Applying Sensor-Based Technology to Optimize Blood Glucose Time-in-Range (TIR), Quality of Life, and Health Metrics Across the Comprehensive Spectrum of Diabetes Care

Implications and Action Steps for the Managed Care Physician-Specialist

Welcome and Program Overview

CME-certified symposium jointly provided by the University of Massachusetts Medical School and CMEducation Resources, LLC

Commercial Support: Supported by an educational grant from Abbott Diabetes Care

From Clinical Trials to the Front Lines of Diabetes Care

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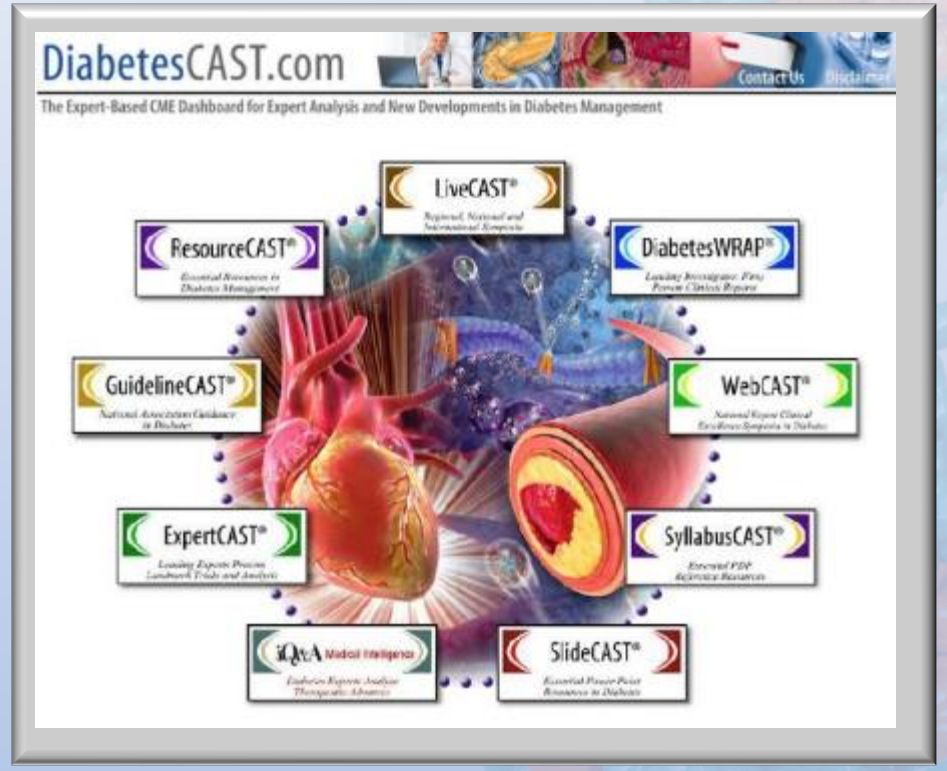
Continue Learning With Us

Access Enduring Materials from This Symposium

- This entire program, and additional diabetes CME offerings, will be available as a Clinical Excellence WebCAST on multiple clinical websites, including **www.DiabetesCAST.com**

- PowerPoint slides from today's program will be available for download

- Clinical questions about diabetes management may be submitted to **www.iQandA-CME.com**



Rationale for the Use of Continuous Glucose Monitoring In a Managed Care Environment

Establishing a New, Guideline- and Evidence-Based Standard of Care and Policies in the **Managed Care/HMO** Setting

Jerry Frank, MD – Program Chair
Principal, COPE Health Solutions

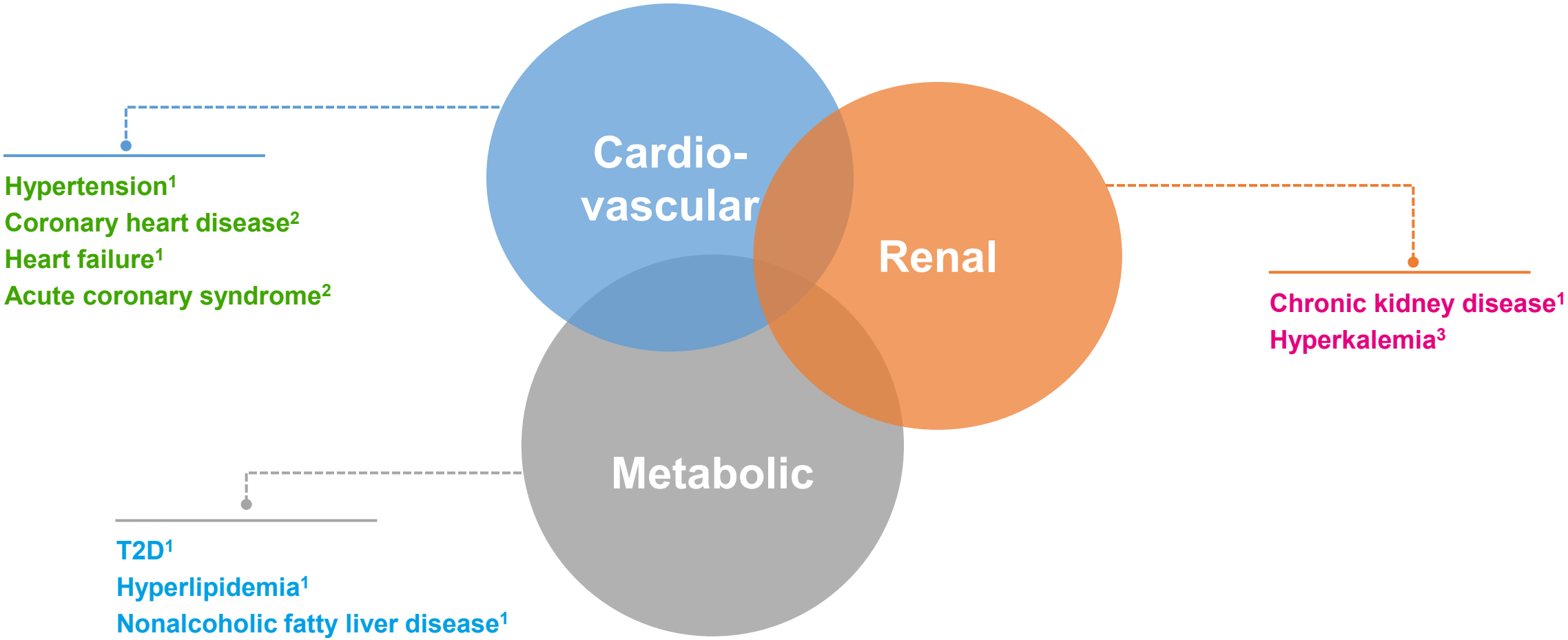
Diabetes

Fast Facts*

- Total: 34.2 million people have diabetes (10.5% of the US population)
- Diagnosed: 26.9 million people, including 26.8 million adults
- Undiagnosed: 7.3 million people (21.4% are undiagnosed)
- 1.4 million adults aged 20 years or older—or 5.2% of all US adults with diagnosed diabetes—reported both having type 1 diabetes and using insulin.
- 2.9 million adults aged 20 years or older—or 10.9% of all US adults with diagnosed diabetes—started using insulin within a year of their diagnosis

CDC National Diabetes Statistics Report 2020

T2D is a Multifaceted Disease Comprising Cardiovascular, Metabolic, and Renal Complications



T2D, Type 2 diabetes

1. Whaley-Connell A, Sowers JR, *J Am Soc Hypertens* 2014;8:604–606; 2. Shah AD, et al. *Lancet Diabetes Endocrinol* 2015;3:105–113; 3. Jarman PR, et al. *Postgrad Med J* 1995;71:551–552

Diabetes: Cost of Care*

DIRECT COSTS

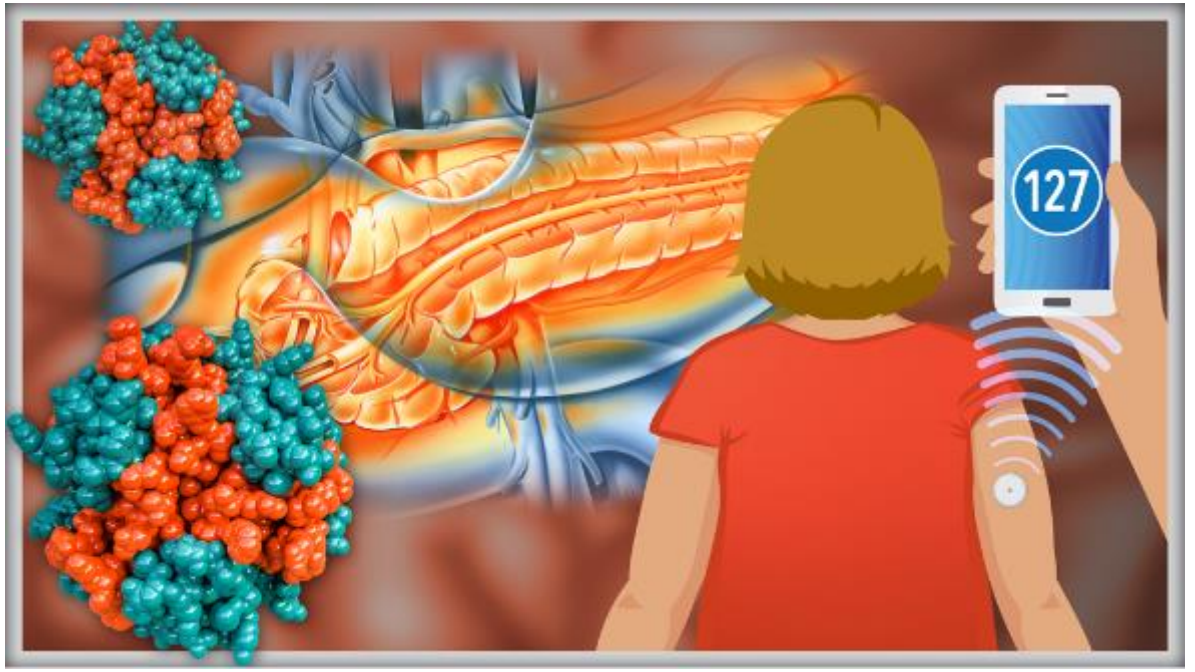
- Annual cost of diabetes treatment $327B
- Diabetes is 2.3 times more expensive than average person
- Costs have increased 26% in 5 years
- Inpatient hospital care - 30% of total cost
- Prescription costs for complications - 30% of total cost
- Anti-diabetic agents and supplies – 15% of total costs
- Physician visits – 13% of total costs

INDIRECT COSTS

- Increased absenteeism - $3.3 B
- Reduced productivity while at work - $26.9B
- Reduced productivity for those not formally employed - $2.3B
- Inability to work due to disability - $37.5B
- Lost productivity due to early mortality - $19.9B

**American Diabetes Association Economic Costs of Diabetes in the U.S. in 2017*

Why Is This So Important Now?



Value Based Care

Value: Health outcomes achieved per dollar spent

OUTCOMES/COST = VALUE

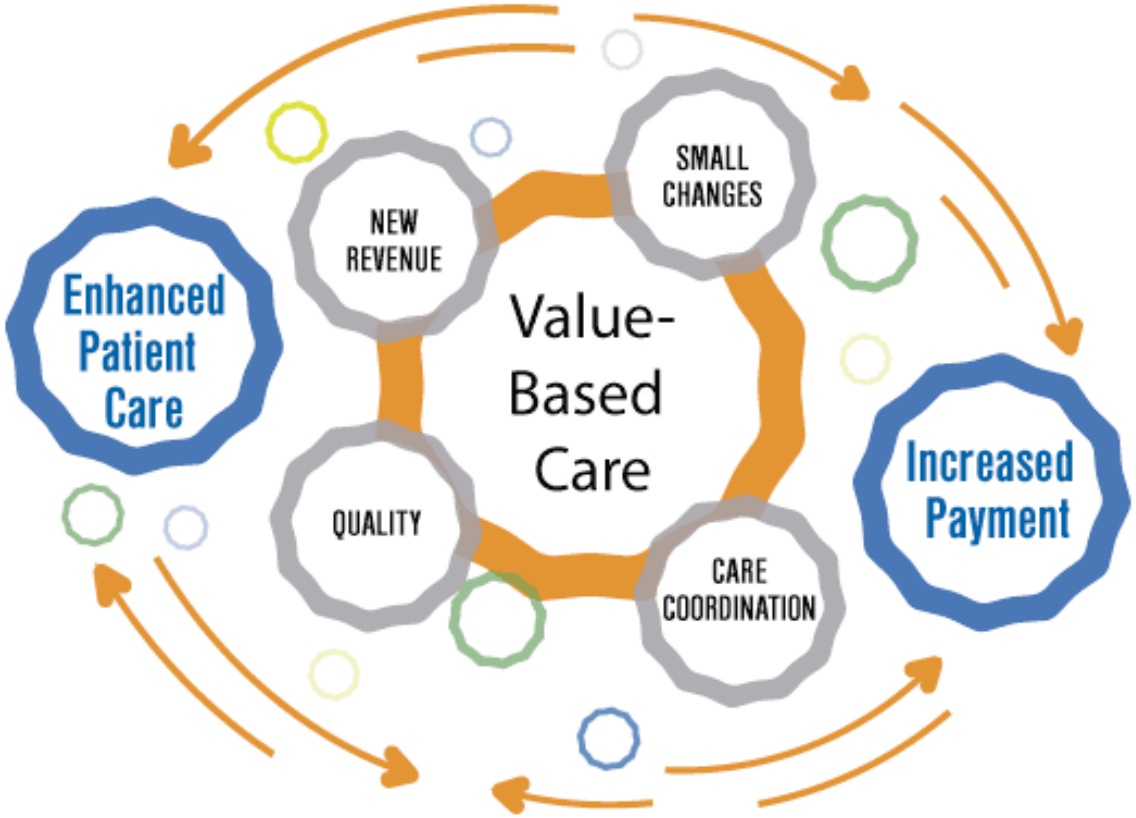
- Aligns all stakeholders in the system
- Should be defined around the customer…the patient
- Should be measured by outcomes achieved, not by volume of services delivered or process measures performed

Value Based Care

Pay for Performance

- Based on quality measures
  - Most commonly HEDIS (Healthcare Effectiveness Data and Information Set) or STARS (use of HEDIS type measures to achieve ratings demonstrated by using ★)
  - CAHPS (Consumer Assessment of Healthcare Providers and Systems)
  - Focus on triple weighted scores
  - May include review of all-cause readmissions
- Typically no focus on cost of care or spend

Value Based Care



GAINSHARING

- Quality measures as noted from HEDIS and STARS
- CAHPS
- Assessing total cost of care
  - Budget set for cost of care based on risk-based patient mix
  - Savings are shared with the plan
  - Losses are absorbed by the plan
    - Upside potential only

Proprietary and confidential — do not distribute

Value Based Care

Capitation/Percent of Premium/Full Risk

- Work within a budget
- Self determined most cases
- Quality component
- Total cost of care based on PMPM or capitated target
- Attribution of members
- Risk Scores to determine PMPM
  - Age/Sex as well
- How does this translate to the individual provider?
  - FFS
  - Capitation
  - Base salary + Bonus

Diabetes

Cost related to glucose monitoring*

- Hospital admissions for hypoglycemia cost: $2811-17564
- Total cost per year for self blood glucose monitoring: $1602-1712 per person
- Total cost for flash CGM per year: $1438 per person

Potential savings associated with better glucose monitoring:

- Reduction in hospitalizations related to hyperglycemia and hypoglycemia
- Delay in long term sequelae related to better glucose control

Cost comparison of flash CGM with self monitoring blood glucose in adults with type 1 or type 2 diabetes using intensive insulin. Shi, L; Hellmund, R TouchEndocrinology.com April 4, 2020

Diabetes

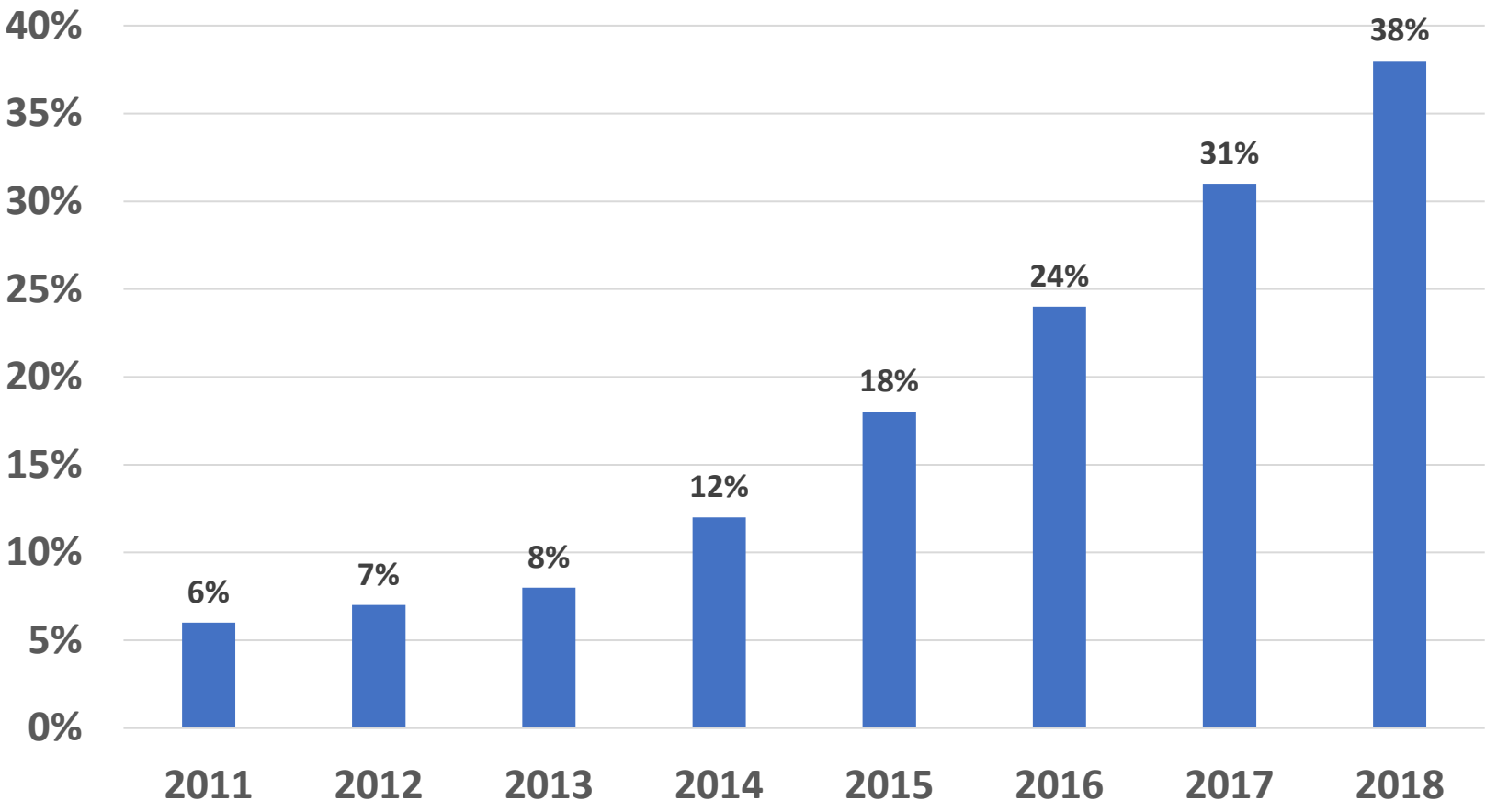
Number and rate of hospitalizations among adults aged ≥18 years with diabetes, USA, 2016*

Cause of hospitalization	Number, in thousands	Crude rate per 1,000 persons with diabetes (95% CI)
Diabetes as any listed diagnosis	7,833	339.0 (317.6–360.4)
Major cardiovascular disease	1,740	75.3 (70.4–80.2)
Ischemic heart disease	438	18.9 (17.6–20.2)
Stroke	313	13.6 (12.7–14.5)
Lower-extremity amputation	130	5.6 (5.3–6.0)
Diabetic ketoacidosis	188	8.1 (7.6–8.7)

**Cost comparison of flash CGM with self monitoring blood glucose in adults with type 1 or type 2 diabetes using intensive insulin. Shi, L; Hellmund, R TouchEndocrinology.com April 4, 2020*

CGM Use Over Time

T1D Exchange Registry (USA) 2011–2018

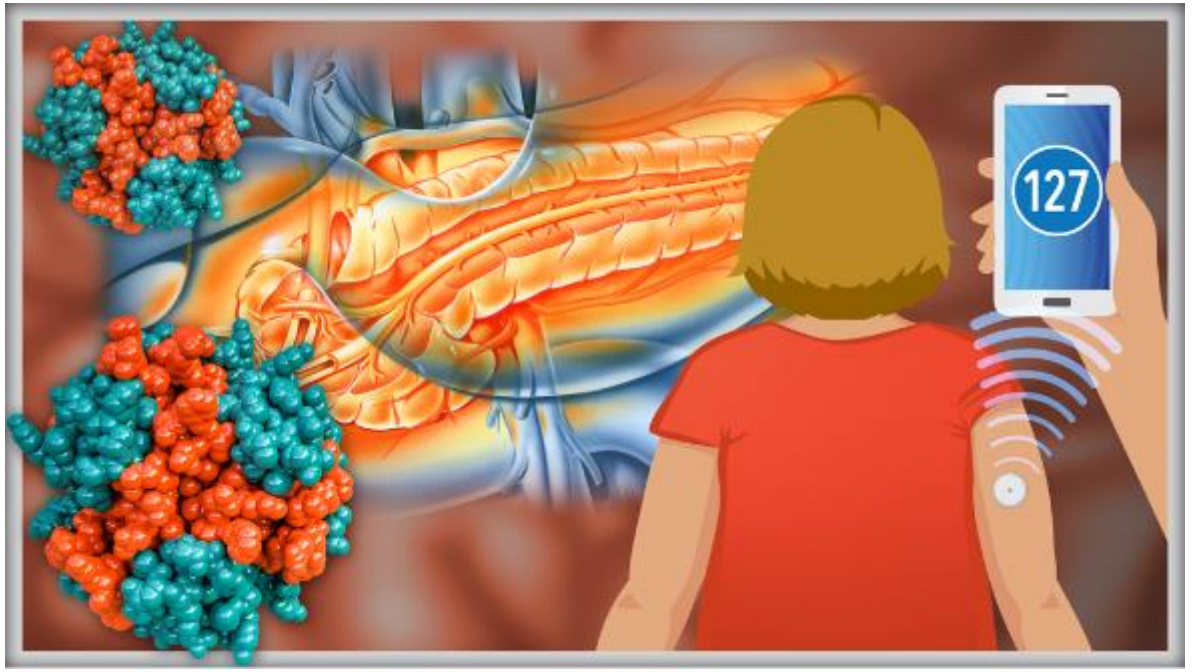


Foster et al. Diabetes Technology & Therapeutics 2019

Questions

- Does the use of CGM make sense for patients?
- Should plans purchase CGMs? Should they cover CGMs?
- Should groups at risk for cost of care and quality measures insist on the use of CGMs for patients?
- Should there be guidelines established to approve CGMs for patients over fingerstick supplies and monitors? If so, what are they?

Thank you



Applying Sensor-Based Glucose Monitoring (CGM) to Reduce Cost-Intensive, Adverse Drug Events Associated with Diabetes Treatment

A Health Metrics Focus on Reducing Hospitalizations and Improving Patient Satisfaction/Quality of Life and Resource Utilization—Implications for the Managed Care Clinician

Irl B Hirsch, MD

Professor of Medicine | Diabetes Treatment and Teaching Chair
University of Washington Medical Center | Medical Director
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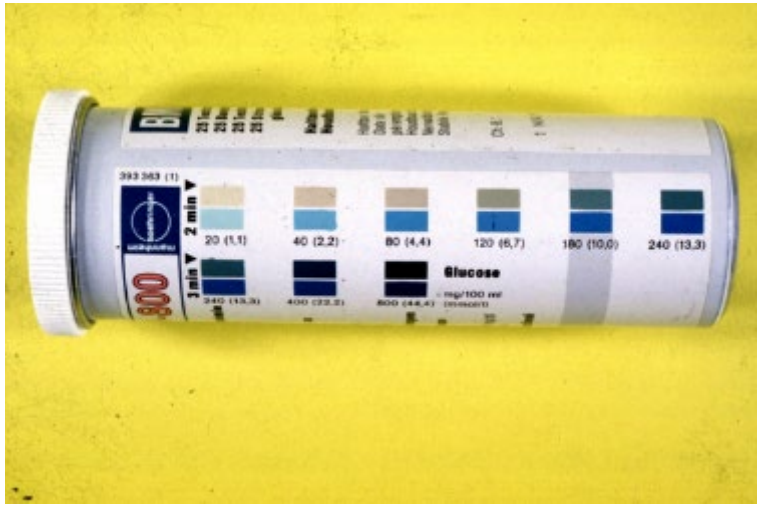
Dualities

- Research: Medtronic, Insulet, Beta Bionics
- Consulting: Abbott Diabetes Care, Bigfoot, Roche, GWave

Do Our Home Monitoring Tools Improve Outcomes and Costs?



During this 100th anniversary of the discovery of insulin, do we have data to suggest our older tools had an impact on acute complications and costs?

What About our Newer Tools?

CGM: Will it Reduce Visits to the ED?

