



Plain Language Summary

Closed loop systems and the artificial pancreas for managing type 1 diabetes

SHTG Recommendation | January 2022

What is type 1 diabetes?

Type 1 diabetes is a serious condition where blood glucose (sugar) levels become too high because the body cannot make a hormone called insulin. Insulin allows the sugar in our blood to enter the cells of our body to produce energy. People with type 1 diabetes need to administer insulin by injection or using an insulin pump multiple times a day.

It is important for people with type 1 diabetes to keep their blood sugar levels as close as possible to the normal range. This avoids complications and harms caused by high (hyperglycaemia) or low (hypoglycaemia) blood sugar. These harms and complications include blindness, limb amputation, stroke, seizures, and even death.

What are closed loop systems and the artificial pancreas?

A closed loop system or artificial pancreas consists of three linked medical devices that, when combined, help people to manage type 1 diabetes. The three parts of closed loop systems and the artificial pancreas are:

- a continuous glucose monitoring (CGM) sensor that checks sugar levels in the body every few minutes
- a pump that delivers insulin, and sometimes other hormones, into the body, and
- a digital controller that analyses data from the CGM sensor and instructs the pump to deliver the correct dose of insulin to return blood sugar levels to normal.

People using a closed loop system or artificial pancreas still need to perform routine tasks to help manage their condition, such as changing the CGM sensor or filling the pump with insulin.

A closed loop system delivers only insulin through the pump, and sometimes requires people to calculate the carbohydrate content of their food and administer an extra insulin dose at mealtimes. The artificial pancreas is a closed loop system that administers more than one hormone.

Why is this important?

In 2019 there were 33,452 people living with type 1 diabetes in Scotland. Type 1 diabetes is associated with physical and mental health problems that can be caused by the demands of managing diabetes daily, coping with diabetes-related complications, and worrying about future complications. Diabetes-related complications place a substantial burden on the NHS in the UK, which spends £10 billion annually on diabetes, mostly on treating complications.

Giving people with type 1 diabetes access to the right technologies to manage their condition is a priority in the [Scottish Government's Diabetes Improvement Plan](#). Demand for closed loop systems and the artificial pancreas is increasing, with many people with type 1 diabetes expected to benefit from these systems in the future.

What we did

We looked at the published evidence on how effective and safe closed loop systems and the artificial pancreas are for managing type 1 diabetes. We created an economic model to determine whether closed loop systems were good value for money. Diabetes UK, the Juvenile Diabetes Research Foundation (JDRF), and the Insulin Pump Awareness Group (iPAG) submitted evidence about patient experiences of diabetes and closed loop systems. We used all this information to produce recommendations for NHSScotland on the use closed loop systems and the artificial pancreas.

What we found

Trials of closed loop systems generally recruited people with well controlled type 1 diabetes who have had the condition for many years. The trials often have a small number of participants and test the closed loop system over short periods of time (hours, days, weeks or months). The closed loop systems tested in trials may also be older versions of devices that may not perform as well as newer versions.

We found four studies that combined results from multiple trials of closed loop systems. In these studies, people with type 1 diabetes who used a closed loop system spent, on average, around 2 hours more each day in the normal range for blood sugar compared with people using insulin pumps with or without a CGM sensor. People using closed loop systems also spent significantly less time each day in hyperglycaemia or hypoglycaemia.

We are not certain how frequently people using closed loop systems experience severe hypoglycaemia or diabetic ketoacidosis (severe hyperglycaemia) because these outcomes were rarely reported in the studies we looked at. Device-related safety issues in closed loop systems mainly related to loss of connectivity between devices, often owing to them being too far apart.

In the studies we looked at, people with type 1 diabetes who used closed loop systems described experiencing a range of benefits. These included improved control of blood sugar levels, increased flexibility around eating and exercising (which both affect sugar levels), and a gave them a sense of time off from managing their diabetes. People also described the

demands of using closed loop systems, including the need to respond to frequent alarms, replace sensors and deal with technical problems. Some people expressed concerns about how trustworthy closed loop systems were or found them difficult to use when exercising.

Three patient organisations described experiences of living with type 1 diabetes and using closed loop systems. Their submissions [can be found on our website](#).

We found evidence that there are inequalities in access to closed loop systems and other diabetes technologies. An audit in NHS England and Wales found that children who were from a relatively affluent area and of white ethnicity were the most likely to have a CGM sensor or insulin pump. Children of black ethnicity who lived in poor areas were the least likely to have these technologies. iPAG Scotland described inequalities in access to closed loop systems in Scotland caused by people needing to self-fund these systems, a cost that many from lower income areas cannot afford.

In our economic model, closed loop systems were compared with other ways of measuring sugar levels and administering insulin. We found that closed loop systems offered the biggest improvements in quality of life, but were also likely to be associated with the highest costs. Closed loop systems are associated with additional upfront costs, but will hopefully lead to future reductions in costs to the NHS for managing diabetes-related complications.

