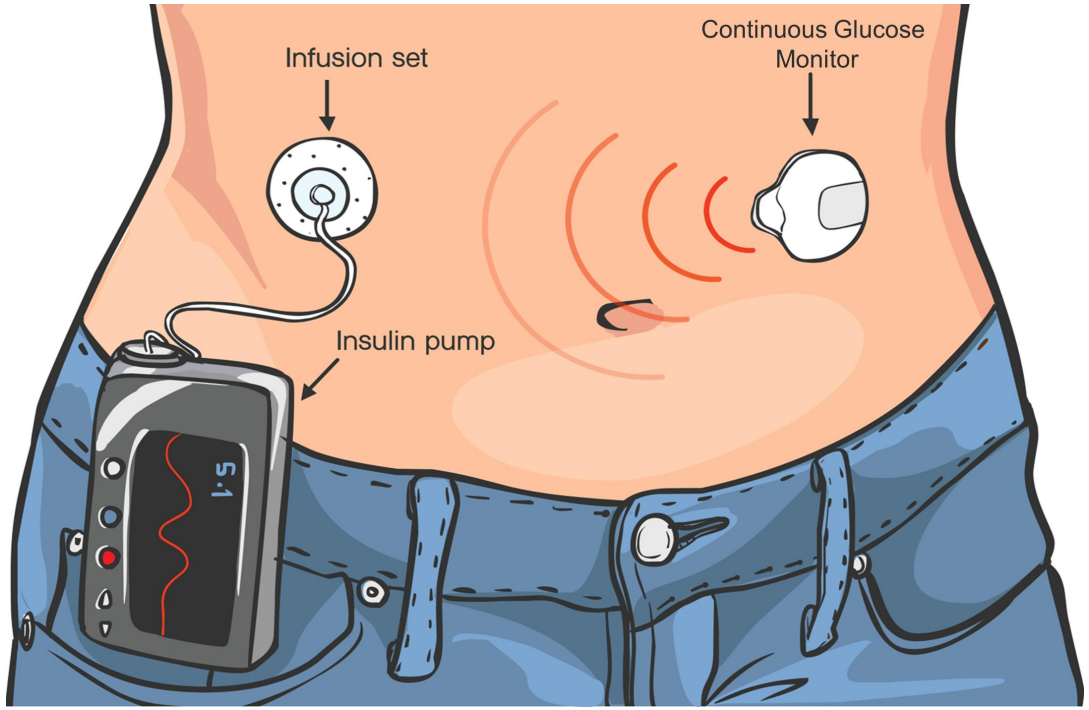
Hybrid Closed Loop

Wednesday 29th January 2025



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NHS
King's College Hospital
NHS Foundation Trust

Disclosures

- Payments for Speaking and Advisory boards
  - Insulet, Dexcom, Abbott Diabetes Care, Medtronic

Overview

HCL – basics

Do HCL systems improving outcomes?

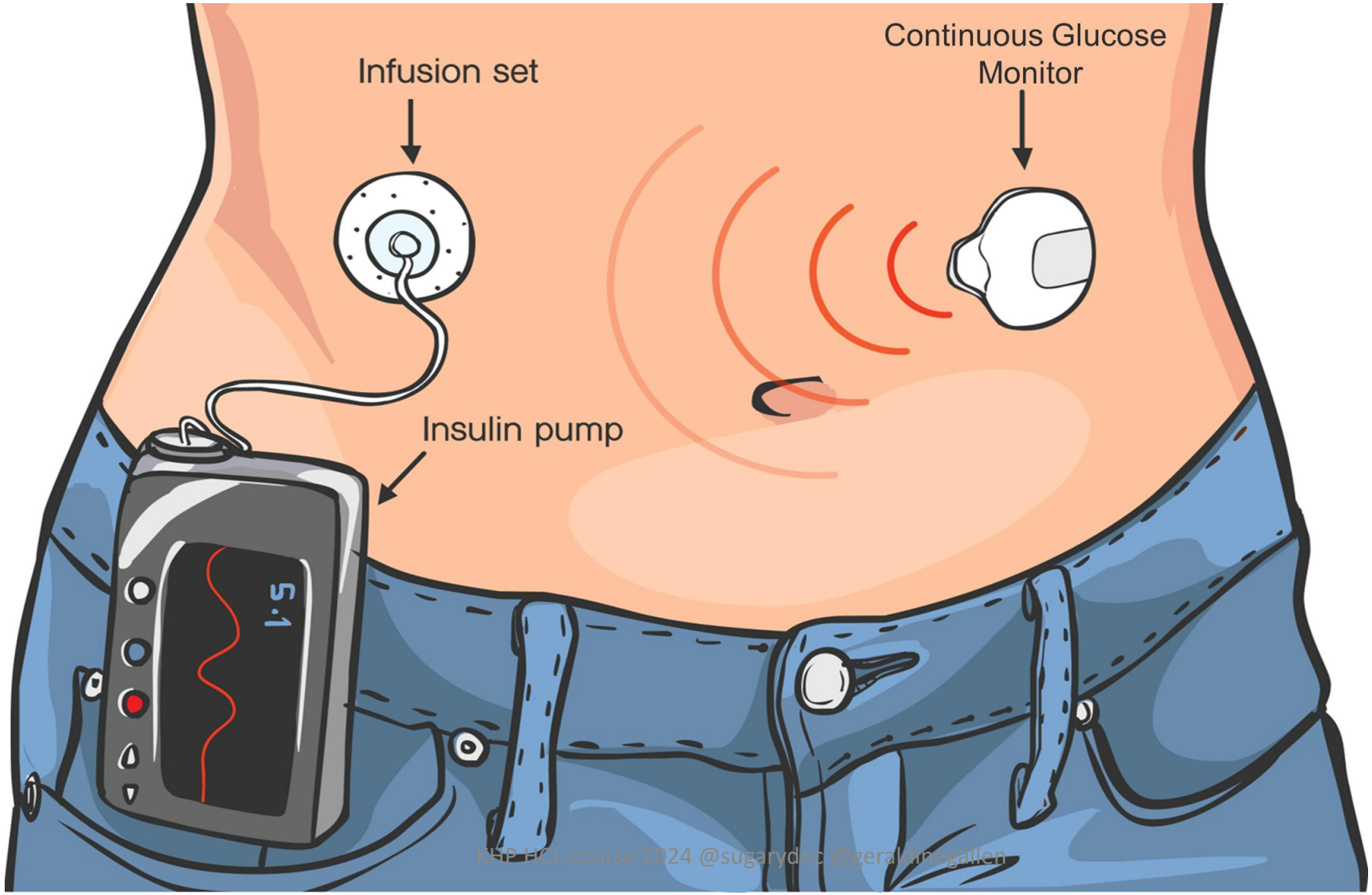
NICE technology appraisal

What does it mean for us?

