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Hybrid-closed loop systems: Right tech for the right job

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Disclosures

Consultancy services for Medtronic and Ypsomed; previous recipient of personal fees from Roche and Dexcom

What is our job?

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

https://onlinelibrary.wiley.com/doi/epdf/10.1111/dme.15078

- Be an expert – what systems are you offering? Which systems do you feel you need more experience with? What are you doing about this?
- Provide guidance and support the patient with the selection process
- Know how to identify those who may benefit from additional support before, during, after initiation – psychology, carb counting, bolus timing.

Hybrid Closed Loop Systems

Medtronic 780G

Cam APS

Tandem Control IQ

Omnipod 5

Considerations when choosing a system

Licence	Algorithm location	CGM sensor	Adaptive learning	Glucose target	Auto-mode exit	Activity mode?	How do you bolus?	Data
▪ Age limitations? ▪ Pregnancy?	▪ Pump? ▪ App?	▪ Cost ▪ Calibration requirements ▪ Accuracy ▪ Supply	▪ Daily,day-to-day and diurnal. ▪ Does it use one or more of these?	▪ Can you customise the target? ▪ Will it bring people down too fast?	▪ Does it force you out of auto mode?	▪ Can you boost and ease off? ▪ Is activity mode possible?	▪ From pump or phone?	▪ How is data monitored?

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C|A|R|E|S™ Framework for Advanced Diabetes Devices

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]

CARES Framework_1pLtr (pantherprogram.org)

Potential barriers to HCL therapy

- Difficulty in using insulin pump therapy safely
- Skin reactions to multiple CGM adhesives
- Suboptimal CGM accuracy
- Prefer to remain in control of insulin delivery
- Achieving higher TIR than can be achieved by HCL
- Information overload
- Alarm fatigue

Griffin TP, Gallen G, Hartnell S, Crabtree T, Holloway M, Gibb FW, Lumb A, Willmot EG, Choudhary P, Hussain S. UK's Association of British Clinical Diabetologist's Diabetes Technology Network (ABCD-DTN): Best practice guide for Hybrid Closed-Loop Therapy. Diabetic Medicine. 2023 Mar 18:e15078.

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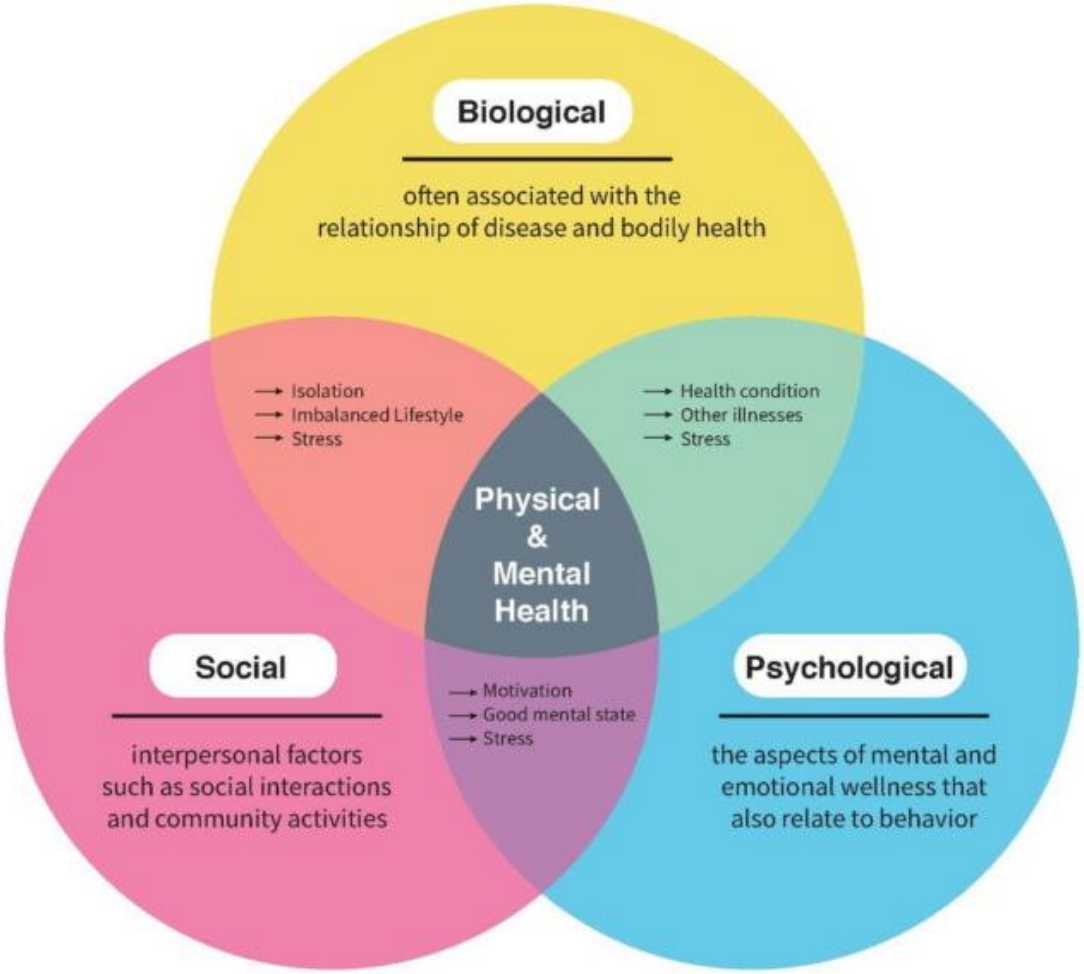
diabetes psychology network

