Hybrid Closed Loop Therapy for Women with Type 1 Diabetes who are Pregnant

Tuesday 8 October 2024

12:30 – 14:00

Housekeeping

Candice Ward

Cambridge Diabetes Education Programme (CDEP)

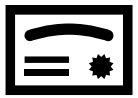
Housekeeping

Please say “Hi” via **Chat.**

Please ask a question via the **Q&A**.

If you have any technical issues, please leave and join again.

This webinar is being **recorded** and will be shared widely.



Certificate of attendance and the slides will be emailed after the webinar.

Welcome

Eleanor Scott

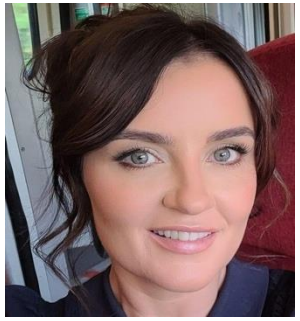
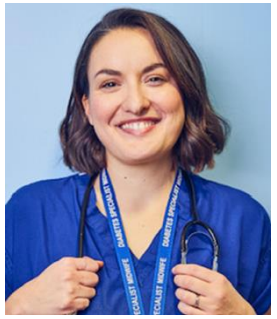
Professor of Medicine, University of Leeds & Leeds Teaching Hospitals Trust

Item	Lead	Timing
Welcome, aims & objectives	Eleanor Scott	12:30 - 12:35
HCL – The story so far	Partha Kar	12:35 - 12:40 (5 mins)
Hybrid Closed Loop in pregnancy – clinical evidence	Helen Murphy	12:40 - 12:55 (15 mins)
Supporting rollout of HCL to pregnant women with type 1 diabetes in your ICS	Karen Kennedy	12:55 - 13:15 (20 mins)
Onboarding to HCL in pregnancy	Nina Willer Emma Wilmot	13:15 - 13:35 (20 mins)
Question & Answer session	Candice Ward	13:35 - 13:55 (20 mins)
Concluding remarks	Eleanor Scott	13:55 - 14:00 (5 mins)

Hybrid Closed Loop Therapy for Women with Type 1 Diabetes who are Pregnant

Speakers & panelists



Partha Kar – Type 1 Diabetes & Technology Lead. Consultant in Diabetes, Portsmouth Hospitals University NHS Trust

Helen R. Murphy – Professor of Medicine, University of East Anglia (UEA), Norwich UK, Honorary Consultant Physician, Norfolk & Norwich University NHS Hospital Trust, Chair National Pregnancy in Diabetes (NPID) Audit

Eleanor M. Scott – Professor of Medicine, University of Leeds & Leeds Teaching Hospitals Trust

Karen Kennedy – Assistant Director, National Diabetes Programme, NHS England

Nina Willer – Diabetes Specialist Midwife, Norfolk & Norwich University NHS Hospital Trust

Emma Wilmot – Associate Professor, University of Nottingham, Honorary Consultant Diabetologist, University Hospitals of Derby and Burton NHS FT and founder of the ABCD Diabetes Technology Network UK

Verity Hawkes – Senior Programme Manager, National Diabetes Programme, NHS England

We would also like to acknowledge the policy development and analytical work of Mark Brodigan and Fiona Earnshaw within NHS England.

Disclosures

Eleanor Scott Research Support: Medical Research Council, Diabetes UK, National Institute for Health Research (NIHR), Abbott Diabetes Care. Speakers Bureau: Abbott Diabetes Care, Ypsomed, Lilly.

Helen Murphy serves on the Medtronic European and the Ypsomed UK Scientific Advisory Boards, reports research devices at reduced and no cost from Abbott Diabetes Care (no cost), Dexcom (reduced cost) and Medtronic (no cost), speaker honoraria from Abbott Diabetes Care, Dexcom, Eli Lilly, Medtronic, Novo Nordisk, Sanofi and Ypsomed. She chairs the National Pregnancy in Diabetes (NPID) audit and is a member of the editorial boards for Diabetes Care and Diabetologia journals.

Nina Willer has previously worked on a consultancy basis for Dexcom, Ypsomed and CamDiab.

Emma Wilmot EGW has received personal fees from Abbott, AstraZeneca, Dexcom, Eli Lilly, Embecta, Insulet, Medtronic, Novo Nordisk, Roche, Sanofi, Sinocare, Ypsomed

Candice Ward works as a consultant for CamDiab as their Training and Outreach Manager.

Aim:

By March 2027, all pregnant women with Type 1 diabetes will be offered Hybrid Closed Loop (HCL) therapy.

Session objectives

By the end of this session, you will understand:

- ✓ Why HCL therapy for women with Type 1 Diabetes who are pregnant is important.
- ✓ The evidence on which HCL systems improve outcomes in pregnancy.
- ✓ For ICB Leads: Supporting HCL pregnancy rollout in your system.
- ✓ For diabetes pregnancy healthcare professionals: Onboarding to HCL in pregnancy.

The webinar will not cover wider aspects of Hybrid Closed Loop policy.

HCL – The Story So Far

Partha Kar

Type 1 Diabetes & Technology Lead, NHS England.

Consultant in Diabetes, Portsmouth Hospitals University NHS Trust

HCL in T1D pregnancy – the clinical evidence

Helen Murphy

Professor of Medicine, University of East Anglia (UEA), Norwich UK, Honorary Consultant Physician, Norfolk & Norwich University NHS Hospital Trust, Chair National Pregnancy in Diabetes (NPID) Audit

Women with T1D have large babies

- ~50% of babies Large for Gestational Age
- LGA associated with preterm birth, neonatal care unit admission, and birth injuries (shoulder dystocia/fetal hypoxia leading cause of NHS litigation £££)
- Predisposes offspring to developing obesity, type 2 diabetes and cardiovascular disease in later life…..

Nothmann M NEJM archive 1941;224: 275-280

Murphy HR et al. Lancet Diabetes and Endocrinology 2021; 9:153-164

Challenges to managing T1D diabetes in pregnancy

1st trimester: HbA1c <48 mmol/mol (<6.5%)

Tighter CGM pregnancy targets 70% TIRp

2nd – 3rd trimester: HbA1c <43 mmol/mol (<6.0%)

Changing insulin sensitivity & rising post-meal resistance

Increased day to day variability

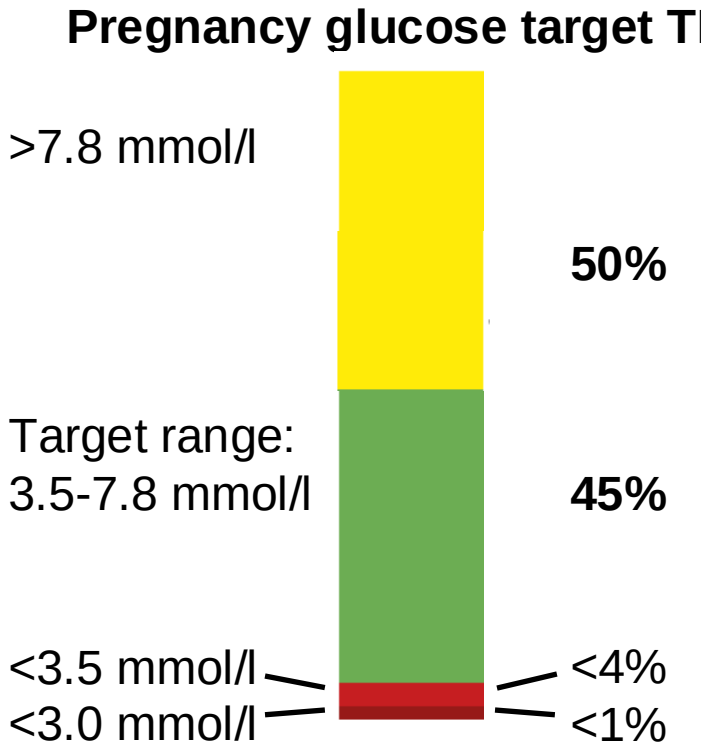
Fear of **hyperglycaemia** and effect on baby

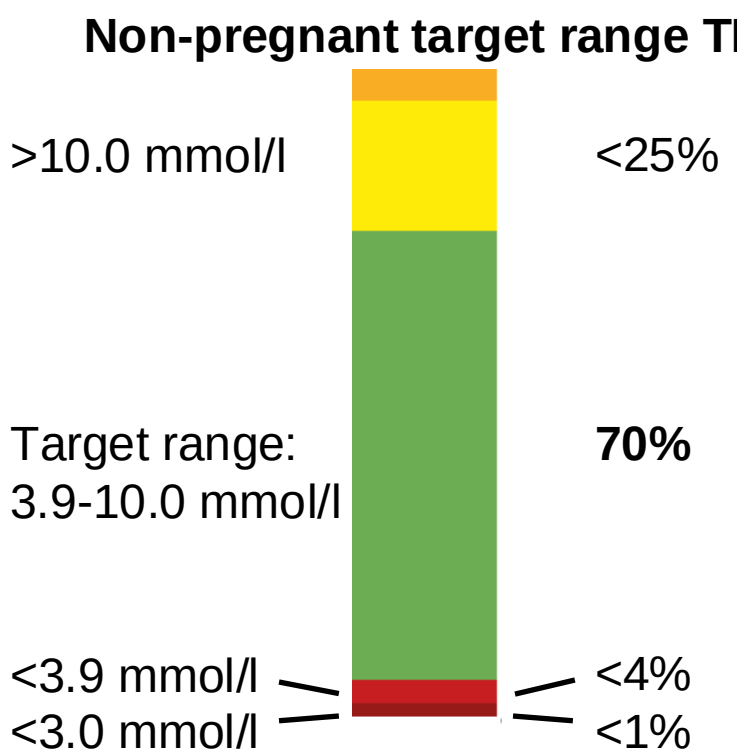
Gestation	What to expect?
4-8 weeks	Very labile levels
8-16 weeks	Increased insulin sensitivity ~ hypos
16 weeks +	Increasing insulin resistance ~ every few days
End of 3rd trimester	Increase in insulin sensitivity
Post-partum	Immediate decrease in insulin doses

Huge mental burden of self-management

Mc Lean A et al Diabetologia 2024, Lawton J et al DTT 2023

CGM Time in T1D Pregnancy Range (TIRp)





Battelino T et al. *Diabetes Care* 2019;42:1593-1603

Continuous glucose monitoring in pregnant women with type 1 diabetes (CONCEPTT): a multicentre international randomised controlled trial

*Denice S Feig, Lois E Donovan, Rosa Corcoy, Kellie E Murphy, Stephanie A Amiel, Katharine F Hunt, Elizabeth Asztalos, Jon F R Barrett, J Johanna Sanchez, Alberto de Leiva, Moshe Hod, Lois Jovanovic, Erin Keely, Ruth McManus, Eileen K Hutton, Claire L Meek, Zoe A Stewart, Tim Wysocki, Robert O'Brien, Katrina Ruedy, Craig Kollman, George Tomlinson, Helen R Murphy, on behalf of the CONCEPTT Collaborative Group**

Summary

Background Pregnant women with type 1 diabetes are a high-risk population who are recommended to strive for optimal glucose control, but neonatal outcomes attributed to maternal hyperglycaemia remain suboptimal. Our aim was to examine the effectiveness of continuous glucose monitoring (CGM) on maternal glucose control and obstetric and neonatal health outcomes.

Lancet 2017; 390: 2347–59

Published Online
September 15, 2017
http://dx.doi.org/10.1016/
S0140-6736(17)32400-5

Unequivocal evidence on the clinical & health economic benefits of using CGM to improve maternal glucose and neonatal outcomes in T1D pregnancy.

Feig DS et al. Continuous glucose monitoring in pregnant women with Type 1 diabetes (CONCEPTT): a multicentre randomised controlled trial. Lancet. 2017;390, 2347-2359
Murphy HR et al. Modelling potential cost savings from use of real-time continuous glucose monitoring in pregnant women with Type 1 diabetes. Diabetic Medicine 2019;36(12):1652-1658

NATIONAL DIABETES AUDIT

95% of women with **type 1** diabetes wore **continuous glucose monitors** in 2022

95%

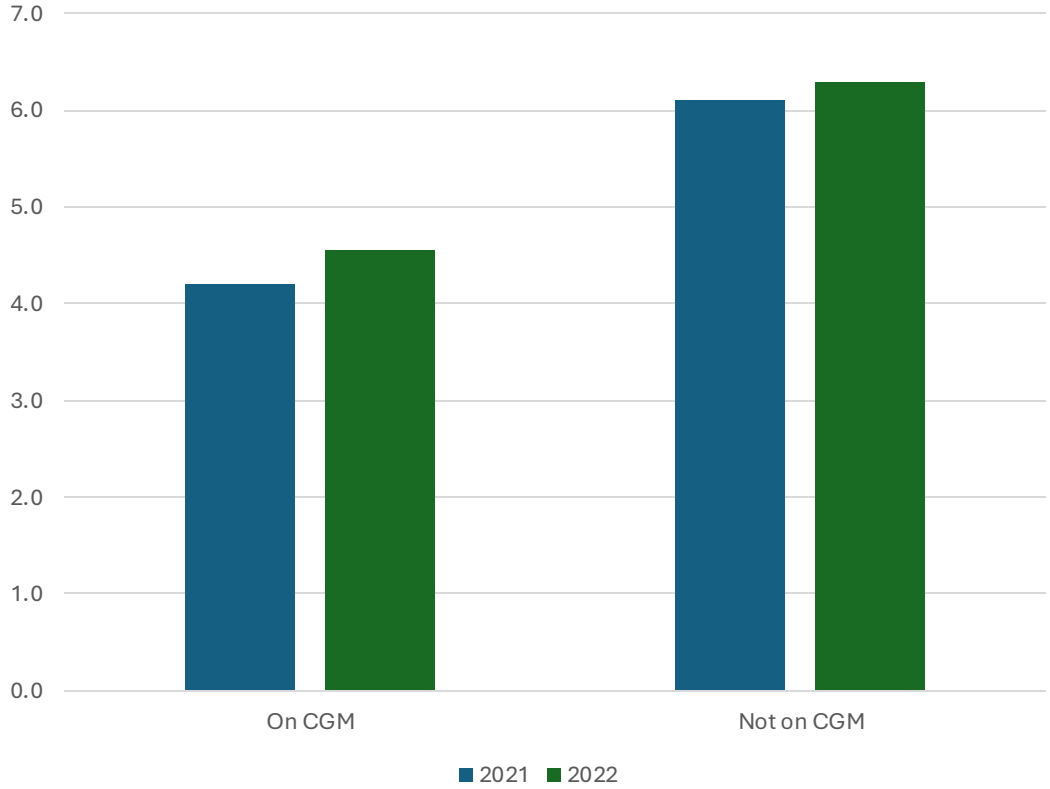
Real-world CGM use – N=2055

NATIONAL DIABETES AUDIT

Wearing continuous **glucose montiors** improved:

- **glucose levels** for mothers
- **outcomes** for women and babies

Serious adverse pregnancy outcomes (Birth defects, stillbirth, baby death)



Improved pregnancy glucose levels with:

- ✓ Fewer LGA babies
- ✓ Fewer preterm births
- ✓ Fewer neonatal care admissions

Scott EM, Murphy HR, Kennedy K, Kar P. CONCEPTT to care: the science of implementation in diabetes care. Lancet Diabetes Endocrinol. 2024 Feb 26:S2213-8587(24)00039-1.

