Best Practices in the Time of COVID-19 and Beyond

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Disclosure of Potential Conflicts of Interest

Advisory Boards

- Abbott Diabetes Care
- Lilly
- Medscape
- NovoNordisk
- Zealand

Research Funding

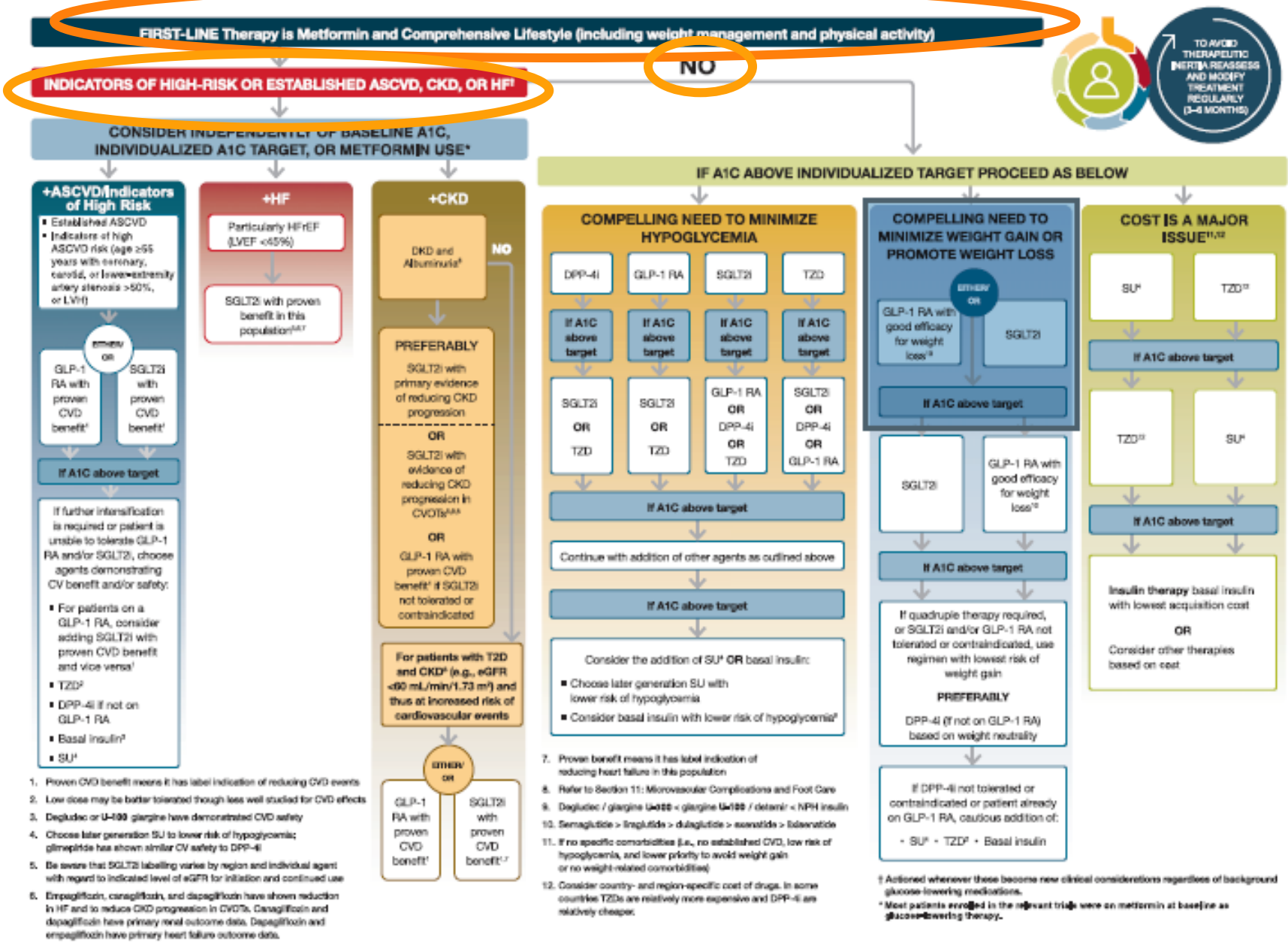
- Dexcom
- vTv Therapeutics
- Devices from Abbott Diabetes Care

Stock Options

- Omada Health
- Teladoc/Livongo

Management of Diabetes Has Changed

- New, non-glycemic paradigm for treating people with T2DM and CVD/HF/CKD
- CGM technology changes us from an A1C focus to a TIR focus
- T1DM management has been revolutionized by technology

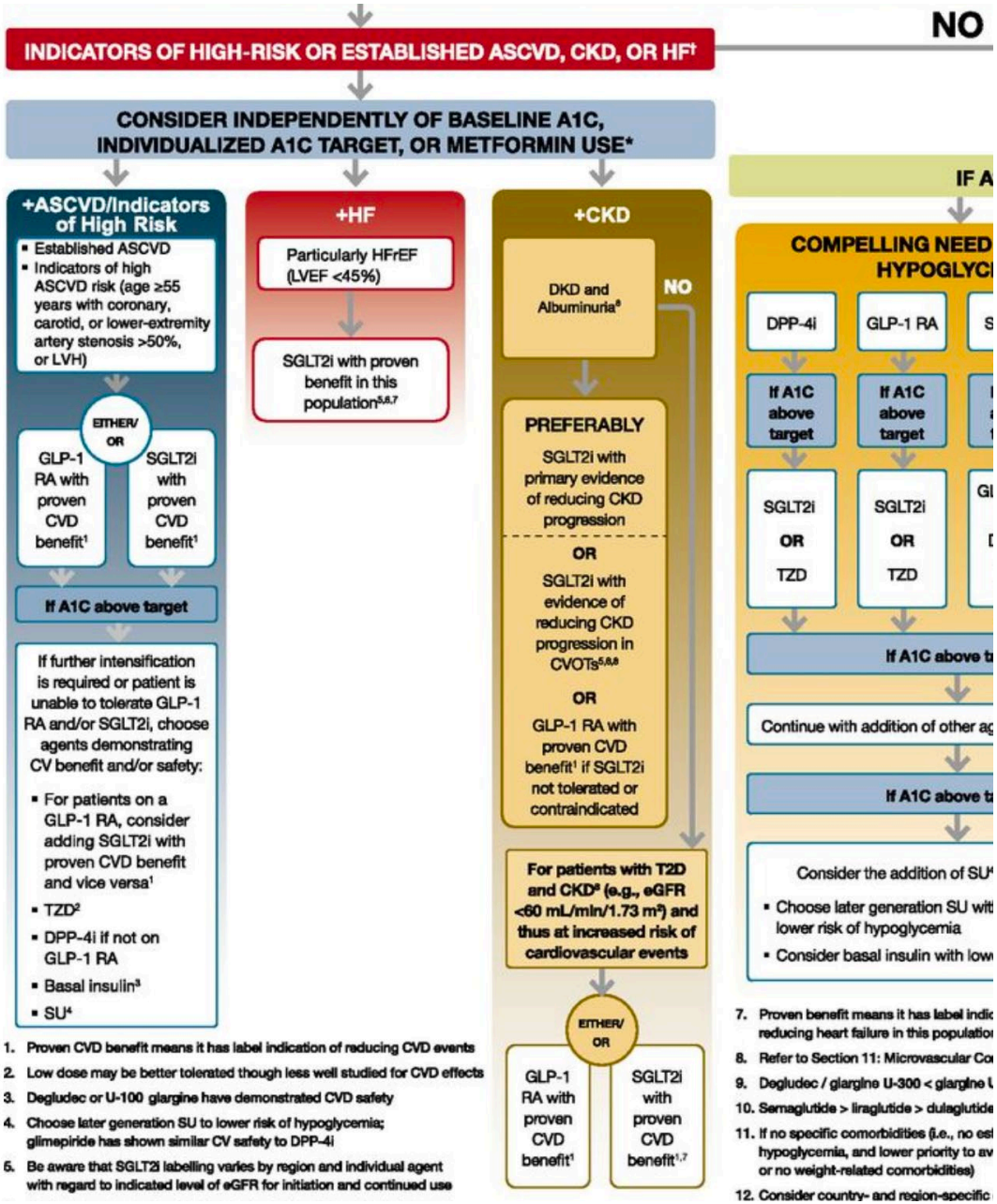


1. Proven CVD benefit means it has label indication of reducing CVD events
2. Low dose may be better tolerated though less well studied for CVD effects
3. Degludec or U-100 glargine have demonstrated CVD safety
4. Choose later generation SU to lower risk of hypoglycemia; glimepiride has shown similar CV safety to DPP-4i
5. Be aware that SGLT2i labelling varies by region and individual agent with regard to indicated level of eGFR for initiation and continued use
6. Empagliflozin, canagliflozin, and dapagliflozin have shown reduction in HF and to reduce CKD progression in CVOTs. Canagliflozin and dapagliflozin have primary renal outcome data. Dapagliflozin and empagliflozin have primary heart failure outcome data.
7. Proven benefit means it has label indication of reducing heart failure in this population
8. Refer to Section 11: Microvascular Complications and Foot Care
9. Degludec / glargine U-300 < glargine U-100 / detemir < NPH insulin
10. Semaglutide > lixisenatide > dulaglutide > exenatide > liraglutide
11. If no specific comorbidities (i.e., no established CVD, low risk of hypoglycemia, and lower priority to avoid weight gain or no weight-related comorbidities)
12. Consider country- and region-specific cost of drugs. In some countries TZDs are relatively more expensive and DPP-4i are relatively cheaper.

† Actioned whenever these become new clinical considerations regardless of background glucose-lowering medications.

* Most patients enrolled in the relevant trials were on metformin at baseline as glucose-lowering therapy.

Standards of Medical Care in Diabetes - 2021. Diabetes Care 2021;44(Suppl. 1):S111-S124



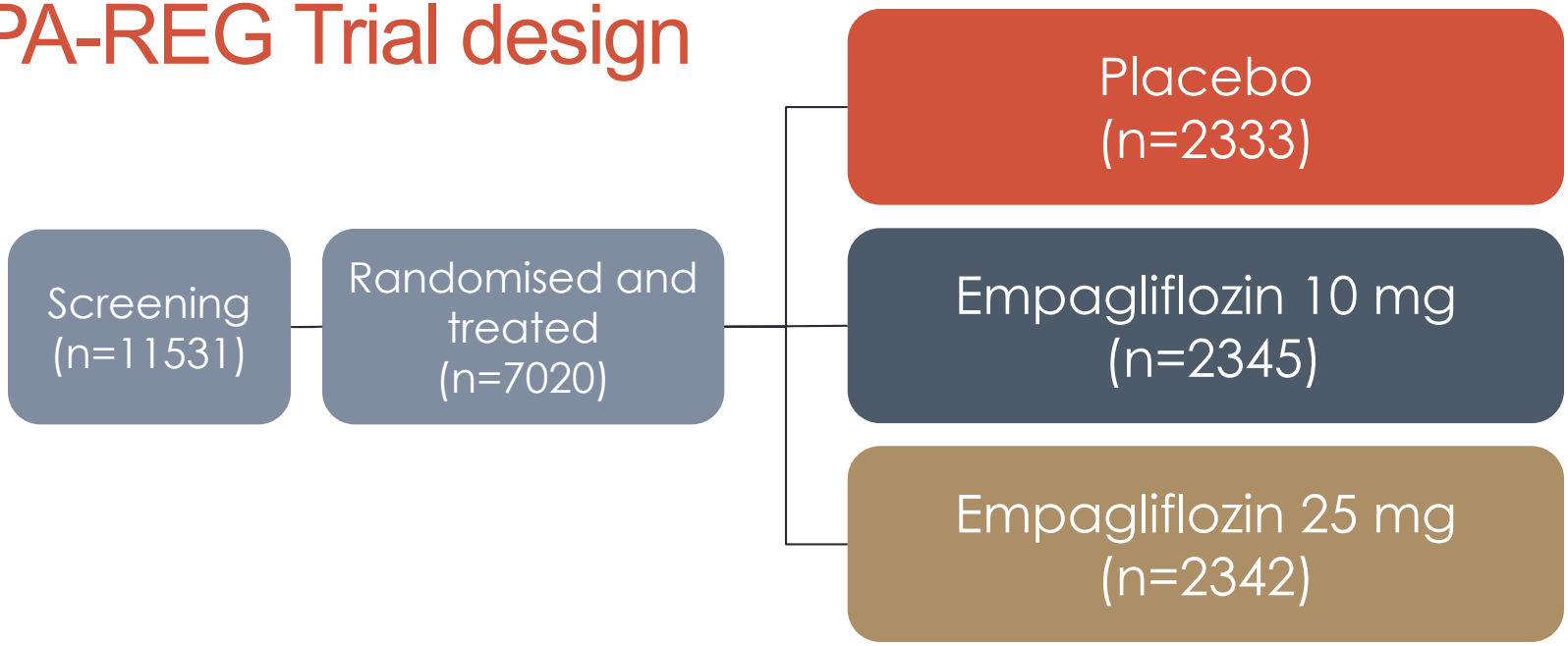
Diabetes Care 2021;44(Suppl. 1):S1–S12 | https://doi.org/10.2337/dc21-S006

CV Outcomes Trials in Diabetes: SGLT-2 I

Study	EMPA-REG	CANVAS Program	DECLARE-TIMI	VERTIS-CV
SGLT-2 I	empagliflozin	canagliflozin	dapagliflozin	ertugliflozin
N	7028	10,142	17,276	2846
Reported	2015	2017	2018	2020
CVOT Outcome	Benefit	Benefit	Benefit	Noninferior
Renal and HF Outcome	Benefit	Benefit	Benefit	Benefit

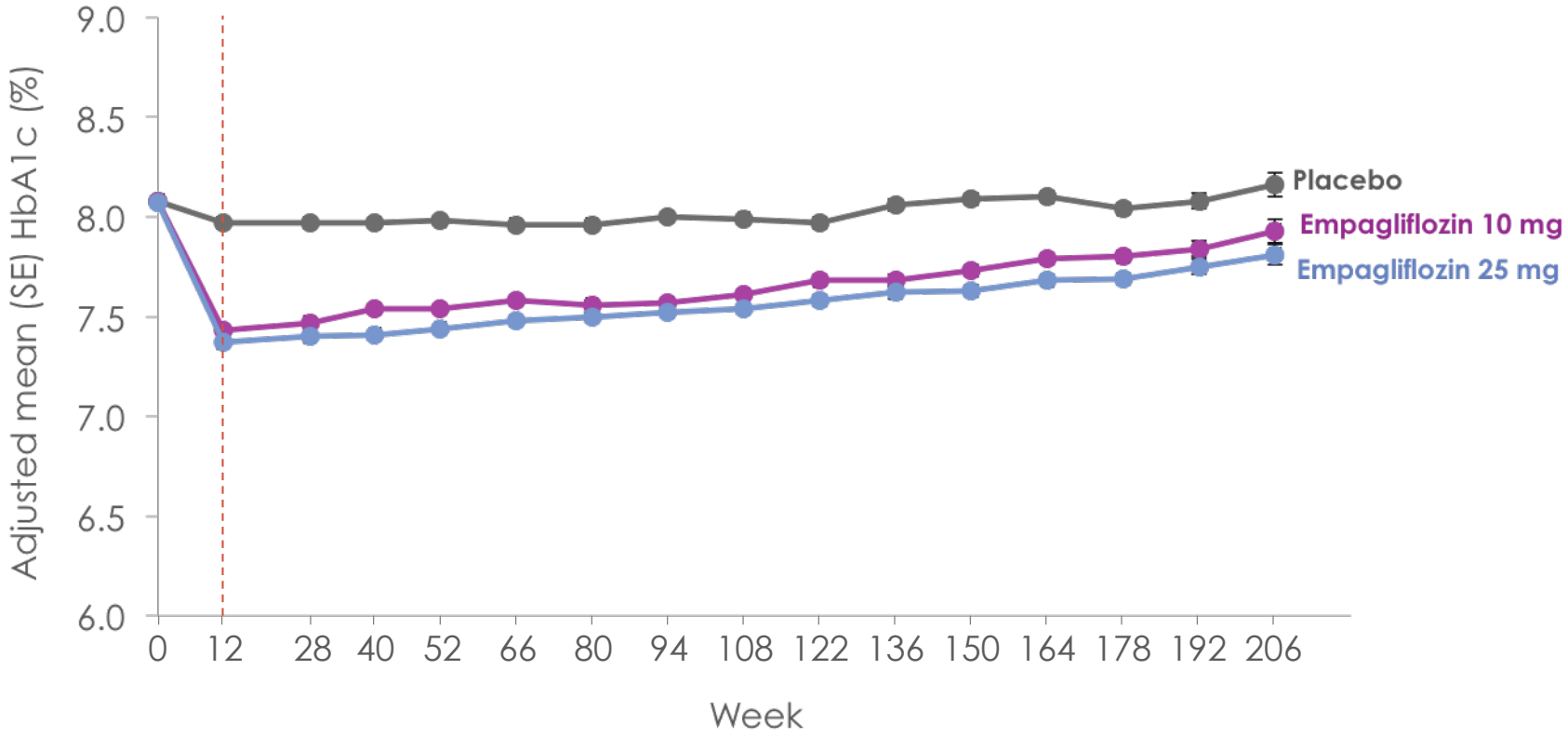
N Engl J Med 2015; 373:2117-2128, N Engl J Med 2017; 377:644-657,

