PUSHING THE LIMITS of WHAT SENSING CAN DO for T1D and T2D

Focus on Pivotal Advantages in **Dual Monitoring—Glucose and Ketones**—for Improving Glycemic Metrics and Reducing the Risk of DKA

*Leveraging **Dual Analyte Sensing** to Optimize Therapeutic Interventions*

American Diabetes Association. | 2026 SCIENTIFIC SESSIONS NEW ORLEANS, LA | JUNE 5–8

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The Current State of Preventing DKA: Prevalence, Shortcomings, and New Opportunities

Richard M. Bergenstal, MD
International Diabetes Center
HealthPartners Institute
Minneapolis, MN

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Disclosures: Richard M. Bergenstal, MD

- **I have no personal financial disclosures**
- My employer, the non-profit HealthPartners Institute, contracts for my services, and I receive no personal income from the following activities:
  - I have participated in clinical research, been a member of a scientific advisory board, and served as a consultant for:
    - Abbott Diabetes Care, Ascensia, Bigfoot Biomedical, Inc., CeQur, Dexcom, Eli Lilly, Embecta, Hygieia, Insulet, Mannkind, Medtronic, Medscape, NCQA, Novo Nordisk, Onduo, Roche Diabetes Care, Sanofi, Tandem, United Healthcare, Vertex Pharmaceuticals and Zealand Pharma
    - HealthPartners Institute holds a patent for display screen with graphical user interface
    - HealthPartners Institute receives NIH/NIDDK, PCORI & Helmsley Charitable Trust funding

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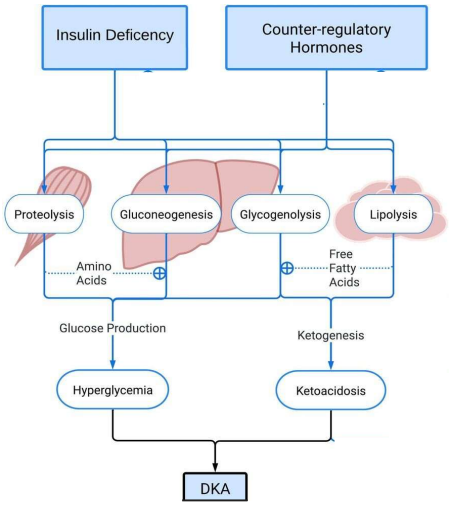
New DKA Diagnostic Criteria

D	**Diabetes/hyperglycaemia**	Glucose ≥200 mg/dl (11.1 mmol/l) **or** prior history of diabetes
K	**K**etosis	β-hydroxybutyrate ≥3.0 mmol/l or urine ketone strip 2+ or greater
A	Metabolic **A**cidosis	pH <7.3 and/or bicarbonate concentration <18 mmol/l

Umpierrez GE et al Diabetes Care 2024;47(8):1257-1275
Umpierrez GE et al Diabeteologia 2024;67(8):1455-1479

4

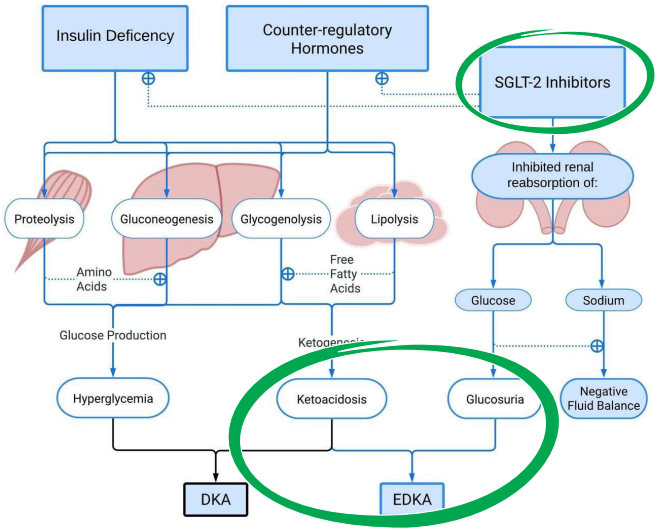
DKA Pathophysiology



Chow E, et al. BMJ Open Diabetes Res Care. 2023;11:e003666.

5

DKA Pathophysiology Euglycemic DKA DKA Treatment



INSULIN

FLUIDS (K+)

CARBOHYDRATE

Rx PRECIPITATING CAUSE…

- **Stop SGLT2**
- **Rx Infection**
- **EtOH Excess**
- **Substance Abuse**
- **Stroke, CVD**
- **Trauma**
- **Missed Insulin (injection *or* infusion set)**

Chow E, et al. BMJ Open Diabetes Res Care. 2023;11:e003666.

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DKA is A Major Health Problem – For All Types Of Diabetes

Common

- Most common **acute event leading to hospital admission** in persons living with diabetes[1]
- US: **4-8% Annual Incidence Rate** DKA in T1D

Costly

- In the US **$21,000-$36,000/per admission**[2]
- Recurrent DKA is common

Dangerous

- DKA is a **leading cause of death** among children and adults < 58 yrs with diabetes[3]

All Types of DM

- **Hospitalization for DKA 1 in 5 cases – T2D**
- **Higher mortality for T2D (0.85%) with DKA than T1D (0.2%)**

DKA, diabetic ketoacidosis.
1. Riveline JP, et al. Diabetes Technol Ther. 2022;24:611-618; 2. Umpierrez GE, et al. Diabetologia. 2024;67:1455-1479; 3. Nguyen KT, et al. J Diabetes Sci Technol. 2022;16:689-715; 4. Shand JAD, et al. Acta Diabetol. 2022;59:1485-1492.

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DIABETES TECHNOLOGY & THERAPEUTICS
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DOI: 10.1177/15209156251387160

Nov 2025

DTT

BRIEF REPORT

Automated Insulin Delivery Is Associated with Reduced Hospital Admissions and Costs for Acute Diabetes Complications in Children with Type 1 Diabetes

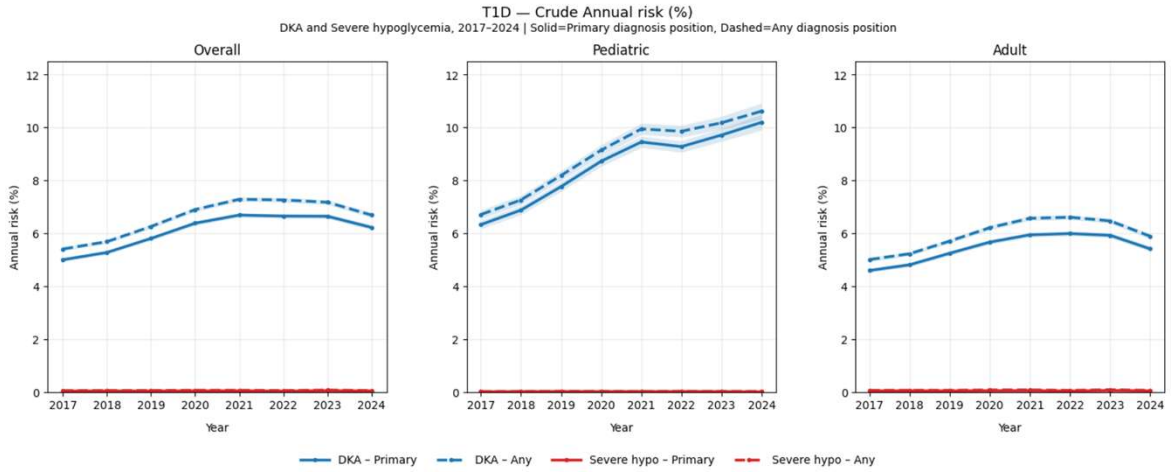
Mercedes J. Burnside,[1,2,*] Katrina Ellis,[2] Timothy W. Jones,[1,2] Ella Zomer,[3] Sophia Zoungas,[3] Mary B. Abraham,[1,2,4] Grant Smith,[1] Kathleen Irwine,[2] Elizabeth A. Davis,[1,2,5] and Craig E. Taplin[1,2,4]

TABLE 1. ACUTE DIABETES COMPLICATION ADMISSION RATES, COSTS, AND ADJUSTED HOSPITALIZATION RATE RATIOS BY INSULIN REGIMEN

Regimen	*Hypo admissions*	*DKA admissions*	*Patient-years*	*Hypo rate (/100 py)*	*DKA rate (/100 py)*	*Total admission rate (/100 py)*	*Cost (/100 py)*	*Adjusted rate[a] (95% CI)*	*P-value[b]*
AID	2	10	606.48	0.33	1.65	1.98	$20,132	1.00 (ref)	—
Pump	11	21	957.40	1.15	2.19	3.34	$34,008	1.62 (0.84–3.14)	0.150
MDI	19	46	1110.13	1.71	4.14	5.86	$59,574	2.74 (1.39–5.42)	0.0036

8

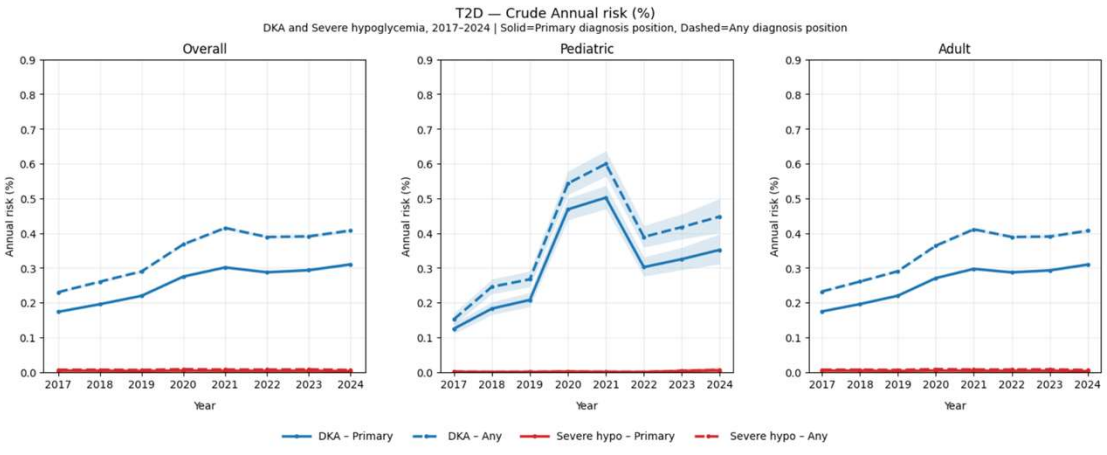
Trends in the Prevalence of Diabetic Ketoacidosis and Severe Hypoglycemia in Type 1 Diabetes



Sherr J, Wysham C, et al. ADA 2026

9

Annual Prevalence of Diabetic Ketoacidosis and Severe Hypoglycemia in Type 2 Diabetes



Sherr J, Wysham C, et al. ADA 2026

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Clinical Characteristics and Economic Burden of Diabetic Ketoacidosis in People with Type 1 Diabetes in the U.S

- In this study, the authors assessed the clinical characteristics and costs of DKA hospitalizations in people with type 1 diabetes (T1D).
- Authors searched the 2022 National Inpatient Sample database for people with T1D (E10.xx any position) and DKA hospitalizations using ICD-10 codes.
- Authors reported incidence, length of stay (LOS) using mean and standard deviation (SD), mortality using frequency (%), and hospitalization costs.

Results: Among 382,460 hospitalizations in patients with T1D:
- 34.1% had DKA as the principal diagnosis, corresponding to 341.1 per 1,000 T1D hospitalizations
- Average LOS was 3.1 (4.7) days
- Inpatient mortality was 0.3% (n: 385)
- Mean cost per hospitalization was $10,140 ($12,350)

Conclusion
This analysis provides recent national estimates of the incidence, LOS, mortality and cost of hospitalizations for DKA in people with T1D. One-third of hospitalizations in people with T1D in the U.S. were for DKA in 2022, with a total cost exceeding $1.24 billion, highlighting a significant burden to patients and the health system.

Galindo RJ, et al. ADA 2026

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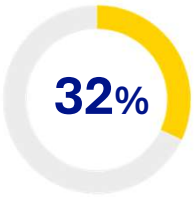
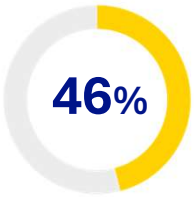
DKA Unawareness

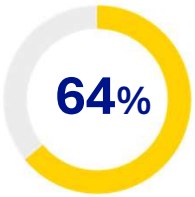
Multinational, multicenter survey of endocrine outpatient clinic patients with average duration of T1D of 22 years (N=333)



Were not familiar with the term DKA



Were unable to name a single symptom of DKA



Did not test for ketones at all

Hepprich M et al BMJ Open DRC 2023;11(6):e003662

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Real-World Ketone Testing Patterns Among People Using FreeStyle Libre

DIABETES TECHNOLOGY & THERAPEUTICS

May 2026

STUDY OVERVIEW

- Data on blood ketone readings performed with the FSL reader from 89 countries from **2014 – 2024**
- **135,000 patients** using **readers** with ketone data analyzed both CGM data and when ketone tests were done

CGM **Ketone Meter**

KEY FINDINGS

92.5%
Most patients did not test ketones: 92.5% of readers had **no ketone testing performed**

Delayed Testing
Delayed ketone testing (5 – 8 hours) after glucose >250 mg/dL

Rare
Ketones rarely rechecked within 24–72 hours even with elevated ketones

12.5%
Elevated ketones even at lower glucose: 12.5% had ketones ≥0.6mmol/L, while glucose <250 mg/dL

DTT Bergenstal, R et al.

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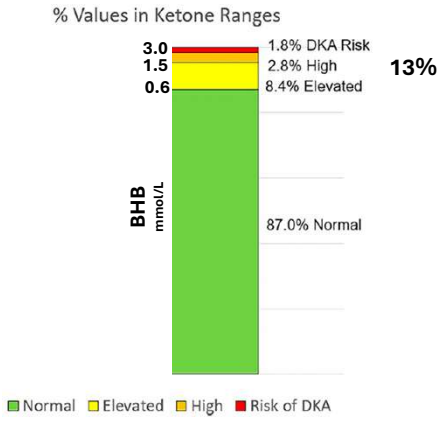
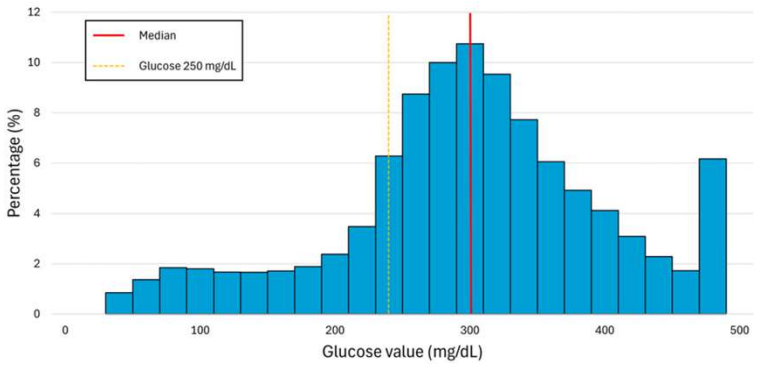
Real-World Ketone Testing Patterns Among People Using FreeStyle Libre





311 mg/dL median glucose within 20 minutes prior to a ketone test

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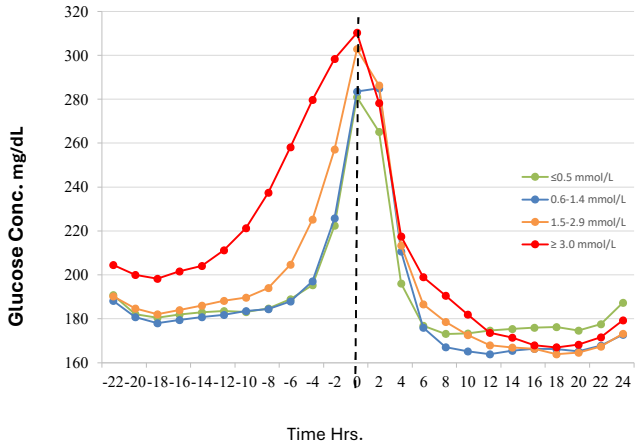
Real-World Ketone Testing Patterns Among People Using FreeStyle Libre

Number of Hours Prior to A Ketone Test Patients Had A Glucose Concentration Consistently >250 MG/DL

Ketone Level	Median Hours
• ≤ 0.5 mmol/L	2.0 [1.0, 4.0]
• 0.6–1.4 mmol/L	2.8 [1.5, 5.5]
• 1.5–2.9 mmol/L	5.0 [2.5, 7.8]
• ≥3.0 mmol/L	7.8 [4.5, 11.3]



DTT Bergenstal, R et al.

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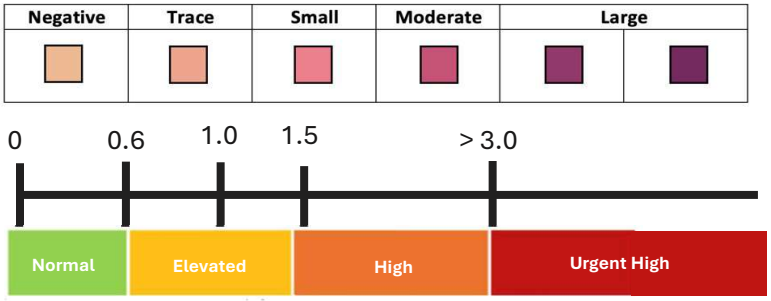
Current Methods to Measure Ketones

Acetoacetate measured via urine is semiquantitative



BHB via POC capillary test is quantitative

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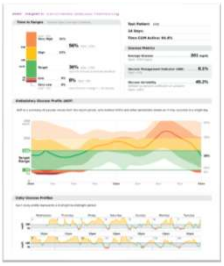
Do We Need to Monitor Both Glucose (CGM) and Ketones?

Continuous Glucose Monitoring

AGP Report



Ketone mmol/L

Images courtesy of Richard M. Bergenstal, MD.

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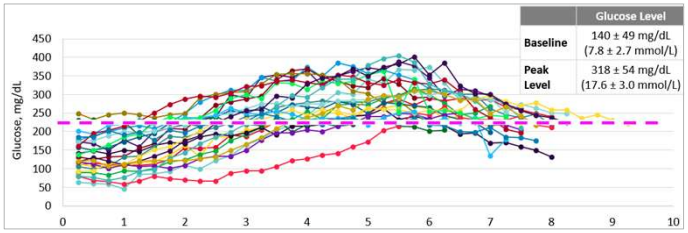
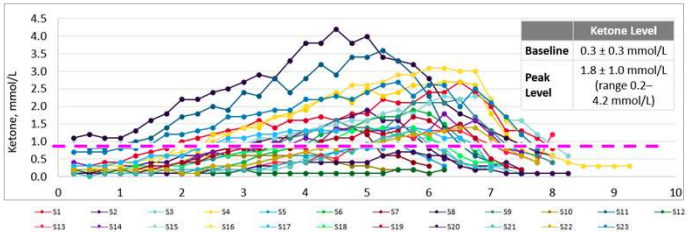
Glucose and Ketone Variability

Glucose Profiles During Pump Suspension



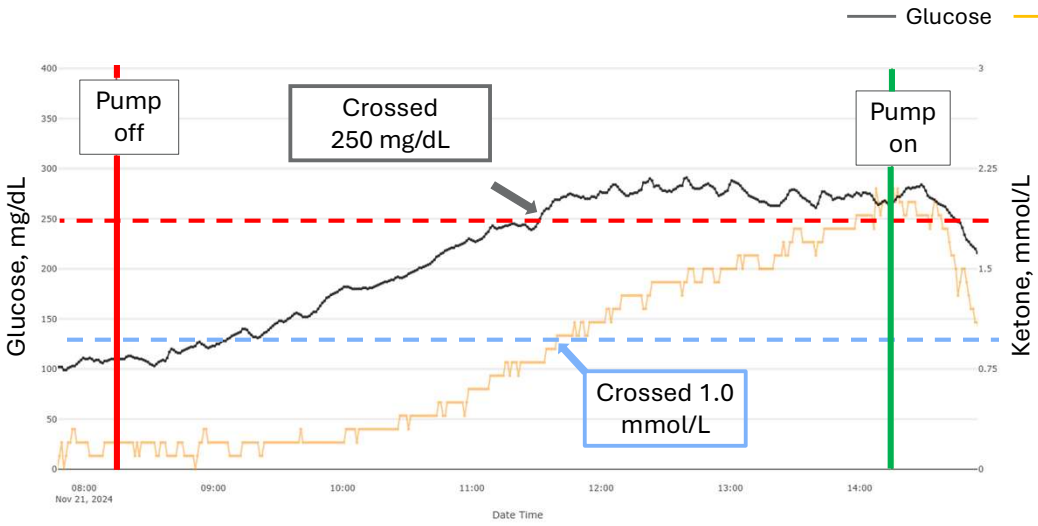
Ketone Profiles During Pump Suspension



Data on file. Abbott Diabetes Care

18

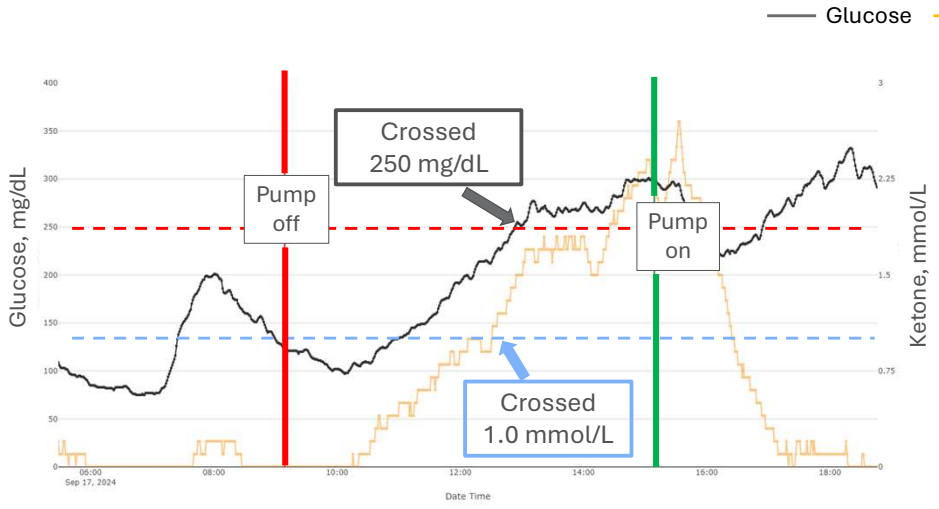
16-Year-Old Boy's Insulin Interruption Profile



Investigational technology.
Sherr JL. 51st Annual Conference of the International Society for Pediatric and Adolescent Diabetes. Highlights HL-01.