Closed loop systems were good value for money compared with using a CGM sensor plus an insulin pump. Closed loop systems were less likely to be good value for money compared with flash glucose monitoring (FreeStyle Libre®) or a CGM sensor plus multiple daily injections of insulin. Our economic model was not able to include day-to-day quality of life improvements associated with using a closed loop system, which may affect costs and whether these systems are good value for money.

What SHTG considered when developing advice for NHSScotland

1. When writing the recommendations, the Council took into account the published evidence, the SHTG economic model, and the views of clinical experts and patients.
2. The Council understood that closed loop systems are developing over time. It is therefore likely that some of the evidence we looked at relates to devices that have since been upgraded. The Council felt it was important that the evidence on closed loop systems be reviewed regularly to allow updating of recommendations for NHSScotland.
3. The Council noted that the published evidence included trials that recruited people with well controlled diabetes. The Council recognised that people with less well controlled diabetes may experience a greater benefit from closed loop systems.
4. Clinical experts stated that very few people in Scotland currently get a closed loop system on the NHS.

5. When considering value for money, the Council noted that costs could be expected to be lower in future. In particular, costs could be lower if the NHS can negotiate a discount with manufacturers of closed loop systems.
6. The Council discussed the best way to define and measure diabetes-related distress. They agreed that validated tools should be used to provide information to aid in discussions between patients and clinicians about whether a closed loop system would be suitable for the individual. Appropriate tools for measuring diabetes-related distress were identified as the Problem Areas In Diabetes (PAID) scale and the Diabetes Distress Scale (DDS).
7. The Council discussed the lack of trials comparing closed loop systems with flash (FreeStyle Libre®) glucose monitoring plus an insulin pump. This means that we are uncertain about the additional benefits of closed loop systems for people currently using flash glucose monitoring and an insulin pump.
8. The Council discussed the need for educational programmes to help people with type 1 diabetes to use closed loop systems and agreed these should be available. These programmes should be designed for people with a range of knowledge and should be accessible to people with English as a second language.
9. Three patient organisations highlighted the daily burden of managing type 1 diabetes and the impact this has on people's lives. These organisations particularly noted the effects on physical health and mental health, including diabetes-related distress and quality of life.
10. The Council recognised the mental health and wellbeing benefits of using closed loop systems in addition to their physical health benefits, regardless of people's previous levels of blood sugar control.
11. The Council acknowledged that a growing number of people with type 1 diabetes are using 'do it yourself' (DIY) closed loop systems. DIY closed loop systems are not regulated and are not covered in these SHTG Recommendations. Diabetes UK has developed a [position statement on DIY closed loop systems](#).
12. The Council noted the link between poor glucose control and developing diabetes-related complications in later life. They acknowledged that this placed a heavy burden on patients and represented a substantial cost to NHSScotland.
13. The Council noted there is an ongoing trial of closed loop systems in NHS England that should provide useful data for future advice in Scotland.
14. The Scottish Care Information (SCI) Diabetes database currently holds data on diabetes care in Scotland. This system should be used to gather data on closed loop systems to ensure consistency of data collection across Scotland.

What is our advice to NHSScotland?

The SHTG recommendation applies to single hormone (insulin) closed loop systems. No evidence was found on the artificial pancreas; a closed loop system delivering two or more hormones.

To minimise inequalities in accessing diabetes technologies, clinicians should pro-actively discuss with all patients with type 1 diabetes, the suitability of a closed loop system for their individual circumstances.

Single hormone closed loop systems should be available to people with type 1 diabetes (children and adults) who:

- under their current diabetes care plan, continue to have poor blood sugar control, a high risk of severe hypoglycaemia, or impaired awareness of hypoglycaemia, or
- experience severe diabetes-related distress, measured using a validated tool, that adversely affects quality of life or their ability to manage diabetes, and which is likely to be improved by moving to a closed loop system.

The following people with type 1 diabetes, who achieve the desired blood sugar control, should be supported to remain on their current diabetes care plan subject to their circumstances and quality of life:

- people using finger prick testing plus multiple daily insulin injections
- people using flash (FreeStyle Libre®) glucose monitoring plus multiple daily insulin injections
- people using CGM plus multiple daily injections, and
- people using flash (FreeStyle Libre®) glucose monitoring plus an insulin pump.

People who are currently using both a CGM sensor and an insulin pump should be offered a closed loop system.

Discussions between patients and clinicians must consider the day-to-day requirements of managing a closed loop system. For example, responding to alerts or changing sensors when required. Support on how to use their closed loop system effectively should be provided to everyone offered the technology.

The SCI-Diabetes database should be used to collect data from Scottish patients using closed loop systems. These data will be used to inform quality of care improvements and future advice for NHSScotland.

Future work

More trials are needed that test closed loop systems in larger groups of people, over a longer time period, and in a wider variety of participants (for example people with poor glucose control). Trials assessing the artificial pancreas are also required. Trials that collect data to support value for money assessment in the UK would be very beneficial.

This plain language summary has been produced based on SHTG Recommendation in January 2022, [available here](#).