Welcome to this SCIENCE-*to*-STRATEGY SUMMIT

TRANSLATING CLINICAL EVIDENCE FOR SENSOR-BASED GLUCOSE MONITORING AND TECHNOLOGICAL INNOVATIONS TO THE FRONT LINES OF CLINICAL PRACTICE

Focus on Evidence-, Trial-, and Guideline-Based Roadmaps for Deploying Patient-Centric, **Sensor-Based Continuous Glucose Monitoring (CGM)** Technology to Optimize Effectiveness and Safety of Pharmacologic and Behavioral Interventions in Persons with Diabetes

A Year 2020, Best Practice, Technology-Based Advances Program in Diabetes Care: Roadmaps to Clinical Success in Diabetes Management

Translating Clinical Evidence for Sensor-Based Glucose Monitoring to the Front Lines of Clinical Practice

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Welcome and Virtual Symposium Overview

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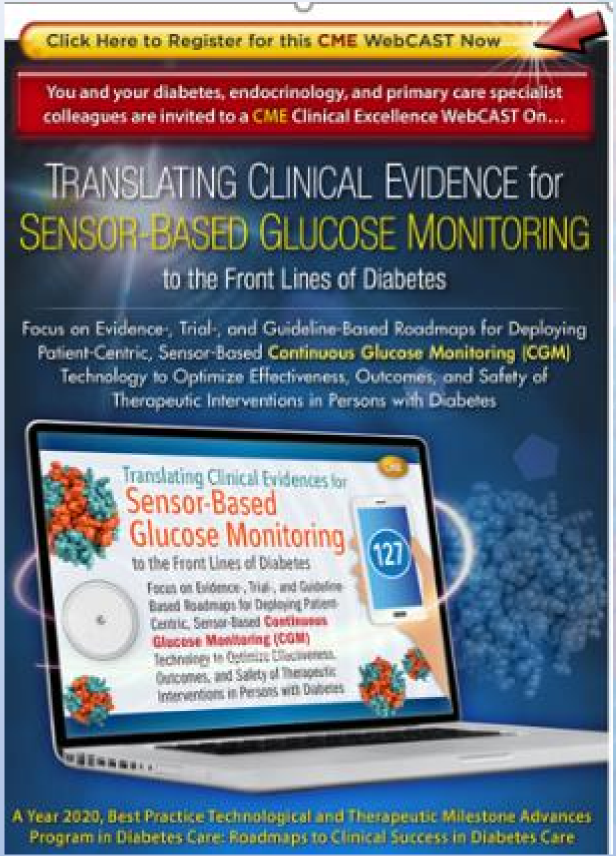
Commercial Support: Supported by an educational grant from Abbott Diabetes Care



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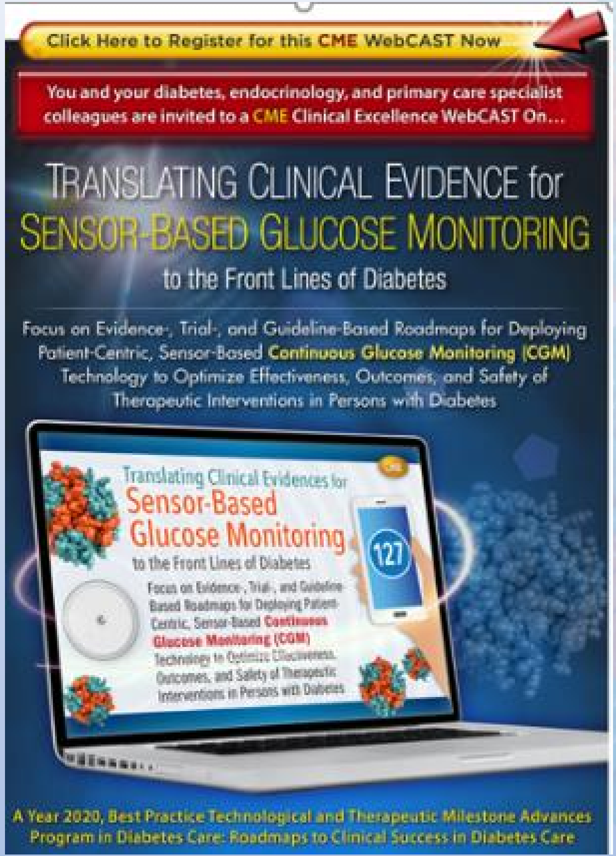

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- This entire virtual symposium, and additional diabetes CME offerings, will be available as a Clinical Excellence WebCAST on multiple clinical websites, including **www.DiabetesCAST.com**
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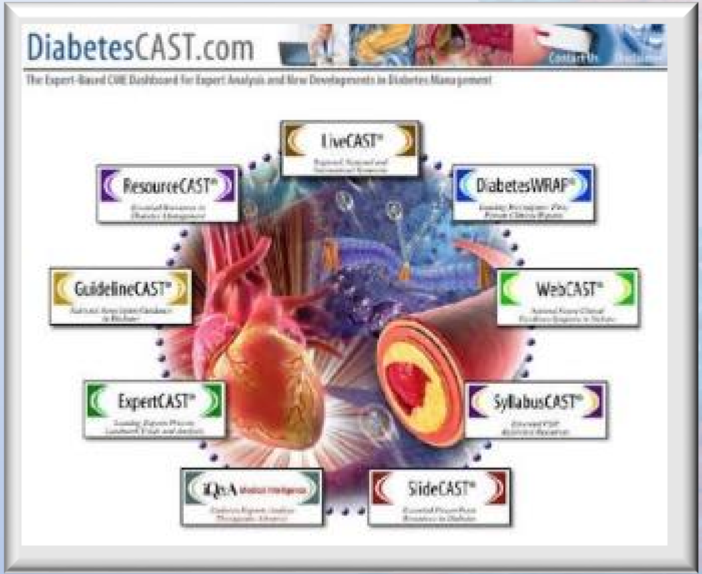
- Clinical questions about diabetes management may be submitted to **www.iQandA-CME.com**



Sensor-Based Technology to Optimize Glucose Time-in-Range (TIR)

Establishing Evidence-Based Standard of Care for Persons with Diabetes

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Disclosures - Tadej Battelino

- Served on advisory boards of Novo Nordisk, Sanofi, Eli Lilly, Boehringer, Medtronic, DreaMed Diabetes and Bayer Health Care.
- Has received honoraria for participating on the speaker's bureaux of Eli Lilly, Bayer, Novo Nordisk, Medtronic, Abbott, Sanofi and Roch. Owns stocks in DreamMed Diabetes.
- His institution has received research grant support, with receipt of travel and accommodation expenses in some cases, from Abbott, Medtronic, Novo Nordisk, GluSense, Sanofi, Sandoz and Diamyd.

TIR – The New Treatment Target - Agenda

- Background – something doesn’t go well
- The striking efficacy of CGM/flash glucose monitoring
- TIR targets
- The COVID-19 Era

TIR – The New Treatment Target - Agenda

- **Background – something doesn't go well**
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Diabetes Care Volume 41, December 2018 2579

Fasting Glucose Variability in Young Adulthood and Cognitive Function in Middle Age: The Coronary Artery Risk Development in Young Adults (CARDIA) Study

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Diabetes Care 2018;41:2579–2585 | https://doi.org/10.2337/dc18-1287

Diabetes Care. 2018 Dec;41(12):2579-2585

Association Between FG CV During Young Adulthood with Cognitive Function in Middle Age

Table 2—Multivariable association between FG CV during young adulthood with cognitive function in middle age

	Difference in year 25 cognitive test score per 1 SD CV-FG (95% CI)					
	Model 1*	Model 2†	Model 3‡	Model 3A§	Model 3B‖	Model 3C¶
DSST, *n* = 3,292	−1.07 (−1.57, −0.58)	−0.61 (−1.08, −0.14)	−0.59 (−1.07, −0.12)	−0.59 (−1.06, −0.11)	−0.95 (−1.54, −0.36)	−0.55 (−1.04, −0.07)
RAVLT, *n* = 3,287	−0.16 (−0.26, −0.06)	−0.09 (−0.19, 0.00)	−0.11 (−0.21, −0.01)	−0.11 (−0.21, −0.01)	−0.14 (−0.27, −0.02)	−0.11 (−0.21, −0.01)
Stroop Test, *n* = 3,280	0.43 (0.08, 0.79)	0.23 (−0.13, 0.58)	0.21 (−0.14, 0.57)	0.23 (−0.13, 0.58)	0.49 (0.04, 0.94)	0.26 (−0.10, 0.63)
Global *z* score, *n* = 3,254	−0.07 (−0.10, −0.04)	−0.04 (−0.07, −0.01)	−0.04 (−0.07, −0.01)	−0.04 (−0.07, −0.01)	−0.06 (−0.09, −0.03)	−0.04 (−0.07, −0.01)

A 1-SD unit increment in CV-FG at year 25 is 3.4%. *Adjustments: Model 1: age, sex, race, field center. †Adjustments: Model 2: Model 1 plus highest level of educational attainment, and cumulative values for: number of years as a current smoker, grams of weekly alcohol consumption, BMI, physical activity, systolic BP, use of BP-lowering medications, LDL-C, and cholesterol-lowering medications. ‡Adjustments: Model 3: Model 2 plus weighted average of FG. §Adjustments: Model 3A: Model 3 plus the incidence of diabetes, diabetes medication use, and diabetes duration. ‖Adjustments: Model 3B: Model 3 plus change in FG level during variability measurement. ¶Adjustments: Model 3C: Model 3 plus year 25 FG level.

Diabetes Care. 2018 Dec;41(12):2579-2585

Table 3—Multivariable association between FG CV during young adulthood with cognitive function at examination year 30 (2015–2016)

	Difference in year 30 cognitive test score per 1 SD CV-FG (95% CI)					
	Model 1*	Model 2†	Model 3‡	Model 3A§	Model 3B‖	Model 3C¶
DSST, n = 2,996	−1.00 (−1.55, −0.45)	−0.43 (−0.95, 0.10)	−0.38 (−0.91, 0.15)	−0.39 (−0.92, 0.14)	−0.77 (−1.43, −0.10)	−0.32 (−0.86, 0.22)
RAVLT, n = 3,011	−0.16 (−0.27, −0.04)	−0.07 (−0.18, 0.04)	−0.07 (−0.19, 0.04)	−0.07 (−0.19, 0.04)	−0.10 (−0.24, 0.04)	−0.06 (−0.18, 0.05)
Stroop Test, n = 2,939	0.26 (−0.15, 0.67)	−0.02 (−0.43, 0.38)	−0.03 (−0.43, 0.38)	−0.02 (−0.42, 0.39)	0.07 (−0.44, 0.58)	−0.03 (−0.45, 0.38)
MoCA, n = 2,994	−0.23 (−0.36, −0.10)	−0.11 (−0.23, 0.01)	−0.10 (−0.22, 0.02)	−0.11 (−0.23, 0.01)	−0.21 (−0.36, −0.06)	−0.11 (−0.23, 0.01)
Category fluency, n = 2,986	−0.17 (−0.36, 0.02)	−0.06 (−0.25, 0.13)	−0.07 (−0.26, 0.12)	−0.09 (−0.28, 0.10)	−0.21 (−0.44, 0.03)	−0.09 (−0.28, 0.10)
Letter fluency, n = 2,938	−0.40 (−0.86, 0.06)	−0.06 (−0.51, 0.39)	−0.04 (−0.49, 0.41)	−0.10 (−0.55, 0.35)	−0.22 (−0.78, 0.35)	−0.04 (−0.50, 0.42)
Global z score, n = 2,852	−0.06 (−0.09, −0.02)	−0.02 (−0.05, 0.01)	−0.02 (−0.05, 0.01)	−0.02 (−0.05, 0.01)	−0.03 (−0.07, 0.004)	−0.02 (−0.05, 0.01)

A 1-SD unit increment in CV-FG at year 30 is 3.3%. *Adjustments: Model 1: age, sex, race, field center. †Adjustments: Model 2: Model 1 plus highest level of educational attainment, and cumulative values for: number of years as a current smoker, grams of weekly alcohol consumption, BMI, physical activity, systolic BP, use of BP-lowering medications, LDL-C, and cholesterol-lowering medications. ‡Adjustments: Model 3: Model 2 plus weighted average of FG. §Adjustments: Model 3A: Model 3 plus the incidence of diabetes, diabetes medication use, and diabetes duration. ‖Adjustments: Model 3B: Model 3 plus change in FG level during variability measurement. ¶Adjustments: Model 3C: Model 3 plus year 30 FG level.

Large biracial sample: individual variability in FG during young adulthood before diabetes

No Diabetes

Diabetes Care. 2018 Dec;41(12):2579-2585

Greater variability was associated with worse cognitive processing, attention, and memory in midlife

Association Between Fasting Glucose Variability in Young Adulthood and the Progression of Coronary Artery Calcification in Middle Age

https://doi.org/10.2337/dc20-0838 - online July 30, 2020

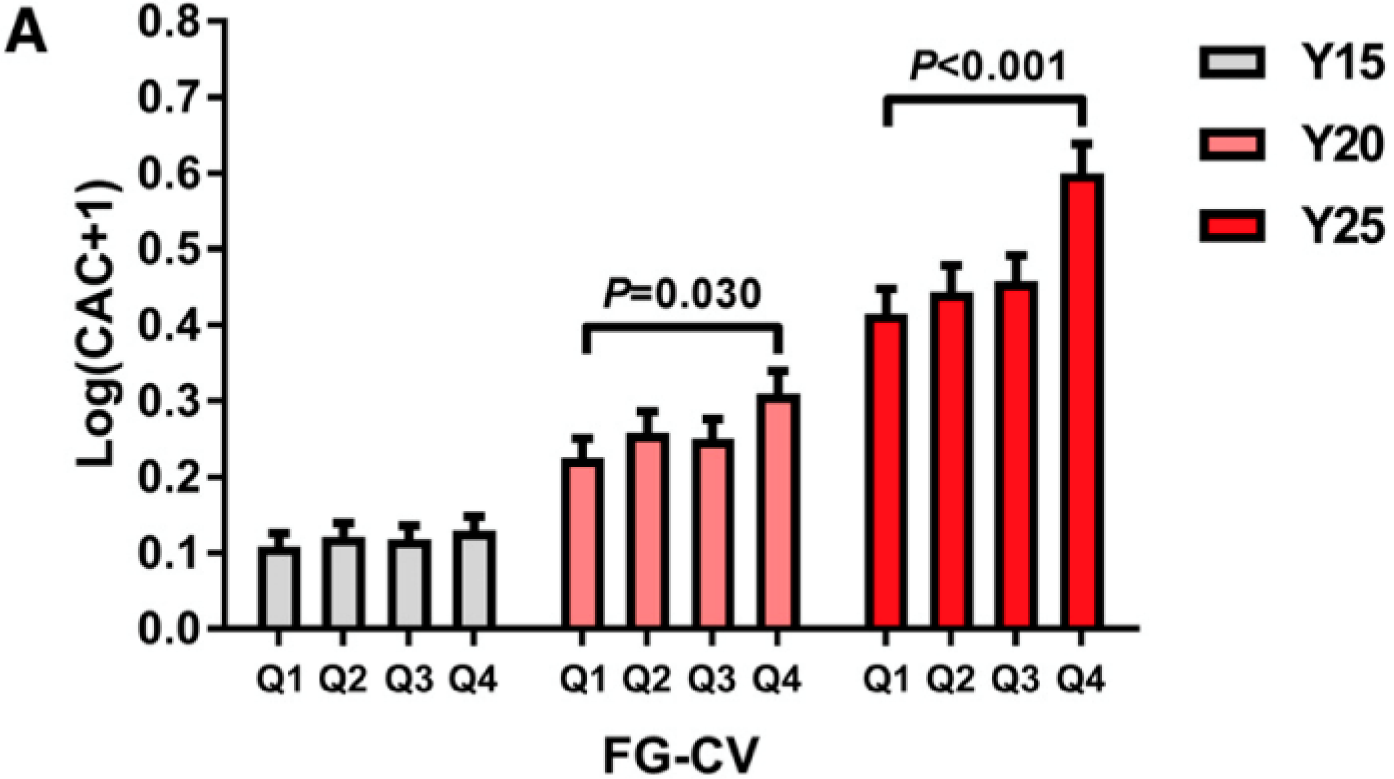
Fasting Glucose Variability in Young Adulthood and the Progression of Coronary Artery Calcification in Middle Age

Table 1—Baseline characteristics of 2,256 participants by quartile of FG-CV from 2000–2001 to 2010–2011

	FG-CV (%)				
	Quartile 1	Quartile 2	Quartile 3	Quartile 4	*P**
N	563	564	566	563	
Age at Y15 (years), mean (SD)	40.7 (3.5)	40.2 (3.5)	40.4 (3.6)	40.5 (3.6)	0.148
Sex, *n* (% male)	252 (44.7)	244 (43.3)	250 (44.2)	253 (44.9)	0.949
Race, *n* (% black)	202 (35.8)	232 (41.1)	237 (41.9)	304 (54.0)	<0.001
BMI at Y15 (kg/m^2), mean (SD)	28.0 (5.8)	28.1 (5.8)	27.9 (5.6)	30.0 (6.6)	<0.001
BMI at Y25 (kg/m^2), mean (SD)	29.2 (6.4)	29.3 (6.0)	29.3 (6.0)	31.7 (7.1)	<0.001
FG at Y15 (mg/dL), mean (SD)	87.8 (7.7)	84.7 (8.7)	81.6 (9.9)	89.8 (32.0)	<0.001
FG at Y20 (mg/dL), mean (SD)	91.1 (7.6)	92.8 (9.1)	94.9 (10.9)	113.6 (46.6)	<0.001
FG at Y25 (mg/dL), mean (SD)	90.9 (7.8)	92.7 (9.8)	94.7 (11.1)	121.3 (50.6)	<0.001
Change in FG (mg/dL), mean (SD)	4.5 (2.8)	9.4 (3.8)	13.9 (5.3)	40.5 (43.0)	<0.001
Incident diabetes by Y25, *n* (%)	13 (2.3)	13 (2.3)	21 (3.7)	101 (17.9)	<0.001
FG variability					
FG-SD (mg/dL), mean (SD)	3.4 (1.2)	6.4 (1.0)	9.4 (1.4)	26.6 (25.7)	<0.001
FG-CV (%), mean (SD)	3.8 (1.3)	7.2 (0.9)	10.4 (1.1)	21.9 (12.4)	<0.001
FG-ARV (mg/dL per year), mean (SD)	4.2 (1.9)	7.6 (2.1)	11.0 (2.8)	30.5 (32.3)	<0.001

https://doi.org/10.2337/dc20-0838 **online July 30, 2020**

Fasting Glucose Variability Associated with Artery Calcification



https://doi.org/10.2337/dc20-0838 **online July 30, 2020**

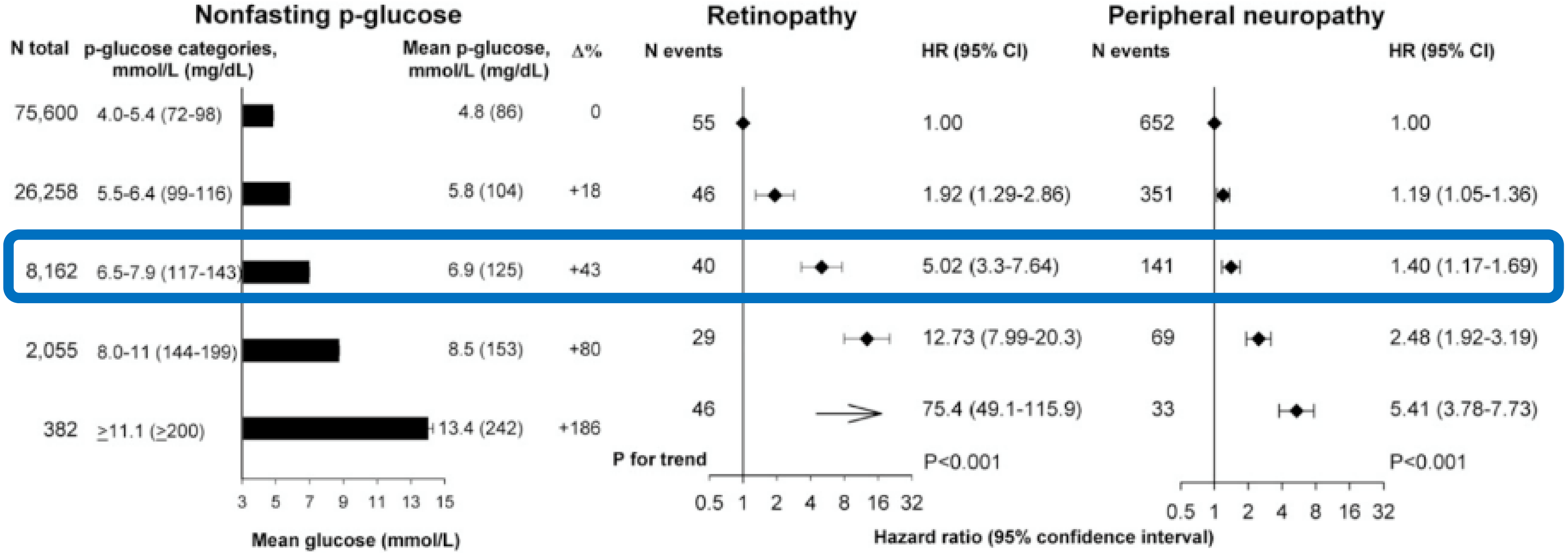
Impact of Glucose Level on Micro- and Macrovascular Disease in the General Population: A Mendelian Randomization Study

Frida Emanuelsson,[1,2,3] Sarah Marott,[1,2,3] Anne Tybjærg-Hansen,[1,2,3,4] Børge G. Nordestgaard,[2,3,4,5] and Marianne Benn[1,2,3]

