



# Diabetes in Pregnancy Update

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# Presenter Disclosures

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Research Support: Abbott Diabetes Care

Speaker's Bureau: Abbott Diabetes Care, Ypsomed

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# Let's start, as it does clinically, with a couple of cases.....

19 year old nursery nurse

- Referred to antenatal clinic following episode of DKA as found to be 11 weeks pregnant
- **T1DM** since age of 5yrs
- On insulin pump
- HbA1c 96 mmol/mol
- Known background retinopathy
- Not using contraception
- No Folic acid



# Let's start, as it does clinically, with a couple of cases.....

42 year old cleaner



- Referred following A&E attendance with abdominal pain (found to be 22 weeks pregnant)
- 3 previous children (age 26, 21 & 15 yrs)
- Had GDM last pregnancy
- Diagnosed **T2DM** 10 years ago, when had cholecystectomy
- BMI 46; PCOS; Hypertension; Depression; Smoker
- Under c/o GP
- Metformin 1g bd; Sitagliptin 100mg od; Dapagliflozin 10mg od;
- Atorvastatin 40mg od; Ramipril 10mg od; Sertraline;
- Not using contraception, No Folic acid
- HbA1c 78 mmol/mol

# What are the chances of a successful pregnancy outcome?

- a) 25%
- b) 50%
- c) 80%
- d) 90%

# What are the chances of a successful pregnancy outcome?



What does successful mean?

- No congenital malformations
- Live mother + no stillbirth/neonatal death
- No neonatal intensive care
- Uncomplicated delivery
- No neonatal hypoglycaemia, jaundice, respiratory distress
- Baby normal size (<90<sup>th</sup> centile)

# Women with diabetes have obstetric and neonatal complications

## LGA

1 in 2 women with **T1DM**

1 in 4 women with **T2DM**

## Caesarean section

3 in 4 of babies of mums with **T1DM**

1 in 2 of babies of mums with **T2DM**

## Preterm birth

1 in 2 women with **T1DM**

1 in 4 women with **T2DM**

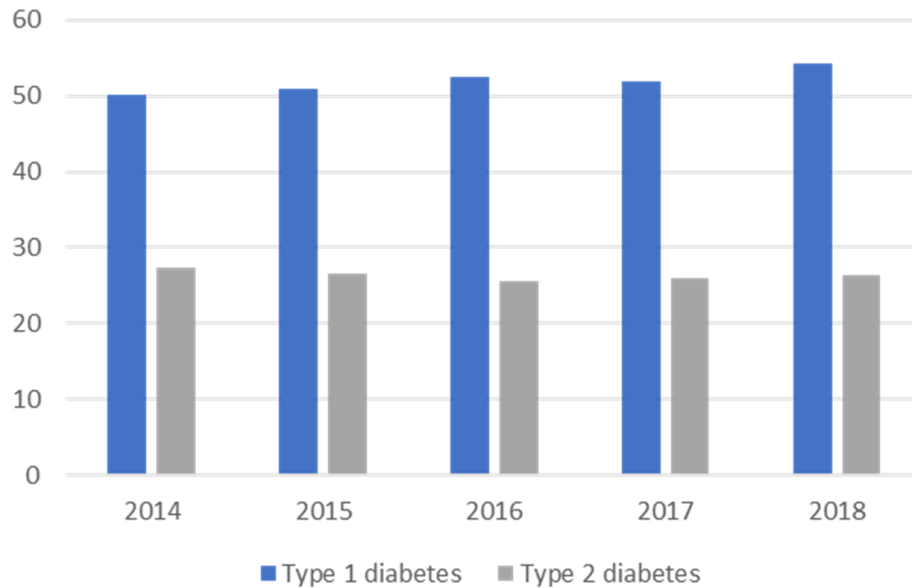
## NICU

1 in 2 babies of mums with **T1DM**

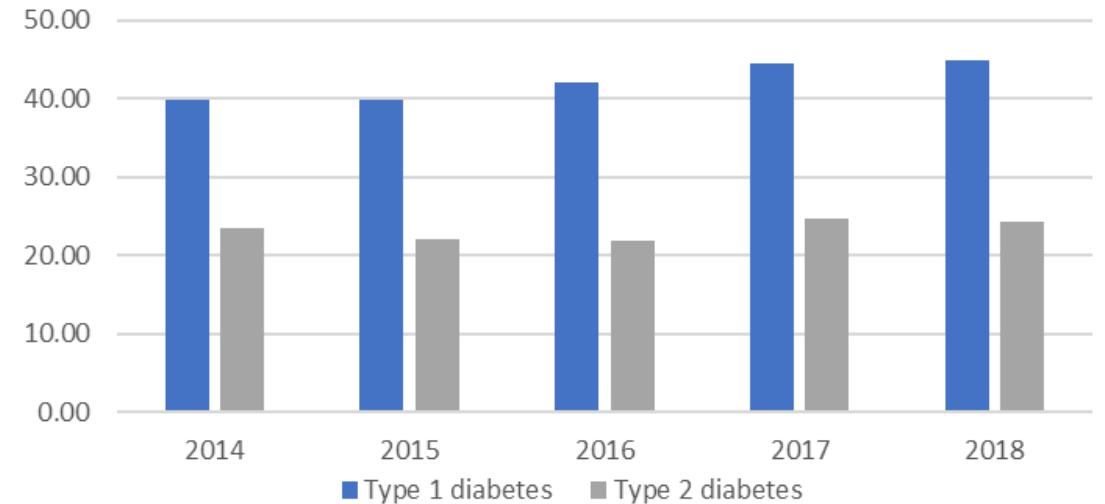
1 in 3 babies of mums with **T2DM**



# Pregnancy complications are common and not improving over 7 years



**Large for Gestational Age (>90<sup>th</sup> centile)**



**Preterm births (< 37 weeks gestation)**



# Common themes:

- 🚩 Lack of contraception use with poor glucose control (and lack of folic acid) suggests no pre-pregnancy care planning with HCPs = increased risk of poor outcome
- 🚩 Late booking to clinic = missed opportunity to improve glucose control in 1st trimester (= increased risk congenital malformations and worse pregnancy outcomes)
- 🚩 Long duration of diabetes with micro and macrovascular disease = increased complications in pregnancy
- 🚩 Uncontrolled diabetes (and DKA) = high risk of congenital abnormality, stillbirth, LGA, NICU
- 🚩 Young women with T1DM and socioeconomically deprived women with T2DM more likely to have adverse outcomes (NPID audit)

# What HbA1c is recommended prior to pregnancy?

- a)  $\leq 58$  mmol/mol
- b)  $\leq 51$  mmol/mol
- c)  $\leq 48$  mmol/mol
- d)  $\leq 43$  mmol/mol

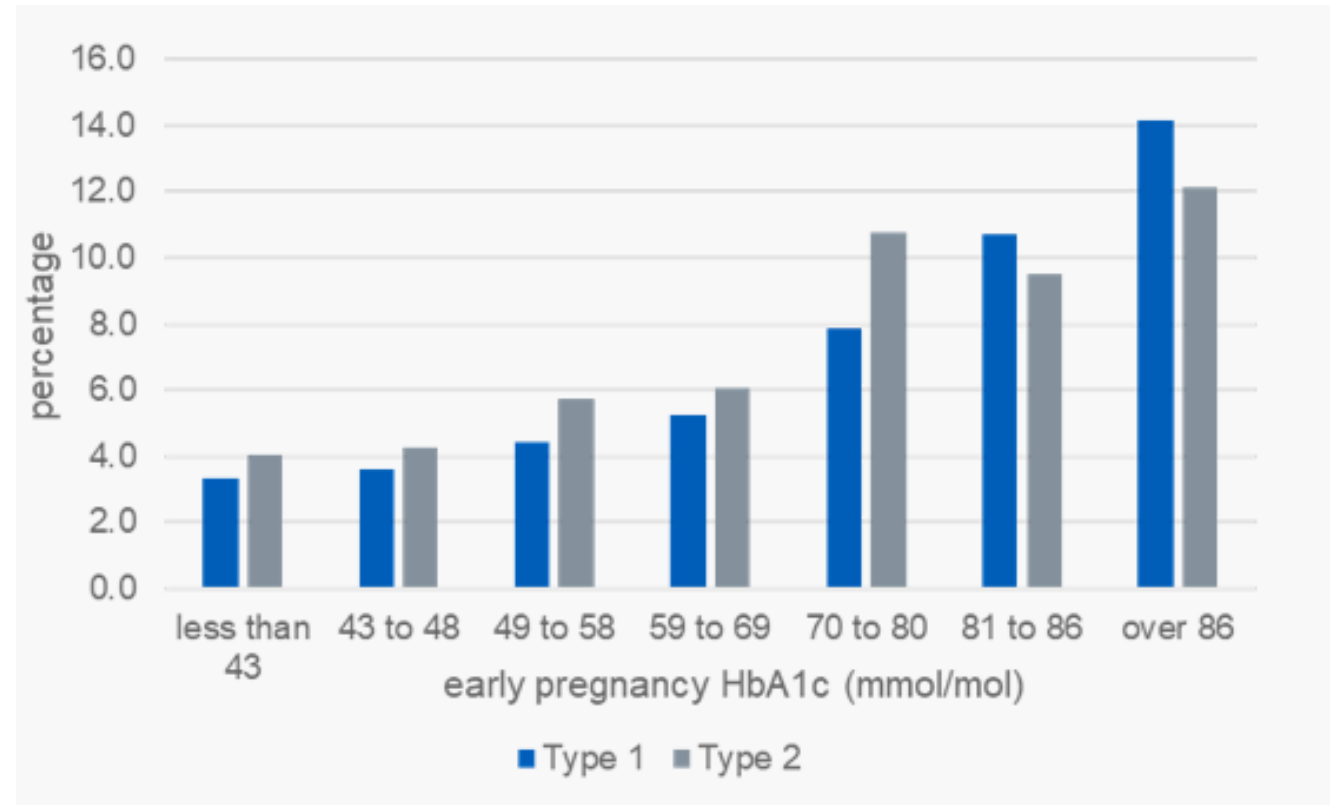
Answer c)  $\leq 48$  mmol/mol

(NICE NG3 Diabetes in Pregnancy 2015 (updated 2020))

Advise against pregnancy if HbA1c  $> 86$  mmol/mol

# Maternal glucose is key risk factor for serious adverse outcomes

- High (HbA1c > 48 mmol/mol) at the start of pregnancy is the key risk factor for serious adverse pregnancy outcomes (congenital malformations and stillbirth or neonatal death)
- Aiming for HbA1c < 48 mmol/mol at start of pregnancy

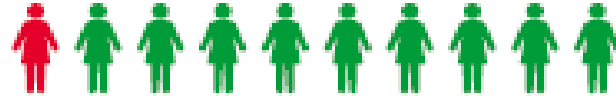


# What could have been different?

Planning for a safe & healthy pregnancy



## Risks and complications



For women with diabetes who do not plan their pregnancy, the risk of a serious complication (e.g. stillbirth, serious heart or birth defect) is about 1 in 10.

- ✓ Working with diabetes team to get 'pregnancy ready' reduces these risks to 1 in 50
- ✓ Using contraception until 'pregnancy ready' also helps
- ✓ HbA1c less than 48 mmol/mol (advise women with HbA1c >86 mmol/mol to avoid pregnancy i.e. SAFE EFFECTIVE CONTRACEPTION)
- ✓ Check all medication is safe and on folic acid 5mg od

# How many women with diabetes are adequately prepared for pregnancy?

a) 12%

b) 25%

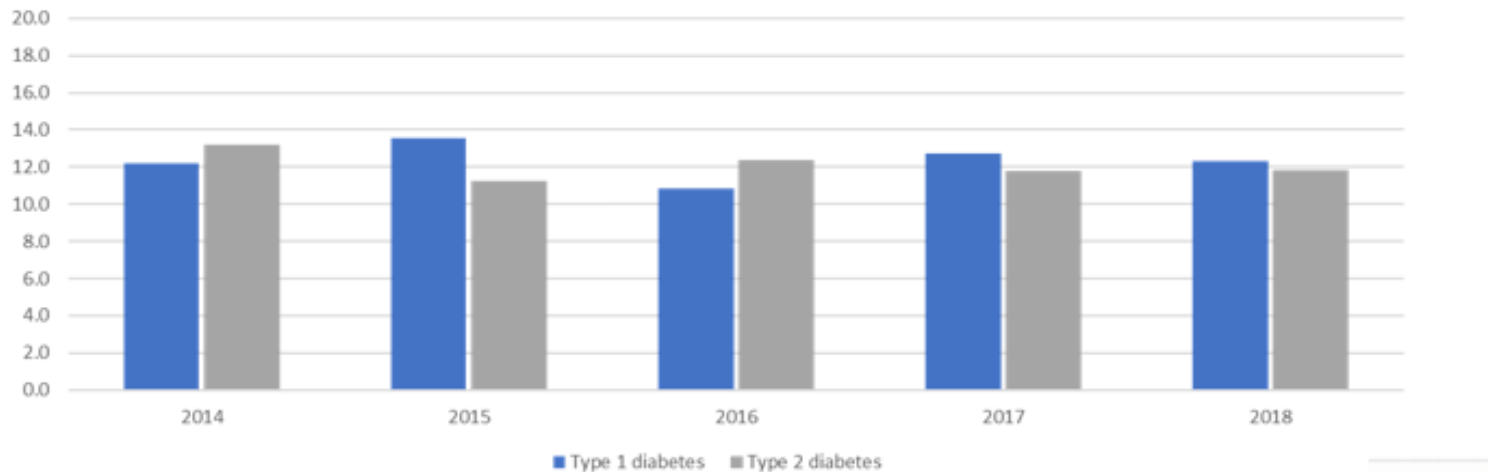
c) 33%

d) 50%

# How many women with diabetes are well prepared for pregnancy?

- The definition of “well prepared for pregnancy” is that prior to the LMP women have started 5mg/d folic acid and stopped all adverse medication and have a first trimester HbA<sub>1c</sub> below 48mmol/mol.
- Only one in eight women were well prepared for pregnancy – the proportions are similar for women with Type 1 and Type 2 diabetes and have not changed since 2014.