19

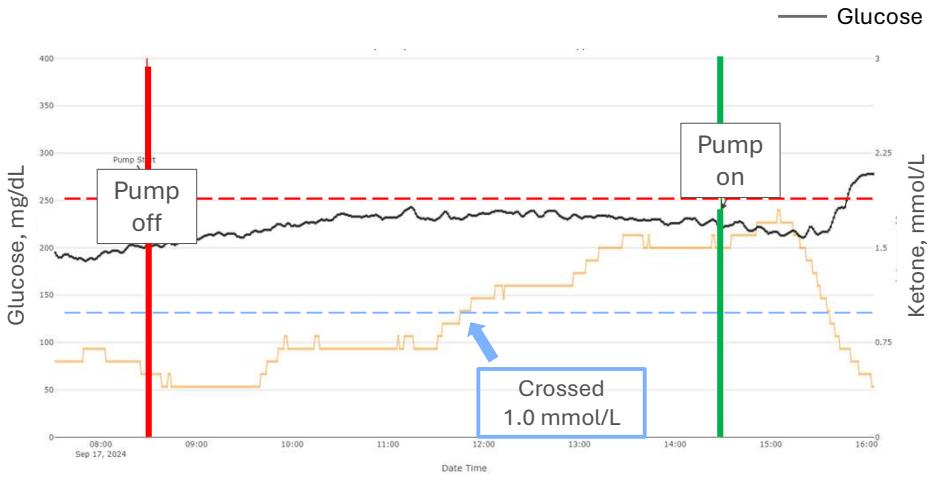
52-Year-Old Woman's Insulin Interruption Profile



Investigational technology.
Sherr JL. 51st Annual Conference of the International Society for Pediatric and Adolescent Diabetes. Highlights HL-01.

20

72-Year-Old Man's Insulin Interruption Profile



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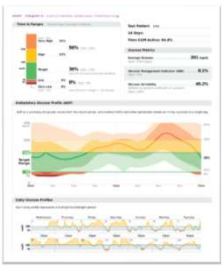
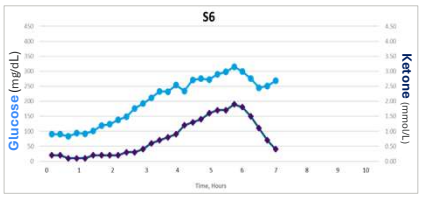
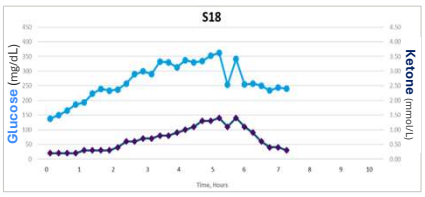


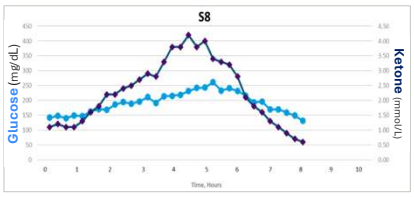
Glucose and Ketones Rise Together at Similar Rate



Glucose Rises Faster Than Ketones



Ketones Rises Faster Than Glucose



Glucose Ketone

Images courtesy of Richard M. Bergenstal, MD.

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CE Mark Approval for Dual Sensing Technology

Abbott secures CE Mark for world's first dual glucose-ketone sensing technology for people with diabetes

PR Newswire
Wed, May 27, 2026 at 9:00 AM EDT • 7 min read

- First-of-its-kind biowearables combine continuous glucose and ketone monitoring in a **single sensor** to support both daily diabetes management and help detect rising ketone levels.
- **Integrates** with the Libre digital health ecosystem, allowing people to share glucose and ketone data with caregivers and healthcare providers
- Designed for **compatibility** with leading automated insulin delivery (AID) systems

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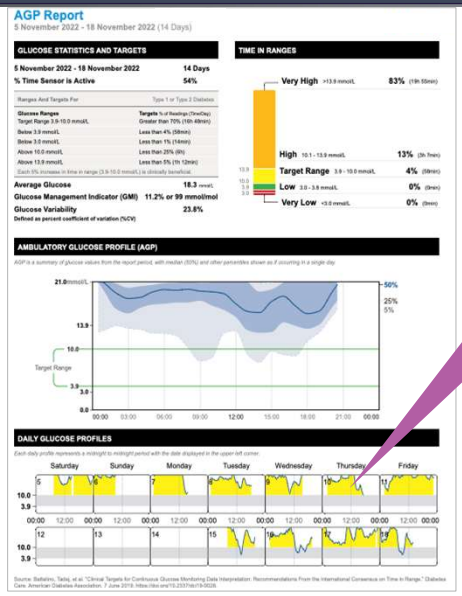
DKA: It Won't Happen to Me!

Patient with T1D on MDI therapy



Which of these "HYPERs" will lead to DKA?

Images courtesy of Richard M. Bergenstal, MD.

MDI, multiple daily injections.

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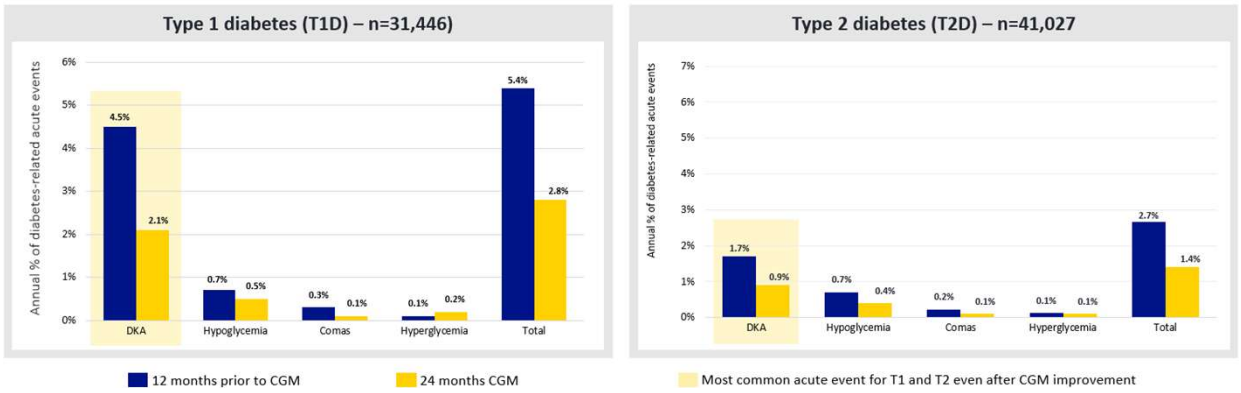
CGM Use Reduces DKA by 50% But It is Still the Most Common Acute Event

RELIEF Study



Riveline et al, *Diabetes Technol Ther.* (2022):
doi.org/10.1089/dia.2022.0085

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Subgroups of People With Diabetes at Heightened Risk of DKA

- **Recurrent DKA**
- SGLT2 inhibitor treatment
- Pregnant women with pregestational diabetes or gestational diabetes
- Insulin pump users, including AID users
- Low carbohydrate or ketogenic diet
- Older and frail individuals
- Young adults with T1D
- Rural populations
- Comorbid mental health disorders
- CKD
- History of CVD or advances neuropathy associated with foot ulcers or amputation

Recurrent DKA

Responsible for > 20% of all DKA hospitalizations

High use of healthcare resources

The list order indicates potential priorities for application once CKM technology is approved for use as a medical device.
Dhatariya K, Bergenstal R, et al. Lancet Diabetes Endocrinol. 2026;14:82-92.

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Subgroups of People With Diabetes at Heightened Risk of DKA

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The list order indicates potential priorities for application once CKM technology is approved for use as a medical device.
Dhatariya K, Bergenstal R, et al. Lancet Diabetes Endocrinol. 2026;14:82-92.

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Summary: Current Impact of DKA and Steps to Prevent DKA

- DKA is common, costly, and dangerous
- People with diabetes do not understand DKA … *very well*
- People with diabetes do not test ketones … *anywhere close to Standards of Care*
- Testing glucose *(even CGM)* is not a reliable approach to prevent DKA
- T1D at highest risk for DKA but DKA also seen in T2D and pregnancy and DM
- Special attention: Hx of DKA, SGLT2i use, AID use, very low-carb, medically underserved

❖ I look forward to my colleagues' suggestions to improve **DKA prevention going forward**

Thank You

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Beyond CGM: Dual Sensing Technology as the Cornerstone of Adult DKA Prevention

Carol H. Wysham, MD
Clinical Professor of Medicine
University of Washington
Spokane, Washington

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Disclosures

Abbott Diabetes	consultant, speaker's bureau
AbbVie	research funding*
Bayer	research funding*
Eli Lilly	research funding*, consultant, speaker's bureau*
Novo Nordisk	research funding, consultant, speaker's bureau

**relationship has ended*

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Burden of Diabetic Ketoacidosis

TYPE 1 DIABETES

1 – 13% annual prevalence of DKA in adults with T1D* (likely underestimated due to care outside of the hospital)

Most common reason for admission for acute diabetes event

Leading cause of death in adults with T1D below the age of 58

TYPE 2 DIABETES

1 in 5 hospitalizations for DKA are attributed to people with T2D*

Higher mortality for T2D with DKA (0.85%) compared to those with T1D (0.2%)

Having an episode of DKA is associated with **increased long-term risk** for:

- MACE
- Advance kidney disease
- Reduced cognitive function
- Recurrent DKA

Umpierrez GE, et al. *Diabetes Care*. 2024; Nguyen KT, et al. *JDST*. 2022; Zhong VW, et al. *Diabetes Care*. 2018; Canales SP, et al. *Endocrine Pract*. 2024; Budhram DR et al. Can *J Diabetes* 2024;48:462

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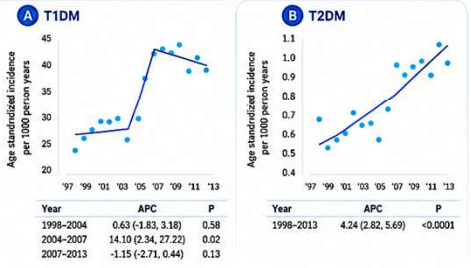
Increase in Proportion of People With T2D Hospitalized for DKA[1,2]

1998 to 2013[1]

Studies of hospital admission for DKA in T1D and T2D in England

1 in 5 admissions for DKA attributed to T2D[1]



Year	APC	P
1998–2004	0.63 (-1.83, 3.18)	0.58
2004–2007	14.10 (2.34, 27.22)	0.02
2007–2013	-1.15 (-2.71, 0.44)	0.13

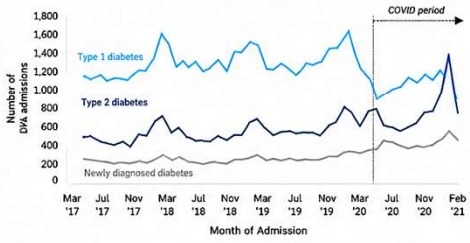
Year	APC	P
1998–2013	4.24 (2.82, 5.69)	<0.0001

Trends in hospital admission for DKA in adults with T1DM *(A)* or T2DM *(B)*

2017 to 2021[2]

Studies of hospital admission for DKA in T1D and T2D in England

1 in 4 admissions for DKA attributed to T2D[2]* *(pre-COVID period)*



Number of emergency hospital admissions in England coded with DKA by type of diabetes from March 2017 to February 2021

DKA=diabetic ketoacidosis; T1D=type 1 diabetes; T2D=type 2 diabetes.

DKA remains a leading acute diabetes event, especially in T2D.

Continued efforts are needed to reduce and prevent DKA across all diabetes types.

*Calculated based on overall mean in equivalent time periods in 2017-20 as shown in Table of emergency hospital admissions coded with DKA.

1. Zhong, VW, *Diabetes Care* (2018): https://doi.org/10.2337/dc17-1583. 2. Misra, S, *Lancet Diabetes Endocrinol* (2021): https://doi.org/10.1016/s2213-8587(21)00208-4.

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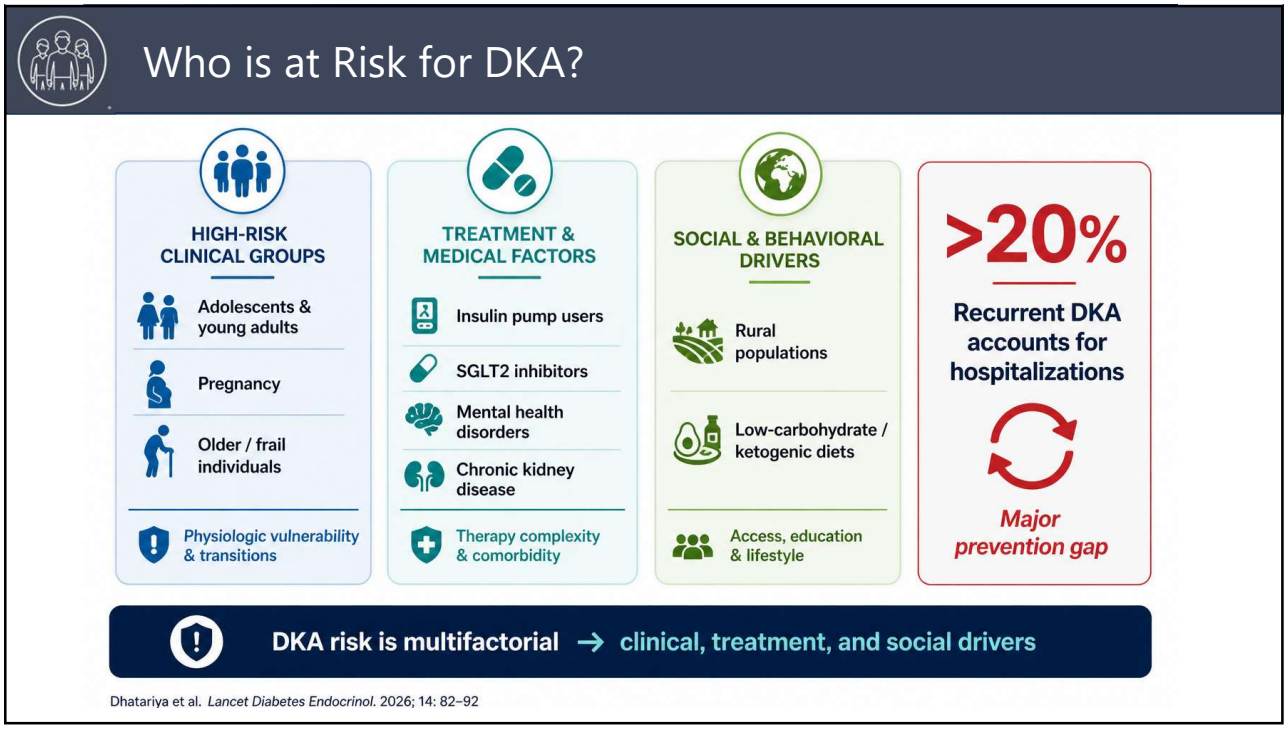
Who is at Risk for DKA?
HIGH-RISK CLINICAL GROUPS
Adolescents & young adults
Pregnancy
Older / frail individuals
Physiologic vulnerability & transitions
TREATMENT & MEDICAL FACTORS
Insulin pump users
SGLT2 inhibitors
Mental health disorders
Chronic kidney disease
Therapy complexity & comorbidity
SOCIAL & BEHAVIORAL DRIVERS
Rural populations
Low-carbohydrate / ketogenic diets
Access, education & lifestyle
>20%
Recurrent DKA accounts for hospitalizations
Major prevention gap
DKA risk is multifactorial → clinical, treatment, and social drivers
Dhatariya et al. Lancet Diabetes Endocrinol. 2026; 14: 82–92

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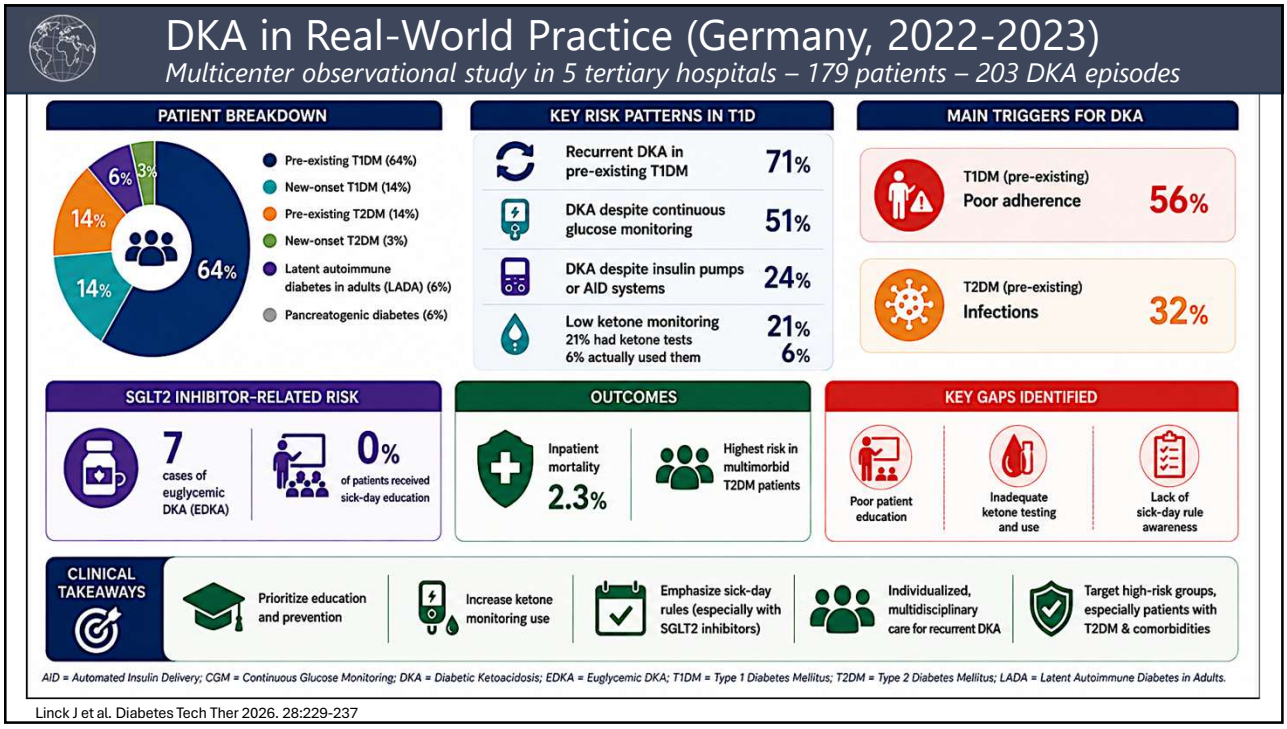
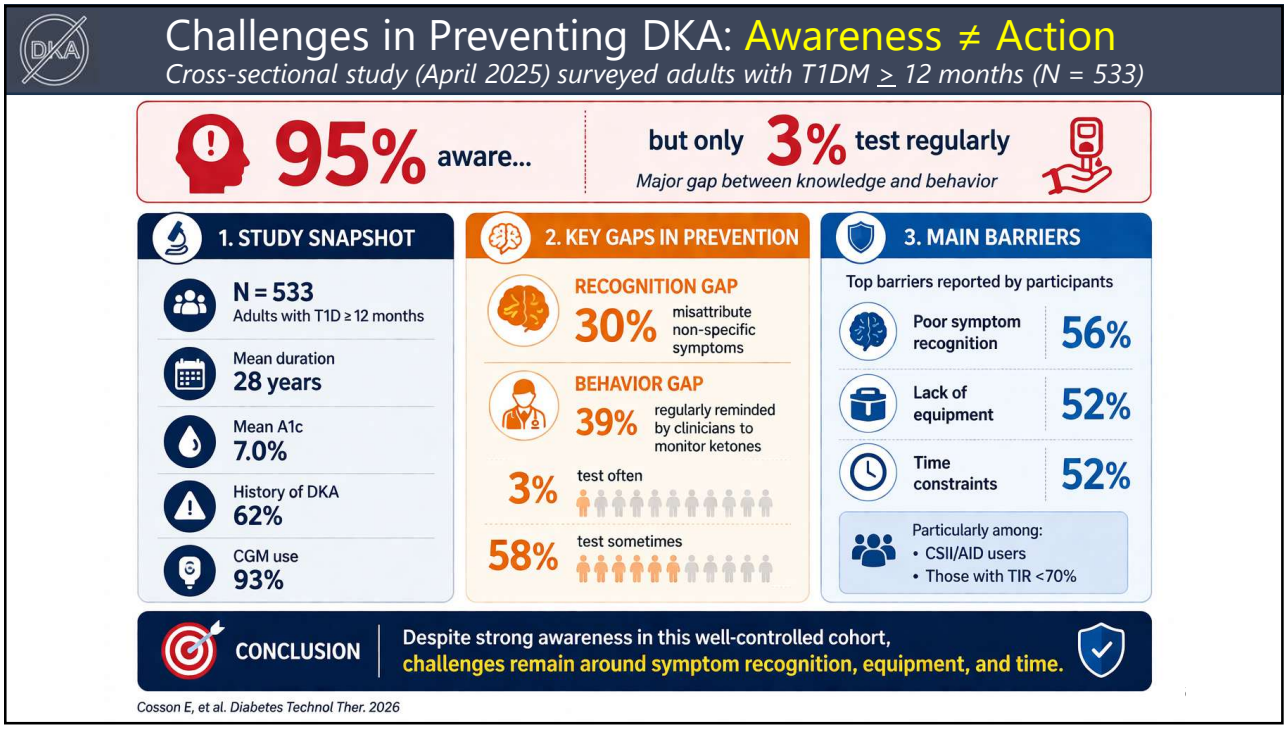

