MANAGED CARE CGM.com

Presents:

The Value of Streamlined Coverage for Real-Time CGM TO OPTIMIZE OUTCOMES AND RESOURCE UTILIZATION FOR MEMBERS WITH DIABETES

Jointly provided by

MEDICAL EDUCATION RESOURCES

Impact Education LLC

This activity is supported by an independent educational grant from Dexcom, Inc.

Agenda

6:30 AM	Welcome and Pre-Activity Assessment Dana McCormick, RPh, FAMCP
6:35 AM	*The Latest Findings Demonstrating Improved Outcomes and Reduced Resource Utilization with rtCGM in T1 and T2D* Monica Peek, MD, MPH
7:05 AM	*Real-Time Continuous Glucose Monitoring Case Scenarios and Follow-up Panel Discussions* •Enhancing Patient Engagement and Self-Management •Addressing SDOH in Comprehensive Diabetes Programming •The Role of Streamlined Coverage and Access in Timely and Effective Care Dana McCormick, RPh, FAMCP; Monica Peek, MD, MPH; Samir Mistry, PharmD, MBA; Kelly L. Close
7:45 AM	Audience Q&A Session
7:55 AM	Key Takeaways and Closing Comments; Post-Activity Assessment and Evaluation
8:00 AM	Adjournment

Learning Objectives

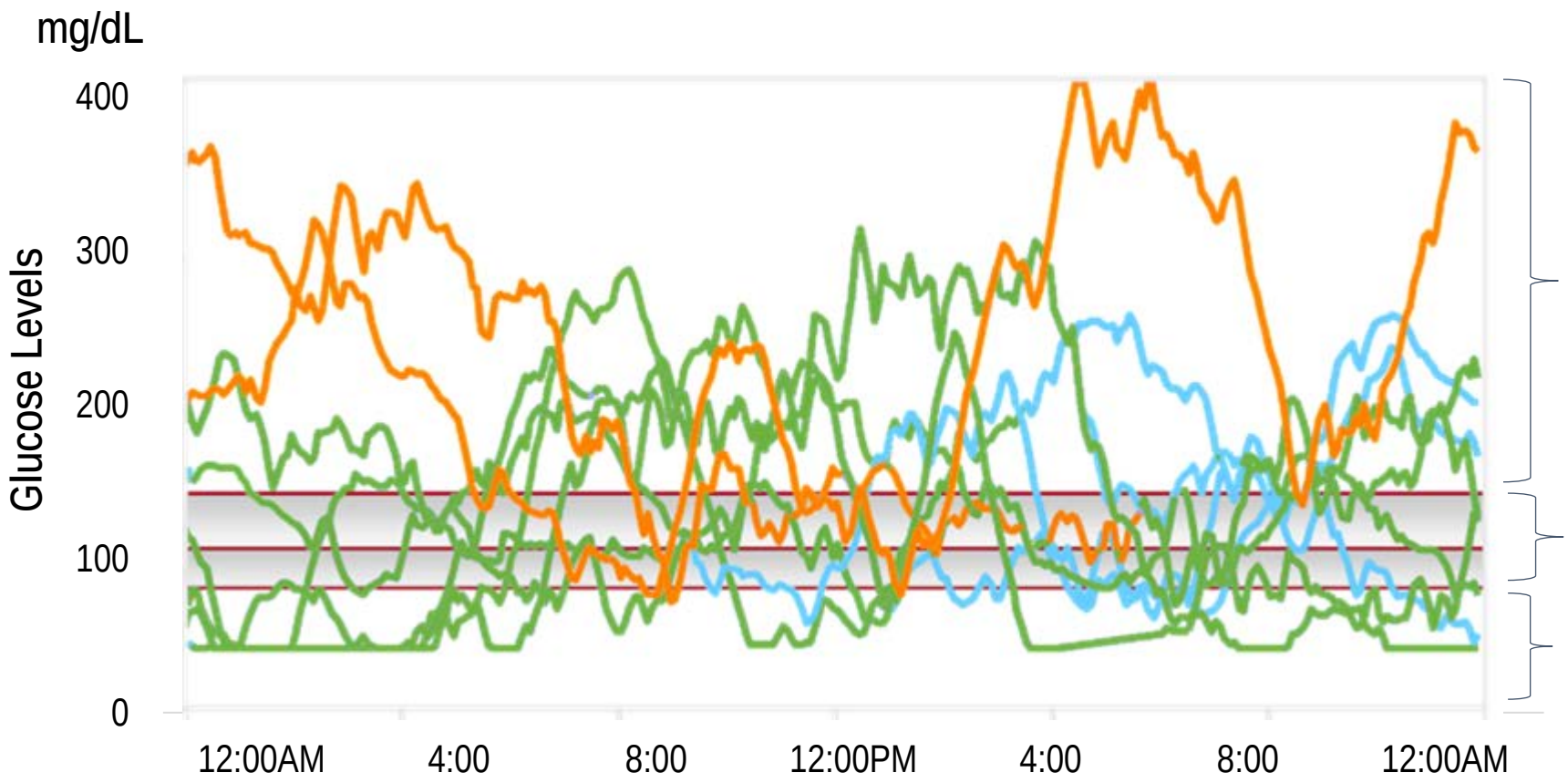
- Review the latest data supporting the use of rtCGM to improve patient outcomes and reduce resource utilization in T1 and T2D
- Assess the impact of social determinants of health (SDOH) on outcomes in diabetes among low-income and racial/ethnic minority populations
- Describe the role of diabetes technology in increasing patient engagement and self-management across diverse member populations of varying age, race/ethnicity, income, and insurance type
- Discuss the positive impact of electronic prior authorization for rtCGM under the pharmacy benefit in terms of provider administrative burden, access, and total cost of care

The Latest Findings Demonstrating Improved Outcomes and Reduced Resource Utilization with rtCGM in T1D and T2D

Monica Peek, MD, MPH, MS
Professor of Medicine
Associate Director, Chicago Center for Diabetes Translational Research
The University of Chicago Medicine

Ideal HbA1c Does Not Equate to Optimal Control

24-Hour CGM Data From Nine "Well-Controlled" Patients (Mean HbA1c=6.7%)



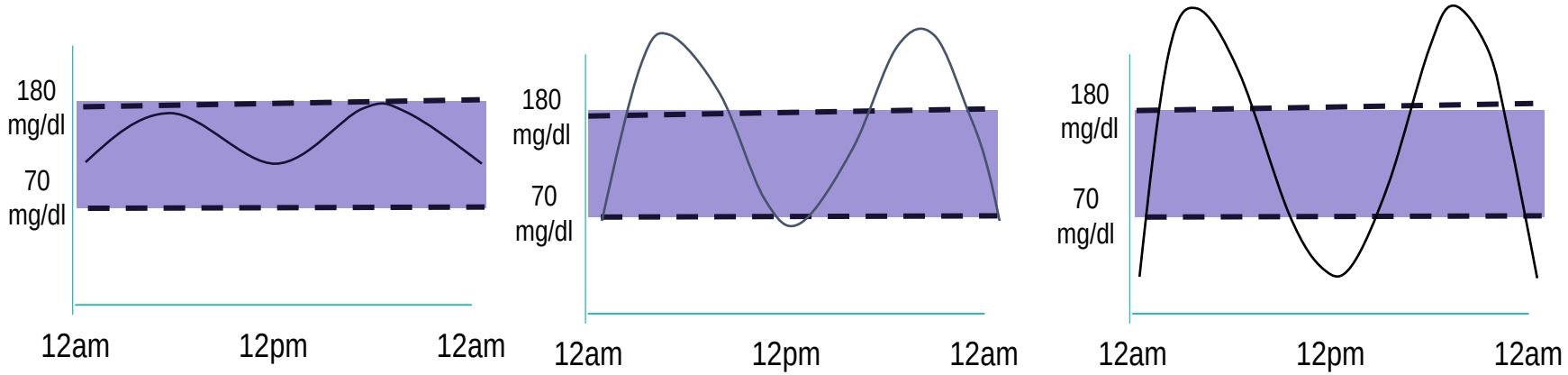
Hyperglycemia
- Cardiovascular disease
- Blindness
- Kidney failure
- Nerve degeneration

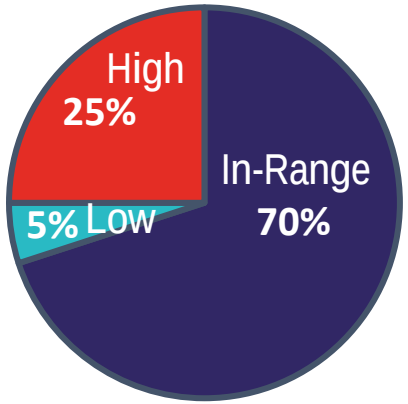
Hypoglycemia
- Diminished cognitive function
- Loss of consciousness
- Potential death

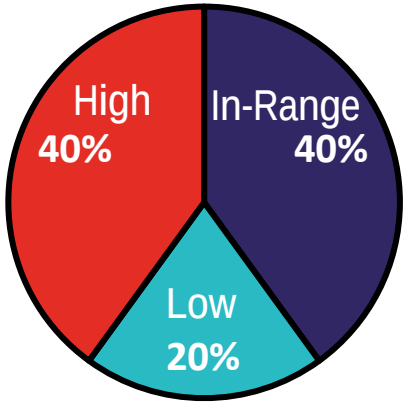
Diabetes Care. 2017 Aug;40(8):994-999. doi: 10.2337/dc17-0636.