JAMA Network Open

Original Investigation | Diabetes and Endocrinology

Association of Cumulative Multimorbidity, Glycemic Control, and Medication Use With Hypoglycemia-Related Emergency Department Visits and Hospitalizations Among Adults With Diabetes

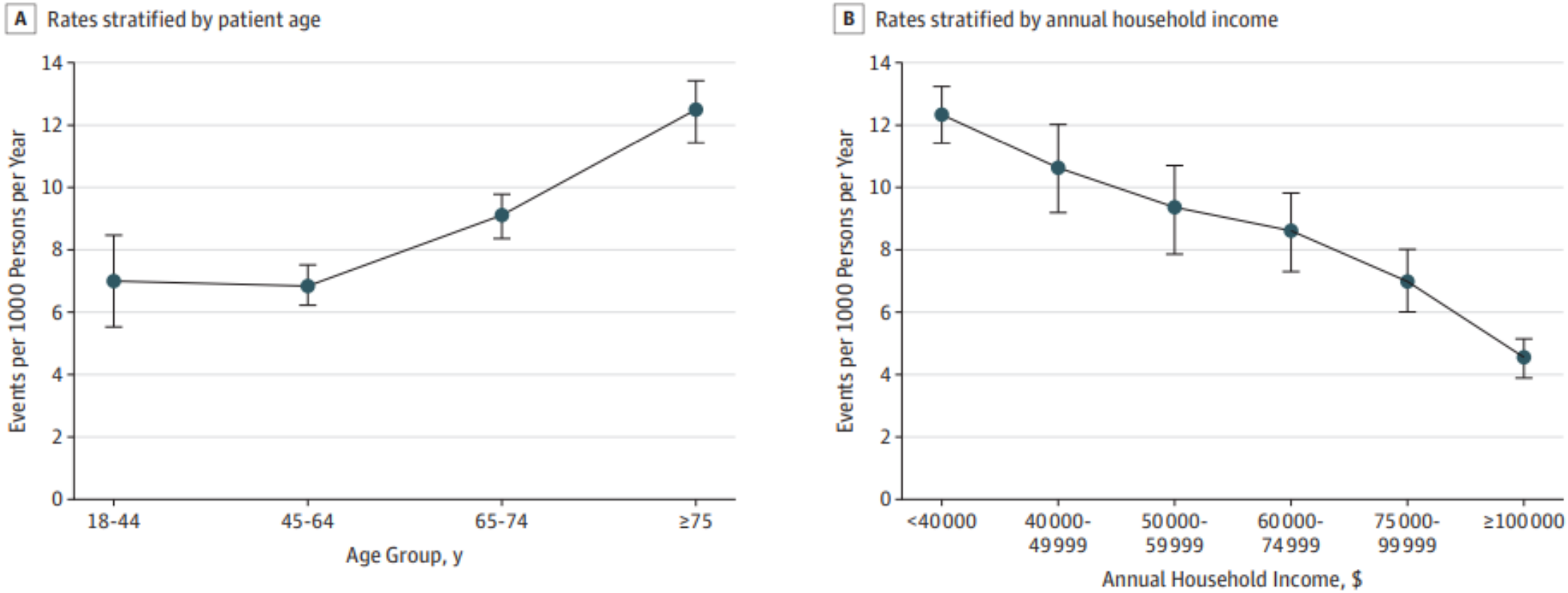
Rozalina G. McCoy, MD, MS; Kasia J. Lipska, MD, MHS; Holly K. Van Houten, BA; Nilay D. Shah, PhD

- N=201,705 adults with diabetes (age 65.8 yr, HbA1c 7.2± 1.5%)
- 96.3% type 2 diabetes and 69.3% of them on insulin ± SFU
- Data from January 1, 2014, to December 31, 2016, were analyzed

JAMA Network Open. 2020;3(1):e1919099

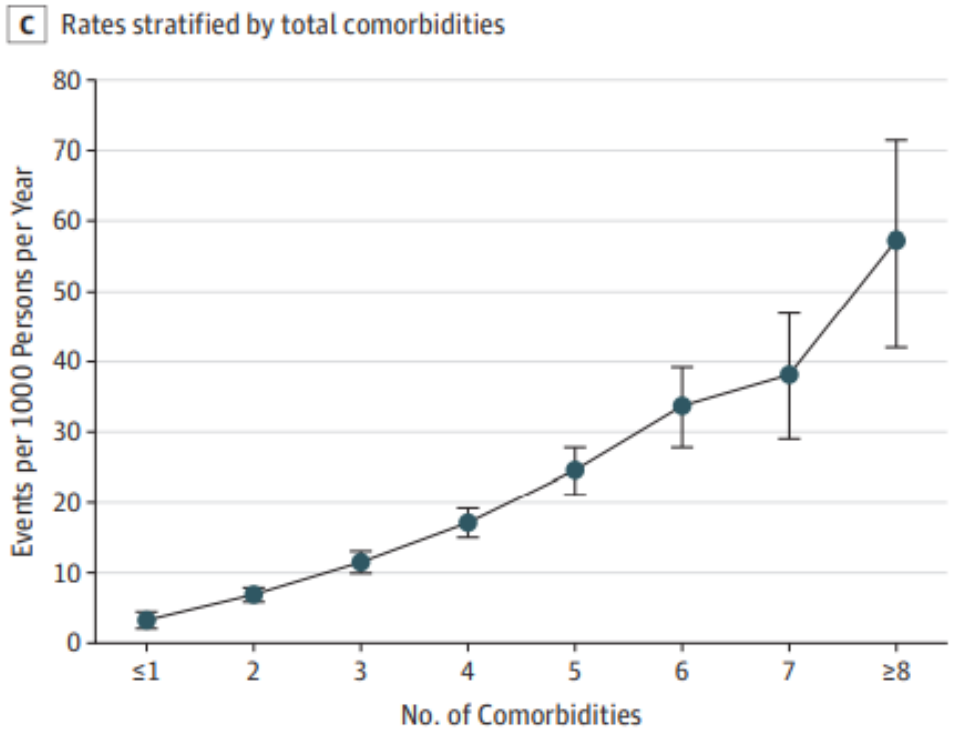
Hypoglycemia Rates: ED and Hospitalizations

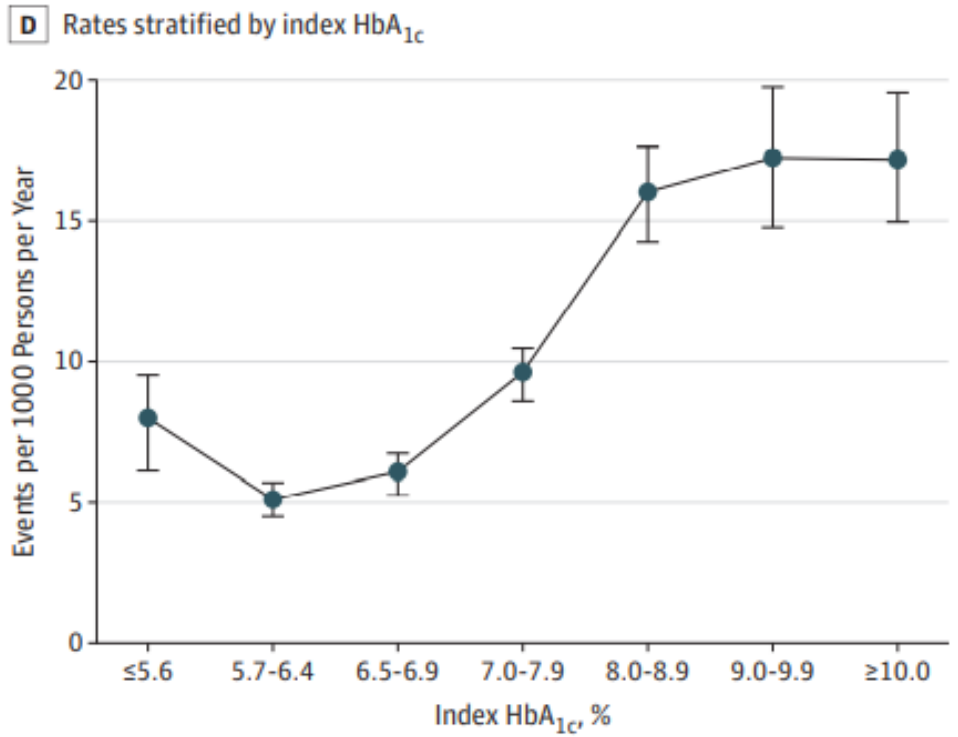
Figure 1. Crude Rates of Hypoglycemia-Related Emergency Department Visits and Hospitalizations



JAMA Network Open. 2020;3(1):e1919099

Hypoglycemia Rates: ED and Hospitalizations



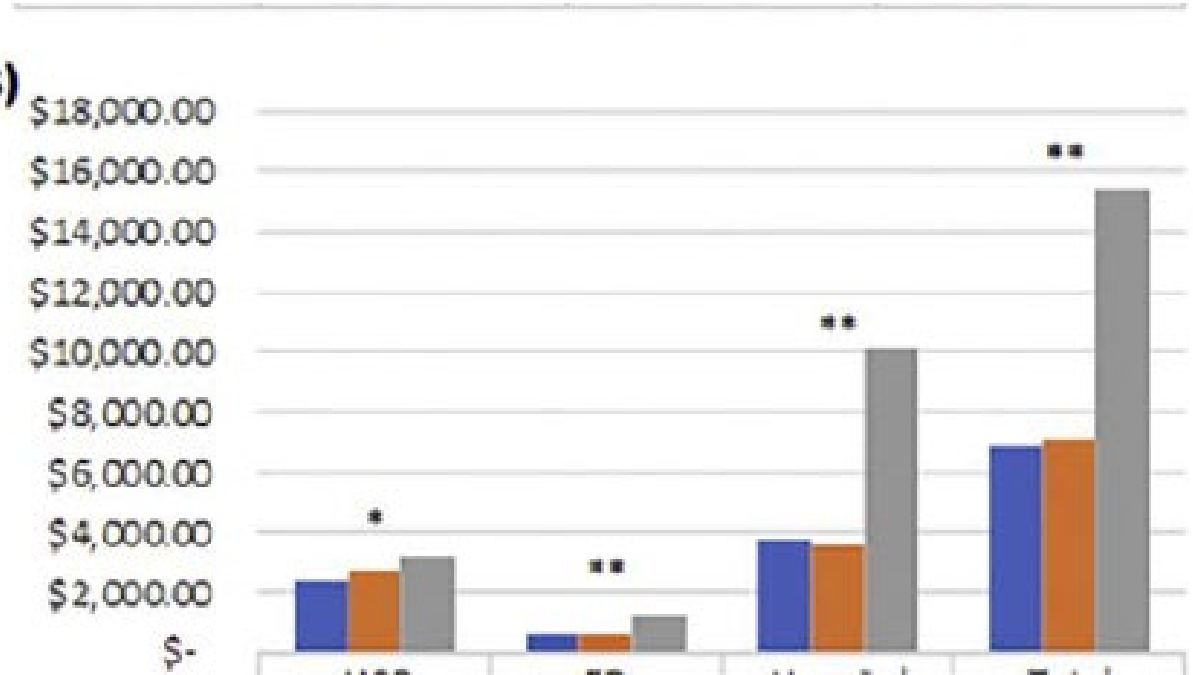


Having type 1 diabetes resulted in a 34% increased risk in hypoglycemia-related ED visits or hospitalizations

JAMA Network Open. 2020;3(1):e1919099

Annual Cost of Healthcare Resource Use from Hypoglycemia

(B)



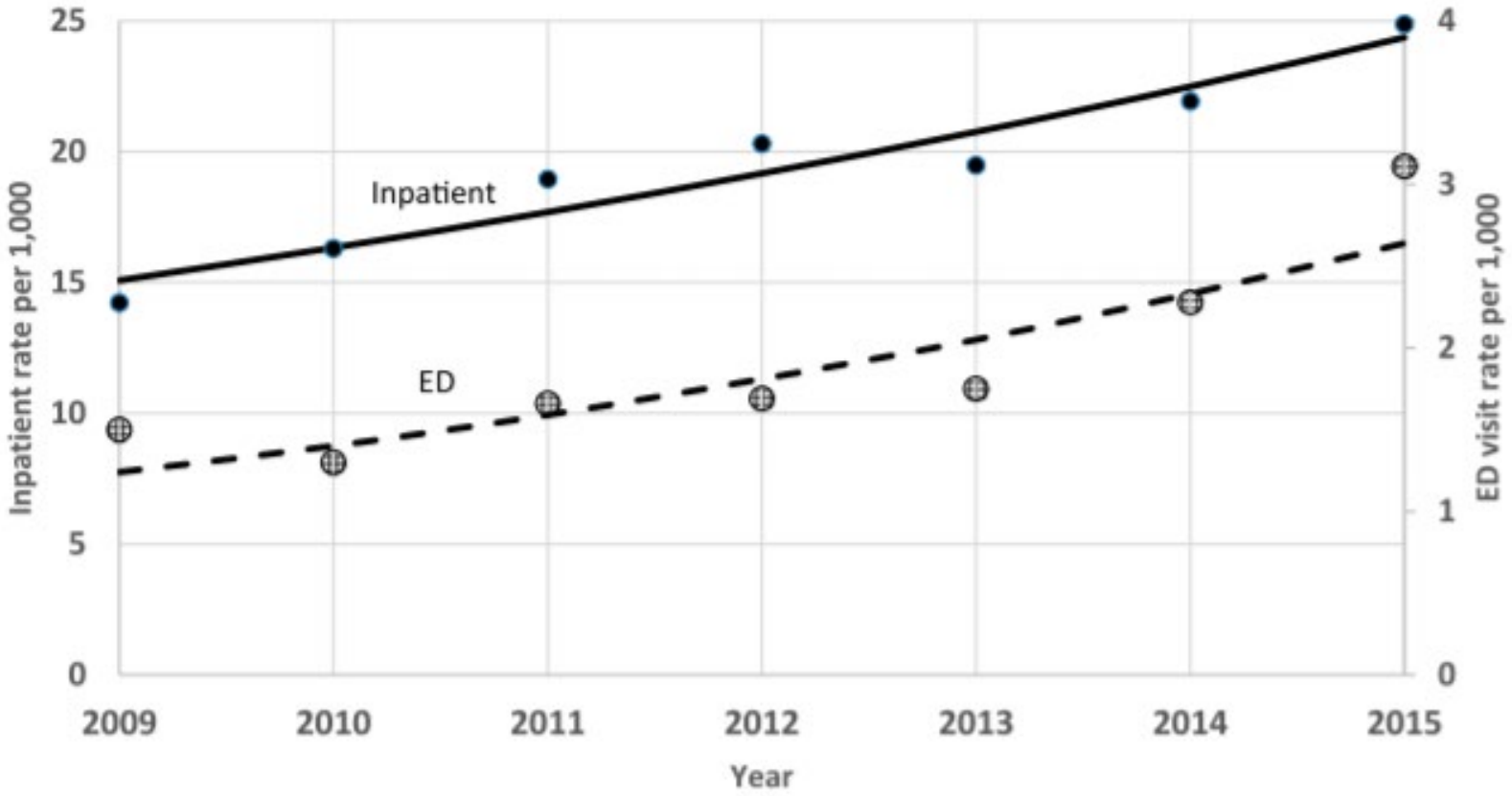
	HCP	ED	Hospital	Total
No hypo	$2,396.80	$577.00	$3,772.80	$6,908.30
Non-severe	$2,768.00	$601.80	$3,576.30	$7,131.80
Severe	$3,217.50	$1,265.20	$10,169.90	$15,410.40

2013 Dollars

What about DKA and hyperglycemia emergencies?

J Diab Complications 2018;32:451-457

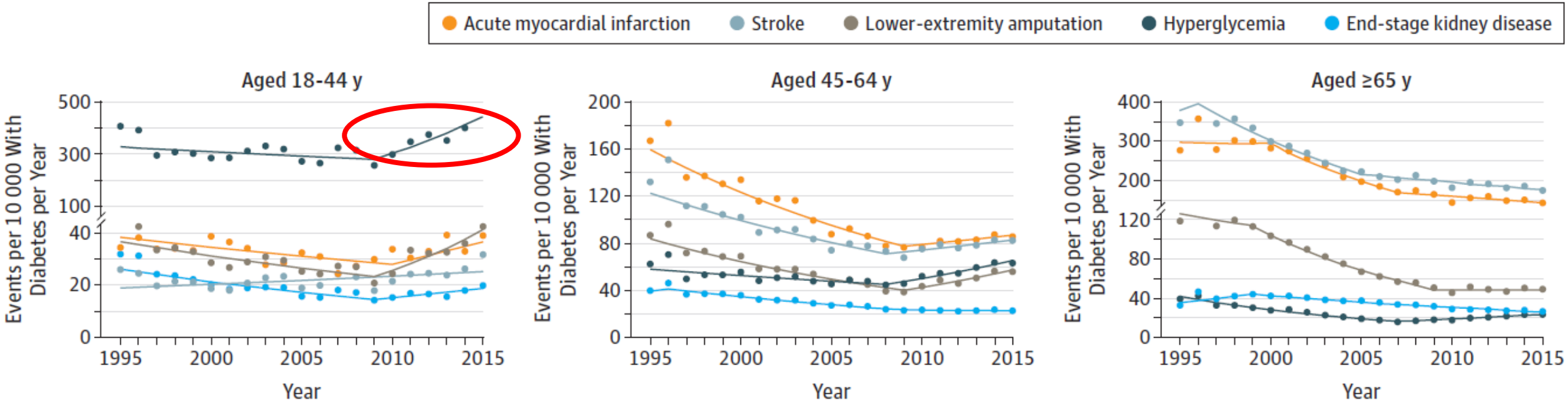
US DKA Rates, 2009-2015



Diabetes Care 2020;43:1057–1064

Hospitalization in US Population by Age Group

Figure. Incidence of Hospitalization for Major Diabetes-Related Complications Among the US Population With Diagnosed Diabetes by Age Group



Overall, between 2009 and 2015, hyperglycemic crisis increased by 81%

JAMA 2019;321:1867-1867

LOS Went Down While Cost Rose*

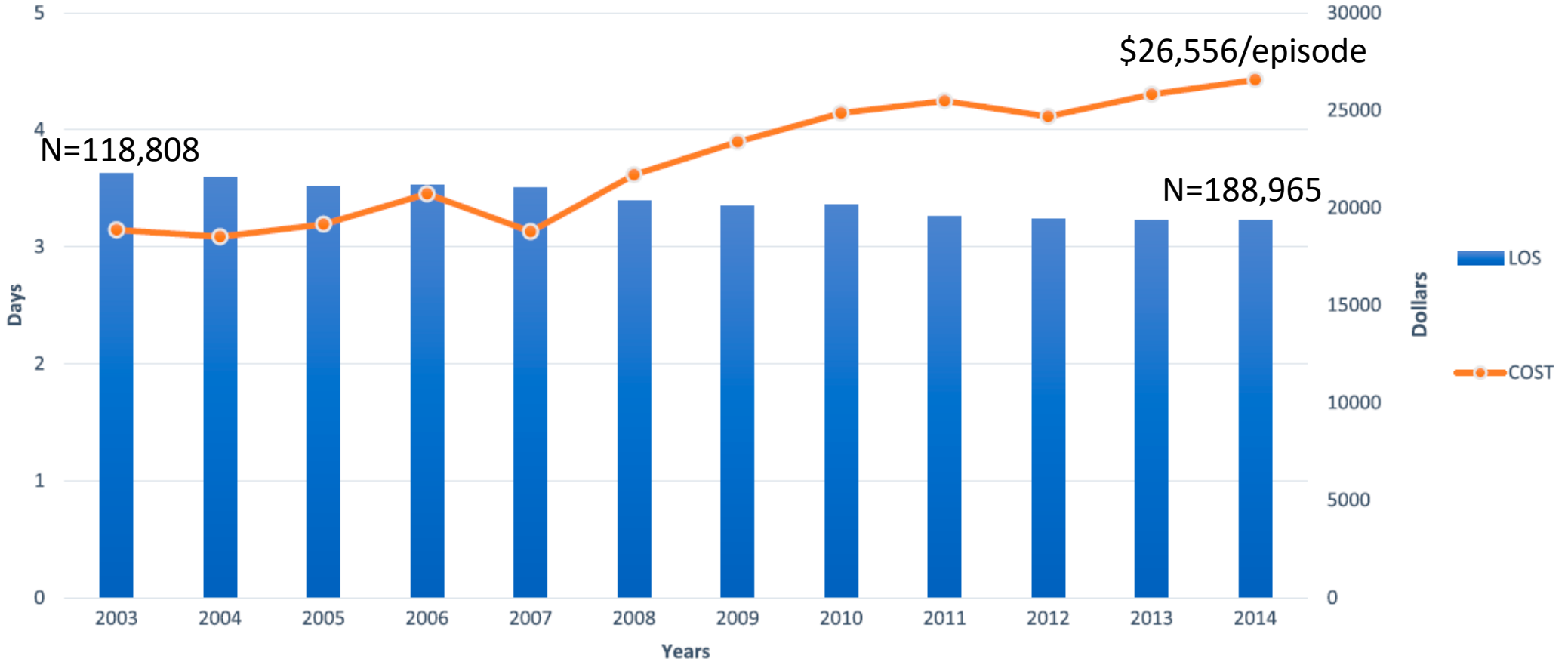


Figure 2—Length of stay (LOS) and mean cost of each hospitalization for patients with DKA.

Diabetes Care 2018;41:1631-1638

*adjusted for inflation

Let's Do The Math (Can Only Convert to 2020)

2014: 188,965 admission X $26,556/admission = $5.02 billion US

2020: calculated using Tom's Medical Inflation Calculator (https://www.halfhill.com/inflation_js.html)

$5.98 billion

The number of cases of DKA in the US cost well in excess of $6 billion in 2020 (due to increased DKA)

DKA is Expensive! Can CGM Reduce the Cost?

Change in DKA with Freestyle Libre in the UK

- N = 2438 with T1D from 30 hospitals in the UK
- Mean age 34 years, 54% female, diabetes duration 14 years, BMI 24 kg/m^2
- Hospital admission for hyperglycemia/DKA reduced from 5% to 1% for 6 months (80% reduction)

Diabetes 2019 Jun; 68(Supplement 1): 299-OR

Another UK Analysis with Freestyle Libre

Different Population

- Prospective observational study of T1D: 900 with Freestyle Libre
- Age 45 years, diabetes duration ~20 years
- DKA reduced from 10 to 2 episodes in the 6 months following initiation of Freestyle Libre (80% reduction)

Diabetologia. 2019 Aug;62(8):1349-1356

Two Studies With the Same Result

What If We Reduced the DKA Costs in the US by 80%?

$5.98 billion x 0.20 = $1.20 billion cost with a *savings of $4.78 billion*

Similar Reductions in Acute Diabetes Complications in France: RWE

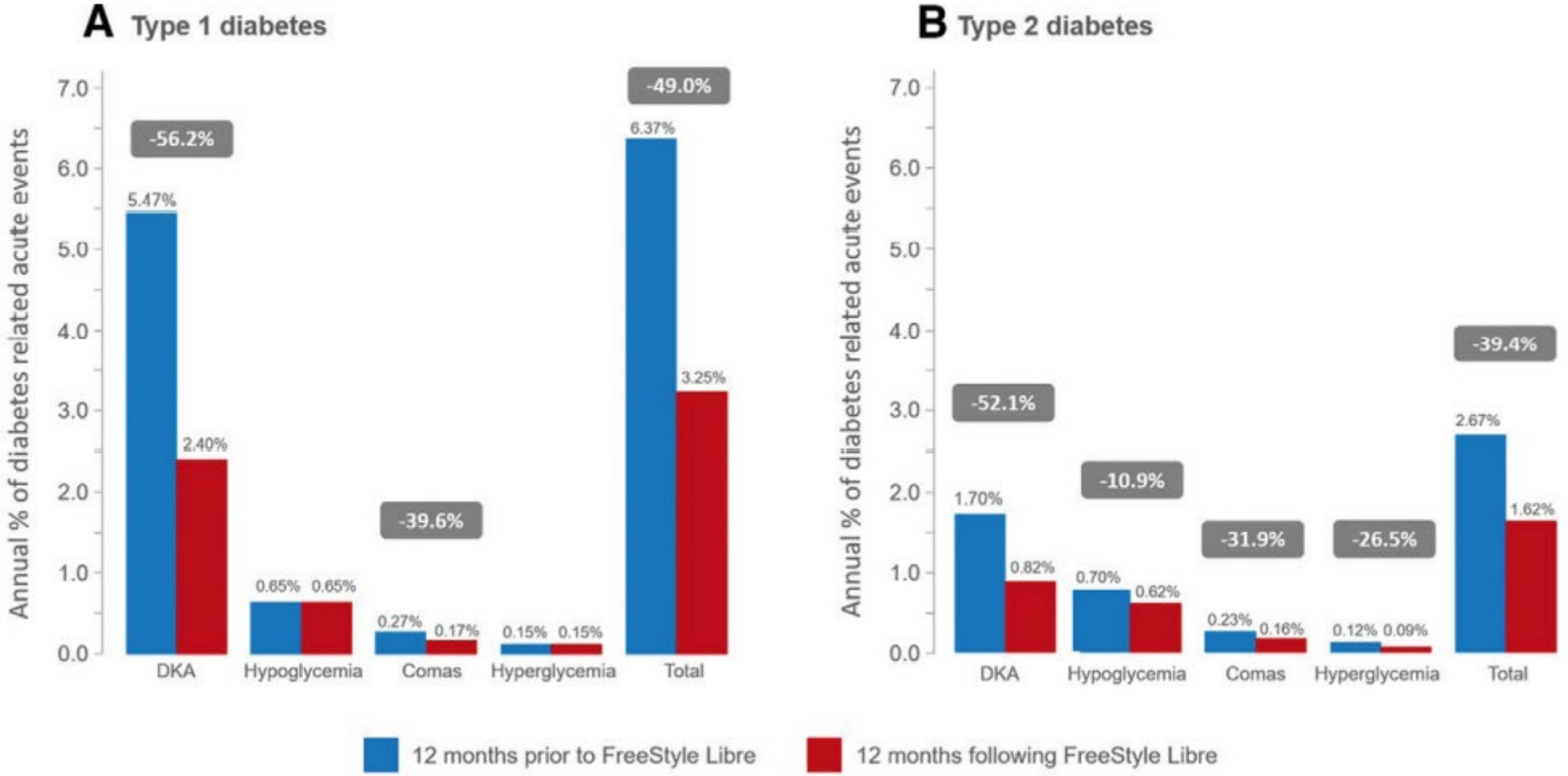
Important Drop Rate of Acute Diabetes Complications in People With Type 1 or Type 2 Diabetes After Initiation of Flash Glucose Monitoring in France: The RELIEF Study

Ronan Roussel,[1,2,3] Jean-Pierre Riveline,[2,3,4] Eric Vicaut,[5] Gérard de Pouvourville,[6] Bruno Detournay,[7] Corinne Emery,[7] Fleur Levrat-Guillen,[8] and Bruno Guerci[9]