DKA in Real-World Practice (Germany, 2022-2023)
Multicenter observational study in 5 tertiary hospitals – 179 patients – 203 DKA episodes
PATIENT BREAKDOWN
64%
14%
14%
6%
3%
Pre-existing T1DM (64%)
New-onset T1DM (14%)
Pre-existing T2DM (14%)
New-onset T2DM (3%)
Latent autoimmune diabetes in adults (LADA) (6%)
Pancreatogenic diabetes (6%)
KEY RISK PATTERNS IN T1D
Recurrent DKA in pre-existing T1DM 71%
DKA despite continuous glucose monitoring 51%
DKA despite insulin pumps or AID systems 24%
Low ketone monitoring 21% had ketone tests 6% actually used them 21% 6%
MAIN TRIGGERS FOR DKA
T1DM (pre-existing) Poor adherence 56%
T2DM (pre-existing) Infections 32%
SGLT2 INHIBITOR-RELATED RISK
7 cases of euglycemic DKA (EDKA)
0% of patients received sick-day education
OUTCOMES
Inpatient mortality 2.3%
Highest risk in multimorbid T2DM patients
KEY GAPS IDENTIFIED
Poor patient education
Inadequate ketone testing and use
Lack of sick-day rule awareness
CLINICAL TAKEAWAYS
Prioritize education and prevention
Increase ketone monitoring use
Emphasize sick-day rules (especially with SGLT2 inhibitors)
Individualized, multidisciplinary care for recurrent DKA
Target high-risk groups, especially patients with T2DM & comorbidities
AID = Automated Insulin Delivery; CGM = Continuous Glucose Monitoring; DKA = Diabetic Ketoacidosis; EDKA = Euglycemic DKA; T1DM = Type 1 Diabetes Mellitus; T2DM = Type 2 Diabetes Mellitus; LADA = Latent Autoimmune Diabetes in Adults.
Linck J et al. Diabetes Tech Ther 2026. 28:229-237

34


Challenges in Preventing DKA: Awareness ≠ Action
Cross-sectional study (April 2025) surveyed adults with T1DM ≥ 12 months (N = 533)
95% aware...
but only 3% test regularly
Major gap between knowledge and behavior
1. STUDY SNAPSHOT
N = 533
Adults with T1D ≥ 12 months
Mean duration
28 years
Mean A1c
7.0%
History of DKA
62%
CGM use
93%
2. KEY GAPS IN PREVENTION
RECOGNITION GAP
30% misattribute non-specific symptoms
BEHAVIOR GAP
39% regularly reminded by clinicians to monitor ketones
3% test often
58% test sometimes
3. MAIN BARRIERS
Top barriers reported by participants
Poor symptom recognition 56%
Lack of equipment 52%
Time constraints 52%
Particularly among:
• CSII/AID users
• Those with TIR <70%
CONCLUSION
Despite strong awareness in this well-controlled cohort, challenges remain around symptom recognition, equipment, and time.
Cosson E, et al. Diabetes Technol Ther. 2026

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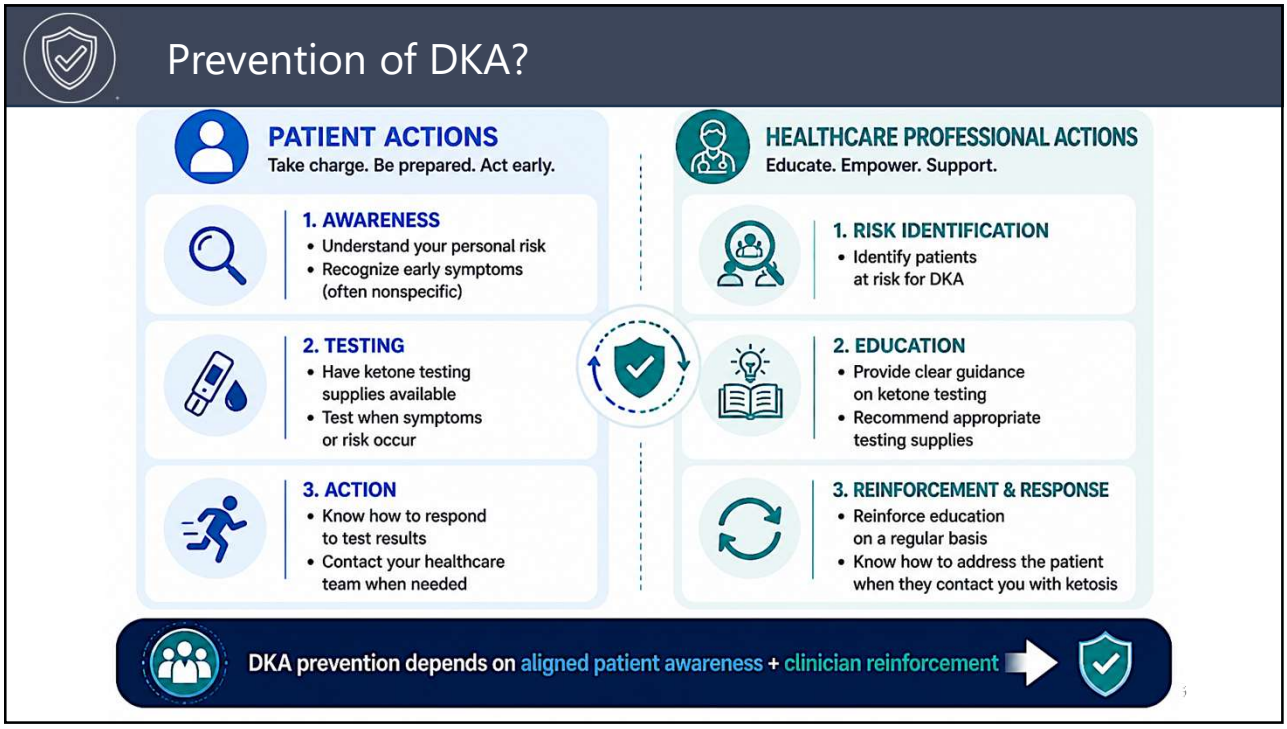
Prevention of DKA?
PATIENT ACTIONS
Take charge. Be prepared. Act early.
1. AWARENESS
• Understand your personal risk
• Recognize early symptoms (often nonspecific)
2. TESTING
• Have ketone testing supplies available
• Test when symptoms or risk occur
3. ACTION
• Know how to respond to test results
• Contact your healthcare team when needed
HEALTHCARE PROFESSIONAL ACTIONS
Educate. Empower. Support.
1. RISK IDENTIFICATION
• Identify patients at risk for DKA
2. EDUCATION
• Provide clear guidance on ketone testing
• Recommend appropriate testing supplies
3. REINFORCEMENT & RESPONSE
• Reinforce education on a regular basis
• Know how to address the patient when they contact you with ketosis
DKA prevention depends on aligned patient awareness + clinician reinforcement

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People with diabetes, especially those on intensive insulin therapy*, should be aware of the most common precipitating factors for DKA[1]

These factors can be unpredictable and hard to avoid[1]:

Missed/Underdosed insulin[2]

- Presentation of new-onset diabetes
- Mental health disorders (e.g., diabetes distress)[1]
- Insulin pump system failure, blocked infusion set, leakage in syringe[1,3]

Acute illness or injuries[2]

- Infections
- Trauma
- Surgery
- Major events (e.g., MI, pulmonary embolism, pancreatitis)[1]

Medications[2]

- Corticosteroids
- High-dose thiazides
- Sympathomimetic agents
- Atypical antipsychotics
- Checkpoint inhibitors[1]
- SGLT2 inhibitors (euglycemic DKA)

Drug or alcohol misuse[2,4]

- Cocaine
- Cannabis (association)[4]

DKA=diabetic ketoacidosis; MI=myocardial infarction; SGLT2=sodium-glucose co-transporter-2.
*Intensive insulin therapy includes multiple daily injections and continuous insulin infusions[2].

References: 1. Umpierrez, G. E. *Diabetes Care* (2024). https://doi.org/10.2337/dci24-0032. 2. Lizzo, J. M. *StatPearls* (2024). https://www.ncbi.nlm.nih.gov/books/NBK560723/. 3. Heinemann, L. *Diabetes Care* (2015). https://doi.org/10.2337/dc15-0168. 4. Kinney, G. L. *Diabetes Care* (2020). https://doi.org/10.2337/dc19-0365. 5. Hirsch, I. B. *Diabetes Care* (1990). https://doi.org/10.2337/diacare.13.12.1265.

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Suggestions for Application of Chronic Ketone Monitoring

Personal View

Continuous ketone monitoring for people with diabetes: international expert recommendations on the application of a new technology

Ketan Dhatariya, Richard M Bergenstal*, Mohammed Al-Sofiani, Anastasia Albanese-O'Neill, Tadej Battelino, Kelly Close, Christophe De Block, Sanjoy Dutta, Rodolfo J Galindo, Amin Ghaneḿjad, Ahmad Haidar, Julie Heverly, Davida Kruger, Lori M Laffel, Julianne Lally, David M Maahs, Claudio Maffeis, Chantal Mathieu, Eden Miller, Medha Munshi, Rimei Nishimura, Kirsten Nørgaard, Tal Oron, David N O'Neal, Monica Oxenreiter, Bruce A Perkins, Moshe Phillip, Eric Renard, Jonathan Rosen, Mauro Scharf, Jennifer Sherr, Carol Wysham, Thomas Danne*

Dhatariya K et al *Lancet Diab Endocrinol* 2026;14(1);82-92

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Suggested Thresholds

Ketone (BHB) Ranges		Watch for symptoms*	Action to be taken by person with diabetes†
≥ 3.0 mmol/L	URGENT HIGH KETONES	Deep breathing, Dry lips, Fruity breath, Confusion or difficulty paying attention, Nausea, Vomiting, Abdominal pain, Excess thirst, Frequent urination	**Seek immediate medical attention** at a hospital or emergency care facility • Monitor glucose levels frequently • Check insulin pump is working as expected or confirm insulin injections have not been missed • Take fluids, carbohydrates and insulin as recommended by your HCP
1.5 – 3.0 mmol/L	HIGH KETONES	Difficulty breathing, Fruity breath, Confusion or difficulty paying attention, Nausea, Vomiting, Abdominal pain, Fatigue	**Follow your HCPs guidance (including changes in medication) and:** • Monitor glucose levels frequently • Check insulin pump is working as expected or confirm insulin injections have not been missed • Take fluids, carbohydrates and insulin as recommended by HCP • Contact your HCP
0.6 – 1.5 mmol/L	ELEVATED KETONES	Nausea, Vomiting, Abdominal pain, Fatigue	**Follow your HCPs guidance (including changes in medication) and:** • Monitor glucose levels frequently • Check insulin pump is working as expected or confirm insulin injections have not been missed • Take fluids, carbohydrates and insulin as recommended by HCP
0.0 – 0.6 mmol/L	NORMAL KETONES	No symptoms expected	No action necessary

* Symptoms may vary between individuals.
† Always follow the advice of your healthcare professional (HCP).

Dhatariya K et al. Lancet Diab Endocrinol 2026;14(1):82-92

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Suggested Graphics

Orientation	Interpretation
Rising (↗)	Ketones are **rising faster** than 0.4 mmol/L/h
Stable (→)	Ketones are **changing slowly**, less than or equal to **0.4 mmol/L/h**
Falling (↘)	Ketones are **falling faster** than 0.4 mmol/L/h

Dhatariya K et al. *Lancet Diab Endocrinol* 2026;14(1):82-92

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Suggested Actions

STOP DKA considerations for bolus insulin and CHO

Continuous ketone concentration (mmol/L)	Blood glucose meter / CGM value (check every hour)*		
	4.0–8.0 mmol/L (70–150 mg/dL)	8.1–14.0 mmol/L (151–250 mg/dL)	>14 mmol/L (>250 mg/dL)
<0.6 Normal	• No extra insulin • Usual bolus to cover CHO + usual correction		• 5–10% TDD supplemental insulin or usual correction bolus • Usual bolus to cover CHO
0.6–1.5 Elevated Ketonemia *Consider rate of change arrow*	• 5% TDD supplemental insulin + usual bolus to cover CHO • 30 – 45 g CHO every 2–4 hours	• 10% TDD supplemental insulin or 1.5x correction bolus • Usual bolus to cover CHO • 30 g CHO every 2–4 hours	• 10% TDD supplemental insulin or 1.5x correction bolus • Usual bolus to cover CHO every 2–4 hours
1.6–2.9 High Impending DKA *Consider rate of change arrow*	• 10% TDD supplemental insulin + usual bolus to cover CHO • 30 – 45 g CHO every 2–4 hours	• 20% TDD supplemental insulin or 2x correction bolus • Usual bolus to cover CHO • 30 – 45 g CHO every 2–4 hours	• 20% TDD supplemental insulin or 2x correction bolus • Usual bolus to cover CHO every 2–4 hours
≥3.0 Urgent High Probable DKA	• 10% TDD supplemental insulin + usual bolus to cover CHO • 30 – 45 g CHO every 2–4 hours	• 20% TDD supplemental insulin or 2x correction bolus • Usual bolus to cover CHO • 30 – 45 g CHO every 2–4 hours	• 20% TDD supplemental insulin or 2x correction bolus • Usual bolus to cover CHO every 2–4 hours

DKA is likely if ketones remain ≥3 mmol/L (Continuous Ketone System Alarm) despite supplemental insulin

* Check every hour while adjusting insulin and carbohydrate intake.

Dhatariya K et al Lancet Diab Endocrinol 2026;14(1):82-92

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A Vision for an Integrated Continuous Glucose and Ketone Monitoring System

Images are for illustration only

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CE Mark Approval for Libre Duo

World First: Abbott Launches Dual-Sensor Technology to Combat Rising DKA Rates

The Libre Duo system offers real-time ketone monitoring to prevent diabetic emergencies as diabetic ketoacidosis (DKA) rates rise.

- ✓ Libre Duo systems continuously monitor both glucose and ketone levels to **reduce the reliance on tests that capture a single moment in time.**
- ✓ Libre Duo offers up to **15 days** of wear for adults ages 18 and older under CE Mark.

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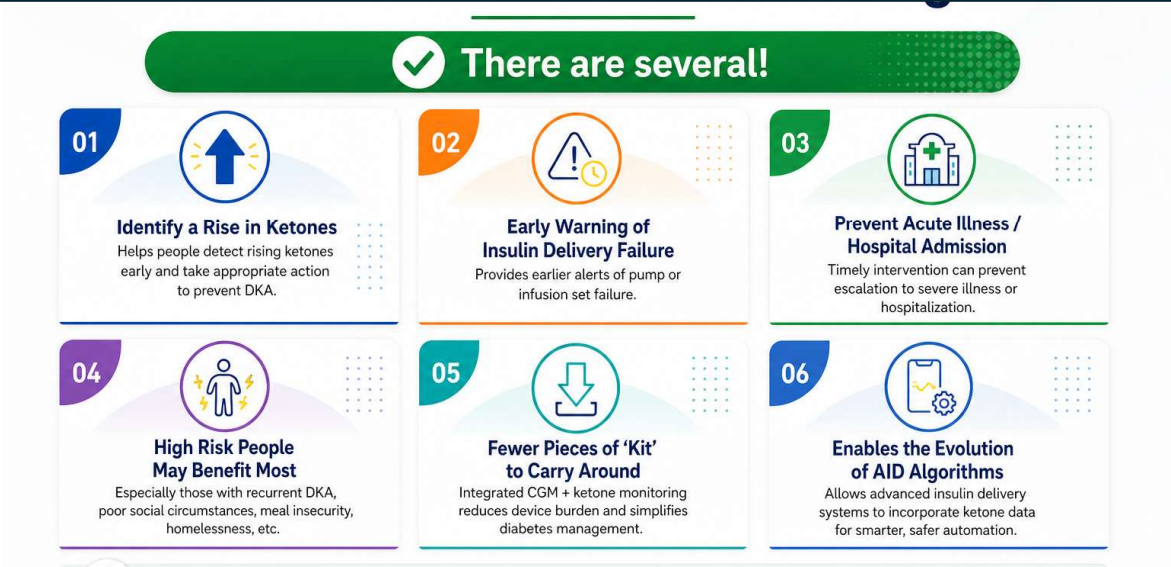
Potential Benefits of Continuous Ketone Monitoring



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Challenges and Unknowns

THERE ARE SEVERAL!

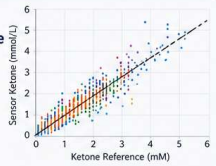
1. **Education of people with diabetes –** what do the numbers mean?
2. **Education of health care professionals –** what do the numbers mean?
3. **When does physiological become pathological?**
4. **Are there significant differences between** blood / capillary and interstitial fluid?
5. **T1DM vs T2DM**
6. **How to manage euglycemic ketonemia/DKA**
7. **Reimbursement?**

Addressing these challenges is essential to unlock **the full potential of continuous ketone monitoring** and improve clinical outcomes.

Ketone Testing
Understanding what the numbers mean

Point-of-Care Monitoring
Timely insights for early intervention

Data & Evidence
Correlations and clinical implications



Alva et al. Journal of Diabetes Sci Technol 2021;15(4):768-774

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Continuous Ketone Monitoring Detects Overt Euglycemic Ketosis in Type 1 Diabetes with SGLT2i Use, Low-Carbohydrate Diet, and Exercise

CASE REPORT

Patient 30-year-old woman with type 1 diabetes

Therapy Automated insulin delivery

SGLT2i Use Empagliflozin 10 mg daily

Low-Carbohydrate Diet <50 g/day

Increased Physical Activity

Monitoring Continuous Ketone Monitoring (CKM) with wearable ketone sensor

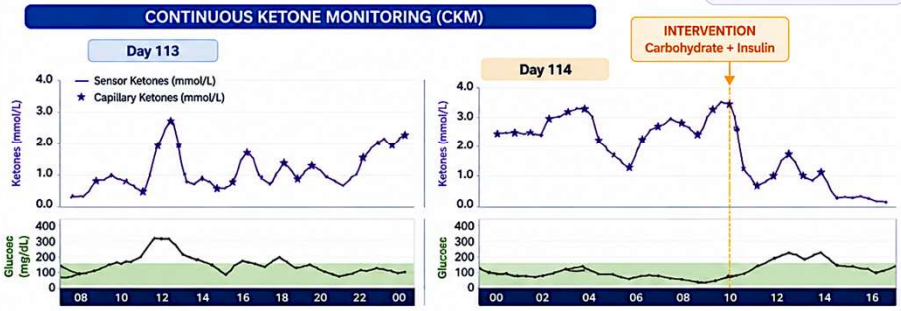
CLINICAL COURSE
The combination of SGLT2 inhibitor therapy, carbohydrate restriction, and exercise led to prolonged euglycemic ketosis despite the absence of marked hyperglycemia.