**Percentage of women who had first trimester HbA<sub>1c</sub> less than 48 mmol/mol, had taken 5mg folic acid and were not on adverse medication at LMP, 2014 to 2018**



# Lets' progress with them through pregnancy.....

- ✓ Seen by Diabetes in Pregnancy MDT



## 24 week update

- ✓ Anatomy scans normal
- ✓ Improved glucose control
  - ✓ HbA1c 54 mmol/mol in 19 year old with **T1DM**
  - ✓ HbA1c 64 mmol/mol in 42 yr old with **T2DM**

## 32 week update

- ✓ Growth scans show LGA and polyhydramnios
- ✓ 19 year old with **T1DM** - admission with DKA
- ✓ 42 year old with **T2DM** - massive social issues, abuse from partner

# What HbA1c is recommended during pregnancy?

- a)  $\leq 58$  mmol/mol
- b)  $\leq 51$  mmol/mol
- c)  $\leq 48$  mmol/mol
- d)  $\leq 43$  mmol/mol

Answer c)  $\leq 43$  mmol/mol

(National Pregnancy in Diabetes (NPID) audit (2020)

Saving Babies Lives Version 3 (2023)

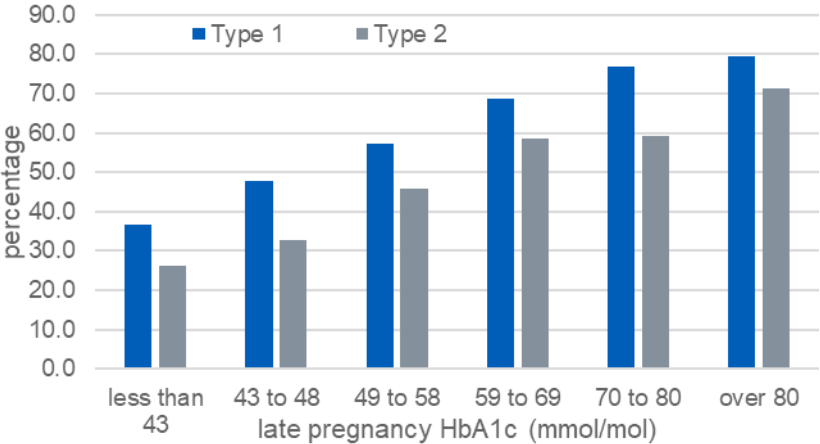
[National Pregnancy in Diabetes Audit Report 2020 - NHS Digital](#)



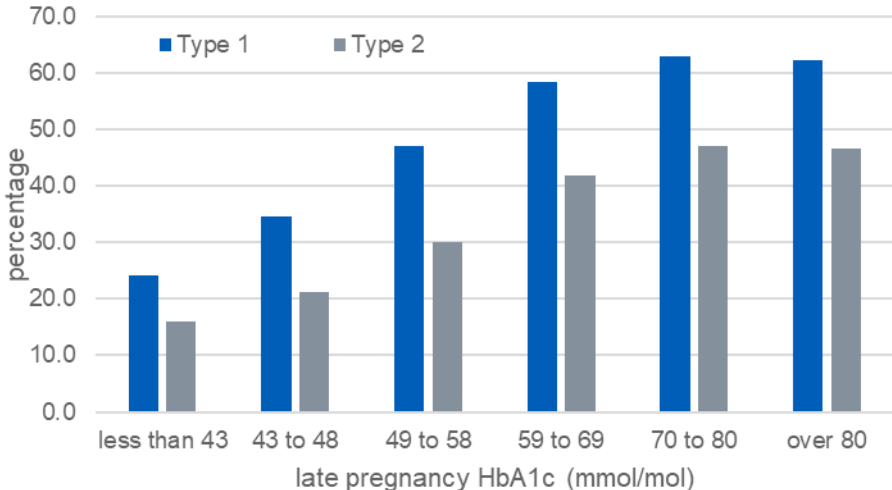
# Pregnancy complications and maternal HbA1c during pregnancy?

- Preterm births, LGA and neonatal care admissions were lowest in pregnancies with late HbA1c <43mmol/mol

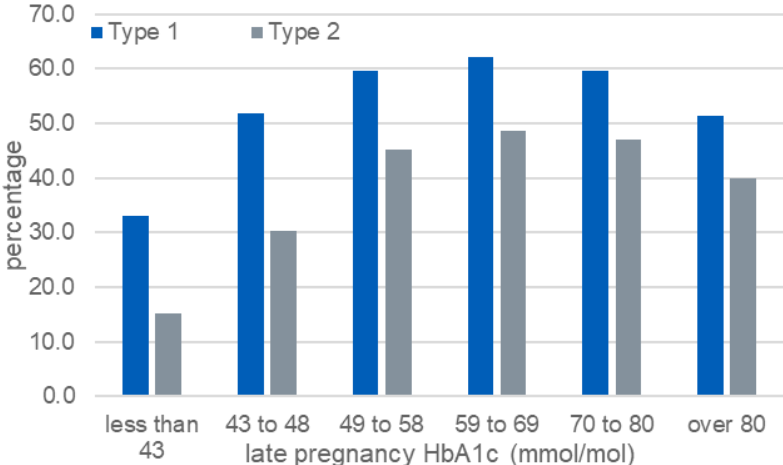
## NICU admissions



## Preterm births < 37 weeks



## Large for gestational age (LGA) babies



# What now?

## Red flags again

- 🚩 Above target HbA1c
- 🚩 LGA and polyhydramnios
- 🚩 DKA
- 🚩 Domestic abuse and social issues
- 🚩 Started pregnancy with numerous red flags

= Extremely high risk pregnancies

# Diabetic Ketoacidosis



- 82 women notified with DKA in pregnancy in the UK 01/02/2019-30/11/2020
  - 6.3 per 100,000 maternities
  - 70 Type 1, 5 Type 2, 7 GDM
  - 16.6/1000 T1DM women giving birth, 1.1/1000 T2DM
  - Almost half (35/82, 43%) were euglycaemic
- Perinatal mortality 12/73 (16%)
  - 11 stillbirths, 7 at the time of the DKA episode

# Diabetic Ketoacidosis – causes

	Type 1 diabetes N=70	Type 2 diabetes N=5	Gestational diabetes N=7
<b>Infection</b>	15 (21)	1 (20)	1 (14)
<b>Medication error</b>	6 (9)	2 (40)	0
<b>Steroid administration</b>	8 (11)	0	3 (43)
<b>Other medication or mechanism</b>	6 (9)	0	0
<b>First diagnosis of diabetes</b>	3 (4)	0	0
<b>Vomiting / hyperemesis</b>	16 (23)	0	1 (14)
<b>Not known</b>	16 (23)	2 (40)	2 (29)

# Diabetic Ketoacidosis



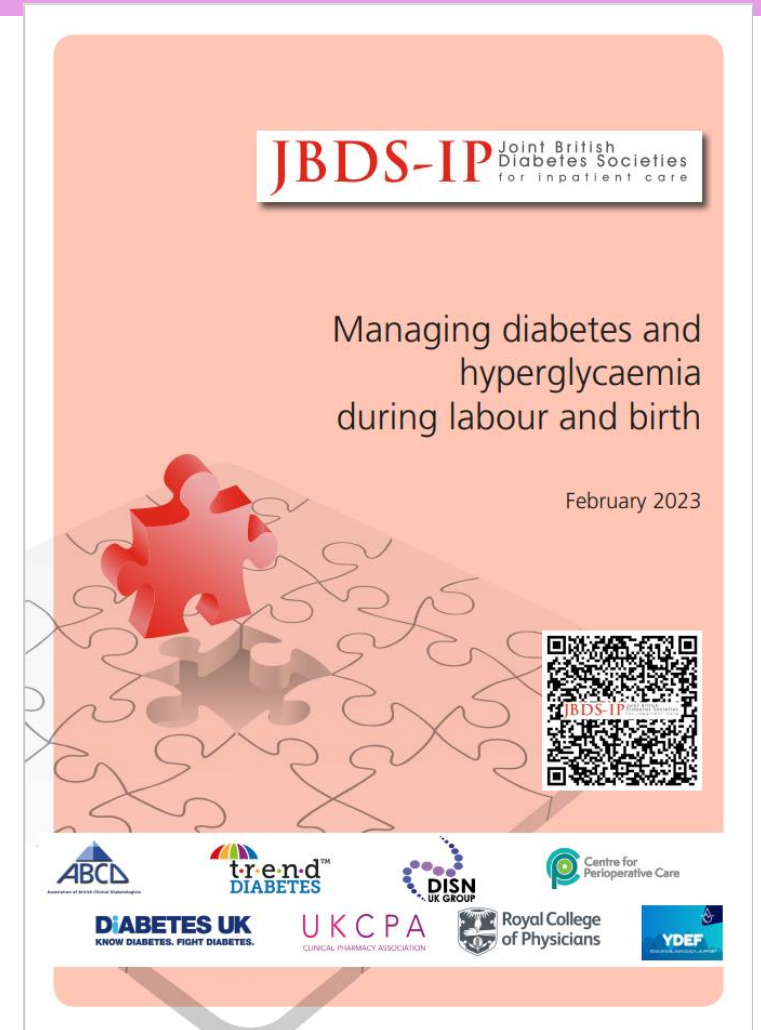
## DKA

- Poor outcomes resulted when not treated promptly
- May occur at lower blood glucose
- (Capillary) ketones less frequently tested in maternity settings compared to medical
- May cause a variety of symptoms and signs
- May result from antenatal steroid administration

# Saving Babies Lives Version 3

## Agreed pathway for women presenting to secondary care with Diabetic Ketoacidosis (DKA)

- ✓ High risk of fetal demise
- ✓ No clear pathway to know who is looking after, where the pregnant woman will receive best care
- ✓ Having a documented pathway that is right for your hospital, is key to managing this
- ✓ Demonstrate an agreed pathway (between maternity services, emergency departments and acute medicine) for the management of women presenting with DKA during pregnancy.
- ✓ Escalation pathway for specialist obstetric HDU or ITU input, with the agreed place of care depending on patients gestational age, DKA severity, local facilities and availability of expertise.

