Session 1: Overview of CGM

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HealthPartners® Institute

Disclosures

Gregg Simonson, faculty for this educational activity, has the following relevant financial relationships:

Consultant, advisor, or speaker for Abbott, Dexcom, Sanofi

All grants, honoraria and payments for the above activities are paid directly to my employer, the International Diabetes Center/Park Nicollet, and none are directly paid to Gregg Simonson.

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International Diabetes Center

Ensuring that every individual with diabetes or at risk for diabetes receives the best possible care

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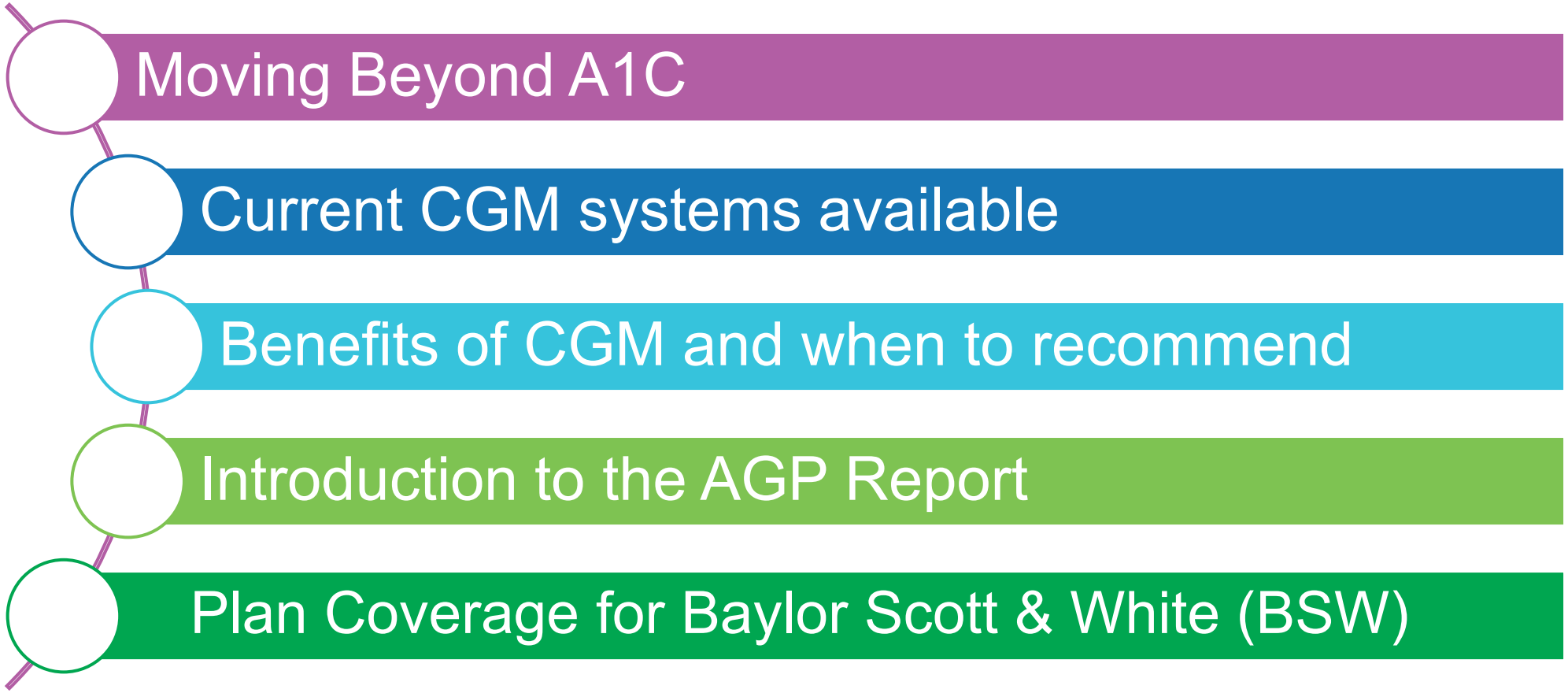
Presentation Outline



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DCCT (1983-1993): Relationship of HbA1c to Risk of Microvascular Complications

HbA1c
- **Guide to Management**
- **Measure of Quality**

The New England Journal of Medicine

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Volume 329 SEPTEMBER 30, 1993 Number 14

THE EFFECT OF INTENSIVE TREATMENT OF DIABETES ON THE DEVELOPMENT AND PROGRESSION OF LONG-TERM COMPLICATIONS IN INSULIN-DEPENDENT DIABETES MELLITUS

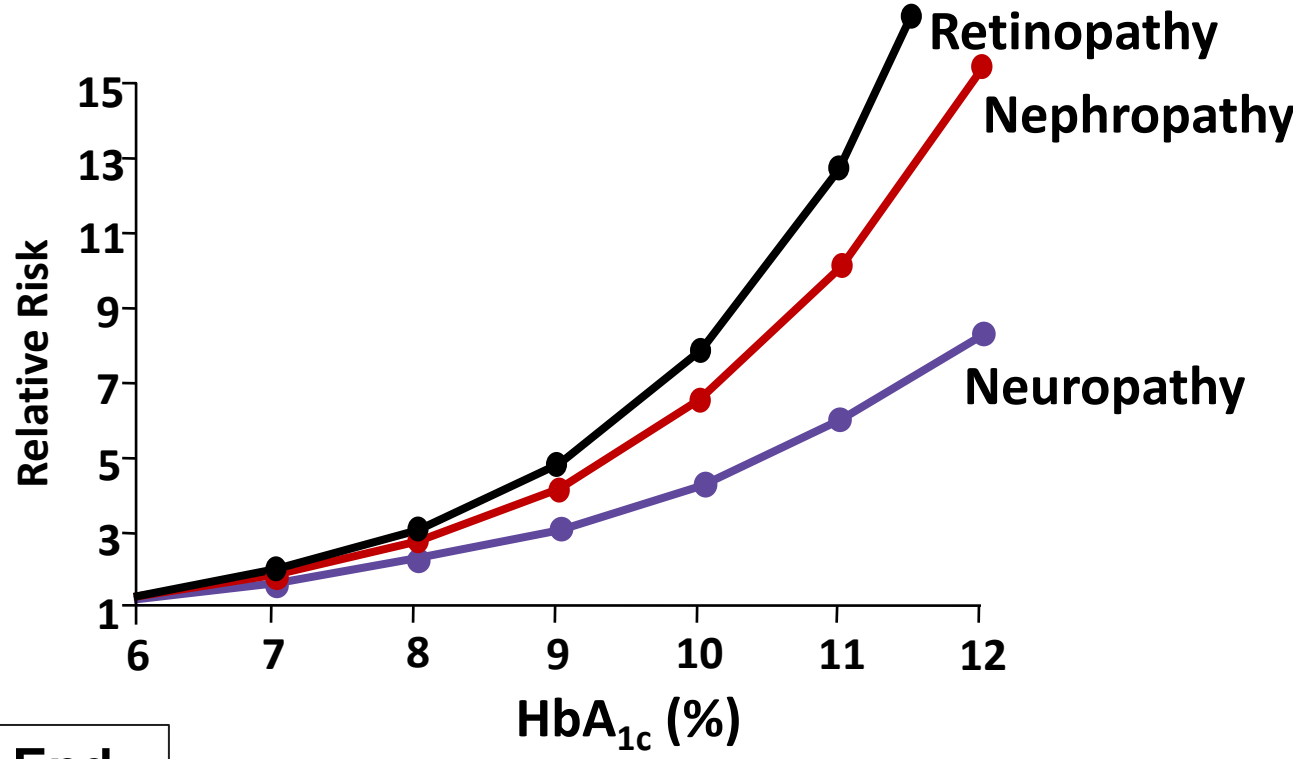
THE DIABETES CONTROL AND COMPLICATIONS TRIAL RESEARCH GROUP*

Abstract *Background.* Long-term microvascular and neurologic complications cause major morbidity and mortality in patients with insulin-dependent diabetes mellitus (IDDM). We examined whether intensive treatment with the goal of maintaining blood glucose concentrations close to the normal range could decrease the frequency and severity of these complications.

Methods. A total of 1441 patients with IDDM — 726 with no retinopathy at base line (the primary-prevention cohort) and 715 with mild retinopathy (the secondary-intervention cohort) were randomly assigned to intensive therapy administered either with an external insulin pump or by three or more daily insulin injections and guided by frequent blood glucose monitoring or to conventional therapy with one or two daily insulin injections. The patients were followed for a mean of 6.5 years, and the appearance and progression of retinopathy and other complications were assessed regularly.

Results. In the primary-prevention cohort, intensive therapy reduced the adjusted mean risk for the development of retinopathy by 76 percent (95 percent confidence interval, 62 to 85 percent), as compared with conventional therapy. In the secondary-intervention cohort, intensive therapy slowed the progression of retinopathy by 54 percent (95 percent confidence interval, 39 to 66 percent) and reduced the development of proliferative or severe nonproliferative retinopathy by 47 percent (95 percent confidence interval, 14 to 67 percent). In the two cohorts combined, intensive therapy reduced the occurrence of microalbuminuria (urinary albumin excretion of ≥40 mg per 24 hours) by 39 percent (95 percent confidence interval, 21 to 52 percent), that of albuminuria (urinary albumin excretion of ≥300 mg per 24 hours) by 54 percent (95 percent confidence interval, 19 to 74 percent), and that of clinical neuropathy by 60 percent (95 percent confidence interval, 38 to 74 percent). The chief adverse event associated with intensive therapy was a two-to-threefold increase in severe hypoglycemia.

Conclusions. Intensive therapy effectively delays the onset and slows the progression of diabetic retinopathy, nephropathy, and neuropathy in patients with IDDM. (N Engl J Med 1993;329:977-86.)



