



Do it yourself (DIY) closed loop for people living with Type 1 diabetes

Position Statement (January 2020)

Why have we produced this position statement

Diabetes UK is aware that growing numbers of people with Type 1 diabetes are using DIY closed loop (also known as open source APS). While these technologies are not approved by regulatory bodies and are not commercially available, users of them report improvements in HbA1c and time in range, as well as reduced burden of diabetes. Information on DIY closed loop systems, including how to build them, is readily available on the internet, as is help and support for people who wish to build or are using the technology for themselves or their child.

Healthcare professionals have expressed their concern that legal or regulatory body actions could ensue through advising people on diabetes management based on data obtained from DIY closed loop systems.

How did we develop this position?

Diabetes UK has developed this position statement through our knowledge and insight gained through:

- Discussion with the diabetes community who are using DIY closed loop systems, and their carers
- Discussion with diabetes clinicians who have patients who use the technology
- Discussion with Diabetes UK's Council of Healthcare Professionals (comprising nurses, doctors, dietitians and pharmacists) and Council of People Living with Diabetes
- Discussion with the Association of British Clinical Diabetologists (ABCD) Diabetes Technology Network (DTN)
- Researching the on-line information available on the different types of DIY technology, their advantages and disadvantages

What we say about this issue

Diabetes UK believes that people with Type 1 diabetes should have access to the technology they need for optimal management of their diabetes. We look forward to

regulated and CE marked closed loop systems being available to all who would benefit from them. However, DIY closed loop systems are not approved by any regulatory body, have no published, high quality research trials to support their use or provide reassurance on their safety, have no robust methods of reporting adverse incidents and have no CE mark. Therefore any individual using them does so at their own risk. Diabetes UK respects an individual's right to make their own informed decisions about their diabetes management but cannot recommend the use of DIY closed loop systems due to a lack both of regulatory body approval and published research to support safety or effectiveness.

This position statement offers clinical guidance, and is not a legal position.

Recommendations

- People who wish to use DIY closed loop systems should continue to receive support and care from their diabetes team
- Diabetes healthcare professionals should respect an individual's right to make informed choices about their own care, or that of their child. They should continue to offer people who use DIY closed loop systems the care and support they are entitled to as detailed in Diabetes UK's [15 healthcare essentials](#) and [Type 1 essentials for children and young people](#)
- Healthcare professionals cannot recommend the use of DIY closed loop systems as they are not approved by any regulatory bodies, and must ensure that people with diabetes who are using them are aware that they do so at their own risk
- Healthcare professionals should not initiate a discussion with people with diabetes about using a closed loop system. However, in order to ensure openness around treatment, they should engage in the conversation if the person initiates it.
- Healthcare professionals should document in the person's notes that they have discussed with the user that DIY closed loop systems are unregulated and have no published, high quality research trials to support their use. Therefore the person with diabetes uses the technology at their own risk.
- Healthcare professionals should document in the person's notes that they have discussed the risks of using DIY closed loop systems, including the use of out of warranty equipment if relevant
- Healthcare professionals should continue to support the supply of NHS funded insulin pump, continuous glucose monitoring (CGM) or Flash Glucose Monitoring (Flash GM) if they are used for DIY closed loop systems, unless it is deemed unsafe or clinically inappropriate to do so
- Healthcare professionals who have people with diabetes using DIY closed loop systems should work closely together to deliver a consistent approach to managing the systems and document how they have done so
- Healthcare professionals should participate in the ABCD audit in order to support a better understanding of benefit and risk of DIY closed loop systems
- People intending to use DIY closed loop systems should discuss their intention with their healthcare professional. This allows full consideration of potential risks and clinical factors that may preclude use of the technology, eg retinopathy
- People intending to use DIY closed loop systems should be aware that they do this at their own risk, they may not get support from their healthcare professional

with any technical issues and that liability is unclear if there is a malfunction, error or problem.