EMPA-REG Trial design



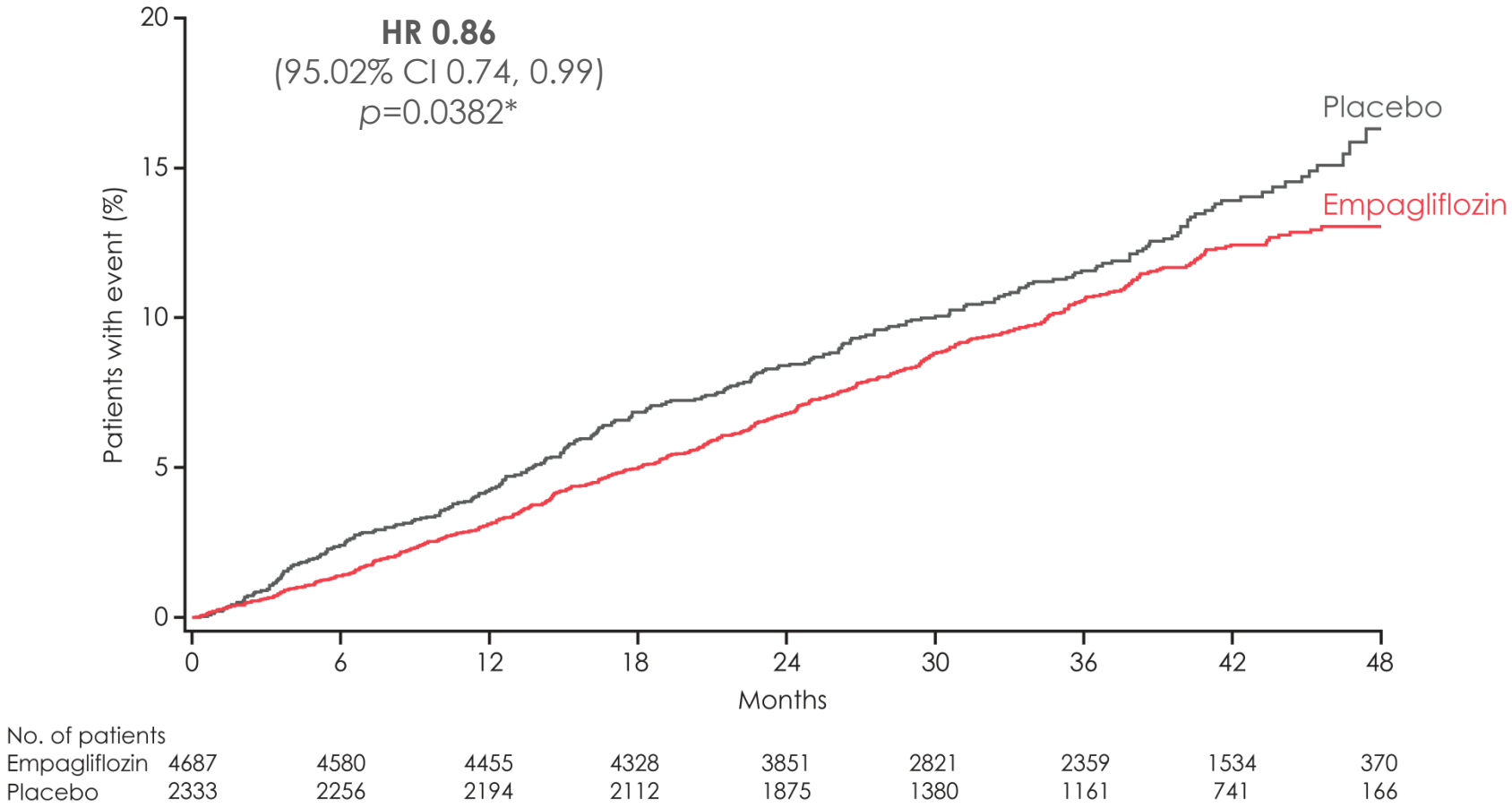
- Study medication was given in addition to standard of care
  - Glucose-lowering therapy was to remain unchanged for first 12 weeks
- Treatment assignment double masked
- The trial was to continue until at least 691 patients experienced an adjudicated primary outcome event

HbA1c

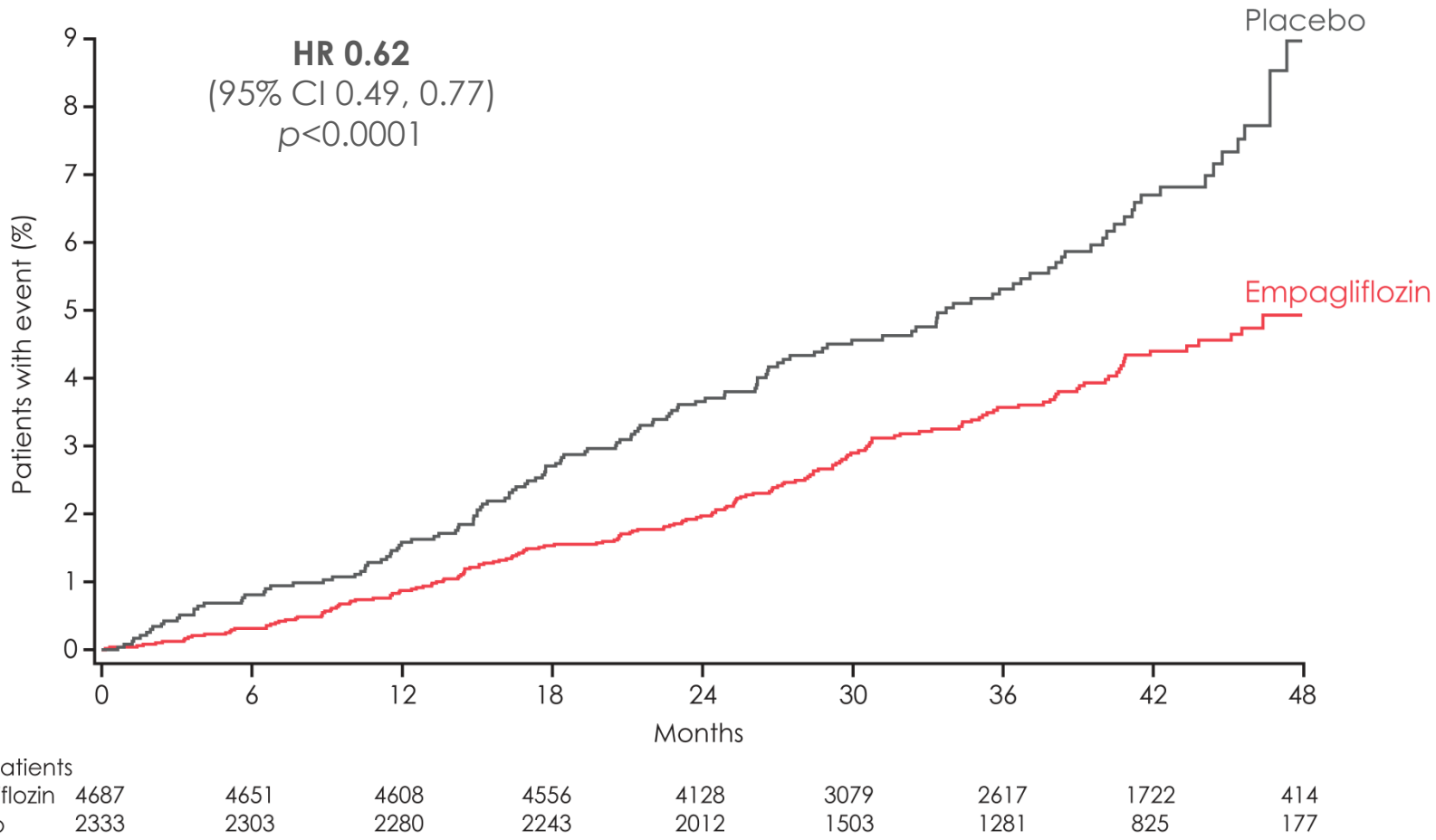


Placebo	2294	2272	2188	2133	2113	2063	2008	1967	1741	1456	1241	1109	962	705	420	151
Empagliflozin 10 mg	2296	2272	2218	2150	2155	2108	2072	2058	1805	1520	1297	1164	1006	749	488	170
Empagliflozin 25 mg	2296	2280	2212	2152	2150	2115	2080	2044	1842	1540	1327	1190	1043	795	498	195

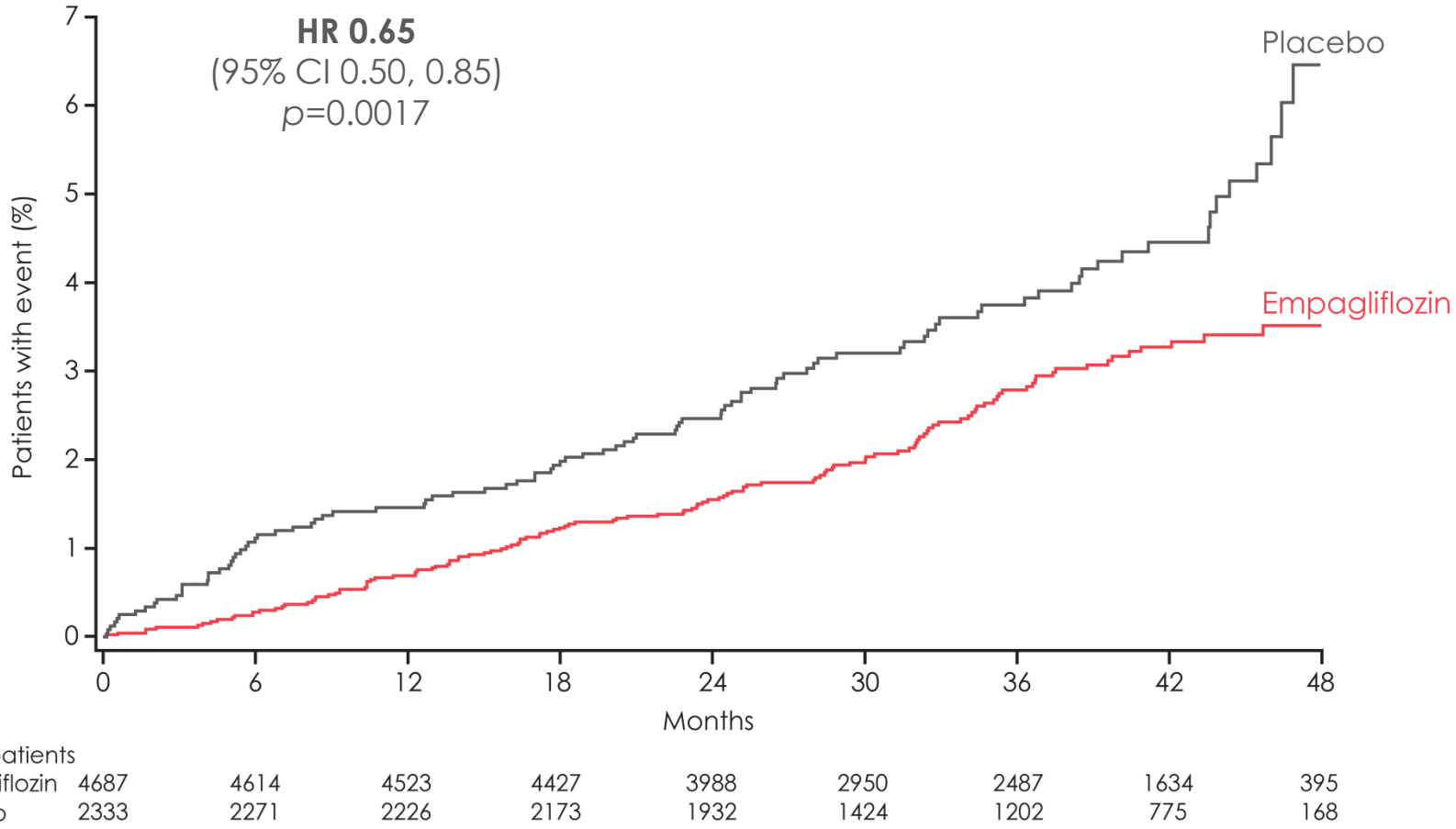
Primary outcome: 3-point MACE



CV death


HR 0.62
(95% CI 0.49, 0.77)
p<0.0001
Placebo
Empagliflozin
Patients with event (%)
0
1
2
3
4
5
6
7
8
9
0
6
12
18
24
30
36
42
48
Months
No. of patients
Empagliflozin 4687 4651 4608 4556 4128 3079 2617 1722 414
Placebo 2333 2303 2280 2243 2012 1503 1281 825 177

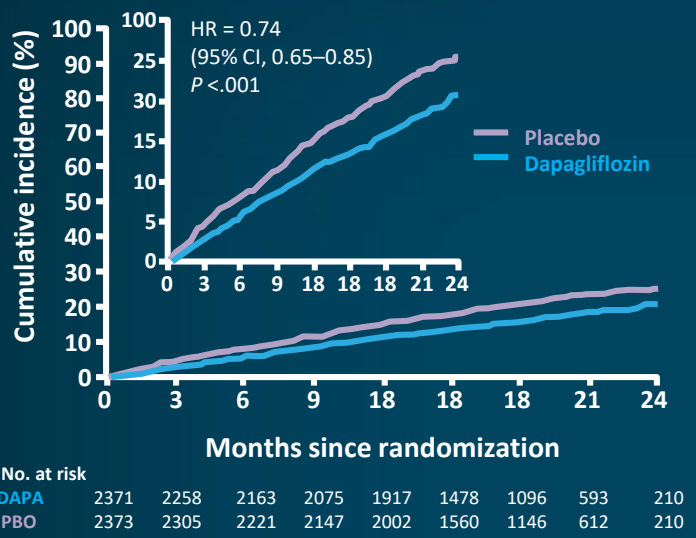
Hospitalisation for heart failure



Cumulative incidence function. HR, hazard ratio

DAPA HF Primary Outcomes: DM vs Non-DM Subgroups

Primary outcome



No. at risk

DAPA	2371	2258	2163	2075	1917	1478	1096	593	210
PBO	2373	2305	2221	2147	2002	1560	1146	612	210

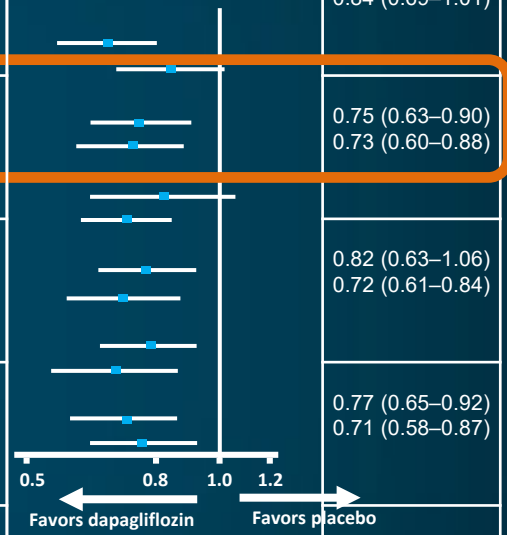
DAPA = dapagliflozin; AFib = atrial fibrillation; ECG = electrocardiogram; IV = intravenous.

McMurray JJV, et al. *N Engl J Med.* 2019;381:1995-2008.

Primary outcome was composite of worsening HF (*hospitalization for HF or urgent visit resulting in IV treatment for HF*) or CV death, which occurred in a significantly lower (*P* <.001) percentage of patients in dapagliflozin group (16.3%) vs placebo (21.2%).

Primary outcome subgroup analysis

Subgroup	DAPA n = 2373	PBO n = 2371	Hazard Ratio (95% CI)
	Patients/total, no.		
Hospitalization for heart failure			
Yes	195/1124	279/1127	0.67 (0.56–0.80)
No	191/1249	223/1244	0.84 (0.69–1.01)
Type 2 diabetes at baseline			
Yes	215/1075	271/1064	0.75 (0.63–0.90)
No	171/1298	231/1307	0.73 (0.60–0.88)
Afib or flutter on enrollment ECG			
Yes	109/569	126/559	0.82 (0.63–1.06)
No	277/1804	376/1812	0.72 (0.61–0.84)
Main cause of heart failure			
Ischemic	223/1316	289/1358	0.77 (0.65–0.92)
Non-ischemic or unknown	163/1057	213/1013	0.71 (0.58–0.87)
Body-mass index			
<30	259/1537	320/1533	0.78 (0.66–0.92)
≥30	127/834	182/838	0.69 (0.55–0.86)
Baseline eGFR (ml/min/1.73m^2)			
<60	191/962	254/964	0.72 (0.59–0.86)
≥60	195/1410	248/1406	0.76 (0.63–0.92)

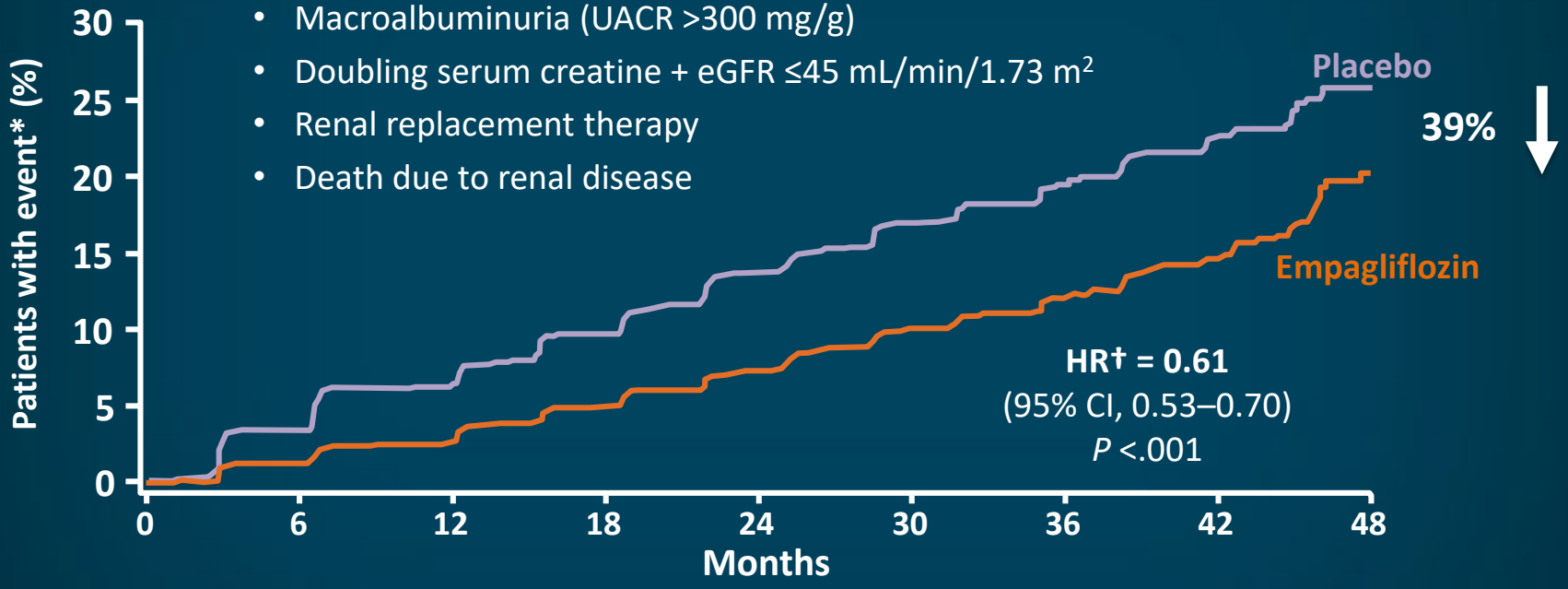


EMPA-REG OUTCOME: Secondary Outcome

Cumulative Incidence of Incident or Worsening Nephropathy

Incident or worsening nephropathy includes:

- Macroalbuminuria (UACR >300 mg/g)
- Doubling serum creatine + eGFR ≤45 mL/min/1.73 m^2
- Renal replacement therapy
- Death due to renal disease

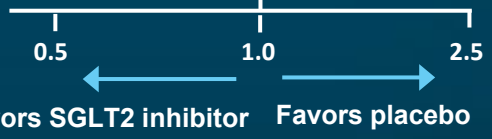


*Kaplan-Meier estimate; †Hazard ratio based on Cox regression analyses.

