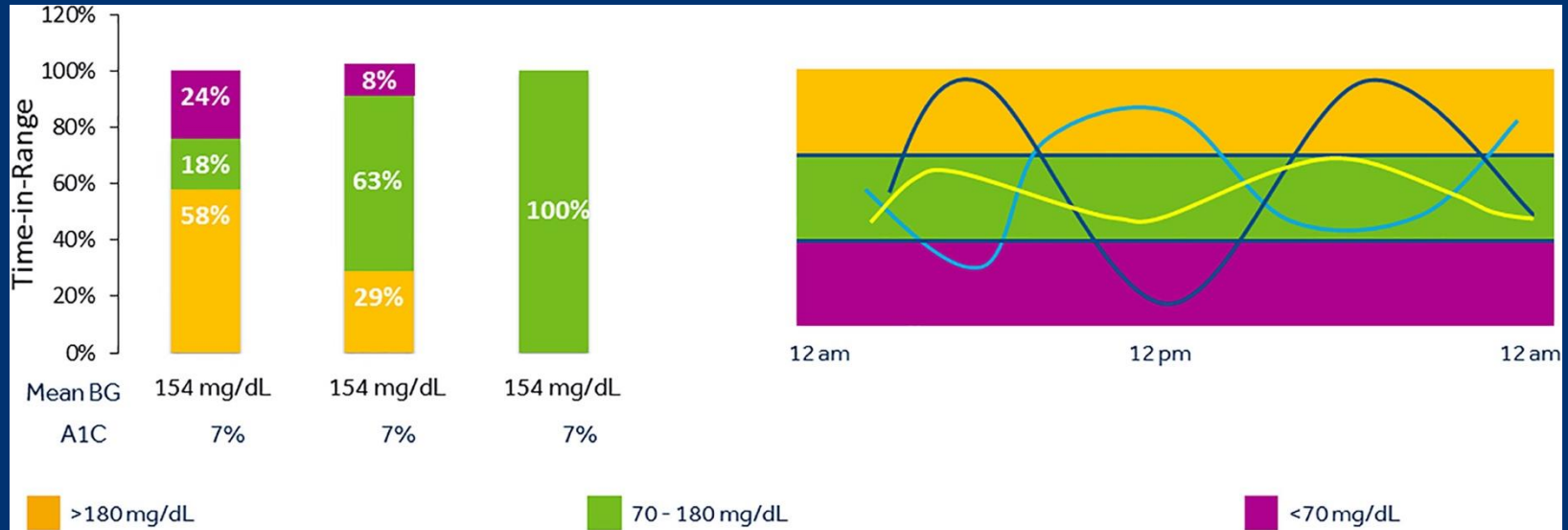
TABLE. Selected Randomized Clinical Trials of CGM <sup>15-22</sup>

Name (reference)	Population	Design	Goal(s)	Device(s)	Key Outcome(s)
DIAMOND Type <sup>15</sup>	T1D A1C 7.5%-9.9%	Randomized 2:1 to CGM (n = 105) or usual care (n = 53) for 24 weeks	A1C reduction	Dexcom G4	Between-group difference of 0.6 percentage points in favor of CGM (P < .001). Significant reduction in hypoglycemia in the intervention group.
DIAMOND Type 2 <sup>16</sup>	T2D A1C 7.5%-9.9%	Randomized 1:1 to CGM (n = 79) or usual care (n = 79) for 24 weeks	A1C reduction	Dexcom G4	Between-group difference of 0.3 percentage points in favor of CGM (P = .022).
GOLD <sup>17</sup>	T1D A1C $\geq$ 7.5%	Crossover CGM vs usual care; Randomized 1:1 to 26 weeks of CGM before (n = 82) or after (n = 79) 26 weeks of usual care	A1C reduction	Dexcom G4	Between-group difference of 0.43 percentage points in favor of CGM (P < .001). Significant reduction in hypoglycemia in the intervention group.
I HART CGM <sup>18</sup>	T1D GOLD score $\geq$ 4 or recent severe hypo	Randomized 1:1 to CGM (n = 20) or flash glucose monitoring (n = 20) for 8 weeks	Hypoglycemia reduction, CGM vs flash glucose monitoring	Dexcom G5, Abbott FreeStyle Libre	CGM reduces hypoglycemia more effectively than flash glucose monitoring.
HypoDE <sup>19</sup>	T1D History of impaired hypo awareness or severe hypo in past year	Randomized 1:1 to CGM (n = 75) or usual care (n = 74) for 26 weeks	Hypoglycemia reduction in high-risk individuals	Dexcom G5	Incidence of hypoglycemic events fell by 72% for CGM group (P < .0001).
Comisair <sup>20</sup>	T1D/MDI or CSII A1C 7.0%-10%	Nonrandomized: CGM (n = 27) or SMBG (n = 38) for 52 weeks	A1C and hypoglycemia reduction	Dexcom G4, Medtronic Enlite	Comparable reductions in A1C and hypoglycemia in CGM/MDI and CGM/CSII groups
IN CONTROL <sup>21</sup>	Adults T1D/MDI Impaired hypo awareness (Gold score $\geq$ 4)	Randomized crossover: CGM then SMBG (n = 26) or SMBG then CGM (n = 26)	Hypoglycemia reduction in high-risk individuals	Medtronic Enlite	Periods of CGM use associated with more TIR, less time in hypo- and hyperglycemia, fewer severe hypoglycemic events
CONCEPT <sup>22</sup>	T1D with existing or planned pregnancy	Parallel arms, to 34 weeks in pregnant women; for 24 weeks in those planning pregnancy	A1C reduction	Medtronic Guardian REAL-Time	Between-group difference of 0.19 percentage points in favor of CGM (P = .02) in pregnant women; no difference in women planning pregnancy. CGM group had fewer LGA babies, fewer ICU stays of >24 hours, and fewer neonatal hypoglycemia events

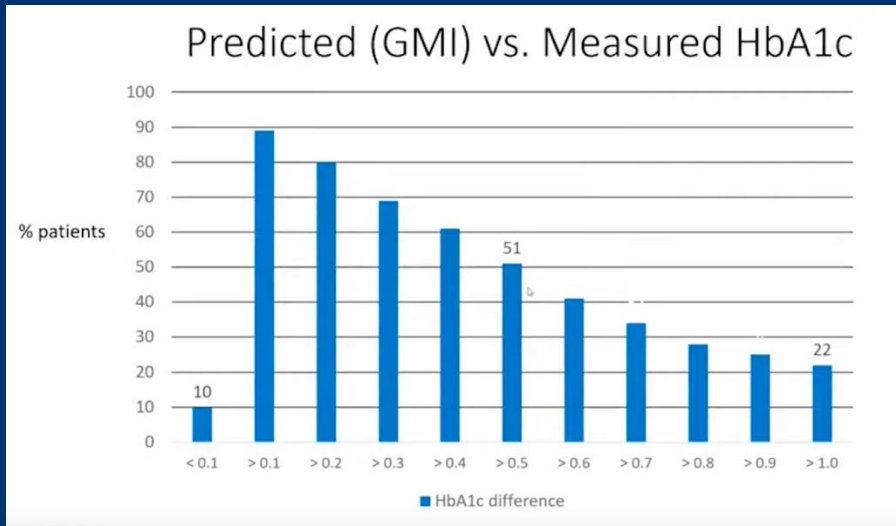
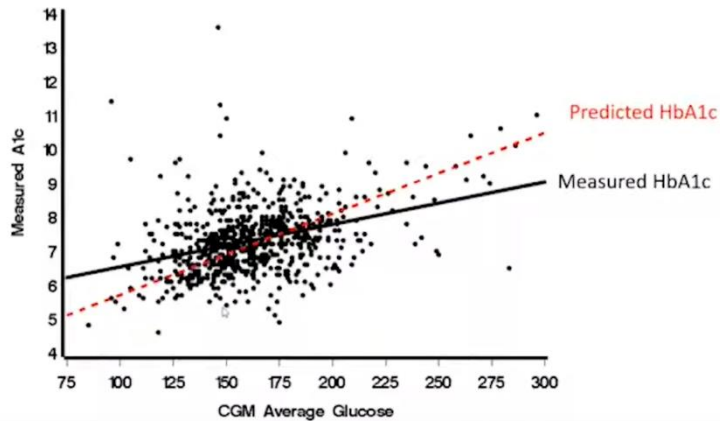
A1C indicates glycated hemoglobin; CGM, continuous glucose monitoring; CSII, continuous subcutaneous insulin infusion; ICU, intensive care unit; LGA, large for gestational age; MDI, multiple daily injections; SMBG, self-monitoring of blood glucose; T1D, type 1 diabetes; T2D, type 2 diabetes; hypo, hypoglycemia; TIR, time in range (70-180 mg/dL).