INTERVENTION
Carbohydrate intake and insulin were administered to reverse ketosis.

OUTCOME
CKM identified >14 hours of euglycemic ketosis (peak 2.9 mmol/L) and demonstrated resolution following intervention.

KEY LEARNING POINT
In people with type 1 diabetes using SGLT2 inhibitors, especially with low-carbohydrate diets and increased exercise, continuous ketone monitoring may enable earlier detection and management of euglycemic ketosis, potentially reducing progression to DKA.

CONTINUOUS KETONE MONITORING (CKM)



CKM captured >14 hours of euglycemic ketosis (peak 2.9 mmol/L) and tracked resolution.

NCT06753994

CONCLUSION: Continuous ketone monitoring enabled early recognition and management of euglycemic ketosis in a person with type 1 diabetes facing multiple metabolic stressors, supporting its potential role in improving safety in clinical settings.

REFERENCE: Elisabeth Lawton, Linden Perz, Melissa-Rosina Pasqua, Michael Tsoulkas, and Ahmad Haidar

DOI: 10.1177/15209156261420167

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CASE STUDY: T2D and DKA

INITIAL ASSESSMENT

- **60 year old female** with 20-year history T2D presents to ER with 2-day history of nausea, vomiting and dyspnea.
- **Current medications:** Metformin 1000 mg BID, Empagliflozin 25 mg, Rosuvastatin 20 mg, Losartan 100 mg, Amlodipine 5 mg
- She had done well on above medications for 2 years, with **A1c 6.3 – 7.1%.** About two weeks before ER visit, she started a low carbohydrate diet in preparation for metabolic surgery.
  Max adult weight – 426 pounds.

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CASE STUDY: T2D and DKA

EXAMINATION IN ER

Alert, anxious female with **Kussmaul breathing**.

BP: 135/84 | **Weight:** 406 pounds | Otherwise unremarkable.

LABS IN ER

- **Glu** – 326
- **Na** – 139
- **K** – 4.3
- **Cl** – 106
- HCO_3 – 7
- **Lactate** – 1.5
- **Cr** – 1.2
- Serum ketones not reported
- **Urine ketones** > 80

HOSPITAL COURSE

No other source for DKA was discovered. She was treated with IV insulin and fluid resuscitation and discharged after 3 days. **Empagliflozin was discontinued.** She was discharged on **Metformin, glargine insulin 24 units daily** and **insulin aspart** for correction.

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CASE STUDY: T2D and DKA

FOLLOW UP

- Upon follow up, she was doing well without symptoms. **She continued her low carb diet.**
- She was testing fingerstick glucose four times per day. She reported range of glucose between 74 – 229. **She denied hypoglycemia.**
- Bariatric surgery was scheduled. **CGM was ordered.**
- **Labs:** A1c – 7.3%, fasting glucose – 137 mg/dl, C-peptide – 1.5, Anti-GAD, anti-ZnT8 antibodies were negative

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CASE STUDY: T2D and DKA

POST METABOLIC SURGERY AND CGM

- **Metformin was resumed and insulin was discontinued.** She is feeling well, tolerating diet, without significant gastrointestinal symptoms. **A1c decreased to 6.5%** and **Weight to 294** pounds but both began to slowly increase.
- **Weight – 316 pounds.** Otherwise unremarkable.
- **Semaglutide** was started.

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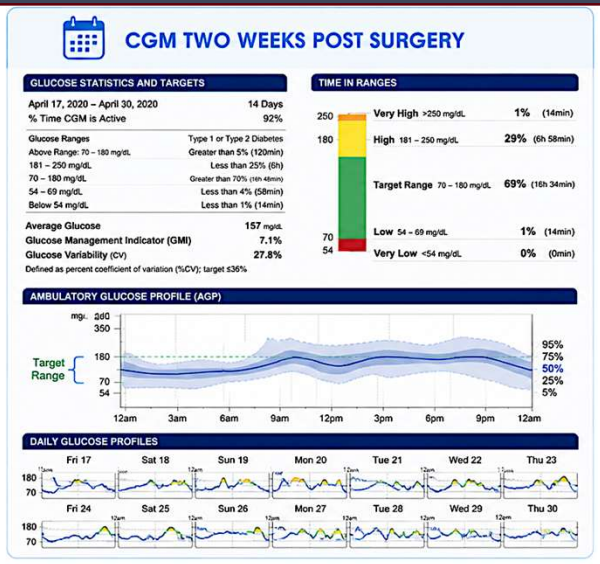
CASE STUDY: T2D and DKA



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CASE STUDY: T2D and DKA

1. **Glargine was discontinued.** Semaglutide was started and titrated to **2 mg weekly**. Her **A1c remained < 7%** for the next four years.

2. At most recent follow up, she is feeling well. Her weight is down to **324 pounds**. Her **A1c – 7.1%**

3. Based upon CGM tracings, **Tirzepatide** was added in place of Semaglutide.

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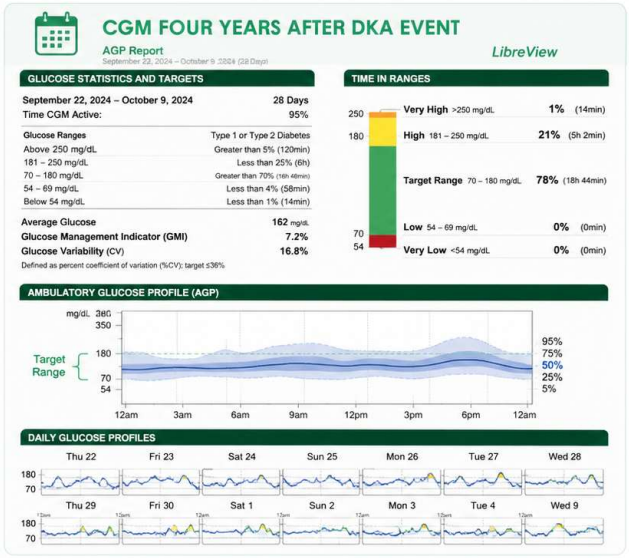
CASE STUDY: T2D and DKA



CGM FOUR YEARS AFTER DKA EVENT

AGP Report — LibreView

September 22, 2024 – October 9, 2024 (28 Days)

GLUCOSE STATISTICS AND TARGETS

September 22, 2024 – October 9, 2024	28 Days
Time CGM Active:	95%
Glucose Ranges	Type 1 or Type 2 Diabetes
Above 250 mg/dL	Greater than 5% (120min)
181 – 250 mg/dL	Less than 25% (6h)
70 – 180 mg/dL	Greater than 70% (16h 48min)
54 – 69 mg/dL	Less than 4% (58min)
Below 54 mg/dL	Less than 1% (14min)
Average Glucose	162 mg/dL
Glucose Management Indicator (GMI)	7.2%
Glucose Variability (CV)	16.8%

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

TIME IN RANGES

Very High >250 mg/dL	1%	(14min)
High 181 – 250 mg/dL	21%	(5h 2min)
Target Range 70 – 180 mg/dL	78%	(18h 44min)
Low 54 – 69 mg/dL	0%	(0min)
Very Low <54 mg/dL	0%	(0min)

AMBULATORY GLUCOSE PROFILE (AGP)

mg/dL; Target Range; 95% 75% 50% 25% 5%; 12am 3am 6am 9am 12pm 3pm 6pm 12am

DAILY GLUCOSE PROFILES

Thu 22 Fri 23 Sat 24 Sun 25 Mon 26 Tue 27 Wed 28

Thu 29 Fri 30 Sat 1 Sun 2 Mon 3 Tue 4 Wed 9

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Learnings from This Case

1. Patients with non-insulin treated T2D are at risk for DKA.
2. Obese patients with T2D are at risk for DKA.
3. In this case, the combination of treatment with SGLT-2 inhibitor and low carbohydrate diet put patient contributed to development of DKA.
4. Ketone monitoring should be considered for patients with T2D on SGLT-2 inhibitor, especially if prolonged duration or on insulin.

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Summary

KEY INSIGHTS

- DKA is **preventable**
- CGM **decreases risk** of DKA, but increased risk still remains
- Real-time ketone monitoring adds **critical insight**

CLINICAL ACTIONS

Dual glucose ketone sensing may reduce DKA risk by alerting the PwD of:

- Early detection of **rising ketones**
- Timely supplemental **insulin + fluid intake**
- Identification of **infusion set / pump issues**
- Clear guidance on when to **contact healthcare providers**

CLINICAL PRIORITY

- **Education** of PwD is essential
  - Importance of ketone **testing**
  - How to **interpret** results
  - When and how to **act**

EARLY DETECTION + INFORMED ACTION CAN PREVENT DKA

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Dual Glucose-Ketone Monitoring: A New Approach to Pediatric Diabetes

David Maahs, MD, PhD
Lucile Salter Packard Professor of Pediatrics and, by courtesy, Of Health Research and Policy (Epidemiology) | Chief of Pediatric Endocrinology | Associate Chair of Academic Affairs, Department of Pediatrics | Associate Director, Stanford Diabetes Research Center | Associate Dean of Academic Affairs | Stanford University School of Medicine | Stanford, CA

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Dual Glucose Ketone Monitoring

Why?

Do we need this?

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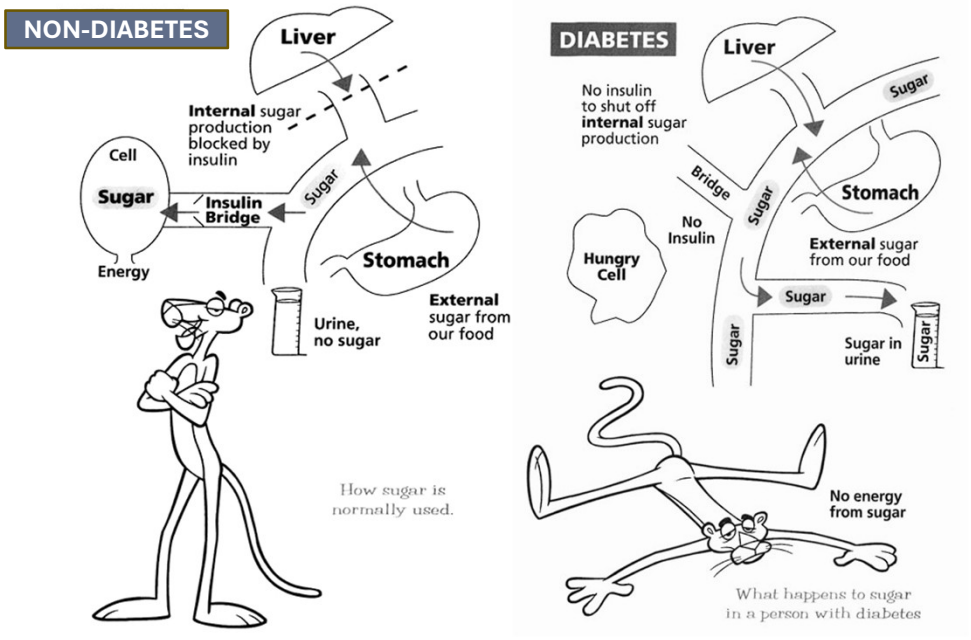

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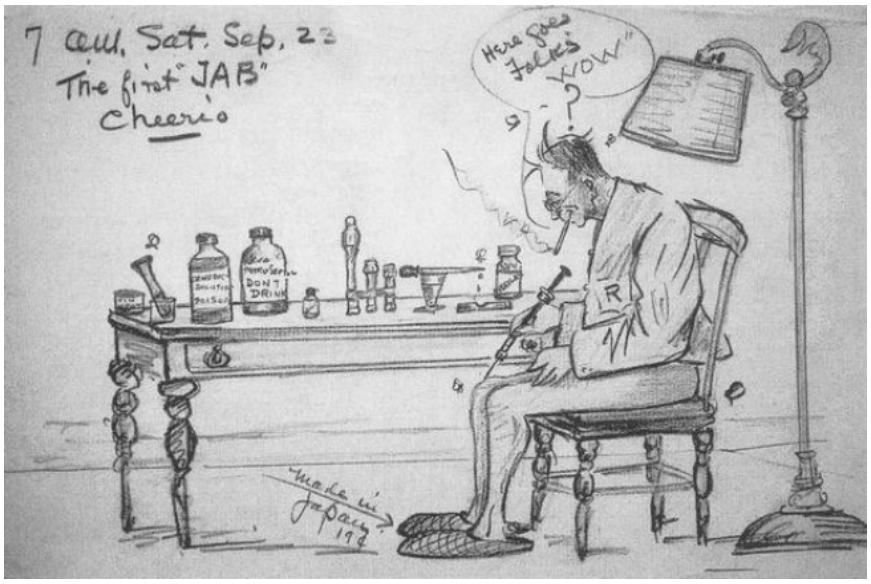
Stanford University



From Bittersweet, Feudtner

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REVIEW

The answer is 17 years, what is the question: understanding time lags in translational research

How are we doing in type 1 diabetes?

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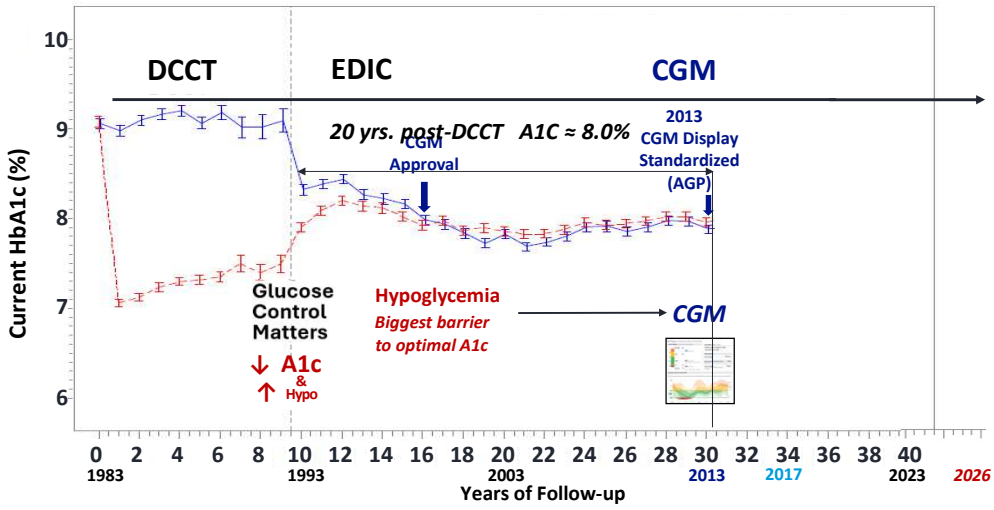
DCCT/EDIC: 40+ Years of Follow-Up of the 1441 DCCT Participants with T1D



DCCT: Diabetes Control and Complications Trial
EDIC: Epidemiology of Diabetes Interventions and Complications
TIR: Time In Range
TBR: Time Below Range

Bergenstal RM, 2025; Personal Communication
Braffett BH...Nathan D et al. Diabetes Care. 2025; 48(7):1089-1100

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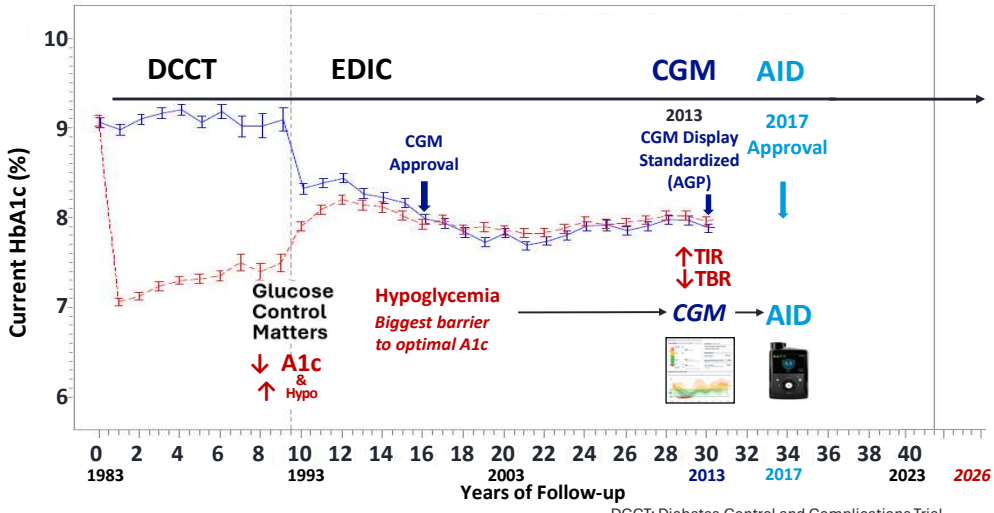
DCCT/EDIC: 40+ Years of Follow-Up of the 1441 DCCT Participants with T1D



DCCT: Diabetes Control and Complications Trial
EDIC: Epidemiology of Diabetes Interventions and Complications
TIR: Time In Range
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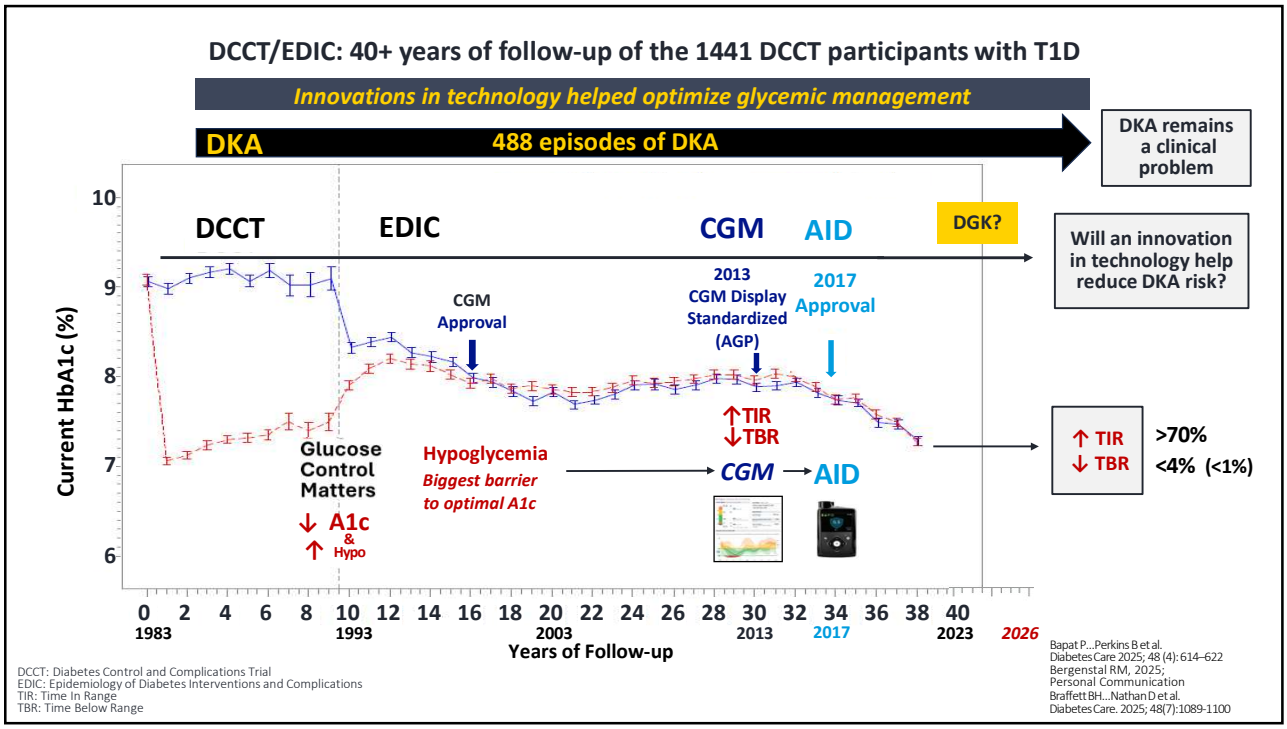