Can HCL further improve maternal glucose?

In CONCEPTT, only ~30% CGM users achieved pregnancy glucose targets of 70% time in range

Still some way to go……

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Closed-Loop Insulin Delivery during Pregnancy in Women with Type 1 Diabetes

Zoe A. Stewart, M.D., Malgorzata E. Wilinska, Ph.D., Sara Hartnell, B.Sc., Rosemary C. Temple, M.D., Gerry Rayman, M.D., Katharine P. Stanley, M.D., David Simmons, M.D., Graham R. Law, Ph.D., Eleanor M. Scott, M.D., Roman Hovorka, Ph.D., and Helen R. Murphy, M.D.

ABSTRACT

BACKGROUND

In patients with type 1 diabetes who are not pregnant, closed-loop (automated) insulin delivery can provide better glycemic control than sensor-augmented pump therapy, but data are lacking on the efficacy, safety, and feasibility of closed-loop therapy during pregnancy.

METHODS

We performed an open-label, randomized, crossover study comparing overnight closed-loop therapy with sensor-augmented pump therapy, followed by a continuation phase in which the closed-loop system was used day and night. Sixteen pregnant women with type 1 diabetes completed 4 weeks of closed-loop pump therapy (intervention) and sensor-augmented pump therapy (control) in random order. During the continuation phase, 14 of the participants used the closed-loop system day and night until delivery. The primary outcome was the percentage of time that overnight glucose levels were within the target range (63 to 140 mg per deciliter [3.5 to 7.8 mmol per liter]).

RESULTS

The percentage of time that overnight glucose levels were in the target range was higher during closed-loop therapy than during control therapy (74.7% vs. 59.5%; absolute difference, 15.2 percentage points; 95% confidence interval, 6.1 to 24.2; P=0.002). The overnight mean glucose level was lower during closed-loop therapy than during control therapy (119 vs. 133 mg per deciliter [6.6 vs. 7.4 mmol per liter], P=0.009). There were no significant differences between closed-loop and control therapy in the percentage of time in which glucose levels were below the target range (1.3% and 1.9%, respectively; P=0.28), in insulin doses, or in adverse-event rates. During the continuation phase (up to 14.6 additional weeks, including antenatal hospitalizations, labor, and delivery), glucose levels were in the target range 68.7% of the time; the mean glucose level was 126 mg per deciliter (7.0 mmol per liter). No episodes of severe hypoglycemia requiring third-party assistance occurred during either phase.

CONCLUSIONS

Overnight closed-loop therapy resulted in better glucose control than sensor-augmented pump therapy in pregnant women with type 1 diabetes. Women receiving day-and-night closed-loop therapy maintained glycemic control during a high proportion of the time in a period that encompassed antenatal hospital admission, labor, and delivery. (Funded by the National Institute for Health Research and others; Current Controlled Trials number, ISRCTN71510001.)

From the Wellcome Trust–Medical Research Council Institute of Metabolic Science, University of Cambridge (Z.A.S., M.E.W., R.H., H.R.M.), and Wolfson Diabetes and Endocrine Clinic, Cambridge University Hospitals NHS Foundation Trust (S.H., D.S., H.R.M.), Cambridge, the Elsie Bertram Diabetes Centre (R.C.T., H.R.M.) and the Department of Obstetrics and Gynaecology (K.P.S.), Norfolk and Norwich University Hospitals NHS Foundation Trust, and the Norwich Medical School, University of East Anglia (H.R.M.), Norwich, the Ipswich Diabetes Centre, Ipswich Hospital NHS Trust, Ipswich (G.R.), and the Division of Epidemiology and Biostatistics, Leeds Institute of Cardiovascular and Metabolic Medicine, University of Leeds, Leeds (G.R.L., E.M.S.) — all in the United Kingdom. Address reprint requests to Dr. Murphy at Norwich Medical School, University of East Anglia, Fl. 2, Bob Champion Research and Education Bldg., Norwich NR4 7UQ, United Kingdom, or at hm386@medschl.cam.ac.uk.

N Engl J Med 2016;375:644-54.
DOI: 10.1056/NEJMoa1602494
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The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

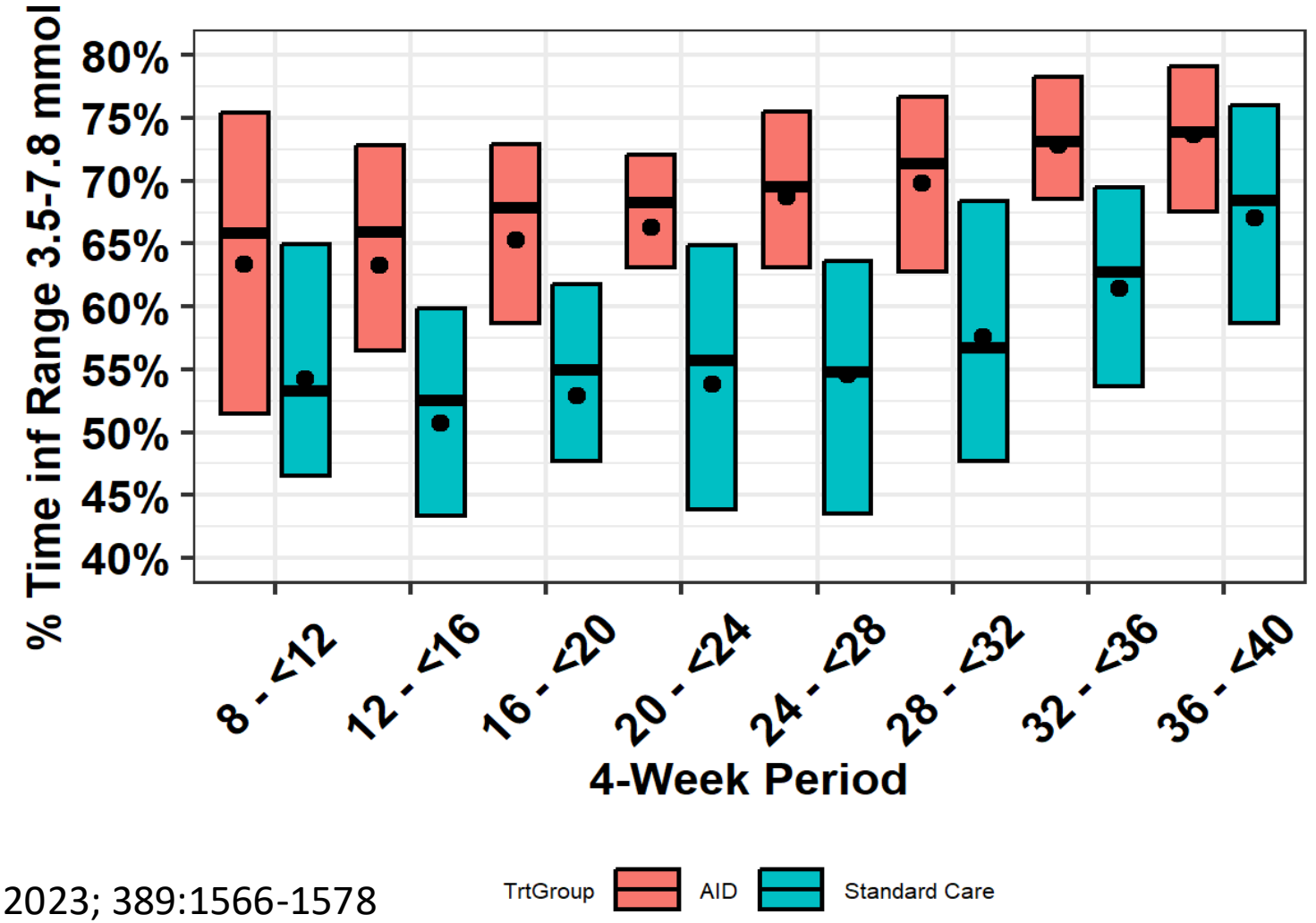
Automated Insulin Delivery in Women with Pregnancy Complicated by Type 1 Diabetes

Tara T.M. Lee, M.B., B.S., Corinne Collett, B.Sc., Simon Bergford, M.S., Sara Hartnell, B.Sc., Eleanor M. Scott, M.D., Robert S. Lindsay, Ph.D., Katharine F. Hunt, M.D., David R. McCance, M.D., Katharine Barnard-Kelly, Ph.D., David Rankin, Ph.D., Julia Lawton, Ph.D., Rebecca M. Reynolds, Ph.D., Emma Flanagan, Ph.D, Matthew Hammond, M.Sc., Lee Shepstone, Ph.D., Malgorzata E. Wilinska, Ph.D., Judy Sibayan, M.P.H., Craig Kollman, Ph.D., Roy Beck, Ph.D., Roman Hovorka, Ph.D., and Helen R. Murphy, M.D., for the AiDAPT Collaborative Group*

Lee T et al N Engl J Med 2023; 389:1566-1578

AiDAPT

CamAPS FX HCL improved maternal glucose from early pregnancy

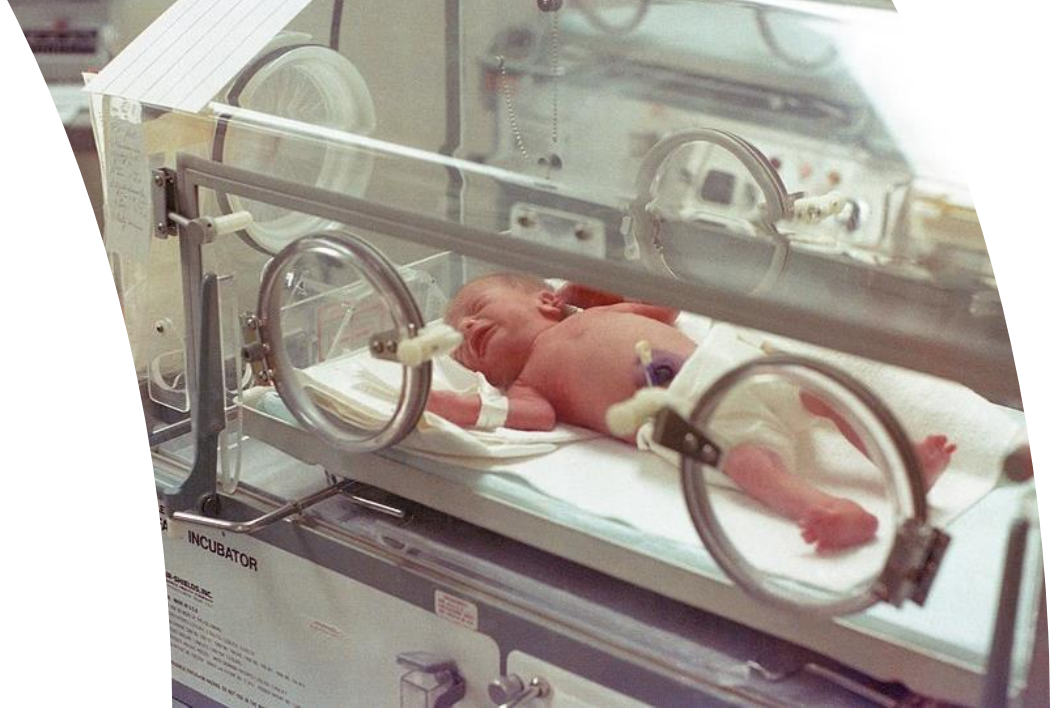


Lee T et al N Engl J Med 2023; 389:1566-1578

AiDAPT

Additional Benefits.....

- ✓ 3.7kg less gestational weight gain
- ✓ Less gestational hypertension
- ✓ Low rates of LGA/NICU
- ✓ Less worry, less work, more enjoyable pregnancy



Listening to women: experiences of using closed-loop in type 1 diabetes pregnancy

Lawton J et al Diabetes Technology & Therapeutics 2023 25:12, 845-855

AiDAPT

CamAPS FX Pregnancy-specific HCL

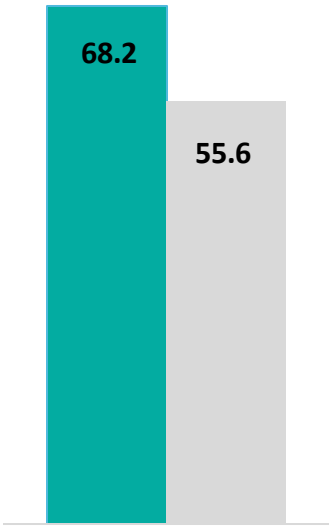
- ✓A license for use in pregnancy
- ✓A glucose target of ≤5.0 mmol/l
- ✓Clinically relevant improvement in maternal glucose (>5% extra time in the T1D pregnancy range) compared to CGM & MDI/Pump

AiDAPT

Differences between HCL systems?