HbA1c is a Flawed Measure by Itself; Additional Metrics are Necessary for Optimal Diabetes Management

The many faces of a 7% HbA1c
(and an average blood glucose of 154 mg/dL)







Metrics that only CGM can provide:

- Time in target Range (TIR)
- Time Above Range (TAR)
- Time Below Range (TBR)
- Glycemic Variability (GV)
- Glycemic Management Indicator (GMI)

CGM=continuous glucose monitoring

American Diabetes Association (ADA) Defines Two Categories of CGM

Real-Time CGM

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

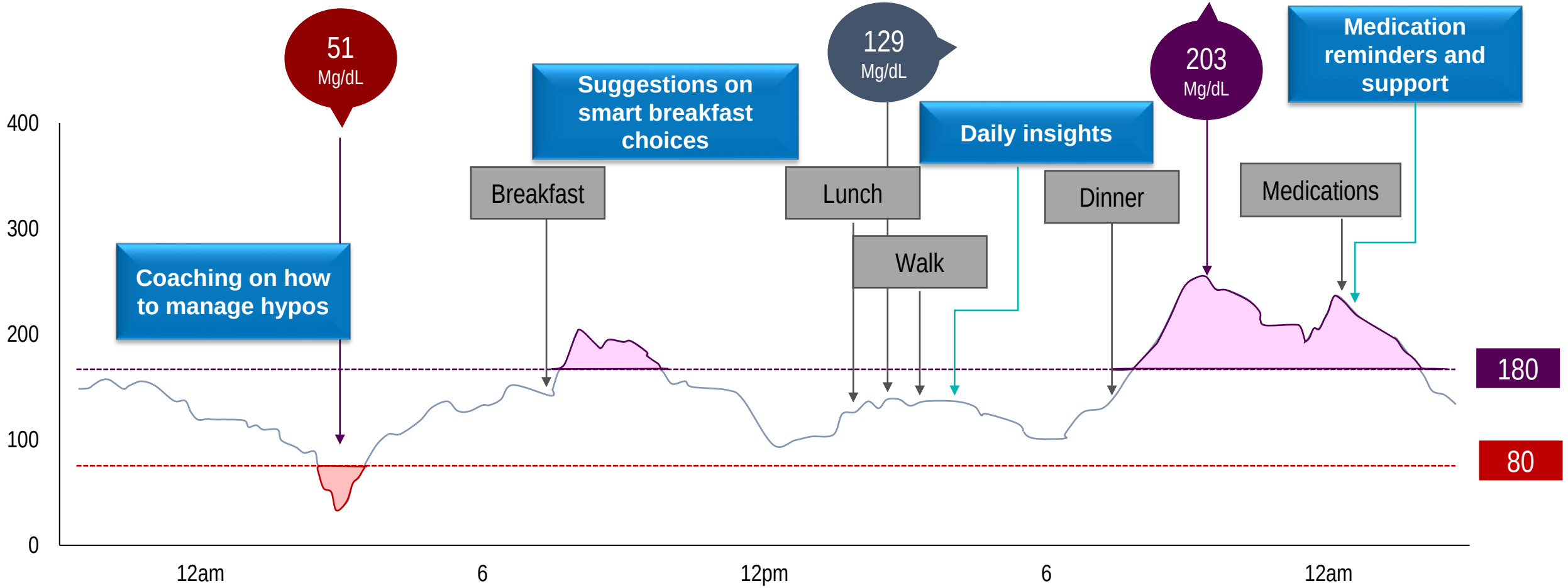
Intermittently Scanned CGM

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

Petrie JR et al. *Diabetes Care*. 2017;40(12):1614-1621.
American Diabetes Association. Diabetes Care. 2021;44(Suppl1):S85-S99.

CGM Highlights Key Diabetes Management Insights

288 passively collected, daily glucose points from CGM inform effects of Rx, exercise and diet and symptoms



Source: Dexcom T2D pilot study. Similar observations using Dexcom CGM have been published in Vigersky et al., "Short- and Long-Term Effects of Real-Time Continuous Glucose Monitoring in Patients With Type 2 Diabetes," *Diabetes Care* 2012, 35(1): 32-38; Ehrhardt et al., "The Effect of Real-Time Continuous Glucose Monitoring on Glycemic Control in Patients with Type 2 Diabetes Mellitus," *J Diabetes Sci Technol* 2011, 5(3): 668-75; Cox et al., "Continuous Glucose Monitoring in the Self-Management of Type 2 Diabetes," *Diabetes Care* 2016, 39(5): 71-73.

Appropriate CGM Use is Endorsed by the Latest Evidence-based Practice Guidelines

ADA Standards of Care 2022[1]

- rtCGM (A) or isCGM (B) **should be offered** for diabetes management in adults with diabetes on MDI or CSII.
- rtCGM (A) or isCGM (C) can be used for diabetes management in adults with diabetes on basal insulin.

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*. 2022;45(Suppl1). 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

ADA Levels of Evidence for CGM Vary in Different Patient Populations

Population	rtCGM	isCGM
Adults with type 1 diabetes on intensive insulin therapy	Grade A	Grade B
Adults with type 2 diabetes on intensive insulin therapy	Grade A	Grade B
Adults with type 2 diabetes on basal insulin	Grade A	Grade C
Youth with type 1 diabetes on intensive insulin therapy	Grade B	Grade E

rtCGM (A) or isCGM (B) **should be offered** for diabetes management in adults with diabetes on MDI or CSII.

rtCGM (A) or isCGM (C) can be used for diabetes management in adults with diabetes on basal insulin.

American Diabetes Association. Introduction: Standards of medical care in diabetes—2022. *Diabetes Care*. 2022; 45:S1.

MDI=multiple daily injections; CSII=continuous subcutaneous insulin infusion

Baseline Results from the MOBILE RCT Demonstrate a Distinct Need for a Shift in the T2D Treatment Paradigm

- 21% time spent >250 mg/dL
- 61% of time spent >180 mg/dL

40% in target

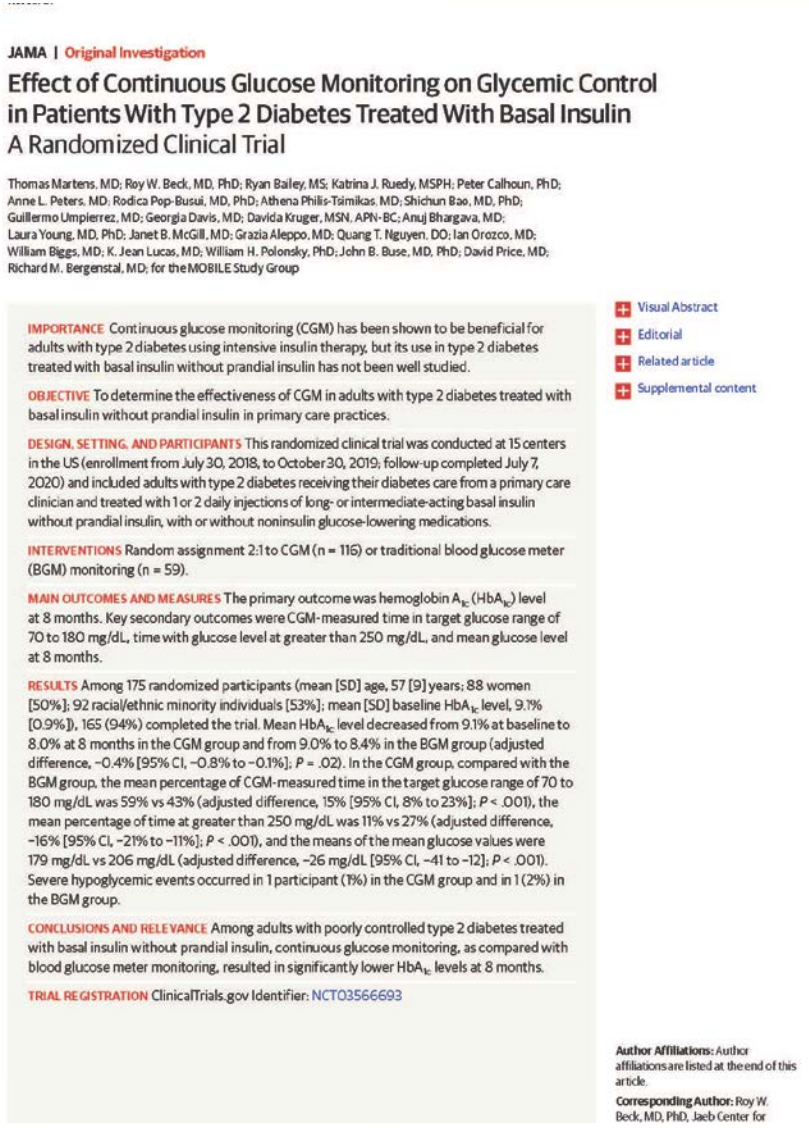
Minimal hypoglycemia across both groups

Participants demonstrated lowest BG in the morning (typically, the sole time a fingerstick is performed)

Participants spent a significant amount of time in hyperglycemia unbeknownst to the patient/provider

Peters A, et al. *Diabetes Obes Metab*. 2021 Feb;23(2):631-636.

The MOBILE Study is the First of its Kind to Find that Patients with T2D Who Use Basal Insulin Alone Benefited From the Use of rtCGM in Primary Care



JAMA | Original Investigation

Effect of Continuous Glucose Monitoring on Glycemic Control in Patients With Type 2 Diabetes Treated With Basal Insulin
A Randomized Clinical Trial

Thomas Martens, MD; Roy W. Beck, MD, PhD; Ryan Bailey, MS; Katrina J. Ruedy, MSPH; Peter Calhoun, PhD; Anne L. Peters, MD; Rodica Pop-Busui, MD, PhD; Athena Philis-Tsimikas, MD; Shichun Bao, MD, PhD; Guillermo Umpierrez, MD; Georgia Davis, MD; Davida Kruger, MSN, APN-BC; Anuj Bhargava, MD; Laura Young, MD, PhD; Janet B. McGill, MD; Grazia Aleppo, MD; Quang T. Nguyen, DO; Ian Orozco, MD; William Biggs, MD; K. Jean Lucas, MD; William H. Polonsky, PhD; John B. Buse, MD, PhD; David Price, MD; Richard M. Bergenstal, MD; for the MOBILE Study Group

IMPORTANCE Continuous glucose monitoring (CGM) has been shown to be beneficial for adults with type 2 diabetes using intensive insulin therapy, but its use in type 2 diabetes treated with basal insulin without prandial insulin has not been well studied.

OBJECTIVE To determine the effectiveness of CGM in adults with type 2 diabetes treated with basal insulin without prandial insulin in primary care practices.

DESIGN, SETTING, AND PARTICIPANTS This randomized clinical trial was conducted at 15 centers in the US (enrollment from July 30, 2018, to October 30, 2019; follow-up completed July 7, 2020) and included adults with type 2 diabetes receiving their diabetes care from a primary care clinician and treated with 1 or 2 daily injections of long- or intermediate-acting basal insulin without prandial insulin, with or without noninsulin glucose-lowering medications.

INTERVENTIONS Random assignment 2:1 to CGM (n = 116) or traditional blood glucose meter (BGM) monitoring (n = 59).

MAIN OUTCOMES AND MEASURES The primary outcome was hemoglobin A_{1c} (HbA_{1c}) level at 8 months. Key secondary outcomes were CGM-measured time in target glucose range of 70 to 180 mg/dL, time with glucose level at greater than 250 mg/dL, and mean glucose level at 8 months.

