Update on Diabetes Technology and the National Closed Loop Pilot

Peter Hammond

Consultant Endocrinologist

Harrogate and District NHS Foundation Trust

Disclosures

Honoraria from

- Medtronic
- Insulet
- Roche
- Abbott
- Novo Nordisk
- Sanofi
- Lilly
- Glooko/Diasend

Overview

- Advances in glucose monitoring –
  - Continuous glucose monitoring and flash monitoring options – NICE guidance and selecting the right option
- Selecting the right technology for the individual person –
  - NICE guidance when to offer a hybrid closed loop, options and optimisation

Continuous Glucose Monitoring vs Flash glucose Monitoring

Intermittent and real-time continuous glucose monitoring systems comparison chart

Diabetes Specialist Nurse Forum UK

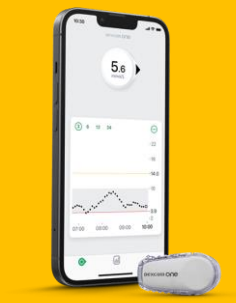
Diabetes Specialist Nurse Forum UK	Freestyle Libre 2	Freestyle Libre 3	Dexcom One	Dexcom G6	Dexcom G7	Medtronic G4	GlucoRx AiDEX	Medtrum Touch Care Nano
Real-time CGM	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes
MARD	9.2	7.8	9.0	9.0	8.2	10.6	9.1	9.1
Published accuracy data	Yes (T1 n=133)	Yes (T1 n=83)	Yes (T1 n=260)	Yes (T1 n=260)	Yes (T1 n=257)	Yes	Yes (T1 n=14)	Yes (T1 n=10)
RCT data	Yes	Yes (FSL/FSL2)	Yes (G4/5/6)	Yes	No	No	No	No
Sensor life	14 days	14 days	10 days	10 days	10 days + 12 hr grace period	7 days	14 days	7-14 days
Sensor warm up time	60 mins	60 mins	120 mins	120 mins	30 mins	120 mins	60 mins	120 mins
Separate transmitter	No	No	Yes	Yes	No	Yes	Yes	Yes
Transmitter Life	N/A	N/A	3 months	3 months	N/A	12 months	4 years	12 months
Smartphone app	LibreLink	Libre 3	Dexcom One	Dexcom G6	Dexcom G7	MiniMed	GlucoRx AiDEX	EasySense
Reader available	Yes	No	Yes	Yes	Yes	No	No	Yes
Capillary glucose calibration	No	No	No	No	No	No	No	Every 12-24 hrs
High & low alarms	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Predictive alarms	No	No	No	Yes	Yes	Yes	No	Yes
Stand-alone use	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes
Pump compatibility	No	YpsoPump	No	Tandem T:slim DANA-i YpsoPump Omnipod 5*	No	Medtronic 780G	No	Touch Care Nano pump
Closed loop compatibility	No	Yes	No	Yes	No	Yes	No	Auto-suspend only
Data share HCP	Libreview	Libreview	Clarity	Clarity	Clarity	CareLink	CGM Viewer	EasyView
Data share friends/family app	LibreLinkUp	LibreLinkUp	N/A	Dexcom Follow	Dexcom Follow	CareLink Connect	GlucoRx AiDEX	EasyFollow
UK approved wearable site	Upper arm	Upper arm	Abdomen Upper arm Buttocks +	Abdomen Upper arm Buttocks +	Abdomen Upper arm Buttocks +	Abdomen Upper arm	Abdomen Upper arm	Abdomen Upper arm

= available on prescription (FP10)

+ 2-17 years old , please check manufacturers' guidelines for age specific licences

* Expected Mid 2023

Version 3.0 May 2023

	Guardian Connect	780G	Dexcom G6/G7	Dexcom One	Freestyle Libre 2
DTN UK collaborate · evolve · support					
Sensor life	7 days		10 days	10 days	14 days
Real-time CGM	**Yes**		**Yes**	**Yes**	**No**
Size (cm)	1.93 x 1.14 x 0.97 (s) 3.56 x 2.79 x 0.76 (t)		3.8 x 2.3 x 1.2 (G6) 2.4 x 2.73 x 0.46 (G7)	3.8 x 2.3 x1.2	3.5: diameter; x 0.5
Site	Arm; abdomen		Arm; abdomen	Arm; abdomen	Arm
Measurement frequency	5 minutes		5 minutes	5 minutes	5 minutes
Alarms	Multiple		Multiple	High/low alert	High/low alert
Calibration	None		None	None	None
MARD	8.6%		8.2% (G7 arm), 9.0%	9.0%	9.7%

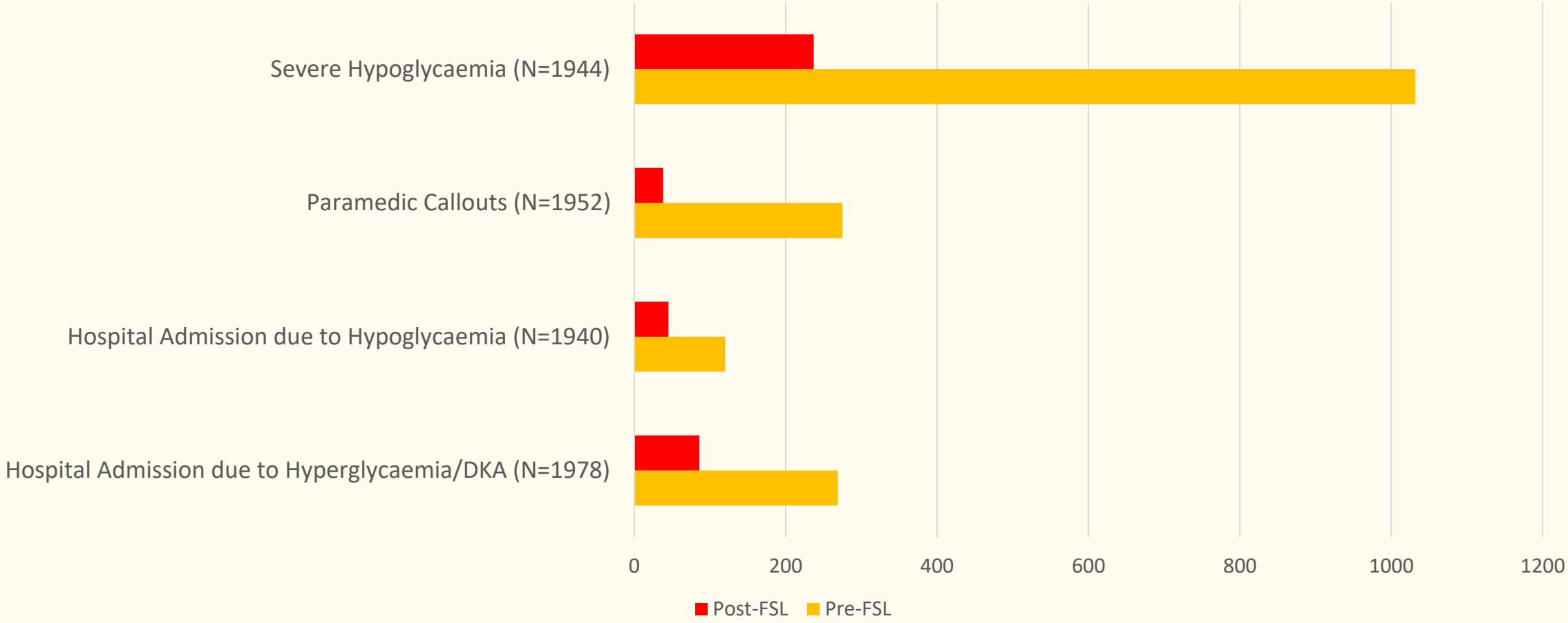
New Glucose Sensors

DEXCOM G7

LIBRE 3

Real-time CGM or Libre?

ABCD Freestyle Libre Audit



Deshmukh H et al. *Diabetes Care* 2020;43(9):2153–2160

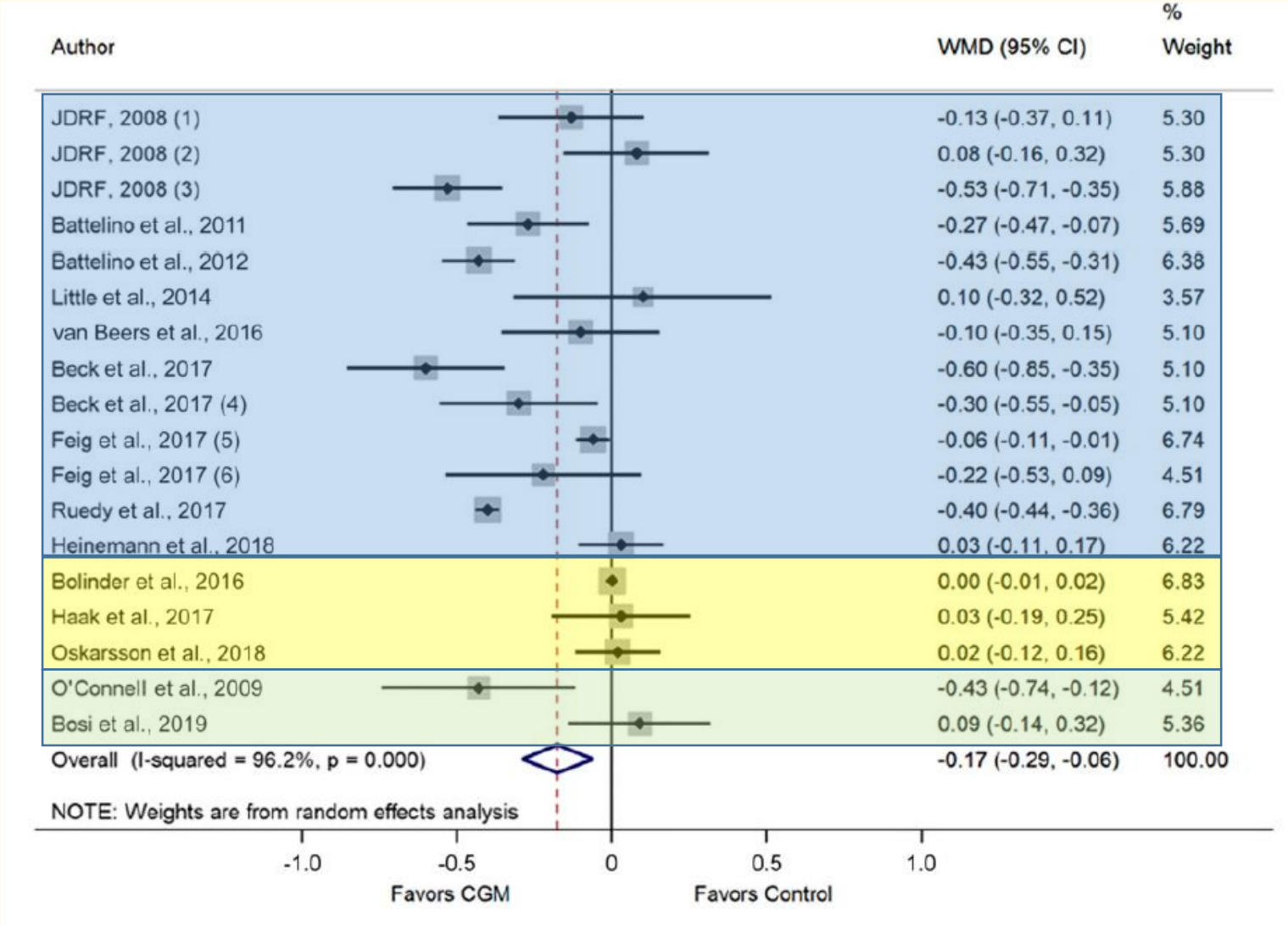
Harrogate and District NHS Foundation Trust
You matter most