CamAPS Fx
CamDiab

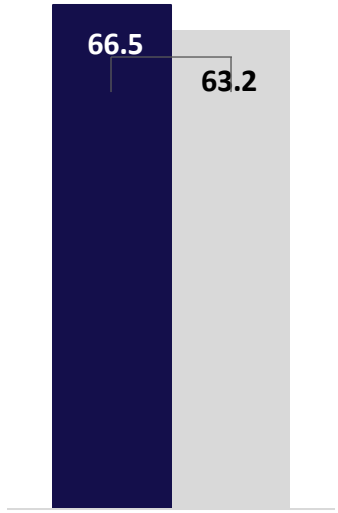
+10.5%
(p < 0.001)



TIR 3.5-7.8 mmol/L
(63-140 mg/dL)

- Broad population
- N=124 age 19-44 yrs
- BMI 18 – 49 kg/m^2
- HbA1c 7.7% (6.0 – 14.0%)
- 50% MDI
- Funded by NIHR

+1.88%
(p = 0.17)



TIR 3.5-7.8 mmol/L
(63-140 mg/dL)

Other leading HCL system

CamAPS FX | CGM + MDI or CSII | Other HCL System

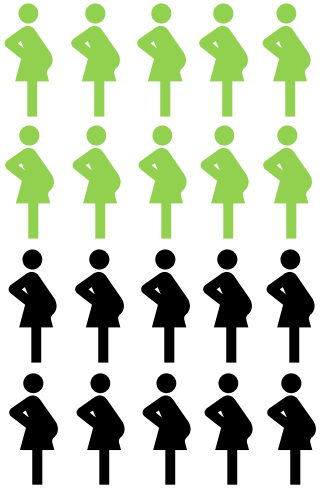
+24 mins overnight TIRp
-19 mins <3.5mmol/L

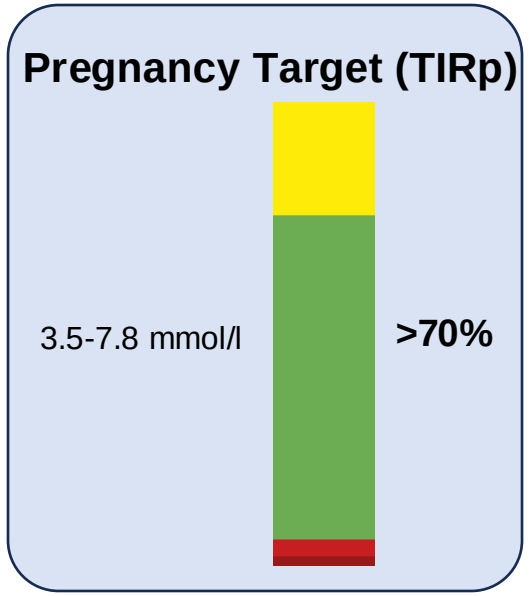
- Select population
- N=95 age 30.8 ± 4.6
- BMI 26.9 ± 5.4kg/m^2
- HbA1c 6.5 ± 0.9%
- 96% CSII users

Lee T et al AiDAPT N Engl J Med 2023; 389:1566-1578 Benhalima K et al Lancet Diab Endo. 2024 Apr 29, and Scott EM (commentary)

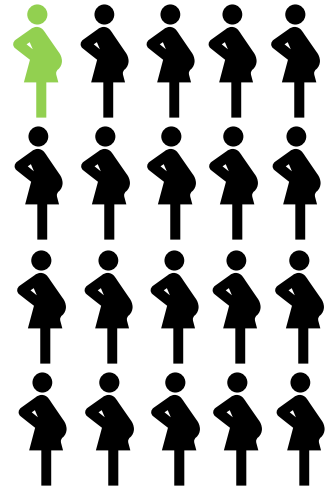
How many HCL users achieve 70% TIRp?

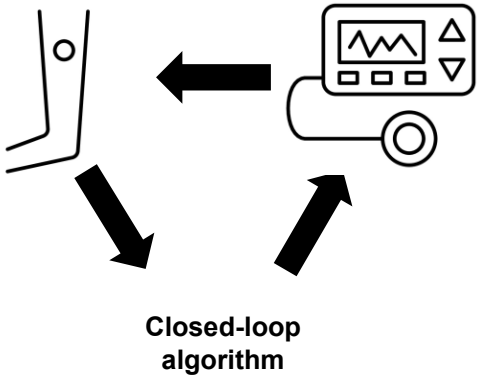
CamAPS Fx
1 in 2 women





Other HCL systems
1 in 20 women





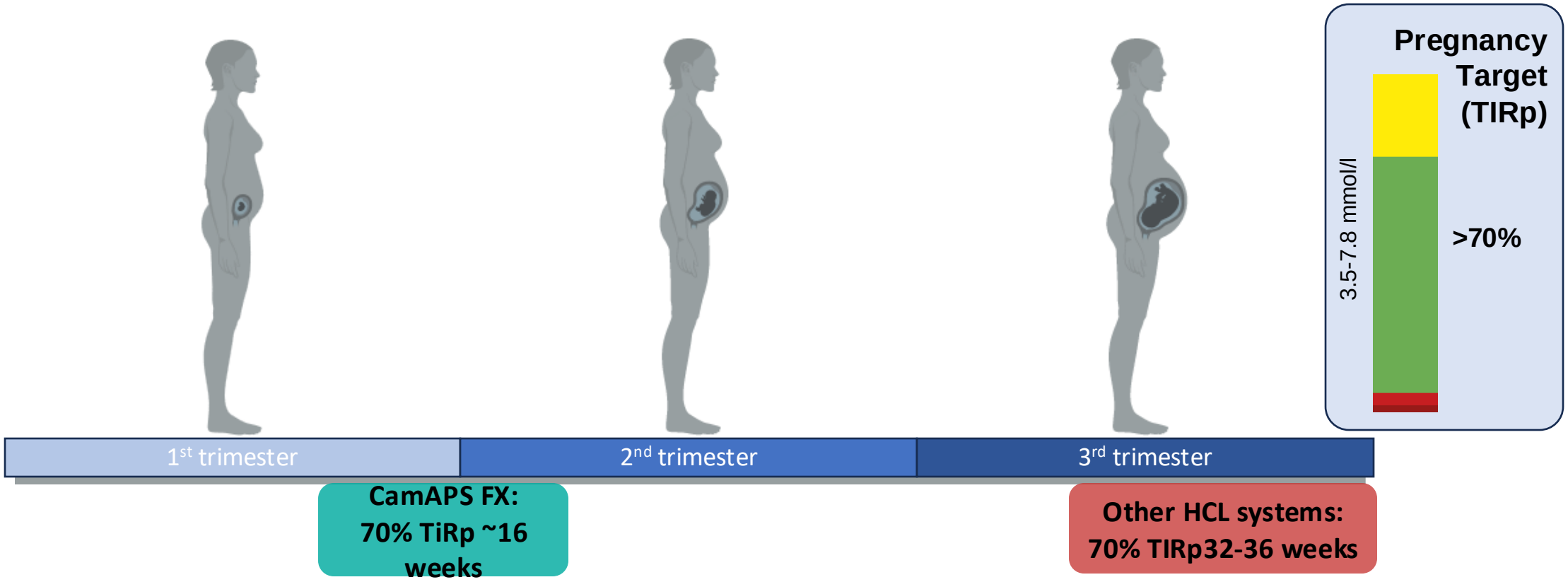
- ✓ 50% achieved 70% TIRp
- ✓ 3.7kg less weight gain
- ✓ LGA 39%

- ✗ 5% HbA1c >6.5% reached 70% TIRp
- ✗ 3.3-5.4 kg more weight gain
- ✗ LGA 69%

Lee T et al AiDAPT N Engl J Med 2023; 389:1566-1578

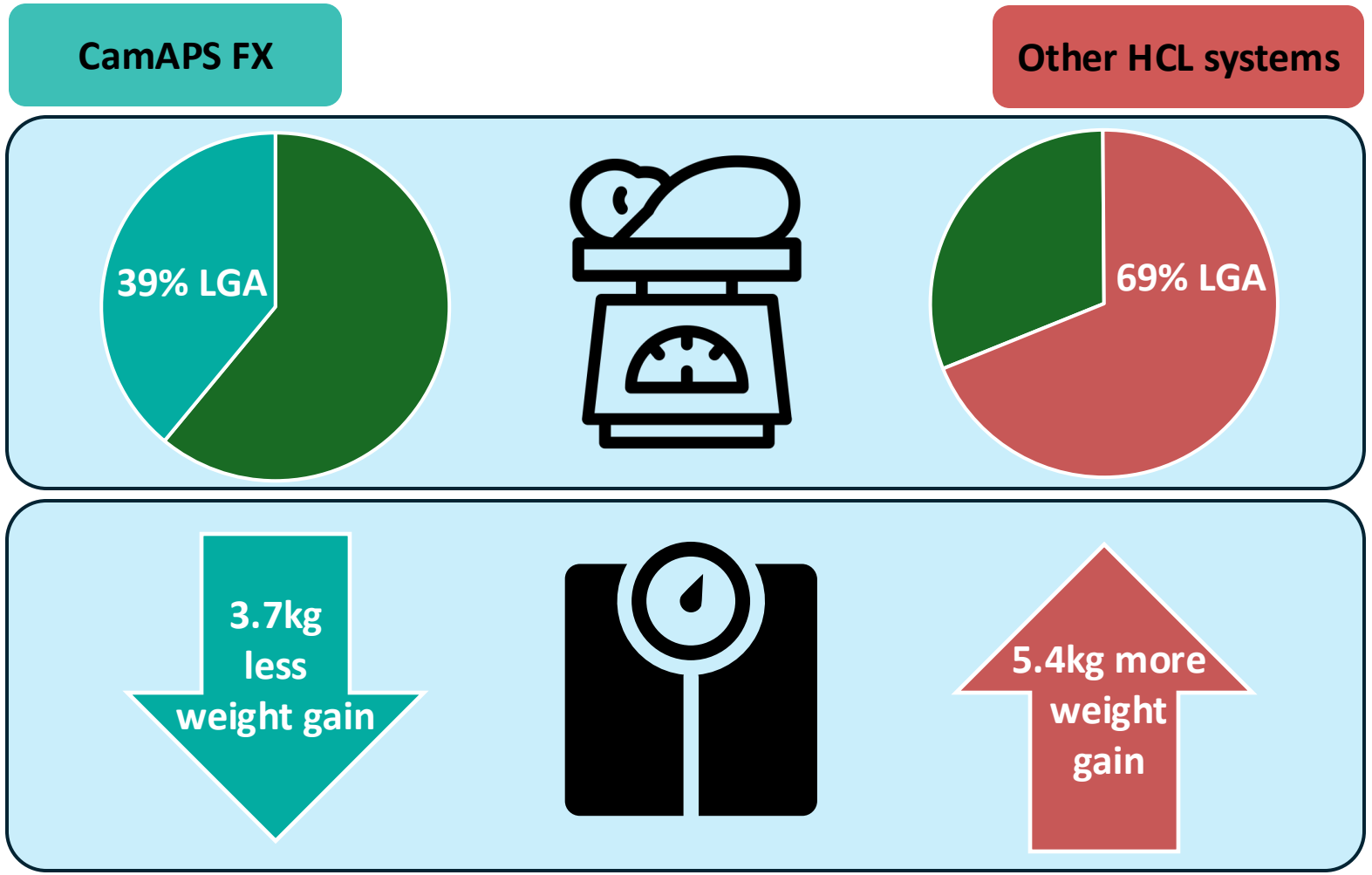
Quiros C et al Diabetes Technol Ther. 2024 Feb 28.

Too little too late with other HCL systems



"Important to refine the algorithm to better align with pregnancy requirements"

Pregnancy HCL benefits are system specific



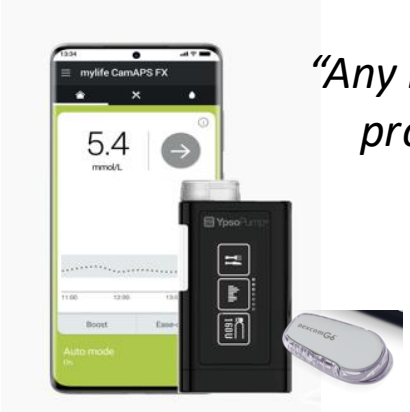
Lee T et al AiDAPT N Engl J Med 2023

Women with HbA1c>6.5%*
Quiros C et al Diabetes Technol Ther. 2024

Created with BioRender.com
Baby weight by Andre Buand from Noun Project (CC BY 3.0)

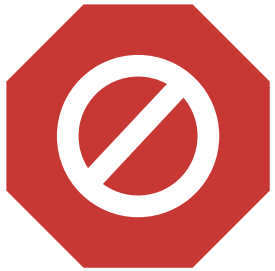
SWAP to CamAPS FX HCL during pregnancy

SWAP to CamAPS FX



*"Any intervention must be based on a shared decision-making process, ensuring the patient is aware of **all options** and supported to make an **informed choice**"*

Carefully consider Montgomery ruling...



https://services.nhslothian.scot/maternity/wp-content/uploads/sites/62/2022/09/RCOG-Impact-of-Montgomery-Ruling.pdf

HCL in T1D pregnancy decision tool

	Cam APS FX (Ypsomed or Dana)	Medtronic 780G	Tandem IQ	Diabeloop	Omnipod 5	Current standard care CGM (with MDI or Pump)
Licensed for use in pregnancy	☑	☒	☒	☒	☒	☑
Achieves glucose target of ≤5.0 mmol/l	☑ 4.4	☒ 5.5	☒ 6.25	☒ 5.6	☒ 6.1	☒
Evidence for clinically relevant improvement in maternal glucose outcomes (>5% improvement in TIRp 3.5-7.8) irrespective of age, BMI, booking HbA1c	☑ NEJM 2023	☒ Lancet D&E 2024; DTT 2024	☒ DTT 2024	☒ DTT 2024	☒	☑ Lancet 2017
Achieves time in pregnancy glucose range (3.5-7.8) TIRp >70% from first trimester	☑ Achieved in 1 in 2	☒ Achieved 1 in 20 in women with early pregnancy HbA1c >6.5%	☒	☒	☒	☒
Chance of having a big baby (Large for Gestational Age)	1 in 3 LGA rates 39%	2 in 3 LGA rates 60-70%	2 in 3 LGA rates 60-70%	2 in 3 LGA rates 60-70%	Unknown	1 in 2 LGA rates 50%
Maternal weight change in pregnancy	**3.7 kg less weight gain**	5.4 kg **more** weight gain in women with early pregnancy HbA1c >6.5%, and 3.3kg more if HbA1c <6.5%	3.3- 5.4 kg **more** weight gain	3.3- 5.4 Kg **more** weight gain	Unknown	Neutral
Development of any hypertensive disorder in pregnancy	20%		Unknown	Unknown	Unknown	42%

Lee TTM et al. **N Engl J Med**. 2023 , Benhalmina K et al. **Lancet Diab and Endo**. 2024, Quirós C et al. **Diabetes Technol Ther**. 2024 Feig DS et al **Lancet**. 2017