RESULTS Among 175 randomized participants (mean [SD] age, 57 [9] years; 88 women [50%]; 92 racial/ethnic minority individuals [53%]; mean [SD] baseline HbA_{1c} level, 9.1% [0.9%]), 165 (94%) completed the trial. Mean HbA_{1c} level decreased from 9.1% at baseline to 8.0% at 8 months in the CGM group and from 9.0% to 8.4% in the BGM group (adjusted difference, −0.4% [95% CI, −0.8% to −0.1%]; $P = .02$). In the CGM group, compared with the BGM group, the mean percentage of CGM-measured time in the target glucose range of 70 to 180 mg/dL was 59% vs 43% (adjusted difference, 15% [95% CI, 8% to 23%]; $P < .001$), the mean percentage of time at greater than 250 mg/dL was 11% vs 27% (adjusted difference, −16% [95% CI, −21% to −11%]; $P < .001$), and the means of the mean glucose values were 179 mg/dL vs 206 mg/dL (adjusted difference, −26 mg/dL [95% CI, −41 to −12]; $P < .001$). Severe hypoglycemic events occurred in 1 participant (1%) in the CGM group and in 1 (2%) in the BGM group.

CONCLUSIONS AND RELEVANCE Among adults with poorly controlled type 2 diabetes treated with basal insulin without prandial insulin, continuous glucose monitoring, as compared with blood glucose meter monitoring, resulted in significantly lower HbA_{1c} levels at 8 months.

TRIAL REGISTRATION ClinicalTrials.gov Identifier: NCT03566693

Visual Abstract
Editorial
Related article
Supplemental content

Author Affiliations: Author affiliations are listed at the end of this article.
Corresponding Author: Roy W. Beck, MD, PhD, Jaeb Center for

- Randomized controlled trial
- 176 patients with T2D randomized into rtCGM and BGM groups and followed up for 8 months
  - CGM initiated/interpreted by diabetes specialists
  - Managed by PCPs in a primary care setting
- Patients were non-intensively treated with 1-2 daily injections of long-or intermediate-acting basal insulin

MOBILE Featured an Ethnically and Socioeconomically Diverse Study Population

	CGM Group (N=116)	SMBG Group (N=59)
Age		
Mean (SD) Years	56 (9)	59 (6)
≥60 years	43 (37%)	28 (47%)
Sex		
Female	61 (53%)	27 (46%)
Male	55 (47%)	32 (54%)
Race/Ethnicity		
White non-Hispanic	50 (43%)	33 (56%)
Hispanic or Latino	35 (30%)	14 (24%)
Black non-Hispanic	24 (21%)	8 (14%)
Asian	4 (3%)	4 (7%)
More than 1 race	2 (2%)	0 (0%)
American Indian	1 (<1%)	0 (9%)

53%

	CGM Group (N=116)	SMBG Group (N=59)
Highest Education Level		
< High School Diploma	26 (22%)	10 (17%)
High School	39 (34%)	21 (36%)
Bachelor's Degree	35 (30%)	24 (41%)
Advanced Degree	15 (13%)	4 (7%)
Insurance Coverage		
Private	51 (44%)	22 (37%)
Medicare	42 (36%)	26 (44%)
Medicaid	11 (9%)	6 (10%)
Other government agencies	9 (8%)	3 (5%)
None	3 (3%)	2 (3%)
DM Duration mean (SD) yrs	14 (9)	15 (10)
A1c at Randomization (mean)	9.1%	9.0%

Martens T et al. JAMA, June, 2021.

rtCGM Significantly Reduced A1c and Glycemic Variability

- Adjusted A1c Reduction from Baseline

-0.4% *P = 0.02*

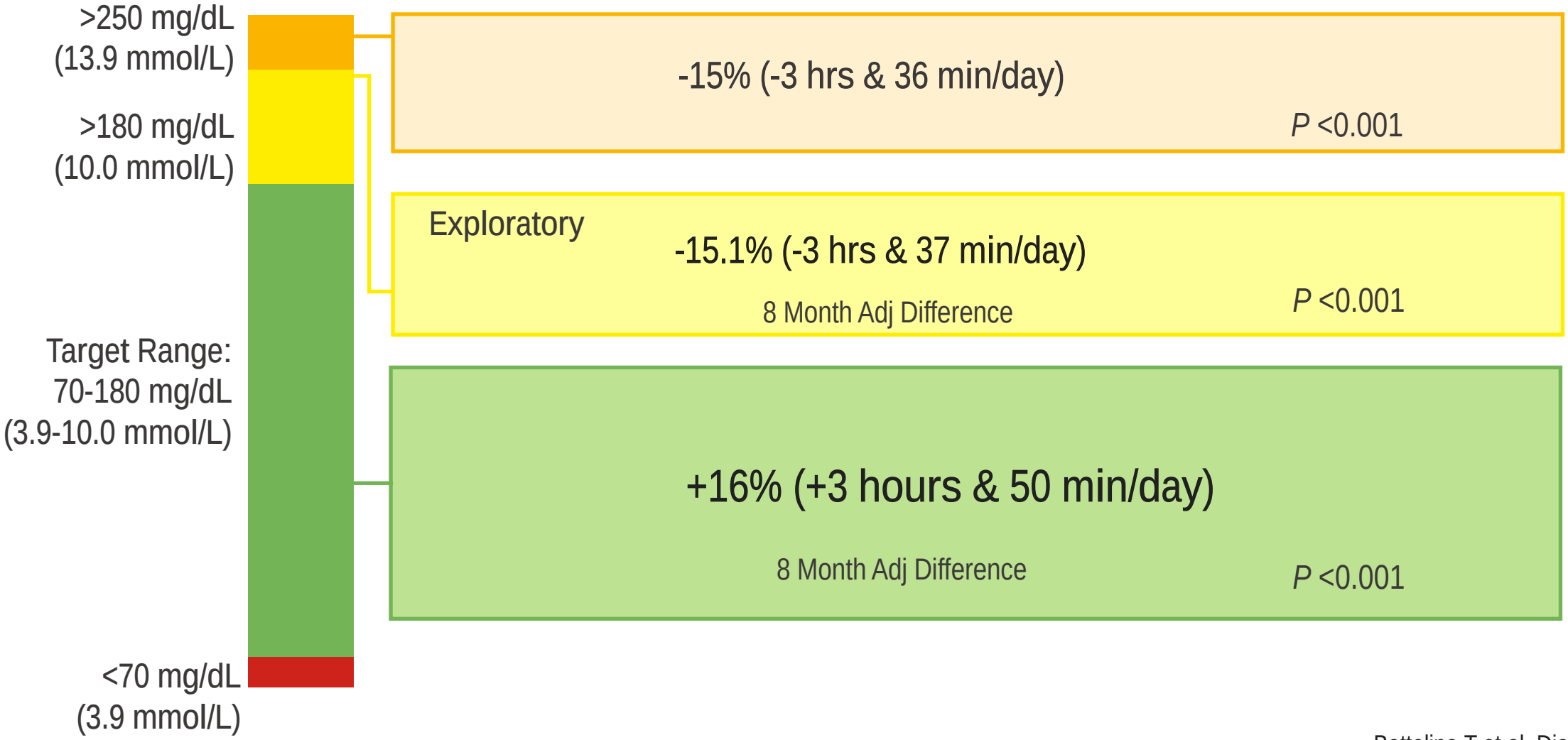
-1.1% Within CGM group – Baseline to 8 months

- Reduction of Coefficient of Variation

-1.8% *P = 0.05*

Martens T et al. JAMA, June 2021

rtCGM Increased TIR by Nearly 4 Hours Per Day and Decreased TAR by More Than 3 Hours Per Day



Battelino T et al. Diabetes Care. 2019
Martens T et al. JAMA, June 2021

There was a 25.8% Absolute Change in the Number of Participants in the rtCGM Group Able to Meet the HEDIS Measure of HbA1c <8%

MOBILE Study: Topline Findings

	rtCGM	Optimized BGM*
Participants with HEDIS-compliant HbA1c (< 8%)	63%	39%
Time Spent in Target Range (70-180 mg/dL)	59% (3.6 hours more each day)	43%
Time Spent in Hyperglycemia (>250 mg/dL)	11% (3.8 hours less per day)	27%
Mean glucose levels	179 mg/dL	206 mg/dL

*Optimized BGM defined as ≥3 fingerstick tests per day

Martens T et al. JAMA, June, 2021.

The MOBILE Extension Phase Demonstrates the Sustained Clinical Benefits of rtCGM and Disadvantages of Discontinuation

The Effect of Discontinuing rtCGM in Adults with T2D Treated with Basal Insulin (MOBILE 2)

Study Characteristics	Outcomes	Conclusion
MOBILE extension phase • 6 mos. (between 8 mos. and 14 mos. from initiation) • N=165 T2D • NIT (basal-only)	TIR (primary outcome): Continued rtCGM group: • Sustained improvements from first MOBILE study for TIR and A1c from month 8 to 14 Discontinued rtCGM group: • -12% reduction from first MOBILE study in TIR (p =.01) and A1c increased (p=.06) from month 8 to 14	Continued use of rtCGM is needed to maintain improved TIR and A1c in T2D basal only patients

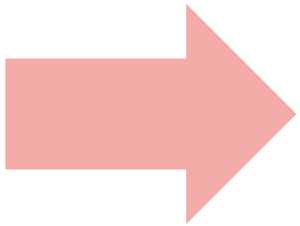
Aleppo G, et al. *Diabetes Care*. 2021 Dec;44(12):2729-2737..