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Ski Camp 1980s

64

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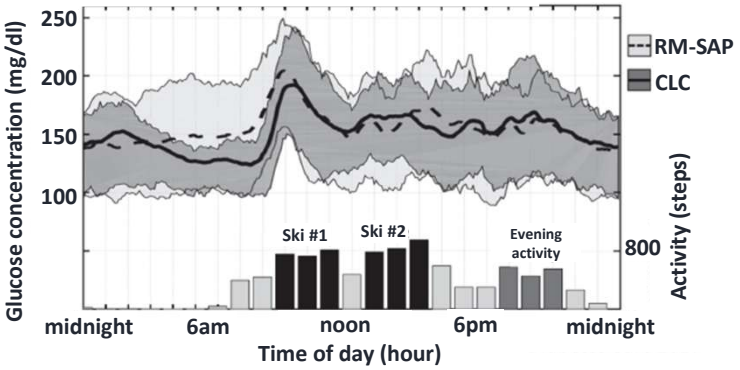
Closed Loop Control During Intense Prolonged Outdoor Exercise in Adolescents With Type 1 Diabetes: The Artificial Pancreas Ski Study

Marc D. Breton,[1] Daniel R. Cherñavvsky,[1] Gregory P. Forlenza,[2] Mark D. DeBoer,[1] Jessica Robic,[1] R. Paul Wadwa,[2] Laurel H. Messer,[2] Boris P. Kovatchev,[1] and David M. Maahs[2,3]

https://doi.org/10.2337/dc17-0883

Diabetes Care 2017



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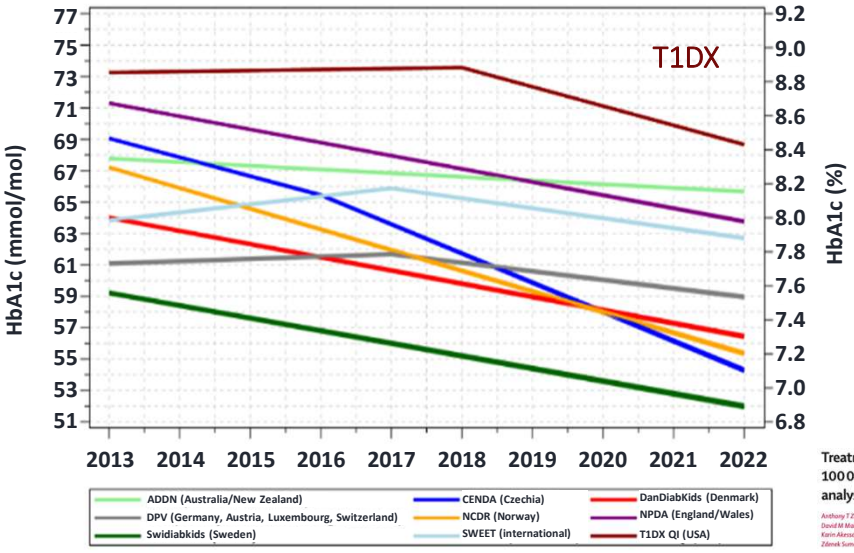
Despite Technological Advances, A1Cs Are Still High



Increased use of diabetes technology:

CGM, Pumps, Automated Insulin Delivery in parallel to HbA1c decreases and reduction in SH

Treatment regimens and glycaemic outcomes in more than 100 000 children with type 1 diabetes (2013–22): a longitudinal analysis of data from paediatric diabetes registries

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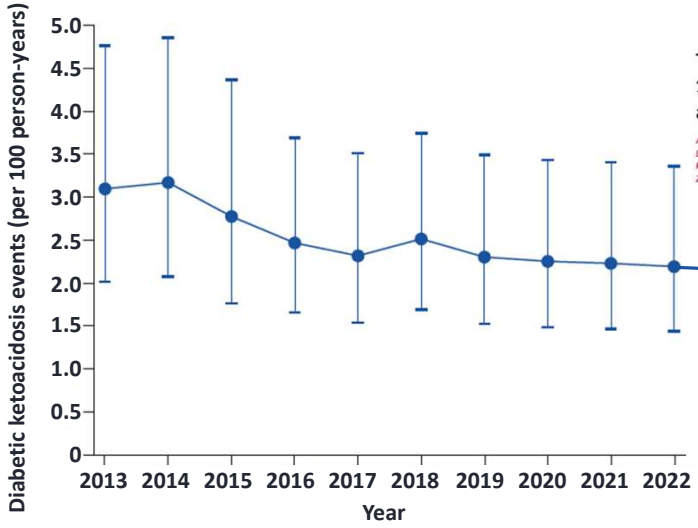

Treatment regimens and glycaemic outcomes in more than 100 000 children with type 1 diabetes (2013–22): a longitudinal analysis of data from paediatric diabetes registries

Anthony T Zimmermann, Stefanie Lanzinger, Siv Janne Kummernes, Nicolai A Lund-Blix, Reinhard W Holl, Elke Fröhlich-Reiterer, David M Maahs, Osagie Ebekozien, Saketh Rompicherla, Justin T Warner, Saira Pons Perez, Holly Robinson, Maria E Craig, Stephanie Johnson, Karin Akesson, Alexander Thorén, Katarina Eeg-Olofsson, Ajenthen G Ranjan, Mette Madsen, Michael Witsch, Heiko Bratke, G Todd Alonso, Zdenek Sumnik, Vit Neuman, Ondrej Cinek, Torild Skrivarhaug*, Jannet Svensson*

2026

Can we lower the slope with DGK?

Figure 4: Aggregate event rate of diabetic ketoacidosis across all registries over the study period (2013-22)
Error bars show 95% CIs

67

Burden of Diabetic Ketoacidosis Among Youth With Diabetes
A Hospital Claims Analysis

- Authors assessed DKA-related hospitalizations in children with type 1 (T1D) or type 2 diabetes (T2D), and estimated differences in mortality, and cost of hospitalizations.
- After adjusting to national estimates, authors tracked incidence, length of stay (LOS), mortality, and hospitalization costs.
- **Results**: In 2022, among 38,874 pediatric hospitalizations in youth with T1D or T2D, 23,983 (59.1%) hospitalizations associated with a DKA diagnosis code [T1D, N=22,577 (58.1%); T2D, N=1,406 (3.6%)].
- **49 deaths associated with DKA hospitalizations**, LOS range (2.4-7.3 days), costs ($9,461-38,074)

Conclusion

DKA is commonly coded during hospitalizations of youth with diabetes. While the present analysis could not address if DKA occurred at disease onset, our findings highlight the **substantial burden of DKA in terms of incidence, cost, and duration of admission.**

Sherr J, et al. ADA 2026

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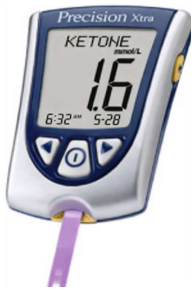
What Happens in the Real World?

- A 6 y/o with type 1 diabetes on an automated insulin delivery system
- Overnight she began having episodes of vomiting and her parents were worried she had developed a viral gastroenteritis
- As glucose was in range, they had been administering small amounts of honey to keep glucose levels stable
- After hours of doing this, they contact our team at 6:30a.m. for guidance
- We recommend checking ketones…



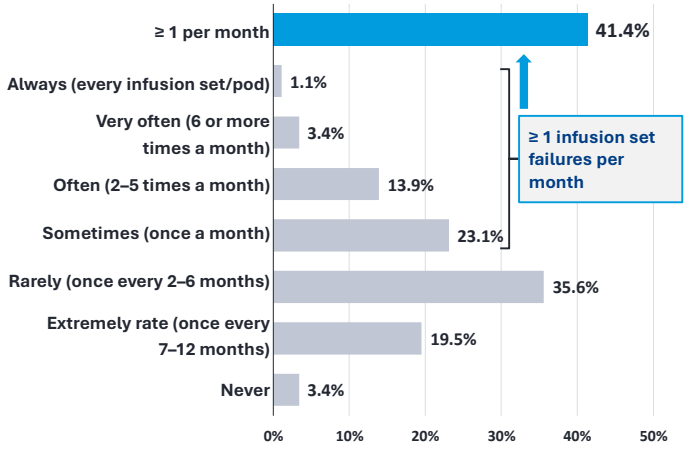
It wasn't a stomach bug; it was an infusion set failure

Slide courtesy, J Sherr

69

Issues with Insulin Infusion Sets are Common

Insulin infusions sets are the "Achilles heel" of any subcutaneous insulin delivery device



Hughes M et al, Frequency and Detection of Insulin Infusion Site Failure in the Type 1 Diabetes Exchange Online community, Diabetes Techn Ther (2023): 25:426–30. Image on file at Abbott.

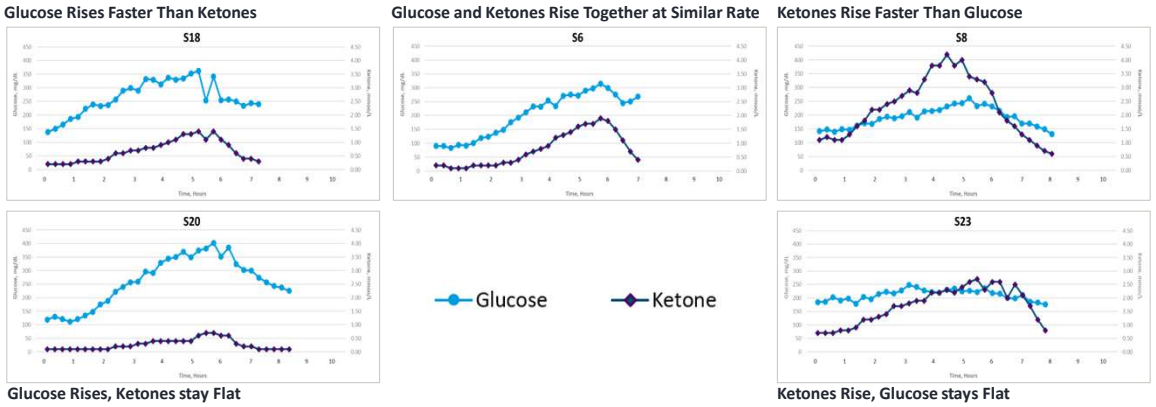
Slide courtesy, J Sherr

70

70

Rates of Glucose and Ketone Changes Do Not Consistently Correlate

Individual Profiles From Adult Pump Interruption Study



Investigational technology.
Sherr JL. ISPAD 51st Annual Conference 2025. Highlights HL-01.

Slide courtesy, J Sherr

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Pediatric DKA

ISPAD 2026 Guidelines: Evidence and Updates

Nicole Glaser
University of California, Davis
School of Medicine

ISPAD DKA 2026 co-authors: Yeray Nóvoa Medina, G. Todd Alonso, Douglas Fraser, Brynn E. Marks, Vit Neuman, Thereza Piloya-Were, Jannet Svensson, Mariana Zoron, Leena Priyambada

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Continuous ketone monitoring for people with diabetes: international expert recommendations on the application of a new technology

Ketan Dhatariya*, Richard M Bergenstal*, Mohammed Al-Sofiani, Anastasia Albanese-O'Neill, Tadej Battelino, Kelly Close, Christophe De Block, Sanjoy Dutta, Rodolfo J Galindo, Amin GhavamiNejad, Ahmad Haidar, Julie Heverly, Davida Kruger, Lori M Laffel, Julianne Lally, David M Maahs, Claudio Maffeis, Chantal Mathieu, Eden Miller, Medha Munshi, Rimei Nishimura, Kirsten Nørgaard, Tal Oron, David N O'Neal, Monica Oxenreiter, Bruce A Perkins, Moshe Phillip, Eric Renard, Jonathan Rosen, Mauro Scharf, Jennifer Sherr, Carol Wysham, Thomas Danne

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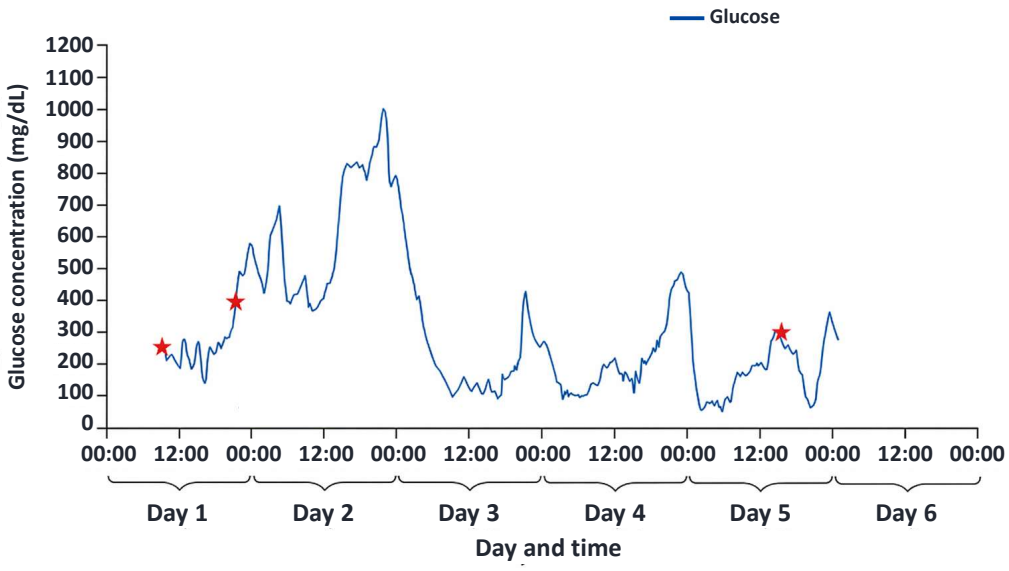

Figure adapted from: Dhataryia K, et al. International expert recommendations on the application and utility of continuous ketone monitoring for people with diabetes. Lancet Diabetes and Endocrinology. 2026; 14:1, P82-92.

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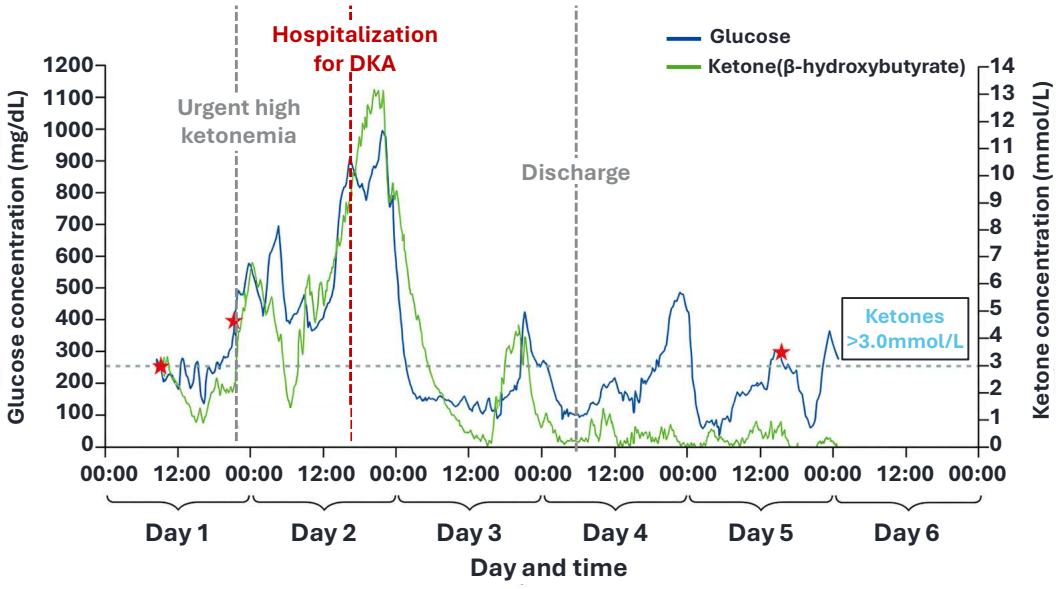

Figure adapted from: Dhataryia K, et al. International expert recommendations on the application and utility of continuous ketone monitoring for people with diabetes. Lancet Diabetes and Endocrinology. 2026; 14:1, P82-92.

75

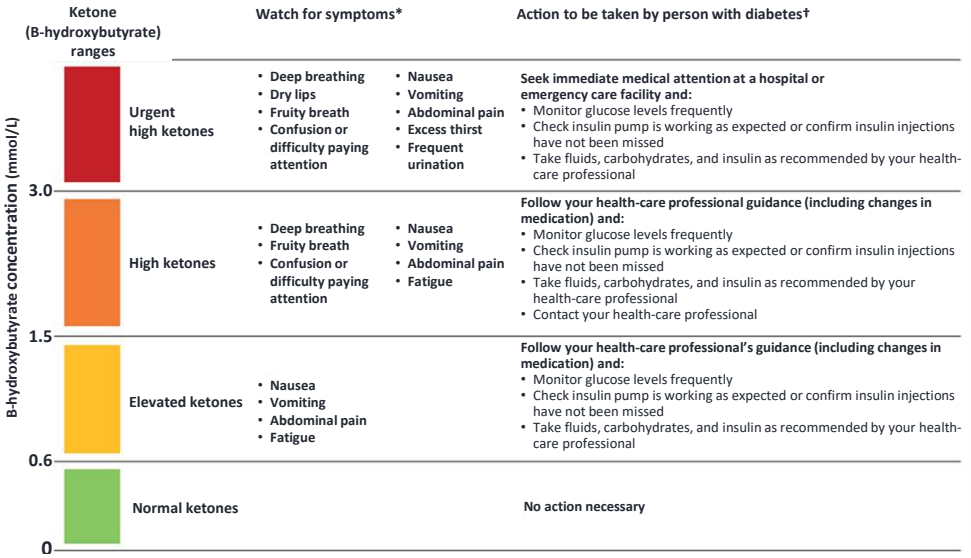

Figure 2: **Template schema for developing practical recommendations on continuous ketone monitoring thresholds**
* If continuous ketone monitoring readings do not match symptoms then perform a capillary blood ketone test. †See appendix (p 5) for possible action-based recommendations for health-care professionals to consider as part of possible clinical decision support functionality.

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Expert Panel Kick-Off

April 17, 2025

Connected for Life.

American Diabetes Association.
Connected for Life.

Ketone Monitoring and Elevated Ketone Management

Paper in review

Diabetes Care

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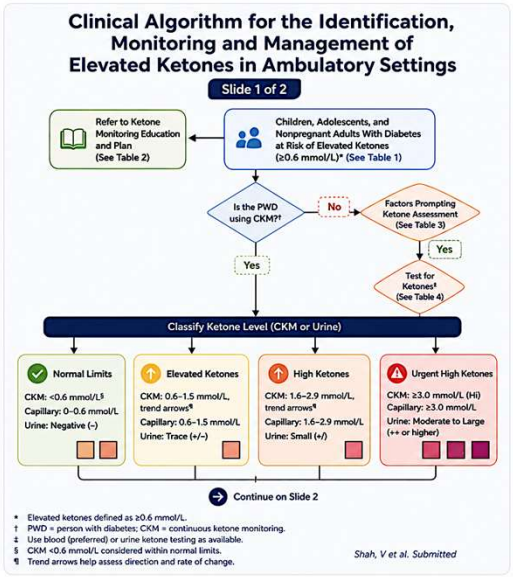
Clinical Algorithm for the Identification, Monitoring And Management of Elevated Ketones In Ambulatory Settings: An ADA Evidence Synthesis Project



Adapted from Shah, V et al. Submitted

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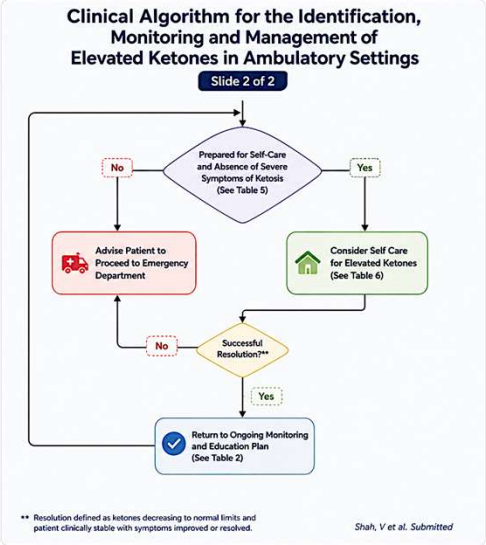
Clinical Algorithm for the Identification, Monitoring And Management of Elevated Ketones In Ambulatory Settings: An ADA Evidence Synthesis Project



Adapted from Shah, V et al. Submitted

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CE Mark for Libre Duo 10 Day for Pediatric Use

Abbott wins CE mark for dual glucose-ketone sensor

MAY 27, 2026 BY SEAN WHOOLEY

Abbott (NYSE:ABT) announced today that it received CE mark approval for its dual glucose-ketone sensing technology for people with diabetes.