System comparison

Be ready to answer some questions!

Hybrid Closed Loop Insulin Pump Therapy



Why do we all need to know about HCL?

- Environment of diabetes technology, particularly hybrid-closed loop systems is rapidly evolving
- Access to these systems is increasing with recent updates to funding and commissioning
- Anybody who works with T1D needs to understand how HCL works.

The challenge in type 1 diabetes

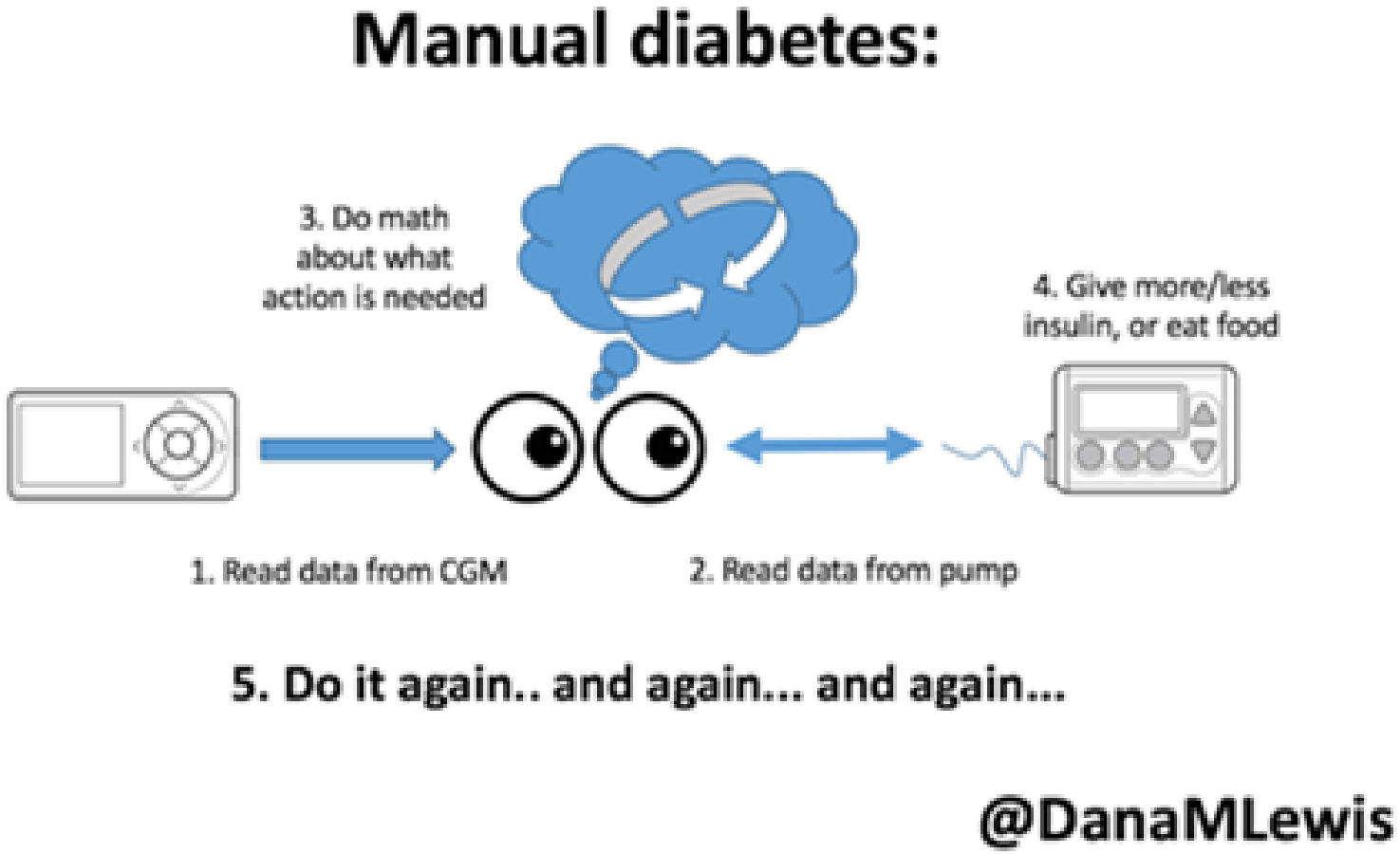
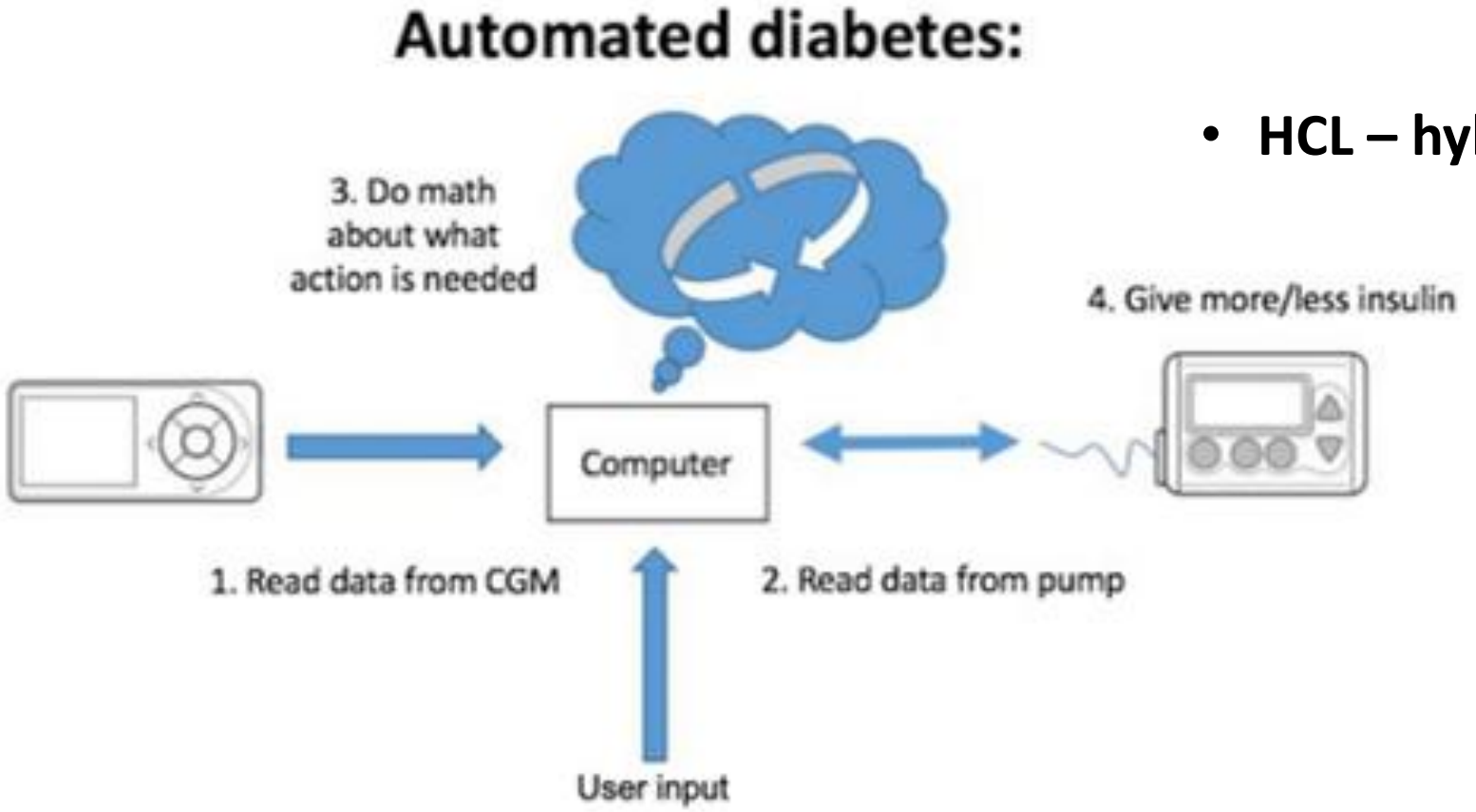