Barriers / perceived barriers

Clinician Inertia

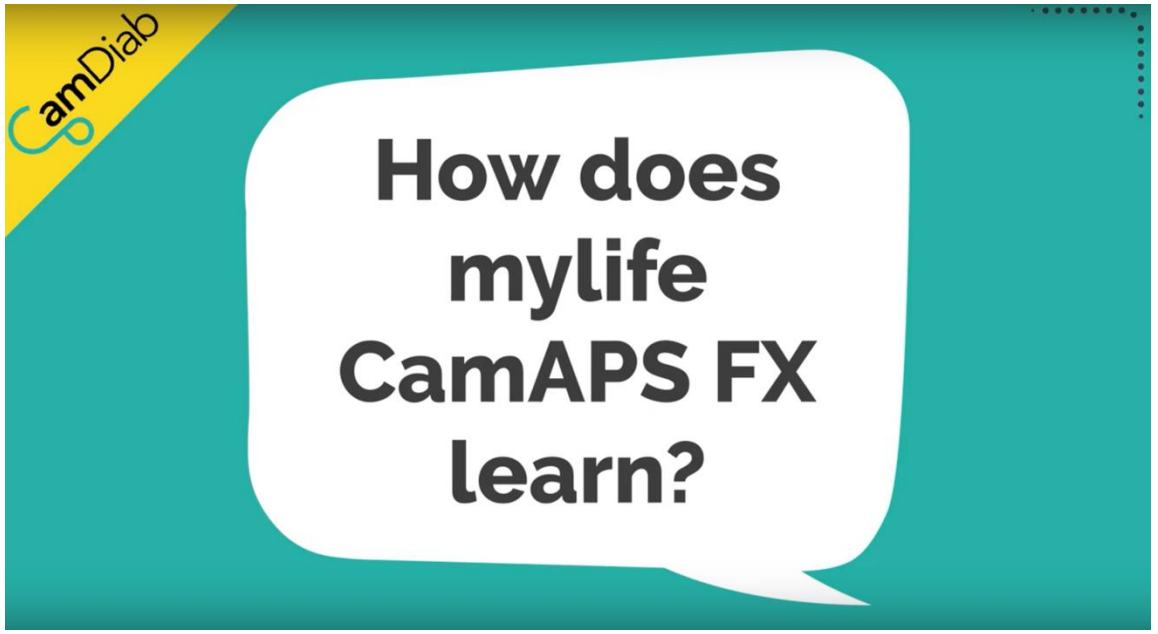
Patient Choice

Incompatible Phone

Existing Pump Warranty

Further Learning - https://youtu.be/JnckRXs2VWE?si=hoSJuxjq-pvND0Wi

https://www.youtube.com/watch?v=FjRgsgoxk4k



https://www.youtube.com/watch?v=98X3X9ie8uM


Diabetes
pregnancy teams
DO ONE
THING
NATIONAL DIABETES AUDIT

Supporting rollout of HCL to pregnant women with type 1 diabetes in your ICS

Karen Kennedy

Assistant Director Diabetes Programme – NHS England

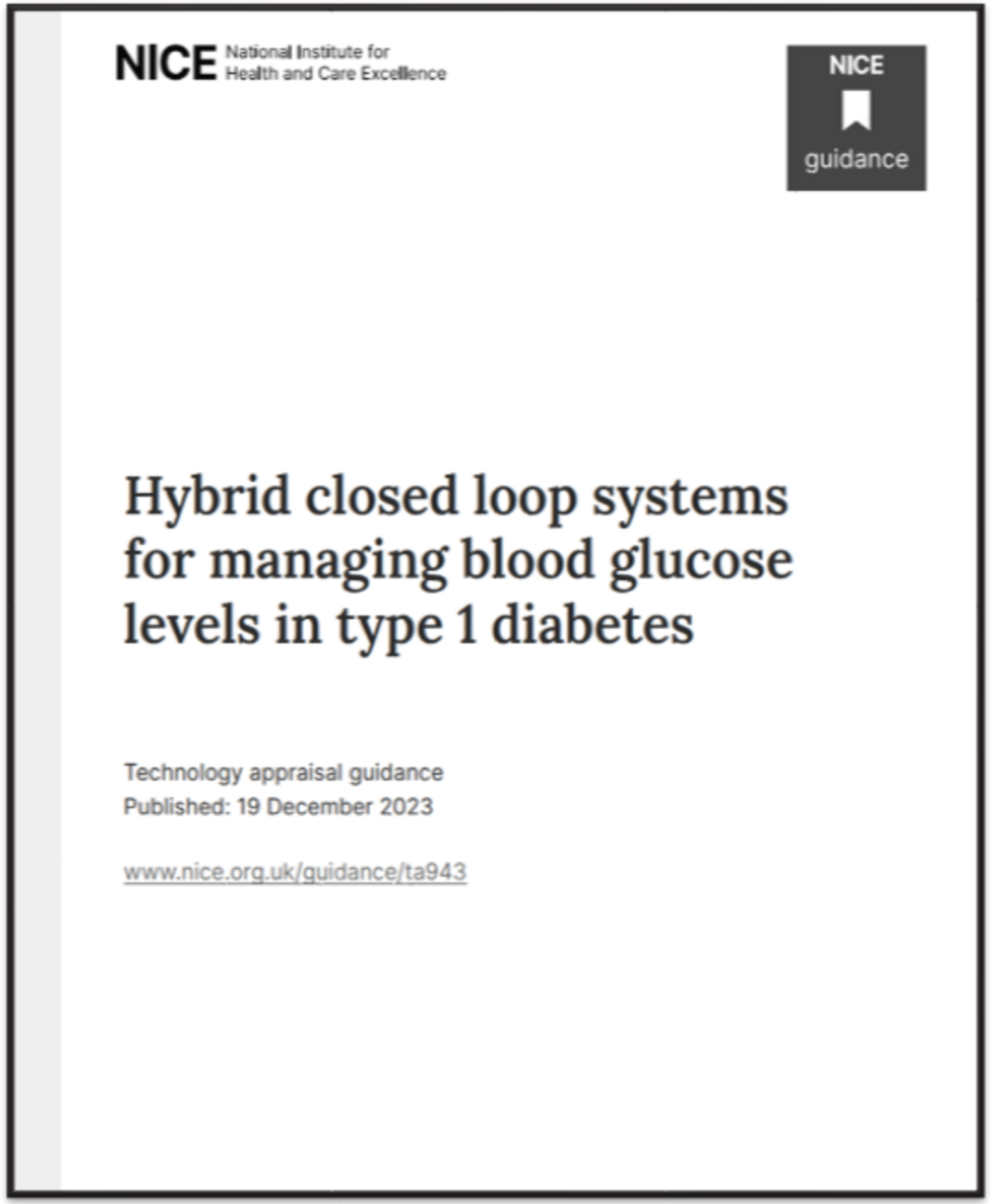
Hybrid Closed Loop

In Dec 2023 NICE TA943 recommended HCL for:

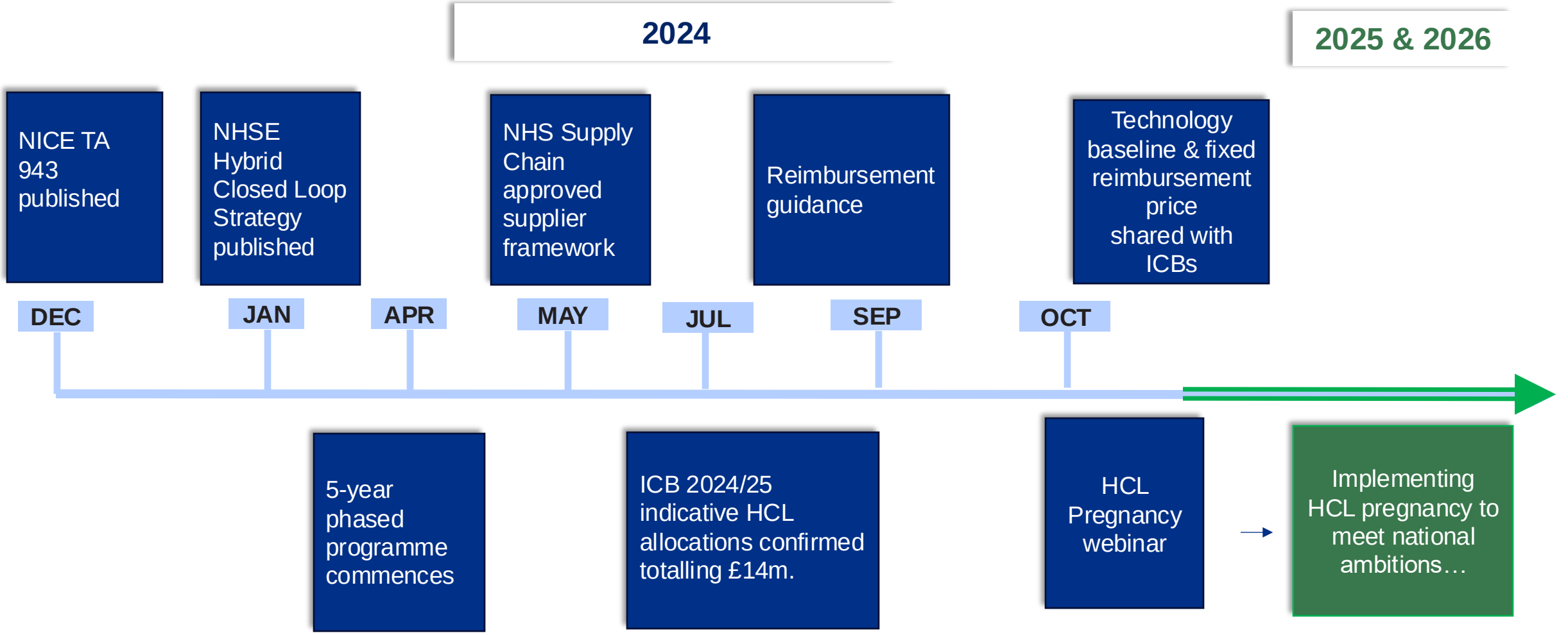
1) Adults who have an HbA1c of 58 mmol/mol (7.5%) or more, or have disabling hypoglycaemia, despite best possible management with at least 1 of the following – CSII, rtCGM, isCGM.

2) Children and young people

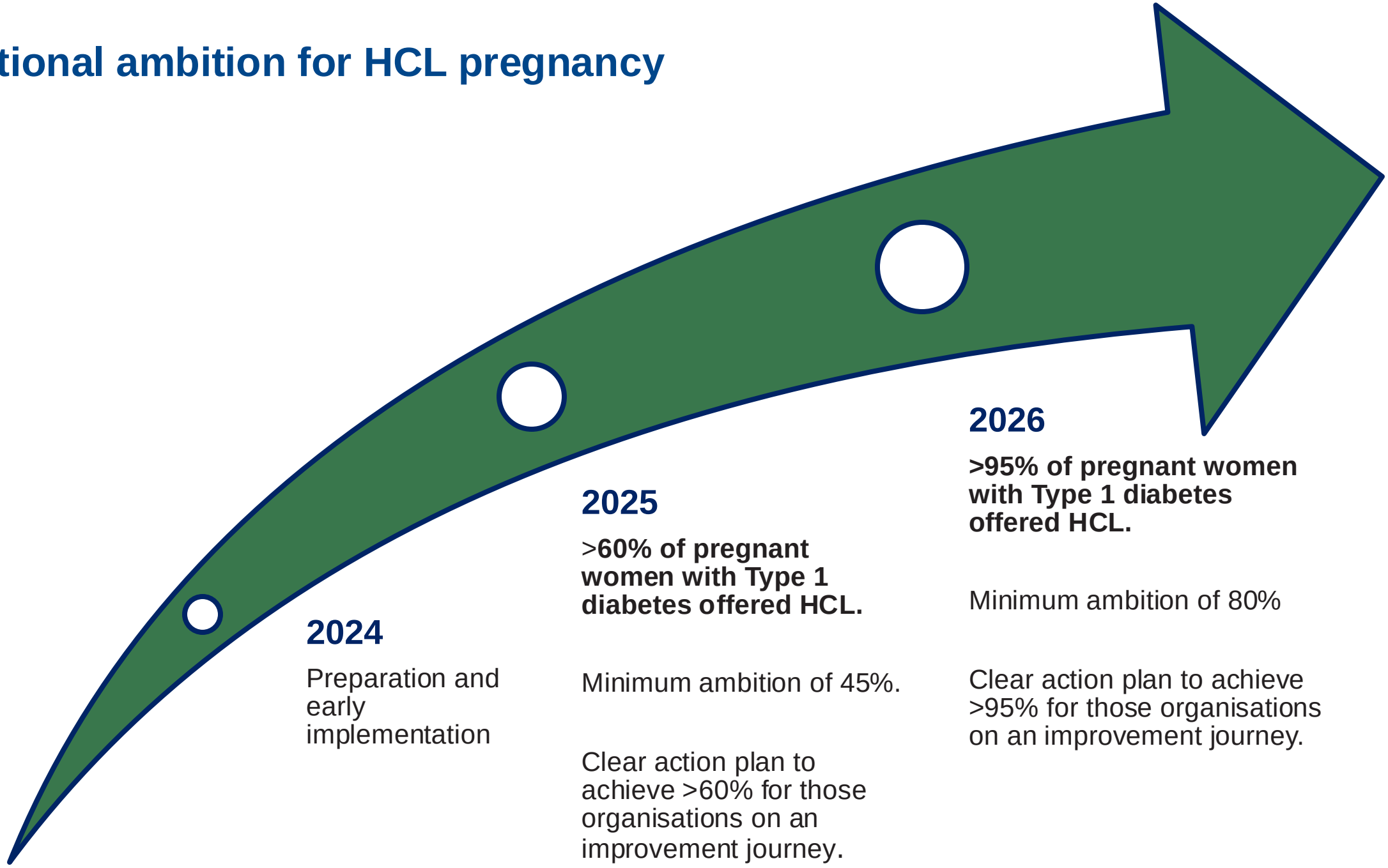
3) Women, trans men and non-binary people who are pregnant or planning to become pregnant



Timeline


2024
2025 & 2026
NICE TA 943 published
NHSE Hybrid Closed Loop Strategy published
NHS Supply Chain approved supplier framework
Reimbursement guidance
Technology baseline & fixed reimbursement price shared with ICBs
DEC
JAN
APR
MAY
JUL
SEP
OCT
5-year phased programme commences
ICB 2024/25 indicative HCL allocations confirmed totalling £14m.
HCL Pregnancy webinar
Implementing HCL pregnancy to meet national ambitions…

National ambition for HCL pregnancy



2024

Preparation and early implementation

2025

>60% of pregnant women with Type 1 diabetes offered HCL.

Minimum ambition of 45%.

Clear action plan to achieve >60% for those organisations on an improvement journey.

2026

>95% of pregnant women with Type 1 diabetes offered HCL.

Minimum ambition of 80%

Clear action plan to achieve >95% for those organisations on an improvement journey.

What funding is available to support implementation of HCL in pregnancy?

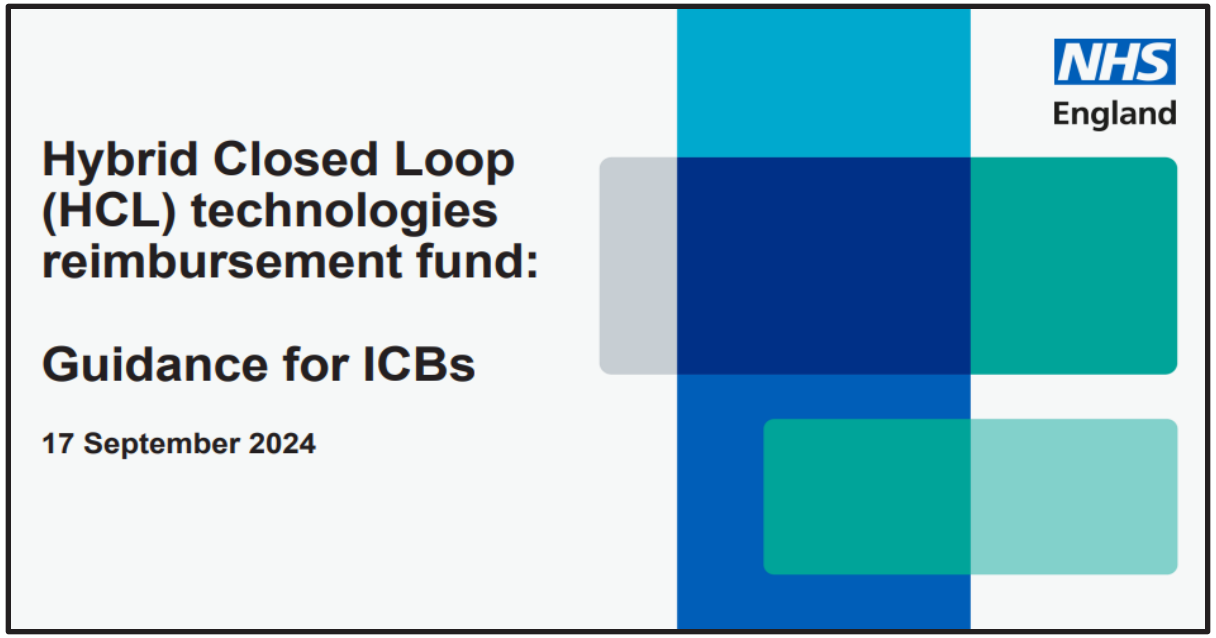
ICB 2024/25 funding allocations for eligible HCL reimbursements - July 2024

- Sets out 1-year maximum funding envelope that ICS can be reimbursed within.
- 75% of the incremental (additional) costs of starting a person on HCL
- Retrospective payment to ICB based on quarterly NDA data submissions.

