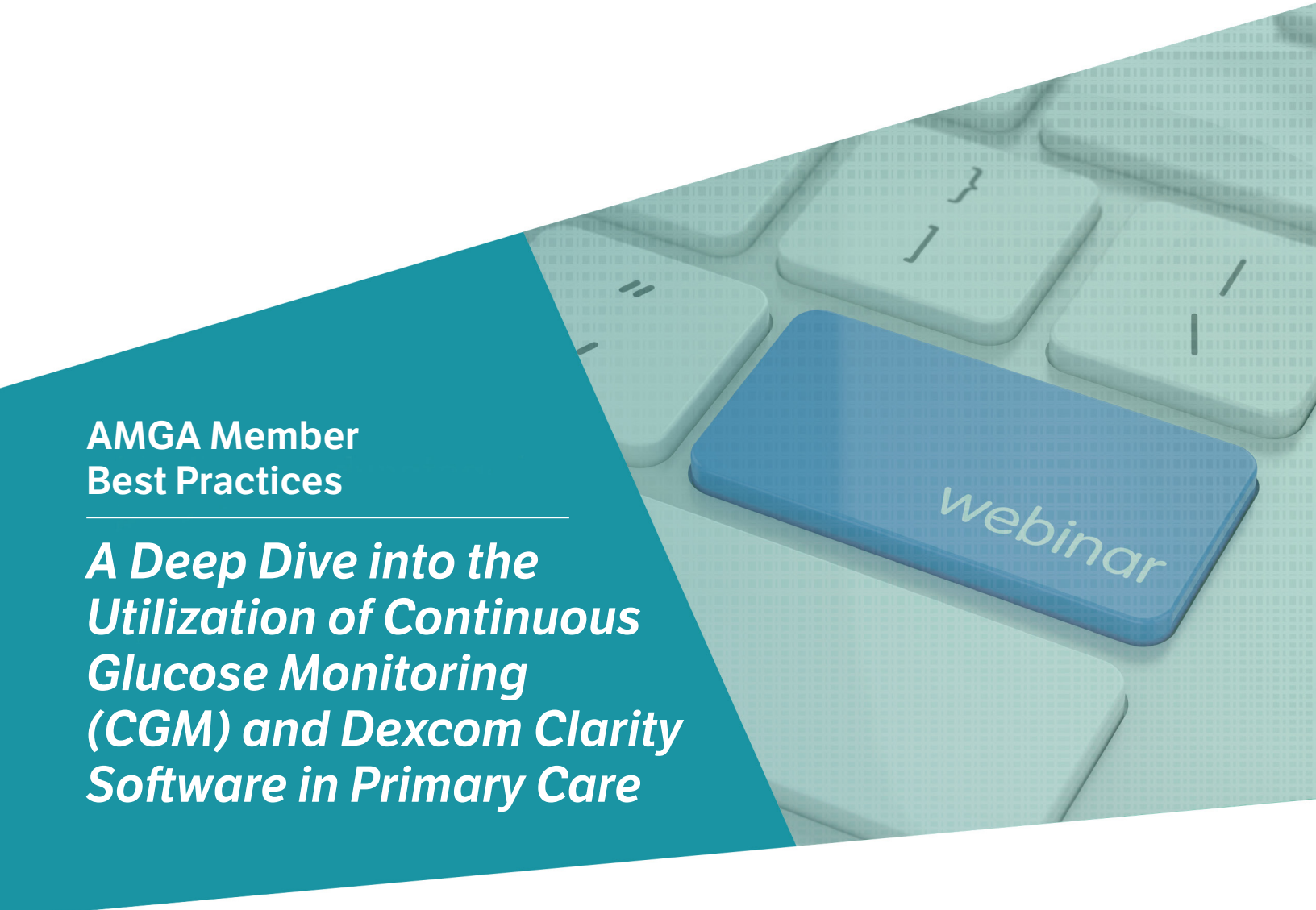# AMGA
Advancing High Performance Health

AMGA Member Best Practices

A Deep Dive into the Utilization of Continuous Glucose Monitoring (CGM) and Dexcom Clarity Software in Primary Care

A Deep Dive into the Utilization of Continuous Glucose Monitoring (CGM) and Dexcom Clarity Software in Primary Care

Davida Kruger, M.S.N., APN-BC, BC-ADM,
Henry Ford Health System

Webinar, November 30, 2021

"We have conducted randomized controlled trials for Dexcom, and these show improved clinical outcomes, high usage, and high patient satisfaction."

— **Davida Kruger, M.S.N., APN-BC, BC-ADM**, Henry Ford Health System

An estimated 34 million US individuals of all ages live with diabetes.[1] Type 2 diabetes accounts for about 90% of all diagnosed cases of diabetes and type 1 diabetes accounts for approximately 10% of cases.[2] Early diagnosis and treatment can delay disease progression and reduce the risk of diabetes-related complications.[3] Primary care clinics are the main source of care for patients with diabetes.[4] Because primary care providers (PCPs) are at the forefront of diabetes care, they need to be equipped with essential resources proven to improve health outcomes in persons with diabetes.[3,4]

CGM Technology Enhances Existing Models of Care

Davida Kruger, M.S.N., APN-BC, BC-ADM, advanced practice nurse and board-certified advanced diabetes management practitioner with more than 35 years at the Henry Ford Health System (HFHS) in Detroit, MI, stated, "I strongly believe that we need to think about using continuous glucose monitoring (CGM) to manage diabetes at all levels, and it should be a right rather than a privilege." CGM has become the gold standard for the clinical management of diabetes at the HFHS. Ms. Kruger explained that "without CGM, we must rely on quarterly A1C checks, which really neglects what happens in the reality of life in-between visits." She also explained how "A1C alone may not be helpful to the patient because it gives them an average of what's happened over the past 90 days and does not talk about periods where they had a high or low glucose value."

"Patients are responsible for managing their diabetes and if we give them the right tools to manage their diabetes, they just do better and they have ownership," stated Ms. Kruger. Wearing a CGM allows for personal discovery as patients engage in their care.

The professional guidelines from the American Diabetes Association and the American Association of Clinical Endocrinology also support the use of CGMs, specifically real-time CGM (Figures 1 and 2).