Figure taken with permission from Lewis D, Automated Insulin Delivery, ISBN 9781797763699, https://www.artificialpancreasbook. com Dana Lewis 2019

Automated Insulin Delivery systems



- **HCL – hybrid closed loop**

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

Improving outcomes?

Diabetes Ther (2023) 14:839–855
https://doi.org/10.1007/s13300-023-01394-5

REVIEW

A Systematic Review of Commercial Hybrid Closed-Loop Automated Insulin Delivery Systems

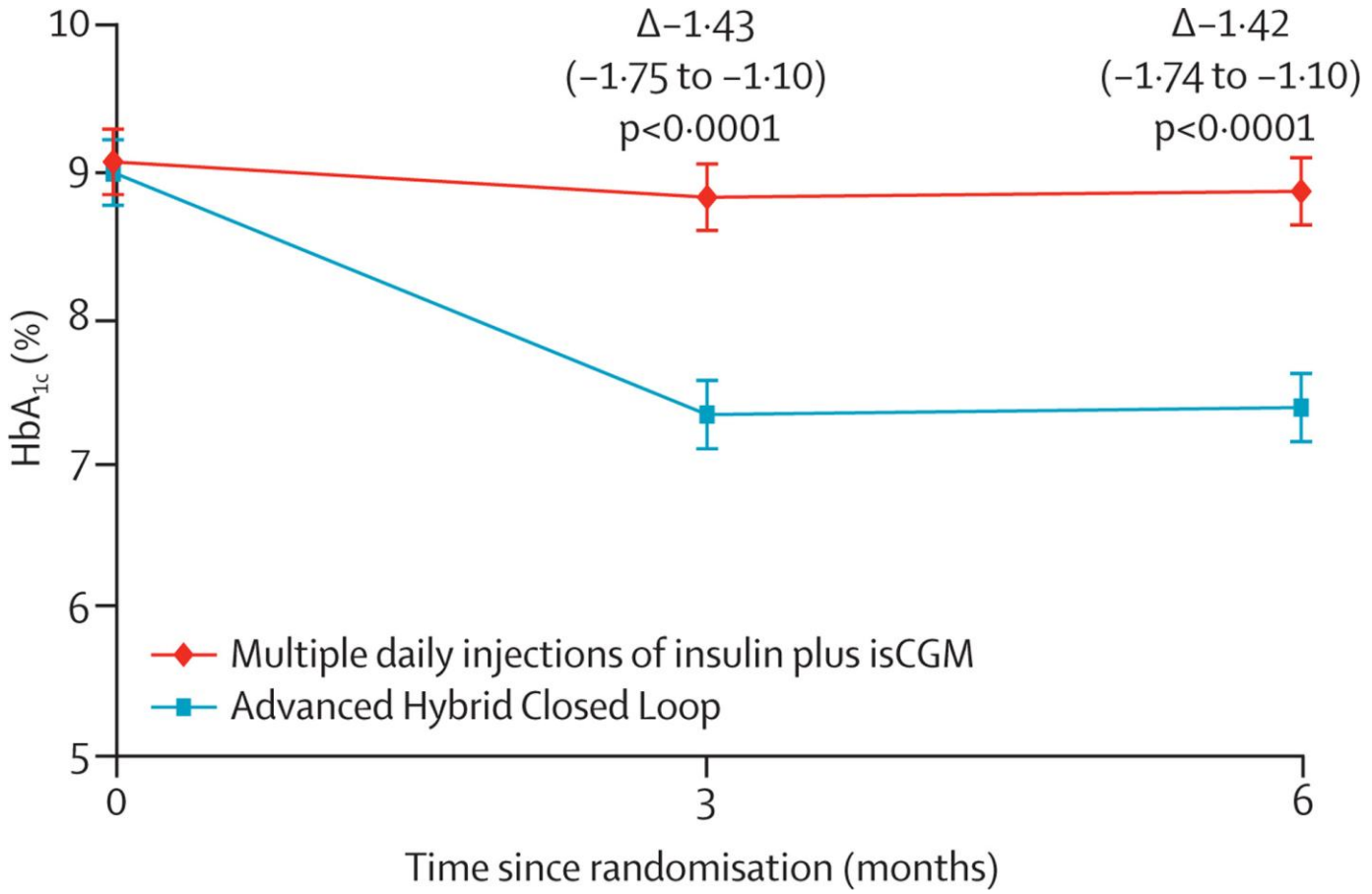
Sofia Peacock · Isolda Frizelle · Sufyan Hussain

→HCL systems improve time In range (TIR)

