mylife Loop
CamAPS FX

Shorter planning
Safer pregnancies
Healthier mothers

Managing type 1 diabetes with mylife Loop before, during, and after pregnancy.

Welcome!

We live in extraordinary times in diabetes management. Times of technological innovation that make us dream of a not-so-distant future where type 1 diabetes is not an impediment for having a healthy baby and a safe pregnancy. As a healthcare professional, you are a lead character in re-writing the story for many soon-to-be parents!

There are good reasons for optimism:

Advancements in closed loop technology

mylife Loop hybrid closed-loop (HCL) was designed with the demanding pregnancy targets in mind. The CamAPS FX algorithm is the first HCL indicated for pregnancy.

Solid clinical and real-world evidence

The recently published AiDAPT study supports the safety and efficacy of the mylife CamAPS FX algorithm.[1]

Encouragement from healthcare systems

More and more national guidelines recommend HCL as the standard of care for women with type 1 diabetes planning to become pregnant.[2]

In this guide, you will find detailed information about the management of type 1 diabetes with mylife Loop hybrid closed-loop at each stage of the pregnancy journey. With the goal of shortening the planning phase, achieving safe pregnancies & deliveries, and caring for healthy mothers for many years to come!

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1. Let's discuss type 1 diabetes and pregnancy

The risks of an unplanned pregnancy outweighs the risks of any currently available contraception option; therefore, long-acting, reversible contraception should be discussed and prescribed if desired by the patient.[3] When counselling a woman of childbearing age living with type 1 diabetes, emphasise the importance of family planning for improved maternal and foetal outcomes.

Women with type 1 diabetes who are planning pregnancy should aim to maintain their HbA1c below 6.5 % (48 mmol/mol) as **any reduction in HbA1c is likely to reduce the risk of congenital malformations.**[4] Because of the high risks for women and foetuses, people whose HbA1c is above 10 % (86 mmol/mol) should be strongly advised to avoid pregnancy, until better HbA1c results are achieved.[5]

Diabetes technology such as CGMs and Automated Insulin Delivery (AID) make diabetes management easier.

Offering intense support with diabetes management has proven to be effective towards achieving better glucose management.[1] Today, diabetes technology such as CGMs and closed-loop makes diabetes treatment easier while improved glycaemic management. Additionally, lifestyle interventions such as weight and stress management, exercise, and diet, will also contribute towards overall health and achieving more stable glucose values.[6]

Both endocrinologists/diabetologists and OBGYNs play a decisive role in supporting the safety and well-being of the expectant mother and her child. While endocrinologists typically focus on diabetes management and OBGYN's lead pregnancy care, both professionals work together to provide the best possible care for the pregnant woman and developing baby, with healthcare teams often including a diabetes educator nurse, dietitian, and midwife. Everyone part of the healthcare team should be informed about the plans for pregnancy care and delivery – including diabetes management.

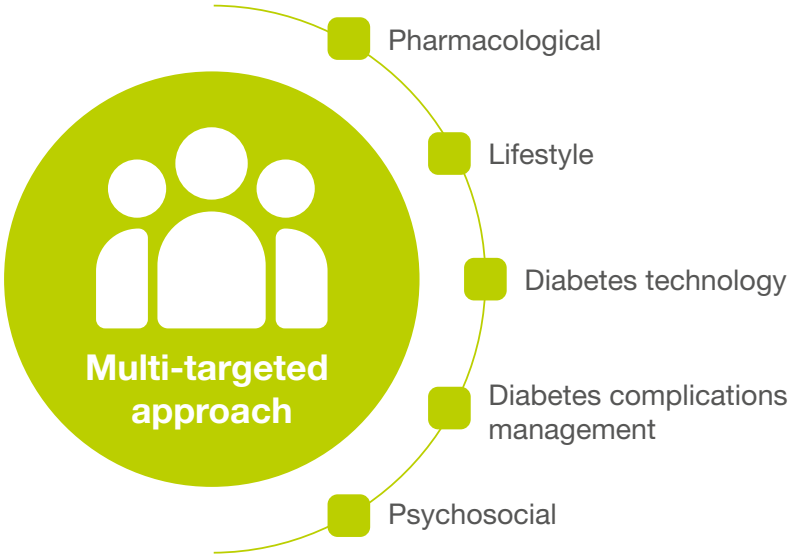

Figure 1: Taking a multi-targeted approach to management of pregnancies in women with type 1 diabetes, including pre-pregnancy care, lifestyle, pharmacological, psychosocial, and technology approaches, helps to reduce the risk for perinatal complications.[7]

Diabetes technology is breaking barriers. Such advancements also include the management of type 1 diabetes during pregnancy. **Today, women can manage their diabetes with an AID system not only at the planning stage, but also during and after pregnancy.** The latest results of the AiDAPT randomised controlled trial support the safety and efficacy of hybrid closed-loop therapy during pregnancy.[1] These excellent study results answer a very important question: How does a type 1 diabetes pregnancy look when women achieve pregnancy glycaemic targets thanks to the use of mylife CamAPS FX hybrid closed-loop technology? The future is bright!

Women in the AiDAPT randomised controlled trial described how hybrid closed-loop lessened the physical and mental demands of diabetes management, enabling them to feel more normal and sleep better.[8]

1.1 Managing diabetes in the context of pregnancy

Every medical visit with a woman of child-bearing age is an opportunity for pregnancy counselling. Topics that should be discussed include the risks of an unplanned pregnancy and suboptimal glycaemic management as well as the benefit of improved maternal and foetal outcomes with appropriate pregnancy planning and diabetes treatment.[9]

The 2020 UK National Institute for Health and Clinical Excellence (NICE)[5] guidelines recommend advising women with diabetes who are planning to become pregnant:

- that the risks associated with diabetes in pregnancy will increase the longer they have had diabetes,
- to use contraception until they have good blood glucose management (assessed by HbA1c levels),
- that blood glucose targets, glucose monitoring, medications for treating diabetes (including insulin regimens) and medications for complications of diabetes will need to be reviewed before and during pregnancy and
- that extra time and effort is needed to manage diabetes during pregnancy, and that more frequent contact is needed with healthcare professionals.

As every healthcare system defines their own pregnancy guidelines for women with type 1 diabetes, we recommend that you follow the guidelines applicable in your respective country.

1.2 Managing pregnancy in the context of type 1 diabetes

Close cooperation between the gynaecologist and the diabetologist is important. Additional ultrasound examinations are often useful to develop a **joint treatment strategy** to get through the pregnancy as safely and stress-free as possible.[5]

As with any preconception counselling, the woman (and her partner, if possible) should be informed about the availability of expanded carrier genetic screening – if available in your country.[3] You can find more details about pregnancy planning in section 3.3 of this guide.

Women who fall short of achieving the pregnancy glycaemic targets are at increased risk of several of the complications associated with diabetes pregnancies:[10]

Birth defects
Birth defects occur in around 4.5 percent of women with type 1 diabetes.[11] Defects of the heart, brain, spine, and skeleton can occur in the early weeks of pregnancy when these organs are developing.

Preeclampsia
High blood pressure during pregnancy increases the risk of preeclampsia, a serious condition that can lead to seizures and kidney or liver problems in the mother.

Polyhydramnios
In this condition, there is an increased amount of amniotic fluid in the amniotic sac that surrounds the foetus. It can lead to preterm labour and delivery.

Macrosomia
The foetus receives too much glucose from the mother and can grow too large. A large foetus can make delivery more difficult and increases the risk of having a caesarean birth.

In addition, avoiding **excessive gestational weight gain** in women with type 1 diabetes is also important as high gestational weight gain is associated with hypertensive disorders of pregnancy and increased offspring birthweight independent of glycaemic management and pre-pregnancy BMI.[12]

When it comes to considering delivery options, the presence of complications like the ones mentioned above might already indicate the best way to proceed. Otherwise, it is important to include the woman in the discussion and make the plan together. Part of this plan will be how to approach diabetes management during delivery. The main goal is to preserve the safety and health of mother and baby at all times.


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1.3 Why hybrid closed-loop

The goal of hybrid closed-loop is to help to get as close to the pre-pregnancy glucose target as it may be safely possible and, once pregnant, to tackle the challenges of managing diabetes in a way that minimises the disturbances to the glucose levels, as well as the lifestyle and wellbeing of the woman.