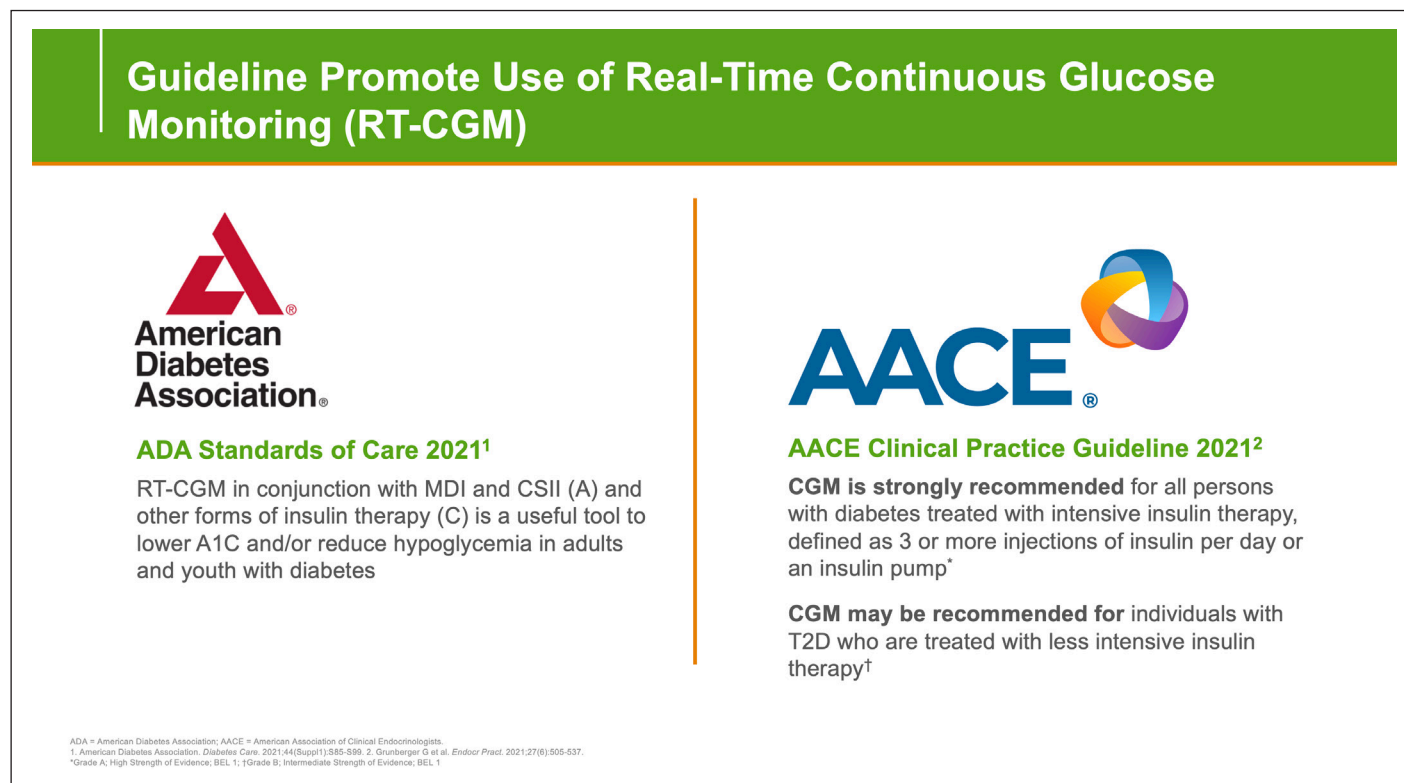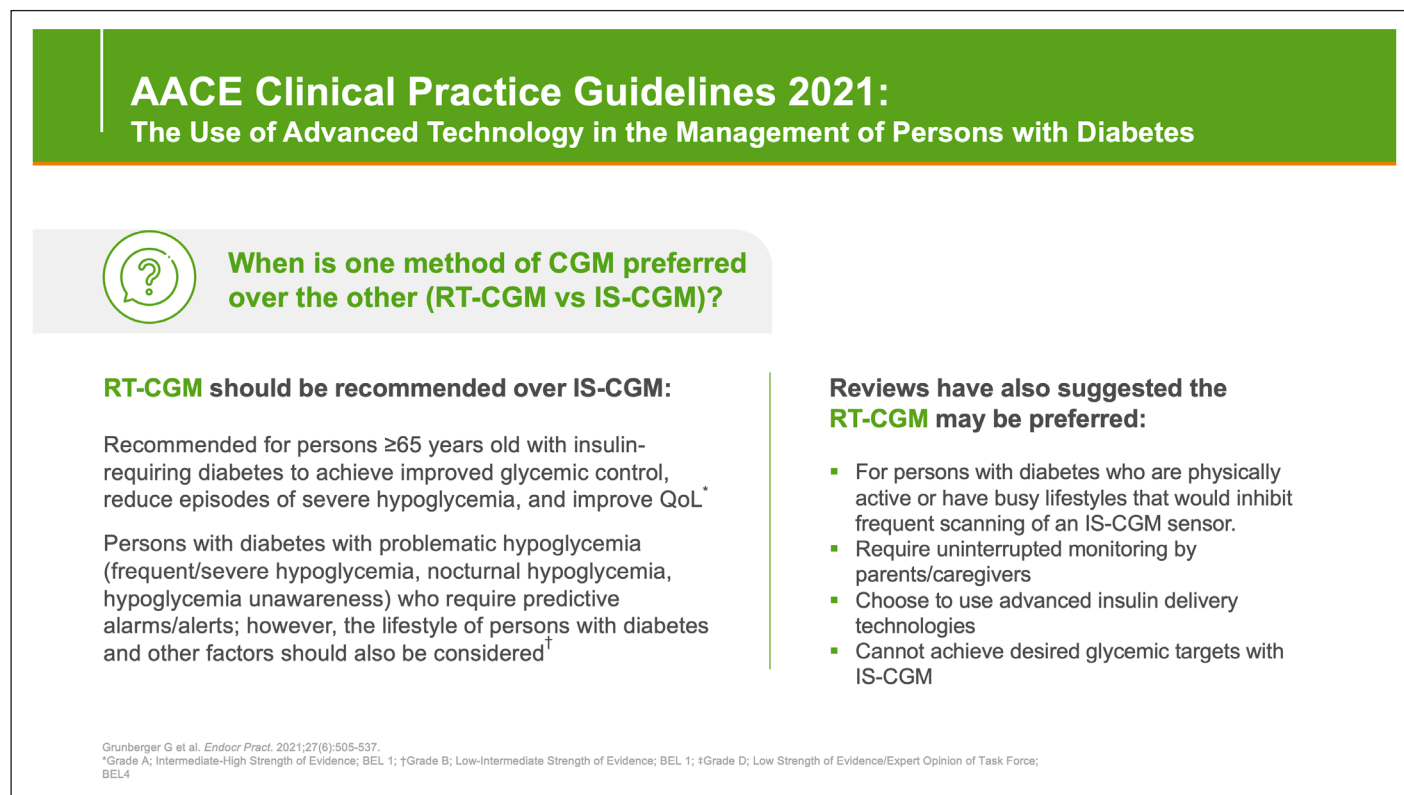## Figure 1. 2021 ADA and AACE Clinical Practice Guidelines

Guideline Promote Use of Real-Time Continuous Glucose Monitoring (RT-CGM)

ADA Standards of Care 2021[1]

RT-CGM in conjunction with MDI and CSII (A) and other forms of insulin therapy (C) is a useful tool to lower A1C and/or reduce hypoglycemia in adults and youth with diabetes

AACE Clinical Practice Guideline 2021[2]

CGM is strongly recommended for all persons with diabetes treated with intensive insulin therapy, defined as 3 or more injections of insulin per day or an insulin pump*

CGM may be recommended for individuals with T2D who are treated with less intensive insulin therapy†

ADA = American Diabetes Association; AACE = American Association of Clinical Endocrinologists.
1. American Diabetes Association. *Diabetes Care.* 2021;44(Suppl1):S85-S99. 2. Grunberger G et al. *Endocr Pract.* 2021;27(6):505-537.
*Grade A; High Strength of Evidence; BEL 1; †Grade B; Intermediate Strength of Evidence; BEL 1

Figure 2. 2021 AACE Clinical Practice Guidelines

AACE Clinical Practice Guidelines 2021:
The Use of Advanced Technology in the Management of Persons with Diabetes

When is one method of CGM preferred over the other (RT-CGM vs IS-CGM)?