Wanner C, et al. *N Engl J Med*. 2016;375:323-334.

Meta-analysis of Effects of SGLT2 Inhibitors on Major Kidney Outcomes

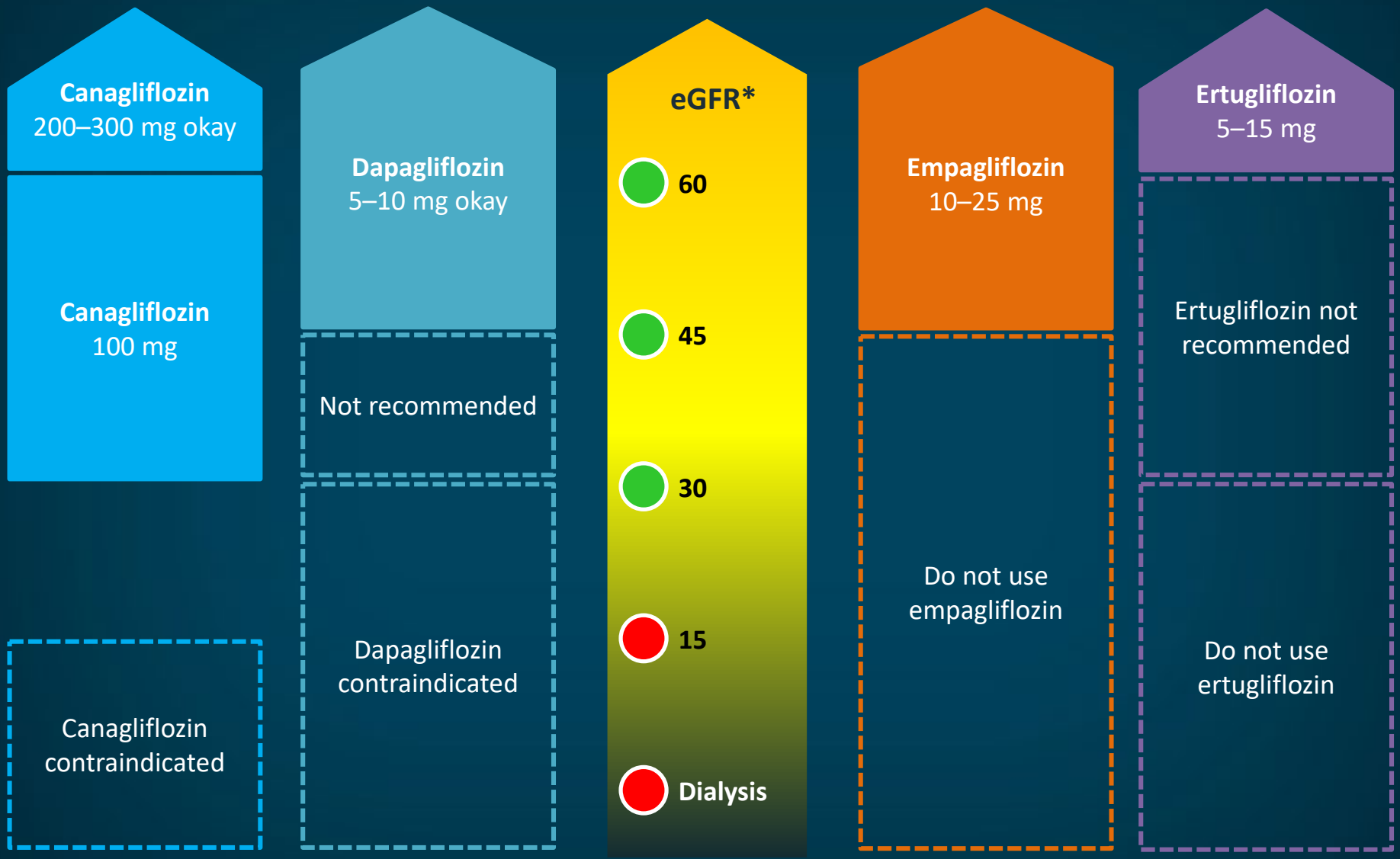
Major kidney outcomes	Events	Patients	RR (95% CI)
Dialysis, transplantation, or death due to kidney disease	252	38,723	0.67 (0.52–0.86)
ESKD	335	38,723	0.65 (0.53–0.81)
Substantial loss of kidney function, ESKD, or death due to kidney disease	967	38,671	0.58 (0.51–0.66)
Substantial loss of kidney function, ESKD, or death due to CV or kidney disease	2323	38,676	0.71 (0.63–0.82)
Acute kidney injury	943	38,684	0.75 (0.66–0.85)



RR = relative risk.

Neuen BL, et al. *Lancet Diabetes Endocrinol.* 2019;7:845-854.

Current Renal Restrictions: SGLT2 Inhibitors



*eGFR in mL/min/1.73m^2.

Prescribing information for canagliflozin, dapagliflozin, empagliflozin, and ertugliflozin.

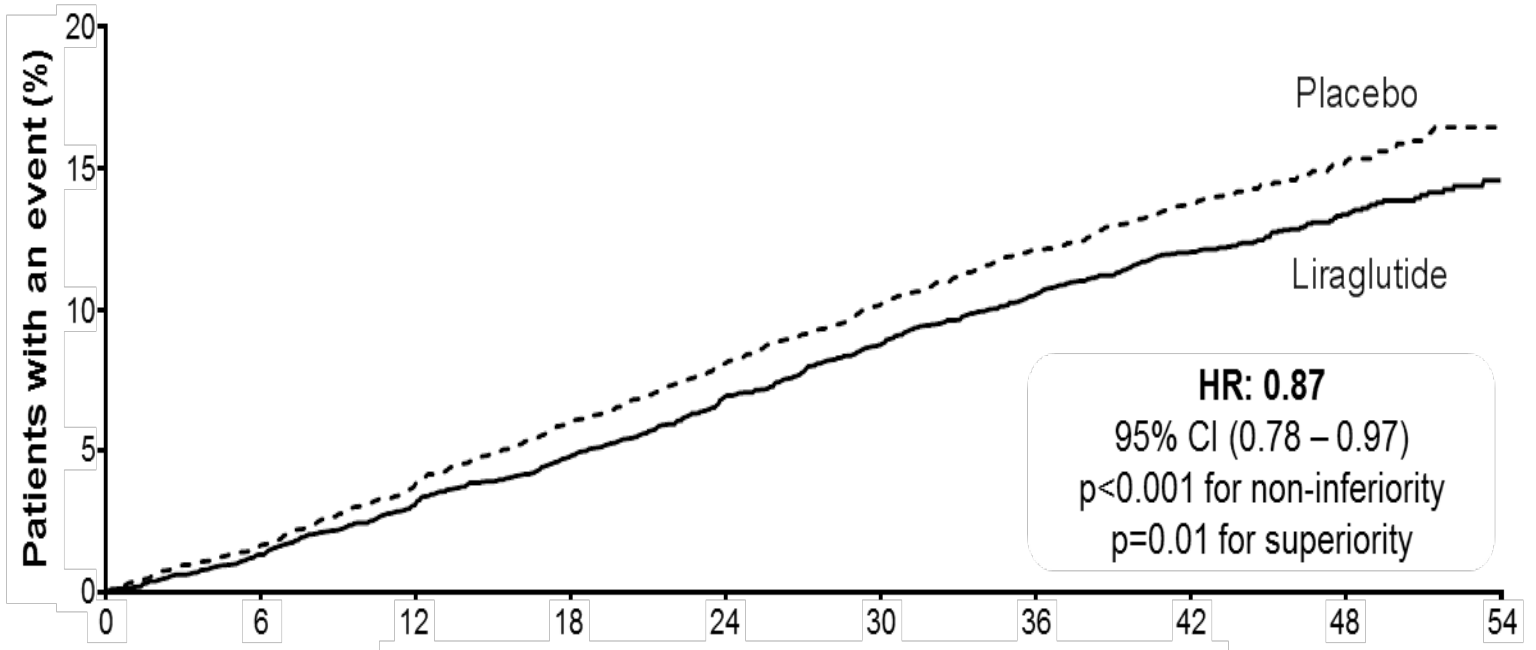
CV Outcomes Trials in Diabetes: GLP1-RA

Study	ELIXA	FREEDOM -CVO	LEADER	SUSTAIN 6	EXSCEL	REWIND
GLP1-RA	Lixi-senatide	ITCA-650 exenatide	liraglutide	semaglutide	Exenatide LR	dulaglutide
N	6,068	~4,000	9,340	3,297	14,752	9,901
Reported	2015	2016	2016	2016	2017	(2018)
CVOT Outcome	Neutral	Neutral	Benefit In label	Benefit	Neutral	Benefit
Other			Renal benefit	Worsening retinopathy		31% CVD; A1C = 7.3%

N Engl J Med 2016; 375:1834-1844, N Engl J Med 2016;375:311-322, Diab Obes Metab 2018;20:42-49, N Engl J Med 2017;377:1228-1239, NEJM 2015;373:2247-2257

Primary outcome

CV death, non-fatal myocardial infarction, or non-fatal stroke



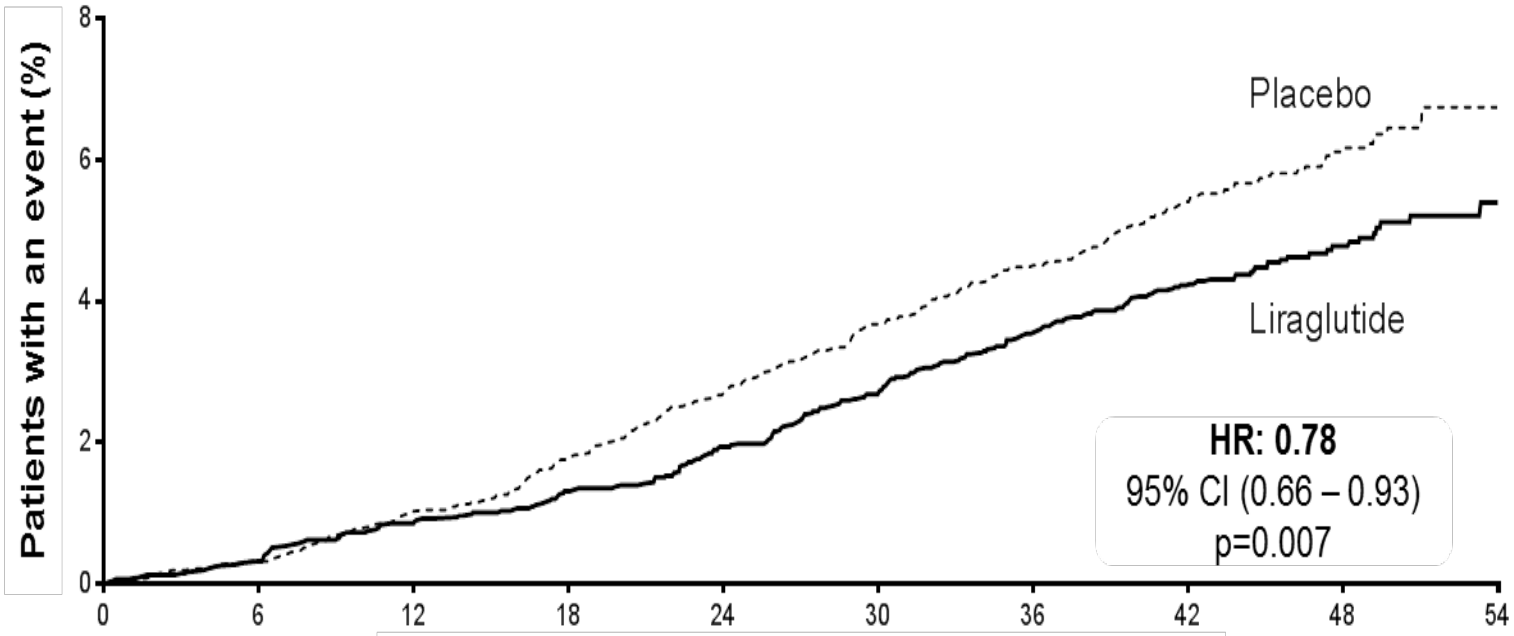
Patients at risk

Liraglutide	4668	4593	4496	4400	4280	4172	4072	3982	1562	424
Placebo	4672	4588	4473	4352	4237	4123	4010	3914	1543	407

The primary composite outcome in the time-to-event analysis was the first occurrence of death from cardiovascular causes, non-fatal myocardial infarction, or non-fatal stroke. The cumulative incidences were estimated with the use of the Kaplan–Meier method, and the hazard ratios with the use of the Cox proportional-hazard regression model. The data analyses are truncated at 54 months, because less than 10% of the patients had an observation time beyond 54 months. CI: confidence interval; CV: cardiovascular; HR: hazard ratio.

Presented at the American Diabetes Association 76th Scientific Sessions, Session 3-CT-SY24. June 13 2016, New Orleans, LA, USA.

CV death



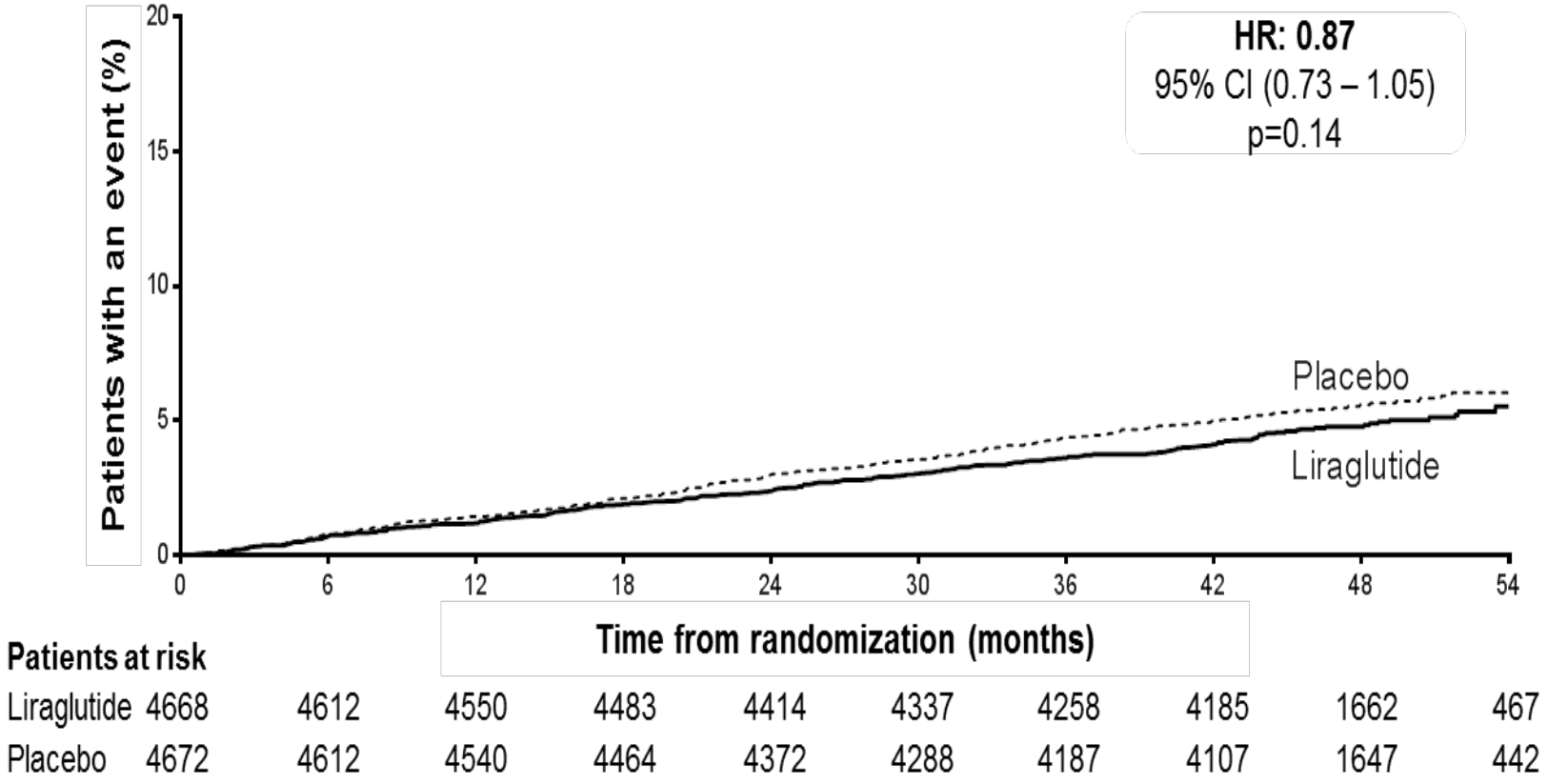
Patients at risk

Liraglutide	4668	4641	4599	4558	4505	4445	4382	4322	1723	484
Placebo	4672	4648	4601	4546	4479	4407	4338	4267	1709	465

The cumulative incidences were estimated with the use of the Kaplan–Meier method, and the hazard ratios with the use of the Cox proportional-hazard regression model. The data analyses are truncated at 54 months, because less than 10% of the patients had an observation time beyond 54 months.
CI: confidence interval; CV: cardiovascular; HR: hazard ratio.

Presented at the American Diabetes Association 76th Scientific Sessions, Session 3-CT-SY24. June 13 2016, New Orleans, LA, USA.