Assessing for, mitigating and addressing psychological issues in people with diabetes accessing hybrid closed loop systems

Diabetes Psychology Network, December 2023

Hybrid Closed Loop (HCL) systems offer significant benefits in diabetes management, diabetes outcomes and quality of life. However transitioning to HCL, particularly for those new to pump therapy, can sometimes be a stressful experience for both the person with diabetes and the diabetes healthcare team. The following guidance document has been developed in order to support teams to work collaboratively with people living with diabetes to ensure the best possible outcomes, before, during and after moving on to HCL therapy.

Biopsychosocial (BPS) model



Special considerations

- Pump naïve individuals
- People with T1D for many years
- People with pre-existing retinopathy
- People with very high HbA1c
- People with learning disabilities
- People who are neurodivergent
- Frailty

- Transient worsening retinopathy
- Insulin neuritis
- Transient oedema
- Worsening albuminuria

Consider: Period of open-loop mode
Higher glucose targets
Using exercise targets
More frequent follow up

Adapted pre-pump/HCL training options
Review education options available

How will your patients be choosing their pump systems?

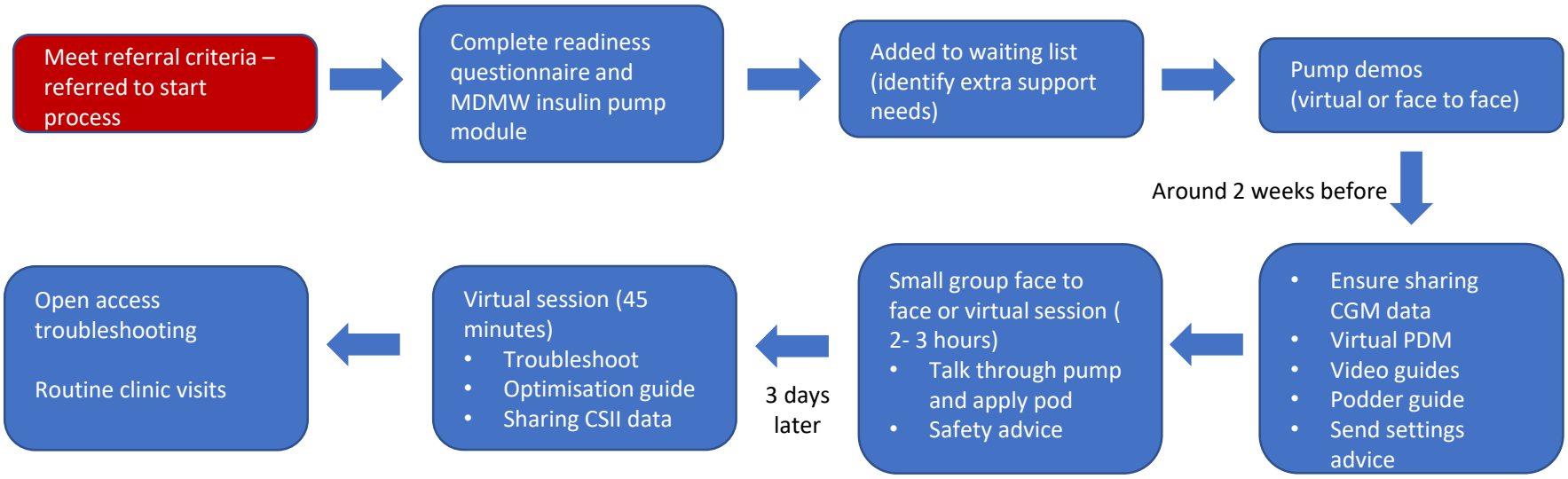
- Will they have a choice?
- Will they have free reign to choose without bias?