RT-CGM should be recommended over IS-CGM:

Recommended for persons ≥65 years old with insulin-requiring diabetes to achieve improved glycemic control, reduce episodes of severe hypoglycemia, and improve QoL*

Persons with diabetes with problematic hypoglycemia (frequent/severe hypoglycemia, nocturnal hypoglycemia, hypoglycemia unawareness) who require predictive alarms/alerts; however, the lifestyle of persons with diabetes and other factors should also be considered†

Reviews have also suggested the RT-CGM may be preferred:

- For persons with diabetes who are physically active or have busy lifestyles that would inhibit frequent scanning of an IS-CGM sensor.
- Require uninterrupted monitoring by parents/caregivers
- Choose to use advanced insulin delivery technologies
- Cannot achieve desired glycemic targets with IS-CGM

Grunberger G et al. *Endocr Pract.* 2021;27(6):505-537.
*Grade A; Intermediate-High Strength of Evidence; BEL 1; †Grade B; Low-Intermediate Strength of Evidence; BEL 1; ‡Grade D; Low Strength of Evidence/Expert Opinion of Task Force; BEL4

Time in Range Metric

Guided by the International Consensus in Time in Range, CGM provides opportunities to identify factors that impact glucose and help clinicians and people with diabetes make informed decisions about health behaviors. At HFHS, clinicians integrate time in range in their practice. The metric includes key measurements: Percentage of readings and time per day within target glucose range (TIR), time below target glucose range (TBR), and time above target glucose range (TAR) (Figure 3).