Diabetes Care 2020;43:894–902

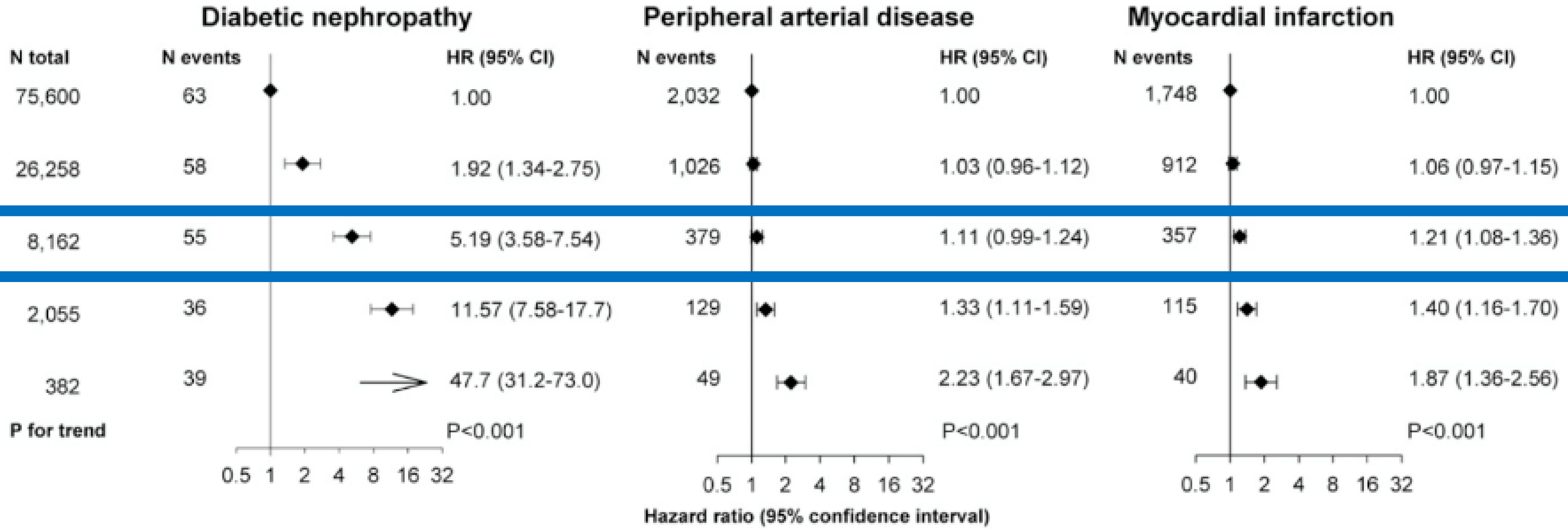
		Random plasma glucose in individuals without diabetes, mmol/L (mg/dL)					
	All individuals	4.0–4.5 (72–98)	5.5–6.4 (99–116)	6.5–7.9 (117–143)	8.0–11.0 (144–199)	≥11.1 (≥200)	*P* for trend
Individuals	117,193 (100)	75,600 (66)	26,258 (23)	8,162 (7)	2,055 (2)	382 (0.3)	
Glucose							
mmol/L	5.1 (4.7–5.7)	4.9 (4.6–5.1)	5.8 (5.5–6.0)	6.9 (6.6–7.3)	8.6 (8.2–9.3)	13.7 (12.0–16.3)	<0.001
mg/dL	92 (85–103)	88 (83–92)	104 (101–108)	124 (119–131)	155 (148–167	246 (216–293)	<0.001

Higher Glucose is Associated with Increased Risk in People Without Diabetes



Diabetes Care 2020;43:894–902

Higher Glucose is Associated with Increased Risk in People Without Diabetes



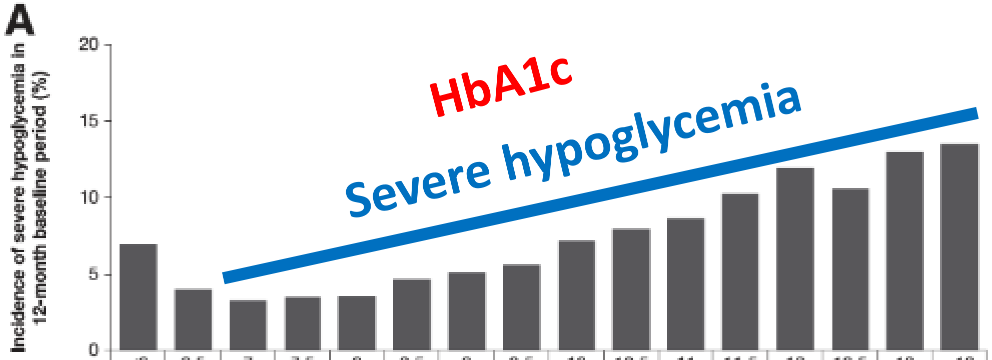
Diabetes Care 2020;43:894–902

Glucose variability (GV) and
Hyperglycemia - Time Above Range (TAR)
are associated with
damage to
the brain and
the cardiovascular system

TIR – The New Treatment Target - Agenda

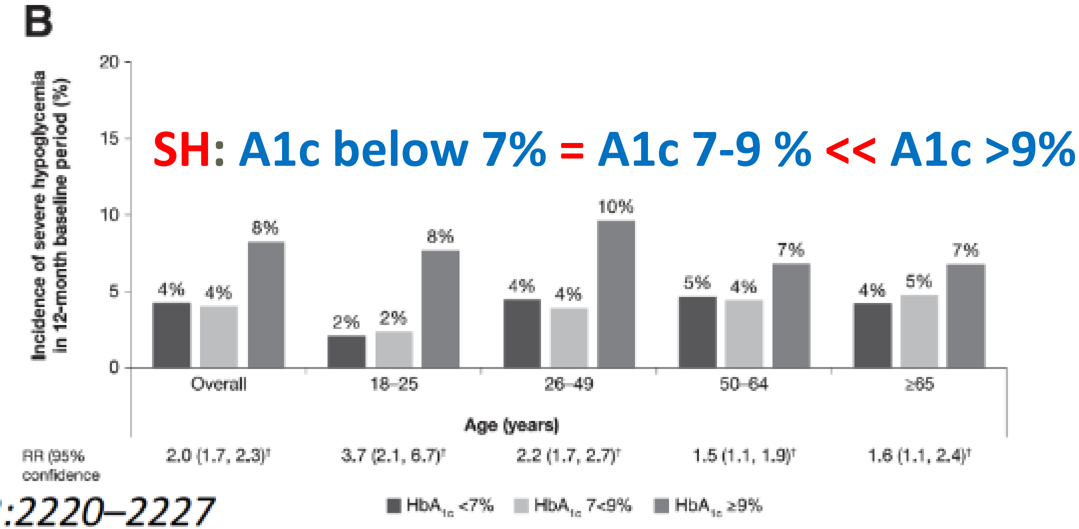
- Background – something doesn’t go well
- **The striking efficacy of CGM/ flash glucose monitoring**
- TIR targets
- The COVID-19 Era

~~DCCT~~



HbA$_{1c}$ (%)	≤6	6.5	7	7.5	8	8.5	9	9.5	10	10.5	11	11.5	12	12.5	13	>13
Percent	6.9%	4.0%	3.3%	3.5%	3.6%	4.7%	5.1%	5.6%	7.1%	7.9%	8.6%	10.2%	11.9%	10.5%	13.0%	13.5%
Count	90	85	123	165	170	174	152	123	107	84	72	66	54	35	33	106
# of patients	1,304	2,106	3,776	4,701	4,779	3,728	2,976	2,199	1,501	1,057	833	645	453	332	254	786

HbA$_{1c}$ (%)



Diabetes Care 2019;42:2220–2227

Reduction in Diabetic Ketoacidosis and Severe Hypoglycemia in Pediatric Type 1 Diabetes During the First Year of Continuous Glucose Monitoring: A Multicenter Analysis of 3,553 Subjects From the DPV Registry

Diabetes Care 2020;43:e40–e42 | https://doi.org/10.2337/dc19-1358

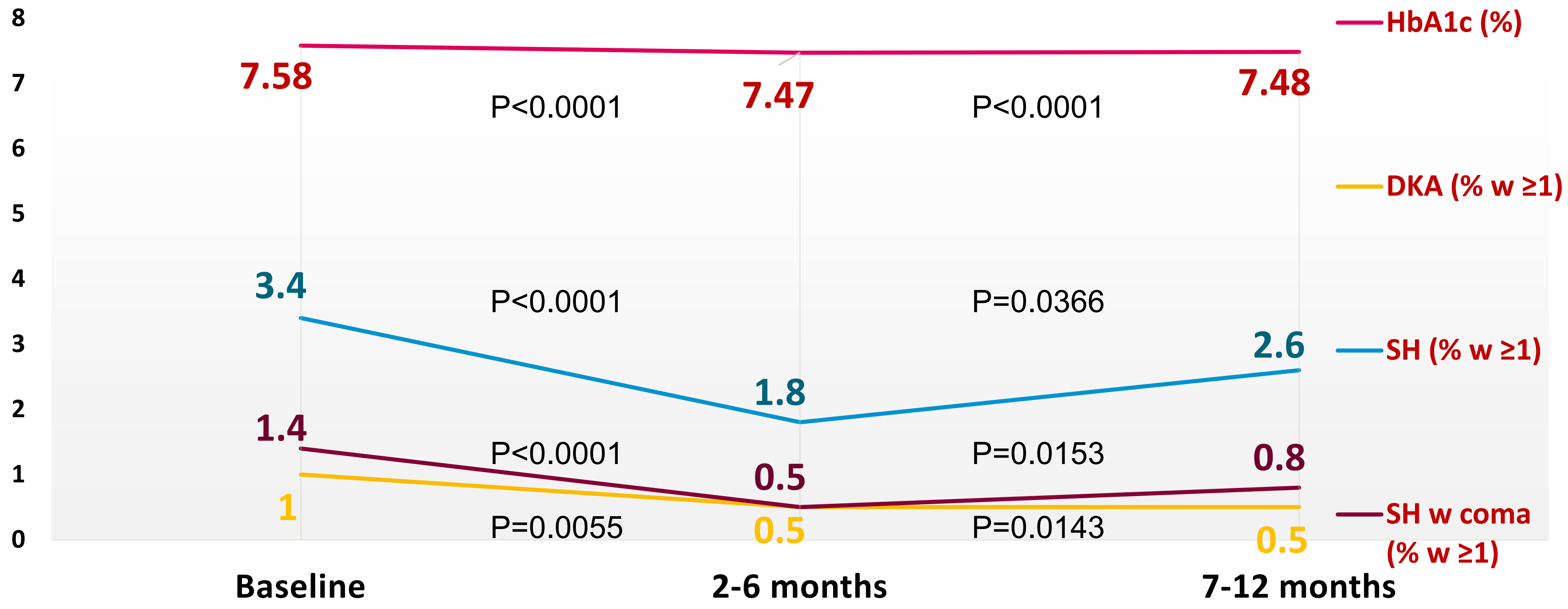
Martin Tauschmann,[1] Julia M. Hermann,[2,3] Clemens Freiberg,[4] Matthias Papsch,[5] Angelika Thon,[6] Bettina Heidtmann,[7] Kerstin Placzeck,[8] Dirk Agena,[9] Thomas M. Kapellen,[10] Bernd Schenk,[11] Johannes Wolf,[12] Thomas Danne,[13] Birgit Rami-Merhar,[1] and Reinhard W. Holl,[2,3] on behalf of the DPV Initiative

Use of continuous glucose monitoring (CGM) systems has become standard of care in type 1 diabetes (T1D) in many countries, particularly in children and adolescents (1,2). Results from clinical trials indicate that use of CGM leads to improved metabolic control and reduction in nonsevere hypoglycemia compared with self-monitoring of capillary blood glucose (3,4). Benefits are seen irrespective of insulin delivery method (pump or pen) (4,5) but are conditioned on (DPV) registry to longitudinally assess HbA_{1c}, SH, and DKA during the first year after initiation of CGM, including real-time CGM and intermittently scanned/viewed CGM. Anonymized patient registry records were analyzed. SH was defined as events requiring external assistance by another person and events resulting in coma/convulsion. DKA was defined by pH level <7.3. All HbA_{1c} values were Diabetes Control and Complications Trial over the 6-month periods. Data for this analysis were collected from 2005 to 2018 (2018, 23% of data; 2017, 49%; 2016, 24%; and ≤2015, 4%). Comparisons (follow-up periods vs. baseline) were performed using nonparametric tests for paired data (McNemar test and Wilcoxon signed rank test). Event rates were analyzed based on generalized estimation equation models with Poisson distribution and 1st-order autoregressive correlation

Diabetes Care 2020;43:e40-42

Diabetes Care 2020;43:e40–e42

Events after CGM initiation



3,553 participants: median age 12.1 years;
T1D duration 4.2 years]; 53% males; **62% on insulin pumps**

Diabetologia (2019) 62:1349–1356
https://doi.org/10.1007/s00125-019-4894-1

ARTICLE

Check for updates

Marked improvement in HbA_{1c} following commencement of flash glucose monitoring in people with type 1 diabetes

Victoria Tyndall[1] · Roland H. Stimson[2,3] · Nicola N. Zammitt[2] · Stuart A. Ritchie[1] · John A. McKnight[1] · Anna R. Dover[2] · Fraser W. Gibb[2,3]

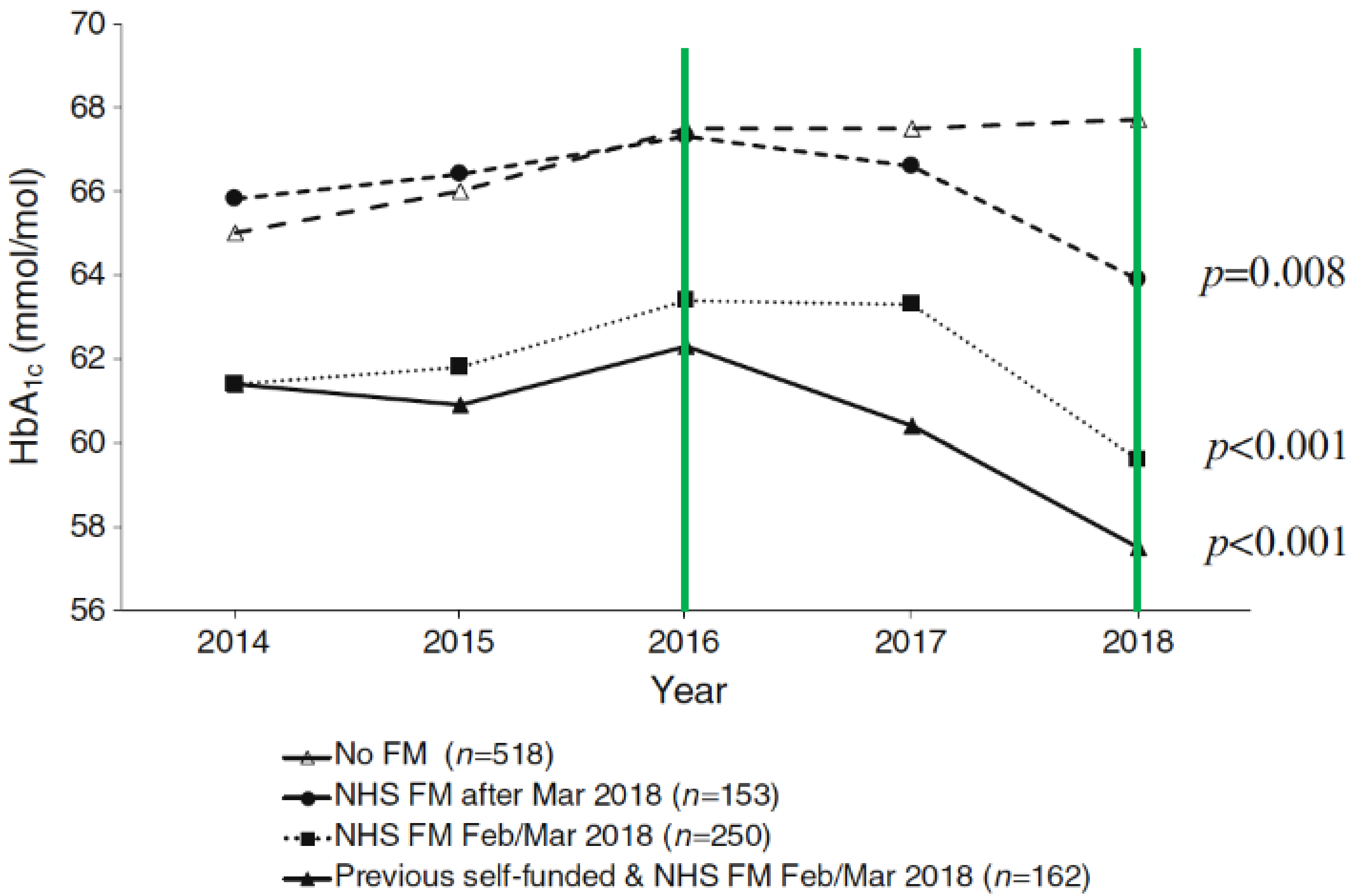
Received: 24 February 2019 / Accepted: 15 April 2019 / Published online: 9 June 2019

Abstract

Aims/hypothesis Minimal evidence supports the efficacy of flash monitoring in lowering HbA_{1c}. We sought to assess the impact of introducing flash monitoring in our centre.

Methods We undertook a prospective observational study to assess change in HbA_{1c} in 900 individuals with type 1 diabetes following flash monitoring (comparator group of 518 with no flash monitoring). Secondary outcomes included changes in hypoglycaemia, quality of life, flash monitoring data and hospital admissions.

Tyndall V et al. Diabetologia 2019; 62: 1349–1356



Tyndall V et al. Diabetologia 2019; 62: 1349–1356

Diabetes Care Volume 43, September 2020

Effect of Flash Glucose Monitoring on Glycemic Control, Hypoglycemia, Diabetes-Related Distress, and Resource Utilization in the Association of British Clinical Diabetologists (ABCD) Nationwide Audit

Diabetes Care 2020;43:2153–2160 | *https://doi.org/10.2337/dc20-0738*

OBJECTIVE

The FreeStyle Libre (FSL) flash glucose-monitoring device was made available on the U.K. National Health Service (NHS) drug tariff in 2017. This study aims to explore the U.K. real-world experience of FSL and the impact on glycemic control, hypoglycemia, diabetes-related distress, and hospital admissions.

RESEARCH DESIGN AND METHODS

Clinicians from 102 NHS hospitals in the U.K. submitted FSL user data, collected during routine clinical care, to a secure web-based tool held within the NHS N3 network. The *t* and Mann-Whitney *U* tests were used to compare the baseline and follow-up HbA_{1c} and other baseline demographic characteristics. Linear regression analysis was used to identify predictors of change in HbA_{1c} following the use of FSL. Within-person variations of HbA_{1c} were calculated using adjusted SD for $HbA_{1c} = SD/\sqrt{n/[n-1]}$.

Diabetes Care 2020;43:2153-2160

Table 2—Baseline and post-FSL HbA_{1c} and Gold score in various strata of age, duration of diabetes, baseline BMI, and baseline HbA_{1c}

		Pre-FSL HbA_{1c}	Post-FSL HbA_{1c}	*P* value	Pre-FSL Gold score	Post-FSL Gold score	*P* value
All	(n = 3,182)	69.8 (±18.2)	62.3 (±18.5)	<0.0001	2.7 (±1.8)	2.4 (±1.7)	<0.0001
Age (years)							
≤18		63.3 (±19.02)	58 (±14.9)	<0.0001	NA	NA	NA
19–60		71.3 (±17.5)	62.7 (±31)	<0.0001	2.5 (±1.7)	2.2 (±1.5)	<0.0001
>60		65.3 (±13.5)	60.4 (±11.4)	<0.0001	3.1 (±1.9)	2.6 (±1.8)	<0.0001
Sex							
Male		69.1 (±18.5)	61.9 (±22.4)	<0.0001	2.70 (±1.7)	2.3 (±1.6)	<0.0001
Female		70.4 (±17.8)	60.0 (±14.7)	<0.0001	2.7 (±1.7)	2.4 (±1.6)	<0.0001
Baseline BMI (kg/m^2)							
≤25		69.7 (±19.9)	62.6 (±23.5)	<0.0001	2.8 (±1.6)	2.4 (±1.7)	<0.0001
25–30		69.3 (±13.8)	61.8 (±16.9)	<0.0001	2.6 (±1.7)	2.3 (±1.6)	<0.0001
>30		70.6 (±15.3)	63.4 (±13.7)	<0.0001	2.6 (±1.7)	2.4 (±1.7)	<0.0001
Duration of diabetes (years)							
≤5		68.8 (±19.7)	60.4 (±15.0)	<0.0001	2.69 (±1.7)	2.55 (±1.6)	0.10
5–15		73.1 (±19.3)	66.9 (±28.4)	<0.0001	2.44 (±1.6)	2.15 (±1.4)	<0.0001
>15		68.4 (±16.6)	61.2 (±12.7)	<0.0001	2.89 (±1.8)	2.4 (±1.7)	<0.0001
Baseline HbA_{1c} (mmol/mol)							
≤69.5 (8.5%)		57.7 (±7.7)	56.2 (±17.4)	<0.0001	2.8 (±1.7)	2.4 (±1.6)	<0.0001
>69.5 (8.5%)		85.5 (±16.0)	73.1 (±15.8)	<0.0001	2.5 (±1.7)	2.3 (±1.6)	0.0005
Diabetes education							
Yes		68.3 (±16.2)	61.7 (±19.2)	<0.0001	2.7 (±1.7)	2.4 (±1.6)	<0.0001
No		72.6 (±21.2)	63.8 (±16.3)	<0.0001	2.8 (±1.7)	2.5 (±1.6)	0.0007

Flash Glucose Monitoring Effect on HbA1c, Gold Score and DDSC
The ABCD National UK Audit