According to Tara Lee, lead author of the AiDAPT study, some of the widely documented management challenges during pregnancy are:[13]

Increased day to day variability; a person could do the exact same activities every day, eat the exact same, inject the exact same, yet still her glycaemia would be different. No wonder it builds up some frustration.

Changes in insulin resistance and sensitivity mostly linked to the different stages of pregnancy. However, it can also change day-to-day depending on stress, sleep, overall health, etc.

Fear of hyperglycaemia and effect on the baby as hyperglycaemia is correlated to adverse foetal outcomes, pre-eclampsia, and LGA (large for gestational age) babies, pregnant women fear going above range 7.8 mmol/L (140 mg/dL) – which is a very ambitious and hard-to-reach target.

Huge mental burden of self-management; all the above challenges may result in high levels of self-imposed pressure to improve type 1 diabetes management, therefore women's mental wellbeing might be affected.

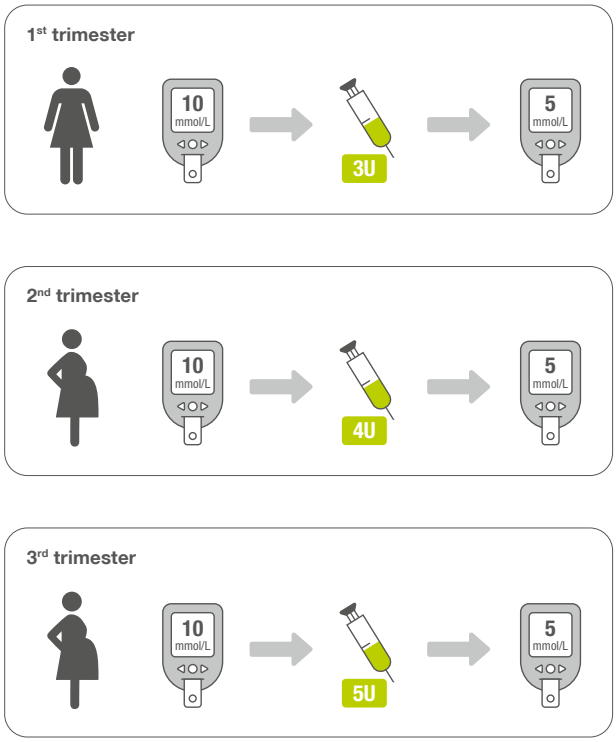


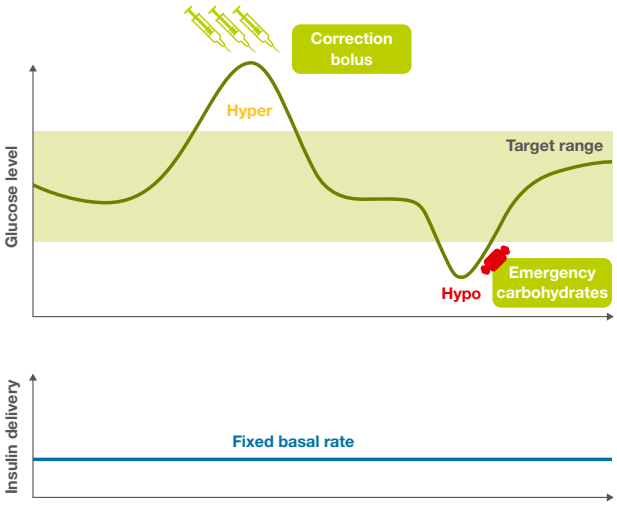
Figure 2: As the pregnancy progresses, insulin resistance increases and the amount of insulin must be increased to reach the same outcome. Numerical values are for illustrative purposes only.

Communication across all members of the healthcare team is key to support pregnant women with type 1 diabetes.

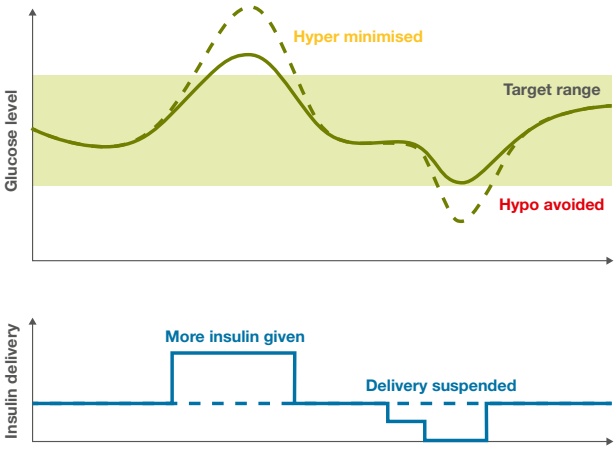
Non-automated insulin delivery: MDI and insulin pumps

Avoiding or minimising pronounced glucose excursions is a constant for any person living with type 1 diabetes. For people managing diabetes with multiple daily injections (MDI), such glycaemic fluctuations are often the consequence of excess correction boluses to treat hyperglycaemia, or emergency carbohydrates to “rescue” a hypo. Clinical data shows every % increase in time in range (TIR) can help reduce the risk of long-term complications.[14]

The challenges of managing type 1 diabetes with multiple daily injections (MDI)



AID systems dynamically adapt to the insulin needs of the user



Automated Insulin Delivery (AID)

AID systems adjust insulin delivery based on individual needs of the user thanks to the input from a CGM, and the calculations performed by an algorithm. By increasing and decreasing insulin delivery, the system aims to reduce glycaemic variability and to increase the time in range. The insulin delivery adjustments are done automatically through an insulin pump, reducing the work of required from the patient.

Women in the AiDAPT study who spent increased time in range, also worried less about risks to their baby and being judged negatively by healthcare professionals.[8]

mylife Loop is powered by mylife CamAPS FX, the Automated Insulin Delivery (AID) algorithm designed and indicated for pregnancy.

More information about mylife Loop in section 3.1 of this guide.

2. Best care for safe and healthy type 1 diabetes pregnancies

Optimal glycaemic management at conception and throughout the pregnancy have been associated with lower risk for obstetric and neonatal complications, such as LGA, admission to neonatal intensive care unit (NICU), preterm birth and perinatal death.[15]

According to Prof. Helen Murphy, a researcher and lead authority in type 1 diabetes management and pregnancy, the greatest challenges in using AID systems for pregnant women with type 1 diabetes are[16]:

- Managing high-carbohydrate meals
- Developing an AID system that can deliver insulin quickly enough to avoid post-meal high glucose levels
- Knowing when to increase insulin delivery (such as illness and rising insulin resistance during the third trimester of pregnancy) versus knowing when to reduce or stop insulin delivery (such as following low blood sugar events, hot weather, or physical activity)

2.1 Safety considerations in type 1 diabetes pregnancies

Diabetes treatment goals are much stricter for pregnant women as it is critical to protect the foetus from exposure to high glucose levels.

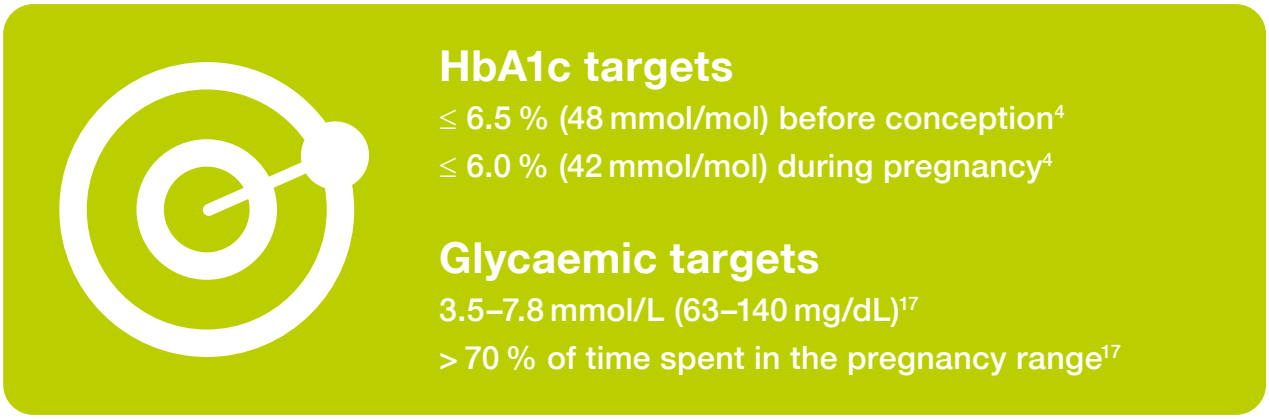
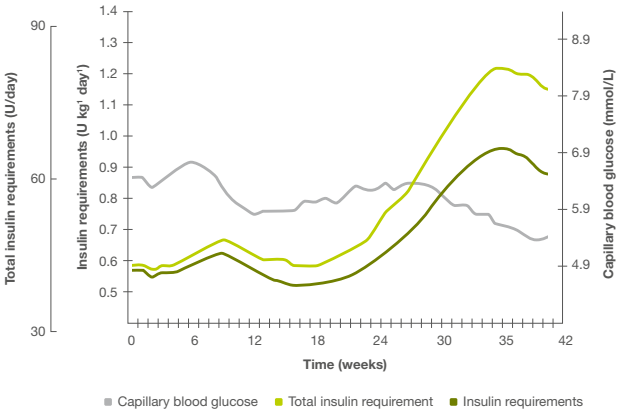


Figure 3: General consensus on type 1 diabetes management goals pre- and during pregnancy.

