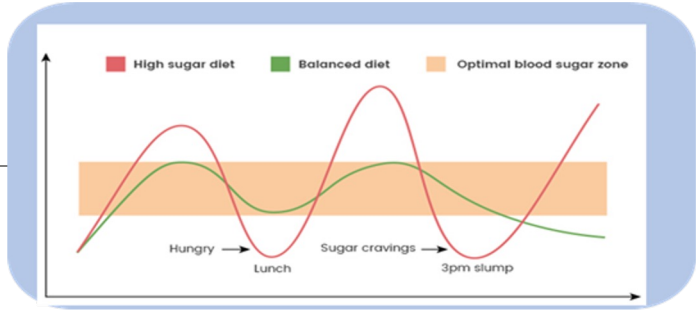
Smart Diabetes Management: Navigating CGM Technologies for Better Outcomes



MAISY MOK

RN, BNS, MASTER OF NURSING

FELLOW OF HKAN (MEDICAL NURSING – DM)

September 12 2026

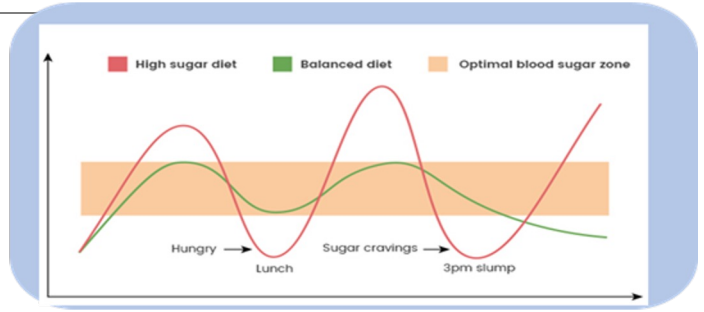
Disclosure

Potential conflicts of interest: None

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6. Common CGM models in Hong Kong

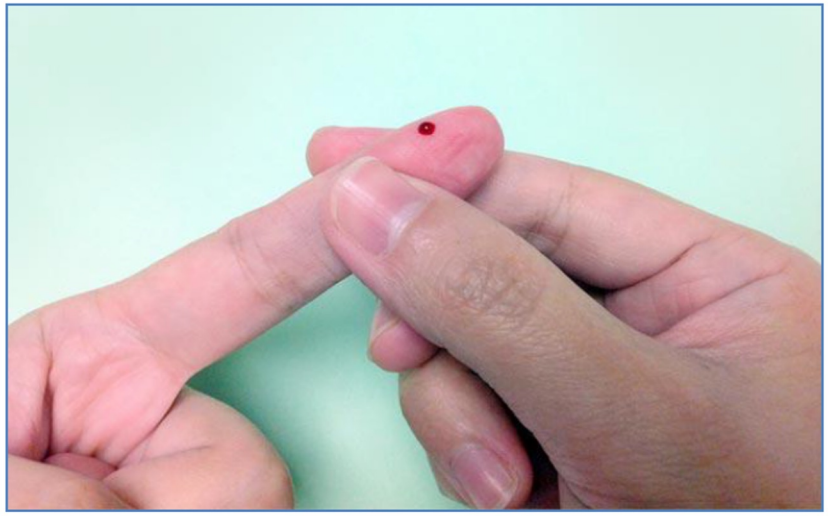
Overview of CGM and clinical indications



What is Continuous Glucose Monitoring System (CGMS)?

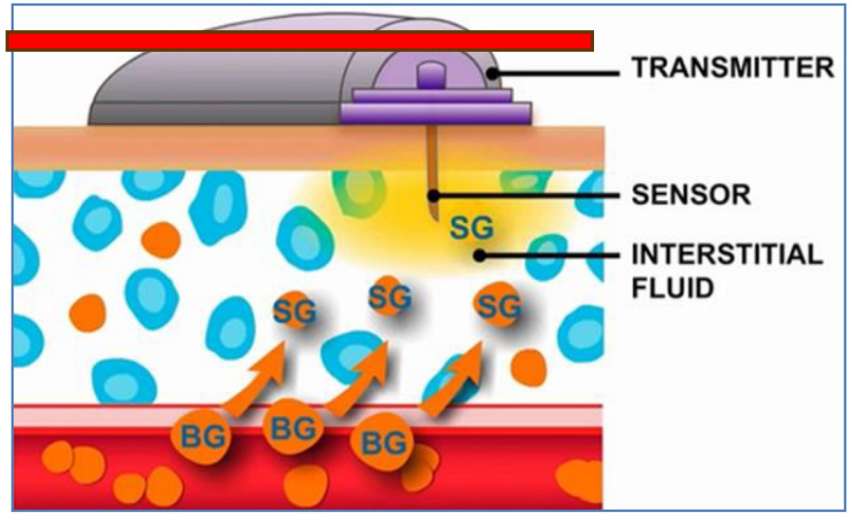
CGMs continually monitor the glucose level and give the real-time glucose value.

Fingerstick Measurement



Measured by blood glucose meter

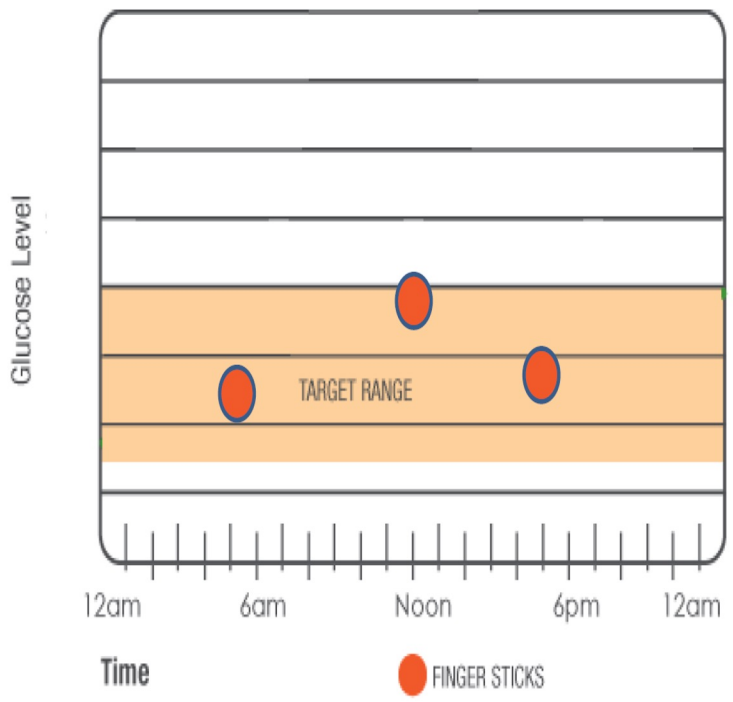
Interstitial Fluid Glucose Measurement



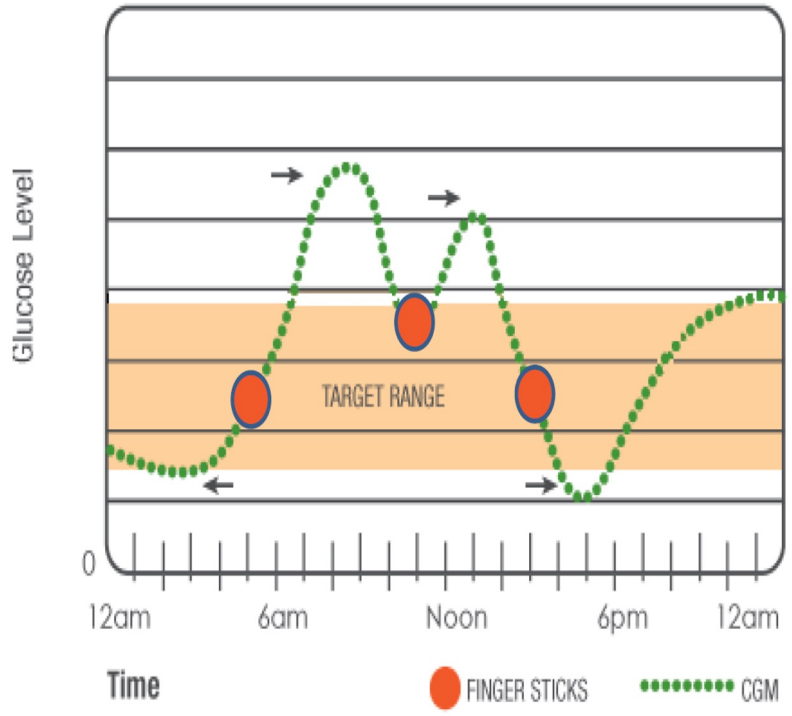
Measured by Continuous Glucose Monitor

What is the reason for invention of the CGMS?

BGM: A Snapshot of One Moment in Time

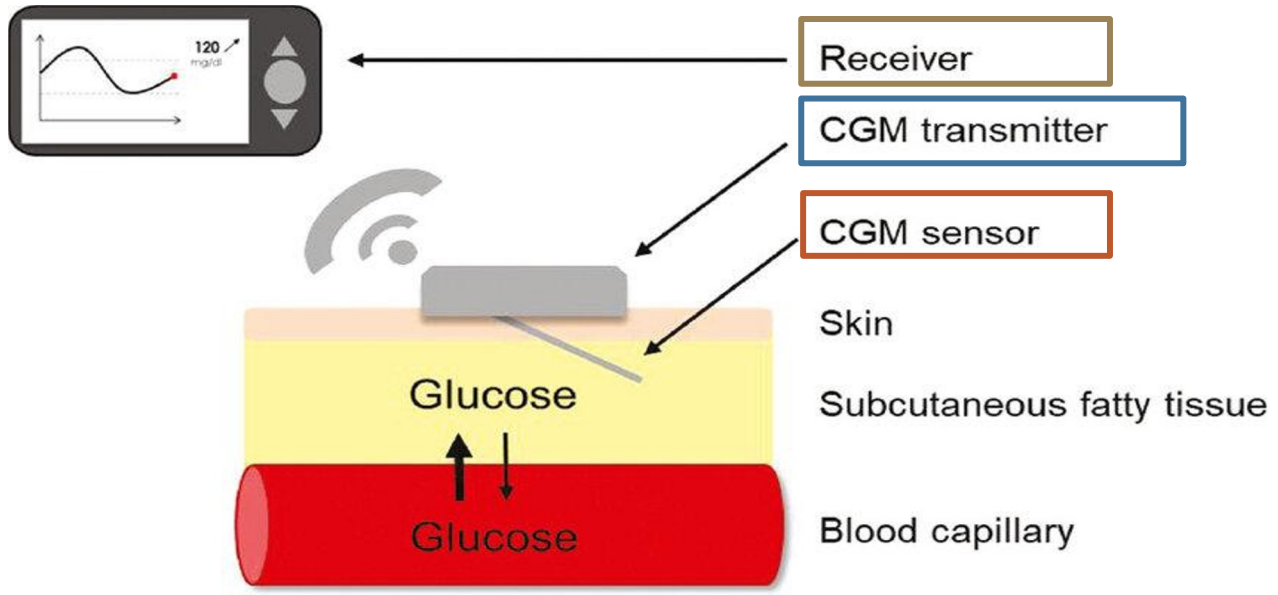


CGM: The Whole Story



Continuous Glucose Monitoring System

Basic Components



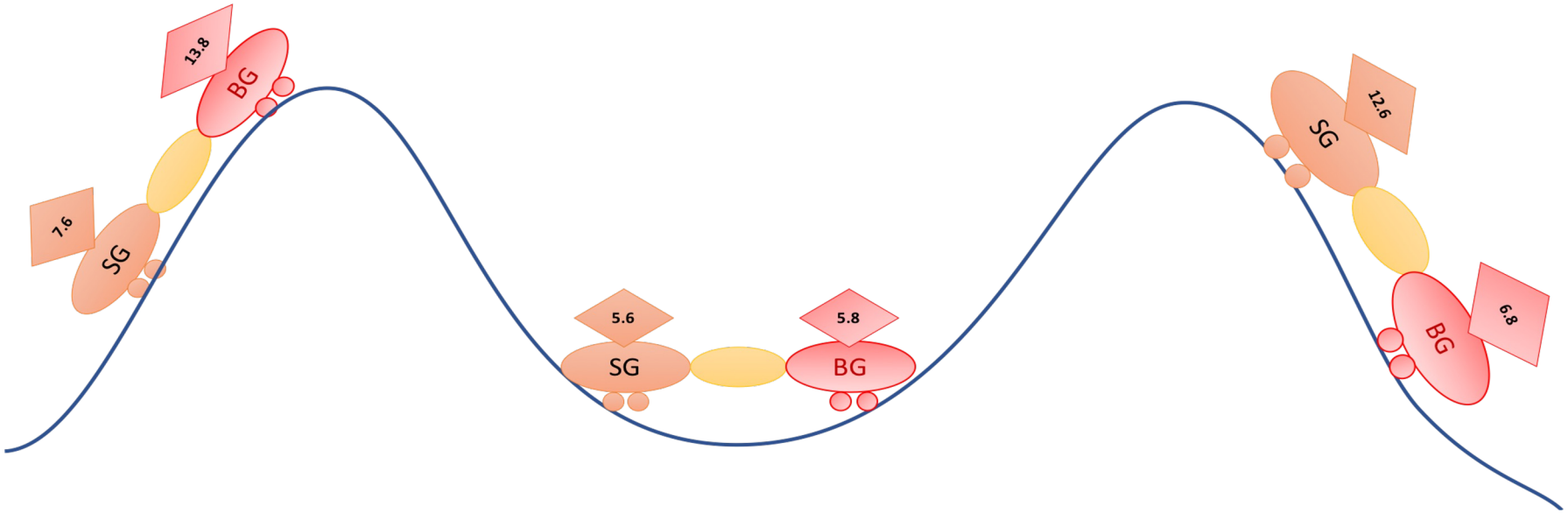
1. Sensor → 2. Transmitter → 3. Smartphone App / Receiver

Interstitial fluid Glucose vs Capillary Blood Glucose

10-15 mins lag time due to the glucose diffusion from capillary to interstitial space in the steady state

ATTENTION:

1) Do the accuracy check in the steady state
2) Confirmation by finger prick glucose after treatment of hypoglycemia



Great discrepancy between senor glucose and blood glucose in rapid change glucose levels

Interstitial fluid Glucose vs Capillary Blood

Interstitial Fluid (IF) glucose is lower than capillary glucose during decreasing glucose and reach the nadir value (push-pull phenomenon)

Glucose

ATTENTION:

1) confirmation by finger prick glucose during low senor glucose reading

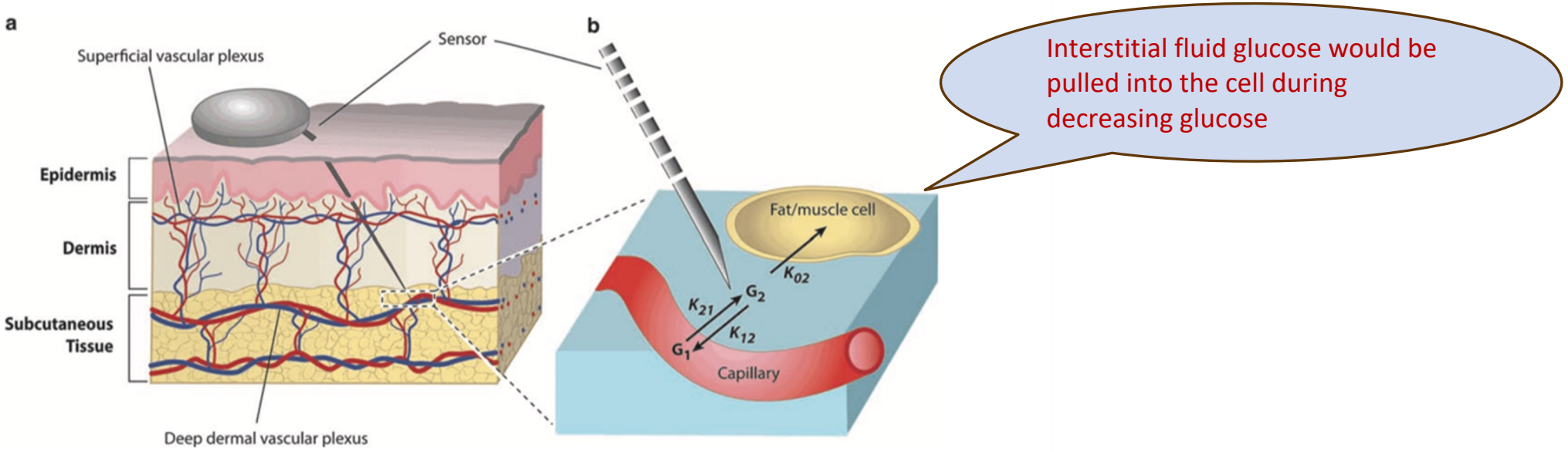


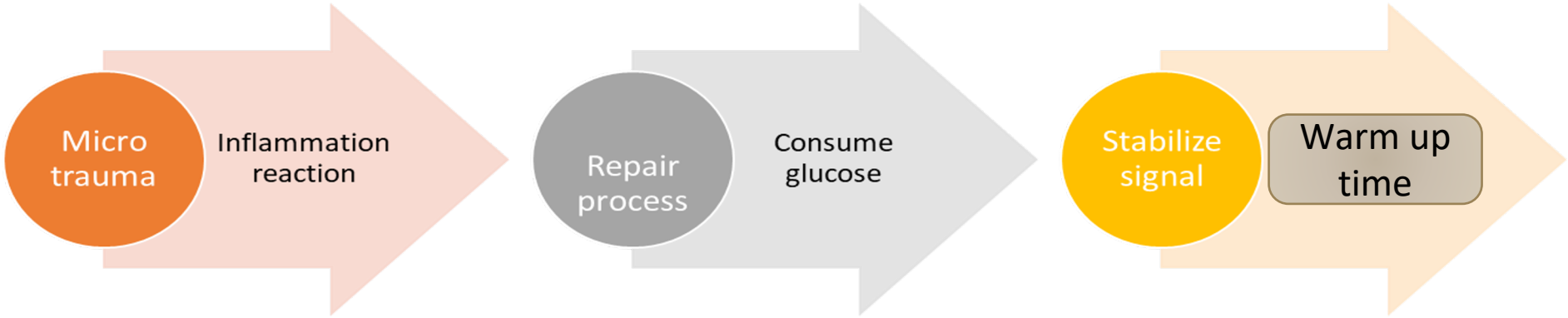
FIG. 1. Skin layers with the magnified IF space. (**a**) Vasculature in different skin layers with the CGM inserted into the subcutaneous tissue. (**b**) Diffusion of glucose from plasma to IF is in proportion to the concentration in each compartment. IF glucose is cleared by the surrounding cell uptake. Insulin may increase cellular glucose uptake after binding its membrane receptor. Adapted from Steil et al.[23] and Rebrin et al.[24]

Interstitial fluid Glucose vs Capillary Blood Glucose

Sensor insertion causes trauma to disrupt the tissue structure and provoke the inflammation reaction > consume the glucose for repair process > need to waiting a period of time for the senor signal to stabilize

ATTENTION:

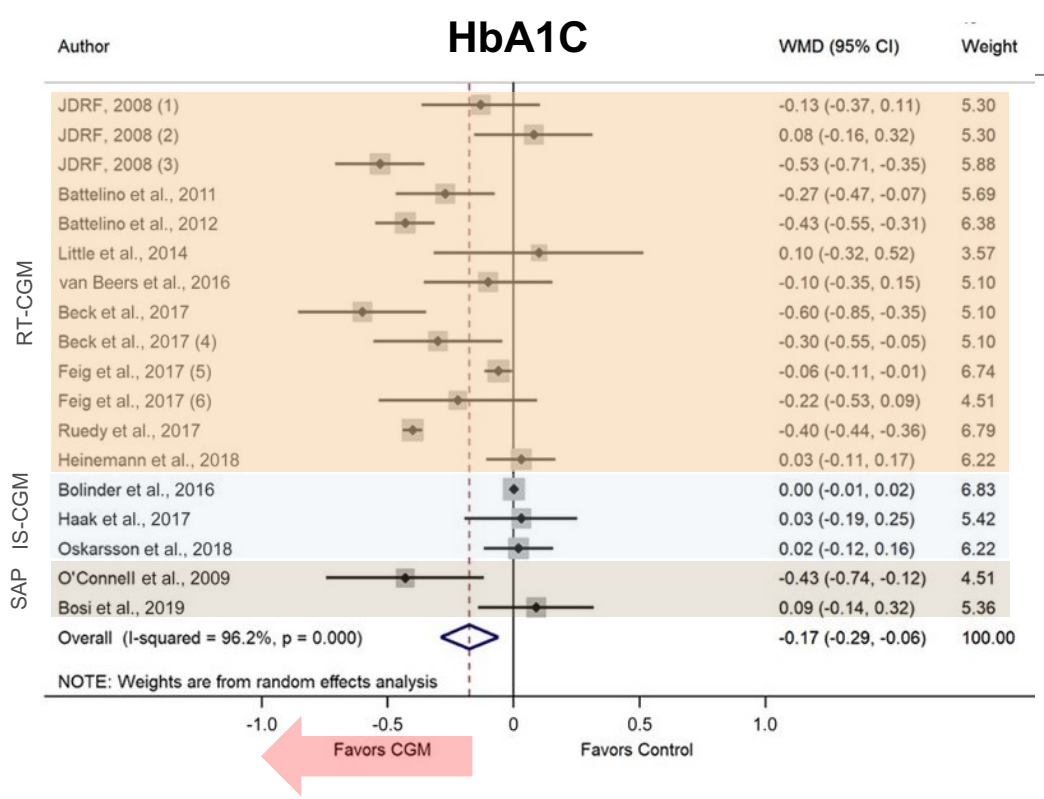
1) Importance of following the warm up time and better to do the finger pricking before using sensor glucose

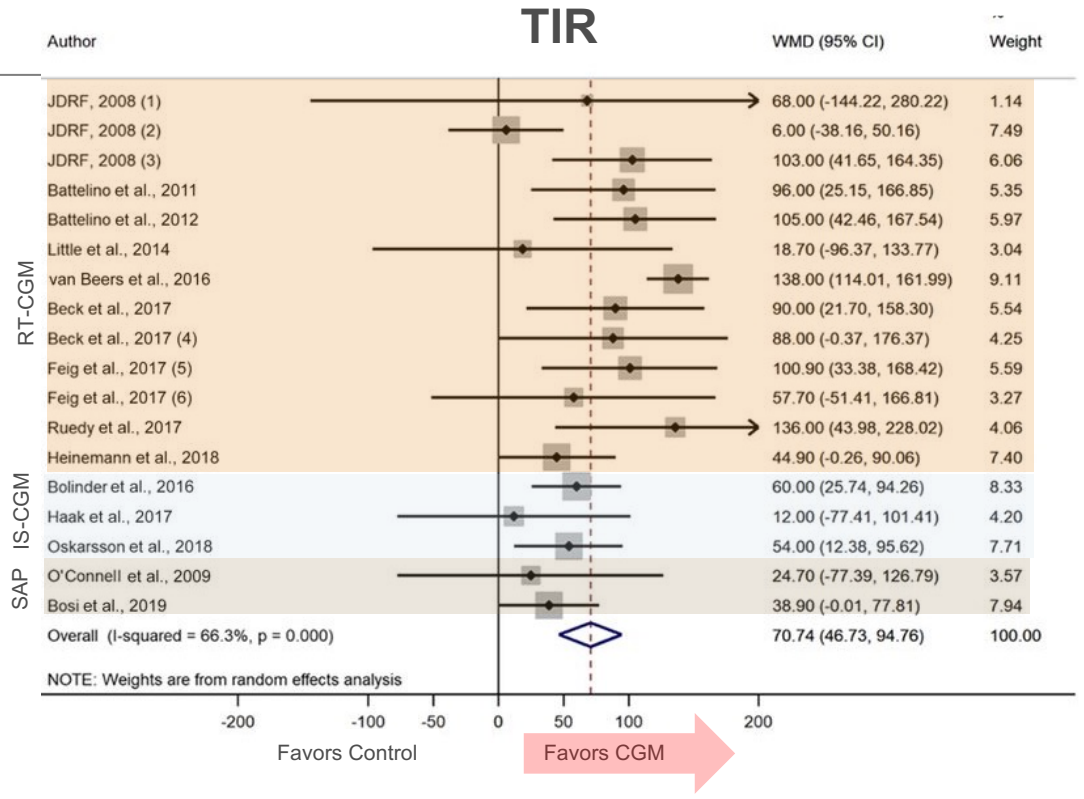


Types of CGM

1. Professional CGM
   - Usually Blinded (Masked): The patient cannot see glucose data, which prevents changes in daily behavior during the monitoring period.
   - Also apply to clinical trial
   - Not available in Hong Kong
2. Flash CGM (isCGM) – scan the sensor by reader or mobile phone by patient to get CGM data
   - Faded out in Hong Kong
3. Real time CGM + follower app – available in Hong Kong Market
   - See data on the smartphone or a reader, allowing them to see how food, exercise, and stress affect the glucose levels immediately for lifestyle modification and treatment adjustment.

RCTs demonstrate use of RT-CGM led to improvement in A1C, TIR, and TAR





15 RCTs published through June 2019
Participants of any age with T1D or T2D
Treated with IIT (MDI or CSII)

Comparison of RT-CGM, IS-CGM, and SAP
Duration of trials: 12-36 weeks
Coprimary outcome: Change in A1C & TIR

CSII = continuous subcutaneous insulin infusion; IIT = intensive insulin therapy; MDI = multiple daily insulin injections; SAP = sensor-augmented pump; T1D = type 1 diabetes; T2D = type 2 diabetes.

Maiorino MI, Signoriello S, Maio A, Chiodini P, Bellastella G, Scappaticcio L, Longo M, Giugliano D, Esposito K. 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 May;43(5):1146-1156. doi: 10.2337/dc19-1459. PMID: 32312858.

Real-time CGM is the emerging **standard of care in diabetes**

CGM is highly recommended to all persons on intensive insulin therapy (≥3 injections/day or pump) **(A)**[5].

rtCGM preferred over intermittently isCGM for Individuals with problematic hypoglycemia, those needing predictive alerts and integration with AID systems. Lifestyle & other factors should be considered **(B)** [5].

T2DM Management Algorithm 2023 Update[1]

CGM is highly recommended to assist persons with diabetes in reaching goals safely.

'CGM is the standard for glucose monitoring for most adults with type 1 diabetes'[6]

In individuals with type 2 diabetes treated with insulin[2]

"CGM has gained traction, with evidence that **CGM results in better overall glucose control** as defined by HbA1c and time in range (3.9–10.0 mmol/l [70–180 mg/dl]), **fewer hyperglycaemic and hypoglycaemic episodes and improvements in diabetes distress."**

- Diabetes devices should be offered to people with diabetes[4] **(A)***
- **Recommend CGM (A)*** to youth **(C)** and adults **(B)** with diabetes on any type of insulin therapy[4].

  Consider using CGM in adults with T2DM treated with glucose-lowering medications other than insulin[4] **(B)**.
- Initiation of CGM **early, including at diagnosis**, in the treatment of diabetes can be beneficial[4] **(C)§**

  CGM devices should be used as close to daily as possible for maximal benefit[4] **(A)**.

