



Patient Organisation Submission Form

Subject of SHTG Assessment

Closed loop systems and the artificial pancreas for type I diabetes mellitus (T1DM)

Name of patient organisation

Diabetes Scotland

Health/medical conditions represented

Diabetes

Contact name for this submission

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Role of contact person

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https://www.diabetes.org.uk/in_your_area/scotland

Date of submission

1 November 2021

Please complete the SHTG Declaration of Interest form.

Please complete this form using the accompanying guide and do not include patient identifiable information.

Accessible Language: Where not specifically required for scientific/technical explanation, please use plain language, explaining acronyms and other non-lay terms.

Please note that the information submitted on this form will be held by the SHTG in accordance with Healthcare Improvement Scotland's [policies](#). This information may be published on the SHTG website or disclosed to third parties in accordance with the Freedom of Information (Scotland) Act 2002 (FOISA).

1. Tell us about the sources you used to gather information for this submission. (See page 6 of guidance.)

Diabetes UK membership consists of people with all types of diabetes and health care professionals working in all disciplines of diabetes care. We have members in all four nations of the UK.

We have a membership of over 80,000 people living with diabetes and their carers.

We also talk and support people via our telephone helpline and we host a diabetes forum with over 23,000 active members who discuss all aspects of diabetes care

https://www.diabetes.org.uk/how_we_help/community/diabetes-support-forum

We also gather views from people living with diabetes via face to face and online events, surveys and focus groups.

For this submission we have also spoken directly to people living with or caring for people with type 1 diabetes.

2. What is the health condition and how does it affect the day-to-day lives of patients and their carers? (See page 7 of guidance.)

Diabetes is the fastest growing and potentially most devastating health crisis of our time with more than 4.8m people currently living with the condition in the UK. The number of people diagnosed with diabetes has more than doubled in the last 20 years. Over 312,000 people are currently living with diabetes in Scotland and Type 1 diabetes accounts for approximately 10% of diabetes in Scotland¹.

Type 1 Diabetes is a serious, life-long health condition that occurs when the amount of glucose in the blood is too high because the body can't make the hormone called insulin. This happens because the body attacks the cells in the pancreas that make insulin, meaning the body can't produce any at all.

Everyone needs insulin to live. It does an essential job by allowing the glucose in the blood to enter the cells and fuel the body. If left untreated, high blood glucose levels can cause serious health complications, even death. T1 diabetes has a rapid onset and is an auto immune response. It is a serious condition and over time high blood sugar levels can cause damage to the heart, eyes, feet and kidneys.

¹ Diabetes Annual Survey 2019

People living with diabetes are twice as likely to be admitted to hospital and every week diabetes leads to more than 185 amputations², 770 strokes, 590 heart attacks and more than 2300 cases of heart failure across the UK³.

Diabetic Ketoacidosis (DKA) is a serious complication of type 1 diabetes. DKA occurs when blood sugar levels are too high for too long and is a medical emergency that needs urgent medical attention and can lead to death if untreated. Recent research⁴ has shown that deaths from DKA in Scotland have been steadily increasing since 2004 and were more than twice as high in 2018 compared to 2004. People living in more socially deprived areas were much more likely to be hospitalised or die from DKA throughout the study period than those from less socially deprived areas.

Before the pandemic, one in five hospital beds in Scotland were occupied by a person with diabetes⁵ and diabetes costs 10% of NHS Scotland's budget⁶, at around a billion pounds. 80% of this is on avoidable complications.

Living with diabetes is relentless. People living with type 1 diabetes make an extra 180 health-related decisions a day than someone without diabetes. That's an extraordinary amount of extra decisions to be made – about once every 5 minutes when you are awake.

Most people living with type 1 diabetes will spend no more than 2-3 hours a year with a diabetes healthcare professional – they spend the other 8757 hours managing their condition alone.

"It's a numbers game – you're always watching what you eat. An artificial pancreas would be like a co-pilot – dedicated to doing the maths – taking away some of the burden."

Learning to live with diabetes can be overwhelming and cause worry, stress and uncertainty. Simple things such as going out, family events, and travel require more planning which can lead to frustration, anger, resentment and more stress.

"For me it's a job in itself (managing type 1 diabetes). I give it my all. Learning to accept that you have this condition is a lifelong thing. It does wear you down. I would love something that took the hard work away."