Hospitalization for heart failure



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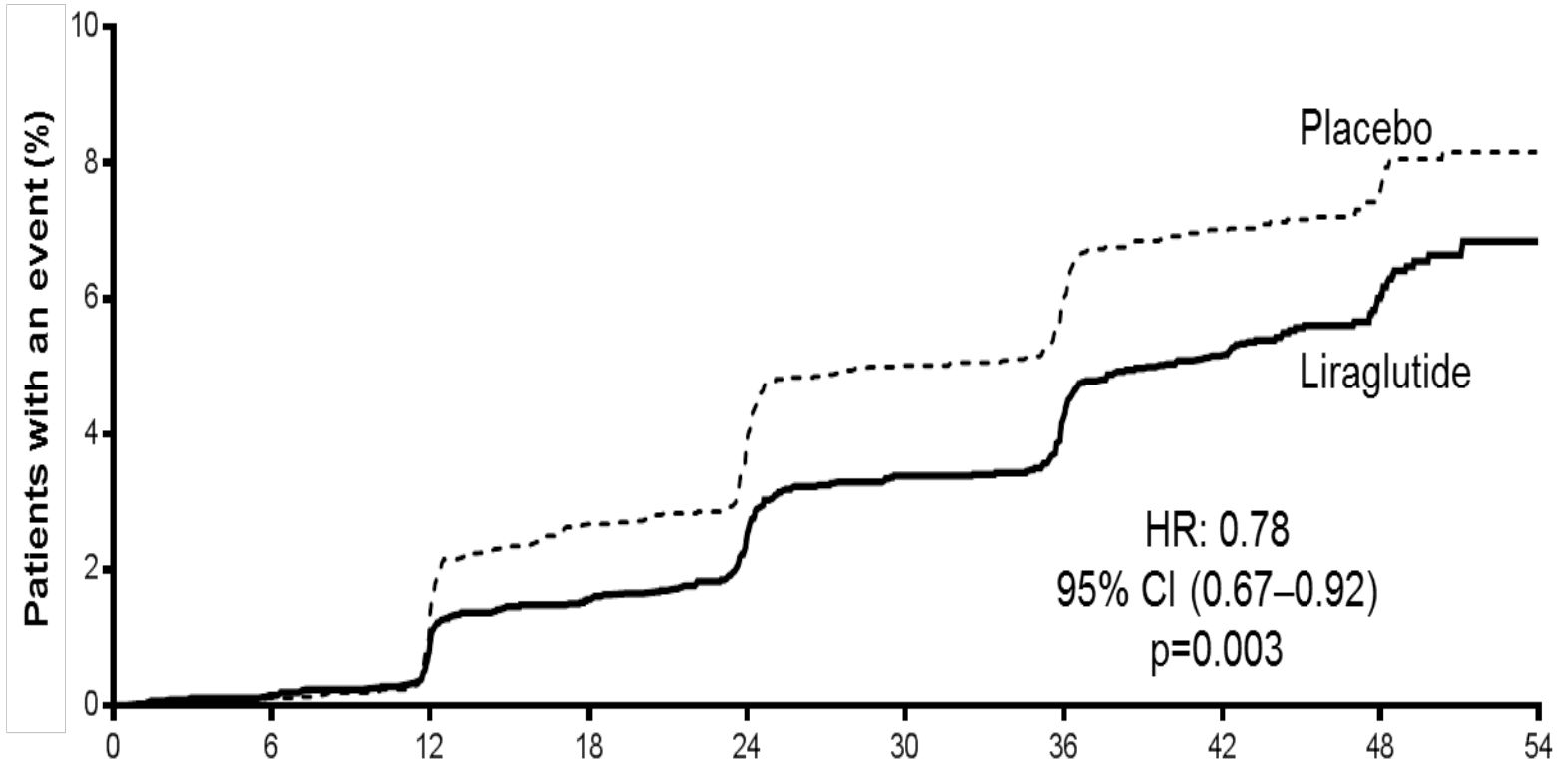
Presented at the American Diabetes Association 76th Scientific Sessions, Session 3-CT-SY24. June 13 2016, New Orleans, LA, USA.

Time to first renal event

Macroalbuminuria, doubling of serum creatinine, ESRD, renal death



Patients at risk										
Liraglutide	4668	4635	4561	4492	4400	4304	4210	4114	1632	454
Placebo	4672	4643	4540	4428	4316	4196	4094	3990	1613	433

The cumulative incidences were estimated with the use of the Kaplan–Meier method, and the hazard ratios with the use of the Cox proportional-hazard regression model. The data analyses are truncated at 54 months, because less than 10% of the patients had an observation time beyond 54 months. CI: confidence interval; ESRD: end-stage renal disease; HR: hazard ratio.

Presented at the American Diabetes Association 76th Scientific Sessions, Session 3-CT-SY24. June 13 2016, New Orleans, LA, USA.

Case

- JR is a 60 yo male with a 6 year history of type 2 diabetes
- He has always been well controlled on metformin 1 gm BID with an A1C of 5.8 – 6.5%
- 10 years ago he had an MI from which he fully recovered
- He runs walks 5 miles daily for exercise; he eats fairly well but consumes rice/bread with most meals.
- He is on a statin, an ARB and an aspirin.
- His BP = 128/78, BMI = 23.4 kg/m^2, LDL = 65, eGFR = 70
- His most recent A1C is 6.1% and his blinded CGM tracing is as follows.

Type 2 Diabetes with CVD on Metformin

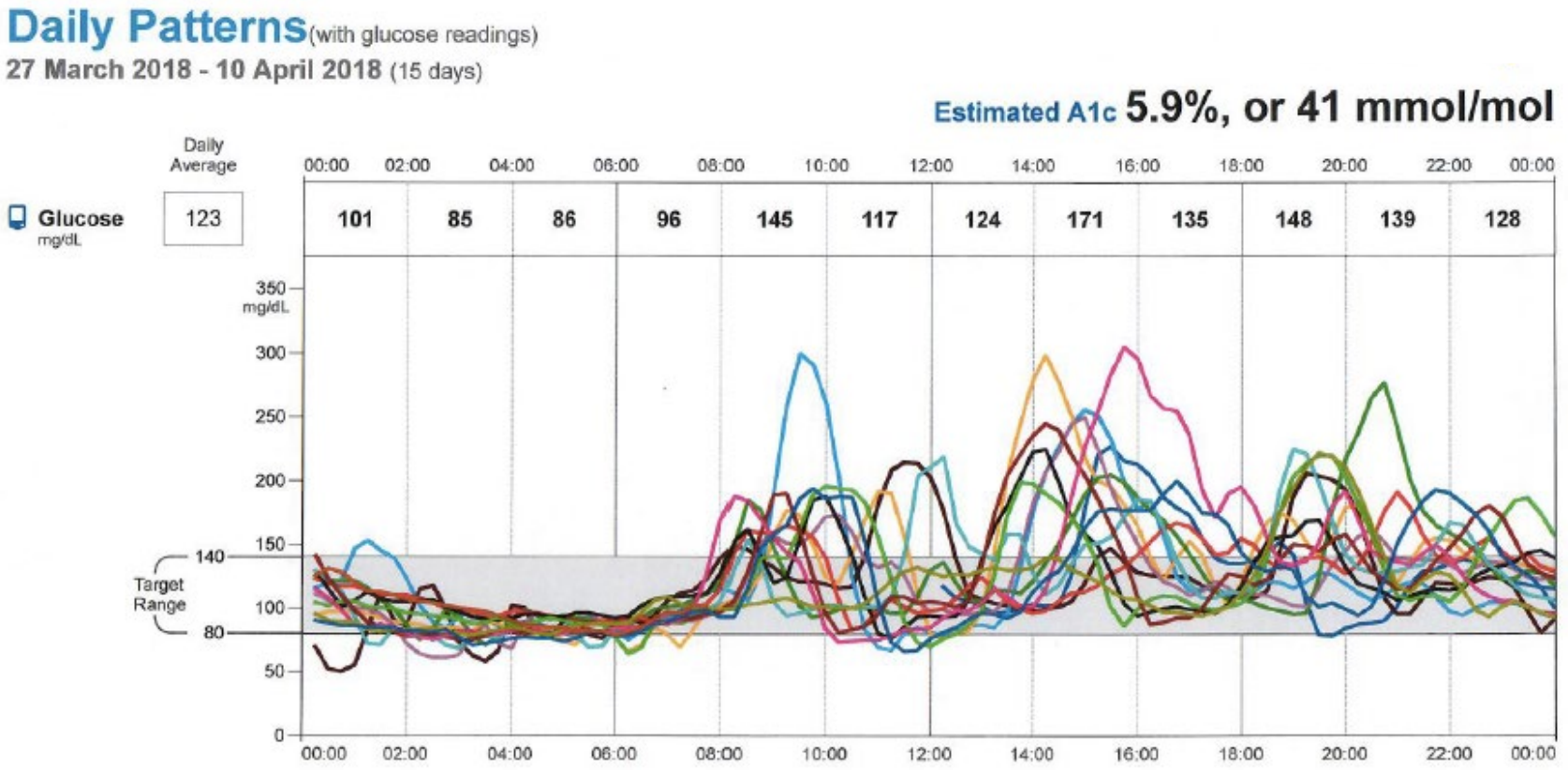


Image courtesy of Anne Peters, MD.

Follow-up

- Reduced metformin by 50%
- After discussion with patient started dulaglutide 0.75 mg weekly. Developed nausea/vomiting/abdominal pain.
- Switched to a low dose of a semaglutide and uptitrated to 0.5 mg weekly
- He changed his diet
- Over time he lost 12 pounds and his A1C fell to 5.1%
- His metformin was stopped.

Follow-Up Blinded CGM

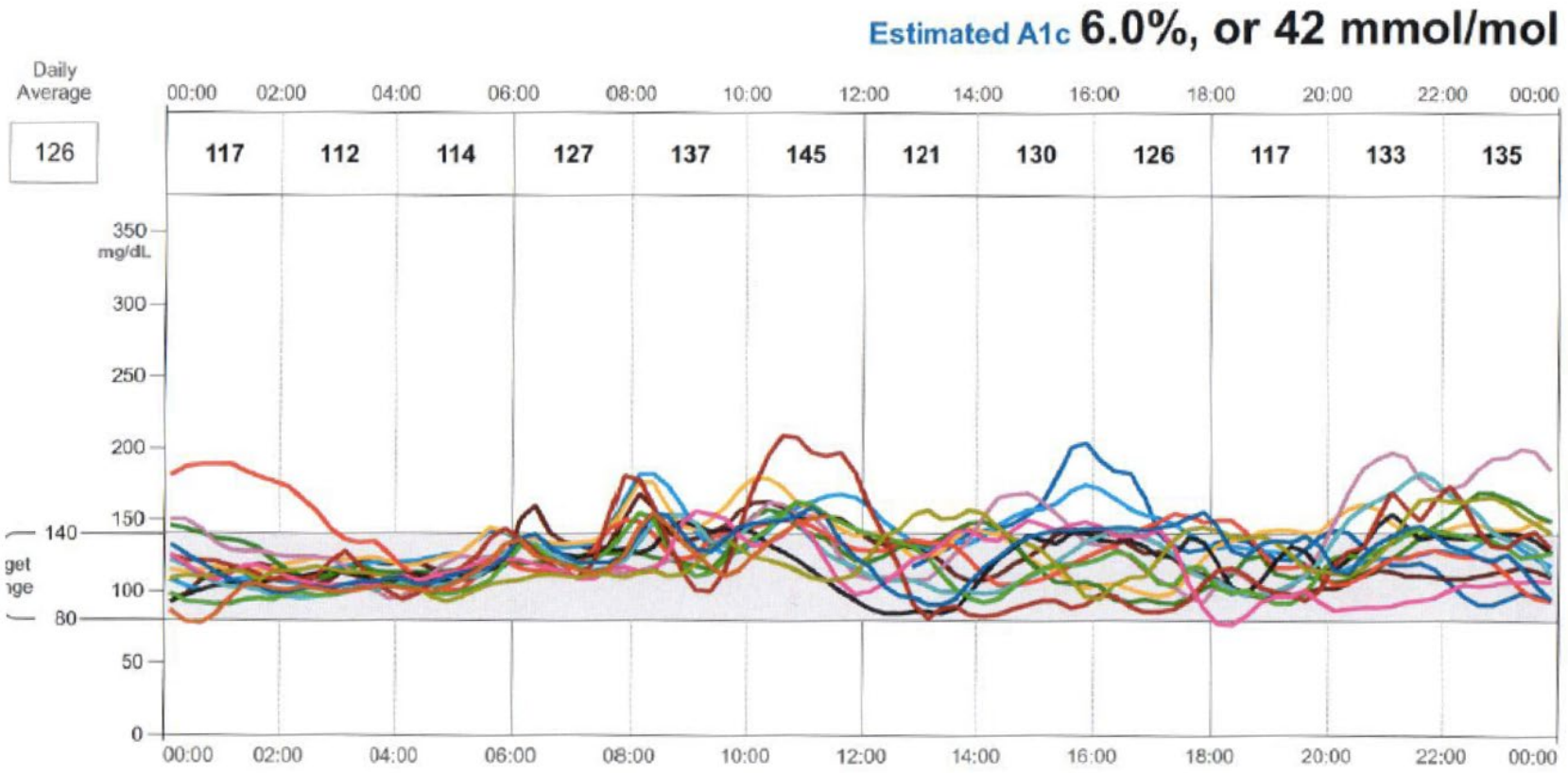


Image courtesy of Anne Peters, MD.

Conclusions/Considerations for Therapy

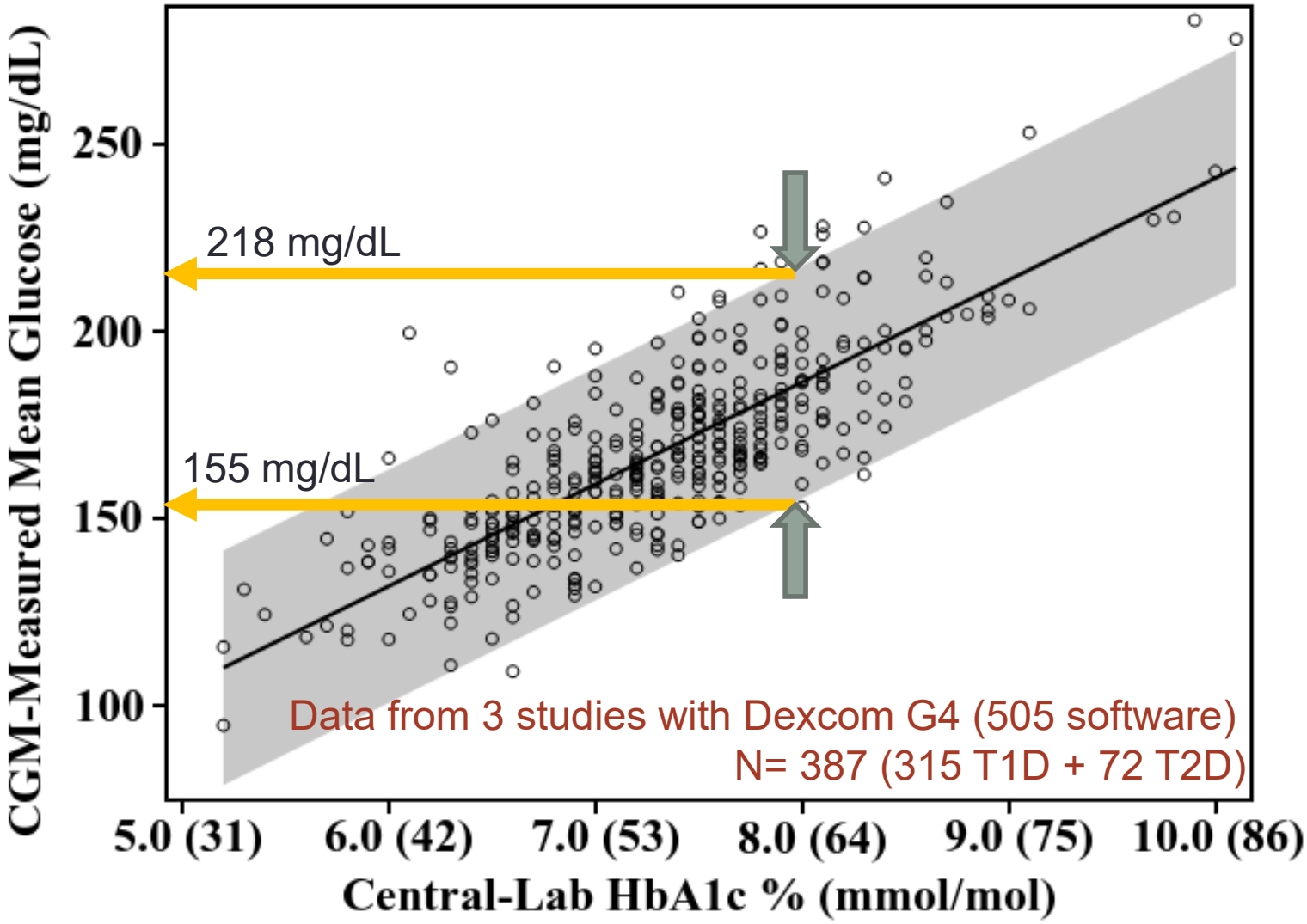
- Target additional CVD risk reduction
- Give options for therapy
- Discuss nutrition
- Watch for too much weight loss
- However, what would you do under these circumstances? Is A1C irrelevant?
  - A1C = 6.1% on a sulfonylurea agent
  - A1C = 6.1% on insulin
  - A1C = 10% with symptoms of uncontrolled diabetes

Is A1c Enough To Help Us Manage Patients?