Diabetes Care 2021;44:1–9 | https://doi.org/10.2337/dc20-1690

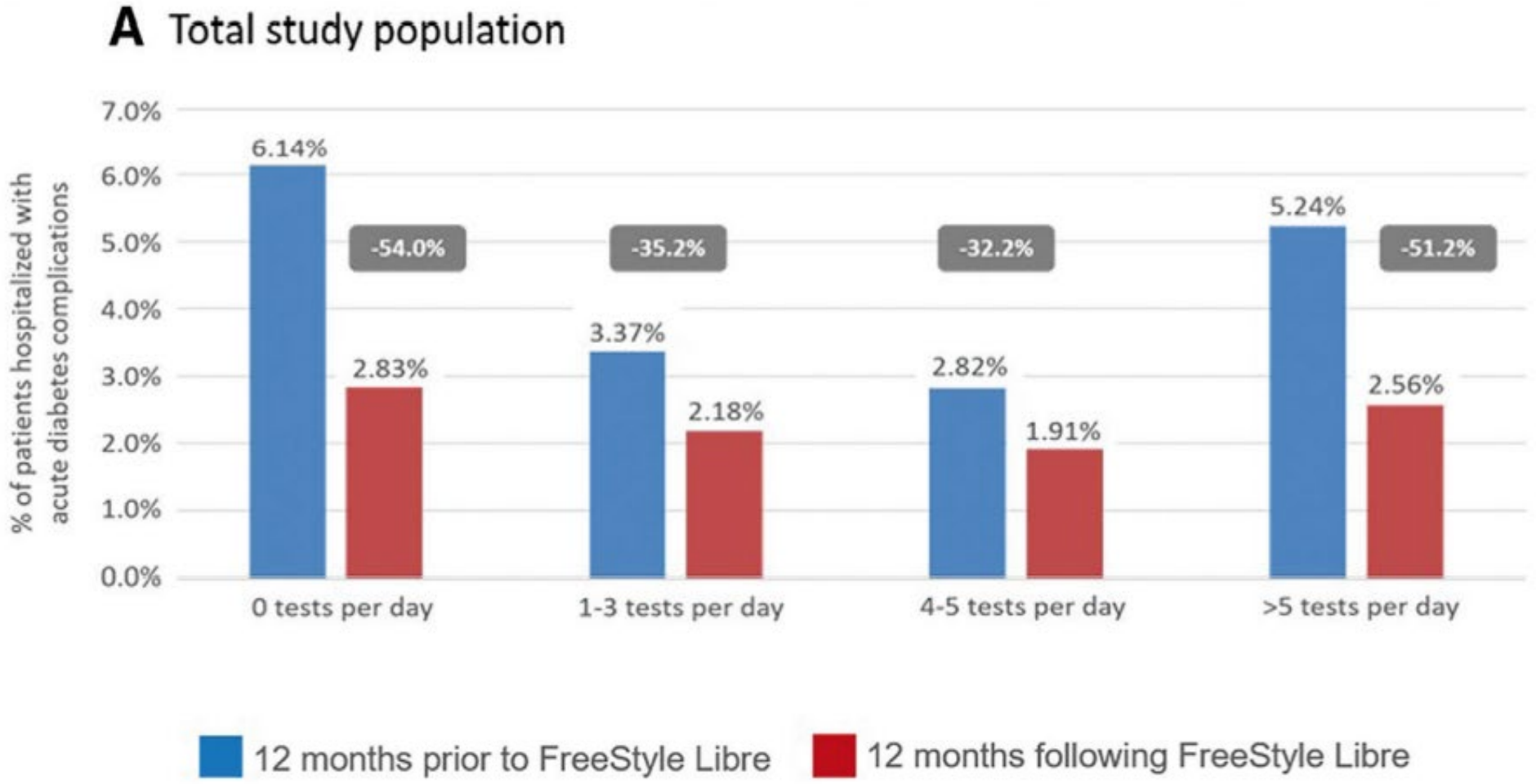
N=74,011 with T1D or T2D initiating Freestyle Libre in French national claims database

Reduction in Acute Glycemic Emergencies 12 Months After Starting Freestyle Libre



Diabetes Care 2021;44:1-9

Reduction in Hospitalizations 12 Months After Starting Freestyle Libre



Diabetes Care 2021;44:1-9

Translating to US DKA Cost: ~54% Reduction

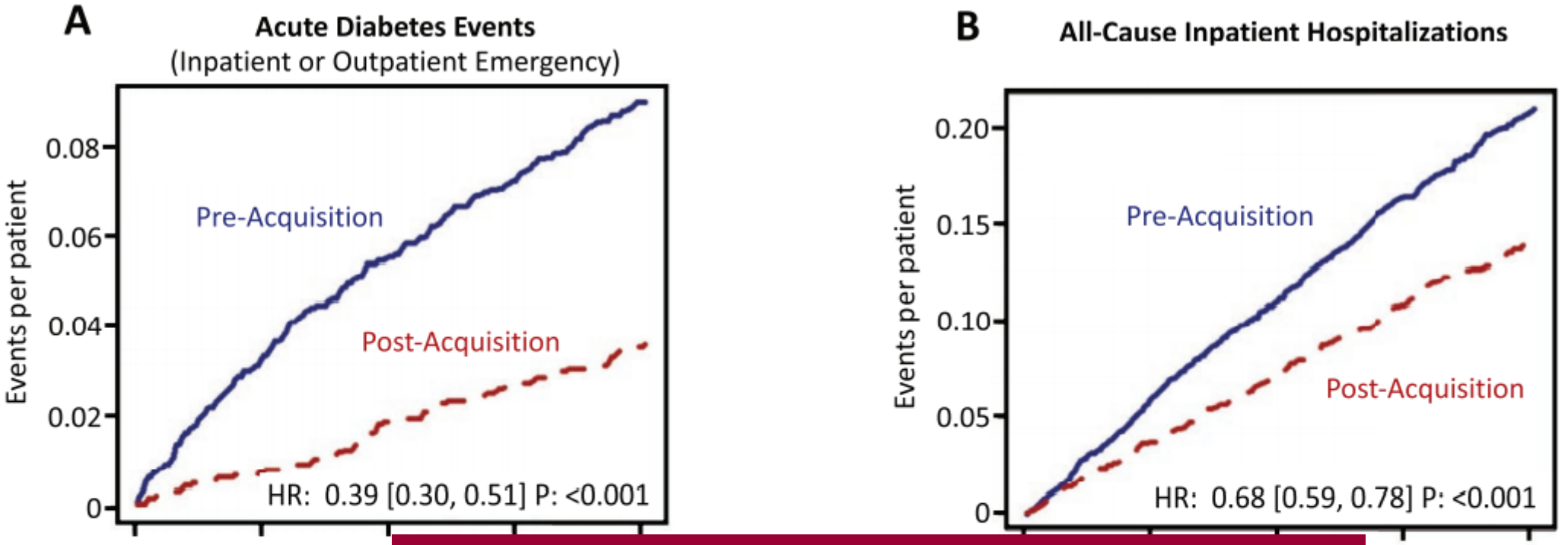
$5.98 billion x 0.46 = $2.75 billion cost with a *savings of $3.23 billion*

More Data: Can CGM Improve Outcomes and Cost? RWE in US

- **Acute Diabetes Events**—combination of inpatient and emergency outpatient events, including
  - Hyperglycemia, Hypoglycemia, Ketoacidosis, Hypoglycemic coma, Hyperosmolarity
- **Secondary: All-cause inpatient hospitalization**
- N = 2463 with *type 2 diabetes* receiving multiple daily injections **before and 6 months after starting Freestyle Libre**
- Age = 54.2 ± 9.6 years

Journal of the Endocrine Society, 2021, Vol. 5, No. 4, 1–9

Results: Reduction in Acute Diabetes Events and Hospitalizations



Days from index						
Pre	0	-45	-9		-135	-180
Post	0	45	9		135	180
Patients at risk						
Pre	2,463	2,463	2,4		2,463	2,463
Post	2,463	2,421	2,3		2,276	2,186

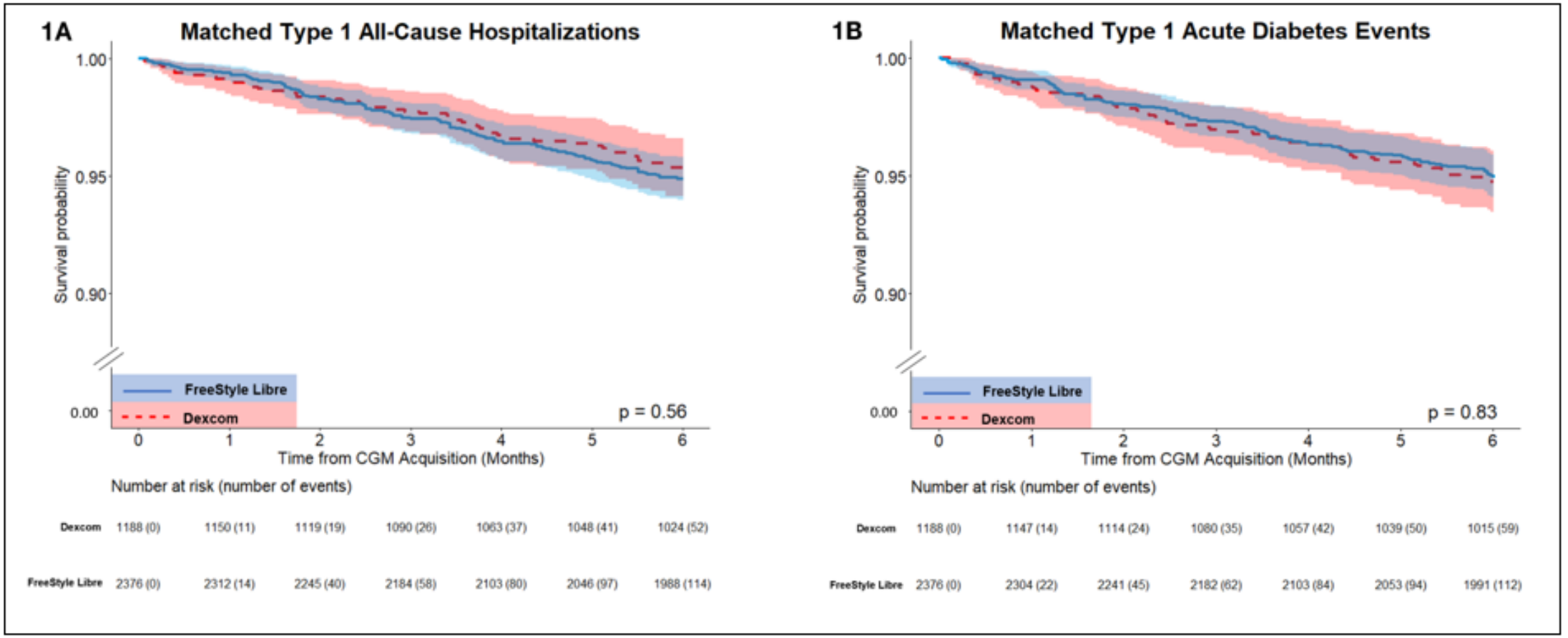
"These findings provide support for the use of CGM in type 2 diabetes patients treated with short- or rapid-acting insulin therapy to improve clinical outcomes and potentially reduce costs"

Journal of the Endocrine Socie

More RWE: Two Types of CGM

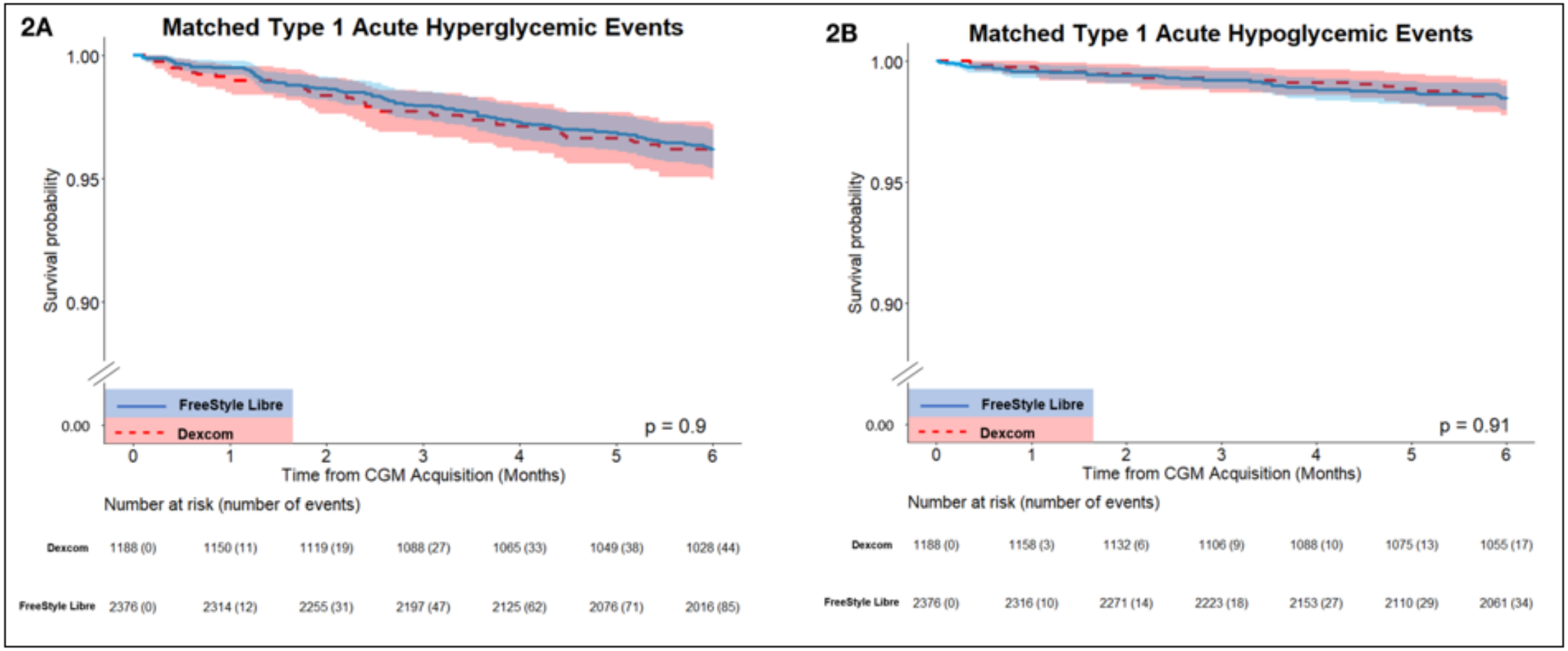
- IBM® MarketScan® Research Databases
- Reviewing Dexcom (DEX) and Freestyle Libre (FSL)
- N = 3,564 T1D (DEX, n=1,188; FSL, n= 2,376) and 3,930 T2D (DEX, n=655; FSL, n=3,275 all using multiple injections) adults
- For both T1D and T2D, FSL and DEX users were propensity score matched on demographics, provider visits, comorbidities, insulin pump use, and baseline events

Results: Reduction in All-Cause Hospitalizations and Acute Diabetes Events in T1D



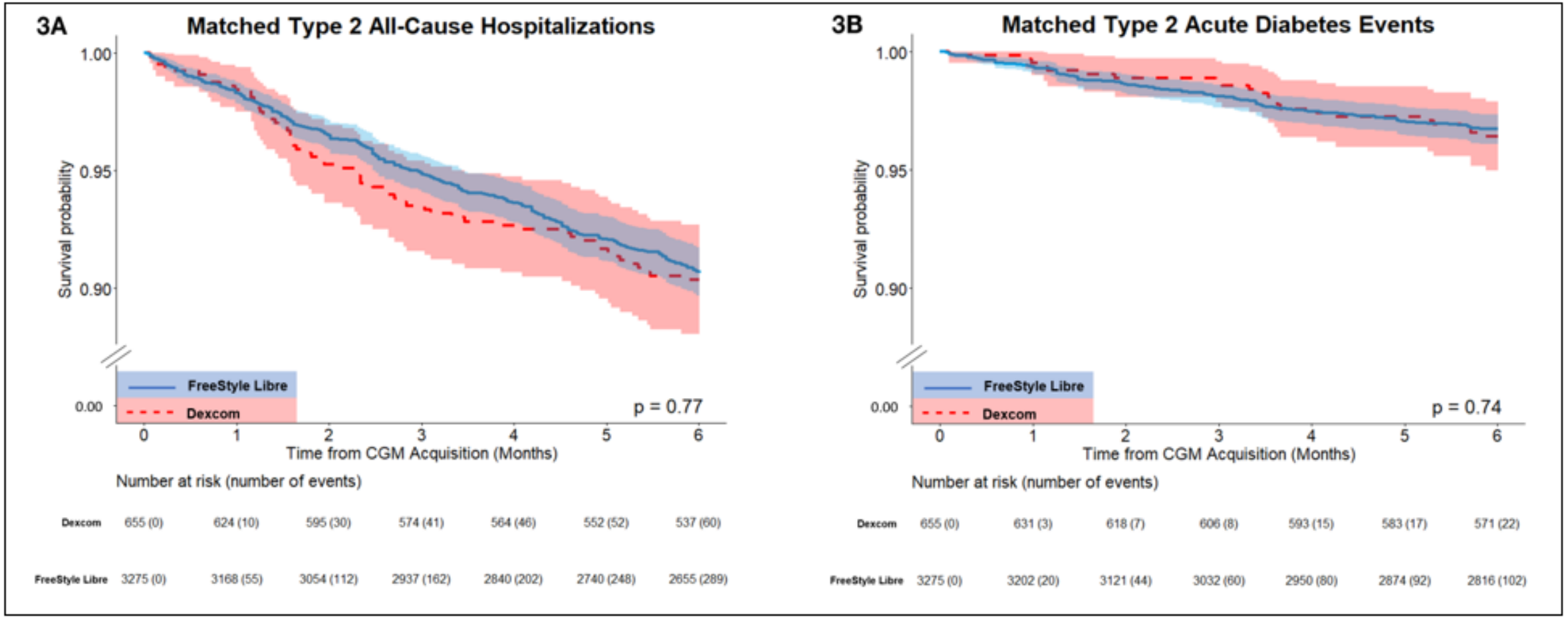
ADA 2021 LB-6636

Results: Reduction in Acute Diabetes Events in T1D



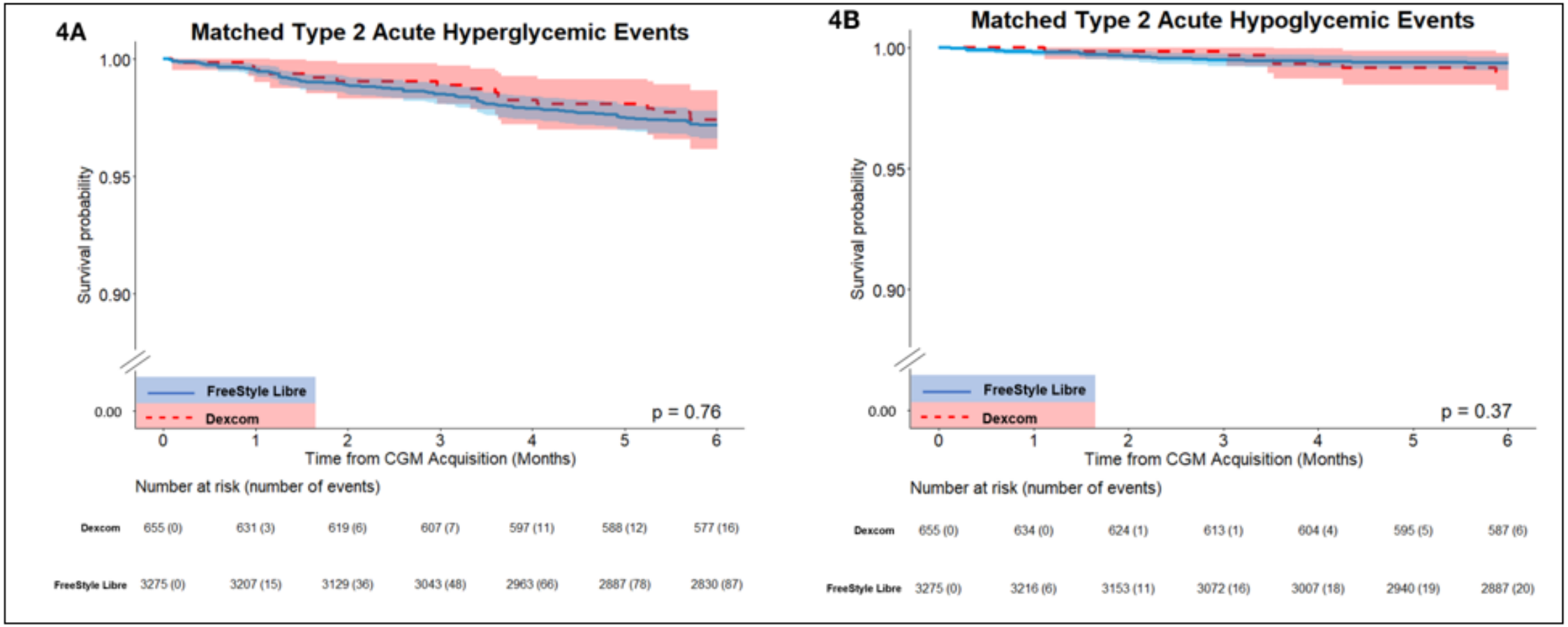
ADA 2021 LB-6636

Results: Reduction in All-Cause Hospitalizations and Acute Diabetes Events in T2D



ADA 2021 LB-6636

Results: Reduction in Acute Diabetes Events in T2D



ADA 2021 LB-6636

RWE Conclusion

Patients with either type 1 or type 2 diabetes experienced similar reductions of acute diabetes events and all-cause hospitalizations when using either brand of CGM

Last Point: Penetration of CGM Will Only Increase

Easier for both patient and provider

Conclusions

- Acute diabetes emergencies are increasing in the US
- Data continues to accumulate from around the world that CGM reduces the incidence of these life-threatening events
- More formal cost-effectiveness studies assessing the impact of this technology in different countries are now needed

Thank You

A Practical Roadmap for Guiding and Incorporating Sensor-Based Glucose Monitoring into Health Plans

CGM As a Foundational Element of Diabetes Care in **Managed Health Systems**

Vivian Fonseca, MD

Professor of Medicine and Pharmacology | Assistant Dean for Clinical Research

Tullis Tulane Alumni Chair in Diabetes | Chief, Section of Endocrinology

Tulane University Health Sciences Center | New Orleans, Louisiana

Type 2 Diabetes in the US Managed Care Setting: The Burden of Disease

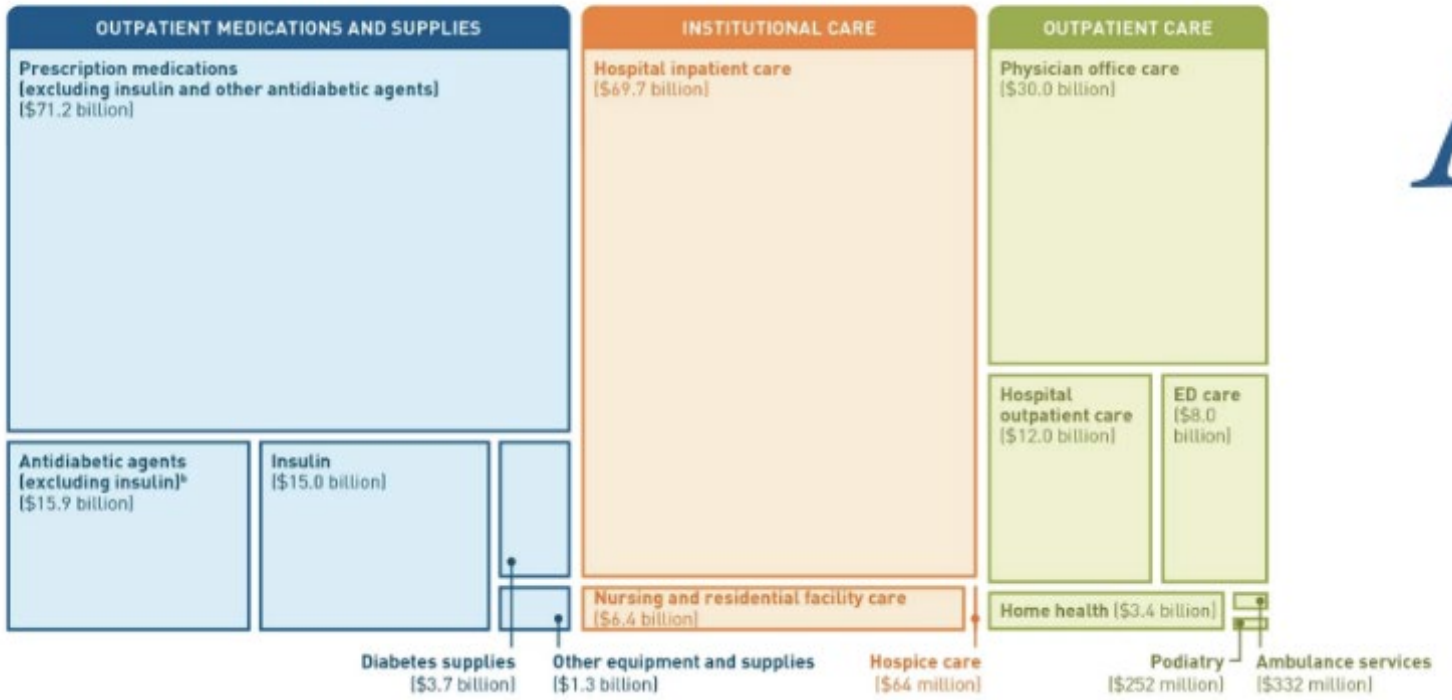
December 14, 2020

Tanya Dougherty, PharmD, BCPS, Michael Heile, MD, FAAFP

The American Journal of Managed Care

AJMC®

FIGURE 2. Estimated Direct Health Care Expenditure Attributed to Diabetes in the United States in 2017[5,a]



ED, emergency department.

[a]Each rectangle within the figure represents a discrete cost, and the amount of expenditure is reflected by the area of the rectangle. Total direct health care expenditure attributed to diabetes was $237 billion.

[b]Includes oral medications and injectable agents, excluding insulin.

The Cost of Diabetes

The Managed Care Environment

- A retrospective analysis in a large MCO found that total diabetes-related costs for patients whose A1c exceeded the target level of 7% was $1,540 per patient during the 1-year follow-up period, **32% higher than the total diabetes-related costs ($1,171) for patients at or below the 7% level.**
- Similarly, a longitudinal analysis using managed care claims data found direct medical costs attributable to T2DM were **16% lower ($1,505 vs. $1,801)** for patients with good glycemic control (A1c ≤ 7%) compared with those with fair control (A1c > 7% and ≤ 9%), and **20% lower ($1,505 vs. $1,871)** for those with good glycemic control compared with those with poor control (A1c > 9%).

Shetty S, Secnik K, Oglesby AK. Relationship of glycemic control to total diabetes-related costs for managed care health plan members with type 2 diabetes. *J Manag Care Pharm.* 2005;11(7):559-64.
Oglesby AK, Secnik K, Barron J, Al-Zakwani I, Lage MJ. The association between diabetes related medical costs and glycemic control: a retrospective analysis. *Cost Eff Resour Alloc.* 2006;4:1

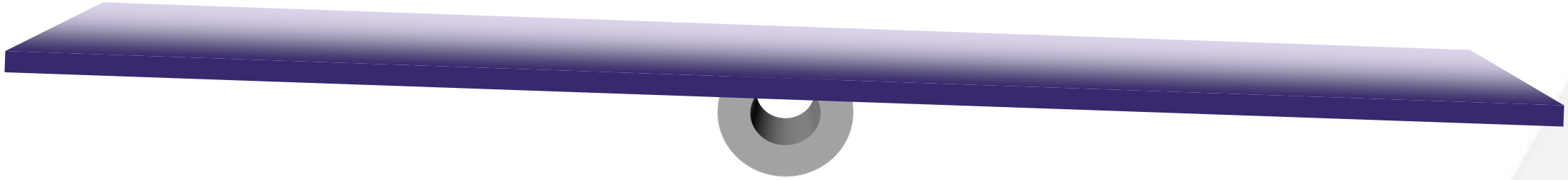
Effective T2DM Therapy Requires Balance Across Multiple Risk Factors but Glucose is the Benchmark for Overall Control and Level of Residual Risk

Timely, effective and stable glycemic control

- Improved achievement of HbA1c targets
- Prevention of complications and lower healthcare utilization
- Less restrictive regimens may improve adherence

Low risk of hypoglycemia

- Reduced fear of hypoglycemia
- May allow for optimal dose titration and improved glycemic control
- May improve adherence
- Reduced morbidity and healthcare utilization



Pogach L & Aron D. JAMA 2010;303:2076–7; Khunti K, et al. Diabetes Obes Metab 2016;18:907–15; Riddle M, et al. Diabetes Technol Ther 2016;18:252–7; Peyrot M, et al. Diabet Med 2012;29:682–9; Russell-Jones D, et al. Diabetes Obes Metab 2018;20:488–96; Davies MJ, et al. Diabet Med 2013;30:512–24; Willis WD, et al. Expert Rev Pharmacoecon Outcomes Res 2013;13:123–30; Ahrén B. Vasc Health Risk Manag 2013;9:155–63

Assessment of Glycemic Control

- Older techniques available for health providers and patients to assess effectiveness of management plan on glycemic control
  1) Patient self-monitoring of blood glucose (SMBG) – never proven to improve control or complications – yet using insulin without it is like driving blinded
  2) A1C – good marker but cannot be used to adjust diet and medications short term

- CGM or interstitial glucose real time. Can be used to change treatment and doses.