- **Concomitant significant improvement of:**
  - HbA1c
  - Gold score

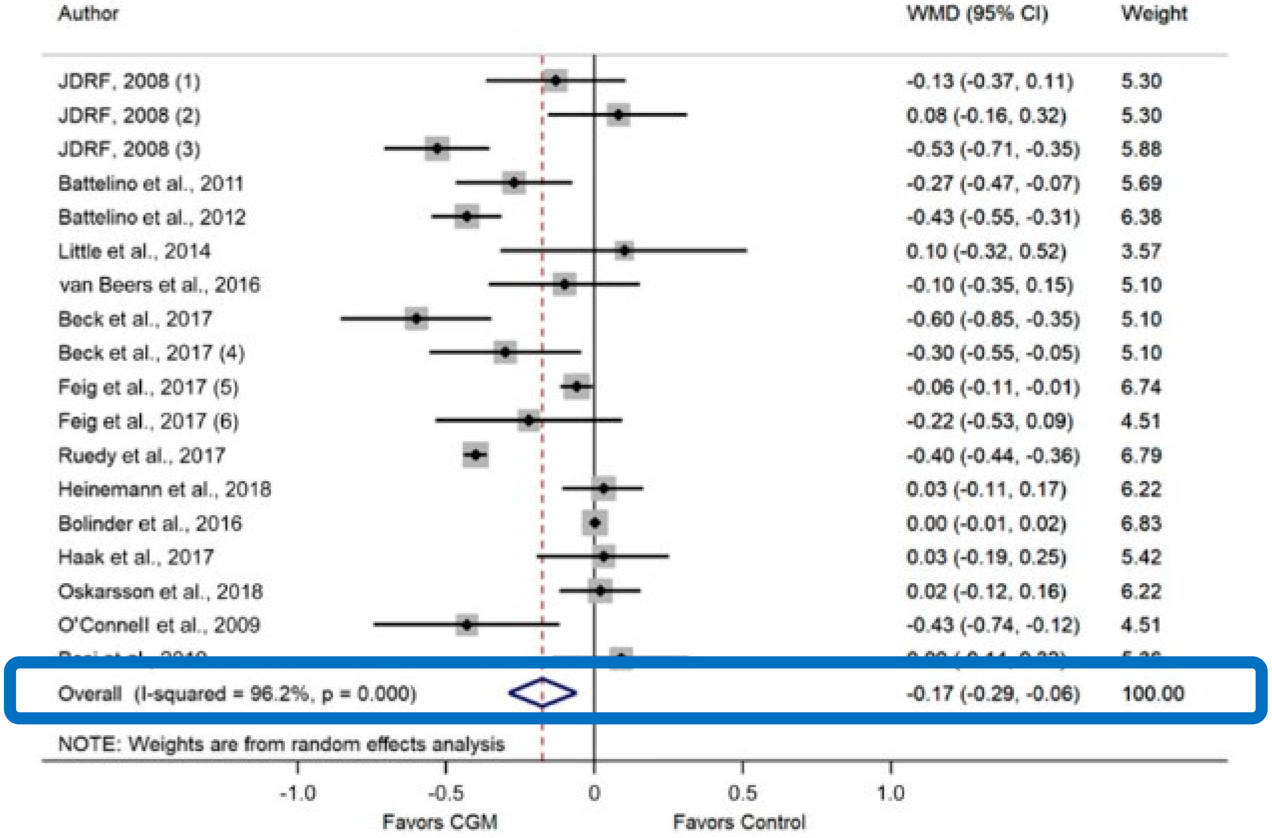
- **Significant improvement in DDSC**:
  - "feeling overwhelmed by the demands of living with diabetes"
  - "feeling that I am often failing with my diabetes regimen"

Diabetes Care 2020;43:2153–2160

Effects of Continuous Glucose Monitoring on Metrics of Glycemic Control in Diabetes: A Systematic Review With Meta-analysis of Randomized Controlled Trials

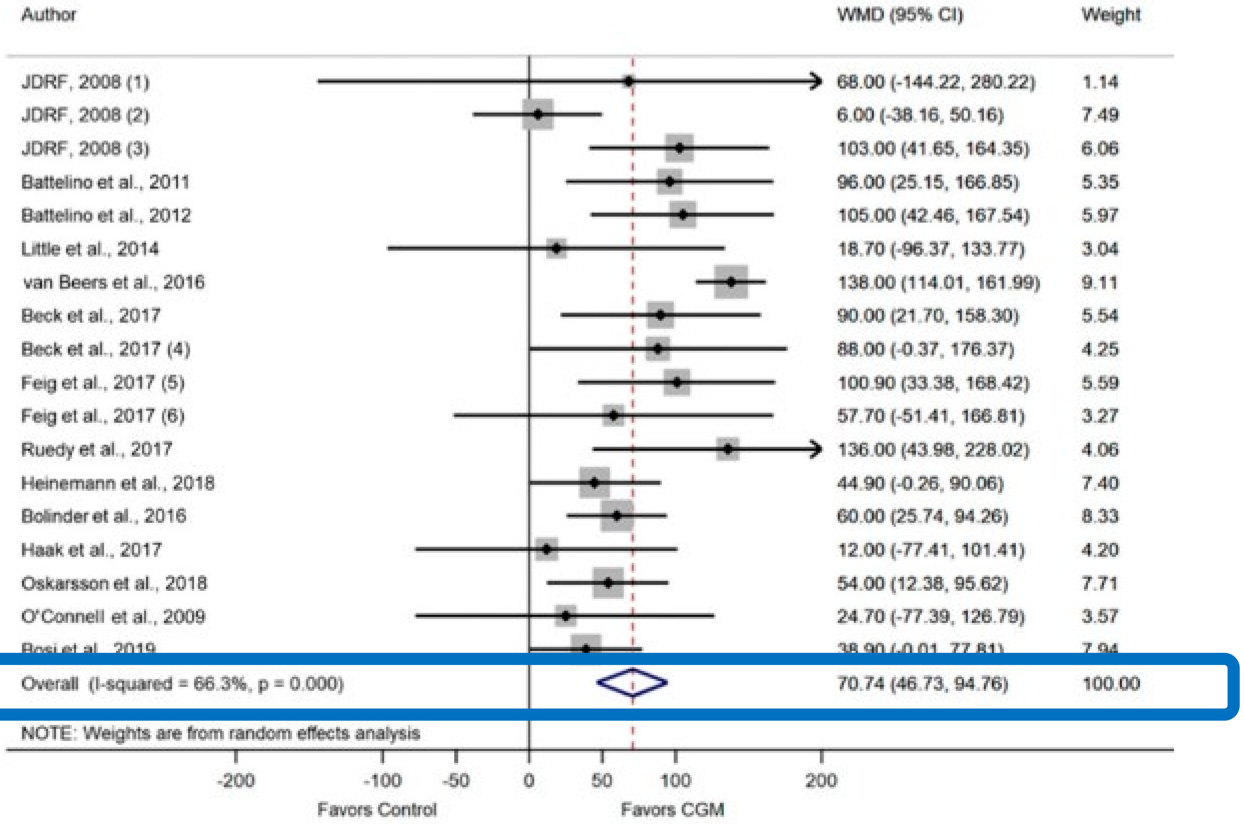
Diabetes Care 2020;43:1146-1156

Effect of CGM on HbA1c



Diabetes Care 2020;43:1146–1156

Effect of CGM on TIR



Diabetes Care 2020;43:1146–1156

CGM and flash glucose monitoring significantly improve:

HbA1c

TIR (& TBR, TAR)

GV

TIR – The New Treatment Target - Agenda

- Background – something doesn’t go well
- The striking efficacy of CGM
- Does more technology help?
- **TIR targets**
- The COVID-19 Era

Diabetes Care 2019;42:1593–1603

Guidance on targets for assessment of glycemic control:

Type 1 / Type 2 and Older / High-Risk Individuals

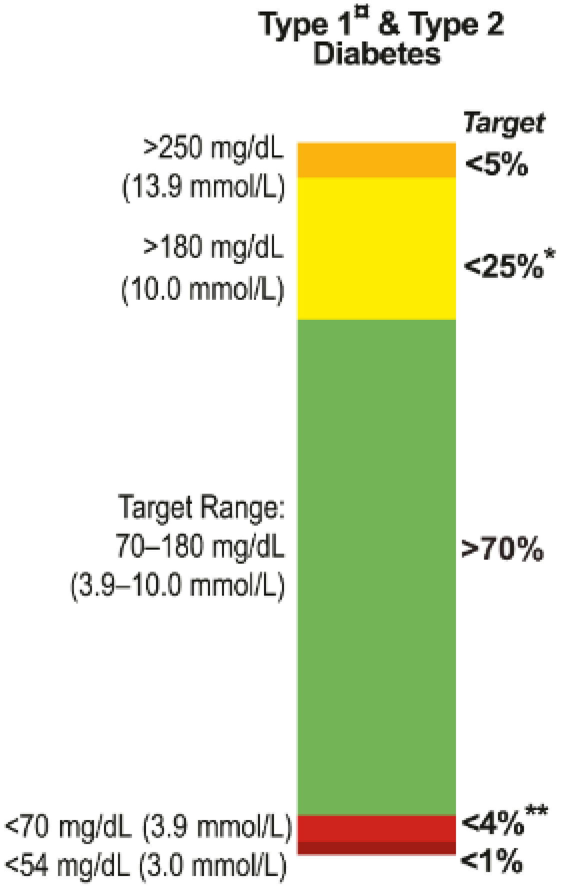
1% of the day is ~15 minutes

Diabetes Group	Time in Range (TIR)		Time Below Range (TBR)		Time Above Range (TAR)	
	% of readings time/day	Target Range	% of readings time/day	Below Target Level	% of readings time/day	Above Target Level
Type 1/Type 2	**>70% >16hr, 48 min**	70-180 mg/dL 3.9-10.0 mmol/L	**<4% <1 hr**	<70 mg/dL <3.9 mmol/L	**<25% <6 hr**	>180 mg/dL >10.0 mmol/L
			<1% <15 min	<54 mg/dL <3.0 mmol/L	**<5% <1 hr, 12 min**	>250 mg/dL >13.9 mmol/L
Older/High-Risk# Type 1/ Type 2	**>50% >12 hr**	70-180 mg/dL 3.9-10 mmol/L	**<1% <15 min**	<70 mg/dL <3.9 mmol/L	**<10% <2 hr, 24 min**	>250 mg/dL >13.9 mmol/L

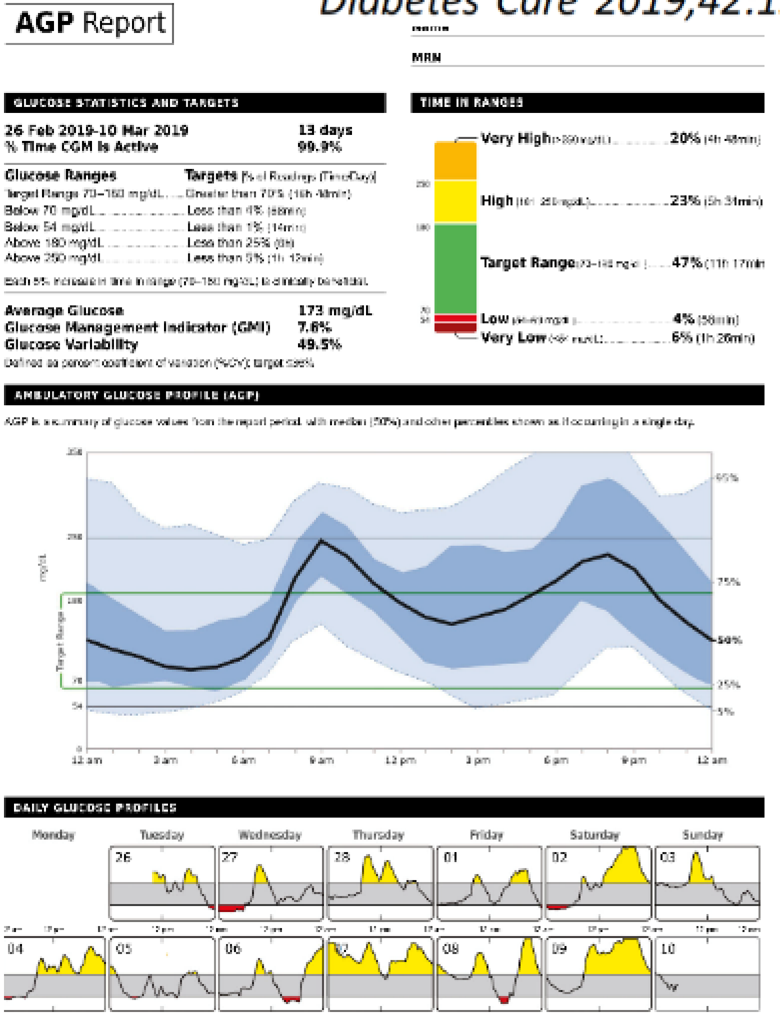
Each incremental 5% increase in TIR is associated with clinically significant benefits for Type 1 / Type 2 [7, 8]

7. Beck RW, et al. J Diabetes Sci Technol. 2019 Jan 13:doi: 10.1177/1932296818822496; 8. Vigersky RA, et al. Diabetes Technol Ther. 2019;21(2):81-85.

Ambulatory Glucose Profile



Diabetes Care 2019;42:1593–1603



Improved Time in Range Over 1 Year Is Associated With Reduced Albuminuria in Individuals With Sensor-Augmented Insulin Pump–Treated Type 1 Diabetes

https://doi.org/10.2337/dc20-0909 - **published online September 4, 2020**

Improved TIR is associated with improved UACR

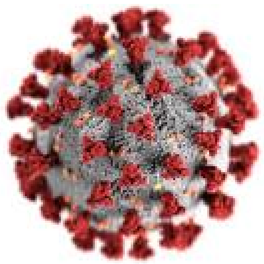
Table 1—Overview of the study outcomes at each visit

	Month						
	0	3	6	9	12	$Change_{end-baseline}$	*P* value
Days from baseline	0± 0	103 ± 25	193 ± 27	289 ± 28	392 ± 33		
HbA_{1c}, mmol/mol	76.0 ± 12.5	69.8 ± 11.7	64.0 ± 11.4	62.6 ± 13.5	61.8 ± 11.4	−14.4 (−17.4; −10.5)	<0.0001
HbA_{1c}, %	9.1 ± 1.1	8.5 ± 1.1	8.0 ± 1.0	7.9 ± 1.2	7.8 ± 1.04	−1.3 (−1.6; −0.96)	
UACR*, mg/g	95.8 ± 3.7	93.5 ± 3.5	70.1 ± 4.4	65.6 ± 4.0	76.3 ± 3.8	−15 (−38; 17)	0.049
MAP†, mmHg	98.9 ± 9.7	96.2 ± 14.0	94.3 ± 11.9	96.6 ± 9.8	97.9 ± 12.4	−1.9 (−6.3; 2.5)	0.90
BMI, kg/m^2	27.5 ± 5.1	27.6 ± 5.5	27.7 ± 5.1	27.5 ± 5.2	27.4 ± 5.6	0.3 (−0.2; 0.7)	0.18
CGM uploads, *N*	26	24	24	25	22		
CGM readings, %	81 ± 31	63 ± 30	55 ± 20	61 ± 32	78 ± 51		
CGM readings, h	116 ± 45	961 ± 462	1,717 ± 623	1,403 ± 732	1,938 ± 1,267		
$\%TAR_2$	18 ± 13	15 ± 12	11.4 ± 8.7	11.5 ± 10	9.0 ± 7.7	−7.0 (−10.9; −3.3)	0.002
$\%TAR_1$	42.3 ± 16.9	49.7 ± 19.4	42.5 ± 17.2	38.8 ± 18.2	32.3 ± 14.4	−7.4 (−12.9; −1.9)	<0.0001
%TIR	46.9 ± 20.1	47.1 ± 19.0	53.5 ± 20.0	57.9 ± 19.9	64.3 ± 13.4	13.2 (6.2; 20.2)	0.0003
$\%TBR_1$	10.7 ± 12.5	3.2 ± 9.8	4.0 ± 11.4	3.3 ± 5.1	3.4 ± 2.6	−6.3 (−11.1; −1.6)	0.008
$\%TBR_2$	3.3 ± 3.8	0.2 ± 0.3	0.3 ± 0.3	0.4 ± 0.4	0.6 ± 0.7	−2.7 (−3.8; −1.9)	<0.0001
$Mean_{SG}$, mmol/L	9.6 ± 1.8	10.3 ± 1.6	9.7 ± 1.4	9.4 ± 1.6	8.9 ± 1.3	−0.5 (−1.02; −0.03)	0.0001
SD_{SG}, mmol/L	4.0 ± 1.0	3.2 ± 0.5	3.1± 0.4	3.2 ± 0.5	3.2 ± 0.6	−0.7 (−1.0; −0.4)	<0.0001
CV_{SG}, %	41.9 ± 8.4	31.1 ± 3.9	32.4 ± 3.7	34.2 ± 3.6	36.3 ± 4.6	−5.6 (−8.1; −3.1)	<0.0001
GMI_{SG}, mmol/mol	58.0 ± 8.2	61.2 ± 7.6	58.2 ± 6.5	57.0 ± 7.3	54.4 ± 6.0	−2.5 (−4.8; −0.1)	0.0001

https://doi.org/10.2337/dc20-0909 - **published online September 4, 2020**

TIR – The New Treatment Target - Agenda

- Background – something doesn’t go well
- The striking efficacy of CGM/ flash glucose monitoring
- TIR targets
- **The COVID-19 Era**



COVID-19 and Diabetes Management

Try to start digital/virtual diabetes clinic

Disseminating Data Through a Virtual Clinic

Individuals can view their data and share with their HCP via the cloud

Prof. Pratik Choudhary

HCPs can view and analyse data, before contacting their patient to discuss options and next steps

HCP, healthcare professional

Diabetes and COVID-19: The Current Situation in Germany

WhatsApp is not GDPR compliant

German Diabetes Association: Try to achieve good control

AUF DER BULT
KINDER- UND JUGENDKRANKENHAUS

Email/letter to individuals to prepare for telemedicine consultation

Our guidance on treatment targets

PWD upload data and consultation by phone or approved video server

Video information for PWD

Video mit Prof. Danne

Kinder mit Typ-1-Diabetes und COVID-19: Antworten auf offene Fragen

PWD, people with diabetes

Thomas Danne, Children's Hospital Auf Der Bult

Slide represents the presenter's own opinion and experience in his country

Diabetes and COVID-19: The Current Situation in Slovenia

- PWDs send in their downloads – pdf – by e-mail – we save them to EMR
- PWDs download via approved platforms – we access directly and save the pdf to EMR
- We send to PWDs a Zoom link with the date and hour of tele-consultation
- The Zoom tele-consultation takes place
  - Downloads are discussed
  - Limited physical inspection is performed
- A consultation report is dictated to the EMR and sent to the national e-repository and to the PWD

EMR, electronic medical record; PWD, people with diabetes

Tadej Battelino, University Children’s Hospital Ljubljana, University of Ljubljana

Slide represents the presenter’s own opinion and experience in his country

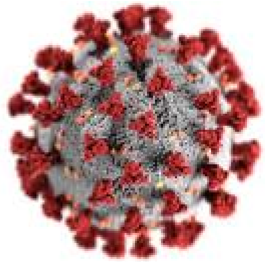
Diabetes and COVID-19: The Current Situation in Slovenia

TELEMEDICINA

Danes je imel mali redni pregled .... tako na daljavo.... nič odpadlo ali prestavljeno.

Bravo celotno osebje endo oddelka za tako tiktak postopek in uporabo tehnologije. Pa sej ste že od nekdaj top

- A FB post of a happy adolescent with diabetes attending the **diabetes tele-clinic** on April 10th



COVID-19 and Diabetes Management

#stayhealthy

#govirtual

Time in Range

Physical Activity

Program Agenda

Applying Sensor-Based Glucose Monitoring and Telemedicine to Optimize Real World Impact and Diabetes Management in the Age of Covid-19—What Have the Studies Taught Us?

PROFESSOR PARTHA KAR, FRCP
Consultant in Diabetes & Endocrinology | Portsmouth Hospitals NHS Trust | NHS England

A Practical Roadmap for Using Registry Data and Trial-Based Evidence to Guide Use of Sensor-Based, Glucose Monitoring: Focus on Results from the Swedish National Diabetes Register (NDR) to Optimize Multi-Dose Insulin (MDI) Therapy in Persons with Diabetes

KATARINA EEG-OLOFSSON, MD, PhD
Senior Consultant, Diabetes Clinic | Institute of Medicine, Sahlgrenska University Hospital | Gothenburg, Sweden

Translating Guidelines and Meta-Analysis Trials to Guide Practical Aspects of Diabetes Care: Using Sensor-Based Glucose Monitoring to Improve Time in Range (TIR) for Persons with Diabetes on Non-Insulin Regimens

RICHARD BERGENSTAL, MD
International Diabetes Center-Park Nicollet Minneapolis, United States

Welcome to this SCIENCE-*to*-STRATEGY SUMMIT

TRANSLATING CLINICAL EVIDENCE FOR SENSOR-BASED GLUCOSE MONITORING AND TECHNOLOGICAL INNOVATIONS TO THE FRONT LINES OF CLINICAL PRACTICE

Focus on Evidence-, Trial-, and Guideline-Based Roadmaps for Deploying Patient-Centric, **Sensor-Based Continuous Glucose Monitoring (CGM)** Technology to Optimize Effectiveness and Safety of Pharmacologic and Behavioral Interventions in Persons with Diabetes

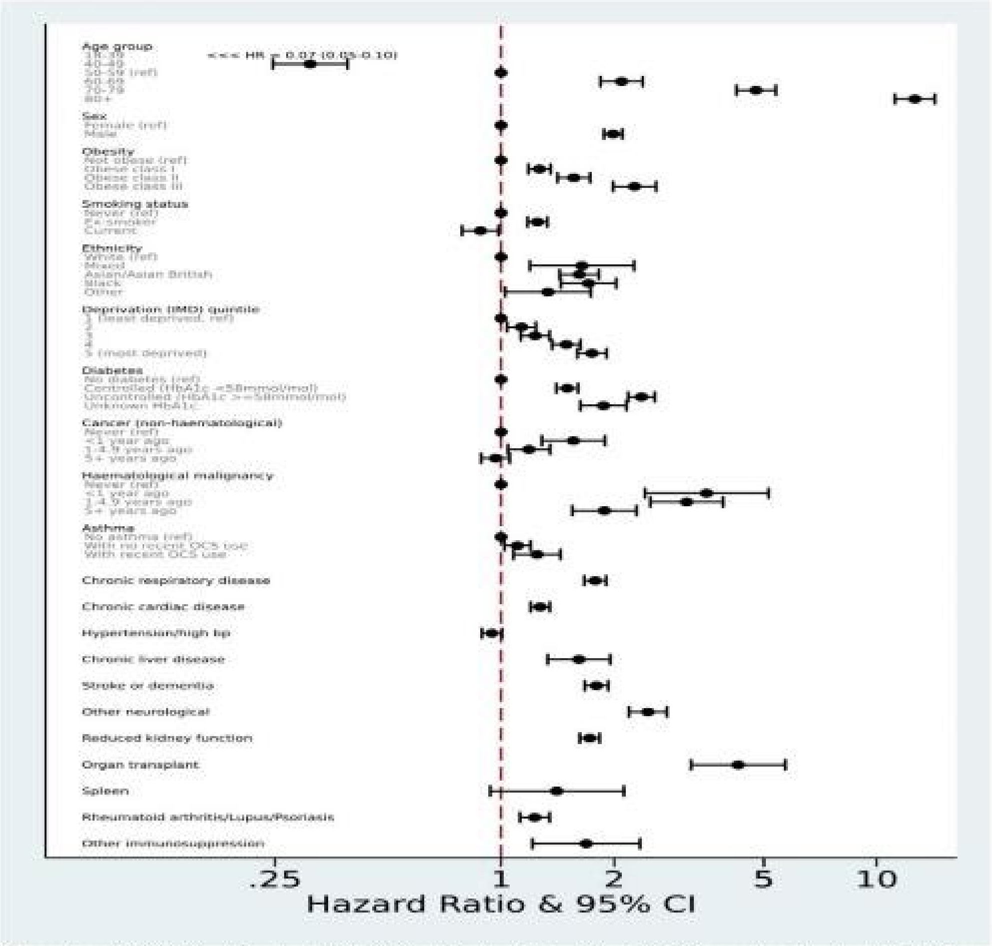
A Year 2020, Best Practice, Technology-Based Advances Program in Diabetes Care: Roadmaps to Clinical Success in Diabetes Management

Telemedicine, Virtual Working, Sensor-Based Technology… Where to Next in The Time of COVID19?