Insulin sensitivity

Insulin requirements and glucose management vary throughout pregnancy with three changes of direction[18]:

1. Up to week 16, insulin requirements are more unstable. Because of sudden changes in insulin sensitivity, events of severe hypoglycaemia are more frequent.
2. At week 16, an upwards trend in total insulin requirements begins, peaking at week 37.
3. Capillary blood glucose improves as insulin resistance increases. The best glycaemic management is achieved from week 30 onwards.



Unexpected swings in insulin requirements put the mother at risk of hypoglycaemia and hyperglycaemia. Certain obstetric and neonatal complications correlate to hyperglycaemia episodes at a certain stage of a pregnancy; for instance, sustained hyperglycaemia during the first and/or third trimester increases the risk of LGA babies[19].

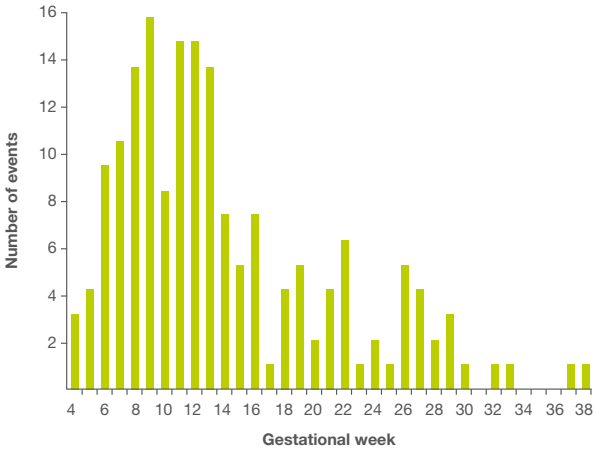
Hypoglycaemia

Risk factors for severe hypoglycaemia during pregnancy include a history with severe hypoglycaemia in the year preceding pregnancy, impaired hypoglycaemia awareness, long duration of diabetes, low HbA1c in early pregnancy, fluctuating plasma glucose values and excessive use of supplementary insulin injections between meals[20].

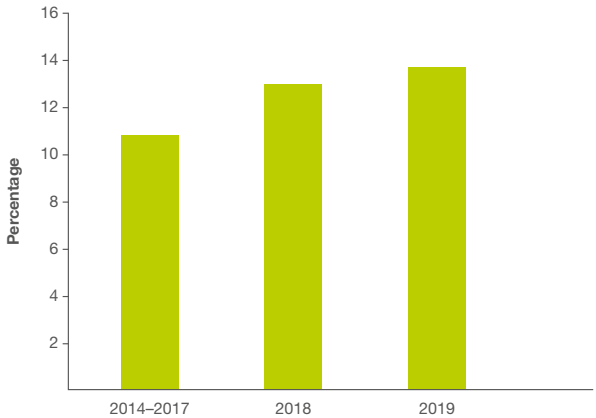
Achieving a tight glucose management to protect the foetus from sustained hyperglycaemia without increasing the risk of maternal hypoglycaemia is challenging. Literature review including data from 108 pregnant women with type 1 diabetes showed that[20]:

- Severe hypoglycaemia occurred 3 to 5 times more frequently in early pregnancy than in the period prior to pregnancy.
- In the third trimester, the incidence of severe hypoglycaemia was lower than in the year preceding pregnancy.
- 80 % of severe hypoglycaemias happened within the first 20 weeks.

Number of severe hypoglycaemic events per week during pregnancy in 108 women with type 1 diabetes.



Women with type 1 diabetes with at least one hospital episode with diagnosed hypoglycaemia during pregnancy, 2014–2019



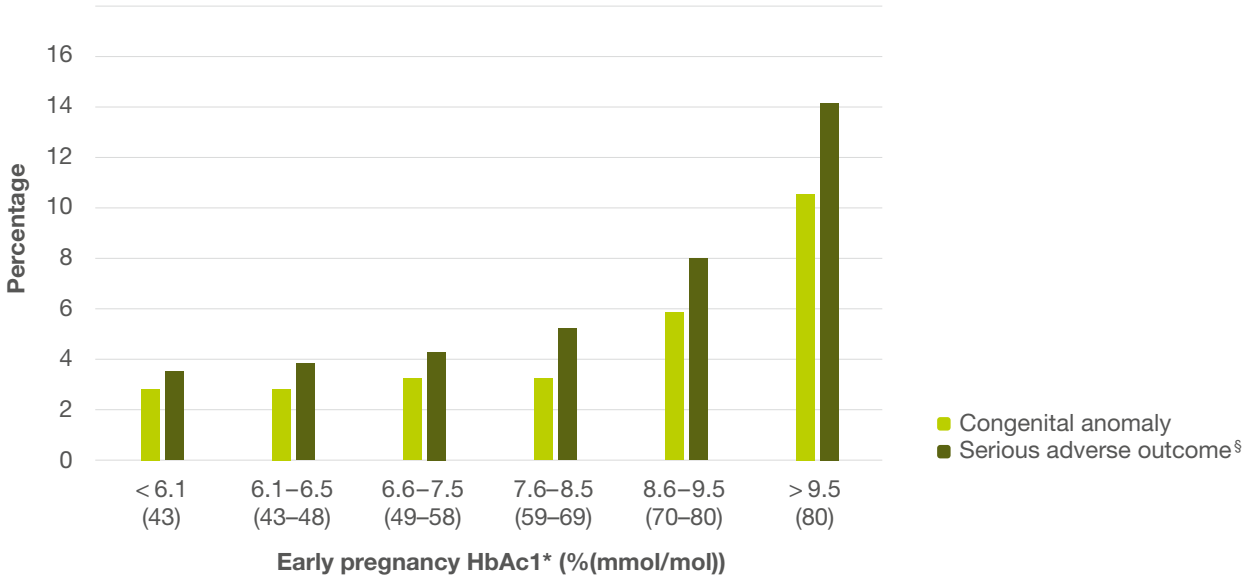
Data from the last three National Pregnancy in Diabetes (NPID) Audit Reports in the UK, shows that severe hypoglycaemia in pregnant women with type 1 diabetes continues to be a reason for concern. In the last Audit Report from 2020, 13.5 % of 4160 participants with type 1 diabetes had at least one hospital episode with diagnosed hypoglycaemia[15].

