Type 1 Diabetes Pregnancy Workshop

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YDEF Diabetes Technology Course delivered by DTN-UK

Nottingham

23 July 2025

Disclosures

- **Speakers honoraria from:** OmniaMed, Novo Nordisk, ABCD DTN UK, ABCD, SBK

- **Travel/accommodation/registration expenses from**:
  - CONCEPTT, AiDAPT
  - ABCD Diabetes Technology Network (UK)
  - SBK

- **Advisory board:** Abbott (Libre)

- **Trial Management Group/Data & Safety Monitoring Board**
  - AiDAPT study (Closed loop in pregnant women with T1D, Norwich) (TMG)
  - AP-Renal (Closed loop in adults with T2D requiring dialysis, Cambridge) (DSMB)
  - CLEAR study (Closing the loop in adults with type 1 diabetes, Cambridge) (DSMB) (2021)

Outline

- Background
- Evidence for CGM and hybrid closed loop systems in pregnancy in women with type 1 diabetes
- Optimising glucose levels in pregnancy
  - The essentials
  - Know what settings can be adjusted to impact insulin delivery when in hybrid closed loop
  - Approach to looking at the upload
- Keeping hybrid closed loop users safe in pregnancy
- Using hybrid closed loop for steroids
- Using hybrid closed loop through birth and post birth

Pregnancy in diabetes

- Increased risk of adverse pregnancy outcomes:
  - ↑Congenital malformation, ↑ Miscarriage,
  - ↑ Pre-eclampsia,
  - ↑ Fetal macrosomia, ↑ Birth trauma (to mother and baby),
  - ↑ Stillbirth (10.4 per 1,000 births (4-5xbackground) (NPID)
  - ↑ Induction of labour or caesarean section,
  - ↑ Neonatal morbidity (Hypoglycaemia, Hyperbilirubinaemia),
  - ↑ Neonatal death (7.4 per 1,000 livebirths (4-5xbackground (NPID)

- Increased risk of
  - maternal hypoglycaemia (1st trimester), (12% of pregnant T1DM have ≥1 severe hypo (NPID 2018)
  - Increased risk of DKA (2-3% of pregnant T1DM have ≥1xDKA (NPID 2018)
  - deterioration of maternal diabetes complications

- Increased risk of obesity and/or T2DM in offspring

> Better glycaemic control (pre-pregnancy & throughout pregnancy) is associated with reduced risk of adverse pregnancy outcomes
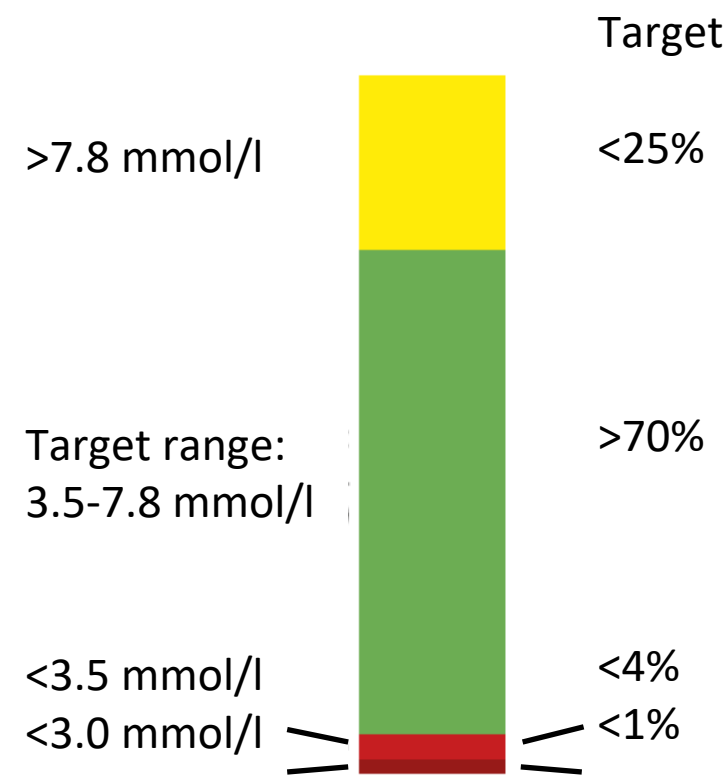
Glucose targets in pregnancy

Increased time in glucose target range (pre-pregnancy & throughout pregnancy) is associated with reduced risk of adverse pregnancy outcomes

- Target glucose continuous glucose monitoring
  - Range 3.5-7.8 mmol/l (TIRp)
  - Mean 6-6.5 mmol/l
- Target blood glucose levels
  - Pre meals <5.3.mmol/l
  - 1 hour post meals <7.8 mmol/l
  - and ≥4 mmol/l
- HbA1c targets
  - <48 mmol/mol early pregnancy
  - ≤43 mmol/mol in later pregnancy

Aim to achieve targets as early as possible in pregnancy and then maintain

Each 5% increase in TIRp improves neonatal outcomes

Without increasing hypoglycaemia or diabetes distress/burden

Target

>7.8 mmol/l   <25%

Target range:
3.5-7.8 mmol/l   >70%

<3.5 mmol/l   <4%
<3.0 mmol/l   <1%

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

Feig D et al, Lancet 2017 390: 2347-2359
Battelino T et al. Diabetes Care 2019;42:1593-1603

Achieving pregnancy glucose targets is difficult

- Changing insulin requirements
  - Hypos in first trimester,
  - Increasing requirements from mid-second trimester,
  - Sudden drop immediately post birth (to pre-pregnancy or lower)

- Change in insulin kinetics
  - In later pregnancy, delayed peak, prolonged action

- Nausea/vomiting/hyperemesis
- Weight gain

- Often caring for young children and working
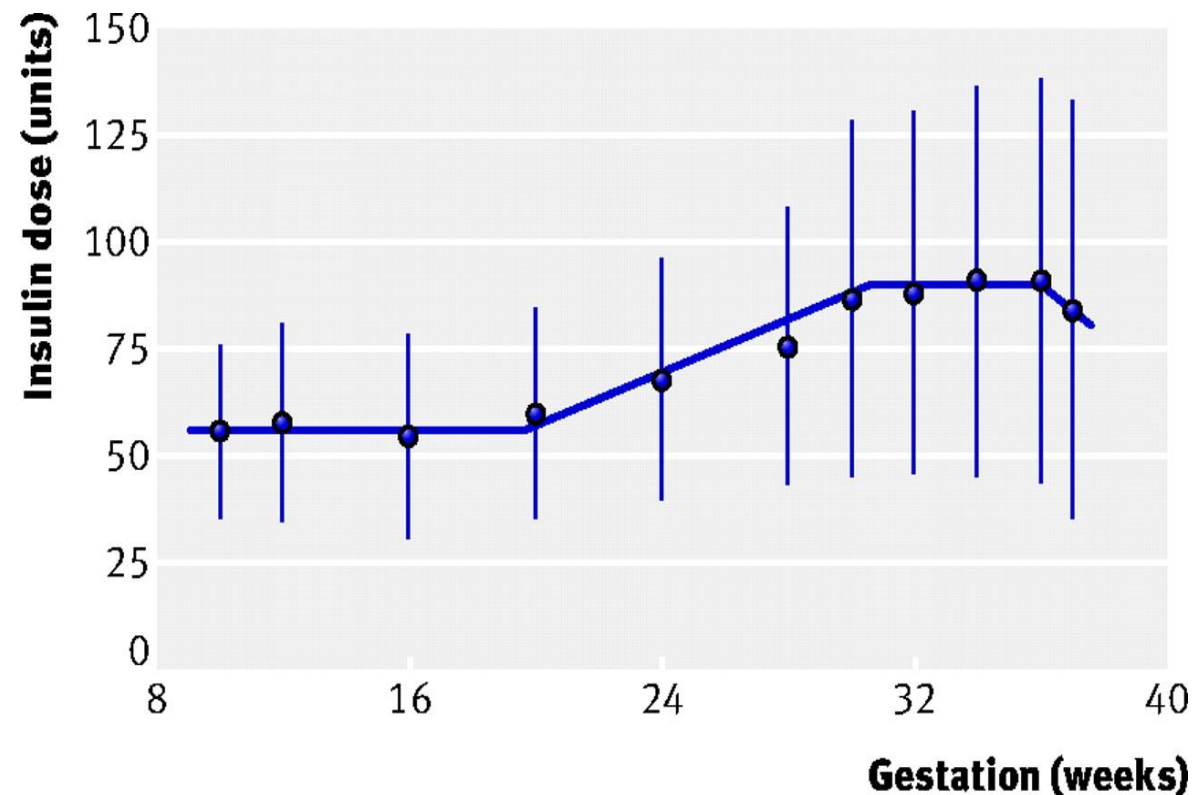
Insulin doses (mean ± SD) in 107 pregnancies (T1DM).

Taylor R et al & Davison JM. BMJ, 2007. (334) 742.

Evidence and guidance for diabetes technology in T1DM pregnancy

RT-CGM in pregnancy in women with T1DM

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, Elisabeth 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*

- 215 pregnant women, T1DM,
- HbA1c 6.5-10%
- MDI or pump
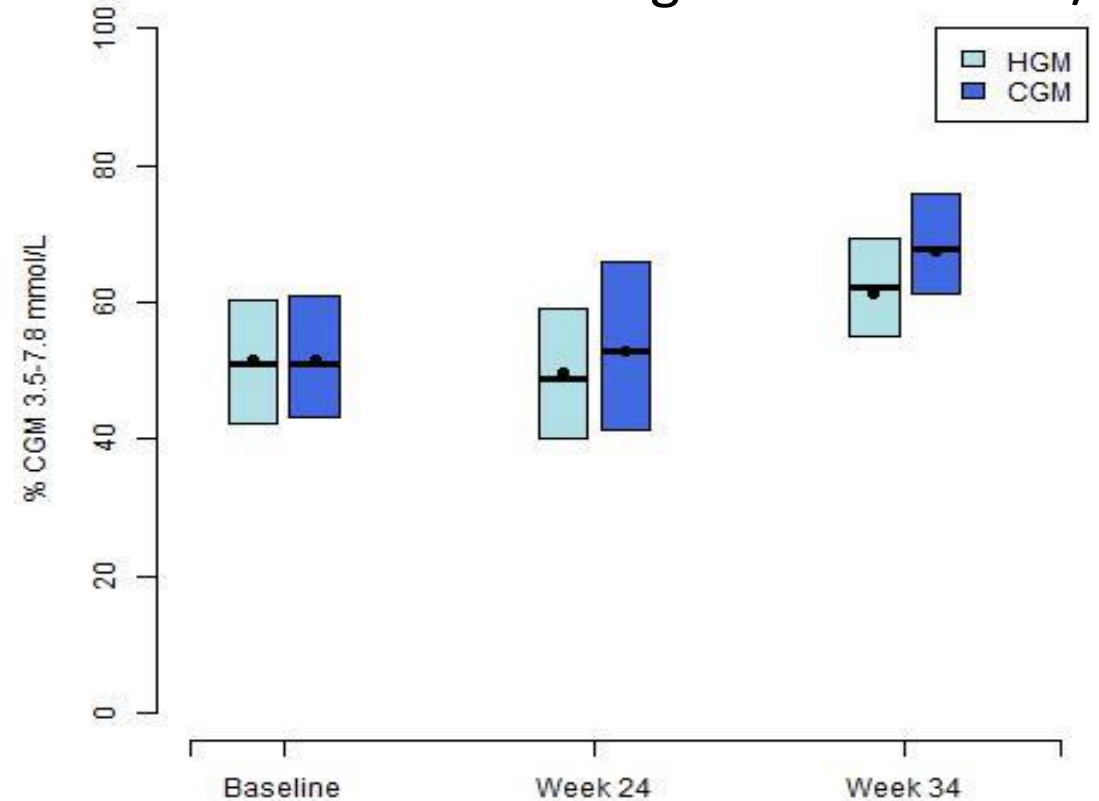- Randomised to RT-CGM or usual care starting in the 1st trimester

CONCEPTT results

HbA1c

Time in range 3.5-7.8 mmol/l
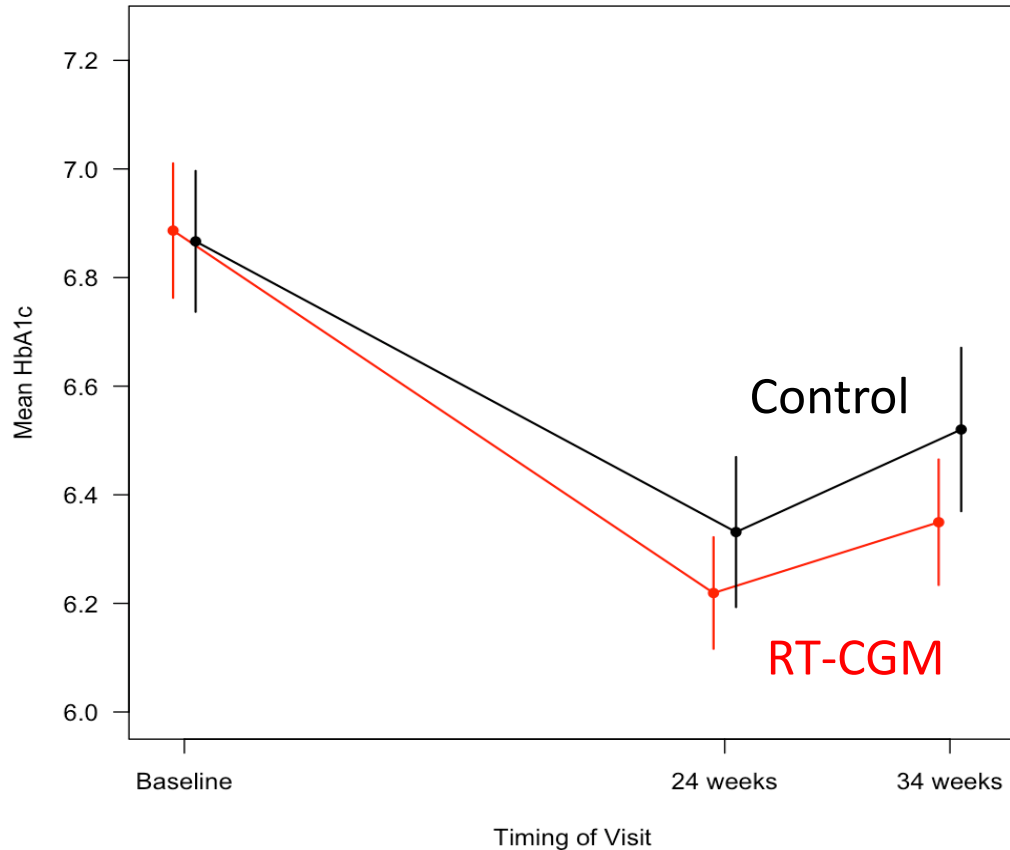
Absolute difference in change (baseline to 34/40) in HbA1c: -0.19% (p=0.021)

Increased time in range 3.5-7.8 mmol/l at 34/40: 68v61%, extra 1.7 hours/day (p=0.003)

Feig DS et al, Lancet 2017:390:2347-59.