[5] The International Consensus Guidelines recommend a TIR goal to be at least 70% of glucose values between 70-180 mg/dL. Time below range (<70 mg/dL) should be less than 4% and time above range (>180 mg/dL) less than 25% of the day. And time significantly above range (>250 mg/dL) should be no greater than 5% per day.[5] These recommended goals are geared toward type 1 and type 2 diabetes. Adjustments may be needed for pregnancy, high-risk individuals, and/or older adults with diabetes.

Dexcom G6

The Dexcom G6 CGM system has demonstrated significant reductions in A1C, less time in hypoglycemia, and a higher rate of CGM use in adults with diabetes.[6] Dexcom G6 is the only CGM system indicated for children aged 2 years and older. It records up to 288 continuous glucose readings per day. It has exceptional accuracy and is an integrated CGM (iCGM) classification, which means it is accurate enough to be integrated into other products such as an insulin pump and automated insulin dosing systems. Zero fingersticks are required with the Dexcom G6. People using the G6 can share glucose data with up to 10 Followers using the Dexcom Follow app. There are customizable alerts for hypoglycemia and hyperglycemia, as well as a predictive Urgent

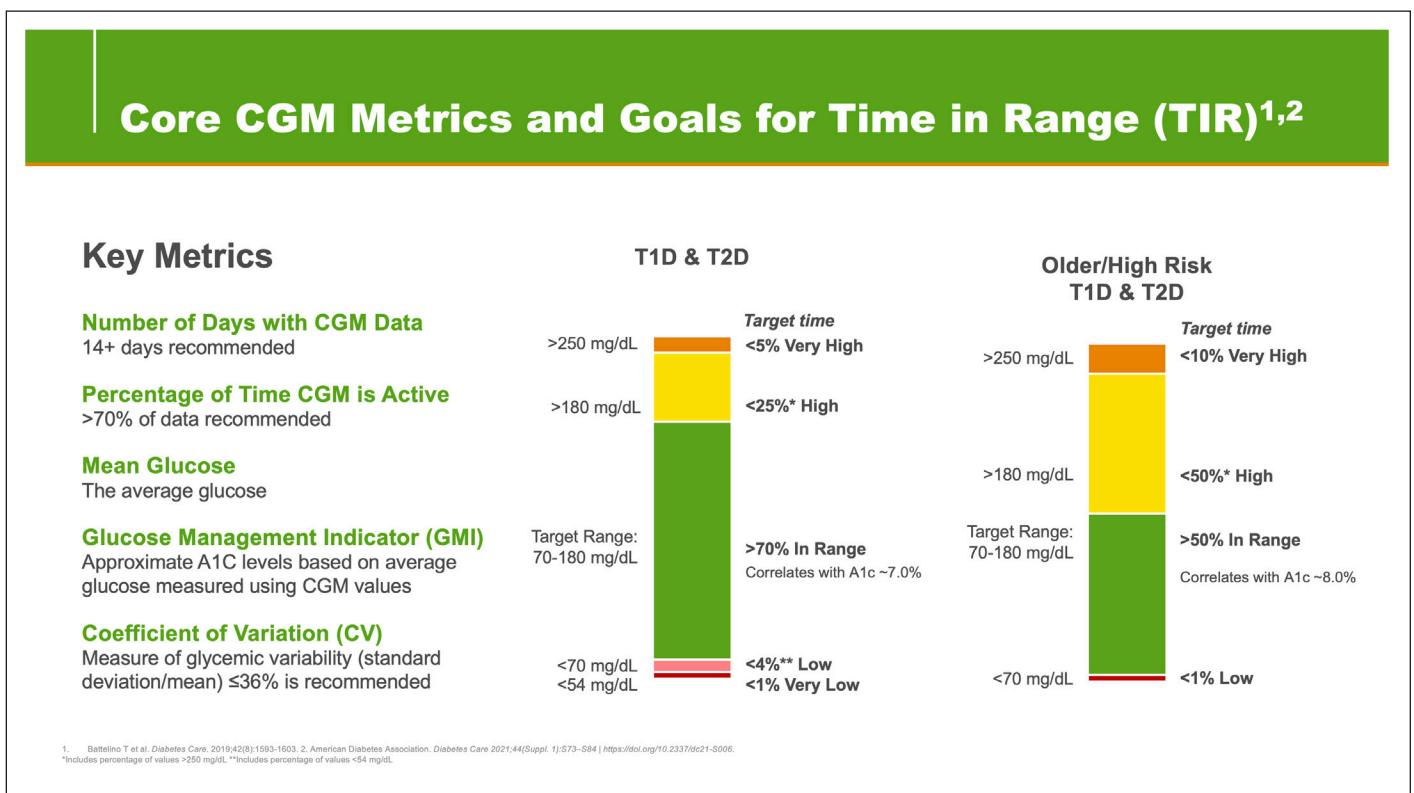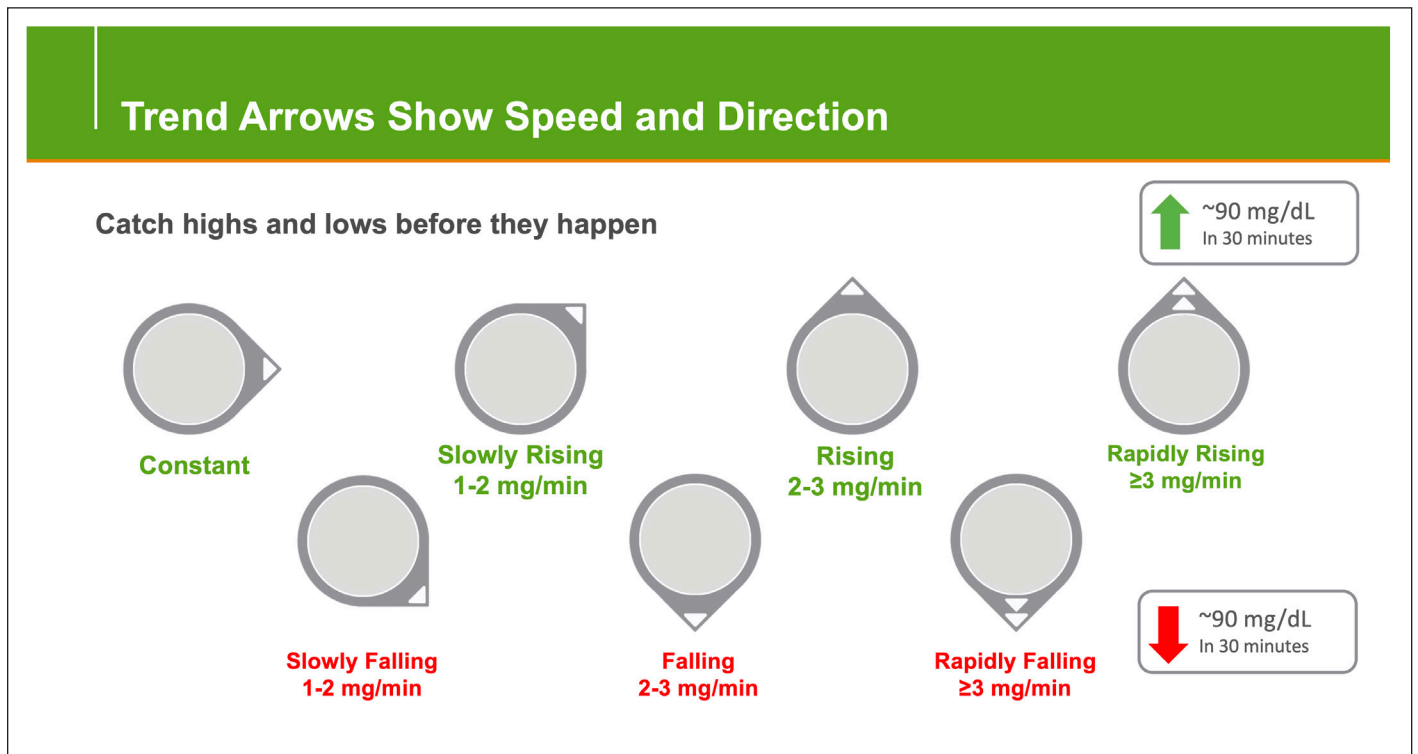## Figure 3: Core CGM Metrics and Goals for Time in Range (TIR)