Options to support choice?

Edinburgh

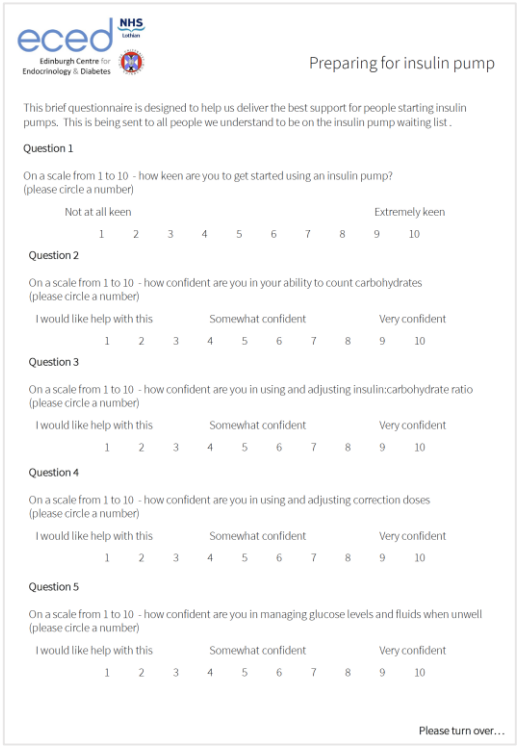
CSII start process

Edinburgh perspective



People preparing for CSII

Assessing readiness and supporting effective starts



eced Edinburgh Centre for Endocrinology & Diabetes — NHS Lothian

Preparing for insulin pump

This brief questionnaire is designed to help us deliver the best support for people starting insulin pumps. This is being sent to all people we understand to be on the insulin pump waiting list .

Question 1

On a scale from 1 to 10 - how keen are you to get started using an insulin pump?
(please circle a number)

Not at all keen — Extremely keen

1 2 3 4 5 6 7 8 9 10

Question 2

On a scale from 1 to 10 - how confident are you in your ability to count carbohydrates
(please circle a number)

I would like help with this — Somewhat confident — Very confident

1 2 3 4 5 6 7 8 9 10

Question 3

On a scale from 1 to 10 - how confident are you in using and adjusting insulin:carbohydrate ratio
(please circle a number)

I would like help with this — Somewhat confident — Very confident

1 2 3 4 5 6 7 8 9 10

Question 4

On a scale from 1 to 10 - how confident are you in using and adjusting correction doses
(please circle a number)

I would like help with this — Somewhat confident — Very confident

1 2 3 4 5 6 7 8 9 10

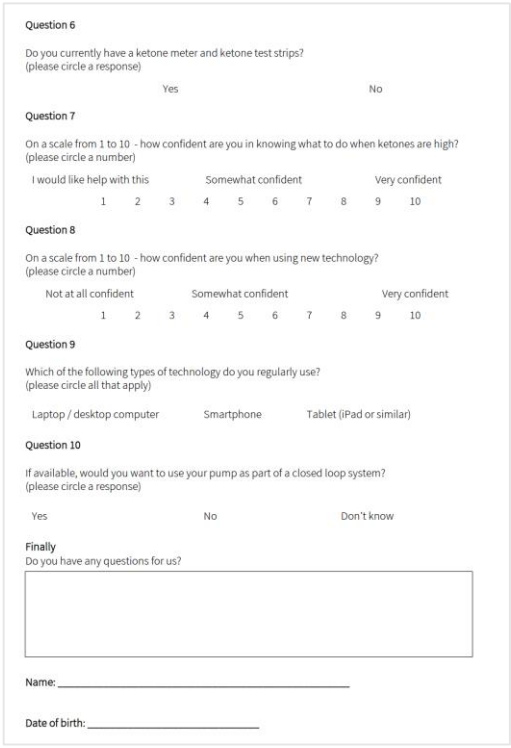
Question 5

On a scale from 1 to 10 - how confident are you in managing glucose levels and fluids when unwell
(please circle a number)