Asia-Pacific consensus recommendations for application of CGM in diabetes management[3]

Statement 1: CGM should be considered in all individuals with type 1 diabetes or type 2 diabetes on intensive insulin therapy **(Level of evidence: A)**

Statement 3: Early initiation of CGM (as soon as possible) after the diagnosis of type 1 diabetes is recommended **(Level of evidence: B)**

*Grade A: Clear evidence from well-conducted, generalizable randomized controlled trials that are adequately powered; §Grade C: Supportive evidence from poorly controlled or uncontrolled studies. CGM, continuous glucose monitoring; T2D, type 2 diabetes; ADA, American Diabetes Association; AID, automated insulin delivery; CSII, continuous subcutaneous insulin infusion; IS-CGM, intermittently scanned continuous glucose monitoring, MDI, multiple daily injection; T1D, type 1 diabetes. **References**: 1. Samson SL et al. *Endocr Pract.* 2023;29(5):305-340; 2. Davies MJ, et al. *Diabetologia.* 2022;65: 1925–1966; 3. Kong APS et al. 2023. *Diabetes Res Clin Pract*. 201:110718. doi: 10.1016/j.diabres.2023.110718. 4. American Diabetes Association. *Diabetes Care*. 2025;48 (Supplement_1): S146–S166. https://doi.org/10.2337/dc25-S007. 5. American Association of Clinical Endocrinology Clinical Practice Guideline: The Use of Advanced Technology in the Management of Persons With Diabetes Mellitu Grunberger, George et al. Endocrine Practice , Volume 27, Issue 6, 505 – 537, DOI: 10.1016/j.eprac.2021.04.008. 6 Holt, R.I.G., DeVries, J.H., Hess-Fischl, A. et al. The management of type 1 diabetes in adults. A consensus report by the American Diabetes Association (ADA) and the European Association for the Study of Diabetes (EASD). Diabetologia 64, 2609–2652 (2021). https://doi.org/10.1007/s00125-021-05568-3

Indication for using CGM

Type 1 diabetes - adult / children /adolescents

- Continues Subcutaneous Insulin Infusion (CSII) or Multiple Daily Injections (MDI) with suboptimal control
- Impaired hypoglycemia awareness
- High glucose variability
- Severe or frequency of hypoglycemia

Landmark Randomized Controlled Trials for Type 1 Diabetes

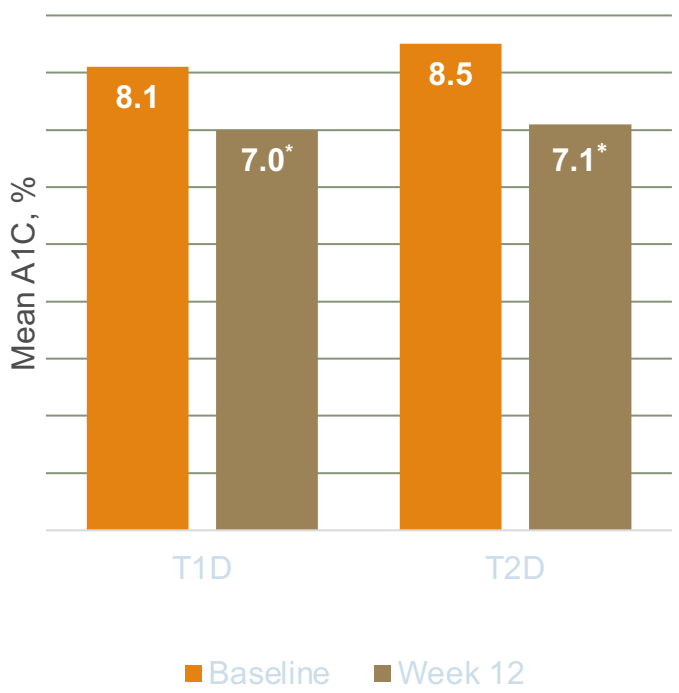
Study / Trial	Year / Journal	Design	N	Population	Intervention vs Comparator	Key Results
JDRF CGM RCT	2008, NEJM	Multicenter RCT, 26 weeks	322	Age ≥8y, HbA1c 7.0–10.0%	Real-time CGM vs home blood glucose monitoring (BGM) ≥4×/day (Dexcom, Medtronic, and Abbott FreeStyle Libre)	HbA1c benefit significant only in adults ≥25y: −0.53 pp (95% CI −0.71 to −0.35, P<0.001); no benefit in 8–24y groups. Composite of HbA1c <7% with no severe hypoglycemia: 30% vs 7% in adults (P=0.006)
DIAMOND	2017, JAMA	RCT 2:1, 24 weeks	158	Adults on MDI, baseline HbA1c 8.6%	CGM + usual care vs usual care (Dexcom G4 and G5)	HbA1c fell 1.0% vs 0.4%; adjusted difference −0.6% (95% CI −0.8 to −0.3, P<0.001). Median time <70 mg/dL: 43 vs 80 min/day (P=0.002)
GOLD	2017, JAMA	Open-label crossover, 26 weeks/period	161	Adults on MDI, baseline HbA1c 8.6%	CGM vs conventional SMBG (Dexcom G4)	HbA1c 7.92% vs 8.35%; −0.43% (95% CI −0.57 to −0.29, P<0.001). Severe hypoglycemia: 1 vs 5 events
IMPACT	2016, Lancet	Multicenter open-label RCT, 6 months	241	Well-controlled adults (HbA1c ≤7.5%)	Flash CGM (FreeStyle Libre) vs SMBG	Time <3.9 mmol/L reduced from 3.38 to 2.03 h/day (38% relative reduction, P<0.0001); nocturnal hypoglycemia −40%; no HbA1c deterioration
REPLACE-BG	2017, Diabetes Care	Non-inferiority RCT 2:1, 26 weeks	226	Adult pump users, baseline HbA1c 7.0%	CGM without routine confirmatory BGM vs CGM+BGM (Dexcom G5)	TIR 63±13% vs 65±11%, non-inferior (P=0.81). HbA1c change 0.0% both arms
IN CONTROL	2016, Lancet Diabetes Endocrinol	Randomized crossover	52	Adults with impaired hypoglycemia awareness (Gold ≥4)	Real-time CGM vs SMBG (masked) (DexcomTM)	Severe hypoglycemia events: 14 vs 34 (P=0.033). Time ≤3.9 mmol/L: −4.7 pp (P<0.0001)
HypoDE	2018, Lancet	6-month multicenter open-label RCT	149	Adults on MDI with impaired awareness or prior severe hypoglycemia	Dexcom G5 Mobile vs SMBG	72% reduction in hypoglycemic events ≤3.0 mmol/L ≥20 min (IRR 0.28, 95% CI 0.20–0.39, P<0.0001)
WISDM	2020, JAMA	RCT 1:1, 6 months	203	Adults ≥60 years	CGM vs BGM (Dexcom G5)	Time <70 mg/dL: −27 min/day (95% CI −40 to −16, P<0.001). HbA1c −0.3% (P<0.001). Severe hypoglycemia: 1 vs 10 events
CITY	2020, JAMA	RCT 1:1, 26 weeks	153	Age 14–24 years, baseline HbA1c 8.9%	CGM vs BGM (Dexcom G5 & G6)	HbA1c −0.37% (95% CI −0.66 to −0.08, P=0.01); significant in 8 of 9 CGM metrics
ALERTT1 — 6 mo	2021, Lancet	Parallel RCT 1:1	254	Adults already using first-generation flash CGM	Real-time CGM with alerts vs flash CGM (Dexcom G6)	TIR +6.85 pp (95% CI 4.36–9.34, P<0.0001). Severe hypoglycemia: 3 vs 13 participants (P=0.0082)
ALERTT1 — 24 mo	2023, Lancet Diabetes Endocrinol	Extension study	119+123	Same cohort	Real-time CGM, within-group (Dexcom G6)	TIR gains sustained: +11.7 pp and +10.5 pp at 24 months (both P<0.0001)

Improvements in A1C and Quality of Life in First-Time Users of Dexcom RT-CGM

Study description:

- Real-world, prospective study that included 248 patients (182 with T1D and 66 with T2D) who were 25-65 years old
- Evaluated A1C and QOL before and after 12 weeks of use of RT-CGM

Mean A1C%



QOL improvement

Significantly reduced hypoglycemia concern by 18 percent*

Significantly reduced stress about diabetes by 24 percent*

*P<0.001.
IIT=intensive insulin therapy; QOL=quality of life.

Change in Hemoglobin A1c and Quality of Life with Real-Time Continuous Glucose Monitoring Use by People with Insulin-Treated Diabetes in the Landmark Study

Gilbert TR et al. *Diabetes Technol Ther.* 2021;23(Suppl 1):S35-S39.

Randomized Controlled Trials (RCTs) Show Improved Clinical Outcomes, High Usage, and High Satisfaction Using Dexcom CGM in Diverse Populations

SENCE[1,2]
(ages 2-7)

- Reduced # of severe hypoglycemic events (<54 mg/dL)[1]
- Reduced parental burden and fear of hypoglycemia[1]
- Hypoglycemia reductions sustained at 52 weeks[2]
- 92% CGM use maintained at 52 weeks[3]

Type 1

CITY[3,4]
(ages 14-24)
MILLENNIAL[5]
(ages 16-25)

- ~ 0.4% reduction in A1c; increased TIR; high treatment satisfaction[4]
- 86% CGM use at 52 weeks[3]
- Rapid ~ 0.5% reduction in baseline A1c; significant improvements in TIR and TAR at 8 weeks[5]

Type 1

DIaMonD[6,7]
(ages 25+)
GOLD[8] , SILVER[9]
(ages 18+)

- ~ 1.3% and 1.4% reduction in baseline A1c in poorly controlled T1D[6] and T2D[7] patients, respectively
- 93% CGM use ≥6 days/week at 24 weeks[6,7]
- 80% decrease in severe hypoglycemia[8]
- Sustained benefits in glycemic, QoL, and satisfaction outcomes at 2.5 years[9]

Type 1 & 2

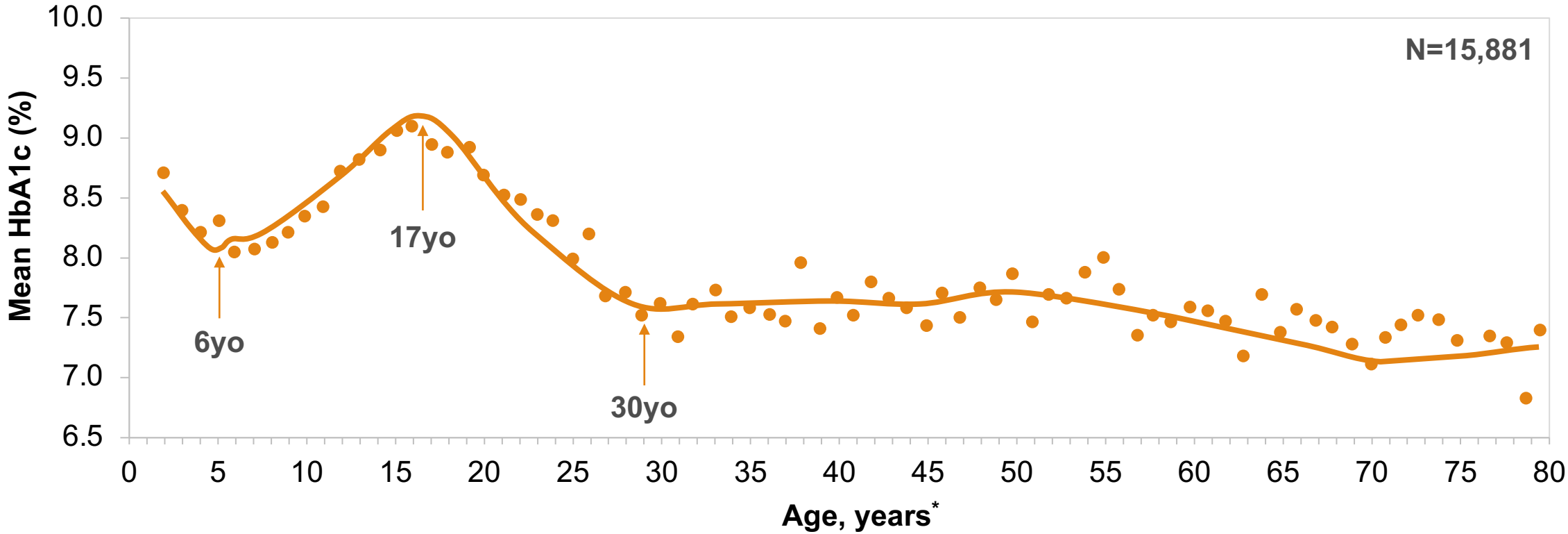
DIaMonD[10]
(ages 60+)
WISDM[11,12]
(ages 60+)

- ~ 0.9% reduction in baseline A1c in seniors with T1D and T2D[10]
- High treatment satisfaction[10]
- 97% CGM use ≥6 days/week at 24 weeks[10]
- Rapid decrease in time spent <70 mg/dL, TIR increased by 2.1 hrs/day.[11] Glycemic benefits sustained at 52 weeks[12]

1. DiMeglio LA et al. *Diabetes Care*. 2020;44(2):464-472. 2. Data presented at ADA Virtual June 12-16, 2020. Van Name M et al. Benefit of reduced hypoglycemia with continuous glucose monitoring is sustained through 12 months among young children with type 1 diabetes. 3. Data presented at ADA Virtual June 12-16, 2020. DeSalvo D et al. Durability of continuous glucose monitoring use in young children, teens, and young adults with type 1 diabetes. 4. Laffel LM et al. *JAMA*. 2020;323:2388-2396. 5. Data presented at ADA Virtual June 12-16, 2020. Thabit H et al. Comparison of Dexcom G6 RT-CGM with self-monitoring blood glucose in young people with type 1 diabetes – The MILLENNIAL Study. 6. Beck RW et al. *JAMA*. 2017;317(4):371-378. 7. Beck RW et al. *Ann Intern Med*. 2017;167:365-374. 8. Lind M et al. *JAMA*. 2017;317(4):379-387. 9. Data presented at ADA Virtual June 12-16, 2020. Lind et al. Sustained intensive treatment and long-term effects on HbA1c reduction by CGM in persons with type 1 diabetes treated with MDI (SILVER study). 10. Ruedy KJ et al. *J Diabetes Sci Technol*. 2017;11:1138-1146. 11. Pratley RE et al. *JAMA*. 2020;323:2397-2406. 12. Data presented at ADA Virtual June 12-16, 2020. WISDOM 6-month extension data.

A1C Across the Lifespan

A1C **Average A1C From Early Childhood to Older Adult in T1D Exchange**

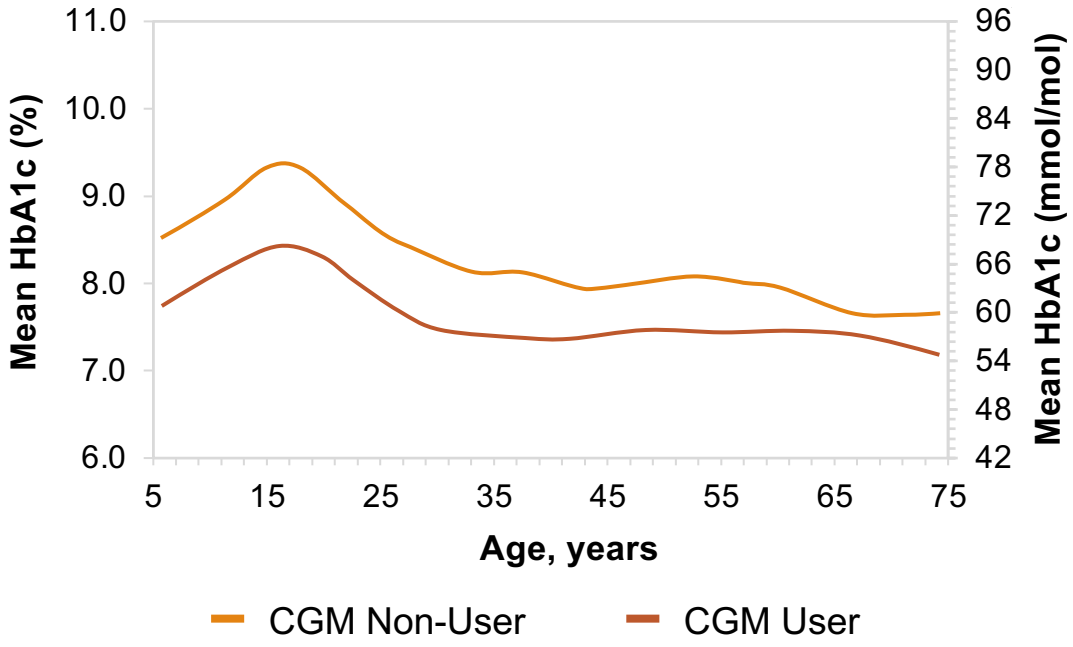


*Participants ≥80 years old are pooled.