Improved neonatal health outcomes

RT-CGM versus usual care

- **↓ LGA**: 53% RT-CGM vs 69% control

    OR 0.51; 95% CI 0.28-0.90 p=0.0210

NNT 6

- **↓ Hypoglycaemia** requiring dextrose infusion

    15% RT-CGM vs 28% control

    OR 0.45; 95%CI 0.22-0.89 p=0.0250

NNT 8

- **↓ NICU admission** >24h:

    27% RT-CGM vs 43% control

    OR 0.48; 95% CI 0.26-0.86; p=0.0157

NNT 6

↓ length of hospital stay by 1 day

    3.1 (2.1-5.7) RT-CGM vs 4.0 (2.4-7.0) p=0.0157

Feig DS et al, Lancet 2017:390:2347-59.

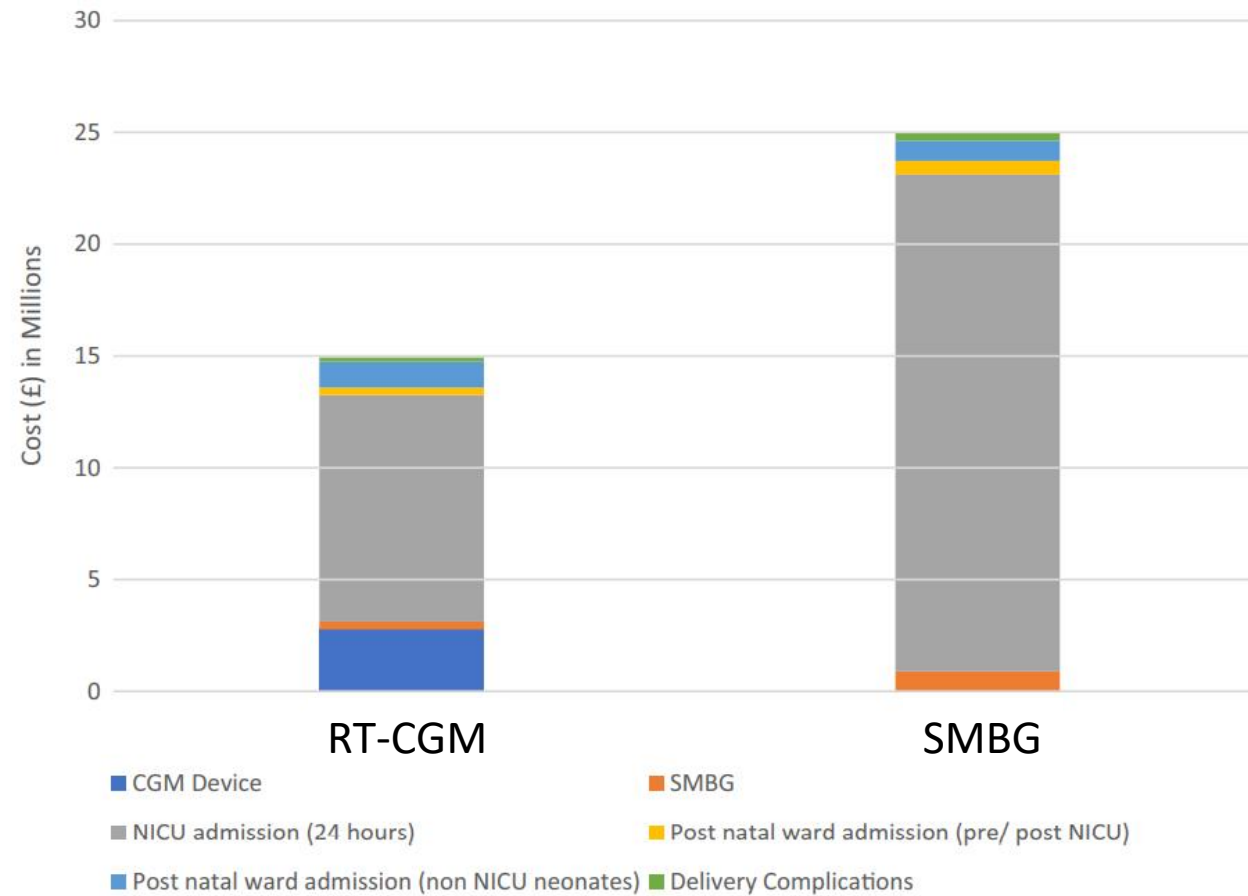# Financial modelling of cost of RT-CGM

FIGURE 2 Modelled cost of type 1 diabetes in pregnancy (10-38 weeks gestation) with real-time continuous glucose monitoring (RT-CGM) and self-monitoring of blood glucose (SMBG), compared to SMBG alone.

Guidance

NHS Long term Plan (www.longtermplan.nhs.uk, Jan 2019)

> '...by 2020/2021, all pregnant women with type 1 diabetes will be offered continuous glucose monitoring, helping to improve neonatal outcomes.'

**NICE guideline [NG3], updated 16 Dec 2020**

1.3.17 Offer continuous glucose monitoring (CGM) to all pregnant women with T1DM...

1.3.20 For pregnant women who are using isGGM or CGM, a member of the joint diabetes & antenatal care team with expertise in these systems should provide education & support
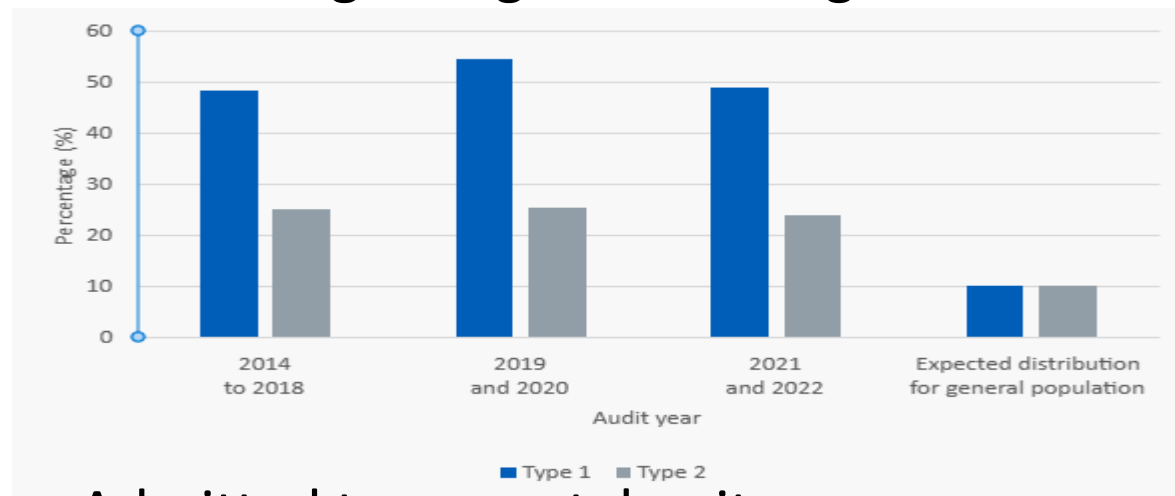
National (England & Wales) data

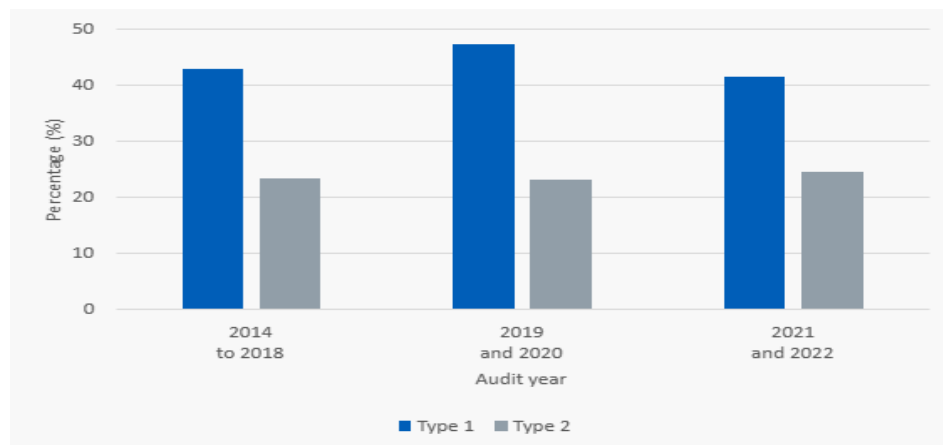T1DM: 95% of pregnant women with T1DM used CGM in 2022

HbA1c <43 mmol/mol in late pregnancy
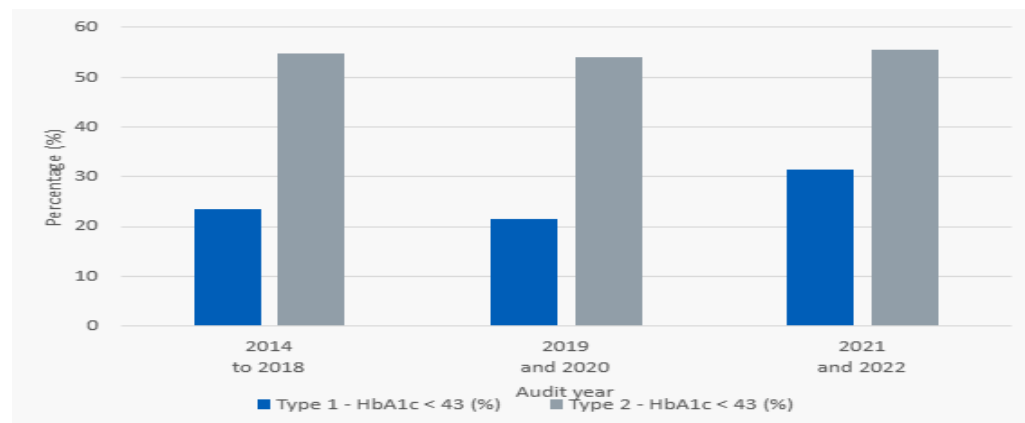
Babies large for gestational age

Preterm births

Admitted to neonatal unit
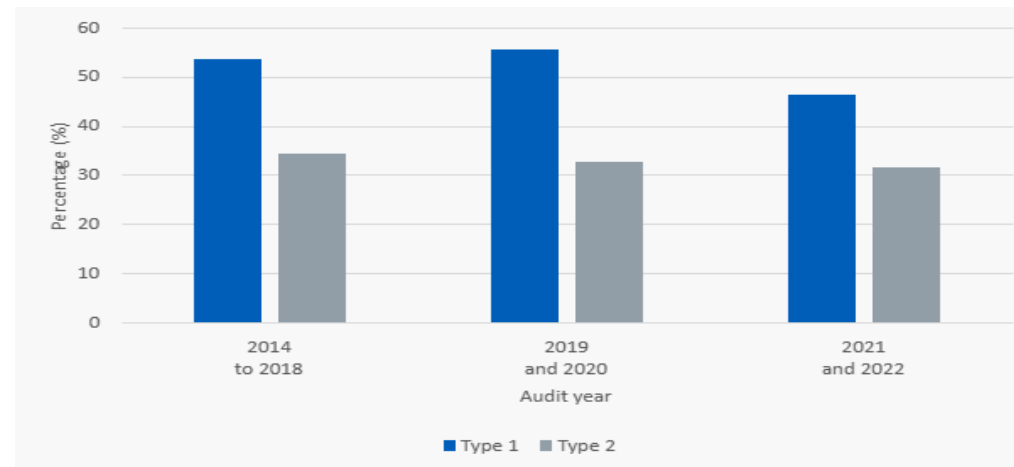
Hybrid closed loop in pregnancy in women with T1DM

- Hybrid closed loop algorithms are not the same
- Most are designed to achieve non-pregnant glucose targets
- Evidence using one HCL algorithm in pregnancy cannot be extrapolated to other systems

CamAPS FX

- CamAPS FX HCL
  - Glucose targets can be set at levels suitable for pregnancy (target can be set 4.4-11 mM)
  - can programme different glucose targets at different times of day/night
  - Adaptive learning

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*

- 124 pregnant women with T1DM, randomised to CamAPS FX HCL versus usual care (with RT-CGM)
  - HbA1c ≥ 48mmol/mol early pregnancy, ≤86mmol/mol at randomisation
  - Randomised before 14 weeks of pregnancy

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

CamAPS FX AiDAPT. Increased % Time In Range 3.5-7.8 mmol/L

End Points	Baseline		16 weeks' gestation until delivery		
	Closed loop (N=59)	Standard care (N=59)	Closed loop (N=59)	Standard care (N=61)	P-value[a]
% TIR 3.5-7.8 mmol/l	47.8% ± 16.4%	44.5% ± 14.4%	68.2% ± 10.5%	55.6% ± 12.5%	NA
Change from baseline	NA	NA	20.4% ± 13.8%	11.0% ± 11.6%	NA
Adjusted difference[a] mean (95% CI)			10.5% (7.0%, 14.0%)		<0.001

Data are mean ± SD

[a] Model adjusted for baseline % TIR, insulin delivery, and site as a random effect