End DCCT 1993

"HbA1c Era"

2025

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Limitations of HbA_{1c}

1. HbA_{1c} can be impacted by:
    - Hemoglobinopathies
    - Iron deficiency
    - CKD
    - Liver disease
    - Individual changes in RBC lifespan
    - Unknown genetic factors affecting glycation
    - Race
    - Age

2. HbA1c does not identify hypoglycemia or glucose variability

CKD, chronic kidney disease

www.ngsp.org. Last accessed May 2021

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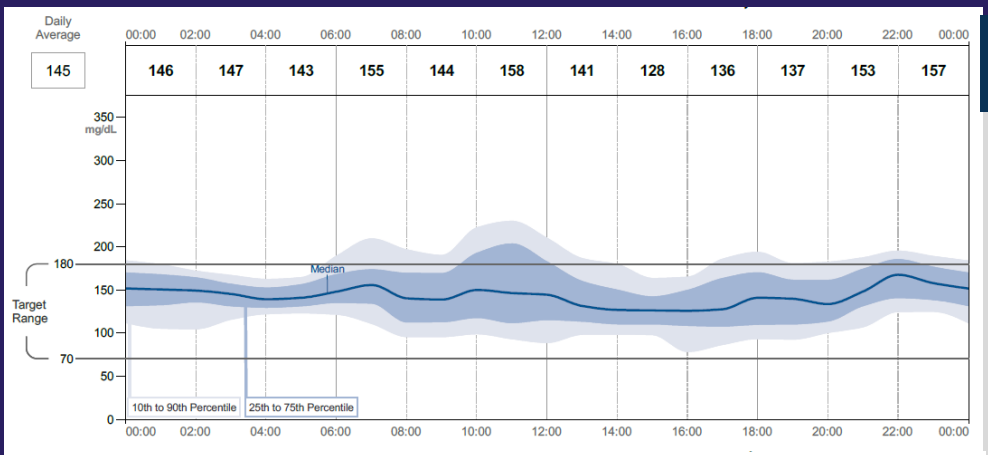
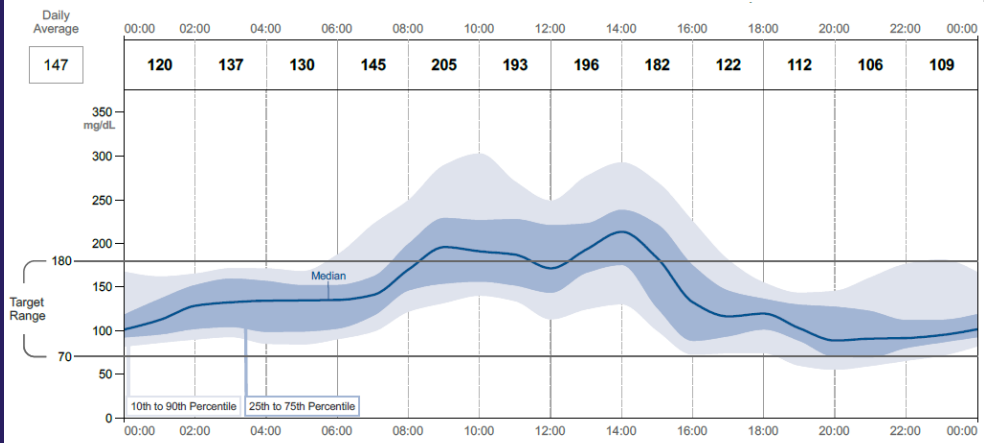
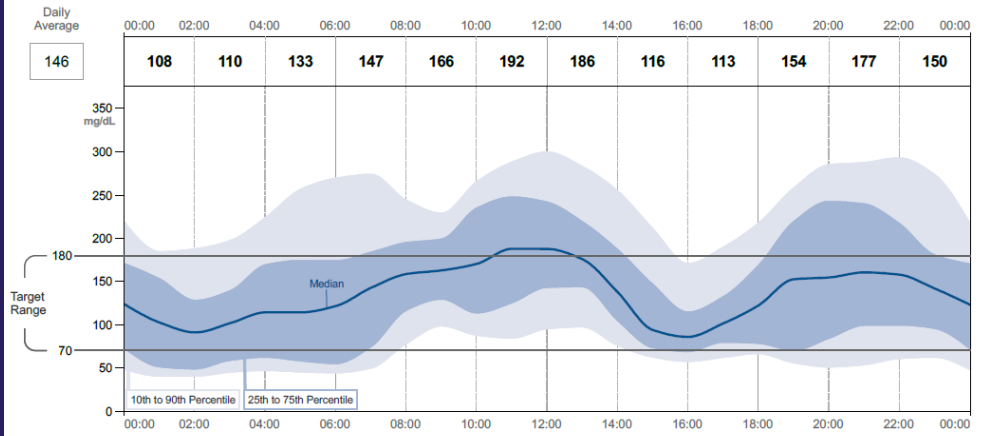
A1C or CGM for management?







A1C (%)	% Time Hypo (< 70 mg/dL)	Glu. Variability (CV %)	% Time TIR (70-180 mg/dL)
6.7%	1%	26%	83%
6.7%	6%	42%	69%
6.7%	9%	53%	51%

CV= coefficient of variation

Limitations of HbA_{1c}

1. HbA_{1c} can be impacted by:
    - Hemoglobinopathies
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    - CKD
    - Liver disease
    - Individual changes in RBC lifespan
    - Unknown genetic factors affecting glycation
    - Race
    - Age
2. HbA_{1c} does not identify hypoglycemia or glucose variability
3. **Using HbA_{1c} alone to guide improvement in HbA_{1c} is not working**

CKD, chronic kidney disease

www.ngsp.org. Last accessed May 2021

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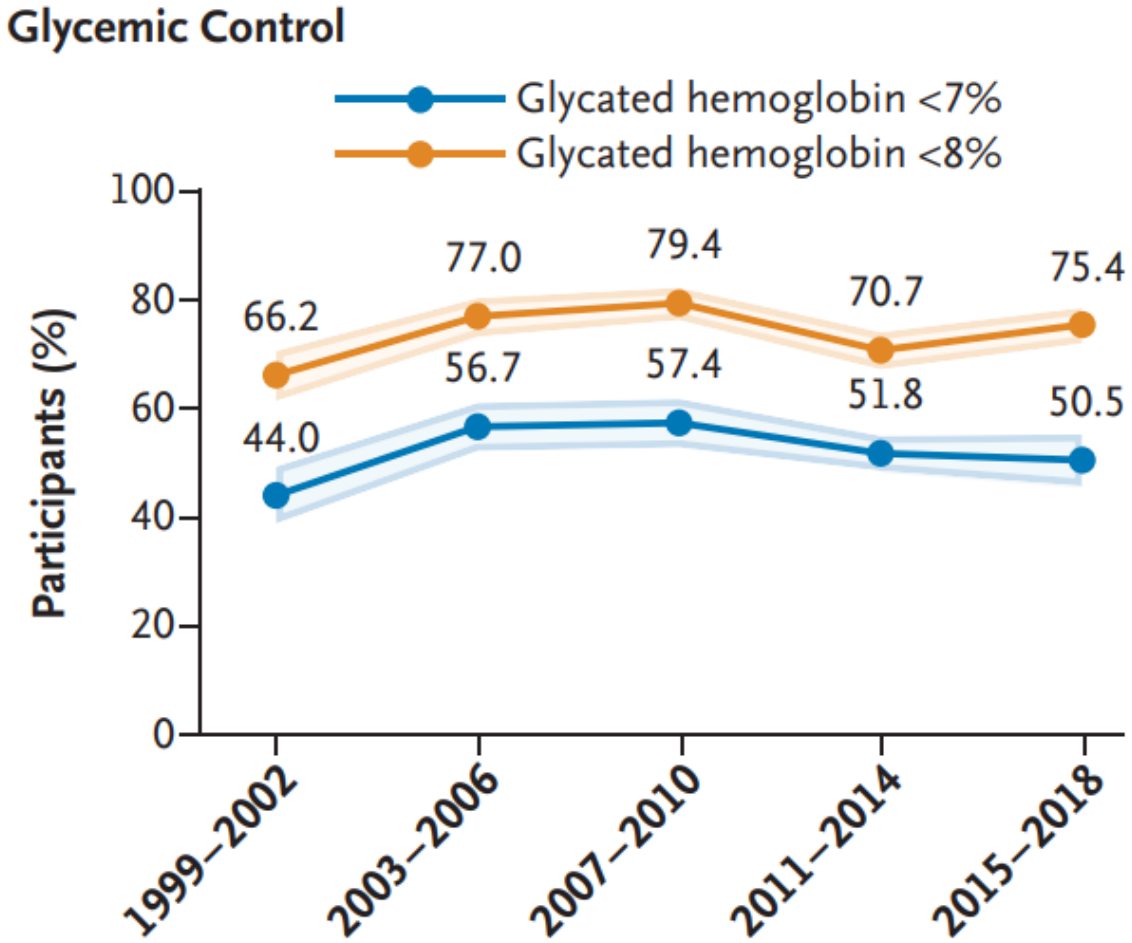
Trends in Diabetes Treatment and Control in U.S. Adults, 1999–2018

Michael Fang, Ph.D., Dan Wang, M.S., Josef Coresh, M.D., Ph.D., and Elizabeth Selvin, Ph.D., M.P.H.



Can continuous glucose monitoring (CGM) help?

N ENGL J MED 384;23 NEJM.ORG JUNE 10, 2021

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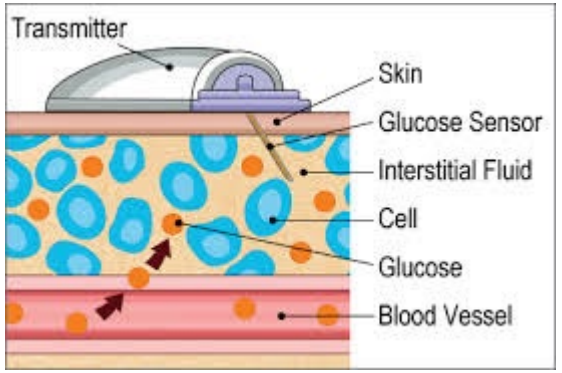
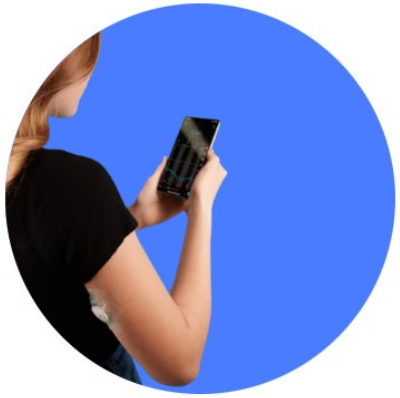
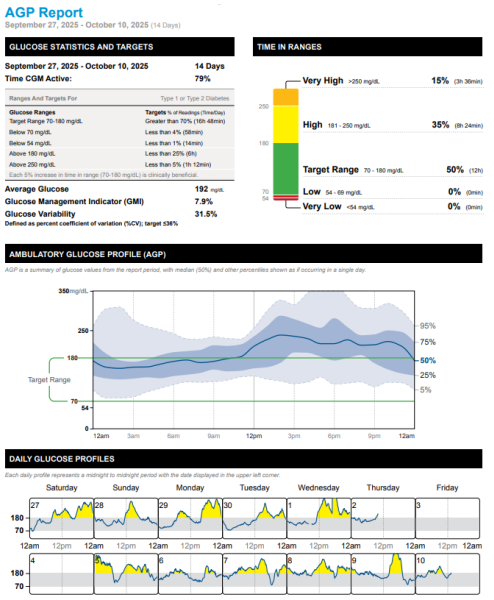
What is continuous glucose monitoring (CGM)?