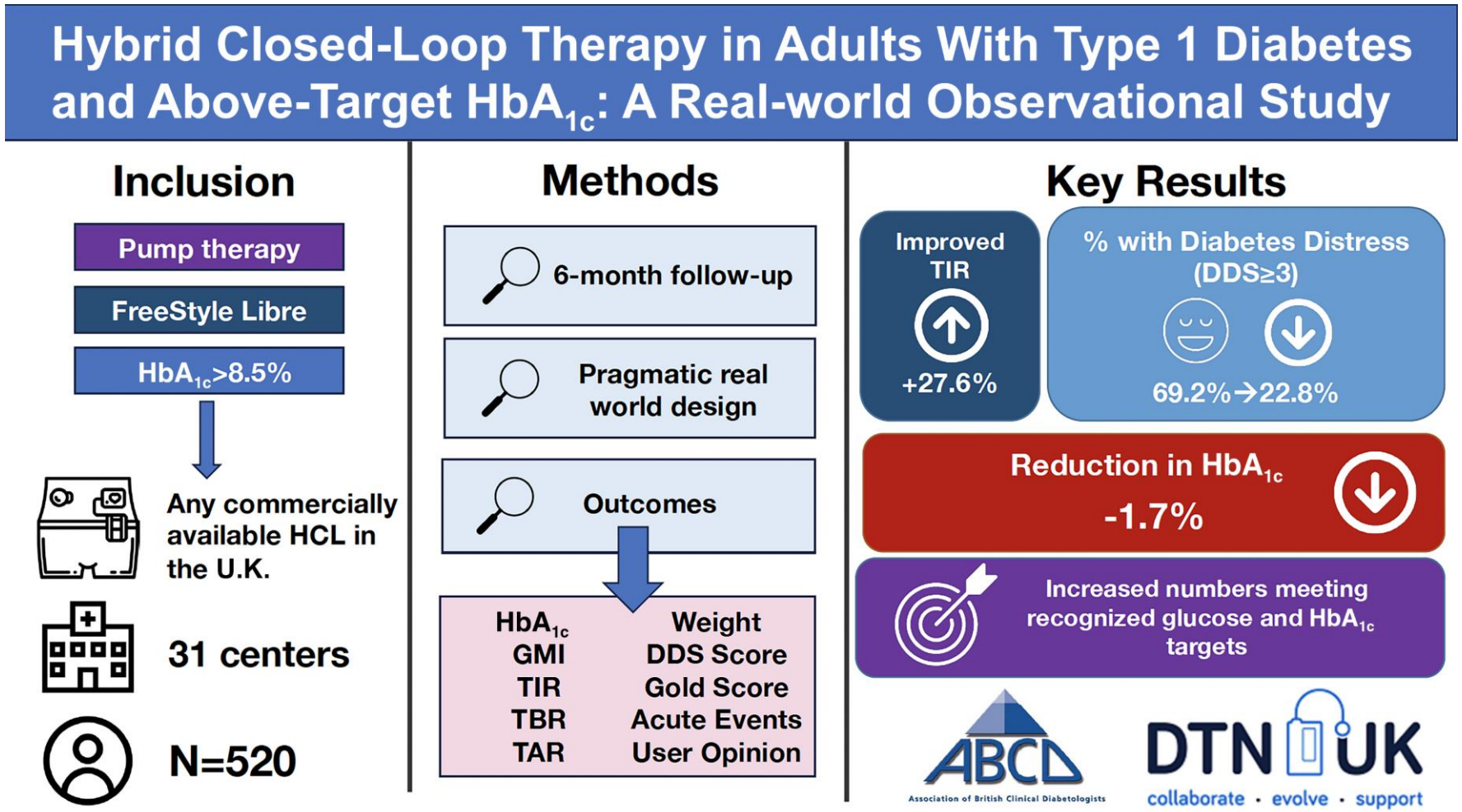
→Minimal concerns around severe hypoglycaemia

→Psychological outcomes require further study

MDI vs HCL? ADAPT study



Choudhary P, et al. Lancet Diabetes Endocrinol. 2022 Oct;10(10):720-731.
doi: 10.1016/S2213-8587(22)00212-1. Epub 2022 Sep 1.



DDS, Diabetes Distress Scale; GMI, glucose management indicator; HCL, hybrid closed loop; TAR, time above range; TBR, time below range; TIR, time in range.

Diabetes Care. 2023;46(10):1831-1838. doi:10.2337/dc23-0635

NICE TA 943

Hybrid closed loop systems for managing blood glucose levels in type 1 diabetes

Technology appraisal guidance [TA943] Published: 19 December 2023 Register as a stakeholder

What are the recommendations?

Hybrid closed loop systems for managing blood glucose levels in type 1 diabetes

Technology appraisal guidance [TA943] Published: 19 December 2023 Register as a stakeholder

Recommendations

1.1 Hybrid closed loop (HCL) systems are recommended as an option for managing blood glucose levels in type 1 diabetes for adults who have an HbA1c of 58 mmol/mol (7.5%) or more, or have disabling hypoglycaemia, despite best possible management with at least 1 of the following:

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

HCL systems are only recommended if they are procured at a cost-effective price agreed by the companies and NHS England, and implemented following NHS England's and NHS Wales' implementation plans.

1.2 HCL systems are recommended as an option for managing blood glucose levels in type 1 diabetes for children and young people. HCL systems are only recommended if they are procured at a cost-effective price agreed by the companies and NHS England, and implemented following NHS England's and NHS Wales' implementation plans.

1.3 HCL systems are recommended as an option for managing blood glucose levels in type 1 diabetes for women, trans men and non-binary people who are pregnant or planning to become pregnant. HCL systems are only recommended if they are procured at a cost-effective price agreed by the companies and NHS England, and implemented following NHS England's and NHS Wales' implementation plans.

1.4 Only use HCL systems with the support of a trained multidisciplinary team experienced in CSII and continuous glucose monitoring in type 1 diabetes.

1.5 Only use HCL systems if the person or their carer:

- is able to use them, and
- is offered approved face-to-face or digital structured education programmes, or
- is competent in insulin dosing and adjustments.

1.6 These recommendations are not intended to affect use of HCL systems that was started in the NHS before this guidance was published. People using HCL 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.

https://www.nice.org.uk/guidance/ta943/chapter/1-Recommendations

Hybrid closed loop systems for managing blood glucose levels in type 1 diabetes

Technology appraisal guidance [TA943] Published: 19 December 2023 Register as a stakeholder

Implementation

4.2 Based on the commercial framework and the recommendations in this guidance, NHS England will develop a 5-year national strategy with advice and guidance to NHS providers on the phased uptake approach. The strategy will centre on improving health outcomes and reducing health inequalities. The phased rollout will initially start with:

- children
- young people
- women, trans men and non-binary people who are pregnant or planning to become pregnant and
- adults who already use pumps who want to transition to an HCL system (over time, this will be extended to people who want to start using a pump for the first time).