American Diabetes Association Standards of Medical Care in Diabetes. Glycemic targets. Diabetes Care 2017; 40 (Suppl. 1): S48-S56

Information from Current Glucose Monitoring Methods: Why Do We Need More and What Kind?

HbA1c

- Is considered to be the Standard of Care across clinical disciplines
- Provides a single laboratory value that represents a 90-day average
- Does not detect daily high or low blood glucose levels
- Glucose fluctuations throughout the day and night are unknown

SMBG

- Provides glucose information for only points in time when tested
- Even frequent testing can often miss hypoglycemia and hyperglycemia
- Overnight data is impractical
- Identifying glucose patterns from patient logbooks is time consuming and difficult

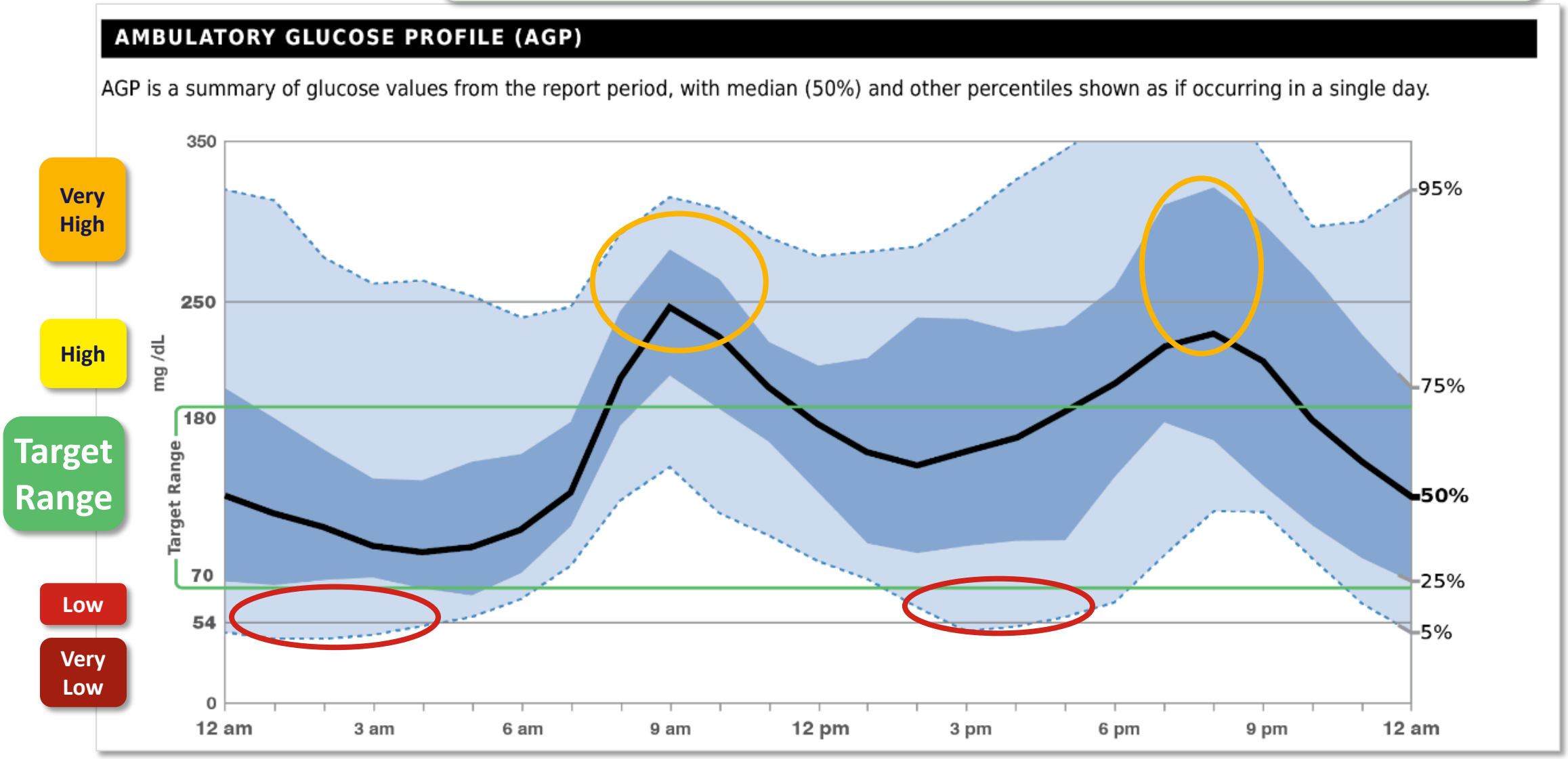
CGM

- Facilitates digital connectivity and data transfer
- Provides a lot of glucose data, especially RWE through EHR and large databases; however, reports can be difficult to interpret and gain insight
- Too much information that can be time-consuming to assess
- Low penetration due to lack of reimbursement; start up costs can be high for certain devices

*Benhamou P-Y, Catargi B, Delenne B, et al. *Diabetes Metab.* 2012;38(suppl 4):S67-S83.
**Bergenstal et al, J Diabetes Sci Technol Vol 7, Issue 2, March 2013

AGP Report

Tools to detect where is the problem?



http://www.agpreport.org/agp/agpreports

TIR Targets

GLUCOSE STATISTICS AND TARGETS

1 **26 Feb 2019–10 Mar 2019** **13 days**

2 **% Time CGM is Active** **99.9%**

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

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

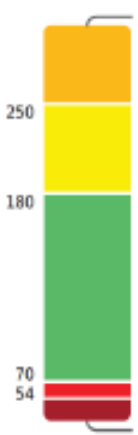
3 **Average Glucose** **173 mg/dL**

4 **Glucose Management Indicator (GMI)** **7.6%**

5 **Glucose Variability** **49.5%**

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

TIME IN RANGES



6 **Very High** (>250 mg/dL) **20%** (4h 48m)

High (181–250 mg/dL) **23%** (5h 31m) 7

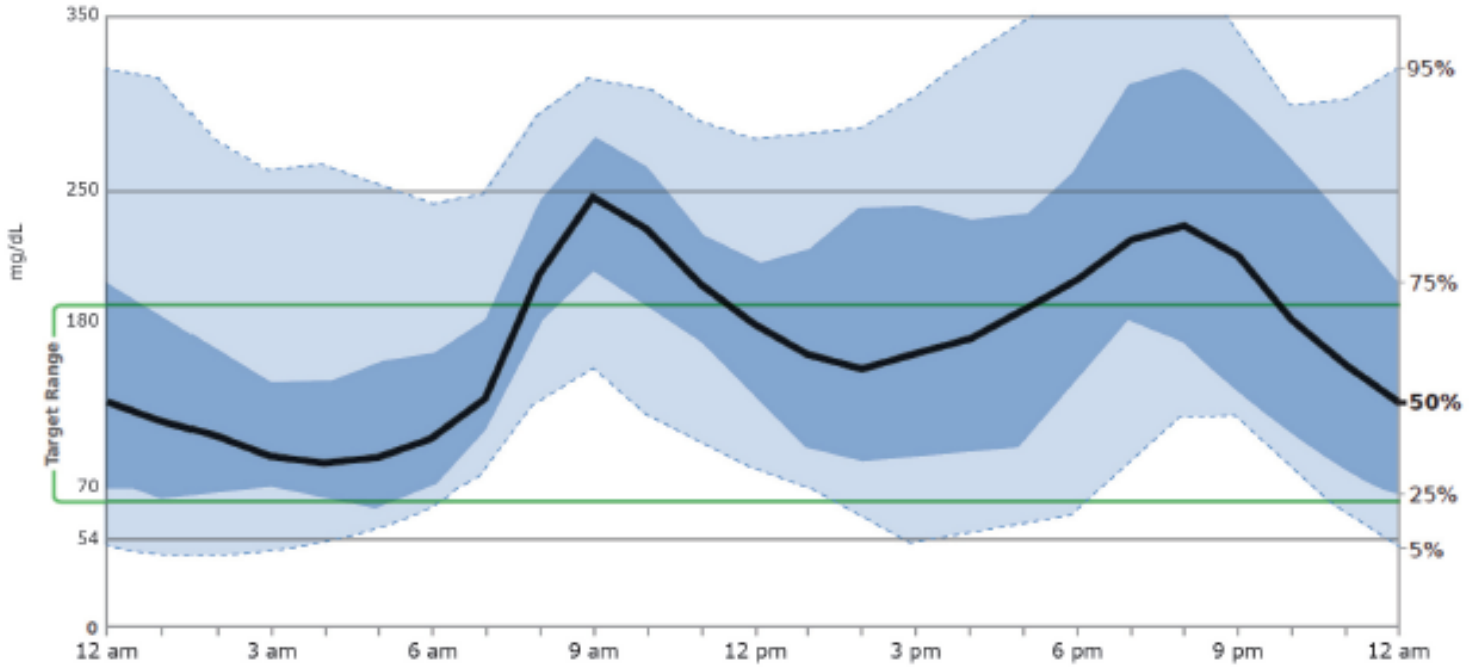
Target Range (70–180 mg/dL) **47%** (11h 17m) 8

Low (54–69 mg/dL) **4%** (58m) 9

Very Low (<54 mg/dL) **6%** (1h 26m) 10

AMBULATORY GLUCOSE PROFILE (AGP)

AGP is a summary of glucose values from the report period, with median (50%) and other percentiles shown as if occurring in a single day.



Hypoglycemia is Associated with Increased Risk of Mortality in Patients with Diabetes

In clinical trials

History of severe hypoglycemia nearly doubled the risk of mortality in both ACCORD and ADVANCE[1,2]

In observational studies

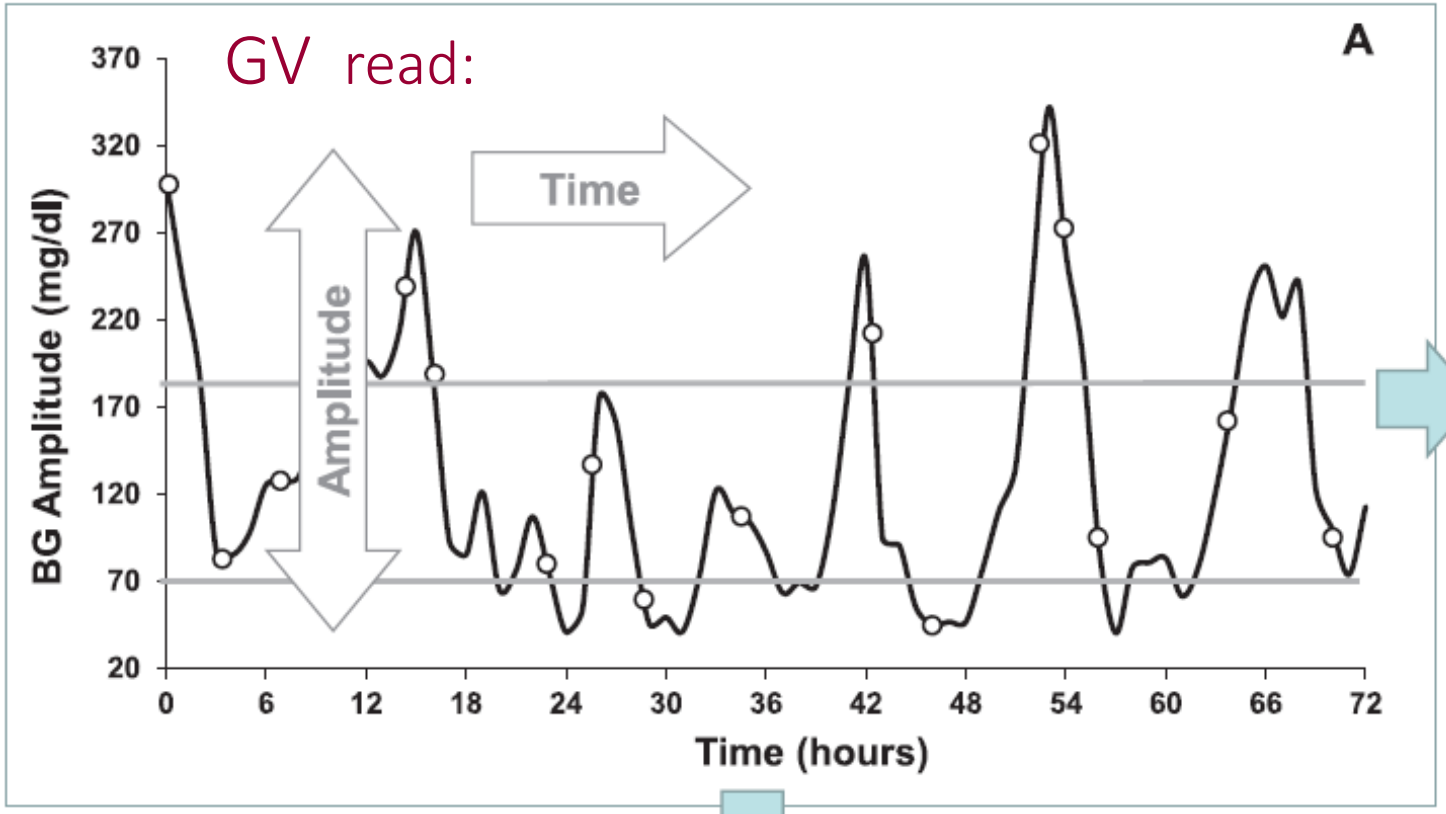
Retrospective clinical-based study of 1000+ showed that those with a history of severe hypoglycemia at baseline had OR for mortality of 3.4 at 5 years (95% CI: 1.5–7.4, p = 0.005)[3] . These patients are also most likely to reduce or D/C their medications

1. Bonds DE, et al. BMJ. 2010;340:b4909; 2. ZouNgas S, et al. N Engl J Med. 2010 Oct 7;363:1410–8;
3. McCoy RG, et al. Diabetes Care. 2012;35:1897–901.

The Essential Challenge to Glucose Control in DM is Glycemic Variability: Risk Factors, Assessment, and Control

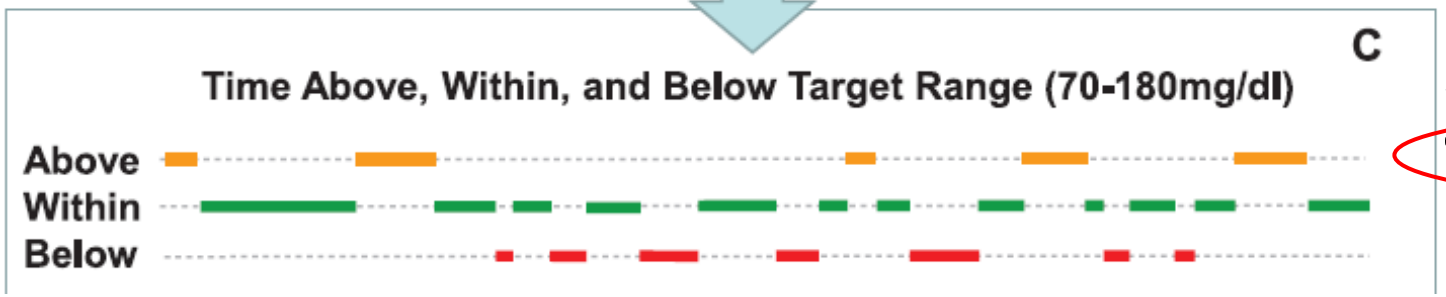
Boris Kovatchev, PhD – JDST 2019

GV read:



Y Axis related

- **CV**
- **SD**
- **MAGE**
- **MAG**
- **M Value**
- **Lability Index**
- **Others**



X Axis related – time component

$TIR^{70\text{-}180}$, $T^{<70}$, $T^{<54}$ $T^{>180}$ $T^{>250}$

MODD, CONGA

The Impact of New Technology and New Treatments in Diabetes is Fundamentally the Opportunity to Solve Persistent Problems!

- Glucose variability is one of the most persistent problems in DM, especially when contributing to **hypoglycemia, one of the key problems in DM!**
- In order for HCPs, whether PCPs or specialists, to know what the optimal treatment approach is for an individual, glucose information is required
- New technology, e.g., CGM can help meet these needs if properly used
- Usually, the guidance and insights regarding such tools derives from **RCTs** where the outcome information is generated under controlled conditions
- Thus, while avoidance of hypoglycemia is a key goal in glucose management, what is required to achieve this goal in the setting of RCTs may not adequately reflect what is necessary in the managed care environment

How CGM has Changed Management of Diabetes

DexCom G5

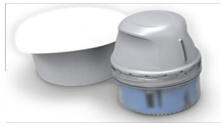
dexcom CONTINUOUS GLUCOSE MONITORING

+ verily

G6

April, 2018

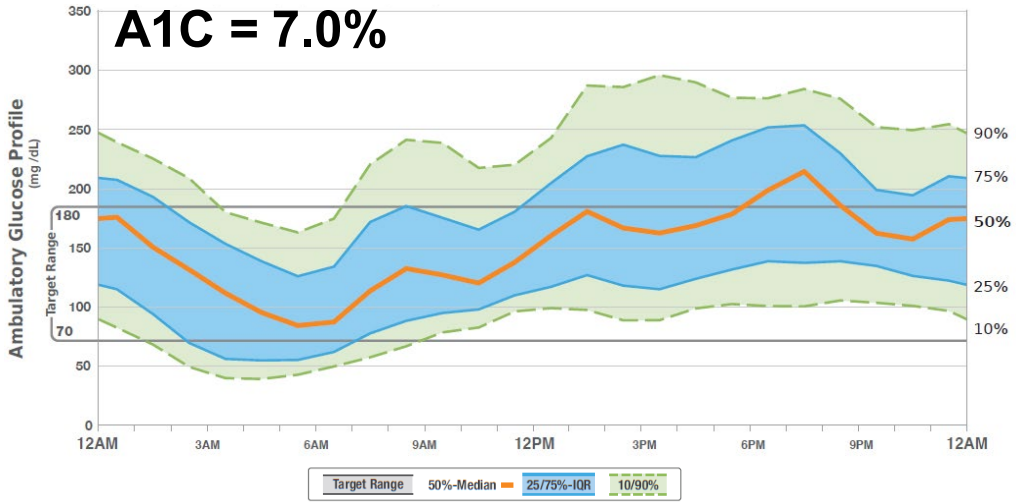
Abbott FreeStyle Libre



Eversense XL CGM Senseonics 2018

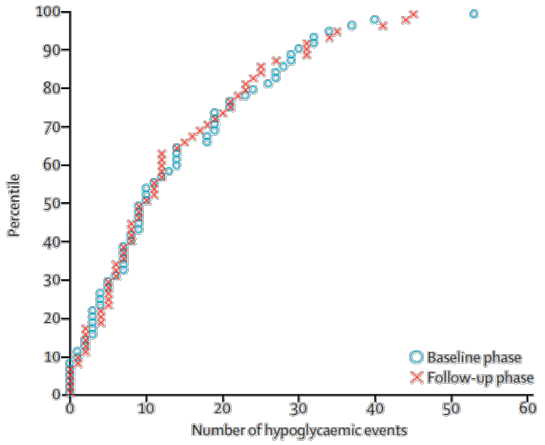
Medtronic Guardian Connect CGM (March, 2018)

Ambulatory glucose profile

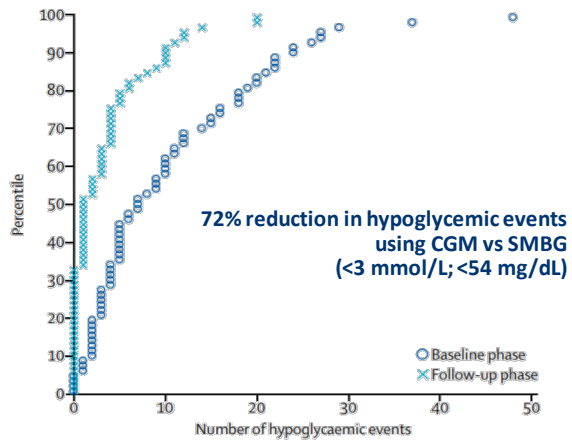


The HypoDE study (baseline vs intervention)

Control group



CGM group

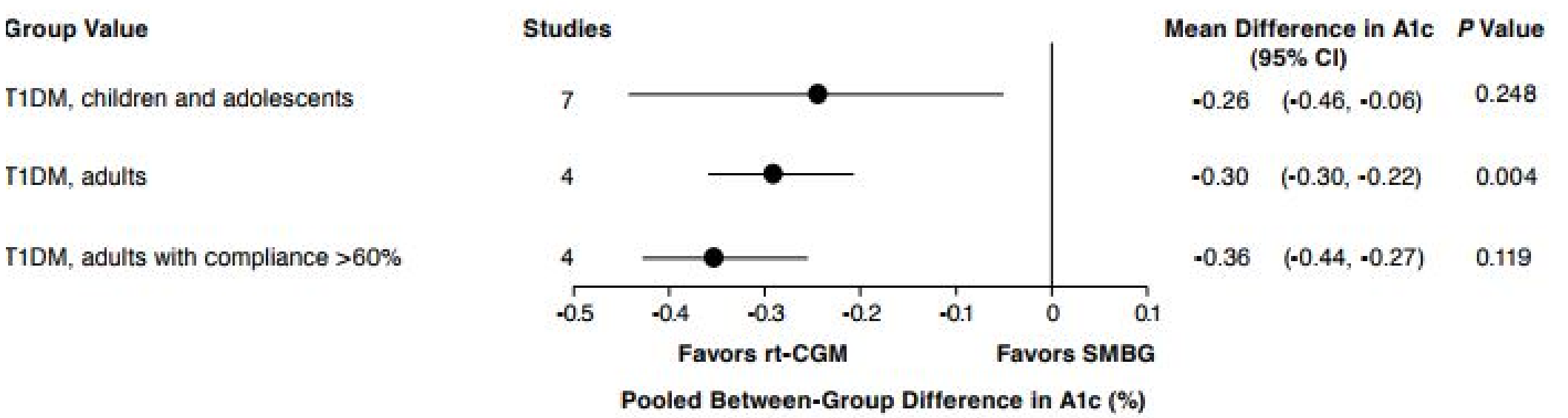


72% reduction in hypoglycemic events using CGM vs SMBG (<3 mmol/L; <54 mg/dL)

Heinemann L, et al. Lancet 2018;391:1367–77.

Meta-Analysis A1C Change

FIGURE 2 Pooled Between-Group Difference in A1c Change from Baseline (%) Comparing rt-CGM and SMBG Among Children, Adolescents, and Adults with T1DM



Adapted from: Golden SH, Brown T, Yeh H, et al. Methods for insulin delivery and glucose monitoring: comparative effectiveness. Comparative effectiveness review no. 57. July 2012.[24]

A1c = hemoglobin A1c; CI = confidence interval; rt-CGM = real-time continuous glucose monitoring; SMBG = self-monitoring of blood glucose; T1DM = type 1 diabetes mellitus.