Prof. Partha Kar, FRCP

Consultant in Diabetes & Endocrinology | Portsmouth Hospitals NHS Trust | National Clinical Director, Diabetes | NHS England

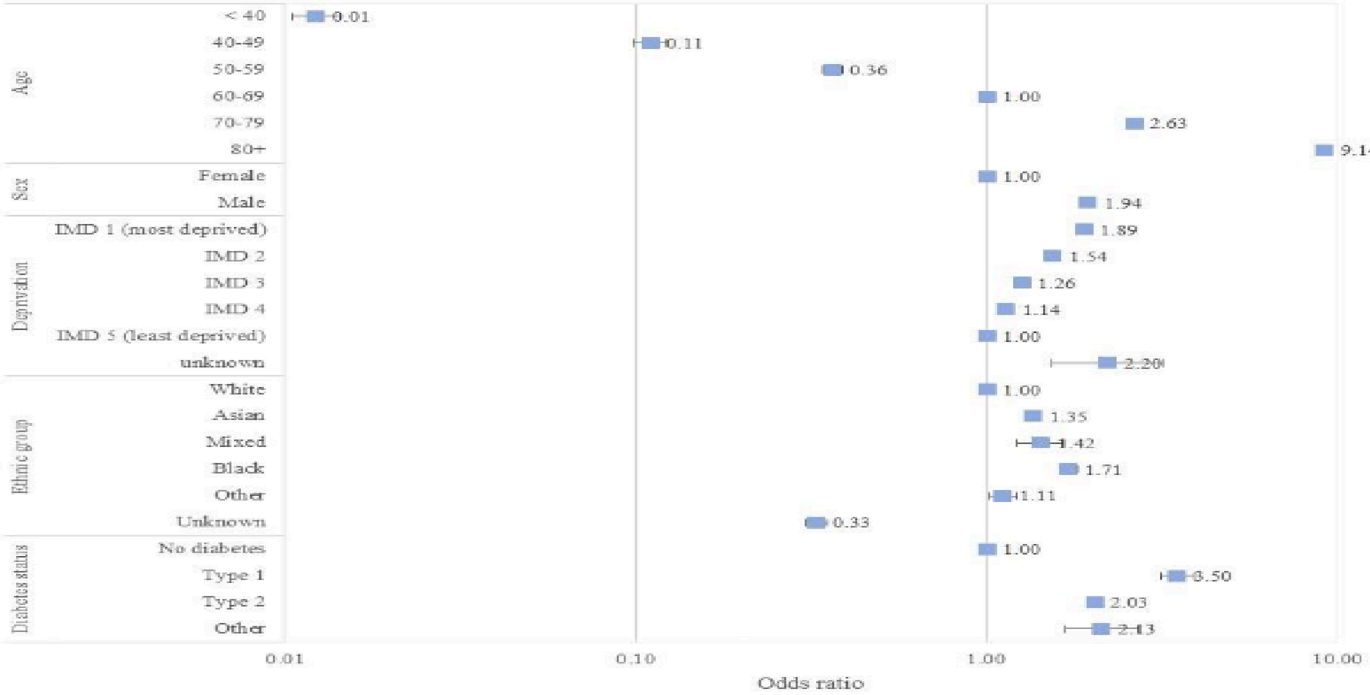
Figure 3. Estimated Hazard Ratios (shown on a log scale) for each potential risk factor from a multivariable Cox model



Obese class I: 30-34.9kg/m², class II: 35-39.9kg/m², class III: >=40kg/m². OCS = oral corticosteroid. All HRs are adjusted for all other factors listed other than ethnicity. Ethnicity estimates are from a separate model among those with complete ethnicity data, and are fully adjusted for other covariates.

The OpenSAFELY Collaborative: factors associated with COVID-19-related hospital death in the linked electronic health records of 17 million NHS patients – Available from: https://www.medrxiv.org/content/10.1101/2020.05.06.20092999v1.full.pdf - Accessed June 2020

Figure 2: Adjusted odds ratios for in-hospital deaths with COVID-19 in England (number of deaths=23,804) between 1st March 2020 and 11th May 2020 by different risk factors

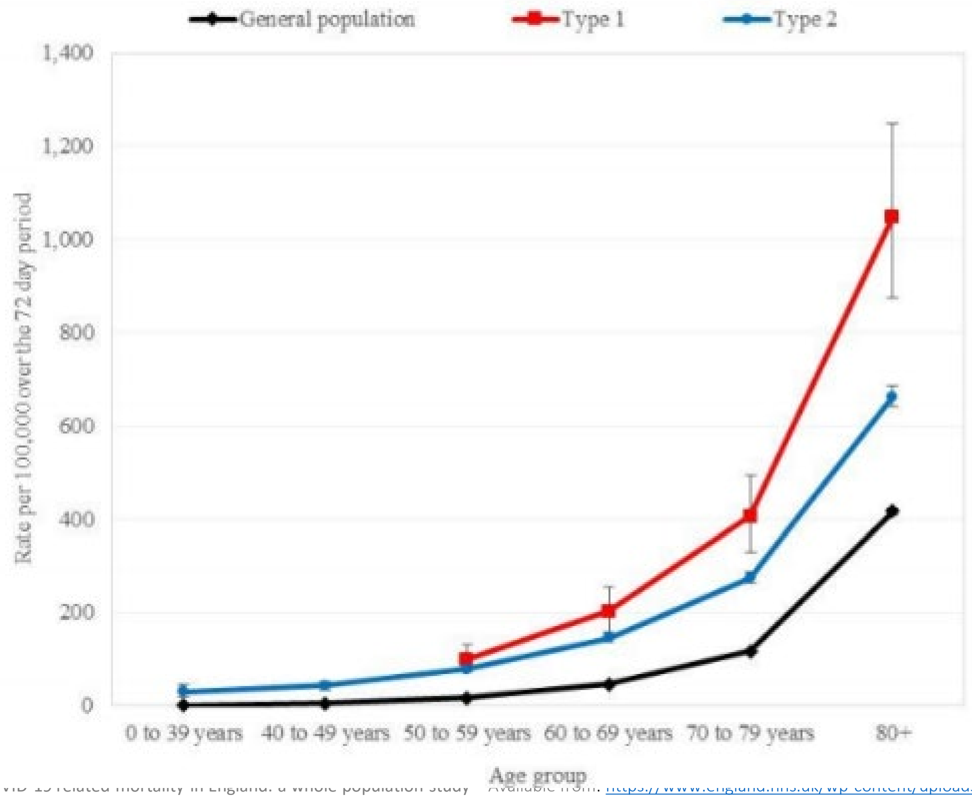


***Data shown are the results of a multivariable logistic regression which included the explanatory variables shown, plus region, in a population of 61,414,470 people.**

NHS England. Type 1 and Type 2 diabetes and COVID-19 related mortality in England: a whole population study – Available from: https://www.england.nhs.uk/wp-content/uploads/2020/05/valabhji-COVID-19-and-Diabetes-Paper-1.pdf - Accessed June 2020

This version posted 19th May 2020. The copyright holder of this pre-print (which has not been certified by peer review) is NHS England.

Figure 1: Unadjusted in-hospital COVID-19 mortality rate per 100,000 persons between 1st March 2020 to 11th May 2020 by type of diabetes



NHS England. Type 1 and Type 2 diabetes and COVID-19 related mortality in England: a whole population study – Available from: https://www.england.nhs.uk/wp-content/uploads/2020/05/valabhji-COVID-19-and-Diabetes-Paper-1.pdf - Accessed June 2020

Figure 1a: Weekly number of deaths in people with Type 1 diabetes in England January 2017-April 2020

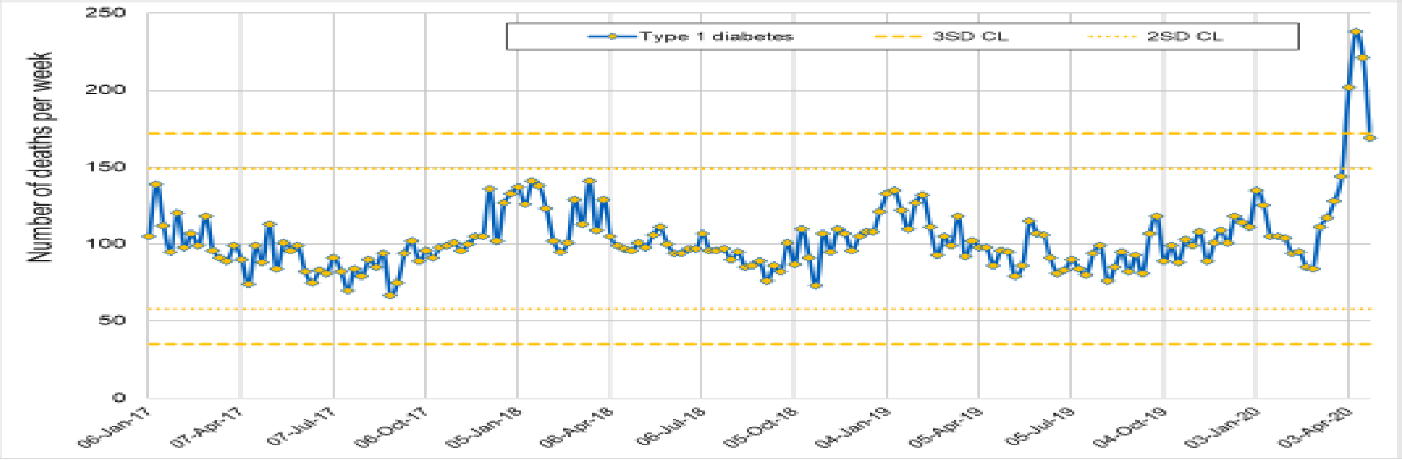
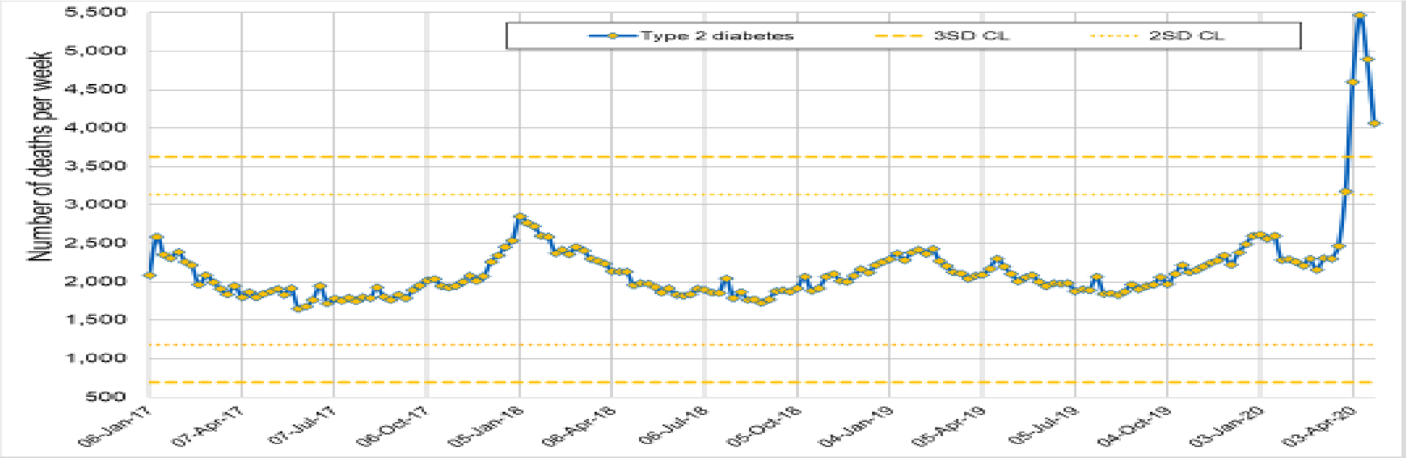


Figure 1b: Weekly number of deaths in people with Type 2 diabetes in England January 2017-April 2020



NHS England. Type 1 and Type 2 diabetes and COVID-19 related mortality in England: a cohort study in people with diabetes - Available from: https://www.england.nhs.uk/wp-content/uploads/2020/05/Valabhji-COVID-19-and-Diabetes-Paper-2-Full-Manuscript.pdf - Accessed June 2020

Salient Points

HIGHER RISK

SOCIAL DISTANCING (HAND WASHING / MASKS WHERE APPROPRIATE)

LESS PHYSICAL CONTACT WITH CLINICIANS

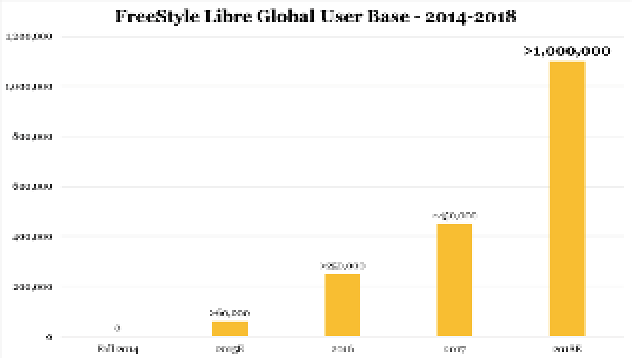
THE VIRTUAL SPACE

Relationship Between TIR 3.9-10mM and HbA1c

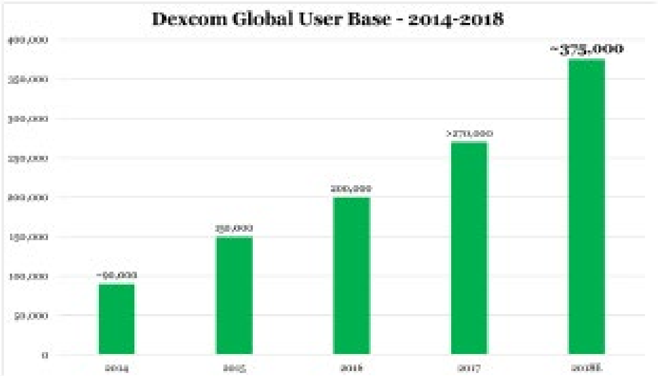
Time-in-range	Hba1c (%)	Hba1c (mmol/mol)
0%	12.1	109
10%	11.4	101
20%	10.6	92
30%	9.8	84
40%	9.0	75
50%	8.3	67
60%	7.5	59
70%	6.7	50
80%	5.9	42
90%	5.1	32
100%	4.3	23

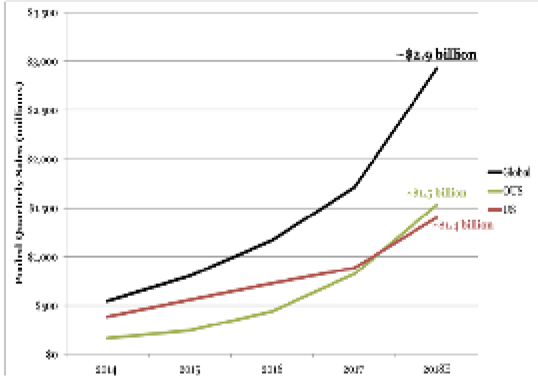
Vigersky et. al. Diabetes Technology and Theraputics 2019; 21 (2)

Libre/Real-Time CGM Growth



- *Estimated global users of flash and real-time CGM > 1.5 million*
- *2018 Global sales close to 3 billion USD*





Source: Close Concerns' Reflections 2018, www.closeconcerns.com

Original Research

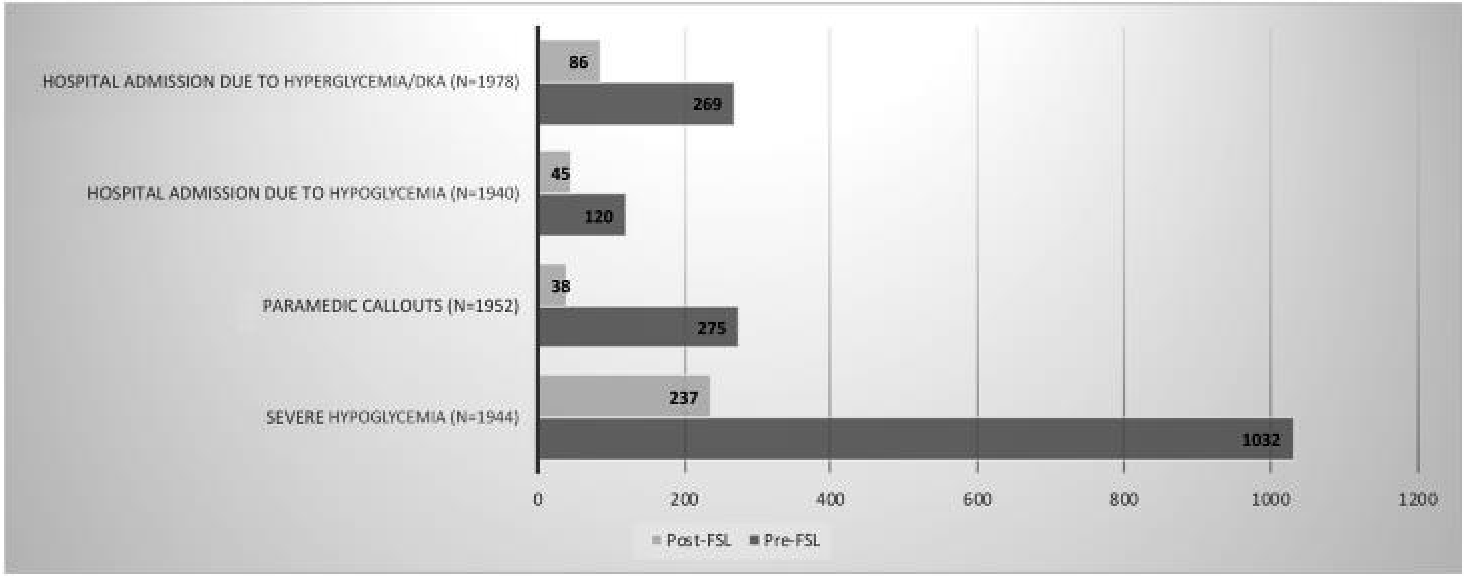
Effect of Flash Glucose Monitoring on Glycemic Control, Hypoglycemia, Diabetes-Related Distress, and Resource Utilization in the Association of British Clinical Diabetologists (ABCD) Nationwide Audit

Harshal Deshmukh, Emma G. Wilmot, Robert Gregory, Dennis Barnes, Parth Narendran, Simon Saunders, Niall Furlong, Shafie Kamaruddin, Rumaisa Banatwalla, Roselle Herring, Anne Kilvert, Jane Patmore, Chris Walton, Robert E.J. Ryder, Thozhukat Sathyapalan

Diabetes Care 2020 Jul; dc200738.
https://doi.org/10.2337/dc20-0738

Paramedic Callouts, Severe Hypoglycemia, and Hospital Admissions

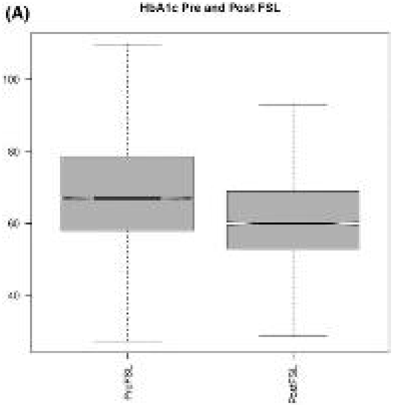
The 12 months before and the 7.5 months of follow-up using FSL in the ABCD nationwide audit.