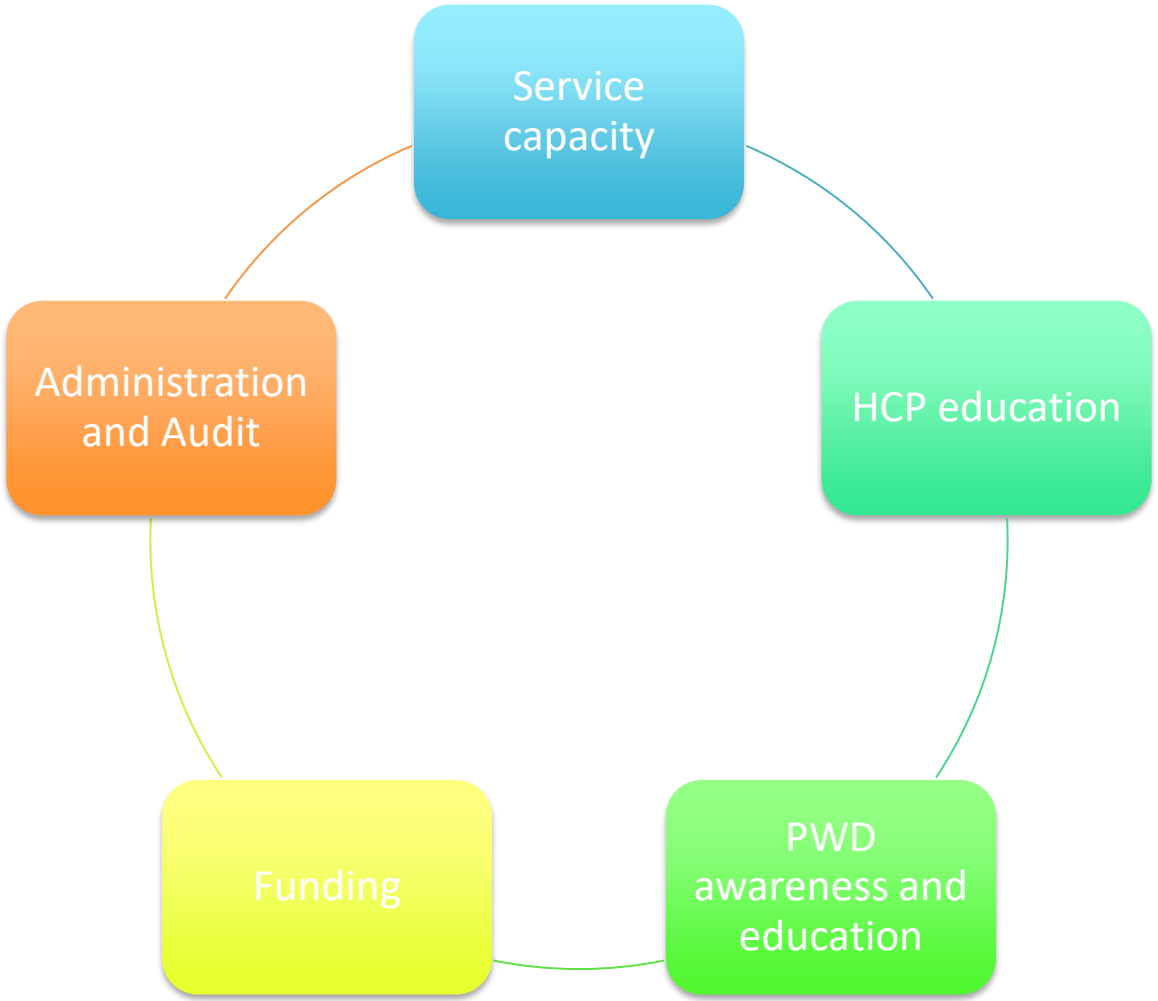
Key elements of the strategy will include workforce, patient education, commercial, stakeholder engagement and data.

https://www.nice.org.uk/guidance/ta943/chapter/4-Implementation

What is the challenge?

- Based on NDA report 2021 – there are **236,000 people** aged 19 and over living with T1D
  - 85,840 are seen in specialist care
  - **137,765 are in primary care only**
- Data from the NDA suggests that approximately **140 000 adults** across England and Wales may be eligible for HCL treatment based on the HbA1c criteria alone.
- NICE TA151 for insulin pump therapy in people with type 1 diabetes was published in July 2008.
  - Only 11.5% of people with type 1 diabetes in England are using CSII and 16.7% of those in Wales.
  - That corresponds to just over **26 000** people from a total population of 227 435 who have accessed insulin pump therapy over a 15-year period.
  - Estimated that just under **60 000 people met HbA1c criteria** for insulin pump therapy
- To roll out HCL to the eligible population who would like to access it, the pace of offering access to technology will need to increase rapidly.
- This represents a significant challenge to services keen to offer access to this life-changing technology.
- We have 5 years to do this……..
- We must do something different

HCL implementation: key considerations



What do you think are the key considerations for a service trying to implement HCL?

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]

Griffin, TP, et al. Diabet Med. 2023; 40:e15078. doi:10.1111/dme.15078

Need for Educator time

Context	Process	Time
HCL start – Pump Naïve 8 hours	Pump start	4 hours
	Daily calls/ troubleshooting	~2 hours
	1st Pump set change	1 hour
	HCL switch/training	1 hour
HCL start – Pump upgrade 4 hours	Pump upgrade	3 hours
	HCL switch / training	1 hour
HCL start – existing pump 1 hour	HCL switch / training	1 hour

Griffin, TP, et al. Diabet Med. 2023; 40:e15078. doi:10.1111/dme.15078

Funding

- NHSE national procurement framework is now in place with all HCL systems and combinations
- Trusts need to submit quarterly audit data for reimbursement.

Summary

HCL systems represent an important technological advancement for the management of T1D

Can offer significant glycaemic benefits and improved QoL to users

NICE HCL TA is an important step forward in making HCL the standard of care for T1D, but implementation will be a challenge

Comparison of Hybrid Closed Loop Systems

Medtronic 780 G

Cam APS

Tandem Control iQ

Omnipod 5

Which system is best?

	Medtronic 780G	Tandem Control IQ	Cam APS	Omnipod 5
Pump				
CGM				
Target	5.5 (default), 6.1 or 6.7 mmol/L	Range 6.1-8.9 mmol/L daytime; 6.1-6.7 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: 6.1mmol/l- 8.3 mmol/L
Variables	Active insulin time I:C ratio	I:C ratio Insulin sensitivity factor Basal rates	I:C ratio	I:C ratio Insulin sensitivity Factor Active insulin time
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
CE license (age)	>7 years	>6 years	>1 years Pregnancy	>2 years