- People intending to use DIY closed loop systems should be competent and confident in optimizing their diabetes management using an insulin pump and CGM or Flash GM
- People intending to use DIY closed loop systems can access support from the on-line DIY technology community for advice and trouble shooting. However they must be aware that this advice is not regulated and they do so at their own risk
- Diabetes technology companies should consider ways to make their systems more responsive to the needs of individuals with Type 1 diabetes - eg by allowing more customization and providing improved interoperability between devices.
- The General Medical Council should provide guidance on the professional liability of their members who care for people with Type 1 diabetes using DIY closed loop systems. Nurses and midwives must work within the NMC Code and where available follow local policies and guidelines.
- The Medicines and Healthcare products Regulatory Agency (MHRA) should provide guidance on regulation, including the use of disclaimers on products and reporting of adverse incidents
- Specific recommendations for children
 - Parents who express an interest in DIY closed looping for their child should be made aware of regulated, CE marked hybrid closed loop systems that are commercially available, and offered these systems if appropriate and available
 - Healthcare professionals should consult their local safeguarding team if they have concerns regarding the safety of a child using a DIY closed loop system

Evidence and analysis - the reasons why we are saying what we do

Technology has become an important part of managing Type 1 diabetes, and for some people a vital part. However, commercially available systems do not always meet the needs of people with Type 1 diabetes. For example, they may wish to keep their blood glucose level within a tighter range than possible with these systems, set more personalized targets or want enhanced connectivity between devices.

The development of technology that can be more responsive to an individual's need and intergrate better with other devices has been slow, which is a source of frustration for many people with Type 1 diabetes. This has led to the development of DIY solutions. The people who use DIY closed loop systems have support from their peers in the DIY technology community. They are generally extremely engaged with their diabetes, and committed to achieving the best blood glucose management they are able to. Within the community, there is an ethos that the technology is only built for personal use – while technical support is available, systems will not be built for third parties and it is not offered for sale.

Insights from both users of DIY closed loop systems and healthcare professionals recommend that potential users should have the following skills before starting to use this technology:

- Be established on insulin pump therapy
- Be confident to self-adjust basal rates, insulin:carbohydrate ratios and correction factor

- Have used insulin pump therapy and continuous glucose monitoring /Flash GM to optimise settings of insulin pump prior to starting closed loop
- Have support from the online diabetes DIY technology community for advice and troubleshooting
- Do not have active retinopathy (a rapid fall in HbA1c might occur with closed loop, leading to a potential deterioration in retinopathy). Anyone with retinopathy should discuss their plans with their ophthalmologist and diabetologist before starting DIY closed loop.

However, there is no published research to support the safety and effectiveness of DIY closed loop systems, the systems are not approved by any regulatory bodies and have no CE mark. The risks in using DIY closed loop systems are not fully known, as there is no robust reporting process of adverse incidents. Risks may include hypoglycaemia, hyperglycaemia and diabetic ketoacidosis.

There is no UK guidance on the use of DIY closed loop systems from the National Institute of Health and Care Excellence (NICE), the Scottish Medicine Consortium or the Scottish Intercollegiate Guidelines (SIGN) Network. Diabetes healthcare professionals have expressed concern about their professional role in supporting people using DIY closed loop systems, eg that they may face legal or regulatory body action if they advise on diabetes management using data from an unregulated system. Healthcare professionals cannot optimize blood glucose management in this situation. Consultations should therefore focus on the need to maintain safety (eg ensuring back up pump/insulin pens, availability of ketone strips), assessment and treatment of any complications, or day to day aspects of living with diabetes (eg emotional health, driving/work/travelling/ etc).

References

The information in this position statement was developed from Diabetes Australia's position statement "People with diabetes and Do It Yourself (DIY) technology solutions" (2018)
<https://static.diabetesaustralia.com.au/s/fileassets/diabetes-australia/ee67e929-5ffc-411f-b286-1ca69e181d1a.pdf>, conversations with people using DIY solutions and healthcare professionals with experience in their use.