\*Dexcom G4 Platinum CGM System with an enhanced algorithm, Software 505, the same algorithm used in Dexcom G5

# BUT: Why HbA1c is a poor metric (and study end point) especially in PwT2D

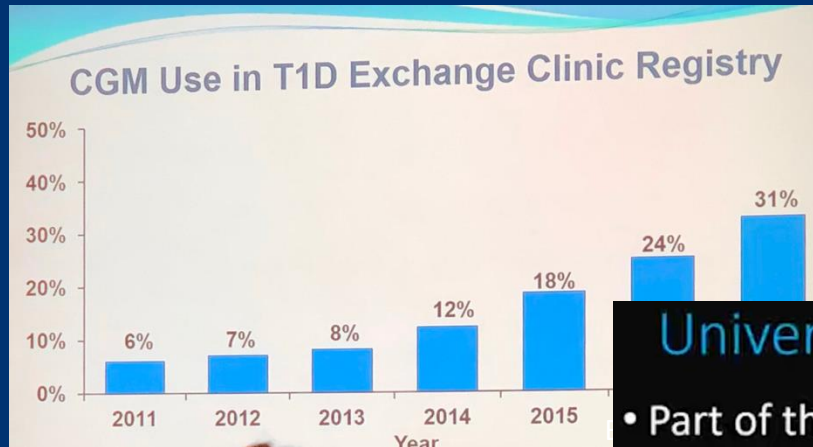


N = 717



# Current state of CGM use and possible barriers

- 3 of 4 potential candidates for CGM don't use it (T1D exchange data)
- Of those who try it, nearly 1/3 quit within a year
- many of those who continue don't wear it as often as prescribed (<50%)
- CGM use in PwT2D on OAD is sporadic at best (UW numbers are terrific exceptions)



## University of Washington Diabetes Institute

- Part of the T1D Exchange (close to 600 in the T1D Ex)
- As of January 2020: CGM use 80-95% in type 1's, 25-33% in type 2's using insulin.

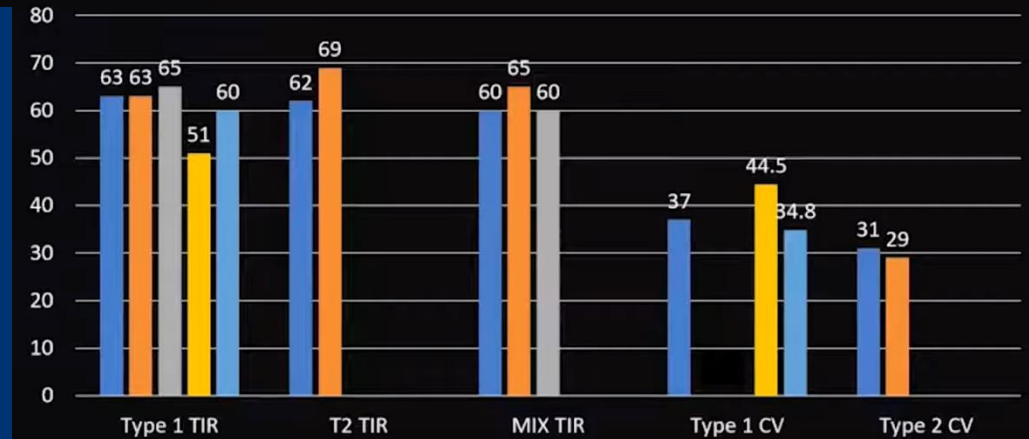


# Current state of CGM use and possible barriers

	CKD (N = 81, eGFR 38)	Control T2D (N = 24)
TIR (%)	62 ± 23	69 ± 22
CV (%)	31 ± 6	29 ± 7
GMI (%)	7.4 ± 1.0	7.1 ± 0.7
HbA1c (%)	7.8 ± 1.6	8.0 ± 1.5

## A Look at Real-World TIRs/CVs

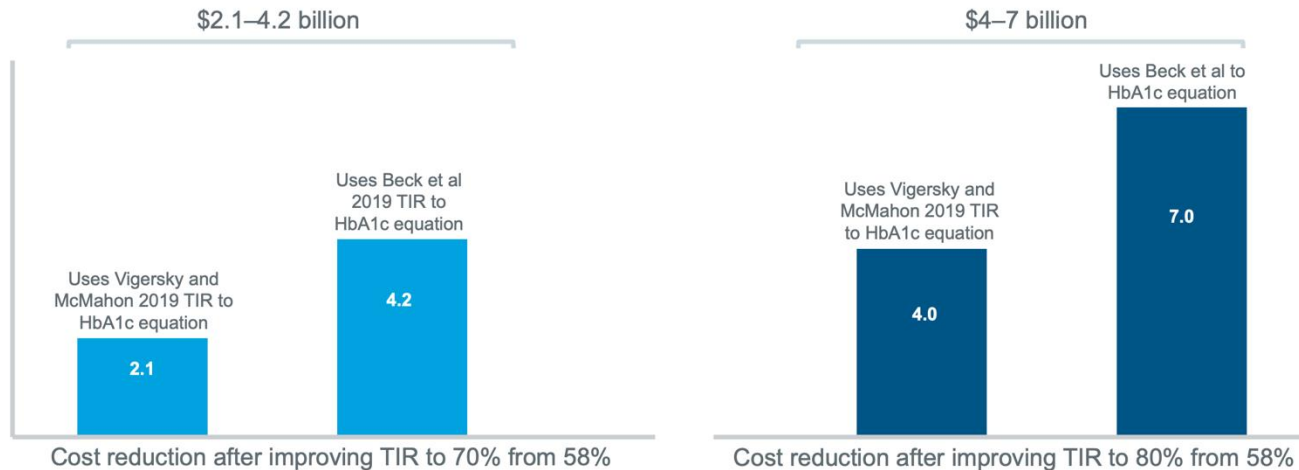
*BMJ Open Diab Res Care*  
2020;8:e000991. doi:10.1136/



Hirsch I, ATTD

# Potential impact of CGM on the cost of T2D

## 10-year cost reduction by improving TIR in people with Type 1 and Type 2 Diabetes to 70% and 80%, US\$Bn



Cost reduction after improving TIR to 70% from 58%

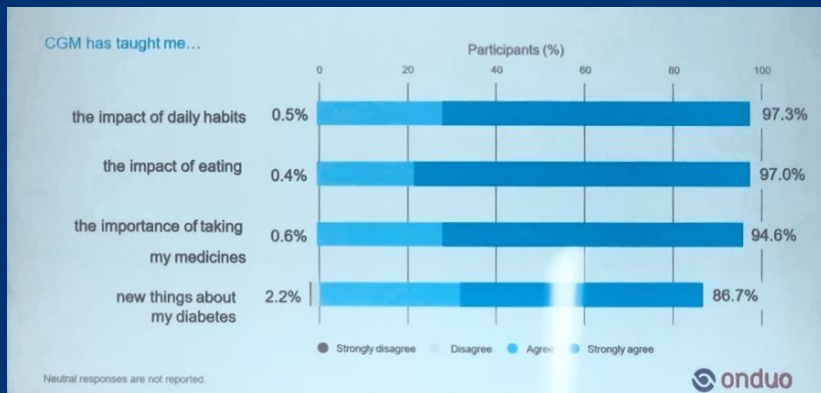
Severe vision loss	9.12	7.99 – 8.44	7.55 – 8.00
Amputation	3.96	3.73 – 3.82	3.57 – 3.73

Cost reduction after improving TIR to 80% from 58%

Severe vision loss	5.18	4.78 – 4.98	4.56 – 4.83
Amputation	1.00	0.97	0.95-0.96

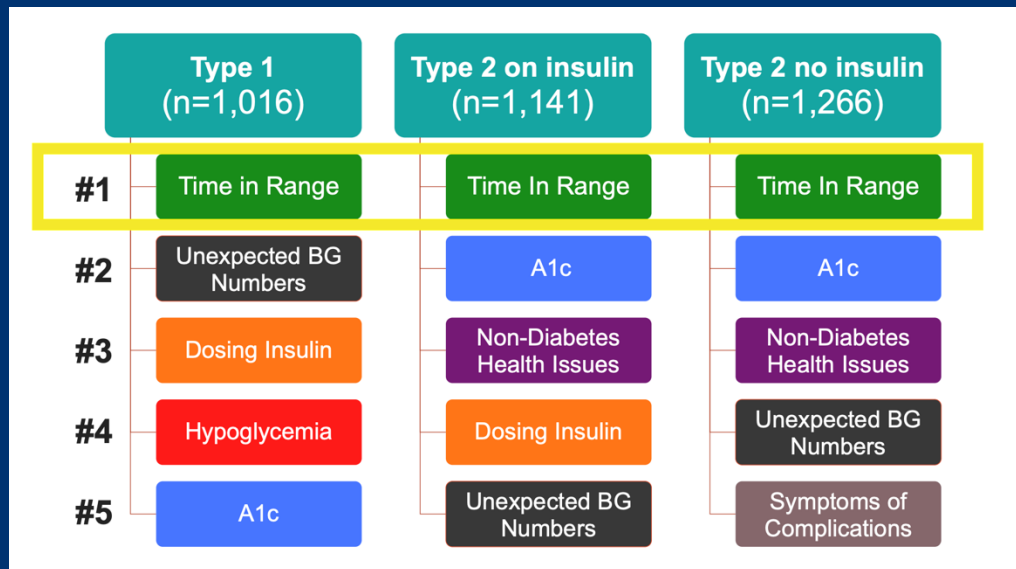
# Added value of CGM use beyond hard metrics