I would like help with this — Somewhat confident — Very confident

1 2 3 4 5 6 7 8 9 10

Please turn over…



Question 6

Do you currently have a ketone meter and ketone test strips?
(please circle a response)

Yes — No

Question 7

On a scale from 1 to 10 - how confident are you in knowing what to do when ketones are high?
(please circle a number)

I would like help with this — Somewhat confident — Very confident

1 2 3 4 5 6 7 8 9 10

Question 8

On a scale from 1 to 10 - how confident are you when using new technology?
(please circle a number)

Not at all confident — Somewhat confident — Very confident

1 2 3 4 5 6 7 8 9 10

Question 9

Which of the following types of technology do you regularly use?
(please circle all that apply)

Laptop / desktop computer — Smartphone — Tablet (iPad or similar)

Question 10

If available, would you want to use your pump as part of a closed loop system?
(please circle a response)

Yes — No — Don't know

Finally

Do you have any questions for us?

Name: _____

Date of birth: _____

How at BCH support choice of AID?

Birmingham Women's and Children's NHS Foundation Trust

- Age:
  - 7yrs or older = MiniMed 780G
  - 6yrs or older – T Slim X2 with Control-IQ
  - 2yrs or older = Omnipod 5
  - 1yr or older = CamAPS FX
- Mobile phone required?
  - Yes: CamAPS FX, Omnipod 5
  - No: Tandem X2 with Control IQ and MiniMed 780G
- Tubing:
  - No: Omnipod 5
- CGM preference:
  - Dexcom G6: Tandem X2 with Control IQ, Omnipod 5, CamAPS FX
  - Libre 3: CamAPS FX
  - Guardian 4: MiniMed 780G
  - Dexcom G7: Tandem X2
- Control over the algorithm:
  - Lots of control: Tandem X2 with Control IQ
  - Moderate control: Omnipod 5 & CamAPS FX
  - Little control: MiniMed 780G

Type 1 Diabetes is a self-management condition, so provide pros and cons and pre-work objectively:

- **Selection https://forms.gle/KrRTenjYuBumTPXE9**

Flipped learning?

Birmingham Women's and Children's NHS Foundation Trust

- Pre-work engagement with T-Slim X2 simulator
- https://forms.gle/LPFdKGq9Ywx4NoDW9

- Pre-work engagement with 780G with simulator
- https://forms.gle/R7nGvibHNpW8UESL9

- Pre-work engagement with OP5 with simulator
- https://forms.gle/HB26ez6pqcWtmeVW8

Salford diabetes team 2022-23

- Referred from a specialist clinic appointment
- Meets criteria; discuss pump contract with patient at MDT appointment with consultant and diabetes educator
- Send patient links to systems offered with clinical advice of which we would recommend (individualised).
- Review in a second clinic appointment with demo pump of choice and prepare for group start – set up with compatible CGMS and prepare any tech required (apps etc)

TIME BECOMING A CONCERN!

Salford diabetes team 2024

ELIGIBLE PATIENTS HAVE BEEN CONTACTED BY TEXT/LETTER TO INFORM OF OPPORTUNITY TO ACCESS HCL SYSTEMS AND PROCESS TO FOLLOW IF INTERESTED

FOUR IN PERSON HCL PUMP SHOWCASES BOOKED FOR 2024 ACROSS OUR DISTRICT – REGISTRATION REQUIRED

PATIENT CAN ATTEND VIRTUAL EVENTS TO LEARN MORE/ASK QUESTIONS – THESE ARE RECORDED FOR ON-DEMAND ACCESS – SPRING 2024

PATIENT COMPLETES QUESTIONNAIRE WITH PUMP CHOICE IDENTIFIED – TRIAGED BY HCP FOR CLINICAL AGREEMENT

TECHNICIAN SUPPORTS PREPARATIONS WITH PATIENT FOR PUMP START IN RELATION TO TECHNOLOGY REQUIRED ON PHONES AND ANY REGISTRATIONS OR TRAINING TO COMPLETE; AND CGM SWAPS

Salford diabetes team 2023-24

- For patients not attending the showcases/virtual meetings, they are offered support to choose the system they would like to proceed with via appointment with consultant and diabetes educator