The company said its dual sensor marks a world first, continuously measuring glucose and ketone levels every minute. Branded as Libre Duo and Libre Duo 10 Day, the sensors provide real-time visibility into glucose levels as a standard CGM like Abbott's FreeStyle Libre system does, but also into rising ketones that can lead to a diabetic ketoacidosis (DKA) emergency.

The Libre Duo dual glucose-ketone sensor
[Image courtesy of Abbott]

- ✓ The sensors are designed to help pediatric users with diabetes monitor glucose levels while also **alerting them to rising ketones** so they can act sooner and potentially avoid a serious DKA emergency
- ✓ Libre Duo 10 Day offers up to 10 days of wear and is intended for **people ages 2 and older**.

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Thank You

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CGM for T2D in the Setting of Basal Insulin and SGLT2/GLP-1: The FreeDM2 Study

Lalantha Leelarathna PhD, FRCP
Clinical Associate Professor in Diabetes
Imperial College London
London, UK

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Disclosures

- Dr Lalantha Leelarathna has received fees and/or honoraria from Abbott Diabetes Care, Insulet, Medtronic, Dexcom, Sanofi, and Vertex.
- The FreeDM2 study was sponsored by Abbott Diabetes Care.

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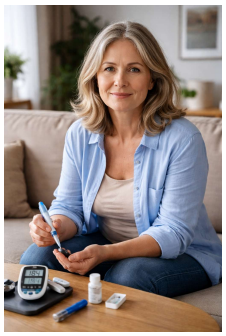
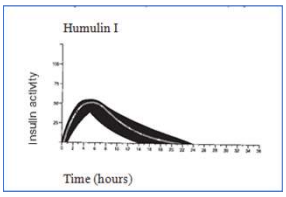
Clinical Case Study

55 year old female

Medical history	Type 2 diabetes for 12 years
Profile	• BMI 29kg/m2 • HbA1c 9.6% (chronically elevated) • Only checks blood glucose for a few days before diabetes clinic
Management	• Humulin I 19u BD (Isophane, intermediate-acting) • Empagliflozin 25mg OD • Gliclazide 160 mg BD Declined statin, Intolerant of metformin and GLP-1





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Glucose Data

	Pre-breakfast	Pre-lunch	Pre-dinner	Pre-bed
Sunday	4.9			
Monday	5.2			
Tuesday				
Wednesday	6.3			
Thursday	5.1			

Question: How will you alter the insulin dosing (Humulin i 19 units BD)?

a) Increase the morning dose
b) Increase the evening dose
c) Add in prandial insulin
d) Wait for more blood glucose data first
e) Wait and give a trial of real-time-CGM first

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MOBILE Study

CGM Benefits for Non-Intensive Insulin Therapy


Research

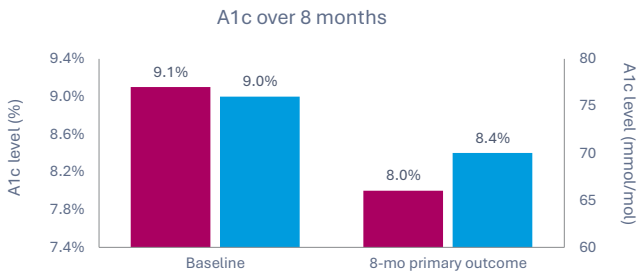
JAMA | Original Investigation

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

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

- To determine the effectiveness of CGM in adults with T2DM treated with **basal insulin (no prandial)**
- Dexcom G6 device vs. SMBG
- HbA1c 7.8 % to 11.5% (62 to 102 mmol/mol)
- 15 Endocrinology practices in the USA, participants under primary care physician for diabetes care
- Between July 30, 2018, and October 30, 2019; use of SGLT2 at baseline was 9%

Adjusted difference in mean change in A1C = −0.4%
(–0.8, −0.1), [−4 mmol/mol], *P*=0.02



% TIR 3.9 to 10 mmol/L (70–180 mg/dL)
- **59% CGM vs. 43% BGM** (adjusted difference, 15%, *P*<0.001)

% TBR < 3.9 mmol/L (< 70 mg/dL)
- **0.2% CGM vs. 0.5% BGM** (adjusted difference, -0.24%, *P*=0.02)

Martens et al, *JAMA* (2021); 325 (22): 2262–2272.

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Rationale for FreeDM2

Individuals treated with basal insulin, SGLT2i and GLP-1 RA therapy represent a **significant proportion** of those living with **T2DM**.

Despite combination therapy, many **do not** achieve **glycaemic targets**.

There is a **lack** of high quality RCT evidence supporting the use of **CGM** in people with T2DM treated with **basal insulin** combined with **modern therapies.**

Our **understanding** of **behavioral changes** associated with CGM use are limited.

Aim

To determine whether use of FreeStyle Libre 3 CGM system improves HbA1c over 32 weeks compared to SMBG in adults with suboptimal glycaemia

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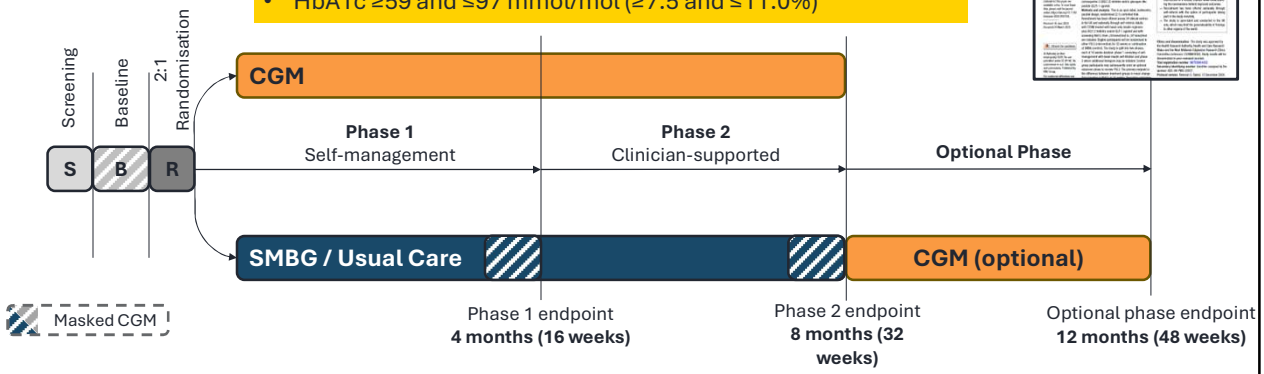
FreeDM2 Study Design

UK study: recruitment from 24 secondary and primary care centres and nationally via self-referral.

Key inclusion criteria

- Adults with T2DM
- Basal-only insulin plus SGLT2i and/or GLP-1 or GIP/GLP-1 RA
- HbA1c ≥59 and ≤97 mmol/mol (≥7.5 and ≤11.0%)



Wilmot EG et al. *BMJ Open* 2025;15:e090154 | NCT05944432

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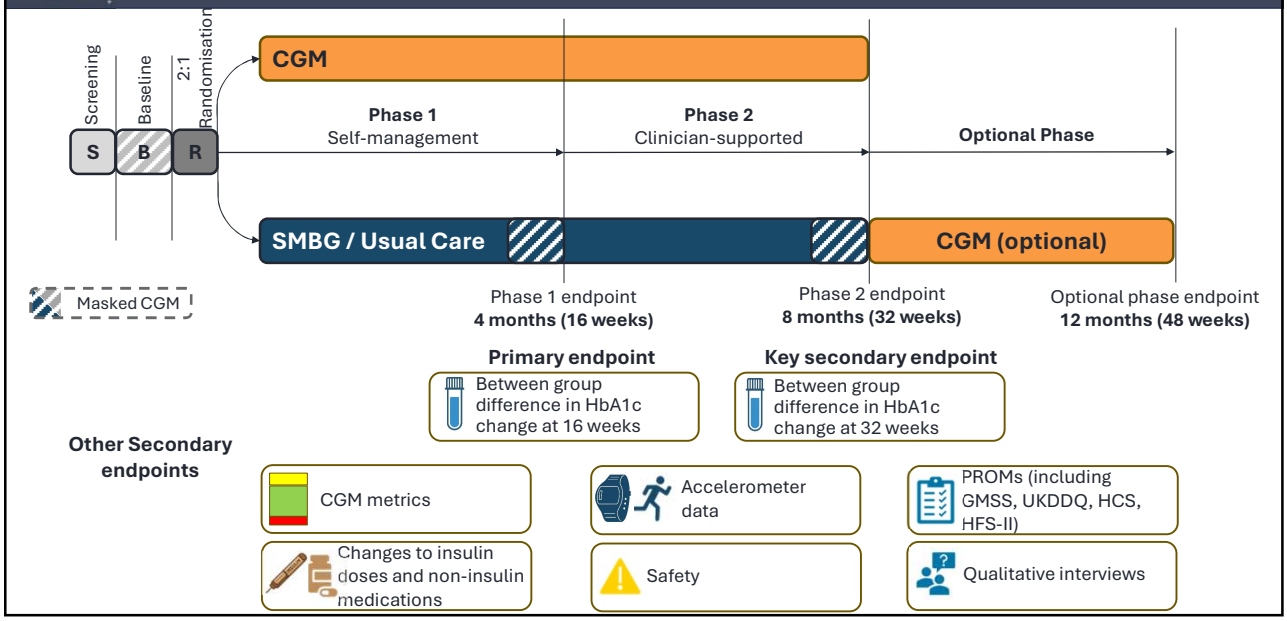
Analysis Endpoints



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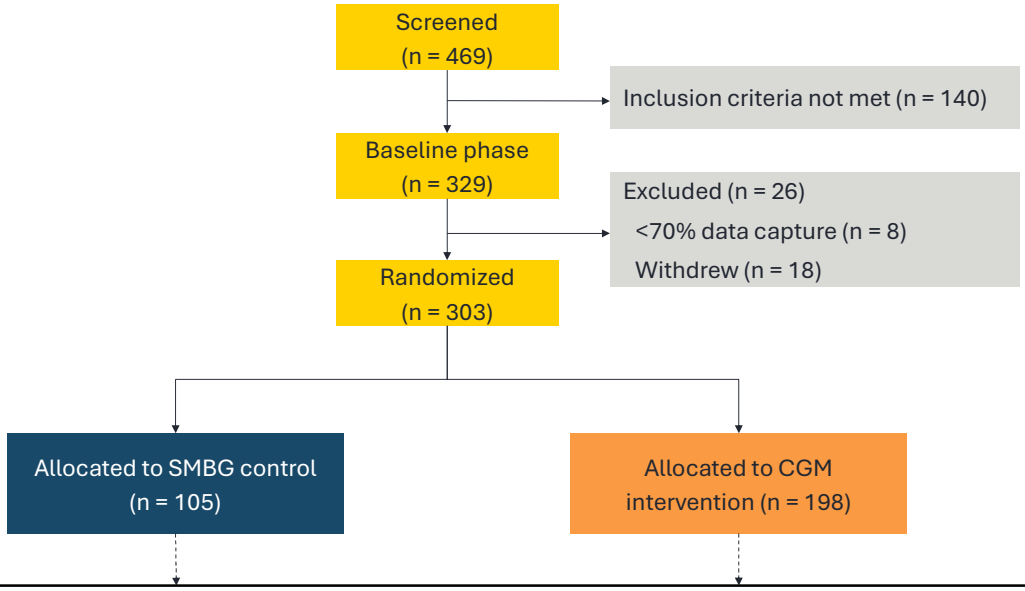
Participant Flow



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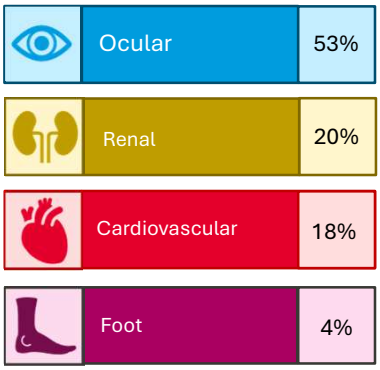
Baseline Data
Demographics and Medical History

Demographic	All (n=303)	SMBG Control (n=105)	CGM (n=198)
Age, years	60.7 ± 9.8	59.8 ± 9.1	61.2 ± 10.2
Male sex, %	67.3	68.6	66.7
BMI, kg/m^2	31.1 ± 5.6	31.3 ± 5.7	31.0 ± 5.6
Diabetes duration, years	16.7 ± 6.9	15.9 ± 7.4	17.1 ± 6.6

mean± SD unless stated otherwise

Diabetes related complications at baseline



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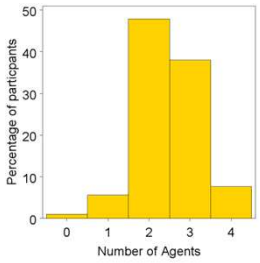
Baseline Data
Medication History

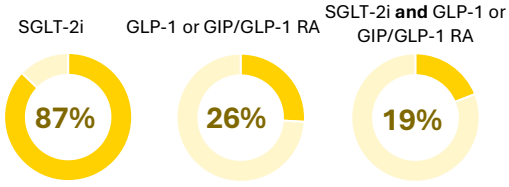
Drug class	All (n=303)	SMBG Control (n=105)	CGM (n=198)
Insulin			
Total daily insulin dose			
Units	34.1 ± 25.4	35.5 ± 32.8	33.3 ± 20.4
Units/kg	0.36 ± 0.23	0.37 ± 0.27	0.36 ± 0.21
Non-insulin medications prescribed at baseline			
SGLT-2 inhibitors, %	87	86	88
Metformin, %	86	82	88
Sulphonylureas, %	33	33	33
Incretins^, %	37	37	36

mean± SD unless stated otherwise
^includes GLP-1- based therapies plus gliptins

Combinations of non-insulin medications
Number of agents



SGLT-2i combined with GLP-1- based therapy



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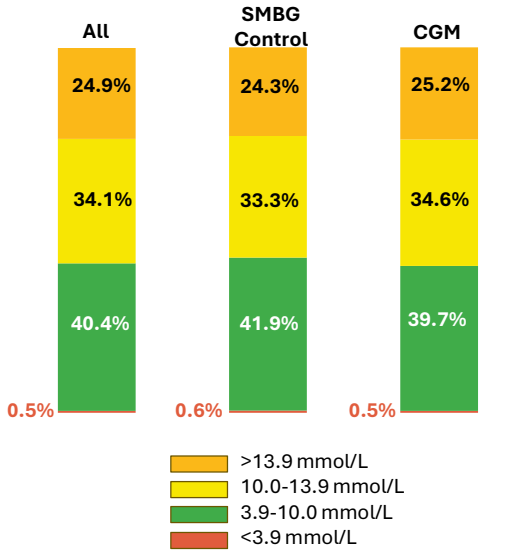
Baseline Data
Glycaemia

Parameter	All (n=303)	SMBG Control (n=105)	CGM (n=198)
HbA1c, mmol/mol	73 ± 11	73 ± 11	73 ± 11
HbA1c, %	8.8 ± 1.0	8.8 ± 1.1	8.8 ± 1.0
Daily fingerstick frequency	2.0 ± 1.9	2.1 ± 2.0	1.9 ± 1.8

mean± SD unless stated otherwise

Mean % time in glucose ranges at baseline



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CGM in Type 2 Diabetes

CHANGE IN HbA_1c
PRIMARY AND KEY SECONDARY OUTCOME

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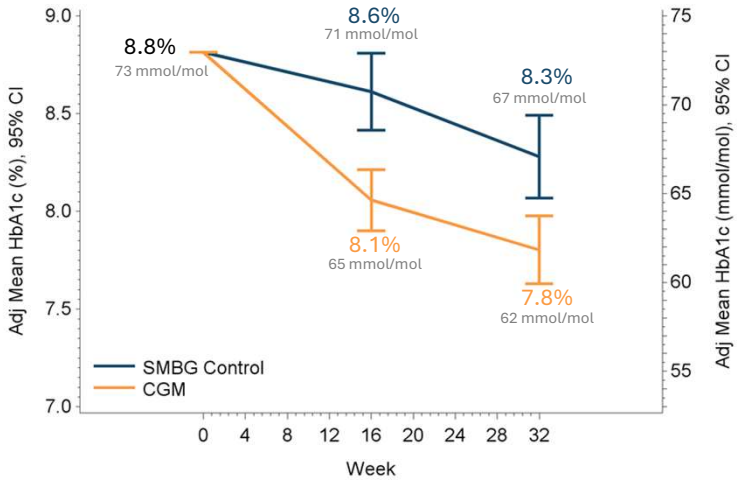
Change in HbA_1c
Primary and Key Secondary Outcome

	Adjusted mean difference (95%CI)
4 months	**-0.6%** (-0.77, -0.34) [-6mmol/mol] **p<0.0001**



Treatment groups compared using a linear mixed model with baseline HbA1c as a fixed effect and site as a random effect.

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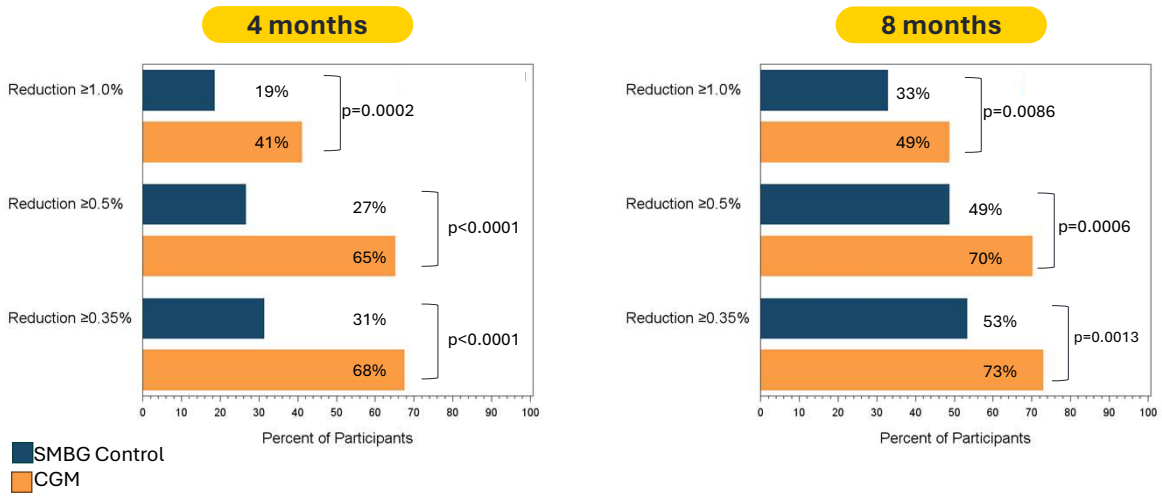
HbA_1c Analysis
Magnitude of Improvements



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CGM in Type 2 Diabetes

SENSOR-BASED METRICS

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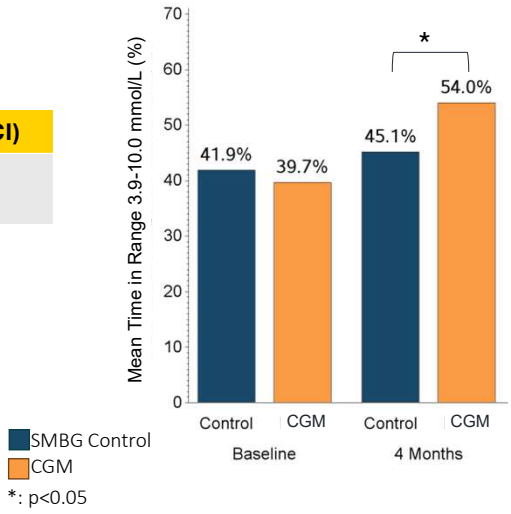
Sensor-Based Metrics
Time in Range 3.9-10.0 mmol/L (70-180 mg/dL)

	Adjusted mean difference (95%CI)
4 months	**+10.4%** (5.4, 15.4) [+2.5h/day] **p<0.0001***



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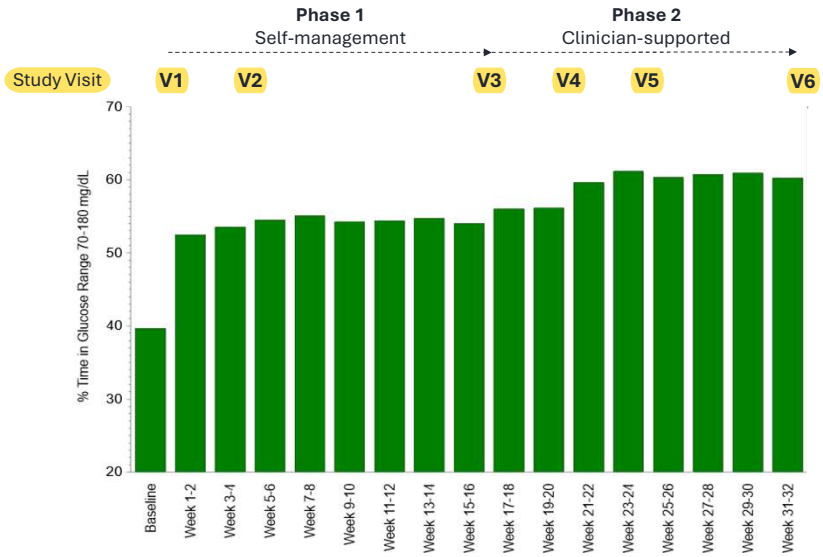
Sensor-Based Metrics
Speed of Improvements in Time in Range