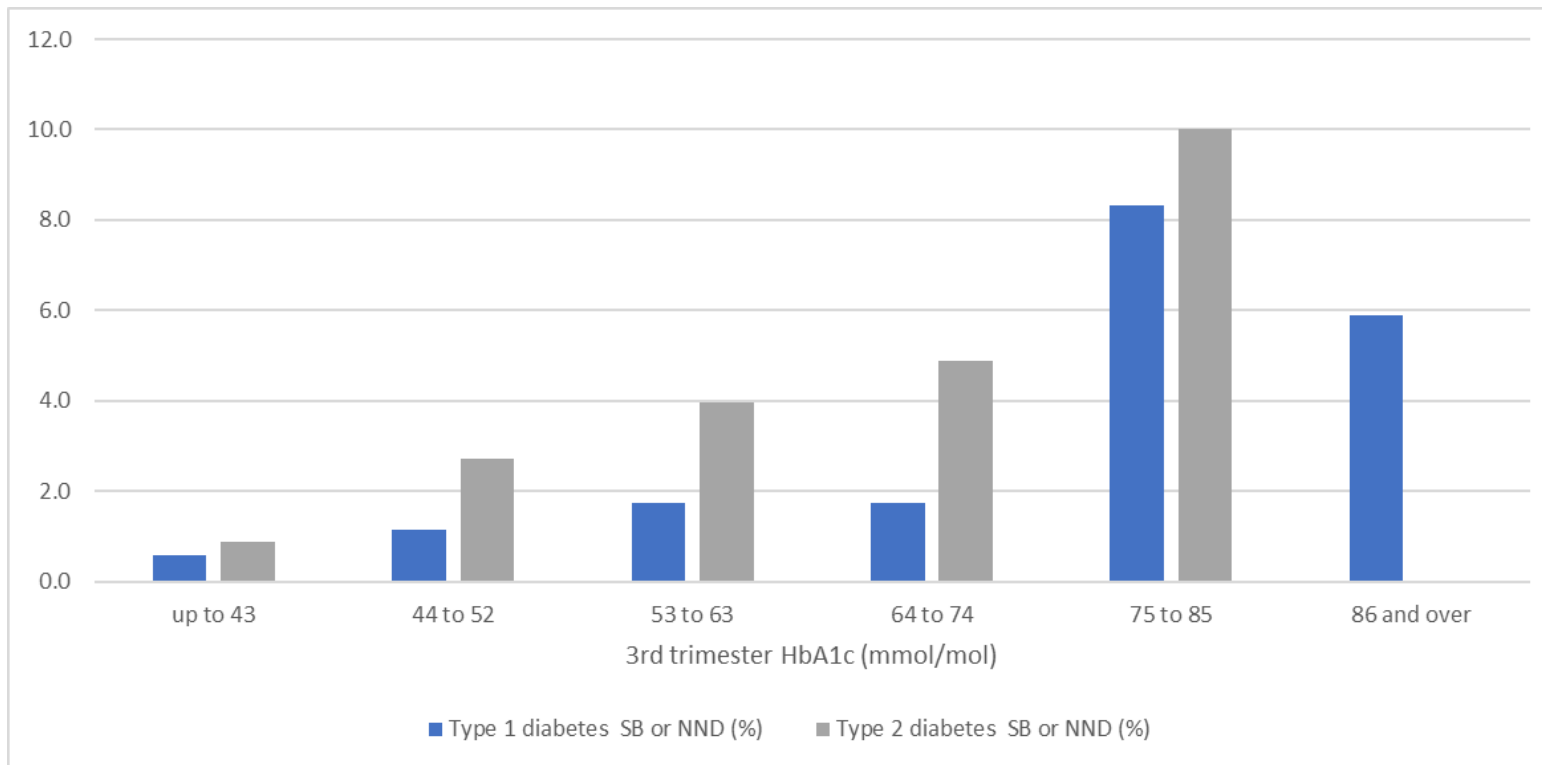


# 34 week update.....



- Increasing number of hypos, has reduced insulin substantially
- Admit for observations and steroids
- Hypertensive, proteinuria – PET screen positive
- Induction of labour at 35 weeks
- Live birth, LGA, neonatal hypoglycaemia, admitted to NICU
  - Attends MAC Feeling unwell
  - Hasn't checked blood glucose for past week as staying at friends house to avoid abusive partner and forgot to take kit
  - Hasn't felt baby move as much as normal
  - Hyperglycemic 20mmol/l
  - No fetal heart beat

# Stillbirths and neonatal deaths are higher in women with T2DM



- Type 2 diabetes: 200 deaths (110 stillbirths, 90 neonatal deaths)
- Type 1 diabetes: 145 (85 stillbirths, 60 neonatal deaths)

## Risk Factors

- Raised HbA1c : OR 3.0
- Deprivation: OR 2.3
- Type 2 diabetes: OR 1.65

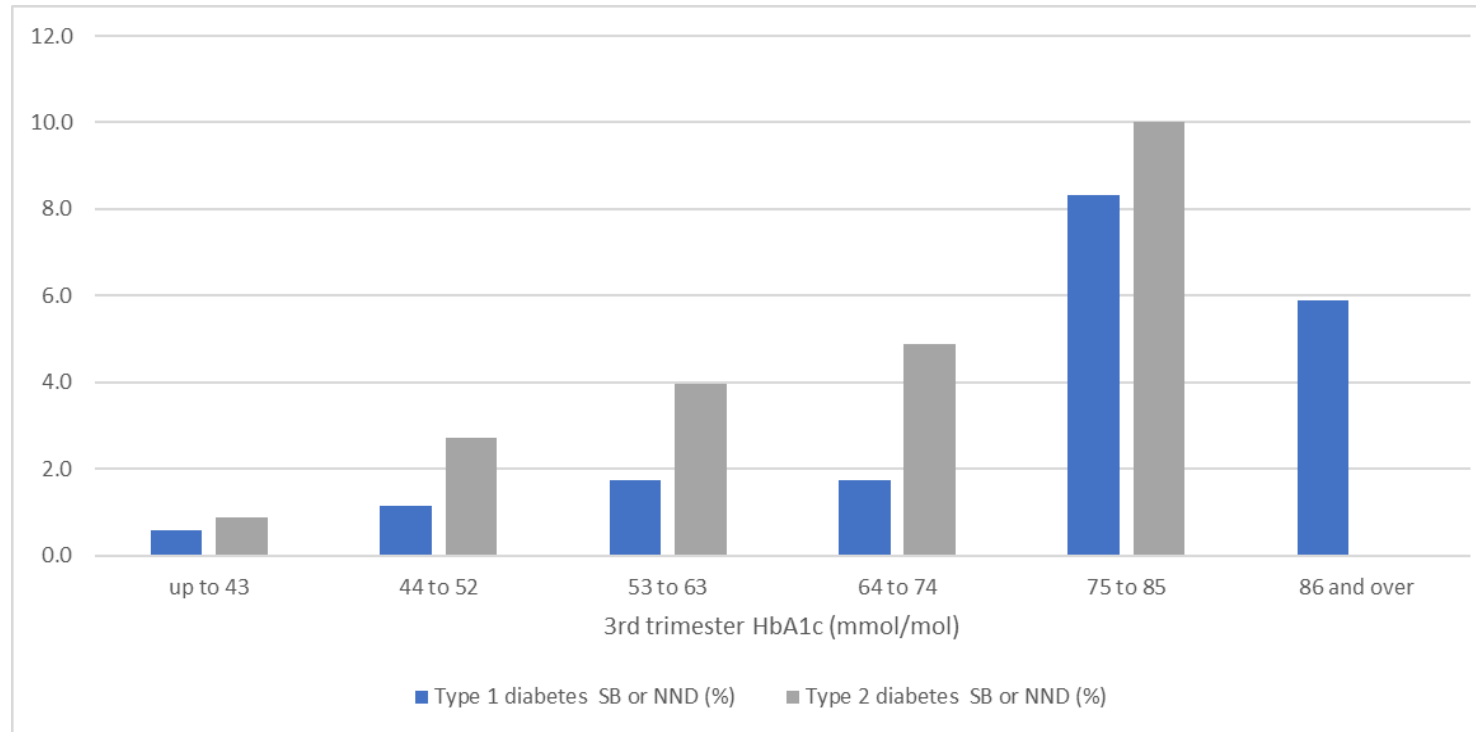


# Saving Babies Lives Version 3

## Measurement of HbA1c in all women at start of third trimester to 'risk stratify' and offer additional support/surveillance

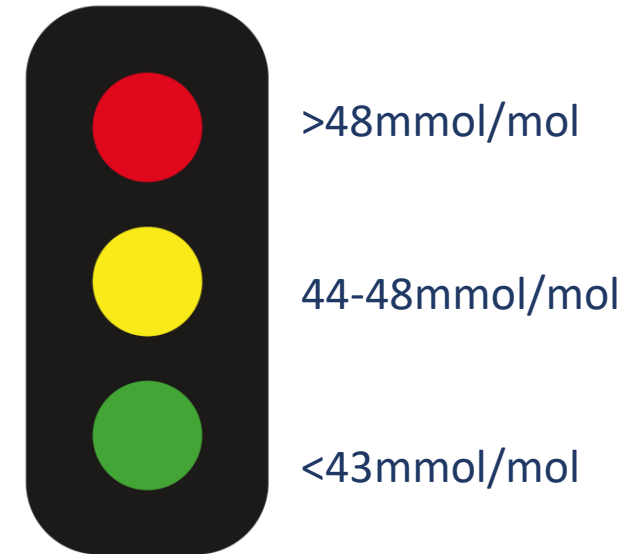
Type 2: 200 deaths (110 stillbirths, 90 neonatal deaths)

Type 1: 145 (85 stillbirths, 60 neonatal deaths)



### Risk Factors

- HbA1c >43mmol/mol: OR 3.0
- Deprivation: OR 2.3
- Type 2 vs T1D : OR 1.65



**HbA1c >43mmol/mol after 24/40 key modifiable risk factor for perinatal death in T2D**

# Saving Babies Lives Version 3

## Measurement of HbA1c in all women at start of third trimester to 'risk stratify' and offer additional support/surveillance



- HbA1c >48 at the start of third trimester is a marker that not all is well
  - Simple test, done at time of 28 week growth scan
  - Still time to help support women before delivery
- 
- There may be a variety of reasons why HbA1c can't be below 48, but given how much more likely the baby is to survive with a glucose below this, then our job is to reach out and offer additional support to those not managing – mental health, more one-to-one appointments with DSN/ Dietitian, offer technology support
  - This allows clinical team to be fully aware, despite changes and lack of continuity in team, that the woman needs a carefully planned delivery and closer surveillance if we are to reduce stillbirth

# Saving Babies Lives Version 3

All women with an HbA1c >48 mmol/mol to have a formal MDT discussion to review care

## MDT discussion for women >48 mmol/mol

Green	HbA1c 43 mmol/mol or less	Continue specialist care
Amber	HbA1c 44-48 mmol/mol	Consider additional input to improve glycemic levels
Red	HbA1c more than 48 mmol/mol	MDT discussion. Offer alternative methods of monitoring treatment, offer increased fetal surveillance, rediscuss increased risk of stillbirth, birth and neonatal complications

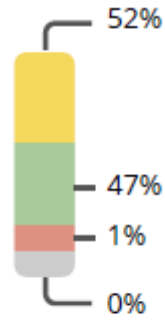
Can we do anything more during pregnancy to improve on these outcomes?



# CGM helps in pregnancy (CONCEPTT study)



N= 107

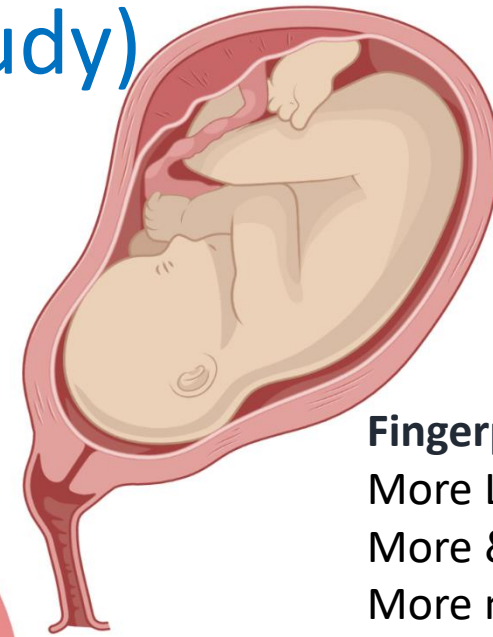
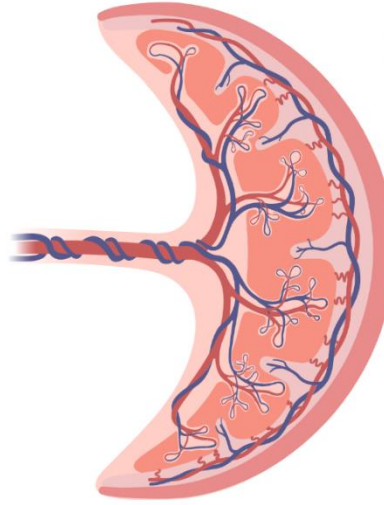


Time in range

**Fingerprick users**  
Higher HbA1c 6.5%  
Less TIR (61% TIRp)



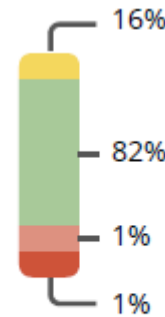
Mum's glucose



**Fingerprick users**  
More LGA (69%)  
More & longer NICU (43%)  
More neonatal hypoglycaemia (28%)

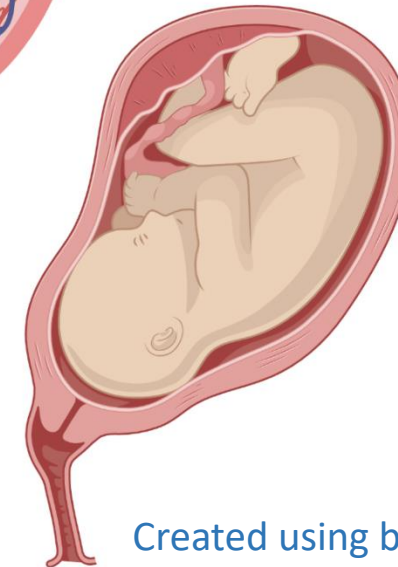


N= 108



Time in range

**CGM users**  
Lower HbA1c 6.3%  
Higher TIR (68% TIRp)



**CGM users**  
Fewer LGA (53%)  
Fewer shorter NICU (27%)  
Less neonatal hypoglycaemia (15%)

# CGM helps in pregnancy (CONCEPTT trial)

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Numbers needed to treat:

- 6 to prevent 1 large-for-gestational-age baby
- 6 to prevent 1 neonatal intensive care admission
- 8 to prevent 1 neonatal hypoglycaemia



# NICE NG3 updated guidance December 2020

## Intermittently scanned CGM and continuous glucose monitoring

- 1.3.17 Offer continuous glucose monitoring (CGM) to all pregnant women with type 1 diabetes to help them meet their pregnancy blood glucose targets and improve neonatal outcomes. [2020]
- 1.3.18 Offer intermittently scanned CGM (isCGM, commonly referred to as flash) to pregnant women with type 1 diabetes who are unable to use continuous glucose monitoring or express a clear preference for it. [2020]
- 1.3.19 Consider continuous glucose monitoring for pregnant women who are on insulin therapy but do not have type 1 diabetes, if:
- they have problematic severe hypoglycaemia (with or without impaired awareness of hypoglycaemia) or
  - they have unstable blood glucose levels that are causing concern despite efforts to optimise glycaemic control. [2015, amended 2020]
- 1.3.20 For pregnant women who are using isCGM or continuous glucose monitoring, a member of the joint diabetes and antenatal care team with expertise in these systems should provide education and support (including advising women about sources of out-of-hours support). [2020]