- **Strengths of A1c**
  - Reflects blood glucose concentrations over ~3 months
  - Only metric of glycemic control that has been prospectively associated with chronic complications
  - Useful for assessing trends in a population over time
- **Limitations of A1c**
  - Affected by other conditions that affect red blood cell lifespan or interfere with glucose binding to hemoglobin
  - A wide range of mean glucose concentrations exist for a given HbA1c level
  - Provides no information about hypoglycemia frequency or severity
  - May under-represent the burden of hyperglycemia in African-Americans

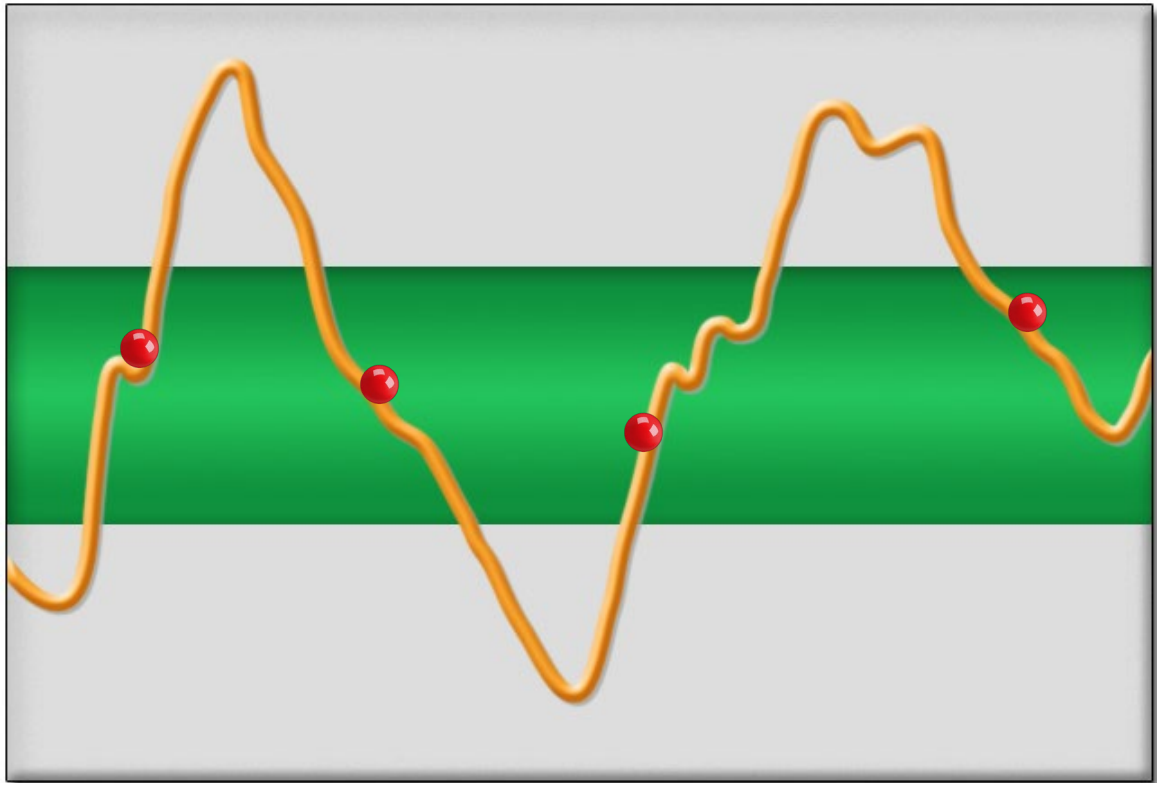
Beck RW, et al. Diabetes Care. 2017;40:994-999.

CGM-measured Mean Glucose Versus Lab-Measured HbA1c

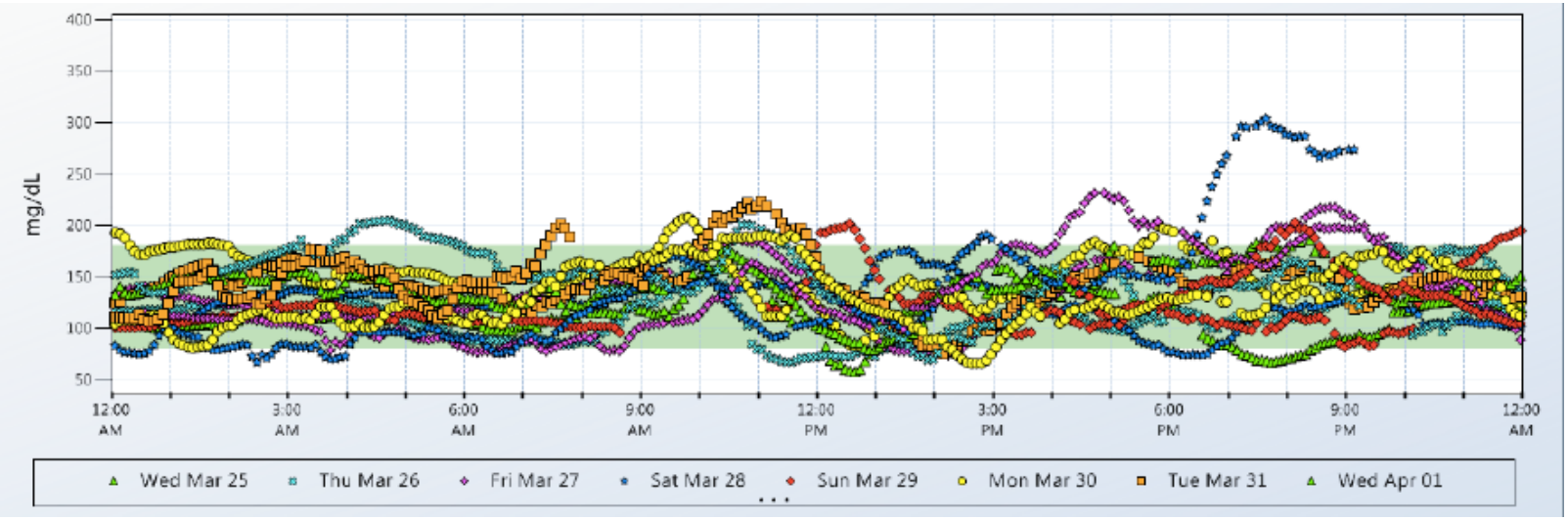


Slide thanks to Roy Beck (Beck RW, et al. Diabetes Care. 2017;40:994-999.)

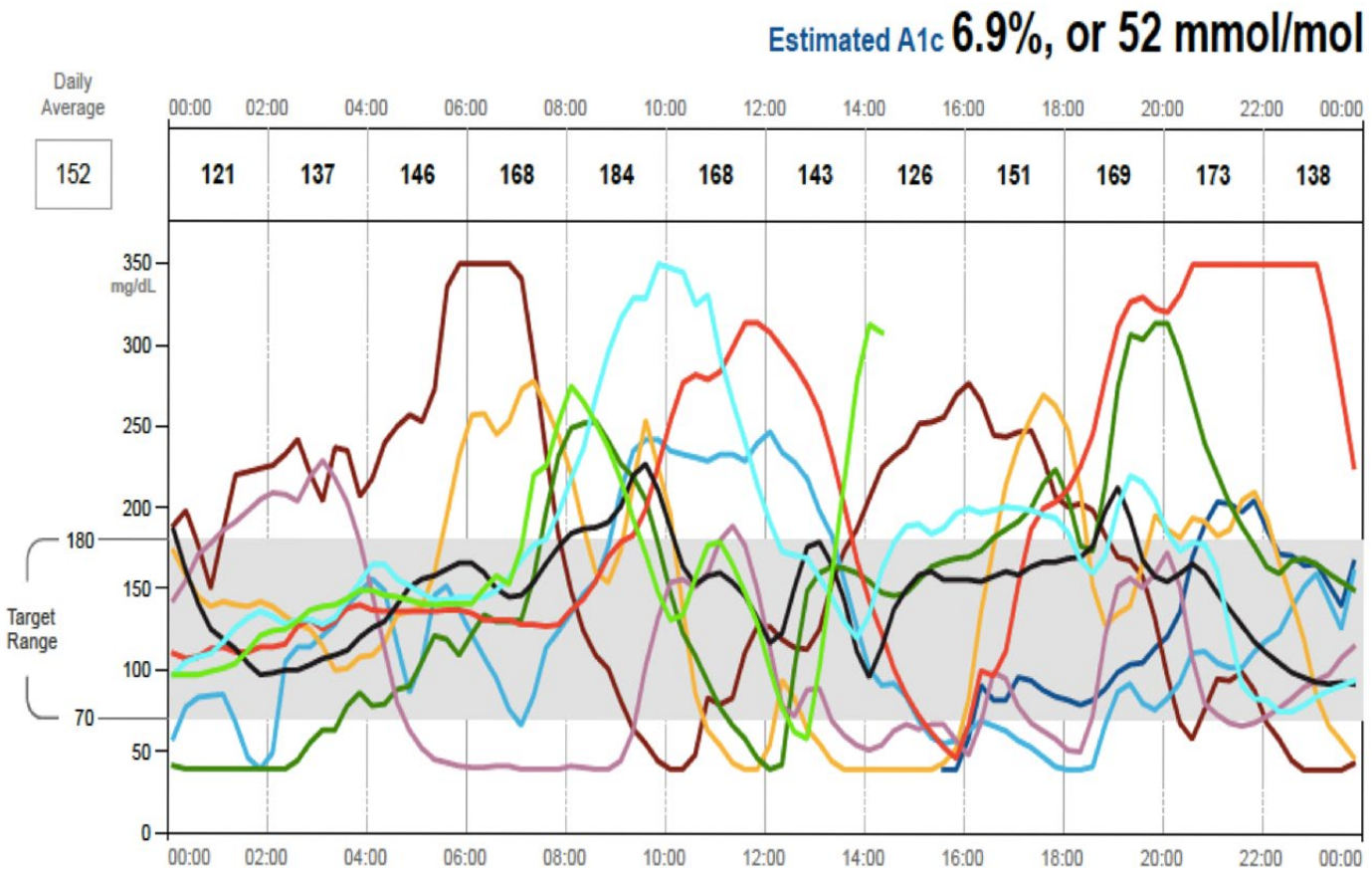
The Value of Continuous Glucose Monitoring



T1DM: A1C = 6.8%, low variability



T1DM: A1C = 6.9%, high variability

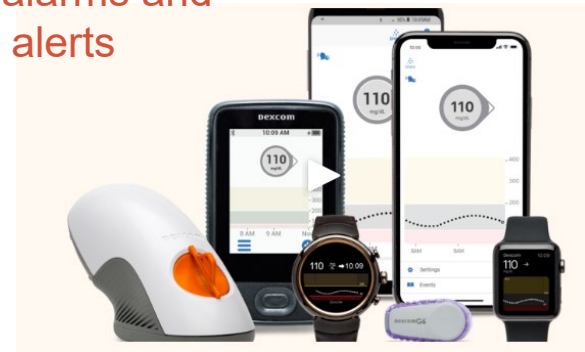


Contrasting CGM and BGM

Factor	BGM	CGM
Hyperglycemia	☑	☑
Hypoglycemia	☑	☑
Glycemic trends (real time)		☑
Alarms and alerts (real time)		☑
24/7 Patterns of glycemia (retrospective)		☑
Time needed for meaningful data	Varies	10-14 days
Frequency of skin poking	4-6 times daily	Every 10 – 14 days

Current CGM Sensors

Has alarms and alerts

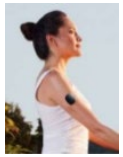


No Fingersticks Required

Requires swiping every 8 hours

Need Fingerstick Calibration

Implanted

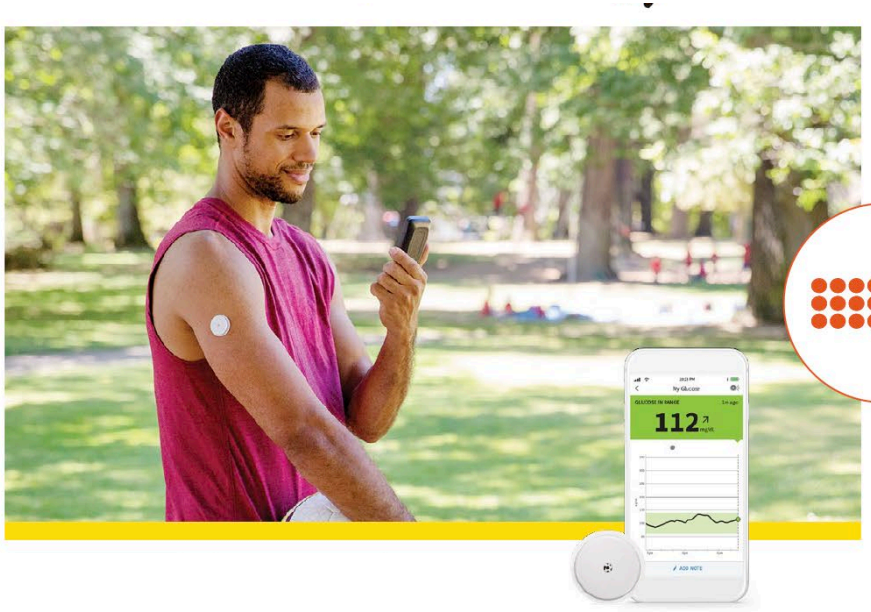


Has alarms and alerts

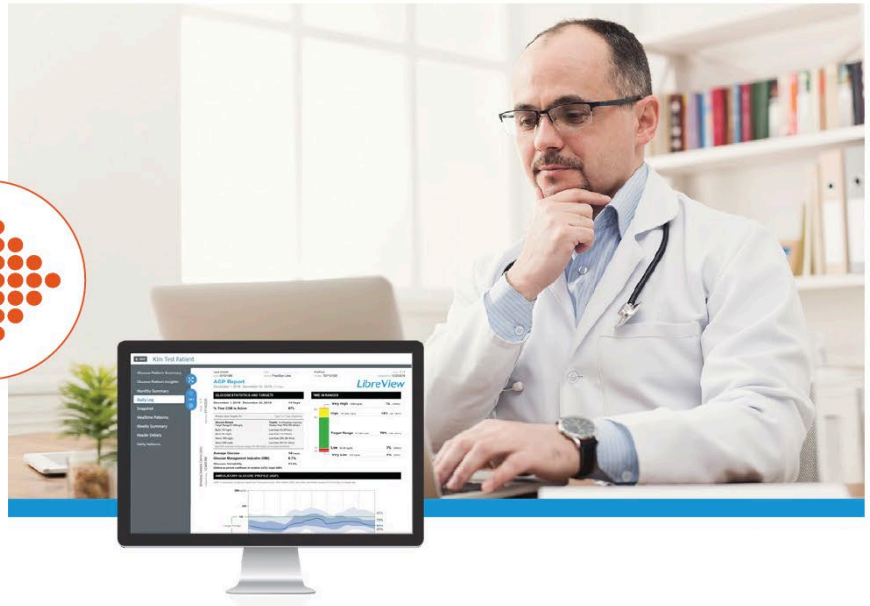
Why Not Fingersticks?

Websites for Data Transfer

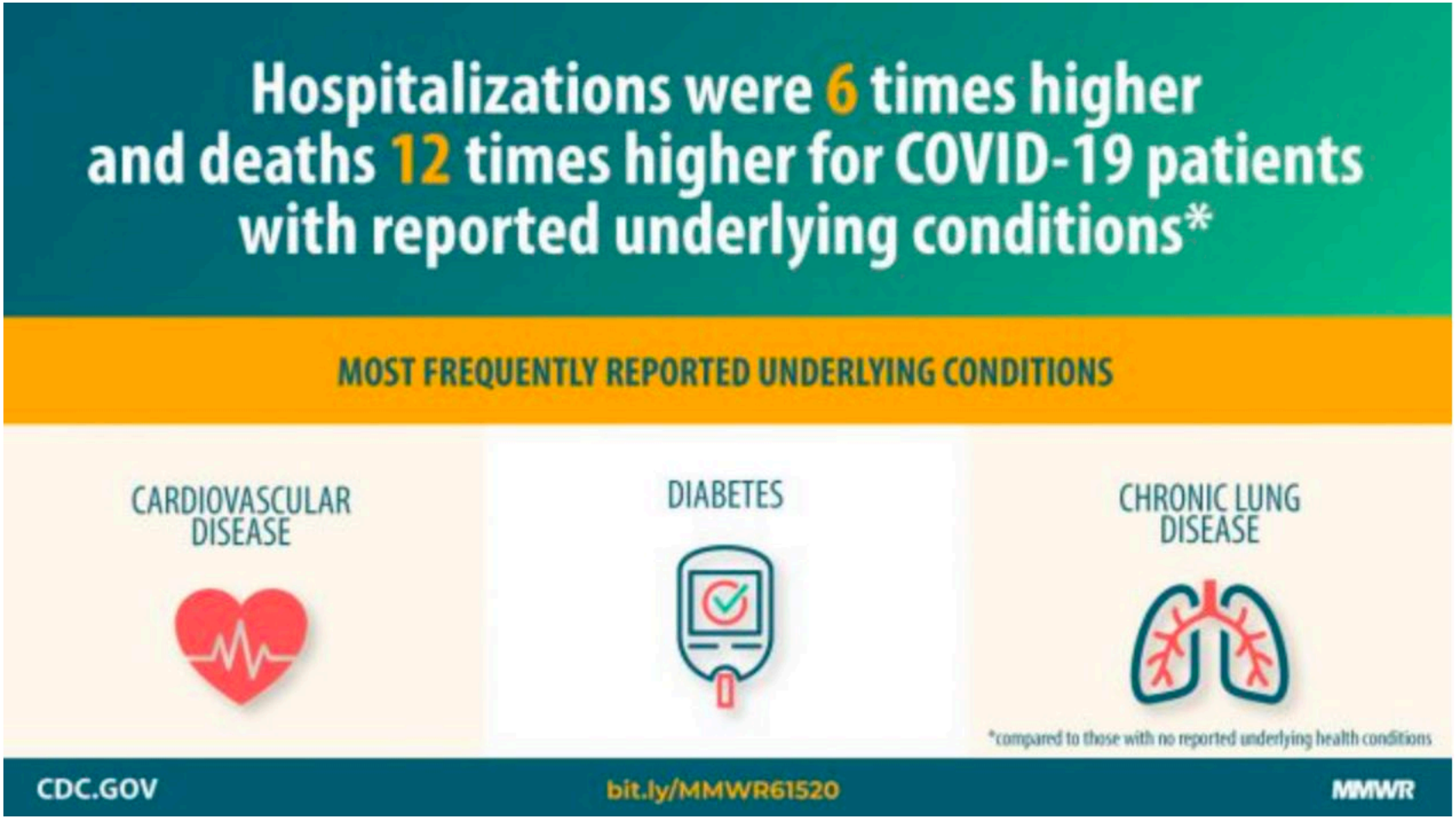
CONNECT TO YOUR DOCTOR'S OFFICE WITH:



AND UPLOAD GLUCOSE DATA TO:

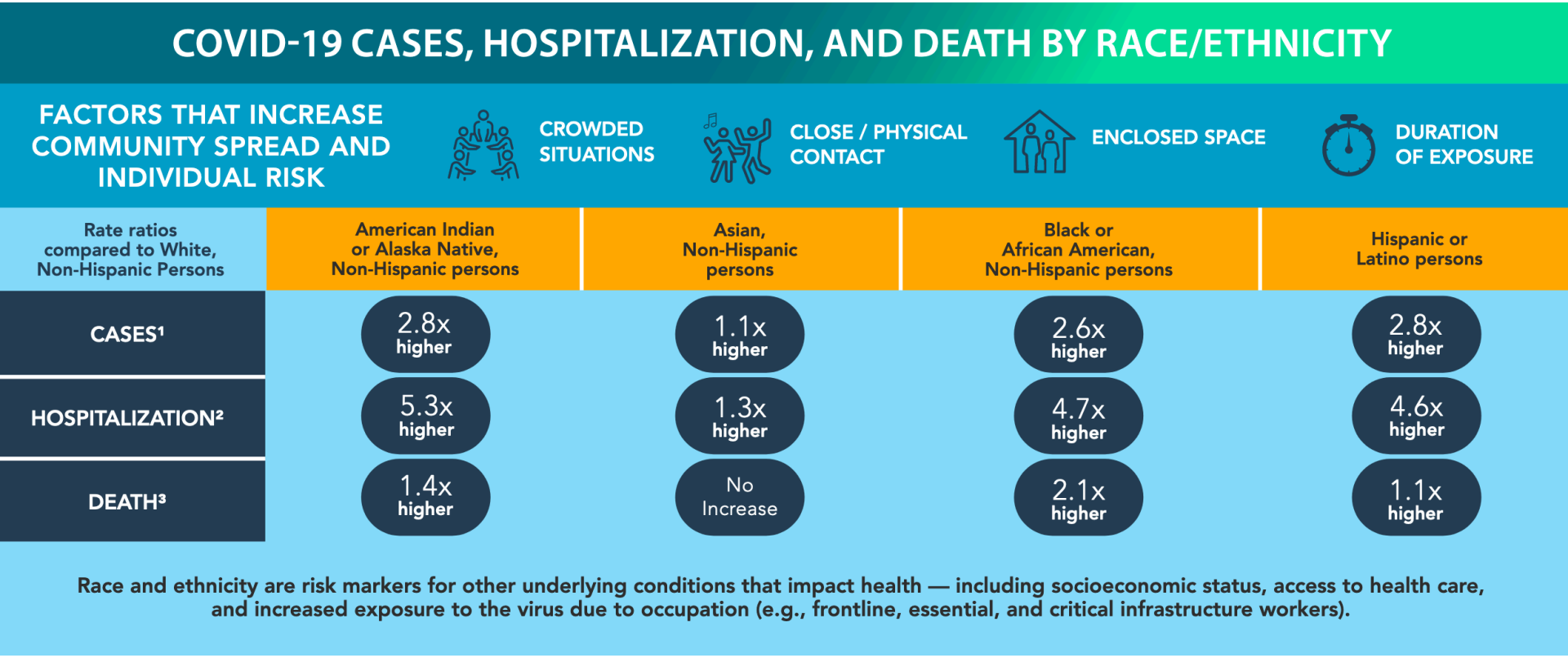


“Professional” (blinded) Systems Exist



MMWR June 19, 2020. 69:759-765

CDC Impact of Ethnicity



https://www.cdc.gov/coronavirus/2019-ncov/downloads/covid-data/hospitalization-underlying-medical-conditions.pdf

Health Services
LOS ANGELES COUNTY

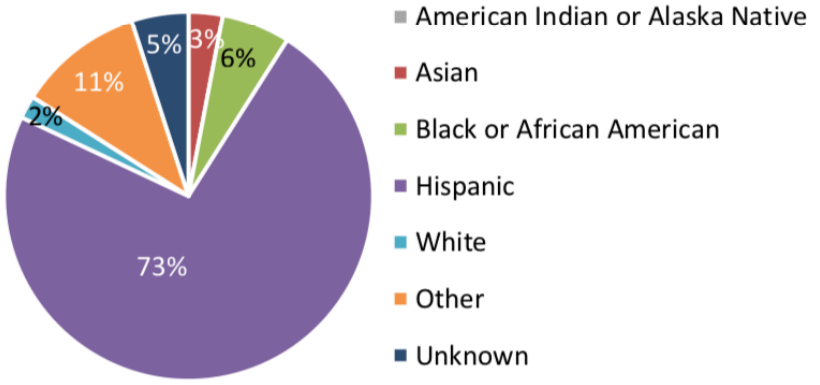
COVID-19 Dashboard

10/13/20

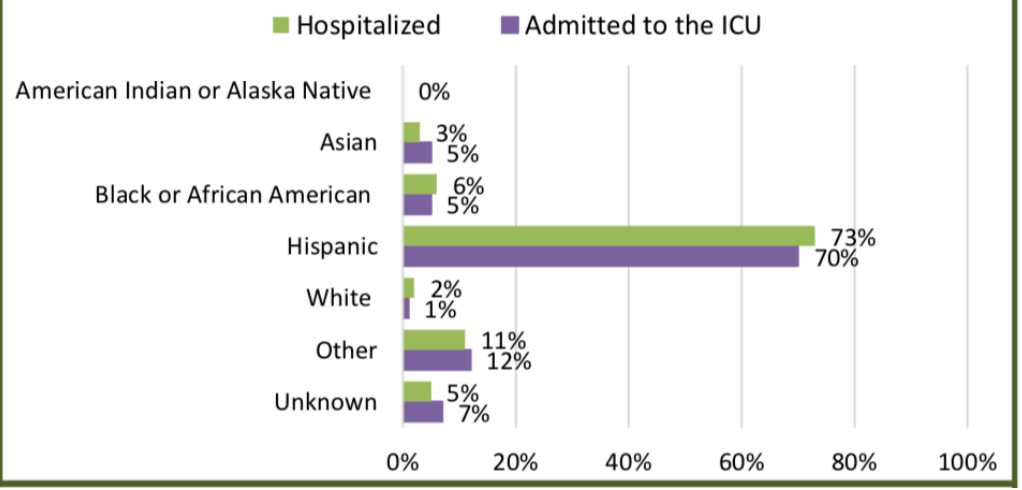
DHS COVID Demographics by Race/Ethnicity[1]

(March 1 – October 10, 2020)

COVID Cases Hospitalized by Race/Ethnicity (% of patients)



COVID Cases Hospitalized by Race/Ethnicity & ICU Admission (% of patients)

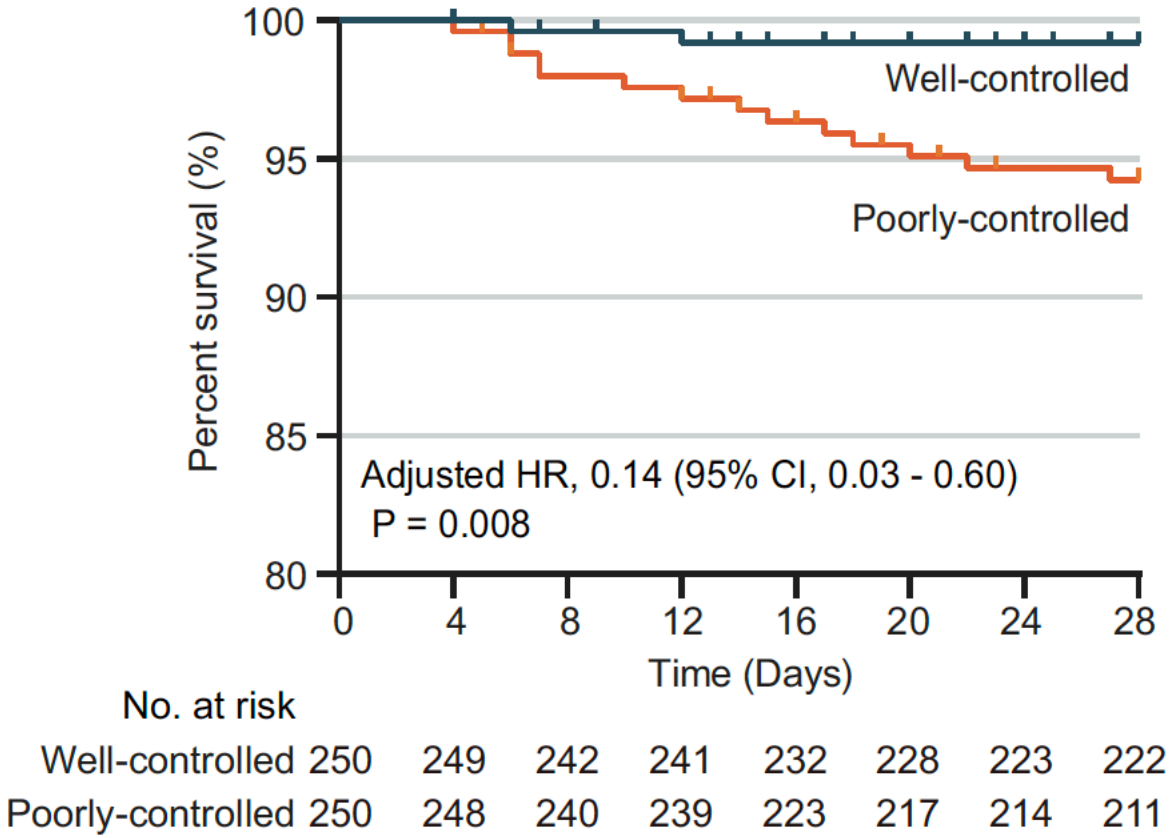


A1C and Risk of Death in China

- Patients in Hubei Province
- 6,385 without T2DM. (A1C = 6.1%)
- 952 with T2DM (A1C = 7.9%)
- 282 well-controlled (A1C = 7.3%) (3.9 – 10); 528 poorly controlled (A1C = 8.1%) (3.9 - >10).
- 250 well-controlled matched with 250 poorly controlled patients (1:1 propensity score-matched analysis)