- Gathers data continuously (alerts, alarms, trend arrows)
- Includes a sensor, transmitter, and receiver device (or phone with corresponding app)
- Data can be transmitted from smartphone to cloud-based repositories for retrospective review
- Lag time of 5-6 minutes between intravascular and interstitial compartments

Images from: www.medtronicdiabetes.com
Carlson, et al. DTT 2017; 19:S4-S11; Basu, et. al Diabetes 2013; 62:4083–4087, 2013

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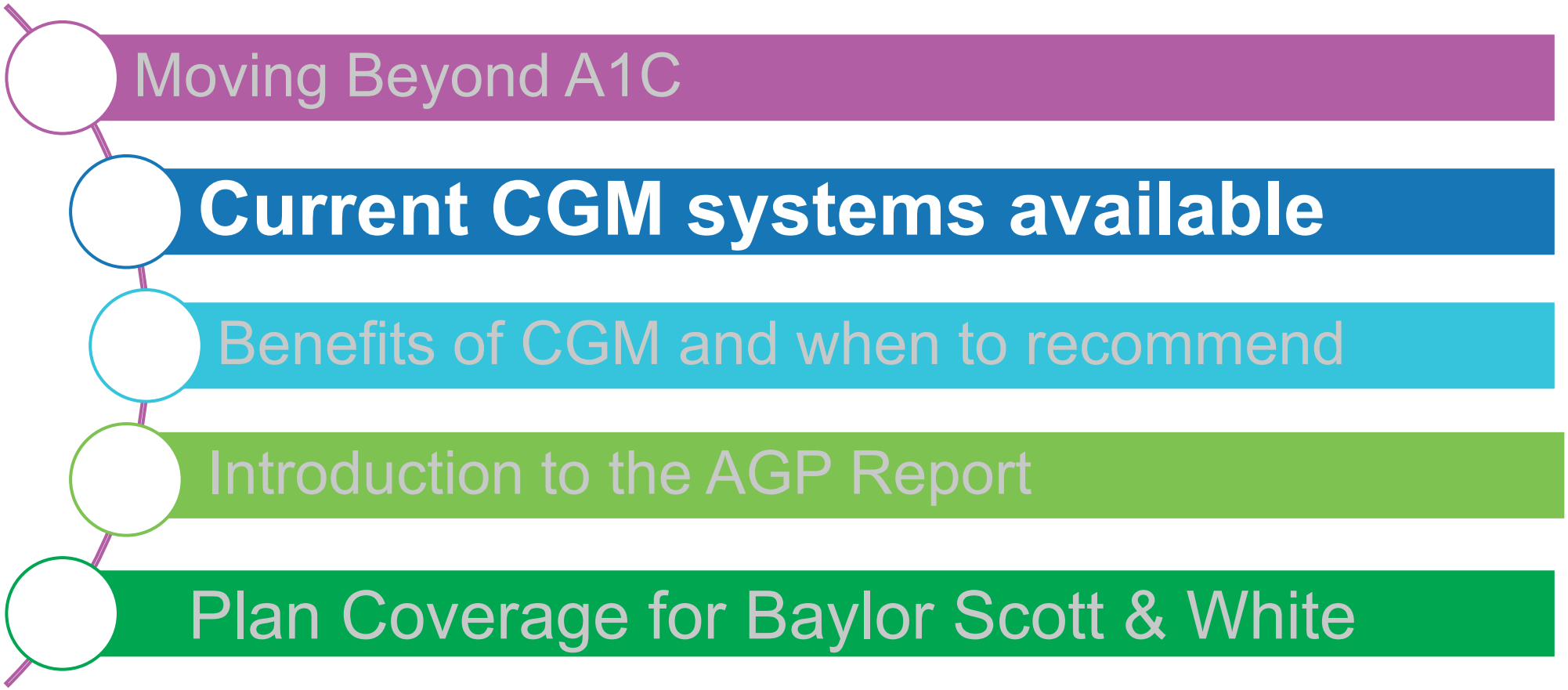
Presentation Outline



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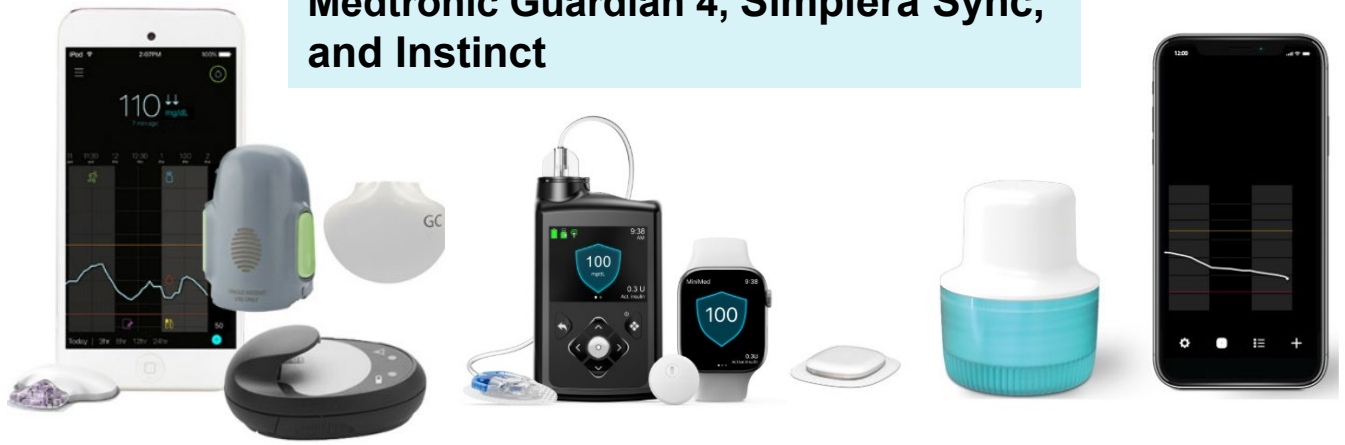
Current Prescription CGM Systems

Abbott Freestyle Libre 2+, Libre 3+

Dexcom G6 (discontinuing July 2026)
G7 (10 day)
G7 15 Day

Eversense 365- Implantable CGM

Medtronic Guardian 4, Simplera Sync, and Instinct



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Over the Counter CGM/Biosensor Systems

Abbott Lingo:

- 14 day biosensor with minute by minute continuous glucose tracking
- No stand-alone reader/receiver, requires the Lingo app (currently only compatible with iPhone 11 or later)

Dexcom Stelo:

- 15 day biosensor with continuous glucose tracking. Readings are taken every 15 minutes
- No stand-alone reader/receiver, requires the Stelo app, available for both iPhone or Android
- No low glucose alerts

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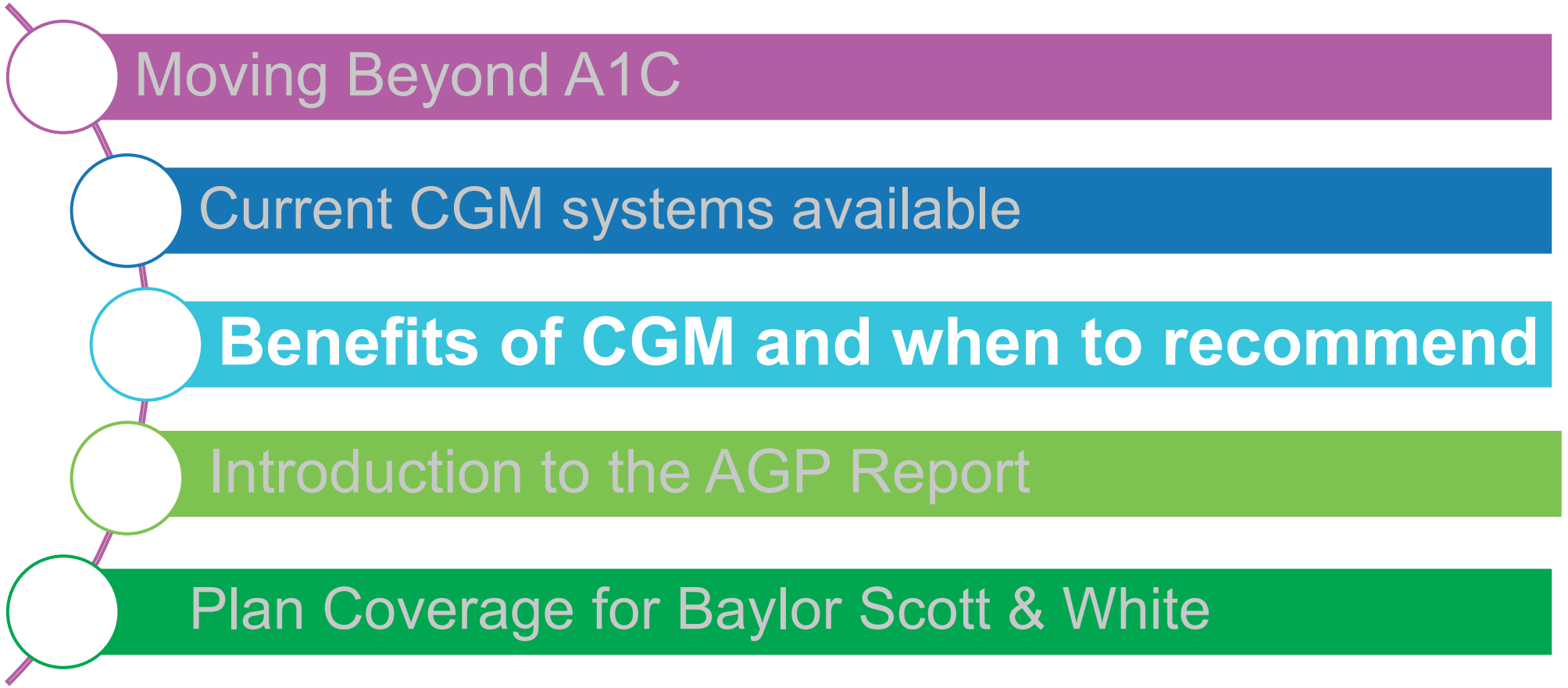