Hyperglycaemia

The outcomes of the UK National Pregnancy in Diabetes (NPID) Audit with 4160 pregnant women with type 1 diabetes in 2020 provide insights into the consequences of hyperglycaemia for the health of the mother and baby.[15]

Good glycaemic management is already important at conception to reduce birth defects and baby deaths; when checking HbA1c after detecting pregnancy, a high HbA1c is associated with higher recurrence of congenital anomaly and birth defect events.[15]

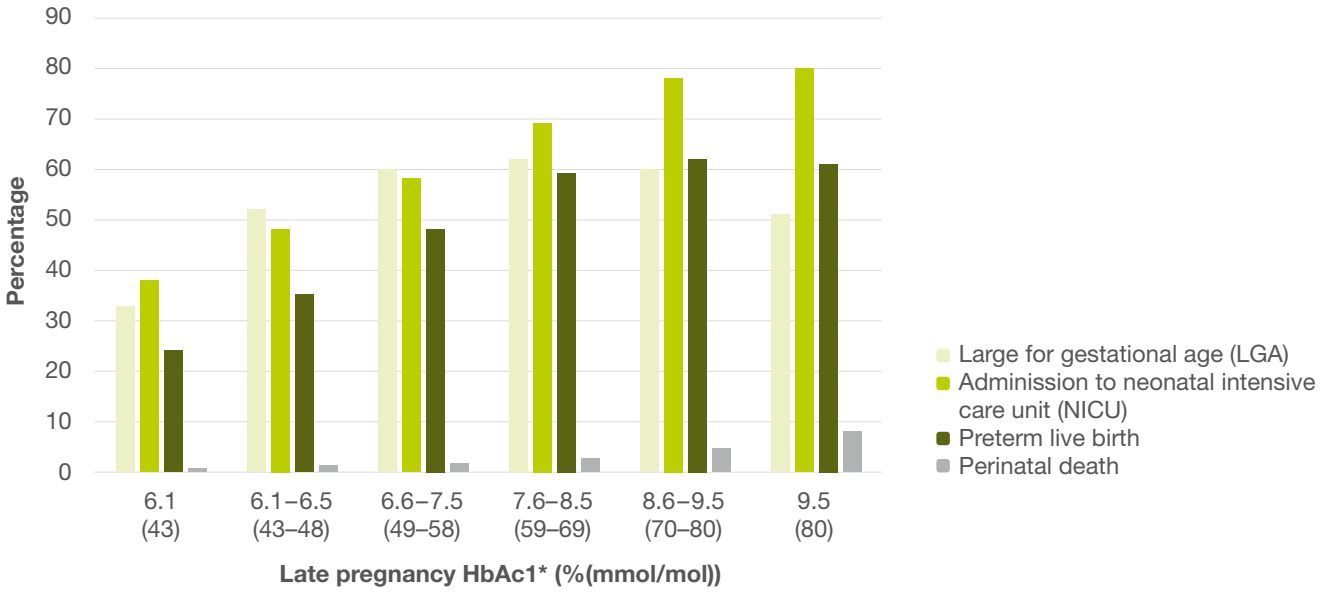
Good glycaemic management is already required at conception to reduce birth defects and baby deaths



* Early pregnancy is defined as pregnancy booking visit (first visit of the maternal care)
§ Serious adverse outcomes include congenital anomaly, stillbirth and neonatal death

Good glycaemic management during the **third trimester** of pregnancy is required to reduce the risks of obstetric and neonatal complications: with a higher HbA1c level in the third trimester, some complications are more common, such as LGA, admission to NICU, preterm birth, and perinatal death.

Good glycaemic management during the third trimester of pregnancy is required to reduce the risks of obstetric and neonatal complications



Pregnancy is a ketogenic state, and women with type 1 diabetes are at **risk for diabetic ketoacidosis (DKA)** at lower glucose levels than in the non-pregnant state.[4] Sickness and vomiting also contribute to this increased threat.[4] To limit the risk, it is possible in most countries to offer blood ketone testing strips and a meter to pregnant women with type 1 diabetes and advise them to test their ketones and to seek urgent medical advice if they become hyperglycaemic or unwell.[21]

To promote foetal lung maturation, especially to women who are at risk of pre-term birth within the next 7 days, **corticosteroids** may be given. **The response to steroids is unpredictable with increases in insulin requirements to around 50 %.** The effect on glucose levels usually persists for about 24 hours after the last steroid dose. In most cases women on insulin pump therapy can use this to effectively manage the elevation in glucose levels. The obstetric team should inform the diabetes team before (or as soon as possible after) steroids are started.[22]

* Late pregnancy is defined at around 34 weeks gestation

2.2 Recommendations for healthy pregnancies

Caring for a soon-to-be mother includes providing recommendations to achieve, not only a safe pregnancy, but also a healthy one. Always tailor lifestyle recommendations to the characteristics and preferences of each woman.

"Honestly, it allowed me to work. I would never be able to work as a waitress at all, if I didn't have the hybrid closed-loop."

AiDAPT study participant[8]

Staying active

A systematic review[23] demonstrated improvements in glucose management and reductions in insulin dose requirements with an exercise intervention in women with gestational diabetes. There was heterogeneity in the types of effective exercise (aerobic, resistance, or both) and duration of exercise (20–50 min/day, 2–7 days/week of moderate intensity)[24].

Being active for 10–15 minutes after eating can lower post meal glucose level as much as 2 mmol/L (36 mg/dL) and so help achieve the post meal glucose target. It can also help manage weight gain, improve sleep and mood, and prepare the body for childbirth[25].

Balanced healthy diet – it is no surprise that the healthier the mother eats, the healthier the baby will be. In type 1 diabetes pregnancies, the "right" food, at the "right" time, with the "right" amount of insulin is a science as well as an art.

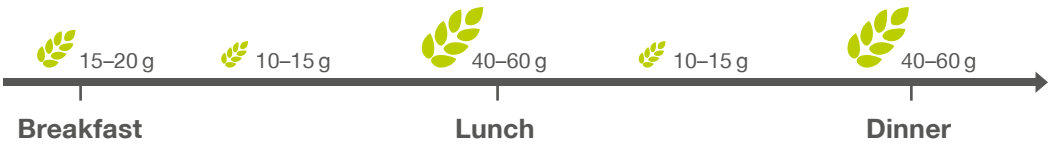
Below some general dietary recommendations by the Diabetes Technology Network UK to achieve a healthy pregnancy[25]:

Eating the right type of carbohydrate

Choosing the right type of carbohydrate can make all the difference to keeping the 1-hour post meal glucose below the target of 7.8 mmol/L (140 mg/dL). Carbohydrates that are unrefined and high in fibre with a low glycaemic index (below 55) create a slower and lower rise in glucose levels.

Eating the right amount of carbohydrate

It is important to eat enough carbohydrate to provide enough energy and nutrition to support a healthy pregnancy. However, too much carbohydrates make it impossible to achieve the post meal glucose targets. Carbohydrates are better tolerated when consumed in smaller quantities, so eating small amounts at meals with carbohydrate containing snacks in-between meals can be very helpful.



Bulking up meals with more protein and vegetables

Eating more protein foods such as meat, fish, chicken, cheese, eggs, tofu, Quorn, pulses and vegetables will fill them up and stop the feeling of hunger. 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.

Avoid eating carbohydrate late in the evening

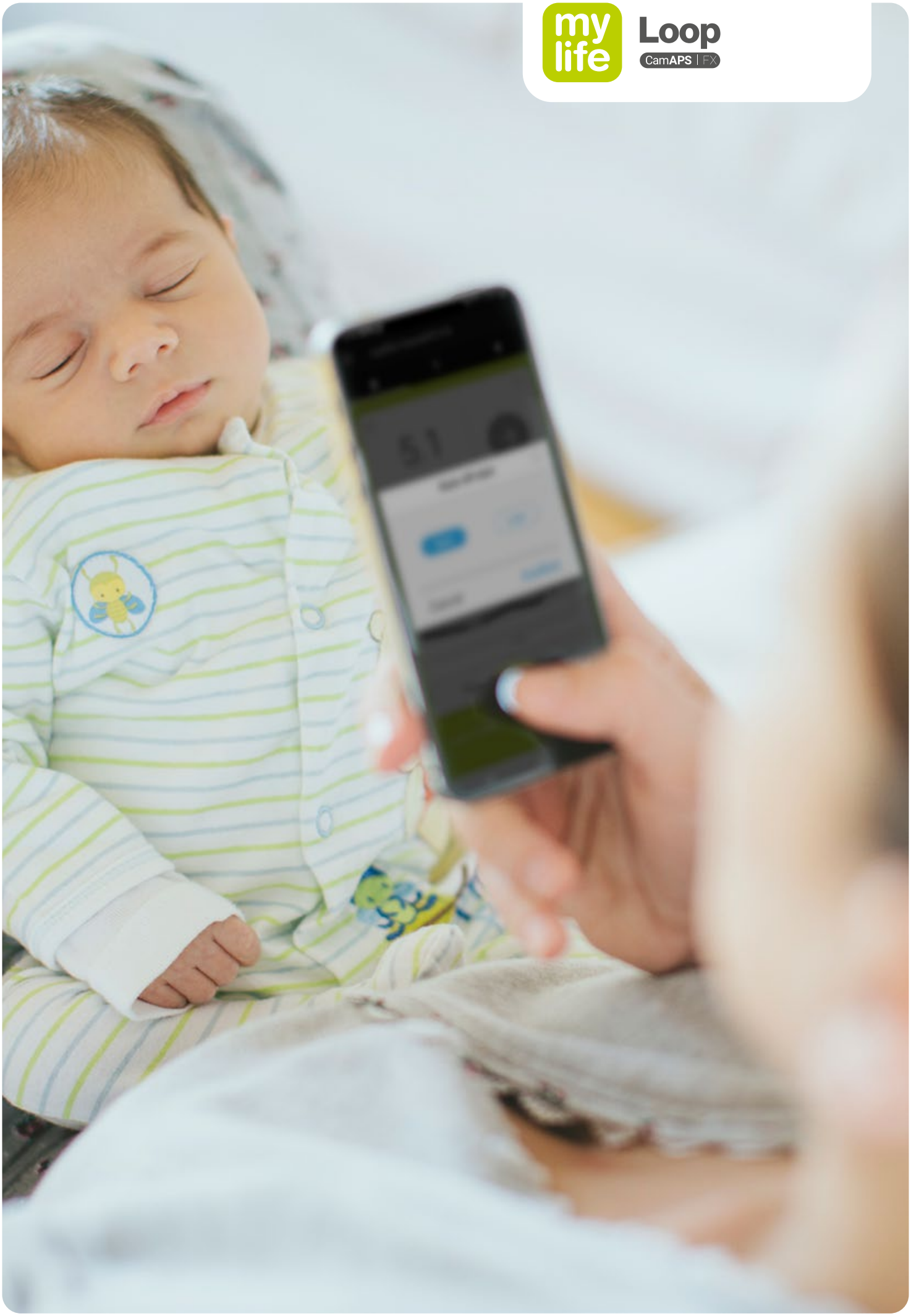
Eating evening meal by 7:30 pm (or at least 3 hours before going to bed). Any snacks taken in the evening should be carbohydrate-free to help maintain stable glucose levels throughout the night.