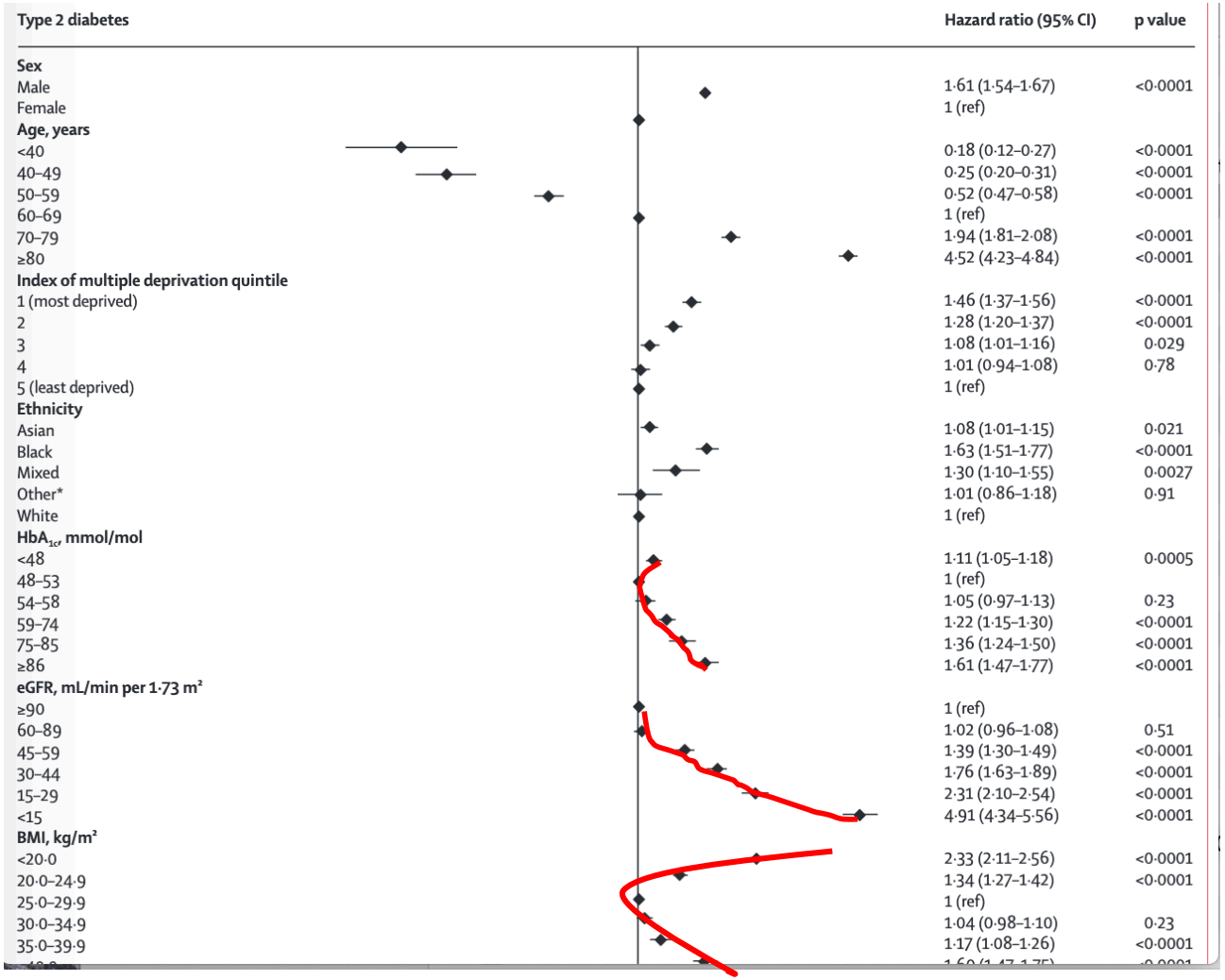
Cell Metabolism 31:1068-1077, 2020

Survival Curves



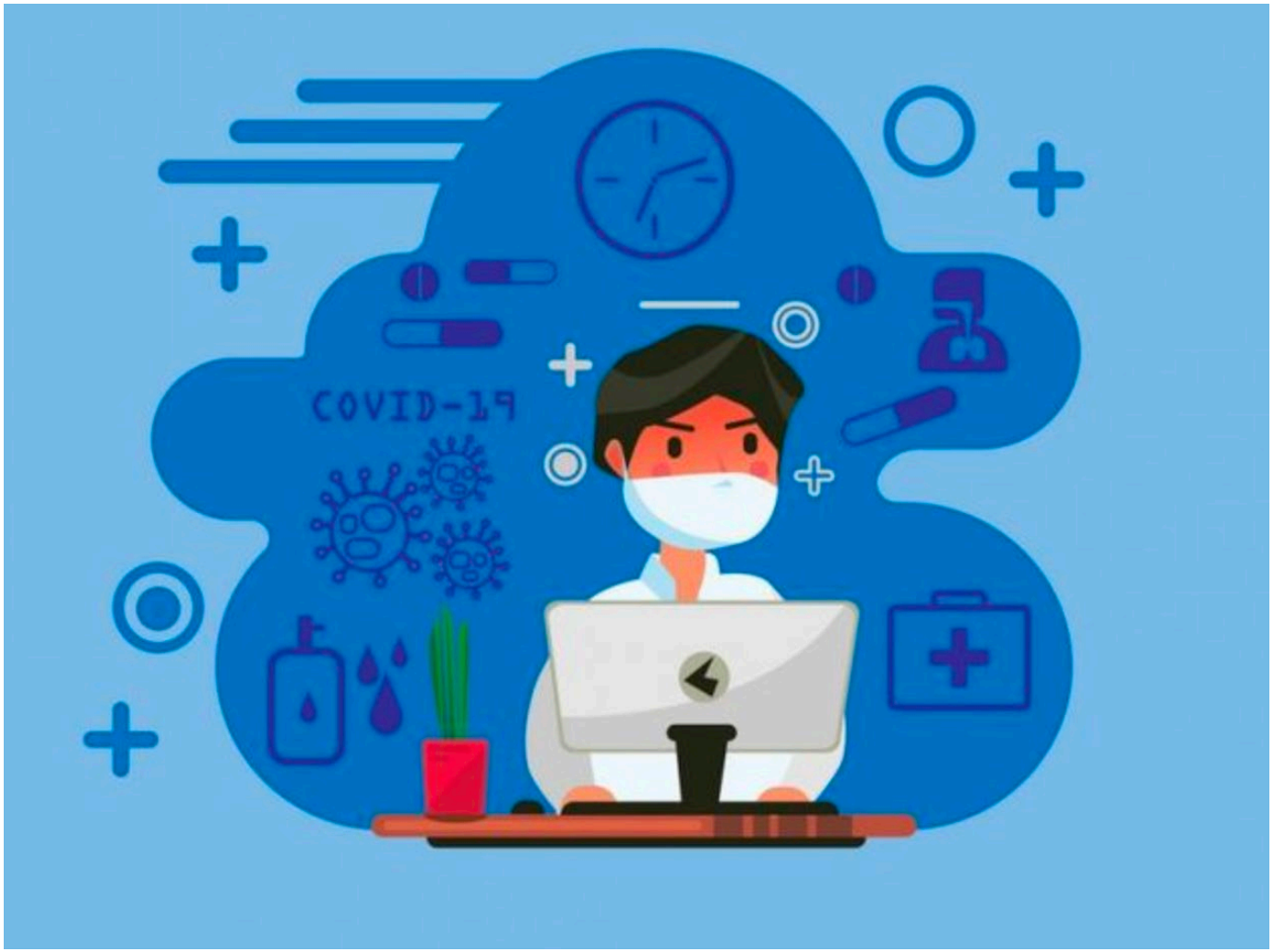
Cell Metabolism 31:1068-1077, 2020

COVID Deaths in the UK—T2DM

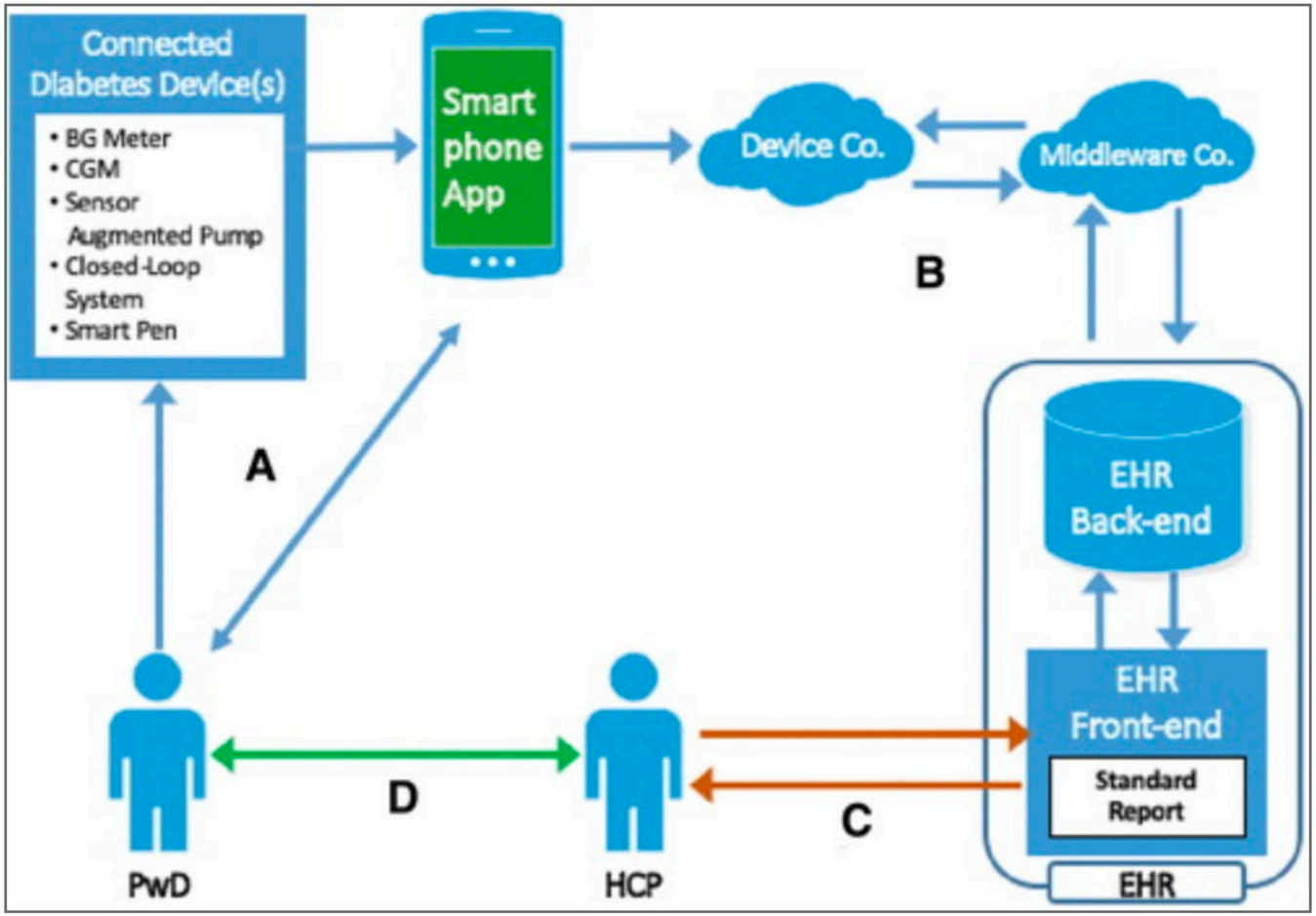


Type 2 diabetes	Hazard ratio (95% CI)	p value
Sex		
Male	1·61 (1·54–1·67)	<0·0001
Female	1 (ref)	
Age, years		
<40	0·18 (0·12–0·27)	<0·0001
40–49	0·25 (0·20–0·31)	<0·0001
50–59	0·52 (0·47–0·58)	<0·0001
60–69	1 (ref)	
70–79	1·94 (1·81–2·08)	<0·0001
≥80	4·52 (4·23–4·84)	<0·0001
Index of multiple deprivation quintile		
1 (most deprived)	1·46 (1·37–1·56)	<0·0001
2	1·28 (1·20–1·37)	<0·0001
3	1·08 (1·01–1·16)	0·029
4	1·01 (0·94–1·08)	0·78
5 (least deprived)	1 (ref)	
Ethnicity		
Asian	1·08 (1·01–1·15)	0·021
Black	1·63 (1·51–1·77)	<0·0001
Mixed	1·30 (1·10–1·55)	0·0027
Other*	1·01 (0·86–1·18)	0·91
White	1 (ref)	
HbA_{1c}, mmol/mol		
<48	1·11 (1·05–1·18)	0·0005
48–53	1 (ref)	
54–58	1·05 (0·97–1·13)	0·23
59–74	1·22 (1·15–1·30)	<0·0001
75–85	1·36 (1·24–1·50)	<0·0001
≥86	1·61 (1·47–1·77)	<0·0001
eGFR, mL/min per 1·73 m^2		
≥90	1 (ref)	
60–89	1·02 (0·96–1·08)	0·51
45–59	1·39 (1·30–1·49)	<0·0001
30–44	1·76 (1·63–1·89)	<0·0001
15–29	2·31 (2·10–2·54)	<0·0001
<15	4·91 (4·34–5·56)	<0·0001
BMI, kg/m^2		
<20·0	2·33 (2·11–2·56)	<0·0001
20·0–24·9	1·34 (1·27–1·42)	<0·0001
25·0–29·9	1 (ref)	
30·0–34·9	1·04 (0·98–1·10)	0·23
35·0–39·9	1·17 (1·08–1·26)	<0·0001

March 2020: A New Era in Medicine



Tele-Connection in Diabetes



Diabetes Tech Therapeutics On-line September 2020 doi: 10.1007/s00592-017-1084-9

CHECKLIST FOR SETTING UP A VIRTUAL CLINIC

J Med Internet Res. 2020 Aug; 22(8): e21609.

FDA NEWS RELEASE

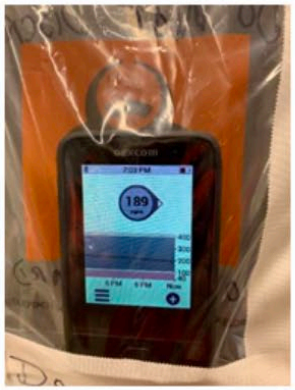
Coronavirus (COVID-19) Update: FDA allows expanded use of devices to monitor patients' vital signs remotely

For Immediate Release: March 20, 2020

Early Real-World Logistics of Inpatient CGM

Placement of sensor

- Skilled endocrine NP
- Proning trend → arm placement



Placement of receiver

- On door facing out, within 20 feet
- Re-used receiver (after cleaning)

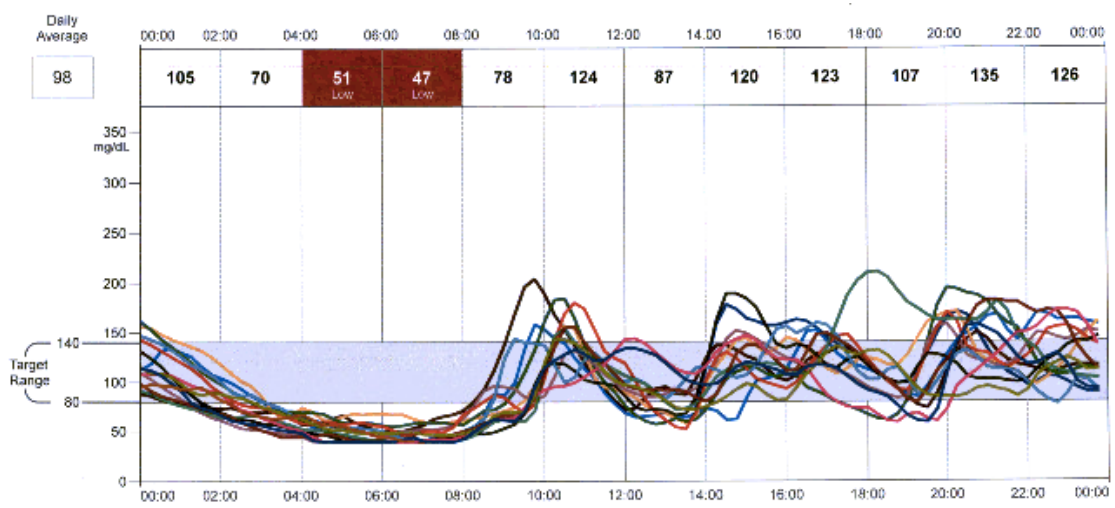
Alerts (100 mg/dL to 250 mg/dL, drop/rise)

Slide courtesy of Dr. Shivani Agarwal

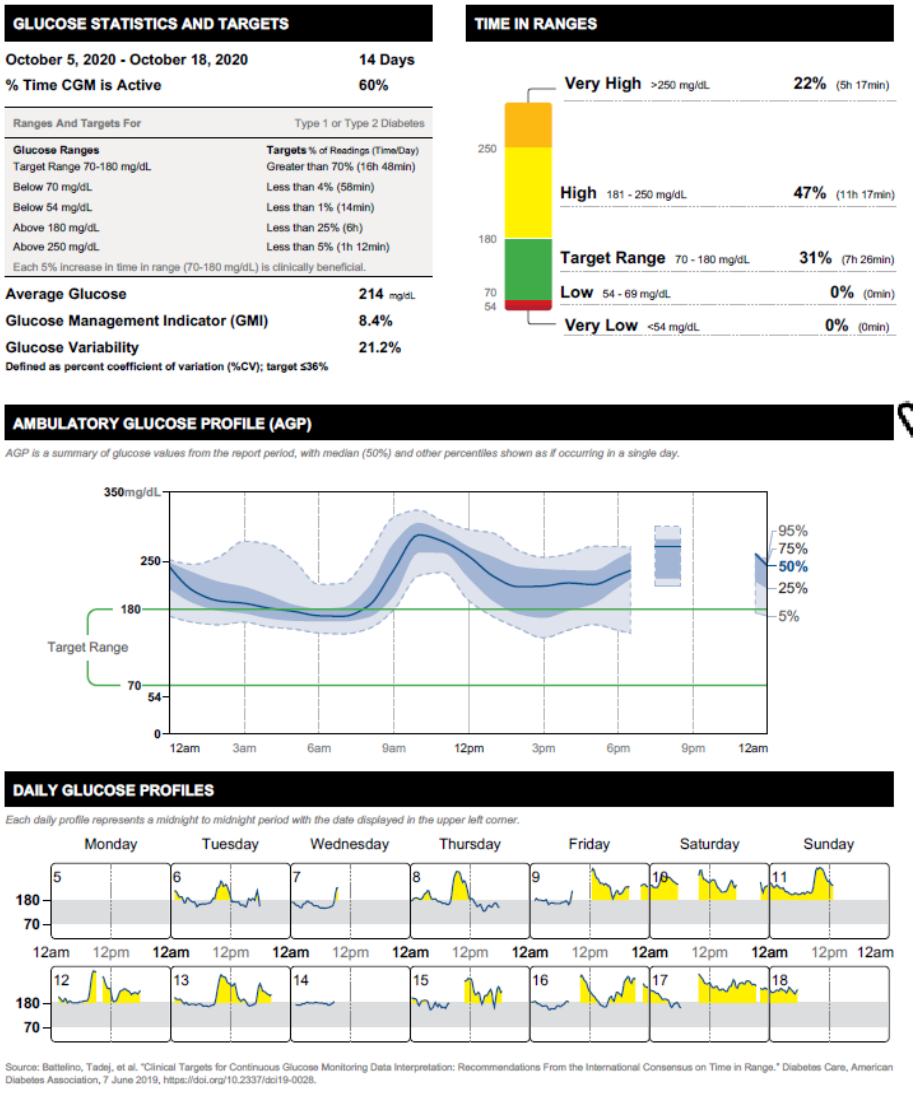
Outpatient Diabetes “ICU”

- New onset or out of control/sick patients
- Use CGM/InPen as much as possible
- Followed daily by my diabetes team
- Feedback provided/adjustments made via telemedicine/email
- Once stable patients go back to routine follow-up

Bedtime Glargine with an A1C = 6.7%



Pandemic—Related Increase in A1C



GLUCOSE STATISTICS AND TARGETS

October 5, 2020 - October 18, 2020	14 Days
% Time CGM is Active	60%

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	214 mg/dL
Glucose Management Indicator (GMI)	8.4%
Glucose Variability	21.2%

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

TIME IN RANGES

Very High	>250 mg/dL	22% (5h 17min)
High	181 - 250 mg/dL	47% (11h 17min)
Target Range	70 - 180 mg/dL	31% (7h 26min)
Low	54 - 69 mg/dL	0% (0min)
Very Low	<54 mg/dL	0% (0min)

250
180
70
54

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.

350mg/dL
250
180
Target Range
70
54
0
12am 3am 6am 9am 12pm 3pm 6pm 9pm 12am
95%
75%
50%
25%
5%

DAILY GLUCOSE PROFILES

Each daily profile represents a midnight to midnight period with the date displayed in the upper left corner.

Monday Tuesday Wednesday Thursday Friday Saturday Sunday

5 6 7 8 9 10 11

180
70

12am 12pm 12am 12pm 12am 12pm 12am 12pm 12am 12pm 12am 12pm 12am 12pm 12am

12 13 14 15 16 17 18

180
70

Source: Battelino, Tadej, et al. "Clinical Targets for Continuous Glucose Monitoring Data Interpretation: Recommendations From the International Consensus on Time in Range." Diabetes Care, American Diabetes Association, 7 June 2019, https://doi.org/10.2337/dci19-0028.

Changed His Lifestyle and Got Vaccinated!

AGP Report

March 9, 2021 - April 5, 2021 (28 Days)

GLUCOSE STATISTICS AND TARGETS

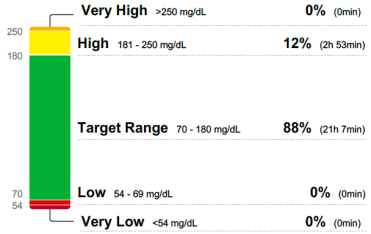
March 9, 2021 - April 5, 2021	28 Days
% Time CGM is Active	64%

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	140 mg/dL
Glucose Management Indicator (GMI)	6.7%
Glucose Variability	23.8%

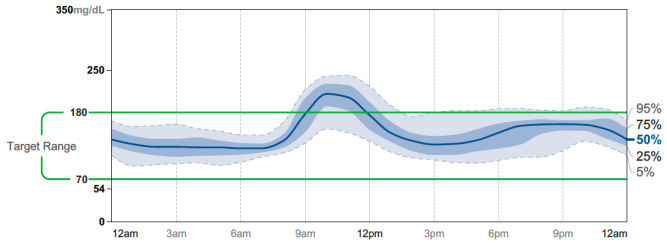
Defined as percent coefficient of variation (%CV); target ≤36%

TIME IN RANGES



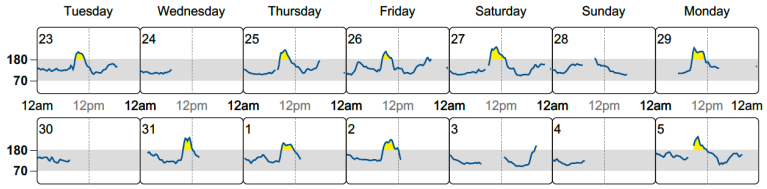
AMBULATORY GLUCOSE PROFILE (AGP)

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.



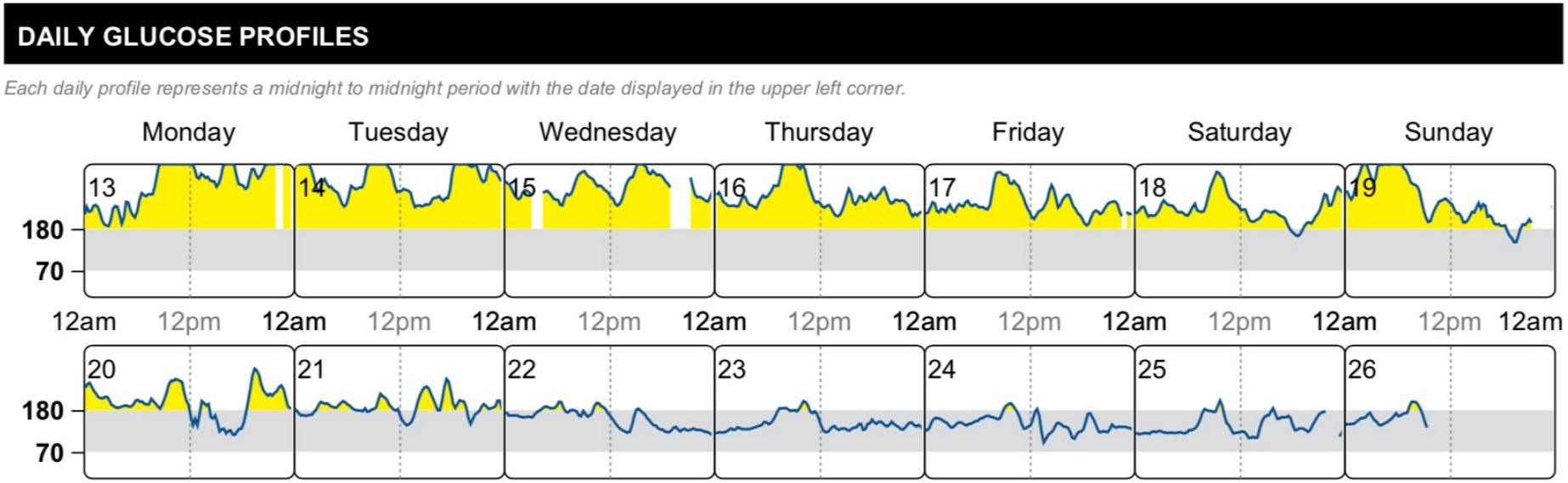
DAILY GLUCOSE PROFILES Most recent 14 days. See Weekly Summary report for more days.

Each daily profile represents a midnight to midnight period with the date displayed in the upper left corner.



Source: Battelino, Tadej, et al. "Clinical Targets for Continuous Glucose Monitoring Data Interpretation: Recommendations From the International Consensus on Time in Range." Diabetes Care, American Diabetes Association, 7 June 2019, https://doi.org/10.2337/dci19-0028.