Miller K et al. *DTT*. 22(9),2020. DOI: 10.1089/dia.2019.0393

CGM Use Across the Lifespan and Different Insulin Delivery Methods

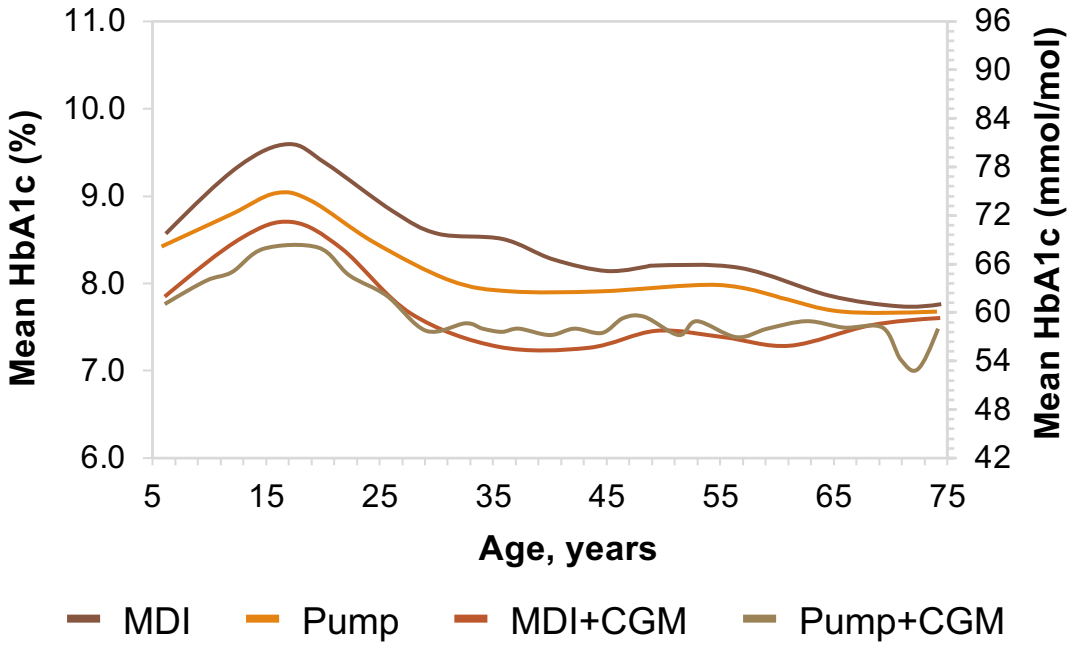
A1C **Average A1C by technology use**



CGM non-users: n=11,199

CGM users: n=4,219

A1C **Average A1C by insulin delivery**

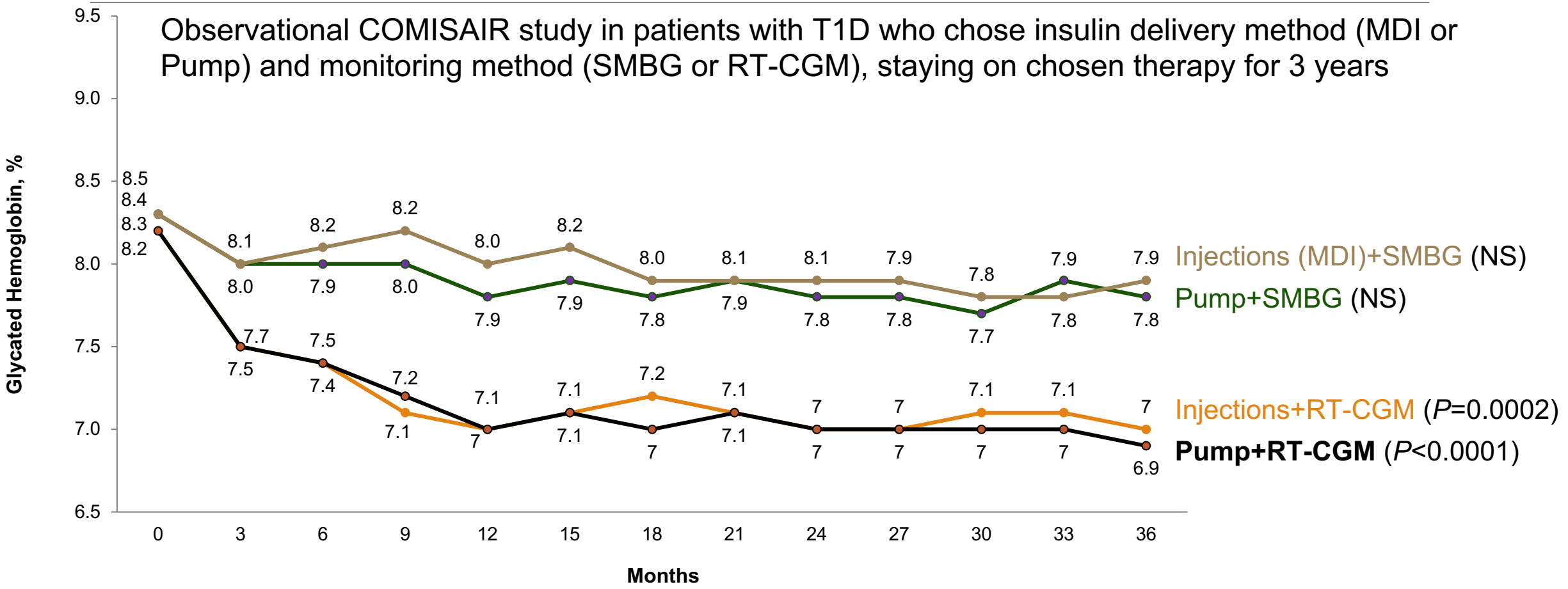


Multiple daily insulin injections (MDI) + CGM users: n=649

Pump + CGM non-users: n=3,507

Miller K et al. *DTT*. 22(9),2020. DOI: 10.1089/dia.2019.0393.

COMISAIR Study: A1C Decreases With CGM Use Regardless of Insulin Delivery Method



NS = not significant.

Šoupal J et al. *Diabetes Care*. 2020;43(1):37-43.

COMISAIR Study: Conclusions

- COMISAIR study is currently the longest prospective, real-life study simultaneously comparing four different treatment strategies for T1D
- Usage of RT-CGM, both with CSII and MDI, provided significant, comparable, and stable improvement of A1C
- Treatment with RT-CGM and MDI was more effective than CSII alone in reducing A1C
- The combination of CGM and MDI can be a suitable alternative to treatment with CSII and CGM for some patients

Šoupal J et al. *Diabetes Care*. 2020;43(1):37-43.

HA Go _ Pilot in Type 1 Diabetes

Insulin Bolus Dose Calculator

$$\text{Bolus insulin} = \text{Meal insulin} + \text{Correction insulin}$$

$$\text{Bolus insulin} = \frac{\text{CHO}}{\text{ICR}} + \frac{\text{Current BG - Target BG}}{\text{CF}}$$

Indication for using CGM

Type 2 diabetes

- Continues Subcutaneous Insulin Infusion (CSII) or Multiple Daily Injections (MDI) with suboptimal control
- Treated with basal insulin
- Continuous Glucose Monitoring Systems in Noninsulin-Treated People with Type 2 Diabetes
  - Reduced HbA1c and Hypoglycemia
  - Less glucose fluctuation
  - Increased Target in range and patient satisfaction

A Systematic Review and Meta-analysis of Randomized Controlled Trials – Type 2 DM (2008 -2023)

Table 1 Characteristics of the RCTs identified

Study (first author, year)	Study design	Intervention duration (weeks)	Study duration (weeks)	*N* intervention/control	Mean age intervention/control (years)	Mean baseline HbA_{1c} intervention/control (mmol/mol)	Mean baseline HbA_{1c} intervention/control (%)	Intervention / sensor type/comparator	Medication use intervention/control (%)	Primary outcome
Ajjan et al (2023) [21]	2-arm RCT	12	43	69/72	63.2/62.0	74.6/77.9	8.97/9.27	isCGM/Freestyle Libre sensor/SMBG	Insulin: 52.2/47.2 SU: 47.8/52.8 Metformin: 72.5/77.8 DPP4-i: 21.7/15.3 SGLT-2i: 10.1/20.8 GLP-1 RA: 7.2/6.9 Thiazolidinedione: 2.9/0.0	TIR
Beck et al (2017) [22]	2-arm RCT	24	24	79/79	60.0/60.0	69/69	8.5/8.5	rtCGM/Dexcom G4 Platinum CGM System/SMBG	Insulin: 100/100 Metformin: 56/52 DPP4-i: 7.6/5.1 SLGT-2i: 13/13 GLP-1 RA: 14/10 Other (not specified): 8.9/13	HbA_{1c}
Bergenstal et al (2022) [26]	2-arm RCT	16	16	59/55	59.3/58.8	66.0/62.3	8.19/7.85	rtCGM/Type not specified/SMBG	Insulin, SU, Metformin, DPP-4i, GLP-1 RA (% not specified)	HbA_{1c}
Cosson et al (2009) [27]	2-arm RCT	12 (2 days at baseline, 2 days at week 12)	12	11/14	57.2/57.3	77.3/75.6	9.22/9.07	rtCGM/Gluco-Day System/SMBG	Insulin: 27/43 Oral agents (not specified): 73/57	HbA_{1c}
Haak et al (2017) [23]	2-arm RCT	24	24	149/75	59.0/59.5	71.0/72.1	8.65/8.75	isCGM/Freestyle Libre sensor/SMBG	Insulin: 100/100	HbA_{1c}
Martens et al (2021) [28]	2-arm RCT	34	34	116/59	56.0/59.0	77/75	9.2/9.0	rtCGM/Dexcom G6 CGM System/SMBG	Insulin: 100/100 SU: 36.2/47.5 Metformin: 79.3/78.0 DPP4-i: 4./13.6 SLGT-2i: 9.5/8.5 GLP-1 RA: 23.3/13.6	HbA_{1c}

Jancev M, Vissers TACM, Visseren FLJ, van Bon AC, Serné EH, DeVries JH, de Valk HW, van Sloten TT. Continuous glucose monitoring in adults with type 2 diabetes: a systematic review and meta-analysis. Diabetologia. 2024 May;67(5):798-810. doi: 10.1007/s00125-024-06107-6. Epub 2024 Feb 16. PMID: 38363342; PMCID: PMC10954850.

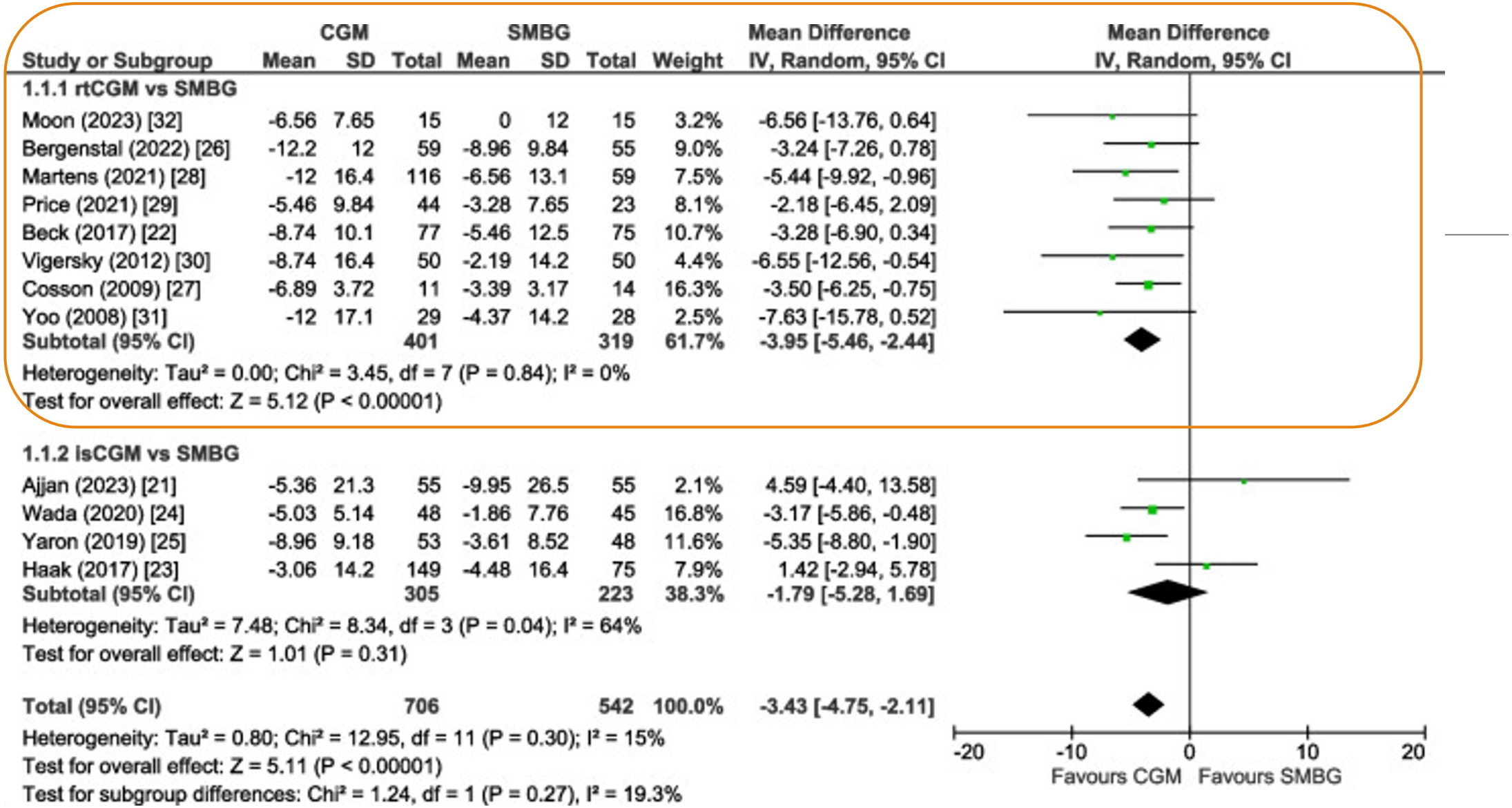
Table 1 (continued)