J Manag Care Pharm. 2012;18(6):S3-S17

FreeStyle Libre in Prospective RCTs

(Insights into effects on Hypoglycemia Across the Diabetes Spectrum)

Type 1 Diabetes: IMPACT

THE LANCET

Novel glucose-sensing technology and hypoglycaemia in type 1 diabetes: a multicentre, non-masked, randomised controlled trial

Jan Bolinder, Ramiro Antuna, Petronella Geelhoed-Duijvestijn, Jens Kröger, Raimund Weitgasser

***Lancet* 2016; 388(10057):2254-2263**

Type 2 Diabetes: REPLACE

Diabetes Therapy

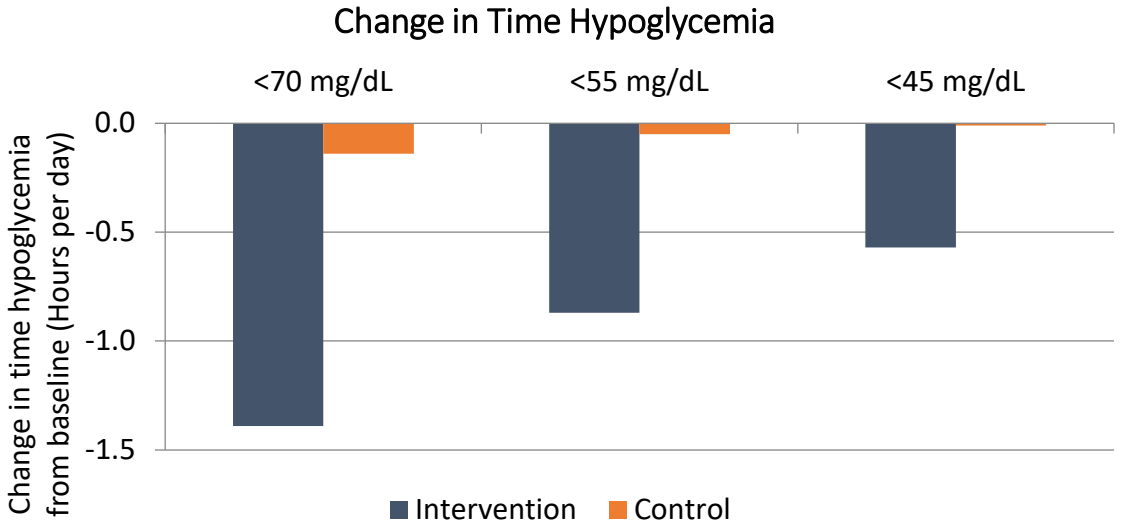
Flash Glucose-Sensing Technology as a Replacement for Blood Glucose Monitoring for the Management of Insulin-Treated Type 2 Diabetes: a Multicenter, Open-Label Randomized Controlled Trial

Thomas Haak · Hélène Hanaire · Ramzi Ajjan · Norbert Hermanns · Jean-Pierre Riveline · Gerry Rayman

***Diabetes Therapy* 2017; 8(1):55-73.**

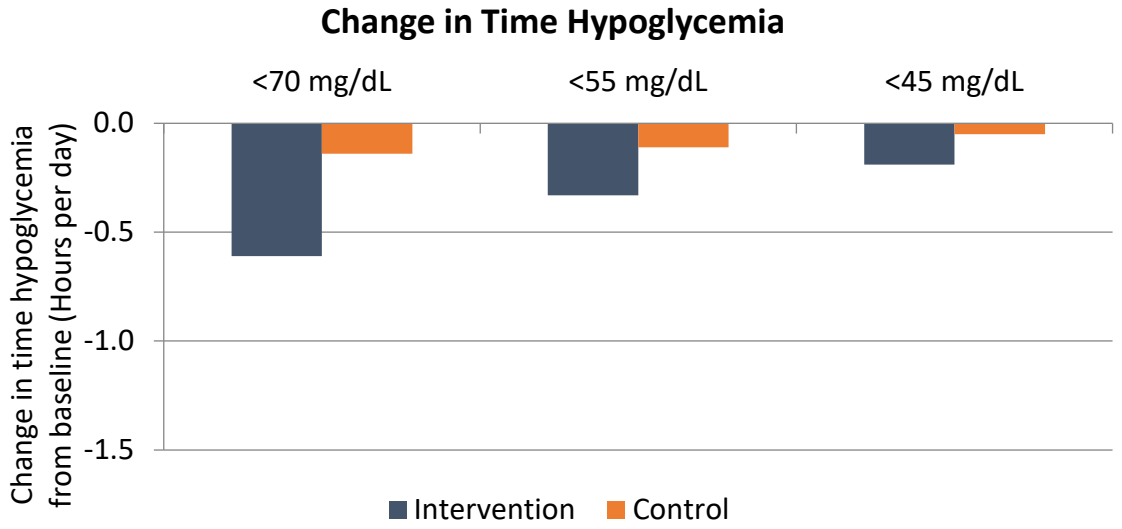
Time in Hypoglycemia

IMPACT



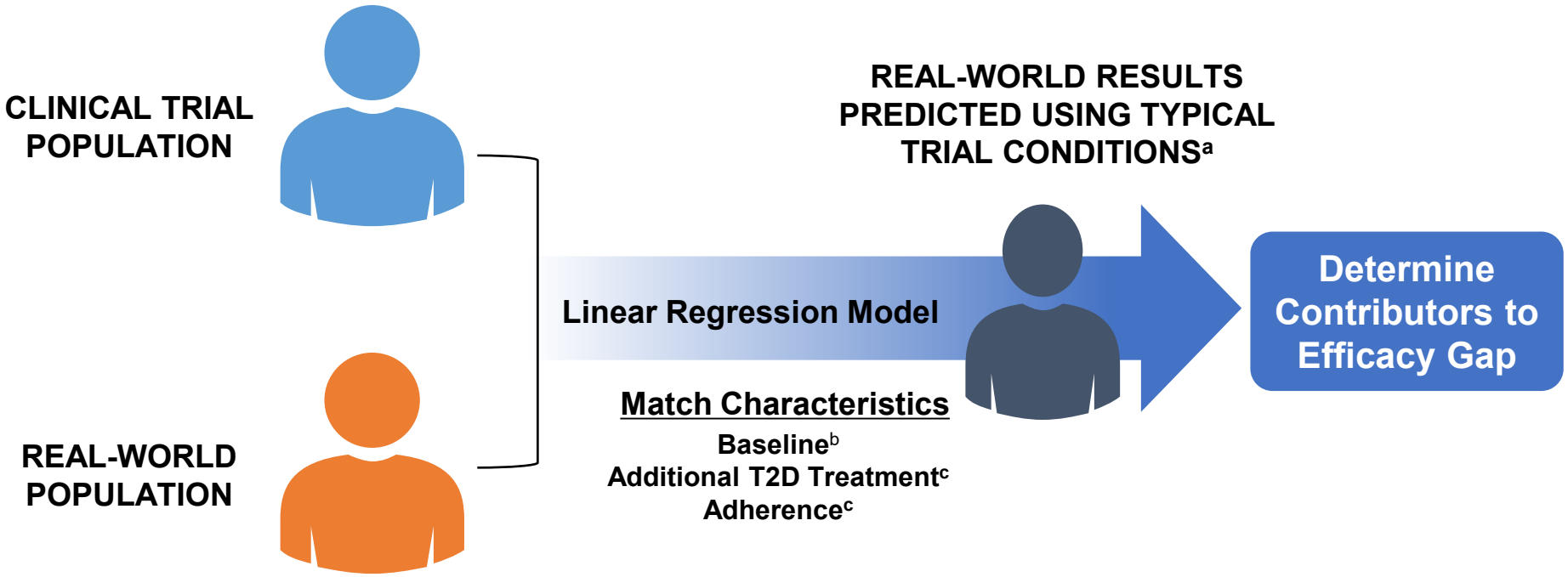
Glucose Level	Difference (vs control) in change from baseline per day	Significance (vs control)	Reduction vs control
<70 mg/dL	-1.24h (-74 min)	P<0.0001	38%
<55 mg/dL	-0.82h (-49 min)	P<0.0001	50%
<45 mg/dL	-0.55h (-33 min)	P<0.0001	60%

REPLACE



Glucose Level	Difference (vs control) in change from baseline per day	Significance (vs control)	Reduction vs control
<70 mg/dL	-0.47h (-28 min)	P<0.001	43%
<55 mg/dL	-0.22h (-13 min)	P=0.0014	53%
<45 mg/dL	-0.14h (-8 min)	P=0.0013	64%

Real-world Trial Design: Investigating The Efficacy Gap Between Clinical Trial and Real-World Results



RCTs are Often Helpful in Reflecting "What's Possible" Using New Tools/Technology but Not Always "What's Likely"

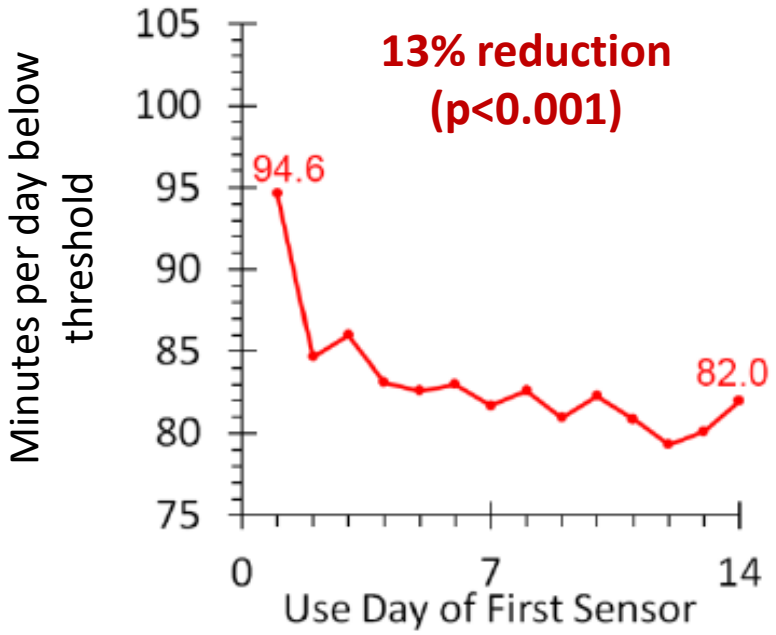
- Many factors differ in the way new tools/technology are used in RCTs versus how they are deployed in Real World Usage
- This includes differences in access, motivation, persistence, level of knowledge, quality of data capture, heterogeneity of populations
- HCPs may have expectations regarding outcomes shaped by RCTs
- Real World Experiences (RWE) may offer sharper refinement of goals
- RWE may provide important and otherwise unavailable data on the effectiveness of an intervention for individual patients, necessary capabilities for patients and the full spectrum of HCPs, especially those in a managed care setting who may need to advocate for CGM

Is there Compelling Evidence that the Tools of CGM Can Make a Difference? Changes in Hypoglycemia During First Sensor Use

Real-world: 1st sensor of 14,617 users

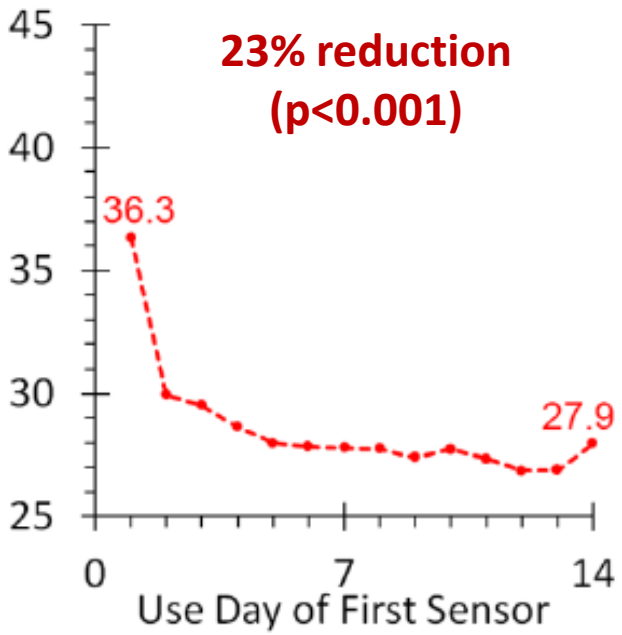
<70 mg/dL
<3.9 mmol/L

13% reduction
(p<0.001)



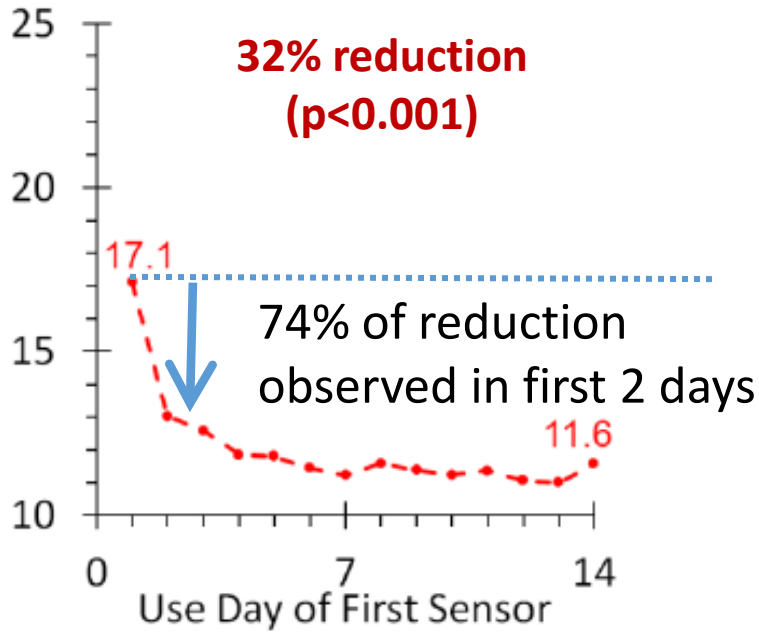
<55 mg/dL
<3.1 mmol/L

23% reduction
(p<0.001)



<45 mg/dL
<2.5 mmol/L

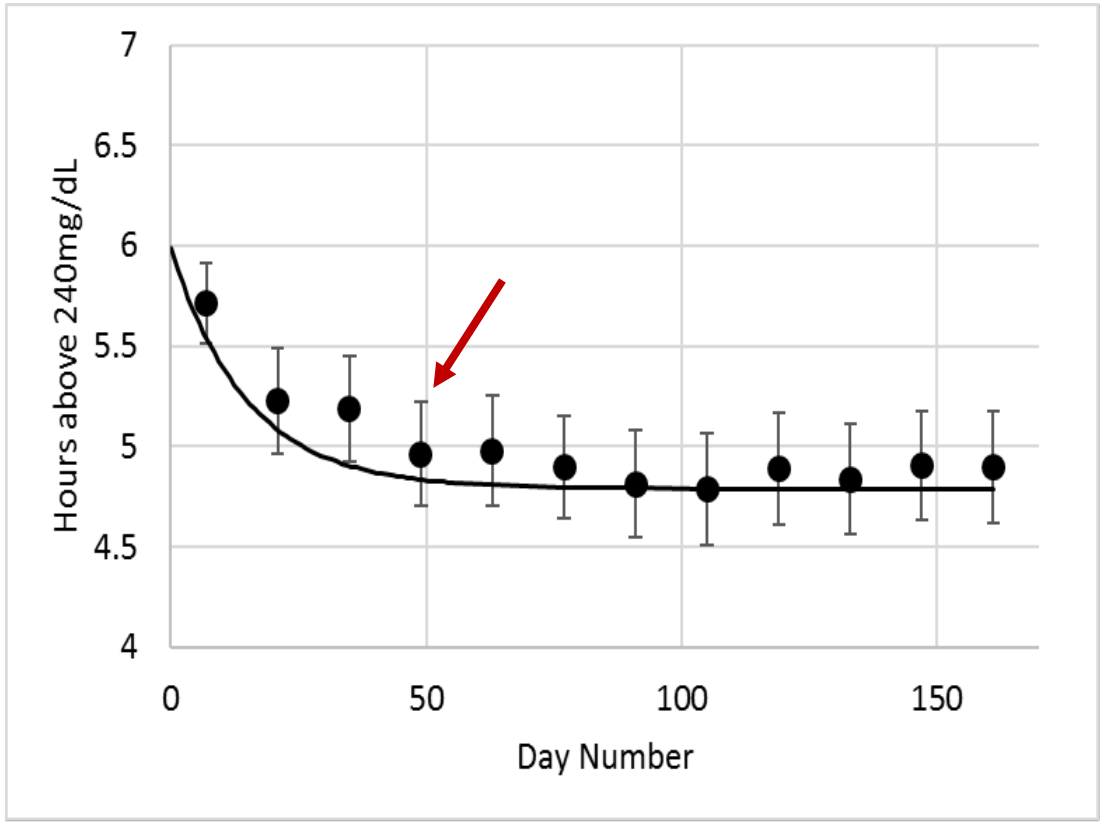
32% reduction
(p<0.001)

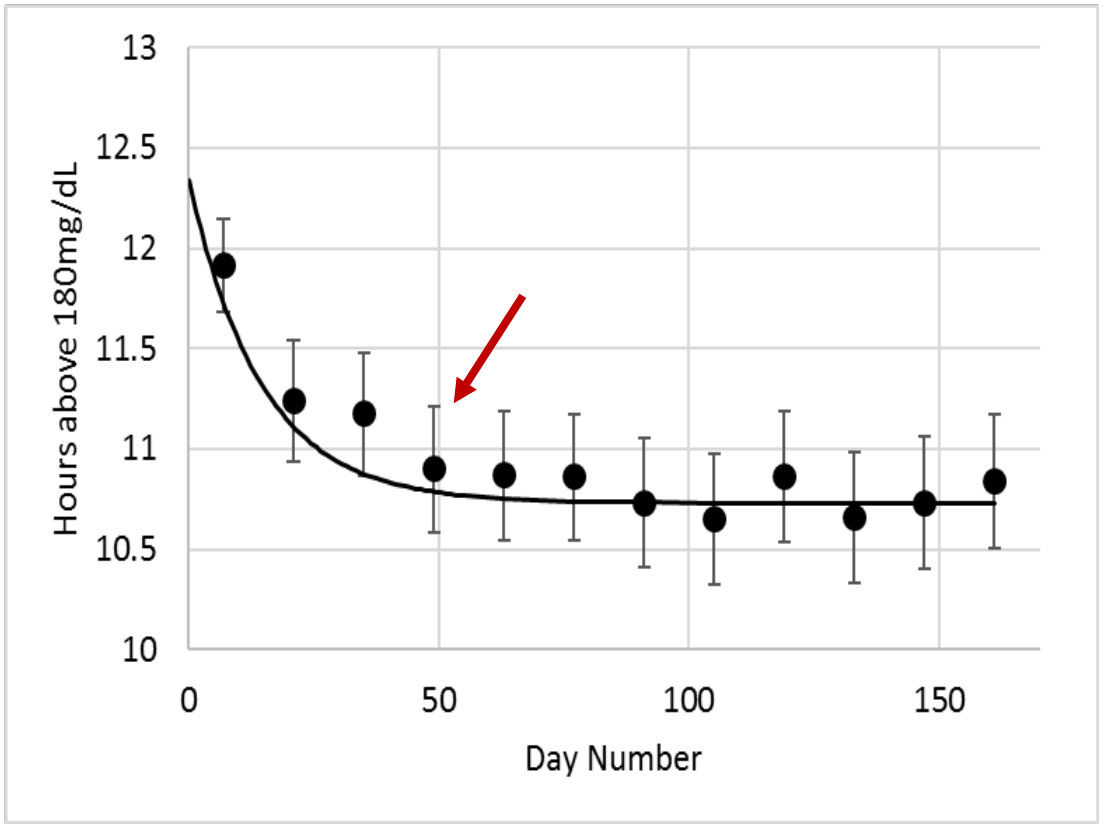


Dunn, et al. Diabetes Research and Clinical Practice, 2018

What About Reduction in Hyperglycemia?

(An especially powerful metric during the pandemic!)





High risk hyperglycemia/high frequency scanners

Jangam, et al. BMJ Diab Res Care 2019; in press

How Has Sensor-Based Glucose Monitoring Evolved to be So Helpful?

- Sensor-based glucose monitoring is an easy way to generate the dense glucose data needed for a complete, interpretable glycaemic picture^ in T1D and T2D
- Its uniqueness rests in part in the 1-second painless scan of the reader over the sensor to collect glucose data easily and often in the 1-second user-friend painless scan
- Another key feature of a sensor-based glucose monitoring system is the small and fully disposable sensor that lasts up to **14 days, requires no user calibration, no routine finger pricks*, and automatically measures, captures and stores glucose data^**
- Digital connectivity is widely available and easily-used by all HCPs
- RWE strongly complements RCTs, allowing for identification of most appropriate patient targets and optimal clinical settings for use

*A finger prick test using a blood glucose meter is required during times of rapidly changing glucose levels when interstitial fluid glucose levels may not accurately reflect blood glucose levels or if hypoglycaemia or impending hypoglycaemia is reported by the System or when symptoms do not match the System readings. ^For a complete glycaemic picture scan sensor every 8 hours.

FreeStyle, Libre, and related brand marks are trademarks of Abbott Diabetes Care, Inc. in various jurisdictions.

ADCMDP190076 – Date of preparation: June 2019.

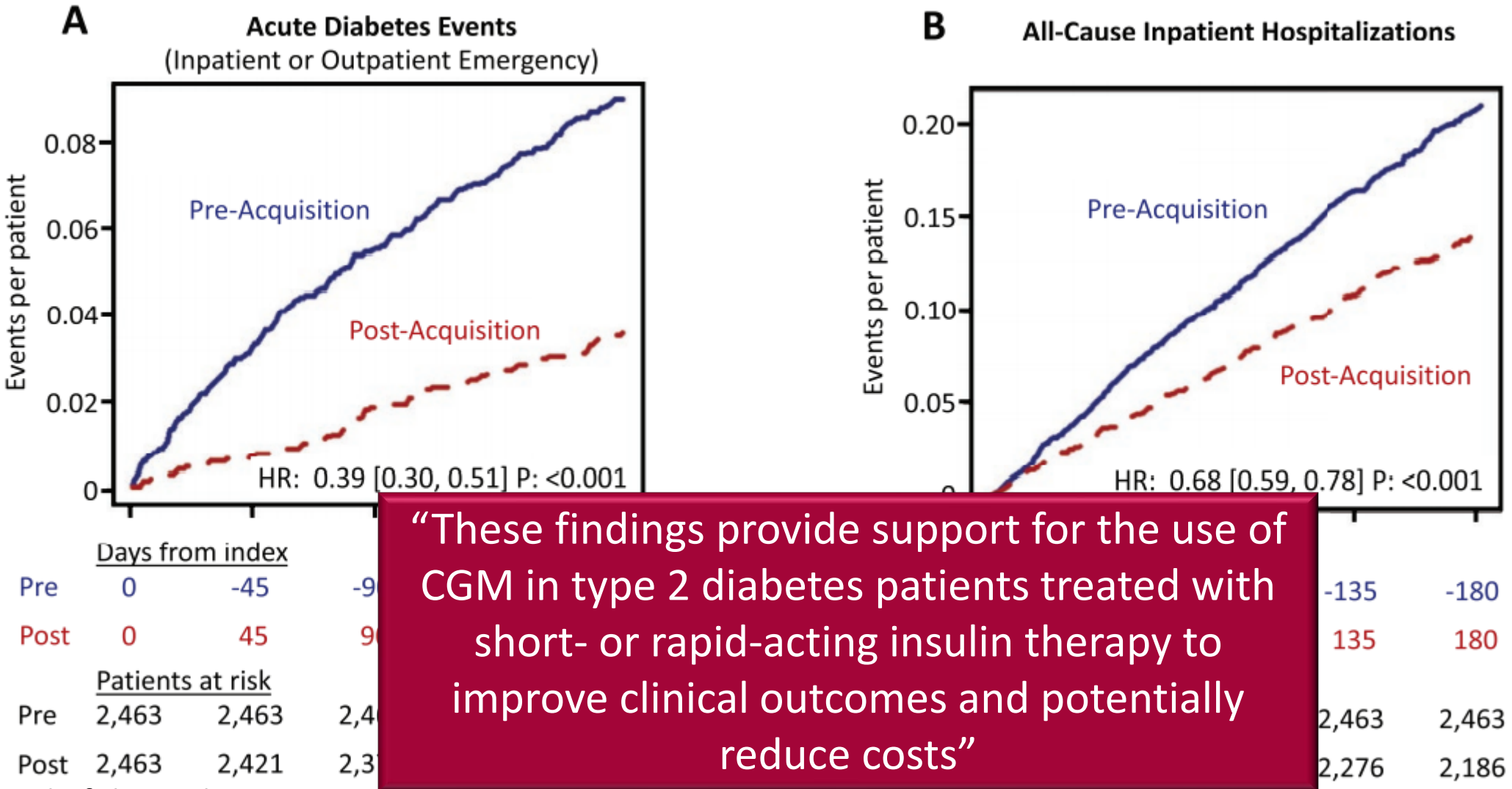
More Data: Can CGM Improve Outcomes and Cost? RWE in US

- **Acute Diabetes Events**—combination of inpatient and emergency outpatient events, including
  - Hyperglycemia, hypoglycemia, ketoacidosis, hypoglycemic coma, hyperosmolarity

- **Secondary: All-cause inpatient hospitalization**
- N = 2463 with *type 2 diabetes* receiving multiple daily injections **before and 6 months after starting Freestyle Libre**
- Age = 54.2 ± 9.6 years

Journal of the Endocrine Society, 2021, Vol. 5, No. 4, 1–9

Results: Reduction in Acute Diabetes Events and Hospitalizations

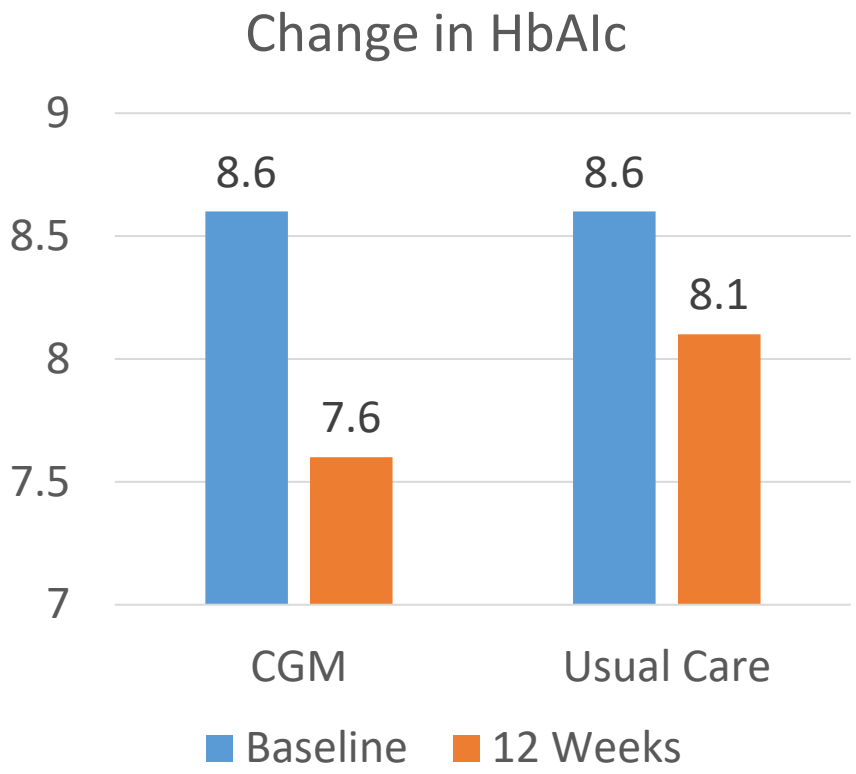


"These findings provide support for the use of CGM in type 2 diabetes patients treated with short- or rapid-acting insulin therapy to improve clinical outcomes and potentially reduce costs"

Journal of the Endocrine Society, 2021, Vol. 5, No. 4, 1–9

Effect of CGM Monitoring

- Review of glycemic control in type 1 diabetic adults.
- 158 patients randomized to CGM or usual care
  - CGM n = 105
  - Usual Care n = 53