ICB code	ICB name	Region	Allocation for pregnancy pump switches	Allocation for eligible HCL reimbursements
England	ENGLAND	ENGLAND	£999,998	£13,100,001
ABC	Anytown ICB	LONDON	£20,000	£280,000

Reimbursement Guidance for ICBs – Sept

- Greater levels of HCL uptake are expected in children and young people, pregnant people and people planning to become pregnant in Year 1 and Year 2.
- Includes details of how to sign up to NHS Supply Chain Framework, how funding was calculated, estimated activity over 5 years, how the allocations will be made, data reporting & payment scenarios.



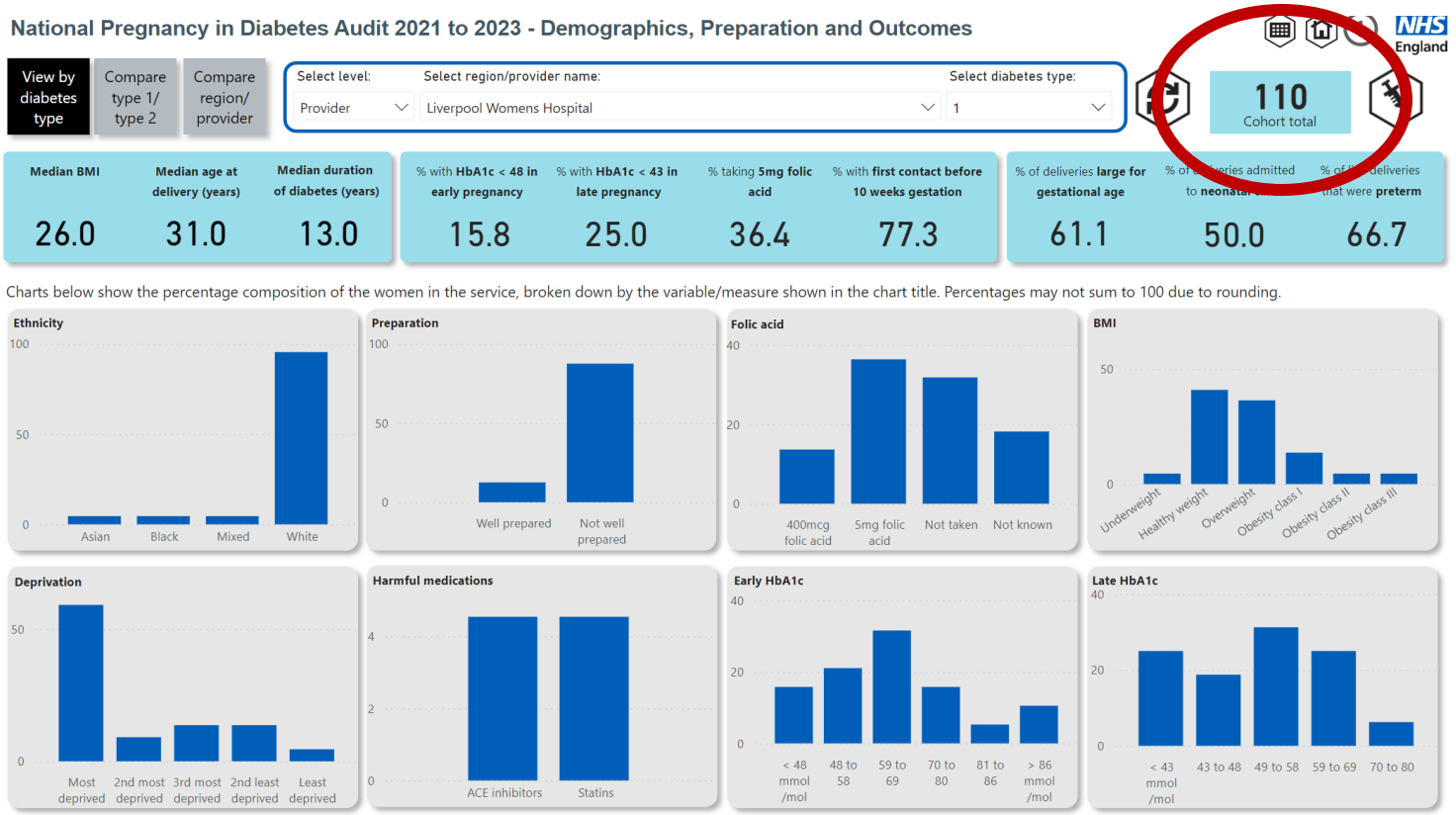
How many Type 1 Diabetes pregnancies are there in my ICS each year?

National Pregnancy in Diabetes (NPID) Audit Dashboard - 'Demographics' section.

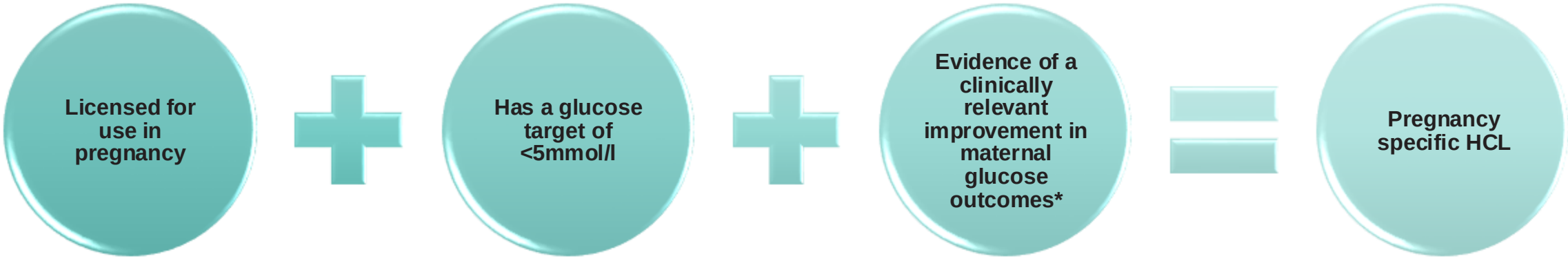
Shows 3-year total (2021 – 2023) of T1D pregnancies **by hospital trust**.

T1D pregnancies **by ICS** are not in the dashboard but information will be shared in the information pack following the webinar.

The range of T1D pregnancies in each ICS ranges from an average of 20 to 110 per year.



What is a pregnancy specific HCL system?



- NHS England reimbursement guidance refers to “pregnancy specific HCL system”.
- There is currently 1 HCL system that meets the above criteria. Not all insulin pumps are compatible with it.
- Those with an incompatible pump should be offered a switch to a compatible pump, so they can benefit from pregnancy specific HCL
- Issue: Who pays for the switch where the woman in still within warranty on the original pump?

*>5% increased time in the pregnancy glucose target range 3.5-7.8 mmol/l compared to standard care with CGM and standard insulin delivery by MDI/pump

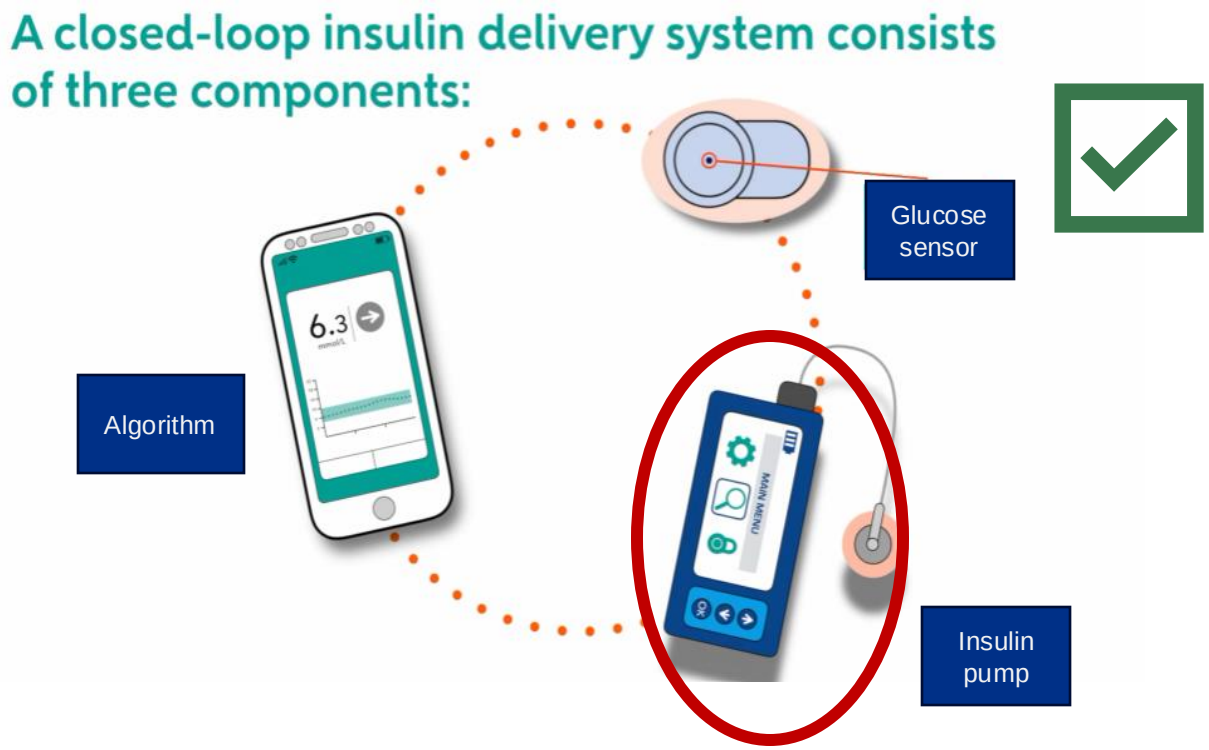
What is the allocation for pregnancy pump switches?

- To overcome this issue, NHS England has therefore made available an **“Allocation for Pregnancy Pump Switches”** worth £1m in 2024 /25.
- This provides a contribution to the costs of moving pregnant women from an incompatible pump to a compatible pump.
- The amount provided to each ICS is calculated on 1-year average T1D pregnancy pump usage in that system (NPID).
- This is a **prospective payment** – ICBs received the allocation in September **that will need to be identified and spent according to purpose.** It will be listed as ‘Hybrid Closed Loop Type 1 Diabetes Pregnancy Pump Switch Fund’

ICB code	ICB name	Region	Allocation for pregnancy pump switches	Allocation for eligible HCL reimbursements
England	ENGLAND	ENGLAND	£999,998	£13,100,001
ABC	Anytown ICB	LONDON	£20,000	£280,000

- It is therefore important to urgently engage with diabetes / maternity teams so that this budget can be used effectively in 2024/25, and as many eligible pregnant women switched as possible.
- Some ICBs are considering using the funding to buy pumps to be loaned and reused.
- Consideration will be given to continuing the switching fund in 2025 / 26 (subject to budget confirmation).

How many Type 1 Diabetes pregnancies are already using an insulin pump in my ICS?



-
- Around 25% of T1D pregnancies are already on a pump on average. The ICS range varies between 11% - 36% (around 5 – 40 people).
- What are your baseline levels of pump usage in T1D pregnancy within your system?
- This data is not currently published in the NPID Dashboard, but we will share ICS level figures of pump usage in T1D pregnancies in the information pack at the end of this webinar to help your planning.

Scenarios where the 2 different funds would apply

NHS England

A

Currently on multiple daily injections (MDI) only

Offer pregnancy specific Hybrid Closed Loop system

B

Currently on multiple daily injections (MDI) & CGM

Offer pregnancy specific Hybrid Closed Loop system

C

Currently using pump & CGM

Offer pregnancy specific HCL system with a switch to a compatible pump if required.

D

Already using Hybrid Closed Loop

If using a pregnancy specific HCL no action.