New Onset Diabetes with COVID-19



First Two Weeks

AGP Report

July 8, 2020 - July 21, 2020 (14 Days)

GLUCOSE STATISTICS AND TARGETS

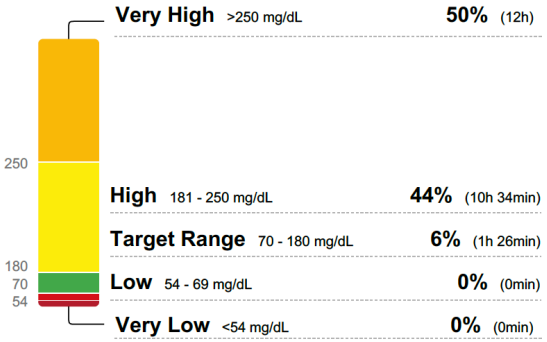
July 8, 2020 - July 21, 2020	**14 Days**
% Time CGM is Active	**60%**

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	**261** mg/dL
Glucose Management Indicator (GMI)	**9.6%**
Glucose Variability	**23.6%**

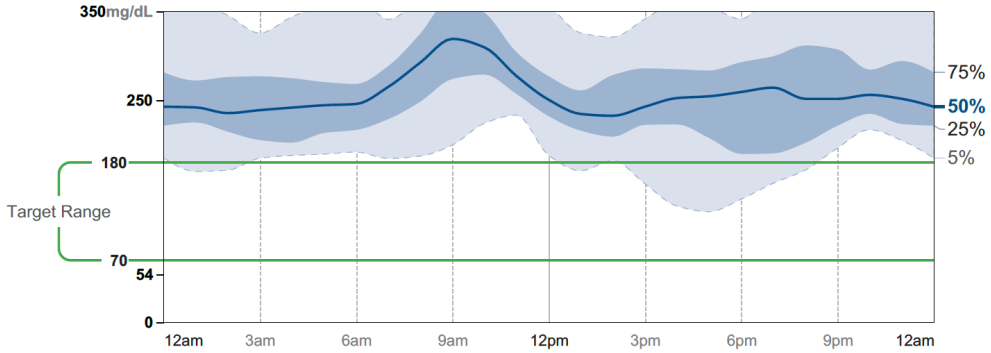
Defined as percent coefficient of variation (%CV); target ≤36%

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.



4 – 6 Weeks Later

AGP Report

August 1, 2020 - August 14, 2020 (14 Days)

GLUCOSE STATISTICS AND TARGETS

August 1, 2020 - August 14, 2020	**14 Days**
% Time CGM is Active	**70%**

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	**105** mg/dL
Glucose Management Indicator (GMI)	**5.8%**
Glucose Variability	**16.1%**

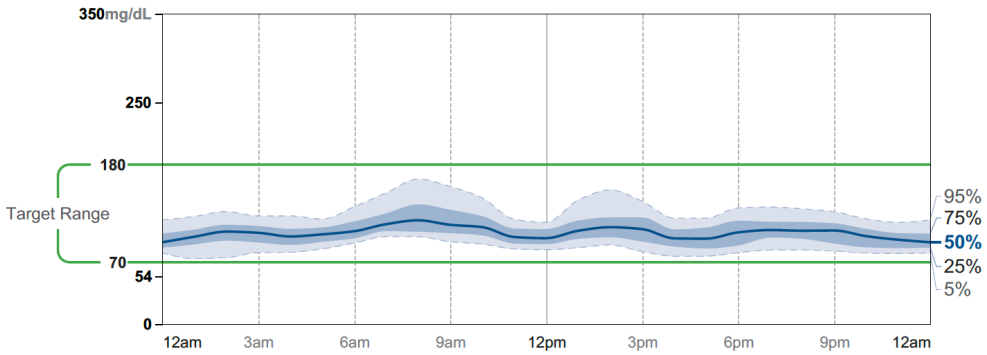
Defined as percent coefficient of variation (%CV); target ≤36%

TIME IN RANGES

Very High >250 mg/dL	**0%**	(0min)
High 181 - 250 mg/dL	**0%**	(0min)
Target Range 70 - 180 mg/dL	**100%**	(24h)
Low 54 - 69 mg/dL	**0%**	(0min)
Very Low <54 mg/dL	**0%**	(0min)

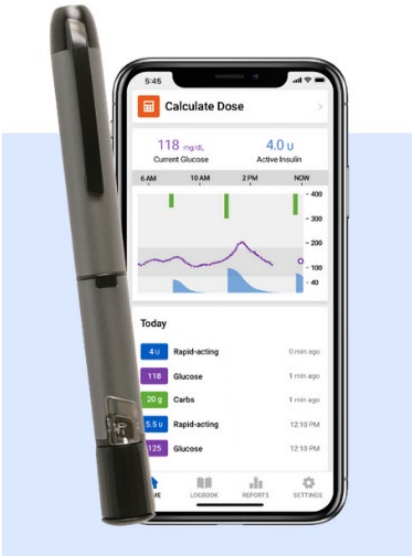
AMBULATORY GLUCOSE PROFILE (AGP)

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.



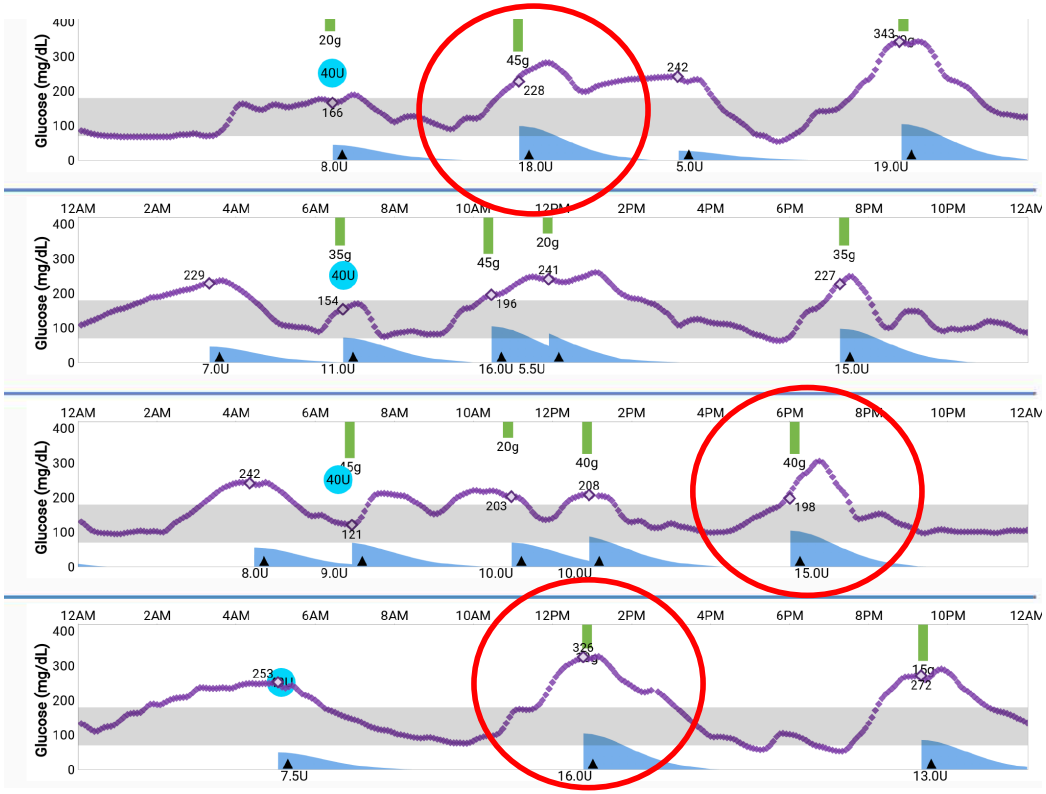
Smart Pen with a Bolus Calculator

- Durable prescription pen with 1 year battery w ½ unit increments
- Compatible with Humalog®, Novolog®, Fiasp® 3-mL pen cartridges
- Bluetooth connection to smart phone app with customizable bolus calculator with 3 different modes
- Missed-dose reminders for meal and basal insulin
- Generates detailed reports, which can be integrated with CGM

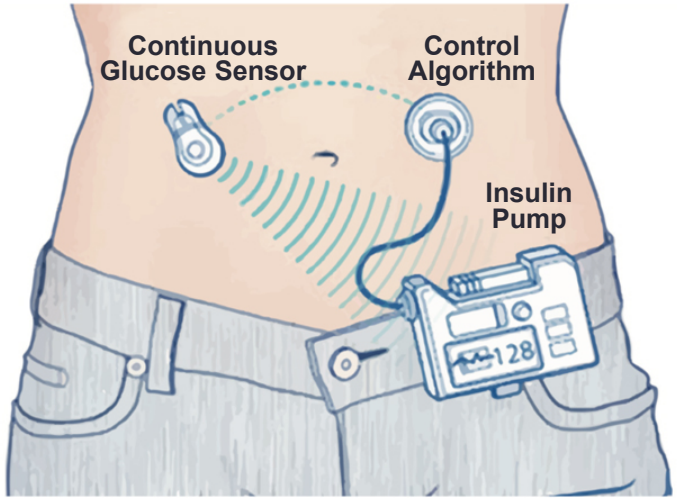


FDA. Accessed March 23, 2021. https://www.accessdata.fda.gov/cdrh_docs/pdf20/K201337.pdf.

Carb Doses during/after Eating

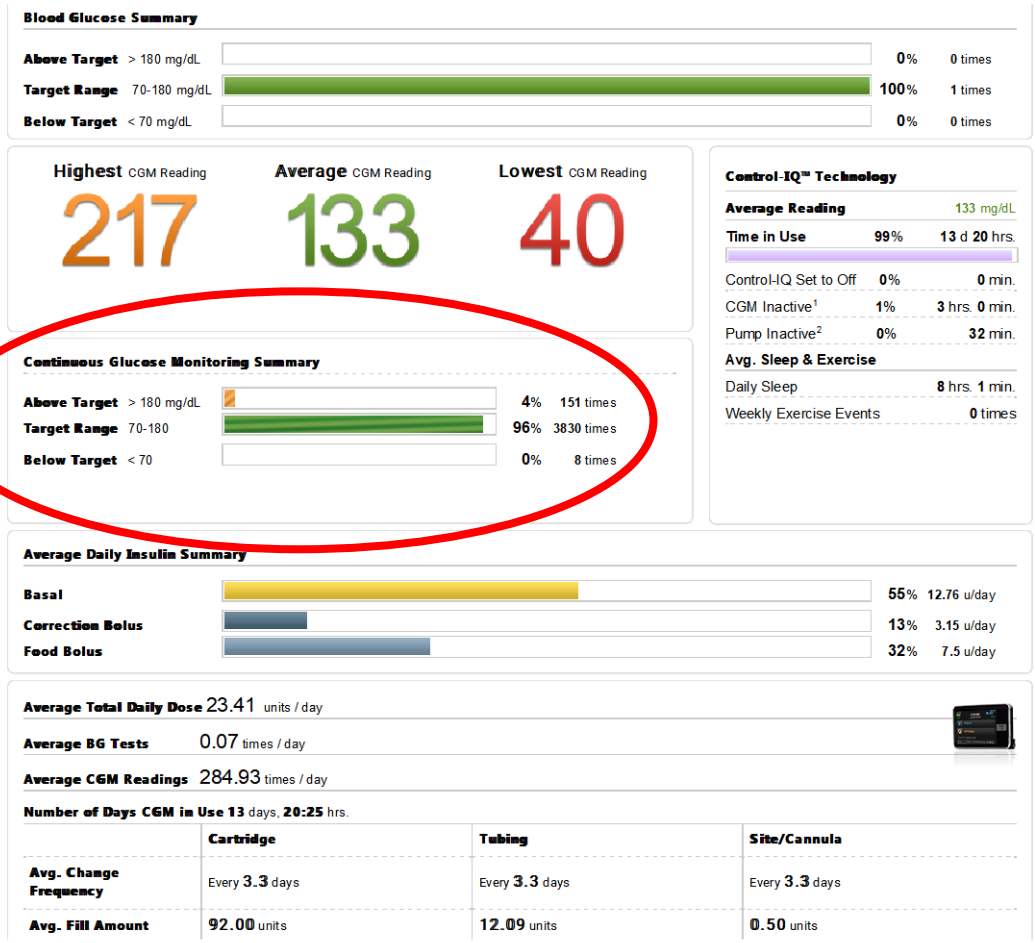


Automated Insulin Delivery Systems: Combining Pumps and Sensors



73 yo patient with a h/o T1D since age 2

73 yo with T1DM since age 2



Blood Glucose Summary

Above Target	> 180 mg/dL	0%	0 times
Target Range	70-180 mg/dL	100%	1 times
Below Target	< 70 mg/dL	0%	0 times

Highest CGM Reading	Average CGM Reading	Lowest CGM Reading
217	133	40

Continuous Glucose Monitoring Summary

Above Target	> 180 mg/dL	4%	151 times
Target Range	70-180	96%	3830 times
Below Target	< 70	0%	8 times

Control-IQ™ Technology

Average Reading		133 mg/dL
Time in Use	99%	**13** d **20** hrs.
Control-IQ Set to Off	0%	**0** min.
CGM Inactive[1]	1%	**3** hrs. **0** min.
Pump Inactive[2]	0%	**32** min.

Avg. Sleep & Exercise

Daily Sleep	**8** hrs. **1** min.
Weekly Exercise Events	**0** times

Average Daily Insulin Summary

Basal	55%	12.76 u/day
Correction Bolus	13%	3.15 u/day
Food Bolus	32%	7.5 u/day

Average Total Daily Dose 23.41 units / day

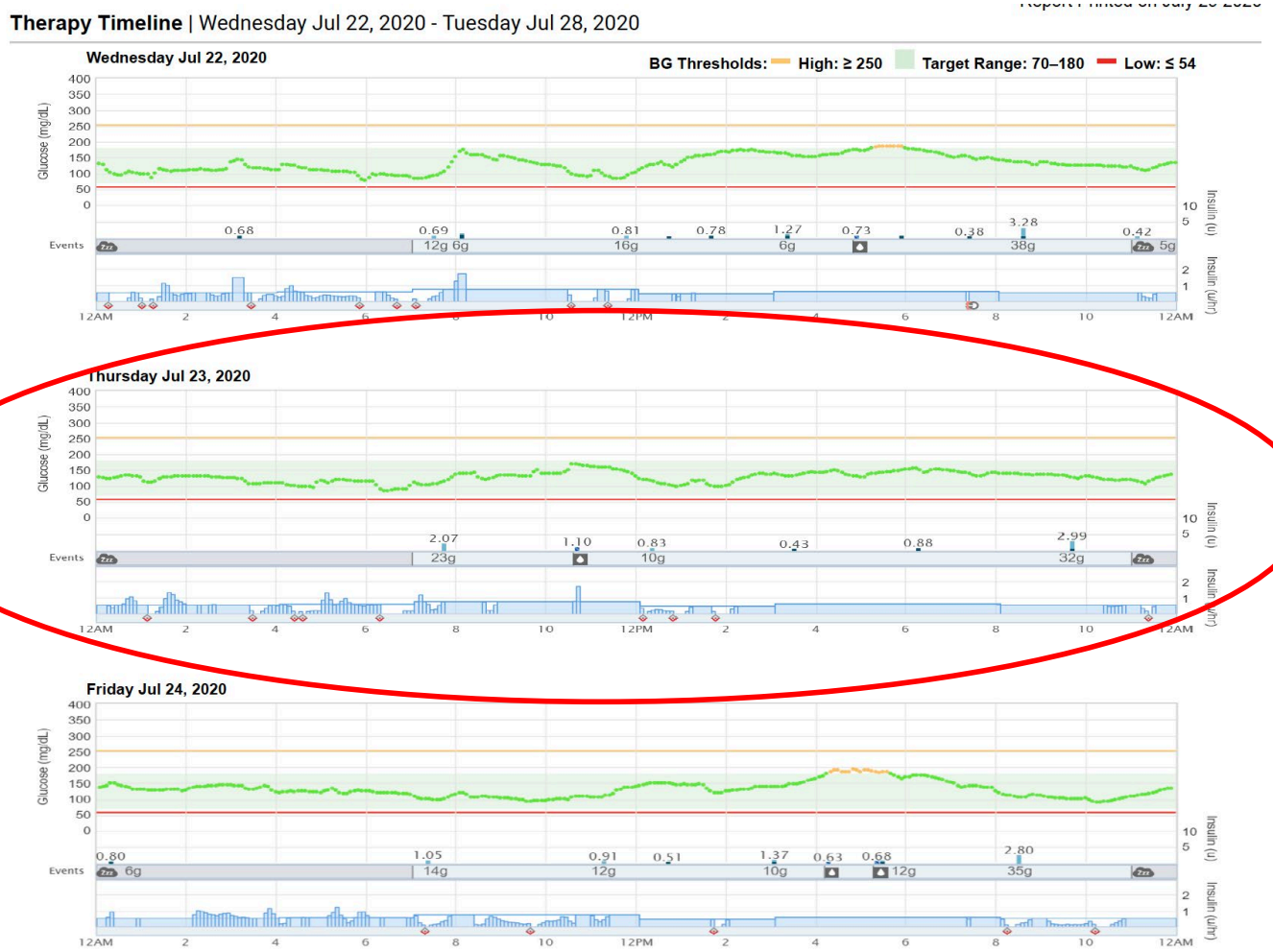
Average BG Tests 0.07 times / day

Average CGM Readings 284.93 times / day

Number of Days CGM in Use 13 days, **20:25** hrs.

	Cartridge	Tubing	Site/Cannula
Avg. Change Frequency	Every **3.3** days	Every **3.3** days	Every **3.3** days
Avg. Fill Amount	**92.00** units	**12.09** units	**0.50** units

As Close to Perfection As I've Seen



Can We Really Manage Patients This Way?

Logbook Overview	Overnight 12:00 am - 6:00 am	Before Breakfast 6:00 am - 9:00 am	After Breakfast 9:00 am - 11:00 am	Before Lunch 11:00 am - 2:00 pm	After Lunch 2:00 pm - 5:00 pm	Before Dinner 5:00 pm - 7:00 pm	After Dinner 7:00 pm - 10:00 pm	Bedtime 10:00 pm - 12:00 am
Saturday Sep 28, 2019			172 10:24 am					
Friday Sep 27, 2019	191 5:42 am						252 9:51 pm	
Thursday Sep 26, 2019	135 5:47 am							195 10:30 pm
Wednesday Sep 25, 2019	135 5:37 am						308 9:36 pm	

THANK YOU