Mental health

A qualitative study[26] reported significant impairment of psychological health and overall quality of life in women with type 1 diabetes who were pregnant or planning pregnancy. Most women reported a lack of support and empathetic engagement from their health-care team, which affected their clinical management. Barriers to optimal management included guilt and concerns about high glucose concentrations, constant pressure to meet glucose targets, and difficult interactions with healthcare professionals.

It can be challenging to keep up with changes in insulin requirements as pregnancy progresses. Women who are in regular contact with the diabetes educators report better glucose levels and feel more in control[1].

Women noted how HCP's intensive input, oversight and emotional support in the initial days of use had been critical to developing confidence in, and adjusting to, the system.[8]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3. Providing care for women managing type 1 diabetes with mylife Loop before, during, and after pregnancy

The largest randomised control trial to evaluate the impact of closed-loop insulin delivery during type 1 diabetes pregnancy – the AiDAPT study – shows that HCL therapy significantly improves maternal glycaemic control.[1]

3.1 mylife Loop, a hybrid closed-loop

mylife Loop hybrid closed-loop is powered by mylife CamAPS FX, the AID algorithm indicated for pregnancy. Qualitative insights from women using CamAPS FX confirm that certain features made glucose management easier during their pregnancies. In particular, the possibility to set a personal glucose target (PGT) within the pregnancy target range.[8]

The Automated Insulin Delivery (AID) system mylife Loop is made up of three key components that communicate with each other: a Continuous Glucose Monitoring (CGM) sensor, the mylife YpsoPump insulin pump and mylife CamAPS FX, an app-based algorithm.

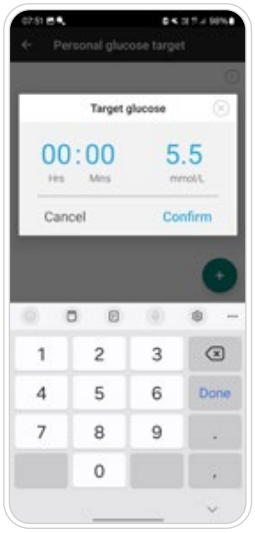
Insulin is delivered with the mylife YpsoPump.

Glucose levels are measured by continuous glucose monitoring sensors, either Dexcom G6 or Abbott FreeStyle Libre 3/ FreeStyle Libre 3 Plus.

mylife CamAPS FX adjusts insulin delivery every 8 to 12 minutes, based on the current and the predicted glucose levels.

Visit our website for detailed information about mylife Loop:
www.mylife-diabetescare.com/pregnancy-HCP

Find below some of the features that support women in the child-bearing age with the management of their type 1 diabetes through the planning, pregnancy, and post-pregnancy journey.

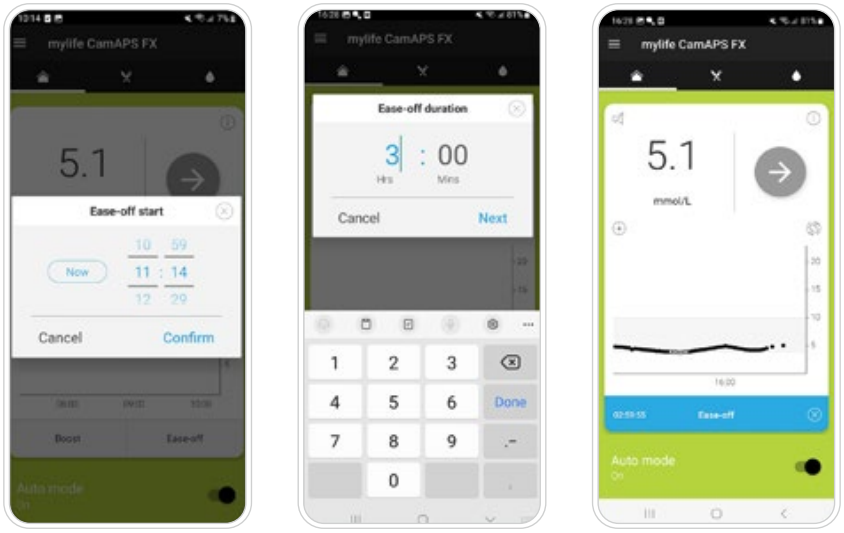


Personal glucose target (PGT)

The own personal glucose target can be adjusted between 4.4–11.0 mmol/L (80–198 mg/dL) in 30 minute segments. A PGT within the pregnancy range is key to achieving glycaemic targets during pregnancy. The algorithm calculates the insulin requirement for the next 2.5–4 hours (predictive control). Insulin delivery is adjusted every 8–12 minutes targeting the defined PGT. That is how mylife Loop takes care of the unexpected glucose swings typical of pregnancy.

Remote bolus delivery

mylife CamAPS FX is a smartphone-based app, allowing the user to discreetly administer boluses. The system compensates for any potential over- or under-dosing of meal boluses to keep the user in range.



“Boost” and “Ease-off” modes

The “Ease-off” mode reduces insulin delivery depending on glucose levels, raises the glucose target temporarily, and stops insulin delivery if the glucose level is predicted to fall below target. On the flip side, the “Boost” mode makes the algorithm more responsive and to increase insulin delivery. Both modes help the person to proactively keep glucose in range, despite the challenges associated with pregnancy.

Remote monitoring

The mylife CamAPS FX app allows user data to be shared with up to 10 “companions”. Companion remote monitoring mirrors the data from the user’s mylife CamAPS FX app. The mylife CamAPS FX app supports SMS based remote monitoring. All app-generated alarms and alerts will be sent via SMS message to up to 5 “followers”. Extra safety for the person – extra peace-of-mind for caregivers.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mylife YpsoPump insulin pump

Swiss engineering is at the core of the mylife YpsoPump insulin pump. Design and functionality make mylife YpsoPump easy to learn and smooth to operate.[27] People with diabetes enjoy the freedom to customise their therapy (type of insulin, infusion set, cartridge, etc.) matching their needs and preferences.

Easy to learn[27]
Train and learn just the essential functions.

Easy to operate[27]
Icon-based menu intuitively operated via touchscreen.

Simply discreet[27]
Small and lightweight device (weighing only 83 grams).

Freedom of choice

- Choice of pre-filled cartridges or self-filled reservoir with the insulin of choice.
- Comfortably and discreetly wear the mylife YpsoPump choosing from a broad selection of carrying systems.
- Flexible site selection with the 360° connector rotation of the mylife YpsoPump Orbit infusion set.