All are spectacular……

They simply cater for different tastes

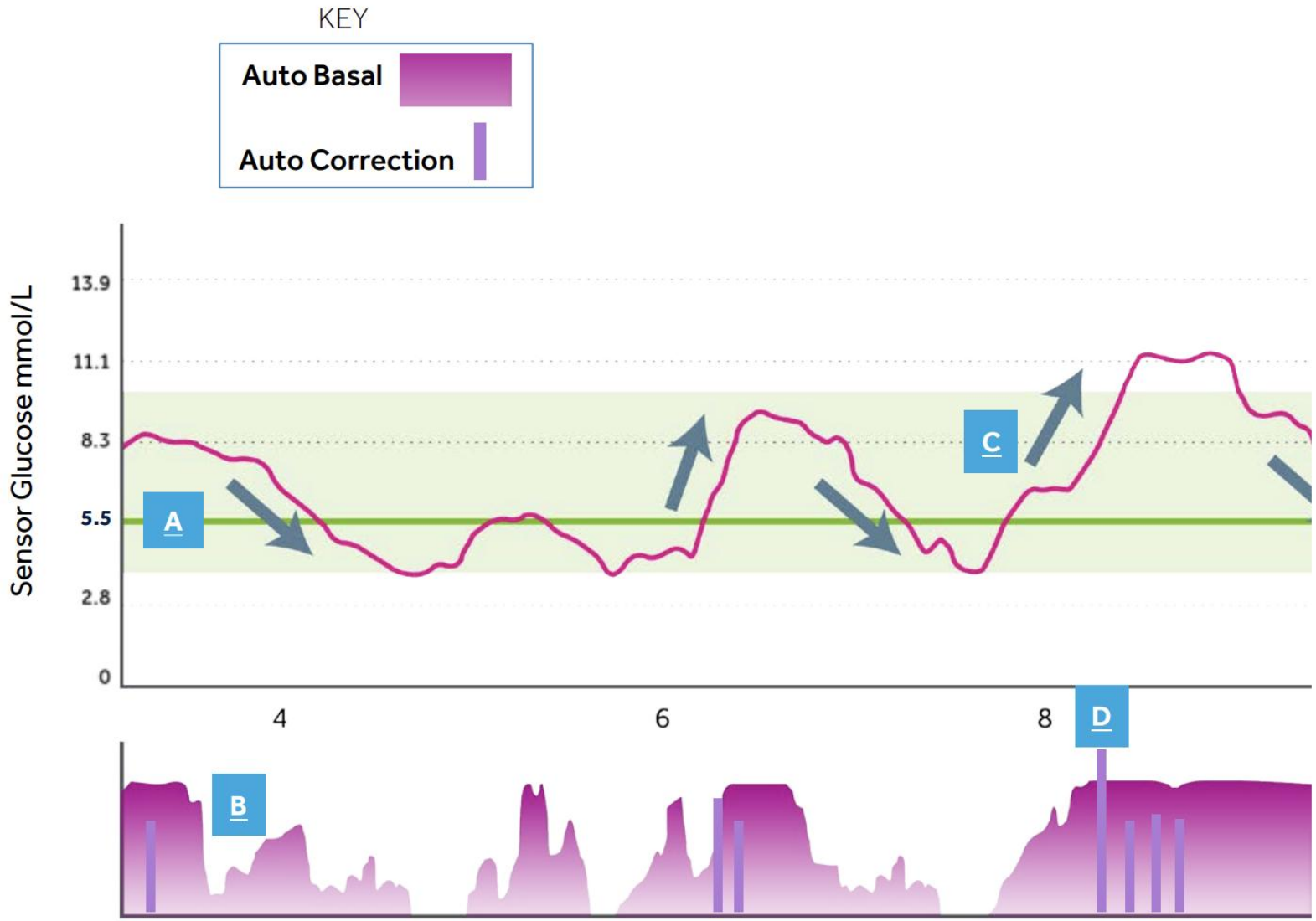
How does Medtronic 780G work?

- Algorithm does not used manual set basal rates, so changing basal rates will not impact Auto Mode
- ↓ basal insulin when sensor glucose is falling below target
- ↑ basal insulin when sensor glucose is rising above target
- Delivers auto-correction boluses if max basal reached, and SG > 6.7 mmol/l
- Adjustable gl

Algorithm uses real-time information to adjust basal every 5 mins aiming for target:

Current SG, How far SG is from the set target, How long SG has been away from target, How rapidly SG has been changing
Estimated total insulin (Basal and Bolus)

Algorithm uses TDD to calculate
- ISF (updated every midnight)
- Max and Min autobasal (updated every 6-12 days)



SUMMARY

A Selection between the default setting of 5.5 mmol/L, and 6.1 mmol/L or 6.7 mmol/L.

B Basal insulin adjusts every 5 mins based on SG values

C The auto correction target is set at 6.7 mmol/L

D Auto corrections delivered every 5 minutes if max basal reached and SG is above 6.7 mmol/L, as determined by the algorithm.
NO automatic corrections if Temp Target is set.

How does Control-IQ work?

- **Uses programmed basal rates** to modulate up and down. (Adjusting these at reviews will help improve how it works.)
- Control IQ Algorithm uses weight, insulin sensitivity from personal profile and the current glucose level, trend and IOB.
- Adjustment depends on predicted BG treatment values in next 30mins *(see next slide)*
- Adjusts set basal rate up and down every 5 minutes according to calculations aiming for a glucose level between 6.3-8.9mmol/l.
- Glucose target is set to 6.1mmol/l for boluses and AIT set at 5 hours

How does Control-IQ modulate insulin?

≥10.0 mmol/l	• Delivers auto-correction bolus (60% expected –IOB per hour) if SG is predicted to be >10 mmol/l
≥8.9 mmol/l	• ↑ basal insulin if SG is predicted to be > 8.9 mmol/l
6.25-8.9 mmol/l	• Maintains personal profile settings
≤6.25 mmol/l	• ↓ basal insulin if SG is predicted to be < 6.3 mmol/l
≤3.9 mmo/l	• Stops insulin delivery if SG is predicted to drop < 3.9 mmol/l

Always targets to 6.1.

How does CAMAPS FX work?

Most complex algorithm

- Predicts glucose over the next 2.5 – 4 hours
- Prediction is based on past insulin and glucose data and parameters which feed into algorithm (AIT, ISF, CHO intake)
- Calculates insulin dose and delivers basal as extended bolus every 10-12 mins
- Adjustable Personal Glucose Target (4.4-11.0 mmol/L)
- Algorithm uses body weight, TDD from last 5 days, learned insulin needs from previous days, current glucose level/trend & carbs on board

How does Omnipod 5 HCL work?