Lee T et al N Engl J Med 2023; 389:1566-1578
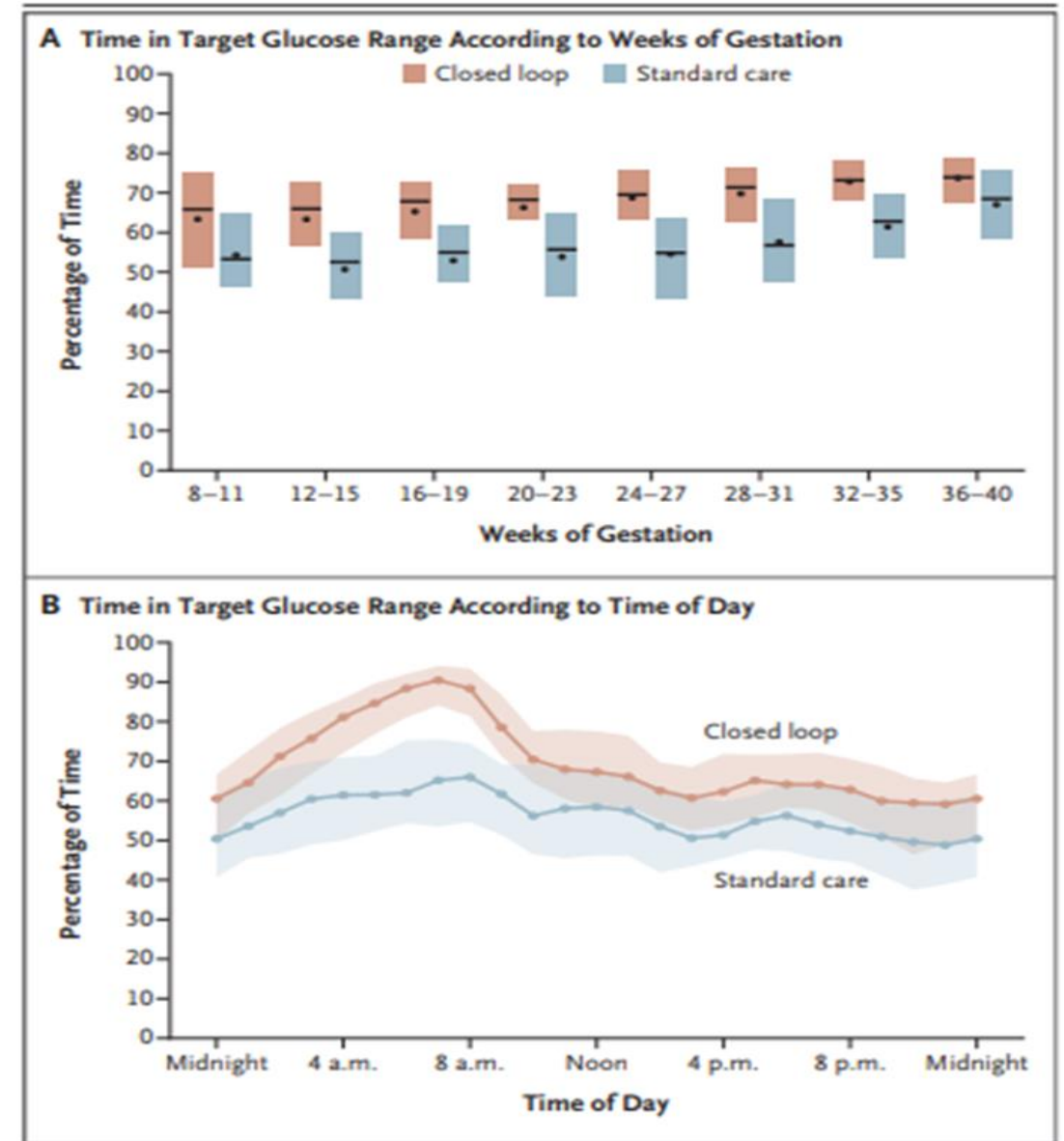
16 weeks until birth. Shaded area interquartile range

CamAPS FX AiDAPT

Hypoglycaemia
- No difference in time below pregnancy target range (TBRp)
  - CamAPS v usual care
  - TBR <3.5 mM 2.3 v 2.0% (p=0.21)
  - TBR <3 mM 0.7 v 0.7% (p=0.20)
- No difference in severe hypos

Maternal weight gain
- Lower maternal weight gain
  - CamAPS v usual care
  - 11.1 ± 6.1 kg v 14.1 ± 6.1 kg (p=0.02)

Less worry, less work, more enjoyable pregnancy (Lawton et al)

CamAPS FX

- CamAPS FX hybrid closed loop system approved for use in pregnancy

Medtronic MiniMed 780G SmartGuard

- Minimed 780G SmartGuard
  - Glucose targets too high for pregnancy
  - Single target 5.5, 6.1, or 6.7 mM (same throughout 24 hours)
  - Adaptive learning

Comparing advanced hybrid closed loop therapy and standard insulin therapy in pregnant women with type 1 diabetes (CRISTAL): a parallel-group, open-label, randomised controlled trial

Katrien Benhalima*, Kaat Beunen*, Nancy Van Wilder, Dominique Ballaux, Gerd Vanhaverbeke, Youri Taes, Xavier-Philippe Aers, Frank Nobels, Joke Marlier, Dahae Lee, Joke Cuypers, Vanessa Preumont, Sarah E Siegelaar, Rebecca C Painter, Annouschka Laenen, Pieter Gillard, Chantal Mathieu

- 95 pregnant women with T1DM, randomised to Medtronic 780G Smartguard HCL versus usual care

Benhalima K et al, Lancet Diabetes and Endocrinology, June 2024

Medtronic 780G CRISTAL results

	Baseline		Antenatal period (over four visits)*		Adjusted mean difference (95% CI)†
	Advanced hybrid closed loop therapy (n=46)	Standard insulin therapy (n=49)	Advanced hybrid closed loop therapy (n=46)	Standard insulin therapy (n=49)	
Primary outcome					
Proportion of time with glucose concentration in range 3·5–7·8 mmol/L	60·5% (14·2)	57·6% (13·7)	66·5% (10·0)	63·2% (12·4)	1·88% (−0·82 to 4·58)
Key secondary outcomes					
Proportion of overnight time with glucose concentration in range 3·5–7·8 mmol/L (2400 h to 0600 h)‡	64·8% (17·6)	60·4% (21·9)	75·1% (13·1)	67·2% (14·6)	6·58% (2·31 to 10·85)§
Proportion of time with glucose concentration <3·5 mmol/L	5·3% (4·9)	5·1% (3·2)	2·5% (2·8)	4·1% (3·4)	−1·34% (−2·19 to −0·49)§
Proportion of overnight time with glucose concentration <3·5 mmol/L (2400 h to 0600 h)‡	5·3% (6·8)	4·0% (3·9)	1·9% (3·2)	4·2% (4·7)	−1·86% (−2·90 to −0·81)§
Exploratory secondary outcomes					
Mean glucose concentration (mmol/L)	7·1 (1·0)	7·3 (1·1)	7·1 (0·7)	7·0 (0·8)	0·14 (−0·04 to 0·33)
HbA$_{1c}$ (%)	6·5% (0·6)	6·5% (0·7)	6·2% (0·6)	6·1% (0·5)	0·07 (−0·07 to 0·20)

Medtronic 780G versus usual care

  TIRp – no difference

  Hypoglycaemia

    <3.5 mM 2.5 v 4.1% (p=0.002)

    <3.0 mM 1.0 v 1.7% (p=0.021)

  Maternal weight gain: 11.8 v 13.9 kg

Tandem T slim Control IQ HCL

- Tandem T slim Control IQ HCL
    - Glucose targets definitely too high for pregnancy
    - Target range 6.25-8.9 mM (sleep 6.25-6.7 mM), (activity 7.8-8.9 mmol/l)
    - NO adaptive learning
- No randomised controlled trials of Tandem T slim Control IQ in pregnancy
- Case series reports

Omnipod 5 hybrid HCL

- Omnipod 5 hybrid closed loop
  - Glucose target: lowest 6.1 mM. Too high for pregnancy.
  - Adaptive learning

- No randomised controlled trials of Omnipod 5 HCL in pregnancy

Pregnancy is a priority area for HCL implementation

- NICE Technology appraisal guidance TA943 Dec 2023

> 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 implementation plan.

- Saving babies' lives: version 3.2 (14 May 2025). A care bundle for reducing perinatal mortality. Element 6

> 6.2 Women with Type 1 diabetes should be offered a pregnancy-specific HCL system (see below for definition) and be provided with appropriate education and support to use this.
> - a licence for use in pregnancy
> - a glucose target of ≤5 mmol/L
> - evidence of a clinically relevant improvement in maternal glucose outcomes (>5% increased time in the pregnancy glucose target range of 3.5–7.8 mmol/L compared to standard care with CGM and standard insulin delivery by multiple daily injections / pump).

Selecting HCL system in pregnancy & pre-pregnancy

- Hybrid closed loop algorithms are not the same

- Most are designed to achieve non-pregnant glucose targets

- Only CamAPS FX meets criteria for pregnancy-specific hybrid closed loop

- Evidence using one HCL algorithm in pregnancy cannot be extrapolated to others

- Pregnant:
  - Offer all pregnant women with type 1 diabetes CamAPS FX hybrid closed loop
  - For those that decide to continue using HCL not approved for pregnancy explain
    - not approved in pregnancy
    - lack of evidence of benefit
    - glucose targets higher than pregnancy targets
      - Continue to support, keep the offer of CamAPS FX open

- Planning pregnancy:
  - If on MDI offer CamAPS FX HCL
  - If already on HCL
    - if achieving targets without problematic hypoglycaemia continue as is until pregnant.
    - If starting HCL, or upgrade, recommend CamAPS FX

Optimising glucose levels in pregnancy

Optimising glucose levels in pregnancy

- The essentials (food, activity, insulin)
- Know what settings can be adjusted to impact insulin delivery when in hybrid closed loop
- Approach to looking at the upload

The essentials

Reflection in real-time. Think diet/activity/insulin

Diet

- Carbohydrate quantity (total 120-200g / day (MINIMUM 120g/day)
  - Breakfast 15-20g, lunch 40-60g, evening meal 40-60g.
- Carbohydrate choice (low glycaemic index & quality)
- If choose (or need) to snack ensure healthy carbohydrate snacks (10-20g)
- Evening meal timing: aim to eat before 19:30

Activity

- 15 min activity after eating

Insulin

- Insulin dose (carbohydrate counting, insulin:carbohydrate ratio (ICR))
- Insulin timing 'Pre-bolusing' where possible
  - Generally 10-15 minutes throughout pregnancy (in those using hybrid closed loop)
  - (some may need 20-30 min particularly in later pregnancy)

Hypoglycaemia

- will usually need less quick acting carb to avoid/treat hypos when on hybrid closed loop (5-10g)
- Make sure treating with QA carbohydrate. Keep on person & by bed

Hypoglycaemia avoidance / treatment

– Will usually need less quick acting carb to treat hypos when in hybrid closed loop

– Make sure treating with QA carbohydrate. Keep on person & by bed

Avoiding / treating hypoglycaemia	
Glucose level/trend arrow	Amount of quick acting carbohydrate when in hybrid closed loop
3.5-5.0 mmol/l ⬇	4-5 g
3.5-5.0 mmol/l ⬇⬇	8-10 g
<3.5 mmol/l but NO bolus in the last 2-3 hours and NO exercise	8-10 g
<3.5 mmol/l AND bolus within last 2-3 hours OR exercise	15g

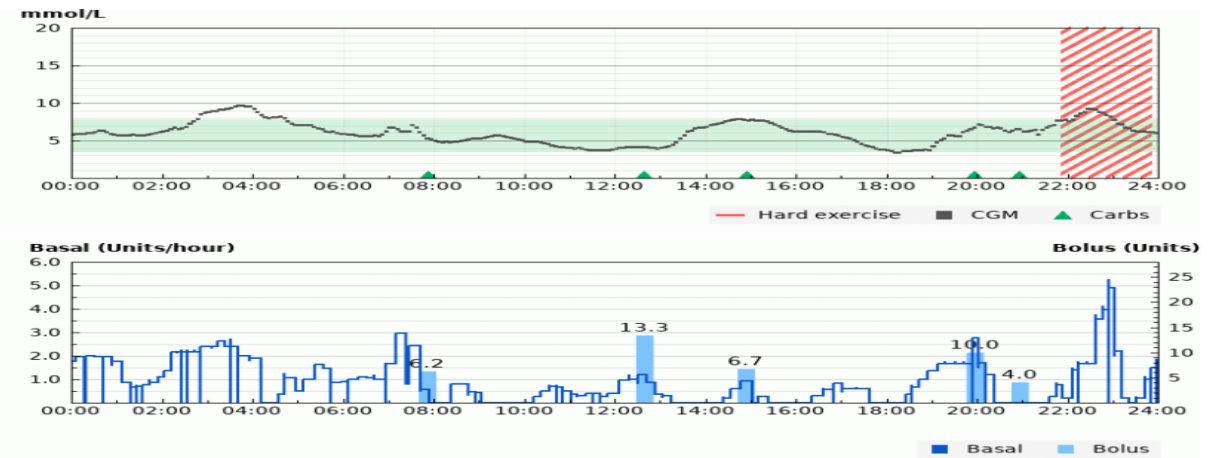– After treating, review sensor glucose in 10-15 min. If <3.5 mM confirm with fingerstick before repeating treatment

CamAPS FX HCL
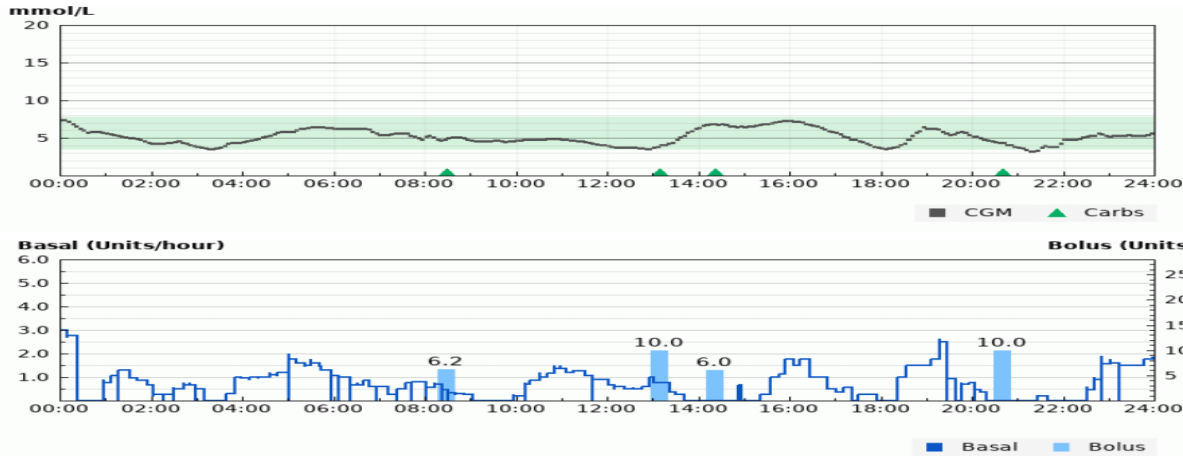
Algorithm aims to get glucose to target overnight and between meals