- Continue to recommend structured education prior to pump start from MDI and update session for CSII to HCL:

  - DAFNE standard / 5 x1 / virtual courses
  - One-day course developed
  - Diabetes MyWay/ Bertie for online learning with assessments
  - New DAFNE online course due to be launched for those progressing to HCL

Salford diabetes team 2023-24

75 / 25 split:

- Group starts where appropriate – in person and virtual

- industry supported when available but team competent to start most systems independently

- One-to-one starts offered where need identified
- Exploring industry offering of virtual switches from CSII to HCL for those identified as “low-risk” which free’s up more time to support complex situations

Hybrid Closed Loop (HCL) Systems Comparison Chart*

Diabetes Specialist Nurse Forum UK

Diabetes Specialist Nurse Forum UK	Medtronic	Tandem	Advanced Therapeutics	Ypsomed	Insulet**
HCL algorithm	SmartGuard	Control IQ	CamAPS FX	mylife Loop (powered by mylife CamAPS FX)	SmartAdjust
Location of algorithm	Pump-integrated	Pump-integrated	App based (Android)	App based (Android)	Pod-integrated
Pump	Medtronic 780g	T-slim X2	DANA-i	mylife YpsoPump	Omnipod 5
Pump type	Tethered (tubed)	Tethered (tubed)	Tethered (tubed)	Tethered (tubed)	Patch (tubeless)
Continuous glucose monitor (CGM)	Guardian 4 (no calibration)	Dexcom G6	Dexcom G6	Dexcom G6, Freestyle Libre 3	Dexcom G6
Control & bolus delivery operation	Pump	Pump	Android smartphone	Android smartphone	Omnipod 5 Controller
Pump charging mechanism	AA battery	Rechargeable	AAA battery	AAA battery	Battery within each pod Controller is rechargeable
Target glucose	5.5, 6.1 or 6.7 mmol/L (default 5.5)	6.25-8.9 mmol/L	Customisable from 4.4 to 11.1 (default 5.8)	Customisable from 4.4 to 11.1 (default 5.8)	6.1, 6.7, 7.2, 7.8, or 8.3 mmol/L
Exercise mode target glucose	8.3 mmols/L	7.8-8.9 mmol/L	No specific target. Ease off mode can be used for exercise	No specific target. Ease off mode can be used for exercise	8.3 mmol/L & delivery of less insulin
Sleep mode target glucose	No	6.25-6.7 mmols/L	Customisable glucose target can be adjusted overnight	Customisable glucose target can be adjusted overnight	Customisable glucose target or exercise feature (see above)
Bolus calculator based on	CGM value, glucose trend data and bolus calculator settings	CGM value only with bolus calculator settings	CGM value only with bolus calculator settings	CGM value only with bolus calculator settings	CGM value, glucose trend data and bolus calculator settings
Automated correction bolus settings	If predictive glucose > 6.7 mmols/L and if max basal rate is reached	If predicted glucose in 30 mins >10 mmols/L & increasing/max delivery is reached	Incorporated into continuous insulin delivery. Adjusts insulin delivery every 8-12 minutes	Incorporated into continuous insulin delivery. Adjusts insulin delivery every 8-12 minutes	Automated micro-boluses every 5 mins. Plus user initiated correction bolus
Active insulin time	Adjustable	Not adjustable (set at 5 hrs)	Adjustable	Adjustable	Adjustable
Set up requirements	Basal rates, ICR, ISF & active insulin time	TDD, body weight, basal rates, ICR & ISF	TDD & body weight	TDD & body weight	Basal rates, ICR, ISF & active insulin time
Learning mechanisms	Uses TDD over past 2-6 days. Requires 48 hours of manual mode to learn user profile	Uses body weight & TDD. Predicts glucose 30 mins ahead	Overall insulin needs, diurnal, post meal.	Overall insulin needs, diurnal, post meal	Adapts with each pod using previous TDDs. Predicts glucose 60 mins ahead
Remote monitoring for parents/ carers	Glucose and insulin data via CareLink Connect app	Glucose data via Dexcom follow app.	Glucose data via Dexcom follow app	Glucose and insulin data via 'companion' in mylife CamAPS FX app	Glucose data via Dexcom Follow app
Data share with HCPs	CareLink (via app in real-time)	Glooko (download needed)	Glooko (real-time)	Glooko (real-time)	Glooko (real-time)
Minimum and maximum daily dose	8-250 units per day	10-100 units per day	5-350 units	5-350 units	Min 5 units per day Min 85 units to activate pod
Pump capacity	300 units	300 units	300 units	160 units	200 units
Insulin compatibility	NovoRapid & Humalog	NovoRapid & Humalog	Any rapid and ultra rapid acting	NovoRapid, Humalog, Fiasp, Apidra & Lyumjev	NovoRapid, Humalog & Admelog
Licensed in pregnancy	No	No	Yes	Yes	No
Age Range	7-80 years	6 years & over	1 years & over	1 years & over	2 years & over
Demo pump app/simulator	Yes	Yes	?	Yes	Yes