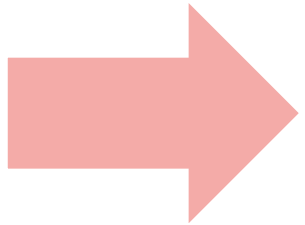
Kaiser Permanente of Northern California Real-World Setting for Analysis of Data from 2014-2019

JAMA | Original Investigation

Association of Real-time Continuous Glucose Monitoring With Glycemic Control and Acute Metabolic Events Among Patients With Insulin-Treated Diabetes

Andrew J. Karter, PhD; Melissa M. Parker, MS; Howard H. Moffet, MPH; Lisa K. Gilliam, MD, PhD; Richard Dlott, MD





N=41,753

T1D = 5,673
T2D = 36,080

- New to rtCGM
- Insulin treated
- Selected by physicians for rtCGM

rtCGM Initiator = 3,806

- Mean age, 42 years
- 51% women
- 91% with type 1 diabetes

Non-initiator = 37,947

- Reference group
- Mean age, 63 years
- 49% women
- 6% with type 1 diabetes

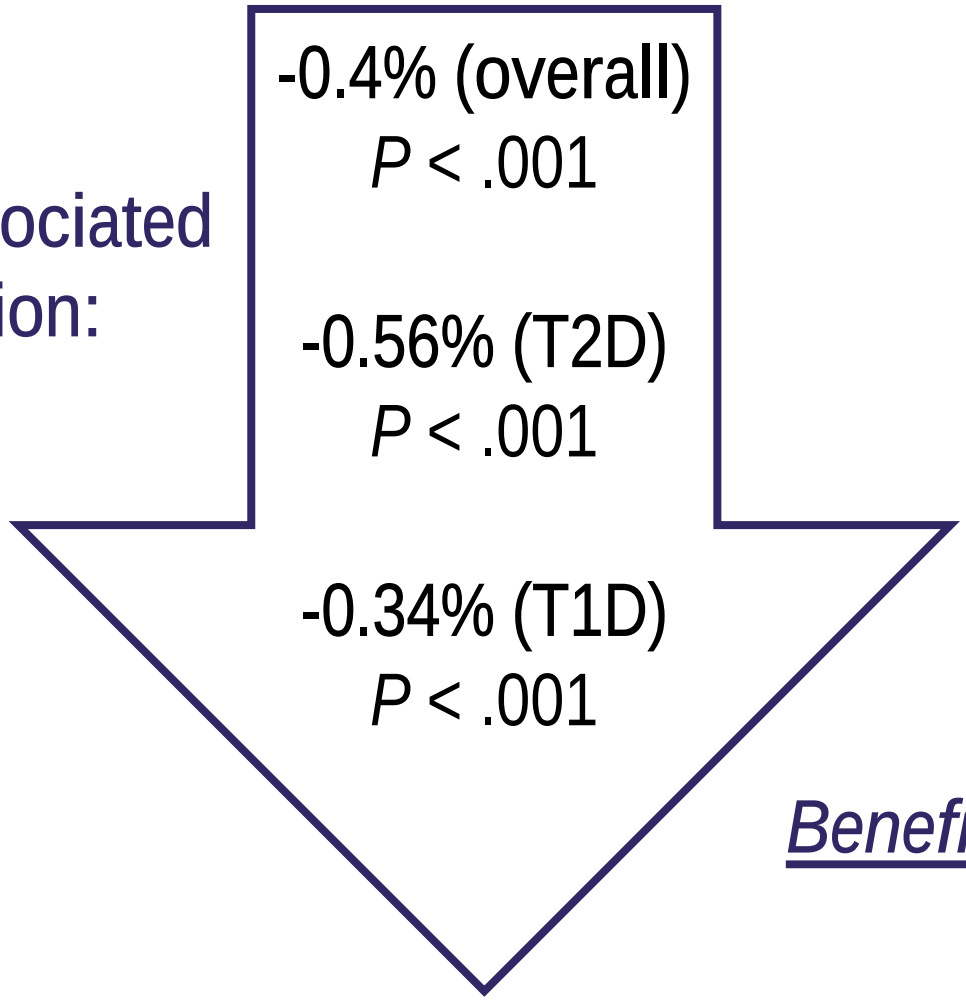
Compare outcomes of rtCGM initiators vs non-initiators

(12 months before vs 12 months after baseline)

Karter AJ, et al. *JAMA.* 2021;325(22):2273–2284.

Initiating rtCGM Improved Glycemic Control

Change in HbA1c associated with rtCGM initiation:

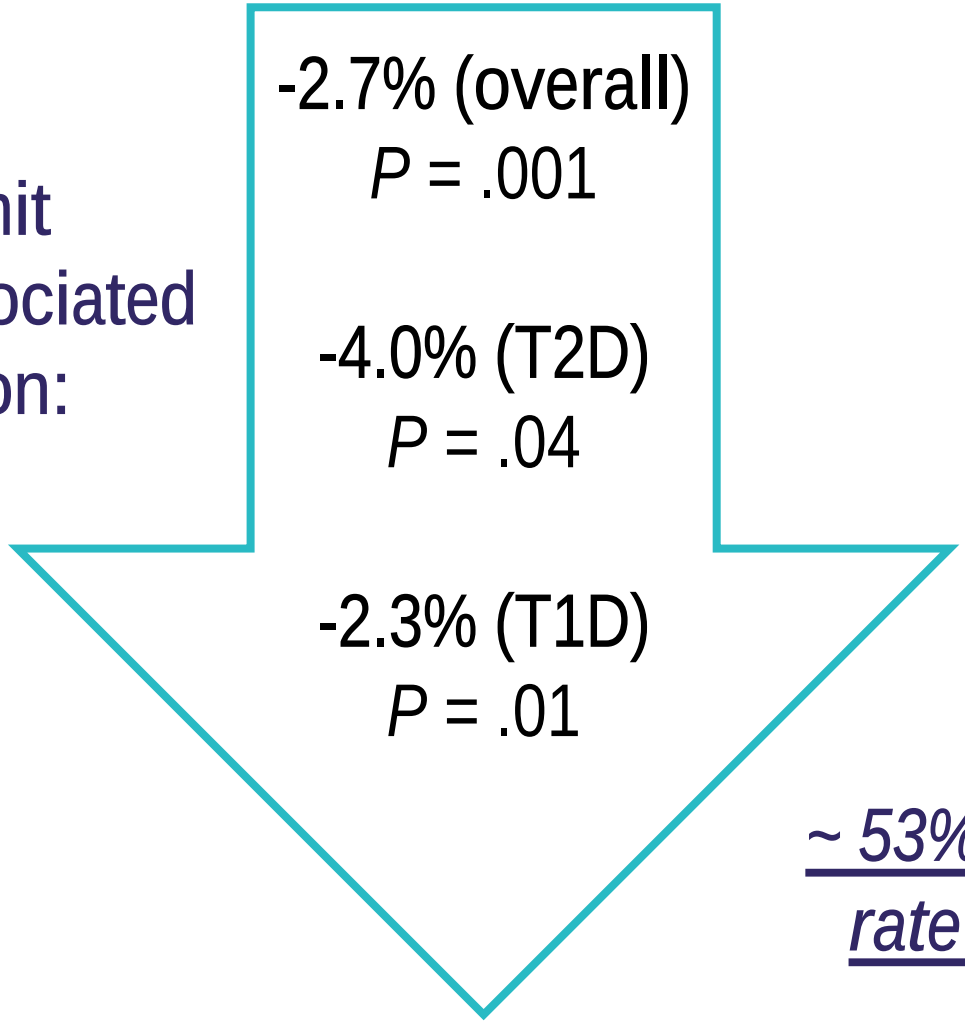


Benefits were greatest in people with T2D

Karter AJ, et al. *JAMA.* 2021;325(22):2273–2284.

Initiating rtCGM Decreased the Rate of ER Visits and Hospitalizations Due to Hypoglycemia

Change in ER/admit hypoglycemia rate associated with rtCGM initiation:



~ 53% reduction in ER/admit rate due to hypoglycemia

Karter AJ, et al. *JAMA.* 2021;325(22):2273–2284.

rtCGM Facilitated a Greater Degree of HEDIS-Compliant HbA1c and Increased Patient Engagement While Decreasing Outpatient Visits

rtCGM initiation was associated with the following:

- Increase in proportion of patients with HbA1c <7%
- Greater proportion of patients with HEDIS-compliant HbA1c <8.0%
- Less patients with HbA1c >9.0%
- Less outpatient visits
- More telephone visits

Karter AJ, et al. *JAMA.* 2021;325(22):2273–2284.

A Sub-analysis of the Retrospective Cohort Study Suggests rtCGM Initiation Was Associated With Improved Glycemic Control Even in Well-managed T2D

17,422 insulin-treated patients with T2D

- HbA1c <8%
- No recent severe hypoglycemia (based on emergency room visits or hospitalizations)

rtCGM initiation occurred in 149 patients (17,273 non-initiators served as reference)

- Changes in HbA1c and severe hypoglycemia rates for the 12 months before and after rtCGM initiation were calculated

- rtCGM initiation was associated with decreased HbA1c (-0.06%)
- Non-initiation was associated with increased HbA1c (+0.32%)

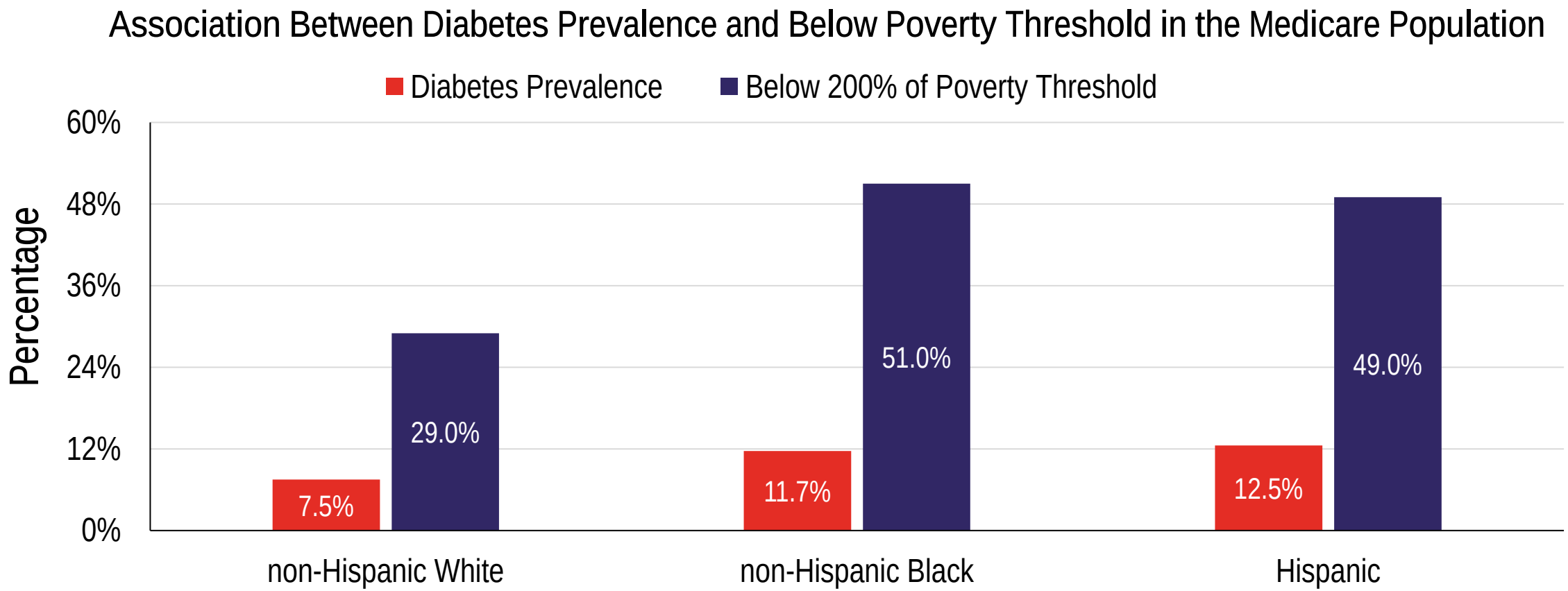
- Change in HbA1c yielded a net benefit of -0.30%; 95% CI -0.50%, -0.10%; *P*=0.004)*
- No significant differences were observed for severe hypoglycemia

* Weighted, adjusted difference-in-difference model

Karter AJ, et al. *Diabetes Technol Ther*. 2022 Feb 18. doi: 10.1089/dia.2021.0450.