Upload:　automatic (GLOOKO)

Automated insulin delivery:

　　After set up, only target glucose, weight (and ease-off and boost) affect automated insulin delivery

　　Target: set at 5.5 mM in pre-pregnancy & early pregnancy.

　　　　from about 16 weeks adjust to 5.0 mM

　　　　once stabilised adjust to 4.5 mM overnight and 5.0 mM during day

　　Remember to adjust weight through pregnancy and post birth (this influences HCL automated insulin delivery)

Meal insulin: Adjust ICR to adjust meal-time bolus dose

Hyperglycaemia:　　Use 'BOOST'

　　　　　　Can give correctives, but NOT encouraged. ISF and bolus calculator target affects recommended corrective

Exercise: 'EASE OFF' as needed

Back up settings: Remember to adjust programmed basal and ISF and bolus calculator targets for if out of HCL
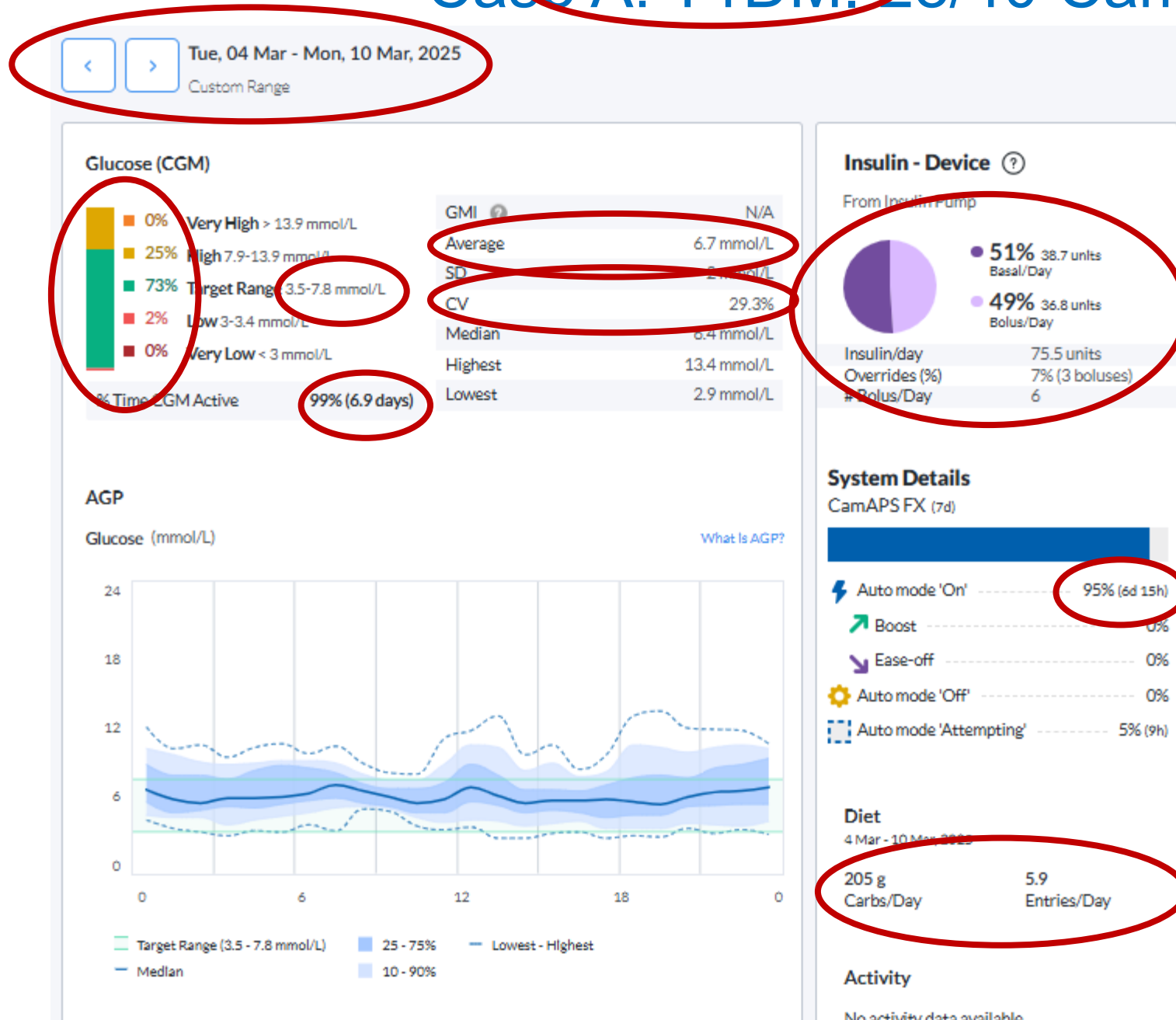
An approach to looking at the upload:

- Review the upload with the woman
  - Make sure to point out the positives throughout
  - Encourage self-review of glucose date, real-time reflection and changes made
  - Ask the woman what they think needs to be addressed
  - Ask when changes were last made

An approach to looking at the upload: summary

- Check name, DOB, date of upload

- Set reporting time period to 1 week

- Glucose targets set to pregnancy targets!

- % sensor wear & % time in HCL (should be >90%)

- Sensor data, and compare with previous

  - TBRp (aim <4%), TIRp (aim >70%), TARp (aim <25%)

  - Average glucose (aim 6-6.5 mM)

  - Co-efficient of variation (aim around 30%)

- Total daily carbohydrate (aim 120-200 g/day)

- Total daily insulin

- Basal:bolus split (should be <50% basal, often around 30% in later pregnancy (remember automated insulin delivery is recorded as 'basal'. If >50% usually means the algorithm is doing a lot of work)

- Set change (every 2-3 days)

Case A: T1DM, 28/40 CamAPS FX

Tue, 04 Mar - Mon, 10 Mar, 2025
Custom Range

Glucose (CGM)

0%	Very High	> 13.9 mmol/L
25%	High	7.9-13.9 mmol/L
73%	Target Range	3.5-7.8 mmol/L
2%	Low	3-3.4 mmol/L
0%	Very Low	< 3 mmol/L

% Time CGM Active   99% (6.9 days)

GMI	N/A
Average	6.7 mmol/L
SD	2.0 mmol/L
CV	29.3%
Median	6.4 mmol/L
Highest	13.4 mmol/L
Lowest	2.9 mmol/L

AGP

Glucose (mmol/L)

What Is AGP?

Target Range (3.5 - 7.8 mmol/L)   25 - 75%   Lowest - Highest
Median   10 - 90%

Insulin - Device ⓘ

From Insulin Pump

- **51%** 38.7 units Basal/Day
- **49%** 36.8 units Bolus/Day

Insulin/day	75.5 units
Overrides (%)	7% (3 boluses)
#Bolus/Day	6

System Details

CamAPS FX (7d)

⚡ Auto mode 'On'	95% (6d 15h)
↗ Boost	0%
↘ Ease-off	0%
⚙ Auto mode 'Off'	0%
⬚ Auto mode 'Attempting'	5% (9h)

Diet

4 Mar - 10 Mar 2025

205 g	5.9
Carbs/Day	Entries/Day

Activity

No activity data available

Overall looks pretty good
Average a little high
TD carbs a bit high
Basal bolus split should probably
have more bolus (especially
given carbs high)

Check/ask about set changes

Looking at the upload: review settings

This is a guide. Only adjust if reason to do so

- Insulin:carbohydrate ratio
    - Up to 20 weeks: around 350/TDD (Breakfast 300/TDD, other 400/TDD)
    - Beyond 20 weeks: moving towards 250/TDD
- Insulin sensitivity factor
    - Up to 20 weeks: around 120/TDD
    - Beyond 20 weeks: around 100/TDD
- Glucose target for HCL
    - CamAPS
        - Up to 16 weeks set at 5.5 mM
        - From about 16 weeks adjust to 5.0 mM, then 5.0 mM during day and 4.5 mM overnight
        - Note the personal glucose target if the HCL target (the glucose target in the bolus calculator is for corrections. Adjust in parallel)
- Programmed basal
    - 40-50% TDD (don't use delivered 'basal' to determine programmed basal)
- Weight: update weight throughout pregnancy and post pregnancy
- Active insulin time
    - For CamAPS FX usually set at 3 hours
- Check max bolus (≥50% TDD)
- Alerts
    - High: waking hours 10-15 mM, sleeping hours 8-10 mM. repeat 2 hours.
    - Low: 3.5-4 mM, (with urgent low soon ON and urgent low ON) repeat 30 min
    - Make sure alert make a sound that will wake them!

Case A: T1DM. 28/40. CamAPS FX TDD 75.5 units

Basal Total Basal Dose 24 units/day	
00:00	1.0 units/hour
Personal glucose target	
00:00	5 mmol/l
Sensitivity factor	
00:00	1.7 mmol/l
Carb ratio	g/unit
00:00	7
06:00	7
09:00	7
12:00	4
15:00	4.5
18:00	6

Calculated programmed basal
(0.45 x TDD) = 34 units
=1.4 units / hour
(note does not affect automated insulin delivery)

Calculated ISF
(100/TDD) = 1.3 mM

Calculated ICR
(250/TDD -350/TDD)
3.3 – 4.6 g

Average a little high
TD carbs a bit high
Basal bolus split should probably have more bolus

ICR too weak, especially at breakfast
Overnight target could be reduced
ISF too weak (no impact on automated insulin delivery
Back-up basal too weak (no impact on automated insulin delivery)

Sensor alert settings 11 mar 2025	
Day	Night
	SOUND at night
Low 3.9 mM **sound**	Low 3.9 mM
Low repeat 30 min	Low repeat 30 min
Urgent low 3.1 mM **sound**	Urgent low 3.1 mM
Urgent low repeat 30 min	Urgent low repeat 30 min
Urgent low soon on	Urgent low soon on
Urgent low soon repeat 30 min	Urgent low soon repeat 30 min
High 9 mmol/l **vibrate**	High 8 mmol/l
High repeat 2 hours	High repeat 2 hours
Rise rate on - likes this	Rise rate on - likes this

Looking at the upload: daily graphs Case A: T1DM. 28/40
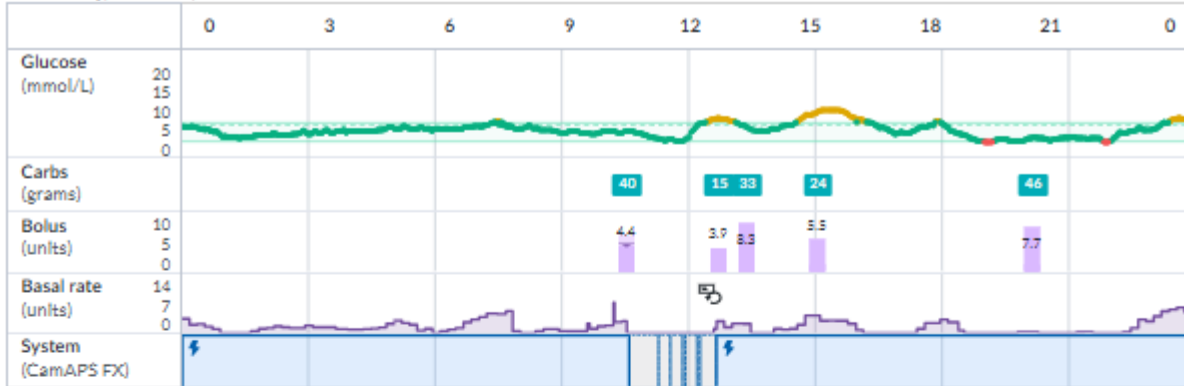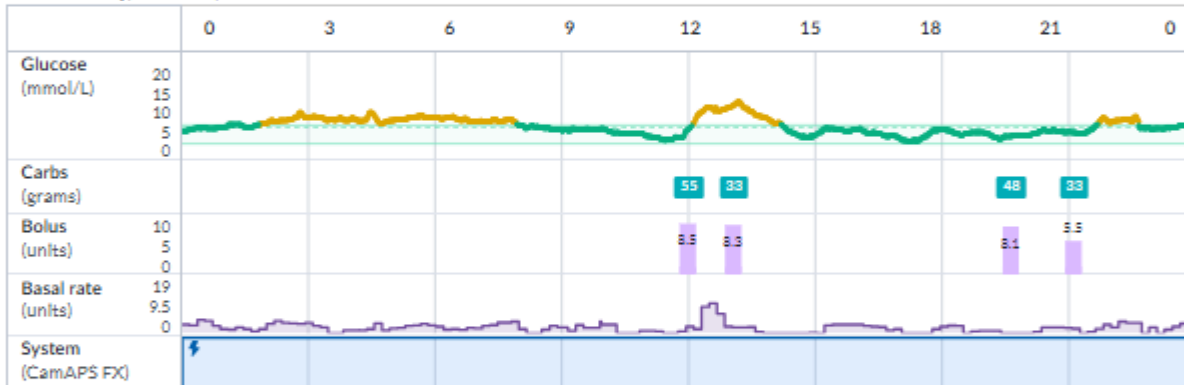
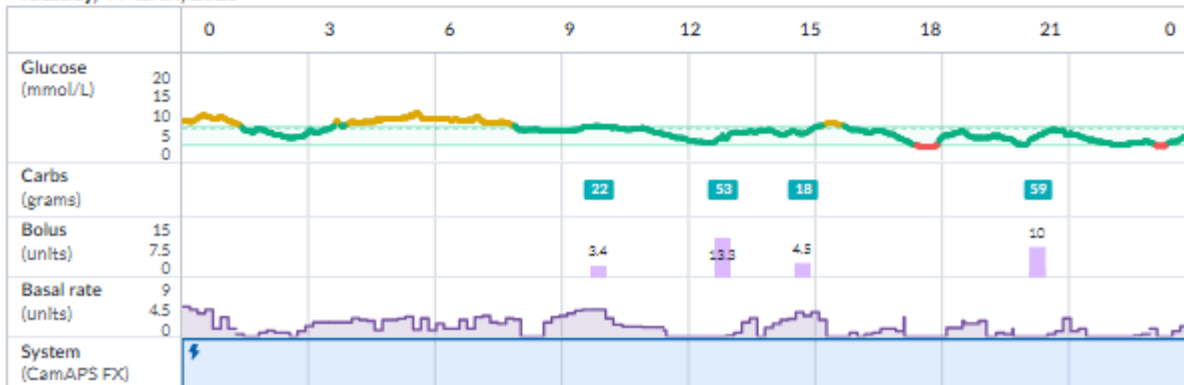Look at last 6-7 days (or since most recent change if lower)
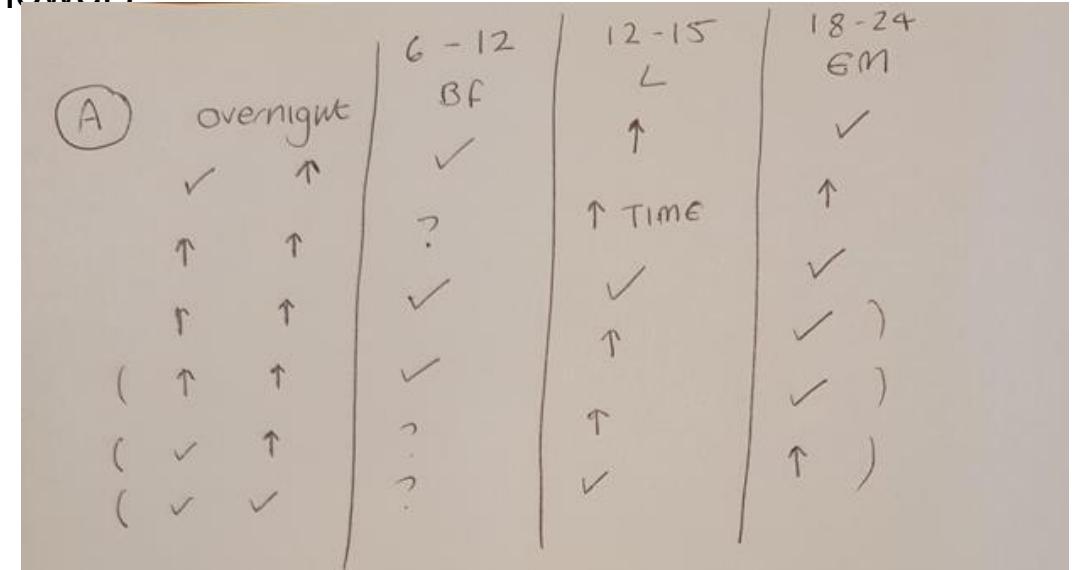
From review of settings
ICR too weak, especially at breakfast
Overnight target could be reduced

