Time in Range: An Intuitive CGM Metric to Integrate in Your Clinical Practice

Presented by: Karen Earle, MD
Moderator:
Deborah Greenwood, PhD, RN, BC-ADM, CDCES, FADCES
Clinical Education Team
Dexcom

Speaker:
Karen Earle, MD
Chief of Endocrinology and Director of Diabetes Services,
California Pacific Medical Center,
Chief of Division of Medical and Surgical Specialties,
Sutter West Bay Medical Group
What is your current experience with CGM?
A. I don’t know anything yet, but I saw the Nick Jonas commercial
B. I know the basics of CGM but I don’t use with patients on a regular basis
C. I’ve worked with CGM several times and feel pretty comfortable
D. Expert – I use CGM often and I am able to interpret AGP reports
Current Model of Care

- Diabetes care that relies on quarterly visits with A1C checks neglects the reality of life with diabetes that is continuous
- Using A1C alone may not be very helpful for people to understand their diabetes
- The majority of diabetes care transpires between visits, outside of clinical encounters
- Self-monitoring of blood glucose (SMBG) has notable limitations
- Wearing CGM allows for personal discovery as patients engage in their own care

- Impact of lifestyle on glycemic management
- No visibility on their response to interventions
- May be reluctant to advance therapy if they don’t understand their glycemic patterns

- Measures blood glucose (BG) at a single point in time
- Patient engagement and use is impacted by associated pain and social stigma

International Consensus on Time in Range Report

A Team Effort

- American Diabetes Association
- American Association of Clinical Endocrinologists
- Association of Diabetes Care and Education Specialists
- European Association for the Study of Diabetes
- Foundation of European Nurses in Diabetes
- International Society for Pediatric and Adolescent Diabetes
- Juvenile Diabetes Research Foundation
- Pediatric Endocrine Society

### Need For Metrics Beyond A1C

<table>
<thead>
<tr>
<th>A1C, %</th>
<th>mg/dL</th>
<th>95% CI</th>
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<tr>
<td>5</td>
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May underestimate or overestimate an individual’s average glucose (example: A1C of 7% could represent a range between 123-185 mg/dL)

## Need For Metrics Beyond A1C

A1C, % | mg/dL | 95% CI
---|---|---
5  | 97  | (76-120)
6  | 126 | (100-152)
7  | 154 | (123-185)
8  | 183 | (147-217)
9  | 212 | (170-249)
10 | 240 | (193-282)
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Does not indicate the extent or timing of hypoglycemia or hyperglycemia

# Need For Metrics Beyond A1C

Does not reveal glycemic variability

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## Need For Metrics Beyond A1C

Limited utility for insulin dosing decisions

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## Need For Metrics Beyond A1C

Unreliable in patients with hemolytic anemia, hemoglobinopathies, or iron deficiency

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Underestimates in those with end stage kidney disease or during pregnancy.

## Need For Metrics Beyond A1C

Correlation with mean glucose can vary among races

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Same A1C, but CGM Patterns Drive Different Treatment Plans

A1C 7%

Adapted from https://diatribe.org/BeyondA1c, Assessed March 18, 2021
Continuous Glucose Monitoring Shows Variability

Polling question 2

- What is the % TIR (time in range) goal and % TBR (Time below range) goal for most people with T1D and T2D
  A. > 70% TIR and < 8% TBR
  B. > 80% TIR and < 4% TBR
  C. > 65% TIR and < 5% TBR
  D. > 70% TIR and < 4% TBR
Core CGM Metrics and Goals for Time in Range (TIR)\textsuperscript{1,2}

**Key Metrics**

**Number of Days with CGM Data**
14+ days recommended

**Percentage of Time CGM is Active**
>70% of data recommended

**Mean Glucose**
The average glucose

**Glucose Management Indicator (GMI)**
Approximate A1C levels based on average glucose measured using CGM values

**Coefficient of Variation (CV)**
Measure of glycemic variability (standard deviation/mean) ≤36% is recommended

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*Includes percentage of values >250 mg/dL **Includes percentage of values <54 mg/dL