Core CGM Metrics and Goals for Time in Range (TIR)[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

T1D & T2D

- >250 mg/dL — *Target time* <5% Very High
- >180 mg/dL — <25%* High
- Target Range: 70-180 mg/dL — >70% In Range, Correlates with A1c ~7.0%
- <70 mg/dL — <4%** Low
- <54 mg/dL — <1% Very Low

Older/High Risk T1D & T2D

- >250 mg/dL — *Target time* <10% Very High
- >180 mg/dL — <50%* High
- Target Range: 70-180 mg/dL — >50% In Range, Correlates with A1c ~8.0%
- <70 mg/dL — <1% Low

1.   Battelino T et al. *Diabetes Care.* 2019;42(8):1593-1603. 2. American Diabetes Association. *Diabetes Care 2021;44(Suppl. 1):S73–S84 | https://doi.org/10.2337/dc21-S006.*
*Includes percentage of values >250 mg/dL. **Includes percentage of values <54 mg/dL.

Figure 4: Trend Arrows Show Speed and Direction

Trend Arrows Show Speed and Direction

Catch highs and lows before they happen

Constant

Slowly Rising
1-2 mg/min

Rising
2-3 mg/min

Rapidly Rising
≥3 mg/min

~90 mg/dL
In 30 minutes

Slowly Falling
1-2 mg/min

Falling
2-3 mg/min

Rapidly Falling
≥3 mg/min

~90 mg/dL
In 30 minutes

Low Soon alert. This feature is unique to the Dexcom G6 and alerts people with diabetes when their glucose is predicted to be at or below 55 mg/dL within 20 minutes. The Urgent Low Alarm cannot be changed or turned off and notifies the person with diabetes that glucose is at or below 55 mg/dL. The use of the trend arrows can help an individual understand the speed and direction of their glucose. For example, when you have two arrows in the upward direction, as seen in Figure 4, the glucose is rapidly rising (≥ 3 mg/min) and the glucose will increase ~ 90 mg/dL in the next 30 minutes. "We teach patients what the arrows mean," stated Ms. Kruger.
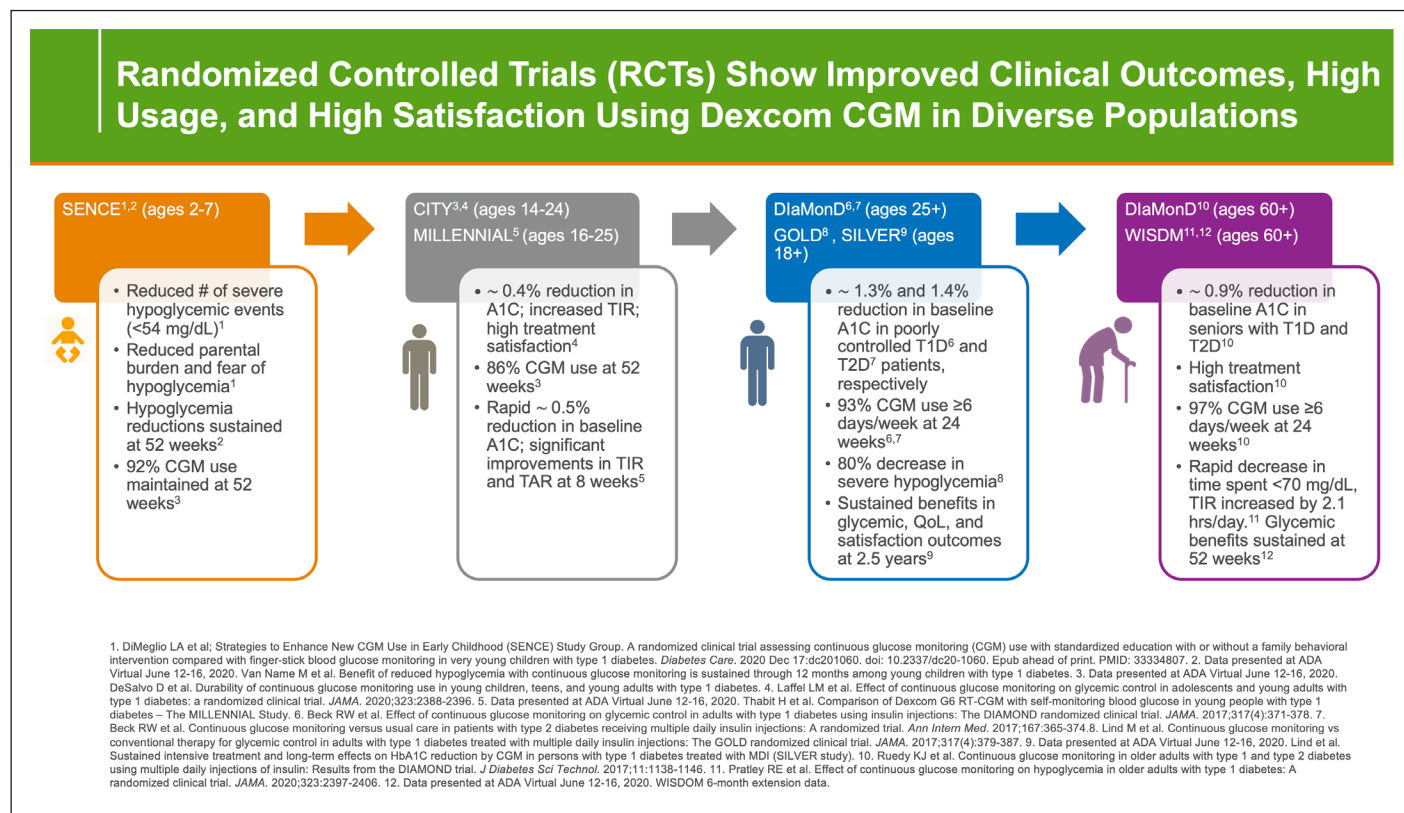
Dexcom CGM and Randomized Clinical Trials

Ms. Kruger also highlighted the robust Dexcom studies conducted: "Across the spectrum of ages, you are seeing less time in hypoglycemia, greater TIR, greater A1C improvements. Patients like it, and patients are wearing it." (Figure 5)

The SENCE study demonstrated a reduced number of severe hypoglycemic events (<54 mg/dL) for children aged 2 to 7 years of age, reduced parental burden and fear of hypoglycemia, reduced hypoglycemia was sustained at 52 weeks.[8] Notably, 92% of the children maintained CGM use at 52 weeks.[9]

In the Diamond® study, there was a ~1.3% and 1.4% reduction in baseline A1C in persons with T1D[6] and T2D[7], respectively. Sustained benefits in glycemic, quality of life, and satisfaction outcomes at 2.5 years were reported in individuals 18 years and older in the SILVER study.[9]

For individuals 60 years and older, there was a ~0.9% reduction in baseline A1C in older adults with T1D and T2D, high treatment satisfaction, 97% CGM use ≥6 days/week at 24 weeks, and a rapid decrease in time spent < 70mg/dL.[10,11] TIR also increased 2.1 hours per day and glycemic benefits were sustained at 52 weeks.[11,12]

Figure 5. Randomized Controlled Trials Across the Spectrum of Ages

Randomized Controlled Trials (RCTs) Show Improved Clinical Outcomes, High Usage, and High Satisfaction Using Dexcom CGM in Diverse Populations

SENCE[1,2] (ages 2-7)

- Reduced # of severe hypoglycemic events (<54 mg/dL)[1]
- Reduced parental burden and fear of hypoglycemia[1]
- Hypoglycemia reductions sustained at 52 weeks[2]
- 92% CGM use maintained at 52 weeks[3]

CITY[3,4] (ages 14-24)
MILLENNIAL[5] (ages 16-25)

- ~ 0.4% reduction in A1C; increased TIR; high treatment satisfaction[4]
- 86% CGM use at 52 weeks[3]
- Rapid ~ 0.5% reduction in baseline A1C; significant improvements in TIR and TAR at 8 weeks[5]

DIaMonD[6,7] (ages 25+)
GOLD[8], SILVER[9] (ages 18+)

- ~ 1.3% and 1.4% reduction in baseline A1C in poorly controlled T1D[6] and T2D[7] patients, respectively
- 93% CGM use ≥6 days/week at 24 weeks[6,7]
- 80% decrease in severe hypoglycemia[8]
- Sustained benefits in glycemic, QoL, and satisfaction outcomes at 2.5 years[9]

DIaMonD[10] (ages 60+)
WISDM[11,12] (ages 60+)

- ~ 0.9% reduction in baseline A1C in seniors with T1D and T2D[10]
- High treatment satisfaction[10]
- 97% CGM use ≥6 days/week at 24 weeks[10]
- Rapid decrease in time spent <70 mg/dL, TIR increased by 2.1 hrs/day.[11] Glycemic benefits sustained at 52 weeks[12]