Overnight above target
Breakfast ok (surprisingly!)
Lunch: above target, think about start of lunch block
Evening meal ok

Ask the woman what they think needs to be adjusted
        Running above target in the night
        High post lunch
Point out the positives!
        Overall looks great
From the upload
        Average a little high
        TD carbs a bit high – checked she is not entering 'fake carbs'
        Overnight above target
        Breakfast ok (surprisingly!)
        Lunch: above target, think about start of lunch block
        Evening meal ok
        ISF too weak (no impact on automated insulin delivery
        Back-up basal too weak (no impact on automated insulin delivery)

Plan
Change hybrid closed loop target overnight from 5 to 4.5 mM
Update weight

Strengthen lunch ratio (from 1:4g to 1:3.5g)
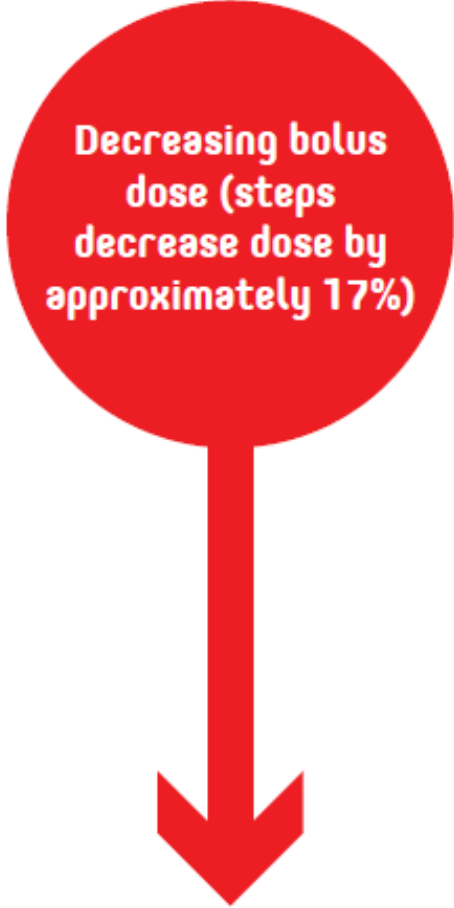Change start of lunch ICR block from 12:00 to 11:00

ISF changed from 1.7 to 1.3 mmol/l in line with total daily dose (will give more for corrections if used)

Programmed basal changed from 1 to 1.4 units/h (note will not affect automated insulin delivery)

Adjusting the insulin:carbohydrate ratio

		1 unit of insulin for X grams of carbohydrate	Units of insulin per 10g carbohydrate portion
Ratios are usually adjusted by about 20%. In this table each step increases insulin dose by approximately 20% (or reduces insulin dose by approximately 17%)			
Increasing bolus dose (steps increase dose by approximately 20%)	Decreasing bolus dose (steps decrease dose by approximately 17%)	1.4 g	7.4 units
		1.6 g	6.2 units
		1.9 g	5.2 units
		2.3 g	4.3 units
		2.8 g	3.6 units
		3.3 g	3.0 units
		4.0 g	2.5 units
		4.8 g	2.1 units
		5.8 g	1.7 units
		6.9 g	1.44 units
		8.3 g	1.20 units
		10 g	1 unit
		12 g	0.83 units
		14 g	0.69 units
		17 g	0.58 units
		21 g	0.48 units
		25 g	0.40 units

ABCD DTN-UK Best practice guide. Using diabetes technology in pregnancy. https://abcd.care/dtn/best-practice-guides

Case B: T1DM. 24/40

Glucose (CGM)

Tue, 04 Mar - Mon, 10 Mar, 2025
Custom Range

1%	Very High	> 13.9 mmol/L
27%	High	7.9-13.9 mmol/L
67%	Target Range	3.5-7.8 mmol/L
3%	Low	3-3.4 mmol/L
2%	Very Low	< 3 mmol/L

% Time CGM Active	98.8% (6.9 days)

GMI	N/A
Average	6.8 mmol/L
SD	2.4 mmol/L
CV	35.5%
Median	6.4 mmol/L
Highest	15.1 mmol/L
Lowest	2.3 mmol/L

AGP

Glucose (mmol/L)
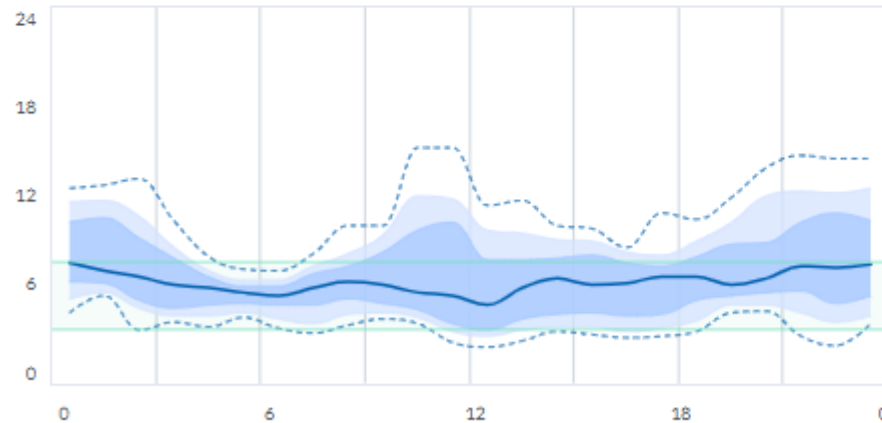
What is AGP?

Target Range (3.5 - 7.8 mmol/L) | 25 - 75% | Lowest - Highest
Median | 10 - 90%

Insulin - Device ?

From Insulin Pump

- 53% 40.4 units Basal/Day
- 47% 35.4 units Bolus/Day
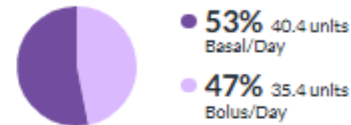
Insulin/day	75.8 units
Overrides (%)	0% (0 boluses)
# Bolus/Day	5.1

System Details

CamAPS FX (7d)

⚡ Auto mode 'On'	----	97% (6d 19h)
↗ Boost	----	40% (2d 19h)
↘ Ease-off	----	0% (1h)
⚙ Auto mode 'Off'	----	0%
⬚ Auto mode 'Attempting'	----	3% (5h)
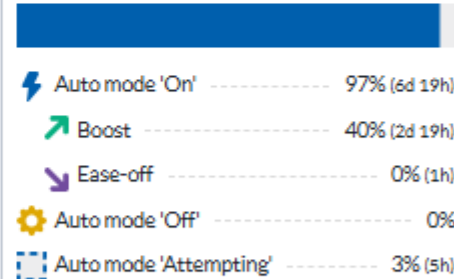
Diet

4 Mar - 10 Mar, 2025

195.7 g	4.9
Carbs/Day	Entries/Day

Activity

Overall looks pretty good
TBRp slightly too high

TIRp a little low
Average a little high

Basal bolus split should probably
have more bolus

Check/ask about set changes

Basal Total Basal Dose 24 units/day 00:00	1.0 units/hour
Personal glucose target 00:00 0300 2100	4.8 mmol/l 5.0 mmol/l 4.6 mmol/l
Sensitivity factor 00:00	2.4 mmol/l
Carb ratio 00:00 06:00 11:00 15:00 17:00	g/unit 4.5 4.5 6 7 5

Calculated programmed basal
(0.45 x TDD) = 34.1 units
=1.4 units / hour
(note does not affect automated insulin delivery)

Calculated ISF
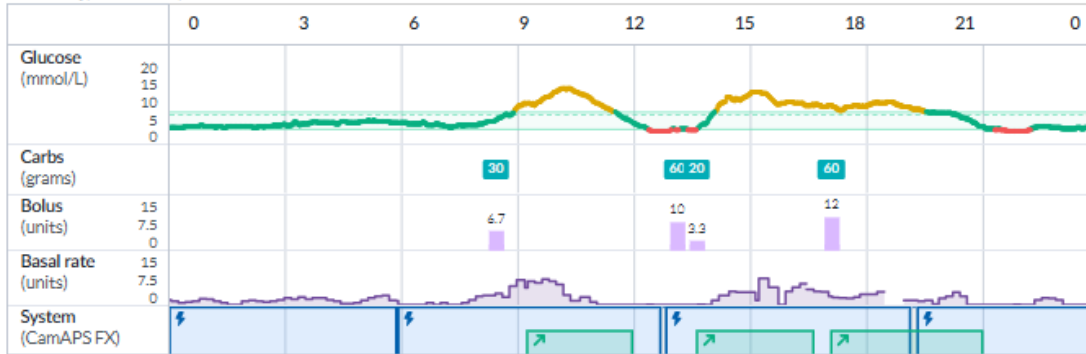*(100/TDD) = 1.3 mM*

Calculated ICR
(250/TDD -350/TDD)
3.3 – 4.6 g

From summary Overall looks pretty good
TBRp too high
TIRp a little low
Average a little high
Basal bolus split should prob have more bolus

ICR weak
ISF too weak (no impact on automated insulin delivery
Back-up basal too weak (no impact on automated insulin delivery)
Alerts on vibrate overnight

Sensor alert settings 11 Mar 2025	
Day	Night
Low 3.5 mM **vibrate**	Low 3.5 mM **vibrate change to sound**
Low repeat 60 min	Low repeat 60 min
Urgent low 3.1 mM on	Urgent low 3.1 mM on
Urgent low repeat 30 min	Urgent low repeat 30 min
Urgent low soon on **vibrate**	Urgent low soon on **vibrate change to sound**
Urgent low soon repeat 30 min	Urgent low soon repeat 30 min
High 7.8 mM she likes this **vibrate**	High 8 mM, **vibrate change to sound**
High repeat 2 hours	High repeat 2 hours