Adapted for health care professionals from Tim Street's Hybrid closed loop systems: Version 2.0 April 2023

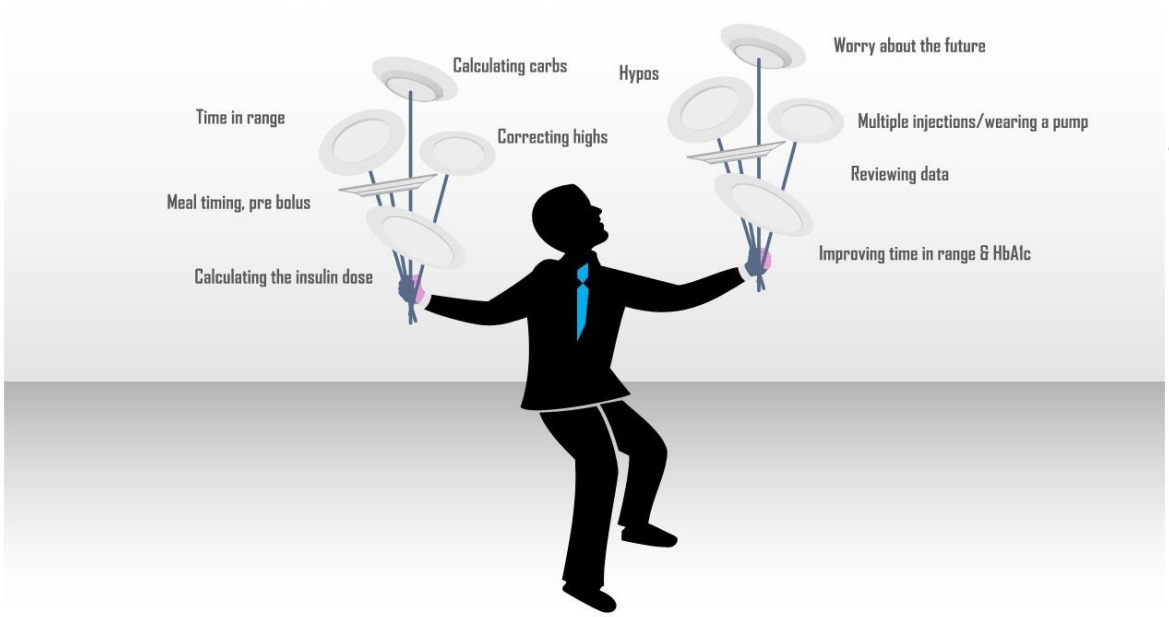
*Availability of systems will be dependent on agreement with NHS England work, led by Prof Partha Kar **expected mid 2023

ICR – insulin carbohydrate ratio
TDD – total daily dose of insulin
ISF – insulin sensitivity factor

What are the options for:

- Weekend hiker (office day job); currently uses temp basal reductions and reduced bolus' during hike
- Using pump therapy, lives alone and has a carer to support set changes/sensor changes
- Grazer through the day
- Uses >150units insulin a day on MDI therapy
- Does not consent to download pump/share pump and sensor data
- Plays sport (cardio) three times a week and gym (weights) two days a week
- Would like to be able to keep pump in clothes/hidden
- On 3rd phone in last 12 months – lost two and smashed two screens. Has lost a laptop on the train last week.
- Gets confused with carb counting and guesses (MDI therapy)
- Young female recently married reports not currently planning a pregnancy
- HbA1c >80mmol/mol for past 10 years; current sensor wear >85% and average glucose 21mmol/l

There is no best device – just the best device for the person in front of you



Key Points

- The person is at the centre of all care decisions
- Utilise peer support

At a peer support event for people with Type 1 diabetes last year we asked: Describe your diabetes in 1-2 words