Study (first author, year)	Study design	Intervention duration (weeks)	Study duration (weeks)	*N* intervention/control	Mean age intervention/control (years)	Mean baseline HbA_{1c} intervention/control (mmol/mol)	Mean baseline HbA_{1c} intervention/control (%)	Intervention / sensor type/comparator	Medication use intervention/control (%)	Primary outcome
Moon et al (2023) [32]	3-arm RCT	12 (1 week at baseline, 1 week at week 12)	24	15/15	53.9/50.7	66/65	8.2/8.1	rtCGM/Guardian 3 sensor (Medtronic MiniMed)/SMBG	Insulin: 0/0 SU: 73.3/40.0 Metformin: 100/100 DPP4-i: 80.0/86.7 SLGT-2i: 26.7/13.3 Thiazolidinedione: 40.0/66.7	HbA_{1c}
Price et al (2021) [29]	2-arm RCT	12 (10 days each at weeks 0, 4 and 8)	36	46/24	58.9/60.9	68/69	8.4/8.5	rtCGM/Dexcom G6 CGM System/SMBG	Insulin: 0/0 SU: 75.6/56.5 DPP4-i: 28.9/43.5 SGLT-2i: 57.8/39.1 Thiazolidinedione: 11.1/13.0 Biguanide: 82.2/82.6 Meglitinide: 0.0/4.3 Other (not specified): 35.6/34.8	HbA_{1c}
Vigersky et al (2012) [30]	2-arm RCT	12 (four cycles of 2 weeks/1 week off)	52	50/50	55.5/60.0	68/66	8.4/8.2	rtCGM/Dexcom SEVEN/SMBG	Insulin: 38/28 Oral agents only: 48.0/54.0 Oral agents/exenatide: 8.0/10.0 Diet and exercise only: 6.0/8.0	HbA_{1c}

Table 1 (continued)

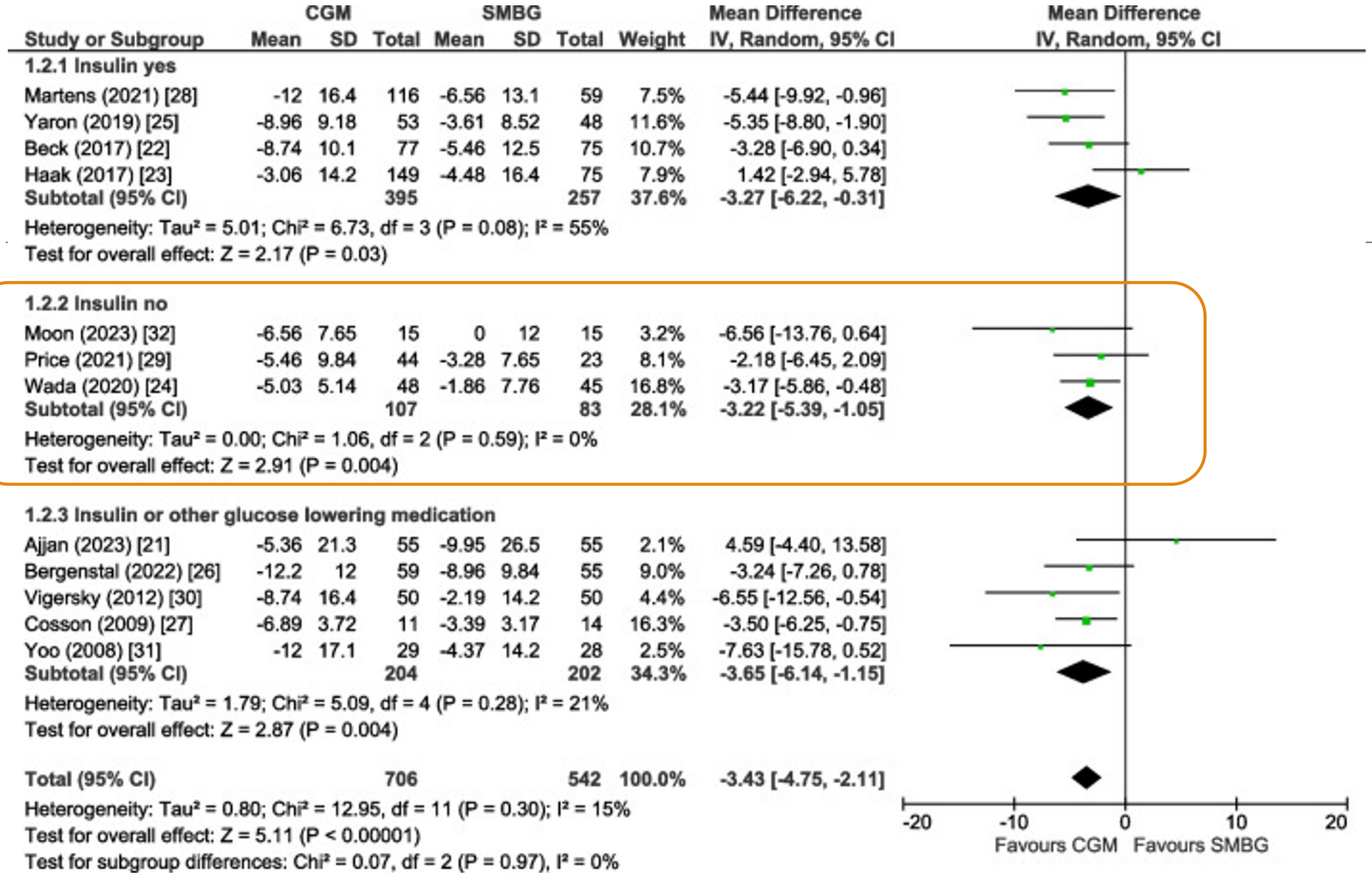
Study (first author, year)	Study design	Intervention duration (weeks)	Study duration (weeks)	*N* intervention/control	Mean age intervention/control (years)	Mean baseline HbA_{1c} intervention/control (mmol/mol)	Mean baseline HbA_{1c} intervention/control (%)	Intervention / sensor type/comparator	Medication use intervention/control (%)	Primary outcome
Wada et al (2020) [24]	2-arm RCT	12	24	49/51	58.1/58.7	61.1/62.3	7.83/7.85	isCGM/Free Style Libre System/SMBG	Insulin: 0/0 SU: 32.7/27.5 Metformin: 69.4/62.7 DPP4-i: 81.6/78.4 SGLT-2i: 42.9/37.3 GLP-1 RA: 2.0/5.9 Glinide: 20.4/21.6 α-Glucosidase-i: 26.5/35.3 Pioglitazone: 8.2/13.7	HbA_{1c}
Yaron et al (2019) [25]	2-arm RCT	10	10	53/48	67.6/65.9	71.4/67.7	8.68/8.34	isCGM/Free Style Libre System/SMBG	Insulin: 100/100 SU: 0.0/4.2 Metformin: 71.7/72.9 DPP4-i: 7.5/14.6 SGLT-2i: 24.5/27.7 GLP-1 RA: 35.8/31.3	Treatment satisfaction
Yoo et al (2008) [31]	2-arm RCT	12 (once a month for 3 days)	12	32/33	54.6/57.5	76/72	9.1/8.7	rtCGM/Guardian RT CGM System/SMBG	Insulin: 13.8/17.9 Oral agents only: 44.8/35.7 Combination of insulin and oral medications: 37.9/42.9	HbA_{1c}

DPP4-i, dipeptidyl peptidase-4 inhibitor; GLP-1RA, glucagon-like peptide-1 receptor agonists; α-Glucosidase-i, α-glucosidase inhibitor; SGLT-2i, sodium–glucose cotransporter 2 inhibitor; SU, sulfonylurea



Forest plot of pooled analysis of change in HbA_{1c} (mmol/mol) in individuals with type 2 diabetes using rtCGM or isCGM compared with SMBG

Jancev M, Vissers TACM, Visseren FLJ, van Bon AC, Serné EH, DeVries JH, de Valk HW, van Sloten TT. Continuous glucose monitoring in adults with type 2 diabetes: a systematic review and meta-analysis. Diabetologia. 2024 May;67(5):798-810. doi: 10.1007/s00125-024-06107-6. Epub 2024 Feb 16. PMID: 38363342; PMCID: PMC10954850.



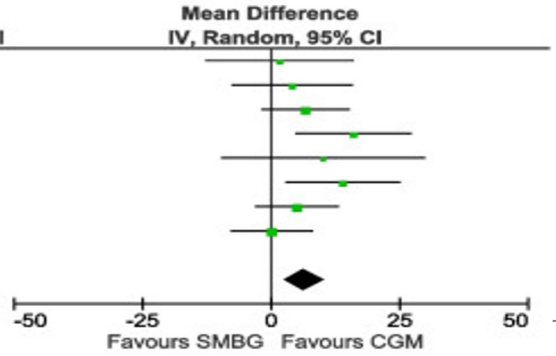
Forest plot of pooled analysis of change in HbA_{1c} (mmol/mol) in individuals with type 2 diabetes using rtCGM or isCGM compared with SMBG, stratified according to type of glucose-lowering therapy (insulin users, no insulin users or mixed population of insulin users and no insulin users)

Jancev M, Vissers TACM, Visseren FLJ, van Bon AC, Serné EH, DeVries JH, de Valk HW, van Sloten TT. Continuous glucose monitoring in adults with type 2 diabetes: a systematic review and meta-analysis. Diabetologia. 2024 May;67(5):798-810. doi: 10.1007/s00125-024-06107-6. Epub 2024 Feb 16. PMID: 38363342; PMCID: PMC10954850.

a

Study or Subgroup	CGM Mean	CGM SD	CGM Total	SMBG Mean	SMBG SD	SMBG Total	Weight	Mean Difference IV, Random, 95% CI
Ajjan (2023) [21]	8.73	38.57	54	7.1	36.57	50	6.9%	1.63 [-12.81, 16.07]
Moon (2023) [32]	3.1	17.9	15	-1	14.9	15	10.0%	4.10 [-7.69, 15.89]
Bergenstal (2022) [26]	18.21	23.3	59	11.55	23.5	55	17.7%	6.66 [-1.94, 15.26]
Martens (2021) [28]	19	36.07	116	3	36.07	59	10.8%	16.00 [4.70, 27.30]
Price (2021) [29]	-3.2	35.36	42	-13.3	37.15	19	3.7%	10.10 [-9.73, 29.93]
Wada (2020) [24]	18.2	23.89	41	4.3	25.4	35	11.1%	13.90 [2.75, 25.05]
Beck (2017) [22]	4	24.83	78	-1	26.25	75	19.6%	5.00 [-3.10, 13.10]
Haak (2017) [23]	-1.2	26.82	149	-1.3	29.77	75	20.1%	0.10 [-7.90, 8.10]
Total (95% CI)			554			383	100.0%	6.36 [2.48, 10.24]

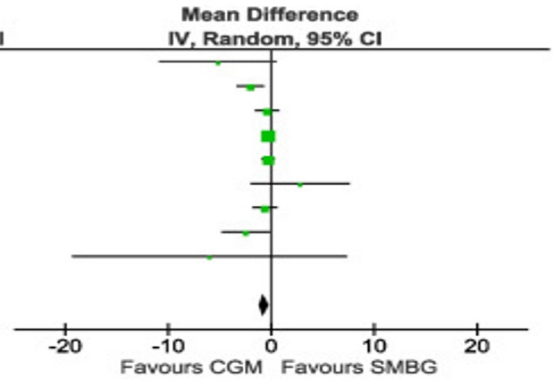
Heterogeneity: Tau² = 2.90; Chi² = 7.70, df = 7 (P = 0.36); I² = 9%
Test for overall effect: Z = 3.21 (P = 0.001)



b

Study or Subgroup	CGM Mean	CGM SD	CGM Total	SMBG Mean	SMBG SD	SMBG Total	Weight	Mean Difference IV, Random, 95% CI
Ajjan (2023) [21]	-3.91	11.92	54	1.29	17.15	50	0.9%	-5.20 [-10.92, 0.52]
Bergenstal (2022) [26]	-0.8	4.4	59	1.22	2.8	55	11.2%	-2.02 [-3.36, -0.68]
Moon (2023) [32]	-0.4	2.3	15	0	0.2	15	13.4%	-0.40 [-1.57, 0.77]
Martens (2021) [28]	-0.1	0.64	116	0.2	1	59	32.0%	-0.30 [-0.58, -0.02]
Price (2021) [29]	-0.3	1.62	42	0	0.92	19	23.6%	-0.30 [-0.94, 0.34]
Wada (2020) [24]	1.2	4.9	41	-1.6	13.78	35	1.2%	2.80 [-2.01, 7.61]
Beck (2017) [22]	-0.9	3.9	78	-0.3	3.72	75	12.8%	-0.60 [-1.81, 0.61]
Haak (2017) [23]	-2.9	8.17	149	-0.4	8.5	75	4.7%	-2.50 [-4.83, -0.17]
Cosson (2009) [27]	-4	15.52	7	2	12.04	12	0.2%	-6.00 [-19.36, 7.36]
Total (95% CI)			561			395	100.0%	-0.66 [-1.21, -0.12]

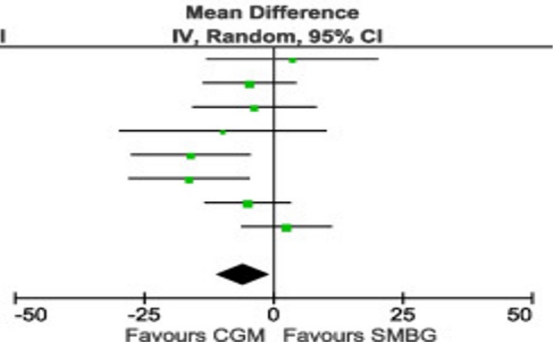
Heterogeneity: Tau² = 0.22; Chi² = 14.47, df = 8 (P = 0.07); I² = 45%
Test for overall effect: Z = 2.39 (P = 0.02)



c

Study or Subgroup	CGM Mean	CGM SD	CGM Total	SMBG Mean	SMBG SD	SMBG Total	Weight	Mean Difference IV, Random, 95% CI
Ajjan (2023) [21]	-5	42.92	54	-8.63	43.5	50	7.2%	3.63 [-13.00, 20.26]
Bergenstal (2022) [26]	-17.41	24.9	59	-12.77	24.2	55	16.5%	-4.64 [-13.66, 4.38]
Moon (2023) [32]	-2.7	18.5	15	1	14.9	15	11.7%	-3.70 [-15.72, 8.32]
Price (2021) [29]	3.4	35.78	42	13.2	37.46	19	5.3%	-9.80 [-29.82, 10.22]
Martens (2021) [28]	-18	36.07	116	-2	37.48	59	12.2%	-16.00 [-27.60, -4.40]
Wada (2020) [24]	-19.1	24.53	41	-2.8	27.12	35	12.1%	-16.30 [-28.01, -4.59]
Beck (2017) [22]	-4	25.46	78	1	26.97	75	17.9%	-5.00 [-13.32, 3.32]
Haak (2017) [23]	4.1	28.88	149	1.6	33.02	75	17.0%	2.50 [-6.29, 11.29]
Total (95% CI)			554			383	100.0%	-5.86 [-10.88, -0.84]

Heterogeneity: Tau² = 18.56; Chi² = 11.06, df = 7 (P = 0.14); I² = 37%
Test for overall effect: Z = 2.29 (P = 0.02)



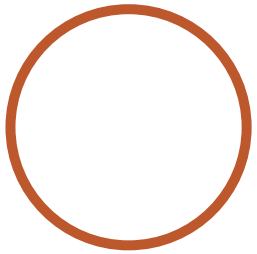
Forest plot of pooled analysis of change in TIR (**a**) TBR (**b**) and TAR (**c**) in individuals with type 2 diabetes using rtCGM or isCGM compared with SMBG

Jancev M, Vissers TACM, Visseren FLJ, van Bon AC, Serné EH, DeVries JH, de Valk HW, van Sloten TT. Continuous glucose monitoring in adults with type 2 diabetes: a systematic review and meta-analysis. Diabetologia. 2024 May;67(5):798-810. doi: 10.1007/s00125-024-06107-6. Epub 2024 Feb 16. PMID: 38363342; PMCID: PMC10954850.