Automated Insulin Delivery (AID) system with mylife CamAPS FX algorithm

The mylife CamAPS FX app is personalised and adaptive, as it constantly learns and quickly adapts to ever-changing insulin needs. It adjusts to diurnal or day-to-day variations in insulin requirements and compensates for over and under-dosing of the meal bolus. The learning takes place on three levels continuously:

1. **Overall learning:** based on the body's overall insulin need, the insulin needed on average and during the day.
2. **Diurnal learning (over 24 hours):** based on how much insulin is needed for a specific hour in a day.
3. **Post-meal learning:** the system observes whether meal bolus insulin amount was appropriate. If a user constantly over or underestimates carbohydrates, the system will start to adjust insulin delivery post-meal.

> "Before I was on the hybrid closed-loop, every couple of weeks I was having to keep changing all my basal rates to try and keep up, whereas the algorithm just automatically does it."
>
> **AiDAPT study participant[8]**

mylife CamAPS FX allows to target glucose levels in the pregnancy range

mylife CamAPS FX allows to target a wide range of glucose levels to best meet the specific needs of women before and during pregnancy.

- The personal glucose target can be set as low as **4.4 mmol/L** (80 mg/dL), which is a unique advantage during pregnancy
- The default value is 5.8 mmol/L (104 mg/dL)
- Increments of 0.1 mmol/L (1.0 mg/dL)

For detailed recommendations about the use of mylife CamAPS FX during pregnancy, please refer to the section 3.4 of this guide.

A glimpse into 24h of glucose management with mylife Loop

There is a lot of complexity behind a near-perfect CGM glucose curve. mylife Loop does most of the heavy-lifting by modulating insulin delivery to meet the personal glucose target defined by the user. Additionally, patients can use “Boost” and “Ease-off” modes to temporarily increase or decrease the ‘responsiveness’ of the algorithm.

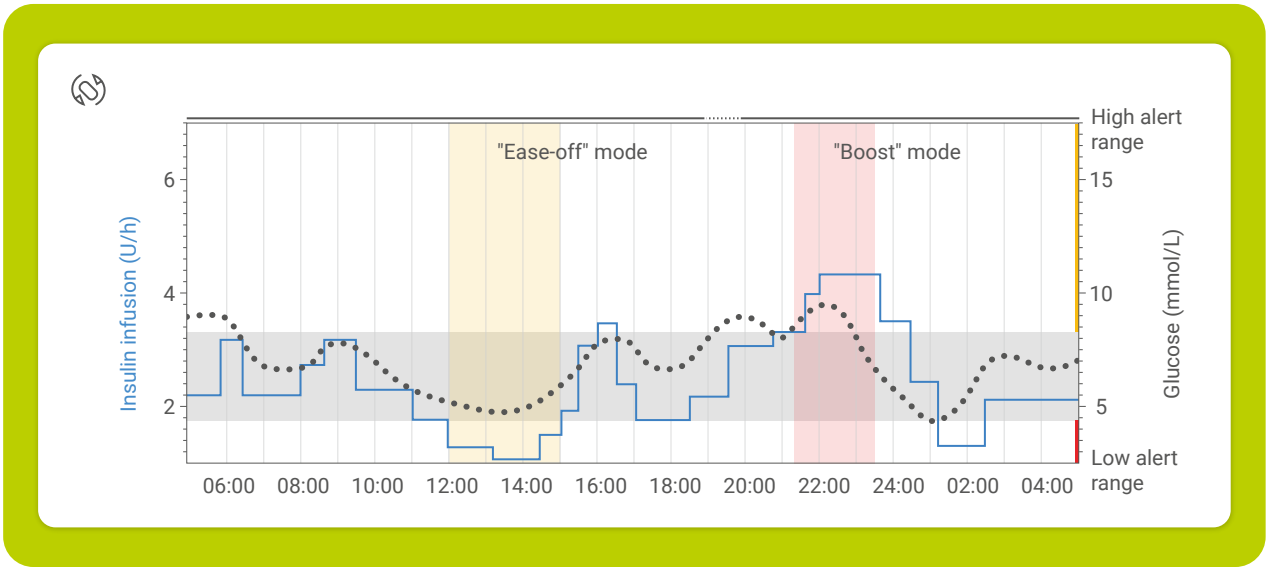
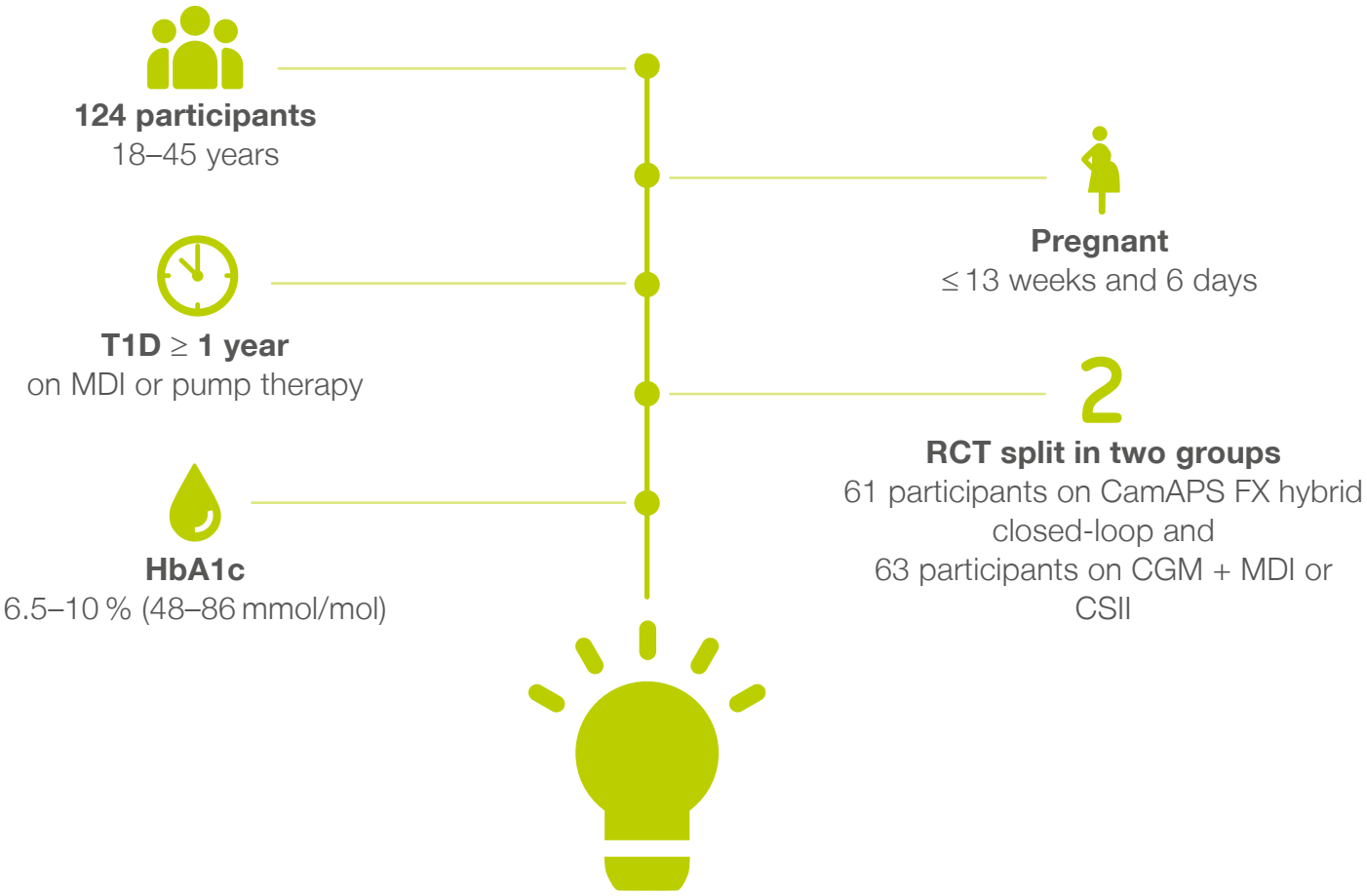


Figure 4: 24 hours graph from mylife CamAPS FX app. Numerical values are for illustrative purposes only.