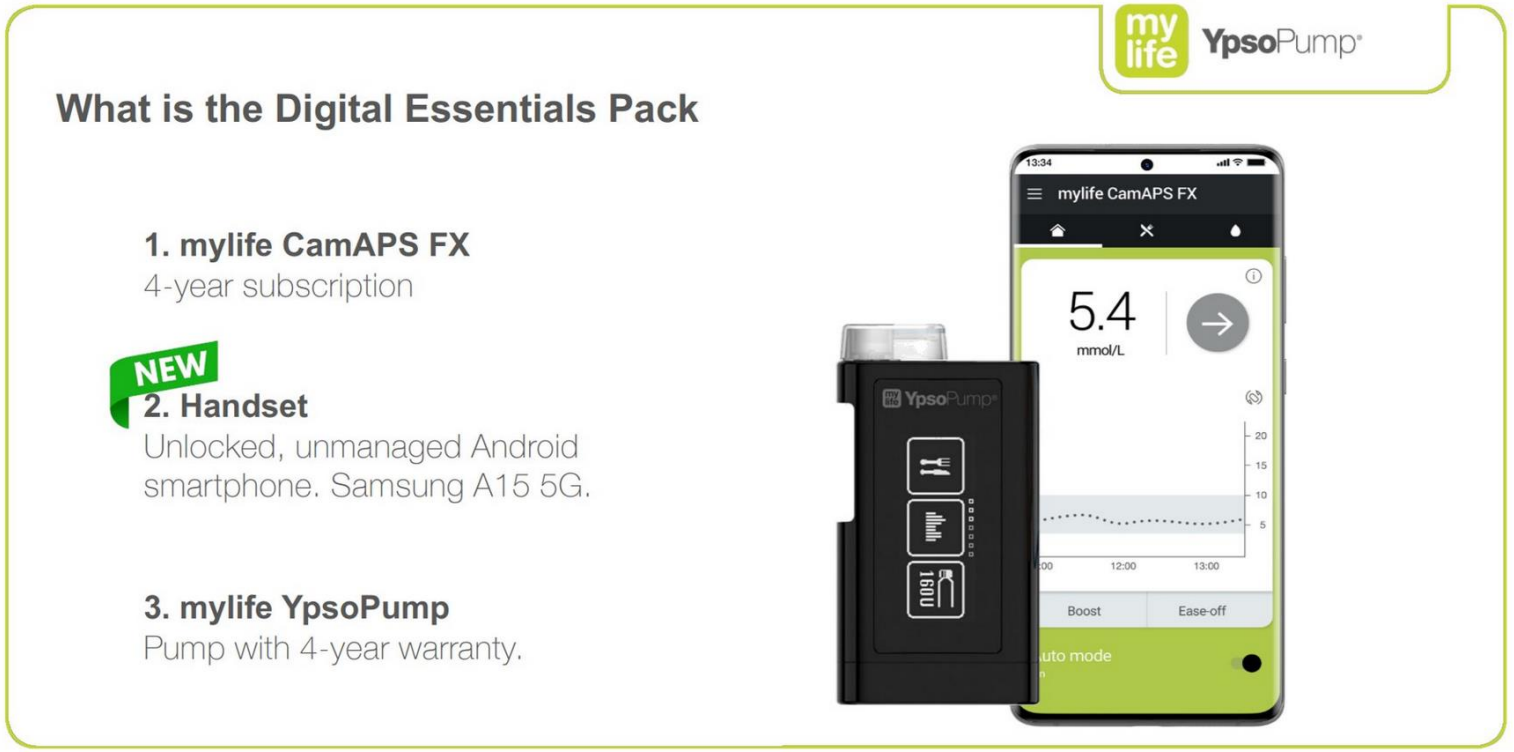
If not, refer to Box C

Main HCL allocation (reimbursed retrospectively)

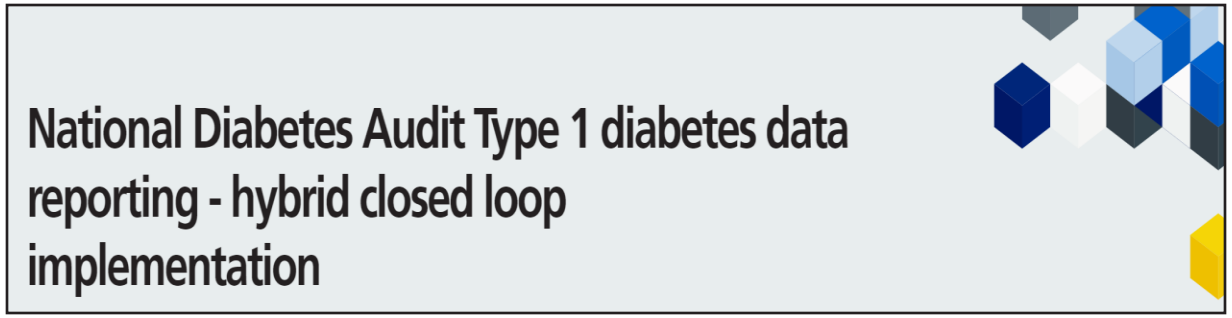
Switching Fund

What if a women wants to accept the offer of a pregnancy specific HCL system but doesn't have a compatible android smartphone?

- One pregnancy specific HCL system is offering all patients who need it a pack with a compatible android phone, eliminating the barrier of needing to purchase a compatible smartphone to access to HCL technology.
- This option is now available on the national NHS Supply Chain framework. Updated URNs are in the process of being sent out.
- To find out more contact info@ypsomed.co.uk local rep or NHS Supply Chain at urninsulinpumps@supplychain.nhs.uk



What are the data reporting requirements?



Frequency: Quarterly. Next submission deadline 15 January. Your submissions enable us to count new HCL users, confirm they meet the eligibility criteria and ensure your ICB is reimbursed from the national fund.

Frequency: Continuous. Annual deadline in February. Your submissions enable audit of care and outcomes. This data will also inform annual allocations and help us to track switches to pregnancy specific HCL systems.

Complete and accurate data submissions are vital. If you are having any problems with submissions, you can contact the NHS England Service Desk. Full details available here -

National Diabetes Audit Type 1 diabetes data reporting – Hybrid Closed Loop implementation - NHS England Digital

Key system level actions

1. **Ensure the ICB has signed up to the NHS Supply Chain Framework.**

2. **Work with ICB finance to identify** the Hybrid Closed Loop T1D Pregnancy Pump Switch Fund' transferred in Sept and work with maternity diabetes colleagues to consider how this will be used.

3. **Review the NPID dashboard and data shared in the webinar pack** - what the average number of T1D pregnancies and pregnant pump users in your ICS? Gives you a baseline estimate to work with.

4. **Engage with those leading diabetes maternity services in trusts and Local Maternity and Neonatal System** colleagues to understand workforce readiness to begin offering HCL in pregnancy.

5. **Promote the available online learning resources** as set out in Slide 29 and the examples of how to onboard on to HCL in Slides 44 – 67.

6. **Ensure that services are aware of the reporting requirements** for both the NDA and NPID set out in Slide 40.

7. **Develop an ICB level plan for implementing HCL in T1D pregnancy** to meet the 2025 and 2026 ambitions for implementation set out in Slide 34.

8. **Feedback any challenges** via the ICS and NHSE Regional team to the national programme team.

9. **Sign up to the Diabetes Programme NHS Futures site** – details will be shared in the info pack.

Transitioning to HCL in pregnancy

Nina Willer

Diabetes Specialist Midwife, Norfolk & Norwich University NHS Hospital Trust

TRANSITIONING TO HYBRID CLOSE LOOP IN PREGNANCY

A STEP BY STEP PROCESS

Nina Willer

DSM

NNUH

RAPID TRANSFER TO HCL

At NNUH we aim to smoothly transition all suitable pregnant people living with Type 1 diabetes, onto a HCL system as soon as possible. The aim is to be on HCL prior to 12 weeks of pregnancy to enable rapid improvement in glycaemia and reduce diabetes burden.

We follow a four step process as follows:

1

Assessment

2

Transitioning to HCL

3

Follow up in pregnancy

4

Long term support

ASSESSMENT

1 DSM INFORMED OF NEW PREGNANCY

DSM takes a full history on first phone call to ascertain history of diabetes including use of technologies
Appt arranged in MDT clinic for next available clinic (usually within one week)

2 FIRST APPOINTMENT

Team ensure appropriate use of existing technologies
Assess safety of pump therapy and discuss with pregnant person
Ascertain if existing pump is HCL suitable for pregnancy

3 VIABILITY CONFIRMATION

Senior team member will discuss suitability of HCL and options and benefits.
DSM Q&A including demo pump, trial cannula, pump info leaflet, and compatible phones list.

MOVING TO HCL FROM MDI OR AN INSULIN PUMP WHICH IS NOT CAMAPS FX SUITABLE

1

NOTIFY TEAM MEMBERS

If patient wishing to move to HCL therapy inform lead consultant, diabetes centre secretaries and appropriate pump representative.

2

FUNDING AND ORDERING

Request ICB funding for sensor upgrade if applicable
Admin to order pump, consumables and HCL app credentials
Request GP repeat prescription for insulin cartridges/vials. De-prescribe test strips.

3

EARLIEST AVAILABLE HCL START

Video training materials sent to user to watch before HCL start.
Group insulin pump and HCL start with pump representative and DSN ASAP.

LOCALLY THERE IS A RECURRING ROOM BOOKING EVERY TWO WEEKS, OFF THE HOSPITAL SITE RESERVED FOR INSULIN PUMP AND HCL STARTS

MOVING TO HCL FROM AN INSULIN PUMP WHICH IS COMPATIBLE WITH CAMAPS FX

1

NOTIFY TEAM MEMBERS

If patient wishing to move to HCL therapy inform lead consultant, diabetes centre secretaries and appropriate pump/HCL representative.

2

FUNDING AND ORDERING

Request ICB funding for sensor upgrade if applicable.
Ensure pump warranty lasts duration of pregnancy and phone-app compatibility.
Admin to arrange HCL app credentials.

3

EARLIEST AVAILABLE HCL START

Video training materials sent to user to watch before HCL start.
Virtual teaching and HCL switchover with pump/HCL representative as soon as possible.

ONLY FOR PEOPLE USING AN INSULIN PUMP WHICH IS COMPATIBLE WITH A PREGNANCY APPROPRIATE HCL SYSTEM (OTHERWISE FOLLOW MDI PATHWAY)

FOLLOW UP IN PREGNANCY

1

ANTENATAL CLINIC

Data triage, or face to face antenatal clinic within 4 days of HCL start.
ANC weekly until glycaemia stable. Interim data triage as required.

2

OUT OF CLINIC REVIEWS

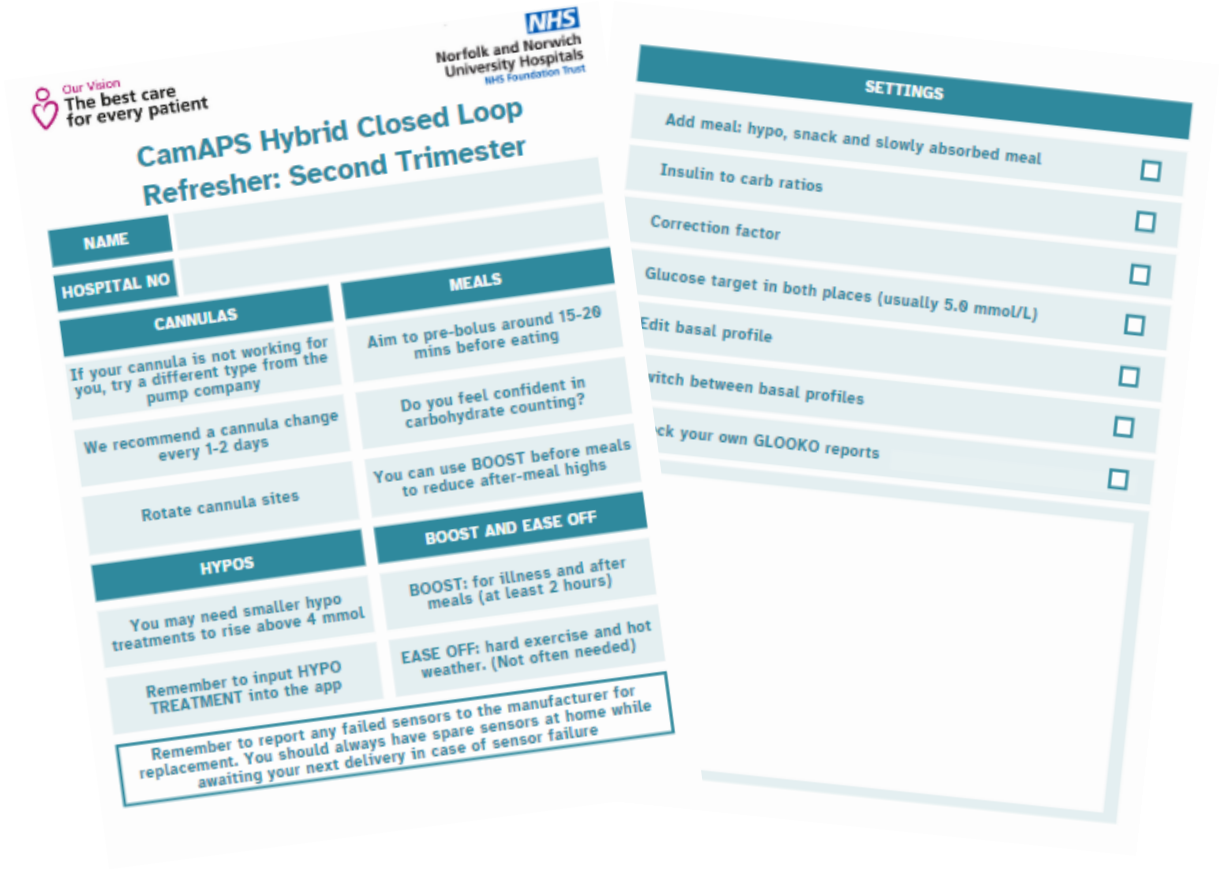
Direct access to DSMs for advice via email or phone (office hours).
DSMs to enhance learning and understanding of the system at each contact, as well as strengthen targets and ratios.

3

CARE DURING ADMISSION

Ward teams inform DSMs of admission.
DSMs maintain staff knowledge and documented individualised care plans in notes.
Updated guidelines and flow charts for out of hours management.

SECOND TRIMESTER AND THIRD TRIMESTER REFRESHER SESSIONS



Our Vision
The best care for every patient

NHS
Norfolk and Norwich University Hospitals
NHS Foundation Trust

CamAPS Hybrid Closed Loop Refresher: Second Trimester

NAME

HOSPITAL NO

CANNULAS

If your cannula is not working for you, try a different type from the pump company

We recommend a cannula change every 1-2 days

Rotate cannula sites

MEALS

Aim to pre-bolus around 15-20 mins before eating

Do you feel confident in carbohydrate counting?