- SmartAdjust algorithm
- Predicts where SG will be in 60 mins and adjusts insulin delivery every 5 mins
- Basal delivered as microboluses every 5 mins
- Customisable target 6.1-8.3 mmol/l
- Smart bolus calculator (↑or↓suggested bolus based on CGM level and trend arrow and can ↓ suggested bolus based on IOB)
- ICR & ISF used for boluses but ISF not used for algorithm
- With each new Pod activation, the system adapts insulin delivery based on physiological needs and TDD (creates an ‘adaptive basal rate’

COMPARISON OF CURRENTLY AVAILABLE HCL SYSTEMS

HCL system	Smartguard	Tandem Control IQ	CamAPS FX	Omnipod 5
Pump	**Medtronic 780G**	**Tandem T:Slim**	**Dana RS/Dana I** **Ypsomed compatible pump**	**Omnipod 5 (with OP5 handset)**
CGM	Medtronic Guardian3 and 4	Dexcom G6	Dexcom G6/Libre 3	Dexcom G6 (with own phone and Clarity App)
License	**7-80 years** **TDD 8-250 units/day** **Weight 10-300kg** **Rapid acting insulins**	**> 6 years** **TDD 10—100 units/day** **Weight 25-140kg** **Rapid acting insulins**	**>1 year** **Pregnancy** **TDD 5-350 units/day** **Weight 10-300kg** **Rapid & ultra rapid insulins**	**> 2 years** **TDD 5u – 200u/d** (to get 3 day pod wear) **Rapid acting insulins**
Parameters for AID	Uses TDD from last 2-6 days to calculate algorithm parameters Ongoing adjustment	Personal profile (basal rates/ICR/ISF) Uses weight and TDD input by user to determine algorithm parameters	Uses weight and TDD input by user to determine algorithm parameters Ongoing learning	Target glucose is only factor affecting insulin delivery. Aggressiveness of algorithm is learnt from TDD history of previous 4-5 pods
Basal insulin	Basal insulin adjusted every 5 mins	Basal insulin adjusted if SG predicted to exit target range	Extended boluses given every 10-12 mins	Adaptive basal rate given as microboluses every 5 mins
Autocorrections	If SG>6.7mmol/l and max auto-basal	If SG predicted > 10mmol/l, 60% correction bolus, 1 per hour	Automatic correction boluses delivered as modulation of basal rate	Automatic correction boluses delivered as modulation of basal rate

HCL system	Smartguard	Tandem Control IQ	CamAPS FX	Omnipod 5
Bolus	Manual bolus No Extended boluses Uses programmed ICR	Manual bolus Extended bolus possible for 2hrs Uses programmed ICR & ISF	Remote bolus (phone app) No Extended boluses Uses programmed ICR	Remote bolus (handset) SmartBolus feature accounts for glucose AND TREND *Ensure reverse correction is on* No extended boluses Uses programmed ICR and ISF
Target	**Default 5.5 mmol/l 6.1 or 6.7 mmol/l**	**6.25-8.9 mmol/l**	**Personalised target 4.4 -11.0 mmol/l Default 5.8 mmol/l Variable targets across 24 hrs**	**Personalised target 6.1-8.3mmol/l** in up to 8 time segments
Adjustable parameters that affect algortihm	**ICR, AIT Target glucose**	**Basal profiles, ICR, ISF, weight Target glucose**	**ICR, weight, add meals Target glucose**	**Target glucose, AIT ICR & ISF (for meals)**
Overrides	Temp target 8.3 mmol/l	Exercise 7.8-8.9 mmol/l Sleep target – 6.36-6.7 mmol/l & no autocorrections	Ease off – reduces delivery by ~ a third Boost – increases delivery	Activity – raised target to 8.3, reduces insulin deliver and limits microbolus corrections
Reverts to manual mode	Loss of CGM data Sensor integrity concerns Max basal limit reached	Loss of CGM data Max insulin delivery reached	Loss of CGM data Loss of connection with pump	Loss of CGM data/warm up – Max deliver reached In LIMITED mode will deliver programmed basal OR learnt basal – whichever is lowest.
Data platform	Carelink	Glooko	Glooko	Glooko

Quirks of the systems

HCL system	Smartguard	Tandem Control IQ	CamAPS FX	Omnipod 5
Onboarding	Needs 48hrs in open loop before SmartGuard on Do not turn on pump out of box until ready to use Active Insulin: 2 hours aggressive/2 ½ hours normal/3 hours safe Set target at 5.5mmol/L	May need stronger ICRs & ISFs due to higher target and longer AIT	Previous settings should be OK Use Target 5.5 unless under 5s or high HbA1c then start higher	May need stronger ICRs & ISFs due to higher target
Rapid changes in activity levels/insulin needs	More active – raise PGT Less active/sick – lower PGT	Create second profile with stronger/weaker settings	More active – raise PGT Less active/sick – lower PGT	More active – raise PGT Less active/sick – lower PGT
Exercise	Temp target 60-90 ins before and before meal if eating in this time. Reduce meal bolus by 20%	Activity mode 60-90 ins before and before meal if eating in this time. Reduce meal bolus by 20%	Ease off 60-90 ins before and before meal if eating in this time. Reduce meal bolus by 20%	Activity mode 60-90 ins before and before meal if eating in this time. Reduce meal bolus by 20%
Food - Missed boluses - HFHP	Most likely system to manage missed boluses/HFPF - Leave it	Half carbs if remember within 60 mins, or push a correction using glucose reading. HFHP – extend	Add meal option for HFHP (complicated!)	Half carbs if remember within 60 mins, or push a correction using glucose reading. HFHP – leave it

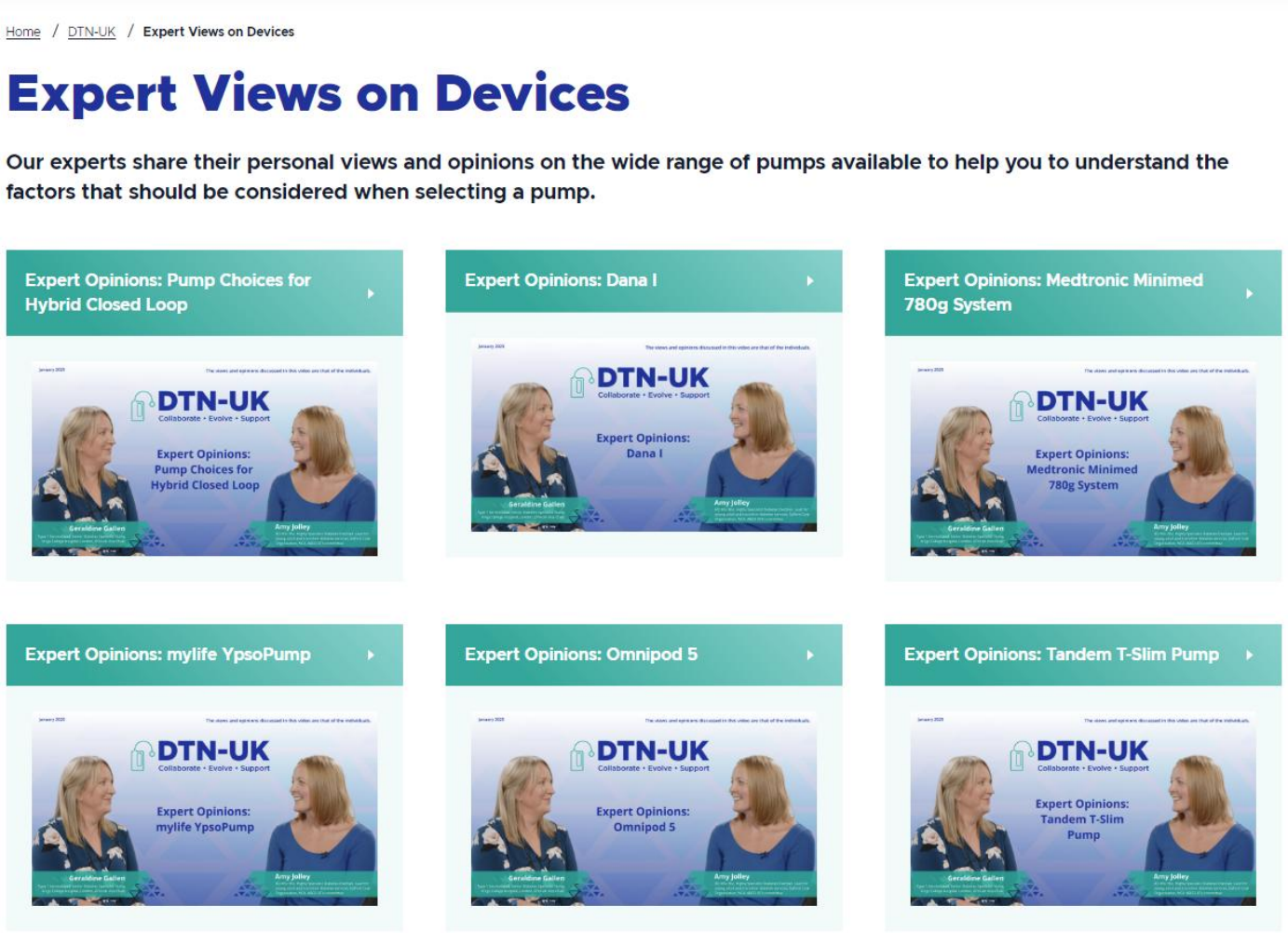
Top tips for getting the most of HCL systems

