Diabetes UK Position Statements

Do-it-yourself closed-loop systems for people living with type 1 diabetes

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Abstract

Growing numbers of people with type 1 diabetes are using do-it-yourself closed-loop systems. While these technologies are not approved by regulatory bodies and are not commercially available, users of the technology report improvements in HbA1c and time in range, and reduced burden of diabetes. Healthcare professionals have expressed their concern that legal or regulatory body actions could ensue if they support people who choose to use do-it-yourself closed-loop systems. Diabetes UK’s position statements make recommendations that aim to provide guidance for both people with diabetes and healthcare professionals, based on the current professional and legal situation. They respect an individual’s right to make their own informed decisions about their diabetes management, and recommend that they should have access to the technology they need for optimal diabetes management. People who wish to use do-it-yourself closed-loop systems should continue to receive support and care from their diabetes team. Healthcare professionals should engage in conversations around do-it-yourself closed-loop systems, if the issue is raised, to allow a balanced discussion of risks and benefits. However, healthcare professionals cannot recommend the use of do-it-yourself closed-loop systems because of a lack of regulatory body approval and robust, published research to support safety or effectiveness. People using this technology should be aware that they do so at their own risk. This position statement recognizes that the development of diabetes technology is a rapidly changing environment, and guidance around do-it-yourself systems is required from professional and regulatory bodies.

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Introduction

Technology has become an important part of managing type 1 diabetes and, for some people living with the condition, a vital part. Over recent years, there have been significant developments in the technology available for people with type 1 diabetes to help them manage their condition [1].

The emotional aspects of living with type 1 diabetes must also be considered, as it is much more than a physical condition. Unlike other conditions, where doses can be stabilized in most people after some initial titration, insulin requirements vary day-to-day depending on a number of factors. Some of these factors are possible to predict, such as food intake, alcohol or planned exercise, while others are altogether much harder to predict such as stress, illness, quality and quantity of sleep and unplanned activity or exercise. Consequently, people living with type 1 diabetes require a comprehensive understanding of diabetes management, in addition to a high level of self-efficacy and resilience [2]. Even though they may perform all the tasks of self-management, including frequent monitoring of blood glucose, administration of insulin, managing food and physical activity and treating hypo- and hyperglycaemia [3], they will almost certainly have some blood glucose readings that are unpredicted or out of range. Unsurprisingly, therefore, emotional and psychological health problems, including diabetes distress, anxiety and depression, are common among adults with diabetes. This can result in poor self-management, diabetes-related complications, and reduced quality of life [4]. Diabetes technology systems can be seen as an attractive solution to the relentlessness of this day-to-day burden.

Flash glucose monitoring is now available in England on prescription for all those who meet NHS England criteria [5], with more than 20% of people in the UK using it. Insulin pumps with hypoglycaemia- and predicted-hypoglycaemia-suspend features are also now available, as are continuous glucose monitors that do not require calibration.
The first commercial closed-loop systems, which can adjust basal insulin every 5 min based on continuous glucose monitor (CGM) readings, are now becoming available, improving overall time in glucose range. Data presented from more than 3000 users of the Medtronic 670G show a mean time in range of >70% [6]. Tandem has recently published data from their pivotal trial of the Control IQ system, showing 74% time in range [7]. Similarly the Cambridge group are awaiting the CE mark for their system that has been tested in many randomized clinical studies [8,9], and other systems are in development from BetaBionics, Insulet, Bigfoot, Diabeloop and Tidepool. Common themes across all these commercial or academic systems are the ability to achieve glucose concentrations within range >70% of the time, with significant improvements for time in range. They all highlight the importance of automation in both reducing the burden of living with type 1 diabetes and achieving glucose targets that reduce the development of complications of diabetes.

These commercial systems, however, do not necessarily meet the needs of people with type 1 diabetes. Many are still a few years away from reaching the market, and some have individual issues that are relevant and important to people living with diabetes. Some do not allow sufficient individualization of blood glucose targets, and users may wish to keep their blood glucose level within a tighter range than currently possible with a commercially available system. Interoperability is also an issue, as a lack of connectivity between devices requires users to adhere to one manufacturer of technology.

The development of technology that can be more responsive to an individual’s need and integrate better with other devices has been slow. This is a source of frustration for many people with type 1 diabetes, and has led to the development of do-it-yourself (DIY) solutions (#wearenotwaiting).

A DIY closed-loop involves the use of continuous glucose monitoring (CGM) or flash glucose monitoring with the addition of hardware that allows conversion to real-time CGM), an algorithm that calculates insulin doses, a communication device and an insulin pump. Together, these systems automatically adjust basal rates and bolus doses in response to CGM values. In simple terms, as blood glucose rises, the system automatically delivers more insulin, and as it drops, the system delivers less. There are currently three types of DIY closed-loop system: Open APS, Looping and Android APS. The types differ in the combination of pumps, user communication devices, hardware and algorithms they use [1].