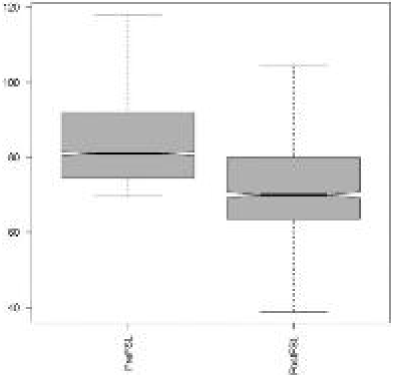
Harshal Deshmukh et al. Dia Care 2020;43:2153-2160

Distribution of HbA1c Change Pre- and Post-FSL Use in the ABCD Nationwide Audit of FSL

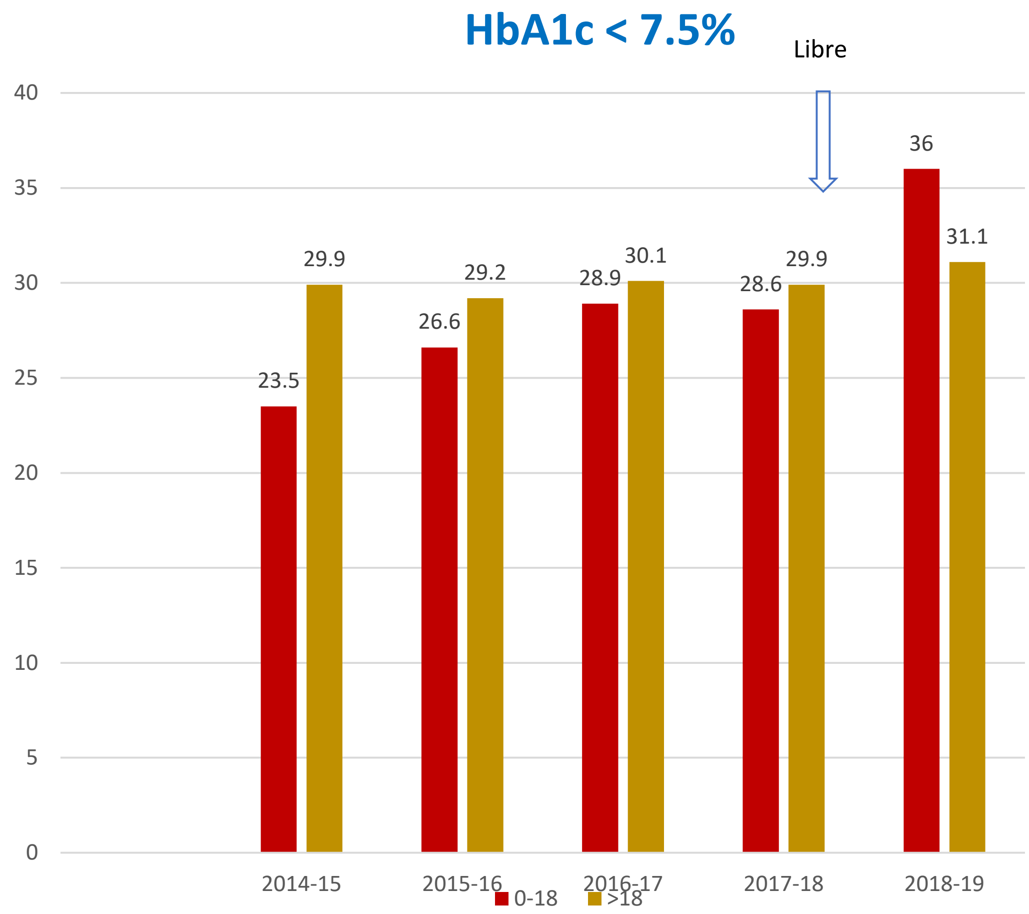
(A) study population



(B) Baseline HbA1c of ≥69.5 mmol/mol



Harshal Deshmukh et al. Dia Care 2020;43:2153-2160



HbA1c improvement:

RED BAR: AGE 0-18

Brown bar: AGE >18

Evidence…

J Dia
Publ
Usi
Tec
Davi
Au

Research article | Open Access | Published: 13 July 2018

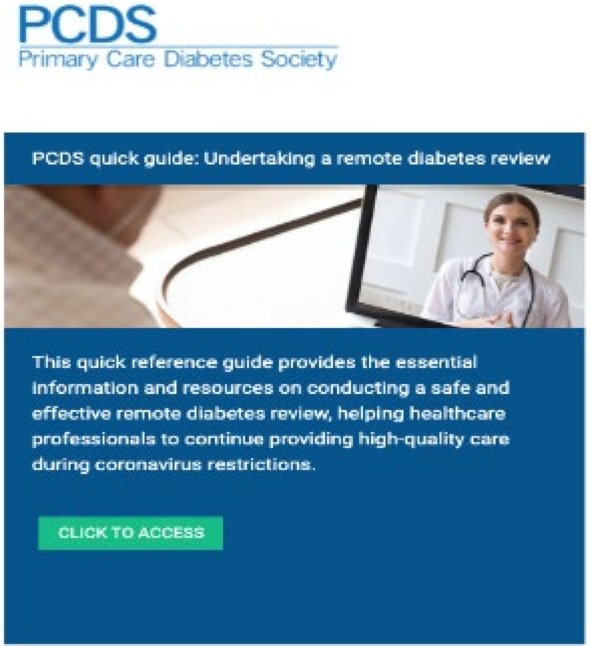
Patients' perception of using telehealth for type 2 diabetes management: a phenomenological study

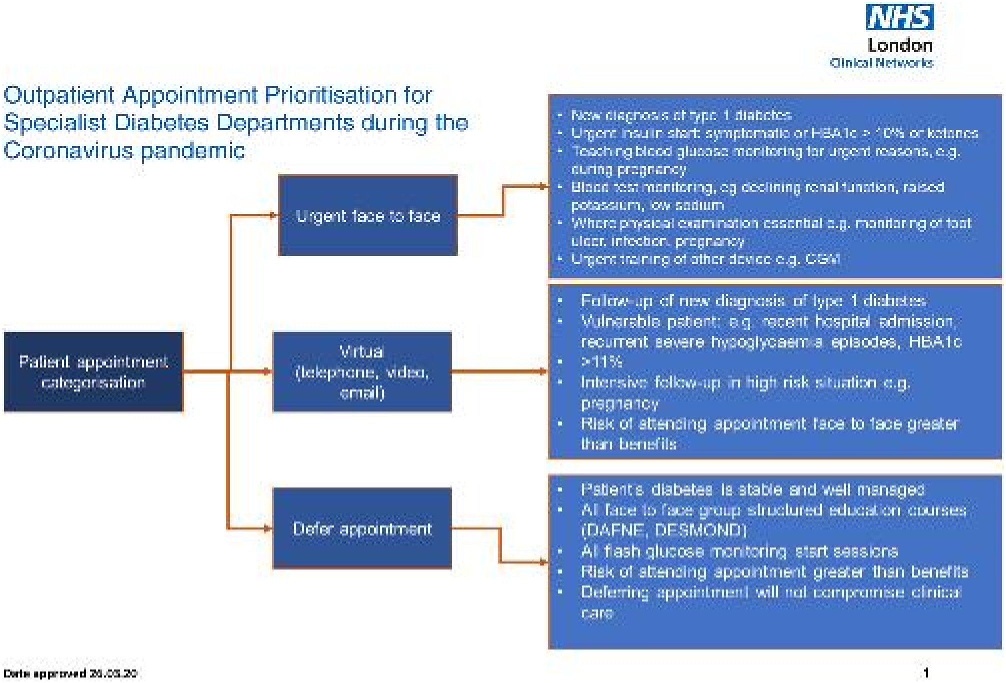
Puikwan A. Lee, Geva Greenfield & Yannis Pappas

BMC Health Services Research **18**, Article number: 549 (2018) | Cite this article

View article Tools Share

Views and opinions..





Clinical Practice Guidance | D J Wake and others | Diabetes service delivery and COVID-19 | **183**:2 | **G67**–G77

ENDOCRINOLOGY IN THE TIME OF COVID-19

Remodelling diabetes services and emerging innovation

Deborah J Wake[1,2], **Fraser W Gibb**[2], **Partha Kar**[3], **Brian Kennon**[4], **David C Klonoff**[5], **Gerry Rayman**[6,7], **Martin K Rutter**[8,9], **Chris Sainsbury**[4,10] and **Robert K Semple**[2,11]

[1]Usher Institute, University of Edinburgh, Edinburgh, UK, [2]Edinburgh Centre for Endocrinology & Diabetes, NHS Lothian, Edinburgh, UK, [3]Portsmouth Hospital NHS Trust, Portsmouth, UK, [4]NHS Greater Glasgow and Clyde, Glasgow, UK, [5]Mills-Peninsula Medical Center, San Mateo, California, USA, [6]Ipswich Hospital, East Suffolk and North East Essex NHS Trust, Colchester, UK, [7]University of East Anglia, Norwich, UK, [8]Division of Diabetes, Endocrinology and Gastroenterology, School of Medical Sciences, University of Manchester, Manchester, UK, [9]Manchester Diabetes Centre, Manchester University NHS Foundation Trust, Manchester Academic Health Sciences Centre, Manchester, UK, [10]Institute of Applied Health Research, University of Birmingham, Birmingham, UK, and [11]Centre for Cardiovascular Sciences, The Queens Medical Research Institute, University of Edinburgh, Edinburgh, UK

This manuscript is part of a commissioned series of urgent clinical guidance documents on the management of endocrine conditions in the time of COVID-19. This clinical guidance document underwent expedited open peer review by Ingrid Willaing (Steno Diabetes Center, Copenhagen, Denmark), Sean Dinneen (NUI Galway, Ireland), David Simmons (Western Sydney University Macarthur Clinical School, Australia)

Correspondence should be addressed to D Wake
Email
d.wake@ed.ac.uk

Personal views…

Lessons…

- Acceleration of much needed work
- Care with access
- Socioeconomic determinants
- Cultural sensitivity
- Don’t widen the gap!
- Industry role


Innovation is the ability
to see change as an opportunity
not a threat
Steve Jobs

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Focus on Evidence-, Trial-, and Guideline-Based Roadmaps for Deploying Patient-Centric, **Sensor-Based Continuous Glucose Monitoring (CGM)** Technology to Optimize Effectiveness and Safety of Pharmacologic and Behavioral Interventions in Persons with Diabetes

A Year 2020, Best Practice, Technology-Based Advances Program in Diabetes Care: Roadmaps to Clinical Success in Diabetes Management

A Practical Roadmap for Using Registry Data and Trial-Based Evidence to Guide the Use of Sensor-Based Glucose Monitoring

Focus on Results from the Swedish National Diabetes Register to Optimize Therapy in Persons with Diabetes

Katarina Eeg-Olofsson, MD, PhD
Senior Consultant, Diabetes Clinic
Institute of Medicine, Sahlgrenska University Hospital,
University of Gothenburg
Gothenburg, Sweden

Presenter Disclosures

- Lecturing fees from Novo Nordisk, Lilly, Bayer and Abbott and research support from Abbott

Outline

- The National Diabetes Register in Sweden
- Lessons from registry based on clinical studies on sensor based continuous glucose monitoring
- How can registry data help patients optimise glucose treatment

The Swedish National Diabetes Register

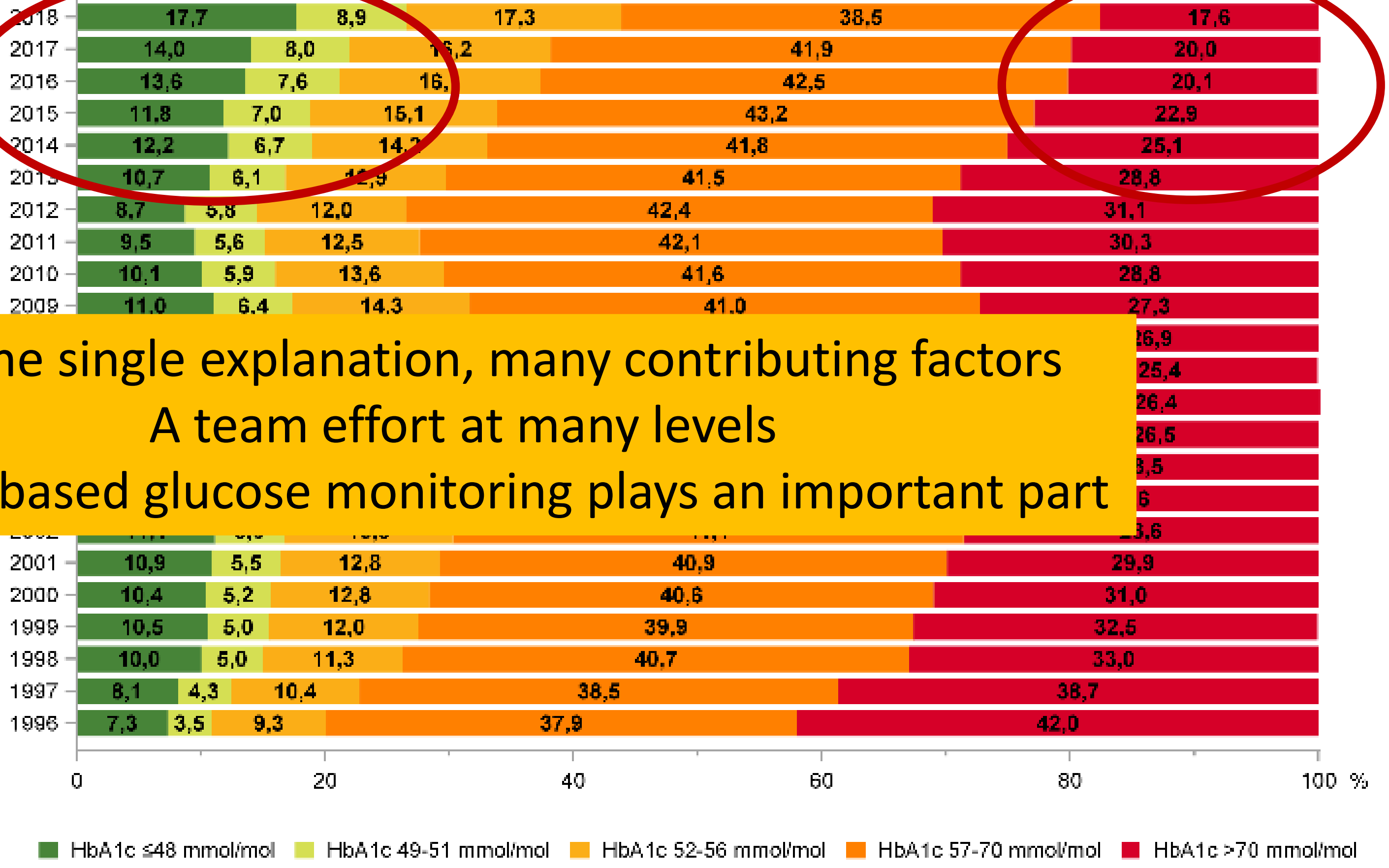
- Internet-based national quality registry
- Important clinical variables based on guidelines (HbA1c, blood pressure etc)
- 90% of patients included (both primary and secondary care)
- Interactive statistical reports
- Local quality control
- Benchmarking-public results
- Database for epidemiological research

https://www.ndr.nu/#/english

Proportions of adults with type 1 diabetes in Sweden with different l

of HbA1c

1996-201



Not one single explanation, many contributing factors

A team effort at many levels

Sensor-based glucose monitoring plays an important part

Background

- ► Glucose management is fundamental in diabetes treatment
- ► Glucose monitoring is an essential tool to help people with diabetes to self-manage their diabetes
- ► Sensor-based glucose monitoring simplifies and helps diabetes management
  - by removing the need for multiple daily finger-stick blood samples
  - giving continuous glucose data with trends
  - warnings of low and high glucose levels

Sustainable HbA_{1c} decrease at 12 months for adults with Type 1 and Type 2 Diabetes using the FreeStyle Libre® system: a study within the National Diabetes Register in Sweden

- Analyses of HbA1c in T1DM and T2DM patients prior to and after 12 months initiating FreeStyle Libre system usage
  - Retrospective, open cohort design based on data available through NDR
  - Index date: 1st record in NDR of FreeStyle Libre system use
  - Prior/after FreeStyle Libre system usage methodology
- Outcome: HbA_{1c} value (%) at 12 months

Eeg-Olofsson et al Poster presentation at ADA 2020, study funded by Abbott

- Study period: 1 January 2014 - 25 June 2019
- Individuals with at least one registrations of FreeStyle Libre (FSL) system in the NDR (June 2016 - June 2019):
  - T1DM n=36,352 T2DM n= 3,202
- 9,898 with T1DM or T2DM and registration of FSL use had HbA1c measurements within the study period
- The population was divided into 3 groups:
  - Truly naïve FreeStyle Libre system users,
  - New to FreeStyle Libre system but unknown prior status,
  - new to FreeStyle Libre system but previous use of CGM

Eeg-Olofsson et al Poster presentation at ADA 2020, study funded by Abbott

Results

Change in HbA_{1c} after 12 months	T1DM				
FSL incident users subgrouped according prior use of CGM:	Change in HbA_{1c} (%)	CI, mean %-point change in HbA_{1c} (%)	HbA1c baseline mean (%)	Group size (n)	p-value*
Total incident users	-0.33	-0.36 to -0.31	8.1	8316	< 0.0001
Truly naive	-0.44	-0.48 to -0.41	8.2	3220	< 0.0001
Prior use unknown	-0.28	-0.31 to -0.25	8.0	4497	< 0.0001
Prior use of CGM	-0.18	-0.27 to -0.10	8.2	599	< 0.0001

*Paired samples t-test

Change in HbA_{1c} after 12 months	T2DM				
FSL incident users subgrouped according prior use of CGM:	Change in HbA_{1c} (%)	CI, mean %-point change in $Hb_{A1}c$ (%)	HbA1c baseline mean (%)	Group size (n)	p-value*
Total incident	-0.52	-0.63 to -0.40	8.6	538	< 0.0001
Truly naive	-0.66	-0.84 to -0.49	8.7	203	< 0.0001
Prior use unknown	-0.49	-0.65 to -0.33	8.6	298	< 0.0001
Prior use of CGM	0.10	-0.30 to 0.49	8.3	37	0.6147

*Paired samples t-test

- Baseline mean HbA_{1c} was 8.2% and 8.7% for truly naive T1DM and T2DM FSL users respectively
- HbA_{1c} was significantly reduced in T1DM and T2DM FSL users during follow-up
  - T1D: 0.44% lower HbA1c in truly naïve users and 0.33% in total incident users
  - T2D: 0.66 % lower HbA1c in truly naïve users and 0.52 % in total incident users

Eeg-Olofsson et al Poster presentation at ADA 2020, study funded by Abbott

Summary and Conclusion

This large real-world study on a well-established National Diabetes Registry in Sweden concluded that people with T1DM and T2DM using FSL for between 9 to 15 months significantly reduced their HbA_{1c} (-0.33 %-point for T1DM and -0.52 %-point for T2DM)

Eeg-Olofsson et al Poster presentation at ADA 2020, study funded by Abbott

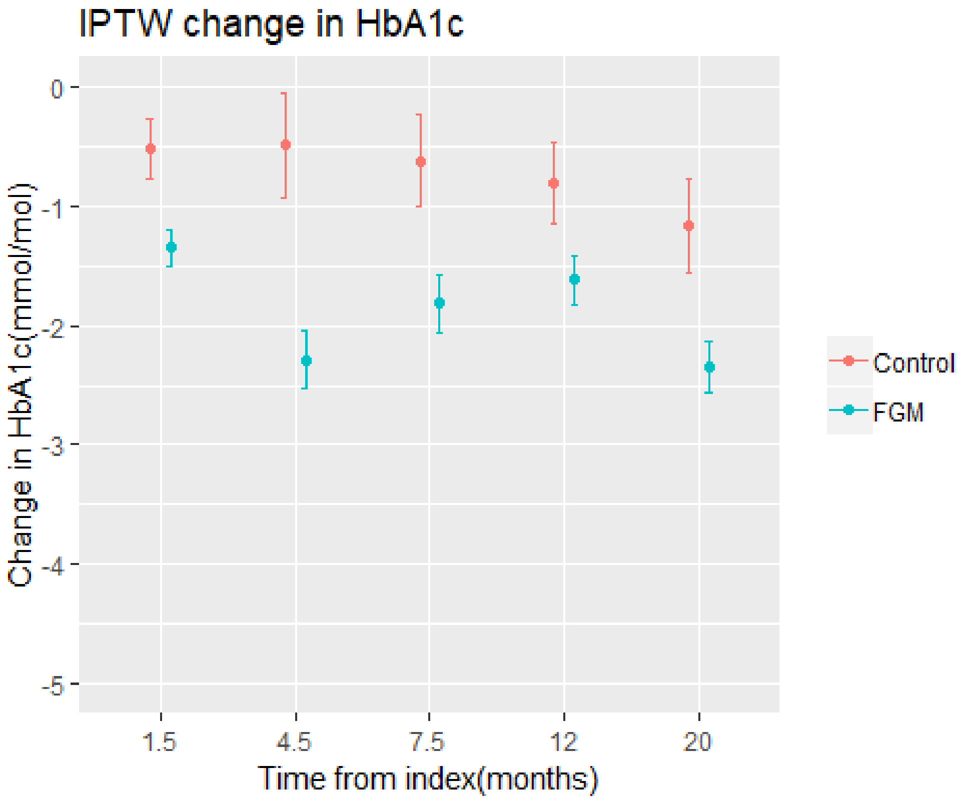
Effect of Flash Glucose Monitoring on Glycaemic Control in Adults with Type 1 Diabetes Compared to Controls on SMBG

- Register-based cohort study of patients from routine clinical practice, July, 2016, through December, 2018
- The primary aim of the study was to **evaluate changes in HbA1c after initiation of FGM in comparison to a weighted control group using Self Monitoring Blood Glucose**
  - HbA1 values 3 years before and two years after index were retrieved from the NDR
  - Other clinical characteristics from the NDR before index
- Propensity scores and inverse probability of treatment weighting (IPTW) were used to balance FGM users with controls
  - Age, sex, diabetes duration baseline Hba1c, BMI, blood pressure, LDL, pump use, smoking, physical activity, albuminuria, retinopathy, previous CHD and stroke
- **N = 14372 unique patients (FGM users) and N = 7691 unique patients (Controls)**

Nathanson el al. Oral presentation, EASD 2019

Results

The difference in IPTW change in HbA1c was significantly greater in Flash glucose monitoring (FGM) users compared to controls at 0-3, 3-6, 6-9, 9-15 and 15-24 months



Nathanson el al. Oral presentation, EASD 2019

Conclusions

- This study using a nationwide register to include data from a large number of patients seen in routine clinical practice comparing the effect of FGM use with weighted controls using SMBG
- FGM use was associated with lower HbA1c compared to weighted SMBG using controls

Nathanson el al. Oral presentation, EASD 2019

Diabetes Care Volume 43, January 2020 37

CGM FOR TYPE 1 DIABETES

Glycemic Outcomes in Adults With T1D Are Impacted More by Continuous Glucose Monitoring Than by Insulin Delivery Method: 3 Years of Follow-Up From the COMISAIR Study

Jan Šoupal, Lenka Petruželková, George Grunberger, Aneta Hásková, Milan Flekač, Martin Matoulek, Ondřej Mikeš, Tomáš Pelcl, Jan Škrha Jr., Eva Horová, Jan Škrha, Christopher G. Parkin, Štěpán Svačina, and Martin Prázný

Diabetes Care 2020;43:37–43 | https://doi.org/10.2337/dc19-0888

- Clinical impact of 4 treatment strategies in type 1 diabetes
  - Real time CGM + MDI
  - Real time CGM + CSII
  - SMBG + MDI
  - SMBG + MDI
- N= 84, 3 year follow-up
- Outcomes: change in HbA1c, time in range, time in hypoglycaemia

Soupal et al, Diabetes Care 2020;43:37–43

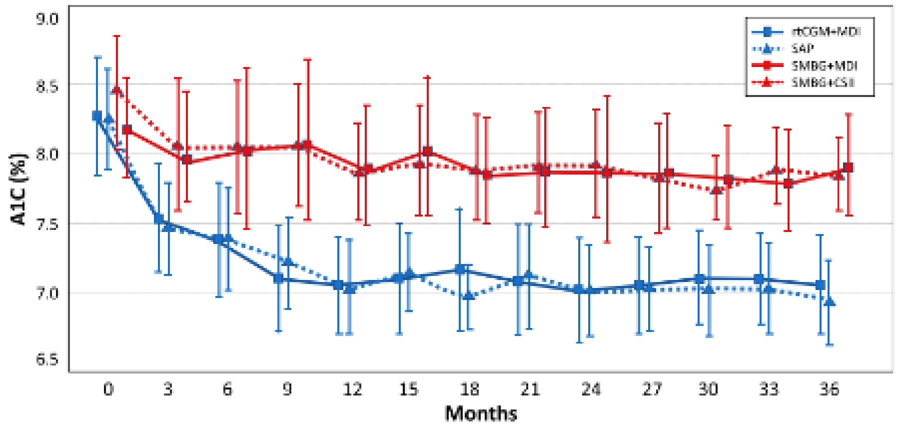


Figure 1—Change in A1C from baseline by study group. SAP, sensor-augmented pump.