- Pre-bolus for food by 10-15 mins
- Announce exercise
- Less hypo treatment
- Suspend insulin if removing pump
- Keep sensor accurate and connected
- Change cannula on schedule and keep sites healthy
- Respond to alerts/alarms
- Notice when out of loop and do what is needed to get back in
  (calibrate, re-enter automode on Omnipod from limited mode)

Resources- DTN UK videos

- Large number of devices to choose from
- Need to be aware of pros and cons
- DTN resources to support choice
- No “preferred” system – patient choice remains key

[Expert Views on Devices | The Association of British Clinical Diabetologists]



Resources….

SEE ALL RESOURCES

DTN-UK
Collaborate • Evolve • Support

Getting started on Hybrid Closed Loop Systems - Tandem t:slim X2 Insulin Pump with Control-IQ™

Resource Type

Diabetes Technology Network (DTN-UK)

Video

Getting started on Hybrid Closed Loop Systems - Medtronic MiniMed™ 780G

Resource Type

Diabetes Technology Network (DTN-UK)

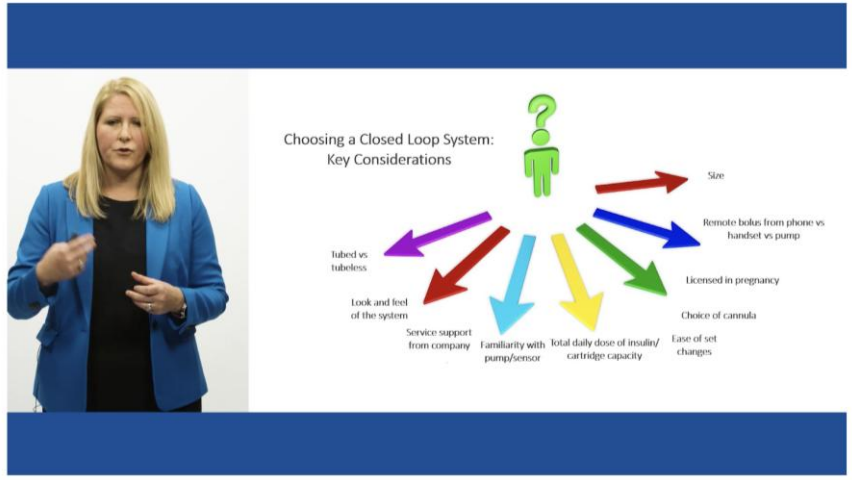
Getting started on Hybrid Closed Loop Systems - CamAPS FX

Resource Type

Diabetes Technology Network (DTN-UK)

Home / Resources / Choosing your Hybrid Closed Loop System

Choosing your Hybrid Closed Loop System



Presented by Professor Pratik Choudhary and Dr Emma Wilmot

Home / Resources / Hybrid Closed Loop Systems and Exercise

Hybrid Closed Loop Systems and Exercise

HCL modules now available on Glooko academy

Reviewing hybrid closed loop (HCL) systems

General Considerations

- Review time in automode, time in range, time below range and AGP.
- Dive into daily reports to look for patterns.
- Is automode > 80%? If not, assess why.
- If TIR is less than expected:
- Behaviour vs structure- are the settings correct? Have the automode settings been optimised?
- Review timing of bolus, advise importance of pre-bolus timing.
- Assess for missed bolus or snacks, If given late could cause initial hyperglycaemia then post prandial hypos. Educate if late bolus < 1 hr from meal only enter half of carbs eaten as system would have already started correcting, >1hr correct through bolus calculator.
- Review is user is accurately carbohydrate counting
- Check if user is over-riding the bolus calculator or entering fake carbs
- Review if pump is correcting or stopping basal after meals, if so the ICR may need adjusting.
- Check if hyperglycaemia is secondary to hypo treatments and revisit education. Overtreatment of hypos could cause the pump to correct
- Does the user know what to do with unexplained highs, If above 15.0mmol/l for >2hrs change cannula.
- Check set changes are appropriate e.g. steel cannulas usually need changing every 2 days & silicone every 3 days or 7 days depending on cannula.
- Assess the user knows when/how to use the special features 'exercise mode' to avoid hypoglycaemia
- Update user weight every 6 months if using Ypsomed or Tandem T-slim x2 pum

Illness Management

- Check user has a ketone meter and blood ketone strips on prescription
- Check user had a management plan for illness management/sick days
- Check user has back up insulin pens

Quick reference guide - adjustments that can be made in automated HCL mode

Pump	Basal rates	ICR	ISF	Active insulin time	Target level	Exercise/activity mode
Medtronic 780G	❌	✅	❌	✅	✅	✅
Omnipod 5	❌	✅	✅	✅	✅	✅
Tandem T-slim x2	✅	✅	✅	❌	❌	✅
CamAPS Ypsopump & Dana I	❌	✅	❌	❌	✅	✅

Take Home Messages

- Basic approach is similar across all HCL systems
- Confidence building
- Lets support each other
- Good luck!