While it is difficult to estimate the number of people with type 1 diabetes in the UK using a DIY closed-loop system, Diabetes UK’s insight would suggest that numbers are rising. The topic is being discussed with increasing frequency by people living with diabetes and healthcare professionals alike.

A survey of healthcare professionals demonstrated their anxiety and concerns and the challenges experienced by both healthcare professionals and people with diabetes when talking about DIY closed-loop systems. What neither group wants is for this technology to exist ‘underground’, hidden from healthcare professionals [10]. Diabetes UK’s position statement on DIY closed-loop systems includes recommendations (see below) surrounding the use of DIY closed-loop systems in terms of safety, responsibility, professional liability and legal aspects. The aim is to support a balanced discussion around the risks and benefits of these systems. There are recommendations for both people living with diabetes and for healthcare professionals. This position statement reflects the situation as it is at present, but acknowledges that further guidance is needed from regulatory and professional bodies.

**Methodology**

Developing the position statement required a robust understanding of the different types of DIY closed-loop system. The vast majority of practical information on systems is web-based, so an online search of available information was undertaken. The views of people with diabetes, including users of DIY closed-loop systems, and healthcare professionals were sought via email and telephone conversations.

Users reported improvements in HbA1c and time in range, as well as reduced burden of diabetes; however, they were often unwilling to be open about using the systems with their healthcare professional because of fears that National Health Service (NHS) funding might be discontinued for their insulin pump, CGM or flash glucose monitor if these were used for DIY closed-loop systems. Diabetes UK’s insight gathering revealed that 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. Within the community, there is an ethos that the technology is only built for personal use; although, technical support is available, systems will not be built for third parties and are not offered for sale.

Healthcare professionals had mixed opinions. While there was appreciation from most that DIY closed-loop systems improved diabetes management and quality of life, there were also concerns that legal or regulatory body actions might ensue if they advised people on diabetes management based on data obtained from DIY closed-loop systems. Safety was also raised as an issue, as there is no published research to support the safety and effectiveness of DIY closed-loop systems. In particular, there were concerns about liability in the instance of a patient coming to harm from either hyper- or hypoglycaemia as a result of using a DIY system. The systems are not approved by any regulatory bodies and have no CE mark. Added to that, the risks in using DIY closed-loop systems are not fully known, as there is no robust

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reporting process of adverse incidents. Some users of the systems have older, out-of-warranty insulin pumps where there is no guarantee that the insulin delivered is what the pump was programmed to deliver. Paediatric clinicians questioned whether a parent building such a system for their child could potentially be a 'safeguarding' issue.

Our discussions highlighted how difficult it may be to assess liability from any adverse incident, as this may involve a range of people including the developers of the DIY closed-loop systems, the manufacturers who allow their technology to be used in these systems, through to healthcare professionals who support people with diabetes using the systems and finally the individual users themselves.

**Main recommendations**

Based on their insight gathering, Diabetes UK has made the following recommendations regarding DIY closed-loop systems.

- 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 [11] and type 1 essentials for children and young people [12].
- 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 DIY 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 pumps, CGM or flash glucose monitoring devices if they are used for DIY closed-loop systems, unless it is deemed unsafe or clinically inappropriate to do so.
- Healthcare professionals who are caring for 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 Association of British Clinical Diabetologists audit in order to support a better understanding of the benefits and risks 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, e.g. retinopathy.
- People intending to use DIY closed-loop systems should be aware that they do this at their own risk, they may not receive 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 glucose monitoring device.
- People intending to use DIY closed-loop systems can access support from the online 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, e.g. 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 Nursing and Midwifery Council Code and, where available, follow local policies and guidelines.
- The Medicines and Healthcare Products Regulatory Agency should provide guidance on regulation, including the use of disclaimers on products and reporting of adverse incidents.

**Conclusion**

People with diabetes should have access to the technology they need for optimal management of their diabetes and they
have the right to make their own informed decisions about their diabetes management. However, individuals using DIY closed-loop systems do so at their own risk as they are not approved by any regulatory body, have no published, high-quality research trials to support their use or to provide reassurance on their safety, have no robust methods of reporting adverse incidents and have no CE mark.

Diabetes UK respects an individual’s right to use DIY closed-loop systems, but cannot recommend them because of the lack of regulatory body approval and published research to support safety or effectiveness. DIY closed-loop systems are here to stay, at least until regulated systems that allow individualization, interoperability and that are supported by robust evidence of safety and effectiveness are available and funded. They cannot be ignored and so their use must be made as safe as possible until regulated and CE-marked closed-loop systems, with the ability to individualize targets, are available to all who would benefit from them.

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