CGM RCTs – systematic review

rtCGM

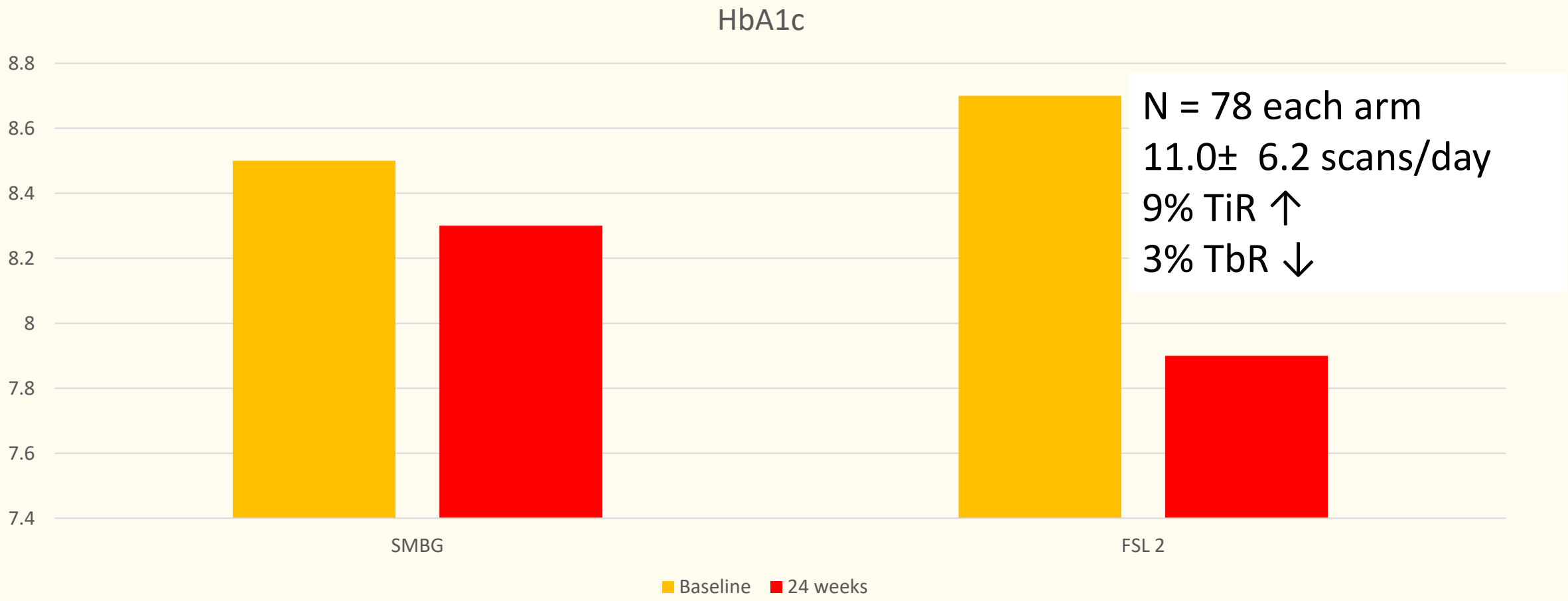
isCGM

SAP



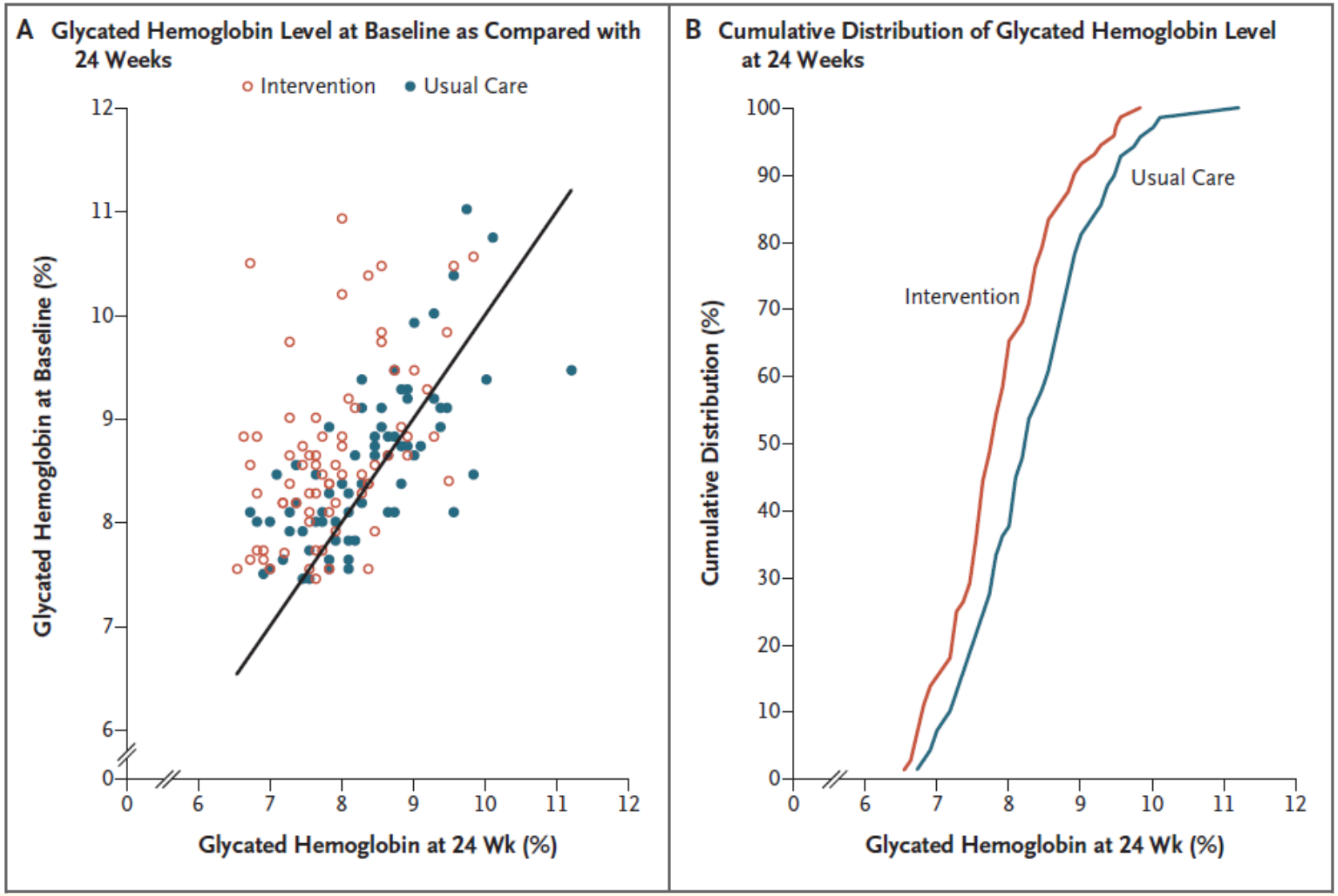
Maiorino I et al. *Diabetes Care* 2020;43:1146-56.

FLASH-UK Trial



Leelarathna L et al. *N Engl J Med* 2022;387:1477-87.

FLASH-UK Trial



Leelarathna L et al. *N Engl J Med* 2022;387:1477-87.

FSL 1 vs 2 real-life study

- Lothian region
- 672 patients converted – 12 months follow-up
- 410 reported on use of alarms
  - 308 actively used low-glucose alarms
  - 225 actively used high-glucose alarms
- TbR: reduced from 3.0% to 2.0% (89 to 77 minutes)
- TaR: increased from 42.0 to 45.0%

Gibbs et al. *EASD 2022*

CORRIDA real-life study

- 191 adults, mean HbA1c 65 mmol/mol
- 81 started CGM, 110 started FGM
- HbA1c: 54.1 mmol/mol (CGM) vs 61.2 mmol/mol (FGM)
- TiR: 67.5% vs 57.8%
- TbR: 4.3% vs 6.4%
- Time below 3.0 mmol/L: 0.9% vs 2.3%

Radovnicka L et al. *Diab Tech Ther* 2022 published online 25.11.22.

ALERTT1 study

- 254 patients using FGM
- Randomly assigned to FGM (127) or CGM (127)
- 122 FGM and 124 CGM participants completed
- HbA1c at baseline 7.4% in both groups
- HbA1c: 7.4% in FGM, 7.1% in CGM group at 6 months
- Severe hypoglycaemia events: 30 FGM, 3 CGM

Visser M et al. *Lancet* 2021;397:2275-83.

Yorkshire and the Humber Guidance for Implementing NICE CGM Recommendations

Criteria for choice of advanced rt-CGM rather than prescribable FGM / CGM for adults with Type 1 diabetes

Background

The updated NICE guideline, NG17, has recommended that all adults with type 1 diabetes should be offered either flash glucose monitoring (FGM) or continuous glucose monitoring (CGM) as their primary tool for monitoring glucose levels. FGM or Dexcom One can be regarded as the default monitoring technology with more advanced real-time continuous glucose monitoring (rt-CGM), as the more expensive technology, being considered when certain additional criteria are met. The guideline advised considering the following factors when making a decision as to which monitoring technology to offer:

- Accuracy of the device
- Whether the device provides predictive alerts or alarms and if these need to be shared with anyone else (for example, a carer)
- Whether using the device requires access to particular technologies (such as a smartphone and up-to-date phone software)
- How easy the device is to use and take readings from, including for people with limited dexterity
- Fear, frequency, awareness and severity of hypoglycaemia
- Psychosocial factors
- The person's insulin regimen or type of insulin pump, if relevant (taking into account whether a particular device integrates with their pump as part of a hybrid closed loop or insulin suspend function)
- Whether, how often, and how the device needs to be calibrated, and how easy it is for the person to do this themselves
- How data can be collected, compatibility of the device with other technology, and whether data can be shared with the person's healthcare provider to help inform treatment
- Whether the device will affect the person's ability to do their job
- How unpredictable the person's activity and blood glucose levels are and whether erratic blood glucose is affecting their quality of life
- Whether the person has situations when symptoms of hypoglycaemia cannot be communicated or can be confused (for example, during exercise)
- Clinical factors that may make devices easier or harder to use
- Frequency of sensor replacement
- Sensitivities to the device, for example local skin reactions
- Body image concerns

Default glucose monitoring systems

The default glucose monitoring systems are the Freestyle Libre or the Dexcom One, both of which can be prescribed on an FP10 prescription, and the person with diabetes should be offered whichever of these two devices they prefer.

We would recommend that Dexcom One is the preferred option to Freestyle Libre for the following indications:

- For MDI users who are not achieving target glycaemic control - people using multiple daily injections (MDI) and FGM who have HbA1c ≥ 69 mmol/mol should be switched to Dexcom One and if there is still no improvement in glycaemic control then insulin pump therapy should be considered in line with NICE TA 151

- For people experiencing recurrent DKA (diabetic ketoacidosis): a switch to Dexcom One should be considered after a second episode of DKA whilst using FGM with MDI or pump therapy. If episodes continue then a switch to advanced rt-CGM should be considered.

- For those with occupational factors, dexterity issues or caring requirements which mean that DEXCOM One provides them and/or their carers with more consistent information about their glucose status than intermittent scanning with FGM would.

- Women planning pregnancy: if Dexcom One is used pre-pregnancy women can then use Dexcom G6 (or G7 when available) during pregnancy, for the 12 months of NHS funded advanced rt-CGM, and then revert to Dexcom One post-partum.

These two devices should be offered and prescribed via an FP-10, unless the person with type 1 diabetes meets the criteria below.

Criteria for offering advanced rt-CGM* rather than FGM (Freestyle Libre)/DEXCOM One

- Problematic hypoglycaemia:
  - Recurrent episodes of severe hypoglycaemia – at least two events in 12 months, or
  - Impaired hypoglycaemia awareness – GOLD score ≥ 4
  - High volume of hypoglycaemia on FGM/DEXCOM One > 7% time below range < 4 mmol/L, or >1% < 3 mmol/L

- *For use in a hybrid closed loop (HCL) system:*
  - *People using an insulin pump and FGM where HbA1c remains ≥ 69 mmol/mol after at least 6 months using these technologies together. For continued use of an HCL the user must show an improvement in glucose control as evidenced by a fall in HbA1c of at least 5 mmol/mol and/or and increase in Time in Range of 10%*

- Where an adolescent with type 1 diabetes is transitioning to adult services already using advanced rt-CGM

Proposal for implementation of continuous glucose monitoring for people with Type 2 diabetes

Background

The updated NICE guideline, NG28, has made the following recommendations:

1. Offer intermittently scanned continuous glucose monitoring (isCGM, commonly referred to as 'flash' or FGM) to adults with type 2 diabetes on multiple daily injections if any of the following apply:

- they have recurrent hypoglycaemia or severe hypoglycaemia
- they have impaired hypoglycaemia awareness
- they have a condition or disability (including a learning disability or cognitive impairment) that means they cannot self-monitor their blood glucose by capillary blood glucose monitoring but could use an isCGM device (or have it scanned for them)
- they would otherwise be advised to self-measure at least 8 times a day.

2. Offer isCGM to adults with insulin-treated type 2 diabetes who would otherwise need help from a care worker or healthcare professional to monitor their blood glucose.

Consider real-time continuous glucose monitoring (rt-CGM) as an alternative to isCGM/FGM for adults with insulin-treated type 2 diabetes if it is available for the same or lower cost.

Local implementation of NICE guidance

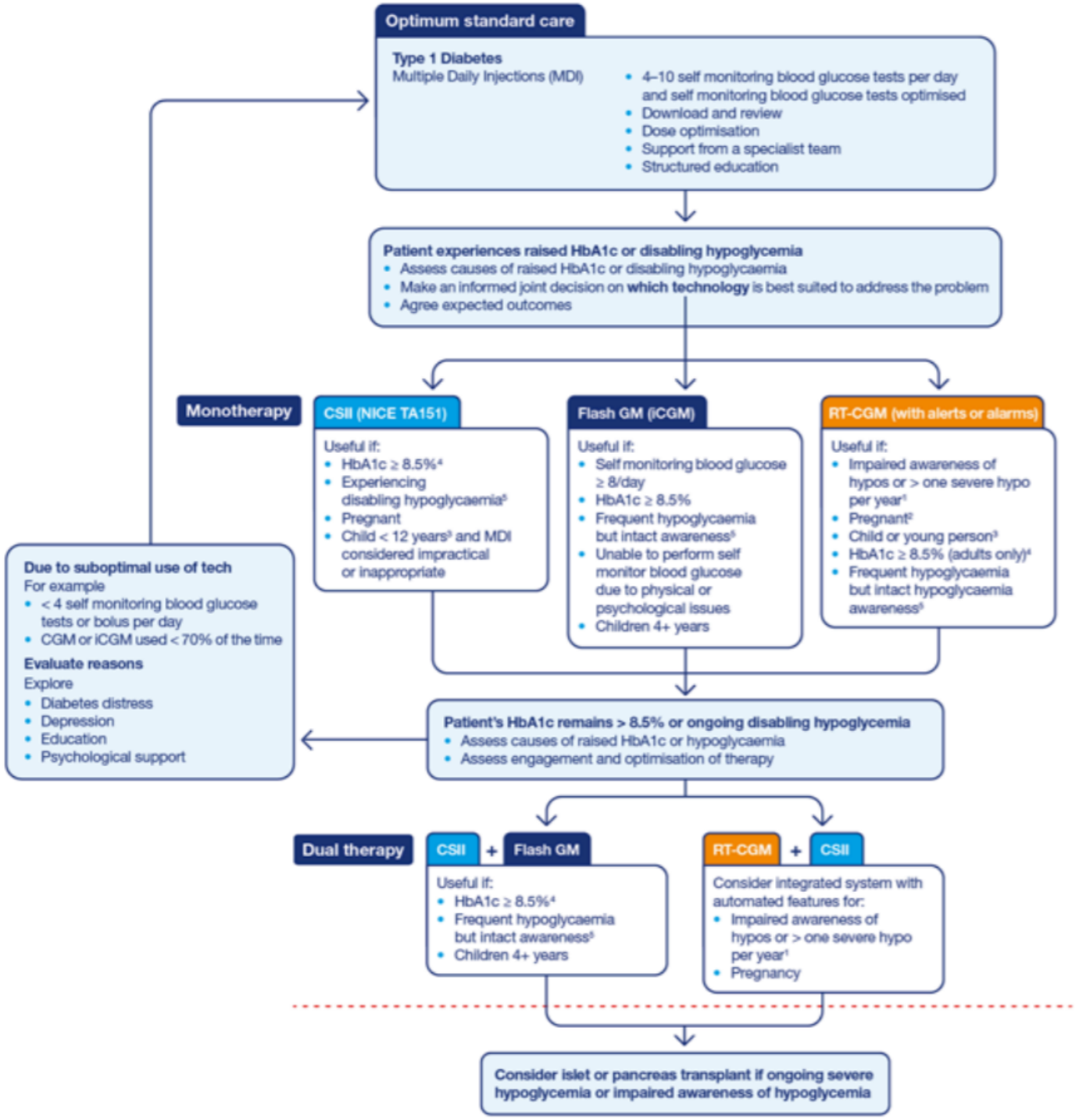
Continuous glucose monitoring options for people with type 2 diabetes are the Freestyle Libre or the Dexcom One, both of which can be prescribed on an FP10 prescription. These should be offered to anyone who is giving two or more insulin injections per day and fulfils any of the above NICE criteria (see flowchart*).