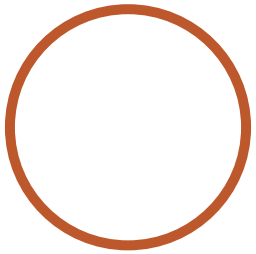
Impact of continuous glucose monitoring on hospitalizations and glucose control in people with type 2 diabetes: real-world analysis

Garg SK, et al. *Diabetes Obes Metab*. 2024

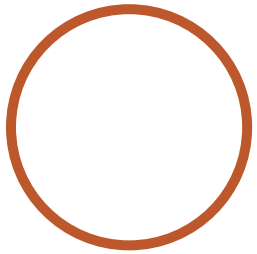
How can people with T2D not using insulin benefit from CGM?



It is difficult for many people with T2D to **achieve glycemic targets**: more than 50% of adults with T2D have an A1C > 8.0%



Increasing prevalence of T2D leads to a rise in **health care resource utilization** (HCRU) and **costs**



There is limited research on how people with T2D **not using insulin** could benefit from CGM

The aim of the study was to evaluate the impact of CGM on HCRU in a broad T2D population:
People treated with non-insulin (**NIT**), basal insulin (**BIT**) and prandial insulin therapy (**PIT**).

A1C, glycated hemoglobin or HbA1C; BIT, basal insulin therapy; CGM, continuous glucose monitoring; HCRU, health care resource utilization; NIT, non-insulin therapy; PIT, prandial insulin therapy; T2D, type 2 diabetes

Garg SK et al. *Diabetes Obes Metab*. 2024;26(11):5202-5210.

Overview

Data source

- Real-world data from Optum's de-identified Market Clarity Database
- ≥ 79 Million patients EMRs in the USA

Study Population

- 74,679 CGM users
- Age ≥ 18 years old
- Diagnosis of T2D
- No CGM claims during 6 months pre-index period
- ≥ 1 claim for CGM between 6/30/2019 and 1/5/22
- Baseline A1C between 7.0% and 15.0%

Methods

Retrospective cohort analysis of people with T2D who transitioned from BGM to CGM

Three groups stratified by diabetes therapy during pre-index period

NIT (n=25,269)

BIT (n=16,264)

PIT (n=33,146)



Pre-index period
6 months before

Index date
Jun 30, 2019 – Jan 5, 2022

Post-index period
12 months after

Outcomes:

- Hospitalization
- Emergency room visits

Subgroup analysis of 6030 people

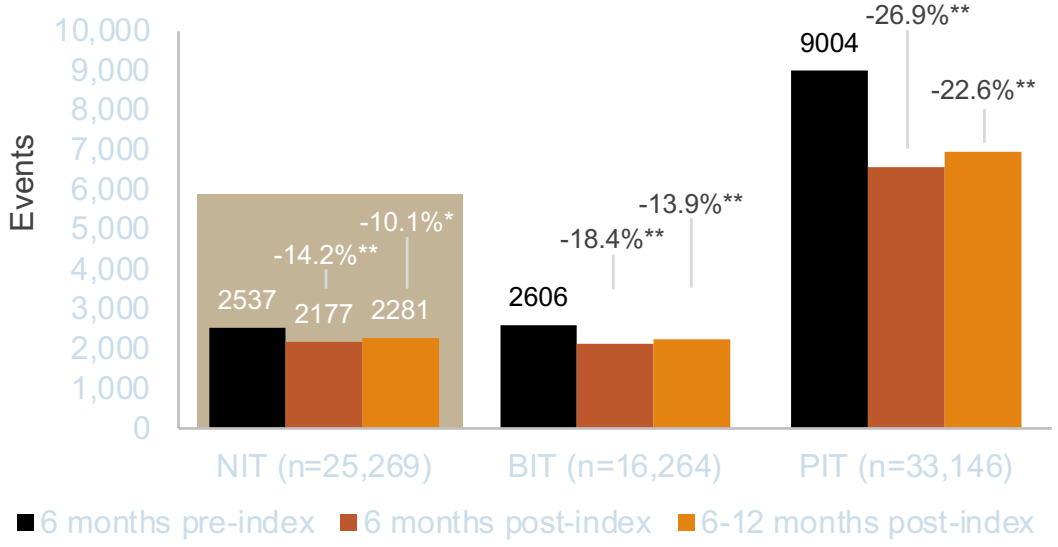
- Glycemic improvements
- Medication adjustments

A1C, glycated hemoglobin or HbA1C; BGM, blood glucose monitoring; BIT, basal insulin therapy; CGM, continuous glucose monitoring; EMRs, electronic medical records, NIT, non-insulin therapy; PIT, prandial insulin therapy; T2D, type 2 diabetes

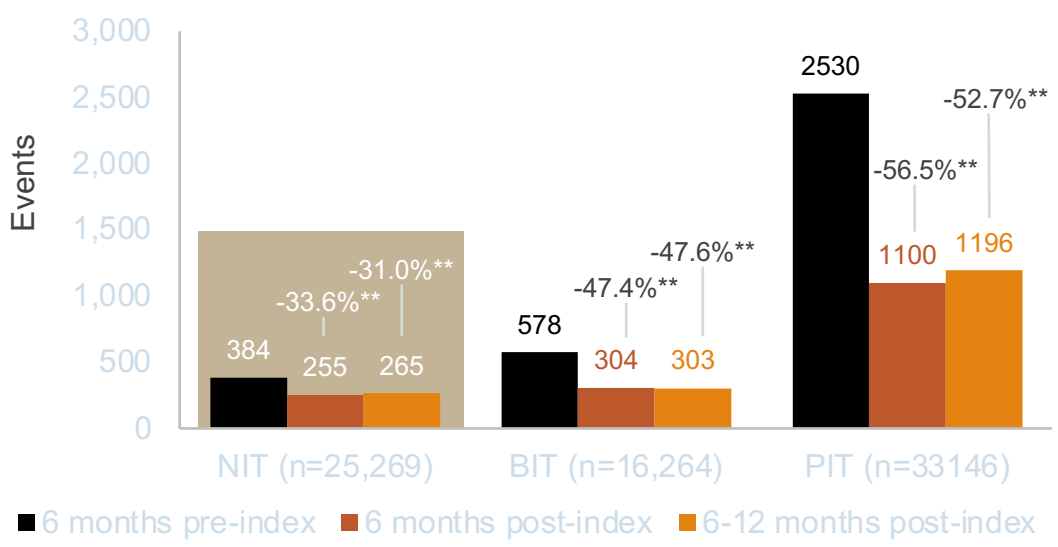
Garg SK et al. *Diabetes Obes Metab*. 2024;26(11):5202-5210.

CGM use led to significant reductions in hospitalizations in all treatment groups

All-cause hospitalizations (ACH)



Acute diabetes-related hospitalizations (ADH)



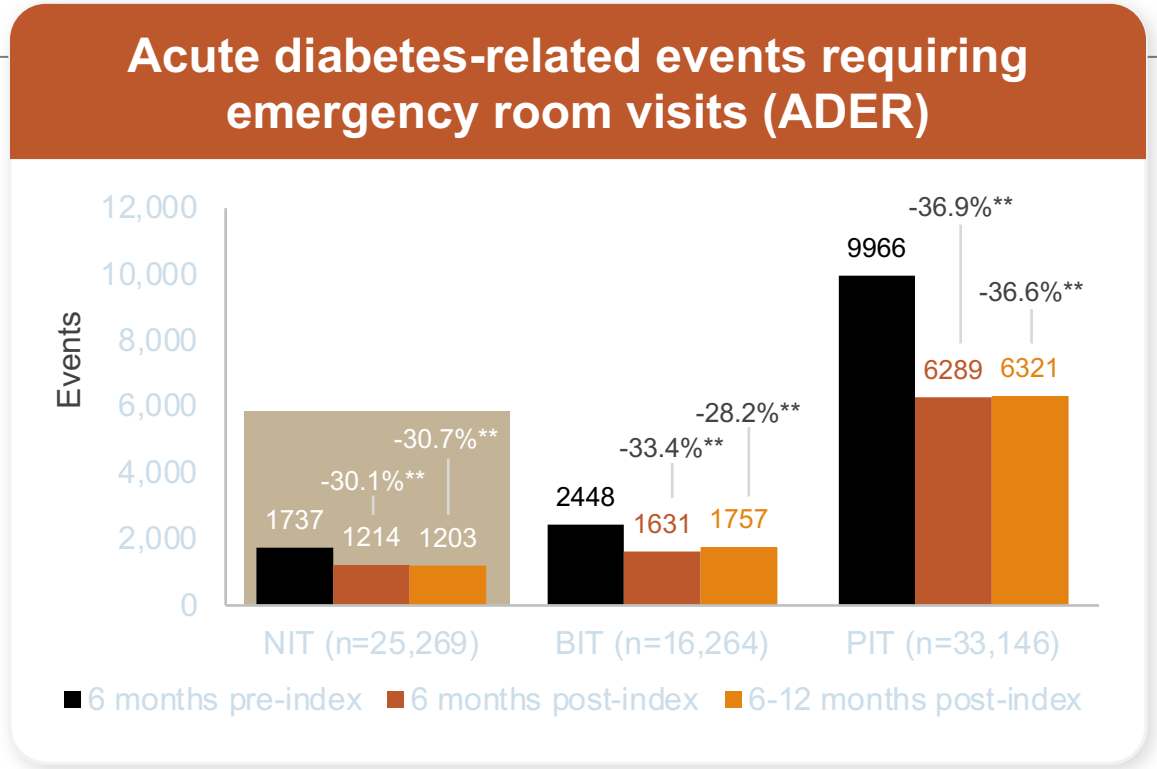
* p<0.01; ** p<0.0001

- CGM use led to significant reduction in ACH and ADH across all groups, with larger reductions in ADH
- ADH reductions accounted for a large proportion of the ACH reductions
- Costs associated with hospitalization of people with T2D are high; CGM use could reduce these costs

ACH, all-cause hospitalizations; ADH, acute diabetes-related hospitalizations; BIT, basal insulin therapy; CGM, continuous glucose monitoring; NIT, non-insulin therapy; PIT, prandial insulin therapy; T2D, type 2 diabetes

Garg SK et al. *Diabetes Obes Metab*. 2024;26(11):5202-5210.

CGM use led to significant reductions in emergency room visits in all treatment groups



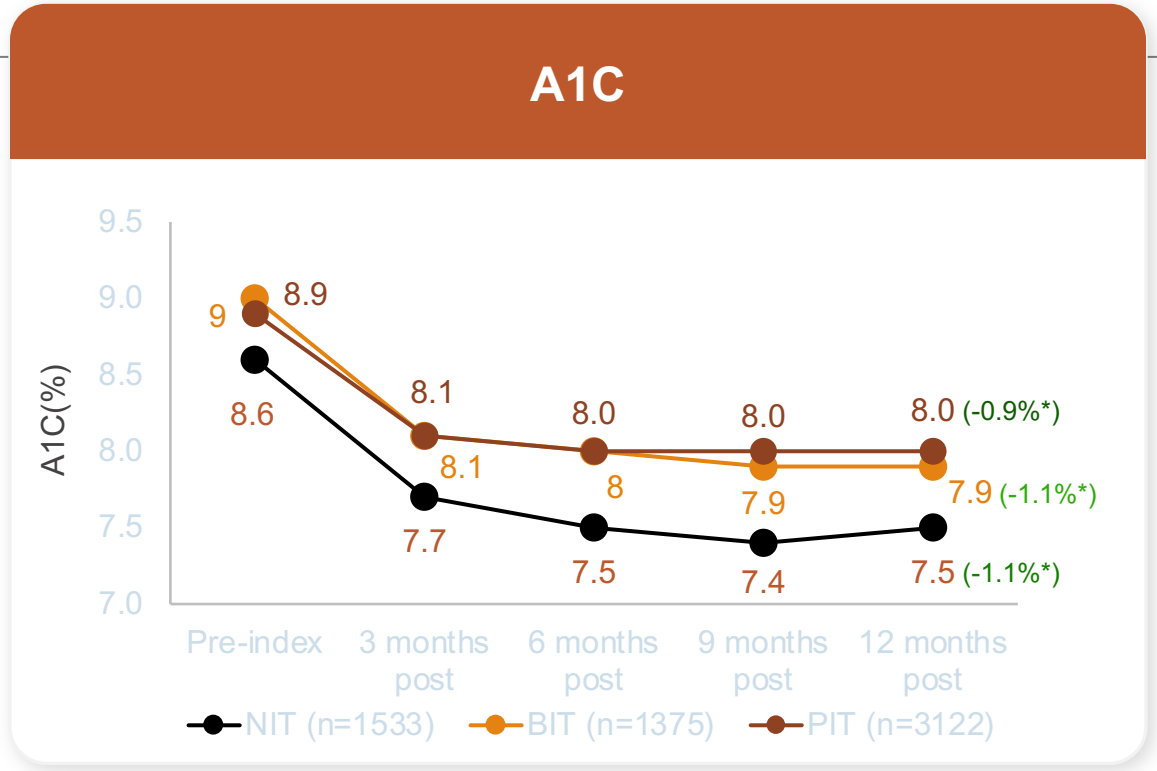
* p<0.01; ** p<0.0001

- CGM use in people with T2D was associated with a reduction in ADER in the 6 months and 6-12 months post-index periods, also in people with NIT

ADER, acute diabetes-related events requiring emergency room visits; BIT, basal insulin therapy; CGM, continuous glucose monitoring; NIT, non-insulin therapy; PIT, prandial insulin therapy; T2D, type 2 diabetes

Garg SK et al. *Diabetes Obes Metab*. 2024;26(11):5202-5210.