The Growing Body of Literature Represents a Call to Action for Expanded Access to CGM, Particularly in Underserved Demographics

"…institutional changes that promote [CGM's] use in primary care will go a long way to improving diabetes control and reducing complications, particularly among the populations most in need."



Peek ME, *JAMA.* 2021;325(22):2255–2257.
Isaacs D, et al. *Diabetes Technol Ther*. 2021;23(S3):S81-S87.

These Demographics of Patients Affected by SDOH Have Historically Diminished Access to Diabetes Technology

- Pediatric/Adolescent[1]
  - Among 1509 pediatric/adolescent T1D patients only 30.5% of Black and 32.5% of Hispanic patients initiated CGM, compared with 54.3% of White patients

- Adult
  - Among 68 adult T1D patients who used CGM, differences in the proportions of CGM users were notable: 47% White, 22% Hispanic, and 14% Black[2]
  - Among Medicare beneficiaries who acquired a CGM device (N=3022), there was a significantly lower proportion of CGM use by Black and Hispanic beneficiaries (0.5% and 2.9%) compared with White (91.0%) and other (5.6%) beneficiaries[3]

1. Lai CS, et al. *Diabetes Care*. 2021;44:255–257.
2. Wirunsawanya K. *J Endocr Soc.* 2020;4(Suppl 1):OR30-03.
3. CMS. https://www.cms.gov/About-CMS/Agency-Information/OMH/research-and-data/information-products/data-highlights/disparities-in-diabetes-prevalence.

Summary

- In the MOBILE study, rtCGM vs. BGM demonstrated a robust, sustained effect on glycemic control with fewer medications and no increase in insulin doses
- Findings from the Kaiser analysis provide an estimate of results expected from a pragmatic RCT of rtCGM vs SMBG
  - rtCGM initiation reduced healthcare resource utilization for ER/admit due to hypoglycemia and thus improved patient safety
  - Clinical benefits for T2D patients were greater or equal to T1D
- Expanded access to rtCGM is warranted based on these findings, particularly in underserved demographics disproportionately affected by diabetes

Continuous Glucose Monitoring Real World Experience and Follow-up Panel Discussions

Samir Mistry, PharmD, MBA
Vice President of Pharmacy Strategy & Services
Capital Blue Cross

Kelly L. Close
Founder, The diaTribe Foundation
President, Close Concerns

Payer Perspective

Samir Mistry, PharmD, MBA
Vice President of Pharmacy Strategy & Services
Capital Blue Cross

Insulin-Treated T2D Represents a Greater Opportunity for Quality Improvement and Cost Management than T1D

A significant driver of clinical and cost burden…

- 30% of patients with T2D are treated with some form of insulin[1]
- Severe hypoglycemia (SH) is common in people with T2D, and the risk of SH increases with longer duration of disease[2]
- SH represents a barrier to optimal glycemic management, a considerable detriment to member quality of life, and a substantial drain on health care resources[3]
- Members with T2D demonstrate a greater tendency to utilize health care resources than those with T1D after experiencing SH[3]

…that often goes undetected

- Only approximately 5% of self-reported events among pharmacologically treated patients with diabetes are captured by health care utilization-based surveillance[4]

1. Peek ME, et al. *JAMA.* 2021;325(22):2255–2257. doi:10.1001/jama.2021.6208 2. International Hypoglycemia Study Group. *Diabetes Care.* 2015;38:1583-1591.
3. Heller SR et al. *Diabetic Medicine*. 2016;33(4):471-477. 4. Karter AJ, et al. *JAMA Intern Med*. 2018;178(7):987-988. doi: 10.1001/jamainternmed.2018.1014.

Hypoglycemia Results in Sizeable Resource Utilization and Resultant Costs, Particularly in T2D

Hypoglycemic Event Requiring Medical Care

Up to 58% involve ambulance service

90% involve an ED visit

Approximately 1/3 require hospitalization

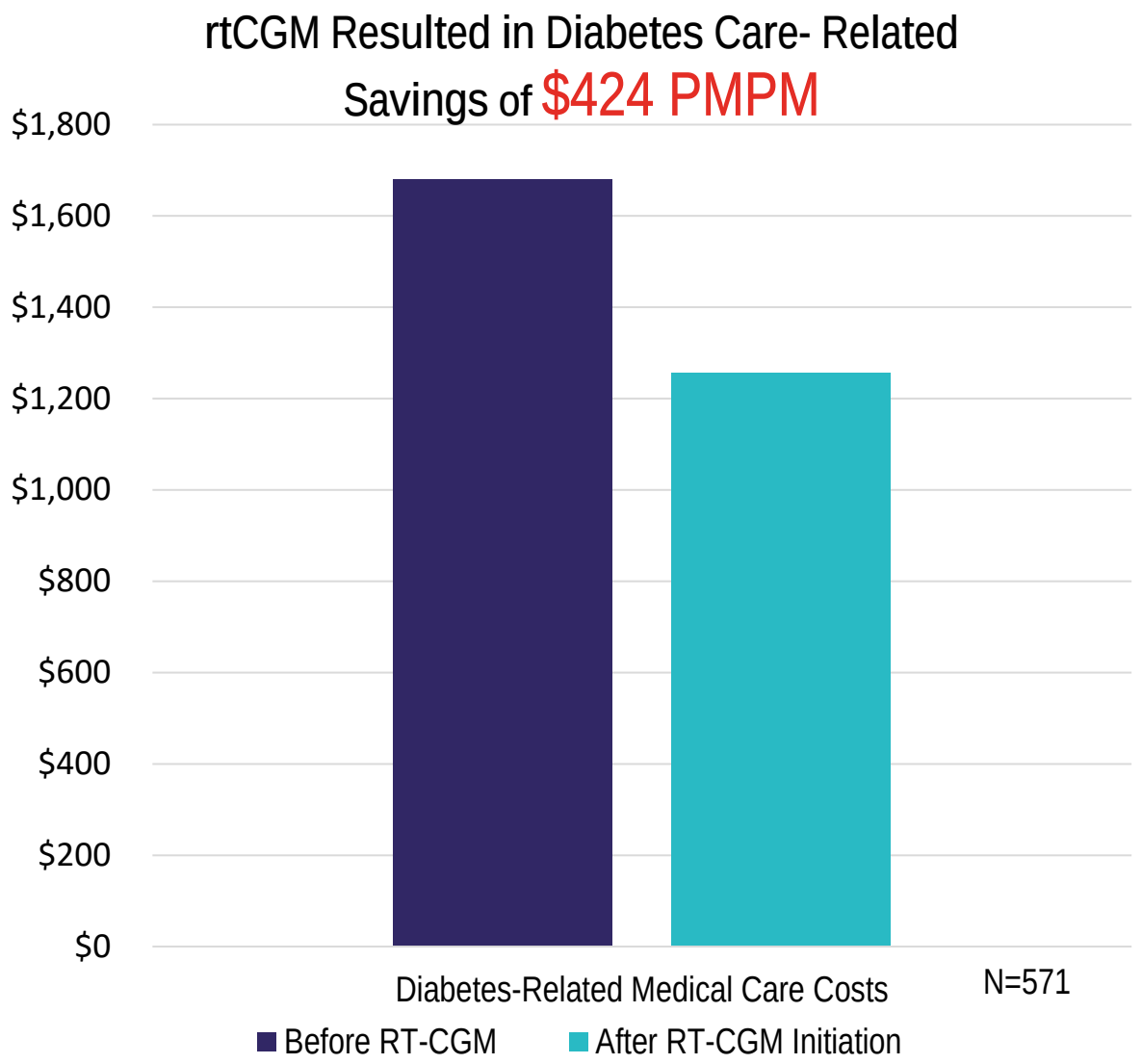
Type of hypoglycemic health care resource	Cost (US dollars)
Ambulance	$664 median cost per event
Emergency Department	$3106 average cost per event
Hospitalization Severe Hypoglycemia (SH)	
T1D, Inpatient SH: 1.7 days, including ER	$3551 cost per hospitalization
T2D, Inpatient SH: 2.8 days	$6896 cost per event
T2D on basal insulin, Inpatient SH: 2.6 days	$5802 cost per event

Shi L, et al. *J Diabetes Complications*. 2021;35(6):107916.
Zhao Y, et al. J Med Econ. 2016;19(9):852-7.
Bajpai S, et al. *J Manag Care Spec Pharm*. 2021;27(3):385-391.

A Retrospective Claims Analysis Shows Reduced Diabetes-related Care Cost in T2D with rtCGM Initiation

OPTUM®

- A total of 571 participants met the study inclusion criteria
  - Mean (SD) age: 51.2 (11.9) years
  - 80% treated with intensive insulin therapy (IIT)
  - 99% commercial insurance
  - 58% see endocrinologist
  - 92% have comorbidity complications



Norman, GJ. *Diabetes* (2021): https://doi.org/10.2337/db21-66-LB.
Diabetes Technol Ther. 2022 Mar 1. doi: 10.1089/dia.2021.0525. Online ahead of print.