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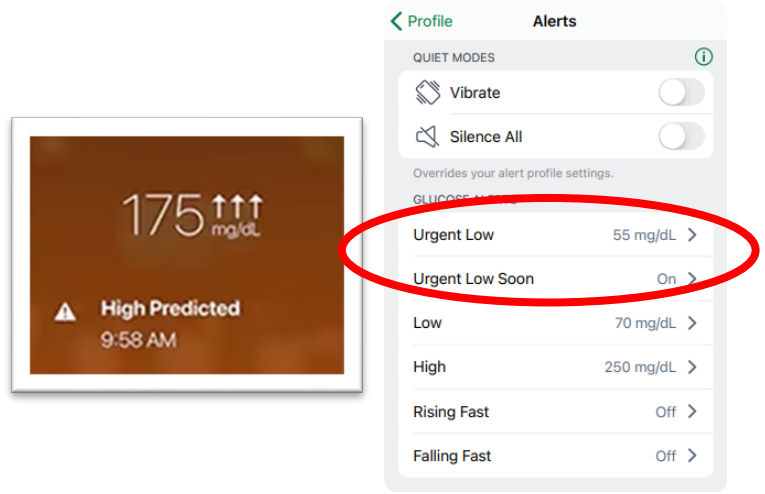
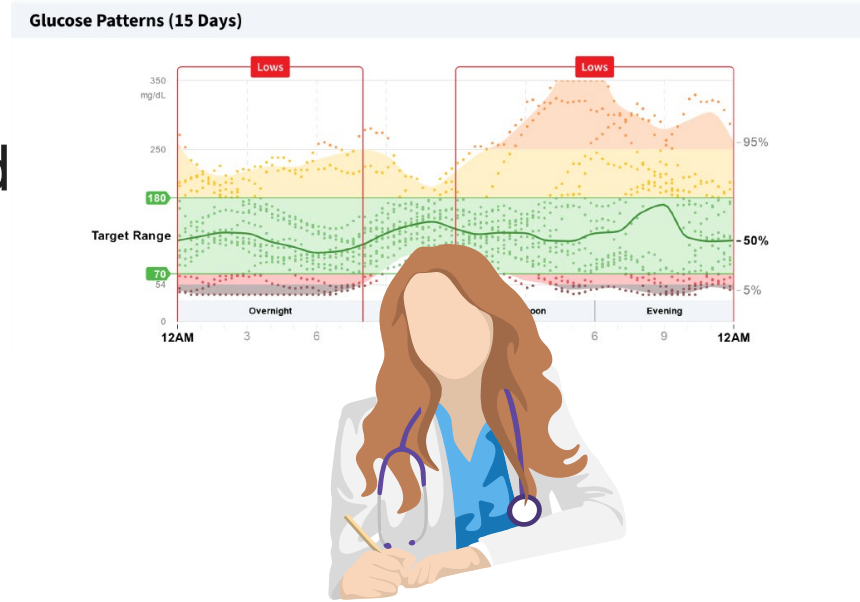
Benefits of CGM use in Diabetes Care

- Improved glycemic management (lower A1C, less hypoglycemia)
- Continuous monitoring – real time data, alerts, alarms, trend arrows
- Empower people with knowledge to make changes
  - Share data with clinic or follower (e.g. parent, spouse, school RN, etc.)
- Convenience
- Support more meaningful conversations and shared decision making
- Valuable tool for virtual diabetes care
- Some CGM systems are compatible with other diabetes technologies (e.g. insulin pumps, AID)





Lee, GS et al. Continuous Glucose Monitoring for the Internist. Med Clin North Am. 2021 Nov;105(6):967-982
Image from FreeStyle Libre 3 User's Manual.

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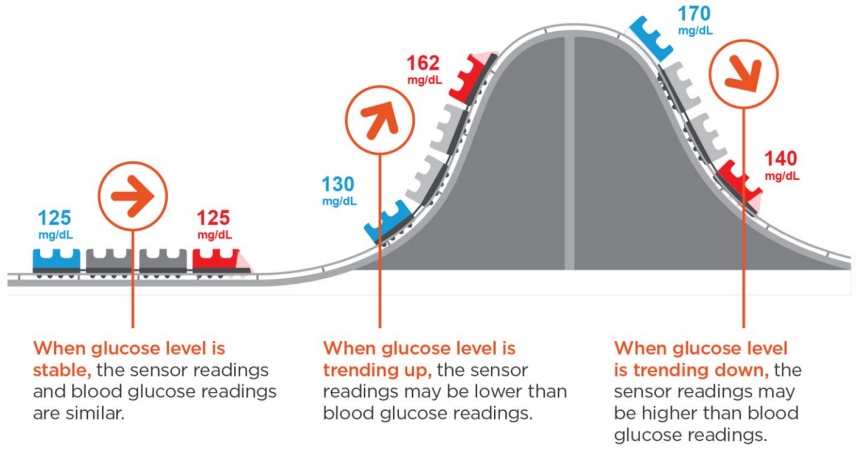
Limitations/Barriers with CGM use in Diabetes Care

- Lag time
- Accuracy (improving with newer models)
- Subcutaneous insertion
- Cost
- Access (racial disparities, geographic location, internet access, provider implicit bias, etc)
- Sensor adhesion
- Skin irritation/adhesive reactions



Lee, GS et al. Med Clin North Am. 2021 Nov;105(6):967-982; Annals of Family Medicine, 2022:20:2689.
Images from: https://www.freestyle.abbott/in-en/bgm-vs-freeStyle-libre.html. Accessed 28 April 2024

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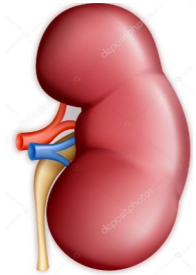
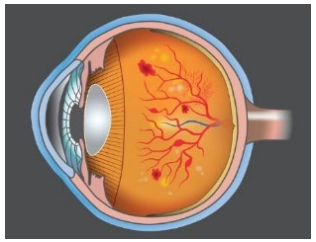
Association of Time in Range (TIR) and Diabetes Complications

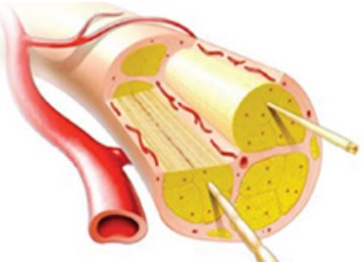


Lower TIR associated with albuminuria
- Beck et al. Diab Care 2019 (T1DM)
- Yoo et al. DTT 2020
- Ranjan et al. Diab Care 2020 (T1DM)



Lower TIR associated with retinopathy
- Lu et al. Diab Care 2018
- Beck et al. Diab Care 2019 (T1DM)
- Bezerra et al. Diab & Meta Syndrome 2023 (T1DM)

Lower TIR associated with higher CV mortality
- Lu et al. Diab Care 2021



Lower TIR associated with peripheral neuropathy
- Mayeda et al BMJ, 2020

Lower TIR associated with cardiac autonomic neuropathy
- Kim et al. DTT, 2021

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Time in Range Is Associated with Incident Diabetic Retinopathy in Adults with Type 1 Diabetes: A Longitudinal Study

Viral N. Shah, MD,[1] Lauren G. Kanapka, MSc,[2] Halis K. Akturk, MD,[1]

TABLE 3. ASSOCIATION OF GLYCATED HEMOGLOBIN AND CONTINUOUS GLUCOSE MONITORING METRICS WITH DIAGNOSIS OF INCIDENT DIABETIC RETINOPATHY

Metric	*Unit of change for calculation of OR*	*Unadjusted*[a]		*Adjusted*[a]	
		OR (95% CI)	P	*OR (95% CI)*	P
HbA1c	0.5% Increase	1.38 (1.18–1.62)	<0.001	1.24 (1.05–1.48)	0.01
	0.4% Increase	1.30 (1.14–1.47)		1.19 (1.04–1.37)	
Time in range 70–180 mg/dL	5% Decrease	1.26 (1.13–1.42)	<0.001	1.18 (1.03–1.35)	0.02
	10% Decrease	1.60 (1.27–2.01)		1.39 (1.06–1.82)	

Shah et al. DTT 2024; 26:246-251.

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What individuals should be considered for CGM?

Type 1 & 2 Diabetes Insulin Therapy	Noninsulin Therapy that can cause hypoglycemia	Any diabetes treatment where CGM helps in management	Type 1 Diabetes and pregnancy
Grade A	Grade C	Grade C	Grade A

- Real time CGM devices should be used as close to daily as possible for maximal benefit
- The choice of device should be made based on patient circumstances, preferences, and needs
- When prescribing a device, ensure PWD/caregiver receive initial and on-going education/training

American Diabetes Association Professional Practice Committee for Diabetes*; 7. Diabetes Technology: Standards of Care in Diabetes—2026. *Diabetes Care* 1 January 2026; 49 (Supplement_1): S150–S165. https://doi.org/10.2337/dc26-S007