Consideration should be given as to whether the use of CGM in these scenarios can be time-limited if the problem is solved by management changes prompted by the use of CGM. For example CGM could be prescribed for 3 months to optimise insulin doses and dietary habits to help people:

- With poor glycaemic control achieve an HbA1c target of <69 mmol/mol suitable for surgery
- Reduce the occurrence of problematic hypoglycaemia
- Discharged from hospital due to hyper- or hypoglycaemia to stabilise their glucose control, to help prevent re-admission

Selecting the Right Technology for the Individual

When to offer Hybrid Closed Loop



Diabetes Technology Pathway

DUK. Type 1 Diabetes Technology: A consensus guideline
Available on www.diabetes.org

Harrogate and District NHS
NHS Foundation Trust
You matter most

Automated Hybrid Closed Loop Insulin Delivery

Automated Insulin Delivery Systems

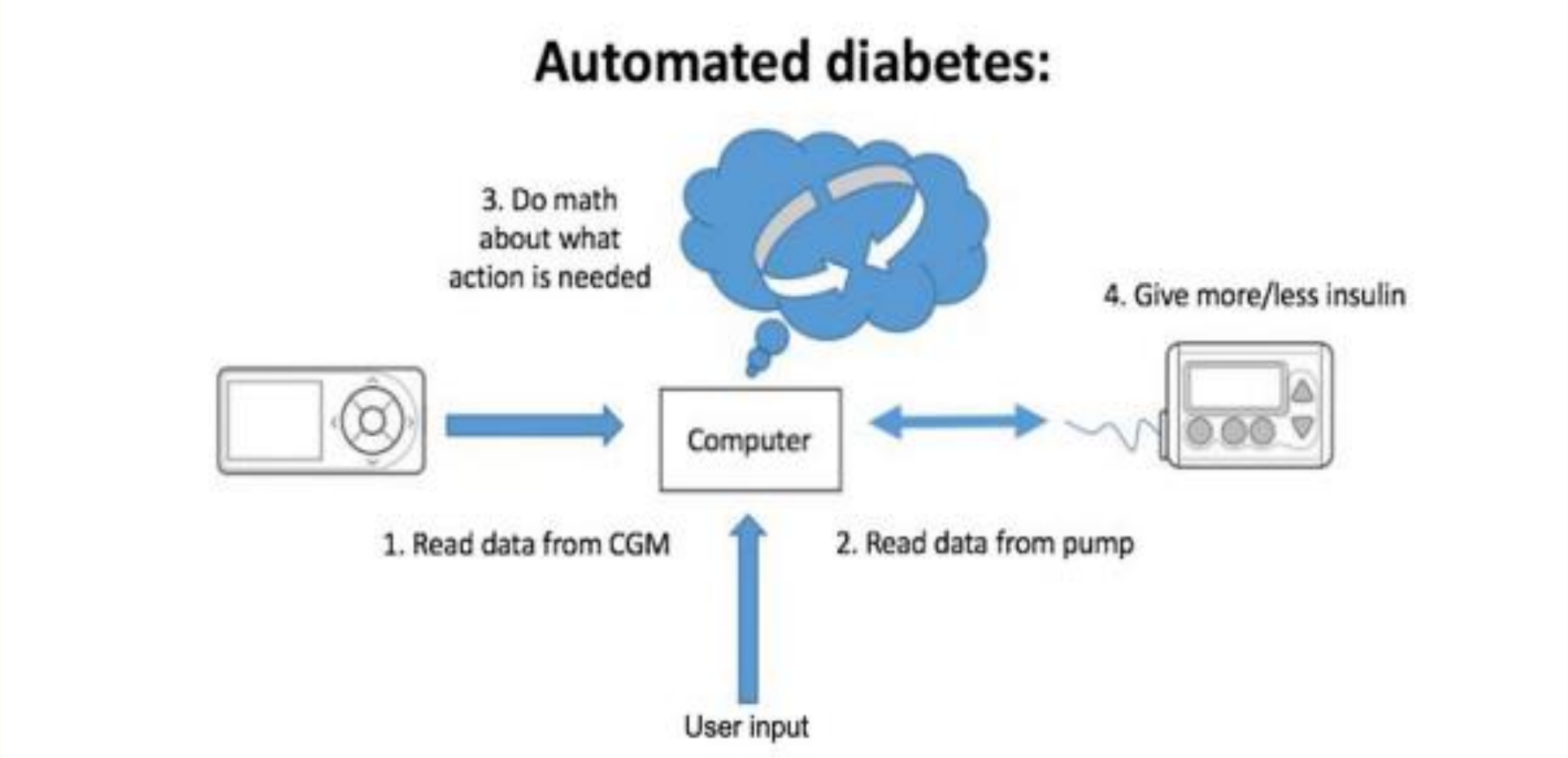


Figure adapted with permission from Lewis D, Automated Insulin Delivery, ISBN 9781797763699, https://www.artificialpancreasbook. com Dana Lewis 2019 and taken from Marshall, Holloway, Korer, Woodman, Brackenridge, Hussain, Diabetes Ther. 2019

Automated Insulin Delivery Systems

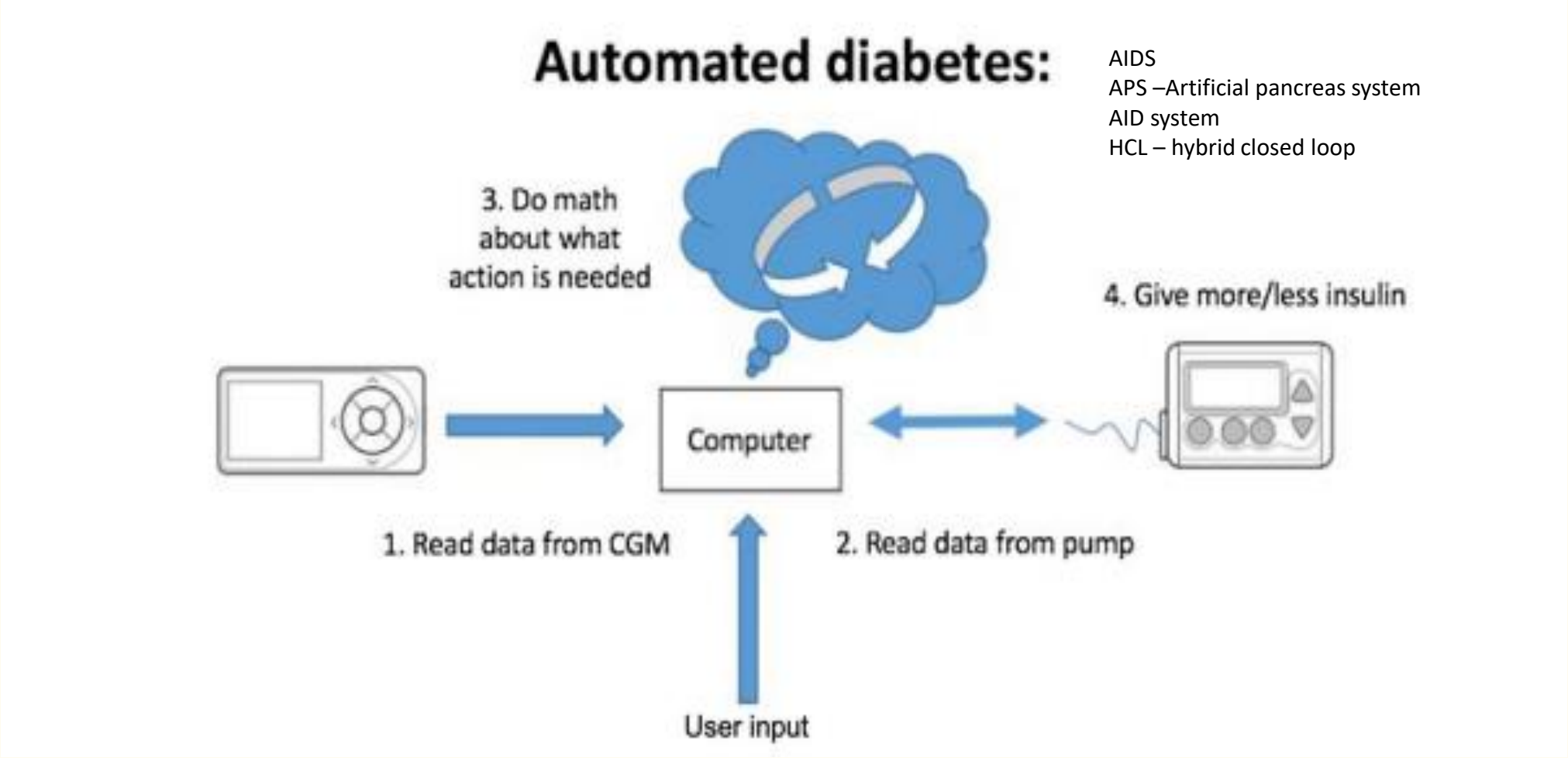


Figure adapted with permission from Lewis D, Automated Insulin Delivery, ISBN 9781797763699, https://www.artificialpancreasbook. com Dana Lewis 2019 and taken from Marshall, Holloway, Korer, Woodman, Brackenridge, Hussain, Diabetes Ther. 2019

Automated Insulin Delivery: Benefits, Challenges, and Recommendations. A Consensus Report of the Joint Diabetes Technology Working Group of the European Association for the Study of Diabetes and the American Diabetes Association

Jennifer L. Sherr,[1] Lutz Heinemann,[2] G. Alexander Fleming,[3] Richard M. Bergenstal,[4] Daniela Bruttomesso,[5] Hélène Hanaire,[6] Reinhard W. Holl,[7,8] John R. Petrie,[9] Anne L. Peters,[10] and Mark Evans[11]

Diabetes Care 2022;45:3058–3074 | https://doi.org/10.2337/dci22-0018

Endocrine Reviews, 2022, **00**, 1–27
https://doi.org/10.1210/endrev/bnac022
Advance access publication 6 September 2022
Review

Consensus Recommendations for the Use of Automated Insulin Delivery Technologies in Clinical Practice