Case B: T1DM. 25/40
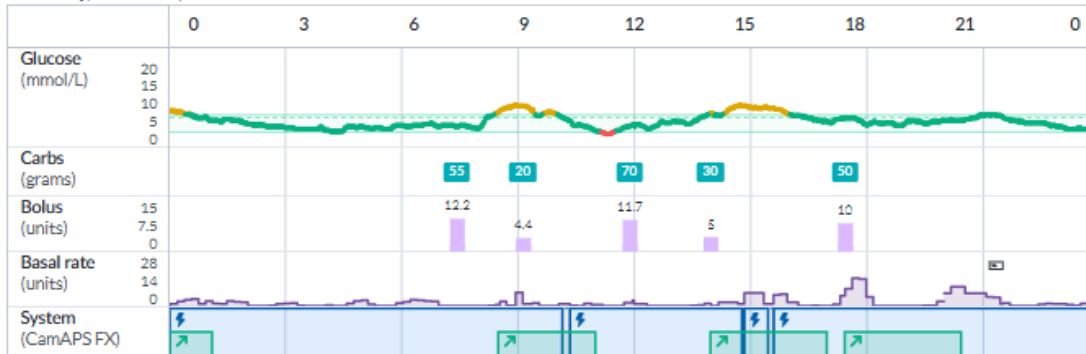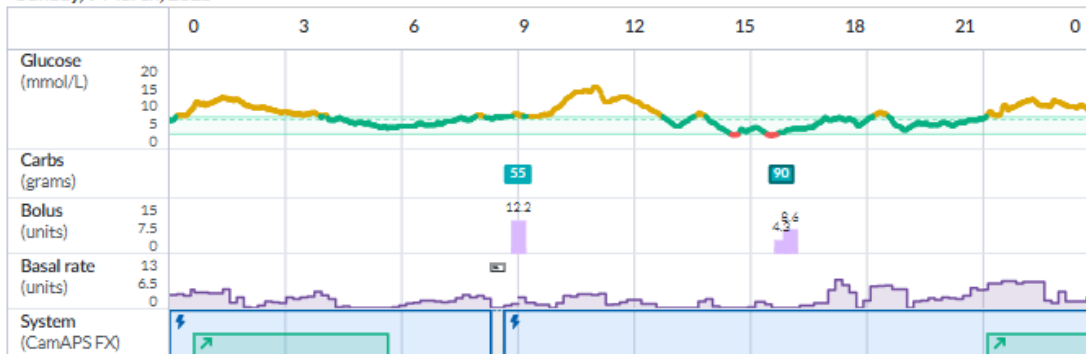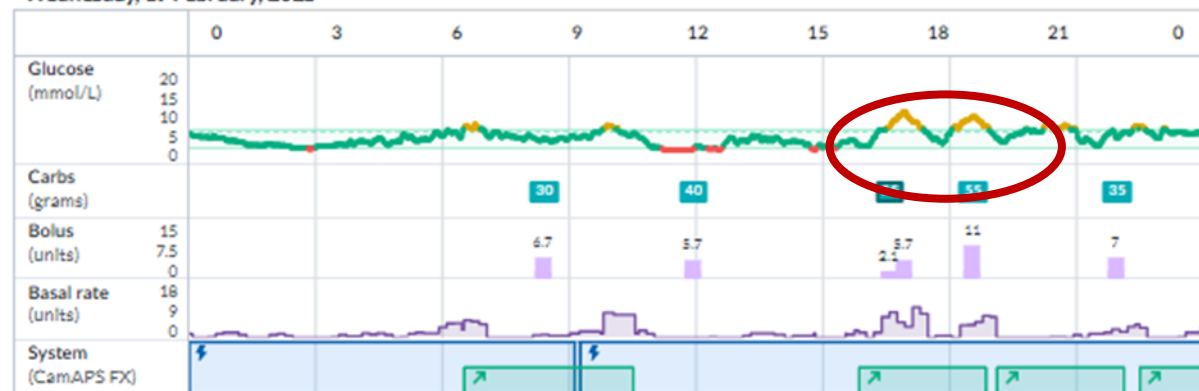

From settings
ICR weak
Alerts on vibrate overnight

Overnight: mainly ok
Breakfast: above target
Lunch: variable (also some late boluses)
Evening meal ?

Lows after above target

Case B: T1DM. 25/40

Patient: overall happy. Struggles when at work with pre-bolusing (day and evening shifts)

Overall looks pretty good
TBRp a little too high
TIRp a little low
Average a little high
Basal bolus split should probably have more bolus

ICR weak
ISF too weak (no impact on automated insulin delivery
Back-up basal too weak (no impact on automated insulin delivery)
Alerts on vibrate overnight

Overnight: mainly ok
Breakfast: above target (think food/activity/insulin
Lunch: variable (also some late boluses)
Evening meal ?

Plan
Keep up the great work!
Routine change overnight personal glucose target to 4.5 mM (2100-0700)
Try to pre-bolus 15 min wherever possible. I will do a letter for work to support longer breaks
Try to change breakfast food from 2x white bread with jam to first slice with peanut butter. If remains above target post-breakfast strengthen breakfast ICR (from 4.5 to 3.5 g)

Change weight in pump from 72 to 75 kg
Change overnight ICR from 4.5 to 6 g (in case eats in the night)
Adjust 'back up settings' for if out of hybrid closed loop / giving correctives
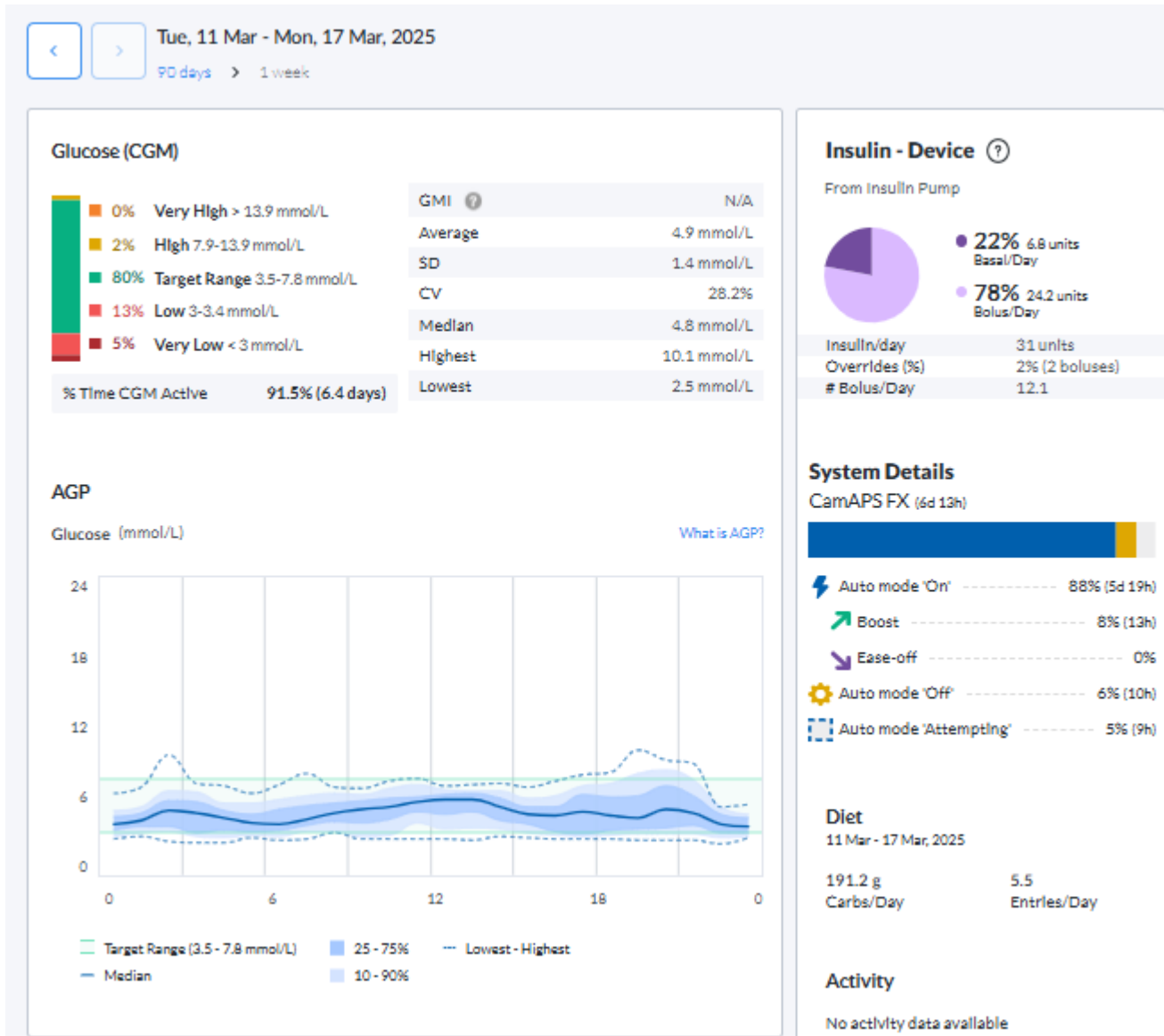   -change ISF from 2.4 to 1.3 mmol/l
    -change programmed basal from 1 to 1.4 units/hour
    -change bolus calculator target from 5.5 to 5 mM
Alerts - turn on sound (rather than vibrate) overnight

Case C: T1DM. 13+/40

Much too much time low

Very bolus heavy

Check/ask about set changes

Basal

1 Active

00:00 (24 hr)   0.65 Units/hr

Total   15.6 Units

0.

0.

Insulin to carbohydrate ratio (ICR)

Bolus Program Active

00:00 (24 hr)   8 g/Unit

Sensitivity (ISF, correction)

Bolus Program Active

00:00 (24 hr)   3.3 mmol/L

Personal glucose target

Bolus Program Active

00:00 (24 hr)   5.5 mmol/L (+0/-0)

Much too much time low

Very bolus heavy

Programmed basal too high
(0.45xTDD=14 units (0.55
units/h)

ICR maybe too strong
(350/TDD = 11g)

ISF maybe too strong
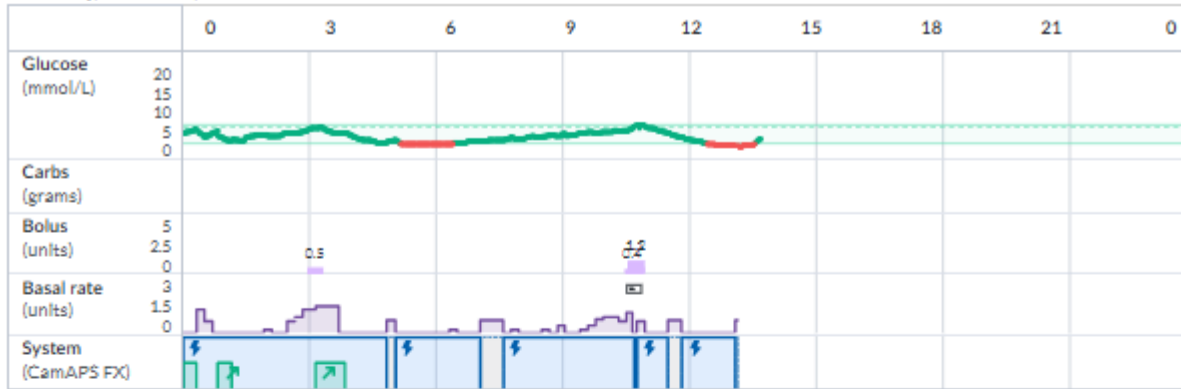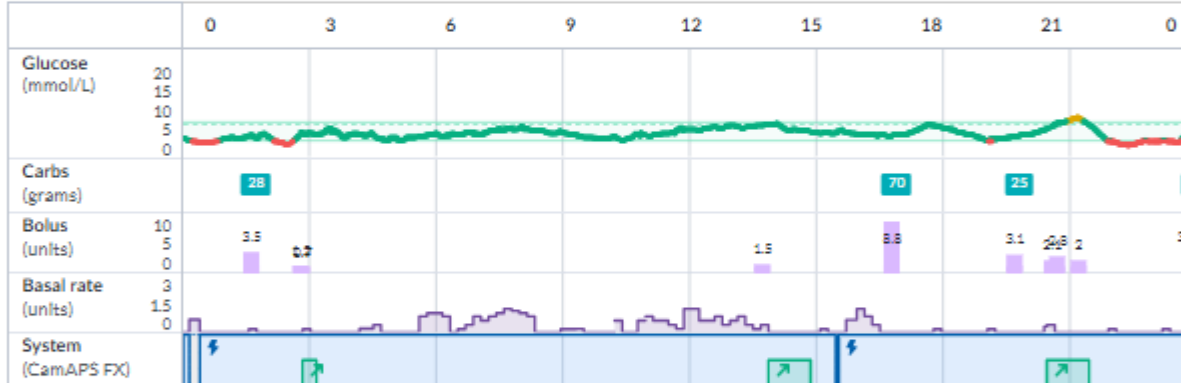(120/TDD = 3.9 mM)

Alerts

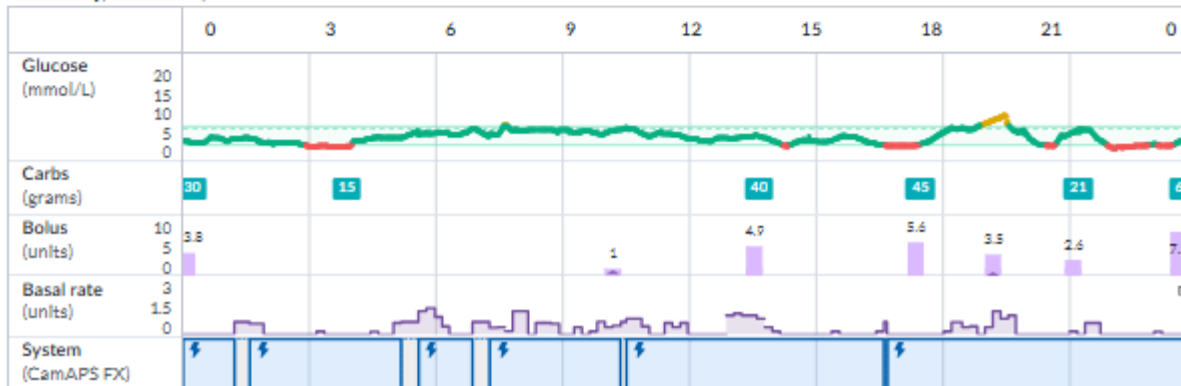High 7.8 mM
Low turned off

Case C: T1DM. 13+/40

Monday, 17 March, 2025

Sunday, 16 March, 2025

Saturday, 15 March, 2025

Much too much time low
Very bolus heavy
Programmed basal too high
ICR maybe too strong
ISF too strong (120/TDD = 3.9 mM)
Alerts: High 7.8 mM. Low turned off
Primarily interested in cause of hypos here
Using correctives on top of boost with hypos
Lows after meal boluses
Plan
Discuss risks of high TBRp (loss of hypo awareness with risk of severe hypos, more difficult to achieve tight control)
Use boost, not correctives
Weaken ISF from 3.3 to 3.9 mM. If decides to give correctives, try not to override
Agreed to adjust ICR from 8g to 9g (we recommended 10g)
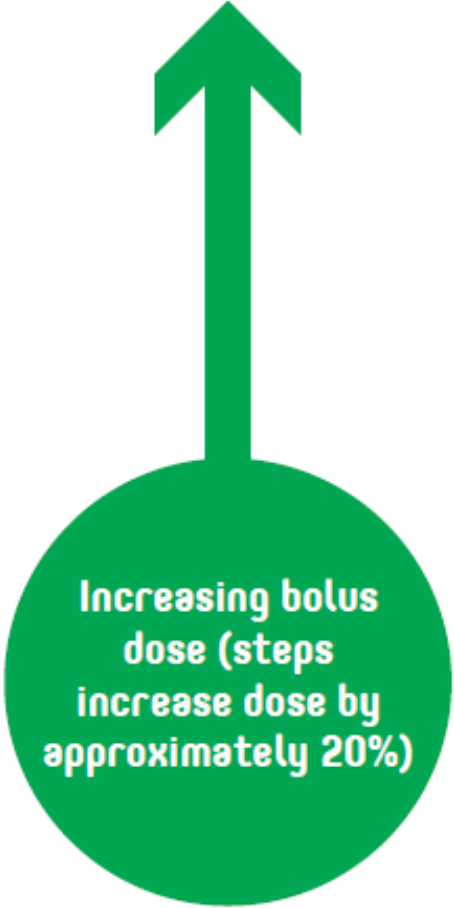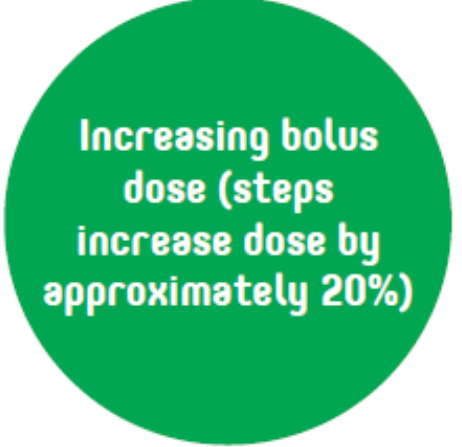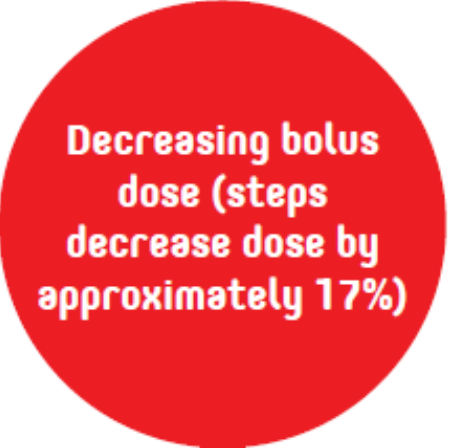Adjusted alerts – low,ULS on. High: day 10 mM, night 8 mM
Adjusted 'back-up' settings if out of HCL or giving correctives
    -programmed basal from 0.65 to 0.55