## Does Time-in-Range Matter? Educational Value of CGM Data



Bergenstal, ATTD 2020

## Does Time-in-Range Matter? Perspectives From People With Diabetes in the Success of Current Therapies and the Drivers of Improved Outcomes



Gopisetty, *Clin Diabetes*. 2018

## What would be the IDEAL CGM for PwT1D (and PwT2D on IIT)?

- Size of the Freestyle Libre
- On body transmitter vibration of the Eversense
- No mandatory calibrations (Dexcom G6)
- Optional calibrations possible
- Smart Guard from Enlite
- iSugr app
- Less waste



## What would be the IDEAL CGM for PwT2D on OAD?

- Intermittent use of professional version
- Blinded or unblinded
- No alarms
- Learning experience rather than immediate effect
- Understand impact of interventions



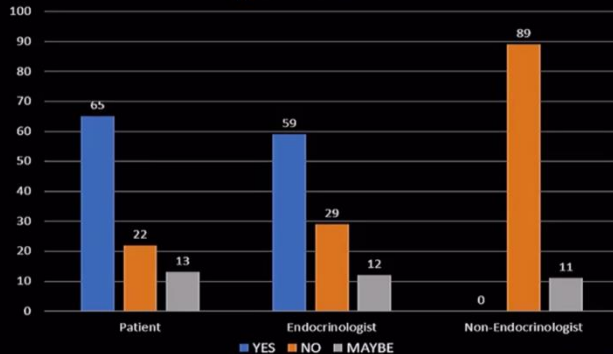
# Barriers to the implementation of CGM

In December, 2018 a 3-question survey was sent to about 100 health-care providers with 3 questions regarding moving to TIR from A1C:

## Who Answered the 3-Questions Survey



## Are Patients, Endocrinologists, or Non-Endocrinologists Ready To Change From A1C To TIR?



- Lack of clear guideline recommendations
- Insufficient clinical evidence demonstrating the value of CGM
- Insufficient real-world experience with CGM
- Uncertainty about which patients are appropriate for CGM
- System-level barriers/inertia to changing current practices
- Classification under the medical benefit category

# Conclusions

- Type 2 Diabetes is extremely undertreated with much “softer” targets than T1D
- CGM has the potential to change this tremendously:
  - lower A1C (Beck 2019; Vigersky 2019);
  - lower probability of developing microvascular complications such as retinopathy (eye damage) and nephropathy (Beck 2019; Lu 2018);
  - Lower risk for heart disease and stroke (Lu 2019);
  - Improvements in the health of babies born to women with diabetes (Kristensen 2019; Feig 2017)
  - Direct measure rather than estimate (surrogate)
  - High patient satisfaction
  - Tool for behavioral change
  - **Facilitate virtual visits → higher adherence**

# How to Remove Barriers to the implementation of CGM in T2D and prediabetes

- Radically change the way we think about CGM metrics (TIR, CV) for blood glucose management (not a replacement for A1C!)
- Increase awareness of the benefits of time in range and CGM among PwT2D and primary care providers.
- Educate governing bodies, payers, and industry worldwide about “time in range”.



# How to Remove Barriers to the implementation of CGM in T2D and prediabetes

- Identify populations within PwT2D that would benefit immediately from CGM technology (post TX, impatient)
- Push CGM use and pick low hanging fruit: PwT2D on insulin, people in clinical trials, post TX, intermittently for every T2D
- Emphasize the role of CGM and data download for the wide implementation of telemedicine: **better and closer patient care becomes possible**

# How to Remove Barriers to the implementation of CGM in T2D and prediabetes

- Facilitate access to technology
- Lower cost of CGM, lower paperwork burden
- Simplify operation (listen to patient needs)
- Help create “big picture” – integrate CGM data, diet, weight, labs to help make “sense”
- Guidance for patients on how to make best therapeutic decisions based on CGM data (teachin modeules, “SPECTRUM”)
- CGM is as good at improving glycemic control as scales are at lowering weight



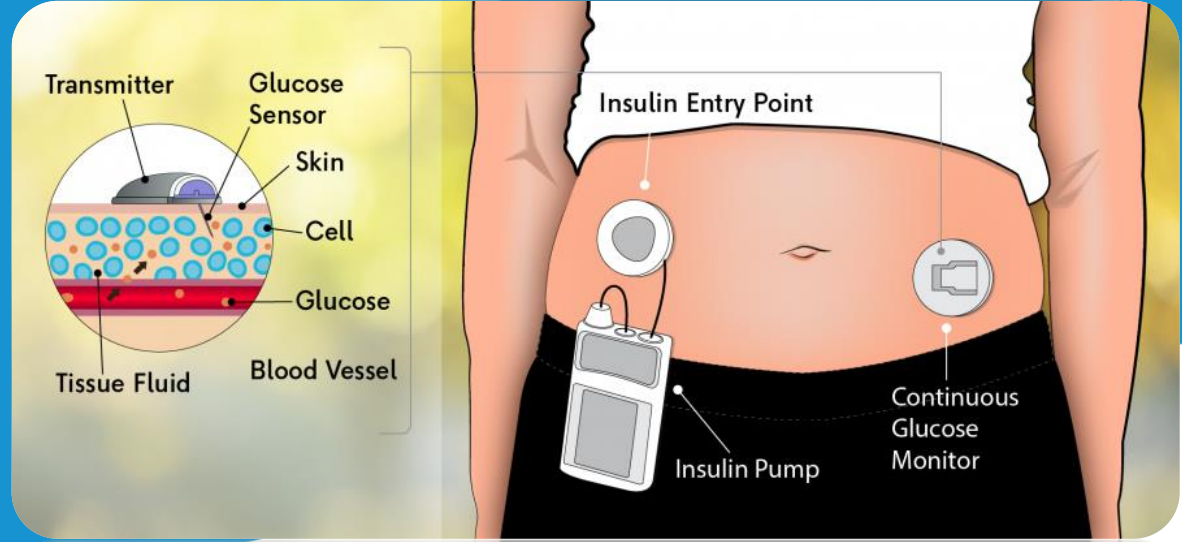
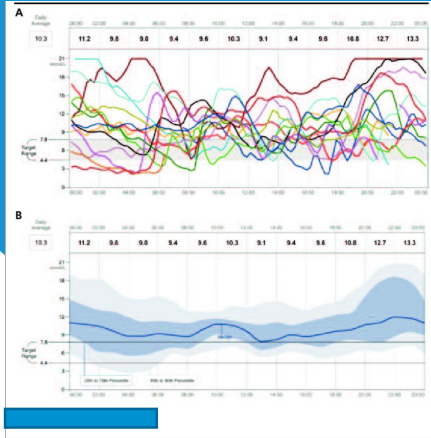


# Discussion:

- Current State
- Approaches
- Examples
- Overcoming barriers
- Future state



# CGMS



Geisinger

# Challenges created

## Information Overload

- 1-4 data points daily has become hundreds
- How do we interpret this data until AI can step in?
- How do we teach patients to interpret data?



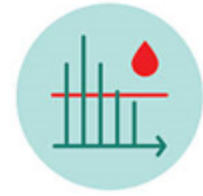
## Different View of the data

- Point in time glucose becomes fluid
- Time in Range can be seen and calculated
- How does it relate to A1C



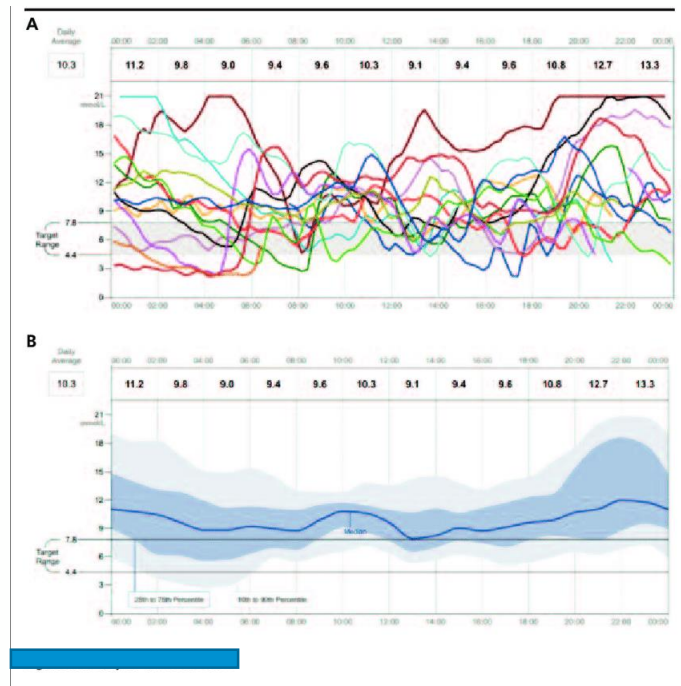
## Inefficient work flows

- How do patients report?
- What do they report?
- Time limited in visits
- How to remain efficient and meaningful