ADA Standards of Care: Recommendations for CGM

"Access to CGM devices should be considered from the outset of the diagnosis of diabetes that requires insulin management"

American Diabetes Association. *Diabetes Care*. 2021;44(Suppl1):S85-S99

Alternative Access Channels for CGM

Wait Times, Administrative Burden, and Member Experience

DME Channel (3-4 Weeks)

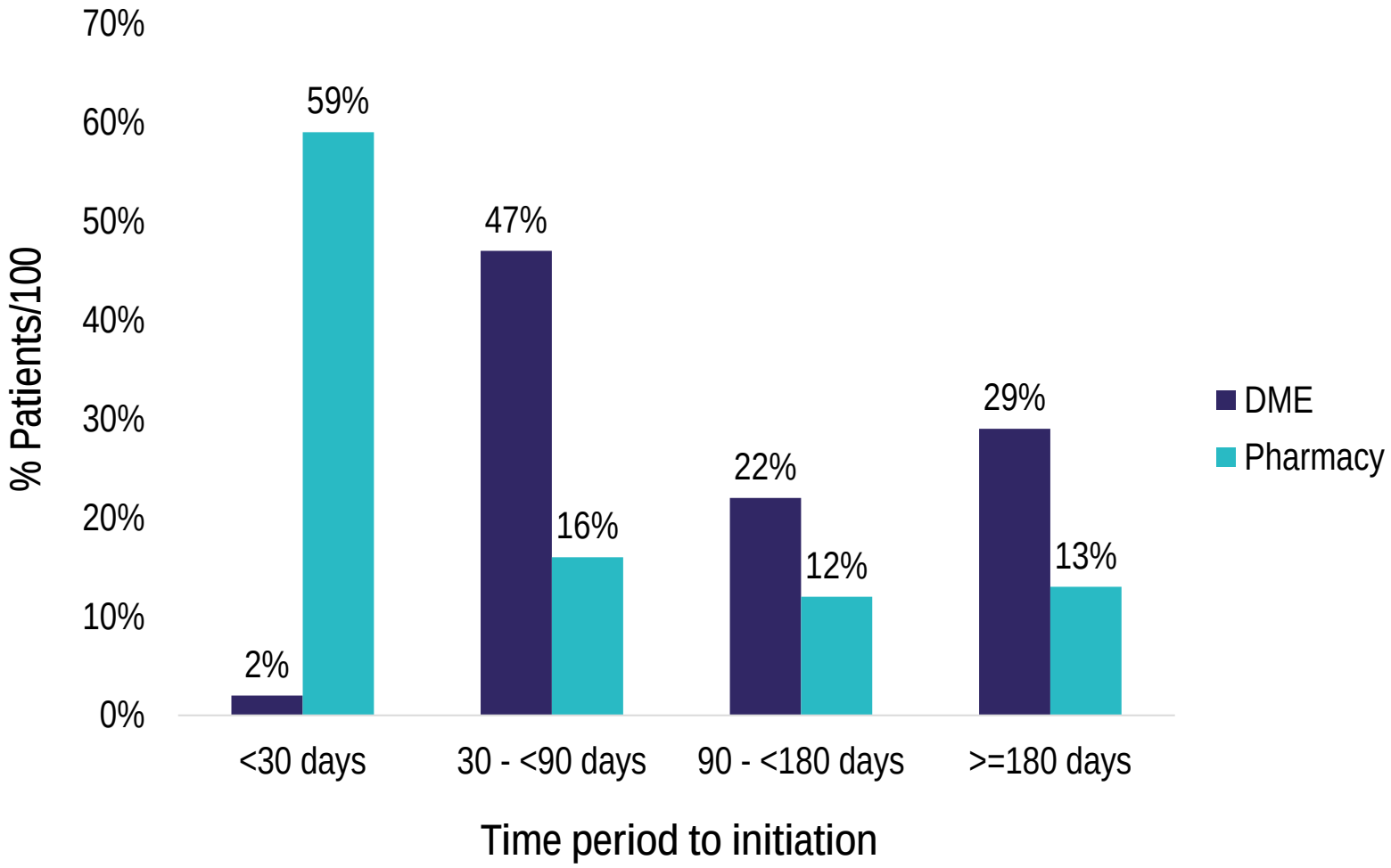
1. Manufacturer receives patient info and Rx
2. Manufacturer identifies payer to determine channel
3. Manufacturer processes order (if in-network) or transfers to distribution partner
4. Manufacturer or distributor conducts benefits check w/insurer
5. Manufacturer or distributor collects necessary information
6. PA to health plan (if required)
7. Manufacturer or distributor collects out-of-pocket and ships product
8. Claims generated and submitted to insurance

Pharmacy Channel (1-2 Days)

1. HCP gives Rx to patient or pharmacy
2. Patient goes to pharmacy where out-of-pocket cost is determined
3. Patient pays out-of-pocket cost
4. Pharmacy distributes product immediately or orders

Pharmacy Coverage of CGM Ensures Timely Access for Plan Members

- Factors associated with initiation of CGM were younger age, *private insurance*, and education with a clinical diabetes educator
- *Identifying as Black or Hispanic was significantly associated with decreased initiation of CGM*
- A1C improved in patients initiated on CGM from 9.06% to 8.22% (p<0.001)



Obtaining CGM through pharmacy benefit was significantly faster than through DME(p < 0.0001)

Modzelewski KL, et al. *Diabetes Technol Ther*. 2022 Feb 16. doi: 10.1089/dia.2021.0557.

Assessment of CGM Pharmacy Access

Stakeholder Analysis

Payer

- Implement smart utilization controls
- Increased visibility to data
- Lower costs in pharmacy vs medical benefit

Provider

- Ease of prescribing
- Less administrative burden
- Improved patient has access to product

Patient

- Faster access to product
- Less frustration from utilization controls
- Convenience of picking up CGM with medications

Convenient and cost-effective access through the pharmacy benefit provides quicker access to the product and lower costs.

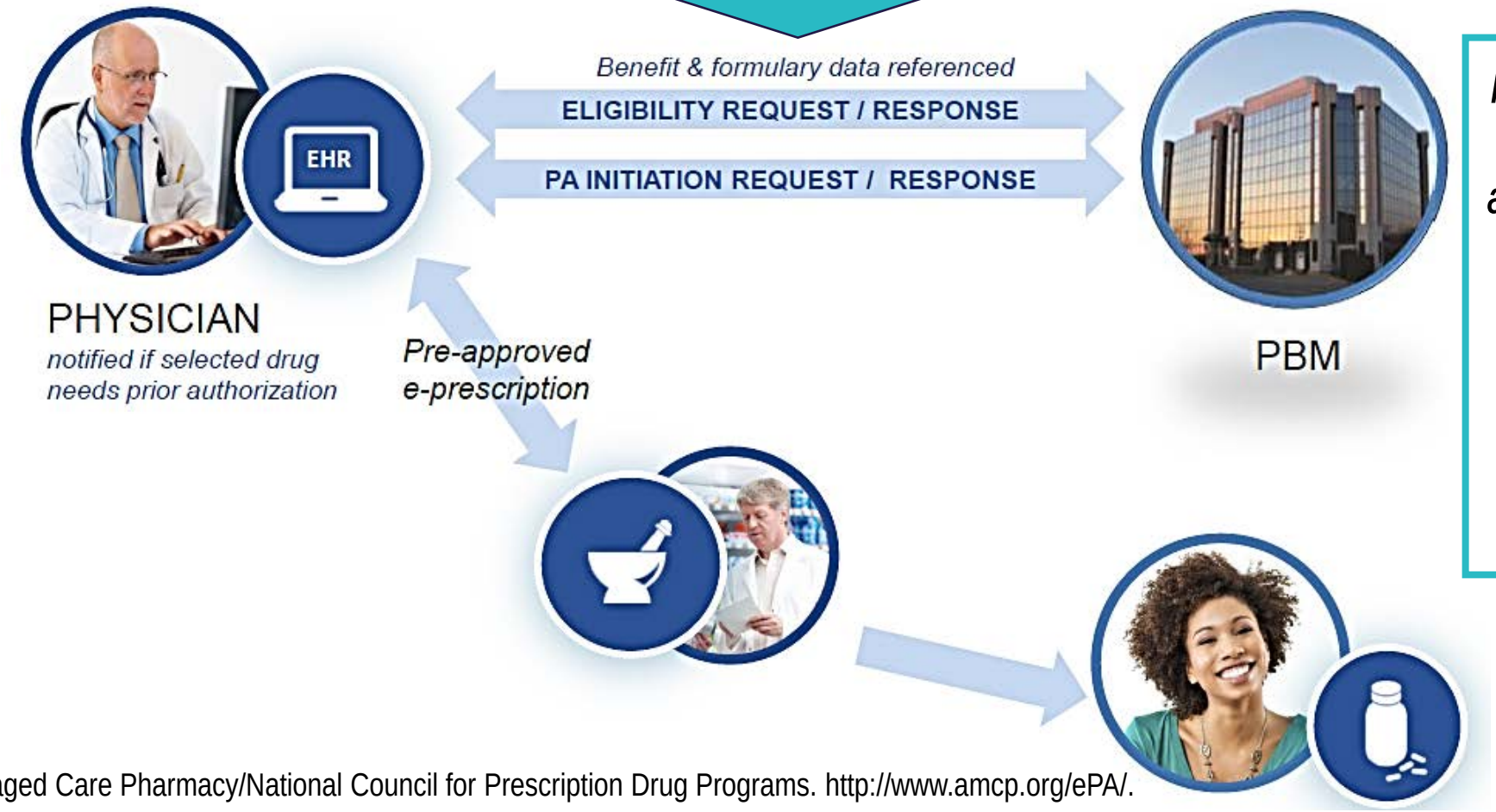
Pharmacy Utilization Management

CGM Benefit Design & Administration

- Enables use of electronic point of sale (POS) look back edits
  - Ability to look for historical claims for insulin to prevent need to apply utilization controls
  - Member able to start prescription for CGM immediately, they are currently taking insulin
  - If newly diagnosed or no documented insulin, then provider can request prior authorization
- Establishes greater transparency in utilization and costs for CGM with pharmacy data vs. complicated medical claims data

Electronic PA Streamlines Access by Approving the Prescription Before it is Sent to the Pharmacy

For CGM, a smart edit featuring an automated look back in claims data for any previous insulin prescription can be used as the criterion for approval with real-time adjudication



Including any previous insulin prescription allows plans to provide appropriate coverage for all insulin-treated members and is consistent with evidence-based practice guidelines

Academy of Managed Care Pharmacy/National Council for Prescription Drug Programs. http://www.amcp.org/ePA/.