You can use BOOST before meals to reduce after-meal highs

HYPOS

You may need smaller hypo treatments to rise above 4 mmol

Remember to input HYPO TREATMENT into the app

BOOST AND EASE OFF

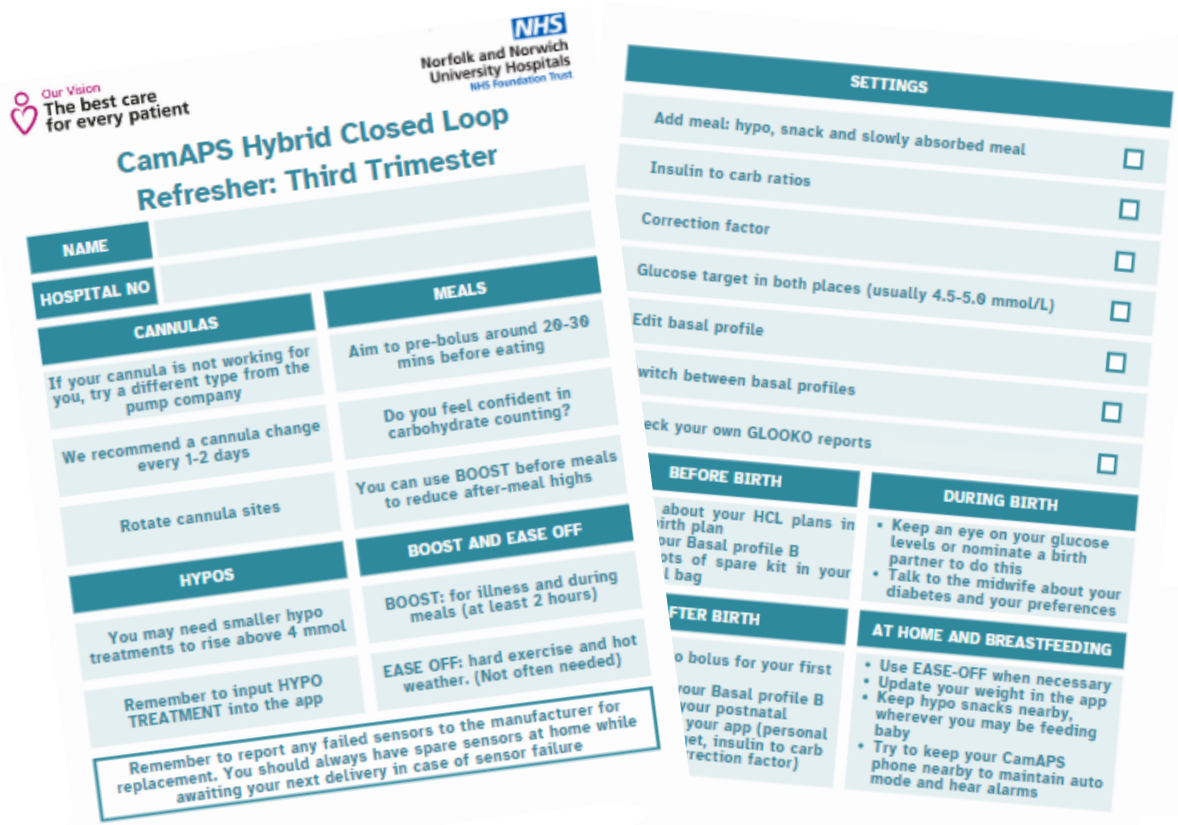
BOOST: for illness and after meals (at least 2 hours)

EASE OFF: hard exercise and hot weather. (Not often needed)

Remember to report any failed sensors to the manufacturer for replacement. You should always have spare sensors at home while awaiting your next delivery in case of sensor failure

SETTINGS

- Add meal: hypo, snack and slowly absorbed meal ☐
- Insulin to carb ratios ☐
- Correction factor ☐
- Glucose target in both places (usually 5.0 mmol/L) ☐
- Edit basal profile ☐
- witch between basal profiles ☐
- ck your own GLOOKO reports ☐



Our Vision
The best care for every patient

NHS
Norfolk and Norwich University Hospitals
NHS Foundation Trust

CamAPS Hybrid Closed Loop Refresher: Third Trimester

NAME

HOSPITAL NO

CANNULAS

If your cannula is not working for you, try a different type from the pump company

We recommend a cannula change every 1-2 days

Rotate cannula sites

MEALS

Aim to pre-bolus around 20-30 mins before eating

Do you feel confident in carbohydrate counting?

You can use BOOST before meals to reduce after-meal highs

HYPOS

You may need smaller hypo treatments to rise above 4 mmol

Remember to input HYPO TREATMENT into the app

BOOST AND EASE OFF

BOOST: for illness and during meals (at least 2 hours)

EASE OFF: hard exercise and hot weather. (Not often needed)

Remember to report any failed sensors to the manufacturer for replacement. You should always have spare sensors at home while awaiting your next delivery in case of sensor failure

SETTINGS

- Add meal: hypo, snack and slowly absorbed meal ☐
- Insulin to carb ratios ☐
- Correction factor ☐
- Glucose target in both places (usually 4.5-5.0 mmol/L) ☐
- Edit basal profile ☐
- witch between basal profiles ☐
- eck your own GLOOKO reports ☐

BEFORE BIRTH

about your HCL plans in irth plan
our Basal profile B
ots of spare kit in your l bag

DURING BIRTH

- Keep an eye on your glucose levels or nominate a birth partner to do this
- Talk to the midwife about your diabetes and your preferences

FTER BIRTH

o bolus for your first
our Basal profile B your postnatal
your app (personal et, insulin to carb rrection factor)

AT HOME AND BREASTFEEDING

- Use EASE-OFF when necessary
- Update your weight in the app
- Keep hypo snacks nearby, wherever you may be feeding baby
- Try to keep your CamAPS phone nearby to maintain auto mode and hear alarms

FOLLOW UP AFTER PREGNANCY

1

ONGOING CARE

Inform diabetes centre of birth or end of pregnancy. Including date of commencement of CGM/HCL.
Refer if patient not known to the service.
DSN phone follow up within 3 weeks. Consultant within 3 months.

2

ONGOING SUPPLIES

The Diabetes centre maintain a record for dates of re-ordering of CGM, HCL, and insulin pump thereafter

CONTACT

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DIABETES SPECIALIST MIDWIFE

Norfolk and Norwich University Hospital
NHS Foundation Trust

nina.willer@nnuh.nhs.uk

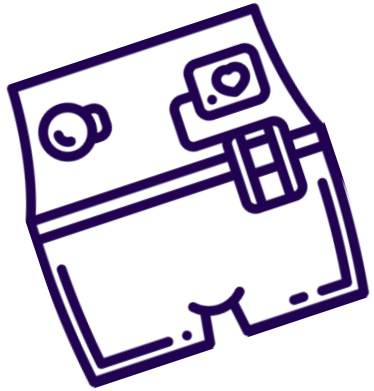
Onboarding to HCL in pregnancy

Emma Wilmot

Associate Professor, University of Nottingham &
Honorary Consultant, UHDB

Hybrid Closed Loop in Pregnancy: onboarding

Dr Emma Wilmot, Associate Professor, University of Nottingham & Honorary Consultant, UHDB

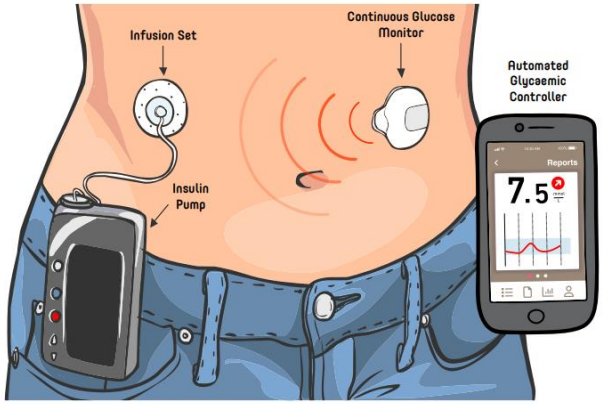


Implementing the TA

- Upskilling the team
- Prioritising pregnancy
- Organising new starts
- ALL HANDS ON DECK

What are we doing in Derby?

- Dedicated pre-conception clinic
- All women with T1DM who are planning pregnancy are encouraged to move across to HCL
- **All** women with T1 in pregnancy are offered HCL
- Whole team very much aware of the benefits of HCL and actively encourage uptake



Onboarding

- Typically, around 30-40 T1 pregnancies/yr

- Since April 24: 11 x CamAPS FX starts in pregnancy (61% uptake)
  - 6 from multiple daily injections to HCL
  - 5 from another pump to CamAPS FX

- Group starts booked with rep every 4 weeks across the year
- One to one starts occasionally needed

Onboarding

Insulin vials/pump cart on prescription? (ideally have in stock at hospital)

Agrees to HCL

Compatible phone?

Order pump and CGM

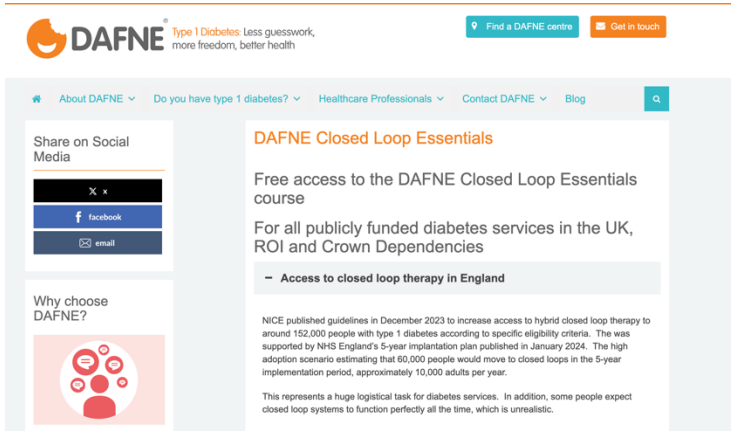
Group F2F pre-pump education

Ensure pre start CamAPS training completed

DAFNE closed loop essentials course offered

HCL start with rep/HCP within 4 weeks

- What is HCL
- Safety aspects
- Scenarios
  - Pump safety
  - Response to high glucose levels
  - Exercise
  - Hypoglycaemia



Follow up

- Achieving optimal TIR >70% is <u>much</u> easier than with MDI

- In our service so far this year:
  - 73% on HCL achieving 3rd trimester HbA1c < 43mmol/mol
  - 91% on HCL achieving 3rd trimester HbA1c < 48mmol/mol

Case: Background

- 29 year old female
- T1DM of 5 years duration, presents with unplanned pregnancy at 10 weeks gestation

- HbA1c 108 mmol/mol (12%)
- Tx Apidra 8 units at meals, Tresiba 21 units OD

- Rarely attends clinic
- Not monitoring glucose levels
- Started on CGM in clinic with plan to move at hybrid closed loop asap

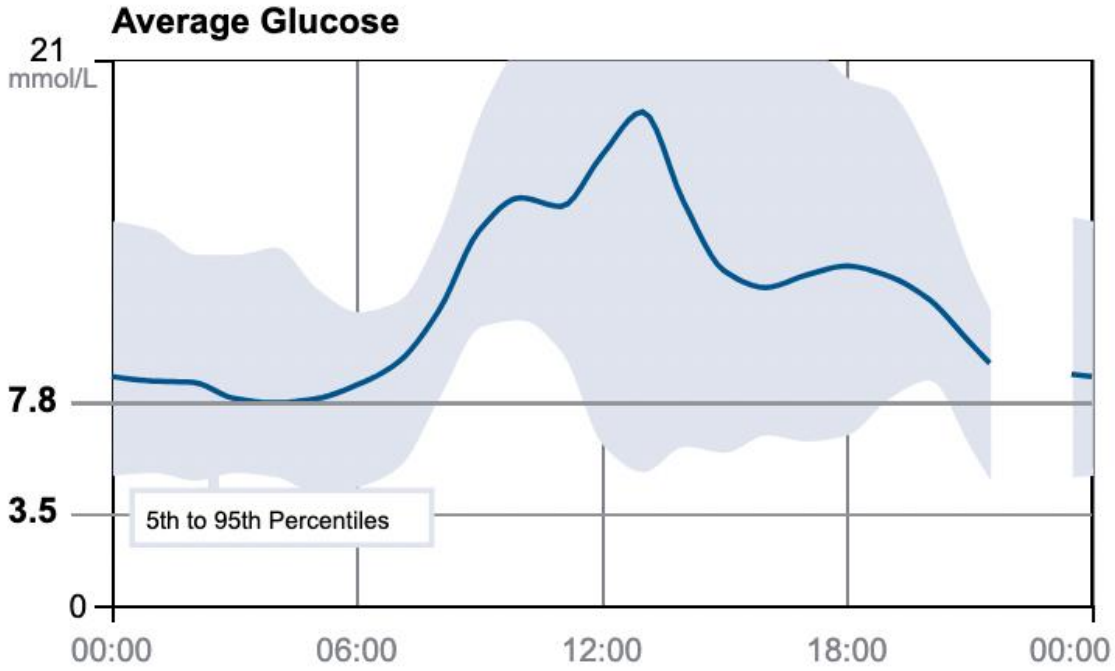
9/40

- Restarted on FSL2 in clinic
- Support with learning to carbohydrate count
- Moved onto ratios 1u:10g ratio, ISF 1:3
- Trying to bolus before meals