CGM use significantly improved diabetes outcomes



* p<0.0001 compared to pre-index

- Mean A1C decreased by 0.9% at 3 months and the effect persisted during the 12 months study period
- People in NIT group achieved slightly greater reductions in A1C compared to other groups despite their lower baseline A1C levels
- Supports the value and utility of CGM in non-insulin-treated people with T2D

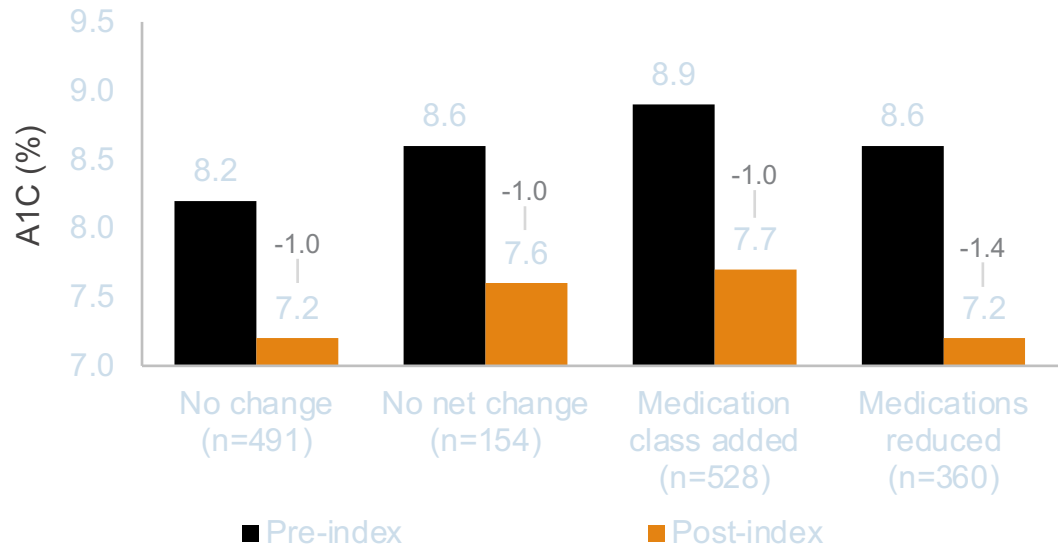
A1C, glycated hemoglobin or HbA1C; BIT, basal insulin therapy; CGM, continuous glucose monitoring; NIT, non-insulin therapy; PIT, prandial insulin therapy; T2D, type 2 diabetes

Garg SK et al. *Diabetes Obes Metab*. 2024;26(11):5202-5210.

CGM use led to significant glycemic improvements regardless of medication adjustments

Non-insulin treated group

Pre- and post-index A1C in different subgroups of medication adjustments



p<0.001 for all groups

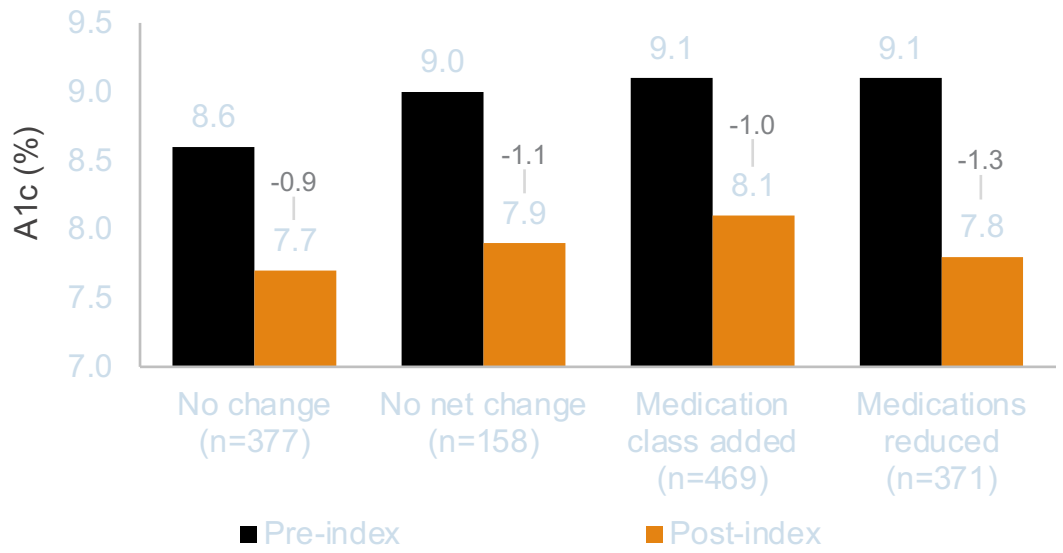
A1C, glycated hemoglobin or HbA1C; CGM, continuous glucose monitoring

Garg SK et al. *Diabetes Obes Metab*. 2024;26(11):5202-5210.

CGM use let to significant glycemic improvements regardless of medication adjustments

Basal insulin treated group

Pre- and post-index A1C in different subgroups of medication adjustments



p<0.001 for all groups

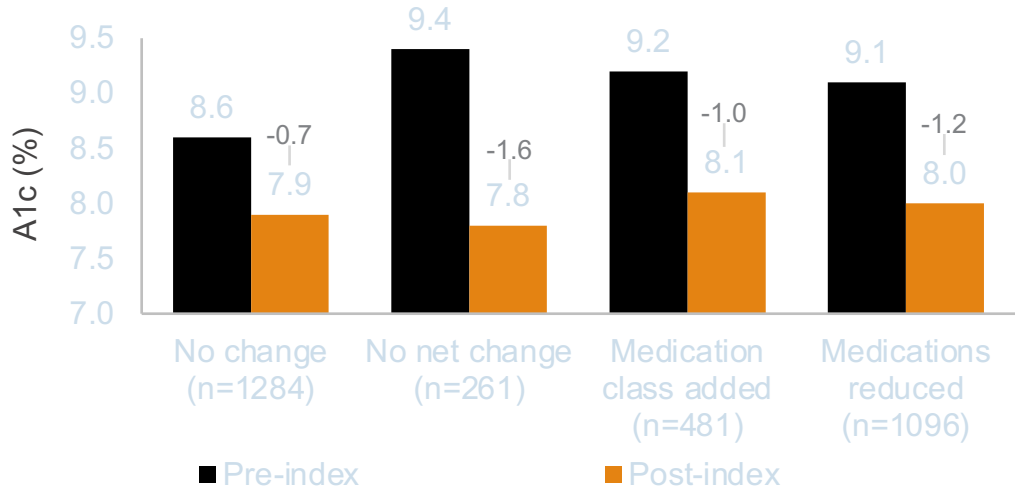
A1C, glycated hemoglobin or HbA1C; CGM, continuous glucose monitoring

Garg SK et al. *Diabetes Obes Metab*. 2024;26(11):5202-5210.

CGM use led to significant glycemic improvements regardless of medication adjustments

Prandial insulin treated group

Pre- and post-index A1C in different subgroups of medication adjustments



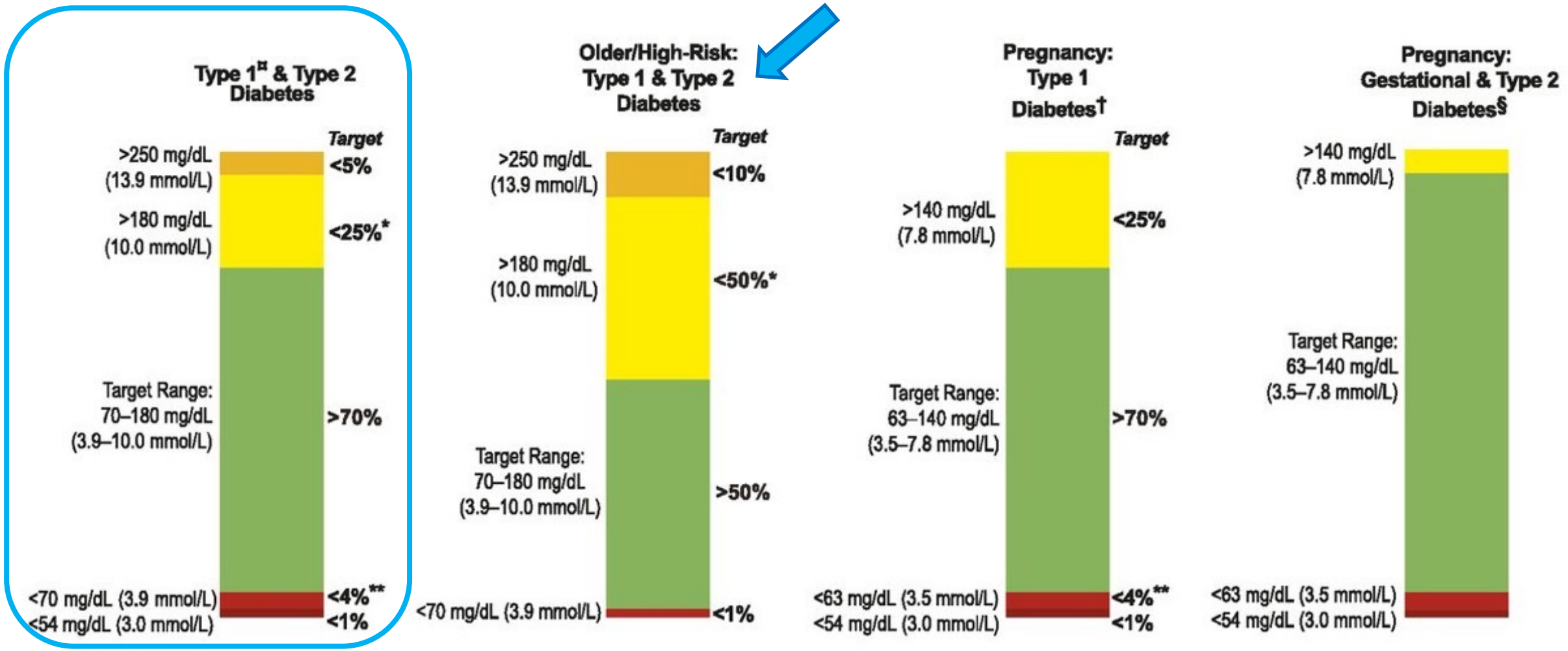
p<0.001 for all groups

- Significant glycemic improvements were observed in all groups, regardless if medications were added, reduced, or unchanged
- Indicates that CGM use improves glycemic outcomes on its own, regardless of medication
- Similar results were observed for people on NIT, BIT, and PIT

A1C, glycated hemoglobin or HbA1C; BIT, basal insulin therapy; CGM, continuous glucose monitoring; NIT, non-insulin therapy, PIT, prandial insulin therapy

Garg SK et al. *Diabetes Obes Metab*. 2024;26(11):5202-5210.

CGM-based Targets for Different Diabetes Populations



High risk individuals refer to those with cognitive deficits, renal disease, joint disease, osteoporosis, fracture and/or cardiovascular disease; and those requiring assisted care. Older/high risk group is more prone to severe hypoglycaemia, thus glycaemic targets need to be conserva

Clinical Targets for Continuous Glucose Monitoring Data Interpretation: Recommendations From the International Consensus on Time in Range (2019). Diabetes Care, 42(8):1593-1603.

Cautions During Interpretation of CGM Reports

	False High	False Low
Interference	Freestyle Libre 2 Plus – Vitamin C 1g over above	
	Simplera – Acetaminophen + hydroxyurea	
	Dexcom G7 – Acetaminophen + hydroxyurea	
Physical condition		Compression lows Dehydration Faulty sensor
After sensor insertion 1st 24 hrs		Micro trauma > inflammation reaction > consume glucose
Environment	High temperature – Sauna, hot bath tub, extreme weather in outdoor	
External chemistry	Insect repellent, sunscreen, perfume, lotion	

Adjunctive vs. Non-Adjunctive CGM

	Adjunctive CGM	Non-adjunctive (therapeutic) CGM
Definition	Complements, does not replace, fingerstick BGM	Sensor value alone can drive treatment decisions
Fingerstick before dosing?	Required, every time	Not required
Calibration fingersticks	Yes	Some devices still require 1–2/day (older systems); most current iCGM devices are factory-calibrated
Example devices	First-gen Dexcom, Medtronic Enlite, FreeStyle Navigator	Dexcom G6/G7, FreeStyle Libre 2/3, Guardian 4 (iCGM-cleared)
Insulin dosing decisions	Must confirm with BGM first	May be based on sensor alone

Klonoff DC, Gabbay M, Moon SJ, Wilmot EG. Importance of FDA-Integrated Continuous Glucose Monitors to Ensure Accuracy of Continuous Glucose Monitoring. J Diabetes Sci Technol. 2025 Sep;19(5):1392-1399. doi: 10.1177/19322968241250357. Epub 2024 May 3. PMID: 38695387; PMCID: PMC11571640.

Adjunctive vs. Non-Adjunctive CGM

Pre-2016: All real-time CGM in the US labeled adjunctive only — every dosing decision required fingerstick confirmation.

2016–2017: Dexcom G5 Mobile becomes the first system approved for non-adjunctive use. FDA advisory panel votes in favor July 2016; label change follows.

2018: FDA creates the **integrated CGM (iCGM)** special controls category, setting the accuracy bar for non-adjunctive clearance going forward.