# The Past becomes the Future

DATE	BLOOD GLUCOSE TEST RESULTS									COMMENTS Dietary, Ketones Activities, Illness etc.
	Breakfast		Lunch		Dinner		Bed-Time	Over-Night		
	Before	After	Before	After	Before	After				
Sunday	Time									
	BG	155	103	112	142	199	178	197		walk
	Insulin									
Monday	Time									busy day
	BG	193	176			171				missed lunch afternoon snack
	Insulin									
Tuesday	Time									sick today
	BG	236		59	249	324	145			missed work SICKNESS!
	Insulin									
Wednesday	Time									lunch out
	BG	126	111		208					pizza/salad
	Insulin									
Thursday	Time									
	BG	104			234			118		
	Insulin									
Friday	Time									spaghetti, bread, cheese cake
	BG	121	142		332	289	403	451		
	Insulin									
Saturday	Time									
	BG	257			144			228		
	Insulin									





# Seeing the trees... and overcoming barriers



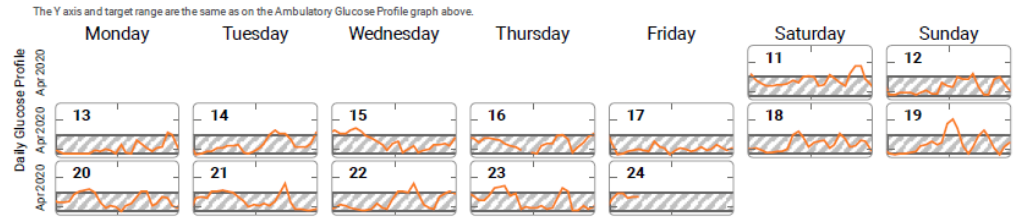
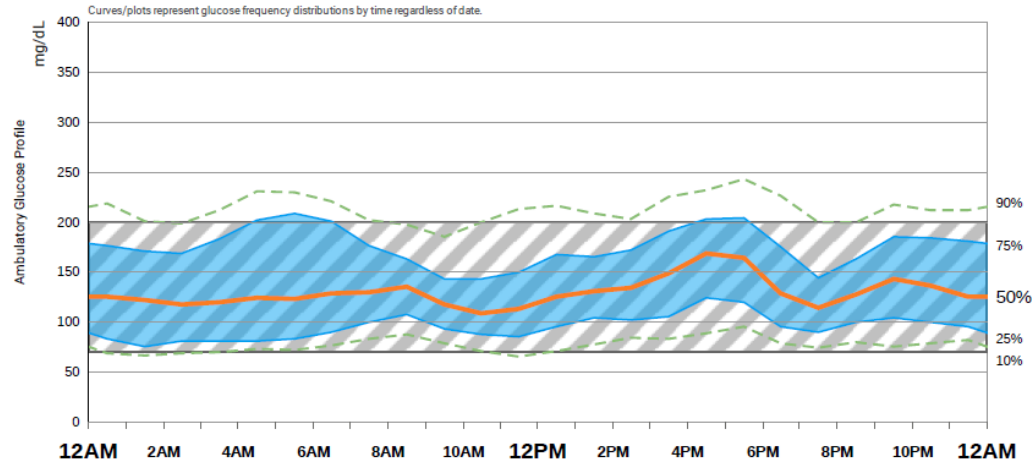
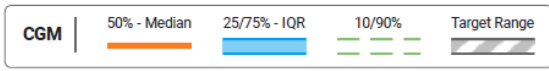
- **Assess compliance**
  - **How much is the patient using it?**
- **Start global and zoom in**
  - **The 10000 ft overlay**
  - **TIR data – the new “A1c”**
  - **Daily trends to find targets of discussion**
- **Set realistic goals**
  - **5% change in TIR is clinically significant**



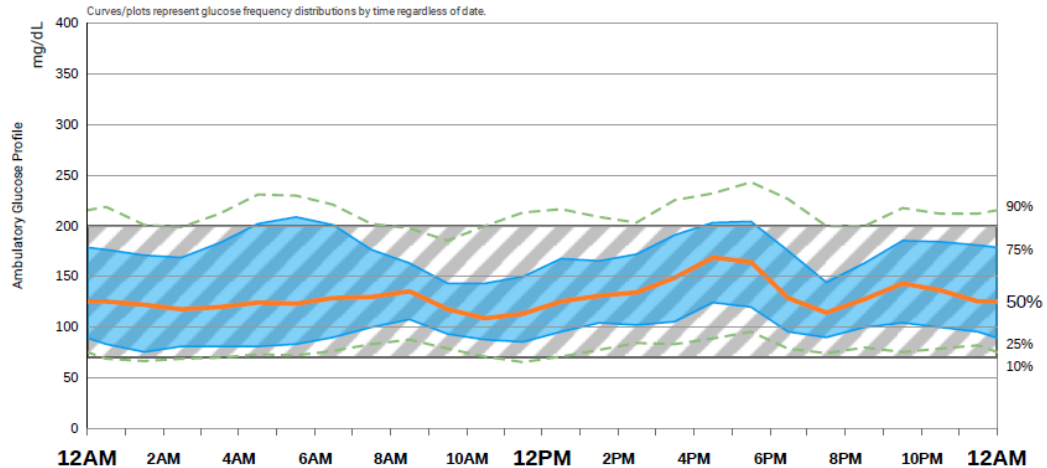
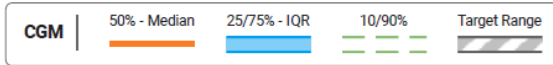
Glucose Statistics	Avg Glucose mg/dL	Very Low	Low	In Target Range	High	Very High	Coefficient of Variation	SD mg/dL	% Time CGM Active
	138 Glucose Exposure	< 54 mg/dL	< 70 mg/dL	70 - 200 mg/dL	> 200 mg/dL	> 250 mg/dL			



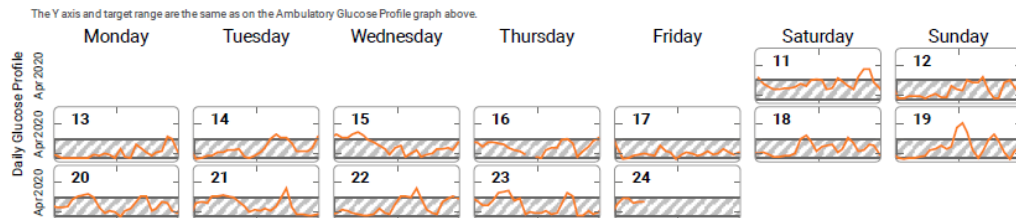
Time of use  
>70%



Glucose Statistics	Avg Glucose mg/dL	Very Low	Low	In Target Range	High	Very High	Coefficient of Variation	SD mg/dL	% Time CGM Active
	138 Glucose Exposure	< 54 mg/dL 0.2%	< 70 mg/dL 6.2%	70 - 200 mg/dL 77.5%	> 200 mg/dL 16.3%	> 250 mg/dL 2.6%			
Glucose Ranges						Glucose Variability		Data Sufficiency	



Overall pattern  
Start overnight  
Look meal to meal

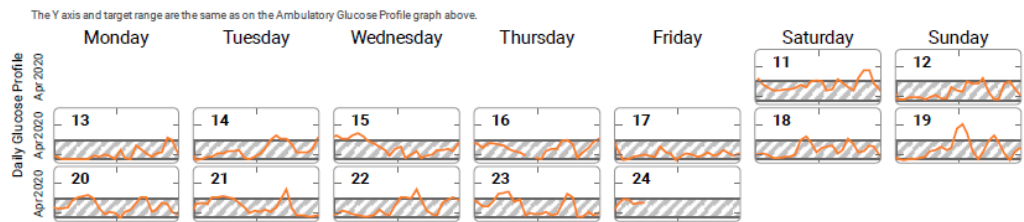
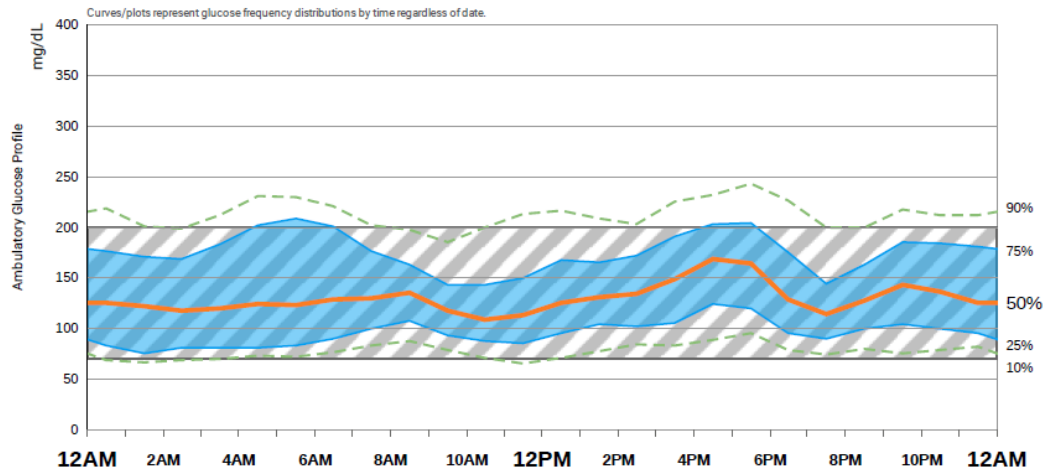