The key benefit, highlighted by all women, was the system’s ability to automatically adjust basal insulin rates. This helped them to reduce their physical and mental workloads whilst improving time spent in target glucose range.[8]

AiDAPT[1]: the largest RCT using HCL during pregnancy



Type 1 diabetes management:
proven safety and effectiveness of HCL insulin delivery in pregnancy

+ 10.5 % time spent in the pregnancy range 3.5–7.8 mmol/L

Met HbA1c pregnancy target of 6.0 % (42 mmol/mol)

No increased risk of mild or severe hypoglycaemia

3.7 kg less gestational weight gain

Key success factors mentioned by HCPs[28]

1. Checklists and straightforward training materials
2. 24/7 telephone access to technical support from manufacturer
3. Consulting and learning from experienced colleagues

3.2 Study outcomes of type 1 diabetes pregnancies with CamAPS FX

The recently published AiDAPT randomised controlled trial[1] is the largest study conducted on this topic to date. It evaluated CamAPS FX in 61 pregnant women and demonstrated significant improvements in maternal glucose levels compared to standard insulin delivery (63 participants).

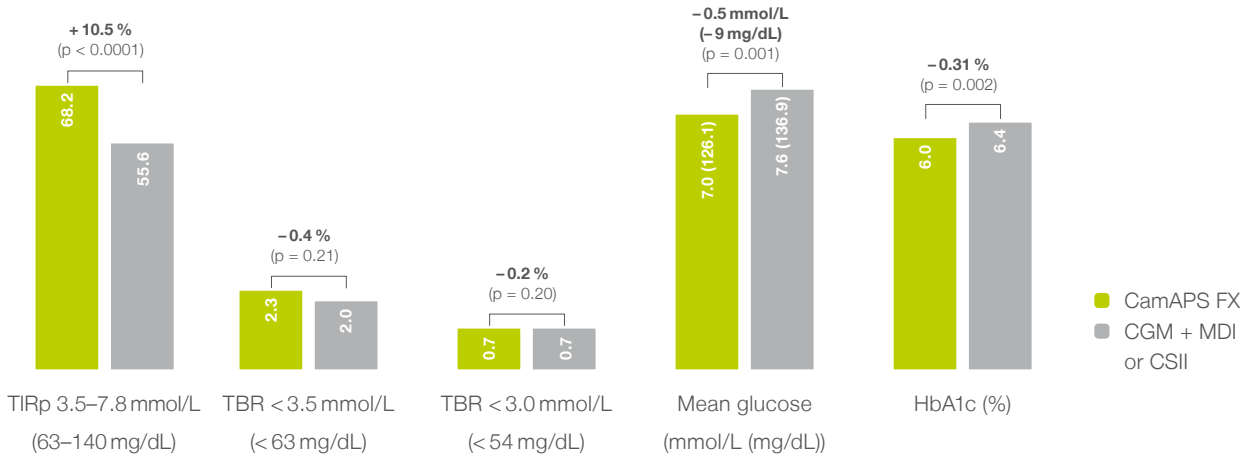
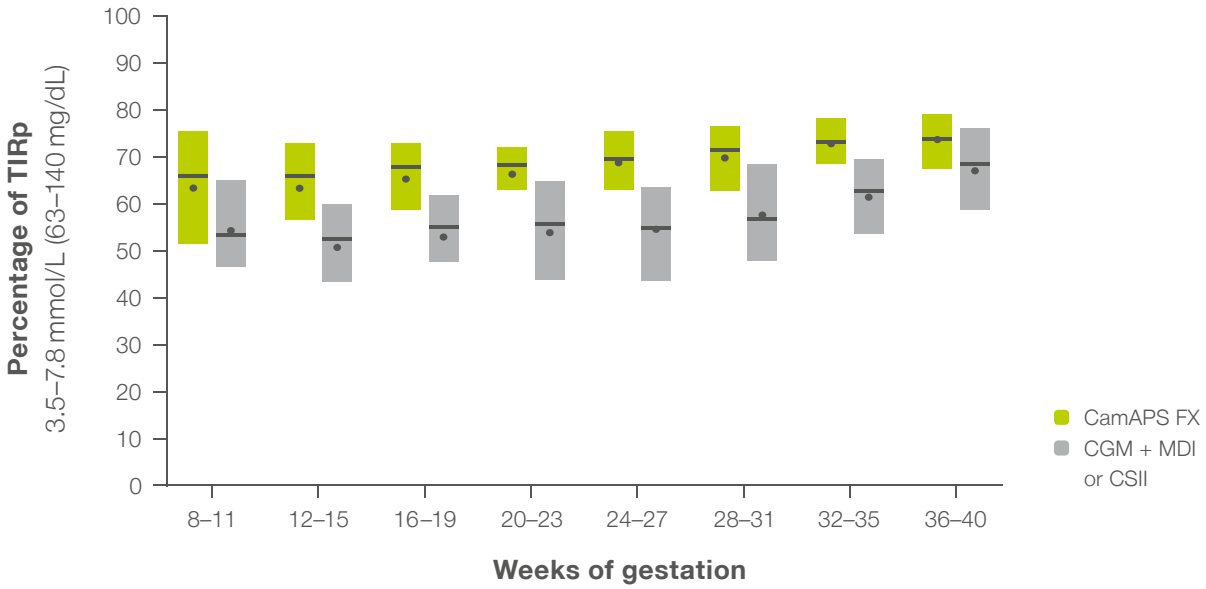


Figure 5: Overall glycaemic control improved with CamAPS FX.

Time in range improvement occurred already immediately upon AID initiation



- Women using CamAPS FX (n=61) spent more time in the pregnancy specific target range and had lower mean glucose and lower HbA1c levels, compared to women in the control group (n=63).
- These improvements were achieved without any difference in the time spent in the hypoglycaemic ranges.
- The benefits were observed immediately after initiating CamAPS FX and were sustained over the pregnancy period.

23 interviewed women reported more enjoyable pregnancy experiences as a result of using closed-loop.[8]

3.3 Planning for pregnancy

Women should let their healthcare team know that they are planning to start a family so that together they can review all the medication, check the eyes and kidneys, and start on 5 mg folate (up until week 12 of gestation).[5] The“pre-pregnancy checklist” will be tailored to each woman’s needs.

While preparing for pregnancy, women should:

- aim to keep glucose levels within the pre-pregnancy target range ideally achieving HbA1c level < 6.5 % (48 mmol/mol)[4],
- follow the regular management for standard optimisation of mylife CamAPS FX and
- adjust the system settings as per the woman’s specific needs to get as close to this goal as it may be safely possible.

“A lot of time and effort was put into diabetes management prior to starting on the mylife Loop system. Once the switch was made, there was a switch in mindset. Letting go of expectations and trusting the system to learn its own way was liberating.”

Tanya Ilkiw, used mylife Loop during her pregnancy

3.4 Pregnancy management by trimester and delivery

There are some glucose and insulin sensitivity patterns repeating from woman to woman. Yet, every individual is unique. In this section we provide some general advice on how to manage type 1 diabetes with mylife Loop at each trimester and during delivery.

Recommended glycaemic targets during pregnancy

Fasting glucose
3.9–5.3 mmol/L (70–95 mg/dL)[4]

Postprandial glucose
1 hour postprandial < 7.8 mmol/L (< 140 mg/dL)[4] or 2 hours postprandial < 6.7 mmol/L (< 120 mg/dL)[4]

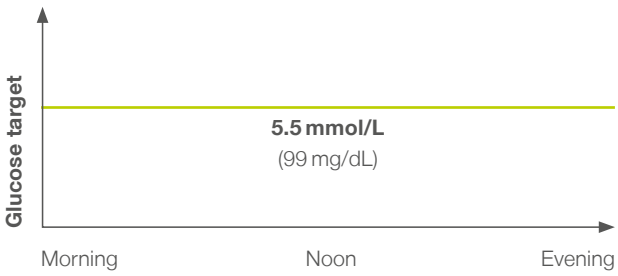
Mean glucose
6.0–6.5 mmol/L (108–117 mg/dL)

Time in pregnancy range
> 70 % (3.5–7.8 mmol/L (63–140 mg/dL))[17]

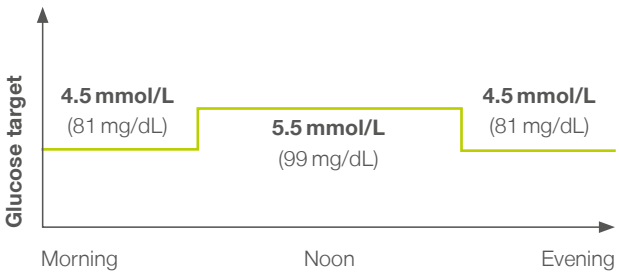
Women who used the hybrid closed-loop technology spent the equivalent to an additional two-and-a-half to three hours in the pregnancy target range (3.5-7.8 mmol/L (63–140 mg/dL)) daily throughout pregnancy, with no increased risk of hypoglycaemia.[1]

Personal glucose target (PGT) recommendations for mylife Loop users

First trimester



Second and third trimester



The mylife Loop **personal glucose target (PGT)** is the only AID system offering a glucose target within the recommended pregnancy range. Moreover, it allows to increase or lower the glucose target in 0.1 mmol/L (1.8 mg/dL) increments. For optimal glucose control, consider the following targets if clinically appropriate:

- 1st trimester: 5.5 mmol/L (99 mg/dL)
- 2nd and 3rd trimester: 4.5 mmol/L (81 mg/dL) overnight and 5.0 mmol/L (90 mg/dL) during daytime
- Women need to adjust PGT as appropriate throughout the pregnancy lower if glucose variability is low and raise in case of frequent hypoglycaemias.