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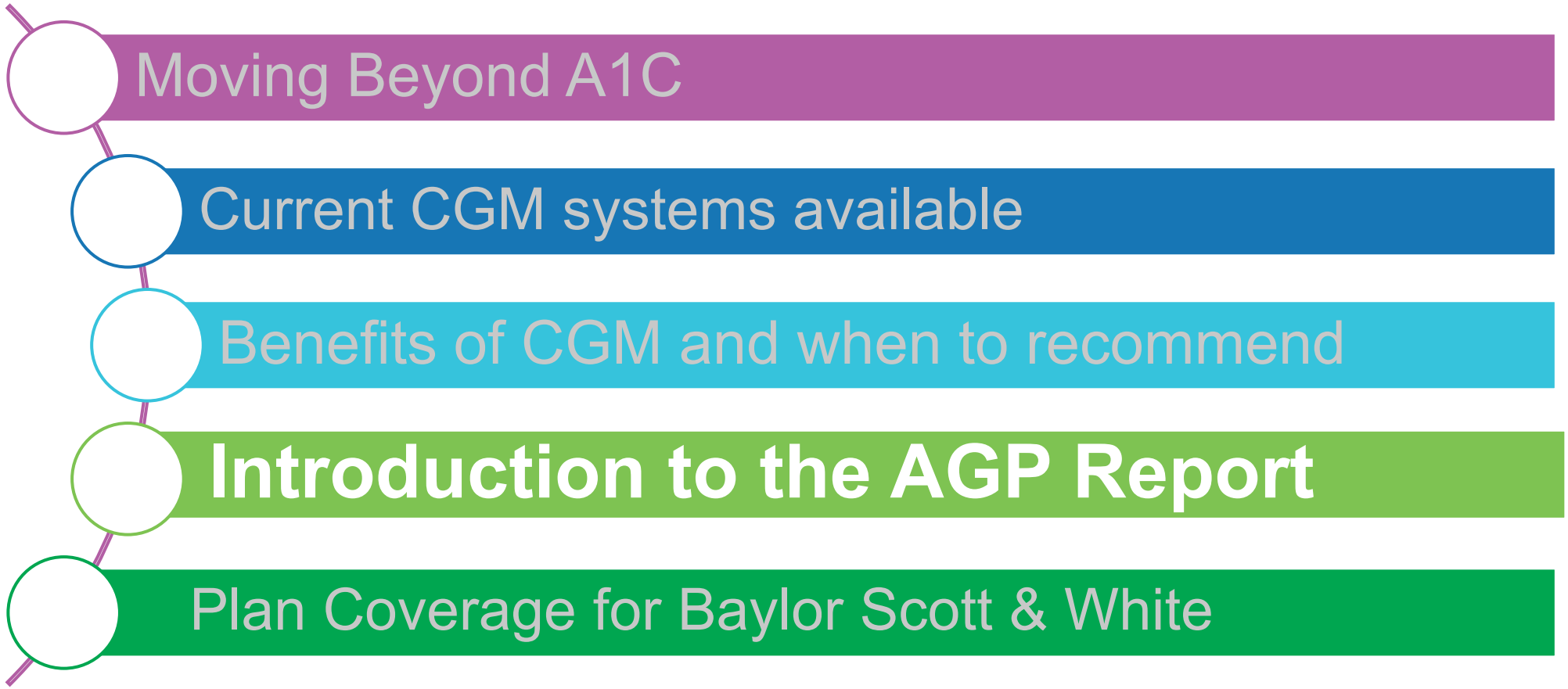

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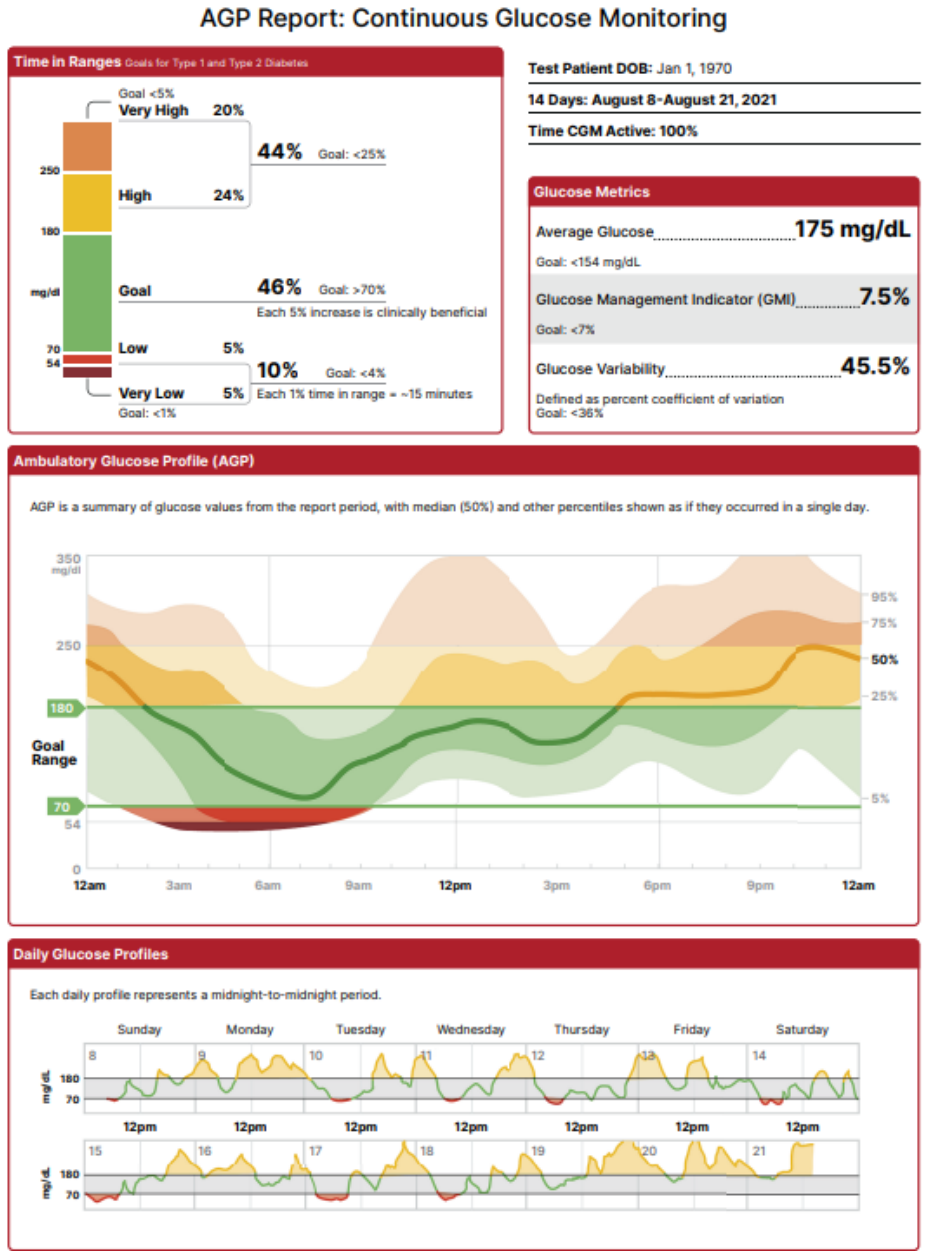
Anatomy of an Ambulatory Glucose Profile (AGP) Report

Time in Ranges Bar and Glucose Metrics →

AGP Curve →

Daily Glucose Profiles →



ADA Standards of Medical Care. Chapter 6: Glycemic Goals. *Diabetes Care* 2025;47(Suppl. 1)

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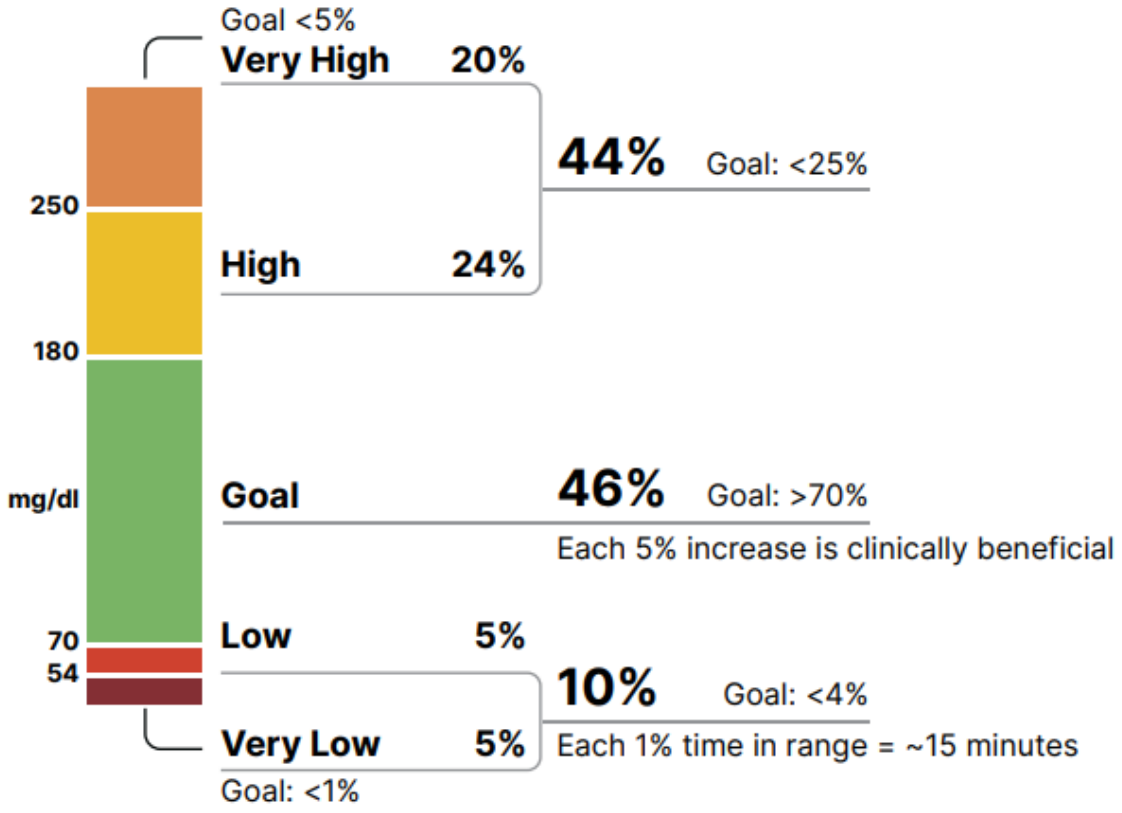
Time in Ranges Goals for Type 1 and Type 2 Diabetes



Test Patient DOB: Jan 1, 1970

14 Days: August 8-August 21, 2021

Time CGM Active: 100%

Glucose Metrics

Average Glucose	**175 mg/dL**
Goal: <154 mg/dL	
Glucose Management Indicator (GMI)	**7.5%**
Goal: <7%	
Glucose Variability	**45.5%**
Defined as percent coefficient of variation Goal: <36%	

ADA Standards of Medical Care. Chapter 6: Glycemic Goals. *Diabetes Care* 2025;47(Suppl. 1)