# What is the pregnancy glucose target range?

- a) 3.9-10.0 mmol/l
- b) 3.9-7.8 mmol/l
- c) 3.5- 10.0 mmol/l
- d) 3.5-7.8 mmol/l

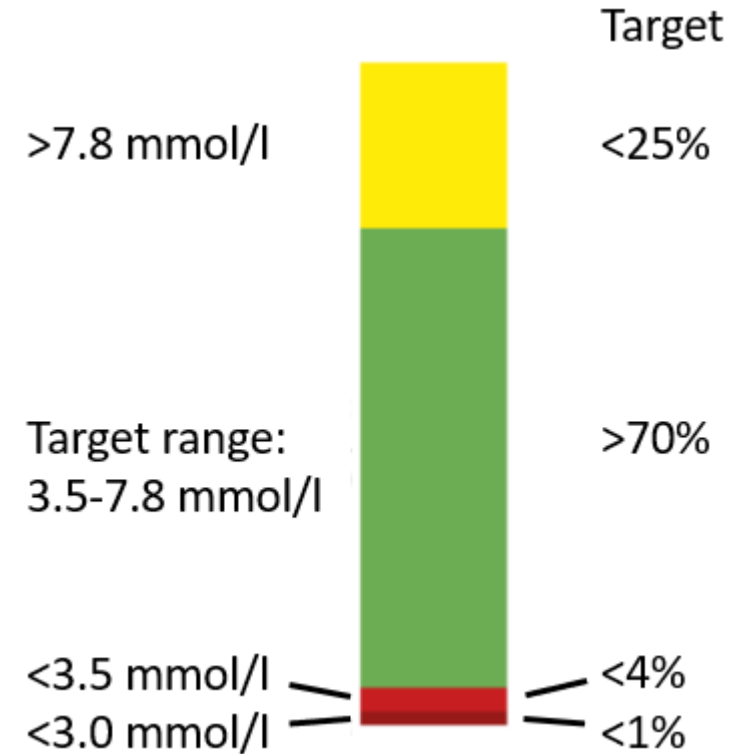
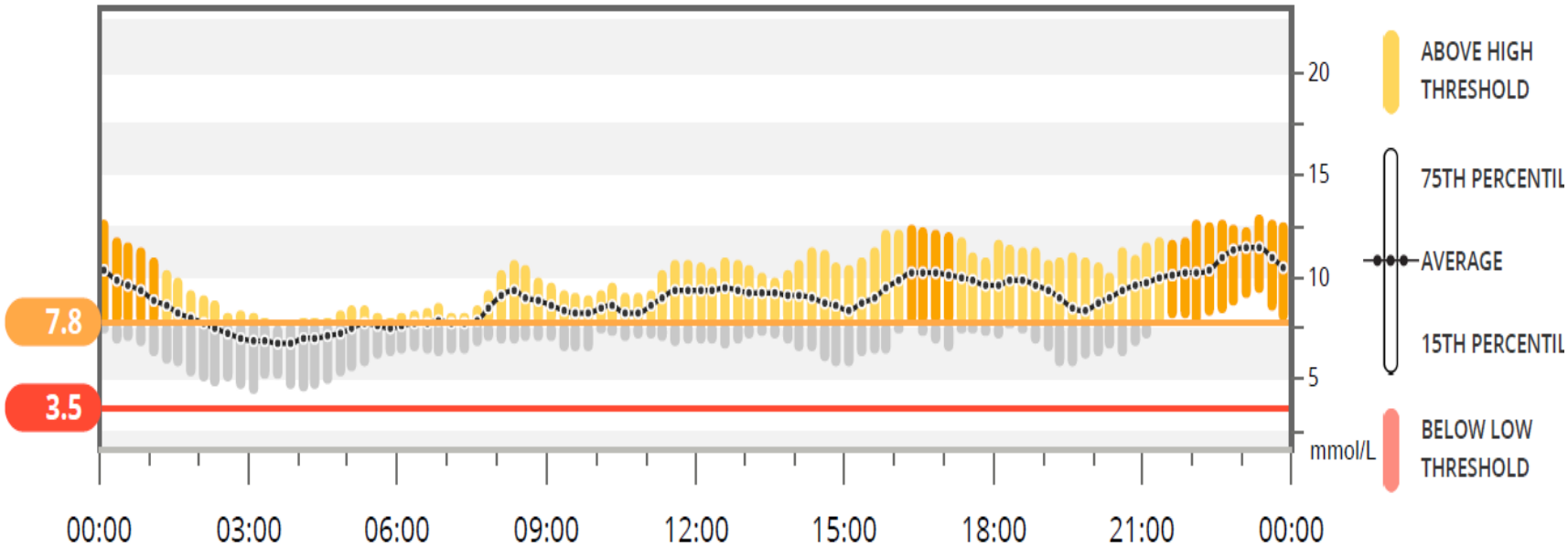


# How much 'time in range' should we be aiming for in pregnancy?

- a) 60%
- b) 70%
- c) 80%
- d) 100%

# Different way of thinking about glucose

This graph shows your data averaged over 14 days



# Ensure staff are trained in supporting women to use CGM

## Diabetes Technology Network Top tips leaflets for women using CGM



### GETTING BREAKFAST RIGHT



Breakfast is the most challenging meal for keeping the post meal glucose in target; carbohydrate is not well tolerated at this time of day. Most women have to spread their breakfast over 2 smaller meals containing 15-20g.

#### Good breakfast choices:

- 1 slice whole-wheat toast (C15g) with a topping e.g. poached or scrambled eggs / mushrooms / tomato / cheese / ham / bacon / avocado.
- 1 small pot yoghurt (C13g) with one small chopped fruit or cup of berries (C7g) topped with nuts / seeds
- 25g jumbo porridge oats (C15g) soaked overnight in crème fraiche and 1 cup berries (C7g), top with nuts / seeds
- 40g jumbo porridge oats (C25g) cooked with water and single cream added to taste

**ACTION DONE (TICK BOX):**

### BULKING UP MEALS WITH MORE PROTEIN AND VEGETABLES / SALAD



Eating more protein foods such as meat, fish, chicken, cheese, eggs, tofu, Quorn, pulses and vegetables will fill you up more and stop you feeling hungry. These foods also flatten out the post meal glucose rise and so help achieve the post meal glucose targets whilst avoiding dips in glucoses later.

**ACTION DONE (TICK BOX):**

### BEING ACTIVE AFTER EATING



Being active for 10-15 minutes after eating can make your post meal glucose level as much as 2 mmols/L lower and so help achieve the post meal glucose target.

This can be going for a walk or being active around the house or work place.

**AVOID BEING INACTIVE IMMEDIATELY AFTER EATING**

**ACTION DONE (TICK BOX):**

### AVOID EATING CARBOHYDRATE LATE IN EVENING



Overnight can be as much as a third of your day so getting glucose levels as near normal pre bed and overnight can really help optimise glucose levels for pregnancy.

Eating your evening meal before 7.30 pm and keeping evening snacks to minimal carbohydrate or carbohydrate free (unless eaten to avoid a hypo) can make all the difference to achieving the pre-bed, overnight and even fasting glucose targets.

**ACTION DONE (TICK BOX):**

# Diabetes Technology Network support videos and user stories for using CGM during pregnancy

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DR EMMA WILMOT

Getting Started with CGM



PROF HELEN MURPHY

Planning for pregnancy



DR KATE HUNT

Starting CGM in pregnancy



PROF ELEANOR SCOTT

Using CGM in Early Pregnancy



DR ANNA BRACKENRIDGE

Using CGM in mid pregnancy



DR PETER HAMMOND

Using CGM in late pregnancy and planning for delivery



KATY DAVENPORT

Using CGM for delivery and the postnatal period



JEANNIE GRISONI

Top tips for using CGM sensors in pregnancy



DR KATE HUNT

Using arrows and alerts for CGM in pregnancy



DR PRATIK CHOUDHARY

Defining hypoglycaemia with CGM

# ABCD/DTN Best Practice Guide: Using diabetes technology in pregnancy

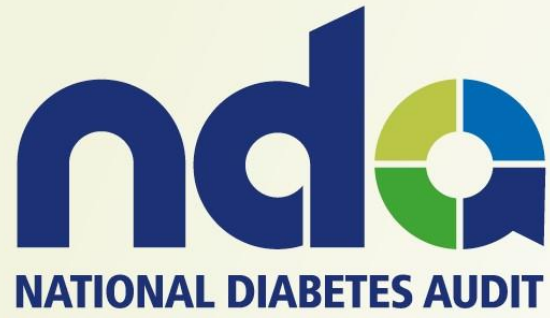


<https://abcd.care/dtn/academy>



**BEST PRACTICE GUIDE:**  
Using diabetes technology  
in pregnancy

<https://abcd.care/dtn/best-practice-guides>

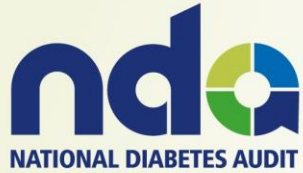


**95% of women with type 1 diabetes wore continuous glucose monitors in 2022**



**95%**

# Improved mum and baby outcomes



Wearing continuous **glucose monitors** improved:



**glucose levels** for mothers

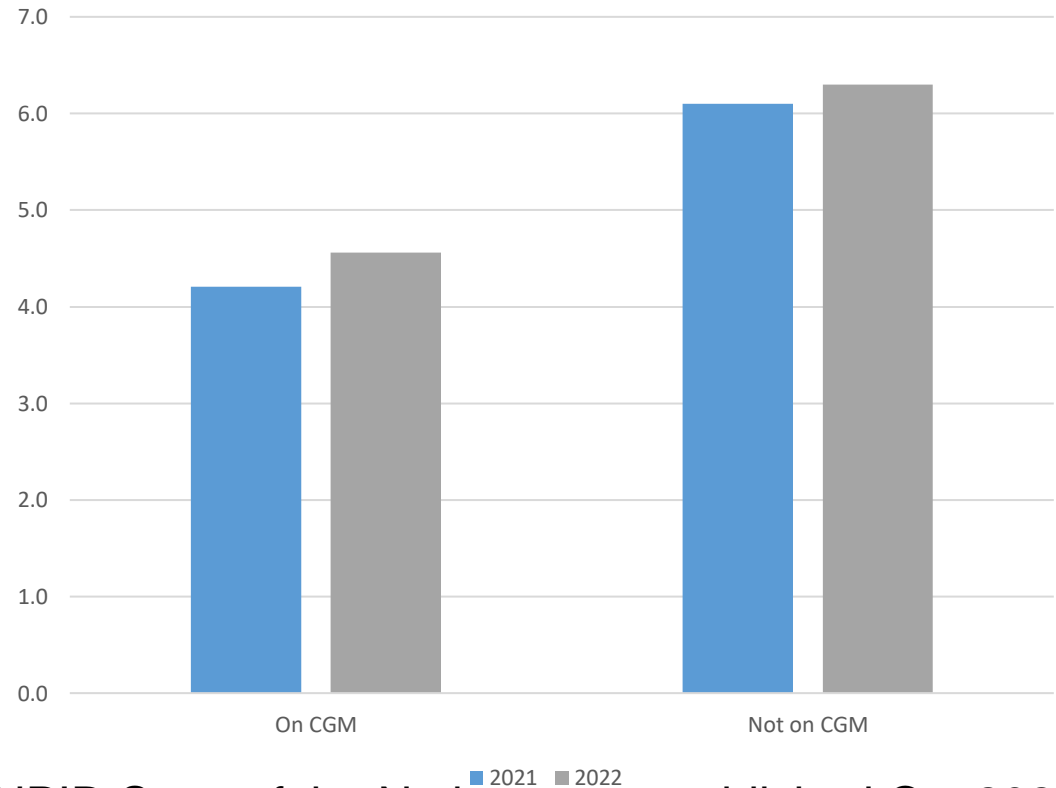
**outcomes** for women and babies

**Improved pregnancy glucose levels with:**

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

**Reduced serious adverse pregnancy outcomes**

**(Birth defects, stillbirth, baby death)**



NPID State of the Nation report published Oct 2023

N=2055 (825 in 2021 + 1230 in 2022) CGM users had reduced risk serious adverse outcomes - OR 0.70 95% CI 0.53-0.94; P=0.015

# LGA rates are still high even in women using CGM

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- Even in CONCEPTT, LGA rates are still occurring in ~50% of women using CGM
- Pregnancy is a dynamic state of continuous metabolic adaptation with changes in insulin sensitivity and glucose tolerance throughout
- So, what can we learn about glucose in pregnancy from CGM data