- ▶ rtCGM superior to SMBG regardless of insulin delivery system (MDI or CSII)
- ▶ Lower HbA1c

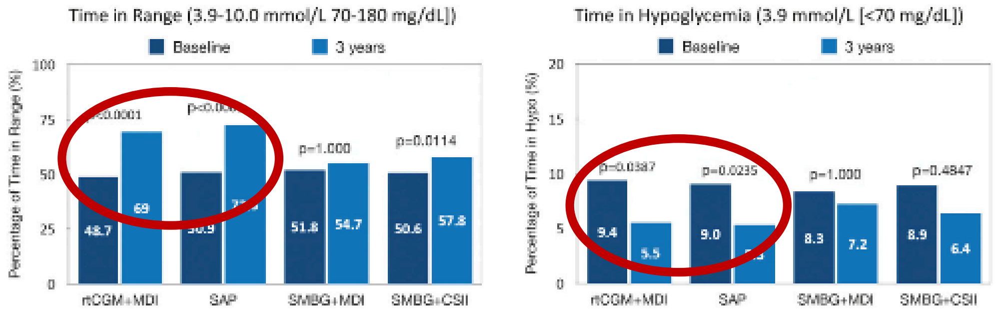
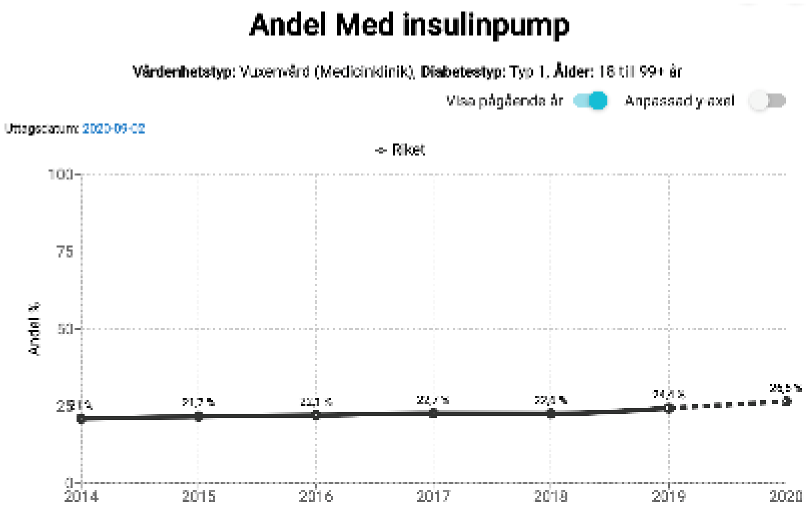


Figure 2—Changes in percentage of time in range and time in hypoglycemia. SAP, sensor-augmented pump.

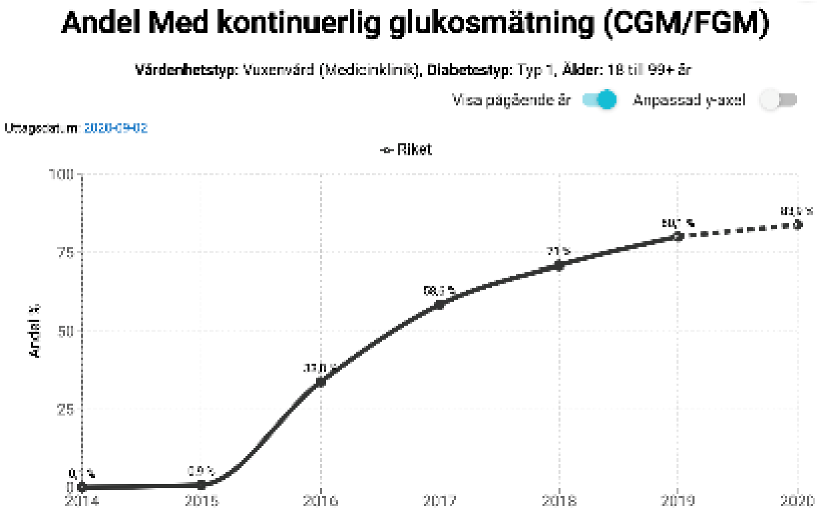
- ▶ Increase in Time in Range
- ▶ Decrease in Time in Hypo

Soupal et al, Diabetes Care 2020;43:37–43

Proportions of Adults with Type 1 Diabetes in Sweden Using Technical Devises

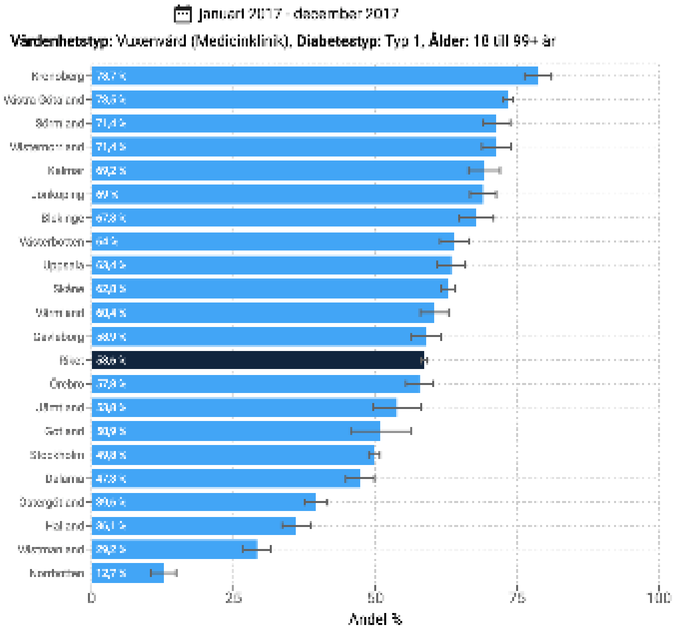


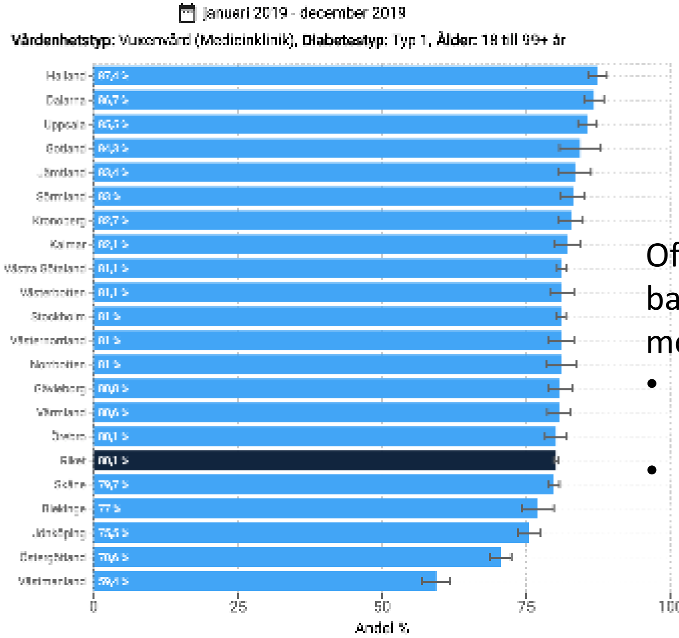
Beneficial for some



Beneficial for many

Proportions of Adults with Type 1 Diabetes Using Sensor-Based Glucose Monitoring in Different Regions of Sweden 2017 and 2019





Of all with sensor-based glucose monitoring 2019

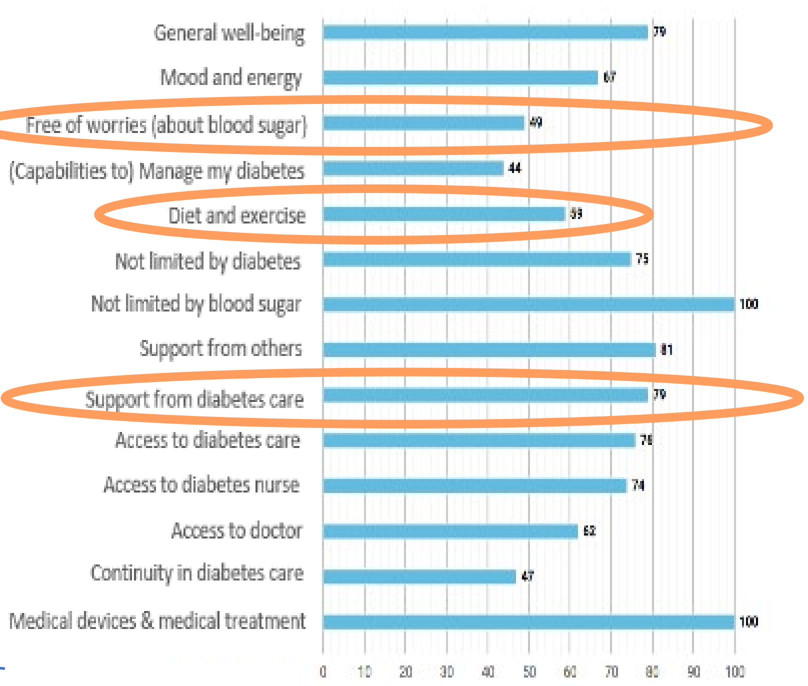
- 77% flash glucose monitoring
- 23% rtCGM

Benchmarking public results in the NDR have helped patients in all parts of Sweden to access sensor technology

The NDR - Constantly Evolving to Support Diabetes Care

Patient reported outcome (PROM) Scales

Patient Reported Experience (PREM) scales



- 2017 - The digital Diabetes questionnaire with patient reported outcomes and experience measures was launched
- June 2020 - Glucose variability variables added Mean sensor glucose, SD, Time in range and time below 4 mmol/L
- New research possibilities in the future
- Help for a more person-centered diabetes care - today

Development of the Swedish Diabetes Questionnaire: Svedbo Engström et al. BMJ Open 2016 and Patient Education and Counserling 2017 and Borg et al. BMJ Open 2019

Diabetologia
https://doi.org/10.1007/s00125-018-4729-5

CONSENSUS REPORT

Management of hyperglycaemia in type 2 diabetes, 2018. A consensus report by the American Diabetes Association (ADA) and the European Association for the Study of Diabetes (EASD)

Melanie J. Davies[1,2] · David A. D'Alessio[3] · Judith Fradkin[4] · Walter N. Kern
Geltrude Mingrone[7,8] · Peter Rossing[9,10] · Apostolos Tsapas[11] · Deborah J

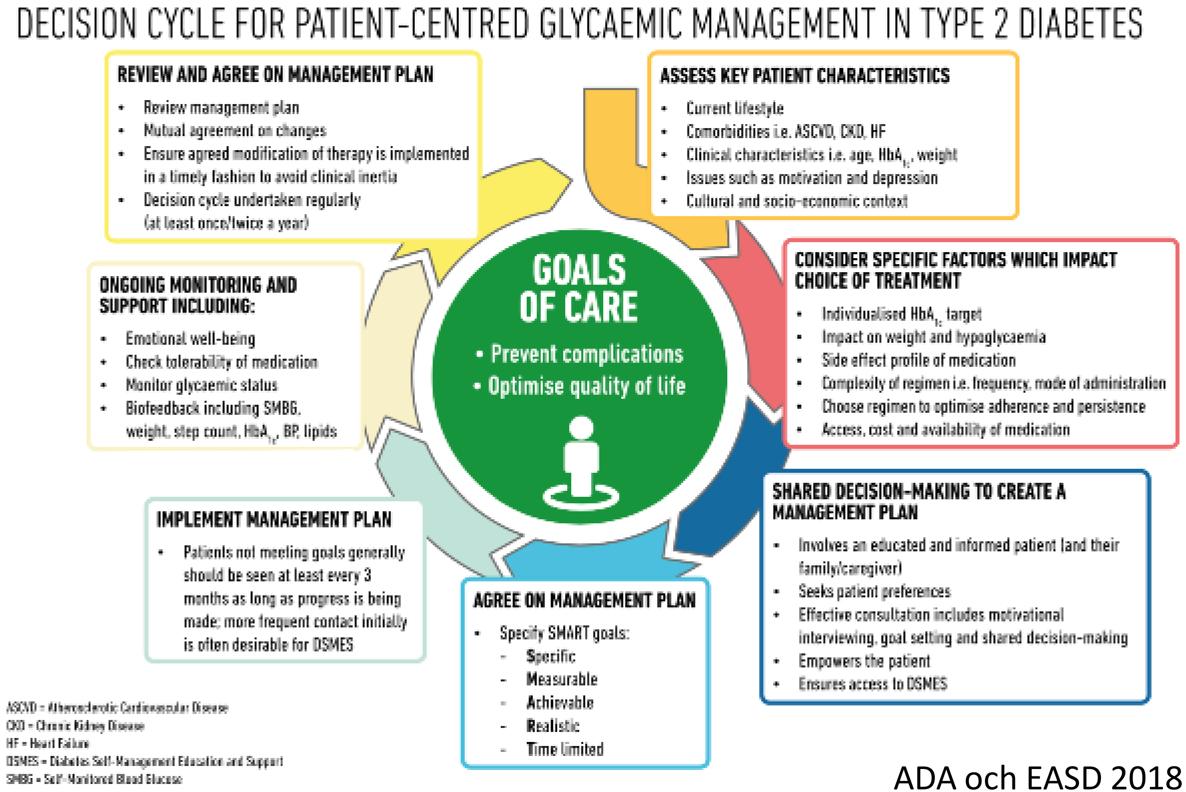


Fig. 1 Decision cycle for patient-centred glycaemic management in type 2 diabetes

ADA och EASD 2018

Summary and Conclusions

- Sensor-based glucose monitoring can help lower and maintaining Hb1Ac, increase time in range and to avoid hypos
- Sensor-based glucose monitoring is a tool - the patient needs knowledge and support to use it for self-management
  - Timing of insulin, composition and carbohydrates in a meal, physical activity, avoiding hypos
- Sensor-based glucose monitoring makes clinicians more aware of the patient struggle and can optimize support
- Register data can facilitate improvement for patients with diabetes
  - Diabetes team discussions
  - Benchmarking - group level results can facilitate access

Welcome to this SCIENCE-*to*-STRATEGY SUMMIT

TRANSLATING CLINICAL EVIDENCE FOR SENSOR-BASED GLUCOSE MONITORING AND TECHNOLOGICAL INNOVATIONS TO THE FRONT LINES OF CLINICAL PRACTICE

Focus on Evidence-, Trial-, and Guideline-Based Roadmaps for Deploying Patient-Centric, **Sensor-Based Continuous Glucose Monitoring (CGM)** Technology to Optimize Effectiveness and Safety of Pharmacologic and Behavioral Interventions in Persons with Diabetes

A Year 2020, Best Practice, Technology-Based Advances Program in Diabetes Care: Roadmaps to Clinical Success in Diabetes Management

Using Sensor-Based Glucose Monitoring to Improve Time in Range (TIR) for Persons with Diabetes on Non-Insulin Regimens

RICHARD BERGENSTAL, MD
Executive Director
International Diabetes Center-Park Nicollet Minneapolis, MN, USA

Disclosures: Richard M. Bergenstal, MD

- I have participated in clinical research, been a member of a scientific advisory board, or served as a consultant for:
  - Abbott Diabetes Care, Ascenia, CeQur, Dexcom, Eli Lilly, Hygieia, Johnson & Johnson, Medtronic, Novo Nordisk, Onduo, Roche, Sanofi, Senseonics and United Healthcare
- My institution receives NIH funding: T1D (DCCT/EDIC) & T2D (GRADE) and Technology (SBIR with Hygieia) and automated insulin delivery systems (FLAIR)
- My employer, the nonprofit HealthPartners Institute, contracts for my services, and I receive no personal income from these activities.
- I am a volunteer for ADA, AACE, Endocrine Society and JDRF

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International Diabetes Center

T2D – Not on insulin

usually → Primary Care Physician / Nurse Practitioner / Phy. Assistant

?

Approach to diabetes

Clinic leadership says:

Worry about the **bigger risk picture**: optimize the D3,D4,D5

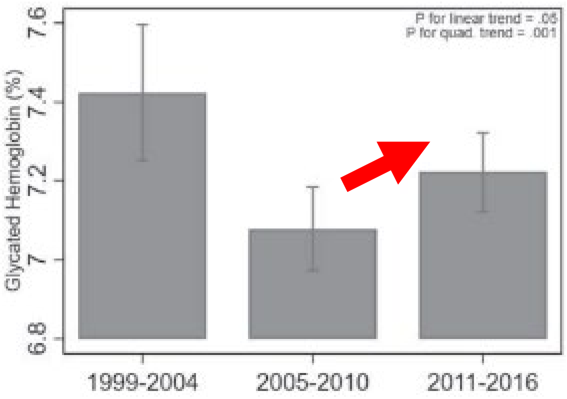
D3	D4	D5
ABC	no smoking	ASA if +CVD

Park Nicollet International Diabetes Center

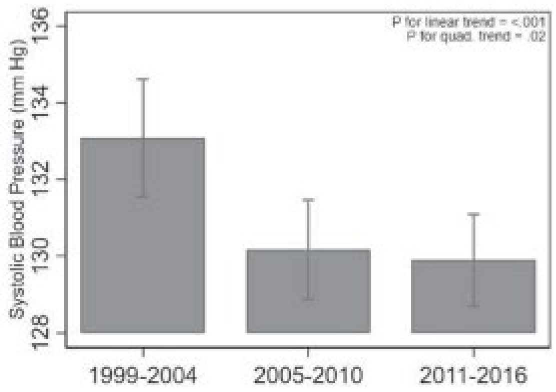
Trends in Diabetes Management Among US Adults:1999–2016

Fang M. J Gen Intern Med 35(5):1427–34, Jan. 2020

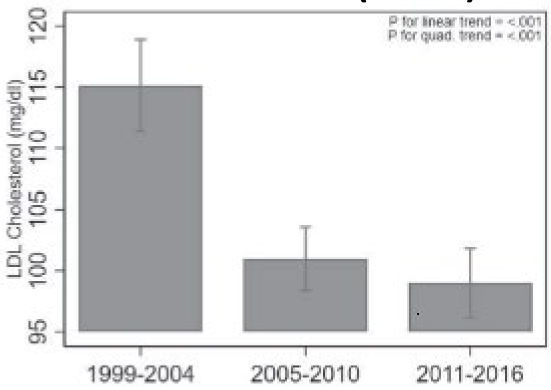
A1C



BP



Chol (LDL)



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the D5 for diabetes

1 BLOOD PRESSURE GOAL
BP less than 140/90mmHg

2 CHOLESTEROL GOAL
Statin use as recommended

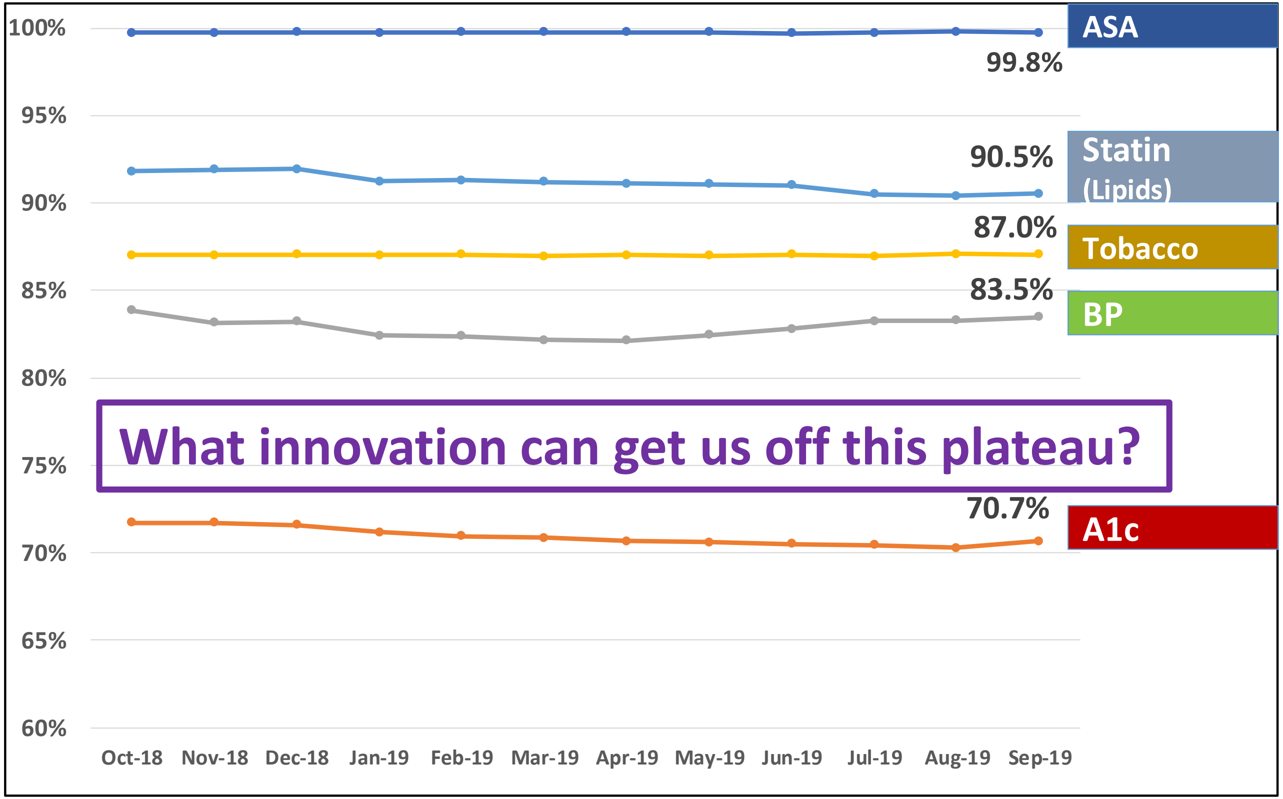
3 BLOOD SUGAR GOAL
A1c less than 8%

4 TOBACCO FREE GOAL

5 ASPIRIN GOAL
As recommended

D5-Individual Components

N >60,000; Minneapolis, MN



How about CGM?