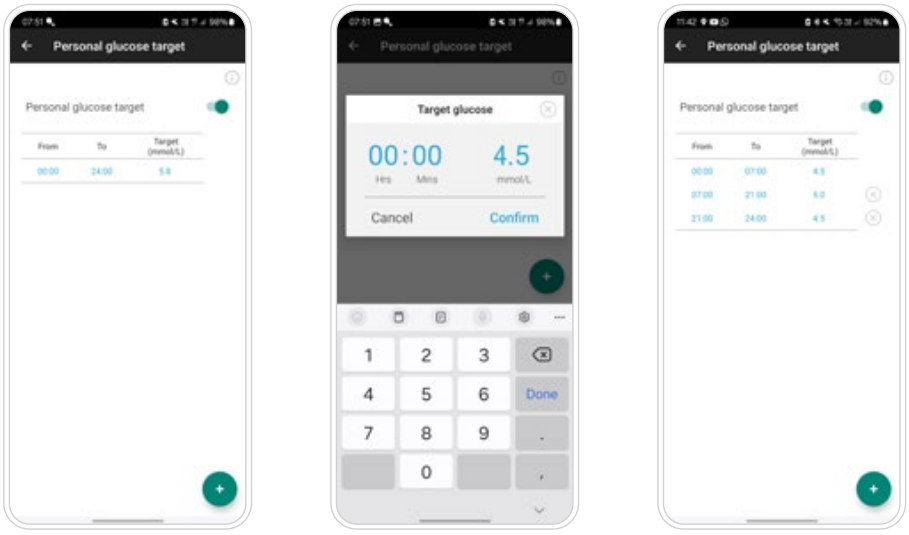


Figure 6: Settings of the personal glucose target in the mylife CamAPS FX app.

Women also described experiencing better sleep and less stress and anxiety despite using tighter glucose targets, due to knowing that the closed-loop was operating in the background to help keep them safe.[8]

The **“Boost” mode** may be used more “liberally” during pregnancy to proactively manage high glucose levels, especially in cases of:

- Post prandial hyperglycemia
- Illness, stress, pain etc. causing high glucose levels
- Post infusion set failure
- Taking steroid medication

Most women described taking several weeks to develop confidence and trust in the system. Women noted how HCP’s intensive input, oversight and emotional support in the initial days of use had been critical to developing confidence in, and adjusting to, the system.[8]

Update the following settings frequently:

Weight:
every 4 weeks

Insulin to carbohydrate ratio (ICR):
as needed per post-prandial readings and response of the algorithm

Preset basal rate:
every 4 weeks (for times when closed-loop is not working, e.g. sensor warm up)

Correction factor:
as needed if manual corrections given via the bolus calculator

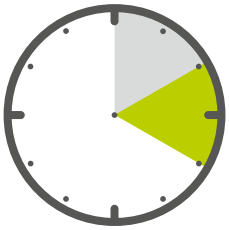
Meal composition:
is important, aiming for higher protein and fat, lower glycaemic index (GI) meal choices

Figure 7: Body weight should be regularly updated during pregnancy in the mylife CamAPS FX app.

Pre-meal bolus timing

Recommend women to spread carbohydrate intake throughout the day to allow small to moderate carbohydrate portions at each meal. Insulin absorption is getting slower as the pregnancy progresses. The following pre-meal bolus timing may be required:[29]

1st trimester



10–20 minutes (standard)

2nd trimester

20–30 minutes

3rd trimester

20–40 minutes

Infusion set change

While insulin resistance and insulin requirements are increasing throughout the second and third trimesters, some women may need to change their infusion set more frequently.

More about our infusion set:
www.mylife-diabetescare.com/orbit

Labour and delivery

mylife CamAPS FX can be continued, in agreement with the obstetric team, if the mother (or partner) is well-enough and confident to self-manage her insulin delivery.

- Continue with the mylife CamAPS FX settings as last programmed
- Use “Boost” and “Ease-off” to further modulate insulin delivery as needed

Caesarean section: mylife CamAPS FX can be continued, in agreement with the obstetric team and anaesthetist.*

- Update the system settings to post-delivery settings prior to caesarean section start (in case of planned procedure)
- Use “Boost” and “Ease-off” modes to further modulate insulin delivery as needed
- Check sensor accuracy if diathermy used

* Labelling of CGM with diatermy may change per device

Post-partum care

The following setting adjustments should be done as soon as possible after the delivery to prevent hypoglycaemia to the mother as her insulin requirements are dropping:

- Increase the personal glucose target (PGT) to at least 6.0 mmol/L (108 mg/dL)
- Increase the insulin to carbohydrate (ICR) back to pre-pregnancy settings to reduce meal boluses amount. If not known, consider using 12–15 g carbohydrates per unit insulin for the ICR. These should be optimised after few days as needed
- Consider not giving insulin for the first meal if shortly after delivery
- Use "Ease-off" to further reduce insulin delivery, as needed
- Update the target range to 3.9–10.0 mmol/L (70–180 mg/dL)
- Use reduced pre-basal rates on pattern B (for situation when mylife CamAPS FX may revert to open loop)
  – Pre-pregnancy levels
  – Or a flat rate corresponding to 25 % of the total daily insulin dose at the end of the pregnancy
- Adjust body weight (mylife CamAPS FX app's main menu ➔ settings ➔ change weight)

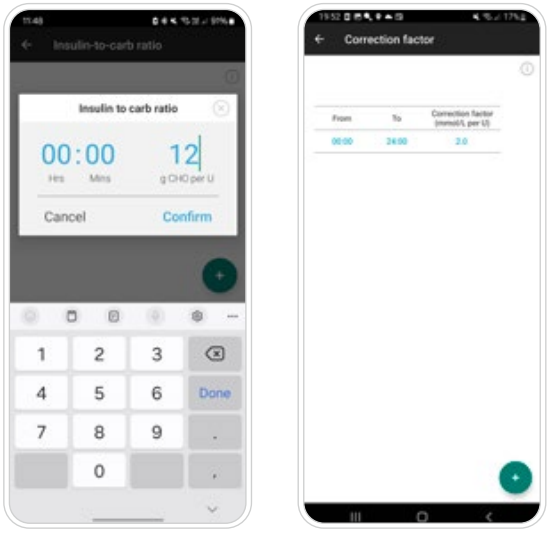


Figure 8: Setting of the insulin to carb ratio within the mylife CamAPS FX app.

"The ability to have a system that works for me whilst I concentrate on my baby was a big help. I felt like someone had my back."

Tanya Ilkiw, used mylife Loop during her pregnancy

Breastfeeding

Glucose levels tend to decrease during breastfeeding. The following recommendations will reduce the risk of maternal hypoglycaemia:

- Have access to hypo treatments/snacks within reach
- Use”Ease-off”
- If still experience hypoglycaemia, consider raising the personal glucose target (PGT) as needed and/or increasing insulin to carbohydrate ratio (ICR)

> “mylife Loop has such key features that supports breastfeeding. Being able to easily adjust glucose targets and ease off when needed was a necessity.”
>
> **Tanya Ilkiw, used mylife Loop during her pregnancy**

These recommendations are taken from experience from the AiDAPT clinical study and might differ from woman to woman. All recommendations need to be discussed between the woman and her diabetes team.

This listing is not exhaustive and only show some of the benefits of using the mylife CamAPS FX algorithm. For more detailed materials, please contact your customer service or visit **www.mylife-diabetescare.com/loop**.

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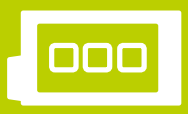

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