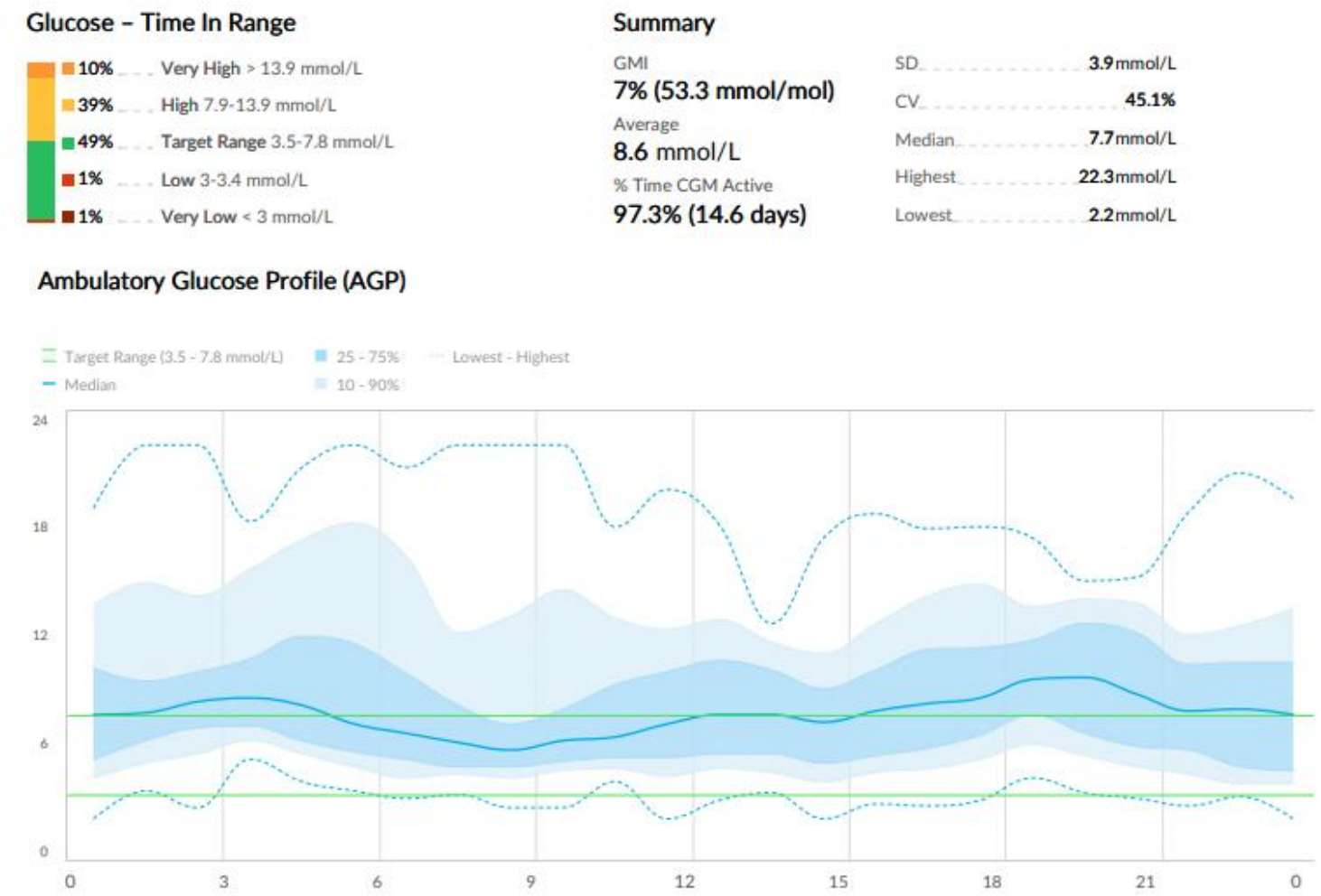
Glucose

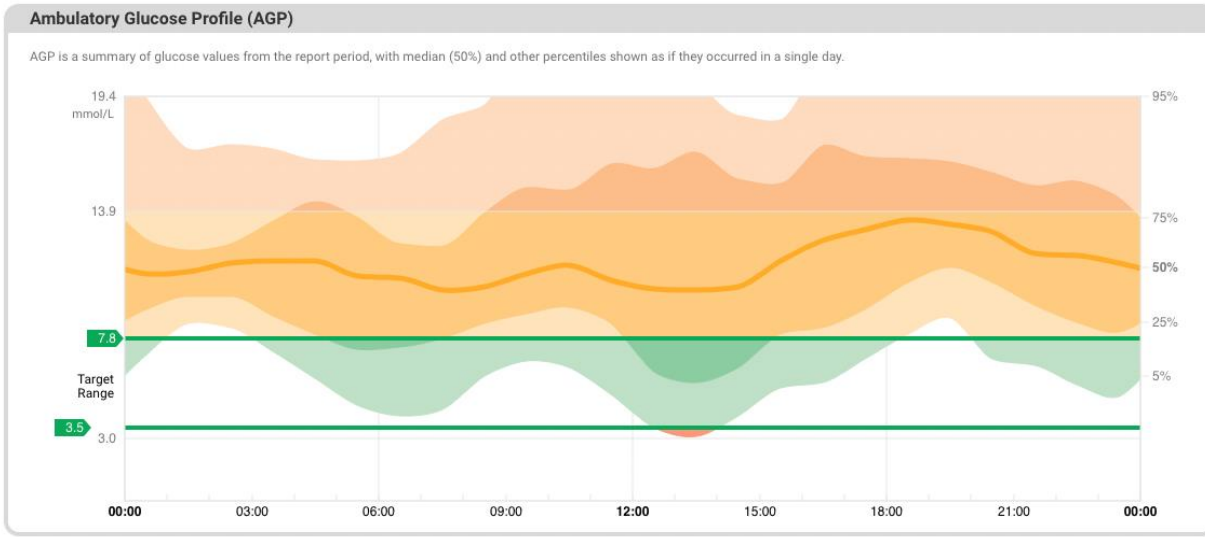
AVERAGE GLUCOSE	12.2 mmol/L
% above target	78 %
% in target	22 %
% below target	0 %

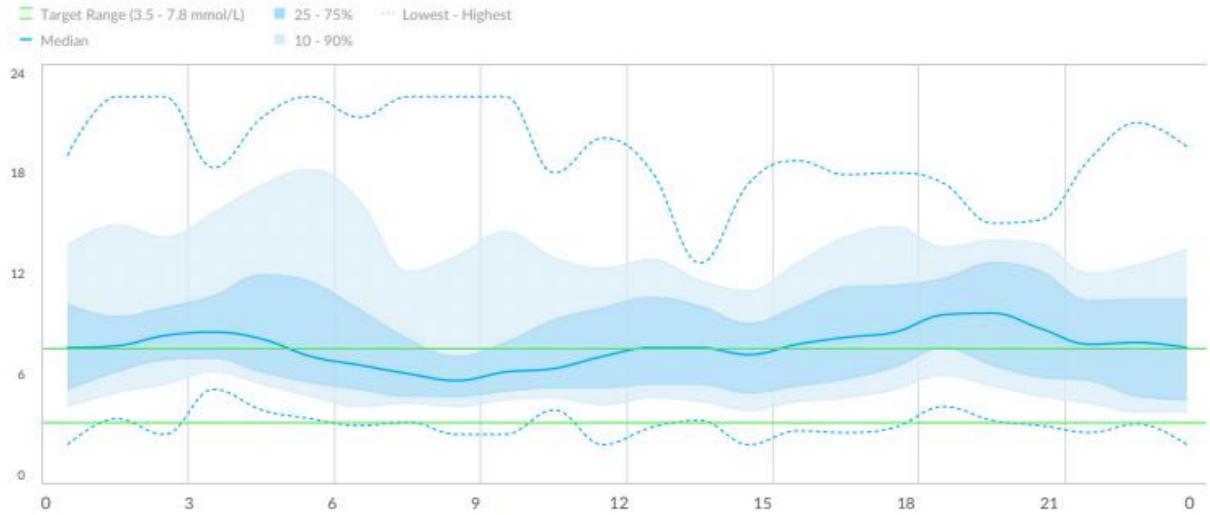
GMI **8.6%** or **70** mmol/mol



15/40 first 2 weeks on mylife Loop with mylife CamAPS FX







Each 5% increase in the Target Range is clinically beneficial.
Each 1% time in range = about 15 minutes per day

31% Very High
Goal: <5%

51% High

82%
Goal: <25%

18% In Range
Goal: >70%

0% Low

<1% Very Low
Goal: <1%

0%
Goal: <4%

Target Range: 3.5-7.8 mmol/L
Very High: Above 13.9 mmol/L
Very Low: Below 3.0 mmol/L

Glucose – Time In Range

10% Very High > 13.9 mmol/L

39% High 7.9-13.9 mmol/L

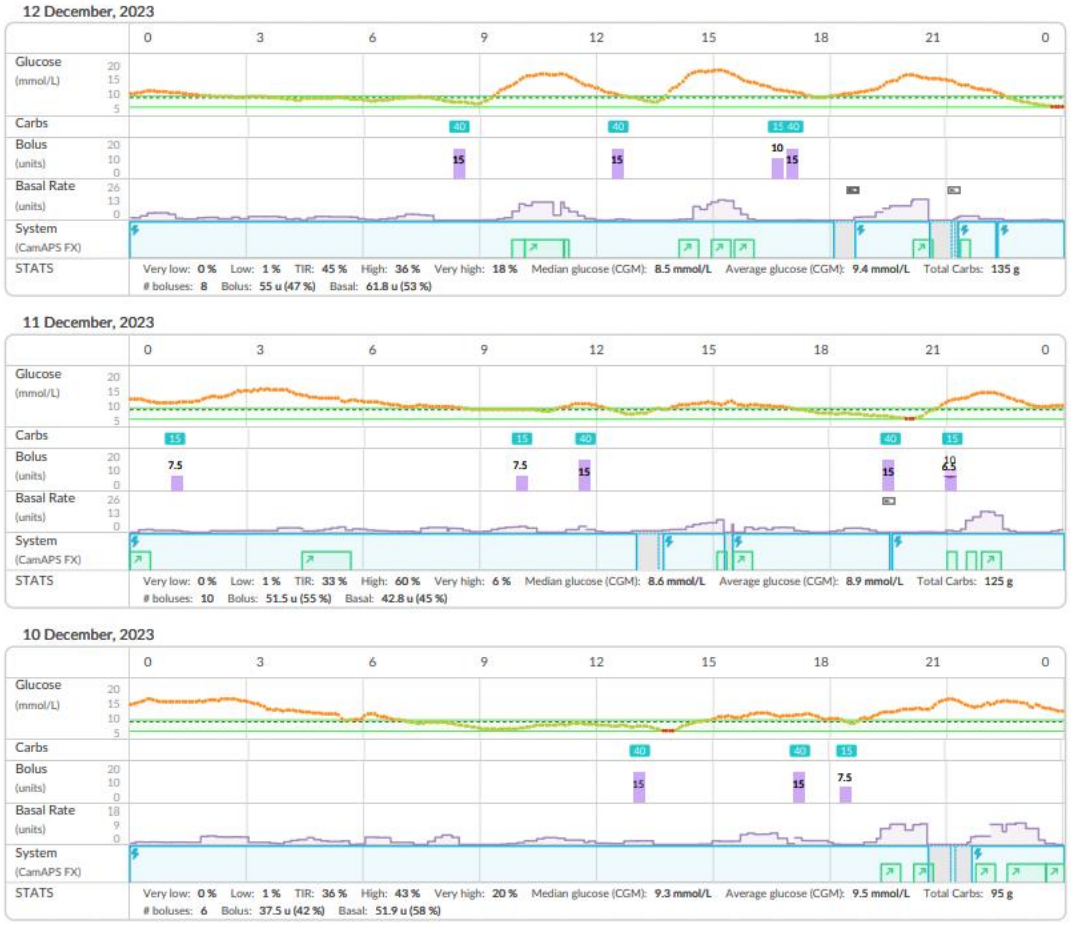
49% Target Range 3.5-7.8 mmol/L

1% Low 3-3.4 mmol/L

1% Very Low < 3 mmol/L

Optimisation

- Ongoing intensive education and support with weekly contact
- Insulin:carb ratios and glucose targets tightened
  - Aim to start glucose target at 5.5mmol/l in 1st trimester changing to 5mmol/l during the day and 4.5mmol/l in the evening/overnight if possible
- Encouraged to bolus before meals, not after

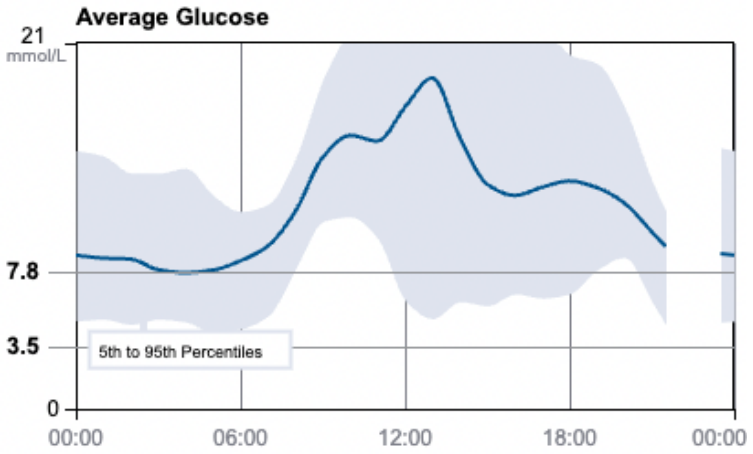


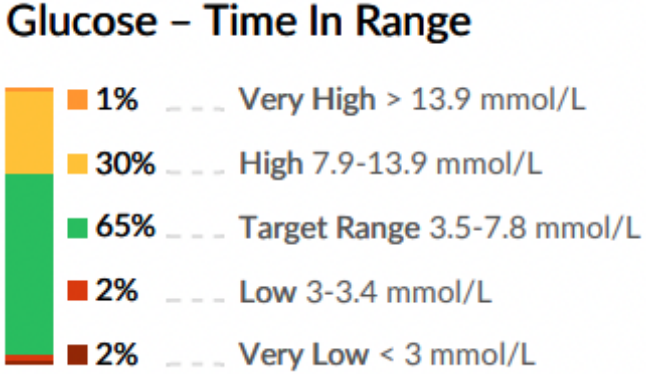
Before and after

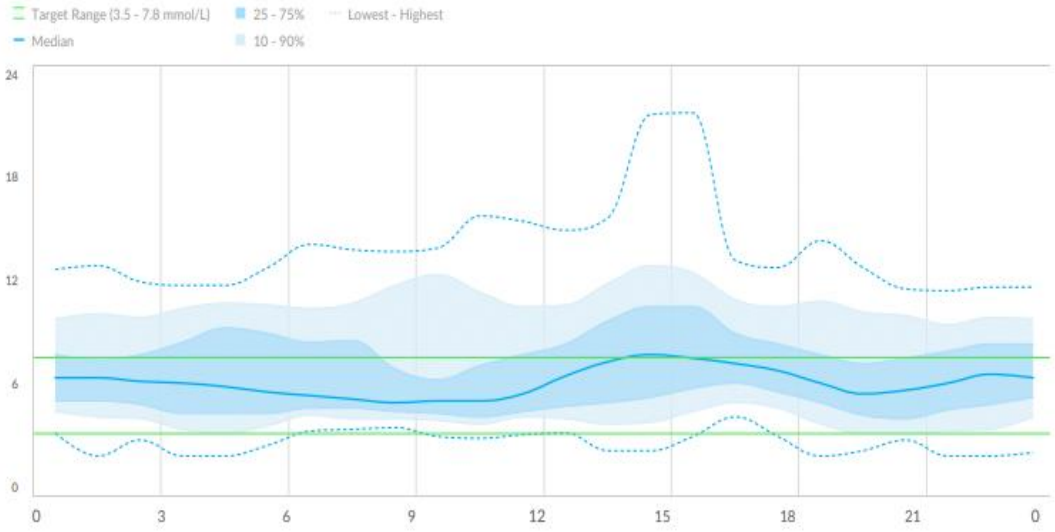
AVERAGE GLUCOSE	12.2 mmol/L
% above target	78 %
% in target	22 %
% below target	0 %

10/40
HbA1c
108mmol
mol

28/40
HbA1c
50mmol/
mol







Healthy baby born at 37/40 weeks

Conclusion

- Hybrid Closed Loop is life changing technology
- Improves HbA1c and Time in Range
- HCL should be offered to all with T1DM in pregnancy
- Watershed moment in the care of T1DM in pregnancy


10.30am to 4.00pm
Tuesday, 12 November 2024
DIABETES
IN PREGNANCY
13th online UK conference
DIABETES UK
KNOW DIABETES. FIGHT DIABETES.

REGISTER NOW

We're pleased to announce registration for our 2024 Diabetes in Pregnancy UK Conference is now open. Book now for this exciting virtual event now, taking place on 12 November 2024

Abstracts from all healthcare professionals are invited. Abstract submissions are invited in the areas of: clinical case presentations, innovative practice, audit and research. Closing date for abstracts is Monday 14th October.

For further information about the conference, to register, and abstract details, please click here: **Diabetes in Pregnancy Conference 2024 I Diabetes UK**

Five reasons to attend

- This is the 13th Diabetes in Pregnancy UK Conference - now the single largest specialist Diabetes in Pregnancy Conference in Europe
- A program designed around all the hot topics and latest in Diabetes in Pregnancy for all professionals
- Hybrid Closed-Loop (HCL) in T1D pregnancy
- Spotlight on women's health from a diabetes perspective T1 and T2D pregnancy priorities, NDA dashboards, GDM Audit
- Diagnosis of GDM past, present & Future

*A recording of the conference will also be available after the event to anyone that has registered

www.diabetes.org.uk

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Register now

Next steps

- Regional Q&A sessions – with clinical and policy leads
- A follow up national webinar to share good practice
- Contact us: england.digitaldiabetes@nhs.net

Q & A

Candice Ward – CDEP Lead,
Cambridge Diabetes Education Programme

After the webinar…

Please complete the brief survey when leaving the webinar.

You will receive a certificate of attendance and a copy of the presentation via email in the next 1-2 weeks.

Please contact CDEP – info@cdep.org.uk if you need any support.

Cambridge Diabetes Education Programme

Thank You

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