Adjusting the insulin:carbohydrate ratio

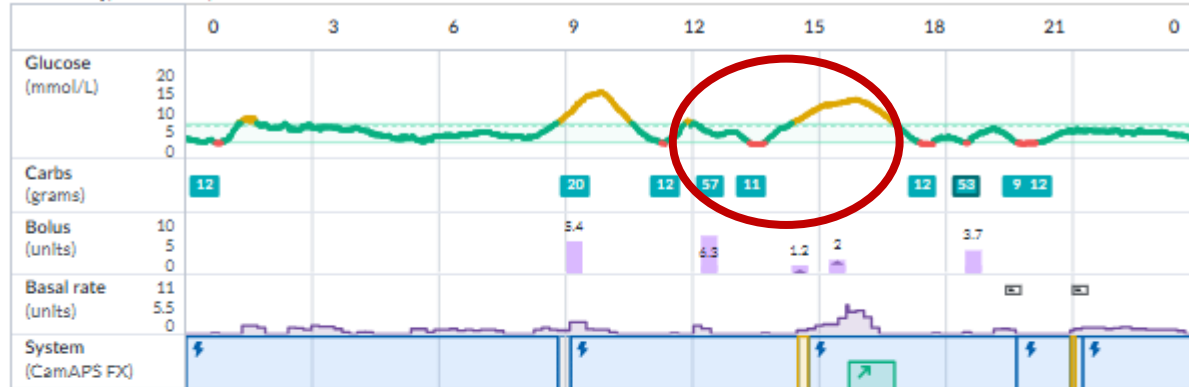|		1 unit of insulin for X grams of carbohydrate	Units of insulin per 10g carbohydrate portion
Ratios are usually adjusted by about 20%. In this table each step increases insulin dose by approximately 20% (or reduces insulin dose by approximately 17%)			
		1.4 g	7.4 units
		1.6 g	6.2 units
		1.9 g	5.2 units
Decreasing bolus dose (steps decrease dose by approximately 17%)		2.3 g	4.3 units
		2.8 g	3.6 units
		3.3 g	3.0 units
		4.0 g	2.5 units
		4.8 g	2.1 units
		5.8 g	1.7 units
		6.9 g	1.44 units
		8.3 g	1.20 units
		10 g	1 unit
Increasing bolus dose (steps increase dose by approximately 20%)		12 g	0.83 units
		14 g	0.69 units
		17 g	0.58 units
		21 g	0.48 units
		25 g	0.40 units

ABCD DTN-UK Best practice guide. Using diabetes technology in pregnancy. https://abcd.care/dtn/best-practice-guides

Case D: T1DM.

Probably pre-bolusing too early

Case F

- 19 year old, supported accommodation
- Early pregnant
- T1DM, MDI, History of DKA, does not carb count
- HbA1c 86 mmol/mol, TIRp 15%

- Offer CamAPS FX
  – Focus on safety: ensure understands risk of DKA, informed choice
  – Supervised cannula change until confident

- Consider using 'small, medium, large, very large' bolus function
  – Assess carb content of her common foods, create lists of S/M/L/VL
  – Set the meal carb size for S/M/L/VL appropriate for her
  – Can enter and bolus for separate components of meal separately

Hybrid closed loop systems not approved in pregnancy

Medtronic 780G HCL in pregnancy (not approved, if choose to use…)

Upload: automatic (CARELINK)

Automated insulin delivery:

     After set up, only target glucose, active insulin time, ICR (and temp target) affect automated insulin delivery.

     Target: set at 5.5 mM (this is the lowest (options 5.5, 6.1, 6.7 mM)) (CAN'T programme different targets at different times of day)

     Set active insulin time to 2 hours

     Review overnight ICR (as this influences autocorrections)

Meal insulin:

     Adjust ICR to adjust meal-time bolus dose – be generous

     'Safe bolus' feature: delivered boluses may result in under-bolusing for meals think diet/activity/insulin

        ??Try to make sure glucose in range and increasing prior to eating

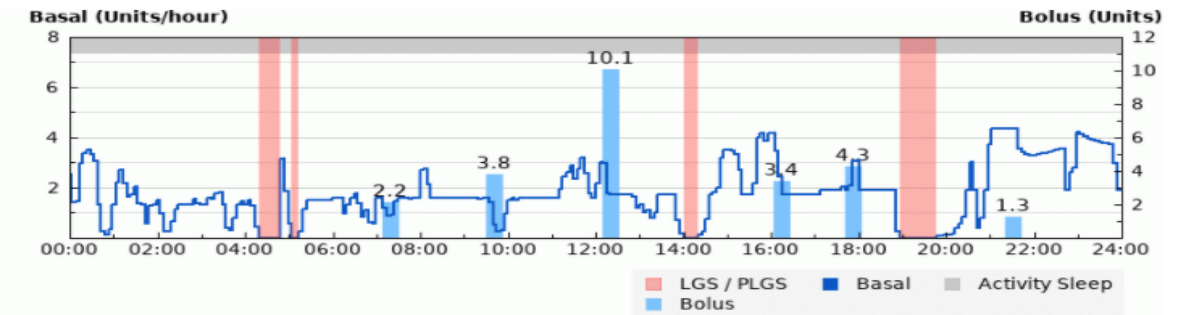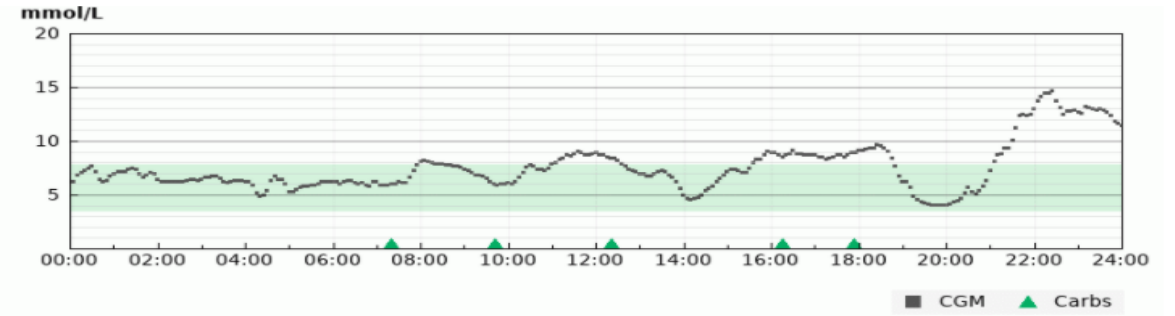   ??Adjust ICR to give more (BUT need to override when out of automode)

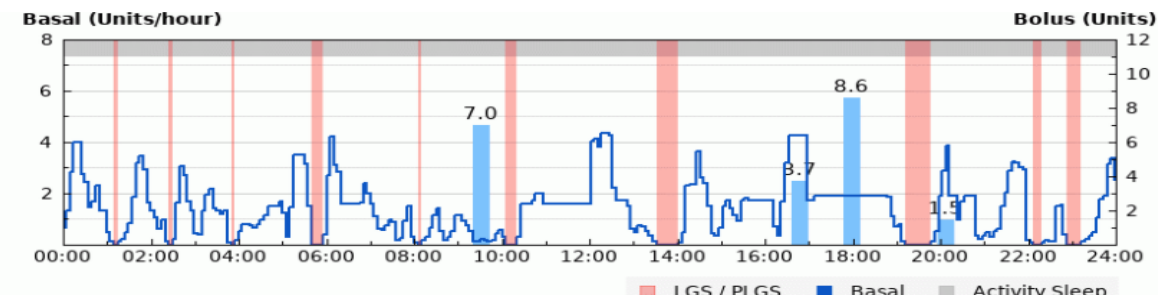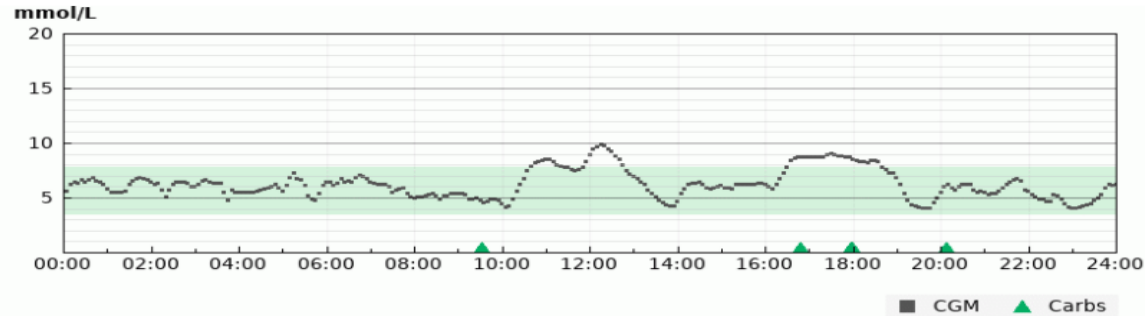   ??? 'Fake carbs

Hyperglycaemia: (no boost function, need to enter blood glucose for user initiated correctives)

Exercise: 'TEMP TARGET'

Back-up settings: Remember to adjust programmed basal and ISF as back-up if out of HCL

Tandem Control IQ HCL in pregnancy (not approved, if choose to use....)

Upload: MANUAL (GLOOKO)

Automated insulin delivery:

NO adaptive learning. Programmed basal, target glucose range, ISF affect automated insulin delivery

can set different ISF/basal at different times of day to manage diurnal variation in insulin requirements

Target: Target range 6.25-8.9 mM (higher than pregnancy target)

Sleep mode (6.25-6.7 mM) BUT no auto correction boluses when in sleep mode)

Usually set sleep mode from >4 hours post last meal of day. OCCASIONALLY set continuously if tight control

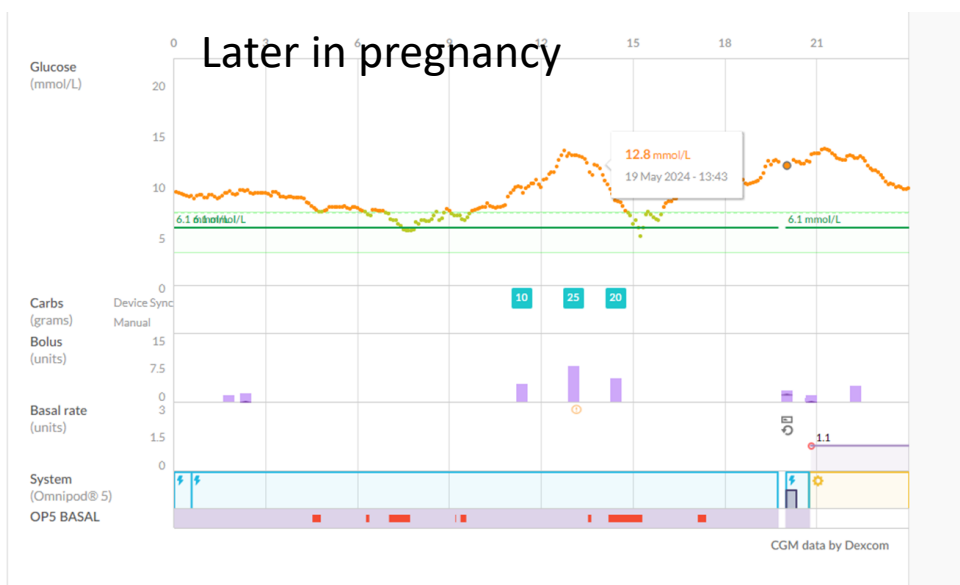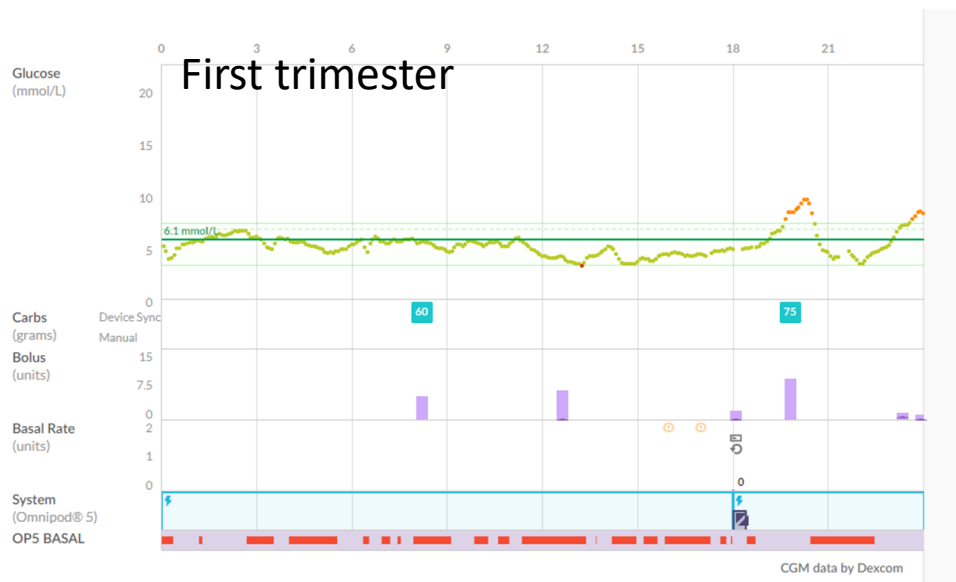**Meal insulin:** Adjust ICR to adjust meal-time bolus dose

Hyperglycaemia: no boost function, can give user initiated correctives

Exercise: EXERCISE MODE

Back-up settings: not applicable

Not recommended if TTD >100 units

Omnipod 5 HCL in pregnancy (not approved, if choose to use....)