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More Green, Less Red: How Color Standardization May Facilitate Effective Use of CGM Data

Richard M. Bergenstal, MD[1], Gregg D. Simonson, PhD[1], and Lutz Heinemann, PhD[2]

Journal of Diabetes Science and Technology
2022, Vol. 16(1) 3–6
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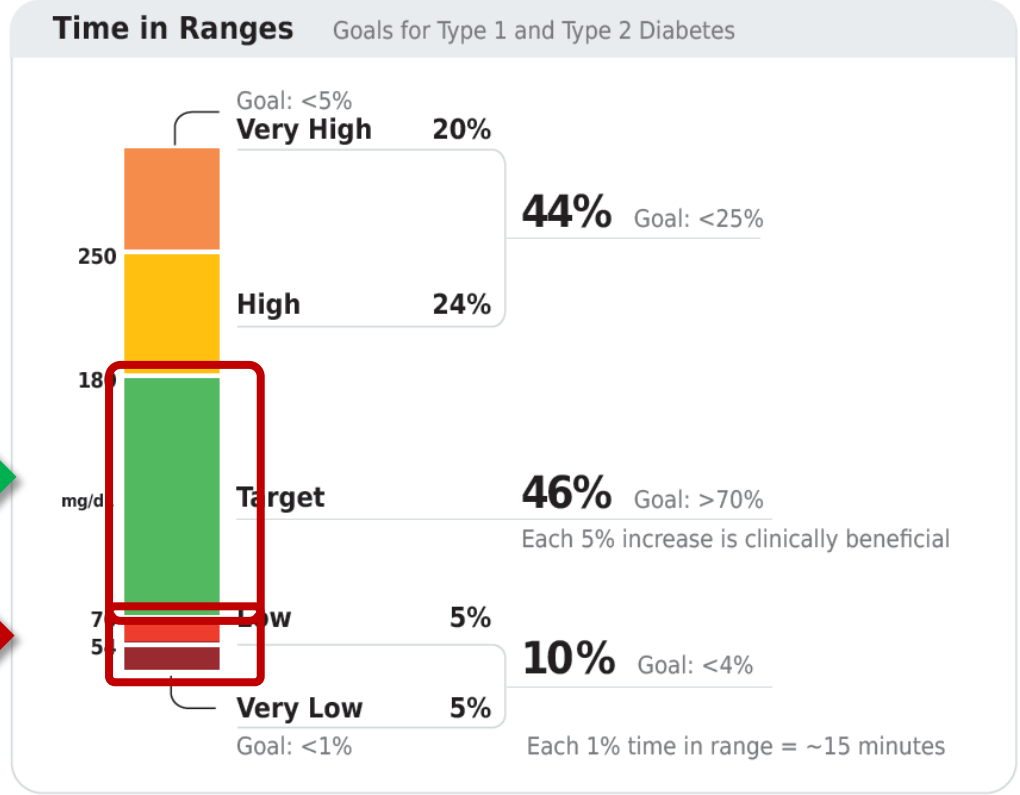
More Green

Less Red



Each 5% ↑ in TIR (70-180 mg/dL) is clinically significant

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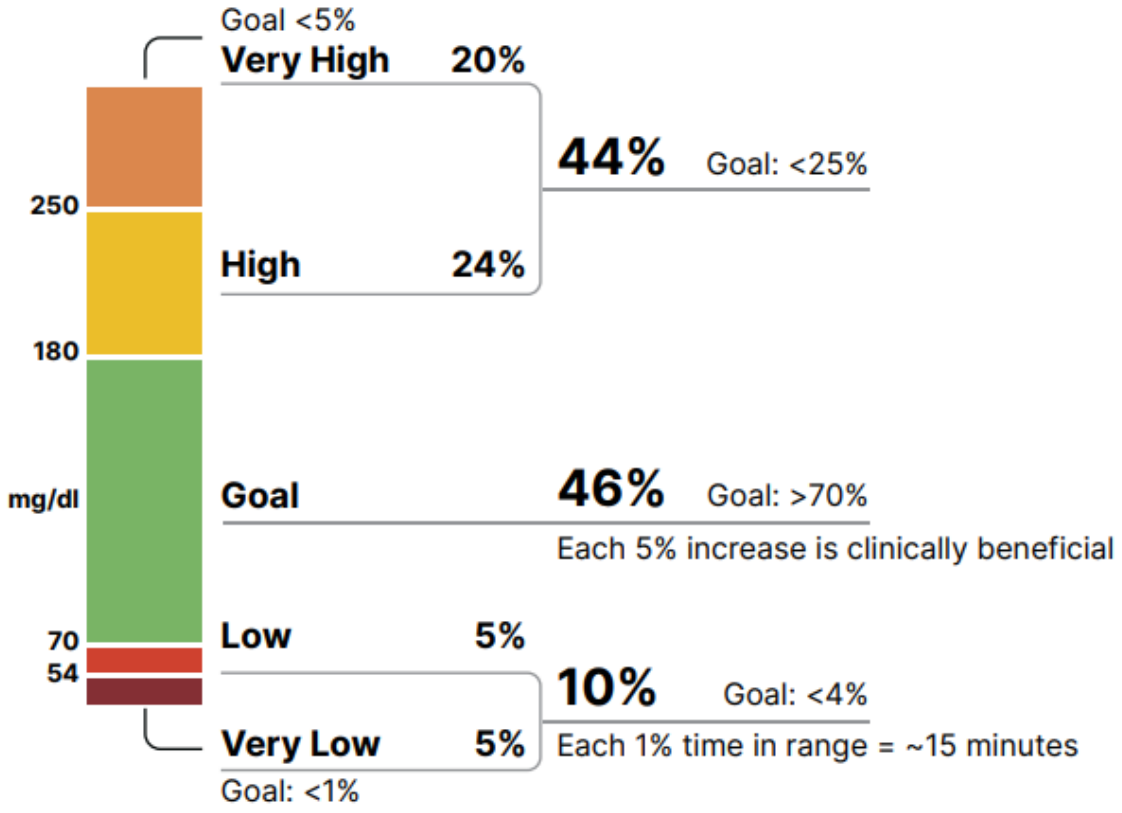
Time in Ranges Goals for Type 1 and Type 2 Diabetes



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ADA Standards of Medical Care. Chapter 6: Glycemic Goals. *Diabetes Care* 2025;47(Suppl. 1)

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Glucose Management Indicator (GMI)

- Replaces estimated A1C (eA1C)
- Avoids confusion when eA1C and laboratory A1C did not match
- GMI and lab A1C discordance common due to differences in red blood cell lifespan, timing of lab vs. CGM data, sudden change in therapy (e.g., starting insulin, steroids) etc.
  - About 50% of time absolute difference between GMI and lab A1C will be ≥0.3%

Bergenstal et al. *Diab Care*. 2018; 41:2275-2280.

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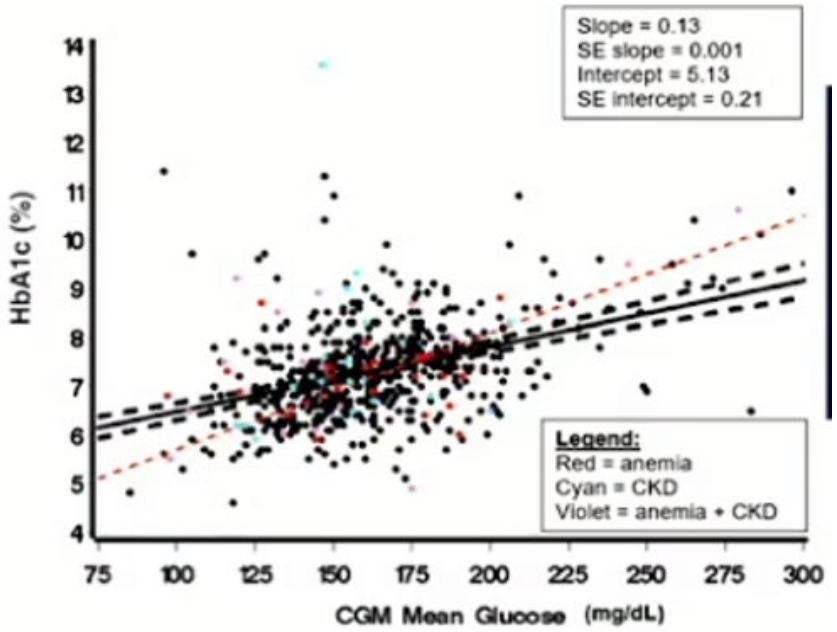
Difference Between GMI and Lab HbA1c

- Only ***19%*** of the estimated and measured HbA1c values ***matched*** *(<0.1%)*
- 51% differed by 0.3% or more
- 28% differed by 0.5% or more
- 19% differed by 0.6% or more
- *12% differed by 0.7% or more*

CGM Discordance:
11% < 0.1%
50% ≥ 0.5%
22% ≥ 1.0%
Increased discordance with eGFR < 60



A1C GMI Discordance: Real-World DTT Apr, 2021. **Hirsch IB**, U. Wash. Endo Clinic

GMI --- HbA1c Mismatches: May be clinically important.
GMI --- represents each person's actual glucose levels and tissue exposure