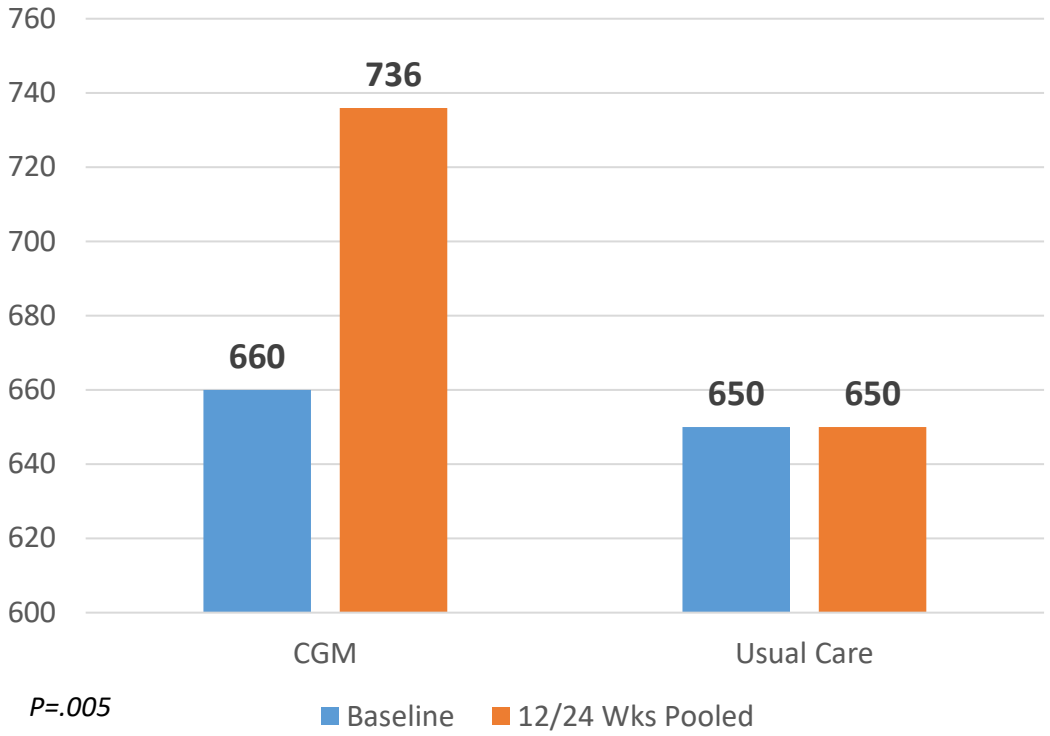


P<0.001

JAMA. 2017;317(4):371-378

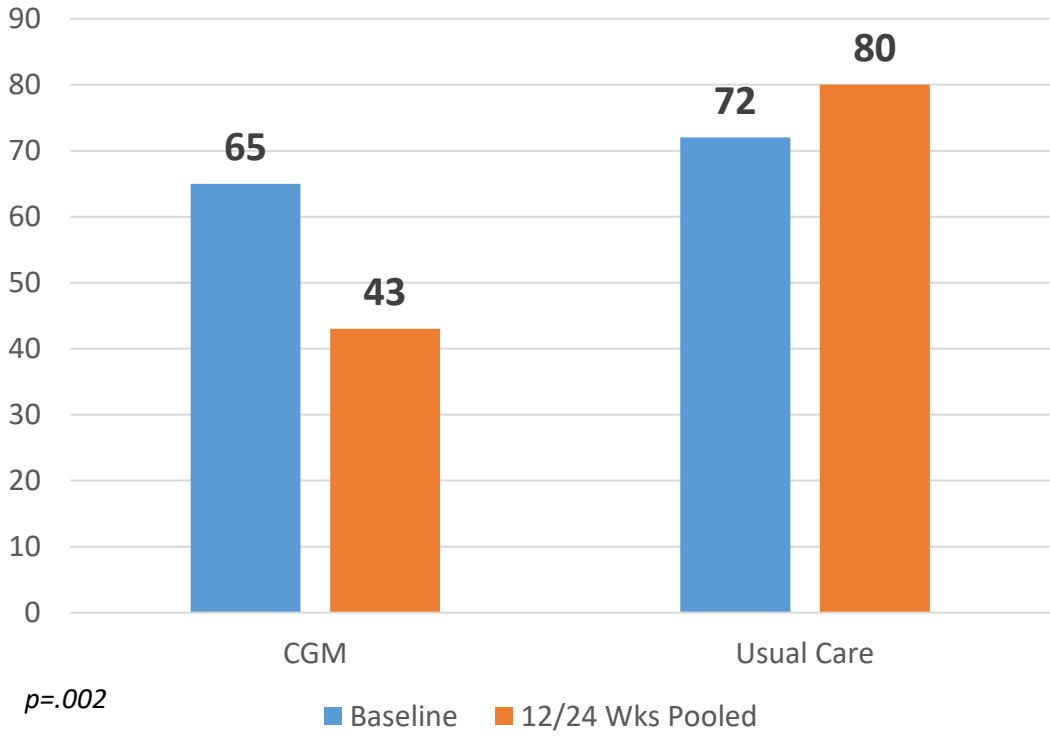
Daily Control and Hypoglycemia

Minutes per Day in Range (70-180 mg/dL)



P=.005

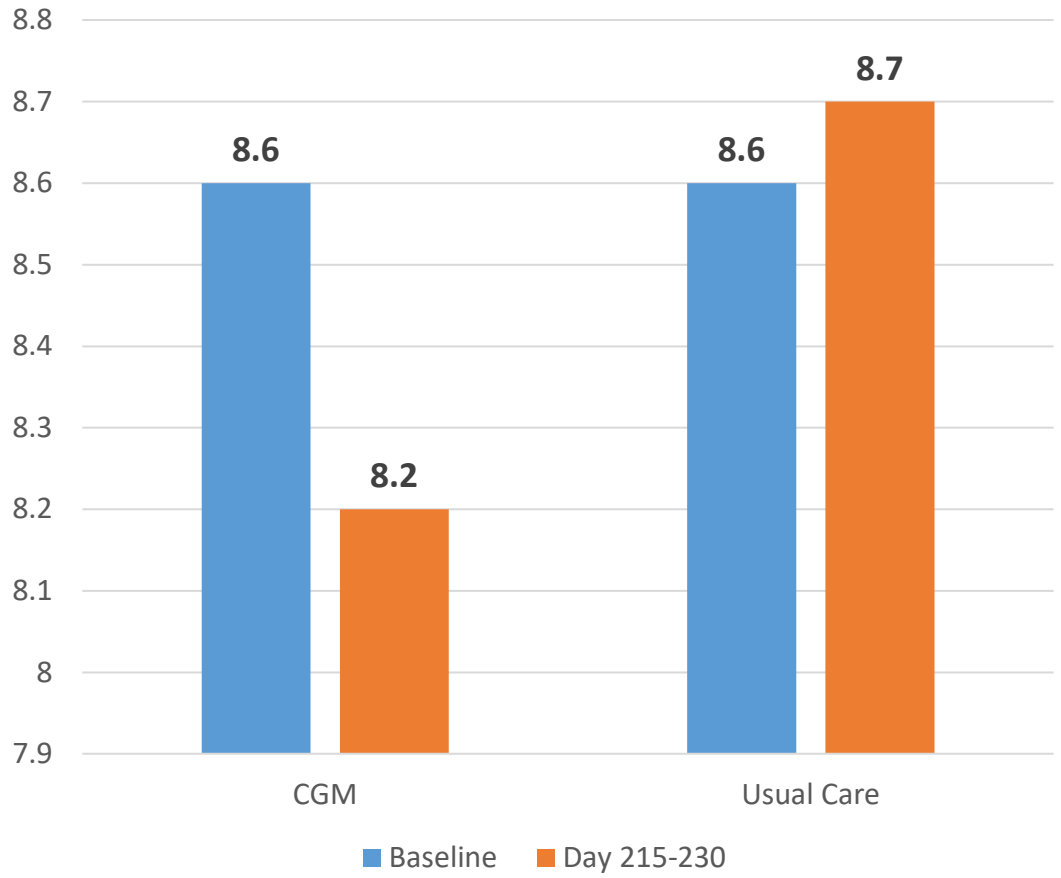
Minutes per Day < 70mg/dL



p=.002

JAMA. 2017;317(4):371-378

CGM Impact in Type 2 Diabetic Insulin Users



- Control Group n = 52
- Intervention Group n = 49
- Severe hypoglycemia in one control group patient
  - No difference in events where glucose was less than 70mg/dL
- No event of
  - Diabetic ketoacidosis
  - Hyperosmolar hyperglycemia

Diabetes & Vascular Disease Research 2019, 16(4) 985-395

Clinical Impact of CGM Use in an Integrated Healthcare System

- Past Limitations of CGM research
  - Heavy focus on type 1 diabetes
  - Limited evaluation in an IDN that can assess:
    - Clinical impact on care
    - Utilization
    - Cost
  - Research has not focused on patients ≥ 65
- 99 patients enrolled (50 – CGM, 49 – FSG)
- 93 patients with Type 2 diabetes and 6 with Type I

IDN = Integrated Delivery Network FSG = Finger Stick Glucometer

J Diabetes Sci Technol 2020 Sep 16.

Results

- HbA1c reductions
  - CGM arm -0.6% reduction
  - FSG arm -0.1% reduction
  - *P*=0.001
- In the CGM arm, the odds of experiencing glycemic excursion events were reduced by 5.15% every 30 days

J Diabetes Sci Technol 2020 Sep 16.

Reduced Diabetes Events and Hospitalizations

- Retrospective real-world study of 2463 type 2 diabetics on short or rapid acting insulin.
- Measurement six months pre and post receipt of a CGM
- Outcomes were measurement of acute diabetes-related events (ADE) and all-cause inpatient hospitalizations (ACH)
- Acute events included: hypoglycemia, hypoglycemic coma, clinical hyperglycemia, diabetic ketoacidosis, and hyperosmolarity.

Journal of the Endocrine Society, 2021, Vol. 5, No. 4, 1–9

Reductions in Diabetes Events and Hospitalizations

ADE

- ADE rates decreased from 0.18 to 0.072 events/patient-year
- $P < 0.001$

ACH

- ACH rate decreased from 0.42 to 0.283 events/patient-year
- $P < 0.001$

Journal of the Endocrine Society, 2021, Vol. 5, No. 4, 1–9

Utilization Data

Utilization Type	CGM mean (SD)	FSG	*p* value
Any visit	5.6 (3.6)	7.0 (5.1)	0.009*
PCP visit	1.8 (1.9)	3.3 (2.0)	0.28
Specialty Visit	2.6 (2.3)	3.2 (4.0)	0.066
ED visit	0.2 (0.5)	0.54 (1.1)	0.018*
Labs ordered	7.7 (7.9)	11.9 (14.1)	<0.001*

- Evaluation of fee for value patients
  - Savings of $417 PMPM for non-Medicare Advantage members
  - Cost for Medicare Advantage patients were $9 PMPM higher

J Diabetes Sci Technol 2020 Sep 16. Online ahead of print

Cost Effectiveness of CGM

A1C ≥ 7%	A1C ≤ 7%
► Reduce A1c -0.53 ► ICER = $98,679/QALY ► CI reflect large degree of uncertainty	► Maintain A1C at 6.5% ► ICER = $78,943/QALY ► CI were narrower but still reflect degree of uncertainty

- Adjustments included benefits from
  - Quality of Life
  - Improved glucose control
  - Reduction in microvascular complications

- CGM is cost effective at $100,000 QALY threshold.
- If limited to long term effects of improved glucose control, the ICER would exceed $700,000/QALY

Diabetes Care. 2010 Sep;33(9):2129

The Real World

The Issues/Barriers

- Use of CGM is becoming the standard of care
- Most of the literature, if not all demonstrate increased incremental costs in every setting, including Type 2 diabetes
- Currently, healthcare plans aren't aware of **short term cost reductions**, which does not drive health plan decision making
- Devices traditionally consider DME but cost reduction opportunities only exist on pharmacy benefit due to manner of tracking different products
- Not all members have pharmacy benefits within same plan, so plan might not see any savings and coverage determinations may not be aligned

The Real World

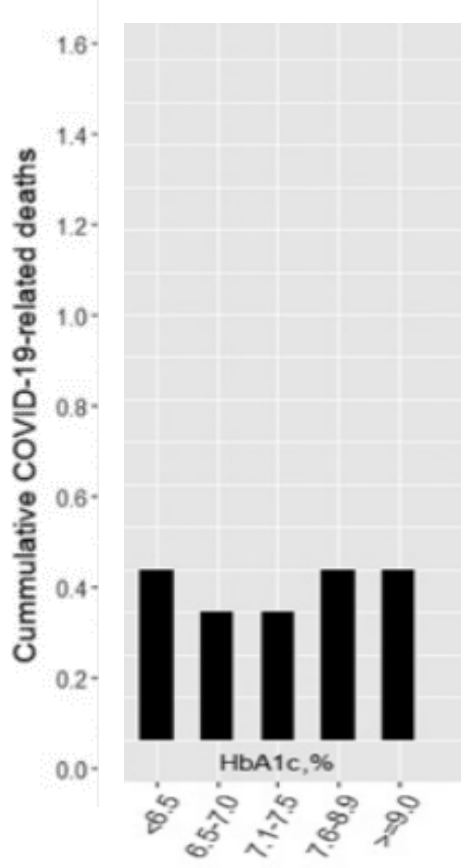
Pharmacy vs Medical

- Pro's:
  - Improved ability to manage by product due to NDC vs HCPCS code billing
  - Opportunity to contract for lower net cost to plan
  - Potential for lower cost to member
  - Member convenience
  - Direct contracting

- Con's:
  - Loss of coordination of care
  - Loss of volume control due to autofills
  - Sometimes loss of coverage control

Diabetes and Covid-19: Population Impact 18 Months Into the Pandemic

Absolute risk of COVID-19–related mortality among English adults with type 2 diabetes



Gregg EW, et al. Diabetes Care 2021 Jul

- Epidemiologic studies indicate that diabetes is a central contributor to severe Covid-19 morbidity, and, conversely, Covid-19 has had a devastating effect on the population with diabetes.
- **~30-40% of people** with Covid-19-related hospitalization, severe morbidity requiring intensive care, and/or death have **T1D or T2D.**
- Among hospitalized individuals with diabetes, **~21-43% required intensive care and case fatality is ~25%.**
- Risk of severe morbidity and mortality is **100-250% higher among people with diabetes** than those without.
- **Overall mortality rates were 50% higher** in persons with diabetes than historical trends, a net increase more than twice that of the general population.
- Many predictors of poor outcomes have been identified, particularly comorbid conditions, including **chronic poor HbA_{1c} control**, that point to the potential to reduce severe morbidity and mortality.

Covid-19 Mortality is Higher in People with Type 1 Diabetes Compared to Type 2 Diabetes

Worse Glycemic Control is Independently Associated

Population Study in England (NHS): 1 Mar 2020 – 11 May 2020: 23,698 COVID-19 Related Hospital Deaths

Unadjusted in-hospital COVID-19 mortality rate by Diabetes status.

- Type 1 and Type 2 diabetes are both associated with a significant increase of in-hospital death with Covid-19
- Odds of in-hospital Covid-19-related death are greater in people with Type 1 diabetes (OR 3.51) than in people with Type 2 diabetes (OR 2.03)

Barron E, et al [published ahead of print, 2020 Aug 13. *Lancet Diabetes Endocrinol.* 2020;S2213-8585(20)30272-2

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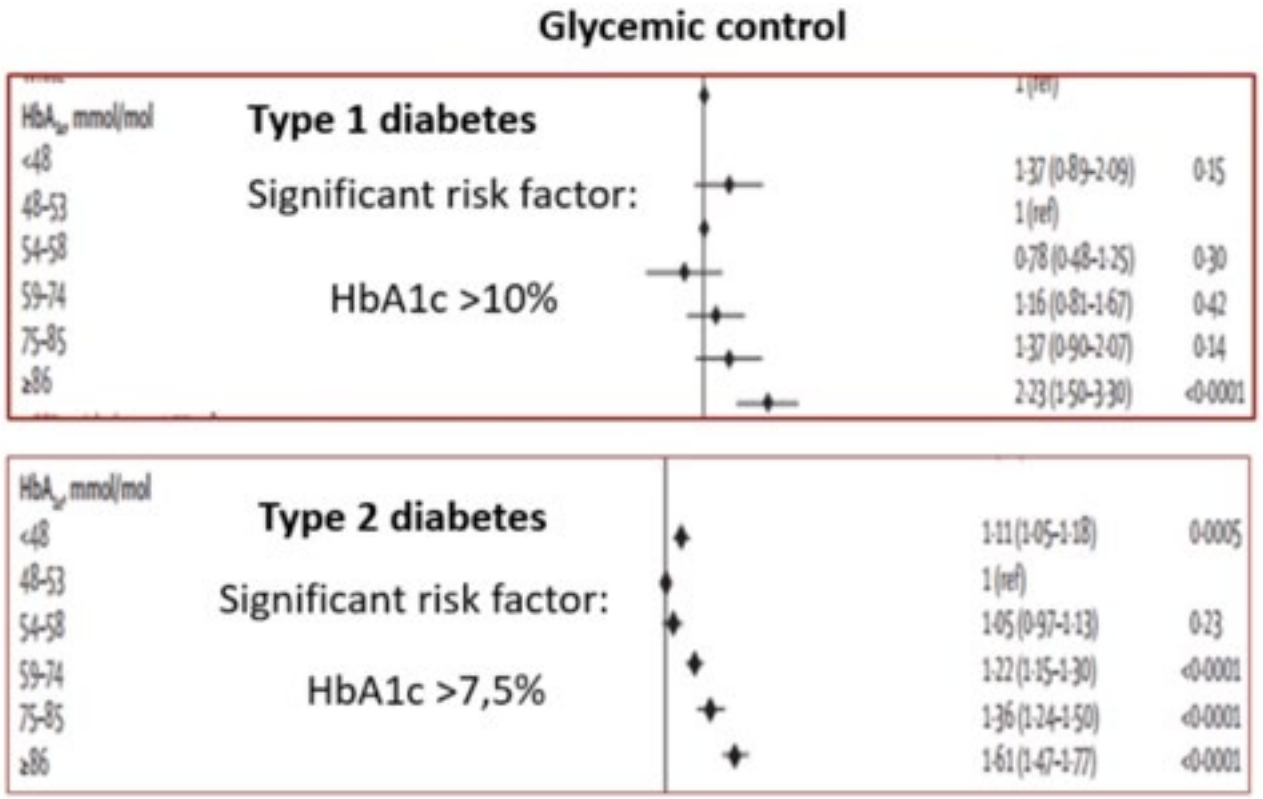
Population Study in England (NHS): 1 Mar 2020 – 11 May 2020: 23,698 COVID-19 Related Hospital Deaths



- Type 1 and Type 2 diabetes are both associated with a significant increase of in-hospital death with Covid-19
- Odds of in-hospital Covid-19-related death are greater in people with Type 1 diabetes (OR 3.51) than in people with Type 2 diabetes (OR 2.03)

Holman N, et al. [published ahead of print, 2020 August 13]. *Lancet Diabetes Endocrinol.* 2020;S2213-8587(20)30271-0.

Covid-19 and Diabetes: Clinical Implications in Managed Care Setting

- Higher prevalence of diabetes in patients with Covid-19 infections
- Patients with diabetes have worse outcomes compared to non-DM:
  - Higher hospital admissions
  - Inpatient hyperglycemia associated with poor outcomes
  - Inpatient management of diabetes: Target BG < 180 mg/dl
  - Insulin therapy is the preferred treatment regimen
  - Glycemic monitoring with CGM of BOTH inpatients and outpatients with T2D/T1D may be advantageous for reducing complications and death

Late-Breaking! Integrating CGM Data Directly into the Electronic Health Record—Implications for Managed Care

First-of-its-kind model integrates continuous glucose monitoring data directly in electronic health record, allowing for easy access to valuable diabetes management information

Presentation at American Diabetes Association's 81st Virtual Scientific Sessions, led by International Diabetes Center, highlights model for integrating continuous glucose monitoring data directly into electronic health record, as well as implications for clinicians

Criego, A. ADA 2021 Scientific Sessions. June 28, 2021

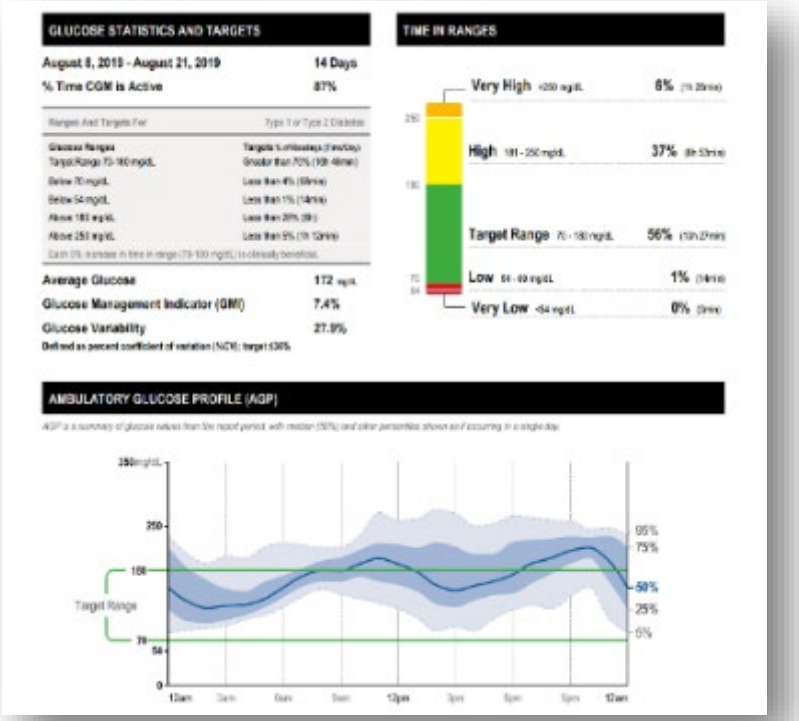
Integrating CGM Data Directly into the Electronic Health Record—Implications for Managed Care

- The International Diabetes Center (IDC) partnered with Abbott on this **first-of-its-kind** initiative to improve diabetes management by making CGM data available at the **point of care**.
- Clinicians can place an order in the EHR for a patient with diabetes who has agreed to share their CGM data.
- In **real time**, the data is transferred from the LibreView cloud-based system, via an EHR platform, allowing physicians to **automatically** view the patients CGM data in their lab results and diabetes flow sheet, and showing time in range and visual alerts for out of range values.

Criego, A. ADA 2021 Scientific Sessions. June 28, 2021

Integrating CGM Data Directly into the Electronic Health Record—Implications for Managed Care

- The **Ambulatory Glucose Profile (AGP)** report, in PDF format, is also integrated into the EHR and allows clinicians to easily track the patient's glucose trends over time and adjust treatment regimens as needed.
- Using this innovative model, clinicians no longer need to log in to a separate system to access their patient's CGM data.
- Integrating CGM data with the EHR can provide an effective way for clinicians to both **view and track this data over time**, which can improve how they're able to manage and support their patients.



Criego, A. ADA 2021 Scientific Sessions. June 28, 2021

Conclusions: CGM as a Foundational Approach to Diabetes Care in Managed Plans

- Diabetes continues to have significant clinical and economic consequences, particularly in the managed care environment— Costs, along with morbidity and mortality, are increased in patients with uncontrolled glucose levels.

- Sensor-based CGM offers an opportunity in appropriately selected persons with Type 2 and Type 1 diabetes in the managed care environment to **improve glucose control, improve outcomes and reduce costs.**

- **CGM is becoming a foundational strategy across the spectrum of diabetes care and managed care plans, in particular, stand to benefit from its incorporation into the standard of care.**

- **Integrating CGM into the Electronic Health Record has special implications for managed care, system-wide approaches to diabetes care.**

From Evidence to Clinic: Translating Guidelines, Meta-Analysis, and Real World Trials to Guide Practical Aspects of Diabetes Care in the Managed Care/HMO Setting

A Case-Based Model for Using Sensor-Based Glucose Monitoring to Improve Time in Range (TIR), GMI and AGP for Persons Across the Spectrum of Diabetes Care

Dr Eden Miller D.O.
Diplomate A.B.O.M.

Speaker Biography

Eden Miller D.O.
Diabetologist
Diplomate of American Board of Obesity Medicine

Executive Director and Co-Founder Diabetes Nation
Diabetes and Obesity Care
St. Charles Hospital Bend, Oregon, USA

Current Challenges in Outpatient Management of Type 2 Patients

- Need for a progressive plan of treatment intensification with *engaged* patients[1]
- Clinical inertia: highly prevalent in the management of T2 DM with the longest delays reported for insulin initiation and titration[2-4]
- Provider and Patient fear of hypoglycemia[2,4]
- Increasing diabetes distress, ongoing treatment and lifestyle nonadherence, and poor treatment persistence [1]
- Increased healthcare resource utilization and healthcare costs[1] through morbidity
- Unawareness of asymptomatic ('silent') or nocturnal hypoglycemia[5]

1. Guerci, Bruno, *et al.* *Diabetes Ther* **10,** 437–449 (2019). https://doi.org/10.1007/s13300-019-0590
2. Davies, Melanie J., et al. Diabetologia 61, no. 12 (2018): 2461-2498.
3. Khunti Kamlish, et al.. Diabetes Obes Metab 2018; 20: 427-37.
4. Pantalone Kevin, M, et al. Diabetes Care 2018; 41(7): e113-e114.
5. Ajjan, Ramzi, et al. Adv Ther 36, 579–596 (2019). https://doi.org/10.1007/s12325-019-0870-x

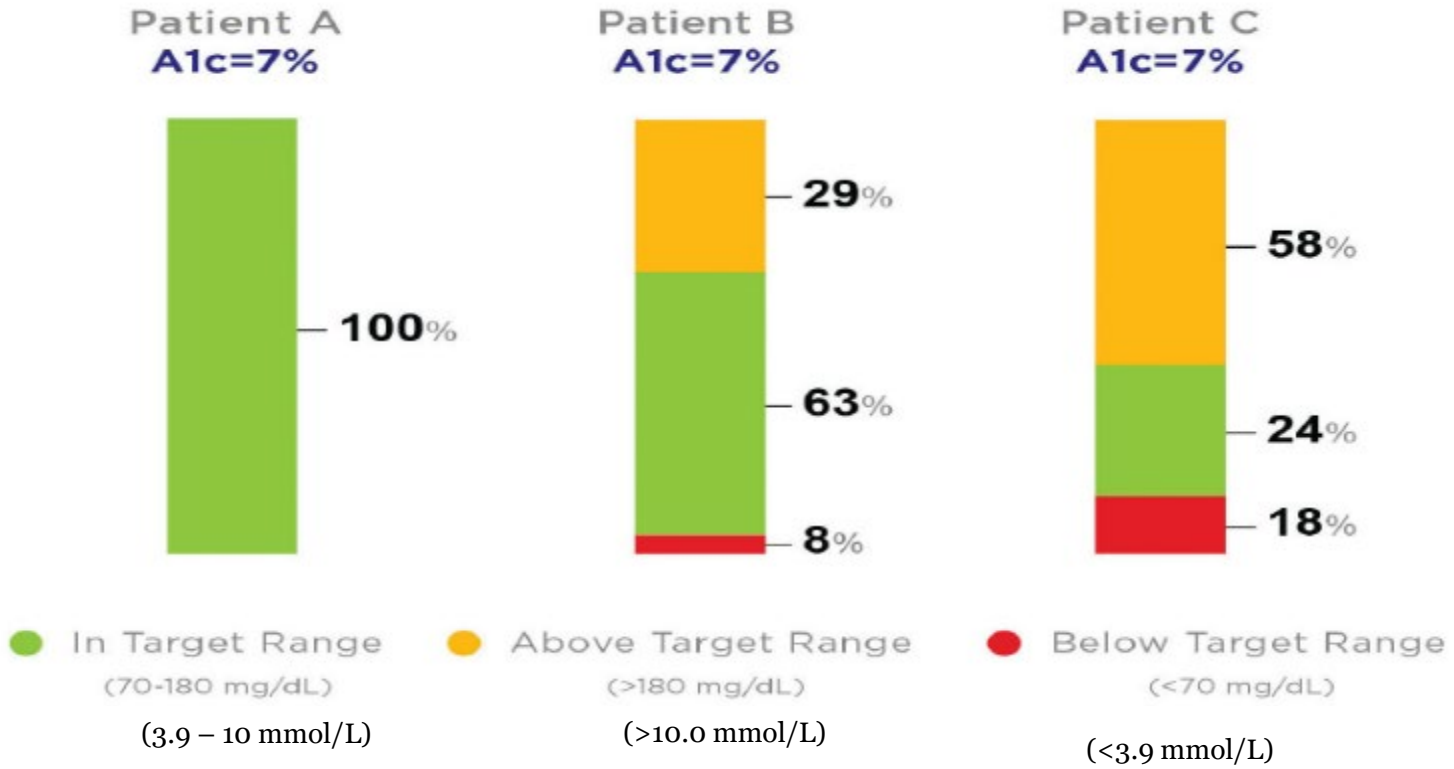
The Trials and Tribulations of HbA1c - *The Average Metric*