FreeStyle Libre

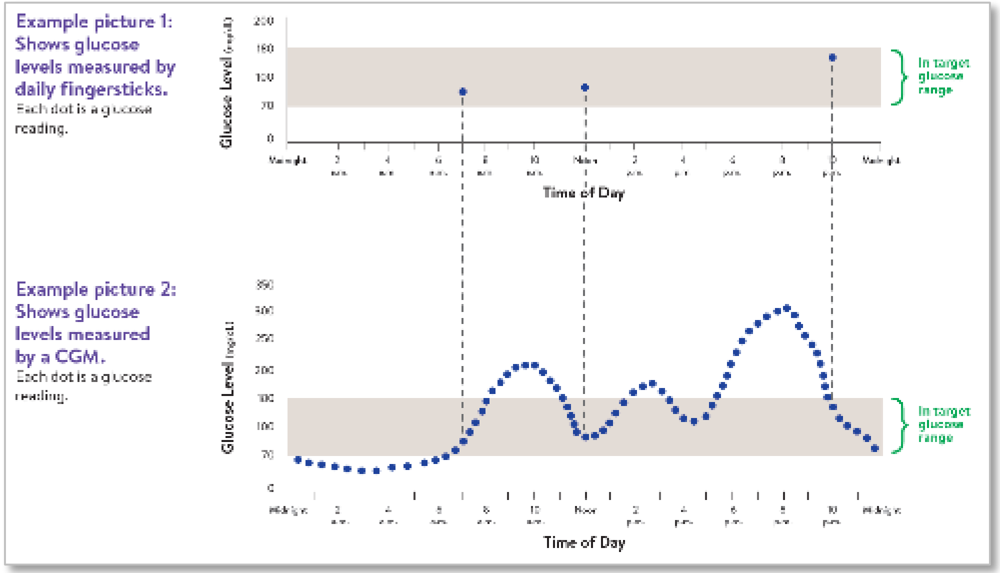
Guardian Connect

G6

Eversense

Sounds complicated – is it?

1-3 BGM/d to 288 daily glucose values



Is CGM really any better than BGM?

Park Nicollet
International Diabetes Center
HealthPartners

Cureus Published 09/12/2019

Open Access Original Article

DOI: 10.7759/cureus.5634

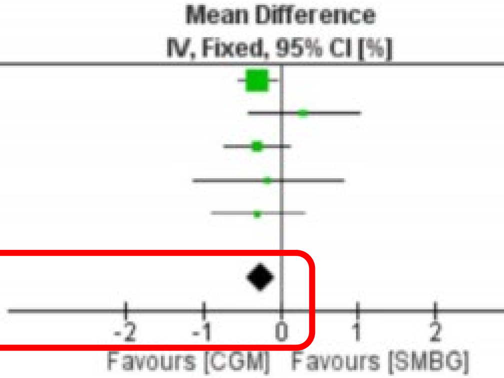
Continuous Glucose Monitoring Versus Self-monitoring of Blood Glucose in Type 2 Diabetes Mellitus: A Systematic Review with Meta-analysis

Rajesh Naidu Janapala [1] , Joseph S. Jayaraj [2] , Nida Fathima [2] , Tooba Kashif [2] , Norina Usman [2] , Amulya Dasari [2] , Nusrat Jahan [2] , Issac Sachmechi [1]

	CGM			SMBG				Mean Difference
Study or Subgroup	Mean [%]	SD [%]	Total	Mean [%]	SD [%]	Total	Weight	IV, Fixed, 95% CI [%]
Beck RW et al., 2017 [7]	7.7	0.7	79	8	0.9	79	58.8%	-0.30 [-0.55, -0.05]
Sato J et al., 2016 [11]	8.2	1.3	17	7.9	0.8	17	7.1%	0.30 [-0.43, 1.03]
Ehrhardt NM et al., 2011 [9]	7.4	1	50	7.7	1.2	50	19.8%	-0.30 [-0.73, 0.13]
Cosson E et al., 2009 [12]	8.59	1.04	11	8.76	1.43	14	4.0%	-0.17 [-1.14, 0.80]
Yoo HJ et al., 2008 [8]	8	1.2	29	8.3	1.1	28	10.4%	-0.30 [-0.90, 0.30]
Total (95% CI)			**186**			**188**	**100.0%**	**-0.25 [-0.45, -0.06]**

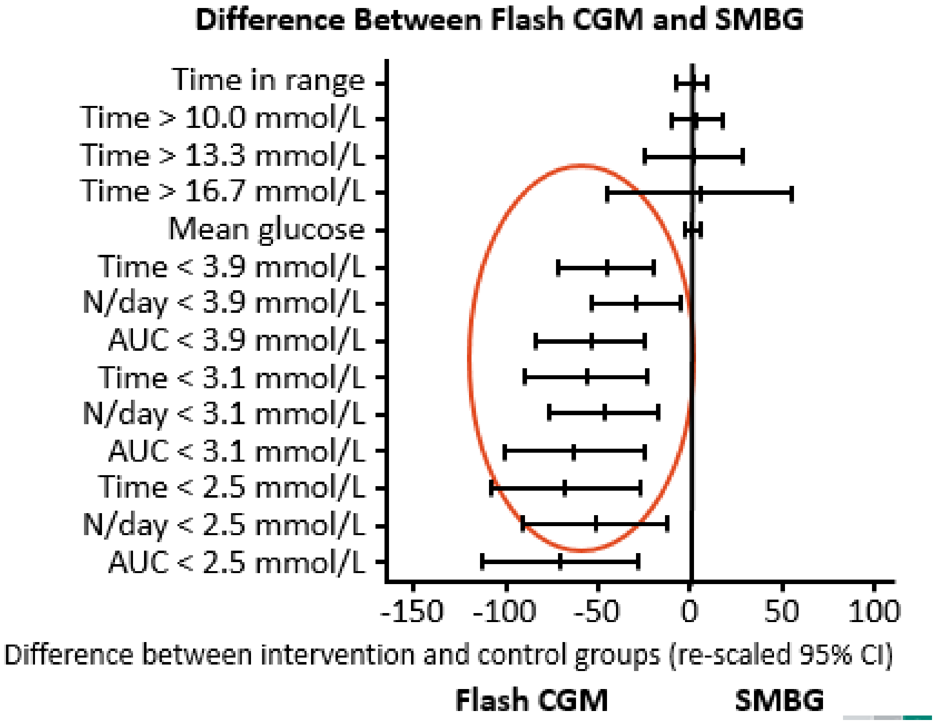
Heterogeneity: $Chi^2 = 2.46$, $df = 4$ ($P = 0.65$); $I^2 = 0\%$

Test for overall effect: $Z = 2.57$ ($P = 0.01$)



REPLACE Trial of Flash CGM in T2D

- Open-label, randomized, controlled study of 224 adults with T2D on intensive insulin therapy
- A1C reduction similar with flash CGM vs SMBG
- Hypoglycemia reduced by 43% ($P < .001$) with flash CGM vs SMBG

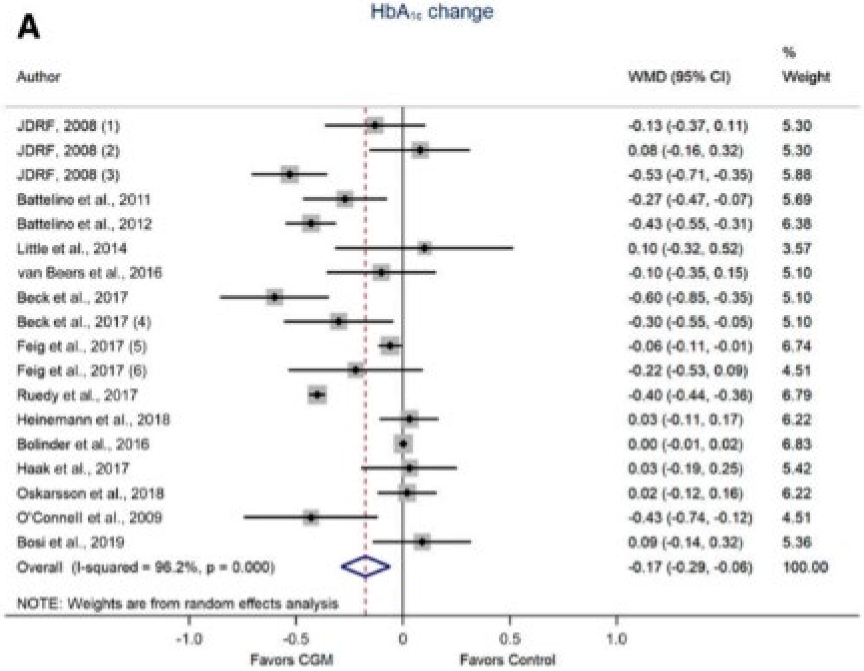


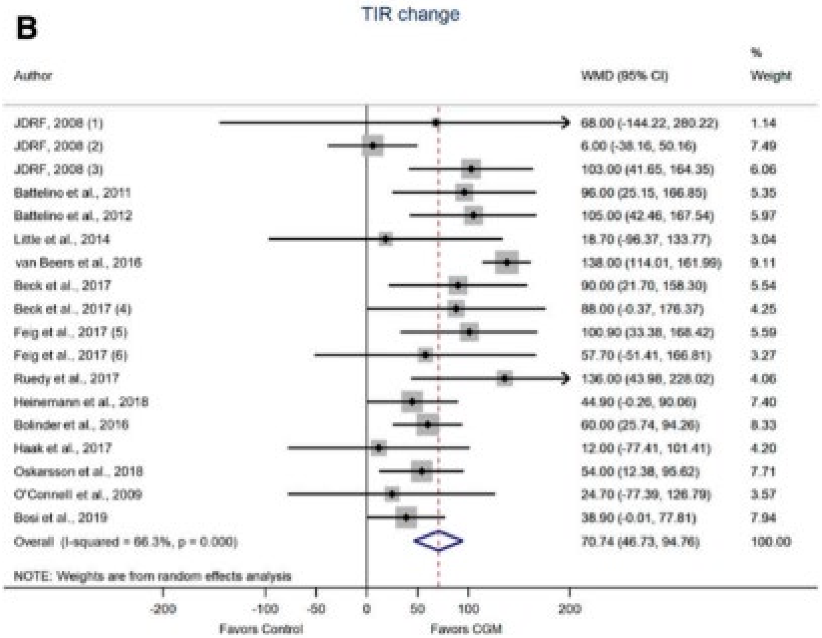
Haak T. Diabetes Ther. 2017;8:55.

Effects of Continuous Glucose Monitoring on Metrics of Glycemic Control in Diabetes: A Systematic Review With Meta-analysis of Randomized Controlled Trials

Maria Ida Maiorino,[1,2] Simona Signoriello,[3] Antonietta Maio,[2] Paolo Chiodini,[3] Giuseppe Bellastella,[1,2] Lorenzo Scappaticcio,[1,2] Miriam Longo,[2] Dario Giugliano,[1,2] and Katherine Esposito[2,4]

Diabetes Care Volume 43, May 2020





CONCLUSIONS

CGM improves glycemic control by expanding TIR and decreasing TBR, TAR, and glucose variability in both type 1 and type 2 diabetes.

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HealthPartners

AGP report

Metrics and targets

GLUCOSE STATISTICS AND TARGETS

21 Nov 2018–3 Dec 2018	13 days
% Time CGM is Active	99.9%

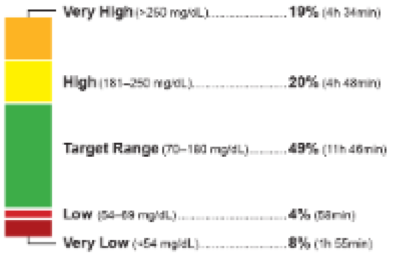
Glucose Ranges	Targets [% of Readings (Time/Day)]
Target Range 70–180 mg/dL	Greater than 70% (16h 48min)
Below 70 mg/dL	Less than 4% (58min)
Below 54 mg/dL	Less than 1% (14min)
Above 180 mg/dL	Less than 25% (6h)
Above 250 mg/dL	Less than 5% (1h 12min)

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

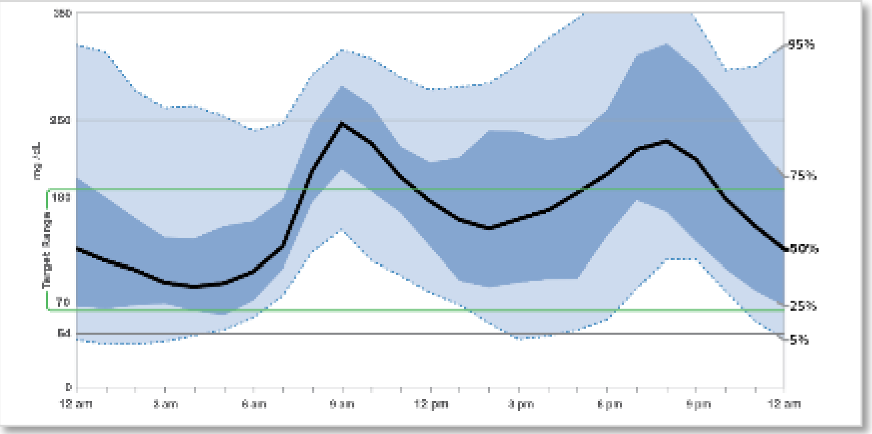
Average Glucose	186 mg/dL
Glucose Management Indicator (GMI)	7.3%
Glucose Variability	49.4%

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

TIME IN RANGES

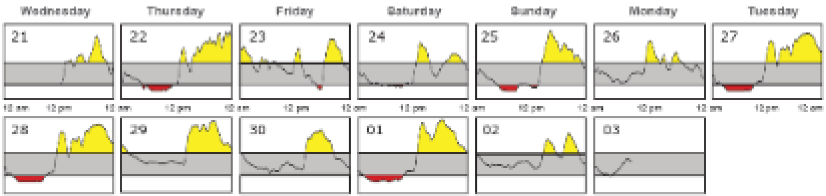


AGP profile (14 days)



Daily views

DAILY GLUCOSE PROFILES



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

captur AGP

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

A1C = 7.7%

AGP Report: Do I have room for improvement?

MGLR

MORE GREEN LESS RED

GLUCOSE STATISTICS AND TARGETS

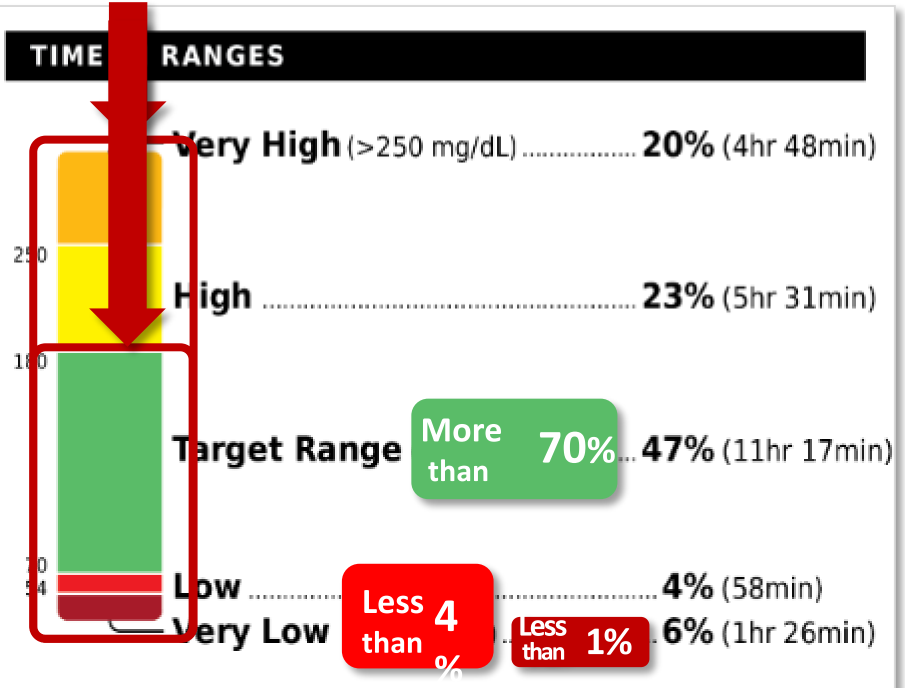
26 Feb 2019 - 10 Mar 2019	**13 days**
% Time CGM is Active	**99.9%**

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 250 mg/dL	Less than 5% (1hr 12min)

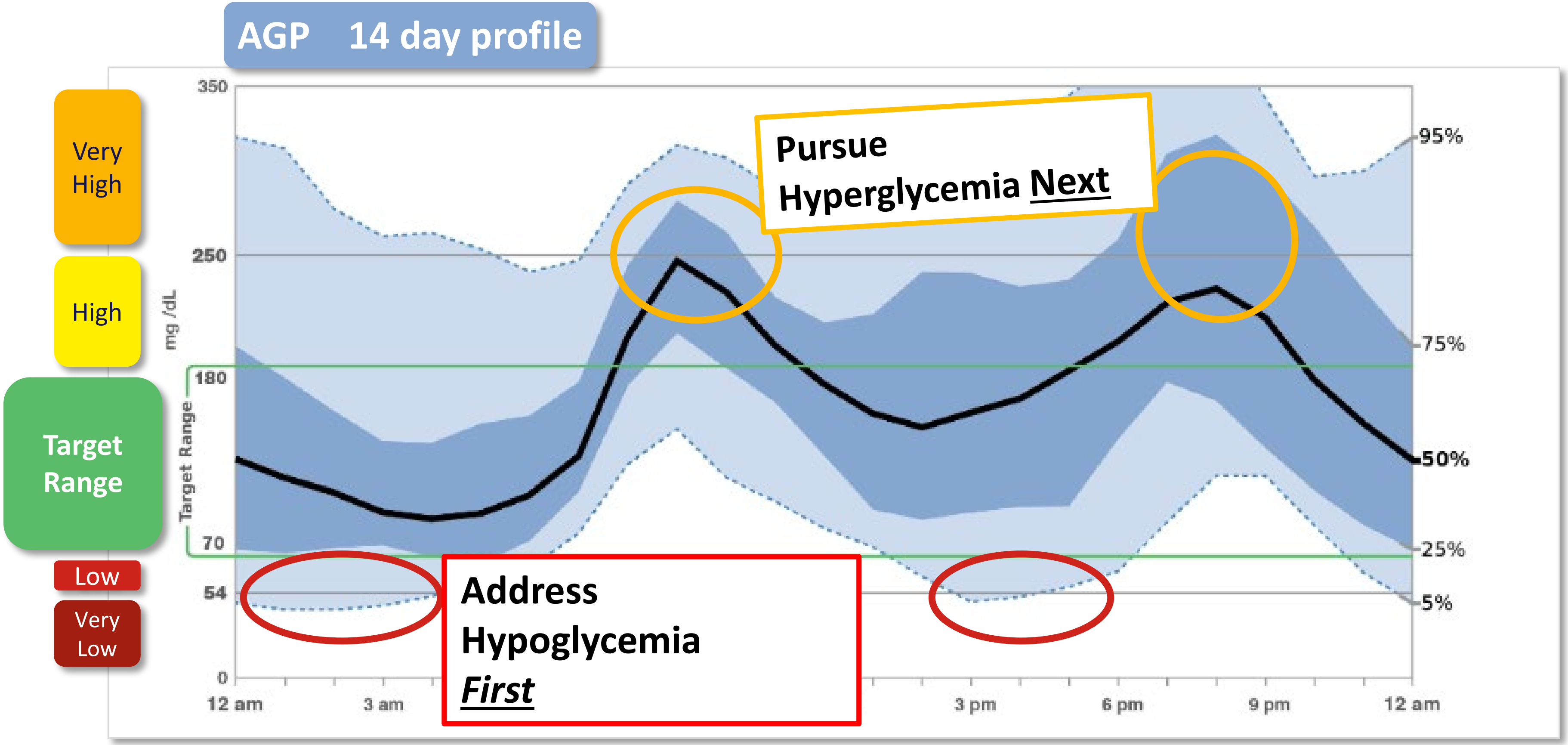
Each 5% increase in time in range (70-180 mg/dL) is clinically beneficial.

Average Glucose	**173 mg/dL**
Glucose Management Indicator (GMI)	**7.6%**
Glucose Variability	**49.5%**

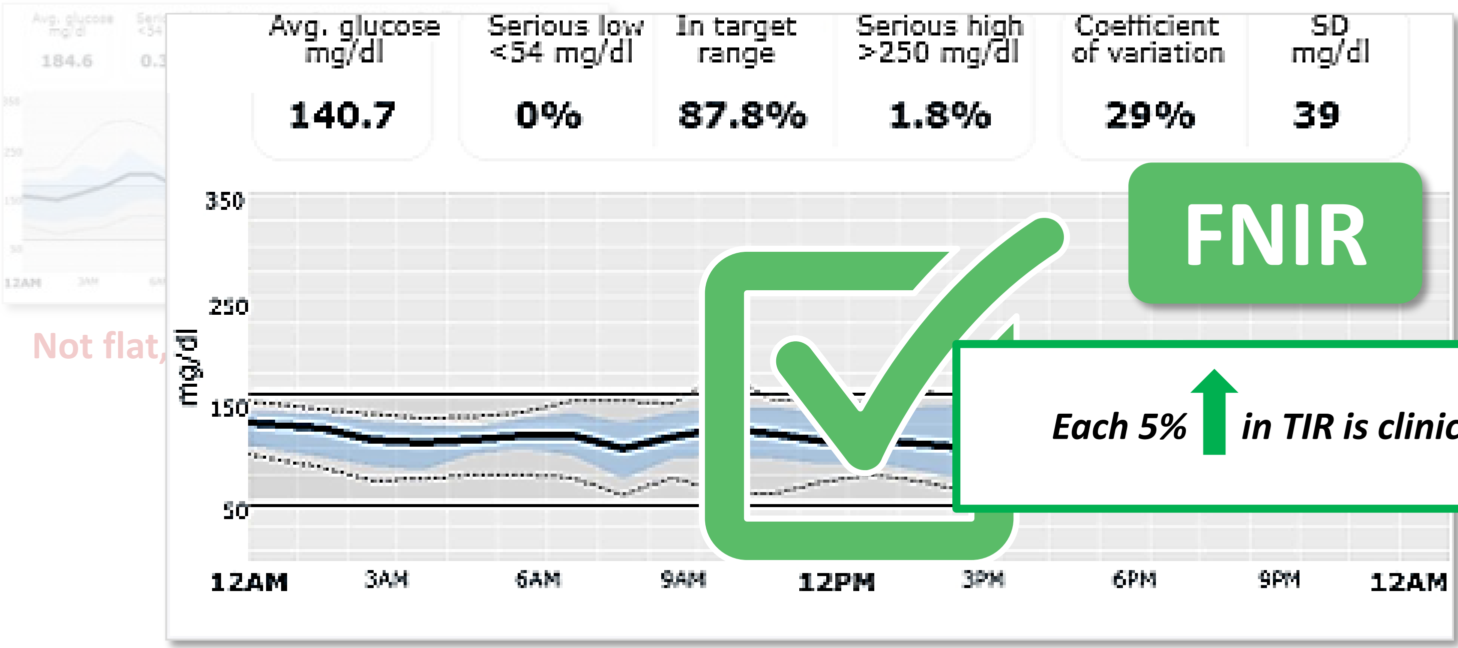
Defined as percent coefficient of variation (%CV); target ≤36%



AGP Report: Where are the out of range values?