FDA iCGM means an **integrated continuous glucose monitoring system**: a Class II CGM device category defined in U.S. regulation at **21 CFR 862.1355**

Klonoff DC, Gabbay M, Moon SJ, Wilmot EG. Importance of FDA-Integrated Continuous Glucose Monitors to Ensure Accuracy of Continuous Glucose Monitoring. J Diabetes Sci Technol. 2025 Sep;19(5):1392-1399. doi: 10.1177/19322968241250357. Epub 2024 May 3. PMID: 38695387; PMCID: PMC11571640.

Integrated CGM

Table 1. iCGM Special Control Performance Requirements.

iCGM special control performance requirement	95% LCL
A: Within 15 mg/dL, <70 mg/dL	>85%
B: Within 15%, 70-180 mg/dL	>70%
C: Within 15%, >180 mg/dL	>80%
D: Within 40 mg/dL, <70 mg/dL	>98%
E: Within 40%, 70-180 mg/dL	>99%
F: Within 40%, >180 mg/dL	>99%
G: Within 20%	>87%
H: CGM < 70 mg/dL & Ref >180 mg/dL	0
I: CGM >180 mg/dL & Ref <70 mg/dL	0
J: CGM ROC >1 mg/dL/min & Ref ROC <−2 mg/dL/min	<1%
K: CGM ROC <−1 mg/dL/min & Ref ROC >2 mg/dL/min	<1%

Klonoff DC, Gabbay M, Moon SJ, Wilmot EG. Importance of FDA-Integrated Continuous Glucose Monitors to Ensure Accuracy of Continuous Glucose Monitoring. J Diabetes Sci Technol. 2025 Sep;19(5):1392-1399. doi: 10.1177/19322968241250357. Epub 2024 May 3. PMID: 38695387; PMCID: PMC11571640.

Table 2. US FDA Definition of Non-Adjunctive CGM and US FDA Standards for CGM Accuracy Studies.

US FDA definition of nonadjunctive CGM

- Indicated to replace information obtained from standard BGM
- Intended to determine glucose levels and direction/rate of change of glucose levels
- Used to make diabetes-related treatment decisions (e.g., insulin dosing)
- Provides historical glucose information, facilitating long-term therapy adjustments

US FDA standards for CGM accuracy studies	Limitations of accuracy studies for non-iCGM-approved CGM devices
Robust clinical data	• Some devices do not have accuracy studies published in peer-reviewed journals. • Some devices have data published only in government letters containing regulatory decisions for the public and some do not even have this type of data. • Study populations for some studies are limited (e.g., n < 100, high proportion of people with T2DM). • Some studies are conducted in a way that the MARD will look better than it would look in real world use, because of protocol particularities, making it difficult to compare performances between CGMs.
Representative of performance across target population	• Studies conducted in adults only (despite indicated ages for some devices being ≥2 years). • Characteristics of subjects in some studies do not represent a likely patient population (e.g., they may have relatively low HbA1c, high proportion of non-insulin users, low proportion of T1DM patients, more stable patients). • For some devices, there is limited information on the characteristics of patients in the accuracy studies (e.g., mean HbA1c, current treatment), thus limiting an assessment of data validity.

Source: Table constructed with data from references.[7,15,17-19,24,29,35]

Abbreviations: BGM, blood glucose monitoring; CGM, continuous glucose monitoring; FDA, Food and Drug Administration; MARD, mean absolute relative difference; T2DM, type 2 diabetes mellitus; T1DM, type 1 diabetes mellitus.

CE-marked CGM Vs FDA - iCGM

EU model is process-based (a Notified Body validates that a manufacturer followed a sound QMS and clinical-evaluation *process*, without a fixed numeric bar the device must clear).

In general, MARD < 10% and At lower reference glucose (<70mg/dL = <3.9 mmol/L), an absolute difference is used: e.g., within ±15 mg/dL. At higher glucose, a relative percentage is used: e.g., within ±15%.

Consensus Error Grid : A high-quality CGM should have almost all paired values in Zones A and B, with very few—ideally none—in Zones D or E.

FDA iCGM model is criterion-based (a device either statistically clears eleven pre-defined accuracy/safety thresholds with 95% confidence or it does not qualify as an "iCGM," regardless of QMS quality).

	EU – CE marked	FDA
Quantitative accuracy criteria — legally mandated numeric thresholds	**None are codified in the MDR itself.** Peer-reviewed sources explicitly state the EU has **"no CGM-specific product-evaluation criteria"**, leaving Notified Bodies "with only the evidence and claims submitted by manufacturers" — MARD, hypoglycemia-detection rate, and rate-of-change accuracy are *reported* but not mandated to any fixed pass/fail bar; manufacturers commonly reference **ISO 15197** (designed for self-monitoring blood glucose meters, not CGM) or the voluntary **CLSI POCT05** guideline by analogy, and the **IFCC Working Group on CGM** only published a *proposed* (non-binding) minimum-requirements framework in 2025 mirroring the FDA numbers	**Fully codified, mandatory numeric criteria** assessed as a **lower one-sided 95% confidence bound**, evaluated separately by glucose range (see next rows) — every iCGM clearance must show these figures in its FDA submission
Point-accuracy criteria (glucose < 70 mg/dL)	No binding numeric threshold. IFCC's *proposed* (voluntary) framework echoes FDA's own numbers: >85% within ±15 mg/dL and >98% within ±40 mg/dL (IFCC proposed table)	(A) >85% of readings within **±15 mg/dL** (95% LCB); (D) >98% within **±40 mg/dL** (95% LCB)
Point-accuracy criteria (70–180 mg/dL)	No binding numeric threshold	(B) >70% within **±15%** (95% LCB); (E) >99% within **±40%** (95% LCB)
Point-accuracy criteria (> 180 mg/dL)	No binding numeric threshold	(C) >80% within **±15%** (95% LCB); (F) >99% within **±40%** (95% LCB)
Overall accuracy across measuring range	No binding numeric threshold (MARD is reported descriptively in CE clinical studies, commonly cited informally as "≤10% is good practice," but this is not an EU regulatory requirement) (hormones-news.com summary)	(G) >87% of all readings within **±20%** of reference (95% LCB) — this is the closest FDA analogue to a single "overall MARD-like" bar
Hypoglycemia/hyperglycemia cross-detection (extreme discordance)	No binding numeric threshold	(H) **0%** tolerance: no reading with true glucose <70 mg/dL may show as CGM >180 mg/dL; (I) **0%** tolerance in reverse (CGM <70 mg/dL when true glucose >180 mg/dL is banned) — a hard, zero-tolerance safety backstop

	EU – CE marked	FDA
Clinical evidence pathway — literature vs. new data	allows **multiple routes**: (a) new clinical investigation, (b) literature-based clinical evaluation demonstrating **equivalence** to an already-marketed device, or (c) a mix — the manufacturer justifies why evidence is "sufficient," and the Notified Body reviews the resulting Clinical Evaluation Report	**No literature-only pathway** for a genuinely new iCGM — special controls mandate a **dedicated, prospective clinical study** generating device-specific accuracy data against an FDA-accepted reference method
Rate-of-change (trend arrow) accuracy	No binding numeric threshold; trend accuracy is reported per CLSI POCT05 methodology as a secondary/voluntary endpoint	(J) & (K): **≤1%** of readings may show a rate-of-change discordant with the true reference direction/magnitude (e.g., CGM shows rising >1 mg/dL/min while true glucose is falling faster than −2 mg/dL/min, or vice versa) — codified, hard cap
Interference, sensor life, usability, data-gap, connectivity controls	Addressed qualitatively through GSPR/state-of-the-art expectations and Notified Body discretion; no fixed acceptance thresholds published	Codified special controls requiring: demonstrated performance against a defined list of interfering substances, hardware/software lockout preventing sensor reuse beyond claimed wear life, a usability study, secure/reliable data-transmission validation, and labeling of alert true/false/missed rates — all as conditions of clearance (21 CFR §862.1355(b)(1)(vi)-(2)-(6))
Pediatric evidence	No CGM-specific pediatric requirement in the MDR; addressed generally through age-appropriate GSPR compliance and CER scope	Explicit special control: sponsor must submit pediatric accuracy/rate-of-change data comparable to adults, **or** provide an FDA-accepted justification for omitting it

FDA device type - iCGM

Manufacturer	FDA-designated iCGM model/system
Dexcom	Dexcom G6 Continuous Glucose Monitoring System
Dexcom	Dexcom G7 CGM System
Dexcom	Dexcom G7 15 Day CGM System
Abbott	FreeStyle Libre 2 plus CGM system
Abbott	FreeStyle Libre 3 CGM system
Senseonics	Eversense AP CGM System

Key sources

EU MDR 2017/745 full text — EUR-Lex

MDR Annex IX (QMS conformity assessment) — medical-device-regulation.eu

MDR Article 61 (clinical evaluation) — medical-device-regulation.eu

MDCG 2020-6 (sufficient clinical evidence) — European Commission

MDR Article 86 (PSUR) — medical-device-regulation.eu

MDR Rule 11 classification analysis — Johner Institute

EN ISO 14971 harmonization in MDR — ISO/TC 210

21 CFR §862.1355 (iCGM special controls, full text) — Cornell Law/LII

FDA De Novo classification order DEN170088 (Dexcom G6) — FDA

FDA QMSR overview/FAQ (effective Feb 2, 2026) — FDA

FDA Medical Device Single Audit Program — FDA

Pemberton et al., "CGM accuracy: Contrasting CE marking with the governmental controls of the USA (FDA) and Australia (TGA)," *Diabetes Obes Metab* 2023 — PubMed

"Diabetes community calls for quality standards for continuous glucose monitoring," *2026* — PMC

IFCC Working Group on CGM, proposed minimum requirements, *Diabetes Obes Metab* 2025 — PubMed

Mathieu et al., "Minimum expectations for market authorization of continuous glucose monitoring devices in Europe—'eCGM' compliance status" — Nottingham repository PDF

Klonoff et al., "Importance of FDA-Integrated Continuous Glucose Monitors to Ensure Accuracy," 2024 — PMC

Most Common CGM models in HK Market

Libre 2



Simplera



iCan 6



i-Sens CareSens Air



LinX





Sibonics GS3



SmartGuide



Dexcom G7



Ottai

Sensor Function

1. Which CGM has the longest sensor duration?
2. How long do we need to wait for warm-up after applying the sensor?
3. Which CGM capture most updated glucose value?
4. What is the maximum distance allowed between the CGMS sensor and the smartphone?
5. Which CGM has predictive alert?
6. What is the maximum backfill data period?
7. Which CGM is required mandatory calibration?

Most Common CGM models in HK Market

		SIBIONICS GS3	Abbott FSL 2+	Roche Accu-Chek SmartGuide	Medtronic Simplera	Dexcom G7	Sinocare iCan i6	i-Sens CareSens Air	Ottai CGM	LinX	SYAI
Practical Features	Real Time CGM	YES	Yes	YES	YES	YES	YES	YES	Yes	YES	Yes
	Certification	EU	FDA	EU	FDA	FDA	EU	Eu	EU	EU	EU
	Sensor Warm Up Time	60 mins	60 mins	60 mins	2 hours	<30 mins	120 mins	120 mins	30 min	60 min	30 min
	Sensor diameter Sensor thickness	24.8 x 17.8 mm x 2.9mm	35 mm x 5 mm	33.3 mm x 5.9 mm	28.6 x 28.6 mm x 4.77 mm	24 x 27.3 mm 4.6 mm	32mm x 5.7mm	35.2 x 19.2 mm x 5mm	24 mm x 3.5mm	22mm x 4.2mm	19.4 × 20 × 3.6 mm
	Sensor weight	1.5g	5.1g	5g	4.6g	Transmitter + sensor : 7.5g	6g	4.9g	1.6g	2.2g	1.2g
	Soft needle length	~ 5mm	~ 5mm	8.2 mm	~ 5mm	5.7mm	N/A	N/A	5mm	N/A	5mm
	Frequency of readings	5 min	1min	5min	5min	5min	3 min	5 min	5 min	1 min	1 min
	Age indication	3 years of age and older	2 years of age and older	18 years of age and older	2 years of age and older	2 years of age and older	2 years of age and older	18 years of age and older	18 years of age and older	2 years of age and older	18 years of age and older
	Approved Wearable Site	Back of Upper Arm	Back of Upper arm	Back of Upper Arm	Back of upper Arm	Buttocks (only 2-6) Abdomen Back ofUpper Arm	Upper Arm / abdomen	Abdomen	Upper arm	Upper Arm / abdomen	Upper arm
	Sensor Life	14days	15 days	14 days	7 days	10 days +12hr grace period	15 days	15 days	15 days	15 days	14 days
	Bluetooth range	10 meters	6 meters	10 meters	6 meters	10 meters	6 meters	6 meters	10 meters	2 meters	not specific
	Max Backfill Data	14 days	8 hours	8 hours	2 days	24 hours	15 days	15 days	14 days	N/A	N/A
	Water resistant	1h - 1 meter	30 min - 1meter	1h - 1meter	30 min - 2.4 meters	24h - 2.4 meters	2 hr - 2 meter	24 h - 1 meter	30 min - 2 meter	30 min - 1.5 meter	30 min - 1.5 meter
	Transmitter Life	N\A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Calibration mandatory	NO	NO	One time calibration routine before use as non-adjunctive	NO	NO	NO	12-24 hours	NO	NO	No
	Calibration optional	NO	NO	NO	NO	YES	NO	YES	No	YES	No
	High & Low Alarms	YES	YES	YES	NO	YES	YES	YES	YES	YES	Yes
	Predictive Alarms	NO	NO	Smartguide predictions 30-min, 2 hrs & 7 hrs	YES	Urgent Low Soon, Delayed First High	NO	NO	No	YES	Yes
	Ultra-Low Alarm	2.2 mmol/L	3.1 mmol/L	2.9 mmol/L	3.3 mmol/L	3.0 mmol/L	3.0 mmo/L	2.8 mmol/L	3.0 mmol/L	3.0 mmol/L	3.1 mmol/L
	Shelf Life	18 months	18 months	18 months	12 months	18 months	12 months	24 months	12 months	16 months	18 months
	MDACS	No	No	Yes	No	No	No	Yes	Yes	No	No

Support System

1. Follower Apps – support 10 -50 persons
   - Children and Elderly

2. Clinic Portal
   - Full report – AGP, daily report, other specific analysis
   - Remote Monitoring

Take Home Message

1. Understanding the concept of CGM
2. Clinical outcome of using CGM in Type 1 and Type 2 DM
3. Insulin bolus dose calculator in HA Go
4. Understanding the meaning of CE-marked and FDA iCGM
5. Characteristics of common CGM models in Hong Kong