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**T1D & T2D**

<table>
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<tr>
<th>Glucose Level</th>
<th>Target Time</th>
<th>Description</th>
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<td>&gt;250 mg/dL</td>
<td>&lt;5% Very High</td>
<td></td>
</tr>
<tr>
<td>&gt;180 mg/dL</td>
<td>&lt;25%* High</td>
<td></td>
</tr>
<tr>
<td>70-180 mg/dL</td>
<td>&gt;70% In Range</td>
<td>Correlates with A1C ~7.0%</td>
</tr>
<tr>
<td>&lt;70 mg/dL</td>
<td>&lt;4%** Low</td>
<td>&lt;1% Very Low</td>
</tr>
<tr>
<td>&lt;54 mg/dL</td>
<td></td>
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**Older/High Risk T1D & T2D**

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Target Range:

- T1D & T2D: 70-180 mg/dL
- Older/High Risk T1D & T2D: 70-180 mg/dL
- <70 mg/dL Correlates with A1C ~8.0%


*Includes percentage of values >250 mg/dL **Includes percentage of values <54 mg/dL
Recommended Time in Range for most people with T1D & T2D

Target Range: 70-180 mg/dL

- **<5% Very High**
  - Time above range (TAR)
    - < 1 hr, 12 min, > 250 mg/dL
    - < 6 hr, > 180 mg/dL

- **<25%* High**
  - Time above range (TAR)
    - < 1 hr, 12 min, > 250 mg/dL
    - < 6 hr, > 180 mg/dL

- **>70% In Range**
  - Time in range (TIR)
    - > 16 hr, 48 min

- **<4%** Low
  - Time below range (TBR)
    - < 1 hr < 70 mg/dL
    - < 15 min < 54 mg/dL

- **<1% Very Low**
  - Time below range (TBR)
    - < 1 hr < 70 mg/dL
    - < 15 min < 54 mg/dL


*T includes percentage of values >250 mg/dL
**Includes percentage of values <54 mg/dL

Less than 1 hour below target range
Less than 6 hours above target range
At least 17 hours in target range

1% OF THE DAY
15 MINUTES
Increase **TIR** while Decreasing **TBR**

See more **Green** and **Less Red** (MGLR) on the TIR bar
GLYCEMIC VARIABILITY is the amplitude, frequency and duration of glucose fluctuations. 

Measured by the Coefficient of Variation (CV) Standard deviation/mean=CV

Targets: CV < 36% for most people

<33% for people at high risk for hypoglycemia (insulin or sulfonylureas)

Predictor of hypoglycemia

Polling Question 3

What is the % increase in Time in Range (TIR) that is considered clinically meaningful?

A. 1%
B. 3%
C. 5%
D. 10%
Estimated A1C for a TIR level

Each 5% increase in TIR is clinically significant.¹

### Vigersky and McMahon²
(n = 1,137 participants with type 1 and type 2 diabetes)

<table>
<thead>
<tr>
<th>TIR 70-180 mg/dL</th>
<th>A1C</th>
</tr>
</thead>
<tbody>
<tr>
<td>20%</td>
<td>10.6%</td>
</tr>
<tr>
<td>30%</td>
<td>9.8%</td>
</tr>
<tr>
<td>40%</td>
<td>9.0%</td>
</tr>
<tr>
<td>50%</td>
<td>8.3%</td>
</tr>
<tr>
<td>60%</td>
<td>7.5%</td>
</tr>
<tr>
<td>70%</td>
<td>6.7%</td>
</tr>
<tr>
<td>80%</td>
<td>5.9%</td>
</tr>
<tr>
<td>90%</td>
<td>5.1%</td>
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</table>

For every 10% increase in TIR = ~0.8% A1C reduction.

### Beck et al.³
(n = 545 participants with type 1 diabetes)

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Post-hoc analysis indicate an association between TIR & diabetes complications

- Post-hoc analysis of SMBG data indicate that each 10-percentage point decrease in TIR was associated with a 64% increase in retinopathy progression and 40% increase in microalbuminuria (P < 0.001 for each).¹

- A 10% increase in TIR associated with 19% reduction in urinary albumin excretion.²

- TIR was significantly associated with prevalence of all stages of retinopathy in T2D even after adjusting for clinical risk factors, including A1C.³

- 10% decrease TIR associated with 5% increase in CVD-related mortality and 8% increase in all-cause mortality.⁴

Ambulatory Glucose Profile (AGP) Report and Time in Range (TIR) Inform Therapeutic Decisions