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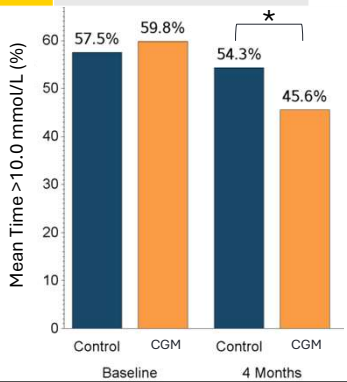
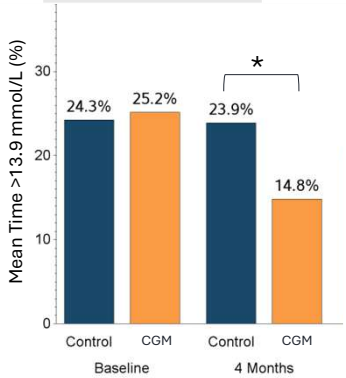
Sensor-Based Metrics
Time Above Range

	%Time >10.0 mmol/L (>180 mg/dL)	%Time >13.9 mmol/L (>250 mg/dL)
	4 months	4 months
Adjusted mean difference (95%CI)	**-10.2%** (-15.3, -5.1) [-2.4h/day] **p=0.0001***	**-9.7 %** (-13.7, -5.8) [-2.3h/day] **p<0.0001***





SMBG Control
CGM
*: p<0.05

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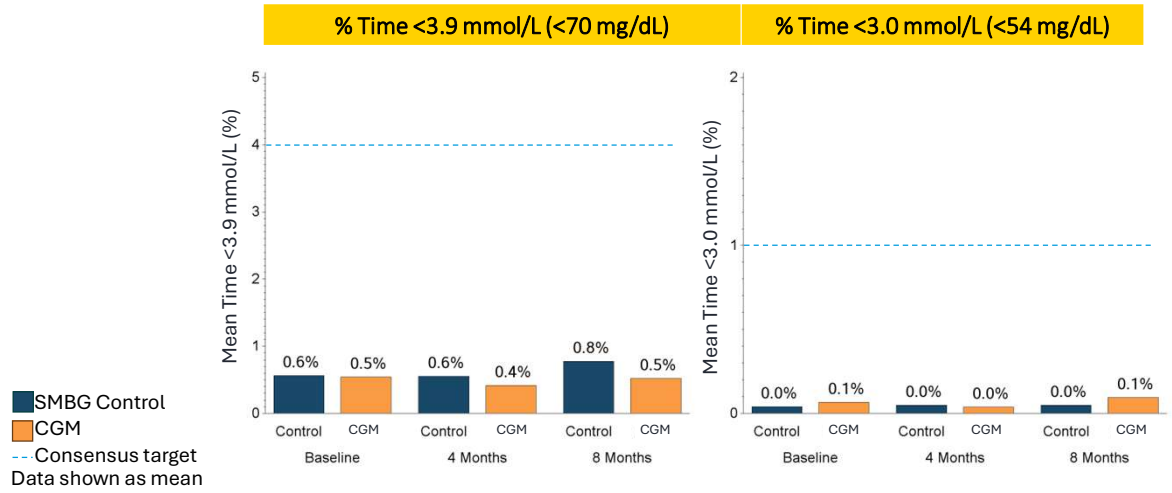
Sensor-Based Metrics
Time Below Range



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Sensor-Based Metrics
Improvements in GMI, Mean and SD Glucose

Outcome	Month	Control (N=105)	CGM (N=198*)	Adjusted mean difference (95%CI)	P value
Glucose management indicator, %	**0**	8.2	8.3	—	—
	4	8.2	7.7	**−0.5** (−0.7, −0.3)	**<0.0001***
	8	7.9	7.5	**−0.5** (−0.7, −0.2)	**0.0001***
Mean glucose, mmol/L	**0**	11.4	11.5	—	—
	4	11.3	10.2	**−1.1** (−1.6, −0.6)	**<0.0001***
	8	10.7	9.7	**−1.1** (−1.6, −0.5)	**0.0001***
SD glucose, mmol/L	**0**	3.29	3.30	—	—
	4	3.35	2.93	**−0.42** (−0.59, −0.24)	**<0.0001***
	8	3.07	2.74	**−0.29** (−0.48, −0.10)	**0.0032***
CV glucose, %	**0**	29.1	29.0	—	—
	4	29.9	28.6	−1.0 (−2.1, 0.0)	0.061
	8	28.6	28.3	−0.1 (−1.3, 1.2)	0.92

Data shown as mean. *: p<0.05

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Sensor-Based Metrics
Day and Night Analysis

Parameter		4 months Adjusted mean difference (95% CI)	4 months p value	8 months Adjusted mean difference (95% CI)	8 months p value
Time in Range (3.9-10 mmol/L), %	☀	**8.7** (3.6, 13.7)	**0.0009***	**8.2** (2.3, 14.0)	**0.0064***
	☾	**15.7** (10.0, 21.3)	**<0.0001***	**17.7** (11.3, 24.1)	**<0.0001***
Time above range (> 10 mmol/L), %	☀	**-8.5** (-13.6, -3.3)	**0.0014***	**-7.9** (-13.8, -2.0)	**0.0091***
	☾	**-15.6** (-21.4, -9.9)	**<0.0001***	**-17.5** (-24.0, -11.0)	**<0.0001***
Time above range (> 13.9 mmol/L), %	☀	**-9.6** (-13.7, -5.4)	**<0.0001***	**-9.0** (-13.3, -4.7)	**<0.0001***
	☾	**-10.2** (-14.4, -6.1)	**<0.0001***	**-10.1** (-14.4, -5.9)	**<0.0001***
Time below range (< 3.9 mmol/L)†, %	☀	—	0.74	—	0.16
	☾	—	0.62	—	0.60
Mean glucose (mmol/L)	☀	**-1.0** (-1.5, -0.5)	**0.0002***	**-0.9** (-1.5, -0.4)	**0.0009***
	☾	**-1.5** (-2.1, -1.0)	**<0.0001***	**-1.5** (-2.1, -0.9)	**<0.0001***

☀: 6am → midnight. ☾: midnight → 6am.
*: p<0.05, † Proportion of participants with zero TBR assessed using mixed logistic regression.

Data shown as mean. *: p<0.05

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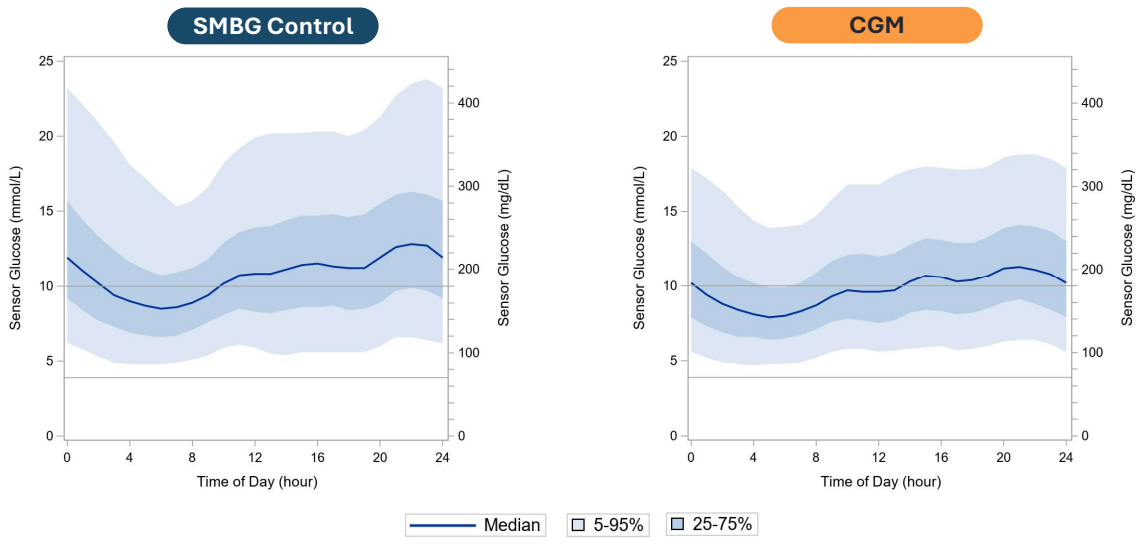
Sensor-Based Metrics
24-Hour Glucose Profile at Four Months



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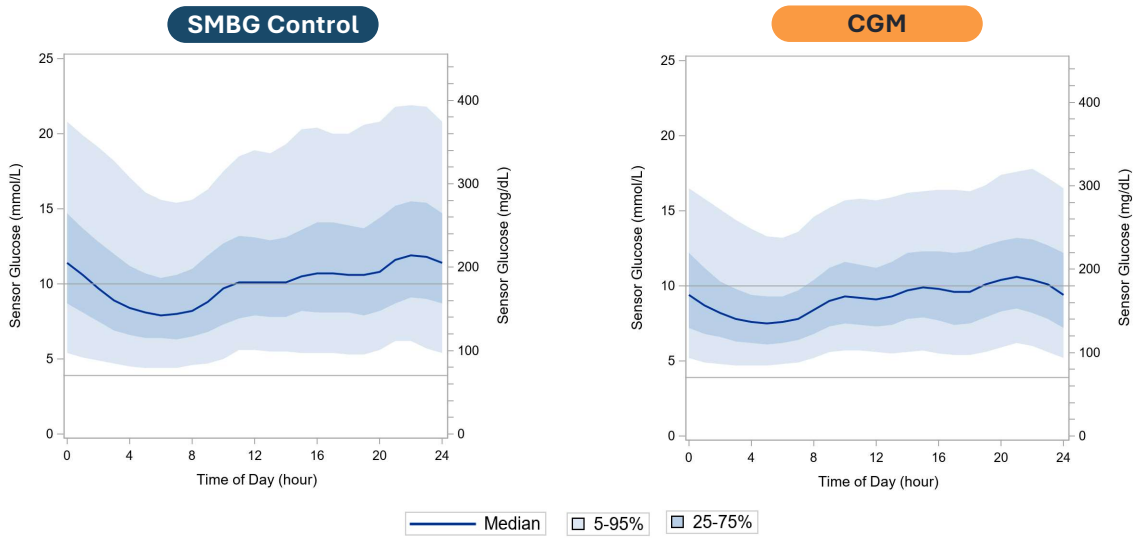
Sensor-Based Metrics
24-Hour Glucose Profile at Eight Months



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Sensor Usage (Intervention) and SMBG Frequency (Control Arm)

	N	Mean	Range	Median (IQR)
Percentage of expected glucose readings collected during weeks 1–16	198	93.4	8.6–99.2	97.6 (93.4, 98.7)
Percentage of expected glucose readings collected during weeks 17–32	198	92.0	0.0–99.6	98.2 (94.8, 98.8)

	Visit					
	Baseline (N=104)	4 weeks (n=98)	16 weeks (n=94)	20 weeks (n=92)	24 weeks (n=93)	32 weeks (n=92)
Mean ± SD number of finger-stick glucose tests per day	2.1 ± 2.0	2.4 ± 1.9	2.2 ± 1.4	2.4 ± 1.6	2.7 ± 2.1	2.2 ± 1.1

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CGM in Type 2 Diabetes

MEDICATION CHANGES

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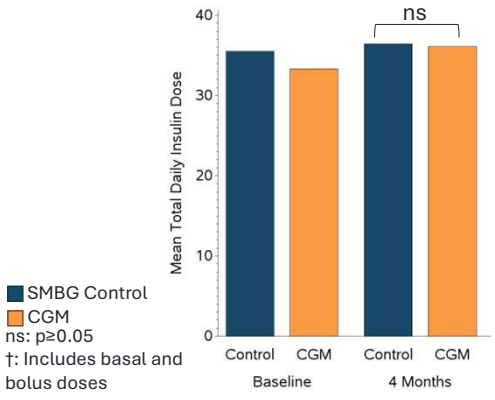
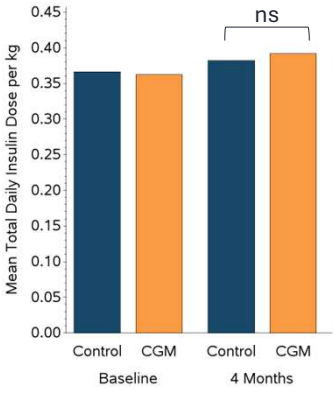
Medication Changes
Changes to Total Daily Insulin Dose†

	Total daily insulin dose†, units	Total daily insulin dose†, units/kg
	4 months	4 months
Adjusted mean difference (95%CI)	-0.1 units (-2.7, 2.5) p=0.92	-0.01 units/kg (-0.03, 0.02) p=0.69





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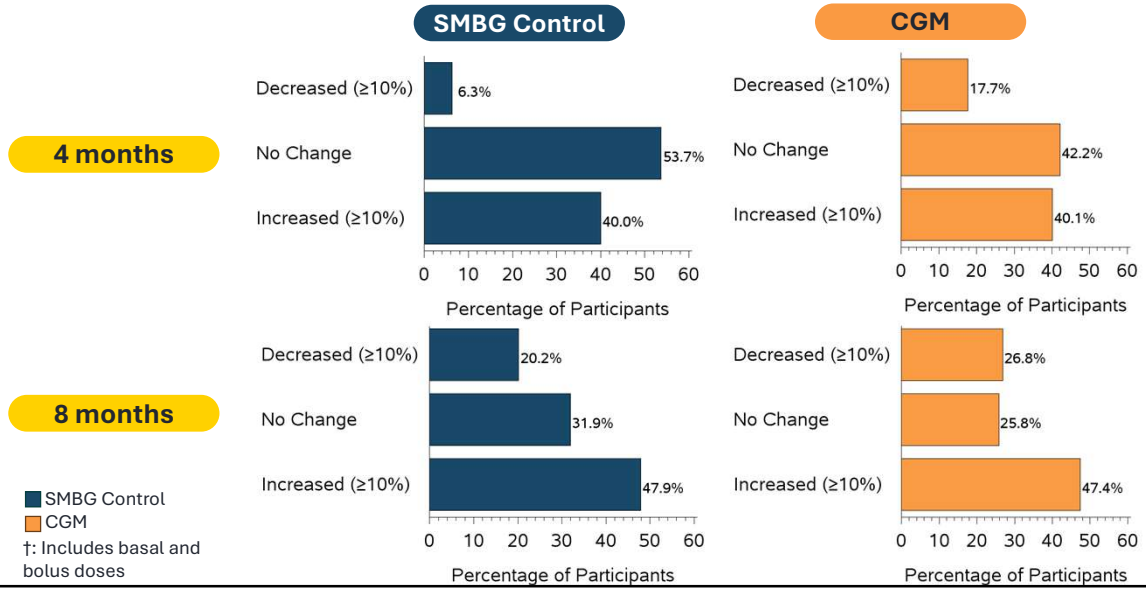
Medication Changes
Changes to Total Daily Insulin Dose†



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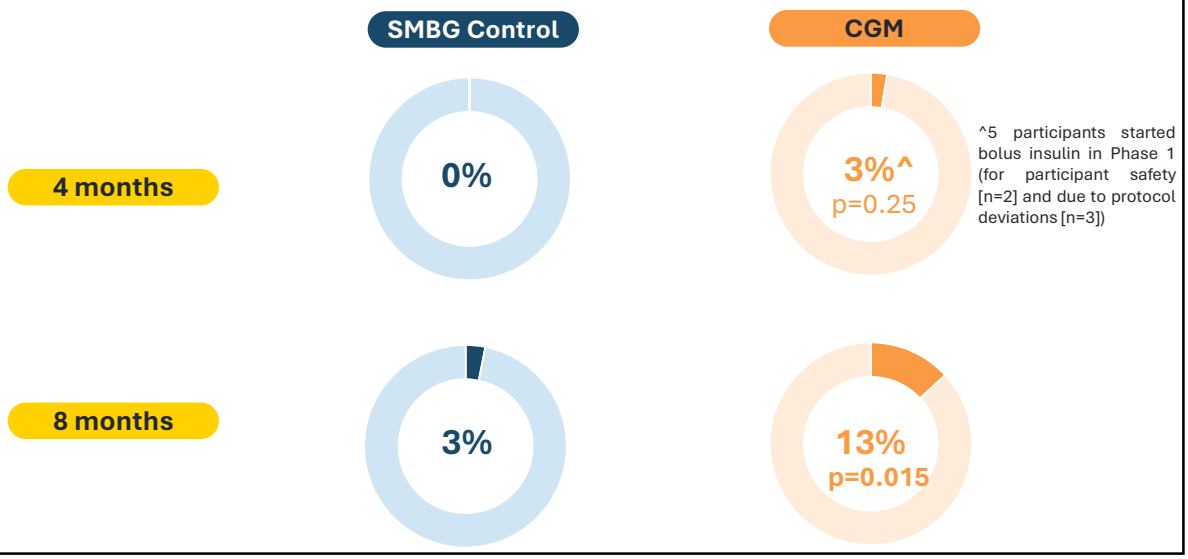
Medication Changes
% of Participants Starting Bolus Insulin



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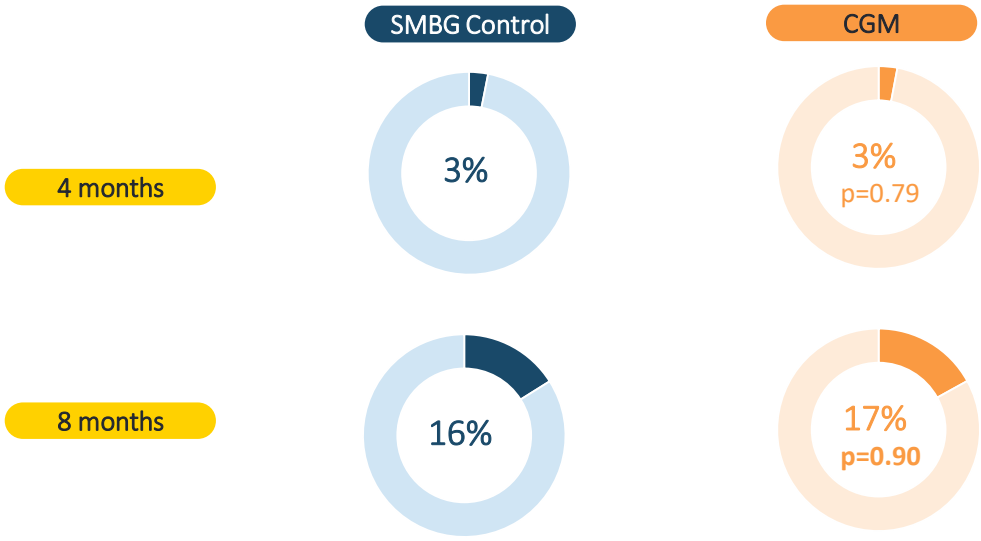
Medication Changes
% of Participants Initiating New Non-Insulin Glucose Lowering Medications



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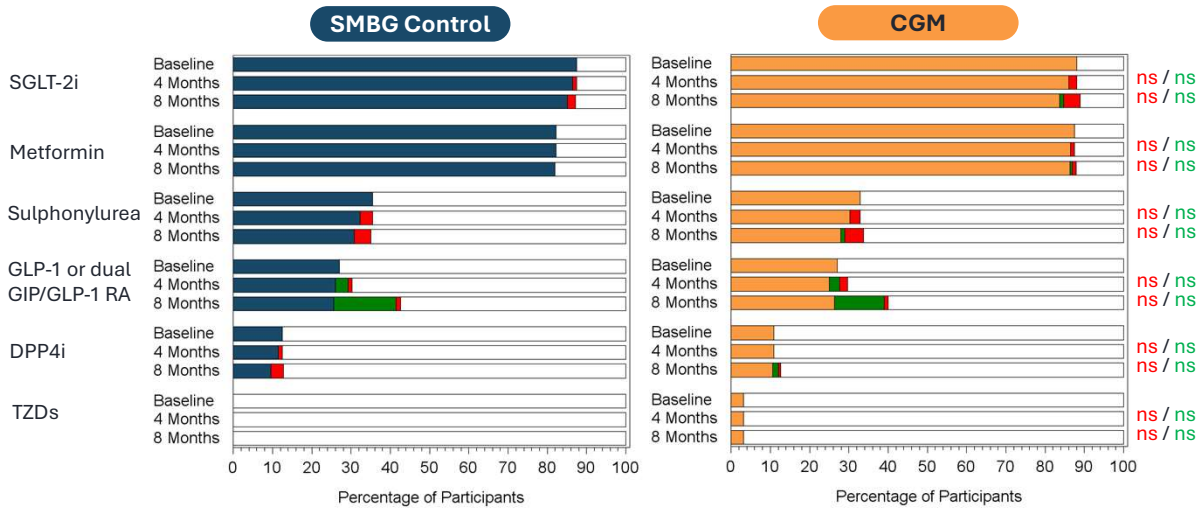
Medication Changes
No Significant Between-Group Changes in Each Non-Insulin Medication Class



ns/ns: : p≥0.05 for difference in proportion of participants stopping/starting.