First trimester

Later in pregnancy

Upload: automatic (GLOOKO)

Automated insulin delivery:

After set up, only target glucose (and activity mode) affect automated insulin delivery. No autoboluses

Target: Set at 6.1 mM (lowest). (can programme different targets at different times of day)

Meal insulin:

Adjust ICR to adjust meal-time bolus dose – be generous

Make sure 'reverse correction' OFF

Hyperglycaemia:

No boost function

Encourage to give corrective doses – be generous with ISF. Set active insulin time at 2 hours

Exercise: EXERCISE MODE

Back-up settings: Remember to adjust programmed basal back-up if out of HCL

Capacity 200 units

Keeping insulin pump users safe in pregnancy

Keeping insulin pump users safe in pregnancy

- Review periodically (eg first visit and every trimester)

- Back-up insulin pens: must carry a rapid-acting insulin pen & needles at all times, should have access to long-acting insulin (at home)

- Functioning glucose & ketone meter with in-date strips

- Hypo treatment, keep on person & by bed, glucagon at home. DVLA rules

- Rules for managing UNEXPLAINED hyperglycaemia in pregnancy

  - Glucose threshold lower (10 mmol/l versus 13 mmol/l)

  - Check for ketones earlier. Ketone threshold lower (1.0 mmol/l versus 1.5 mmol/l)

- Sick day rules for pump users in pregnancy

  – For those using hybrid closed loop, come out of closed loop and follow sick day rules

  – Ketone threshold lower (1.0 mmol/l versus 1.5 mmol/l)

  – Threshold for attending hospital as an emergency earlier

    – Straight away if ketones > 3 mmol/l

    – If no improvement after 2 hours if ketones 1.1-3 mml/l

- Change sets every 2-3 days. Set changes early in the day (not before bed)

- Document pump settings and TDD regularly in case of pump failure

Using HCL after steroids

- ?
- Usually stay in HCL
- CamAPS FX use BOOST
- If not maintaining glucose in target range start VRIII using your trust protocol
- NOTE if insulin pump continued while on VRIII for steroids
  - Come out of hybrid closed loop
  - DON'T give corrections (ie for meals enter carb, but not glucose)

Case G

Combined antenatal diabetes clinic

34 year old woman   G1 P0, 34+3 weeks of gestation

Plan for induction of labour at 38 weeks

PMH

T1DM

- DAFNE trained

- Using CamAPS FX hybrid closed loop insulin delivery prior to pregnancy

- First HbA1c in pregnancy 47 mmol/mol

Treatment

-Novorapid in pump

      ICR 1 unit:4g, back-up ISF 1.5 mM

      TDD 70 units

--Aspirin 150 mg od

-Vitamin D 400 units

What diabetes things do we need to consider?

Case G

Glycaemic control now/Communication with obstetricians/watch for fall in insulin requirements

At birth, insulin requirements fall immediately to pre-pregnancy levels or lower

Plan for managing diabetes through birth

      Offer women on hybrid closed-loop option of continuing it through birth

      Prescribe individualised VRIII plus glucose (as back up if staying on hybrid closed loop)

         If VRIII used, suspend and disconnect own insulin pump

         Consider starting with 'scale 2' (as no basal insulin)

Determine & document post birth settings

Post birth

      The risk is hypos

      Aim for glucose levels 6-10 mM pre-meals/overnight for first 1-2 weeks

      Expect post-meal excursions up to low teens

      Don't pre-bolus (risk of getting distracted)

      Discuss psychological adjustment to lower insulin requirements and higher glucose – avoid the temptation 'to just give a couple more units'

      Adaptive systems may struggle to manage sudden reduction in insulin requirements

      Glucose management around breastfeeding

Review at 4-6 weeks post-birth to ensure targets & settings adjusted to usual non-pregnant, discuss planning next pregnancy and contraception

Determine post birth settings

ICR
- Based on 0.8 x TDD in early pregnancy or at 17/40 (350/(0.8xTDD)) OR
- Pre-pregnancy ICR (if tight glucose levels pre-pregnancy, weaken by 20%) OR
- Between 1:10g and 1:15g

Targets: 6.5 mM (personal glucose target and target in bolus calculator)

Weight: pre-pregnancy weight

ISF
- Based on 0.8 x TDD in early pregnancy or at 17/40 (120/(0.8xTDD)) OR
- Pre-pregnancy ISF (if tight glucose levels pre-pregnancy, weaken by 20%) OR
- Between 3 and 4 mmol/l

Programmed basal
- Based on 0.8 x TDD in early pregnancy or at 17/40 (0.45 x (0.8xTDD)/24) OR
- 0.8 x pre-pregnancy programmed basal / 24 OR
- Total basal 0.2 units/kg (0.25 units/kg if not breastfeeding) / 24

Sensor alerts
- Low 4-4.5 mmol/l. Urgent low on. Urgent low soon on.
- High 15 mmol/l

Glucose targets during labour

- Neonatal hypoglycaemia due to excessive neonatal insulin production in the face of cessation of maternal-fetal glucose transfer post birth

- Conventional glucose target 4-7 mM through labour

- Carries risk of maternal hypoglyceamia (maybe up to 1 in 2)

- Recent data suggests these very tight targets may not be required
  - No high quality research evidence specifically looking at this area
  - CONCEPTT trial data suggests
    - neonatal hypoglyceamia determined by overall maternal glucose levels during second and third trimesters *(Feig et al, Lancet 2017; 390: 2347)*
    - No difference in intrapartum glycaemia between mothers of neonates with and without hypoglycaemia *(Stewart et al, Diabetes Technology &Therapeutics 2018; 20: 501)*
  - Retrospective cohort study: no association between intrapartum glucose and neonatal hypoglycaemia *(Yamamoto, Diabetic Medicine 2020; 37:138)*

Glucose targets during labour

Use what is recommended in your trust

Approach	Advantages	Potential Disadvantages
Traditional intrapartum capillary glucose target range of 4.0 - 7.0 mmol/L	Widely used Supported by NICE	• Increased risk of use of VRIII which is intrusive for women and resource intensive for delivery units • Increased risk of maternal hypoglycaemia • Reduced autonomy for diabetes self-management • May be too late to reverse the consequences of sustained fetal hyperinsulinism and/or to prevent neonatal hypoglycaemia
Pragmatic intrapartum capillary glucose target range of 5.0 – 8.0 mmol/L	• Reduced use of VRIII which allows women more autonomy and mobility during/after birth • Lower risk of maternal hypoglycaemia • Reduced resource burden for delivery unit staff	• Limited evidence-base • Fear of potential increased risk of neonatal hypoglycaemia

JBDS 12, Feb 2023

Planning for using closed-loop during birth

- Prescribe individualised VRIII plus glucose as back up
- To bring all diabetes supplies plus spares, hypo treatment and snacks
- Provide with hospital menu carb content
- Educate woman and her birth partner on using closed loop through birth
  - Check birth partner able to use the basics of the closed loop system
  - Explain responsibilities of the woman, her birth partner & staff
  - Ensure pump & sensor are situated away from potential caesarean section site
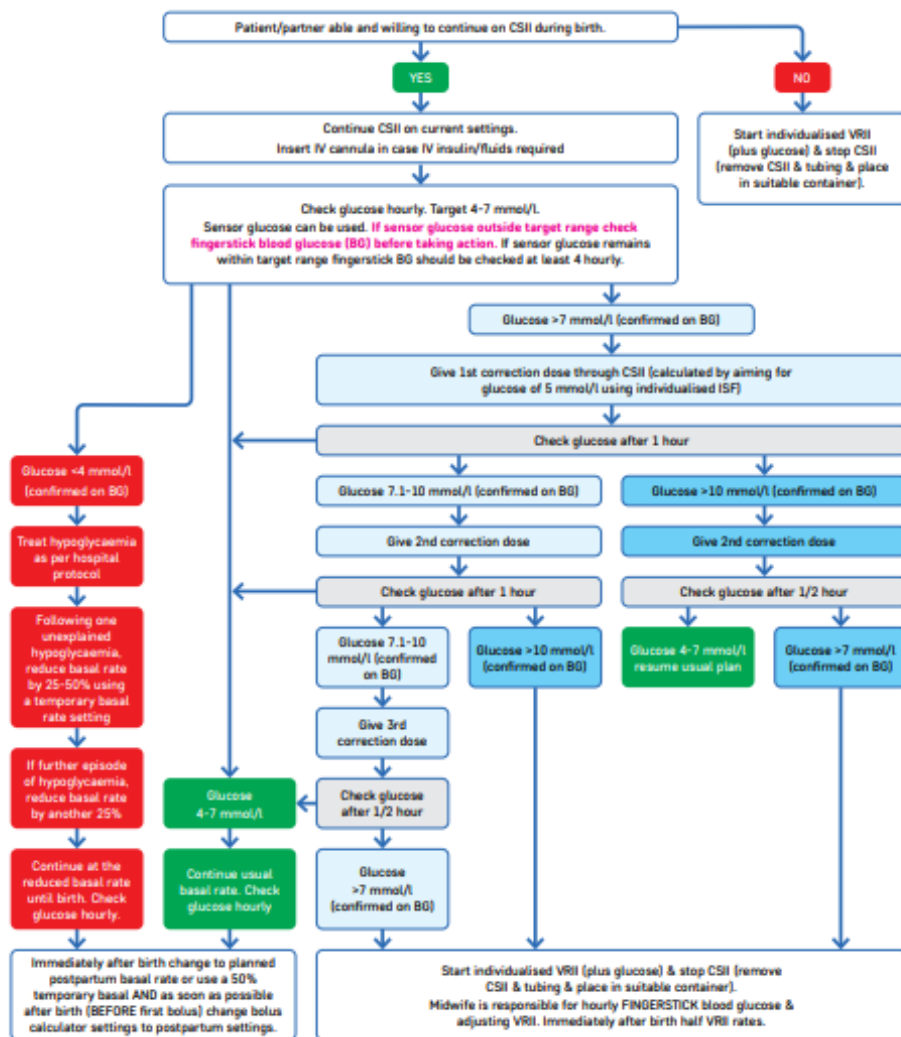
Planning for using closed-loop during birth

- Prior to labour/NBM: continue usual insulin regimen and glucose targets

- For established labour/NBM for caesarean birth
  - Ensure midwife aware using hybrid closed loop. Midwife to check hourly patient & birth partner able and willing to continue using hybrid closed loop
  - Patient to check glucose hourly. Fingerstick every 4 hrs. Target 4-7 mmol/l (or 5-8 mmol/l)
  - CamAPS: if glucose <5 mM set 'ease-off' & increase glucose target to 5.8 mM
                    if glucose >7 mM use 'boost'
  - Medtronic 780G: if glucose <5 mM set 'temp target',
                    if glucose >7 mM give manual bolus (need to come out of hybrid closed loop)
  - Tandem Control IQ: if glucose <5 mM set 'exercise mode'
  - If 2 consecutive glucose readings >8 (or 10) mmol/l, switch to VRIII, suspend & disconnect own pump

- ASAP after birth. Stay in HCL
  - Adjust all pump settings (including back up settings) and sensor alerts to post birth settings
  - CamAPS: set target 6.5 mM, change weight, if glucose below 6 mM use 'ease off',
  - Medtronic 780G: set target 6.7 mM, if glucose below 6 mM use 'temp target'
  - Tandem Control IQ: change weight to pre-preg, if glucose below 6 mM use 'exercise mode'

Planning for using stand-alone insulin pump through birth

Figure 5: Protocol for managing glucose levels for women continuing on insulin pump therapy during labour and birth or during caesarean birth.

Start once in established labour, or on waking on the morning of a planned caesarean, or when made nil by mouth for an emergency caesarean

ABCD DTN-UK Best practice guide. Using diabetes technology in pregnancy. https://abcd.care/dtn/best-practice-guides

Planning for breast-feeding/expressing

- Think of breastfeeding as 'walking-type' exercise
- Keep hypoglycaemia treatment within reach
- Check sensor glucose before feeding
  - If sensor glucose <8 mmol/l, particularly if down arrows, consume 5-15g carbohydrate before feeding (but avoid spiking glucose as this will make HCL system give more insulin)

- Consider checking sensor glucose every 30-60 min during feeding

Summary

- Achieving excellent glycaemic control in pregnancy is extremely hard work for women with diabetes. HCL can make it a little easier

- Hybrid closed loop algorithms are not the same. Evidence using one HCL algorithm in pregnancy cannot be extrapolated to other systems. At present, CamAPS FX is the only system that has evidence of improved TIRp in pregnancy

- Optimising hybrid closed loop in pregnancy
  - The essentials (food, activity, insulin) and hypo treatment
  - Know what settings can be adjusted to impact insulin delivery when in hybrid closed loop
  - Remember to adjust the 'back-up' programmed settings for if out of hybrid closed loop
  - Approach to looking at the upload

- Keeping insulin pump users safe in pregnancy – revise every trimester

-

'The closed loop system I like it a lot – it makes my life so much easier; I still keep a close eye on readings and which way they are heading and know and trust the pump to correct, you don't understand how much that makes me feel normal. I want to stay on this now, new lease of life!'