Provider Satisfaction

- Most comfortable with pharmacy prescribing process (e.g., e-Rx)
- Less administrative burden for all if member is already filling for insulin with point-of-sale lookback edit
- Less chance of patients falling through the cracks or delaying start
- If no insulin on profile, prior authorization follows the typical process

https://chrt.org/publication/e-prescribing-barriers-opportunities/

Member Satisfaction, Safety, and Care

- Members initiate & continuously use CGM to help detect & prevent hypoglycemia events [with alerts/alarm, remote monitoring] and stabilize their insulin management…turn-around time to access is important
    - Automated point-of-sale (POS) insulin look back edit at pharmacy means minimal delays in initiating care and in continuity of care with prevention of possible ER/admit
- Members with diabetes place significant value on the ease, convenience and coordination of access to all their diabetes supplies & support services through pharmacies, either in person or through mail order
    - Pharmacy-based access supports greater convenience, adherence & coordination of care = positive member experience

Cost Savings to the Plan

- Manufacturer provides significant savings through rebates on CGM pharmacy claims vs. DME reimbursement
  - Program delivered immediate cost savings on plan members switching from DME to Pharmacy, and sustainable long-term savings going forward
- Important to engage network director, medical director, plan president, etc. on initiative to cover CGM through pharmacy benefit
  - May look like pharmacy spend is increasing but total cost to plan is decreasing

Plan Sponsor Impact

- Lower overall CGM costs through Pharmacy vs. Medical to plan sponsors
  - Also had discussions with clients, brokers and consultants on value of covering CGM through pharmacy benefit
- Impact of the reductions in hypoglycemic events alone on employee absenteeism, productivity and ability to use treatment appropriately
  - For example, in a survey of 1400 responders with hypoglycemia outside working hours:
    - 22.7% experienced absenteeism, resulting in being late for work or missing a full day
    - Lost productivity highest for nocturnal hypoglycemia, with an average of 14.7 working hours lost
    - In the week following a hypoglycemic event, required an average of 5.6 extra BG test strips and insulin-users decreased their insulin dose by 25% → *Fear of hypoglycemia affecting treatment decisions*

Brod M, et al. *Value Health*. 2011;14(5):665-71. doi: 10.1016/j.jval.2011.02.001.

Summary

- T1 and T2D imposes significant clinical and economic burden in managed care, realized through glycemic complications as well as hypoglycemia and associated resource utilization
- rtCGM offers an opportunity for improved outcomes and proven PMPM savings
- Pharmacy benefit coverage for CGM ensures timely access with potential cost-savings for health plans
- Electronic PA can further streamline the coverage and access process for CGM, improving payer efficiencies and member/provider satisfaction

Patient Perspective

Kelly L. Close
Founder, The diaTribe Foundation
President, Close Concerns

Diabetes management is an ongoing challenge, with only 21% of adults achieving HbA1c <7%

At Least 42 Factors Affect BG

"If you really look at it, having diabetes means you have an additional job to attend to every day."

Aus Alzaid MD. *Diabetes Technol Ther*. 2014 Aug 1; 16(8): 542–544.

Foster NC, et al. *Diabetes Technol Ther*. 2019; 21:61-72.
diaTribe Learn. February 2018. "42 Factors That Affect Blood Glucose?! A Surprising Update. https://diatribe.org/42-factors-affect-blood-glucose-surprising-update.

In addition to clinical burden, persons living with diabetes face numerous psychosocial challenges

Phase of Living with Diabetes		Nonclinical (normative) symptoms/behaviors	Clinical symptoms/diagnosis
	Behavioral health disorder prior to diagnosis	None	• Mood/anxiety disorders • Psychotic disorders • Intellectual disabilities
	Diagnosis	Normal course of adjustment reactions, including distress, fear, grief, anger, initial changes in activities, conduct or personality	• Adjustment disorders
	Learning self-management	Issues of autonomy, independence, and empowerment. Initial challenges demonstrate improvement with training/support	• Adjustment disorders • Psychological factors affecting medical condition
	Maintenance of self-management and coping skills	Periods of waning self-management behaviors, response to booster educational or supportive interventions	• Maladaptive eating disorders • Psychological factors affecting medical condition
	Life transitions impacting self-management	Distress and/or changes in self-management during times of life transition	• Adjustment disorders • Psychological factors affecting medical condition
	Disease progression and onset of complications	Distress, coping difficulties with progression/onset of complications impacting function, OQL, sense of self, roles, interpersonal relationships	• Adjustment disorders • Psychological factors affecting medical condition
	Aging and its impact on disease and self-management	Normal, age-related forgetfulness, slowed information processing, and physical skills potential impacting self-management and coping	• Mild cognitive impairment • Alzheimer's or vascular dementia

ADA. https://professional.diabetes.org/sites/professional.diabetes.org/files/media/psychosocial_care.pdf.

Persons with diabetes spend a miniscule fraction of their time with health care providers

The traditional 15-minute primary care visit must cover numerous topics pertinent to diabetes management

- Assess and examine the patient physical health
- Review relevant metabolic profiles, assess lab values such as HbA1c, LDL, glucose logs
- Review medications along with comorbidities assessment
- Provide health promotion and preventive education to the patient and / or family
- Document all relevant data in EMR

Self-management is integral to piecing together the “Diabetes Puzzle”

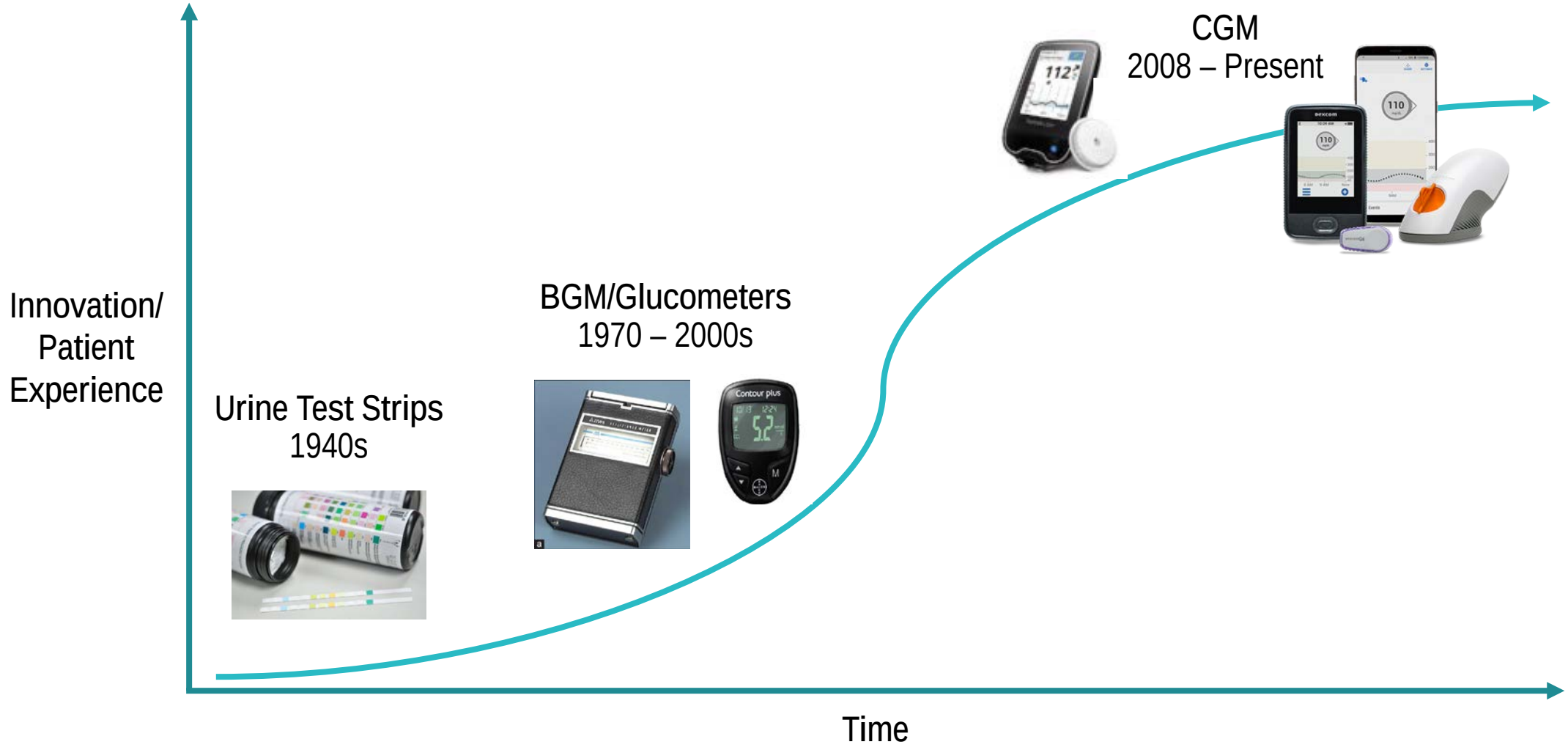
Solutions that support self-management are associated with lower HbA1c levels[2]

[1]These behaviors, defined by the American Diabetes Association (ADA) and the American Association of Diabetes Educators (AADE), address the skills needed in diabetes self-management education; [2]Tufts Health & Nutrition Letter, July 2019; [3]www.dtxalliance.org.