Recommended Time in Range for most people with T1D & T2D

- **Target range**: 70-180 mg/dL
- **<70 mg/dL**: <4%** Low
- **<54 mg/dL**: <1% Very Low
- **>180 mg/dL**: <25%* High
- **>250 mg/dL**: <5% Very High

**Target Time**

- >70% In Range
- Correlates with A1c ~7.0%

**GLUCOSE RANGES**

<table>
<thead>
<tr>
<th>Glucose Range</th>
<th>Very Low</th>
<th>Low</th>
<th>In Target Range</th>
<th>High</th>
<th>Very High</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;54 mg/dL</td>
<td>1%</td>
<td>4%</td>
<td>52%</td>
<td>44%</td>
<td>7%</td>
</tr>
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*QR = interquartile range. †Battelino T et al. Diabetes Care. 2019;42(8):1593-1603

The y-axis scale and target range are the same as on the AGP graph above. 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. Hypothetical patient and AGP report.
Strategies to Help People with Diabetes Increase TIR

Strive for FNIR¹ (flat, narrow, in-range)

Be curious

Discover

Ongoing Learning

“If ____, then ______.”

Approach

Use Patterns

Celebrate

¹: https://diatribe.org/BeyondA1c, Assessed March 18, 2021
Using Strength-Based Language\(^1\) While Talking About TIR

Emotions tied to living with diabetes

Numbers are data, not a judgement\(^*1\)
- Not "good" vs "bad" numbers

Develop SMART goals to move towards more TIR and less TBR

Create an action plan together using shared decision-making
- What is one way you might move towards more TIR?
- Would you prefer to eat fewer carbs at breakfast or increase your insulin?

Celebrate the success!
- Identify the positives

---

\(^1\) extreme hyper- or hypo-glycemic events warrant serious discussion between a HCP and patient

Frequent* Dexcom CLARITY Views are Associated with up to 15% Increased TIR\(^1\)

*Frequent use is defined as four or more monthly log ins to Dexcom CLARITY.

Help Patients Use Dexcom G6 and CLARITY App Settings for More TIR\(^1\)\(^-\)\(^3\)

Dexcom features that may help move towards more **GREEN**

- Wear CGM daily
- Consider incorporating trend arrows into treatment decisions
- Share data with at least one follower\(^1\)
- Customize Dexcom G6 high alert settings\(^2\)
- Use CGM to understand the impact of food, daily activity, stress and medication\(^3\)

Dexcom features that can reduce **RED**

- Keep Urgent Low Soon Alert enabled to predict when glucose will be less than 55 mg/dL within 20 minutes
- Customize Dexcom G6 low alert settings\(^2\)

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Time in Range in Clinical Practice
Incorporate Discovery Learning with a Shared-Decision Making Approach

- Person centered care
- Shared sense of purpose
- Encourages active engagement in learning process
- Empowers self-management

- Open dialogue based on clinical evidence and patient preference
- Collaboration between people with diabetes and the care team
- Builds trust

Dexcom G6 RT-CGM System
Dexcom G6 Overview

The only CGM system indicated for children aged 2 years and older

Up to 288 continuous readings per day

Exceptional accuracy
Class II device designation¹

Zero fingersticks required.*

Hey Siri, what's my glucose?

Customizable alerts and a fixed Urgent Low alarm

Data share features with up to 10 followers†

Robust clinical evidence of improved glycemic outcomes²,³

Studies prove the clinical benefits of the differentiating attributes of Dexcom.⁴,⁵

¹Separate Follow app required.

*If your glucose alerts and readings from the G6 do not match symptoms or expectations, use a blood glucose meter to make diabetes treatment decisions.
Dexcom G6 Urgent Low Soon Alert Enhances Experience

Smarter Alerts

Urgent Low Soon Alert
- Future-alert function
- Provides earlier actionable alert without increasing nuisance factor

Prediction Alerts = 20 minutes warning
Threshold alert = 5 minutes warning

Note: for illustrative purposes only.