- Universally accepted standard for the diagnosis and monitoring of diabetes mellitus
- Ongoing debate about the ‘optimal’ HbA1c—should it be standardized or “validated”
- Agreement that individualized HbA1c targets be established based on the patient’s age, life expectancy, comorbidities and risk of hypoglycemia
- Glycaemic variability drives the risk of complications, HbA1c does not capture GV
- Inability to capture short- term variations in glucose

Klein, K.R., Buse, J.B.. Nat Rev Endocrinol (2020). https://doi.org/10.1038/s41574-020-00425-6

Not All A1cs are Created Equal

HbA1c only provides a broad look at a patient's glucose history. Time in Range provides more actionable information than A1c alone and should complement A1c.[1]

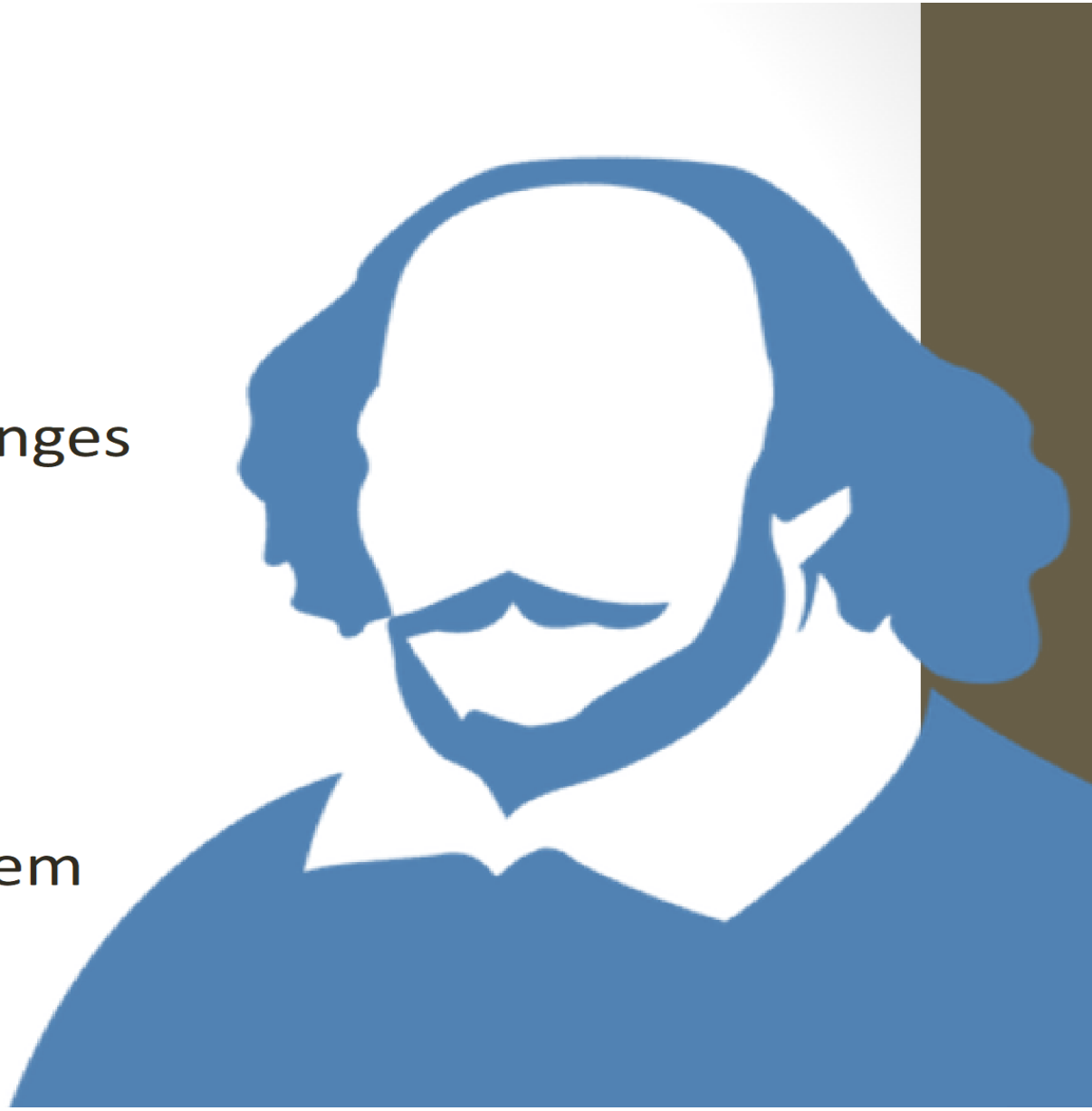


Not actual patient data; for illustrative purposes only.

1. Battelino T, Danne T, Berganstal RM, et al. Clinical targets for continuous glucose monitoring data interpretation: recommendations from the international consensus on time in range. *Diabetes Care.* 2019;42(8):1593-1603.

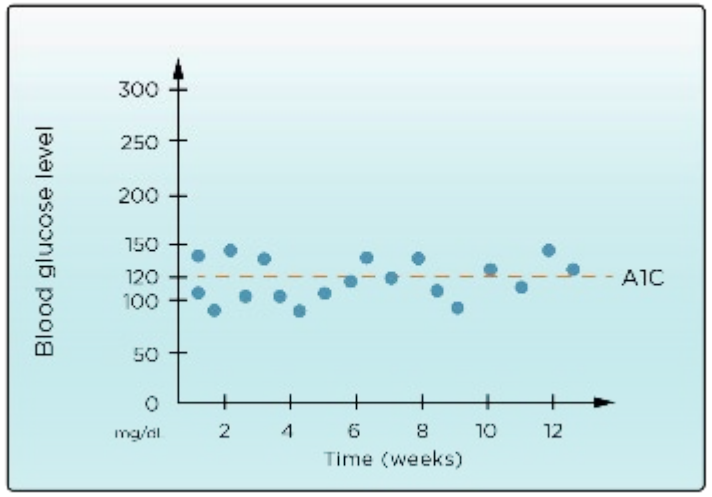
To CGM or not to CGM

- A1c is just an average
- Patients can have the same A1c but have vastly different glucose ranges
- Taking diabetes out of the past
- When things just don't make sense
- Patients are not tracking and participating in their own disease
- The patient treatment plan puts them in danger of hypoglycemia

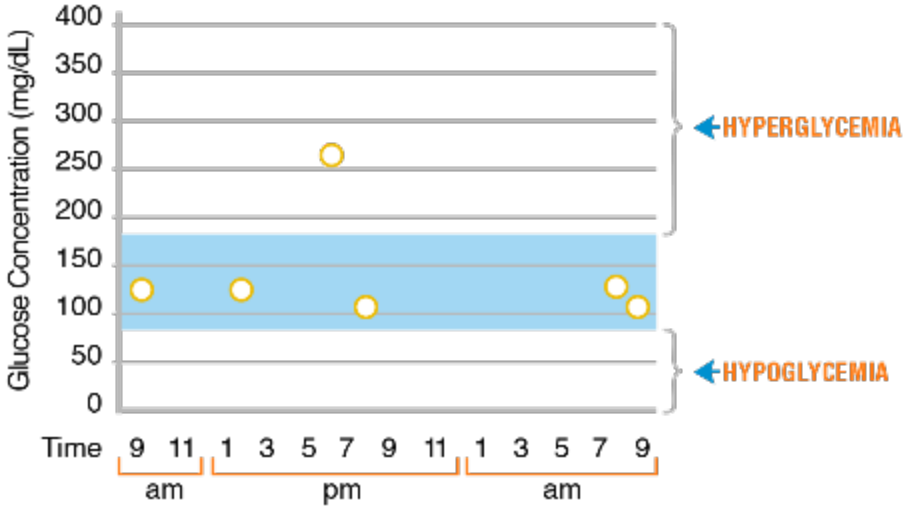


CGM Fills the Information Gaps for a More Complete View

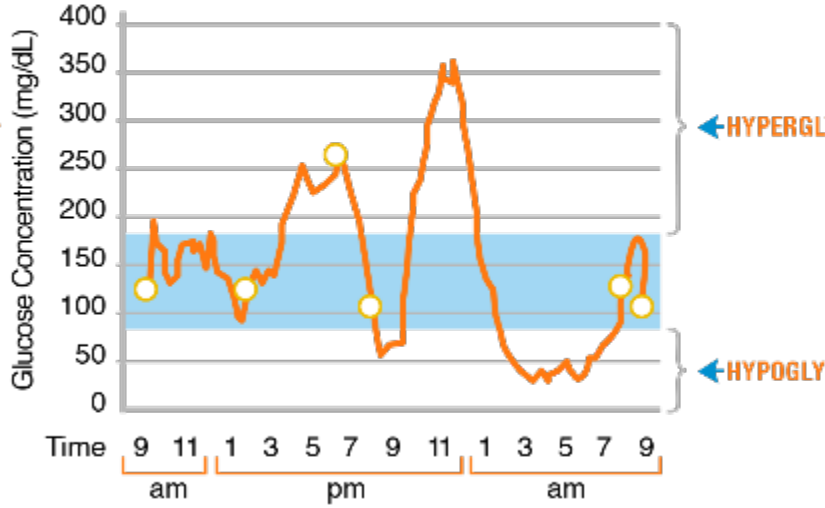
HbA1c testing: a 2-3 month average



Blood Glucose Monitoring: a point in time



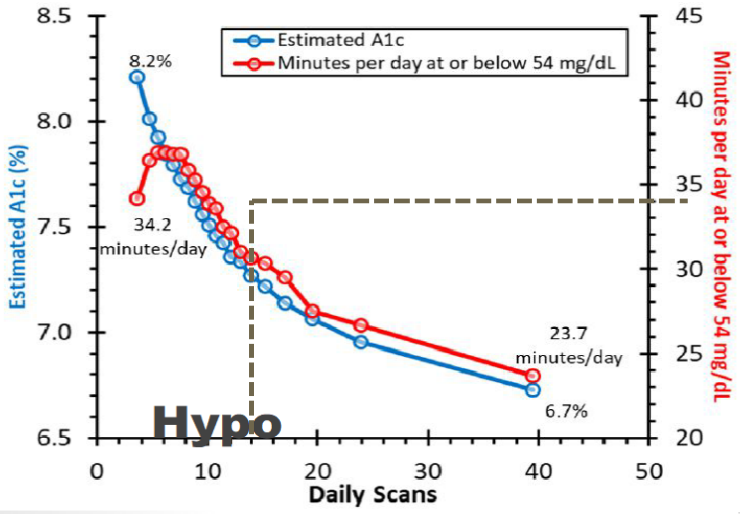
Continuous Glucose Monitoring: a complete picture

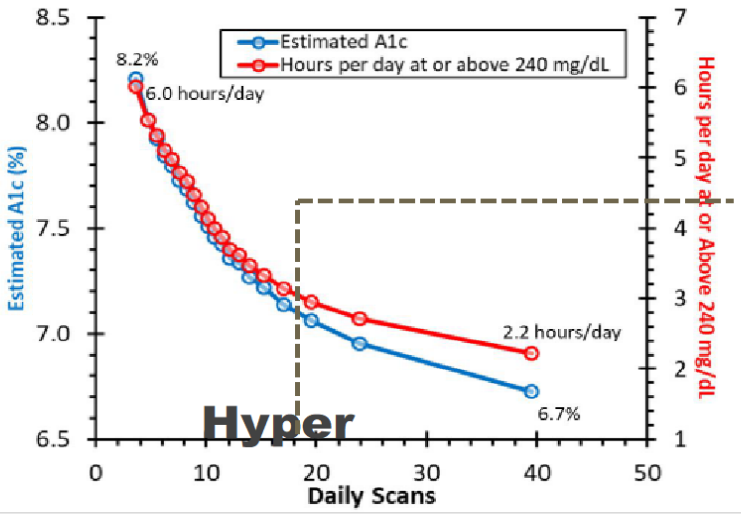


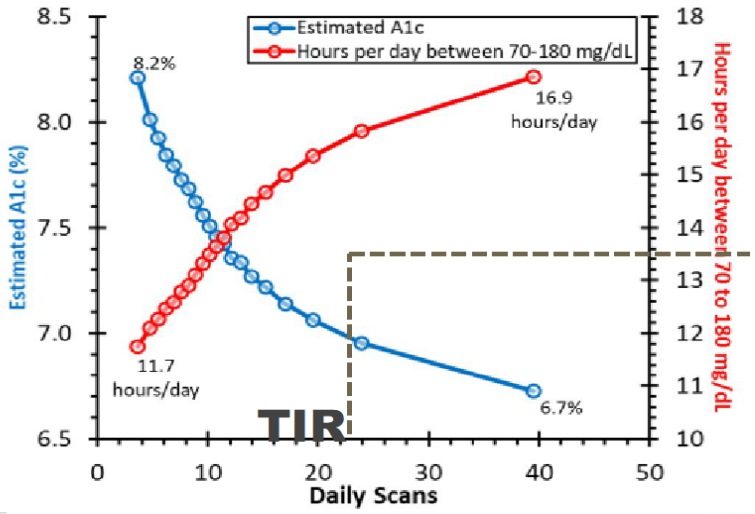
mg/dL in mmol/L, conversion factor: 1 mg/dL = 0.0555 mmol/L

Not actual patient data; for illustrative purposes only.

Increased scanning associated with lower estimated A1C, decreased hypoglycemia, increased time-in-range.







Conversion: mg/dL × 0.0555 = mmol/L.

Lang J, et al. ATTD19-0299 – Expanded Real-World Use Confirms Strong Association Between Frequency of Flash Glucose Monitoring and Glucose Control. ATTD 2019. Feb 22, 2019.

FLARE-NL4 Study: CGM and T12/T2D in Netherlands

- 1365 persons (55% male) were included. Mean age was 46 (16) years, 77% of participants had type 1 DM, 16% type 2 DM and 7% other forms. HbA1c decreased from 64 or 8.0% (95%CI 63 to 65) mmol/mol to 60 or 7.4% (95%CI 60 to 61) mmol/mol with a difference of −4 (95% CI −6 to 3) mmol/mol or 0.6%.
- Persons with a baseline HbA1c >70 mmol/mol or 8.6% had the most profound HbA1c decrease: −9 or 1.6% (95% CI −12 to to 5) mmol/mol. EQ-5D tariff (0.03 (95%CI 0.01 to 0.05)), EQ-VAS (4.4 (95%CI 2.1 to 6.7)) and SF-12^{v2} mental component score (3.3 (95%CI 2.1 to 4.4)) improved.
- For most, PROMs improved. Work absenteeism rate (/6 months) and diabetes-related hospital admission rate (/year) decreased significantly, from 18.5% to 7.7% and 13.7% to 2.3%, respectively.
- Real world data demonstrate that use of FSL-FGM results in improved well-being and decreased disease burden, as well as improvement of glycemic control.

Use of FreeStyle Libre Glucose Monitoring:Prospective nationwide registry in the Netherlands (FLARE-NL4) M. J. Fokkert, A. Damman, P. R. van Dijk, M. A. Edens, S. Abbes, J. Braakman, R. J. Slingerland, L. D. Dikkeschei, J. Dille, and H. J. G. Bilo

HbA1c Reduction After Initiation of the FreeStyle Libre System in Type 2 Diabetes Patients on Long-Acting Insulin or Non-Insulin Therapy

Eden Miller, DO; Laura Brandner, Eugene Wright, MD

Aim:

- Evaluate the change in HbA1c from baseline to 6mo and baseline to 12mo after starting a FreeStyle Libre system for T2D patients on long-acting insulin (LAI) and non-insulin (including GLP-1) therapy

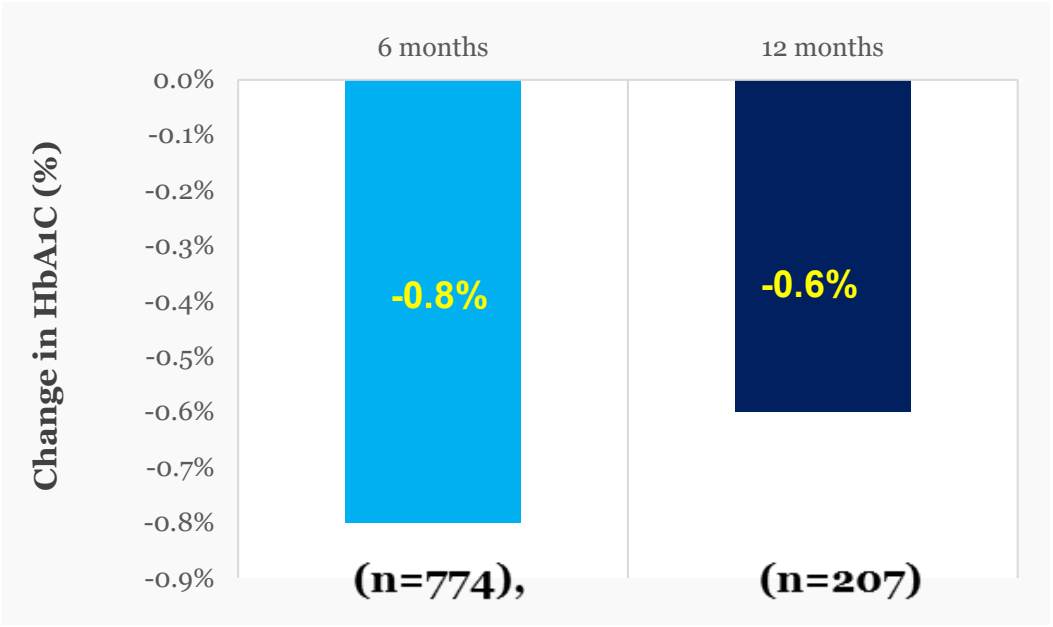
Methods:

- Retrospective, observational analysis of deidentified data
- Data from three different data sets were used and linked together during the analysis timeframe
- *LibreView ®:* Index was the first date of data in LibreView (Nov 2017–Sept 2019)
- *Quest Diagnostics™ :* HbA1c testing results
- *Decision Resources Group (DRG):* Medication and diagnosis derived from DRG
- Inclusion criteria:
  - Baseline A1c must be ≥ 6.5% within 6mo prior to index
  - HbA1c tests closest to +180 days (+150-210) used for 6mo
  - HbA1c tests closest to +360 days (+330-390) used for 12mo

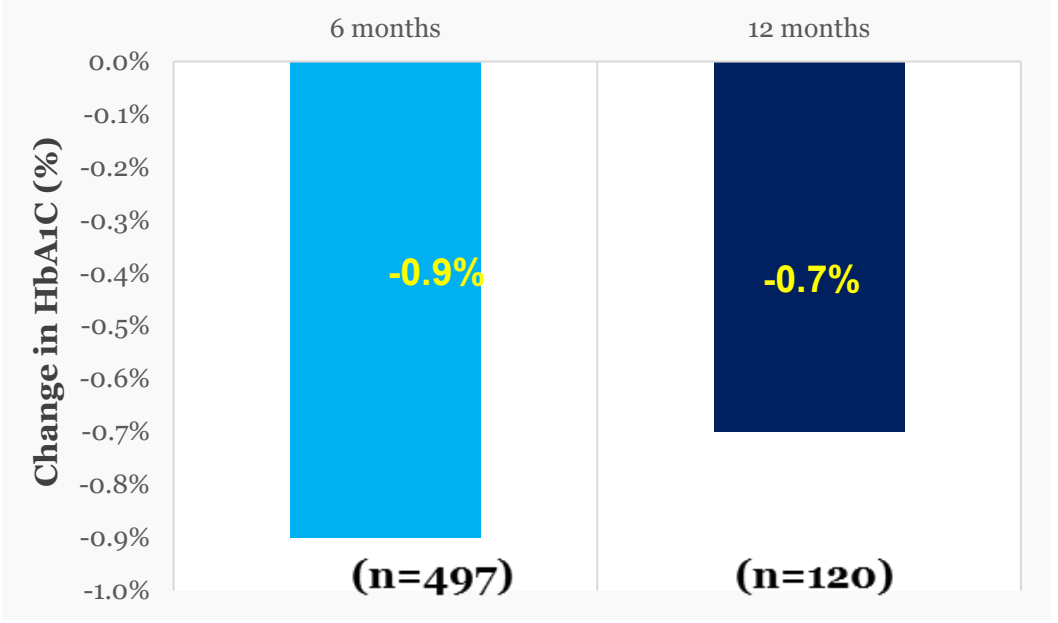
Miller E et al. [84-LB]. Poster presented at: American Diabetes Association 80th Scientific Session; June 12-16, 2020;Virtul.

HbA1c Reduction After Initiation of the FreeStyle Libre System in Type 2 Diabetes Patients on Long-Acting Insulin or Non-Insulin Therapy[1]

Reduction in A1c after FreeStyle Libre initiation was seen in all type of patients
(p<0.0001)



The greatest reduction in A1c was seen in the T2D non-insulin group
(p<0.0001)



1. Miller E et al. [84-LB]. Poster presented at: American Diabetes Association 80th Scientific Session; June 12-16, 2020;Virtul.

Type 2 Diabetes and the Use of Real-Time Continuous Glucose Monitoring

The development of CGM has had a profound impact on the field of diabetes. There is real potential for CGM to improve glycemic outcomes and prevent diabetes complications in patients with T2D. Current evidence is promising, but the majority of trials looking at the role of CGM with T2D management have selected those on intensive insulin therapies, leaving out a large number of T2D patients.

Studies have suggested a role for CGM as a teaching tool to improve lifestyle management, which would be helpful even in early T2D or prediabetes.

These studies have been small, however, and their data often inconclusive. This exciting new field would benefit from large RCTs confirming usefulness of CGM for lifestyle improvement and diabetes self management, which remain the mainstay of diabetes care.

Melanie A. Jackson, MD, Andrew Ahmann, MD, and Viral N. Shah, MD

DIABETES TECHNOLOGY & THERAPEUTICS Volume 23, Supplement 1, 2021 Mary Liebert, Inc. DOI: 10.1089/dia.2021.0007

A Comparison of Continuous Glucose Monitors in Reducing A1c in Type 1 and Type 2 Diabetes: FreeStyle Libre® and Dexcom

In both matched T1D (N=348) and T2D (N=330) cohorts, and in sub-analyses, recipients of both device types exhibited a significant A1c reduction after CGM prescription. T2D patients exhibited the greatest reductions, particularly those with initial poor glycemic control. The amount of reduction was not statistically significantly different between devices.

CGM recipients experienced a significant improvement in A1c regardless of CGM manufacturer.

Authors: Eden Miller, DO; Jennifer M. Joseph, PhD; Ignacio J. Reyes; Yelena Nabutovsky, MS; Naunihal Virdi, MD; Irl B. Hirsch, MD

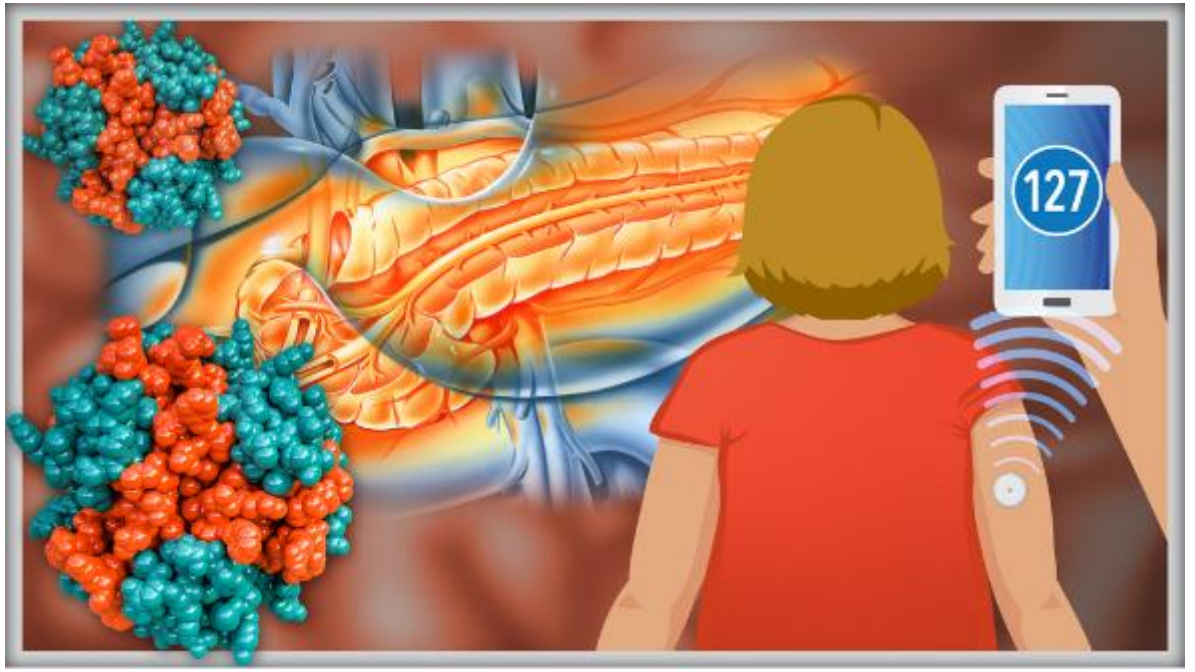
A Comparison of Continuous Glucose Monitors in Reducing A1c in Type 1 and Type 2 Diabetes: FreeStyle Libre® and Dexcom

Upcoming CGM and Type 2 DM Studies

The Vanderbilt Diabetes Center is one of 15 study sites for the observational **MOBILE trial**, which focuses on CGM use in type 2 diabetes basal insulin users who follow a primary care physician for diabetes management. The CGM being tested is the **Dexcom G6®**. Adult patients (over 30 years old) are randomized to either the CGM system or finger stick blood glucose monitoring. Then, Bao and other investigators assess the benefit of CGM use on glycemic control over an eight-month period. During the next six months, the researchers assess if glycemic control worsens upon withdrawal of CGM.