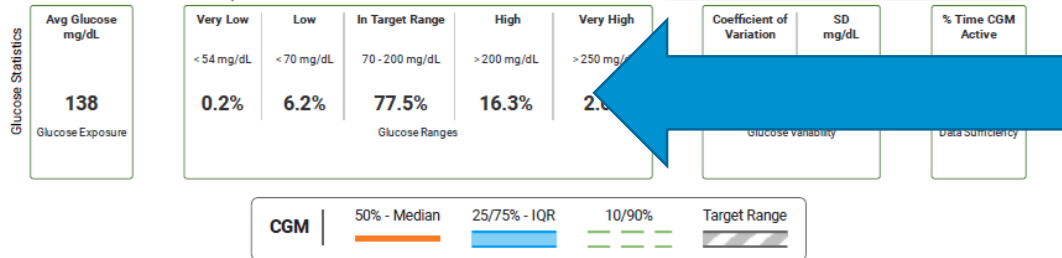
Glucose Statistics	Avg Glucose mg/dL	Very Low	Low	In Target Range	High	Very High	Coefficient of Variation	SD mg/dL	% Time CGM Active	
	138	< 54 mg/dL	< 70 mg/dL	70 - 200 mg/dL	> 200 mg/dL	> 250 mg/dL				39.0%
Glucose Exposure		Glucose Ranges					Glucose Variability		Glucose Efficiency	



CGM | 50% - Median | 25/75% - IQR | 10/90% | Target Range

Time in Range/Variability





Time in Range  
A1c Equivalent

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

**Table 5—Estimate of A1C for a given TIR level based on type 1 diabetes and type 2 diabetes studies**

Beck et al. (26) (n = 545 participants with type 1 diabetes)			Vigersky and McMahon (27) (n = 1,137 participants with type 1 or type 2 diabetes)	
TIR 70–180 mg/dL (3.9–10.0 mmol/L)	A1C, % (mmol/mol)	95% CI for predicted A1C values, %	TIR 70–180 mg/dL (3.9–10.0 mmol/L)	A1C, % (mmol/mol)
★ 20%	9.4 (79)	(8.0, 10.7)	20%	10.6 (92)
★ 30%	8.9 (74)	(7.6, 10.2)	30%	9.8 (84)
★ 40%	8.4 (68)	(7.1, 9.7)	40%	9.0 (75)
★ 50%	7.9 (63)	(6.6, 9.2)	50%	8.3 (67)
★ 60%	7.4 (57)	(6.1, 8.8)	60%	7.5 (59)
★ 70%	7.0 (53)	(5.6, 8.3)	70%	6.7 (50)
★ 80%	6.5 (48)	(5.2, 7.8)	80%	5.9 (42)
★ 90%	6.0 (42)	(4.7, 7.3)	90%	5.1 (32)
Every 10% increase in TIR = ~0.5% (5.5 mmol/mol) A1C reduction			Every 10% increase in TIR = ~0.8% (8.7 mmol/mol) A1C reduction	

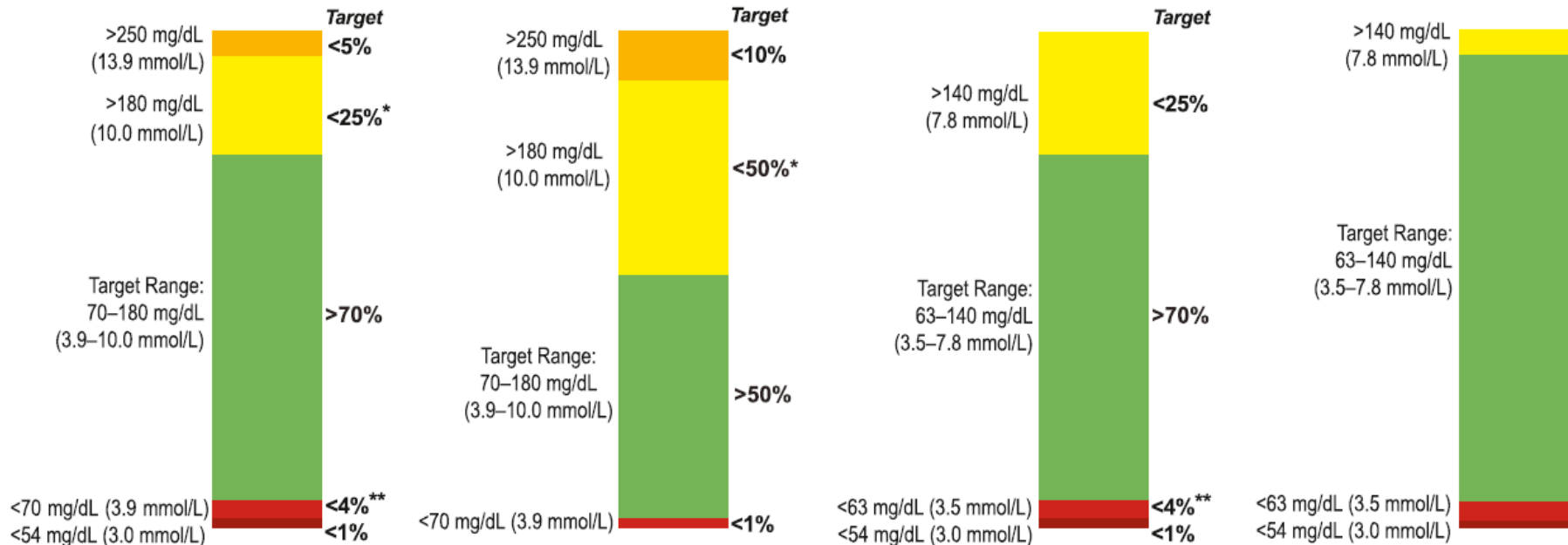
The difference between findings from the two studies likely stems from differences in number of studies analyzed and subjects included (RCTs with subjects with type 1 diabetes vs. RCTs with subjects with type 1 or type 2 diabetes with CGM and SMBG).

### Type 1<sup>†</sup> & Type 2 Diabetes

### Older/High-Risk: Type 1 & Type 2 Diabetes

### Pregnancy: Type 1 Diabetes<sup>†</sup>

### Pregnancy: Gestational & Type 2 Diabetes<sup>§</sup>



▣ For age <25 yr., if the A1C goal is 7.5%, then set TIR target to approximately 60%. (See *Clinical Applications of Time in Ranges* section in the text for additional information regarding target goal setting in pediatric management.)

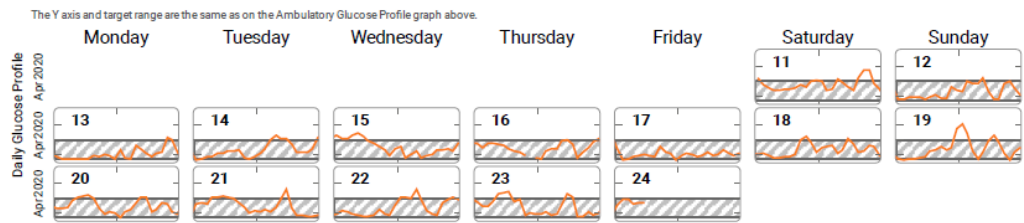
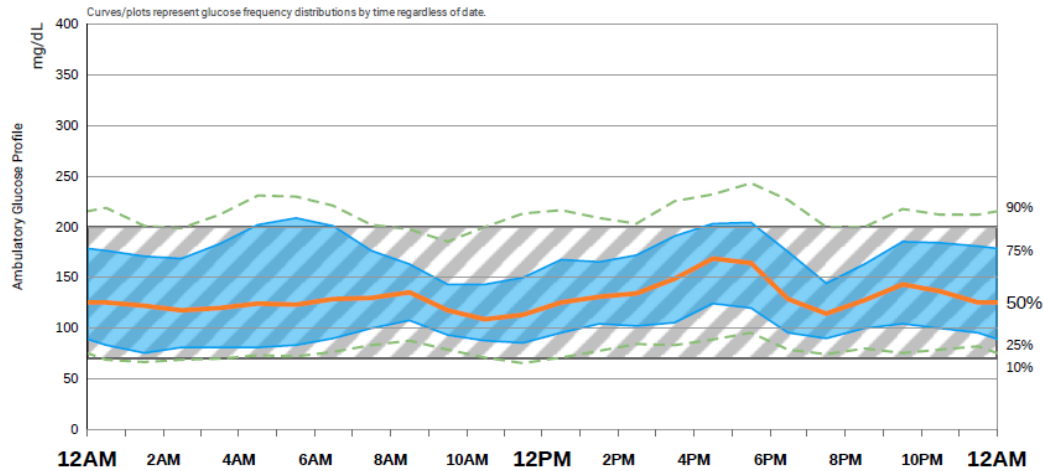
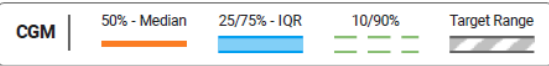
† Percentages of time in ranges are based on limited evidence. More research is needed.

§ Percentages of time in ranges have not been included because there is very limited evidence in this area. More research is needed. Please see *Pregnancy* section in text for more considerations on targets for these groups.

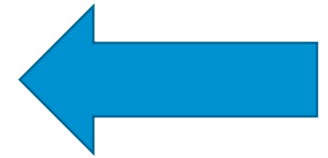
\* Includes percentage of values >250 mg/dL (13.9 mmol/L).