1. DiMeglio LA et al; Strategies to Enhance New CGM Use in Early Childhood (SENCE) Study Group. A randomized clinical trial assessing continuous glucose monitoring (CGM) use with standardized education with or without a family behavioral intervention compared with finger-stick blood glucose monitoring in very young children with type 1 diabetes. *Diabetes Care.* 2020 Dec 17:dc201060. doi: 10.2337/dc20-1060. Epub ahead of print. PMID: 33334807. 2. Data presented at ADA Virtual June 12-16, 2020. Van Name M et al. Benefit of reduced hypoglycemia with continuous glucose monitoring is sustained through 12 months among young children with type 1 diabetes. 3. Data presented at ADA Virtual June 12-16, 2020. DeSalvo D et al. Durability of continuous glucose monitoring use in young children, teens, and young adults with type 1 diabetes. 4. Laffel LM et al. Effect of continuous glucose monitoring on glycemic control in adolescents and young adults with type 1 diabetes: a randomized clinical trial. *JAMA.* 2020;323:2388-2396. 5. Data presented at ADA Virtual June 12-16, 2020. Thabit H et al. Comparison of Dexcom G6 RT-CGM with self-monitoring blood glucose in young people with type 1 diabetes – The MILLENNIAL Study. 6. Beck RW et al. Effect of continuous glucose monitoring on glycemic control in adults with type 1 diabetes using insulin injections: The DIAMOND randomized clinical trial. *JAMA.* 2017;317(4):371-378. 7. Beck RW et al. Continuous glucose monitoring versus usual care in patients with type 2 diabetes receiving multiple daily insulin injections: A randomized trial. *Ann Intern Med.* 2017;167:365-374. 8. Lind M et al. Continuous glucose monitoring vs conventional therapy for glycemic control in adults with type 1 diabetes treated with multiple daily insulin injections: The GOLD randomized clinical trial. *JAMA.* 2017;317(4):379-387. 9. Data presented at ADA Virtual June 12-16, 2020. Lind et al. Sustained intensive treatment and long-term effects on HbA1C reduction by CGM in persons with type 1 diabetes treated with MDI (SILVER study). 10. Ruedy KJ et al. Continuous glucose monitoring in older adults with type 1 and type 2 diabetes using multiple daily injections of insulin: Results from the DIAMOND trial. *J Diabetes Sci Technol.* 2017;11:1138-1146. 11. Pratley RE et al. Effect of continuous glucose monitoring on hypoglycemia in older adults with type 1 diabetes: A randomized clinical trial. *JAMA.* 2020;323:2397-2406. 12. Data presented at ADA Virtual June 12-16, 2020. WISDOM 6-month extension data.
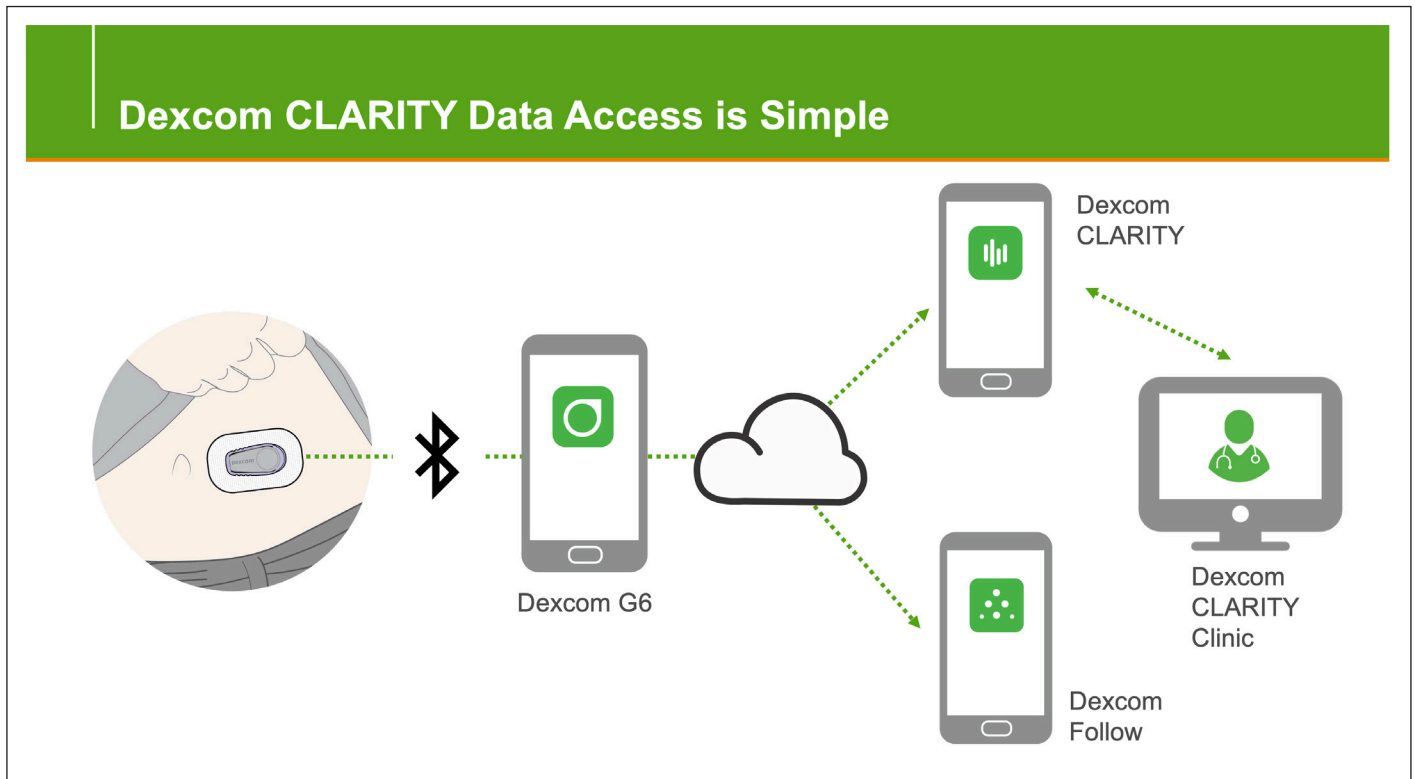
Dexcom Clarity

Patients and PCPs can access clinically relevant glucose patterns, trends, and statistics via a range of interactive reports, at no cost by using Dexcom Clarity. The Clarity app helps patients stay on track with their glucose management with weekly notifications about their progress. Frequent Clarity views (defined as four or more monthly log-ins to Dexcom Clarity) were associated with a 15% increase in TIR.[7] With Clarity, patients can authorize data sharing with their healthcare providers which can streamline workflow.

Sharing Clarity Data with the Dexcom G6 App

The data from the sensor that a patient wears is transmitted via Bluetooth to the Dexcom G6 app on a compatible smart device. The app data is sent to the Dexcom Cloud (via cellular data or Wi-Fi). The Dexcom Cloud can share data to the patient's Clarity app. When sharing is enabled, patients can share data to the Clarity clinic account. When a patient uses a receiver, the data from the sensor that a patient wears is transmitted via Bluetooth to the Dexcom receiver. The receiver needs to be plugged into a computer to get the data to Dexcom Cloud, and this can be done at home or the clinic. If the patient chooses to share, the clinic will see the data every time the patient uploads from home. Ms. Kruger shared her office best practices for Clarity and data sharing. She stated, "Our medical assistants check in the patient and go to the cloud to see if the patient is already connected. If not, they send an invitation to connect and show the patient how to do that. Our IT quality team enables patients to push any updates to our computers. IT can also set up Clarity on the provider's computer."

Figure 6. Dexcom Clarity Data Sharing

Dexcom Clarity has nine reports—all are generated from ADA-backed, industry-standard metrics that can support in-person or remote conversations with your patients. These reports include:

1. **Overview:** Contains key metrics to help address chief concerns; also allows you to bill for CGM review

2. **Patterns:** Identified patterns begin discussions on what, why, and how to address issues

3. **Trends:** Displays patient's glucose trends at different times of day over a selected date range

4. **Overlay:** Each graph contains up to 7 days of all sensor CGM data points to help visualize patterns and individual events

5. **Daily view:** Allows users to analyze all glucose values over individual days, as well as isolated, patient-centered events for each day

6. **Compare:** Displays two date ranges of a patient's values to compare side-by-side

7. **Statistics:** Focus on metrics and glucose targets; TIR can be compared across days or times to identify issues

8. **The Ambulatory Glucose Profile (AGP) report:** An ADA and AACE-recommended standardized report for CGM interpretation created by the International Diabetes Center (IDC). This report shows three distinct sections:

   • Summarization of glucose values to help assess the overall quality of glucose management

   • Trend graph or variability around the mean glucose and patterned areas of highs and lows