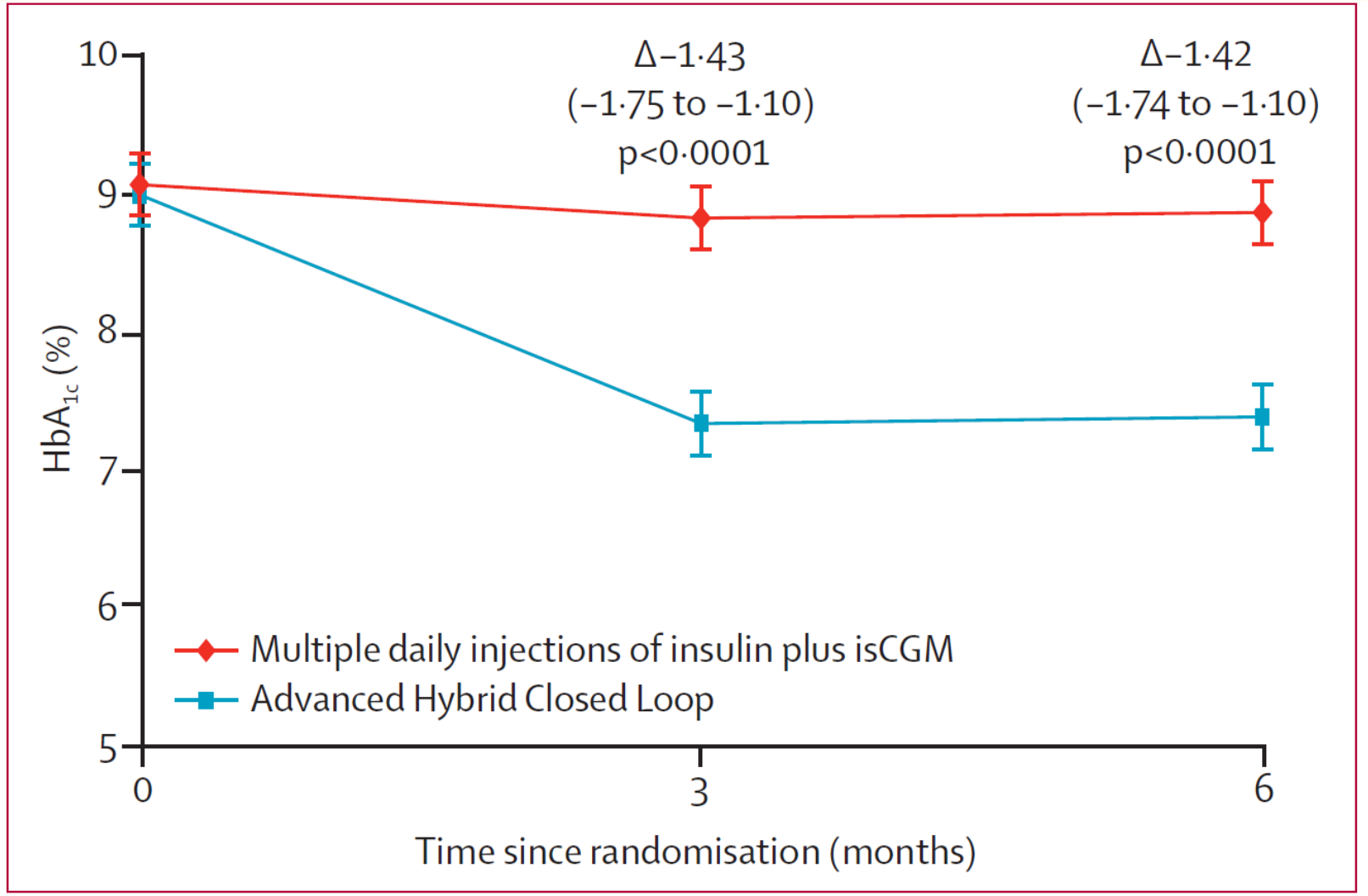
Moshe Phillip,[1,2,*] Revital Nimri,[1,2,*] Richard M. Bergenstal,[3] Katharine Barnard-Kelly,[4] Thomas Danne,[5] Roman Hovorka,[6] Boris P. Kovatchev,[7] Laurel H. Messer,[8] Christopher G. Parkin,[9] Louise Ambler-Osborn,[10] Stephanie A. Amiel,[11] Lia Bally,[12] Roy W. Beck,[13] Sarah Biester,[5] Torben Biester,[5] Julia E. Blanchette,[14,15] Emanuele Bosi,[16] Charlotte K. Boughton,[17] Marc D. Breton,[7] Sue A. Brown,[7,18] Bruce A. Buckingham,[19] Albert Cai,[20] Anders L. Carlson,[3] Jessica R. Castle,[21] Pratik Choudhary,[22] Kelly L. Close,[20] Claudio Cobelli,[23] Amy B. Criego,[3] Elizabeth Davis,[24] Carine de Beaufort,[25] Martin I. de Bock,[26] Daniel J. DeSalvo,[27] J. Hans DeVries,[28] Klemen Dovc,[29] Francis J. Doylelll,[30] Laya Ekhlaspour,[31] Naama Fisch Shvalb,[1] Gregory P. Forlenza,[8] Geraldine Gallen,[11] Satish K. Garg,[8] Dana C. Gershenoff,[3] Linda A. Gonder-Frederick,[7] Ahmad Haidar,[32] Sara Hartnell,[33] Lutz Heinemann,[34] Simon Heller,[35] Irl B. Hirsch,[36] Korey K. Hood,[37] Diana Isaacs,[38] David C. Klonoff,[39] Olga Kordonouri,[5] Aaron Kowalski,[40] Lori Laffel,[10] Julia Lawton,[41] Rayhan A. Lal,[42] Lalantha Leelarathna,[43] David M. Maahs,[19] Helen R. Murphy,[44] Kirsten Nørgaard,[45] David O'Neal,[46] Sean Oser,[47] Tamara Oser,[47]

ADAPT

- 82 patients on MDI + FGM with HbA1c > 64 mmol/mol
- Randomly assigned (1:1) to continue or switch to AHCL
- Medtronic AHCL – equivalent to 780G
- 39 control, 36 AHCL completed study

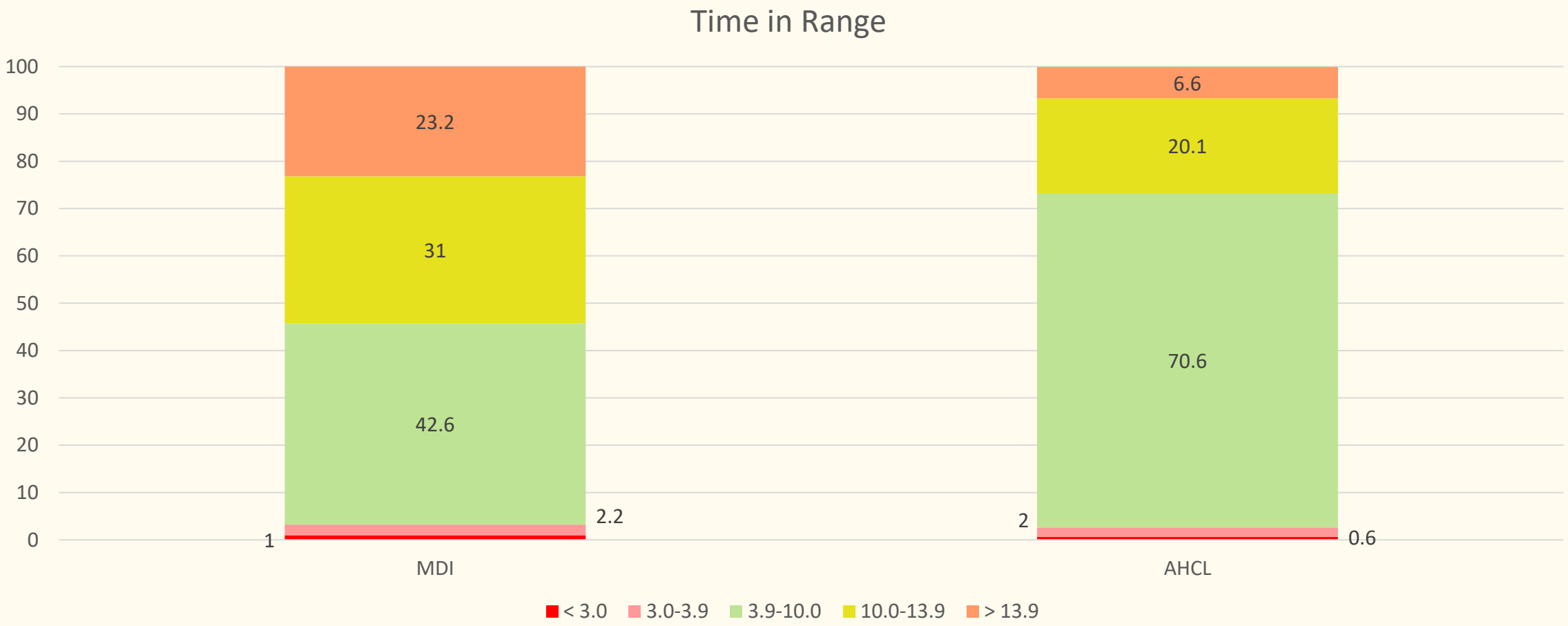
Choudhary P et al. *Lancet Diabetes Endocrinol* 2022;10:720-31.

ADAPT



Choudhary P et al. *Lancet Diabetes Endocrinol* 2022;10:720-31.

ADAPT



Choudhary P et al. *Lancet Diabetes Endocrinol* 2022;10:720-31.

ADAPT – PROMS

	N	Multiple daily injections of insulin plus isCGM group	N	Advanced hybrid closed loop group	Model-based treatment effect
Change in DTSQs scores from baseline					
Treatment satisfaction score	39	0·2 (6·84)	35	6·1 (7·55)	6·2 (2·9 to 9·4; p=0·0003)
Perceived frequency of hyperglycaemia score	39	−0·3 (1·49)	35	−2·0 (1·69)	−1·8 (−2·5 to −1·0; p<0·0001)
Perceived frequency of hypoglycaemia score	39	0·2 (1·44)	35	−0·4 (1·80)	−0·5 (−1·2 to 0·3; p=0·22)
Change in DTSQc scores from baseline					
Treatment satisfaction score	38	3·7 (7·24)	35	13·7 (4·39)	9·8 (7·04 to 12·64; p<0·0001)
Perceived frequency of hyperglycaemia score	38	0·8 (1·42)	35	−1·1 (1·77)	−2·0 (−2·7 to −1·2; p<0·0001)
Perceived frequency of hypoglycaemia score	38	0·1 (1·27)	35	−0·5 (1·80)	−0·5 (−1·2 to 0·3; p=0·22)
Change in Hypoglycaemia Fear Survey scores from baseline					
Behaviour	39	−0·7 (7·52)	35	−4·8 (8·73)	−3·8 (−7·5 to −0·1; p=0·047)
Worry	39	−2·0 (8·58)	35	−5·4 (10·42)	−3·0 (−7·4 to 1·4; p=0·18)
Total score	39	−2·7 (13·08)	35	−10·2 (15·51)	−6·9 (−13·5 to −0·3; p=0·041)
Change in DQoL scores from baseline*					
Treatment satisfaction score	25	−2·7 (13·57)	24	10·3 (16·35)	12·4 (3·9 to 21·0; p=0·0052)
Treatment impact score	24	0·1 (6·69)	24	4·4 (8·05)	4·0 (−0·2 to 8·3; p=0·062)
Social worry score	13	2·3 (10·64)	19	−0·3 (14·78)	−2·1 (−11·2 to 7·0; p=0·64)
Diabetes worry score	16	6·7 (12·99)	19	5·4 (15·41)	−1·7 (−11·3 to 7·8; p=0·72)
Total score	25	1·5 (10·08)	24	5·9 (10·60)	3·8 (−2·1 to 9·7; p=0·20)
General well-being score	24	−1·3 (11·96)	22	6·1 (16·96)	7·2 (−1·4 to 15·8; p=0·10)

Values are mean (SD) unless otherwise stated. DTSQs=Diabetes Treatment Satisfaction Questionnaire–status. DTSQc=Diabetes Treatment Satisfaction Questionnaire–change. isCGM=intermittently scanned continuous glucose monitoring. *QoL assessment was only conducted in study centres in France and the UK owing to the absence of a German validation of the Diabetes Quality of Life Questionnaire (DQoL).

***Table 3*: Patient-reported outcomes during the 6-month study phase**

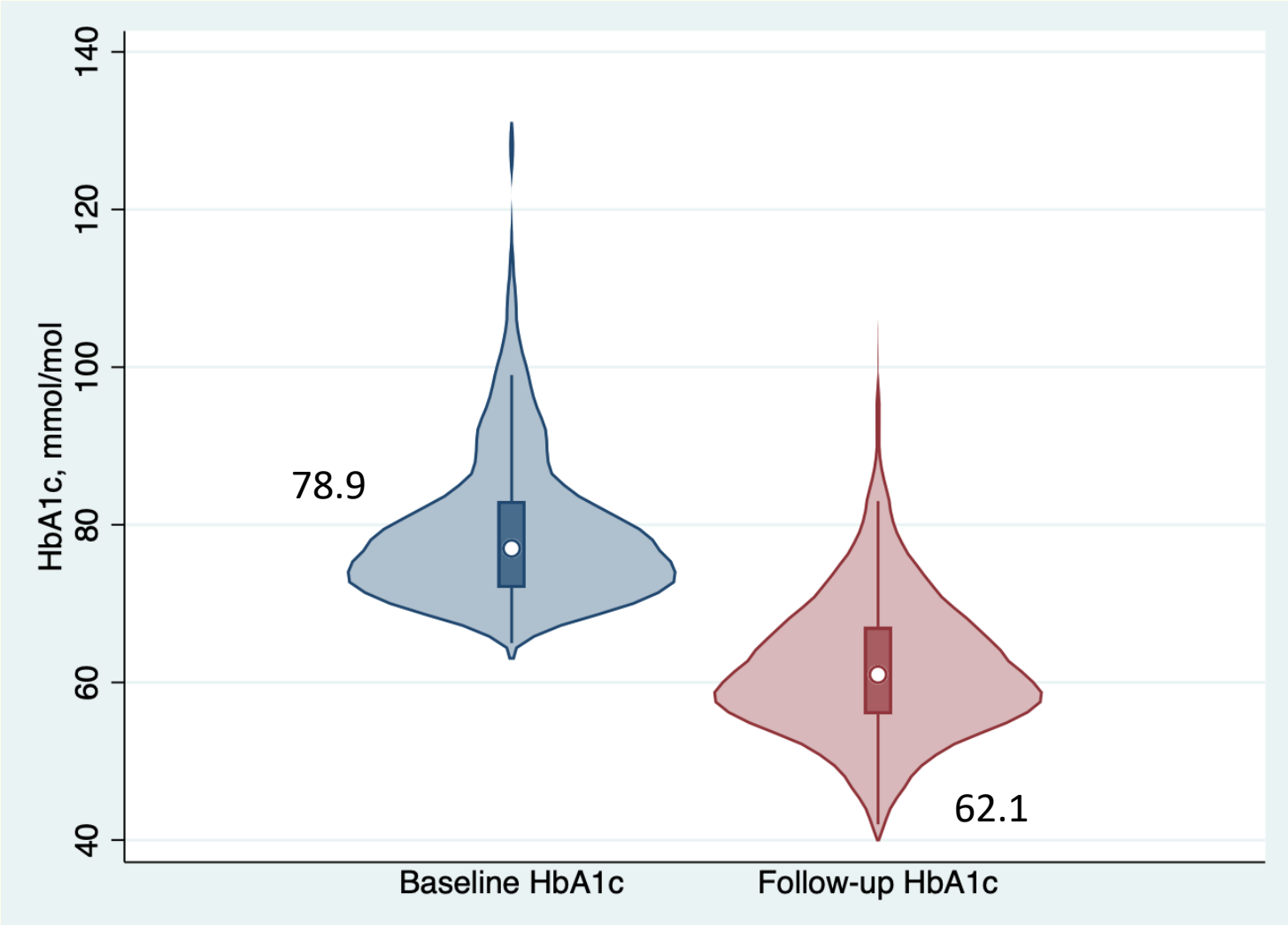
Choudhary P et al. *Lancet Diabetes Endocrinol* 2022;10:720-31.