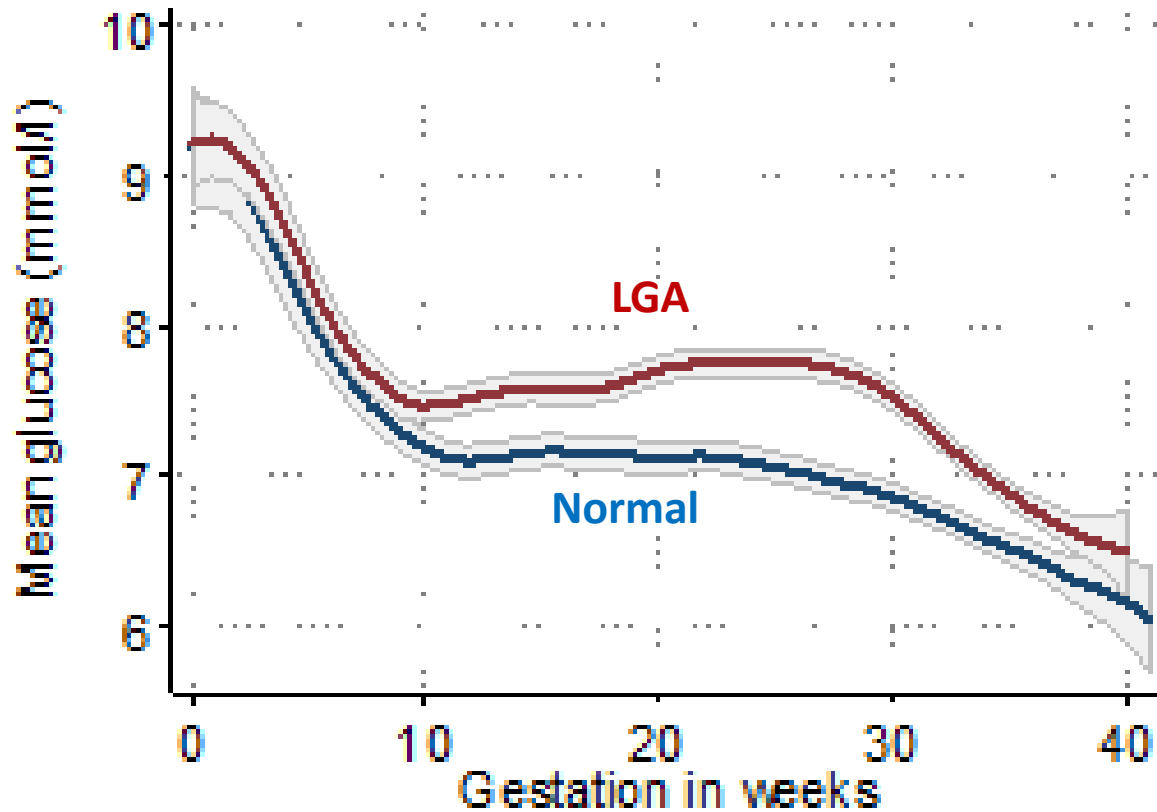


# CGM metrics and birthweight: informing management of type 1 diabetes throughout pregnancy



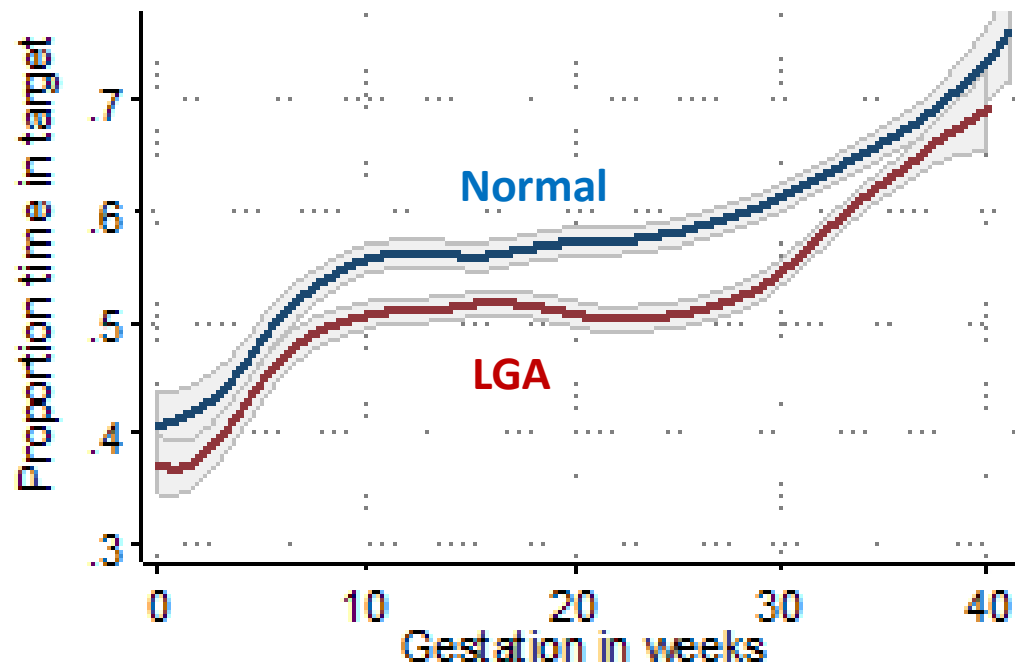
- Weekly CGM glucose metrics and 24hr profiles associated with a normal birthweight baby are unknown
- An analysis of >10.5 million CGM glucose measures from 386 pregnant women (200 from CONCEPTT, 186 from Swedish observational study)

# Mean Glucose (mmol/l)



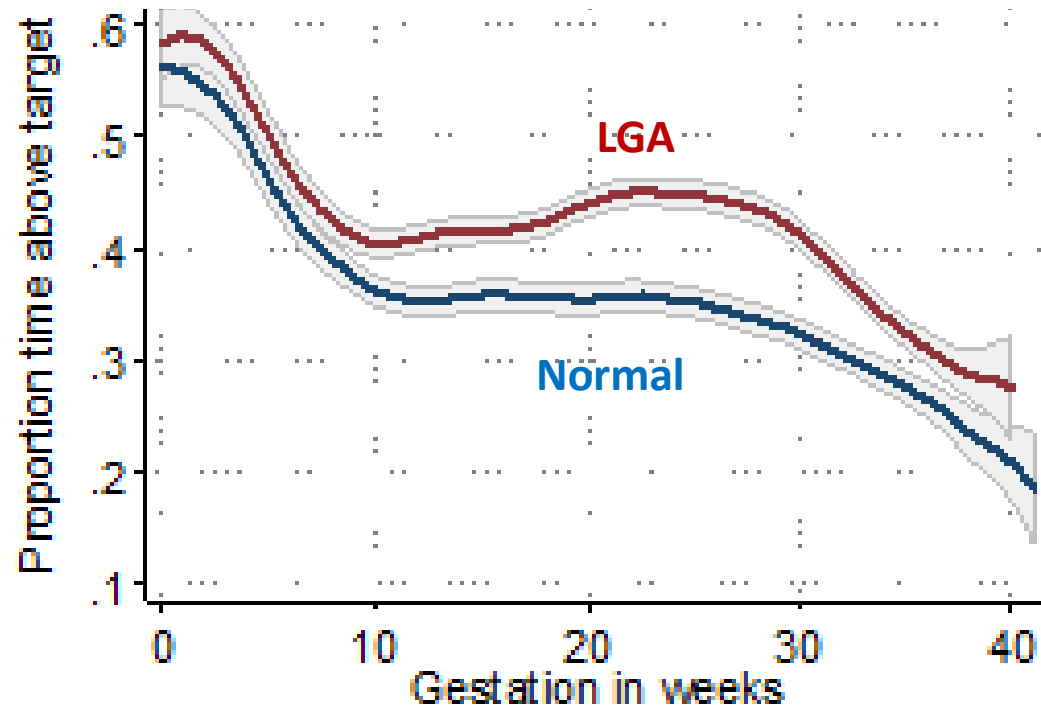
- Irrespective of baseline maternal glycemia, first trimester glucose levels decrease rapidly without initial differences between women who go onto have a normal sized or LGA infant
- However, maternal glucose trajectory achieved by 10 weeks gestation determines the relationship to birthweight for the rest of pregnancy
- Demonstrates central role of maternal glucose to the pathogenesis of LGA from early gestation
- Normal growth associated with mean glucose of  $<7$  mmol/l ( $<126$  mg/dL) (from 10 weeks)

## % Time in pregnancy target range (3.5-7.8 mmol/l or 63 - 140mg/dL)



- International consensus that a TIR target of >70% is recommended in pregnancy
- Majority of women using CGM and intensive insulin therapy only reach this after 34 weeks
- Normal growth is associated with a TIR of 55-60% from 10 weeks
- Aiming to achieve 70% where possible thereafter

# % Time above pregnancy target range (3.5-7.8 mmol/l or 63-140 mg/dL)



- Normal growth associated with spending no more than 35% time above range from 10 weeks gestation

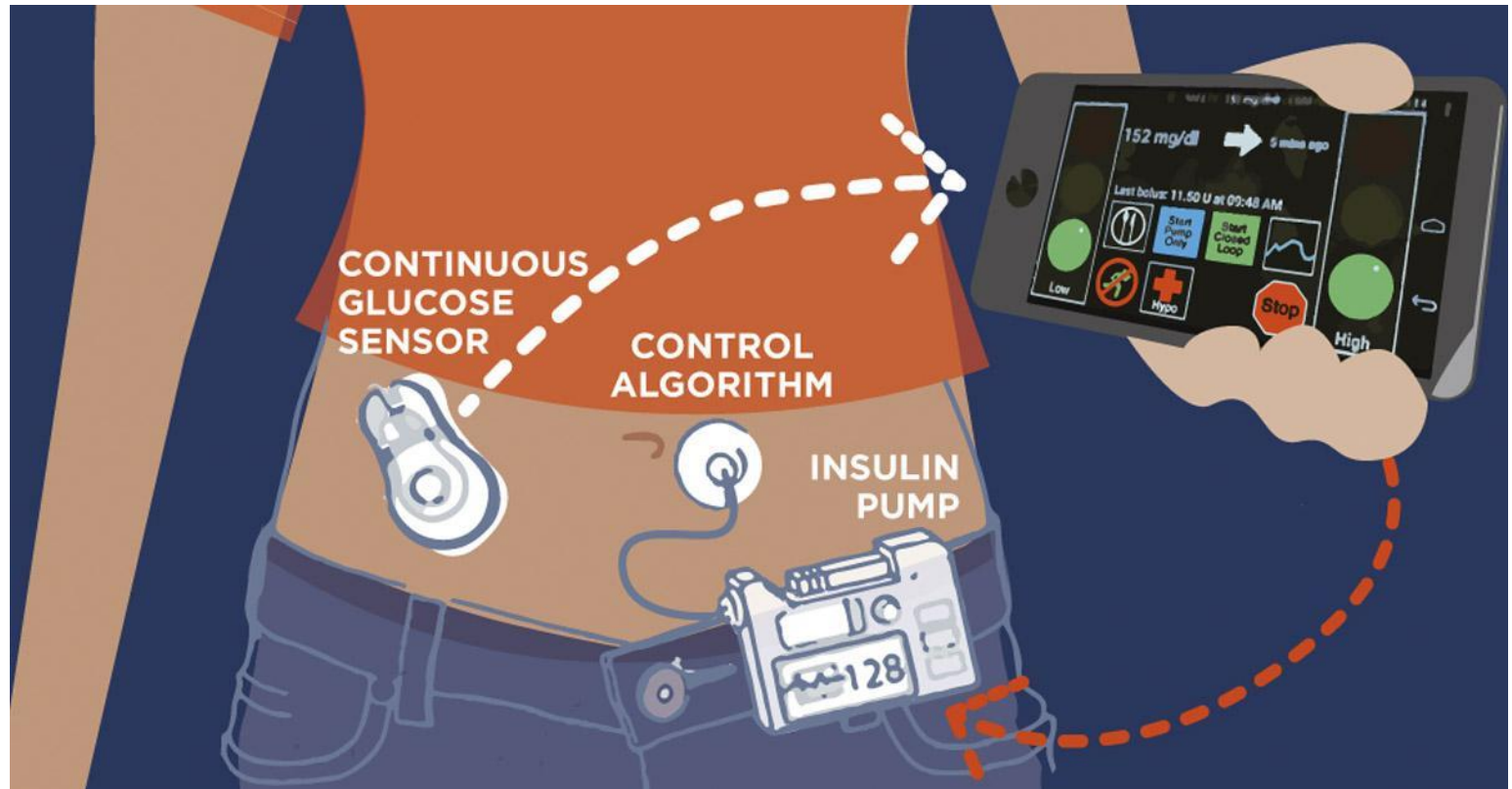
# Hybrid Closed Loop

(aka Automated insulin delivery or Artificial Pancreas Systems)

All short acting insulin as insulin delivery is via pump

Basal rates – determined by algorithm in response to CGM

Bolus insulin for carbohydrates



# Automated insulin Delivery in T1D pregnancy



**CLIP-02**  
Murphy HR et al. (2011)

**Crossover RCT**  
n = 12  
24hr closed-loop vs. SAP  
**2 x 24hr inpatient admissions**  
Snacks, meals and exercise



**CLIP-04**  
Stewart ZA et al. (2018)

**Crossover RCT**  
n = 16  
4 weeks 24hr  
HCL vs. SAP  
**Home setting**



**Commercialised  
HCL (2020)**

CamAPS Fx  
Licensed in  
pregnancy

**CLIP-01**  
Murphy HR et al. (2011)

**Exploratory safety study**  
n = 10  
**2 x 24hr inpatient admissions**  
1<sup>st</sup> : early pregnancy (12-16 weeks)  
2<sup>nd</sup> : late pregnancy (28-32 weeks)  
**High carbohydrate meals**



**CLIP-03**  
Stewart ZA et al. (2016)

**Crossover RCT**  
n = 16  
4 weeks overnight  
HCL vs. SAP  
**Home setting**  
Optional continuation

**Adaptability in labour  
and delivery**  
Stewart ZA et al. (2018)

n = 27  
Continuation phase of  
CLIP-03 and CLIP-4 for rest  
of pregnancy including  
**home and hospital settings**



# Closed loop in pregnancy: better glucose control than CGM and Pump



THE NEW ENGLAND JOURNAL OF MEDICINE

ORIGINAL ARTICLE

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

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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.)