CGM = continuous glucose monitoring.
Dexcom CLARITY is a cloud-based diabetes management software that helps patients and providers understand and analyze glucose patterns²

Home user²:
- View glucose patterns, trends, and statistics

Healthcare Professional³:
  - Graphs show patterns of hypoglycemia and hyperglycemia, allowing providers to prioritize problems and find diabetes management solutions

Dexcom CLARITY Clinic
Simplified Access to Actionable RT-CGM Data
Not the best way to set up your CLARITY clinic account!
Patient list - add new patients in < 1 minute, but do need DOB

<table>
<thead>
<tr>
<th>E</th>
<th>DOB</th>
<th>PATIENT ID</th>
<th>LAST UPLOADED</th>
<th>DATA SHARING</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Feb 2, 1947</td>
<td></td>
<td>Jun 21, 2020</td>
<td>✓ On</td>
</tr>
<tr>
<td></td>
<td>Nov 17, 1936</td>
<td></td>
<td>Mar 30, 2020</td>
<td>✓ On</td>
</tr>
<tr>
<td></td>
<td>Apr 29, 1946</td>
<td></td>
<td>Mar 30, 2020</td>
<td>✓ On</td>
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<tr>
<td></td>
<td>Dec 22, 1960</td>
<td></td>
<td>Dec 21, 2018</td>
<td>× Off</td>
</tr>
<tr>
<td></td>
<td>Apr 15, 1966</td>
<td></td>
<td>Jun 21, 2020</td>
<td>✓ On</td>
</tr>
<tr>
<td></td>
<td>Oct 28, 1999</td>
<td></td>
<td>Jun 21, 2020</td>
<td>✓ On</td>
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<td></td>
<td>Jul 16, 1986</td>
<td></td>
<td>Feb 25, 2020</td>
<td>✓ On</td>
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<tr>
<td></td>
<td>Jul 16, 1986</td>
<td></td>
<td>Aug 9, 2018</td>
<td>× Off</td>
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<tr>
<td></td>
<td>Sep 7, 1957</td>
<td></td>
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Our Patient Named “Dexcom Clarity,” DOB 1-1-2015: Set up an Indefinite Share Quickly
Invite Patient to Share Data

- After clicking Share data option, click invite, print or email.
- Patient needs to have the Dexcom CLARITY app on their phone or computer to enter code.
Share Data with Clinic

- Ask patient to enter code in their Dexcom CLARITY account under Profile
- Then authorize sharing, accept code
- (not generate code)
Case Study #1

53 yo man with long standing diabetes presents as a new patient to DM clinic. He does not check his FSBG on a regular basis.

- MF 2000 mg qd
- Tresiba 10 units qd
- HbA1c 13.2%

No changes to medication, placed a Dexcom G6 during office apt.
Curves/Plots represent glucose frequency distributions by time regardless of date.

Case study provided by Dr. Karen Earle.
Case Study #1

At follow up apt after 2 weeks meal time insulin Humalog started.

- Humalog 10 units TID with a 1:50 correction about 150 mg/dL

Patient returns one month later for a follow up apt.

Case study provided by Dr. Karen Earle.
Compare Report

Baseline

One Month Later

Case study provided by Dr. Karen Earle.
Polling question 4

- Which patient do you think would be the best candidate for RT-CGM?
  A. 30 y.o. man with type 1 diabetes and A1C 7.5%
  B. 55 y.o. woman with type 2 diabetes, A1C 9% on basal insulin
  C. 65 y.o. man with type 1 diabetes with frequent hypoglycemia
  D. 40 y.o. woman with type 2 diabetes, A1C 9% on metformin and Sulfonylurea
  E. All of the above
TAKEAWAY

• Metrics beyond A1C are needed to fully understand the variation in glucose values

GOAL:

• The goal is to increase time in range (TIR) while decreasing time below range

ACRONYMS TO REMEMBER:

• MGLR or more green, less red on the TIR bar
• FNIR or flat, narrow, in range on the trends graph

ADDITIONAL

• TIR discussions can focus on strengths and making positive changes for health
• Avid Dexcom CLARITY users* on average, spend 15% more TIR (70-180 md/dL that non-users)

Polling question 5

How likely are you to discuss RT-CGM with a patient tomorrow?

A. Unlikely, I need more information
B. I think I will, I’m unsure about the time it might take
C. I definitely will, I believe in the value of RT-CGM
D. I’m already discussing RT-CGM every day
Resources to Download

Why Time in Range Matters?