NHSE Pilot

- 570 pilot patients – 520 HCL users
- At baseline on CSII + FGM for at least 6 months and HbA1c $\geq$ 69 mmol/mol
- 69% female; 39% from 2 most deprived quintiles
- 46% Medtronic 780G
- 37% Tandem Control IQ
- 96% time spent in closed loop

Crabtree T et al. *Pending publication*.

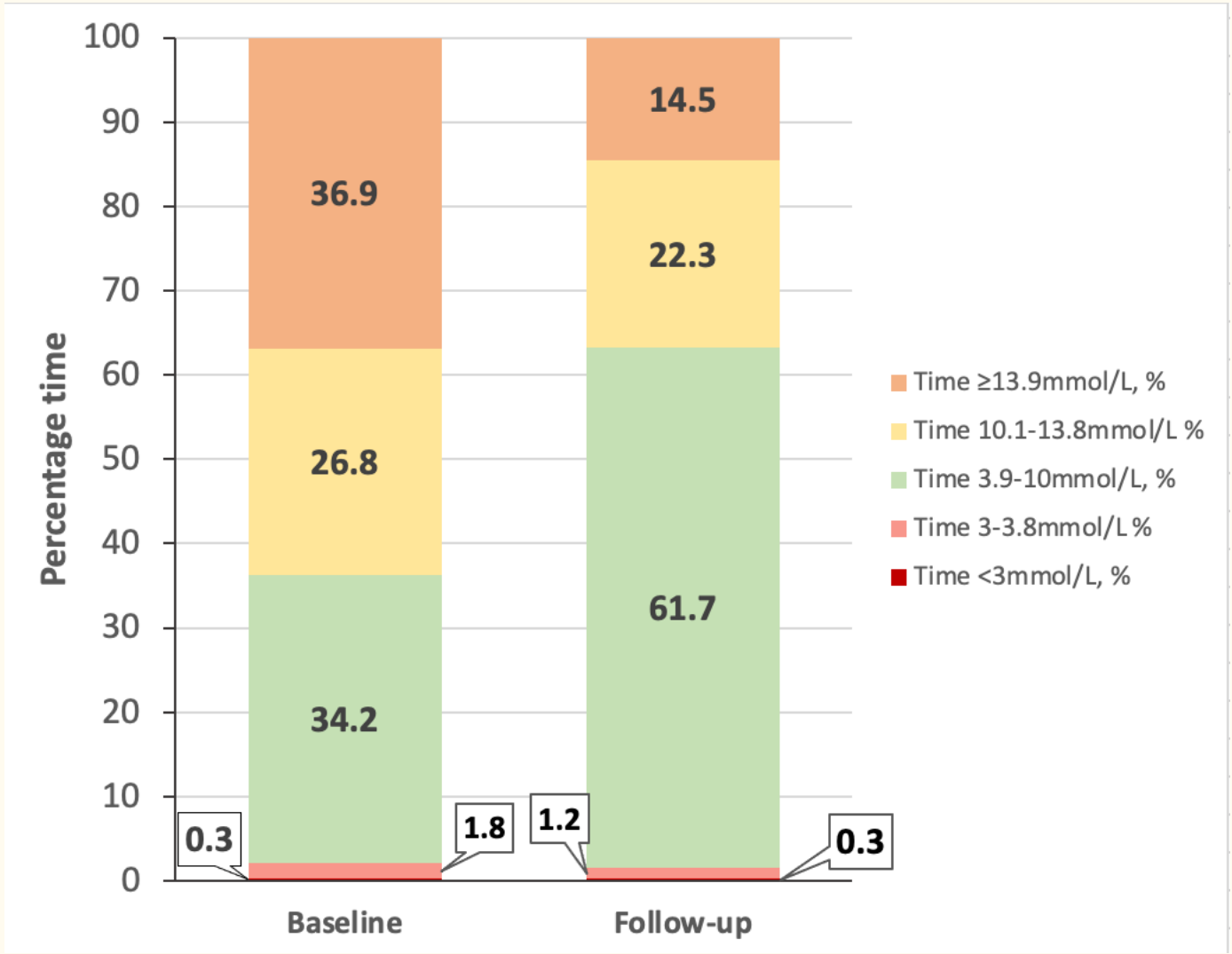
NHSE Pilot – HbA1c



Crabtree T et al. *Pending publication*.

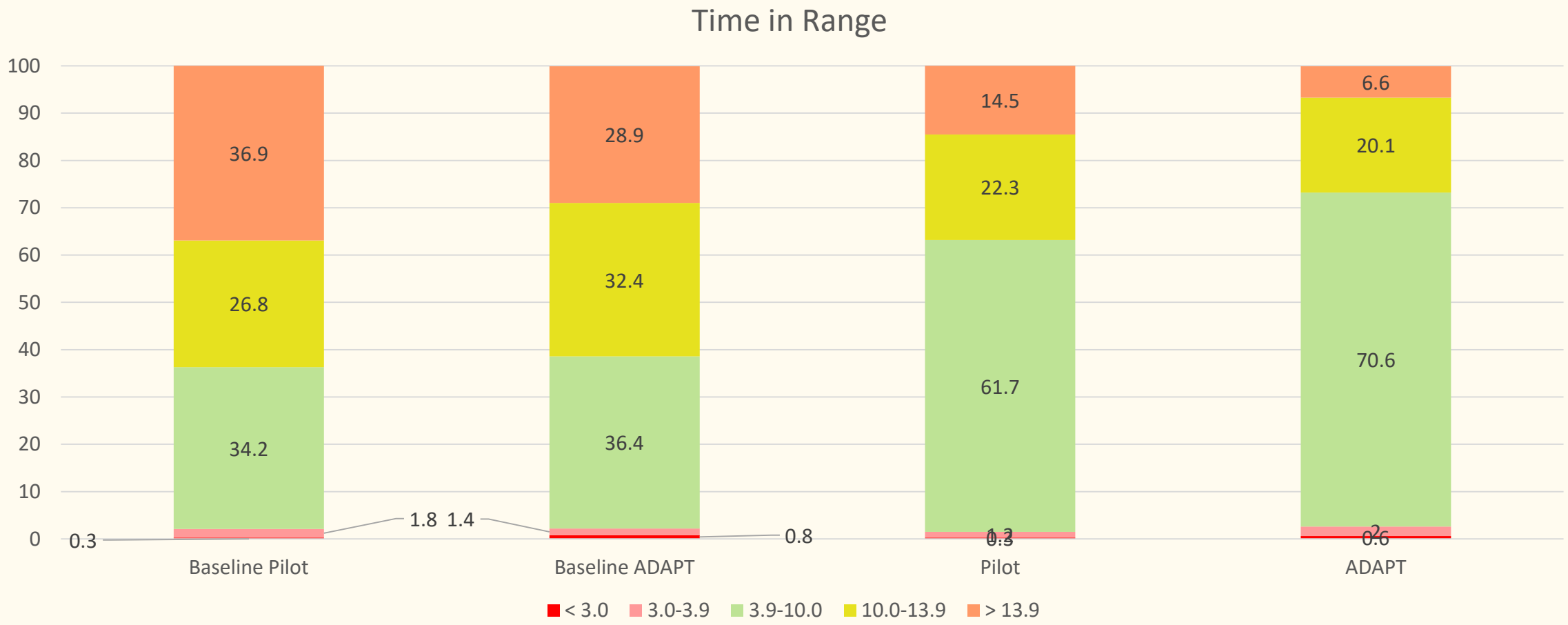
Harrogate and District NHS Foundation Trust
You matter most

NHSE Pilot



Crabtree T et al. *Pending publication*.

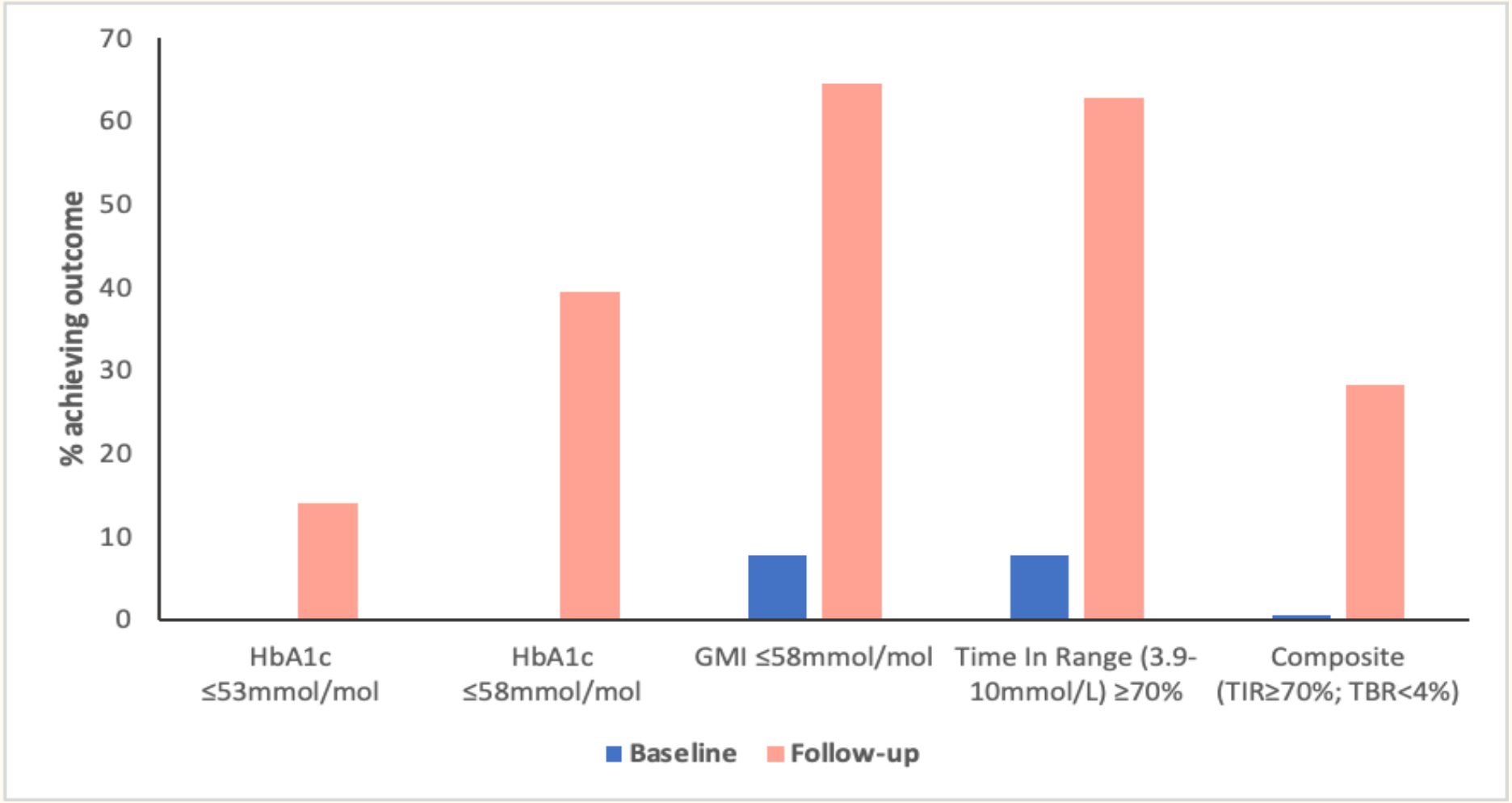
NHSE Pilot vs ADAPT



Harrogate and District NHS Foundation Trust

You matter most

NHSE Pilot - Targets



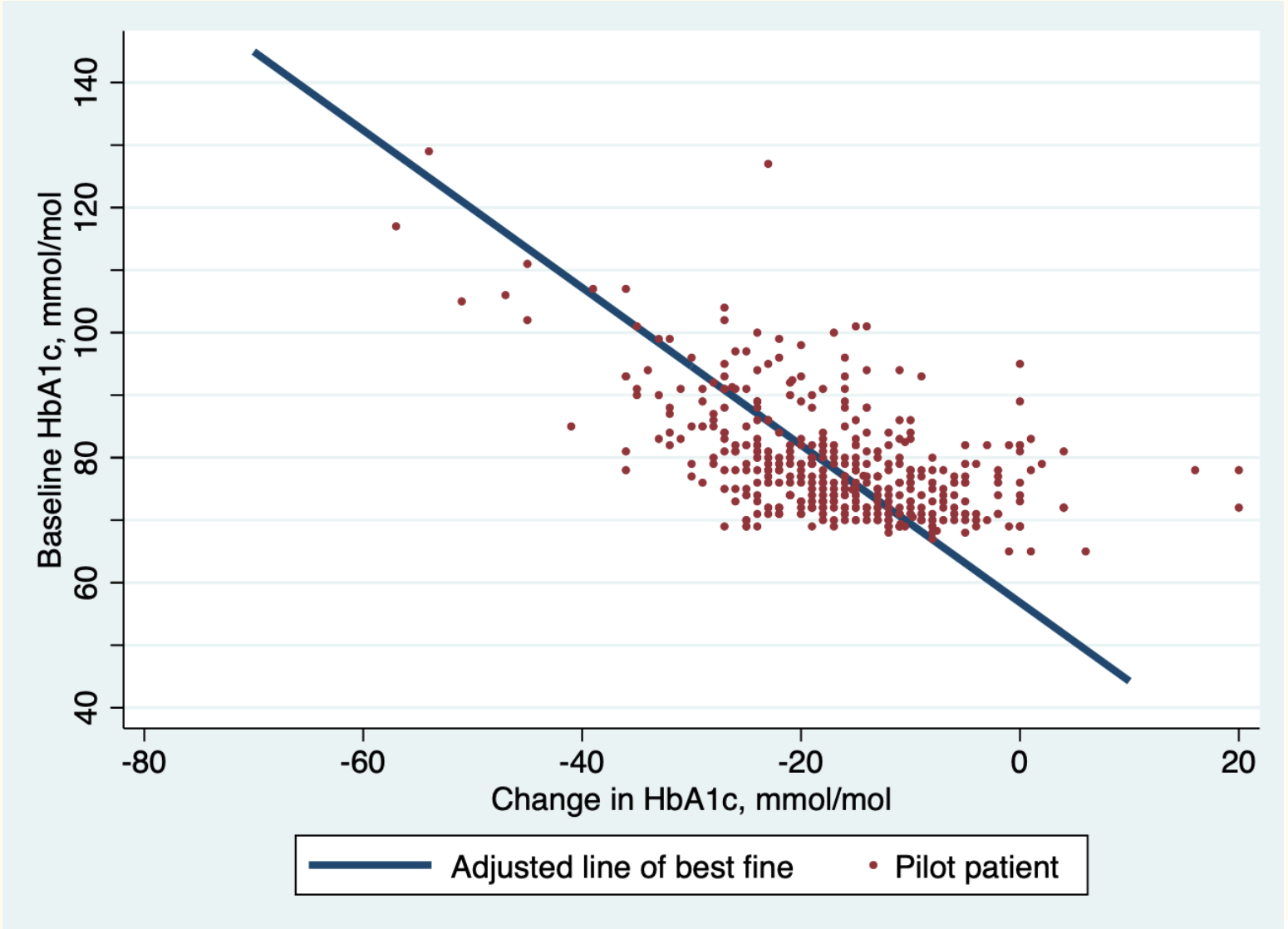
Crabtree T et al. *Pending publication*.