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ORIGINAL ARTICLE

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

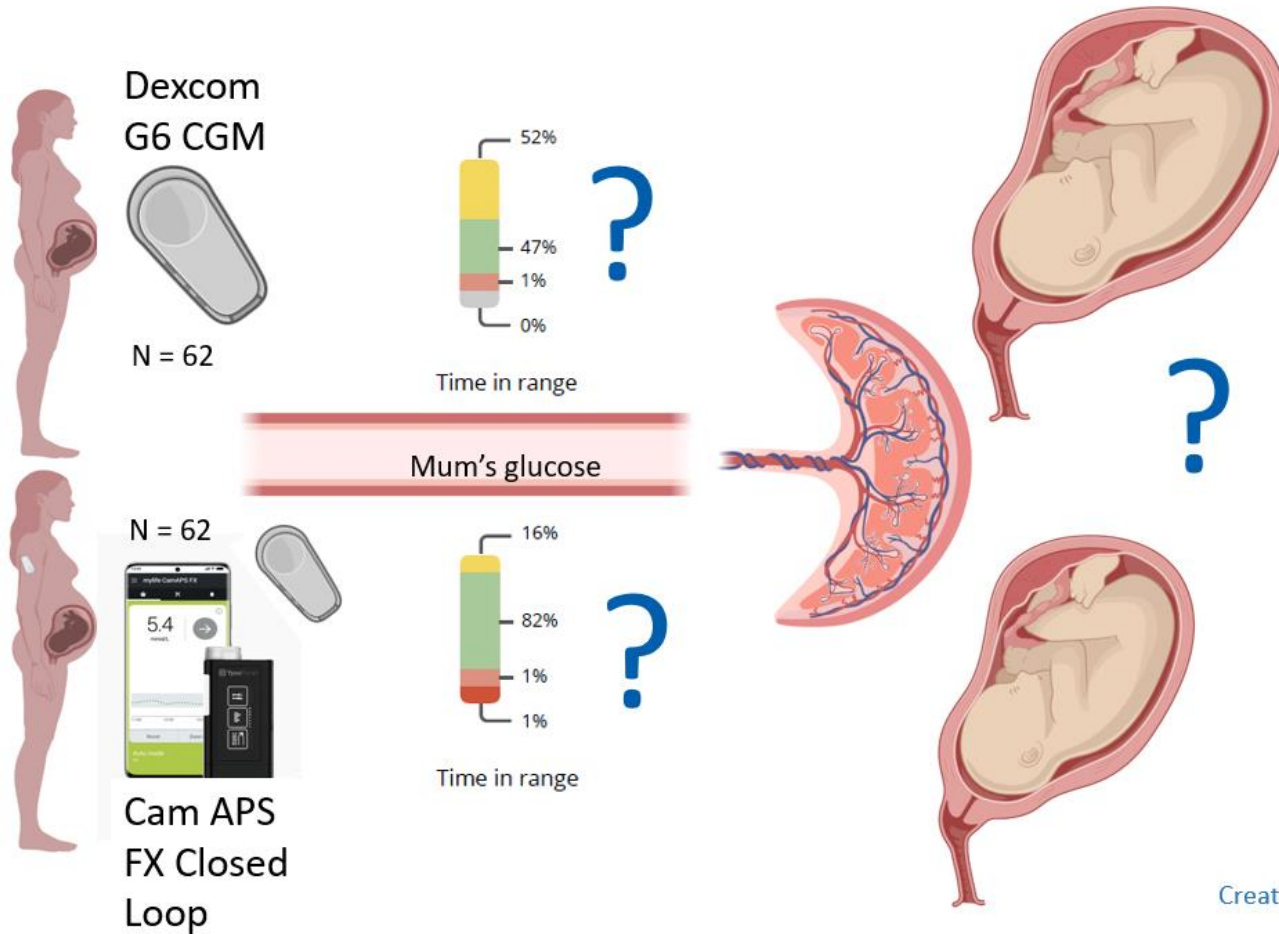
Tara T.M. Lee, M.B., B.S., Corinne Collett, B.Sc., Simon Bergford, M.S., Sara Hartnell, B.Sc., Eleanor M. Scott, M.D., Robert S. Lindsay, Ph.D., Katharine F. Hunt, M.D., David R. McCance, M.D., Katharine Barnard-Kelly, Ph.D., David Rankin, Ph.D., Julia Lawton, Ph.D., Rebecca M. Reynolds, Ph.D., Emma 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\*







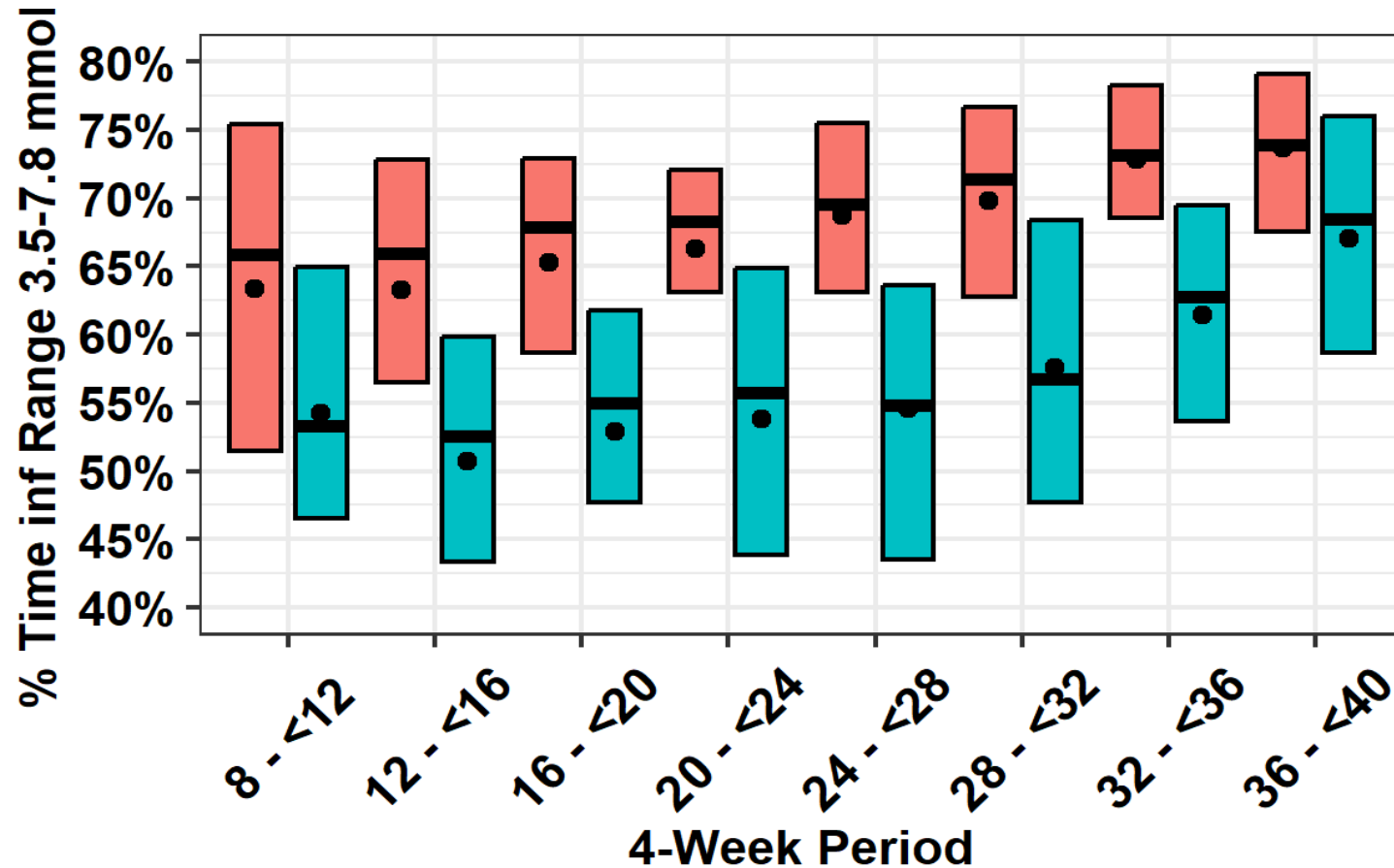
# Automated Insulin Delivery Amongst Pregnant women with Type 1 diabetes



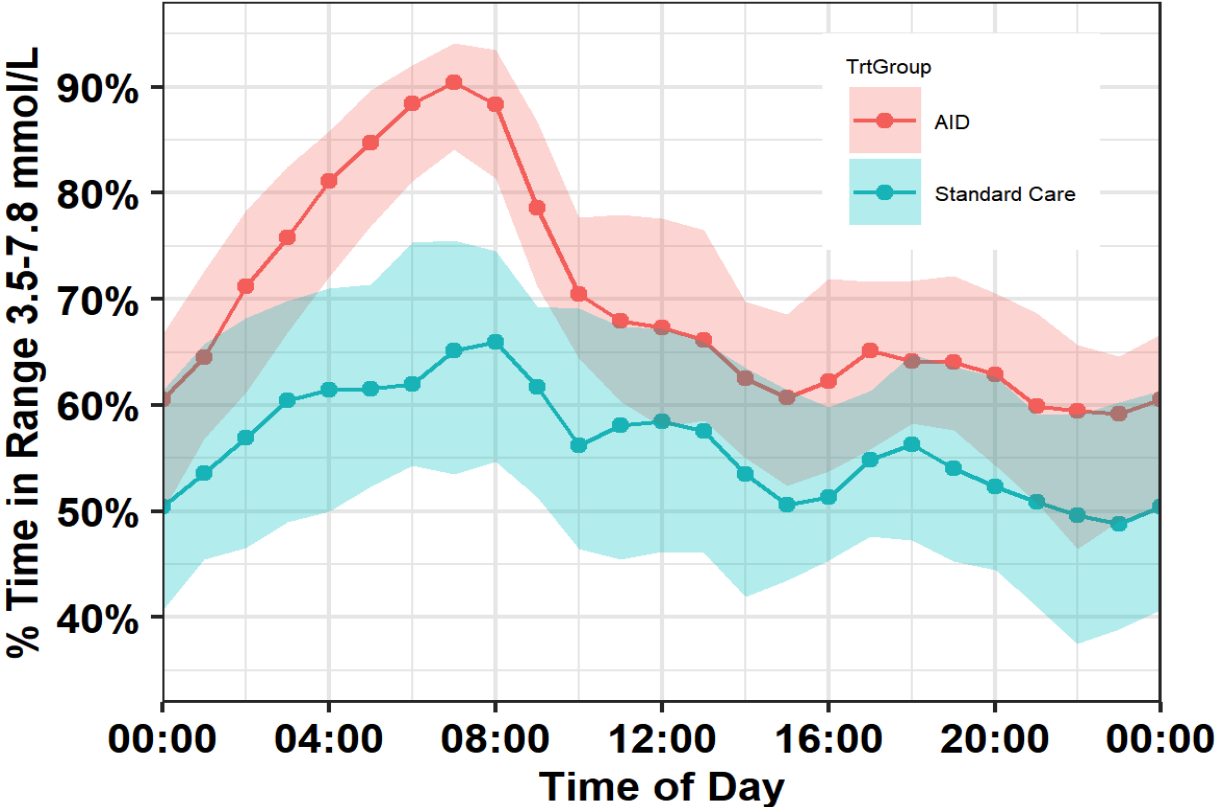
Maternal glucose (time in range)  
Neonatal outcomes (NICU, LGA)  
Qualitative data outcomes  
Health economic outcomes  
Data informed NICE TA

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# Closed loop significantly improved the amount of time spent in glucose range from early in pregnancy