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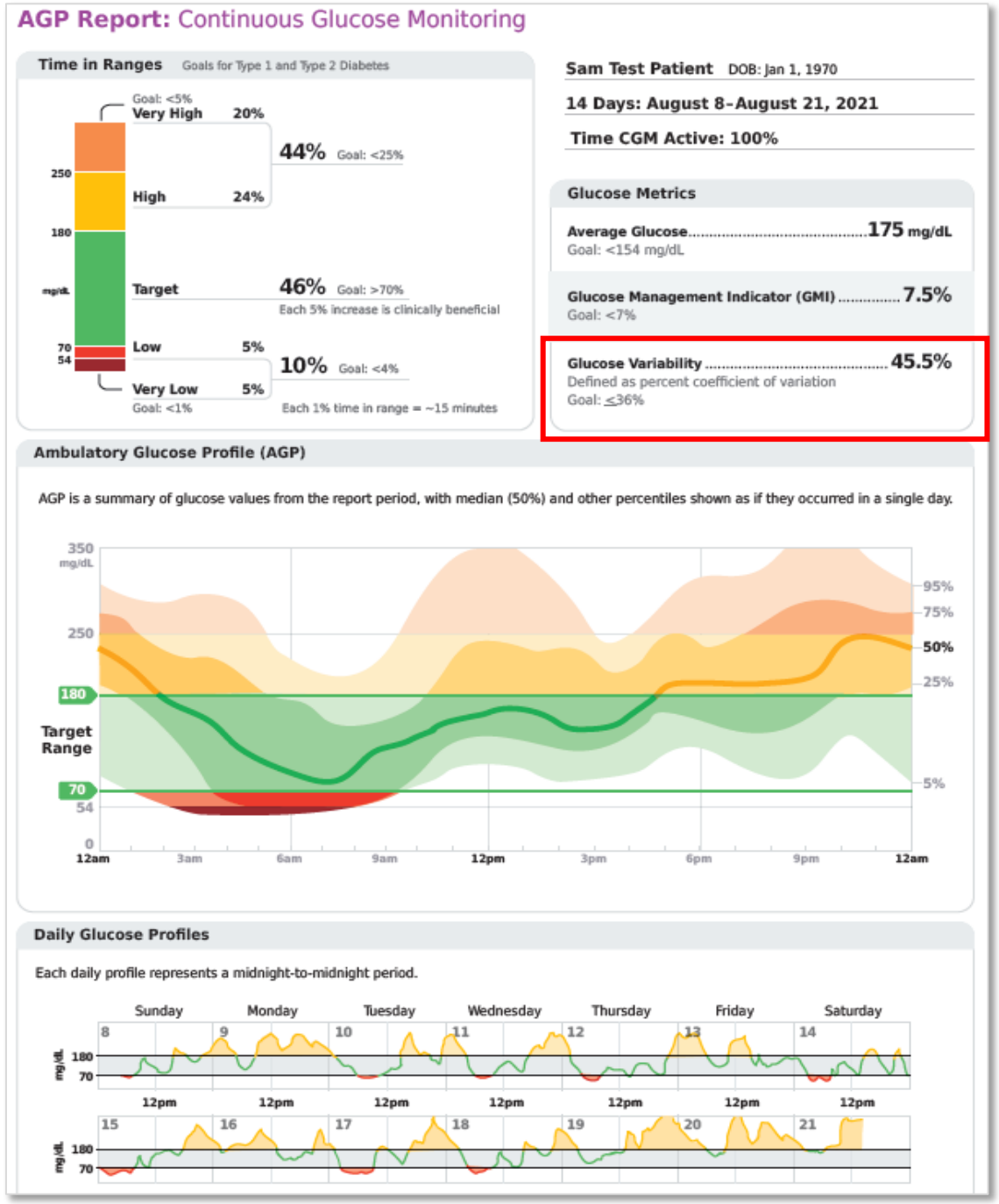
Glucose Variability

Coefficient of Variation = (standard deviation/mean glucose)

CV Target ≤36%

Monnier L, Colette C, Wojtusciszyn A, et al. Toward defining the threshold between low and high glucose variability in diabetes. Diabetes Care 2017;40:832–838



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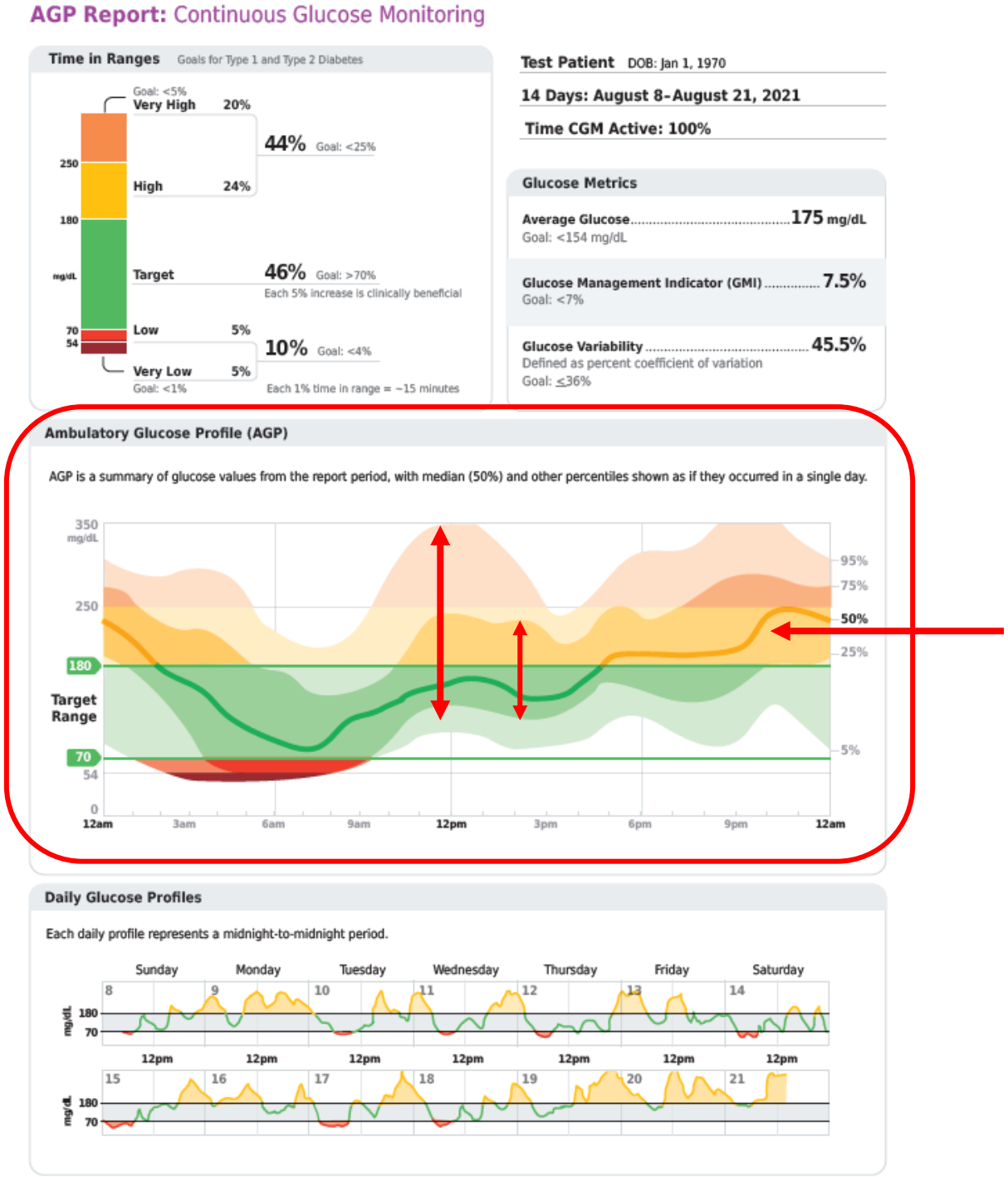
AGP Report

AGP Curve (14 days)



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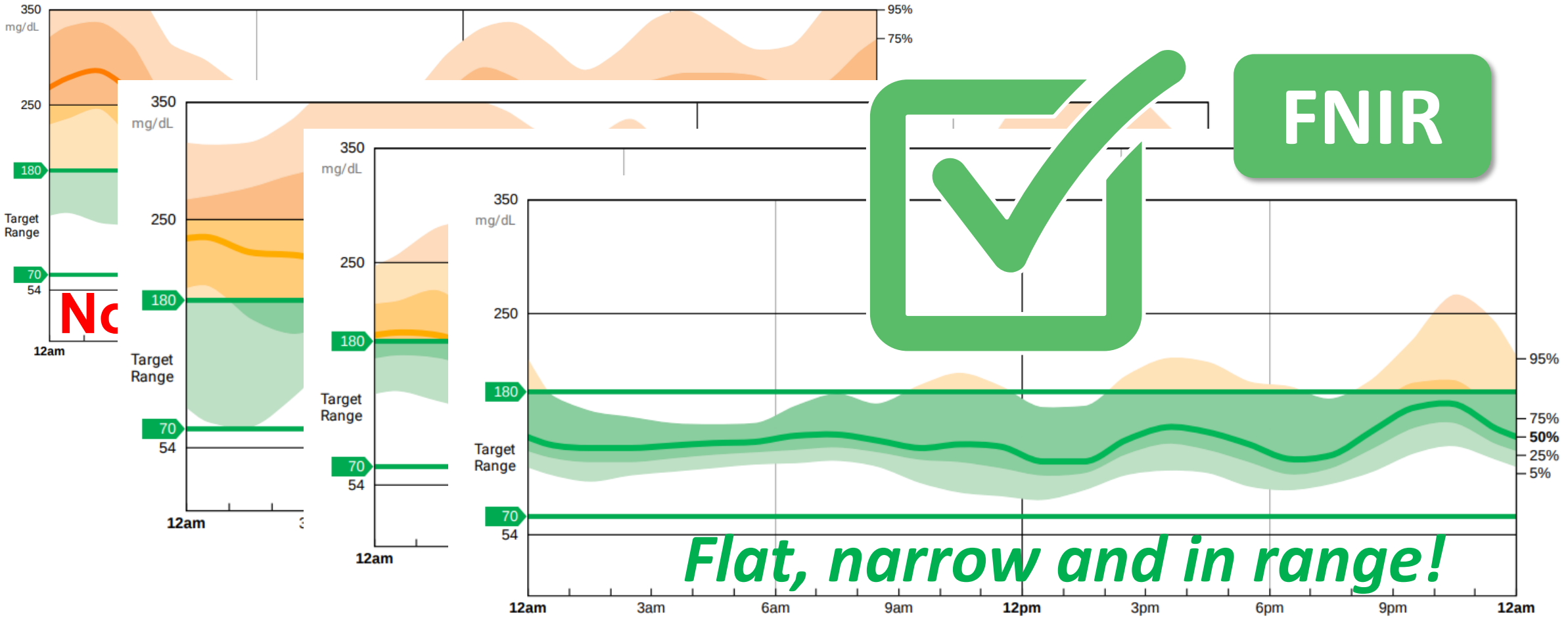
What are we striving for in the AGP?