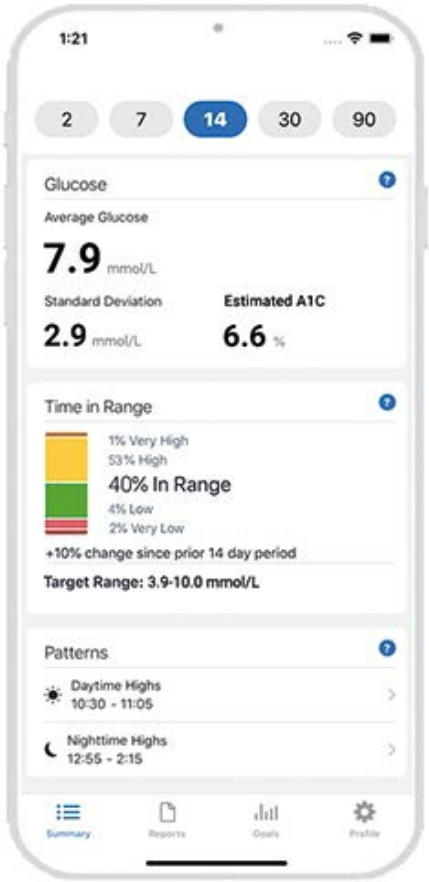
Intermittent BG testing and HbA1c only tell part of the story

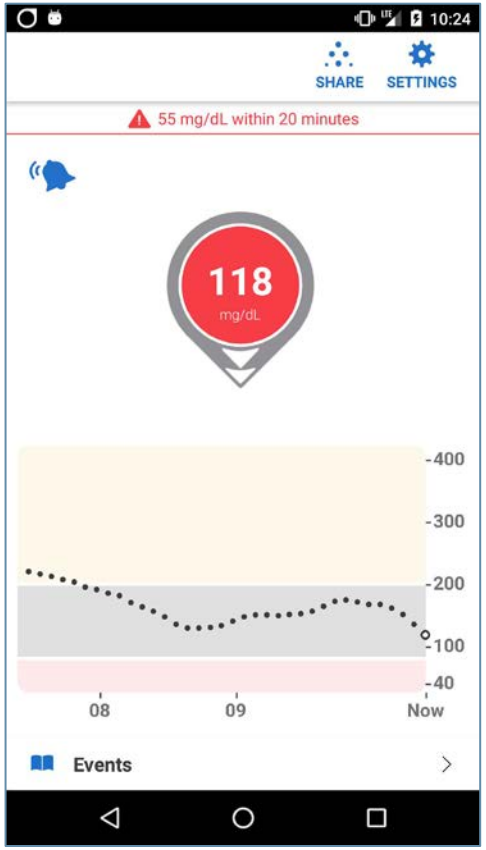
SMBG=Self Monitoring of Blood Glucose

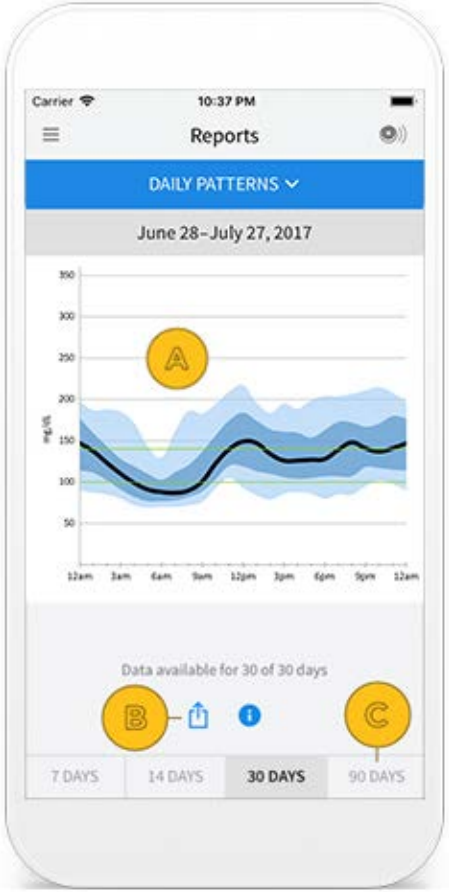
The introduction of CGM represented a revolutionary innovation in the lives of persons with diabetes



CGM arms the patient with knowledge to self-manage easily and effectively







CGM apps and interfaces enable telemedicine and remote monitoring, which is especially important for those in rural areas

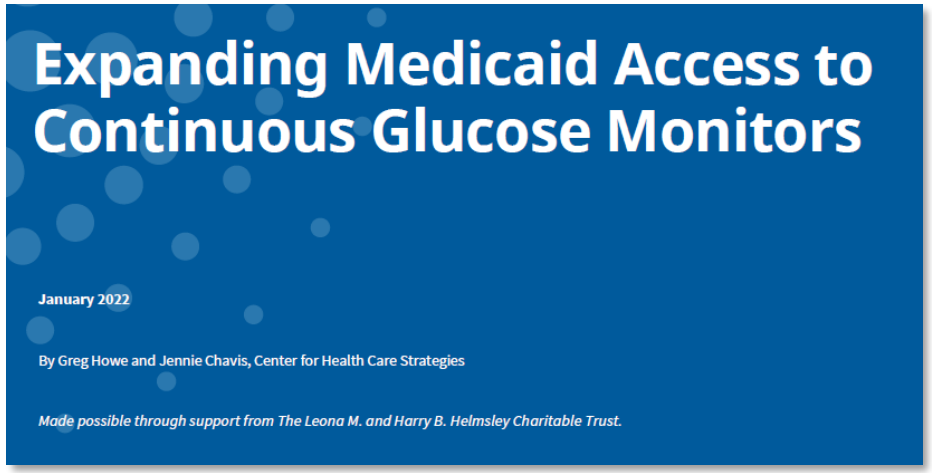
"Leveraging telemedicine whenever possible is the best way to protect patients and staff from COVID-19."

https://www.cdc.gov/coronavirus/2019-ncov/hcp/preparedness-resources.html

Pharmacy access to CGM is crucial for underserved populations

"Compared to people with commercial insurance, Medicaid beneficiaries have higher rates of poor diabetes management, worse glycemic control, experience more barriers to care (including access to and coverage of continuous glucose monitors and other diabetes technologies), and experience more acute- and long-term complications related to diabetes."

"*Cover CGMs as a pharmacy benefit rather than a DME benefit*. Patients report that accessing a CGM and its components is more convenient through a pharmacy than through a DME supplier. Beneficiaries with diabetes who already access insulin and other pharmaceuticals through a pharmacy would not have to navigate the requirements of another entity."



Pharmacy access benefits those who are

…unable to take delivery from DME

…in transient housing situations

…affected by limited access due to the pandemic natural disasters

https://www.chcs.org/media/Expanding-Medicaid-Access-to-Continuous-Glucose-Monitors_011222.pdf

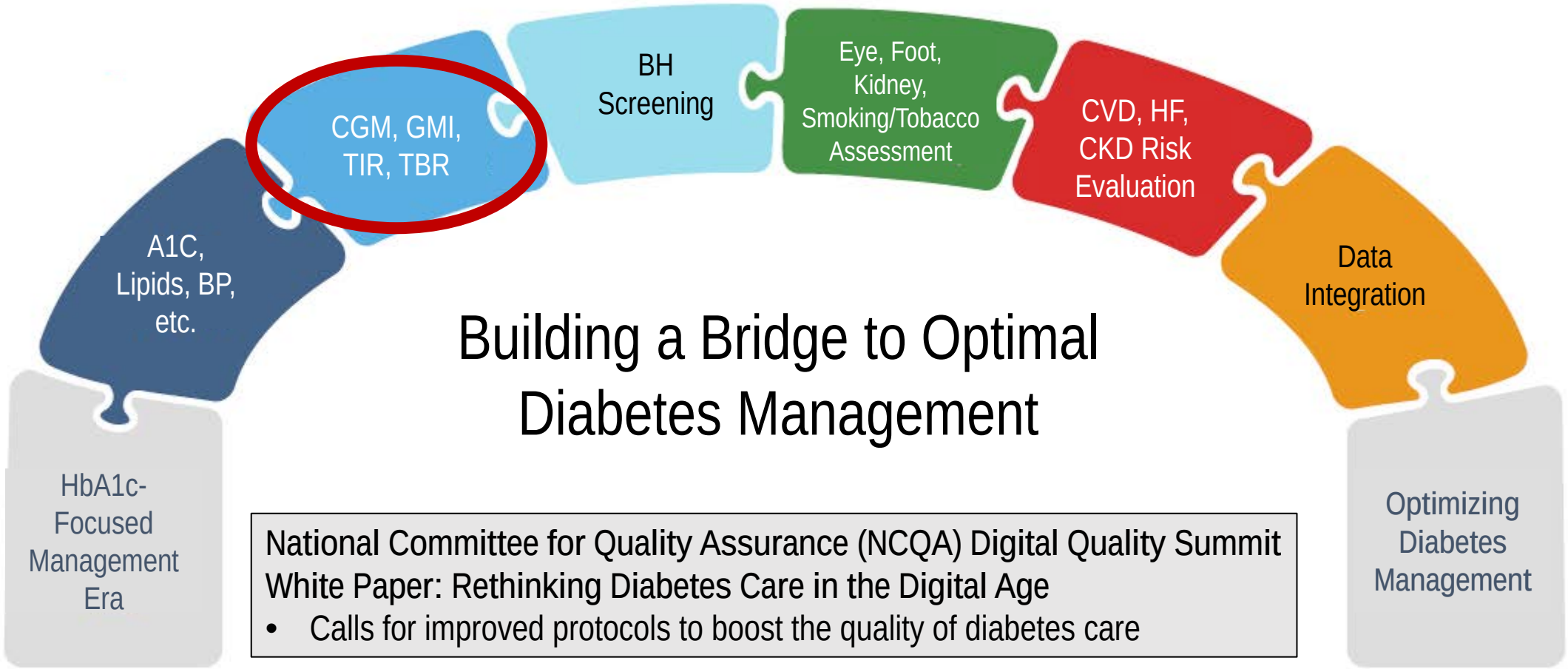
Pharmacy access to CGM enlists the expertise of pharmacists and facilitates interdisciplinary collaborative care

"An important member of your health care team is as close as your local drugstore. With nearly 9 in 10 Americans living within 5 miles of a community pharmacy, your pharmacist may be the health professional you see most often and talk with about your health."

Centers for Disease Control and Prevention

https://www.cdc.gov/heartdisease/pharmacist.htm.

Future Approaches to Optimal Diabetes Management Should Incorporate CGM and Advanced Quality Measures



National Committee for Quality Assurance (NCQA) Digital Quality Summit White Paper: Rethinking Diabetes Care in the Digital Age

- Calls for improved protocols to boost the quality of diabetes care

R. Bergenstal presentation materials - Digital Quality Summit, July 2021.
https://www.ncqa.org/white-papers/rethinking-diabetes-care-in-the-digital-age/


I’ve been thinking about diabetes for a long time…

MANAGED CARE CGM.com

Presents:

The Value of Streamlined Coverage for Real-Time CGM TO OPTIMIZE OUTCOMES AND RESOURCE UTILIZATION FOR MEMBERS WITH DIABETES

Jointly provided by

MEDICAL EDUCATION RESOURCES

Impact Education LLC

This activity is supported by an independent educational grant from Dexcom, Inc.