# Closed loop significantly improved amount of time spent in glucose range across 24-hr day, esp. overnight



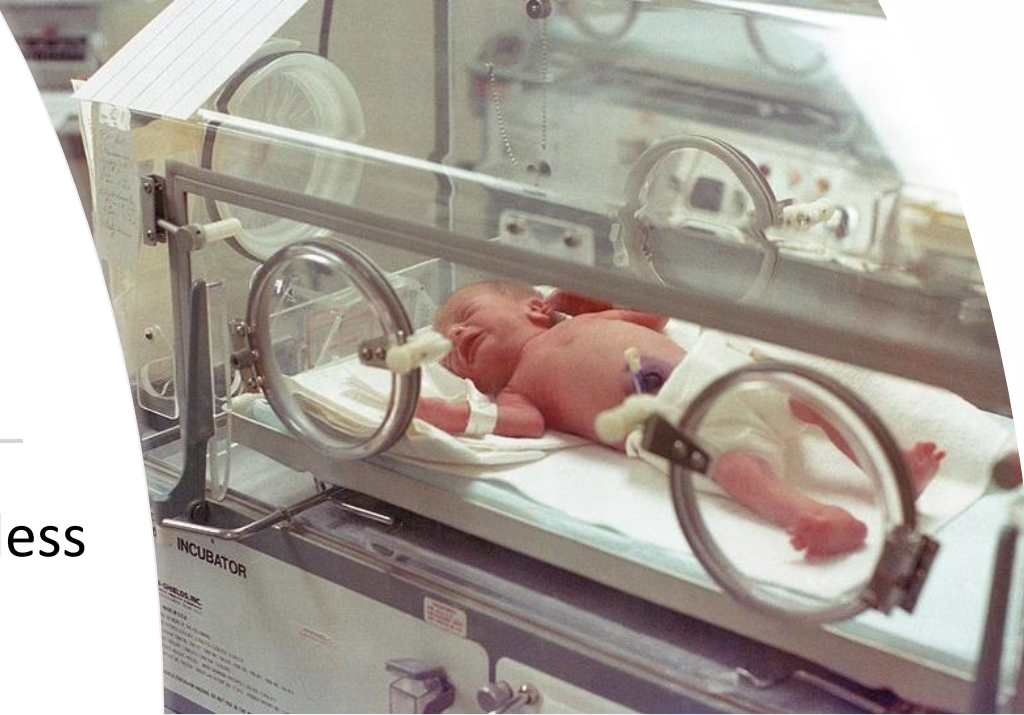
## Additional benefits

Pregnancy experience (less worry, less work, more enjoyable pregnancy)

3.7kg less gestational weight gain

Less gestational hypertension

Lower rates of LGA/NICU



# Hybrid Closed Loop recommended for women with Type 1 diabetes who are pregnant or planning

## NICE RECOMMENDS LIFE CHANGING TECHNOLOGY IS ROLLED OUT TO PEOPLE WITH TYPE 1 DIABETES ✨

### PRESS RELEASE

NICE recommends life changing technology is rolled out to people with type 1 diabetes

An announcement of the recommendations was made today (Tuesday 7 November) at NICE's annual conference in Manchester by NICE chief executive Dr Sam Roberts



Thousands of people with type 1 diabetes could be offered wearable technology to help them manage their condition following the publication of final draft guidance by NICE.

An independent NICE committee has recommended people whose diabetes is not controlled with their current device despite best possible management with an insulin pump, or real-time or intermittently scanned continuous glucose monitoring, are offered a hybrid closed loop system.

### ABOUT THE RECOMMENDATIONS

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

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

2. Hybrid closed loop systems are recommended as an option for managing blood glucose levels in type 1 diabetes for children and young people.



3. Hybrid closed loop systems are recommended as an option for managing blood glucose levels in type 1 diabetes for people who are pregnant or planning a pregnancy.

**NICE** National Institute for Health and Care Excellence

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

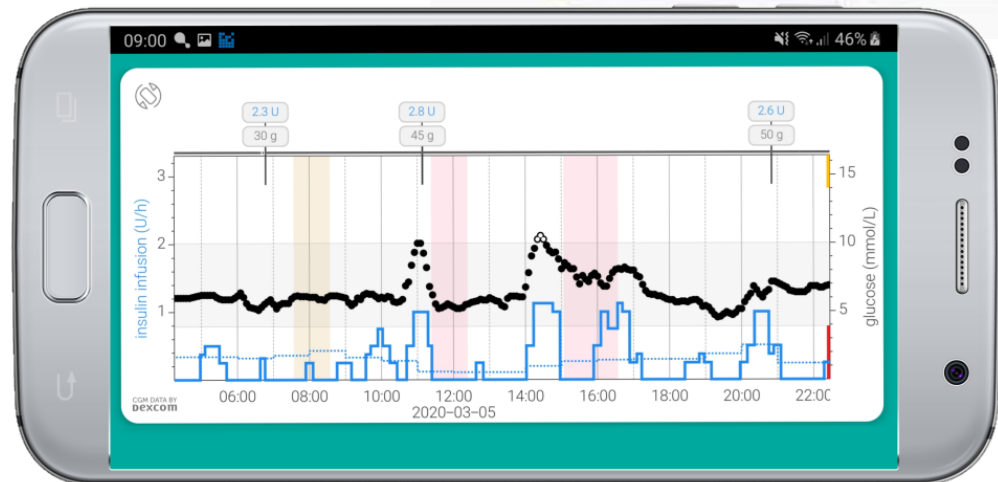
In development [GID-TA10845] Expected publication date: TBC [Register as a stakeholder](#)

07 November 2023

# How does CamAPS FX work?

Modulates basal insulin delivery by:

- Adjusting insulin every 8-12 minutes
- Causes for no delivery (occlusion, low reservoir) will result in pump alarm / vibrate
- **Hybrid closed-loop** → **still requires insulin boluses for carbohydrates**



# How does CamAPS FX work?

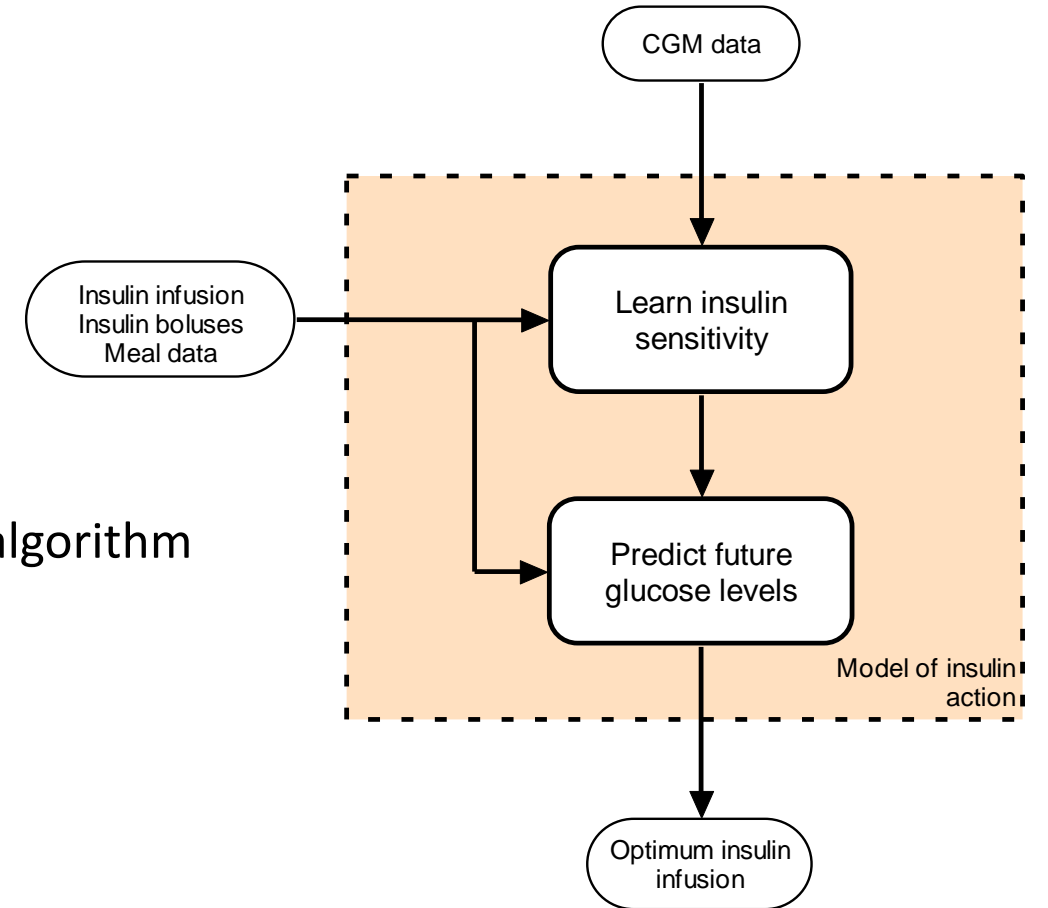
What are the **inputs** to the algorithm?

*Starting the system*

- ✓ **Body weight & Total Daily Dose (TDD)**
- ✓ Insulin sensitivity and active insulin time calculated by algorithm

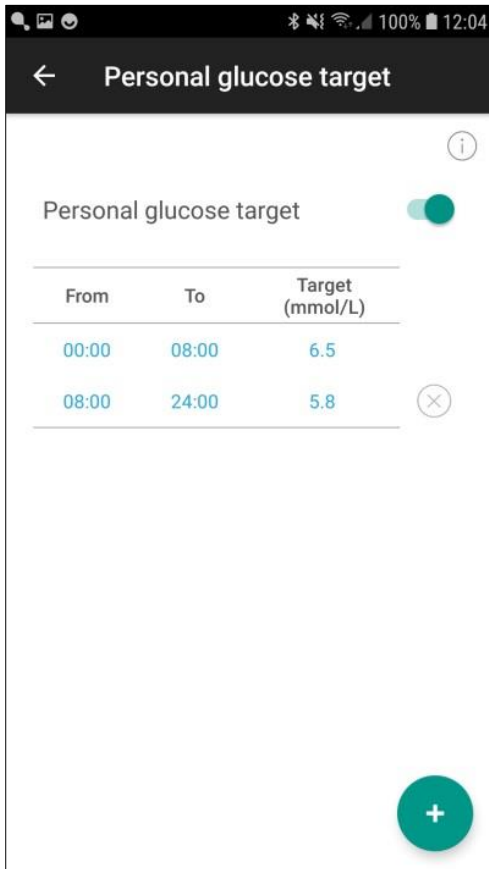
*Ongoing*

- ✓ Real-time CGM
- ✓ Carbohydrates and pre-meal insulin boluses



# Personal glucose target – customisable for pregnancy

Algorithm target (default 5.8 mmol/L) adjustable at different times of day & night



Suggested algorithm targets in pregnancy:

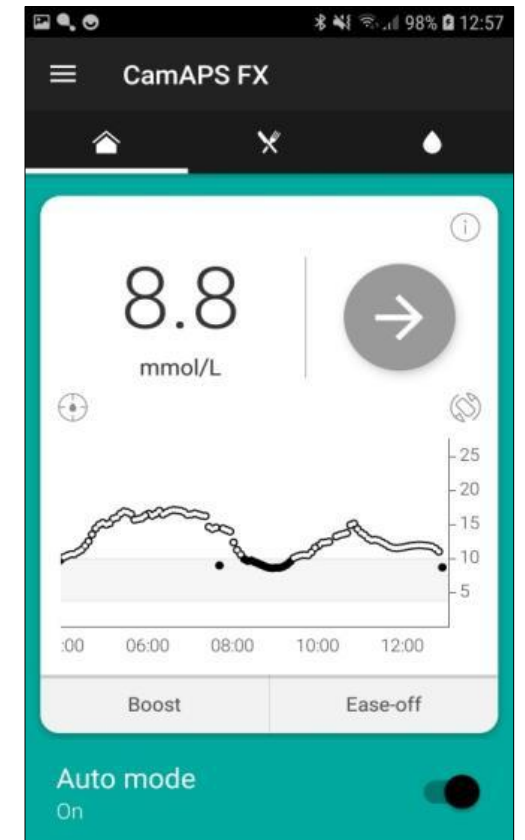
- 1<sup>st</sup> trimester: 5.5 mmol/L
- 2<sup>nd</sup> trimester (or earlier if hypo risk low): 4.5-5.0 mmol/L

Treat to target:

- TIR (3.5-7.8 mmol/L): 70%
- mean glucose: 6.0-6.5 mmol/L

When to adjust target

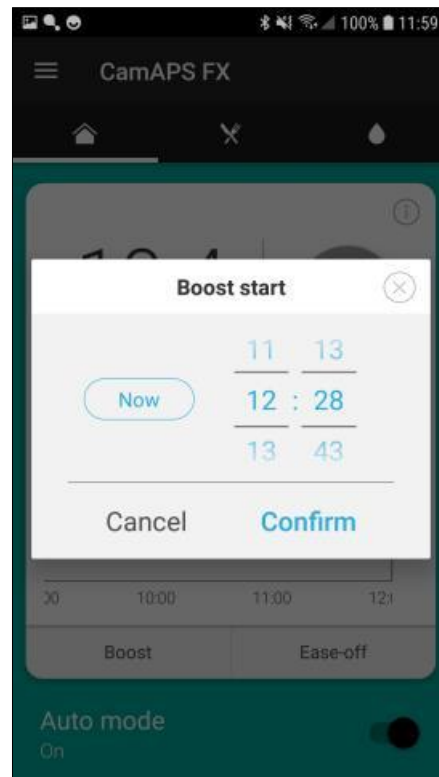
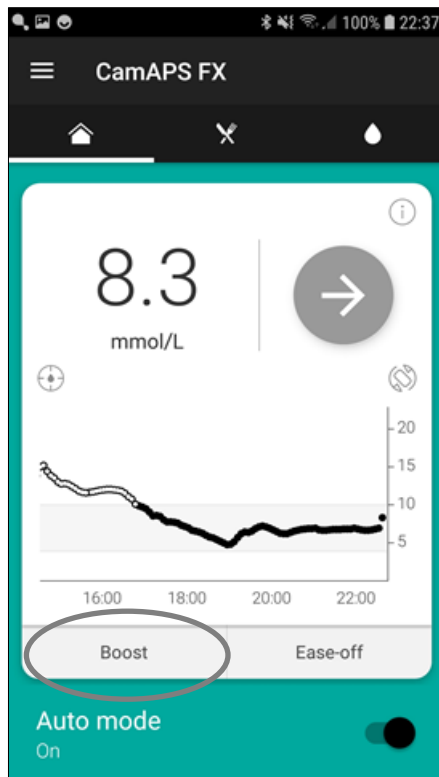
- Lower target if glucose variability low
- Raise target if period of frequent hypoglycaemia