\*\* Includes percentage of values <54 mg/dL (3.0 mmol/L).

Glucose Statistics	Avg Glucose mg/dL	Very Low	Low	In Target Range	High	Very High	Coefficient of Variation	SD mg/dL	% Time CGM Active
	138 Glucose Exposure	< 54 mg/dL 0.2%	< 70 mg/dL 6.2%	70 - 200 mg/dL 77.5%	> 200 mg/dL 16.3%	> 250 mg/dL 2.6%			
Glucose Ranges						Glucose Variability		Data Sufficiency	



Drill down to specific dates to target specific interventions



# If I had a wish...



- **Glucose data becomes an active population management tool**
- **Universal Insurer acceptance of standard of care**
- **Secure HIPAA Compliant data transfer and sharing**
- **EMR interoperability regardless of platform**
- **Leverage technology available (Bluetooth, wifi, cellular, future means)**
- **Real time cost saving (ROI analysis)**



# If I had a wish...



- **Use information to develop 24/7 precision medicine tool**
- **Direct to provider alerts for outlier data points**
- **Simplified recommendations based on algorithms straight to consumer**
- **Bluetooth / text “reminders” for patients**
- **Chatbots (real time practitioners)**
- **Single sign on**
- **Biometric capabilities**
- **Care Team Connectivity**
- **Maximize present use**

# Summary

- 📊 Organize data meaningfully
- 🔧 Industry adopted standards
- ✓ Accepted practices
- 📄 Definitions for data integrity
- ₿ Payor buy-in
- ⊕ Patient practice
- 🐎 The sky is the limit



*CGM and Diabetes Technology: Closing the Gap  
so that Patients can Benefit*

**Tom Martens MD FACP**

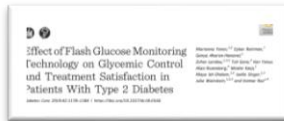
Medical Director, International Diabetes Center, HealthPartners  
Institute

Consultant, Department of Internal Medicine, Park Nicollet Health  
Services

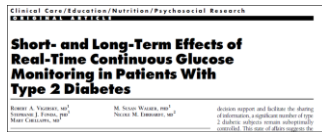
Minneapolis MN, USA

# Identifying patient populations with T2D who benefit most from diabetes technology: What does literature say?

## CGM use either improves A1C or decreases time in hypoglycemia in individuals with T2D on multiple daily dose insulin



## CGM use improves A1C for individuals with T2D on basal insulin

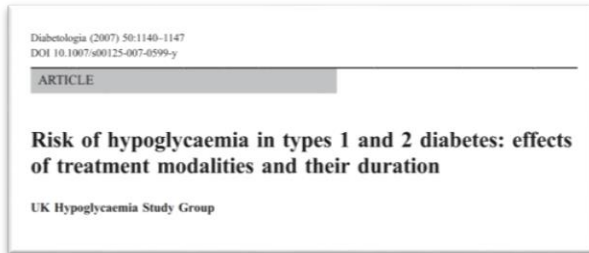


## Non-insulin therapies: Intriguing small and older studies, lots of interest, level of evidence suboptimal

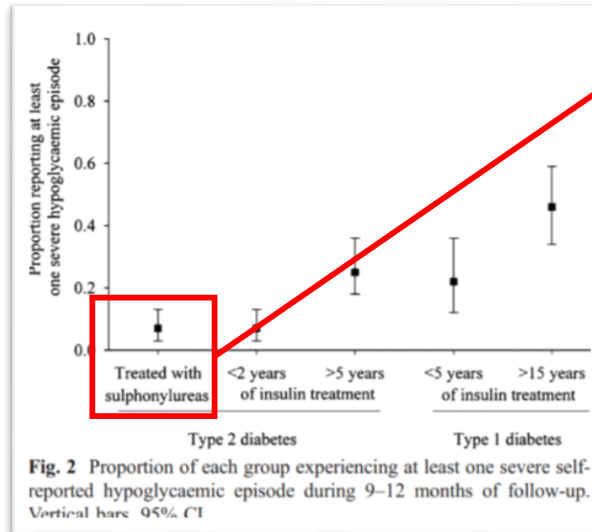
\*compared to SMBG testing

# Identifying patient populations who benefit most from Diabetes Technology: What does literature say?

Hypoglycemia is relatively common in T2D in individuals on therapies predisposing to hypoglycemia (insulin and sulfonylurea therapy); CGM may identify nocturnal hypos better than BGM



UK Hypoglycaemia Study Group. Risk of hypoglycaemia in types 1 and 2 diabetes: effects of treatment modalities and their duration. *Diabetologia*. 2007;50(6):1140-1147.



7% of individuals using sulfonylureas reported an episode of severe hypoglycemia over 9-12 months of study

# Who in T2D would benefit from CGM and Diabetes Technology?

## Bottom line from literature (research-based):

- T2D on multiple daily dose insulin (MDI): fairly strong evidence, analogous to T1D
- T2D on background insulin: Probably yes
- T2D on sulfonylurea therapy: Probably improved safety margin (hypoglycemia)- improved safety not yet directly demonstrated in literature
- Non-insulin therapies, lifestyle based management: Maybe

How does that translate into optimizing care in a real-world primary care setting?

- Answer will depend on our success in managing variables not present in clinical research studies
- Potential to benefit a significant portion of individuals with T2D in a primary care practice, but only if issues of cost and availability, training for clinicians and people with diabetes, and data availability can be addressed.

# Initial Work: 2018

QI Project: Using professional CGM on glucose management in a primary care setting

- Why professional CGM? First on the market with no calibration, disposable sensor
- Two deployment models within our existing primary care team
  - MD model
  - RN and Certified Diabetes Educator (CDE) model, teamed with clinician
- Setting: IM practices at 2 Park Nicollet Clinic sites

Inclusion criteria for quality improvement project:

- Diagnosis of T2D for >1 year
- Most recent A1C  $\geq 7.0$  and  $< 11.0\%$
- Managed with any regimen
- Willingness to use pCGM

2 wk professional CGM, clinician or CDE visit to review data

- Intervention as appropriate
- Follow-up in 3 months for A1c
- Repeat CGM in a subset
- (usual care in interim)



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*International Diabetes Center*

# Real-world perspective: Who struggles the most meeting glycemic goals in T2D?

## Insulin-treated individuals?

- Insulin therapy requires active titration to meet goals
- Insulin therapy carries the highest risk of hypoglycemia
- Insulin therapy typically employed in individuals not meeting goals with less intensive non-insulin therapy
- Insulin therapy typically is a higher burden to patients in terms of monitoring and injection-based therapy



# Who struggles the most meeting glycemic goals in T2D?

**That's what we see in our Primary Care practice in Brooklyn Center Minnesota:**

Inclusion criteria for quality improvement project:

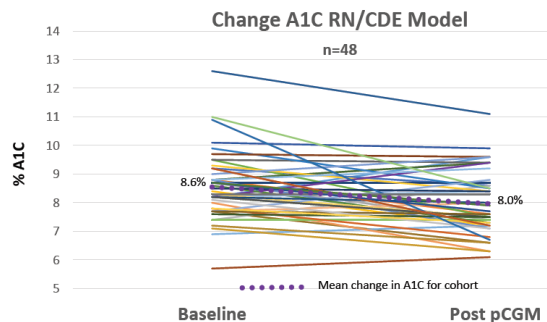
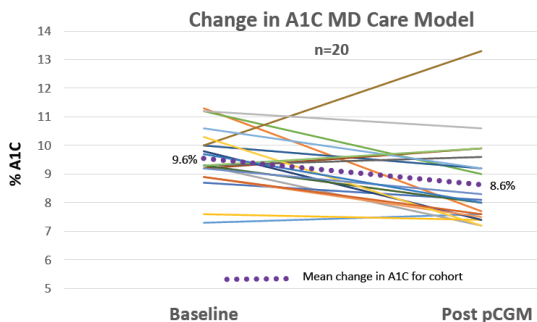
- Diagnosis of T2D for >1 year
- Most recent A1C  $\geq 7.0$  and  $< 11.0\%$
- Managed with any regimen
- Willingness to use pCGM

## Participant Baseline Characteristics (n=68)

Characteristic	Value
Mean Age	61.6 years
Mean Duration of T2D	15 years
Mean A1C	8.8%
Average number of medications	2.7
Prescribed medication:	
Basal insulin	81%
Mealttime insulin	57%
Metformin	62%
Sulfonylurea	21%
GLP-1 agonist	21%
SGLT2 inhibitor	9%
DPP-4 inhibitor	4%
Thiazolidinedione	3%

## Change in A1C for Entire Cohort (n=68)

Pre A1C= 8.8 ± 1.2% Post A1C= 8.2 ± 1.3% (p=0.006)



## Time in Ranges Metrics

MD Care Model (n=13) RN/CDE Care Model (n=24)

Metric	Baseline	Post CGM	Baseline	Post CGM
% Time <54 mg/dL	1.0%	2.1%	1.0%	1.2%
% Time <70 mg/dL	2.9%	5.5%	2.5%	3.4%
% TIR 70-180 mg/dL	40.8%	58.5%	53.7%	58.6%
% Time >180 mg/dL	56.2%	36.0%	43.9%	38.0%
% CV (Coefficient of Variation)	32.8	32.3	31.9	31.1



Data presented as a poster at the 2019 ADA Scientific Meeting

- **A1c improved from 8.8% to 8.2%** for the entire cohort
- Subgroup analysis:
  - TIR 40.8% to 58.5% Clinician group
  - TIR 53.7% to 58.6% RN/CDE group
- Some increase in hypoglycemia in subgroup with second CGM

# CGM in T2D Recommendations: IDC and Pathways Group

## *Highest to Lowest Benefit*

- **Highest benefit:**

- Patient taking multiple daily injections (MDI).
- Patients with severe hypoglycemia (needing assistance to treat) or with frequent mild to moderate hypoglycemia (BG <70 mg/dL).
- Patients with hemoglobinopathies or when A1C is not reliable

- **High benefit:**

- Patients treated with insulin and/or sulfonylurea regardless of A1C.
- Clinician/educator desire CGM for behavior, lifestyle, regimen modifications.
- Patients with high BG fluctuations/variability.
- Patients with diabetes complications (e.g. gastroparesis, renal impairment, diminished visual acuity).
- Insufficient glucose data to make decision on regimen change.