"Even looking at a blood glucose meter feels like you're broken and unfixable. It seems like you will always feel this way and nothing will get better."

"You can't do things on the spur of the moment – for instance if my children want to play football with me – I need to make sure my blood sugars are ok first. You can't be spontaneous."

² NCVIN (2020) Footcare Activity Profile 2016–19

³ Digital (2019), National Diabetes Audit 2017–18 Report 2A: Complications and Mortality

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⁵ NHS Digital (2020) National Diabetes Inpatient Audit 2019

⁶ Hex, N., et al (2012) Estimating the current and future costs of Type 1 and Type 2 diabetes in the United Kingdom, including direct health costs and indirect societal and productivity costs. *Diabetic Medicine*. 29 (7) 855–862

"Finger prick tests can hurt and have caused sores on my fingers. This is problematic as I'm a cellist and need to have good sensitivity in order to play."

One of the most challenging aspects of living with diabetes is the prevention and management of hypoglycaemia (hypos), especially nocturnal (nighttime) hypos.

Hypos are when the blood glucose (sugar) level is too low. They can happen quickly, and it is important to know what the signs are and how to respond. This can impact on quality of life and affect day to day activities.

25% people living with type 1 have hypo unawareness which is particularly dangerous. In some cases, people living with type 1 have to stop driving.

The challenges, fear, and anxiety associated with hypos should not be underestimated. This is one of the most talked about topics covered in calls to Diabetes UK Helpline, in focus and support groups, and online forums. If left untreated severe hypo can lead to seizures, coma, lasting neurological deficits, and even death.

To compensate and avoid hypos individuals often test more frequently or excessively, run their blood glucose level higher than advised targets – thus increasing the risk of micro and macro vascular damage and serious lasting complications such as blindness, stroke, kidney disease, neuropathy and amputation; and/or withdrawing from social events/ interaction because of the fear of hypoglycaemic episodes and the possible consequences such as loss of control, hospital admission, injury through falling, discrimination and stigma.

The impact and time required to recover from a severe hypo varies from individual to individual. On average it can take several hours before the person is able to resume normal tasks of daily living.

Parents of young children frequently report interrupted sleeps for protracted periods - often years- because they have to check their child's blood glucose levels during the night to avoid life threatening and, where necessary, take remedial actions such as waking the child for blood testing or give hypo treatment such as glucose tablets or a sugary drink. This has a significant impact on the parents and the family's quality of life and wellbeing.

All of this can impact on attainment, prospects or life chances, financial security, mental and physical wellbeing and result in premature mortality.

Not everyone with diabetes comes to terms with the fact that they are living with a long-term condition or are able to sustain the relentless monitoring and decisions required to keep healthy. The need for constant vigilance can lead to 'diabetes burnout', anxiety, obsession and eating disorders such as anorexia and T1DE (type 1 diabetes with disordered eating).

3. What do patients and carers want from the health technology? (See page 8 of guidance.)

Over the last decades new technologies have transformed the way diabetes is treated and monitored, empowering people with diabetes with more information, flexibility and the ability to live well with their diabetes.

Hybrid closed-loop technology represents one of the most exciting developments in type 1 diabetes care in recent years.

How does the artificial pancreas work?

A hybrid closed-loop (HCL) system allows your insulin pump to ‘talk’ to your continuous glucose monitor (CGM). It continuously monitors blood glucose levels and calculates the amount of insulin required. Then, it automatically adjusts your background, or basal, insulin based on your blood sugar readings. Some of the systems can also correct for high blood sugars by delivering a dose of quick-acting insulin. But you still need to tell the device when, and the amount of carbohydrate, you’re eating to receive your quick-acting insulin at mealtimes.

It means that people living with diabetes can improve their HbA1c levels, spend more time with their blood glucose in target range and can make day-to-day life with diabetes a lot simpler.

What do people want?

People living with the condition, and their carers, want technology that will help them to confidently manage their/their loved one’s diabetes better, improve HbA1C levels, and spend more time in target blood sugar range; reducing the risk of serious short and long term complications.