   • Single-day glucose values to help identify patterns and progress

Figure 7: AGP Report

AGP images for demonstration purposes only
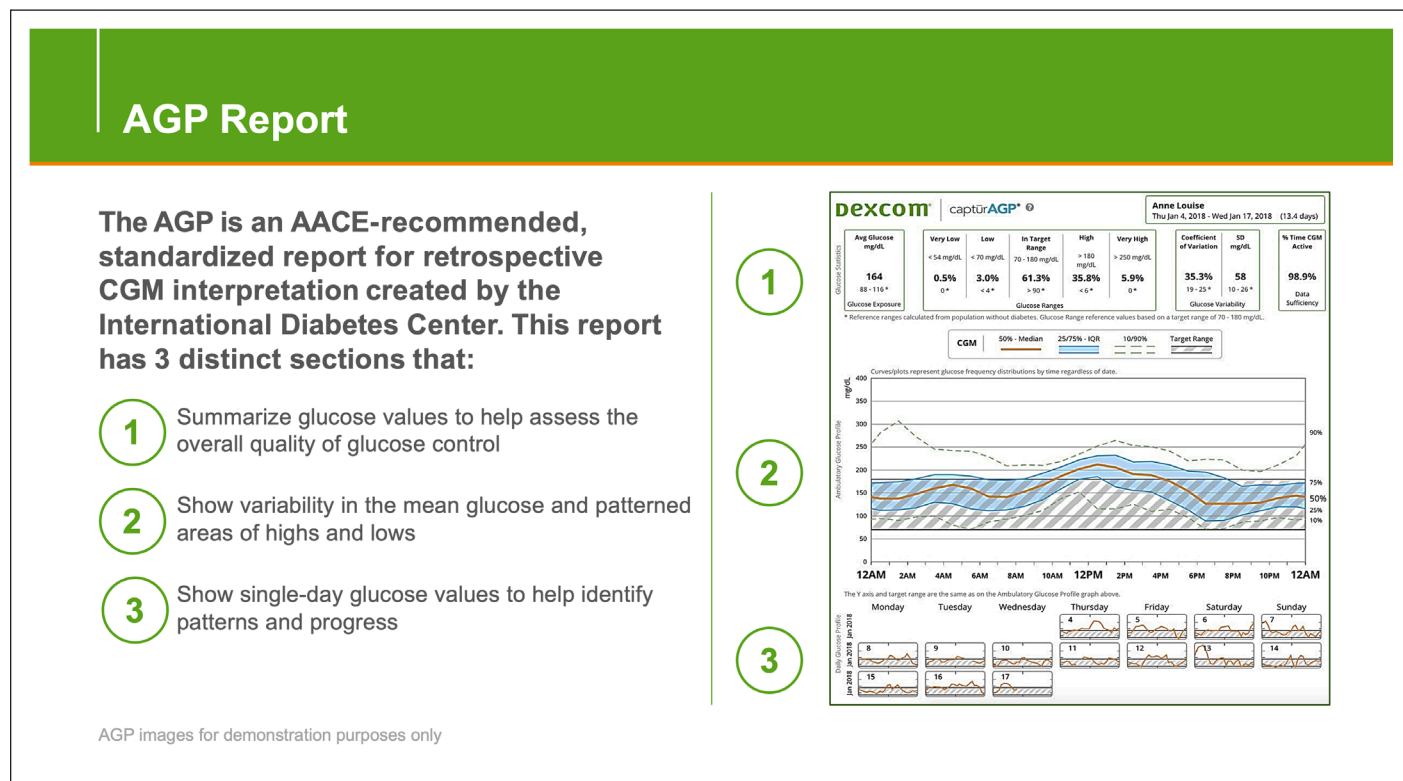
9. **Pro Report:** Patients wear the Dexcom G6 Pro for up to 10 days in blinded or unblinded mode. On the return visit, you can review the data from the Pro report to discuss session insights and make appropriate treatment recommendations. Then, you can submit the report for reimbursement for CGM setup and interpretation.

Strategies to Implement Dexcom G6 and Dexcom Clarity in Your Practice

Ms. Kruger provides encouragement with incorporating Dexcom G6 in the clinic and explains, "The way we have done it at our clinic is that over time it becomes more of just fine-tuning and fine-tuning, and we use a host of clinical staff to support us." She recommends to the clinician that they need to decide within their practice which of their clinical staff, support staff, and healthcare providers are the best to help manage CGMs. Ms. Kruger mentioned

how the medical assistants (MAs) at her office check in the patient, upload Clarity reports, and make sure the patient's Clarity account is connected with the clinic. If they are not, she will have the MA send an invite to the patient. She will also have the MAs ask the patient, "Do you have any devices that need to be uploaded for your healthcare provider to see you today?"

The healthcare providers at her clinic identify other patients who are not on CGMs but who can benefit from using them and will order Dexcom G6. They also review the Dexcom Clarity reports and bill for interpretation.

Rapid Interpretation with the DATAA model

DATAA is a mnemonic that describes a tool to quickly and systematically interpret Dexcom G6 data in a standardized, simplified, and practical way. Ideally,