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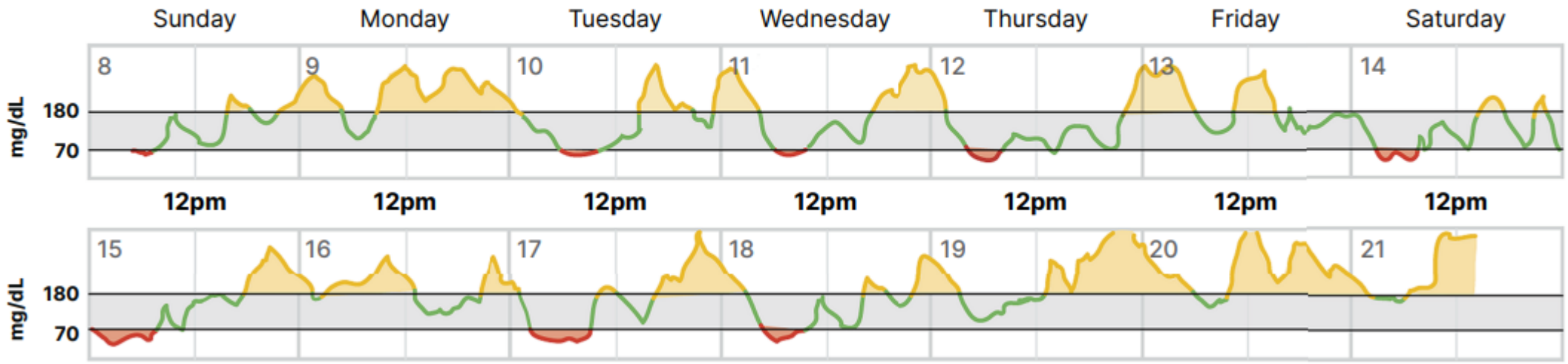
Daily Glucose Profiles

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



- Tracks glucose throughout day and night
- Identify patterns vs. isolated events (e.g. compression low)
- Weekday vs weekend patterns
- Impact of lifestyle modifications on glucose

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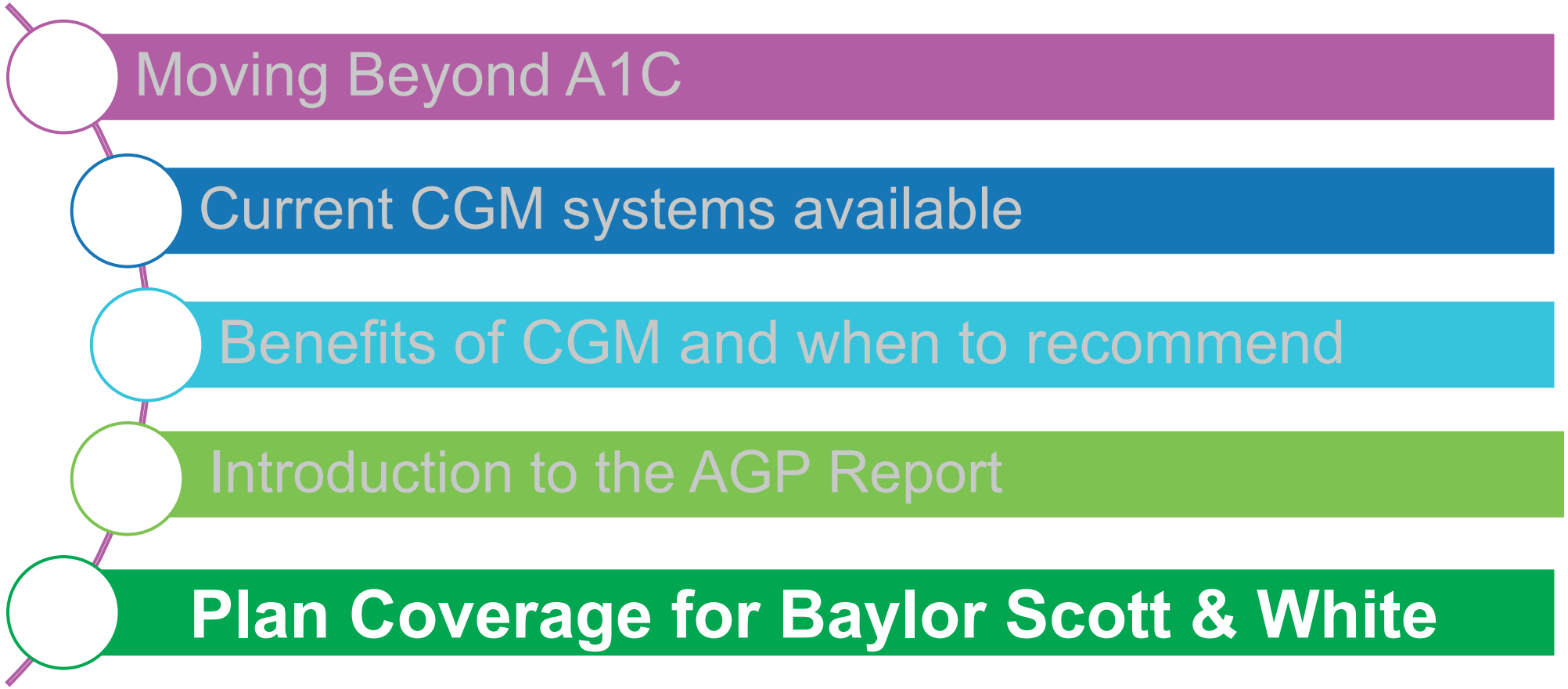
Presentation Outline



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CGM Coverage by Health Plan Type and Population

Population	Baylor Scott & White (BSW)	Medicare
Type 1 diabetes	Yes w/PA	Yes w/PA
Type 2 diabetes with any insulin therapy	Yes w/PA	Yes w/PA
Type 2 diabetes treated with noninsulin therapies	Yes if documented hypoglycemia	Yes w/PA
Gestational Diabetes Mellitus (GDM)	No	Yes w/PA
Prediabetes	No	No

Medicare Coverage criteria:

- ❑ Diagnosis of Type 1 Diabetes, Type 2 Diabetes, Gestational Diabetes
- ❑ Insulin treated **OR**

Documented history of problematic hypoglycemia such as recurrent level 2 hypo (>54 mg/dl) or at least one level 3 event (patient requires help from a third-party)

- ❑ Training – your provider must confirm you or a caregiver are trained to use CGM
- ❑ Provider visit (in-person or telehealth) within the last 6 months.

Prior authorizations are commonly needed

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Baylor Scott & White Plan CGM Coverage

CGM Device	BSW	Medicare
Dexcom G6 (discontinuing in July 2026)	X	X
Dexcom G7	X	X
Dexcom G7 – 15 day	X	X
FreeStyle Libre 2+	X	X
FreeStyle Libre 3+	X	X
Medtronic Guardian 4	⊘	X only in combination w/approved automated insulin delivery (AID) system
Eversense	⊘	⊘

X = covered

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1/1/2026 Preferred Continuous Glucose Monitor (CGM) List

Formulary	Preferred	Non-Formulary
Medicare (Seniorcare)	Dexcom, Freestyle	Eversense, Medtronic, Signos
Group Value (LG/ASO)	Dexcom, Freestyle	Eversense, Medtronic, Signos
Health Insurance Marketplace Formulary - HIM (SG/Individual)	Dexcom	Eversense, Freestyle, Medtronic, Signos

CGM Utilization Management: 1/1/2026

CGMs
Medicare (Seniorcare)
PA and QL requiring a diagnosis of diabetes, sufficient training to use it, prescribed in accordance of an FDA indication for use, use of insulin or problematic hypoglycemia defined as: Medical record documentation of 2 or more episodes of a level 2 hypoglycemic event (glucose <54mg/dl) or Medical record documentation of 1 episode of a level 3 hypoglycemia (glucose <54mg/dL with altered metal and/or physical state the requires third party assistance for treatment), must have a provider visit within the last 6 months before ordering CGM
Group Value (LG/ASO)
PA and QL with a prerequisite use of insulin or if not on insulin, Medical record documentation of 2 or more episodes of a level 2 hypoglycemic event (glucose <54mg/dl) or Medical record documentation of 1 episode of a level 3 hypoglycemia (glucose <54mg/dL with altered metal and/or physical state the requires third party assistance for treatment)
Health Insurance Marketplace Formulary - HIM (SG/Individual)
PA and QL with a prerequisite use of insulin

Baylor Scott & White Diabetes Resources

- Certified Diabetes Care and Education Specialists or care coordinators
- BSW educational handouts and printed resources
- Free diabetes support groups in Frisco (Every other month on the second Wednesday)
- Health Plan offered DM programs:
  - BSW Be Well with Diabetes
  - WebMD
  - Case management
- Other programs offered at BSW:
  - Diabetes Care Baylor Scott & White Medical Center – Centennial
  - Diabetes Boot Camp – Taylor (In-Person Patient Class
  - Diabetes Prevention Program Group Lifestyle Balance

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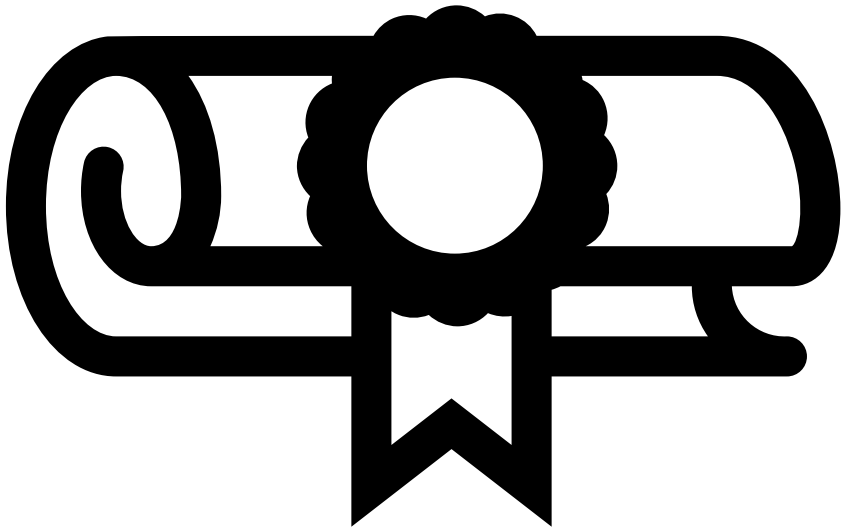
Questions?

HealthPartners® Institute

Instructions for Credit – Live Learners

- To receive CE credit, learners must follow these steps:
  - Visit https://cme.partnersed.com/IDC.BSW.live Complete the activity evaluation
  - Upon completion of all evaluation questions, your credit will be made available for download immediately.



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