Recent focus group work conducted by Diabetes UK revealed people want the following from diabetes technology:

- **Certainty** – that the technology will work and that it will help reduce some of the burden of trying to maintain blood sugar levels within a target range
- **Convenience** – people want diabetes technology to work with the realities of their everyday lives. They want it to be easy to use and take some of the work away from them by automating monitoring and insulin delivery
- **Control** – they want access to their data and insight on trends. People told us they want to be able to pre-empt and plan ahead and they want technology to support them to do this.

The above can be pulled together under the umbrella of **Confidence**. People living with type diabetes want technology to support them to confidently manage their diabetes and live well with the condition.

They want technology that can:

- Give them the information, tools and support to live safe and well with their diabetes
- Avoid debilitating hypoglycaemic episodes.
- Reduce stress and anxiety for them and their families
- Reduce the risk of developing devastating complications such as sight loss, amputation, renal failure, stroke, acute and chronic depression

Fair and Equal Access

Access to the right diabetes technology can be life-changing and allow much easier control of your diabetes and we're pleased to see the significant progress made in recent years towards more people having access. However, there is still huge variation across the country with many patients facing a postcode lottery to get the technology they need and there are significant inequities in access with those living in areas of high deprivation being the least likely to use technology (such as Flash glucose monitoring⁷).

"I choose to self fund the Dexcom G6 CGM due to my individual circumstances its much more suitable for me. Is it affordable for me as a single parent with 2 disabled children, no its definitely not, I've made big sacrifices to be able to pay for it. I find a way because I can't afford to have long term complications and not be around for my children."

"Spending more on tech may be expensive (for Health Boards) but for people who can't/won't self-manage, access to the best tech might save money in the long run."

"I work in tech and want all the tech that I can get but recognise that not everyone does but there needs to be a level playing field in terms of choice. I just want to think about it [diabetes] less."

People living with T1D do not always think the technologies currently available to them are good enough. This is why the growing DIY #WEARENOTWAITING movement has been growing at such a pace both in Scotland and internationally.

"I am very good with tech and I bought an old pump off someone in the pub that I met and refurbished it and it is great and meant I could afford it."

We think it vital that where a person with diabetes is using a DIY system, healthcare professionals are able to support them to do so.

However, the often significant financial and time costs of the DIY systems mean they are self-funded and are inaccessible to many.

⁷ Jeyam, A., Gibb, F.W., McKnight, J.A. et al. Flash monitor initiation is associated with improvements in HbA_{1c} levels and DKA rates among people with type 1 diabetes in Scotland: a retrospective nationwide observational study. *Diabetologia* (2021).

More routine access to hybrid closed-loop technology would mean those unable to use DIY technology do not face unfair health inequalities.

We recognise that the technology will not be right for everyone, but where it is, we believe all those who can benefit from the technology should be considered for access to it. Everyone has the right to good health and this includes access to the treatment, support and technology that's appropriate for them. We must ensure that everyone living with diabetes is given the best opportunity to live well.

4. What difference did the health technology make to the lives of patients that have used it? (Leave blank if you didn't make contact with anyone who had experience of the health technology.) (See page 9 of guidance.)

The quotes below highlight the significant impact current closed loop technology can have on the lives of people living with type 1 diabetes – a relentless life-long condition. Key themes we have found from people living with diabetes using this technology is that it significantly reduces the ‘mental load’ and allows them to spend ‘less time’ managing their condition and more time in ‘target range’.

On average, a person with type 1 diabetes will spend about 2 to 3 hours with a diabetes healthcare professional per year. The other 8,757 hours they are managing their diabetes alone. Hybrid closed-loop technology can help reduce this burden and significantly improve quality of life for people with type 1 diabetes.

It represents what some describe as a ‘practical cure’ for the condition.

“I am aware that I am already thinking less about diabetes and enjoying a lot more sleep, as well as relying on the pump to sort out any miscalculations in carbs, or late snacks.”

“And it’s really improved, over the past eight months my diabetes just done a U-turn like it’s improved my health so much just because I/they can analyse that information so easily.”

“I work full time and I am also in my final year of my MSc (while also running around after a 4 year old and another on the way). Using this system has significantly taken away the “mental load” of constant basal adjustments and it is hard to explain how much that has made a difference even in such a short amount of time.”

“An artificial pancreas would be like a co-pilot – dedicated to doing the maths – taking away some of the burden.”

“They (Closed Loop Systems) definitely help to alleviate some of the burden of diabetes.”