there should be at least 14 days of CGM data to download. The priority is assessing safety and evaluating TBR, then TIR and TAR. Collaborate with your patients to develop an action plan using a shared decision-making approach to facilitate data-driven discussions, as seen in Figure 9.
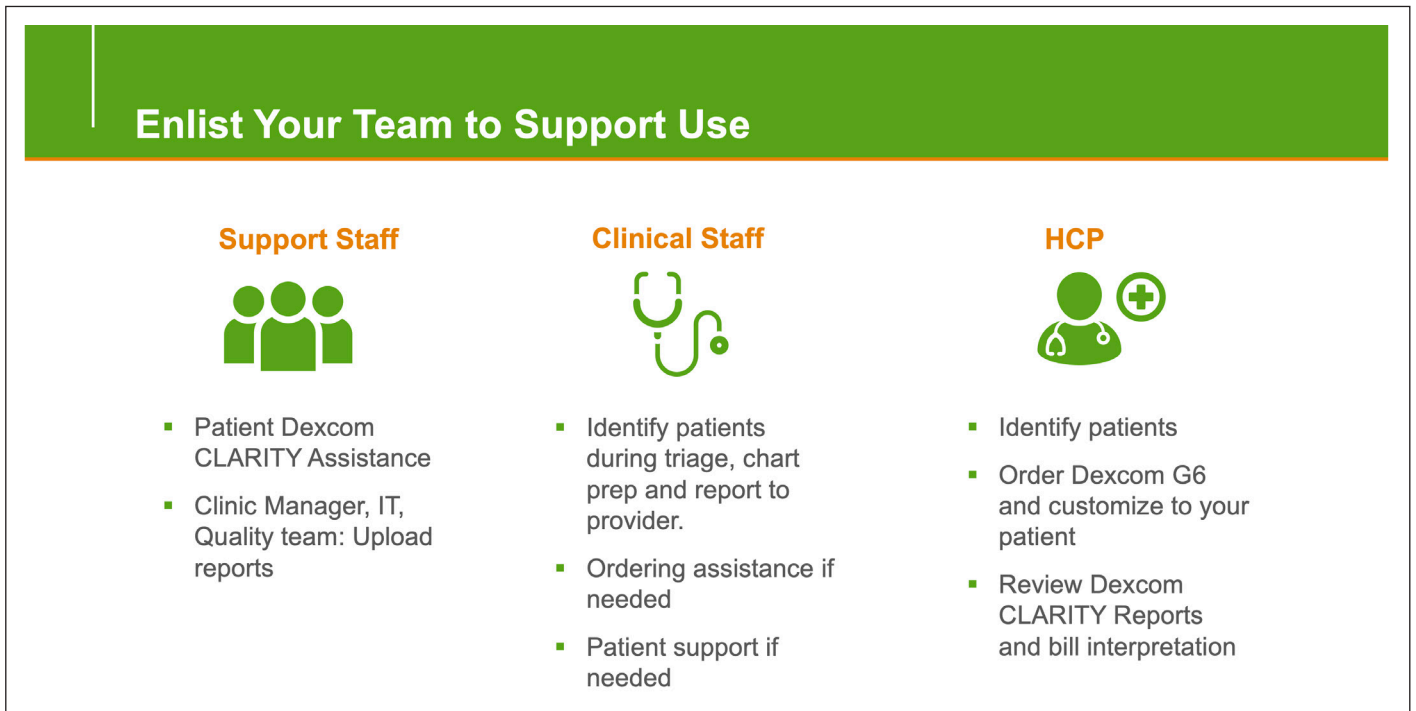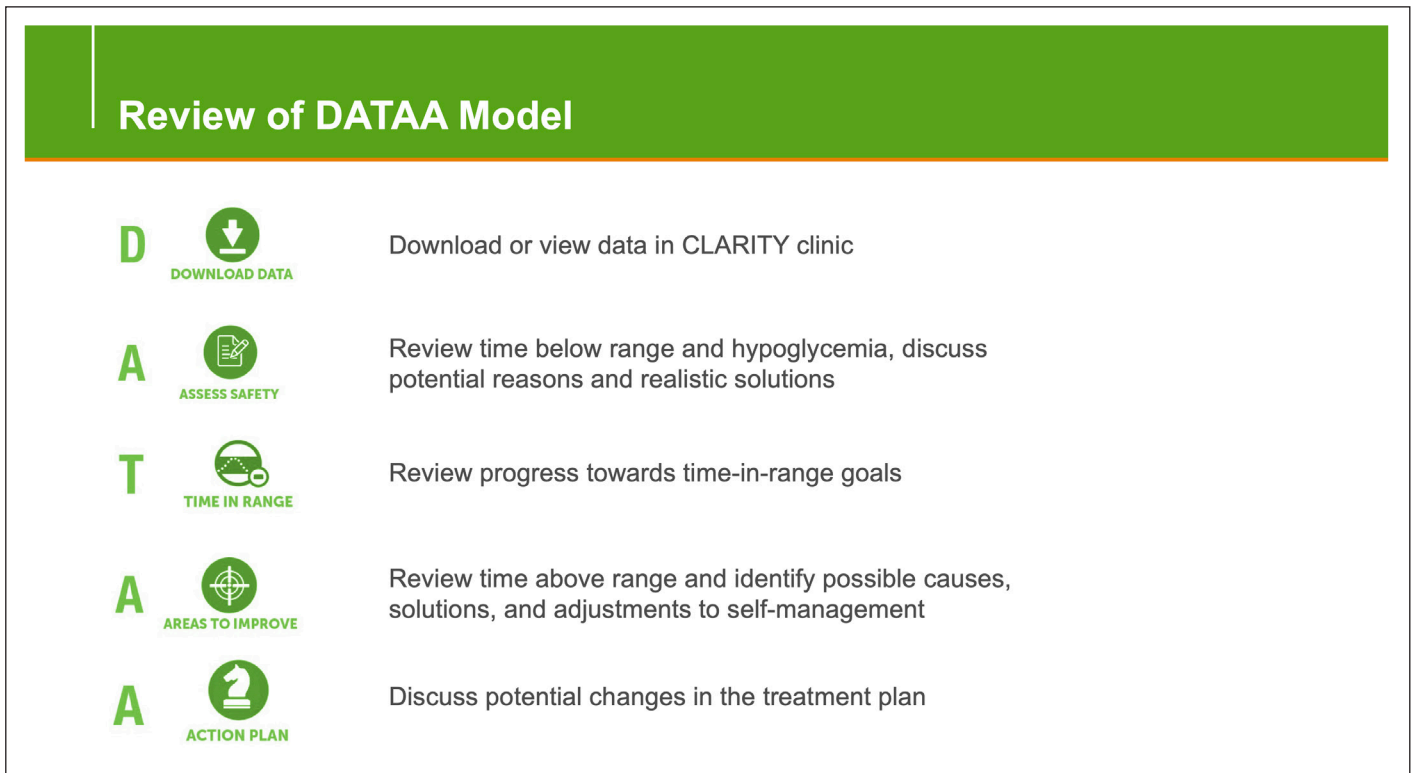
Figure 8. Support Staff and CGM

Enlist Your Team to Support Use

Support Staff

- Patient Dexcom CLARITY Assistance
- Clinic Manager, IT, Quality team: Upload reports

Clinical Staff

- Identify patients during triage, chart prep and report to provider.
- Ordering assistance if needed
- Patient support if needed

HCP

- Identify patients
- Order Dexcom G6 and customize to your patient
- Review Dexcom CLARITY Reports and bill interpretation

Figure 9. DATAA Model

Review of DATAA Model

D — DOWNLOAD DATA — Download or view data in CLARITY clinic

A — ASSESS SAFETY — Review time below range and hypoglycemia, discuss potential reasons and realistic solutions

T — TIME IN RANGE — Review progress towards time-in-range goals

A — AREAS TO IMPROVE — Review time above range and identify possible causes, solutions, and adjustments to self-management

A — ACTION PLAN — Discuss potential changes in the treatment plan

Billing Procedures

Commercial health insurers and government-sponsored plans provide more coverage for CGM systems now than ever before. Many reimbursement challenges that early adopters of CGM faced have been eliminated, supporting a more favorable reimbursement environment overall. Ms. Kruger concluded, "Forty years ago, type 2 diabetes was not considered serious. Now we know it is, and most insurance companies are paying for CGMs."

Davida Kruger, M.S.N., APN-BC, BC-ADM, is a certified nurse practitioner in diabetes with more than 35 years at Henry Ford Health System in Detroit, MI. Her role includes both clinical practice and research. She is board certified by the American Nurses Association Credentialing Center in Primary Care and the American Diabetes Association (ADA) Care and Education Specialist in Advanced Diabetes Management. She is past chair of the ADA Research Foundation and has served on ADA's Research Policy Committee. She is also past President of Health Care and Education of the ADA and has served as editor of Diabetes Spectrum *and editor in chief of* Clinical Diabetes. *Ms. Kruger has been a principal investigator for numerous research projects and has written widely on diabetes care.*

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