NHSE Pilot - PROMS

	N	Baseline	Follow-up	Change (95% CI)	P-Value
Gold Score	415	2.3	1.9	-0.4 (-0.2, -0.5)	<0.001
Diabetes Distress	412	3.3	2.2	-1.1 (-1.0, -1.3)	<0.001
Diabetes Distress (Average Score ≥3), % (n)	412	69.2 (285)	22.8 (94)	-46.4	<0.001
Impaired Awareness of hypoglycaemia (Gold ≥4), %	415	16.9	9.4	-7.5	<0.001

Crabtree T et al. *Pending publication*.

NHSE Pilot



Crabtree T et al. *Pending publication*.

Draft NICE Guidance – MTA AHCL

1.1 Hybrid closed loop systems are recommended as an option for managing blood glucose levels in type 1 diabetes for people who are having difficulty managing their condition and have an average HbA1c of around 64 mmol/mol (8.0%) or more, despite optimal management with at least 1 of the following:

- continuous subcutaneous insulin infusion
- real-time continuous glucose monitoring
- intermittently scanned continuous glucose monitoring.

Hybrid closed loops systems are only recommended if the companies and NHS England agree a cost-effective price for the systems on behalf of the relevant health bodies (see section 2).

1.2 Hybrid closed loop systems are recommended as an option for managing blood glucose levels in type 1 diabetes for people who are pregnant or planning a pregnancy. Hybrid closed loops systems are only recommended if the companies and NHS England agree a cost-effective price for the systems on behalf of the relevant health bodies (see section 2).

Draft NICE Guideline

1.3 Only use hybrid closed loop systems with the support of a trained multidisciplinary team experienced in continuous subcutaneous insulin infusion and continuous glucose monitoring in type 1 diabetes.

1.4 Only use hybrid closed loop systems if the person or their carer:

- understands and is able to use them
- is also attending a type 1 diabetes structured education programme.

1.5 These recommendations are not intended to affect use of hybrid closed loop systems that was started in the NHS before this guidance was published. People using hybrid closed loop systems outside these recommendations may continue until they and their NHS clinician consider it appropriate to stop. For children and young people, this decision should be made jointly by them, their clinician and their parents or carers.

Using Closed Loop Systems

Received: 18 January 2023 | Accepted: 28 February 2023

DOI: 10.1111/dme.15078

DIABETIC Medicine

POSITION STATEMENT

UK's Association of British Clinical Diabetologist's Diabetes Technology Network (ABCD-DTN): Best practice guide for hybrid closed-loop therapy

Tomás P. Griffin[1,2,3,4] | Geraldine Gallen[5] | Sara Hartnell[6] | Thomas Crabtree[7,8] | Melissa Holloway[9] | Fraser W. Gibb[10] | Alistair Lumb[11,12] | Emma G. Wilmot[7,8] | Pratik Choudhary[1,2] | Sufyan Hussain[13,14]

[1]Leicester Diabetes Centre, University Hospitals of Leicester, Leicester, UK

[2]Diabetes Research Centre, College of Health Sciences, University of Leicester, Leicester, UK

[3]School of Medicine, University of Limerick, Limerick, Ireland

[4]Centre for Diabetes and Endocrinology, University Hospital Limerick, Limerick, Ireland

[5]Department of Diabetes, School of Cardiovascular, Metabolic Medicine and Sciences, King's College London, London, UK

[6]Department of Diabetes and Endocrinology, Cambridge University Hospitals NHS Foundation Trust, Cambridge, UK

[7]University Hospitals of Derby and Burton NHS Foundation Trust, Derby, UK

[8]Translational Medical Sciences, University of Nottingham, Nottingham, UK

[9]Expert by Experience, Independent Consultant, London, UK

[10]Edinburgh Centre for Endocrinology & Diabetes, Royal Infirmary of Edinburgh, Edinburgh, UK

[11]Oxford Centre for Diabetes, Endocrinology and Metabolism, Oxford, UK

[12]Oxford NIHR Biomedical Research Centre, Oxford, UK

[13]Department of Diabetes, School of Cardiovascular, Metabolic Medicine and Sciences, King's College London, London, UK

[14]Department of Diabetes and Endocrinology, Guy's & St Thomas' NHS Foundation Trust, London, UK

Indications for Hybrid Closed Loop Therapy

- All those meeting NICE TA 151 criteria for insulin pump therapy
- All those meeting future NICE technology appraisal guidance
- Individuals with high diabetes distress/burden of diabetes care
- Individuals on MDI with suboptimal glycaemic control despite high-level management
- Pregnant women of those planning for pregnancy (licensed devices?)
- Individuals with severe hypoglycaemia, impaired awareness or disabling fear of hypoglycaemia
- Those with other types of diabetes on MDI and CHO counting meeting any of the above criteria
- Those with other complicating factors warranting consideration eg gastroparesis, insulin allergy, needle phobia, insulin resistance or significant lipohypertrophy

Understanding HCL systems

- C – how does each system Calculate insulin delivery
- A – which parameters can be Adjusted
- R – when should users Revert to traditional pump settings
- E – critical Education points
- S – key aspects of the Sensor and Sharing capabilities of the system

C: Calculate	How does the algorithm calculate insulin delivery? Which components of insulin delivery are automated (e.g. basal suspensions, basal modulation, high glucose corrections, food boluses, etc.)?
A: Adjust	• How can the user adjust insulin delivery? • Which parameters can be adjusted to influence insulin delivery during automation (e.g. carbohydrate ratios, insulin action time, basal rates, sensitivity factors)? • Which parameters are fixed?
R: Revert	• When should the user choose to revert to open loop/no automation? • When will the system default to open loop/no automation?
E: Educate	• What are the key education points for the advanced diabetes device (e.g. essential training, tips and tricks, best practices, etc.)? • How does the user optimise time using the automated features? • Where can users and clinicians find additional education?
S: Sensor/Share	• What are relevant sensor characteristics for each device (e.g. calibration and therapeutic blood glucose requirements, duration of sensor wear, etc.)? • • What are the system capabilities for remote monitoring and cloud-based data sharing?

Note: Reproduced with and adapted with permission from Laurel Messer.[21]

Choosing an AHCL system

Accessibility/ Availability/ Evidence	What systems are available? What systems can meet funding requirements? What systems are licensed for user's situation? What evidence is there from RCT and RWE on outcomes with this system?	HCL features	UKCA Mark indications (age, pregnancy considerations, minimum and maximum doses) User variable/settings Glucose targets Special modes and auto-mode suspensions Insulin compatibility (rapid/ultra-rapid insulin)
CSII features	HCL algorithm compatible? Device size Device interface Ability to update software Ease of priming and cannula insertion Cannula options Insulin reservoir size Battery type (rechargeable/replaceable) Smartphone connectivity	Other aspects	App and share function Automatic cloud uploads Alarms
CGM features	Sensor duration Sensor accuracy Sensor calibrations Ease of insertion		

HYBRID CLOSED LOOP (HCL) SYSTEM: INFORMATION LEAFLET

DTN UK collaborate · evolve · support

This leaflet provides a recap on how to keep yourself safe whilst using a hybrid closed loop system, backup supplies, and emergency contact details for clinical or technical concerns.

Name:

Hospital Number:

Type of hybrid closed loop system:

Average Total daily dose (TDD)= units

10% TDD = units 20% TDD = units

AVOIDANCE OF DIABETIC KETOACIDOSIS (DKA)

- Diabetic Ketoacidosis (DKA) on HCL systems have been due to cannula failures, where glucose levels have been raised for a while but the user did not check for ketones or change their set, trusting that the system would sort it out.
- Please remember it is very unusual for someone on HCL to have a glucose level >15.0mmol/L for over 2 hours.
- If you continue to try and correct a high reading through the pump, it will only give you small correction doses because it has been trying to bring your sugars down and thinks there is more insulin on board but the cannula or infusion set are not working.
- See unexplained hyperglycaemia and sick days rules on page 3.

IMPORTANCE OF CANNULA CHANGES AND TIMING

- With HCL systems, the importance is increased as any reduction in insulin absorption either due to poor sites or due to reduced infusion by keeping the cannula in longer may affect the total daily insulin dose and subsequent pump learning.
- Ensuring a full set change is completed every two to three days will minimise variability in absorption.
- Remember cannula/site for unexplained highs, only give the pump 1 chance to get it right, follow flow chart (overleaf) for levels not coming down after 2 hours.

TEMPORARY BASAL RATES:

When blood glucose levels are rising when you are unwell, consider:

- Boost for CamAPS FX
- Strengthening basal rates by 20% for Tandem Control IQ
- Lower Active Insulin Time (AIT) /blood glucose target (if not chosen already) for Medtronic Minimed™ 780G SmartGuard

When positive to ketones follow Sick Day rule flowchart on page 3

HYPOGLYCAEMIA:

When glucose levels approach hypoglycaemia, hybrid closed-loop systems will often not have delivered any insulin for some time prior to this; therefore, less rapid-acting carbohydrate can be used to prevent hypoglycaemia (e.g. 4-5g of rapid acting carbohydrate if glucose 4.0-6.0mmol/l with a ↓ trend arrow) or treat mild hypoglycaemia (e.g. 8-10g of rapid acting carbohydrate if glucose <3.9mmol/l), this applies when little or no active insulin is on board.

Digital version of this leaflet can be accessed here:

Adapted with approval from King's Diabetes team @diabeteskings for ABCD DTN UK

TRAVEL CHECKLIST:

- ☑ Details of holiday insurance if travelling abroad
- ☑ Letter on hospital-headed notepaper confirming diabetes, insulin pump and CGM use and the need to carry sharps.
- ☑ Emergency contact numbers (company, hospital).
- ☑ Extra insulin and supplies of other medication.
- ☑ Adequate supplies e.g. sensors +/- transmitters, cannulas.
- ☑ Long-acting insulin to use and doses in the event of insulin pump failure.
- ☑ Insulin pens/needles or syringes.
- ☑ Phone charger /portable charger (for smartphone enabled systems).
- ☑ Spare pump (if available).
- ☑ Blood glucose meter, test strips, lancets/lancing device.
- ☑ Batteries for pump/pump charger.
- ☑ Blood ketones test strips.
- ☑ Hypo management supplies – dextrose tablets weigh less and are smaller than most liquids. Also, they will not cause a problem in airport security.
- ☑ A method of safe sharps disposal.

DKA AVOIDANCE TOOLKIT:

Ensure you have in date supplies and equipment for avoiding and managing DKA effectively:

- Blood ketone meter.
- Blood ketone test strips (in date).
- Copy of pump sick day rules.
- Rapid- or ultra-rapid acting insulin in the form of a pen/syringe (In date).
- Long-acting insulin in the form of a pen/syringe (in date).
- Conversion doses for going back to injections.
- Emergency contact details (clinical and technical)
- If you have not had your pre-programmed (manual) basal rates reviewed in clinic recently please contact the team for urgent assistance.