# CGM in T2D Recommendations, Continued

## *Highest to Lowest Benefit*

- **Moderate benefit:**

- Patients frequently treated with glucocorticoids (3 times or more/year).
- Situations where barriers to SMBG exist including SMBG avoidance, visual impairment, illness, cognitive issues, care giver assisting with care.
- Dramatic change in existing activity (e.g. knee replacement, stroke, sleep apnea, bariatric surgery).

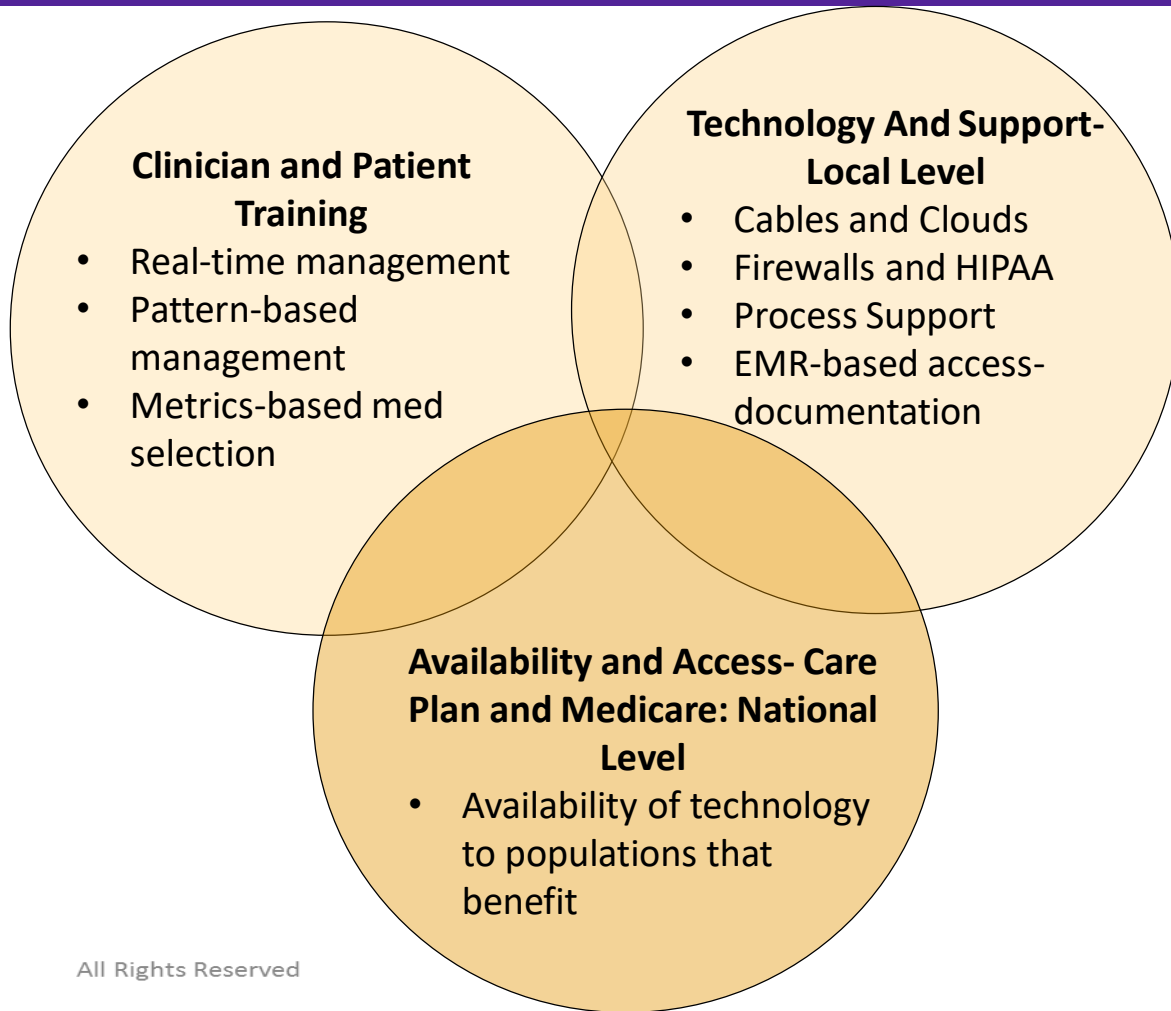
- **Less benefit:**

- The patient desires CGM to improve health and does not meet other criteria.
  - Finger sticks are an issue due to occupation (e.g. musicians).
- Newly diagnosed patients initiating medical nutrition and activity therapy with metformin and other therapies that don't cause hypoglycemia.

# How do we “Close the Gap” so that all who COULD benefit ARE benefiting?

- Accumulating evidence that CGM (intermittent scanned and real time) really is better than SMBG/ fingerstick and A1C-based management in a *research* setting
- Research success isn't the same as real-world success
- What factors need to come together to improve the quality of the care we deliver and improve the lives of individuals with T2D?

## CGM in the real world: Barriers and opportunities



Factors impacting real-world optimization of glycemic management using Diabetes Technology

All 3 are necessary to optimize real-world patient care

**Availability and Access-  
Care Plan and Medicare:  
National Level**

- Availability of technology to populations that benefit

What's needed:

- Real-world research to identify individuals and populations that benefit
- Long range view in evaluating cost-benefit and total cost of care
- Adequate coverage for diabetes technology, including CGM technology, to allow access populations that would benefit, including populations with barriers to care and socioeconomically disadvantaged individuals

# International Diabetes Center is actively working to create the training and tools; we are moving forward in the HealthPartners- Park Nicollet Care System



## Clinician and Patient Training

- Real-time management
- Pattern-based management
- Metrics-based med selection

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**Welcome to the  
Park Nicollet and HealthPartners  
Primary Care WebEx**

**Integrating Continuous  
Glucose Monitoring (CGM)  
in Primary Care**

**Richard Bergenstal, MD  
Thomas Martens, MD**

**Thursday, March 21, 2019  
12:15-12 PM**

**Submit Questions:**  
Click on the **Chat** tab; choose **HOST**; type question; then click **Send**.

**Next Webinars:**  
- Tuesday, April 30 @ 12:15 PM: Shoulder Exam, Diagnosis and Treatment  
- Wednesday, May 29 @ 12:15 PM: Women's Health Topic

**PERFORMING SUCCESSFUL PATIENT CARE**  
step-by-step instructions for interpreting the data

continuous glucose monitoring (CGM) has been shown to improve diabetes management by lowering glucose and reducing the risk of complications. CGM data is shown visually in an ambulatory glucose profile (AGP). See example below. Use this guide to maximize CGM, effectively interpret CGM data and engage patients in shared decision making.

**step 1: Check for adequate data.**  
An example AGP below shows 18 days of data. Make sure your patient has data for at least 7 days. Ideal is 14 days or more of data.


**step 2: Review patient factors that affect AGP.**  
Consider writing these factors on a printed AGP. See example below for using some patient history, diabetes meds (name, dose, timing), and usual times for waking and bedtime, for morning (D1, middle (D2) and evening (D3) meals and snacks (S), and for physical activity.

**step 3: Talk to patient about their AGP.**  
Ask patient, "What do you see in your AGP in terms of glucose patterns?" Emphasize that the profile shows data from midnight to midnight. Explain that generally you need to be in target range 70% or more of the time to have an A1C less than 7%. The goal is to be below target (lower than 70 mg/dL) less than 3% of the time.