**WHAT IS TIME IN RANGE (TIR)?**

Time in Range or TIR is the percentage of time glucose levels are in target range. For most people with diabetes, the target range is between 70 and 180 mg/dL. The daily goal for most people with type 1 diabetes (T1D) and type 2 diabetes (T2D) is >70% TIR or approximately 15 hours, 45 min. See the TIR bar for recommended targets.

**RECOMMENDED TIME IN RANGE**

For most people with T1D & T2D,

- **<100 mg/dL**: Target range 75-180 mg/dL
- **<54 mg/dL**: Time in range (TIR) < 10 hr, 30 min
- **<75 % of patients with A1C <7.0%**
- **<15 mg/dL**: Time below range (TBR) < 6 hr, <70 mg/dL
- **<15 mg/dL**: Time below range (TBR) < 1 hr, <60 mg/dL
- **<15 mg/dL**: Time below range (TBR) < 0.5 hr, <54 mg/dL

**Goal: Increase TIR while decreasing TBR**

See More Green and Less Red (MCLR) on the TIR bar

Each 5% increase in TIR is considered clinically significant. For every 10% increase in TIR = ~0.8% A1C reduction.

Metrics Beyond A1C

**THE VALUE OF METRICS BEYOND A1C**

A1C is the average glucose over the last 2-3 months but does not identify glycemic variability.

CGM data can identify patterns of hypo- and hyperglycemia, assess glycemic excursions, and glucose variability to allow for therapy modification.

**Same A1C but CGM Patterns Drive Different Treatment Plans**

<table>
<thead>
<tr>
<th>TIR 75-180 mg/dL</th>
<th>A1C</th>
</tr>
</thead>
<tbody>
<tr>
<td>20%</td>
<td>10.5%</td>
</tr>
<tr>
<td>30%</td>
<td>9.0%</td>
</tr>
<tr>
<td>40%</td>
<td>8.0%</td>
</tr>
<tr>
<td>50%</td>
<td>7.0%</td>
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<tr>
<td>60%</td>
<td>6.7%</td>
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<tr>
<td>70%</td>
<td>6.7%</td>
</tr>
<tr>
<td>80%</td>
<td>5.9%</td>
</tr>
<tr>
<td>90%</td>
<td>5.1%</td>
</tr>
</tbody>
</table>

**Each 5% increase in TIR is considered clinically significant.**

For every 10% increase in TIR = ~0.8% A1C reduction.

**KEY METRICS**

- Number of days with CGM data: 14+ days recommended
- Percentage of time CGM is active: >70% of data recommended
- Mean glucose: The average glucose
- Glucose Management Indicator (GMI): Approximates A1C levels based on average glucose measured using CGM values
- Coefficient of Variation (CV): Measure of glycemic variability; <10% is recommended
OUR MISSION, TOGETHER

Too many people with diabetes are still unaware of modern diabetes metrics, such as time in range.

We want to change that.

#WHENINRANGE
Dexcom is Here to Support YOU and Your Patients

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Submit a Patient Support Request
Request Sensor Overpatches
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See dexcom.com/contact for current contact hours
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To request membership, scan the QR code
Failure to use the Dexcom G6 Continuous Glucose Monitoring System (G6) and its components according to the instructions for use provided with your device and available at https://www.dexcom.com/safety-information and to properly consider all indications, contraindications, warnings, precautions, and cautions in those instructions for use may result in you missing a severe hypoglycemia (low blood glucose) or hyperglycemia (high blood glucose) occurrence and/or making a treatment decision that may result in injury. If your glucose alerts and readings from the G6 do not match symptoms or expectations or you’re taking over the recommended maximum dosage amount of 1000mg of acetaminophen every 6 hours, use a blood glucose meter to make diabetes treatment decisions. Seek medical advice and attention when appropriate, including for any medical emergency.

The web-based Dexcom CLARITY software is intended for use by both home users and healthcare professionals to assist people with diabetes and their healthcare professionals in the review, analysis, and evaluation of historical CGM data to support effective diabetes management. It is intended for use as an accessory to Dexcom CGM devices with data interface capabilities. Caution: The software does not provide any medical advice and should not be used for that purpose. Home users must consult a healthcare professional before making any medical interpretation and therapy adjustments from the information in the software. Caution: Healthcare professionals should use information in the software in conjunction with other clinical information available to them. Caution: Federal (US) law restricts this device to sale by or on the order of a licensed healthcare professional.

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Questions?

THANK YOU!!