ADVICE:

If in doubt, contact for advice:

Contact the diabetes nurses (Mon-Fri) on

or by email

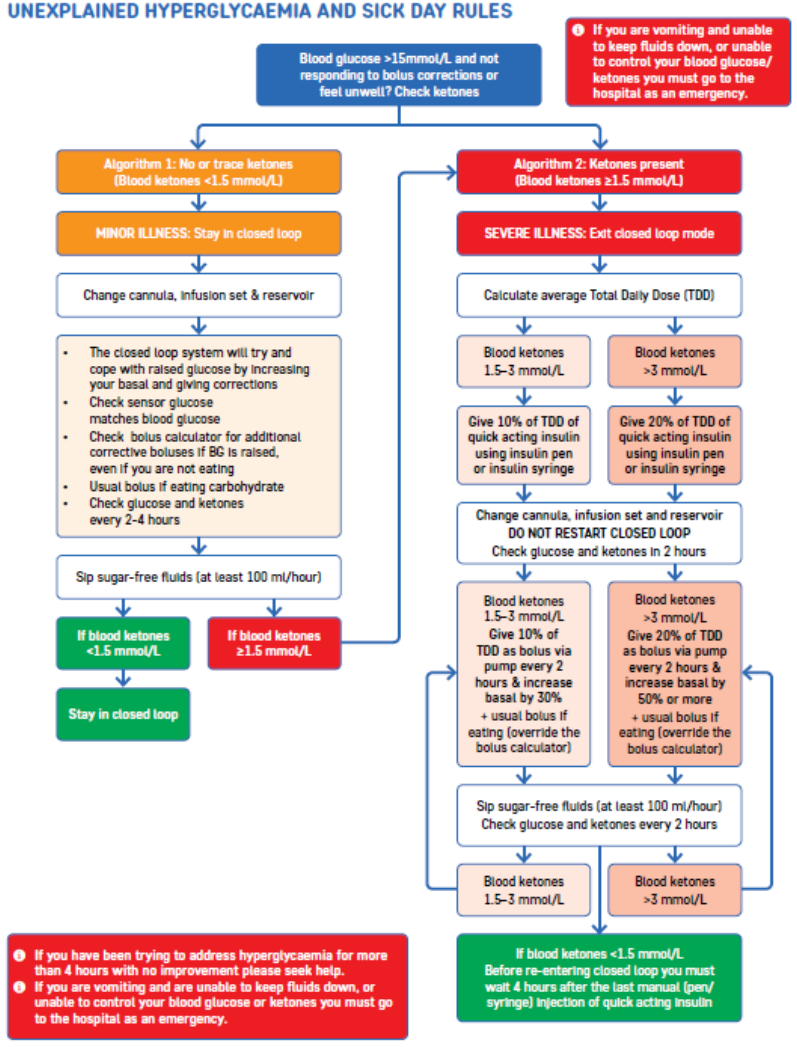
Outside of working hours for medical emergencies that cannot wait until the next working day you can speak to the Diabetes Consultant via the hospital switchboard

TECHNICAL SUPPORT:

Hybrid closed loop pump sick day guidance can be accessed here:

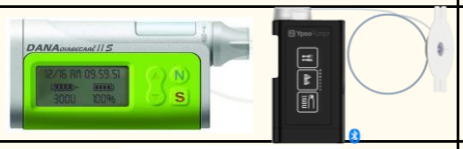
Adapted with approval from King's Diabetes team @diabeteskings for ABCD DTN UK

UNEXPLAINED HYPERGLYCAEMIA AND SICK DAY RULES



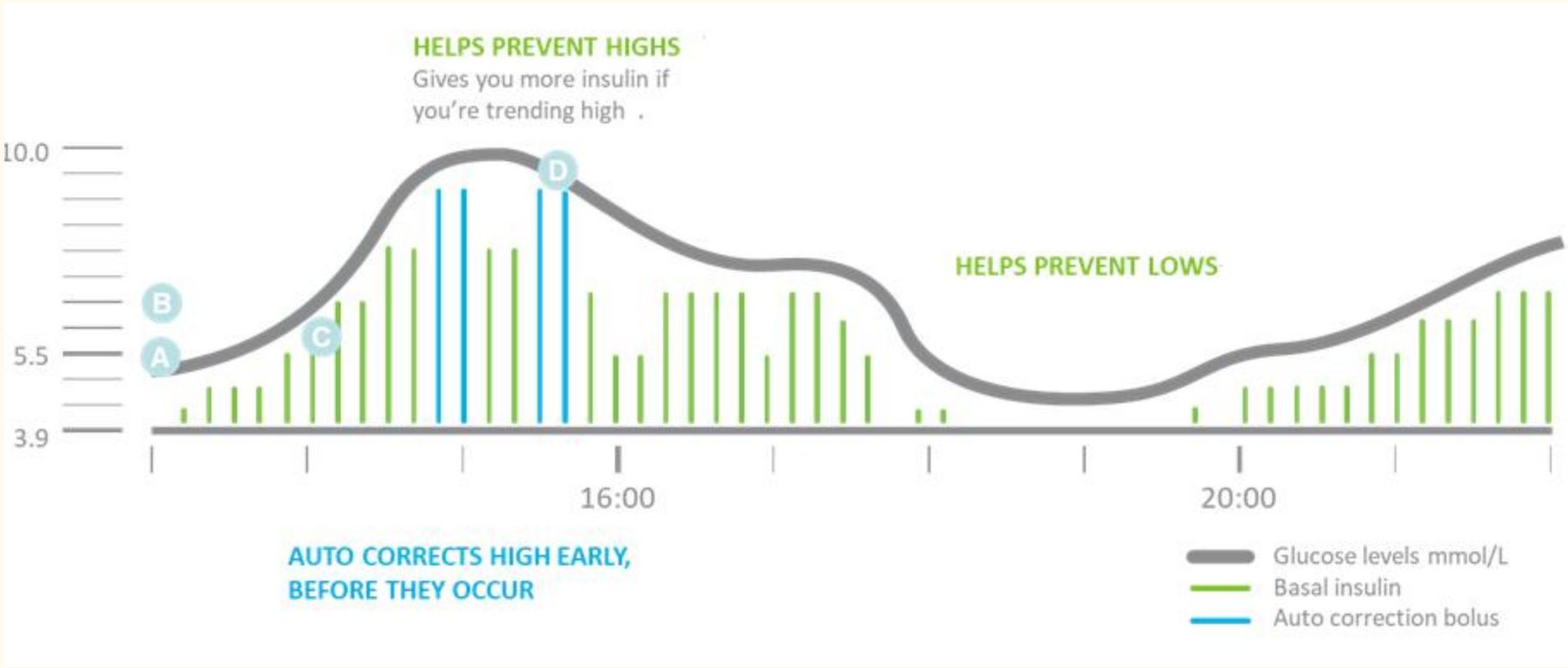
Adapted with approval from King's Diabetes team @diabeteskings for ABCD DTN UK

Commercial Closed Loop Systems

	Medtronic 780G	Tandem Control IQ	Cam APS	Omnipod 5
Pump				
CGM			 *	
Target	5.5 (default), 6.1 or 6.7 mmol/L	Range 6.3-8.9 mmol/L daytime; 6.3-6.7 mmol/L overnight; 7.8-8.9 mmol/L activity	Personalised target: 4.4-11.0 mmol/L – default 5.8 mmol/L	Personalised target: 6.1-8.3 mmol/L
Variables	Active insulin time I:C ratio	I:C ratio Insulin sensitivity factor Basal rates	I:C ratio	Active insulin time I:C ratio Can give manual correction
Insulin delivery	Basal insulin adjusted every 5 minutes	Basal insulin adjusted only if SG predicted to exit range	Basal insulin set to zero: extended bolus given every 10-12 minutes	Basal insulin adjusted every 5 minutes
Connectivity	Minimed Mobile and Carelink Connect App Carelink	Glooko-Diasend	CAMAPS FX App – Android only Glooko-Diasend	Glooko-Diasend
CE license (age)	>7 years	>6 years	>1 years Pregnancy	>2 years

* Recently licensed in UK for Ypsomed and FSL3

Medtronic 780G: How it works



A Selection between a basal target of 5.5 mmol/l - default setting, 6.1 or 6.7 mmol/l

B The Auto correction target is set at 6.7 mmol/l

C Basal insulin adjusts every 5 minutes based on SG valves

D Auto corrections delivered if the algorithm determines they are needed: can be as frequent as every 5 minutes

- Max basal reached
- SG≥ 6.7 mmol/l
- NO automatic corrections if Temp Target is set

CamAPS: How it works

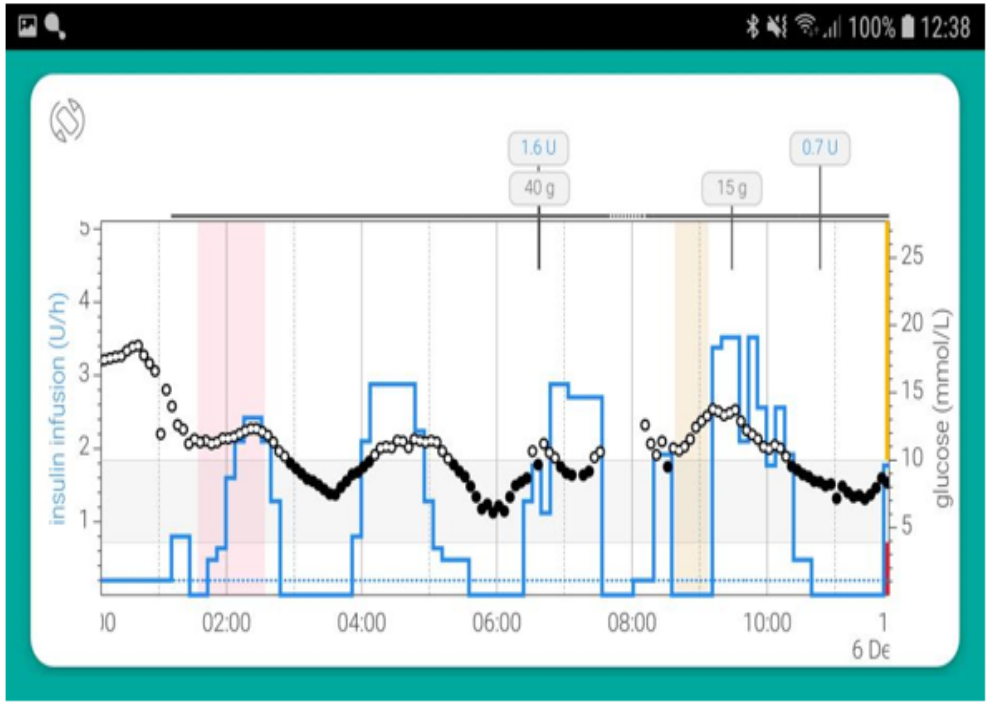
Simple setup

- Body weight (kg)
- Total daily dose

Modulates “basal dose” delivery

Highly adaptive

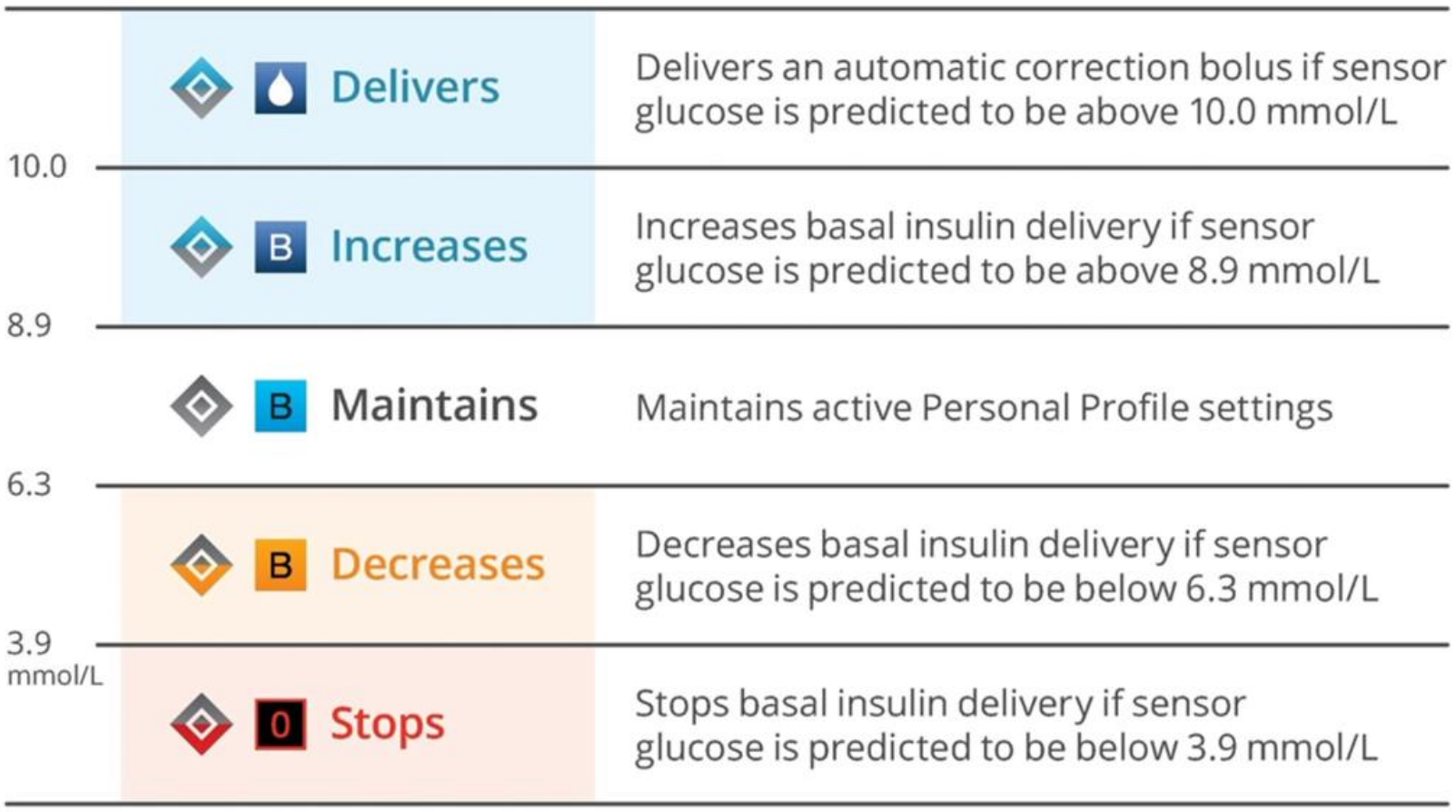
- Daily insulin needs
- Diurnal insulin needs
- Postprandial insulin needs
- Independent of basal dose settings