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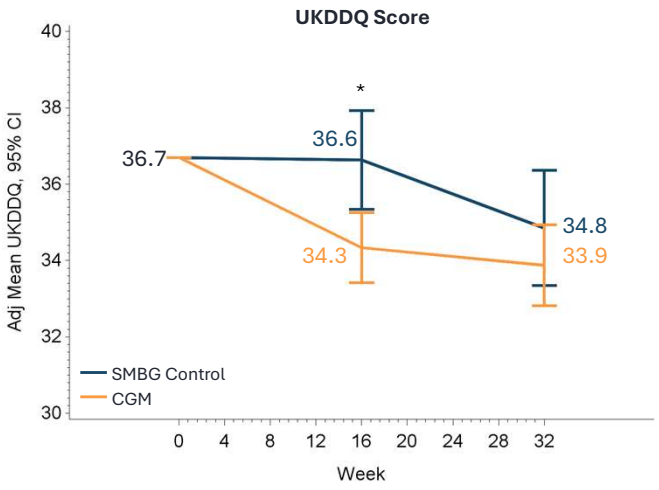
Changes to Diet
UK Diabetes and Diet questionnaire (UKDDQ)[1]

21-item tool to assess dietary habits important in T2DM.

- Assesses frequency and type of food consumption (e.g. cakes, fruits/ vegetables, processed foods, alcohol etc).

	Adjusted mean difference (95%CI)
4 months	**-2.3** (-3.9, -0.7) **p=0.0047***
8 months	**-1.0** (-2.8, 0.9) p=0.30

Score range: 0 – 105
Lower score = better dietary habits.
*:p<0.05



1: England CY et al. *Public Health Nutr* 2017;20(2):191–9

Wilmot EG et al, *ATTD 2026*

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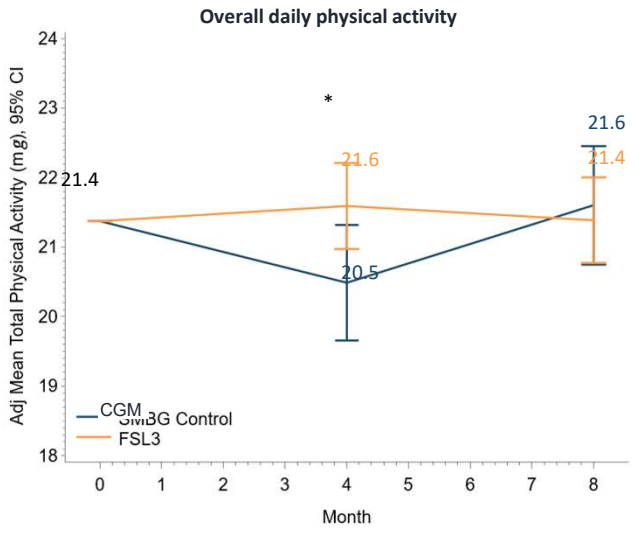
Physical Activity
Overall Daily Activity

Outcome	Month	Adjusted mean difference (95% CI)	P value
Overall daily activity, mg	**4**	**1.1** (0.1, 2.1)	**0.037***
	8	-0.2 (-1.3, 0.8)	0.69
Moderate-vigorous activity, min/day	**4**	1.4 (-3.2, 6.0)	0.54
	8	-3.5 (-8.3, 1.2)	0.14
Light-intensity activity, min/day	**4**	**12.1** (0.3, 23.9)	**0.045***
	8	5.5 (−6.5, 17.6)	0.37
Inactive, min/day	**4**	-0.4 (-16.8, 16.0)	0.96
	8	1.4 (-17.3, 20.2)	0.88

mg: milligravitational units
*: p<0.05



Wilmot EG et al, *ATTD 2026*

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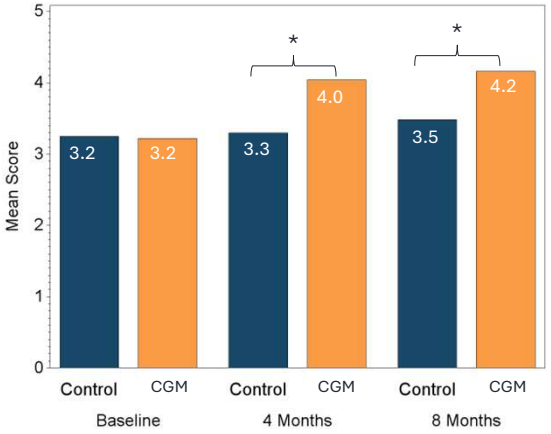
Patient Reported Outcome Measures
Glucose Monitoring Satisfaction Survey (GMSS)[1]

15 item questionnaire assessing satisfaction with glucose monitoring devices

Outcome	Month	Adjusted mean difference (95% CI)	P value
Total scale^	0	—	—
	4	**0.75** (0.60, 0.91)	**<0.0001***
	8	**0.69** (0.53, 0.86)	**<0.0001***
Openness^	0	—	—
	4	**0.72** (0.52, 0.92)	**<0.0001***
	8	**0.89** (0.68, 1.10)	**<0.0001***
Emotional burden†	0	—	—
	4	**−0.55** (−0.76, −0.34)	**<0.0001***
	8	**−0.39** (−0.60, −0.18)	**0.0003***
Behavioural burden†	0	—	—
	4	**−0.95** (−1.15, −0.74)	**<0.0001***
	8	**−0.79** (−1.02, −0.57)	**<0.0001***
Worthwhileness^	0	—	—
	4	**0.81** (0.61, 1.00)	**<0.0001***
	8	**0.70** (0.50, 0.89)	**<0.0001***

1: Polonsky WH et al. *Diabetes Technol Ther* 2015;17:657–63

GMSS total scale



Score range: 1 – 5.
^: Higher score indicates greater satisfaction, openness or worthwhileness.†: Lower score indicates less burden.
*: p<0.05

Wilmot EG et al, *ATTD 2026*

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Patient Reported Outcome Measures
Hypoglycaemia-Related

Outcome	Month	Control (N=105)	CGM (N=198*)	Adjusted mean difference (95%CI)	P value
Hypoglycaemia confidence scale, mean score	0	3.05	3.07	—	—
	4	3.19	3.41	**0.24** (0.10, 0.37)	**0.0006***
	8	3.23	3.41	**0.17** (0.03, 0.31)	**0.018***
Hypoglycaemia Fear Survey-II, mean score	0	21.2	16.2		-
	4	17.9	14.0	-1.9 (-5.0 1.2)	0.23
	8	19.4	14.9	-2.0 (-5.4, 1.5)	0.27

- HCS: 9 item questionnaire with score range 1 – 4. Higher score = increased hypoglycemia confidence.
- HFS-II, worry: 18 item questionnaire with score range: 0 – 72. Lower score = less fear
- Data shown as mean. *: p<0.05

1: Polonsky WH et al. *Diabetes Technol Ther* 2017;19(2):131–6
2: Gonder-Frederick. *Diabetes Care.* 2011;34(4):801-6

Wilmot EG et al, *ATTD 2026*

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Qualitative Interviews
Excerpts

Prof. Katharine Barnard-Kelly
Health Psychologist
Barnard Health, UK

Semi-structured 1:1 interviews with representative subgroups (n=40) at baseline and 8 months.

Baseline

It's very **hard to manage**, I don't know what's right and what's wrong

I really struggle with finger pricking … I'm a part-time musician and finger pricking was making my **fingers sore**…

I'm always **tired**, lethargic and out of energy. It's tough

CGM group at 8 months

It makes life **more manageable**, more normal … it definitely impacts my quality of life

I've **changed how I eat**, I was snacking a lot between meals but I learned a lot about food, what food does to blood sugars …

I'm anxious about the study ending and **not having access** anymore…

Wilmot EG et al, *ATTD 2026*

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Safety

Number of events during randomised period		SMBG Control (N=104)	CGM (N=199)
Death	Number of events	0	1
	Rate	0	0.5%
Severe hypoglycaemia	Number of events	2	0
	Rate	1.0%	0
HHS/ Significant ketosis events	Number of events	0	0
	Rate	0	0
Unanticipated device-related adverse events	Number of events	0	0
	Rate	0	0

- Cause of death: ischaemic heart disease, unrelated to study procedures or study device.
- Severe hypoglycaemia: requiring assistance of another person to actively administer carbohydrates, glucagon, or take other corrective actions
- HHS: hyperosmolar hyperglycaemic state
- Significant ketosis: blood ketones ≥3 mmol/L, or urinary ketones ≥++.

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FreeDM2 and MOBILE Studies

	MOBILE[1,2]	FreeDM2[3]
Population	USA: Participants under primary care. Baseline A1c 9.1% (July 2018 to October 2019)	UK: Primary and secondary care. Baseline A1c 8.8% (July 2023 to January 2025)
Self-monitoring criteria	SMBG at least 3 times / week	No minimum testing criteria
Smartphone requirement	Compatible smartphone	Smartphone provided if needed
Number randomised	CGM= 116, Control=59	CGM= 198, Control=105
Intervention	Dexcom G6	Freestyle Libre 3
% using SGLT2 at baseline	9%	87%
% using GLP-1 at baseline	20%	25%
Participant-driven phase without new medications	None	Yes – first 4 months
HbA1c (%) difference between groups (mean and 95% CI)	3M: −0.6% (−0.9, −0.3) 8M: −0.4% (−0.8, −0.1)	4M: -0.6% (-0.8, -0.3) 8M: -0.5% (-0.7, -0.2)

1. Martens T et al, *JAMA* (2021);325 (22): 2262–2272. 2. Martens TW et al, *BMJ Open Diab Res and Care* (2025); 13(6):e005469. 3. Data on file Abbott Diabetes Care.

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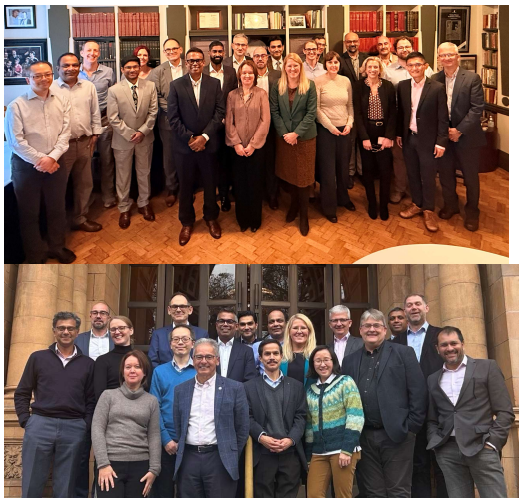
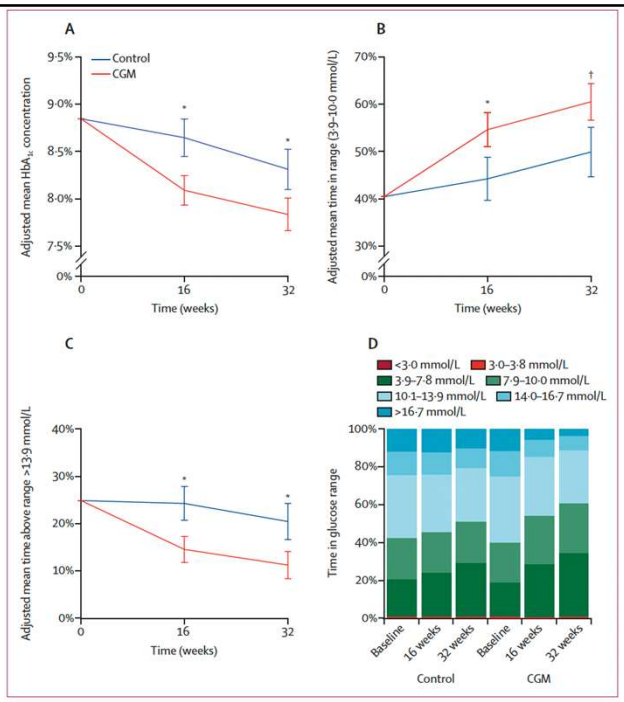
Continuous glucose monitoring versus self-monitoring of blood glucose in individuals with type 2 diabetes: a randomised, multicentre, open-label, superiority trial

Emma G Wilmot, Patrick Moore, Thozhukat Sathyapalan, Pratik Choudhary, Jonathan Z M Lim, Sankalpa Neupane, Thomas S J Crabtree, Ahmed Iqbal, Mark L Evans, Gerry Rayman, Hermione C Price, Ramji A Ajjan, Yee S Cheah, Alistair Lumb, Samiul Mostafa, Iqbal Malik, Iain Cranston, Thinzar Min, Edward B Jude, Shivshankar Seechurn, James McLaren, Katharine Barnard-Kelly, Thomas Yates, Rachel A Elliott, Lalantha Leelarathna, on behalf of the FreeDM2 Study Group*





Lancet Diabetes & Endocrinology 23 April 2026

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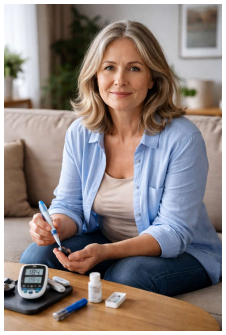
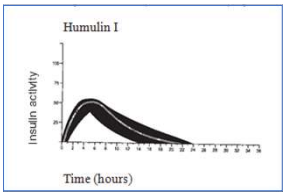
Back to the Clinical Case Study

55 year old female

Medical history	Type 2 diabetes for 12 years
Profile	• BMI 29kg/m2 • HbA1c 9.6% (chronically elevated) • Only checks blood glucose for a few days before diabetes clinic
Management	• Humulin I 19u BD (Isophane, intermediate-acting) • Empagliflozin 25mg OD • Gliclazide 160 mg BD Declined statin, Intolerant of metformin and GLP-1





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Glucose Data

	Pre-breakfast	Pre-lunch	Pre-dinner	Pre-bed
Sunday	4.9			
Monday	5.2			
Tuesday				
Wednesday	6.3			
Thursday	5.1			

Question: How will you alter the insulin dosing (Humulin i 19 units BD)?

a) Increase the morning dose
b) Increase the evening dose
c) Add in prandial insulin
d) Wait for more blood glucose data first
e) Wait and give a trial of real-time-CGM first

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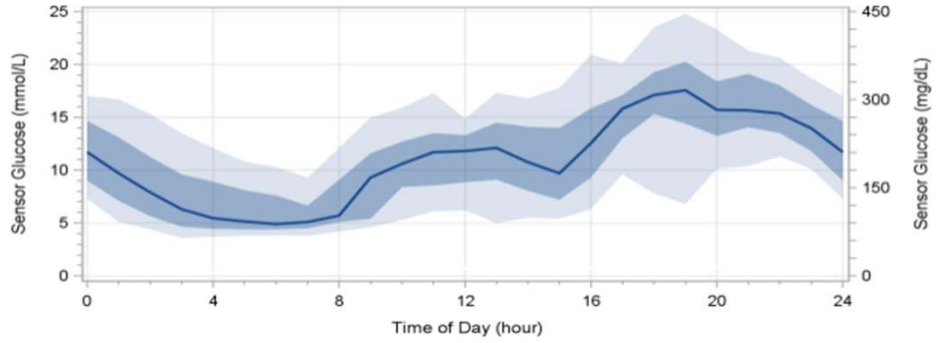
CGM Insights...First Two Weeks

	Pre-breakfast	Pre-lunch	Pre-dinner	Pre-bed
Sunday	4.9			
Monday	5.2			
Tuesday				
Wednesday	6.3			
Thursday	5.1			



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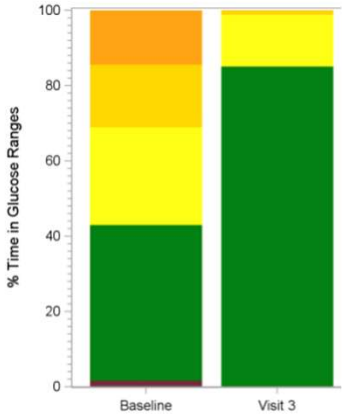
After Four Months

- Patient used Freestyle Libre 3 for 4 months
- Gained insight into the impact of foods on her glucose levels
- Made changes to her diet: avoiding chocolates, sweets and eating less bread
- By 4 months she had reduced her insulin dose from 19u BD to 14u BD
- Time in Range improved from 41 to 85%
- HbA1c improved from 9.6% to 6.9%



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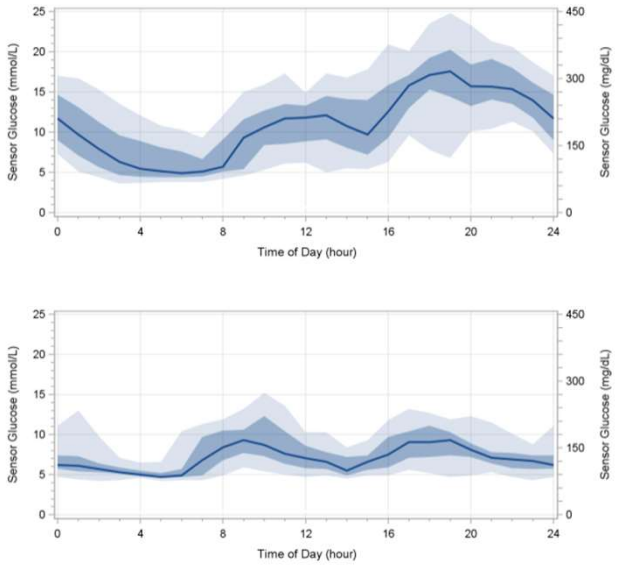
CGM Insights - After Four Months



HbA1c 9.6%
TIR 41%

HbA1c 6.9%
TIR 85%

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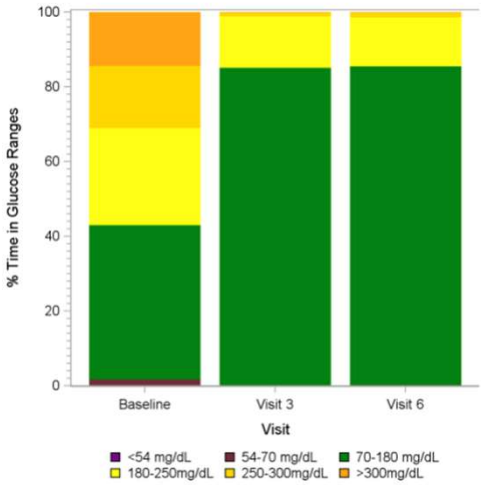
After 8 Months of Freestyle Libre 3

- By 8 months she had further reduced her insulin dose to
  - 10 units morning
  - 12 units at night
- Sustained improvements in dietary intake
- Time in Range 85%
- HbA1c improved
  - 9.6% at start
  - 6.9% at 4 months
  - 6.5% at 8 months
  - 6.6% at 12 months
- Weight reduced 96 to 87kg



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FreeDM2 Conclusions

The use of real-time CGM by people living with T2DM on basal insulin led to a clinically and statistically **significant improvement in HbA1c** vs control at 4 and 8 months

- **Significant improvements** in **sensor-measured** glycaemia and **participant reported outcomes** were also observed.
- Improvements were achieved **without** increased hypoglycaemia.
- Improvements were observed with **self-management** and **sustained** following **clinician intervention.**

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Acknowledgements

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Participant Identification Centres

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Trial Steering Committee

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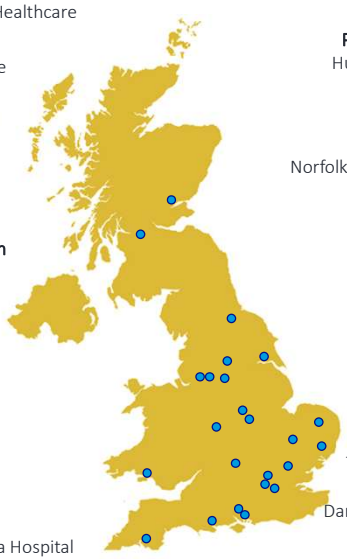

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Tameside General Hospital
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Darlington Memorial Hospital
Dr James McLaren
NHS Lanarkshire
Dr Shivshankar Seechurn
Northwick Park Hospital

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Thank You

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INTERACTIVE DIALOGUE SESSION

Your Questions, Perspectives, and Discussion Points

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