What are we striving for in a CGM/AGP profile?



Each 5% ↑ in TIR is clinically significant

Flat, narrow and in range!

Park Nicollet International Diabetes Center

AGP report

Metrics and targets

GLUCOSE STATISTICS AND TARGETS

21 Nov 2018–3 Dec 2018	13 days
% Time CGM is Active	99.9%

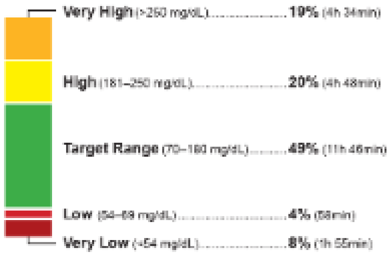
Glucose Ranges	Targets [% of Readings (Time/Day)]
Target Range 70–180 mg/dL	Greater than 70% (16h 48min)
Below 70 mg/dL	Less than 4% (58min)
Below 54 mg/dL	Less than 1% (14min)
Above 180 mg/dL	Less than 25% (6h)
Above 250 mg/dL	Less than 5% (1h 12min)

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

Average Glucose	165 mg/dL
Glucose Management Indicator (GMI)	7.3%
Glucose Variability	49.4%

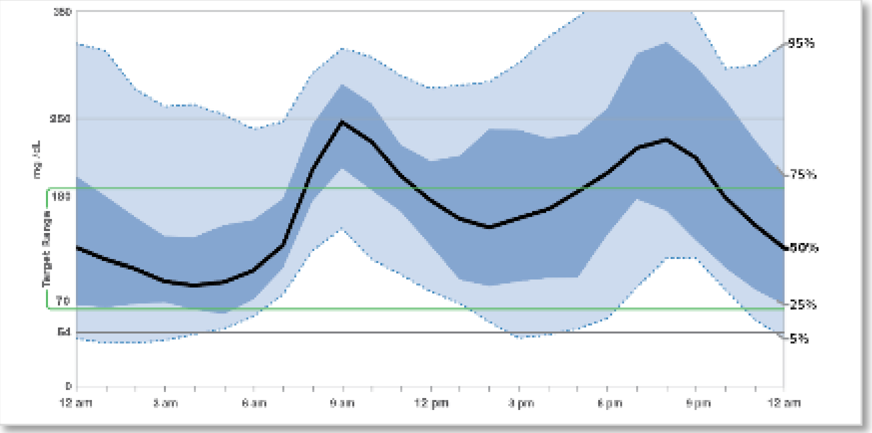
Defined as percent coefficient of variation (%CV); target ≤36%

TIME IN RANGES



MORE GREEN LESS RED

AGP profile (14 days)

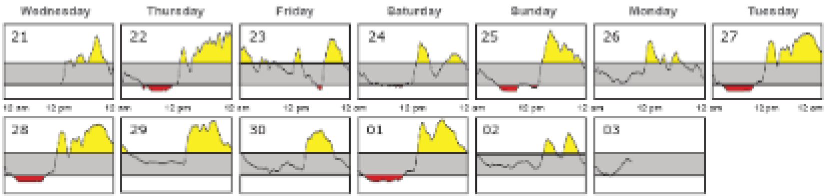


FNIR

Flat
Narrow
In **R**ange

Daily views

DAILY GLUCOSE PROFILES

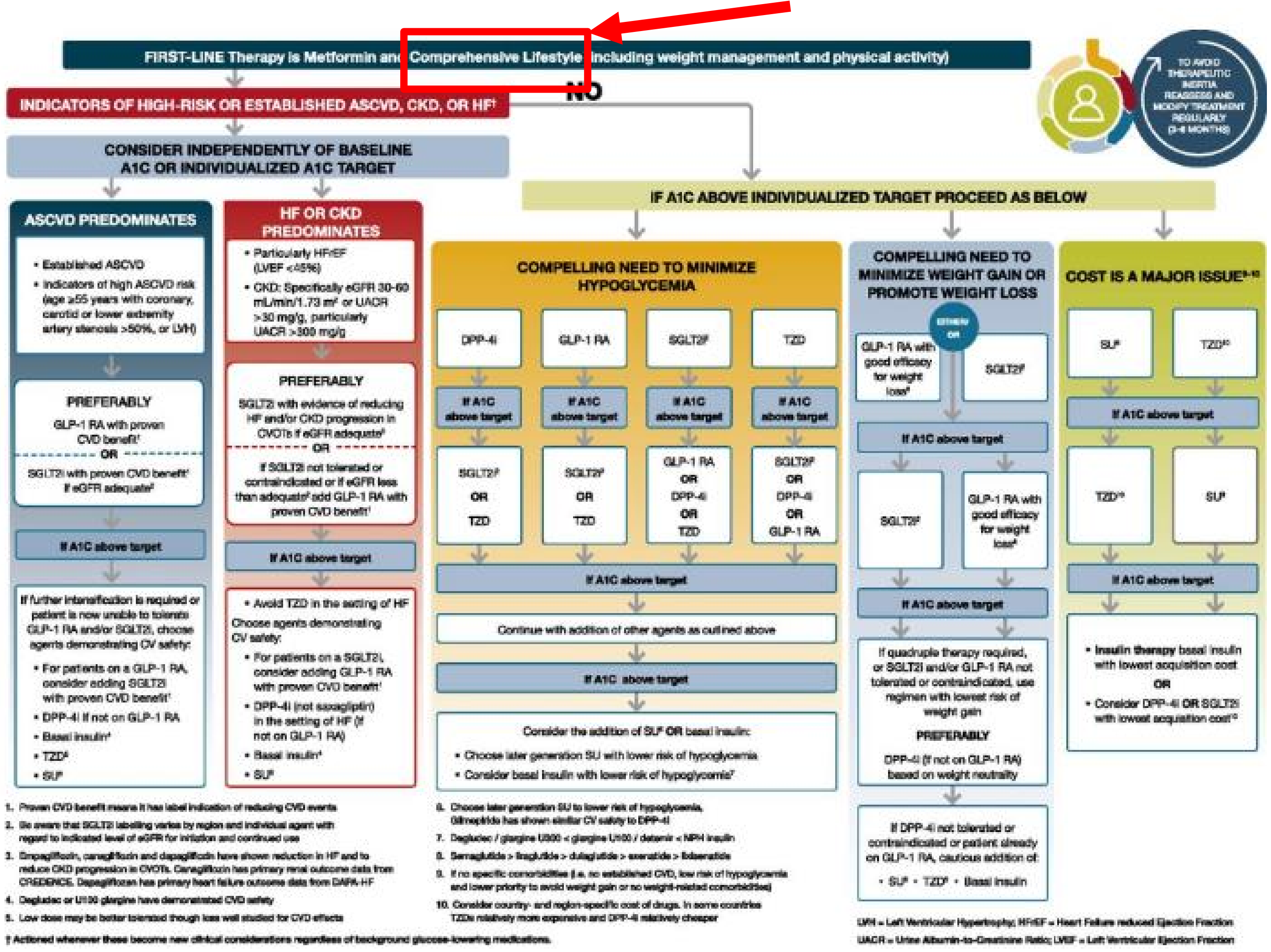


Each daily profile represents a midnight-to-midnight period.

captur AGP

Patterns

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



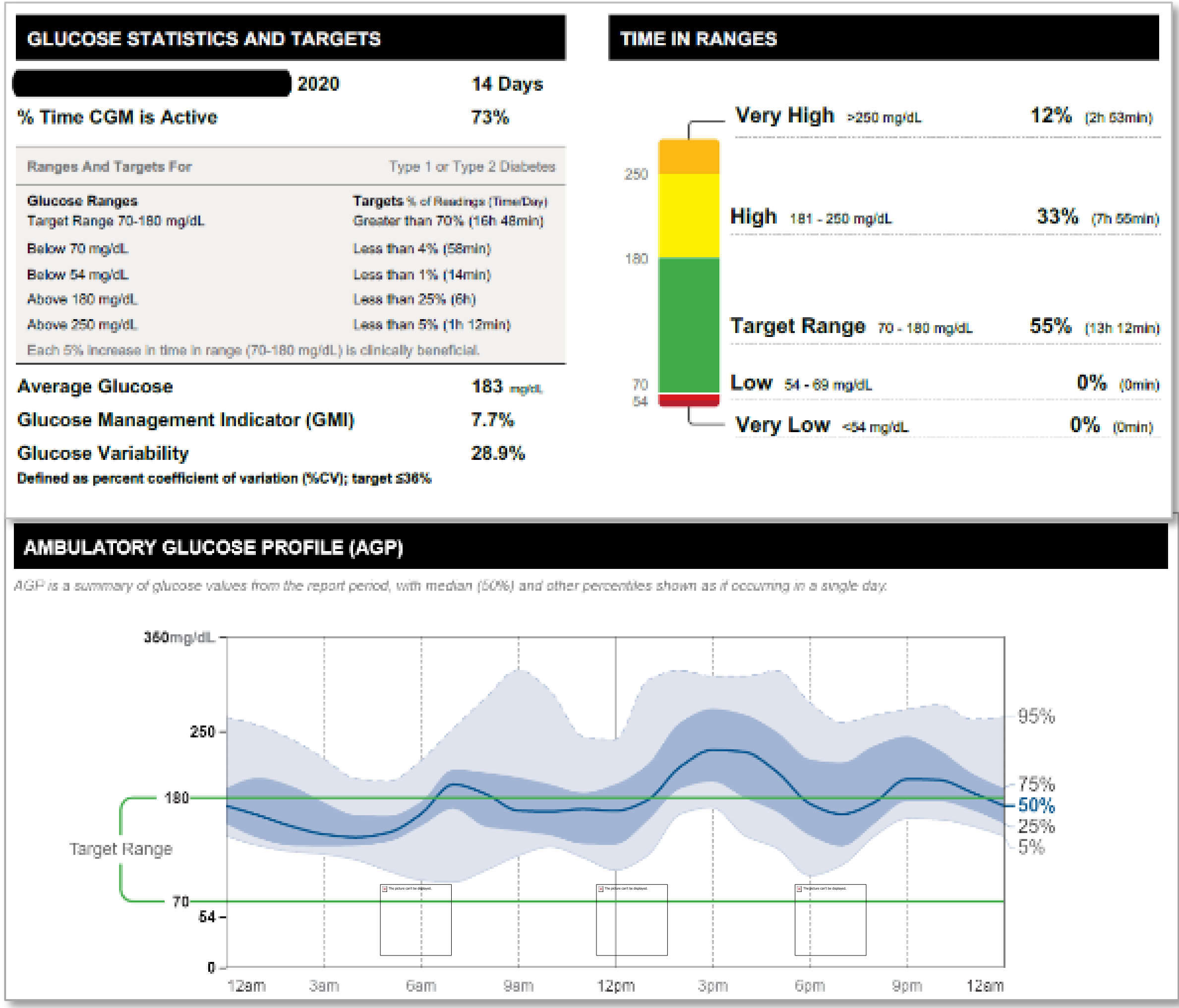
American Diabetes Association Standards of Medical Care in Diabetes 2020. Diabetes Care. January 2020 Volume 43, Supplement 1

AGP Report 1
T2D; non-insulin

3 months ago:
A1C 8.2%; TIR 55%

- Metformin
- SGLT2 inhibitor due to GFR 58

- Reluctant to start 3rd med
- Patient asked for 3 months to make **lifestyle changes**



Continuous Glucose Monitoring

Helping you make lifestyle choices for improved glucose management

Continuous glucose monitoring (CGM) can help you make lifestyle decisions and achieve your glucose targets and your targets for CGM time in ranges. Use this guide to:

- Know your glucose and CGM targets.
- Learn what lifestyle choices affect your glucose levels.
- Choose lifestyle changes that fit into your daily life. You'll know the changes are working when you get closer to your targets.

Knowing your targets

Glucose targets

Fasting and before a meal	1 to 2 hours after a meal
70 to 130 mg/dL	Less than 180 mg/dL

Glucose rises after eating and is highest 1 to 2 hours after a meal or snack. Another target is for your glucose to not rise more than 50 mg/dL after eating.

Getting started

- Look at your CGM glucose readings 10 or more times a day. Best times include:
  - Waking up and before bedtime
  - Before meals and 1 to 2 hours after meals
  - Before and after physical activity
  - When stressed or ill, every 2 to 3 hours
- CGM and fingerstick numbers may differ, especially when glucose is rising or falling. If your symptoms of low glucose don't match your CGM numbers, use your fingerstick number to treat.

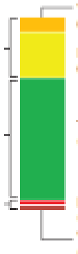
CGM targets

Targets | **Time in ranges**

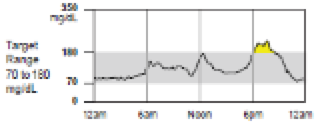
Time above range: target less than 25%

Time in range: target more than 70%

Time below range: target less than 4%



Examples: Bar (left) shows time in target range of 68% over 2 weeks, a little less than the target of more than 70%. Pattern (below) shows glucose for a day that's in target range most of the time.



The yellow shows glucose is above target likely after evening meal. Lifestyle changes can help bring glucose into target. See other side.

Using CGM trend arrows

Use the trend arrows on your CGM to see if your glucose is rising ↑ or falling ↓ or staying steady →. Your trend arrows can help you make changes in your lifestyle choices and medication.

CONTINUED

1 KNOW

2 OBSERVE

3 LEARN

Know your glucose and CGM targets

Knowing your targets

Glucose targets

Fasting and before a meal	1 to 2 hours after a meal
70 to 130 mg/dL	Less than 180 mg/dL

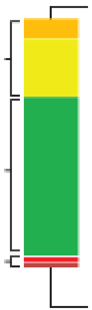
CGM targets

Targets | Time in ranges

Time above range: target less than 25%

Time in range: target more than 70%

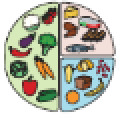
Time below range: target less than 4%



Getting in target more often — What makes a difference for you?

Below are some ideas to keep your glucose in target more often. Circle ideas to try.

Food and Beverages



- Choose whole, fresh foods for meals and snacks.
- Fill ½ your plate with nonstarchy vegetables, such as leafy greens, carrots, broccoli, bell peppers and green beans.
- Decrease portions of foods that you notice usually raise your glucose.
- Avoid sweetened beverages. Choose water from a safe source.
- Limit foods with added sugar, such as cereals, sauces and salad dressings.

Physical Activity

- Move more and sit less every day.
- Increase the intensity of your current activity or try a new activity.
- Walk briskly (or do other activity) for at least 30 minutes, 5 days a week.
- Walk right before or after meals that have the highest glucose peaks.

Medications

Well Being

music, reading or playing with your pet.

Write other ideas to try here: ______________________________

Observing and learning

Compare your glucose to your targets. What's happening when you're in and out of target? Look at the examples below. Write your own example in the space provided.

What I Did	Observe and Compare to Targets		What I Learned
	Before meal 70 to 130 mg/dL	1 to 2 hours after meal Less than 180 mg/dL	
I drank a cup of juice.	128 mg/dL	201 mg/dL	Drinking juice raises my glucose above target, like a sugar-sweetened drink does.
I walked after a meal.	145 mg/dL	175 mg/dL	Activity after a meal helps get my glucose in target.
My example:			

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1 Know 2 Observe 3 Learn

Observe what lifestyle choices impact your glucose

Getting in target more often — What makes a difference for you?

Below are some ideas to keep your glucose in target more often. Circle ideas to try.

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- Walk briskly (or do other activity) for at least 30 minutes, 5 days a week.
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Medications

- Put medication in an easy place to see, and take medication as prescribed.
- Talk to your care team about the need to start or adjust medication, or if you have trouble paying for your medication.

Well Being

- Sleep 7
- Try rela
music, r

Write other ideas to try here: ___

Observing and learning

Compare your glucose to your tar
Look at the examples below. Write

Observing and learning

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1 KNOW 2 OBSERVE 3 LEARN

Learn what choices help you improve your time in range

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AGP Report 2

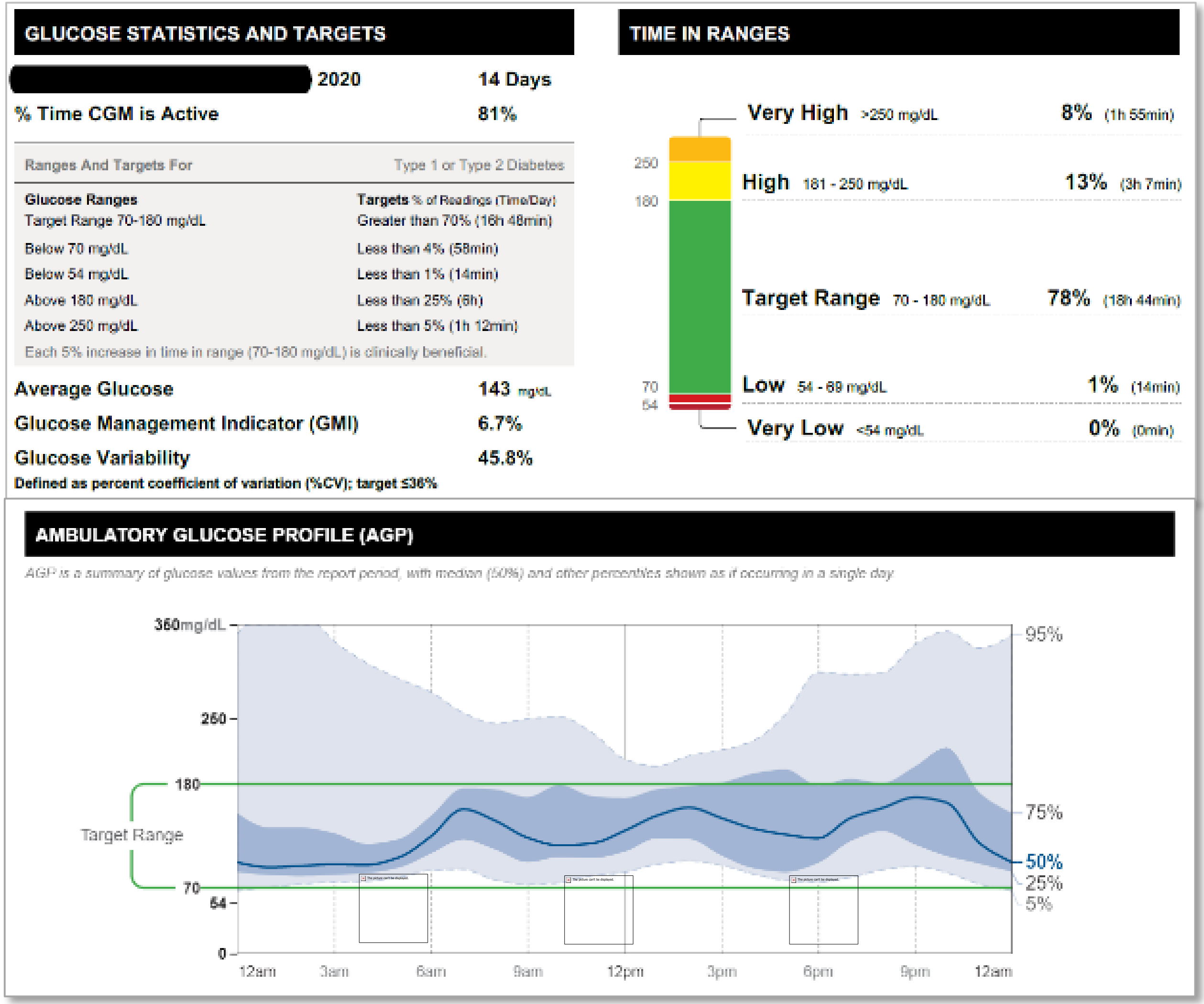
Visit 2 – (4 mo. later)

A1c 7.0 %; TIR 78%

- Metformin
- SGLT2 inhibitor

Changes made with CGM

- **Saw what impacted his glucose.**
- **Focused on:**
  - **Taking meds as prescribed**
  - **Gave up sweet tea at lunch**
  - **Followed plate method**
  - **Increased activity, 4x a week**



Summary: CGM in Primary Care

- **Glucose management** is still a critical component of **comprehensive diabetes care.**
- **CGM /AGP/ Time in Range** may guide glucose management decisions more effectively that A1C
- Many **individuals with T2D** want to a chance to **modify lifestyle** not use more drugs → but it is often unsuccessful
- **CGM /AGP/ Time in Range** has facilitated many **successful lifestyle improvements** → more studies will be helpful to confirm these observations

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Welcome to this SCIENCE-to-STRATEGY SUMMIT

TRANSLATING CLINICAL EVIDENCE FOR SENSOR-BASED GLUCOSE MONITORING AND TECHNOLOGICAL INNOVATIONS TO THE FRONT LINES OF CLINICAL PRACTICE

Focus on Evidence-, Trial-, and Guideline-Based Roadmaps for Deploying Patient-Centric, **Sensor-Based Continuous Glucose Monitoring (CGM)** Technology to Optimize Effectiveness and Safety of Pharmacologic and Behavioral Interventions in Persons with Diabetes

A Year 2020, Best Practice, Technology-Based Advances Program in Diabetes Care: Roadmaps to Clinical Success in Diabetes Management