CamAPS LEARNING

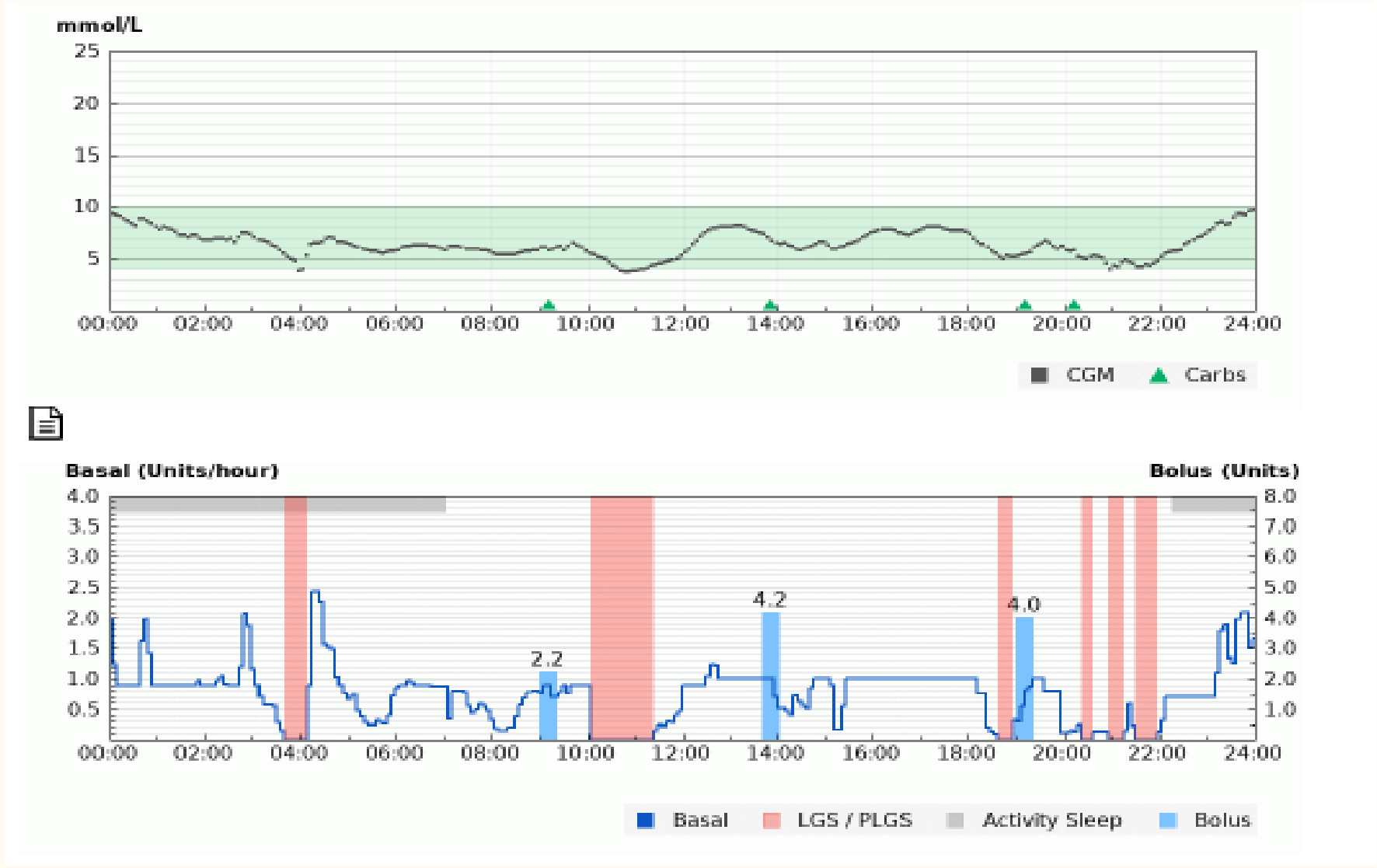
- Analysis of previous day's data
- Analysis of day divided into multi-hour periods
- Analysis of bolus outcome
- Specific learning from hypos
- Forgetting

Control IQ: How it works

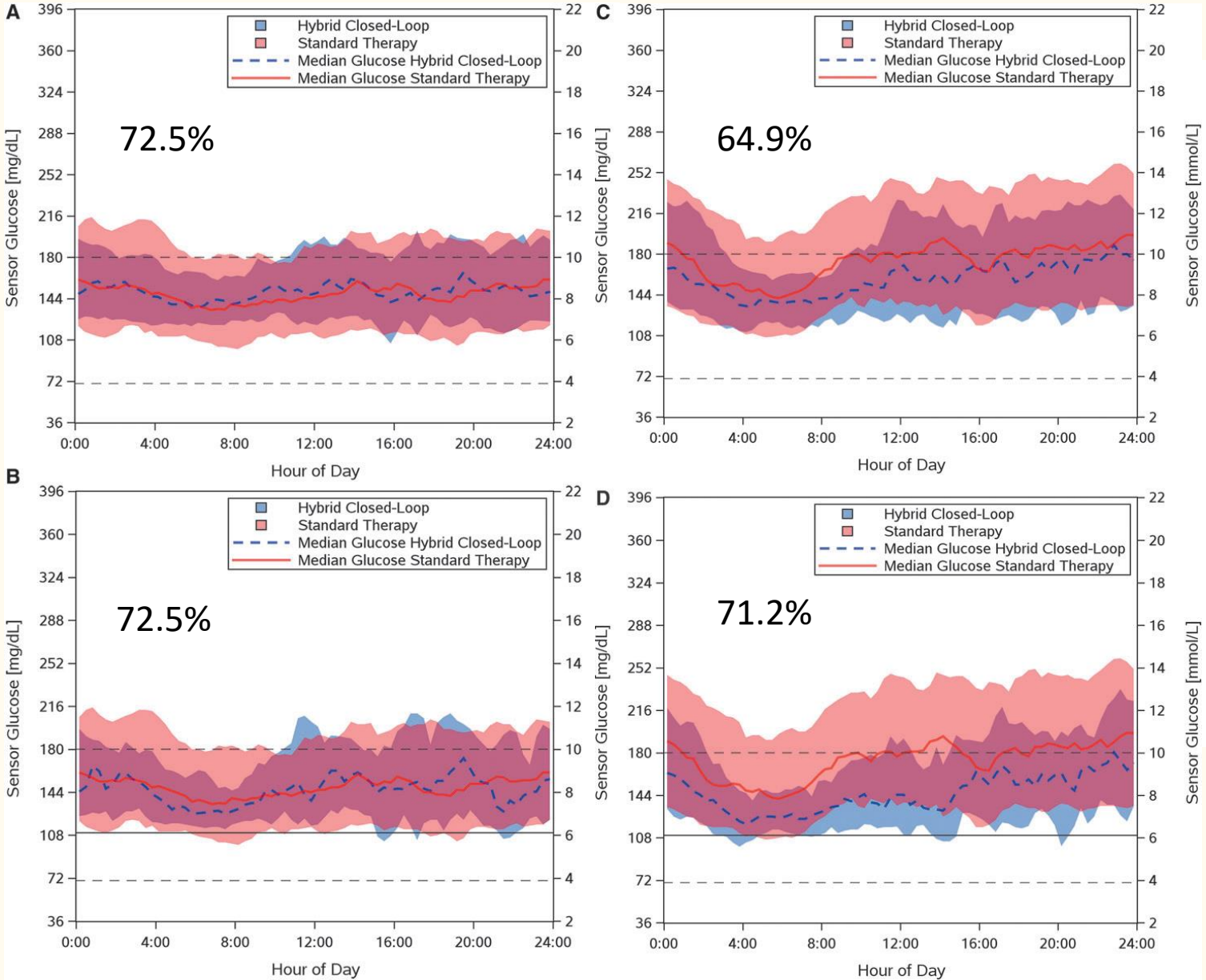


*When an Activity, such as Sleep or Exercise, is not enabled

Control IQ



Omnipod 5



Forlenza D et al. Diabetes Tech Ther 2021; 23:410-24

Harrogate and District NHS
NHS Foundation Trust
You matter most

Training and Support for Hybrid Closed-Loop Therapy

Journal of Diabetes Science and Technology
2022, Vol. 16(1) 218–223

DOI: 10.1177/1932296820955168
journals.sagepub.com/home/dst

Charlotte K. Boughton, MBBS, PhD[1,2], Sara Hartnell, BSc[2], Janet M. Allen, RN[1], Julia Fuchs, MBChB[1], and Roman Hovorka, PhD[1]

Abstract

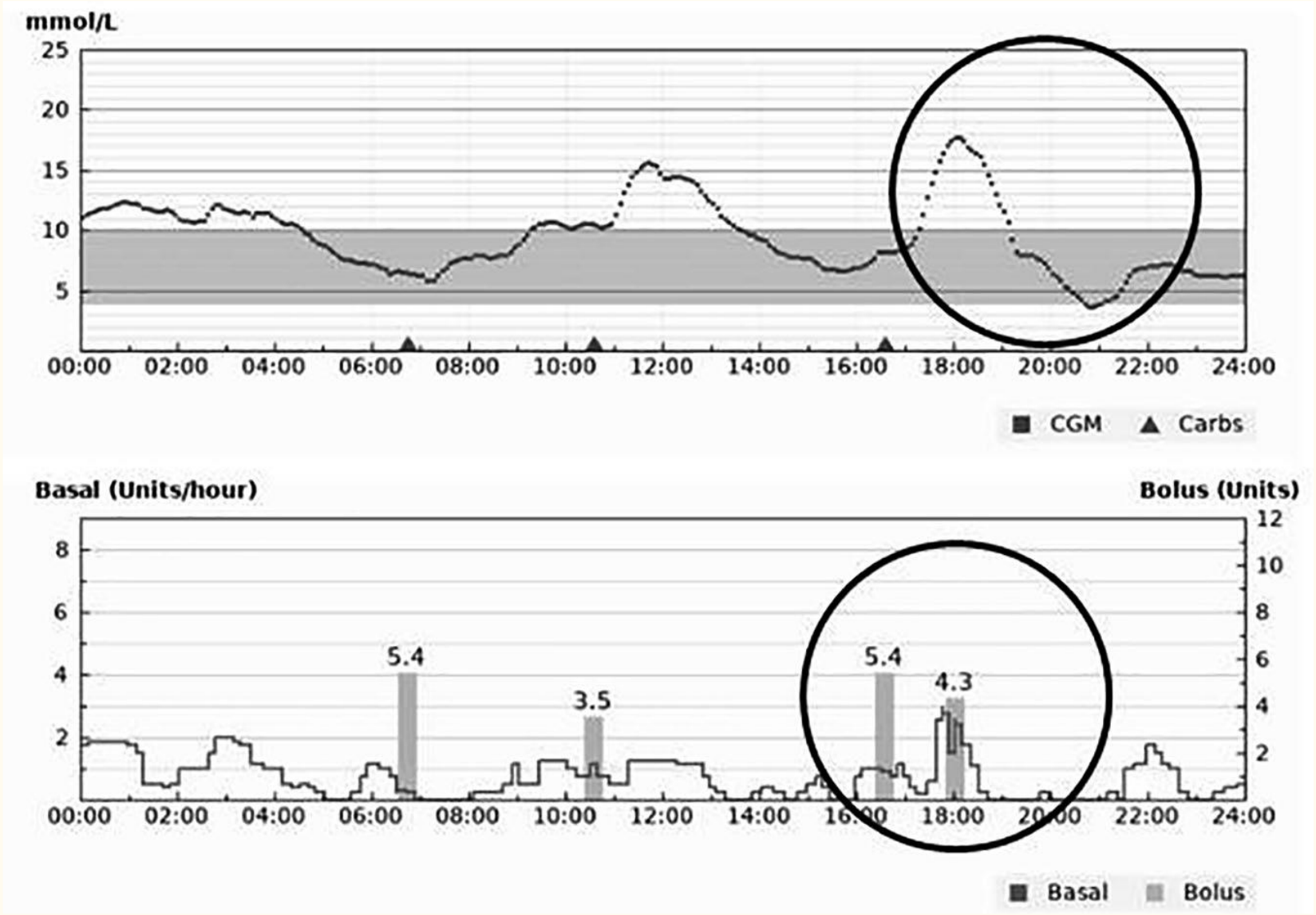
Hybrid closed-loop therapy is an emerging technology transforming the management of type 1 diabetes (T1D). Research studies demonstrate glycemic and quality of life benefits of hybrid closed-loop therapy for people with T1D. Translating these outcomes into standard clinical practice is critical for reimbursement and improving access to this technology.

High-quality training is essential for achieving optimal outcomes with hybrid closed-loop therapy. Basic diabetes skills and tasks are as important, or even more important, with closed-loop therapy than with standard insulin therapy and need to be reiterated. Establishing expectations of hybrid closed-loop therapy clearly at the outset promotes long-term usage and optimal outcomes.

We share key aspects of training and support for users of commercially available hybrid closed-loop systems and consider who may benefit from this technology.

Structured education and Closed loops

- An understanding of the principles of insulin delivery is crucial to optimising closed loop delivery AND in the event of system failure, either reverting to manual mode or to subcutaneous insulin injection
- Whilst looping need to understand how to manage:
  - Meals
  - Exercise
    - Use of temporary targets
    - When to activate and de-activate
    - Manual mode/Pump-off scenarios
    - Caution with carbs
  - Alcohol
    - Don’t challenge the system too much!
    - Carbohydrate intake
    - Use of temporary targets
  - Sick days



Boughton CK et al. J Diab Sci Technol 2022;16:218-23.

Conclusion

- Continuous glucose monitoring
  - Broader indications as per updated NICE guidance
  - RT-CGM offers advantages over FGM for both problematic hypoglycaemia and above target HbA1c
- Closed loop insulin delivery
  - NHSE pilot shows benefit for those on CSII and FGM not achieving HbA1c < 69 mmol/mol
  - Draft NICE guidance supports broader access
  - User education remains crucial to safe and optimal usage