Refer Basal Study - *Efficacy of flash glucose monitoring in type 2 diabetes managed with basal insulin in the United States; a retrospective real-world chart review study and meta-analysis. Abbott Study Completed and Pending Publication*

Clinical Case Studies



Clinical Case # 1

- 63 year old female T2 DM for 3.5 years has diabetes consultative appointment
- Med Hx- HTN, Hyperlipidemia, Class 2 Obesity
- Current diabetes related medications-Metformin with poor medication adherence due to GI related side effects
- Baseline HbA1c 8.4%
- Personal CGM provided for patient to increased engagement and awareness of glucose values

Baseline Ambulatory Glucose Profile

- Duration of wear-14 days
- Data gaps- minimal
- Hypoglycemia- 1%
  (<70 mg/dl)
- TIR- 56% (70-180 mg/dl)
- TAB-43% (>180 mg/dl)
- Variability- 27.9%

GLUCOSE STATISTICS AND TARGETS

August 8, 2019 - August 21, 2019	**14 Days**
% Time CGM is Active	**87%**

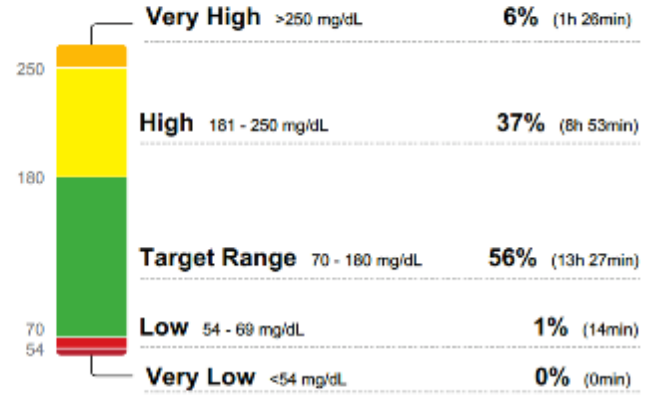
Ranges And Targets For	Type 1 or Type 2 Diabetes
Glucose Ranges	**Targets** % of Readings (Time/Day)
Target Range 70-180 mg/dL	Greater than 70% (16h 48min)
Below 70 mg/dL	Less than 4% (58min)
Below 54 mg/dL	Less than 1% (14min)
Above 180 mg/dL	Less than 25% (6h)
Above 250 mg/dL	Less than 5% (1h 12min)

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

Average Glucose	**172** mg/dL
Glucose Management Indicator (GMI)	**7.4%**
Glucose Variability	**27.9%**

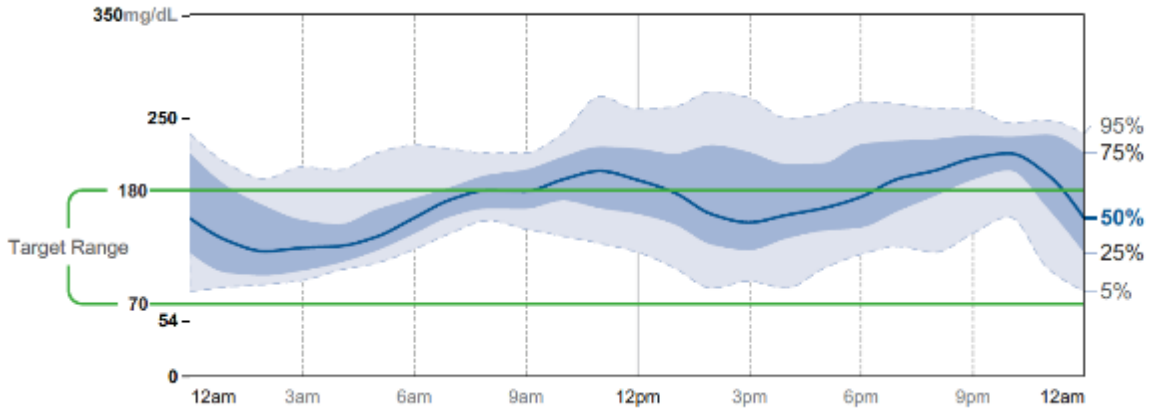
Defined as percent coefficient of variation (%CV); target ≤36%

TIME IN RANGES



AMBULATORY GLUCOSE PROFILE (AGP)

AGP is a summary of glucose values from the report period, with median (50%) and other percentiles shown as if occurring in a single day.



Clinical Intervention from AGP Analysis

- Fully discontinued metformin due to lack of adherence
- Patient reported significant increase of awareness of effect of food, stress, activities, and lack of medication adherence had on her glucose levels
- Addition of GLP-1 RA to patient treatment
- Patient indicates she would like to continue on FreeStyle Libre. She calls it her diabetes accountability partner.

AGP- 14 Months After Initial Baseline

- Sensor wear- 14 days with no data gaps
- Hypoglycemia- 0% (< 70 mg/dl)
- TIR- 90% (70-180 mg/dl)
- TAB- 10 % (180-250 mg/dl)
- Glycemic Variability- 22.3%
- HbA1c 7.1% rapid in office
- GMI 6.6 % for last 14 days

GLUCOSE STATISTICS AND TARGETS

October 14, 2020 - October 27, 2020	14 Days
% Time CGM is Active	97%

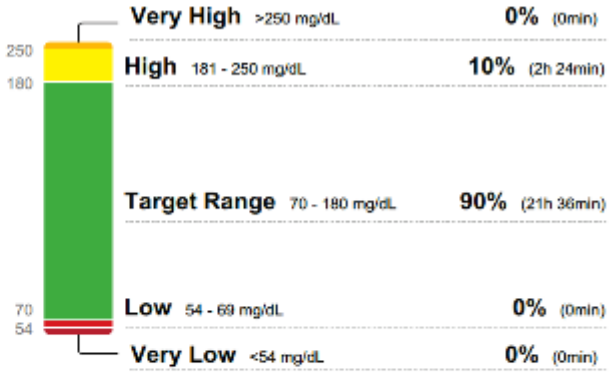
Ranges And Targets For	Type 1 or Type 2 Diabetes
Glucose Ranges	**Targets % of Readings (Time/Day)**
Target Range 70-180 mg/dL	Greater than 70% (16h 48min)
Below 70 mg/dL	Less than 4% (58min)
Below 54 mg/dL	Less than 1% (14min)
Above 180 mg/dL	Less than 25% (6h)
Above 250 mg/dL	Less than 5% (1h 12min)

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

Average Glucose	137 mg/dL
Glucose Management Indicator (GMI)	6.6%
Glucose Variability	22.3%

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

TIME IN RANGES



AMBULATORY GLUCOSE PROFILE (AGP)

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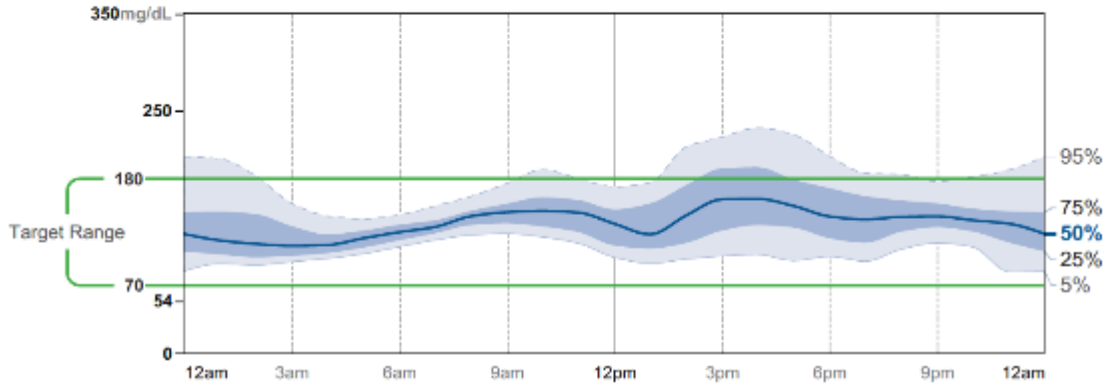


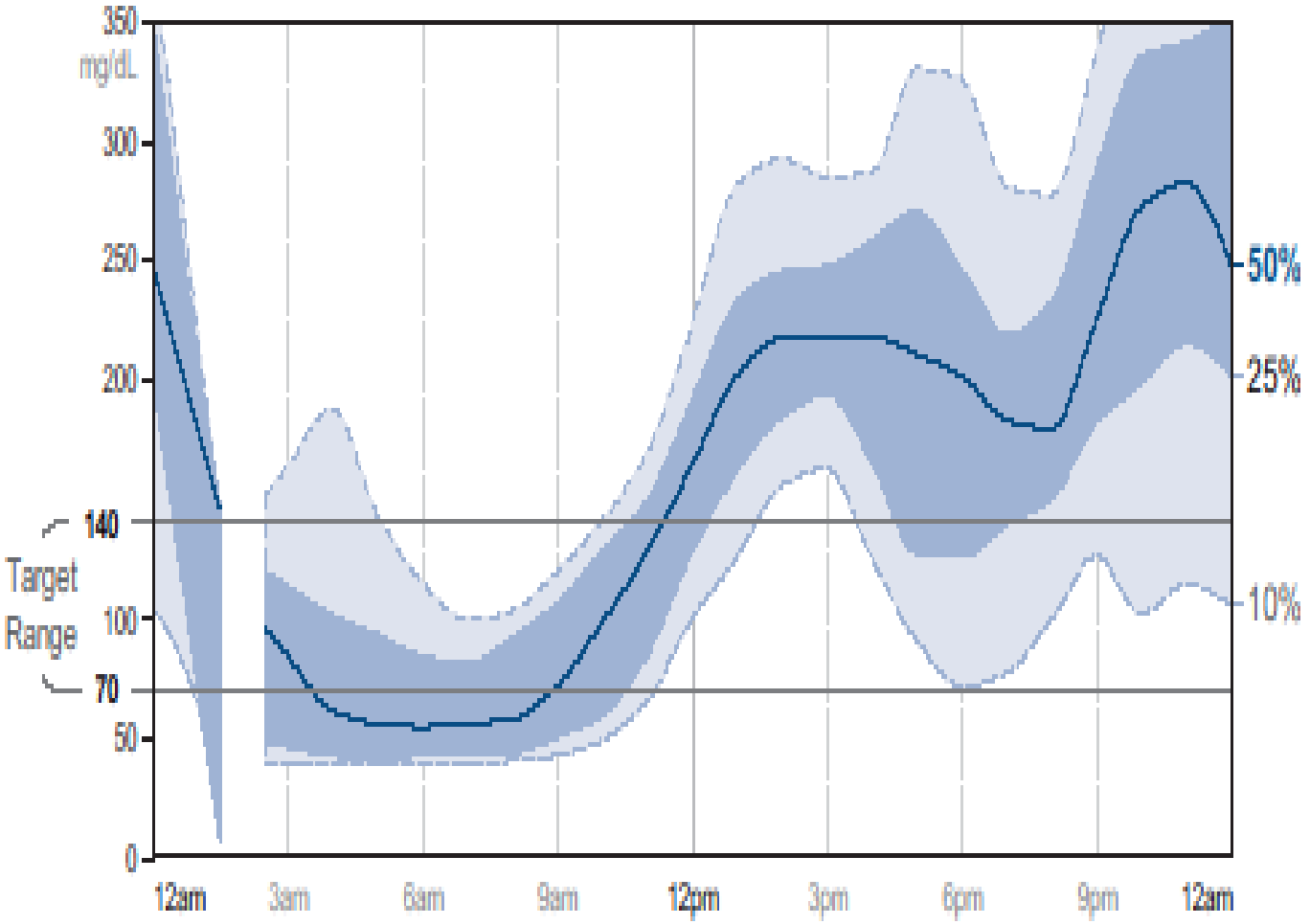
Case #2 : An Elderly Woman with AM Confusion

You are seeing a 72-year-old female with T2D. She takes 12 units glargine in the PM and 3 units in AM, 10 units of Lispro with lunch and dinner and SGLT-2.

- A1c of 7.4%; GFR 47
- Wearing flash glucose monitor for 3 months; first download in office
- Has seen the trend arrows on her receiver, knows they represent glycemic change but doesn't know what to do about them
- Admits to symptomatic hypoglycemic episodes of 1-2 times per week
- Daughter who is with her reports recent change in memory with “some days worse than others”
- Regularly eats dinner, sometimes lunch, and never breakfast

Proprietary and confidential — do not distribute

Glucose Data Revealed



Summary

Average Glucose	Time In Range	Coefficient of Variation (CV)	Standard Deviation (SD)
169 mg/dL	Above 180 mg/dL (above 250 mg/dL: 19%) **45%**	**60.4%**	**102** mg/dL
*88-116**	In Target Range 70-180 mg/dL **33%**	*19-25**	*10-26**
	Below 70 mg/dL (below 54 mg/dL: 12%) **22%**		

- Most Recent CGM
- Decreased basal insulin to morning target
- Added GLP-1 RA
- Rapid acting insulin only for dinner
- What still needs to be done?

AGP Report

October 15, 2019 - October 28, 2019 (14 Days)

LibreView

GLUCOSE STATISTICS AND TARGETS

October 15, 2019 - October 28, 2019	14 Days
% Time CGM is Active	82%

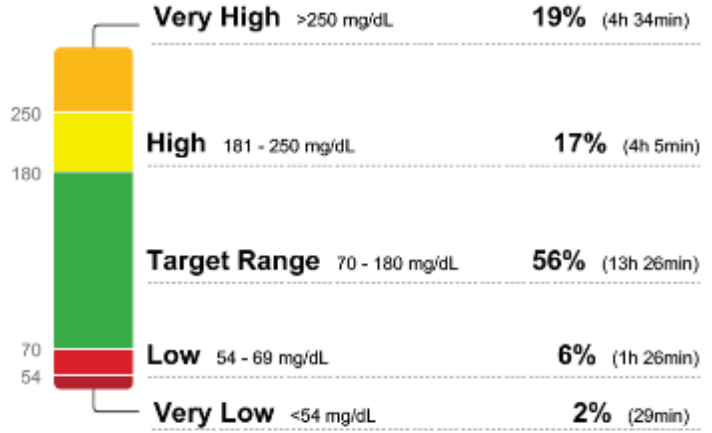
Ranges And Targets For	Type 1 or Type 2 Diabetes
Glucose Ranges	**Targets** % of Readings (Time/Day)
Target Range 70-180 mg/dL	Greater than 70% (16h 48min)
Below 70 mg/dL	Less than 4% (58min)
Below 54 mg/dL	Less than 1% (14min)
Above 180 mg/dL	Less than 25% (6h)
Above 250 mg/dL	Less than 5% (1h 12min)

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

Average Glucose	168 mg/dL
Glucose Management Indicator (GMI)	7.3%
Glucose Variability	50.1%

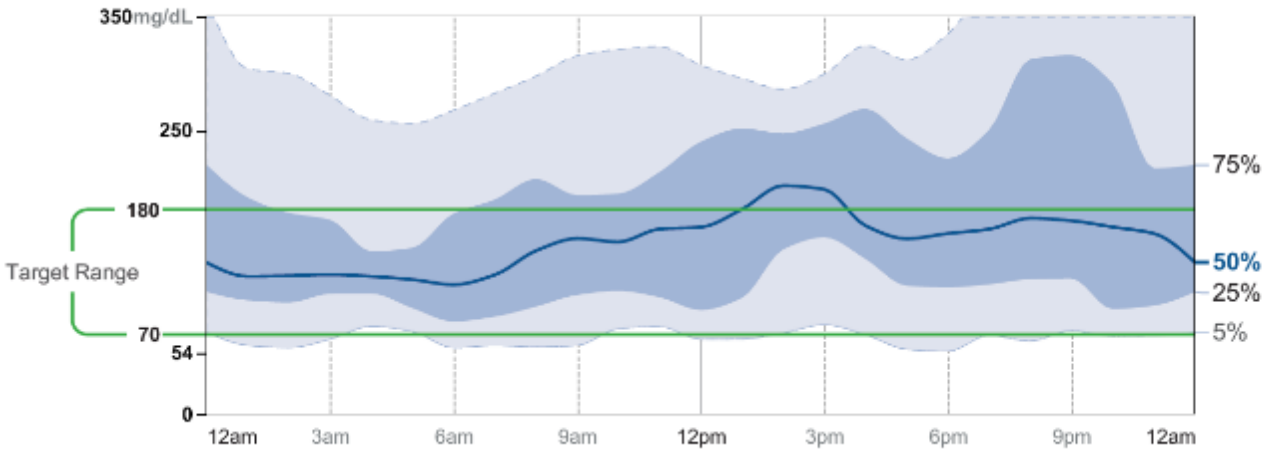
Defined as percent coefficient of variation (%CV); target ≤36%

TIME IN RANGES



AMBULATORY GLUCOSE PROFILE (AGP)

AGP is a summary of glucose values from the report period, with median (50%) and other percentiles shown as if occurring in a single day.



Case Study #3

- 45 year old Hispanic male with T2 DM for the last 13 years
- Presents as consultation for glucose management
- PMHx- HTN, Hyperlipidemia, and Class 3 Obesity BMI over 40
- Medication at Baseline NPH twice daily total daily dose over 60 units rarely testing glucose prior to basal injection, and Metformin 1000mg BID
- HbA1c at baseline 7.9% 6 months prior to appointment
- Initiation of FreeStyle Libre for glucose awareness with insulin dosing, GLP-1 RA added to treatment with reverse titration of NPH to less than 140 mg/dl in the AM.

Baseline AGP

AGP Report

August 2, 2019 - August 15, 2019 (14 Days)

LibreView

GLUCOSE STATISTICS AND TARGETS

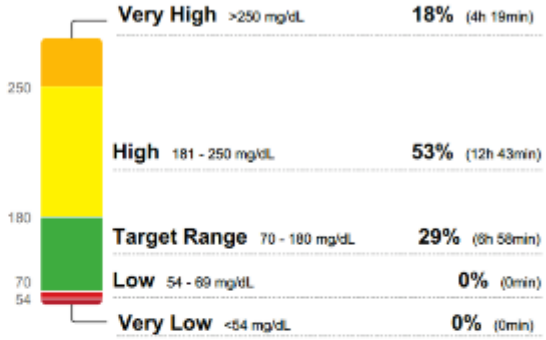
August 2, 2019 - August 15, 2019	14 Days
% Time CGM is Active	62%

Ranges And Targets For	Type 1 or Type 2 Diabetes
Glucose Ranges	**Targets** % of Readings (Time/Day)
Target Range 70-180 mg/dL	Greater than 70% (16h 48min)
Below 70 mg/dL	Less than 4% (58min)
Below 54 mg/dL	Less than 1% (14min)
Above 180 mg/dL	Less than 25% (6h)
Above 250 mg/dL	Less than 5% (1h 12min)
Each 5% increase in time in range (70-180 mg/dL) is clinically beneficial.	

Average Glucose	207 mg/dL
Glucose Management Indicator (GMI)	8.3%
Glucose Variability	19.7%

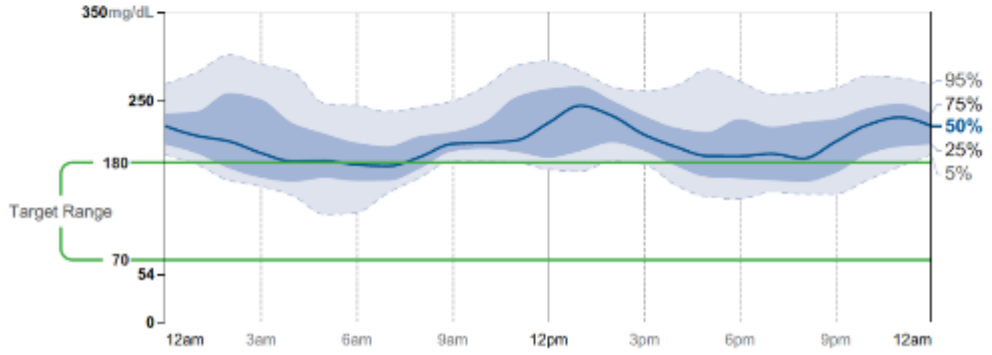
Defined as percent coefficient of variation (%CV); target ≤36%

TIME IN RANGES



AMBULATORY GLUCOSE PROFILE (AGP)

AGP is a summary of glucose values from the report period, with median (50%) and other percentiles shown as if occurring in a single day.



- Duration of wear- 14 days
- Data Gaps- Minimal
- Hypoglycemia- 0% (< 70mg/dl)
- TIR- 29% (70-180 mg/dl)
- TAR- 71% (>180 mg/dl)
- Glucose Variability- 19.7%

Clinical Intervention from AGP Analysis

- Patient reverse titrated off NPH when he got to less than 10 Units BID

  “He states it seemed like I didn’t need it anymore”

- A1c at 6 month follow up not at goal, post meal glucose peak 215

- SGLT2 inhibitor was added

- Patient continued on FreeStyle Libre

- Follow up 6 months later was next encounter

Most Recent AGP One Year After Baseline

- Sensor Wear- 14 days
- Data Gaps- during sleep time
- Hypoglycemia- 1% (70 mg/dl)
- TIR- 79% (70-180 mg/dl)
- TAB- 20% (> 180 mg/dl)
- Variability- 26.1%
- HbA1c 6.5% rapid in office

AGP Report

September 20, 2020 - October 3, 2020 (14 Days)

LibreView

GLUCOSE STATISTICS AND TARGETS

September 20, 2020 - October 3, 2020	**14 Days**
% Time CGM is Active	**54%**

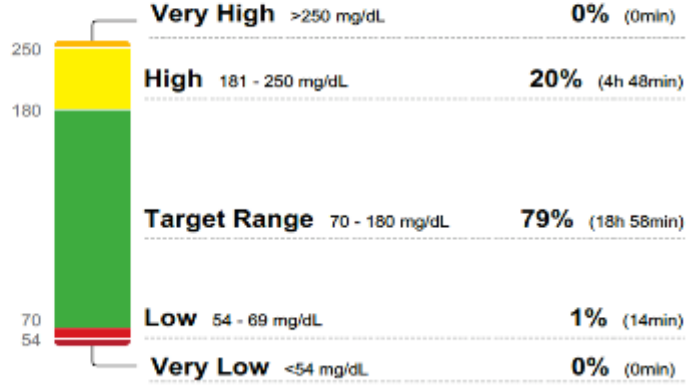
Ranges And Targets For	Type 1 or Type 2 Diabetes
Glucose Ranges Target Range 70-180 mg/dL	**Targets** % of Readings (Time/Day) Greater than 70% (16h 48min)
Below 70 mg/dL	Less than 4% (58min)
Below 54 mg/dL	Less than 1% (14min)
Above 180 mg/dL	Less than 25% (6h)
Above 250 mg/dL	Less than 5% (1h 12min)

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

Average Glucose	**146** mg/dL
Glucose Management Indicator (GMI)	**6.8%**
Glucose Variability	**26.1%**

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

TIME IN RANGES



AMBULATORY GLUCOSE PROFILE (AGP)

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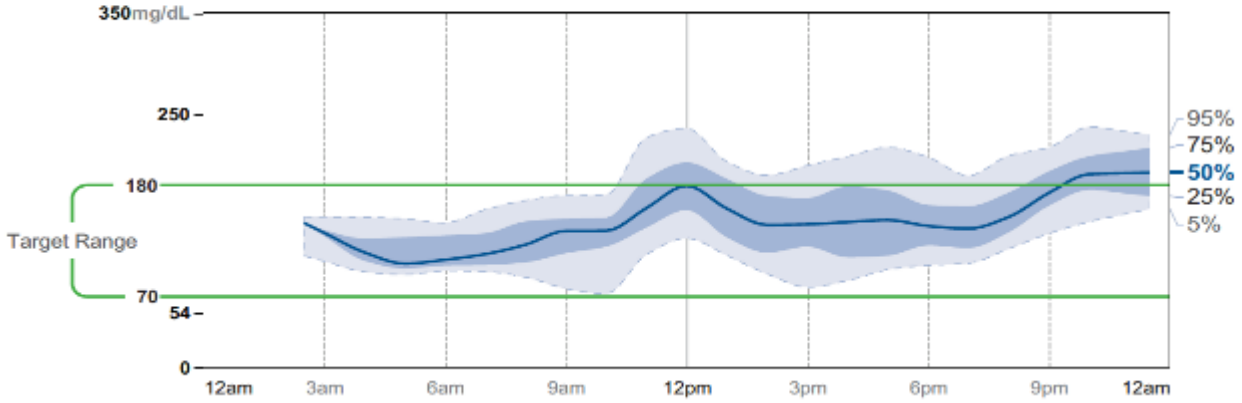

What Does the **Individual** Get with Continuous Glucose Monitoring?

Real-time glycaemic monitoring brings diabetes from the past into the present; and helps persons anticipate the future

- Individually driven – Scan and See
- Trend arrow up/stable/down showing current rate of change
- Glycemic effects of food, time of day, activity level, and illness
- Ease of mind for loved ones or care givers to monitor

What Does the **Provider** Get with Continuous Glucose Monitoring?

- Opportunity for increased individual engagement with their disease
- Increased hypoglycemic awareness that can lead to prevention
- Reveals therapeutic impacts on glucose management
- Compiled printable data revealing hypoglycemic risk, glycemic excursion (high to low), time-in-range, and data visualization known as the AGP

Summary and Key Takeaway

1) Managing T2 patients on Insulin is a next level challenge. However, CGM provides an essential tool to improve patient engagement and illumination of glycaemia to healthcare providers

2) CGM provides a complete glycaemic picture to support you and your patients to make more informed decisions. *The GPS for diabetes management .*

3) There are clinical benefits for T2 patients, including Hb A1c reductions, reductions in acute diabetes events and all-cause hospitalization.

4) Prescribers should think of Continuous Glucose Monitoring beyond a real-time glucose meter and begin to use it as the retrospective and predictive tool that it is.

Rationale for the Use of Continuous Glucose Monitoring In a Managed Care Environment

Conclusion

Jerry Frank, MD – Program Chair
Principal, COPE Health Solutions

Does the Use of CGM Make Sense for Patients?

- LK is a 78-year-old man with a history of Type 2 diabetes who has been on insulin for the last five years. He has a history of smoking 2 PPD for more than 30 years and in 2011 he had a femoral popliteal bypass for severe peripheral vascular disease.
- Over the last three years, he has developed moderate dementia resulting in his forgetting to take his insulin and many times double dosing, as well as noncompliance with taking his fingerstick glucose levels regularly. This has caused several bouts of hypoglycemia with falls, and his wife finding him in the bathroom passed out. During the last event, he was found on the kitchen floor unarousable.
- LK had been taken to the hospital ED at least 6 times over the last year.

Does the Use of CGM Make Sense for Patients?

- RP is a 67-year-old man with a history of Type 1 insulin dependent diabetes since childhood. He has been very compliant with diet and glucose monitoring, as well as exercise (running, biking and playing ball), and has been very compliant with his insulin doses and glucose testing by fingerstick
- During the 1990s RP noted increased bloating and constipation, as well as early feelings of fullness. After an extensive workup he was diagnosed with gastroparesis and slow bowel syndrome secondary to his diabetes
- In 2013 RP noted a non-healing wound on his ankle. He was placed on conservative management but was noted to have worsening of the wound. Peripheral vascular studies noted severe disease, and with little hope of healing, he had a below knee amputation and now has a prosthesis. He continues fully active and leads a high quality of life. He now has a CGM program in place.

Questions

Should plans purchase CGMs? Should they cover CGMs?

*It is not cost effective nor does it make sense for plans to **buy** CGM systems. They should be **covering** the systems for eligible members, and negotiate cost-effective pricing for them.*

Should groups at risk for cost of care and quality measures insist on the use of CGMs for patients?

Since studies show that CGM systems lead to improved outcomes and save money with fewer hospitalizations for hypoglycemia and hyperglycemia, it makes sense for groups at risk to place appropriate patients with insulin dependent diabetes on a CGM system .

Should there be guidelines established to approve CGMs for patients over fingerstick supplies and monitors? If so, what are they?

Yes, at this point it makes sense that there should be some criteria for the use of CGM systems, but these should be limited to insulin dependence since the requirement for glucose testing for oral hypoglycemic agents is limited to once daily.