**step 4: Look for patterns of low glucose levels on AGP.**  
If the 90th percentile low (indicating 90% of all glucose readings are below this line) is below 54 mg/dL, take immediate action to reduce

CONTINUE

**Ambulatory Glucose Profile (AGP)**  
27 February to 17 March, 13 days (number of days in single 24-hour day from midnight to midnight)



**Time in Ranges (mg/dL)**

- 97% Very High
- 26% High
- 47% In Target
- 7% Low
- 2% Very Low

Mean (SD): 102 mg/dL  
102 mg / 2.8 g/L  
1.0 mg / 2.8 g/L  
CGM use: 100%  
No. of days with CGM: 13

Medication: 2-2500 mg  
Glipizide: 5.0 mg  
Lispro: 8 U

3-2500 mg  
Gliclazide: 8.0 mg

Name: \_\_\_\_\_  
MRN: \_\_\_\_\_

**AGP Report**

**GLUCOSE STATISTICS AND TARGETS**

26 Feb 2019 - 10 Mar 2019 13 days  
% Time CGM is Active 99.9%

**Glucose Ranges**      **Targets (% of Readings (Time/Day))**

Target Range 70-180 mg/dL      Greater than 70% (10h 45min)

Below 70 mg/dL      Less than 4% (55min)

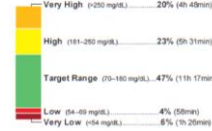
Below 54 mg/dL      Less than 1% (14min)

Above 200 mg/dL      Less than 5% (1h 20min)

Each 1% increase in time in range (70-180 mg/dL) is clinically beneficial.

**Average Glucose** 173 mg/dL  
**Glucose Management Indicator (GMI)** 7.6%  
**Glucose Variability** 49.8%  
Defined as percent coefficient of variation (NVD) target 36%

**TIME IN RANGES**



Very High (>200 mg/dL) 20% (4h 45min)

High (181-200 mg/dL) 23% (5h 31min)

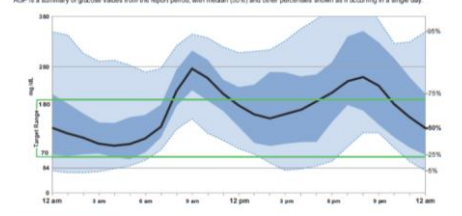
Target Range (70-180 mg/dL) 47% (11h 17min)

Low (64-69 mg/dL) 4% (55min)

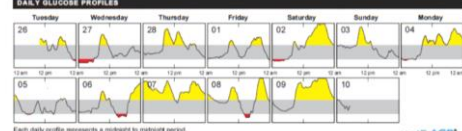
Very Low (<54 mg/dL) 2% (1h 20min)

**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.  
\*Hours during night of profile coincide with International Diabetes Center (IDC) Nighttime 2018.

CPTDRAGP<sup>SM</sup>



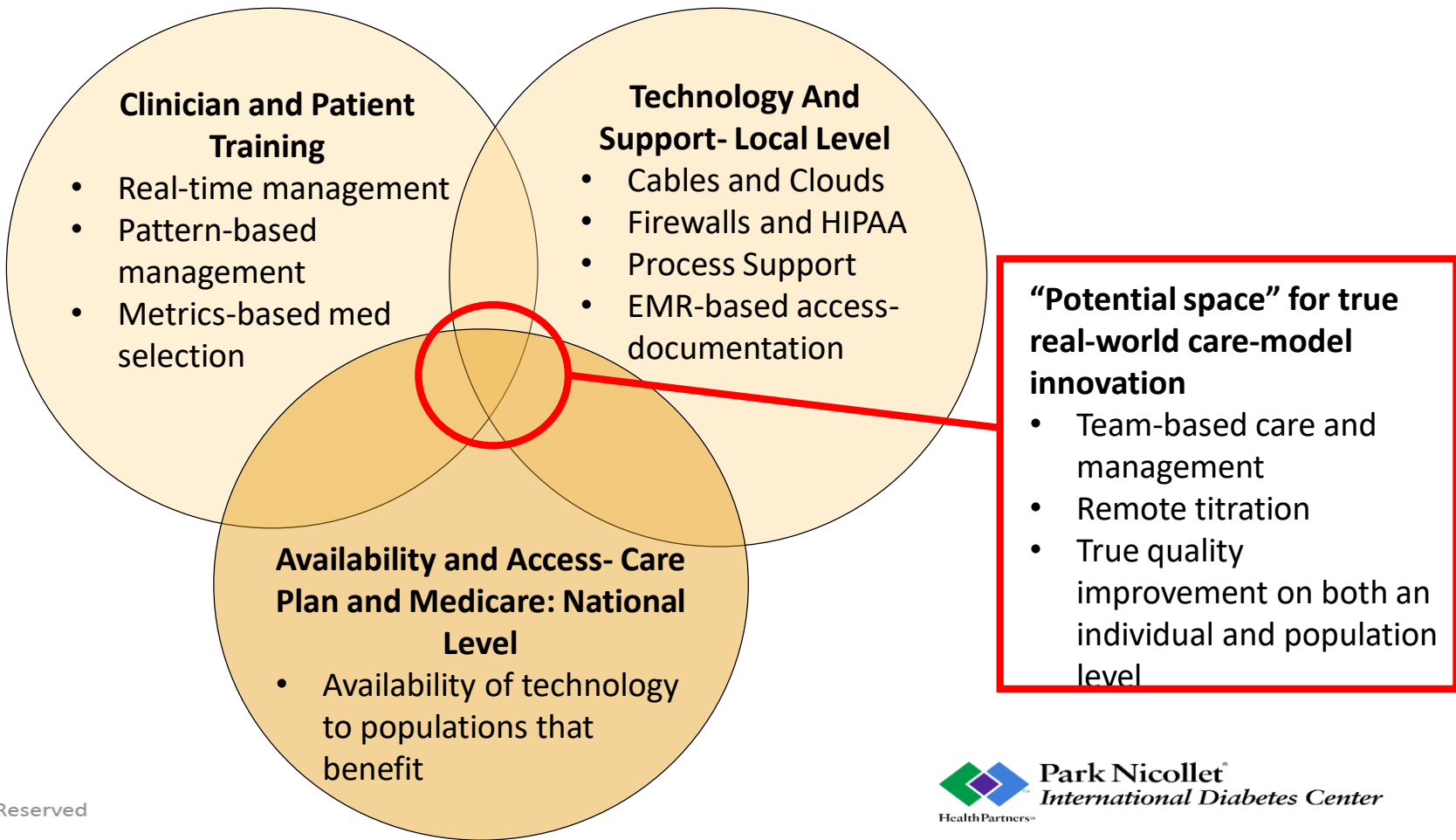
# Without access to data, the impact of even the best technology is minimal

## Technology And Support- Local Level

- Cables and Clouds
- Firewalls and HIPAA
- Process Support
- EMR-based access-documentation

## Data access

- **Barriers to data access/ technology intercompatibility:**
  - Institutional firewalls: Difficulty managing software and importing/exporting data
  - HIPAA confidentiality concerns
  - Lack of ability to directly import data into our EMR
- **Data management: Local vs cloud-based**
  - Software maintenance on many computers difficult
  - Significant data storage if done locally
  - Cloud based data management: accessible to care team more broadly
  - Ultimately cloud based data management shown to be much more feasible/usable

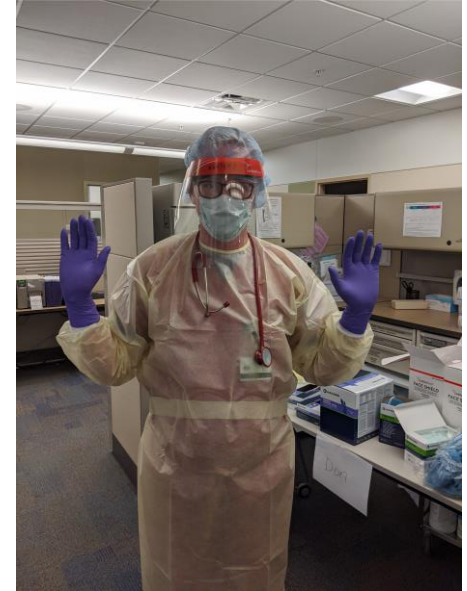


# Using the tool (CGM) to improve the measure (A1C) while decreasing the burden for individuals with diabetes

## Medical management in the time of COVID-19: Remote management goes mainstream

March 2020: HealthPartners–Park Nicollet Endocrinology and Primary Care move almost entirely to remote/ video-based and telephone management

- New urgency to coming-to-terms with remote access to data
- Primary care workforce redeployed to phone-based management or urgent COVID-19 management based on skillset etc.
- Familiar and tested workflows disappeared overnight



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# Using the tool (CGM) to improve the measure (A1C) while decreasing the burden for individuals with diabetes

Park Nicollet Brookdale Clinic: Diabetes educators working to fill in the holes in care

- A1c unavailable
- Remote CGM and BGM data has become a necessary part of care
- Remote start up, remote connectivity, remote management
- Our diabetes educators are actively working on workflows to allow remote AGP-guided management

**COVID-19 is making access to diabetes technology and active use of diabetes technology not just a luxury but a necessity in optimizing the safety and effectiveness of glycemic management in diabetes**



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*International Diabetes Center*

HealthPartners®

*“Using the tool (CGM) to improve the measure (A1C) while decreasing the burden for individuals with diabetes”*

**Thank you!**

**Tom Martens MD FACP**

Medical Director, International Diabetes Center,  
HealthPartners Institute  
Consultant, Department of Internal Medicine, Park  
Nicollet Health Services  
Minneapolis MN, USA



Q&A

Send Questions in Chat to  
Christina Santos