# Boost

- Increases basal insulin delivery by ~35%
- Once glucose reaches target, boost **will not** continue to increase insulin delivery

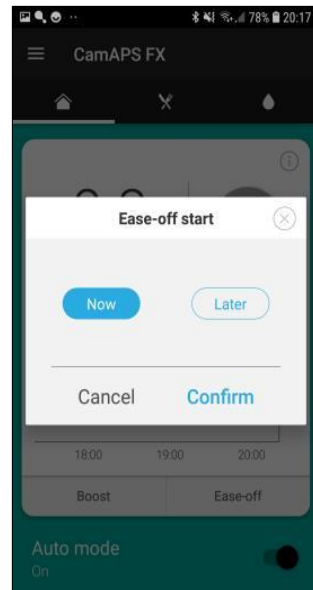
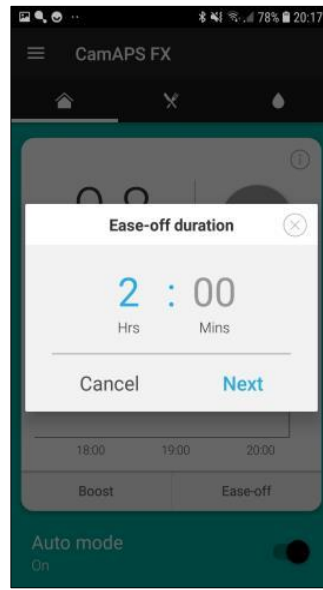


## When to use Boost?

- Post prandial hyperglycaemia
- Low grade illness (not requiring sick day rules)

# Ease-Off

- Substantially reduces basal insulin delivery
- Raises glucose target temporarily by 2.5mmol
- Insulin delivery stops if glucose < 7 mmol/L
- Tries to prevent glucose falling below 6.1mmol



## When to use Ease Off?

- Before, during and/or after exercise/activity
- Following hypoglycaemia
- Hot weather

# Meals and Pre-bolusing

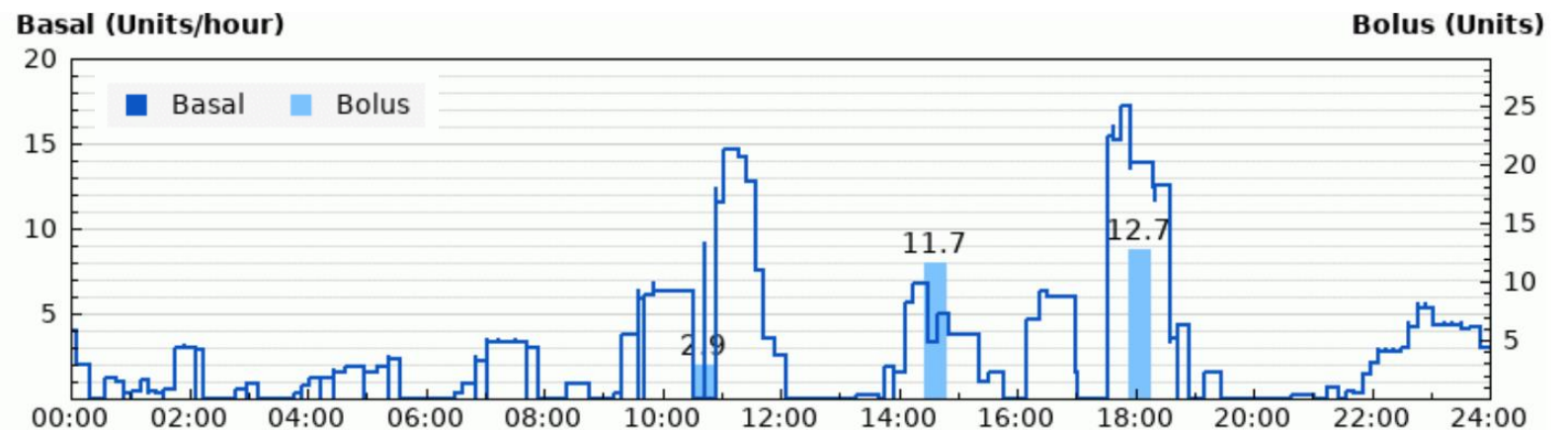
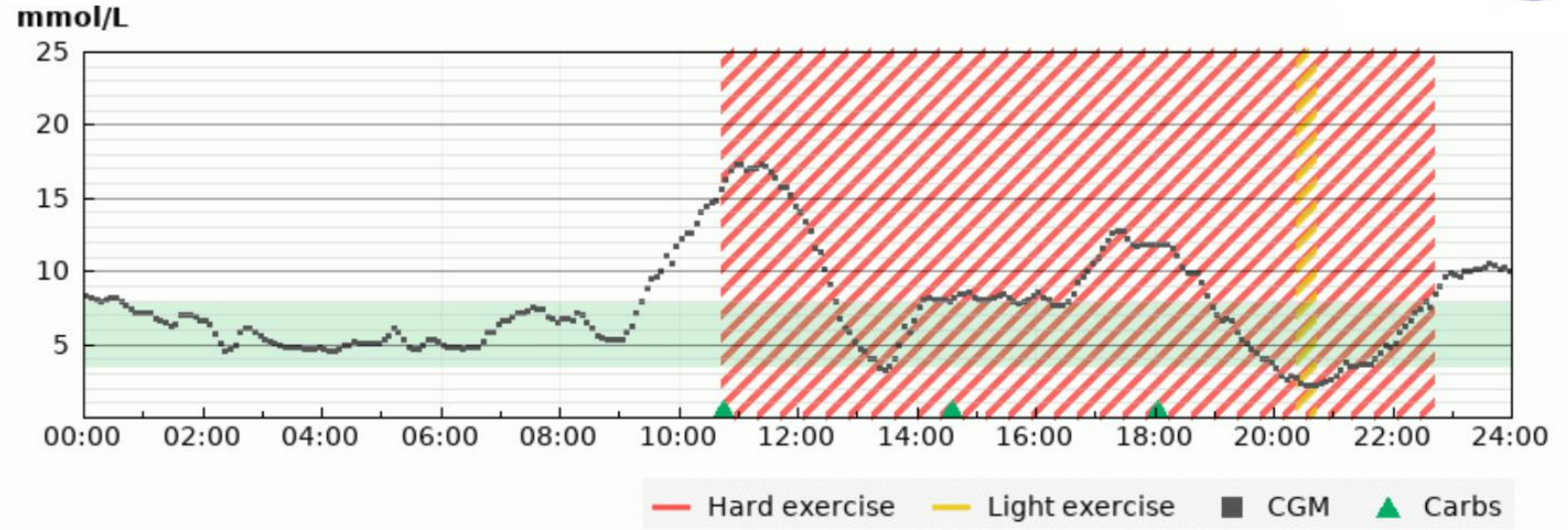


## Strengthen insulin-carbohydrate ratios

To keep up with increasing insulin resistance

## Mismatch of insulin and carbohydrates

- Exaggerated glucose peak (unannounced)
- Delayed insulin peak
- Insulin stacking
- Uncontrolled drop in BG and likely hypoglycaemia



# Meals and Pre-bolusing

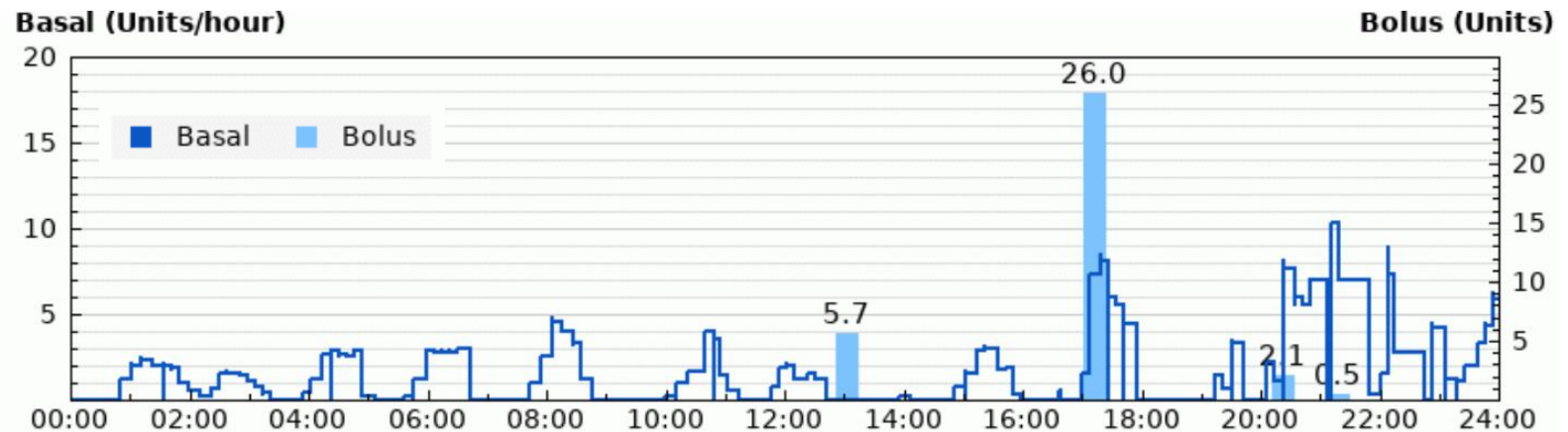
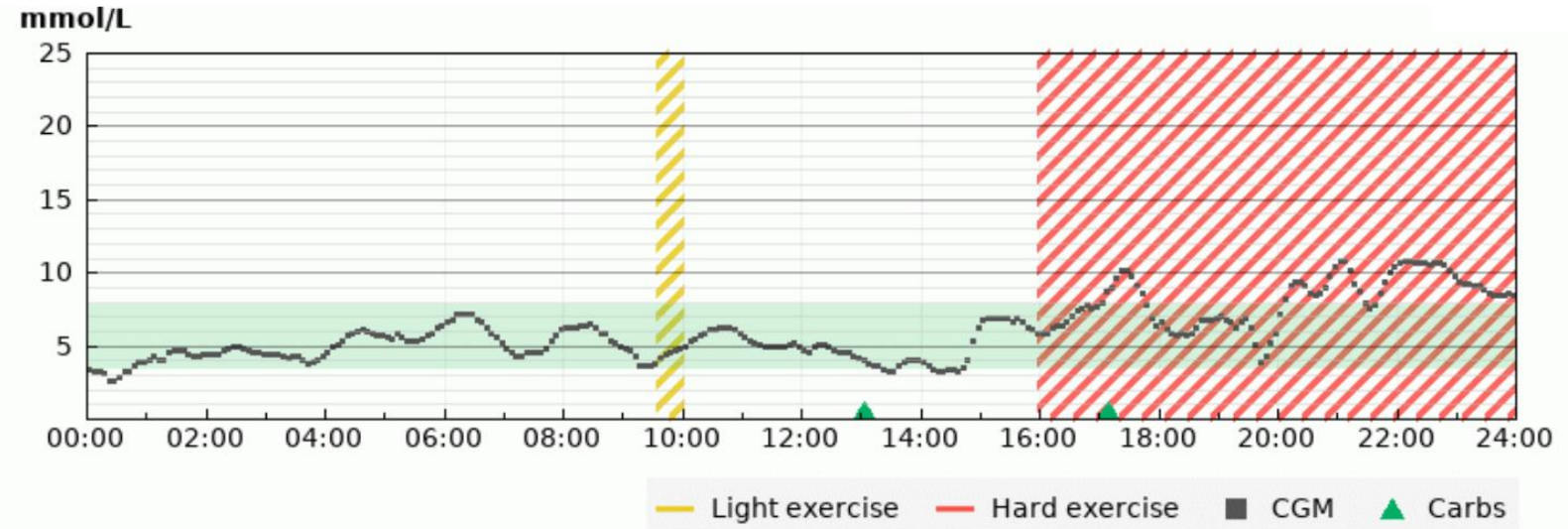


**Suggested bolus interval**

First trimester:  
10-15mins

Second trimester:  
20-30mins

Third trimester:  
45-60mins





**My super  
expensive  
sensor**

**My state  
of the art  
closed  
loop pump**

**Me  
forgetting  
to bolus  
for a meal**