"Essentially, I've gone from being the 'understudy to a pancreas' to being the manager of an 'understudy to a pancreas' where I just input the data and let the system do all the maths every 5 minutes to keep me in range for 90% of the time and with an HbA1c of a non-diabetic"

"The amount of time I spend managing T1 is massively reduced"

"I remember closing my loop for the first time with some intrepidity (sic) and I'm so glad I made the step."

We recognise that the technology will not be right for everyone, but where it is, we believe all those who can benefit from the technology should be considered for access to it. Everyone has the right to good health. And this includes access to the treatment, support and technology that's appropriate for them. We must ensure that everyone living with diabetes is given the best opportunity to live well.

5. Additional information you believe would be helpful for SHTG to consider. (See page 9 of guidance.)

300 words maximum

(below are new references)

Meta-analysis data show that hybrid closed-loop systems are safe and effective in improving glycaemic control and reduce hypoglycaemia in children and adults with type 1 diabetes.

Weisman A, et al. Effect of artificial pancreas systems on glycaemic control in patients with type 1 diabetes: a systematic review and meta-analysis of outpatient randomised controlled trials. Lancet Diabetes Endocrinol 2017;5(7):501–12.

Positive effects on quality of life and reduced burden of diabetes management for users and their carers have also been described with reports of increased reassurance, reduced anxiety, improved sleep and confidence, 'time off' from the demands of diabetes management and the ability to do 'normal' activities without the worry of high or low glucose levels. Studies have shown people report less restrictive eating habits too.

Musolino G, et al. Reduced burden of diabetes and improved quality of life: Experiences from unrestricted day-and-night hybrid closed-loop use in very young children with type 1 diabetes. Pediatr Diabetes 2019;20(6):794–9.

Rankin D, et al. Adolescents' and their parents' experiences of using a closed-loop system to manage type 1 diabetes in everyday life: qualitative study. Chronic Illn 2021 Jan 20;1742395320985924.

The OpenAPS community comprises over 650 individuals globally who have built their own hybrid closed-loop systems, pairing open-source software (OpenAPS), small computing hardware, and currently available diabetes devices (older insulin pumps and CGM). This community has used these closed loop systems in real-world settings for over 4.5 million hours. They have done this in part because access to hybrid closed-loop technology through the health service is so limited. Reported benefits, including reduction of severe hypo and hyperglycaemic events are detailed here:

Lewis D, Leibrand S. #Open APS Community. Real-world use of open source artificial pancreas systems. J Diabetes Sci Technol 2016; 10: 1411.

Five thousand world wide, retrospective data demonstrate improved mean glucose, reduction in HbA1c and increased Time In Range.

Kesavadev J, et al. The Do-It-Yourself artificial pancreas: a comprehensive review. Diabetes Ther 2020; 11(6):1217–35.

Lum JW, et al. A real-world prospective study of the safety and effectiveness of the loop open source automated insulin delivery system. Diabetes Technol Ther 2021;23(5):367–75

This consultation is an opportunity to call for greater access to technology in Scotland, which we know is poor, to close the tech inequality gap and to address the need for adequate training and support for people living with diabetes by health care professionals competent in this area.

Access to technology is important and any intervention must be person centred, ensuring too both health care professionals and people living with diabetes have suitable access to education to use this technology effectively.

6. Please summarise the key points of your submission in up to 5 statements. (See page 9 of guidance.)

- Hybrid closed-loop technology is one of the most exciting developments in type 1 diabetes care in recent years. It represents what some describe as a ‘practical cure’ for the condition.
- Technologies like Flash, CGM, insulin pumps and, now, hybrid closed-loop systems are evidenced to lower HbA1c levels, improve time in range and reduce levels of diabetes distress.
- People with experience of using closed loop systems have reported the enormous benefits and improved quality of life for not just them but also their families/carers.
- More routine access to hybrid closed-loop technology would mean those unable to use DIY technology do not face unfair health inequalities.
- The use of diabetes technology could significantly reduce the strain on the NHS in the long term including preventing avoidable short- and long-term complications.

7. Please give us details of anyone outside your organisation that had a role in preparing your submission. (See page 10 of guidance.)

8. Do you consent for your submission to be posted on the SHTG website? (See page 10 of guidance.)

Yes

No

Thank you for completing this form. It will be given to SHTG members to inform their development of an Advice Statement for this technology.